

Image Navigation

Best-In-Class | High-Accuracy
Real-Time Surgical Navigation



IGI User Manual 5-IG-0402
Version 3

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This manual refers to the Image Guided Implantology (IGI) System P/N AIG0005-V2



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Disclaimer: Some of the figures may not be exactly as seen on your IGI screen

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II. Safety Information for User

A. Explanation of Warning Symbols

Warnings appearing in other sections (other than sections II and III) of the User Manual are marked with the following symbol:



Warnings are precautions necessary to prevent injury or loss of life.

Cautions are precautions necessary to protect the equipment.

B. Electrical Safety

1. Warnings

The safety, reliability and performance of the equipment can be assured only if:
The electrical installation of the facility where the system is installed meets the appropriate regulatory requirements.

The medical grade mains plug is used (with protected terminals) in line with the National Electrical code.



WARNING

To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.

2. Electromagnetic Safety Information

DECLARATION – ELECTROMAGNETIC EMISSIONS		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group1 Class A	The IGI system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Harmonic emissions IEC 61000-3-2	Class A	The IGI system is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/ system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the IGI system or shielding the location.
Voltage Fluctuations and Flicker IEC 61000-3-3:2013	Complies	

DECLARATION – ELECTROMAGNETIC IMMUNITY			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines 1 kV for input/output lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 1 kV line(s) to earth 2 kV Signal input/output) to earth	1 kV line(s) to line(s) 1 kV line(s) to earth 2 kV Signal input/output) to earth	Main power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	0% UT; 0.5cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	Main power quality should be that of a typical commercial or hospital environment. If the user of the IGI system requires continued operation during power mains interruptions, it is recommended that the IGI system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

DECLARATION – ELECTROMAGNETIC IMMUNITY			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3V, 6V	3Vrms, 6V	Portable and mobile RF communications equipment should be used no closer to any part of the IGI system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m	3V/m	$d = \left[\frac{12}{V_2} \right] \sqrt{P}$ $d = \left[\frac{12}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{23}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. D Interference may occur in the vicinity of equipment marked with the following symbol: 
	3V/m from 0.15 to 80MHz; 6V/m from 0.15 to 80MHz and 80% AM at 1kHz	3V/m from 0.15 to 80MHz; 6V/m from 0.15 to 80MHz and 80% AM at 1kHz	
	10V/m from 80MHz to 2.7GHz	10V/m from 80MHz to 2.7GHz	

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE IGI SYSTEM

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM bands $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = \left[\frac{12}{V_2} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{12}{E_1} \right] \sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{23}{E_1} \right] \sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

TEST SPECIFICATIONS FOR ENCLOSURE PORT IMMUNITY TO RF WIRELESS COMMUNICATIONS EQUIPMENT

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance level (V/m)
385	380 390	TETRA 400	Pulse modulation b) 18 Hz	1.8	0.3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0.2	0.3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0.3	28	28
870							
930							
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,4, 25;	Pulse modulation b) 217 H z	2	0.3	28	28
1845							
1970							

		UMTS					
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9	
5500							
5785							
^{a)} For some services, only the uplink frequencies are included. ^{b)} The carrier shall be modulated using a 50 % duty cycle square wave signal. ^{c)} As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.							

TEST	STANDARD	CLASS/ SEVERITY LEVEL	TEST RESULT (COMPLIES OR N/A)
Emission (IEC 60601-1-2 section 7)			
Conducted emission Freq. range: 150 kHz - 30 MHz	CISPR 11	Class B	P
Conducted Emission (Cur .P) Patient Coupled Cables	CISPR 16-1-1, CISPR 11: 2009	24dBuA	P
Radiated emission Freq. range: 30 - 1000 MHz	CISPR 11	Class A	P
Harmonic current emission test	IEC 61000-3-2	Class A	P
Voltage changes, Voltage fluctuations and Flicker test	IEC 61000-3-3	N/A	P
Immunity (IEC 60601-1-2 section 8)			
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2	Indirect Contact: +/- 8Kv Direct Contact: +/- 8Kv ± 2 kV 4 kV, 8 kV, 15 kV AIR	P
Immunity from radiated electromagnetic fields	IEC 61000-4-3	80MHz-2.7GHz (3v/m) 80% AM 1KHz	P
Immunity from Proximity field from wireless communications equipment	IEC 61000-4-3	385-5785 MHz According to Table 9 in Standard	P
Immunity from Electrical Fast transient (EFT)	IEC 61000-4-4	100 kHz repetition frequency +/-2Kv	P
Immunity from Surge	IEC 61000-4-5	Power: ± 0,5 kV, ±1 kV, ±2 kV1 kV line(s) to line(s)	P

		kV line(s) to earth	
Immunity from conducted disturbances induced by radio-frequency fields	IEC 61000-4-3	150KHz-80MHz (6Vrms) 80% AM 1KHz	P
Immunity from power frequency magnetic field	IEC 61000-4-8	(30A/m) 50Hz / 60 Hz	P
Immunity from voltage dips, short interruptions and voltage variations	IEC 61000-4-11	(100 vAc), (240 vA c)	P

C. Equipment Safety



WARNINGS

The greatest possible care and attention must be given when handling the equipment to ensure the protection of the patient. The safety, reliability and performance of the equipment can be assured only if:



WARNING: No modification of this equipment is allowed.



WARNING: Installation, adjustment, maintenance, modifications and service are performed only by an IGI authorized technician using the IGI installation guide #5-IG-0404.



WARNING: Any installation of software or use of internet on the IGI unit is forbidden, except when explicitly instructed by this manual or by an IGI authorized technician.



WARNING: No service or maintenance of the equipment should be done while in use with a patient.



WARNING: The equipment should be used as specified in the User Manual.



WARNING: Use only Image Navigation supplied spare parts and IGI kit elements.



WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.



WARNING: Use of components, accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.



WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the IGI system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment”.



WARNING: Avoid spilling liquids into the interior of the system during cleaning and disinfecting. This may cause damage to the device.



WARNING: IGI system is to be installed in a clinic.



WARNING: Avoid transporting the IGI unit outside the clinic. This is performed by an IGI authorized technician only.

Note: Operating Environmental requirements: Ambient temperature: 15°-30° C
Humidity: max 65% Atmospheric pressure: 500 hPa to 1060 hPa.

D. Manipulation of the IGI unit

Follow the guidelines below to ensure safe and correct manipulation of the IGI unit before and after surgery:

Verify the IGI unit is turned off.

Disconnect the network and power cables and verify no other external cables are connected.

Fold the camera arm and the monitor arm to its fully folded position and locate it above the cart area.



Figure 1: Fully Folded Camera Arm

Verify that cartwheels are not blocked by any objects such as cables, carpet etc.
Grasp the vertical post above the monitor arm with your hand.



Figure 2: Hold on the Pole for moving the cart

Gently roll the cart to the new location.

If mechanical resistance is sensed, stop rolling and check if the wheels are blocked by an object or obstacle on the floor, and clear the path.



Warning: One must be careful not to lean on or push the IGI unit.



Warning: When moving the unit, one must be careful to have the camera arm folded.

Caution: Do not step on the cart base. There is delicate equipment inside that can be damaged.

III. Operational Safety

A. Warnings

- The IGI System may only be used in accordance with local regulations and by qualified surgeons who fully observe the operating instructions and have the required technical training.
- The surgeon should be fully proficient in the use of IGI before using the optional system for the treatment of fully edentulous jaws.
- Failure to follow the instructions in the user manual may result in injury to the patient.
- Make sure to protect patient's files for confidentiality of medical records. Save the patient's CT files on the same computer you are about to use during IGI surgery. After surgery, save the CT images on a separate hard drive or different computer and delete the CT images from the IGI computer.
- Wheels of the IGI cart should be locked before use.
- Prohibition against pushing, leaning, and resting upon of the IGI, as it may overbalance.
- Prohibition against stepping on the surface of the IGI, as it may overbalance
- Any opened components must be checked for damage or missing parts before use. Any damaged components must NOT be used.
- Components that were exposed to environmental conditions outside those specified, even if in closed packages, must be checked for damage before use. Minilock™ trays and wedges which have been exposed to environmental conditions outside those specified, even if in closed packages should not be used.
- It is crucial that the CRD (Customized Registration Device) is stable and maintains the same exact positive seat, both during the CT scan, and during the implantation procedure. Any failure regarding CRD seat or stability, during the CT scan or during the implantation procedure, will have a dramatic negative effect on the system's accuracy.
- The same size wedge should be used for the CT and the implant surgery.
- Perform the CT scan only after verifying that the preparative steps have been successfully completed.
- Marking the nerve canal is the full responsibility of the dental surgeon.
- Users and staff must be careful when standing up in the vicinity of the camera arm.
- During planning and procedure stages, avoid any critical anatomical structures by a distance of at least 1.5 mm.
- The IGI registration bur must be used during fiducial registration procedure.
- The IGI tracing bur must be used during anatomic registration procedure.
- The IGI long bur must be used during functionality test procedure.

- The IGI short and long bur must be used during calibration procedure (by IGI authorized technician only).
- A digital caliper must be used to measure all new burs prior to drilling with them.
- If the bur defined in IGI does not match the bur used for drilling, the guidance will be incorrect (especially in defining the depth) and there will be an error in drilling.
- Constantly check that the system is tracking the handpiece.
- Avoid applying pressure to the CRD, to the pole, or to the Patient Tracker during pre-surgical procedures (tests, registration and bur point measuring) and during surgery.
- Recheck during surgery that the CRD is in place and that the Patient Tracker and pole are not distorted by the patient's chest or chin, or in any other way.
- Avoid obstructing the camera view of the IR emitters both on the Handpiece Tracker and on the Patient Tracker, during pre-surgical procedures (tests, registration and bur point measuring) and during surgery.
- Position the IGI unit so that the power (on/off) button can be reached easily to disconnect the unit.
- All IGI parts supplied are non- sterile. Sterilization or disinfection is required before use. See ***Cleaning, Disinfecting and Sterilizing*** on page **185**.
- Avoid applying pressure to the Minilock™ Device, pole or Patient Tracker by any instrument or by any person.
- If the motor is not fully inserted into the turbine, pressing the pedal at a low RPM setting may allow the bur to turn when operating on soft bone, but not on hard bone.

B. Explanation of Figures, Symbols and Warnings on Equipment

	Single patient multiple use
	Patient ID

	Patient Name
	Date Symbol
	Follow instructions for use
	Manufacturer
	Date of manufacture
	Authorized Representative in the European Community
	ON (power)
	OFF (power)
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Catalogue number
	Serial number

	Type BF applied part
	Fuse
	Rated 100-240VAC 50/60 Hz 150VA
	Protective Earth (ground)
	Dispose of properly after use
	Do not use if package is damaged or open
	Keep away from sunlight
	Keep dry
	This Side up

	Fragile
	Temperature limit (see storage conditions)
	Humidity limit (see storage conditions)
	CE Mark
	Consult instructions for use
	Caution
	Overhead Obstacles
	Stepping prohibited

	Pushing prohibited
	Non Sterile
	Medical Device
	Autoclave Reusable
	Unique Device Identifier
	Lot Number
	Alternating Current
	Quantity

C. Maintenance and Component Disposal

- Preventative and regular maintenance of the IGI system isn't required.
- The System cannot be disposed of as unsorted municipal waste. Please contact your local distributor for unit disposal.

- Consumables must be disposed of as medical waste.

Table 1: Disposable IGI Elements - must be discarded after single patient use

Horseshoe (fully edentulous)
Minilock™ trays
Minilock™ wedges

D. Feedback

Serious Incident means any incident that directly or indirectly led, might have led or might lead to any of the following:

- (a) the death of a patient, user or other person,
- (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
- (c) a serious public health threat.

Any serious incident related to IGI or any of its components should be reported to the manufacturer, Image Navigation. In case you are located in Europe, please make sure to report the incident to the relevant competent authority in the member state in which you are established in.

We welcome any feedback regarding this manual. Please send any comments to: support@image-navigation.com

Thank you.

IV. Connection to Specified Compatible Equipment

During the implantation procedure, the IGI handpiece including a dental shank is used. This item is supplied by Image Navigation with the IGI system.

The IGI system must be connected to a motor with the following specifications:
Max Drive speed: 40000rpm, Speed Transmission: 20:1, Max. Torque 55 Ncm, and conform to IEC 60601-1.

The IGI system must be connected to a monitor. The monitor must have a resolution of at least 1080P and an available HDMI port.

An Image Navigation supplied HDMI optical cable is supplied with the IGI unit. HDMI cables must be approved by Image Navigation for use.

The system may be connected to a network for the purpose of downloading and uploading CT images and surgical plans only. The user is responsible for using a router with a built-in firewall.

The optional DAB (Drilling Autostop Box) may be used with IGI, only with an Image Navigation approved implant motor.

Note: *Connection to the internet and other equipment could result in previously unidentified risks to patients, operators or third parties. The user's IT network personnel should analyze, evaluate and control these risks. Changes to IT network could introduce risks. These changes include: Changes to network configuration; connection of additional items; disconnection of items; update of equipment; and upgrade of equipment.*

The system comes with an antivirus. It is the user's responsibility to renew the antivirus license as required.

The router's firewall must be updated as per the router manufacturer's directions. The user should not install any SW or change any other system settings.

V. IGI Technical Specifications

Table 2: IGI Technical Specifications

Reference/ Part Number	AIG0005-V2
Rated supply voltages:	100-240VAC
Number of phases:	1
Type of current:	AC
Rated frequency (Hz):	50/60 Hz
Rated power input (VA):	150VA
Types and rating of external accessible fuses:	2 Fuses T2.5AH250VAC
System weight including Safe Working Load (SWL)	55kg
Type of protection against electric shock:	Class I medical electrical equipment
Degree of protection against electric shock:	Type BF applied part
Equipment not suitable for use in the presence of flammable mixtures.	NA
Mode of operation:	Continuous operation
Overall system accuracy (RMS):	<1mm
Electrical safety standard:	EN-60601-1
EMC standard:	EN-60601-1-2
Physical dimensions	Height 190 cm, Length 51 cm, Width 99 cm
intended medical indication	Planning (pre-operative) and surgical (intra-operative) phases of dental implantation procedure
intended PATIENT population	Any patient who needs a dental implant
intended part of the body or type of tissue applied to or interacted with	Mouth; Gum;
intended USER PROFILE	Professional dentistry personnel
intended USE ENVIRONMENT	Healthcare (Hospitals and Dental Clinics)
operating principle	Accurate navigational guidance of surgical instruments

VI. Environmental Conditions for Transport and Storage

The IGI transport/storage packaging provides protection against exposure for up to 15 weeks to environmental conditions within the range below:

An ambient temperature range of 0°C to +40°C;

A relative humidity range of 10% - 80%, non-condensing; An atmospheric pressure range of 500 hPa to 1060 hPa.

VII. Information for Clinician

A. Intended Use/ Purpose

The IGI Image-Guided Implantology system is a computerized navigational system intended to provide assistance in both the planning (pre-operative) and the surgical (intra-operative) phases of dental implantation surgery. The system provides accurate navigational guidance of surgical instruments with regard to the pre-operative planning in dental implantation procedures.

B. Target Population

The device is intended for use for partially edentulous and edentulous patients who require dental implants as part of their treatment plan

C. Users

The Image-Guided Implantology (IGI) System is intended for use by a licensed dentist certified in IGI after completing the training course by Image Navigation authorized trainers, and upon certification by Image Navigation of competency with the IGI System.

D. Clinical Benefits

- **Improves accuracy:** Using IGI for dental implant placement improves the accuracy of implant placement, enabling the surgical result to follow the plan within 1.0 mm accuracy. This can improve the aesthetic result and avoid unwanted changes to the plan during surgery.
- **Reduces the risk of clinical complications:** IGI uses minimally invasive surgery, by not having to reflect a surgical flap. This can reduce pain, discomfort, swelling, and infections. Using IGI, increases safety by making it easier to avoid anatomical structures such as nerves, blood vessels, teeth, or sinuses.
- **Facilitates execution of the procedure:** Using IGI allows the clinician to verify accuracy in following the pre-surgical plan in real-time. Using IGI allows the clinician to shorten immediate placement and loading time. The planning results in a restoration-driven implant. IGI gives the surgeon the flexibility to change the plan on the spot.

E. Indications For Use

The IGI Image-Guided Implantology system, is a computerized navigational system intended to provide assistance in both the planning (pre-operative) and the surgical (intra-operative) phases of dental implantation surgery. The system provides accurate navigational guidance of surgical instruments with regard to the pre-operative planning in dental implantation procedures. The device is intended for use for partially edentulous and edentulous patients who require dental implants as part of their treatment plan.

F. Contra-Indications and Precautions

- Any conventional contra-indication regarding the placement of dental implants.
- Registration using the Minilock™ tray: NOT having 3 stable teeth f (at least 2 adjacent teeth).
- For Anatomic registration:
 - 1) Having artifacts on the CT scan

Or not having:

2) 3 cumulative cm of linear teeth

OR

3) 2 cumulative linear cm of teeth within 2 cm of the implant site.

When the patient has no contraindications for implants, however, does have the contraindications for the Minilock™ device, the clinician can follow the instructions for a fully edentulous patient using the optional titanium framework.

- **Precaution-** To prevent contamination, use gloves when using the device.

G. Cleaning, Disinfecting & Sterilizing

In all surgeries, all surfaces that may be touched by the dentist or dental assistant should be covered to prevent cross contamination. When using IGI, this should also include the camera handles, keyboard, and mouse

Instructions for cleaning, disinfecting and sterilizing are described in detail in **Chapter XIV Section B: Disinfecting and Sterilizing the IGI Kit Elements** on page 186.

H. Essential Performance

The IGI system essential performance is that any provided Handpiece drill tip tracking information would be accurate according to system specifications. Loss of essential performance would result in loss of tracking capability.

I. Drilling Autostop Box

The Drilling Autostop Box (DAB) is a recommended component for IGI which can be purchased separately. Only Image Navigation approved implant motors may be used with IGI (as specified in section IV).

The DAB provides the surgeon with additional assistance and security during the surgical (intra-operative) phase of the dental implantation procedure. The DAB is an extra safety feature which, when attached to IGI, prevents drilling when the drill is not in the correct location, angle or within the allocated depth according to the preapproved plan.

 **Warning:** The DAB, as other signals from the IGI software, is only an adjunct to assist the implantologist. It is the surgeon's responsibility to decide when to activate and when to stop drilling. The DAB gives no assistance and has no influence on the motor drilling speed.

 **Warning:** Use only with DAB (ref AIG40760) manufactured by image navigation

J. Service Life and Pre-Use Checks

The IGI System's lifetime expectancy is up to 7 years with normal usage according to the intended use/ purpose.

1. Reusable Components Service Life:

- Handpiece, Patient Tracker, and IGI burs: 7 years if it successfully passes the functionality test.
- Poles Kit: 7 years.
- Minilock™ Kit (tray and wedge): Up to 5 times with a maximum duration of one year based on the dentist's clinical judgement.
- Fully Edentulous Titanium Framework: 7 years.
- Horseshoe (for fully edentulous): Single procedure.

For Cleaning, Disinfecting and Sterilizing *see Cleaning, Disinfecting and Sterilizing* on page **185**.

2. Pre-Use Checks

- Perform a visual inspection of the Minilock™ and registration devices for defects
- Check the Minilock™ device after placement for adequate stability.
- Check the camera position
- Perform functionality tests.
- Perform accuracy validation.

If the functionality test fails twice, the handpiece needs to be sent to Image Navigation for recalibration.

VIII. Device Description and Workflow

The Image-Guided Implantology system is an image-guided surgery system, designed to provide guidance of surgical instruments used in dental implantation procedures. The IGI-system provides accurate guidance of surgical instruments relative to the patient's anatomical structures and to the pre-surgical plan, based on the patient's CT imaging.

The system is an infra-red optics-based navigational system, which utilizes an infra-red camera sensor and light-emitting diodes (LEDs) to monitor objects in a defined space. The system comprises of the following components: computer processing unit, the clinic monitor, tracking camera, a Minilock™ device and trackable appliances (designed to monitor the surgical hand-piece and patient position).

Alignment of the patient and CT images is accomplished through a registration process. The goal of the registration process is to synchronize the patient to the CT scan and to indicate the 3D position of the tracked handpiece and bur in relation to the planned implant location. The registration may be done using the fiducials on the Minilock, provided the CT was taken with the registration device in place. Alternatively, if the CT was taken without the fiducials, the anatomic method of registration is available.

The IGI System utilizes an infrared (IR) tracking system that is comprised of emitters, a camera and a tracking data processor (computer) to determine the location and orientation of the dental handpiece and the patient.



Figure 3: The IGI System

The position and orientation of both handpiece and patient are transmitted to a computer which depicts the handpiece, bur and planned implant location on the CT image. The surgeon places a virtual implant image in an optimal location by using the IGI planning software and available CT data. During implantation, the system correlates between the plan and the actual performance and presents the surgeon's progress on the screen. In case of significant deviation between plan and performance, the system alerts the surgeon.

A. Step-By-Step Process

1. Patient Selection

A patient suffering from partially functional or non-functional dentition and requiring dental implantation, as part of his/her dental treatment plan, is examined by a surgeon.

Which Customized Registration Device (CRD)?

Decide if the patient can use the partial edentulous method (at least 3 periodontally sound and stable teeth to support a Minilock™ tray and wedge; at least two of these teeth must be adjacent to each other, and the third must be located less than two teeth away.). Check for an exostosis or any other reason that will prevent the Minilock™ tray from completely seating on the occlusal table.

Alternatively, does the patient have enough bone height to support the bone screws needed in the optional fully edentulous method?

Choose Registration Method (partially edentulous).

The surgeon must first decide which registration method to use. This determines the workflow.

- **Anatomic Registration** is used when the patient already has a CT without the Minilock™ Device attached, or when there is no concern of artifacts on the CT due to metal fillings, or crowns. For this method, the patient must have 3 stable teeth for the Minilock™ Device in the relevant jaw and has a minimum of 2 cumulative linear cm of teeth (without artifacts) within a maximum gap of 2 molars (approximately 2 cm) from the implant sites or 3 cumulative linear cm of teeth if the gap is larger.
- When using anatomic registration, the CT is taken first, then implant planning, and on the day of surgery, the Minilock™ Device is customized.



Warning: Anatomic registration can be used if there are 3 teeth for the Minilock™ Device in the relevant jaw and has a minimum of 2 cumulative linear cm of teeth (without artifacts) within a maximum gap of 2 molars (approximately 2 cm) from the implant sites or 3 cumulative linear cm of teeth if the gap is larger.

- Fiducial Registration is used when there are too many artifacts on the CT. In this case, the CT must be taken with the Minilock™ Device in place.
- When using fiducial registration, the Minilock™ Device is constructed first, the CT is taken and then implant planning and consequently the surgery.

The following flow is for fiducial registration. When using anatomic registration, the patient first has the CT scan and implant planning. When the patient comes in for surgery, the CRD is prepared and registered with anatomic registration before surgery.

Note: *Image Navigation recommends adding the possibility of soft tissue injury as well as possible damage to teeth to the patient's consent form.*

2. Customized Registration Device (CRD) Preparation

For a **partially edentulous** patient, the surgeon **creates a Customized Registration Device (CRD)**, which can be the Minilock™ tray and wedge. The Minilock™ tray and wedge are used on stable teeth. The Minilock™ tray has radio-opaque silicon nitride markers (for fiducial recognition CT importing and registration) and are filled with an Image Navigation approved dental material, such as LuxaBite®¹.

In the case of a **fully edentulous** jaw, the surgeon can use the titanium framework. The titanium framework is used when 3 bone screws are placed in edentulous bone, an impression is taken and forwarded to the dental laboratory. The laboratory prepares a CRD consisting of a titanium framework and retentive caps which are supported over the bone screws. These bone screws are removed immediately after the surgery.

3. CT scan

When fiducial registration is used in either partial or fully edentulous cases, following final adjustment of the CRD, the patient undergoes a CT scan with the CRD in their mouth.

When anatomic registration is used, the CT is taken without the CRD in place (usually before the CRD is made).

4. Planning the Implants

The detailed and highly accurate digital CT information (0.1-0.3 mm slices) is imported into the IGI software.

The surgeon uses digital CT data and virtual implant images, available in IGI software, to plan the surgical procedure. Considering anatomical and prosthodontic factors, the surgeon selects the appropriate implant.

The surgeon places the virtual implants in the desired location and orientation on the

¹ LuxaBite® is a registered trademark of Ernst Muhlbauer GmbH & Co.

IGI Planning Screen, displaying the patient's CT information in 3 dimensions. The precise location, angulation and type of virtual implant are determined based on the inter-maxillary relations, bone structure and width, and adjacent critical anatomical structures.

Alternatively, the surgeon can import the planning from an Image Navigation approved third party planning software company (See **Appendix Four: Import Planning from Exocad** on page 214. Then final planning is completed in IGI.

5. Registration

The CT images are correlated with the patient's location by registering the silicon nitride markers on the Minilock™ tray, or by tracing teeth using the anatomic registration method.



Warning: Anatomic registration can be used, only if there are 3 cumulative linear cm of teeth without artifacts on the CT scan, or 2 cumulative linear cm of teeth within 2 cm of the implant site without artifacts on the CT (e.g. from metal crowns, or fillings).

6. Implantation Procedure

When the optional Drilling Autostop Box (DAB) will be used, follow the set-up instructions in the DAB manual.

During the implantation procedure, the CRD is attached to a Patient Tracker outside the patient's mouth, for tracking patient movements and updating patient location. The optional fully edentulous CRD has removable components, enabling the surgeon to remove part of it, if necessary, for convenience during surgery.

Using the IGI guiding indicators, the surgeon places the bur at the implant site and starts the procedure. The surgeon uses an IGI handpiece to which a Handpiece Tracker is attached to enable real-time tracking by the system. The surgical implantation is performed according to the pre-operative plan, in the usual manner. During the implantation procedure, the surgeon must refer to the IGI Procedure Screen to view the location and orientation of the implant.

During the actual surgery procedure, the system identifies any deviation from the planned osteotomy. The IGI guiding indicators warn the surgeon both visually and audibly. In addition, the optional drilling Autostop (DAB) will automatically stop the drill when deviating from the preoperative implant plan. After drilling is completed,

the implants are inserted using IGI.



Warning: The DAB, like the other signals from the IGI software, is only an adjunct to assist the implantologist. It is the surgeon's responsibility to decide when to activate and when to stop drilling.

IX. Software Controls

The IGI software has four main screens: Log-In Screen, Archive Screen, Planning Screen and Procedure Screen.

A. IGI Log-In Screen



Figure 4: IGI Log-In Screen

IGI User Manual

To enter the IGI application, type your **Name** and **Password**.

You may use the On-Screen Keyboard. To do this, click the **Keyboard** button.

The On Screen Keyboard window displays

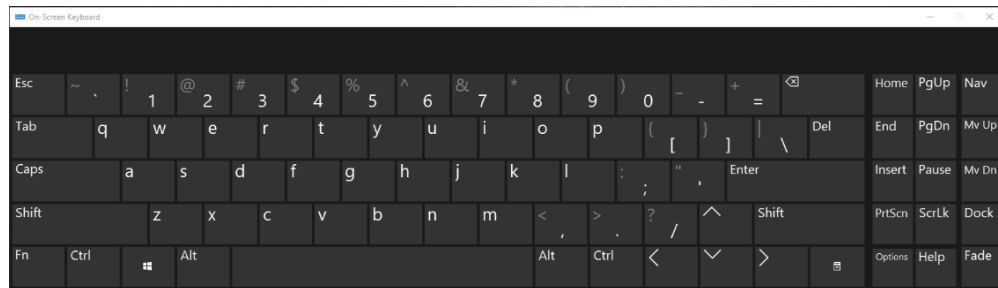


Figure 5: On Screen Keyboard

After typing your name and password, click **Login**.

The Archive Screen displays

B. Archive Screen

The Archive Screen presents a list of CT sessions of patients, and patients' information. Use the Archive Screen to create a new session, import, or to edit an existing one by copying and pasting it to another drive, or by deleting it. Use the **New**, **Import**, **Copy**, **Paste**, and **Delete** buttons accordingly.

To proceed to **Planning** or **Procedure Screens**, click the relevant button located on the bottom right.

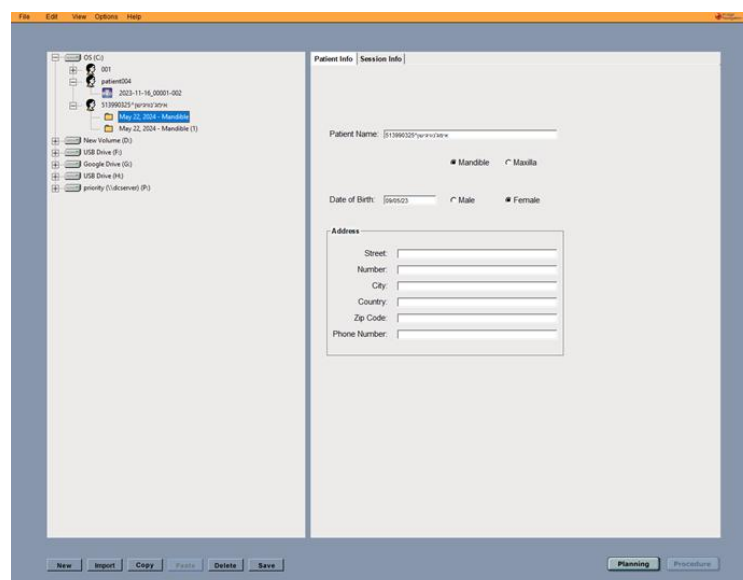


Figure 6: IGI Archive Screen

C. Planning Screen

Use the Planning Screen to perform a pre-surgical plan of the implants based on CT data.

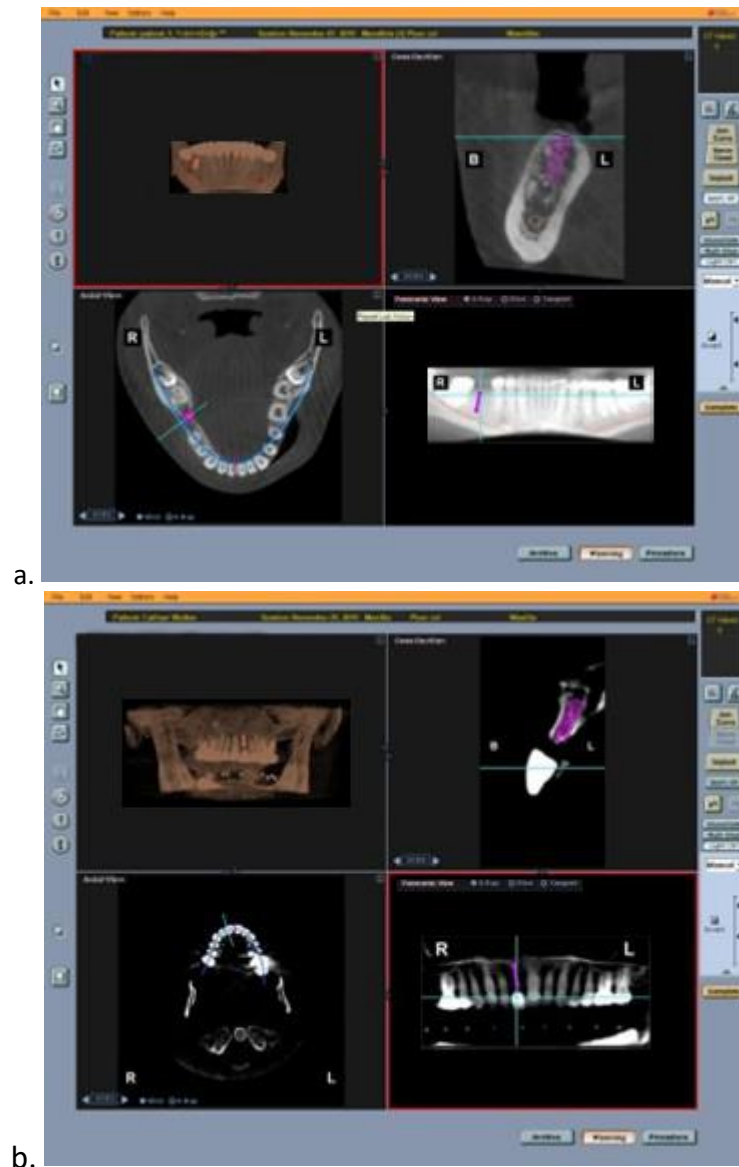


Figure 7: IGI Planning Screen (a. Mandible Session; b. Maxilla Session)

- The Planning Screen displays 4 CT views:
- Panoramic View Axial View
- Cross-Section View 3D View
- Click inside a view to activate it. The active view is outlined with a red

line.

- Click the **square** in the upper right corner of any view to maximize or restore it to its original size.
- To extend a view in one direction, click the small **arrows** on the dividing lines. Click again to restore it to the original size.

In each view, there are azure colored **reference lines** indicating the relation between the different CT views.

- Drag the reference lines on one view to scroll between slices of another view.
- You may also scroll between CT slices, using the Slice Counter (the arrows in the bottom of the view), or scroll the mouse forward and backwards.

Implants' planning is performed using the **control buttons**, located around the Planning Screen. These are detailed below:



Figure 8: Planning Screen Buttons

1. **SELECT** button — Enables you to select and drag objects.
Used for selecting and dragging objects such as implants, guides, restorations, Markings of Jaw Curve or Nerve Canal.
 1. Select the SELECT button and place the mouse pointer on an object or next to it. Select the object and drag it to the desired position.
2. **ZOOM** button — Enables you to magnify the CT image.
 1. Select the ZOOM button and drag the mouse: Drag it from left to right for zoom-in, and from right to left for zoom-out.
 2. On the Planning Screen, you may use a keyboard shortcut: Hold the Ctrl

button and use the mouse as described above.

3. **PAN** button — Enables you to move the CT image.
 1. Select the PAN button, place the cursor on the desired image and drag it in the desired direction.
 2. On the Planning Screen, you may use a keyboard shortcut: Hold the Shift button and use the mouse as described above.
4. **ROTATE** button — Enables you to rotate the CT image in different pivots.
 1. Select the ROTATE button and place the cursor on one of the views. A round image with three different pivot options appears on the screen (marked with arrows). Locate the cursor closest to the desired option and drag the mouse according to arrows.
 2. On the Planning Screen you may use a keyboard shortcut: Hold the Alt button and move the mouse as described above.
5. **DRAW** button — Enables you to plot the Jaw Curve and the Nerve Canal. This button is enabled only in the Jaw Curve mode and Nerve Canal mode.
 1. Select the DRAW button. Place the cursor in the desired location, then click the mouse to mark a point at this location
 2. Repeat this action to draw points along a desired path. The points are automatically joined to configure the Jaw Curve or the Nerve Canal.
6. **ERASE** button — Enables you to erase objects such as implants, guides, markings of Jaw Curve or Nerve Canal.
 1. Select the ERASE button. Place the lower left point of the eraser over the item you wish to erase and click the mouse.
7. **GUIDE** button — Enables you to draw a “Guide”, which marks the long axis of adjacent teeth. The guide can be manipulated in the same way as an implant.
 1. Select the GUIDE button. Place the cursor where you wish to draw a guide, then click the mouse.
8. **LIMIT IMPLANT** button — Enables you to move an implant up and down only. Used to preserve implant’s orientation.
 1. Select the LIMIT IMPLANT button. Place the cursor on the implant and drag the mouse up or down.
9. **RESET** button — Enables you to reset the CT image in the selected view, after magnification, rotation or pan movement have been made.
 1. Click the RESET button to reset the CT image in the selected view.
10. **SCREEN SHOT** button — Enables you to save a screen shot (Print Screen) to a default directory.
 1. Click the SCREEN SHOT button to save a screen shot.
11. **CT VALUES** field — Displays values between 0-4095 which represents the “grey-

level” of the CT image. Available in all three views apart from the X-Ray mode.

1. Place the cursor on the CT image, in the desired area (e.g., bone, tooth, etc.). The CT values are displayed automatically - clicking the mouse is not needed.
- 12. LENGTH & ANGLE VALUES** field— Displays measured distance value in millimeters, (see no. 13 below) or angle between implants, guides and restorations, when using the Parallel Implant tool (see no. 14 below).
- 13. DISTANCE MEASUREMENT** button — Enables you to measure the distance between different objects such as implant, tooth and nerve canal. The accuracy of this measurement is 0.2mm +/- 0.1mm. This tool is enabled in all three views, apart from the X-Ray and Slice modes of the Panoramic View.
1. Select the DISTANCE MEASUREMENT button and place the cursor on one object. Then drag the measuring line to another object and release it to set the distance marker. (To view the measured value, see no. 12 above).
- 14. PARALLEL IMPLANT** button — Use this tool after multiple implants have been placed, to align them perfectly parallel to each other in 3 dimensions. This function is detailed in the section *Positioning the Implant*, on page 96
- 15. JAW CURVE** button — Enables the Jaw Curve mode. In this mode you can use the Draw tool to plot the Jaw Curve (see no. 5 above).
1. Select the JAW CURVE button to enable the Jaw Curve mode.
- 16. NERVE CANAL** button — Enables the Nerve Canal mode. In this mode you can use the Draw tool to plot the Nerve Canal (see no. 5 above).
1. Select the NERVE CANAL button to enable the Nerve Canal mode.
- 17. IMPLANT** button — Enables you to select an implant image from an Implant Menu, according to manufacturer, shape, size and length.
1. Select the IMPLANT button to open the Implant Menu window.
- 18. APPLY ALL** button — Applies the three aids below it (SHOW/HIDE, MULTI-SLICE, and LIGHT CTRL) on all three views (simultaneously).
1. Click the APPLY ALL button to enable it. A second click will disable this button.
- 19. UNDO** button — Cancels the last performed action.
1. Click the UNDO button to delete the last performed action. You may click up to eight times to delete multiple actions.
- 20. REDO** button — Repeats the last cancelled action.
1. Click the REDO button to repeat the last cancelled action. You may click up to eight times to repeat multiple actions.

21. SHOW/HIDE button — Enables displaying or concealing of the planning aids.

1. Click the SHOW/HIDE button to display the planning aids menu, from which you may select the items you wish to be displayed or concealed.

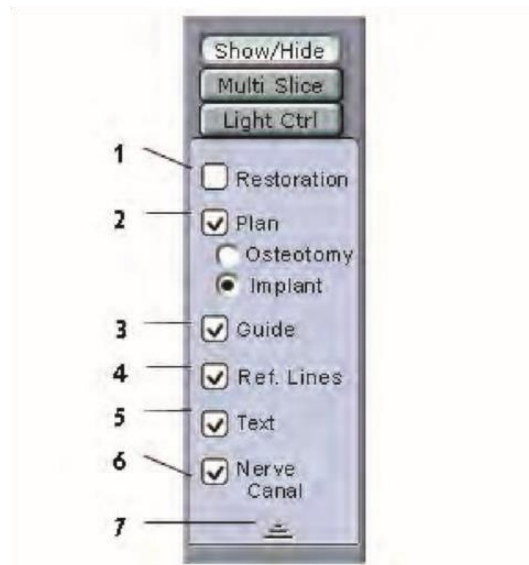


Figure 9: Show/Hide Aid

1. **RESTORATION** — Displays a long axis of restoration on all implants. The restoration can be manipulated as detailed in the section ***Fine Adjustments to Implant Placement***, on page 99.
2. **PLAN** — Displays either planned osteotomy (mesh image), or planned implant (3D image), or no plan.

Note: In the Panoramic View (X-Ray and Slice modes), the implant is represented by a symbolic line. When using an implant added to the database by the user, no 3D image of the implant is available.

3. **GUIDE** — Displays the planned guides (see no. 7 above).
 4. **REF. LINES** — Displays the reference lines.
 5. **TEXT** — Displays the text on CT images (the direction markers: B-L, R-L).
 6. **NERVE CANAL** — Displays the Nerve Canal markings.
 7. **HIDE** — Hides the drop-down menu.
- ## 22. MULTI-SLICE button — Enables displaying or concealing of the multi-slice aids.
- a. Click the MULTI-SLICE button to display the multi-slice aid menu, from which you may control the slices you wish to be displayed or concealed.

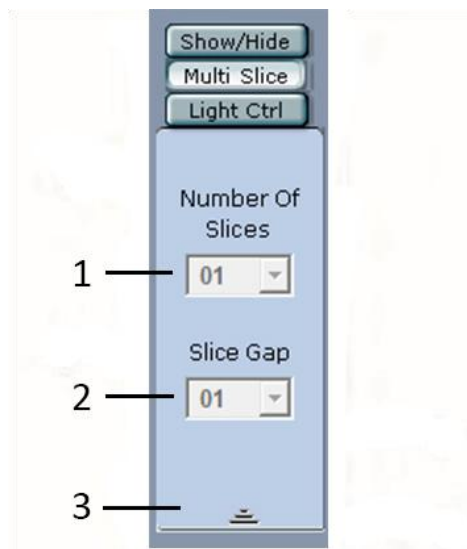


Figure 10: Multi-Slice Aid

1. Number of Slices — Defines the number of slices to be displayed in the selected view.

Note: The default number of displayed slices is 1.

2. Slice Gap — Defines the gap between displayed slices, i.e. consecutive slices, or every 2 slices or more. The gap range is 1-4 slices, and the default gap is 1 slice.
3. Hide — Hides the drop-down menu.

23. LIGHT CTRL button — Enables displaying or concealing of the light control aid.

Click the LIGHT CTRL button to display the light control aid menu, which controls the brightness and the contrast of the screen.

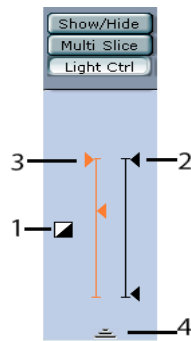


Figure 11: Light Control Aid

1. **Invert** — Enables one to invert the black and white picture. In 3D view, this toggles between surface rendering and volume rendering.
 2. **Black Slide Regulators** — Controls the screen brightness (bottom) and contrast (top) automatically or manually in 2D views. In the 3D view, the top arrow controls the minimum density (soft or hard tissue layers) are seen, while the lower arrow controls the density level for the teeth. Anything below it has a higher density (teeth) and will look whiter.
 3. **Orange Slide Regulator** — Controls the opacity between the limits set with the black arrows (only available in the 3D View). The arrow on the left controls the opacity of the CT, while the arrow on the right controls the opacity of the 3D model. The right arrow is displayed when a 3D model is imported.
 4. **Hide** — Hides the drop-down menu.
-
24. **COMPLETE** — Used for the completion of the Jaw Curve drawing or the Nerve Canal marking and automatically enables the next possible function.
 25. **ARCHIVE** — Displays the Archive Screen.
 26. **PLANNING** — Displays the preceding Planning Screen.
 27. **PROCEDURE** — Displays the Procedure Screen.
 28. **SLICE COUNTER** — Defines the slice number and enables scrolling between slices. To see the scrolling direction, place the cursor close to the arrow. The slice counter is accessible in all views of the Planning Screen, apart from the 3D View.



Figure 12: Slice Counter & Direction Mark

D. Procedure Screen

The Procedure Screen enables performing implantations using the IGI indicators, and other related preparation.

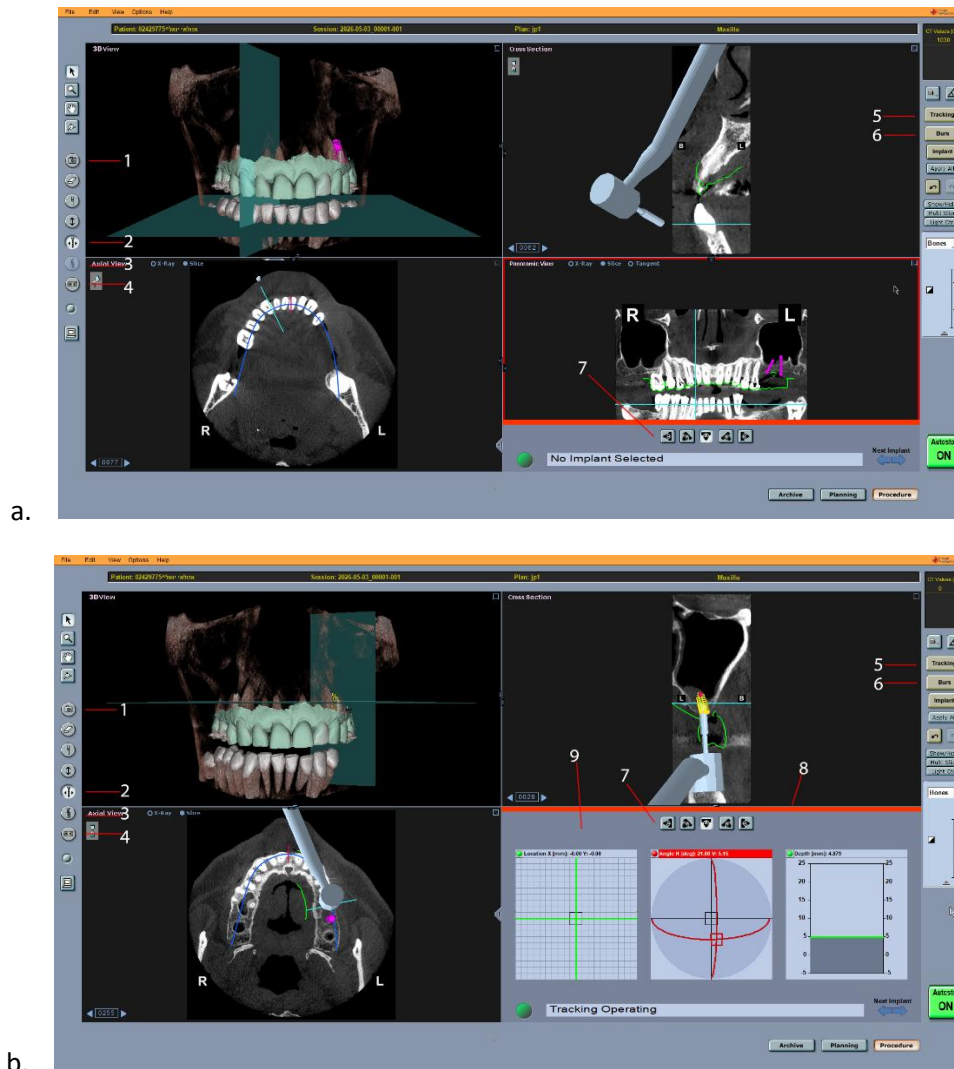


Figure 13: IGI Procedure Screen

a- after accuracy validation, b- after when drill tip is in the implant area

The Procedure Screen is similar to the Planning Screen, with the following differences:

1. Four additional buttons are available:
 - **SNAPSHOT** button (1) — Enables you to take a snapshot of the drill in the bone once the osteotomy is completed. The drilled bone is marked with a grey implant image.
 - **AUTOPAGE** button (2) scrolling of the reference lines in all three views, to the position of the drill tip.
 - **ON THE FLY** button (3) — Enables intuitive implant insertion, not according to a

plan, as well as intra-operative plan changes. The implant image is attached to the drill tip and can be re-positioned by the surgeon.

- **CAMERA POSITION TOOL button (4)** — allows on demand or continuous real time positions of the handpiece 2C and the patient tracker LEDs within the camera's field of view.

Note: These buttons are available only when tracking is operating. Use of these buttons is detailed in the section **Drilling Procedure**, on page **142**.

2. The Jaw Curve and the Nerve Canal buttons, as well as the Complete button, are replaced by two other buttons:
 - **TRACKING button (5)** — Enables you to perform several pre-surgical preparations, which are related to the tracking system.
 - **BURS button (6)** — Enables you to select a virtual bur from a Bur Menu, according to manufacturer, type, diameter and length, to be used during the procedure.
3. Once Registration is completed, the bottom of the panoramic window shows an additional window at the bottom with instructions to validate accuracy.
4. The row of pictures **(7)** are the indicators for surgeons sitting position. See Section XX, Appendix Five: Indicators in Relation to Surgeon's Sitting Position on page 218.
5. After validating the accuracy, the accuracy validation button is pressed. Once the handpiece is held in the area of the implant, the Panoramic View is replaced by the **INDICATORS VIEW (8)**. To extend the Indicators View over the Axial View, click the small arrows on the dividing lines. Click again to restore it to the original size.
6. The line on the top of the indicators view **(9)** is the DAB (autostop) indicator line. This line is green when the DAB is active, red when inactive, and dark grey when turned off.

Note: The indicators are available only when tracking is operating.

Instructions for using the indicators are detailed in the section **Drilling According to IGI Indicators**, found in section **Drilling Procedure** which start on page **142**.

Before drilling, verify that the Minilock™ device is fully seated (every time the drill is used).

7. The **DAB button (8)** on the right side of the screen shows if the autostop is on, off, or disconnected. It can be pushed to change the autostop from on to off or off to on.

X. IGI Kit & Device Controls

A. IGI Kit

1. IGI Handpiece & Handpiece Tracker

During the implantation procedure, a Handpiece Tracker (**Figure 6**) is attached to the IGI Handpiece with a thumb screw and 2 pins which go into the corresponding holes. See **Figure 14: IGI Handpiece & Handpiece Tracker** on page 53 . The thumb screw can be tightened or loosened by hand or with the allen wrench from the poles kit. The Handpiece Tracker has IR emitters, light emitting diodes (LEDs), located on its surface, which enable the IR camera to track the handpiece movements. To enable both maxillary and mandibular implantations, different configurations are available on the IGI Handpiece. These positions are marked with “MAX”, “MND”, and “MND 1”, printed on the IGI Handpiece. “MND” is used when surgeons sit at the 10-12 o'clock position. “MND1” is used when surgeons sit at the 9 o'clock position. Each IGI Handpiece has its own serial number, which is printed on the handpiece. The Handpiece Tracker has the same serial number printed on its back side.

a.



b.



c.



d.



Figure 14: IGI Handpiece & Handpiece Tracker

(a. Mandible Assembly; b. Mandible1 Assembly; c. Maxilla Assembly; d. Dismantled Tracker)

2. Patient Tracker

During the implantation procedure, a Patient Tracker is placed outside the patient's mouth connected to the CRD (comprised of a Minilock™ Device or a titanium framework). This tracker has IR emitters (LEDs) located on its surface, which enable the IR camera to track the patient's movements. Each Patient Tracker has its own serial number, printed on its back side.



Figure 15: Patient Tracker

3. The Minilock™ Device

The Minilock™ Device includes the following:

- Posterior Minilock™ tray and wedge
- Anterior Minilock™ tray and wedge

The Minilock™ tray and wedge are used to temporarily attach the patient tracker to the teeth. It contains radiopaque silicon nitride markers, which act as fiducial points. Therefore, the Fixation Device enables the interface between the CT scan and the patient.

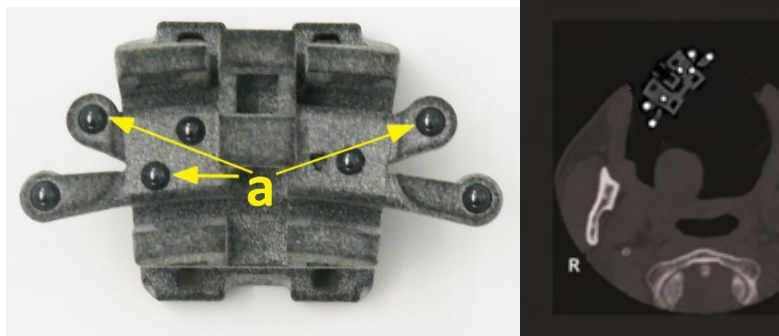


Figure 16: Silicon Nitride Markers of Minilock™ Tray as Shown in CT Scan

During the implantation, the IGI tracking system tracks the patient's location by a Patient Tracker that is connected to the CRD through a pole. The Minilock™ Device kit is divided into two different packs.

The first two kits consist of 10 posterior or 10 anterior **single patient multiple use** patient packets. Each one has the following items:

- 1 posterior Minilock™ tray (1 unit) or 1 anterior Minilock™ tray (1 unit)
- 3 different size wedges
- Additional trays and wedges may be purchased through your distributor or Image Navigation.



Warning: Discard all items after *single patient use*. Failure to do so, may cause cross-infection between patients.

The tracker pole kit contains the following items:

- 7 different Patient Tracker poles
- Metal hex screws (6 units)
- Allen Wrench (1 unit)
- Pole Removal Device



Warning: All these items are reusable. Sterilize before

each use. Failure to do so may cause infection.

The various Minilock™ Devices are shown below:

The Posterior Minilock™ Tray

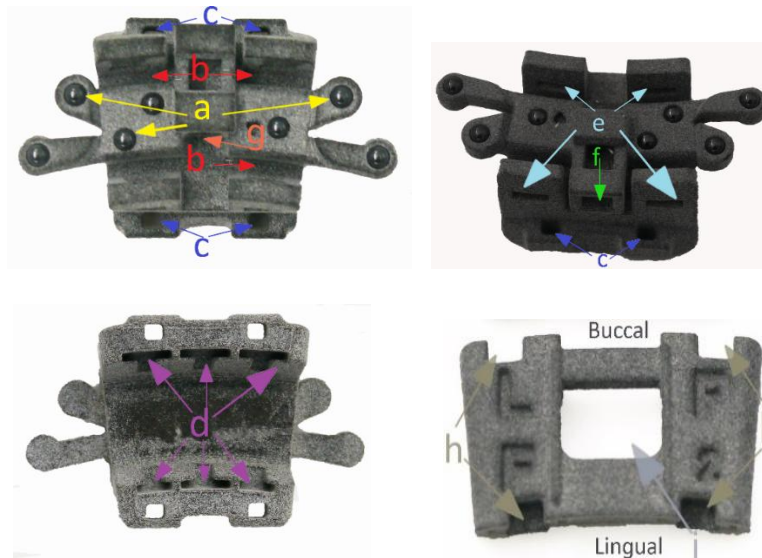


Figure 17: Posterior Minilock™ Tray and Wedge

The Anterior Minilock™ Tray



Figure 18: Anterior Minilock™ Tray and Wedge

The Minilock™ tray has the following features:

- 7 silicon nitride markers (a)-yellow arrows

- Long troughs for the wedge to fit in (b) red arrows
- Notches for the wedge and tray removal instrument to engage the tray, 2 on the buccal and 2 on the lingual of the posterior tray or 2 on the buccal of the anterior tray, (c) blue arrows
- Slots for the LuxaBite® to engage the tray on the lower portion (d) purple arrows
- Rectangular notches for the wedge to lock in, 2 on the mesial and another 2 on the distal (e) turquoise arrows
- 1 rectangular notch for the pole on the buccal side (f) green arrow
- 1 circular notch on the lingual side for the screw to hold the pole (g) orange arrow

Minilock™ Wedge

- Notches for the placement of the wedge and tray removal device (h) tan arrows
- Center hole (in posterior wedges), or occlusal-mesial and occlusal-distal holes (in anterior wedges) for dental floss placement (i) gray arrow

The Pole is used to attach the Minilock™ tray to the patient tracker

- Designated flat area for bur length measurements (green arrow) between the two lines (red arrows as seen in *Figure 18a*)
- Round notch for handpiece functionality test (blue arrow in *Figure 18a*)
- Screw indicating line- the line which should touch or be pulled into the pole housing aspect of the Fixation device (purple arrow in *Figure 18b*)

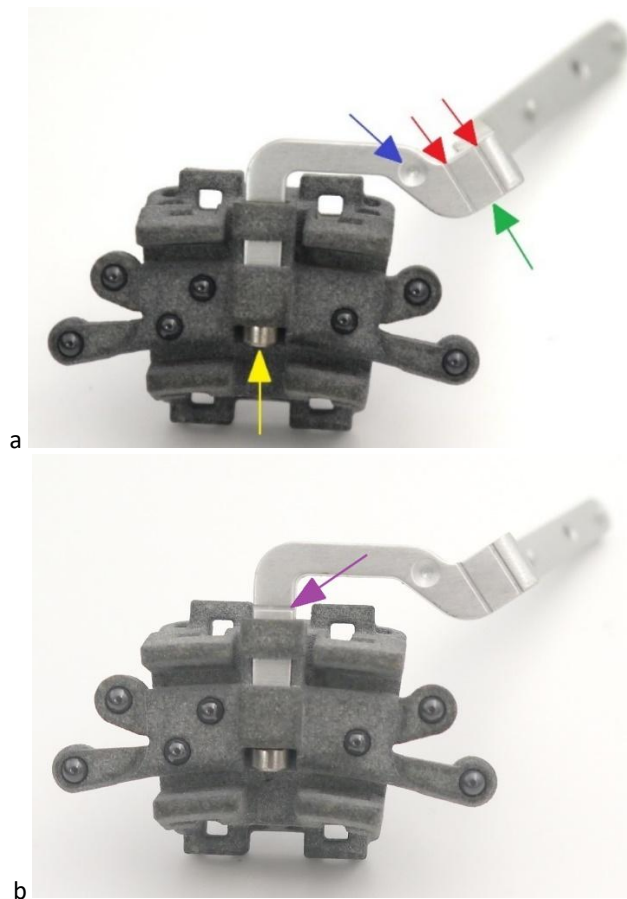


Figure 19: Minilock™ Tray with Pole

(a- bur length measurement; round notch for handpiece functionality test; b- screw indicating line)

- Patient Tracker Poles
- The Patient Tracker pole is attached to the Minilock™ tray during the surgical and pre-surgical stages.
- One end of the pole is inserted into the buccal side of the Minilock™. A metal hex screw (yellow arrow in figure 18) is attached using the allen wrench.
- Screw the pole into the Minilock™ tray or so that the first line (screw indicating line) comes close or disappears into the pole aspect of the Minilock™ tray (purple arrow in Figure 18b). The other end is attached to the Patient Tracker with a metal thumb screw.
- There are seven types of poles:
 - 3 poles for mandible: right (black ring), middle (red ring) and left (blue ring).
 - 4 poles for maxilla: 2 right (orange and white rings), 1 middle (yellow ring) and 1 left (green ring).

Seven different types of poles are presented in **Figure 19: : Mandibular Patient Tracker Poles** on page 58, and **Figure 20: Maxillary Patient Tracker Poles** on page 58. There are 2 pole options for the maxillary right. Use whichever fits the patient's anatomy better.

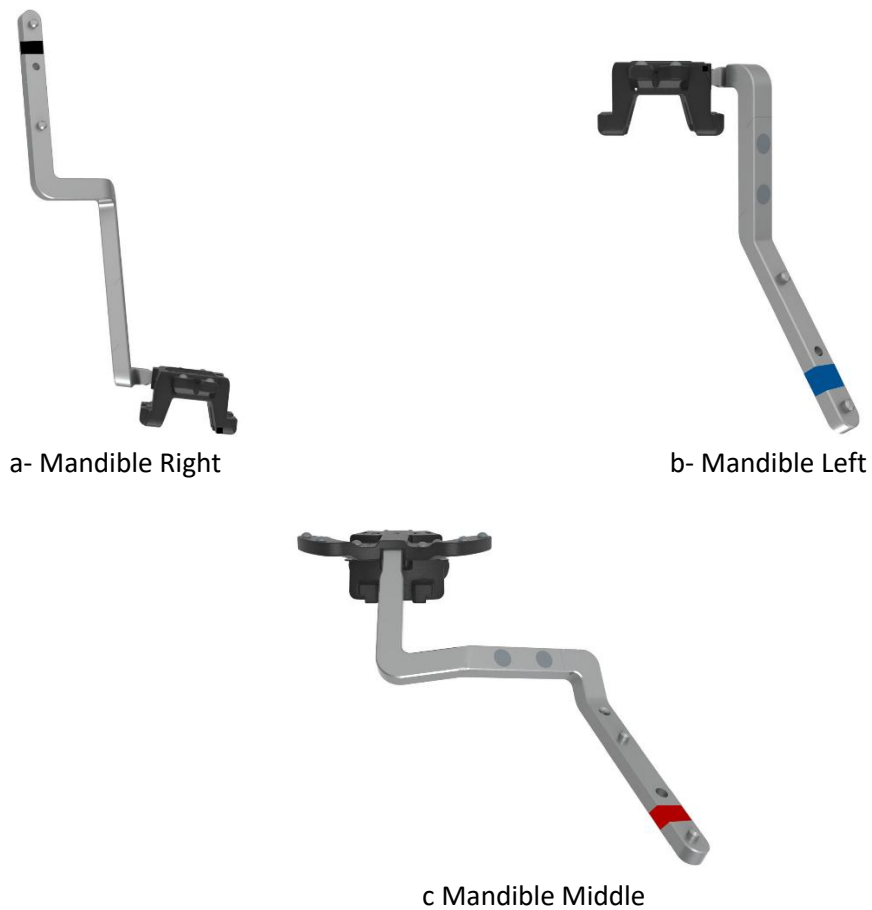


Figure 20: : Mandibular Patient Tracker Poles

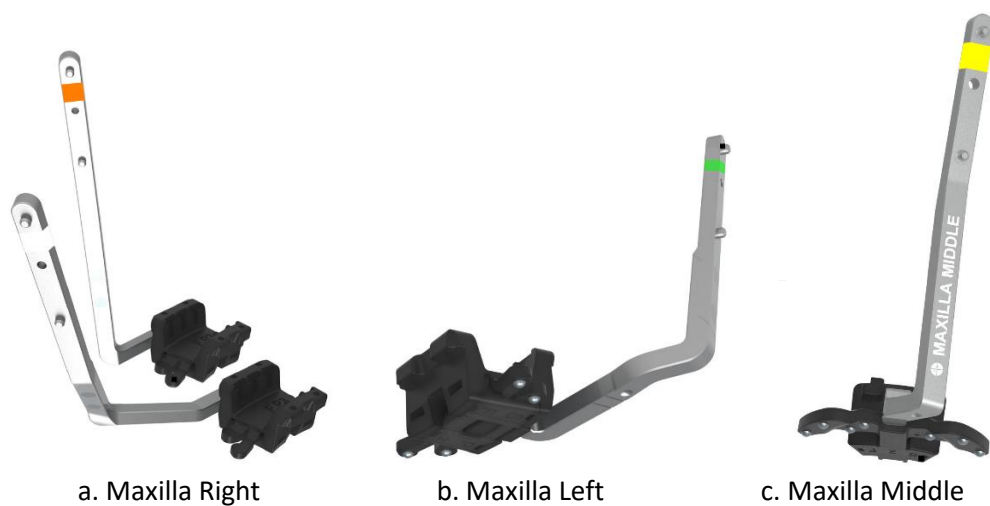


Figure 21: Maxillary Patient Tracker Poles

4. TRI (Tray Removal Instrument)

There are three TRI's, two posterior and one anterior.

Posterior TRI

The posterior TRI has 4 prongs to fit into the 2 buccal and two lingual notches in the posterior Minilock™ tray. **Do not** open the Minilock™ tray by rotating the TRI. For detailed instructions see *Removal of the Fixation Device* on page 73.

In addition, a Rubber Dam Forceps with curved prongs, can be used as a secondary Posterior TRI. This should be used only once the Minilock™ tray with LuxaBite® has been opened once with the original posterior TRI.

Anterior TRI

Place the tray removal instrument (TRI) into the appropriate buccal slots of the Minilock™ tray fully, so that the side flexible locks engage the bottom of the slots. With light to moderate pressure squeeze the TRI handles which opens the 2 sides of the tray. **Do not** open the Minilock™ tray by rotating the TRI.



Figure 22: Posterior TRI and Rubber Dam Forceps as TRI



Figure 23: Anterior TRI

5. IGI Burs

These IGI burs are used during pre-surgical preparations and are found in the bur menu under Image Navigation:

a. IGI LONG BUR

The IGI long bur is used for the handpiece functionality test and for bur point measuring.

- b. IGI SHORT BUR**
The IGI short bur is used for handpiece calibration (together with the long bur). Calibration is performed by IGI authorized technicians only.
- c. IGI REGISTRATION BUR**
The IGI registration bur is used to register the silicon nitride markers of the Minilock™ tray as well as the horseshoe.
- d. IGI TRACING BUR**
The IGI tracing bur is used for tracing with the anatomic method of registration.



Figure 24: IGI Burs

(a. Long Bur; b. Short Bur; c. Registration Bur; d. Tracing Bur)

6. IGI Kit for Fully Edentulous Jaw Implantation (optional)

For details regarding this, see **Table 6: Clinic's components of Kit for Fully Edentulous Jaw**, page 163 .

B. Device Controls

1. Switches

- a. MAIN INPUT SWITCH**
The main input switch is located on the rear panel of the cart base and turns the mains supply **ON** or **OFF** (O).
- b. COMPUTER SWITCH**
The computer switch is a push button in the user interface panel located on the cart pole of the IGI cart (yellow arrow in **Figure 24** on page 61.

To turn the computer **ON**, press this button once.

To turn the computer **OFF**, press this button again.

2. Connectors

The user interface panel contains three different connectors below the power button (yellow arrow):

- a. **HANDPIECE TRACKER** connector (green arrow)
- b. **PATIENT TRACKER** connector (blue arrow)
- c. **1 USB CONNECTOR** (pink arrow)

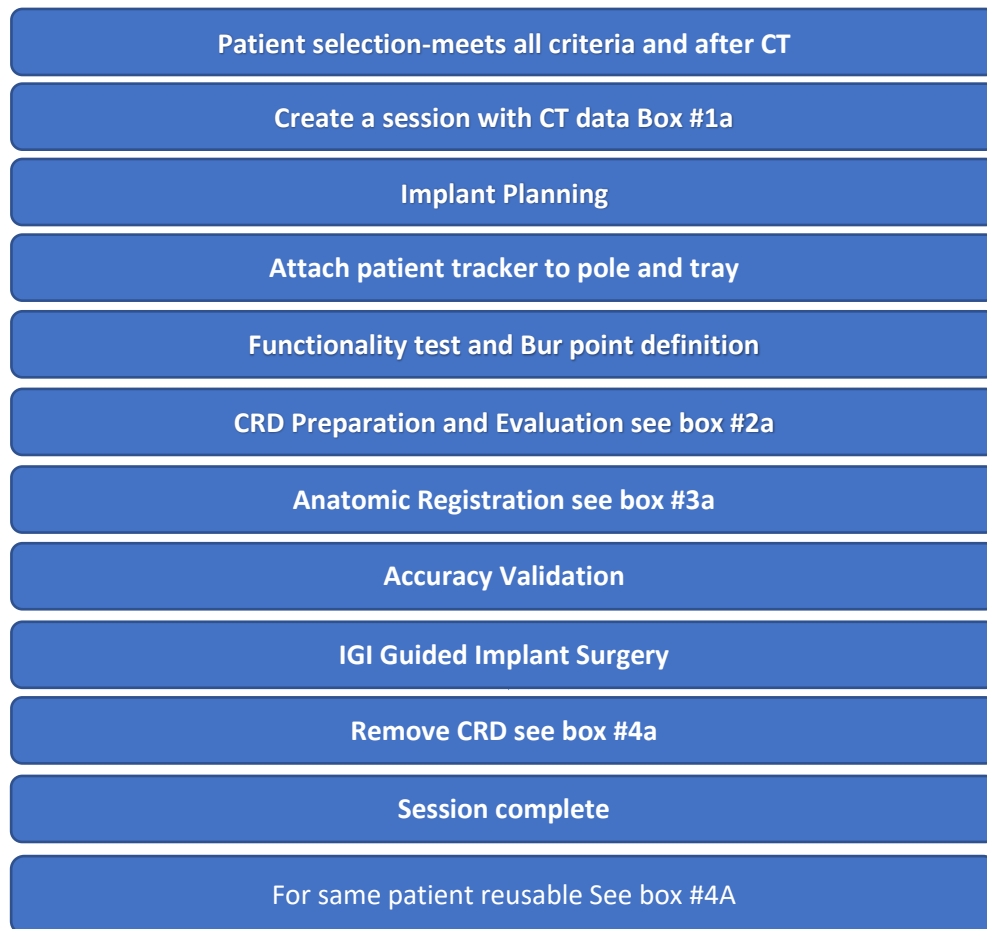


Figure 25: User interface panel

XI. Operating Instructions for Implantation in a Partially Edentulous Jaw

The IGI implantation process in a partially edentulous jaw has 4 main stages: initial preparations, planning the implants, pre-surgical preparations and the implantation procedure. The general workflow of partially edentulous jaw implantation is described in the chart below.

Chart 1: General Workflow of Partially Edentulous Jaw Implantation using Anatomic Registration



BOX #1A

CT must be in a folder called "CT"

Open IGI archive screen, press New to import a new CT and create a new session

BOX #2A

Choose Minilock™ device site based on the specified criteria

If Needed: Block out large undercuts or missing teeth in area of Minilock™

Cover all composite fillings and crowns with glycerin

Minilock™ trays:

Place LuxaBite® in tray, fully seat on the occlusal table. Remove excess. Have patient bite on cotton roll and air cool while material sets (setting time 4 minutes).

Place the appropriate wedge (with attached floss) and lock into place.

Wedge should click into place

If patient complains about excessive heat while using air cooling, remove device

Verify stability (If unstable, start again with a new Fixation)

BOX #3A

In the tracking window of IGI, open the registration tab

mark 4 landmarks on teeth in CT scan

Use the tracing bur to touch the same 4 landmarks in the patient's mouth

Trace buccal, occlusal, and lingual sides without removing bur from the tooth surfaces until change in the audible indicator3 options 1- Continue tracing

2- Hold position for 2 seconds, remove handpiece and stop

3- Proceed with option 2, but instead of stopping completely, move to a new starting point and continue the tracing process

After completing tracing click the register button (✓)

BOX #4A

Minilock™: Remove the wedge by placing the wedge and tray removing device in the buccal or lingual slots of the wedge, then rotate and lift

Repeat on the other side if necessary

Place the wedge and tray removal device in the buccal and lingual slots of the tray and rotate to open (Do not rotate either side more than 45°)

Remove the Minilock™ tray Remove any remaining LuxaBite® from teeth with an explorer or dental floss

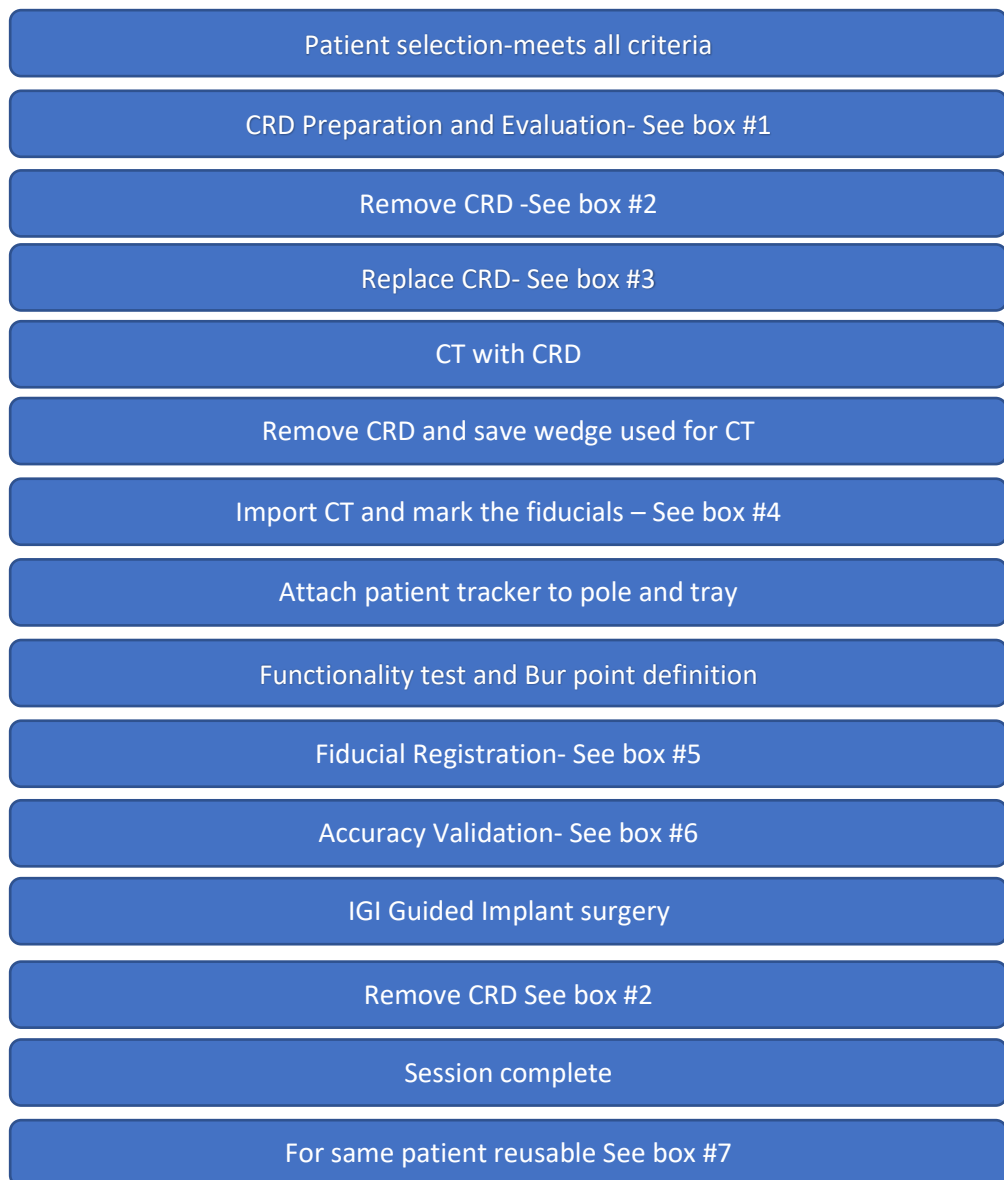
Remove CRD with wedge

With a wire cutter, cut out any large pieces of LuxaBite® that go into the undercut

Using a 3-way syringe, blow out internal part of Minilock™ tray

The Fixation device is ready to use on the same patient after cold disinfection. A new tracing registration must be done if the pole has been removed. After placing the Fixation tray the second time, return to **Anatomic Registration see box #3a**

Chart 2: General Workflow of Partially Edentulous Jaw Implantation using Fiducial Registration



BOX #1

Choose Fixation device site based on the specified criteria

If Needed: Block out large undercuts or missing teeth in area of Minilock™

Cover all composite fillings and crowns with glycerin

Minilock™ trays:

Place LuxaBite® in tray, fully seat on the occlusal table. Remove excess. Have patient bite on cotton roll and air cool while material sets (setting time 4 minutes).

Place the appropriate wedge (with attached floss) and lock into place.

Wedge should click into place

If patient complains about excessive heat while using air cooling, remove device

Verify stability (If unstable, start again with a new Minilock™)

BOX #2

Minilock™:

Remove the wedge by placing the wedge and tray removing device in the buccal or lingual slots of the wedge, then rotate and lift. Repeat on the other side if necessary

Place the wedge and tray removal device in the buccal and lingual slots of the tray and rotate to open (Do not rotate either side more than 45°)

Remove the Minilock™ tray Remove any remaining LuxaBite® from teeth with an explorer or dental floss

Remove CRD with wedge

BOX #3

With a wire cutter, cut out any large pieces of LuxaBite® that go deep into the interproximal area

Using 3-way syringe, blow out internal part of Minilock™ tray

Fully seat the tray and attach the wedge as before Verify stability

(If unstable, start again with a new Minilock™- Box #1)

BOX #4

CT must be in a folder called "CT"

Open IGI archive screen, press New to import a new CT and create a new session

Use the slice with the brightest fiducials. Different slices may be used to mark different fiducials

BOX #5

In the tracking window of IGI, open the registration tab

Select the registration segment

Using the Registration bur, register 5-7 fiducials, always marking the fiducial indicated by the green colored fiducial on the screen

After completing tracing press OK to complete registration

BOX #6

Recommended Accuracy Validation: Verify registration in verification tab, by touching landmarks on teeth, or the fiducials, and verifying proximity to markings on screen

Mandatory Accuracy Validation: Verify registration by touching landmarks on teeth and verifying on the screen

BOX #7

With a wire cutter, cut out any large pieces of LuxaBite® that go into the undercut

Using a 3-way syringe, blow out internal part of Minilock™ tray

Fixation device is ready to use on the same patient after cold disinfection. A new registration must be done if the pole has been removed. After placing the Fixation tray a second time return to Attach patient tracker to pole and tray

A. Initial Preparations

Preparing the patient for implantation with IGI requires several preparatory procedures. After selecting the patient, a CRD is prepared, and a CT scan is performed. For fiducial registration, the CRD must be made before the CT. For anatomic registration, it can be made on the day of surgery.

The following sections describe patient selection, CRD preparation, and CT scan.

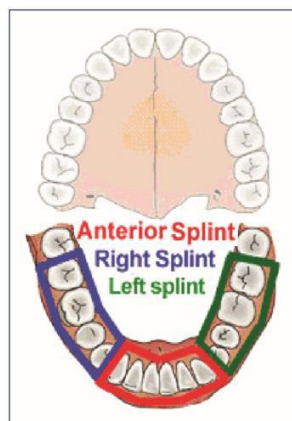
1. Selecting the Patient

Only a patient that meets the following criteria can be a candidate for an IGI dental implantation:

- The patient is clinically evaluated by a dental surgeon and must meet all the clinical conditions that support implant-based rehabilitation.
- The alveolar crest is clinically evaluated to establish if it could accommodate implant placing. If necessary, simple X-rays may be used in addition to the clinical evaluation.
- The patient is only partially edentulous, i.e. at least three to four stable teeth (minimum of 2 adjacent) must be present to support the Minilock™ tray. Alternatively, the Fully edentulous method can be used.
- For anatomic registration, an additional 2 cumulative linear cm of teeth (without artifacts) within a maximum gap of 2 molars (approximately 2 cm) from the implant sites or 3 cumulative linear cm of teeth if the gap is larger.

2. Planning Placement of Fixation Device

A CRD, comprised of a **Fixation Device**, is prepared in the dental office. With fiducial registration, the CRD is placed in the patient's mouth during the CT scan. Throughout the IGI implantation procedure the CRD is used to hold the Patient Tracker by a special pole. It is important that the Fixation Device is seated accurately and is stable to ensure precision during the IGI implantation procedures.



There are three areas for Fixation placement on the lower or upper jaw:

1. **Right posterior area** — sits on teeth 44-47 for lower jaw or teeth 14-17 for upper jaw
2. **Left posterior area** — sits on teeth 34-37 for lower jaw and 24-27 for upper jaw
3. **Anterior area** — sits on teeth 33-43 for lower jaw and 13-23 for upper jaw
 - Minilock™ type and location are determined according to the existing teeth (their location and periodontal condition) or implants and according to the implantation site. The following rules help in planning Fixation Device location:
 - Implantation in both posterior sides of the dental arch — place the **Fixation Device in the anterior position**.
 - Implantation in the posterior region on one side of the dental arch — place the **Fixation Device in the contra- lateral posterior position** to allow improved accessibility.
 - Implantation in the anterior region of the dental arch — place the **Fixation Device in the left posterior position** to allow improved accessibility (right-side approach).
 - The **Fixation Device** must be distanced from the implantation site, to allow the surgeon better accessibility. It is recommended to leave a space of at least *one tooth* from the implantation site. If the clinical condition doesn't permit this, a space of half a tooth is acceptable as well.
 - The Fixation Device must be stable, and the implantation site accessible. Therefore, a posterior Minilock™ tray is usually preferred.



Warning: If there are any large undercuts, missing teeth, a bridge or anything else that will allow a large bolus of material to enter, they **must** be blocked or filled with a material that won't adhere strongly to the LuxaBite®, before using LuxaBite®. Failure to do so, will prevent easy removal of the Minilock™ tray, and may cause injury to the patient.



Warning: Before replacing the Minilock™ tray, remove the blocking material from the tray. Failure to do so may result in improper tray seating and result in patient injury.



Caution: After placing Fixation Device, the stability of the device must be confirmed.

3. IGI Kit for Partially Edentulous Jaw Implantation

There are 3 kits provided, 3 Minilock™ kits (anterior and posterior Minilock) and a pole kit. Below are charts which list the components of each.

Table 3: Fixation Kits (a. posterior Minilock, b. anterior Minilock)

a.

1 Individual Posterior Minilock™ Tray
3 wedges for each tray (S, M, L)
1 Hex screw

b.

1 Individual Anterior Minilock™ Tray
3 wedges for each tray (S, M, L)
1 Hex screw

Table 4: Poles Kit

7 Poles
Rubber Dam Forceps as Posterior TRI
Posterior TRI
Anterior TRI
Allen Wrench
4 Thumb Screws
Pole Removal Device

4. Preparing the CRD

Minilock™ Tray and Wedges:

Important: The walls of the tray must fit passively on the teeth chosen to place the Minilock™ tray. When using the fiducial registration method, check that all fiducial markers are present in the tray before using LuxaBite®.

A. Explanation of wedges:

- There are 3 corresponding wedges to each tray type: anterior and posterior.
- Each wedge has either L, M, or S engraved on the top surface.
- The wedge with an L engraved on it is the widest.
- The wedge with an S engraved on it is the narrowest.
- When placing a wedge, start with the medium wedge, making sure it locks and doesn't come out easily. If it doesn't lock into place, use the small wedge. If the Minilock™ device isn't rigid and stable after placing the wedge, use the large wedge.

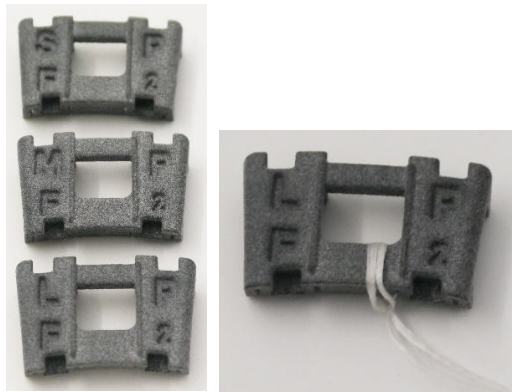


Figure 26: S, M, L wedges for posterior Minilock™ Device

- B.** Loop a long piece of dental floss through the middle of the wedge to be used. Pull the floss through to hold the wedge. Before using a wedge intraorally, attach the ends of the floss to an extraoral part such as the bib using the bib clips.



Warning: Failure to attach the wedge to floss may prevent easy retrieval if the wedge accidentally falls into the patient's mouth.

Place the Minilock™ tray in the desired position covering at least 3 periodontally stable teeth. The dentist may remove the most distal fiducial on the tray by removing the wing of the tray with the fiducial attached. If additional space is necessary, the next fiducial may be removed with its surrounding tray material with a wire cutter.

- C.** All composite fillings and crowns in proximity to the Minilock™ tray must be covered with a barrier layer such as glycerin.

Important: When using fiducial registration, under no circumstances may more than 2 fiducials be removed!

Important: A minimum of 5 fiducials must be used for registration.



Warning: User must check tray and wedge before use. Only complete trays and wedges can be used.



Warning: Lack of a barrier between composite fillings/ crowns and LuxaBite®, may result in patient injury.

- D. When using a **posterior** tray, mix and fill 2/3 of the tray with the Image Navigation approved dental material such as LuxaBite®. Do not fill over the inner recessed slot line.
- E. When using an **anterior** tray, mix and fill the entire tray with the Image Navigation approved dental material such as LuxaBite®.
- F. When filling the tray, place LuxaBite® into the slots on the buccal and lingual sides of the tray.

 **Warning:** Over filling the tray with LuxaBite® may cause a large bolus of material to form, which can cause damage to the patient and/or its easy removal may be jeopardized.

 **Warning:** Under filling the tray with LuxaBite® may reduce the stability and rigidity of the Minilock™ tray, which can result in damage to the patient.

- G. Place and fully seat the tray with the LuxaBite® on the teeth chosen for the Minilock™ device.

 **Warning:** The tray must be fully seated on the occlusal/incisal table. If the tray is not fully seated, it's easy removal will be jeopardized.

 **Warning:** Make sure that the filling material fills the slots of the buccal and lingual walls of the Minilock™ tray. If there isn't enough material, the tray's easy removal may be jeopardized.

 **Warning:** Using other filling materials that aren't approved by Image Navigation may prevent the easy opening of the Minilock™ tray, or negatively influence the accuracy of IGI, resulting in patient injury.

After placing a cotton roll on top, perpendicular to, and in the middle of the tray, have the patient bite down gently without moving the teeth. Alternatively, the dentist can hold the tray in place until it sets.

 **Warning:** The cotton roll must be perpendicular to the tray. If the cotton roll

is parallel to the tray, the patient may bite down on one end and lift the other end of the tray, causing a bolus of material to form on the occlusal surface with consequential difficulty in tray opening.

- H. Air cooling the entire tray while constantly moving the 3-way syringe within close proximity to the Minilock™ tray should start when the LuxaBite® initially sets (hard to the touch with explorer) and continue until LuxaBite® stops its thermal reaction.
If the patient feels the teeth or gingiva getting hot, place the air syringe closer to the tray while cooling.



Warning: If the patient feels the material getting too hot, remove the Minilock™ tray immediately.

5. Removal of the Fixation Device

a. Removal of Posterior Minilock™

After setting (setting time 2 minutes at room temperature) remove the Minilock™ tray as follows:

- Take a dental instrument with a small tip that will fit in between the wedge and the Minilock™ tray. For example, one end of the rubber dam forceps, or a small round burnisher.
 - One end of the instrument is used to remove the wedge.
 - Place one end of the instrument in the appropriate slots on the **wedge** (buccal and lingual) and rotate the forceps to remove the wedge.
-



Warning: Failure to remove the wedge prior to opening the Minilock™ tray may cause irreversible damage to the patient.



Warning: Any tray or wedge may be opened/removed up to 5 times, within 1 year, and **only** on the same patient.

Place the TRI (tray removal instrument) into the appropriate buccal and lingual slots (see **Figure 21: Posterior TRI** on page 59) of the Minilock™ tray. The TRI may have to be turned so that the buccal arm can fit below the pole. With light to moderate pressure close the TRI handles which opens the 2 sides of the tray. **Do not** open the Minilock™

tray by rotating the TRI. Subsequent removal of the Minilock™ tray (After opening the LuxaBite® for the first time) may be easier using the rubber dam forceps in the front two notches (See **Figure 21: Posterior TRI and Rubber Dam Forceps as TRI** on page 59)



Warning: Opening the tray without the TRI may cause harm to the patient's teeth. Using the TRI helps avoid excessive pressure on the teeth.

Caution: Opening the tray more than 30°, may cause the Minilock™ tray to break and render it unusable.



Warning: Trying to open the Minilock™ tray by rotating the TRI handles instead of pulling the handles of the TRI towards each other, will cause damage to the patient.

- Remove the Minilock™ tray.
- Remove any remaining dental material from on or in between the teeth using a dental explorer or dental floss.
- Look at the inside of the Fixation device. The LuxaBite® should closely approximate the teeth without missing any large areas.

Important: Don't over open the tray exposing the fracture line of the dental filler. This may cause alterations in the tray and render it unusable.

b. Removal of Anterior Minilock™

After setting (setting time 2 minutes at room temperature) remove the Minilock™ tray as follows:

- Take a dental instrument with a small tip that will fit in between the wedge and the Minilock™ tray. For example, one end of the rubber dam forceps, or a small round burnisher.
 - One end of the instrument is used to remove the wedge.
 - Place one end of the instrument in the appropriate slots on the **wedge** (mesial and distal) and rotate the forceps to remove the wedge.
-



Warning: Failure to remove the wedge prior to opening the Minilock™ tray may cause irreversible damage to the patient.



Warning: Any tray or wedge may be opened/removed up to 5 times, within 1 year, and **only** on the same patient.

- Place the tray removal instrument (TRI) into the appropriate buccal slots of the Minilock™ tray fully, so that the side flexible locks engage the bottom of the slots (see **Figure 22: Anterior TRI** on page 59). With light to moderate pressure close the TRI handles which opens the 2 sides of the tray. **Do not** open the Minilock™ tray by rotating the TRI.



Warning: Opening the tray without the TRI may cause harm to the patient's teeth. Using the TRI helps avoid excessive pressure on the teeth

Caution: Opening the tray more than 30°, may cause the Minilock™ tray to break and render it unusable.



Warning: Trying to open the Minilock™ tray by rotating the TRI handles instead of pulling the handles of the TRI towards each other, will cause damage to the patient.

- Remove the Minilock™ tray. After removing it from the mouth, press the outer upper part of the side locking arms to disengage the tray.
- Remove any remaining dental material from on or in between the teeth using a dental explorer or dental floss.
- Look at the inside of the Minilock™ tray. The LuxaBite® should closely approximate the teeth without missing any large areas.

Important: Don't open the tray too wide exposing the fracture line of the dental filler. This may cause alterations in the tray and render it unusable.

6. Evaluating the Fixation Device

The dental surgeon evaluates the CRD after fabrication, and every time it is placed in the mouth. This evaluation is important to ensure that the Fixation Device is stable and maintains an exact positive seat, both during the CT scan and during the implantation procedure. Make sure that the Fixation Device sits evenly on the teeth in its intended place.

When positioning the Minilock™ tray:

1. Check that there are no obstructions or space between the Fixation Device and the teeth.
2. Place the appropriate wedge. Try the medium wedge first (M). A *click* should be heard to indicate that the wedge is firmly in place.
3. The Fixation Device must fit tightly on the patient's teeth.
4. Apply light pressure to the Fixation Device and make sure that the Fixation

Device remains firmly in place. There should be no rocking movement in any direction, buccal- lingual or mesial- distal.

5. **Fixation Device Troubleshooting**

While evaluating the Fixation Device two problems may be encountered, refer to the table below.

Table 5: Minilock™ Tray Troubleshooting

PROBLEM	SOLUTION
The Minilock™ tray is not stable and there is a rocking movement.	- Check the underside of the Minilock™ tray for obstructions such as small pieces of LuxaBite® which have come off. Use a 3-way syringe to blow out any small particles. - Check the teeth for any obstructions and clean as necessary.
You cannot position the Minilock™ tray over the patient's teeth.	Check that the Minilock™ tray is placed over the correct teeth the same way as it was originally.

6. After troubleshooting any relevant problems, the Minilock™ tray should sit tightly over the patient's teeth and should be stable.
7. Re-evaluate the Minilock™ tray.
8. If there is still rocking movement the next step depends on the type of registration. When using anatomic registration, prepare a new Minilock™ tray. When using fiducial registration, if before the CT was taken, prepare a new Fixation device. If it is after the CT was taken, follow the directions of **Positioning the CRD** on page 128.



Warning: It is crucial that the Fixation Device is stable and maintains the exact same position, both during the CT scan and the implantation procedure.



Warning: Failure regarding positive seating or stability will have a dramatic negative effect on the system accuracy and may result in injury to the patient.

7. CT scan

When using anatomic registration, the CT scan is performed without the CRD. The CT scanner parameters below (1) must still be followed for IGI to read the CT.

When using fiducial registration, the CT scan is performed with the CRD in the patient's mouth. Perform the CT scan only after verifying that the preparative steps have been successfully completed. Be sure to follow the instructions detailed below and to guide the CT technician accordingly to ensure the CT scan complies with IGI requirements.

Note: Only DICOM standard CT scans are readable by IGI software.

1. Set the scanning parameters.

- The parameters for slice thickness should be identical and must fall within the range of 0.15-0.3mm.
- The slice gap must be within the range of 0.15-0.3mm and must be identical to slice thickness.
- The optimal diameter is 120 mm. The maximum diameter is 180 mm. The minimum is 120 mm.

Maximum number of imported slices is 800.

Important: Ensure that the Minilock™ tray contains all the essential registration markers. If any registration marker is missing or corrupted, the Minilock™ tray must be replaced before performing the CT scan.

2. Place the CRD in the patient's mouth. The Fixation Device must be completely seated and stable in its exact place. If the Fixation Device does not sit correctly, the CT technician should consult the dental surgeon. Do not perform the CT scan if there is any question regarding correct Fixation Device seating.
3. After securing the wedge with dental floss, place the appropriate wedge in place. Start with the medium wedge (M). It should snap into place.
4. If a vacuum form wax-up has been prepared, place it in the patient's mouth as well.
5. Place a cotton roll or a folded gauze on the center and perpendicular to the Minilock™ tray. Ask the patient to bite gently on the cotton roll or gauze. This ensures that when the patient's mouth is closed, pressure is applied on the center of the Minilock™ tray, and it will prevent tipping of the tray. When the Minilock™ tray is in the anterior region, 2-3 cotton rolls may be needed. Alternatively, the dentist may hold the Minilock™ until it sets.
6. The CT scan must be performed **occlusal plane** (of the relevant jaw when the mouth is open).
7. Verify that there was no patient movement during the CT scan. This can be accomplished by checking the boundaries of the outer bone cortex for signs of distortion. If the CT has fiducials, the shape of the fiducials should be round and not oval.

8. Use one side of the rubber dam forceps or similarly shaped dental instrument to remove the wedge, and then the tray as detailed above, see **Removal of the Fixation Device** on page 73.



Warning: Trying to open the tray without the TRI may cause harm to the patient's teeth. Using the TRI helps avoid excessive pressure on the teeth. Opening the tray more than 30°, may cause the Minilock™ tray to break and render it unusable.



Warning: The CT scan must be taken without any patient movement. Patient movement during the CT scan can result in an inaccurate CT which can lead to incorrect planning and patient injury.

Save the CT scan to an external mobile source (e.g. disk on key). This digital data is used to create patients' sessions in the IGI software application.

8. Saving the CRD

After disinfection, see **Partially Edentulous CRD (Minilock™ tray & wedge)** on page 187, the CRD should be saved in the packaging provided. The patient's name, ID number as well as the date should be written on the individual package in the appropriate places.

The symbols are:



for the patient's name; for the patient's ID number; and for the date.

Each Minilock™ tray comes with its own wedges. Don't use a tray from one package and a wedge from a different package.

B. Planning Protocol

Planning an implant involves a set of considerations, some of which may be conflicting. The final position of a planned implant is usually a compromise between the anatomical limitations and the clinical conditions. The IGI planning program provides a powerful tool to address the above considerations.

Note: The dental surgeon is responsible for final decisions regarding implant planning and insertion.

1. Creating a New Session

To create a new session, the CT data is used. The CT digital data contains a series of files, each representing a different axial slice of the teeth and jaw.

Note: Only DICOM standard CT scans are readable by IGI software.

Note: To import a new session from an Image Navigation approved third party software refer to Section XIX, **Appendix Four: Import Planning from Exocad**, page 214.

To create a new session:

- **On the IGI Log-In Screen**, see **Figure 4: IGI Log-In Screen** on page 41 Enter your login name and password. You may use the On-Screen Keyboard.
- **Click Login.**
- The Archive Screen opens
- **On the Archive Screen, click New** and double-click the data drive (root directory) where the CT is located. The CT images must be in a folder called “CT” in a path of “:\ImageNavigation\IGI\Data\CT” after the correct root drive (C or D) for IGI to recognize it (i.e. C:\ImageNavigation\IGI\Data\CT). If the CT is not on a drive but has to be downloaded, place it in a folder called “CT” in the above path.

Important: The CT images must be in a folder called CT and in the correct path for the IGI program to recognize it.

Note: If an “Auto- Run” option loads, close it. Then on the archive screen, click New.

The system automatically creates a named patient folder. In this folder, there are numbered study folders with CT axial slices.

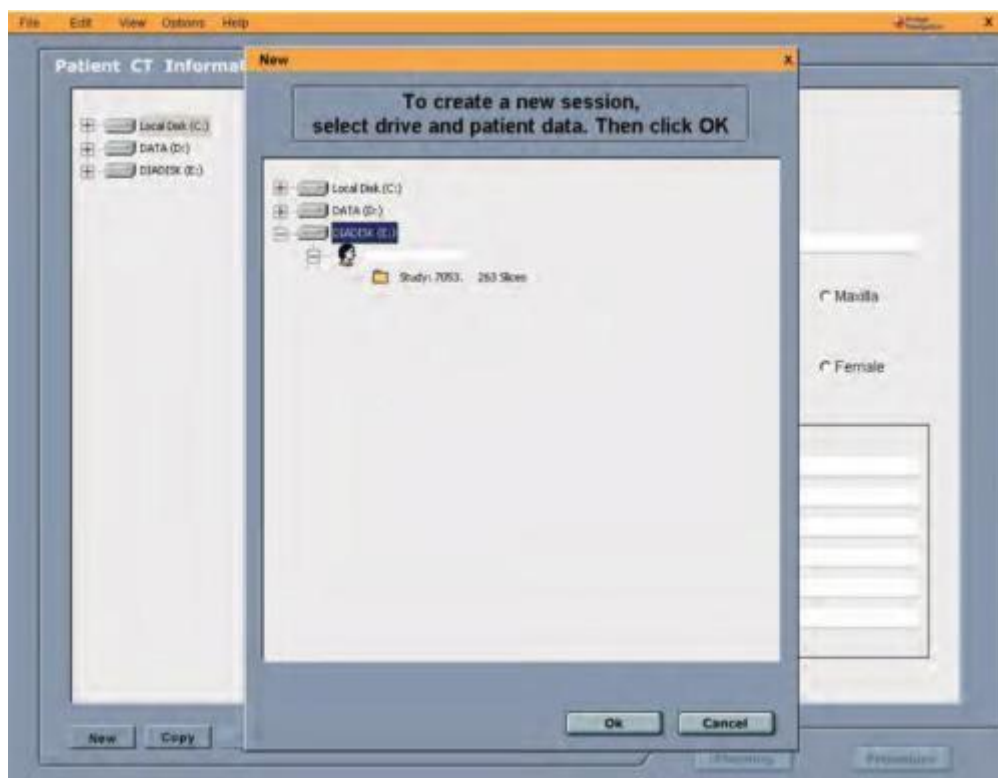


Figure 27: Selecting a Drive and Patient Data

Note: If the drive contains data of two or more patients, IGI arranges the data in separate patient folders (one for each patient)

- **Double-click the name of the relevant patient.**
The patient study folder opens
- **Select the patient study folder and click OK.**
The Import Screen with the CT axial slices opens. The IGI automatically arranges the patient's axial slices from top to bottom and displays the slices according to their serial number.



Figure 28: CT Axial Slices in the Import Screen

Make sure that all slices are present and that the interval between the slices is consistent.

Important: The drive with the CT digital data may contain additional files other than axial slices. The system arranges these additional files in a different serial folder in the patient's main folder. In such a case, select the serial file that contains the axial slices.

2. Locating the Silicon Nitride Markers

Only for Fiducial Registration. For Anatomic Registration, go to step 3- Importing.

Locating the silicon nitride markers is an integral part of the IGI process, since they act as fiducial points for registration. The Minilock™ tray silicon nitride fiducials are marked, and the system identifies the fiducials on the CT.

To locate the silicon nitride markers:

- **Scroll through the axial slices** using the up and down arrows on the right side of the screen.
- **Double-click the orange box** of the axial slice that displays the most silicon nitride markers. The selected slice is automatically enlarged to create a marking window

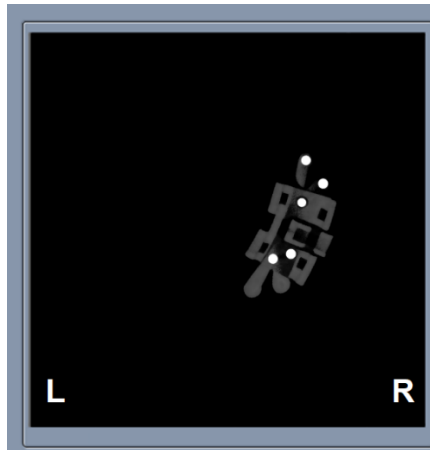


Figure 29: Marking the Minilock™ Tray: Silicon Nitride Markers

- **Use the Arrow buttons** (on bottom left side of the window) to browse through the axial slices to a slice in which there is a clear image of one of the silicon nitride markers.
- **Select the Draw tool**, locate the cursor over the center of the silicon nitride marker and click to mark it. A red X appears over the silicon nitride marker.

Repeat steps 3 and 4 to mark all seven Minilock™ silicon nitride markers in the same way. The marking window displays the number of marked balls

Important: The order in which you mark the silicon nitride markers is not important.

- To erase a mark, use the **Eraser** button. Place the lower left point of the eraser over the mark and click.
- Use the **Undo** and **Redo** buttons as required.
- When you have completed marking all the silicon nitride markers, click **Close**.

Note: A default session name is suggested, including date and jaw type. You may enter a different session name using the On-Screen Keyboard.

3. Importing

To import the session:

- Click Mandible or Maxilla.
- Click the **Save To** arrow and scroll to select a drive. The default drive is the last used drive.
- Click **Import** to save the session to the selected drive.
- After importing the session, erase the CT from the IGI computer. (Save a copy elsewhere if necessary).

Note: The import procedure may take a few minutes. A status window indicates the progress of the import process.

A message appears indicating if the spheres (virtual silicon nitride markers) are located successfully or not.

For Fiducial Registration-If markers locating is successful:

The markers are colored blue, see **Figure 29: Spheres were Located Successfully below**. The system creates a patient session with the name you specified under the main patient folder. (The folder can be seen on the Archive Screen). To proceed to the **Planning Screen**, click **OK**.

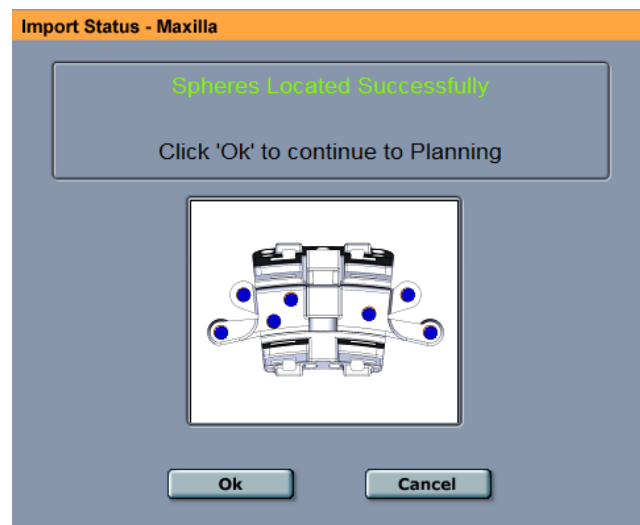


Figure 30: Spheres were Located Successfully

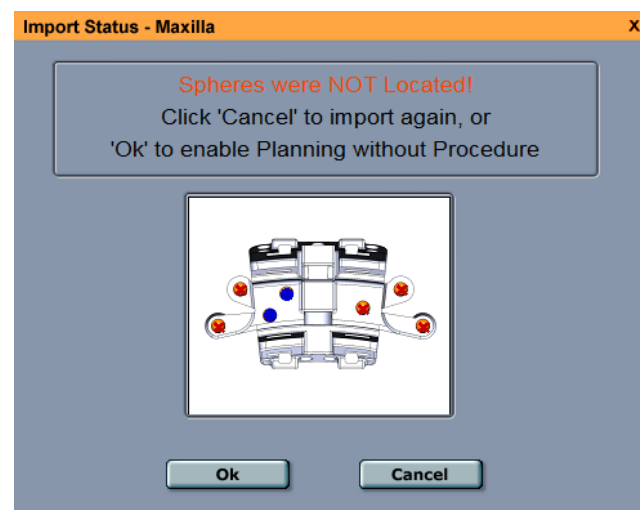


Figure 31: Spheres were not located

If markers locating fails:

The markers which are not located appear in red, see **Figure 30: Spheres were not located above**. Try, with special care, to locate the silicon nitride markers again: For each marker, choose a slice in which the full marker diameter is displayed. Accurately mark each silicon nitride marker in its center.

Note: The system identifies a cell area between 3-5 mm around your mark (the marker itself is 3 mm diameter). After you mark the marker, the system searches for the brightest point in this cell area and marks that as the center of the marker. If a tooth image falls within this area, the system might mistakenly mark the tooth instead of the silicon nitride marker. If this happens, try to mark the marker in an axial slice that shows the marker distanced from the tooth.

If the system identifies distortions in the CT scan: It ignores certain registration markers of the Minilock™ tray to avoid distortions. The ignored markers appear with red X's. There can be other reasons for X's, such as improper marking by the dentist. If the system allows, and there is a minimum of 5 fiducials recognized, the surgeon should click **OK** to proceed to the **Planning Screen**.



Warning: The system will not inform the surgeon if there are enough recognized fiducials. The surgeon must not proceed if there aren't a minimum of 5 fiducials recognized correctly.



Figure 32: Spheres were Located Successfully & Two Ignored Markers

If the scan is over distorted, click Cancel to try marking again or OK to proceed to the Planning Screen as is (see page 90).

Important: If the scan is over distorted, clicking OK enables you to plan implants

on the CT data. However, performing surgical implantation with the system guidance will not be available, as the lack of recognition of silicon nitride markers makes registration impossible.



Figure 33: Scan is Over Distorted

4. Preparations before Planning the Implants

After completing the above stages, you can begin planning the new session. The steps to be taken are:

- Loading the patient's session
- Marking the Jaw Curve
- Marking the Nerve Canal (for lower jaw implantations)
- Loading the Patient Session

On the Archive Screen, you load the patient session on the left hand side of the Patient CT Information window.

On the Patient CT Information window, click the drive to which the patient session was imported and saved. A list of available patients' sessions opens

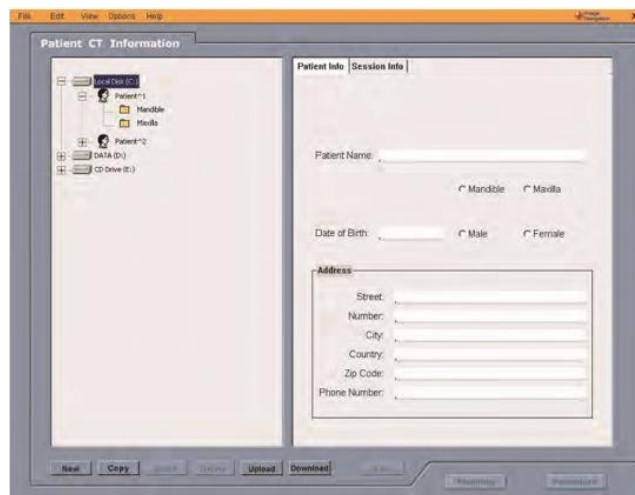


Figure 34: Available Patients' Sessions

Select the desired patient's session and click Planning.

The patient's session is loaded into the Planning Screen and the Jaw Curve window is displayed

Important: A patient session is named when the study is imported to the system archive. Several study files may be available for the same patient (e.g. one study folder with sessions for mandible and another study folder with sessions for maxilla).

If you have just imported the patient session to the system archive, then only the name of the current imported session is displayed.

To select another session for the same patient:

- On the Patient CT Information tree, double-click the opened patient's folder to it.
- Double-click this patient's folder again to open the full session list of this patient.
- To select a session of another patient:
- On the Patient CT Information tree, double-click the opened drive to close it.
- Double-click this drive again to open all other patients' folders.
- Double-click a patient's folder to open his/her session list.

5. Marking the Jaw Curve

At this stage a jaw curve is defined by drawing it on one of the axial slices. It is important to draw the jaw curve accurately especially in a lower jaw implantation plan,

to provide a clear illustration of the nerve canal, on both the panoramic and cross-section views.

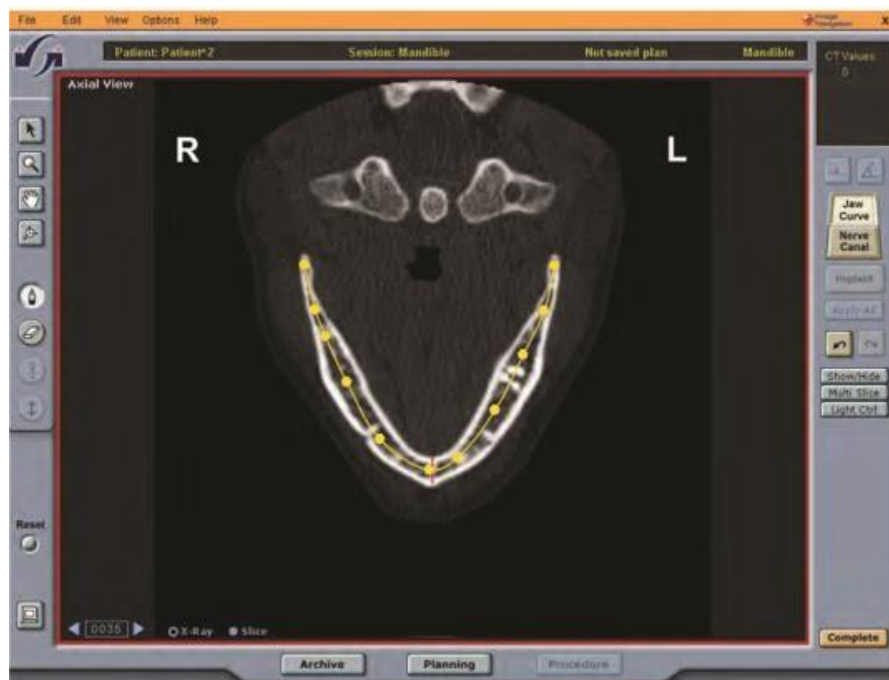


Figure 35: Marking the Jaw Curve in the Planning Screen

- Use the Slice Counter to browse through the axial slices.
- In a maxilla session: Select a slice in which there is an Axial View of the entire jaw at about the level of the teeth roots.
- In a mandible session: It is recommended to select the slice in which the nerve canal opens to the soft tissue (mental foramen), preferably on both sides. This allows better visualization of the nerve canal.
- Use the Draw (pen) tool to plot the points of the jaw curve. To erase a point, use the Erase tool or the Undo tool by placing the lower left point of the eraser over the item you wish to erase, and click the mouse.

You may also clear all markings by selecting **Clear Jaw Curve** from the **Edit** menu.

Important: Any time during the planning, you can return to the jaw curve window by clicking the **Jaw Curve** button, to make changes to the jaw curve markings. All planning data is based on the jaw curve markings. If you change the jaw curve markings, you will lose all planning data and you will have to plan the session from the beginning.

- **Using the Select tool (arrow)**, adjust the position of any marking by clicking and dragging it to the correct position.
- **When finished, click Complete.** The screen displays different CT views, see **Figure 7: IGI Planning Screen (a. Mandible Session; b. Maxilla Session)**, on page 43.
- **Axial View** – Displays the original CT axial slices and X-ray
- **Panoramic View** – Displays reformatted panoramic view in 3 options: X-ray, Slices and Tangent.
- **Cross-Section** – Displays slices which are perpendicular to the Jaw Curve.

Note: In a maxilla session, a **3D View** is also displayed. In a mandible session, a **3D View** is displayed only following marking the nerve canal.

6. Marking the Nerve Canal in a Lower Jaw Implantation

In the case of a lower jaw implantation, the nerve canal must be marked. It is important to mark the canal accurately and precisely.

Note: In the case of an **upper jaw implantation**, click **Complete** and proceed to the next stage of planning.



Warning: Marking the nerve canal is the full responsibility of the dental surgeon.

Each nerve canal (left/right) is marked separately. To change sides, select either **Left Canal** or **Right Canal**.

Important: For left or right lower jaw implants, mark the nerve canal at the corresponding side. If dental implants are planned at both sides, mark the nerve canal on both sides.

The nerve canal is marked in the Panoramic View:

- Maximize the Panoramic View for marking the nerve canal. For further magnification use the Zoom tool. Mark the nerve canal using the panoramic slice view and not the panoramic x-ray view.
- Using the Slice Counter on the lower left side of the screen, start by selecting the panoramic slice in which the distal part of the nerve canal is viewed clearly (e.g. teeth 37- 38, i.e. 17-18). Mark the most distal part of the canal and follow the canal mesially. Viewing the canal clearly throughout its entire length may mean using different slices to mark different areas of the canal.

- Use the Draw tool to mark the nerve canal. To erase a point, use the Eraser tool or the Undo tool.
- Option 1- Mark the uppermost aspect of the canal. Use the Select tool to make any fine adjustments.
- Option 2- Mark the canal in its center. Use the Select tool to make any fine adjustments. Then enlarge and/or change the shape using the cross section as described below in #6.



Warning: Make sure that the upper part of the contour is at the uppermost aspect of the canal.

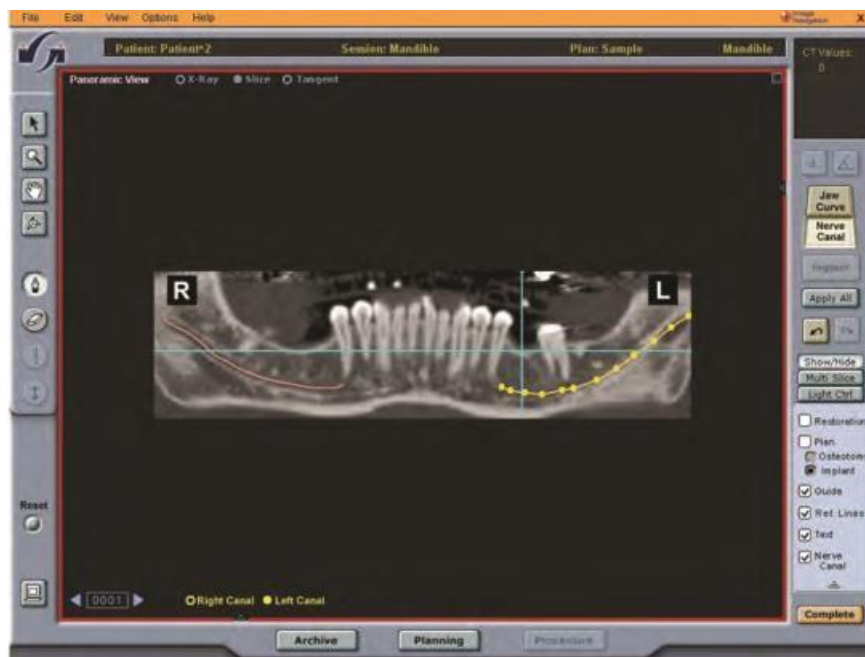


Figure 36: Marking the Nerve Canal on the Panoramic View



Warning: Since the nerve canal changes its BL location along its path, it is necessary to mark different parts of the nerve canal on different panoramic slices. Therefore, mark the nerve canal on the panoramic **slices**, rather than on the panoramic **x-ray** view. Take care to mark each part of the nerve canal on the correct slice (the sharpest view of the canal area being marked), to place the mark in its correct BL location.

Continue marking the nerve canal along its path to the mental foramen.

Important: For anterior lower jaw implantation, mark the nerve canal to the midline

Adjustments and approval of nerve canal markings are performed in the Cross-Section View:

Locate the cursor close to the nerve canal marking. The cursor changes its shape and enables rotations, diameter and shape adjustments.

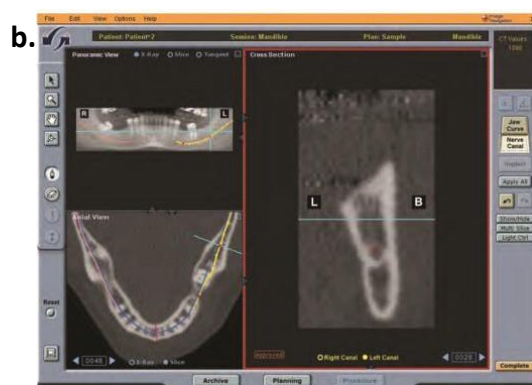


Warning: As the nerve canal may loop back on itself near the mental foramen, it is important to mark the *uppermost aspect* (as only one mark is enabled on each slice of the Cross-Section View).

Approve the nerve canal on each slice of the relevant cross- sections by clicking the Approve button.

A window will open warning of the possible result of inaccurate nerve canal placement.

Nerve canal placement must be approved by the surgeon before proceeding. The approved markings become red in all CT views, and the Cross-Section slice is now marked as approved.



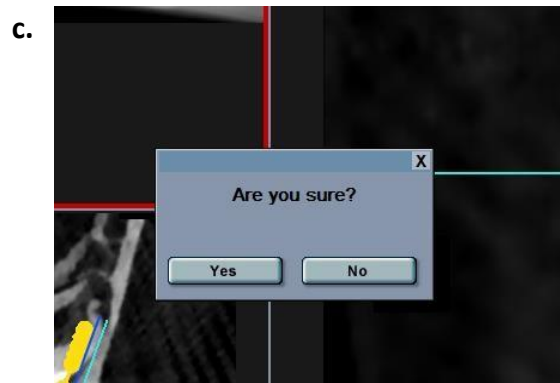


Figure 37: Nerve Canal in the Cross-Section View

**a. Marking the Nerve Canal; b. Approving Nerve Canal Markings;
c. approval of nerve canal placement**

- Repeat the above procedure for the Right Canal or Left Canal as required.
- Click Complete to proceed to the next planning stage.
- A 3D View is displayed

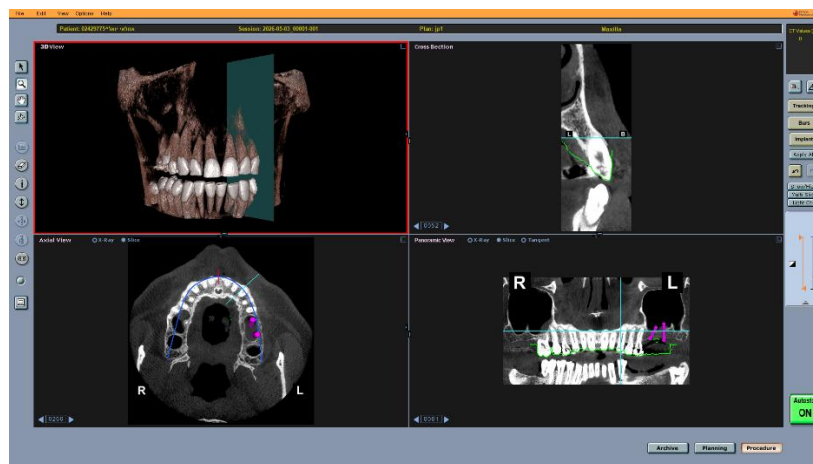


Figure 38: 3D View of the CT Scan

Important: To make changes to the nerve canal markings during planning, click the Nerve Canal button to return to the Nerve Canal window. No planning data is lost when changing nerve canal markings.

C. Planning Implant Placement

1. Measuring the Bone

Before selecting the implants, it is recommended to measure the span of edentulous bone ridge, as well as bone height and width.

To measure the span of edentulous bone ridge in the Axial View:

Use the Slice Counter to scroll to the slice of the implant area. Select the **Distance Measurement** tool. Crosshair cursor appears

Place the cursor on the distal surface of the tooth which is mesial to the edentulous bone.

Drag the measuring line to the mesial surface of the tooth which is distal to the edentulous bone.

Release to set the distance marker.

A yellow measuring line appears and its length value in millimeters is displayed under the CT Values. The accuracy of this measurement is 0.2mm +/- 0.1mm.



Figure 39: Measuring the Span of Edentulous Bone Ridge

To measure the bone height & width in the Cross-Section View:

- Use the Slice Counter to scroll to the relevant slice.
- Select the Distance Measurement tool.
- A crosshair cursor appears
- Place the cursor on the coronal cortex of bone ridge. Drag the measuring line to the relevant point (coronal cortex of nerve canal or coronal cortex of maxillary

sinus). Release to set the distance marker.

- A yellow measuring line appears, and its length value displays under the CT Values.

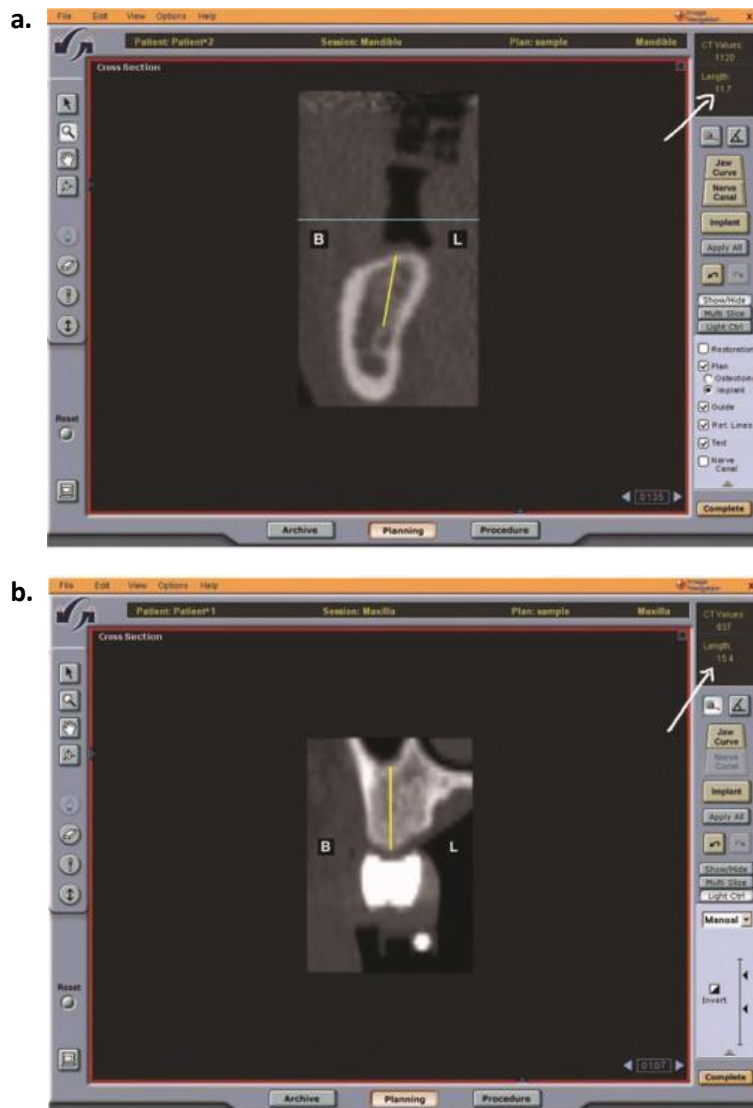


Figure 40: Measuring the Bone Height in the Cross Section View

(a. Mandible; b. Maxilla)

- Place the cursor on the inner buccal cortex of bone ridge and drag the measuring line to the inner lingual cortex. Release to set the distance marker.
- A yellow measuring line appears and its length value in millimeters displays under the CT Values



Figure 41: Measuring the Buccal-Lingual Width of Bone in the Cross Section View

- Repeat measuring in all relevant slices.

2. Adding a New Implant to the Database

- Click Implant.
- The Implant Menu opens

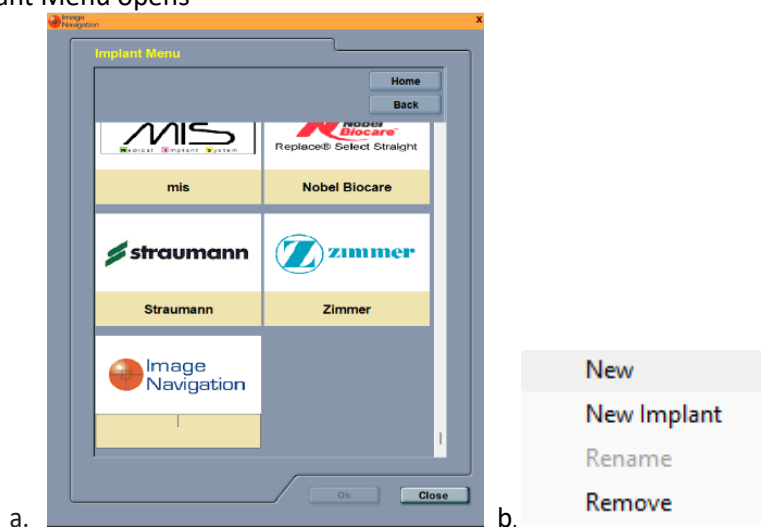


Figure 42: Implant Menu

a- main menu, b- new, rename, remove

Place mouse within the inner window borders. Right click on the mouse and click Add.

- Add a new manufacturer by right clicking with the mouse, and click "New", or pick an existing one using the scroll bar on the right.
- The software will add the logo automatically if it has been saved in the appropriate folder within IGI. If not, the Image Navigation logo will appear. Logos can be added to the folder. For more information, ask your distributor.
- After entering the manufacturer's name press enter to save. Alternatively, click on the manufacturer. Click on the type of implant or right click with the mouse to add a new one.
- Several subtypes can be added.
- When the type and subtypes are completed, right click, choose "new implant" to add the parameters of the implant.
- Add the parameters of the new implant- diameter and length. Add the real diameter and real (exact) length if different from the official name.
- When all the parameters are filled click OK.

Note: Implant manufacturers, types and subtypes buttons have a light-yellow background. Implant diameter and length buttons have a blue background.

- If there are a few implants with the same diameter (from the same manufacturer, type and subtype), they will be found when clicking on the desired diameter button.
- Continue to choose an implant for planning by selecting the length of the desired implant and click OK.
- The cursor changes to an implant shape.
- To go back one step at a time, press the "Back" button.
- To go back to the manufacturers page, press "Home".

Note: The implants are saved in the database even if the planning session isn't saved.

Implants can be added or removed anywhere in the implant folder. Manufacturers or types can be added, removed, or renamed (right click on mouse). This change will affect **all** implants within the chosen folder (button).

Important: Changes cannot be undone.

3. Selecting the Implant

- Click Implant.
- The Implant Menu opens.
- Click the desired implant manufacturer.
- Click the implant type, and subsequent subtypes.

- Click the diameter of the implant.
- Select the length of the implant and click OK.
The cursor changes to an implant shape

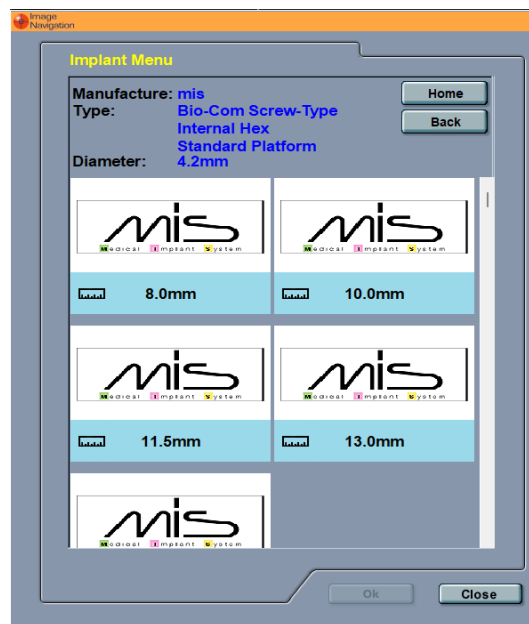


Figure 43: Implant Selection from Menu

- Maximize the Panoramic View. With the mouse, drag the implant to its approximate position. Left click to set the implant in place.
- To insert additional implants of the same type, click in the desired location.
- The new implant appears. The cursor remains with its implant shape
- To insert a different type of implant, return to the Implant Menu.

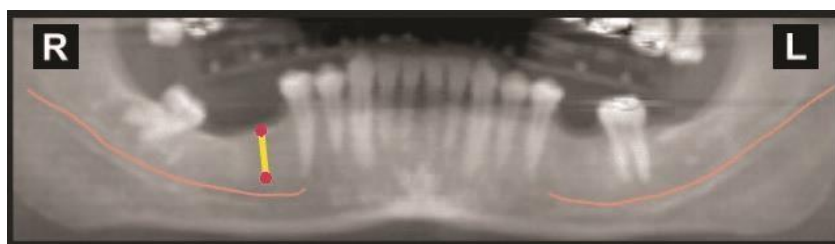


Figure 44: Setting the implant

Important: If while trying to add another implant from the **Implant Menu**, one of the already planned implants is selected, then the system asks if you want to replace the selected implant with a new implant.

- Click No to add a new implant.
- Click Yes to replace the selected implant.

- To stop adding implants, click the Select button.

4. Positioning the Implant

Below is a suggested guideline in planning the dental implants' position. The dental surgeon is, however, free to plan the implants' position according to his/her clinical judgment. The implants appear colored purple. One of the implants can be selected by clicking it with the Select tool. The selected implant is colored yellow with red dots on its upper and lower ends.



Warning: Determining the implants' final planned position is the full responsibility of the dental surgeon.



Warning: Critical anatomical structures should be avoided by at least 1.5 mm.



Warning: Relying on the implant placement in the panoramic view may lead to improper implant placement which can harm the patient. Cross-section, axial, and 3D views must be used to plan the implant position.

The implant MD angle should be parallel to the long axis of the adjacent tooth or implant. If the implant is adjacent to a tooth, place a guide on the long axis of the tooth.

- Select the Add Guide tool.
- The cursor changes to a guide shape
- Place the guide on the adjacent tooth.
- The guide appears colored green

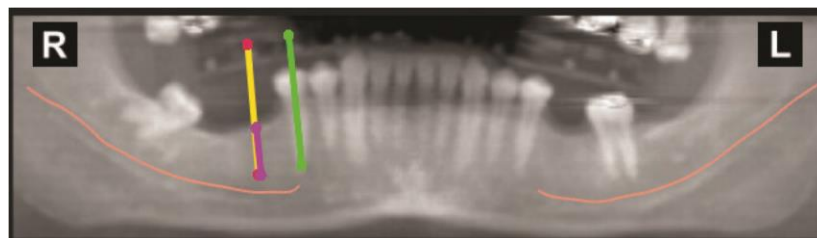


Figure 45: Implant & Guides

- To adjust the guide location on the long axis of the adjacent tooth, use the

Select tool to select the guide.

- The selected guide is colored yellow with red dots on its upper and lower ends, similar to a selected implant.
- Drag the guide by its yellow line to change its position.
- Drag the red dots at the ends of the guide to change the guide angle.
- Adjust the guide angle on the Panoramic View and on the Cross Section View as well.

To make the implant parallel with an adjacent implant or tooth:

- Select the Parallel Implant tool.
- The Parallel Angle window opens.

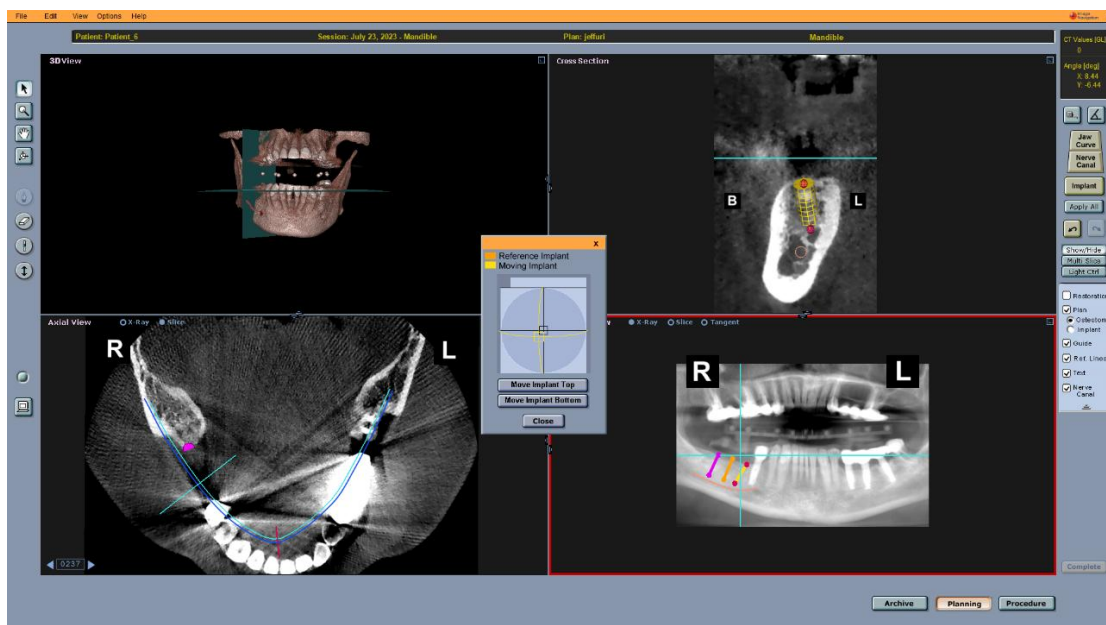


Figure 46: Setting Parallel Angles – Before

Select the adjacent implant or guide as a reference.

- The guide or implant used as a reference is colored orange.
- Select the “Moving Implant” to be positioned parallel or its guide. The selected implant or guide is colored yellow. The angle between the reference implant/guide and the moving implant/guide is displayed under CT values.
- On the Parallel Angle window, click Move Implant Top or Move Implant Bottom buttons. The implant angle is set parallel to the reference. The angle between the two equals zero as displayed under CT Values.

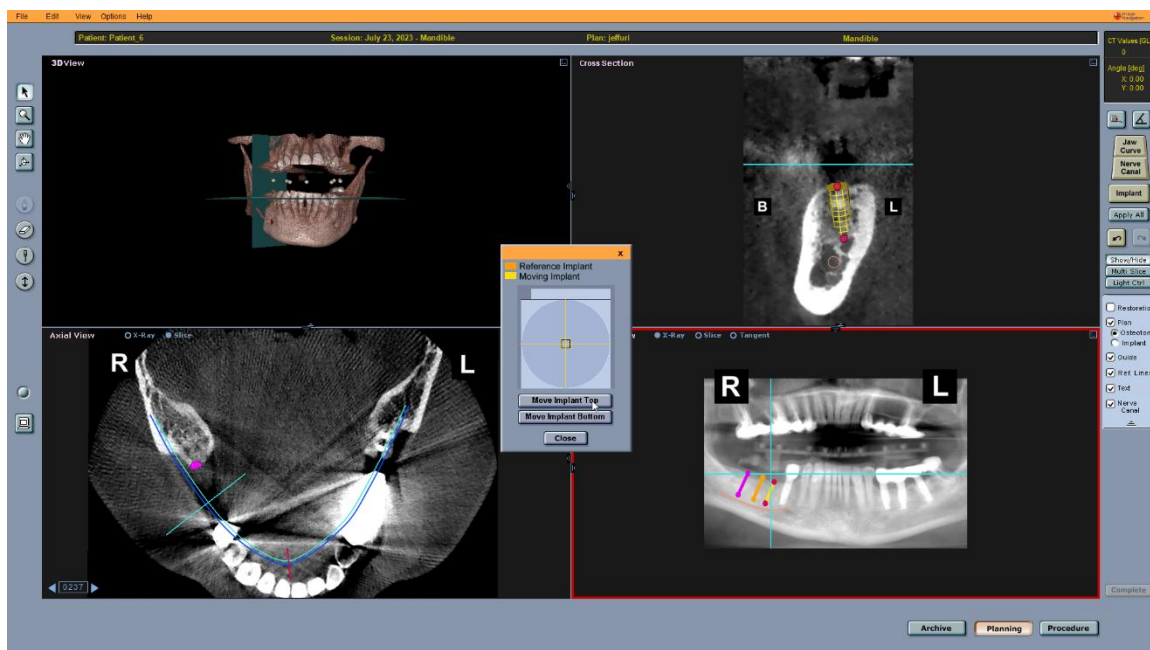


Figure 47: Setting parallel Angles - After

- To erase the guide, use the Eraser button. Alternatively, use the Show/Hide Aid to hide the guide.
- To close the Parallel Angle window, click Close.

5. Distance Measurement

It is important that the implants are spaced adequately from the adjacent tooth/implant.

The distance between adjacent implants is measured in the Axial View:

- Use the Slice Counter to scroll to the relevant slices in the Axial View.
- Select the Distance Measurement tool. The accuracy of this measurement is 0.2mm +/- 0.1mm.
- A crosshair cursor appears
- Place the cursor on the center/surface of the adjacent tooth or implant. Drag the measuring line to the center/surface of the placed implant. Release to set the distance marker.
- A yellow measuring line appears, and its length value displays under the CT Values.
- Adjust the implant location to set the desired distance and measure the distance again.

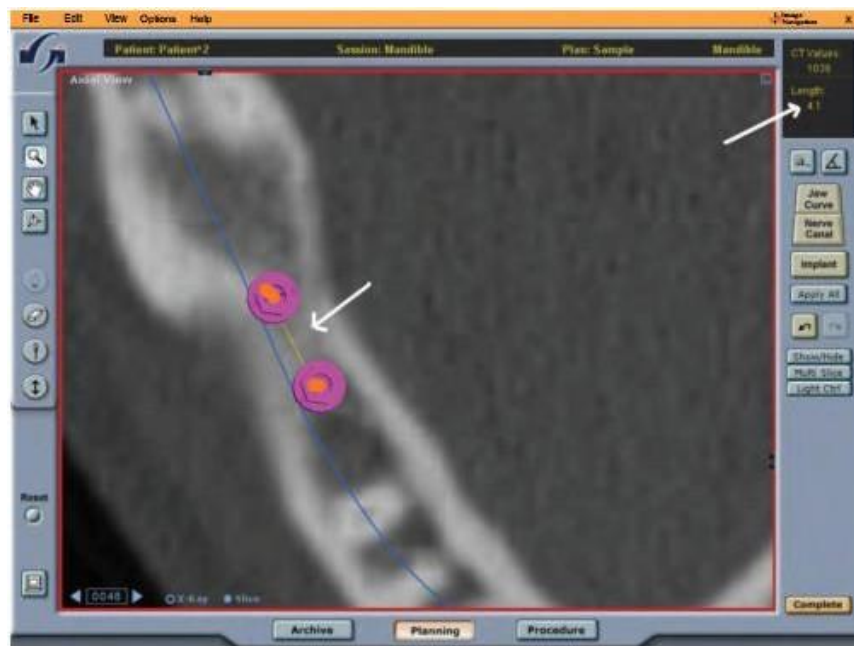


Figure 48: Distance Measurement

6. Fine Adjustments to Implant Placement

The fine adjustments are performed in the Cross-Section View:

Determine the BL location and angle of the implant. The coronal end of the implant must rest within the alveolar crest.

- In the Axial View, drag the azure reference line close to the implant.
- Use the Slice Counter in the Cross-Section View, to scroll to the relevant slices.
- Use the Select tool to select the implant.
- The select implant is colored yellow.
- To make angle adjustments, place the cursor on the red dot of the implant and move the implant to the desired angle.
- To move the implant, drag the implant by the yellow line to the desired position.
- In the case of lower jaw implantation, verify the distance between the apical end of the implant and the upper cortex of the nerve canal using the osteotomy simulation and not the implant simulation which is shorter (yellow arrows).

Note: When using an implant added to the database by the user, no 3D image of the implant is available.

- Verify this distance in all the cross-sectional slices in which the implant appears. Make sure you are in the correct slice by using the azure reference lines or the **Rotate** tool.



Warning: Make sure there is a minimum distance of 1.5 mm in any direction using osteotomy simulation.

- Verify the implant placement in the 3D image. If the CT isn't parallel to the occlusal plane, this view will show the inaccuracy of implant placement.

Important: The threshold chosen in the 3D view is the threshold shown when using registration in the procedure tracking window. Therefore, it is important to choose this parameter carefully.



Figure 49: Verifying the Distance between Implant and Nerve

If the distance between the apical end of the implant and the nerve canal is too small, replace the planned implant with a shorter one.

- Select the relevant implant.
- The Implant Info window opens on the Planning Screen on the lower right corner. See **Figure 53: Bur Menu** on page 104.

Note: On the **Implant Info** window, the **Index** displays the number of the implant.

The implant is automatically numbered according to placement order during planning.

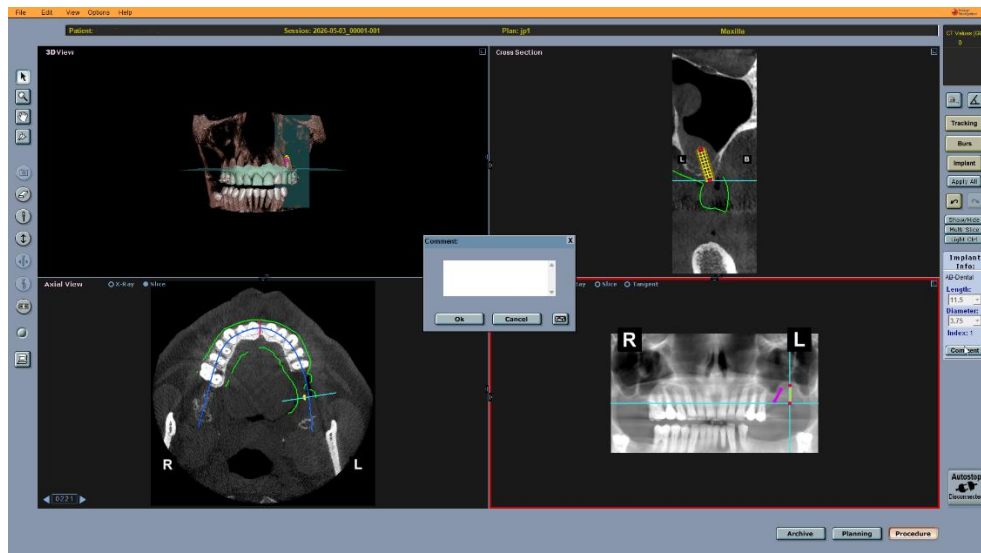


Figure 50: Implant Info and Comment Window

- On the **Implant Info window**, modify the implant length or diameter.

Important: The implant's angle and distance that was previously set remains the same.

The Implant Info window allows you to add a comment relating to the implant:

- On the Implant Info window, click the Comment button.
- A Comment window opens.
- Add any comments using the On Screen Keyboard or a standard keyboard.
- You can add a simulation of the center of the restoration and plan the implant according to it.
- Click the Show/Hide Aid and select Restoration.
- The expected restoration appears as an Implant Projection, colored orange in the Panoramic and Axial Views, it is displayed in relation to the dental arch.
- Verify that the Implant Projection falls within the occlusal table of the expected restoration.
- You can change the length and angle of the Implant Projection.
- Select the Implant Projection.
- The Implant Projection is colored yellow with red dots on its upper and lower ends similar to a selected implant.
- To change the length of the Implant Projection, drag its yellow area as needed.
- To change the angle between the Implant Projection and the implant, drag the red dot on the top of the Implant Projection.

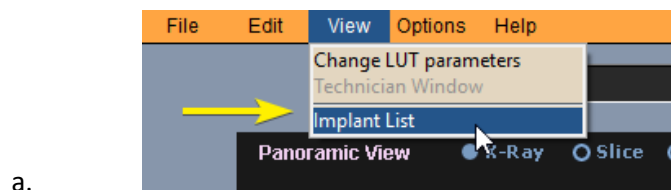
- The Implant Projection length and angle values are displayed under the CT Values.



Figure 51: Implant Projection (Restoration) and its Values

- If required, adjust the implant angle according to restoration using a guide and the Parallel Implant tool (see **To make the implant parallel with an adjacent implant or tooth:** on page 97).
- On completion of planning the first implant, repeat the above procedures for any additional implants.

Note: You may use the *Implant List* option, found under the *View* menu, to view details of all the planned implants. This option is also used when preparing the implants prior to surgery.





b.

Figure 52: Implant List

a. Implant List Selection from View menu; b. Implant List Window

7. Verifying the Dental Arch

After placing all the implants, verify that the implants' projections are in harmony with the residual teeth and form an adequate dental arch.



Figure 53: Verifying the Dental Arch

(at the Level of Adjacent Tooth Contact Point)

- Take the azure reference line on the Panoramic View, to the level of the interdental contact-points of the teeth adjacent to the implants.
- Return to the Axial View at the level of the inter-dental contact points, and make sure that the implants' projections fall within the occlusal table of the expected restoration
- Use the 3D view to verify the implants' positions
- Use the Select tool and select an implant to be re-positioned, as required.

- Change the BL location or angle of the implant according to planning requirements.

8. Adding Drilling Burs to the Database

There is another option of using burs without putting them in the database. See **Bur Point** on page 122.

- Open Procedure window.
- Click Burs. The Bur Menu opens

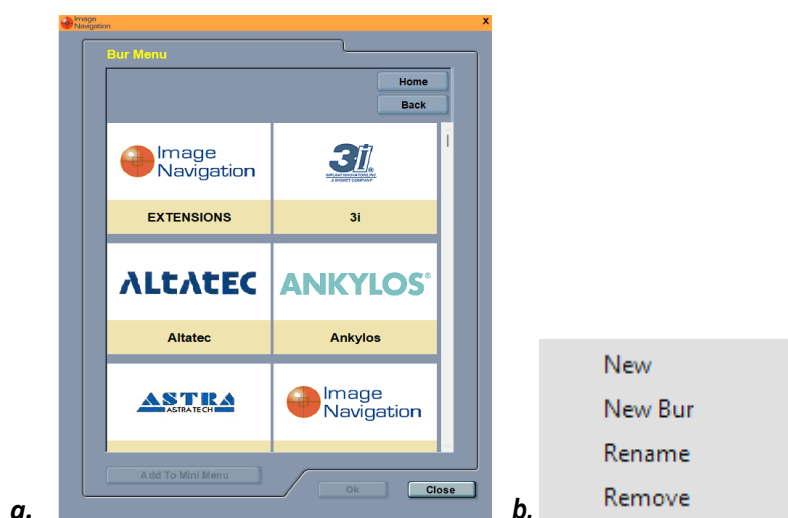


Figure 54: Bur Menu

a.- main bur window; b.-new, rename, remove bur

Place mouse within the inner window borders. Right click, then click "Add".

- Add a new manufacturer by right clicking with the mouse, and click "New", or pick an existing one using the scroll bar on the right.
- The software will add the logo automatically if it has been saved in the appropriate folder within IGI. If not, the Image Navigation logo will appear. Logos can be added to the folder. For more information, ask your distributor.
- After entering the manufacturer's name press enter to save. Alternatively, click on the manufacturer. Click on the type of bur or right click with the mouse to add a new one.
- Several subtypes can be added.
- When type and subtypes are completed, right click, choose "new Bur" to add the parameters of the bur.
- Add the parameters of the new bur- diameter and length. The length default options are extra short, short, regular, long, or extra-long. A different name may

be used. Add the real diameter and real (exact) length.

- When all the parameters are filled click OK.

Note: Implant manufacturers, types and subtypes buttons have a light-yellow background. Implant diameter and length buttons have a blue background.

Important: A digital caliper must be used to measure the exact measurements when adding the diameter and length (tip to tip) of a new bur.



Warning: Recording measurements without the use of a digital calibrator may result in injury to the patient.

When all the parameters are filled in click OK.

Close the window or add burs to the mini menu as described below

Note: The burs are automatically saved in the database. Burs can be added or removed anywhere in the bur folders. Manufacturers or types can be added, removed, or renamed. This change will affect **all** burs lower down on the same branch.

Important: Changes cannot be undone.



Warning: When a bur is replaced with a new one, it must be premeasured with a digital caliper. Failure to do so, may result in patient injury.

9. Creating a Drilling Burs Mini Menu

You may create, in advance, a Mini Menu of the drilling burs that you intend to use during the implantation procedure.

- Click the Procedure button. The Procedure Screen displays.
- Click the Burs button. The Bur Menu opens.
- Select the first drilling bur that you intend to use during the implantation procedure and click **Add to Mini Menu**.
- The Bur Mini Menu opens, listing the selected bur.

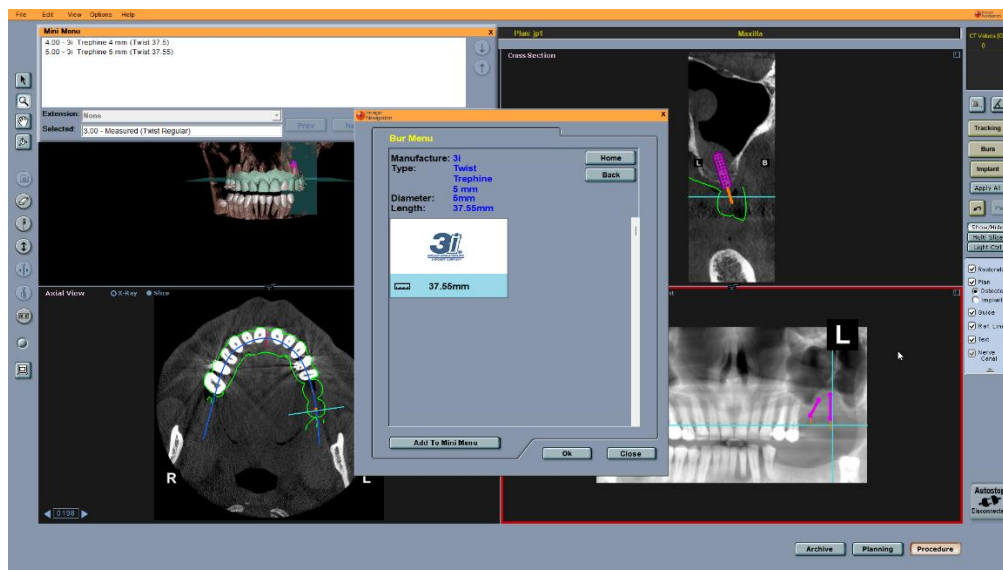


Figure 55: Bur Selection from (Dentist filled) Bur Menu and Bur Mini Menu

- Add the rest of the drilling burs that you intend to use in the same way.

Important: Add the drilling burs to the Mini Menu in the same order you intend to use them during surgery. This simplifies the use of the Mini Menu.

- If you intend to use an extension, select an extension from the **Extension** drop-down menu.

Important: During surgery, you select the extension when you use it and unselect it when you don't use it.

- You may remove a drilling bur that was added to the Mini Menu by selecting it on the Mini Menu and clicking Remove.
- To remove all burs from the Mini Menu, click Clear.
- To page up and down the bur list, use the Arrow buttons in the Mini Menu window.

Note: When saving the plan (see below), the created Mini Menu is automatically saved with the plan and loaded when the plan is loaded. However, you may save the Mini Menu separately, so that it can be loaded and used for any other plan, of any other session, see **Creating a folder of saved Mini Menus**, on page 109.

10. Saving the Plan

After completing the above procedures, you must save your plan.

Note: In mandibular sessions, a plan can be saved only after the Nerve Canal marking stage is complete.

To save the plan:

- From the File menu, select **Save**. A Save As window opens.



Figure 56: File Menu



Figure 57: Save as Window

- Name the plan file and enter the user password (you may use the On Screen Keyboard), then click OK.

The plan is saved to the same folder where the session was opened.

To accept plan changes:

- From the File menu, select Save (see **Figure 56: Save as Window** on page 107). A Planning Protection window opens



Figure 58: Planning Protection Window

- In the Password field, enter the creator's user password, then click OK.
- The changed plan is saved.

Note: Only the creator of the plan can modify it (see **Figure 57: Planning Protection Window**). If any other person wants to modify it, he/she should save a separate plan file.

To save a separate plan file with plan changes:

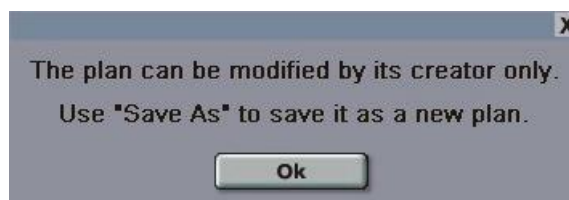


Figure 59: Planning Protection Message

- If you are not the creator of the original plan, then an appropriate message opens (see **Figure 58: Planning Protection Message on page 108**), which instructs you to use the Save As option. Click **OK** to hide this message.
- From the **File** menu, select **Save As** to save a separate file of the modified plan (see **Figure 55: File Menu**, on page 107).
Save the plan in the usual way, as described above.
The changed plan file is saved separately, and the original plan file does not change.

Note: When saving the plan, the created Mini Menu is automatically saved with the plan and loaded when the plan is loaded. However, you may save the Mini Menu separately, so that it can be loaded and used for any other plan, of any other session, see **Creating a folder of saved Mini Menus**, on page 109.

11. Advanced Saving Options

Loading and saving another plan for the same session:

- To load another saved plan of the current session, from the **File** menu, select **Load** (see **Figure 55: File Menu on page 107**).

A Load window opens with a list of plans available for the currently opened session

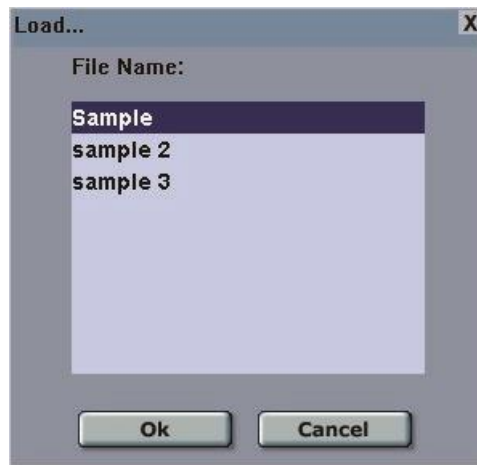


Figure 60: Loading a Plan

- Select the plan you want to load, then click **OK**.
The plan is loaded as a new plan. The currently active plan does not change
- To save a copy of the loaded plan, from the **File** menu, select **Save a Copy** (see **Figure 55: File Menu** on page 107).

The Save As window opens

- Save the plan in the usual way, as described above.
A copy of the loaded plan is saved in the original session folder. The active plan does not change, and it is still displayed.

Note: Only the creator of the plan can modify it. However, saving a copy and modifying it can be done by anyone (like **Save As**).

Creating a folder of saved Mini Menus:

You may save several Mini Menus, with different names, to a certain folder of IGI. A saved Mini Menu can be loaded and used through any plan of any session.

- To save the Mini Menu, firstly close the **Bur Menu**. Then, from the **File** menu, select **Save Mini Menu** (see **Figure 55: File Menu** on page 107). The Save As window, for saving a Mini Menu, opens.



Figure 61: Save As Window for Saving a Mini Menu

- Name the Mini Menu file (you may use the On-Screen Keyboard), then click **OK**.
The Mini Menu is saved to a certain folder of IGI and can be loaded and used

through any plan of any session.

- To load a saved Mini Menu, from the **File** menu, select **Load Mini Menu** (see **Figure 55: File Menu** on page 107).

A Load window opens with a list of available Mini Menus



Figure 62: Load Mini Menu Window

- Select the Mini Menu you want to load, then click **OK**.
The selected Mini Menu is loaded and displayed

Note: The **Load Mini Menu** option is used when preparing the drilling burs for implantation.

- To delete one of the saved Mini Menus, from the **File** menu, select **Delete Mini Menu** (see **Figure 55: File Menu**, page 107).
A Delete window opens with a list of available Mini Menus



Figure 63: Delete Mini Menu Window

- Select the Mini Menu you want to delete, then click OK.
The selected Mini Menu is deleted from the list

D. Pre-Surgical Preparations

After the dental surgeon has completed the planning process, pre-surgical preparations are performed.



Warning: Before pre-surgical preparations, you should sterilize/ disinfect all the elements of IGI kit. (See *Disinfecting and Sterilizing the IGI Kit Elements* on page 186). Therefore, handling these elements at this stage should be done according to accepted dental implant protocol.

1. System Set-Up

The following procedures are performed prior to the implantation procedure. These pre-surgical steps include checking the required equipment, setting up the work area, initializing the system, installing IGI trackers, positioning the camera, verifying functionality of Handpiece Tracker and Patient Tracker, defining a bur point, and if applicable, setting up the optional Drilling Autostop Box.

a. Equipment

Below is a checklist of the necessary equipment for an IGI implantation procedure.

- Sterile Handpiece
- Disinfected Handpiece Tracker
- Disinfected Patient Tracker with a suitable sterile pole
- Sterile metal hex screws for fixing the pole to the Fixation Device
- Sterile metal allen wrench for the hex screw
- Disinfected Fixation Device (tray and wedges)
- Sterile metal thumb screws to fix the pole to the Patient Tracker
- Sterile IGI registration bur and/or Sterile IGI tracing bur
- Sterile IGI long bur for functionality test
- Sterile IGI short bur (for calibration by IGI authorized technician only)
- Drilling Autostop Box (DAB), optional
- Compatible water tube (compatible with IGI handpiece)
- Sterile dental implants compatible with the planned implants

- Complete set of sterile drilling burs and extensions



Warning: Use only implants that appear in the IGI database when performing IGI surgery. To view details of all the planned implants, you may select **Implant List** from the **View** menu. See **Figure 42: Implant Selection from Menu**, on page 95. If the implant is not in the database, see **Adding a New Implant to the Database** on page 93.

Note: If you intend to use the **Mini Menu** option (see **Creating a Drilling Burs Mini Menu**, on page 105), use burs that appear in the IGI database or use the **Bur Point** option (automatic bur measuring). This enables using burs that do not appear in the IGI database (see **Bur Point** on page 122).



Warning: Do not use burs or implants that were not defined in IGI.

b. Work Area Set-Up

Before initializing the system, make sure the work area is setup according to the list below:

IGI unit — adjacent to the patient's chair next to the dental assistant

- **Chair** — height and position
- **Surgeon's position** — standing or sitting, left or right side of the patient
- **Assistant's position** — standing or sitting on the left or right side of the patient
- **Expected angle of the handpiece** during the procedure



Figure 64: IGI Work Area

C. Initializing the System

- **Position the IGI cart at the left side** of the dental chair (left side of the patient) for right-handed dentist.
- **Connect** the system to the power supply.
- The system should warm up for 20 minutes before starting with functionality tests and registration.

Note: It is recommended to connect the system to the power supply, using a **UPS** (Uninterruptible Power Supply) device to overcome power supply failure.

- Switch on the main power supply at the back of the cart base.
- Turn on the system by pressing the push button switch in the user interface panel located on the cart pole of the IGI cart. This will start the IGI system software.
- Double-click the IGI icon to initialize the IGI system.
- Login to IGI.
- On the Archive Screen, select the patient session and plan.
- Click the Procedure button to enter the Procedure Screen.

d. Installing the IGI Trackers**Patient Tracker Preparation**

- The Patient Tracker is connected to the CRD using a pole.



Figure 65: CRD & Patient Tracker at the Pre-Surgical Stage

There are seven different types of poles; See **Figure 19: : Mandibular Patient Tracker Poles** on page 58 and **Figure 20: Maxillary Patient Tracker Poles** on page 58.

Choose a pole suitable for the patient Fixation Device based on the location of the Minilock™.

Note: Pole selection is independent of the implant site and only affected by the Fixation Device position.

- Check that the pole itself is solid and rigid (some of the poles are made from 2 parts which are welded or connected with pins and should be rigid).



Warning: Do not use a pole which is not rigid.

- Connect the Patient Tracker to the pole and secure it with a metal thumb screw.
- Connect the pole to the Fixation Device and secure it with a hex metal screw.

e. Handpiece Preparation

Note: All connections of the handpiece and patient tracker should be performed while the surgeon is holding the handpiece in his left hand (for a right-handed dentist).

- Connect the disinfected Handpiece Tracker to the sterile handpiece.
- The handpiece is attached using a thumb screw connection. Use the Allen wrench provided by Image Navigation to firmly close the thumb screw.

Follow the steps illustrated in *Figure 66: Connecting the Handpiece Tracker to the Handpiece with Thumb Screw*, below.

- For **maxillary** implantation - Connect the Handpiece Tracker over the letters "**MAX**", printed on the IGI Handpiece.
- For **mandibular** implantation, when sitting at the 10-12 O'clock position - Connect the Handpiece Tracker over the letters "**MAND**", printed on the IGI Handpiece.
- For **mandibular** implantation, when sitting at the 9 O'clock position - Connect the Handpiece Tracker over the letters "**MAND1**", printed on the IGI Handpiece.

Note: Ensure the serial number on the Handpiece Tracker is identical to that of the handpiece.

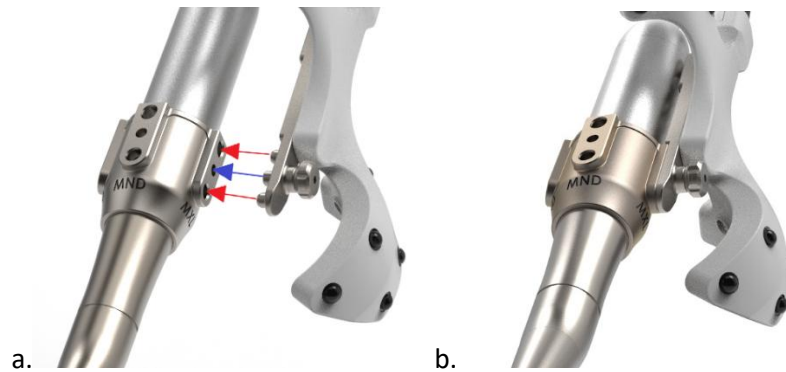


Figure 66: Connecting the Handpiece Tracker to the Handpiece with Thumb Screw

a. how to connect (blue arrow is thumb screw), b. fully connected

f. Patient Tracker and Handpiece Installation

- Connect the data cables of the Patient Tracker and Handpiece Tracker to their connectors located in the user interface panel located on the cart pole of the IGI cart (see **Connectors** page 61).
- On the Procedure Screen, click Tracking.
- The Tracking selection window opens, displaying five tabs. The default tab is Settings & Tests.

Note: To prepare the equipment for surgery, work through the tabs from left to right.

- On the Settings & Tests tab, click Tracker Selection.
- The Tracker Selection window opens.
- On the Tracker Selection window, from the upper Available drop-down list, select the Handpiece Tracker, according to its serial number. Then, click the upper Arrow button to set your selection (see **Figure 66: Tracker Selection Window below**).

Note: In maxillary sessions, only **maxillary** trackers (with “mxl” extension) are available. In mandibular sessions, only **mandibular** trackers (with “mnd” extension) are available.

- From the lower Available drop-down list, select the Patient Tracker, according to its serial number. Then, click the lower Arrow button to set your selection.
- Make sure you have selected the correct serial number for both trackers, then click OK and proceed to the next stage.

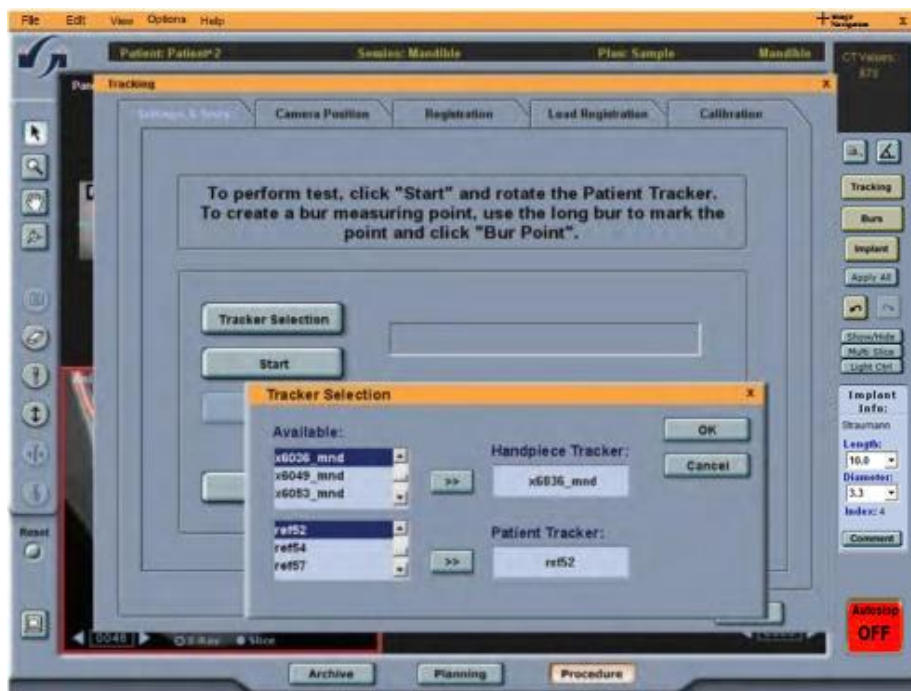


Figure 67: Tracker Selection Window

g. Positioning the Camera

Initial positioning of the camera is carried out according to the work area setup (see **Work Area Set-Up** on page 112). The camera must be able to view the Handpiece Tracker and the Patient Tracker.

Note: Before surgery itself — the camera is positioned according to the segment of implantation (left, middle or right). It is recommended that camera positioning is performed by two people together. For additional assistance regarding camera positioning, see **Guidelines for Camera Positioning**: on page 131.

Camera positioning is carried out with the camera handles (located on either side of the camera), using the IGI indicators guidance. To position the camera using the guiding indicators, follow the instructions below.

- On the Tracking window, select the Camera Position tab.



Figure 68: Selecting a Segment for Camera Positioning

- For pre-surgical procedures, select the Middle segment. The three indicators of camera positioning display:
 1. Arm Adjustment
 2. Camera Distance
 3. Camera Adjustment

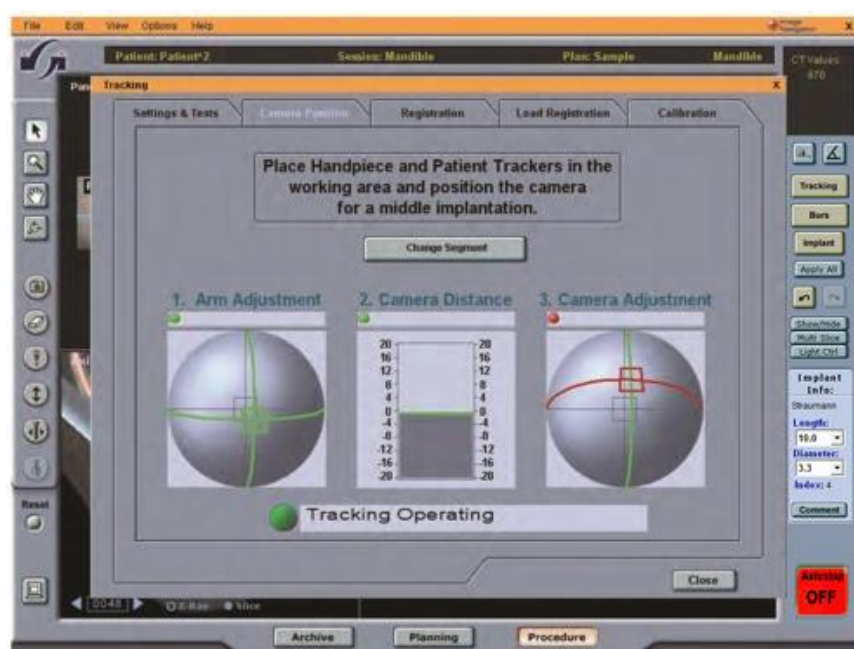


Figure 69: Camera Positioning Indicators

- Position the patient CRD, with the Patient Tracker attached, in the estimated work area — for pre-surgical procedures — above the chair headrest.
- Position the handpiece at its estimated working angle.
- Position the camera facing the handpiece and the Patient Tracker, 1 meter from the middle of the mouth.
- When the Handpiece Tracker and Patient Tracker are in the work area, the system informs you that tracking is operating.
- Follow the three indicators displayed, to adjust the camera position:
- According to the Arm Adjustment indicator - adjust the circumferential position of the camera around the trackers, using large movements of the camera arm.
- Then according to the Camera Distance indicator adjust the camera distance, using back and forth movements. Notice that the scale of the Camera Distance indicator is in centimeters.
- Finally, according to the Camera Adjustment indicator - adjust the camera pivot orientation, using minimal movements of camera.

The on-demand or continuous camera positioning tool is a different way to check the position of the patient tracker and Handpiece 2C LEDS compared to the camera's field of view. See **Camera Positioning Tool Button** on page **132**.

h. Patient Tracker & Handpiece Functionality Test

Functionality of the trackers is verified prior to surgery. By this stage, the work area is set up, and the camera is positioned as instructed.

- On the Tracking window, select the Settings & Tests tab.
- Insert the long bur into the handpiece.
- Place the patient CRD with the Patient Tracker attached to it within the work area.
- Click Start and move the Patient Tracker right and left while keeping the tracker facing the camera.

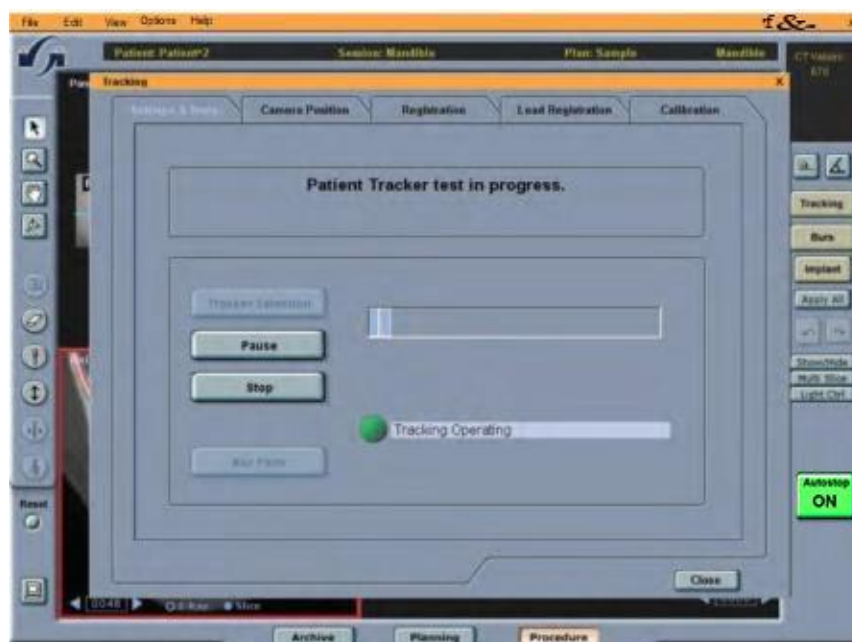


Figure 70: Patient Tracker Test in Progress

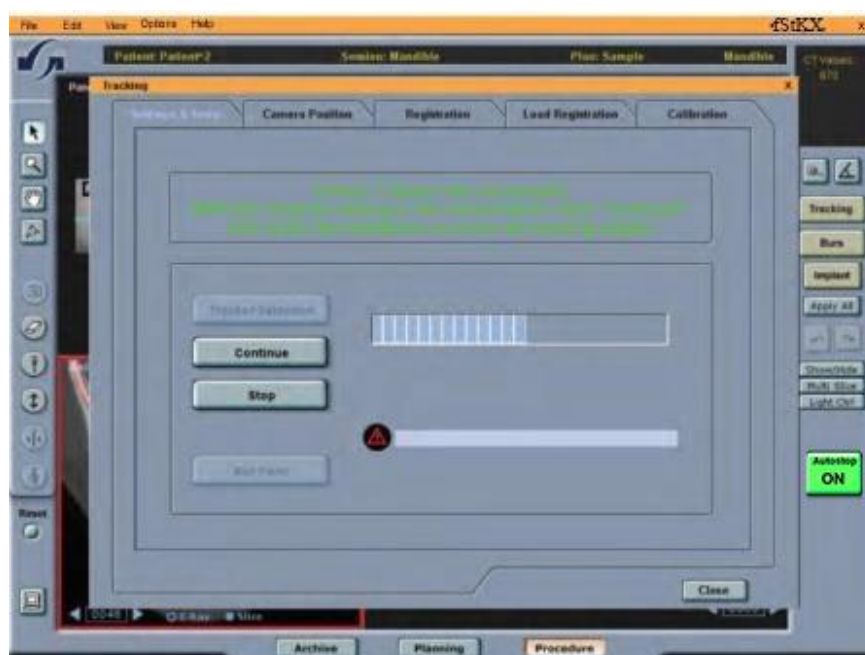


Figure 71: Patient Tracker Test Succeeded

1. After the Patient Tracker test is successful, hold the CRD with your left hand and the handpiece with your right hand (if you are performing the surgery with your right hand).
2. Place the long bur tip in the round notch at 90 degrees to the top flat surface of the metal pole close to the Minilock™ tray, see **Figure 71: Performing Handpiece Functionality Test below**. Click Continue.



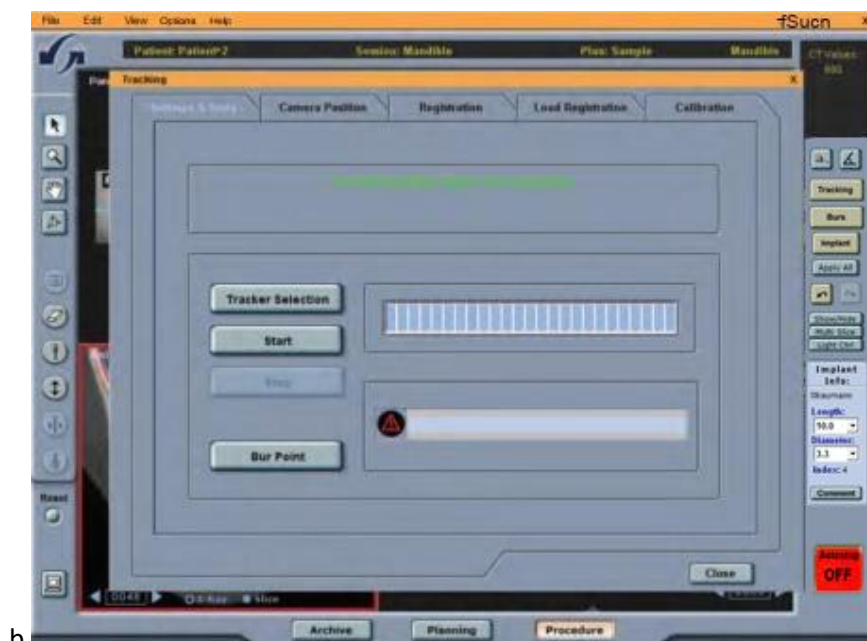
Figure 72: Performing Handpiece Functionality Test

3. With the long bur sitting in the round notch, hold the handpiece still for 5 seconds. Then, move the handpiece in all directions, allowing diverse sampling angles.

Note: A progress bar indicates the progress of this procedure. Error messages indicate problems with sampling of the handpiece tip.



a.



b.

Figure 73: Handpiece Functionality Test

a. Test in Progress; b. Test Succeeded

On completion of testing procedure, the test results display:
If the handpiece test is successful, you may proceed to the next stage.
See **Bur Point**, on page 122.

If the handpiece test is not successful, repeat the testing procedure.

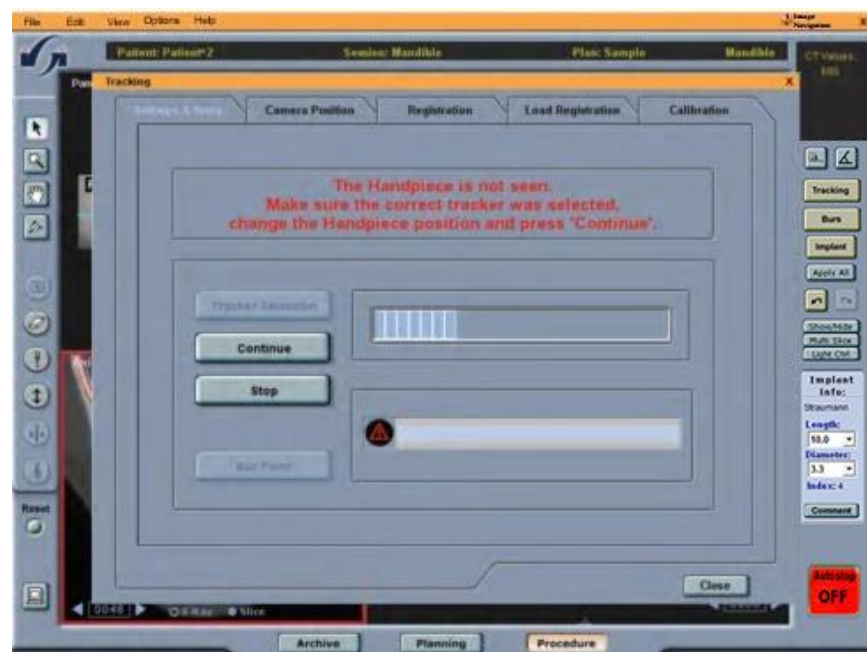


Figure 74: Handpiece Test Ended Unsuccessfully

Important: Make sure that the camera is set in its optimal position and that both Handpiece Tracker and Patient Tracker are within the work area of the camera.

The selected serial number of the handpiece on the screen must match the serial number of the handpiece that you are testing

If the handpiece fails to pass the testing procedure three consecutive times, it should be re-calibrated by an IGI authorized technician.

Caution: Only an IGI authorized technician is allowed to perform recalibration.



Warning: Do not perform an IGI implantation procedure with a handpiece that does not meet the testing criteria.

4. If the handpiece fails to pass the testing 3 consecutive times, use a re-calibrated handpiece or an alternative handpiece and perform the functionality test from the beginning. If the handpiece was replaced, connect its data cable to the IGI unit and update its serial number before beginning the test.

Bur Point

To enable automatic bur measuring during surgery, a Bur Point has to be defined prior to surgery.



Figure 75: Defining the Bur Point

1. Hold the CRD with your left hand and the handpiece with your right hand.

Place the long bur tip at 90 degrees over the **Bur Point** (the flat surface between the two lines marked area on the pole).

2. On the Settings & Tests tab, click the Bur Point button. The progress bar of the Bur Point Measuring displays.



Figure 76: Progress Bar of Bur Point Measuring

3. Hold the bur steady for few seconds. A confirmation message appears, and a confirmation sound is heard.
4. If the bur point is measured *successfully*, proceed to the next stage, see **Fiducial Registration, below**.
5. If the bur point is measured *unsuccessfully*, repeat the process or use the manual bur selection during surgery. To use the manual bur selection, the bur must be in the database see **Adding Drilling Burs to the Database**, on page 104.

2. Fiducial Registration

(For **Anatomic Registration** see page 133)

After performing all pre-surgical steps mentioned above, you are ready for registration. Registration of the Fixation Device silicon nitride markers creates an interface between the CT image and the patient.

a. Performing the Registration

Registration is performed on the segment of the planned implants to ensure optimal accuracy.

Note: If the system identified too many distortions in the CT scan when the session was

created, fiducial registration is impossible, (see **Figure 76: Registration is Impossible Message** on page 124) and procedure is not enabled.

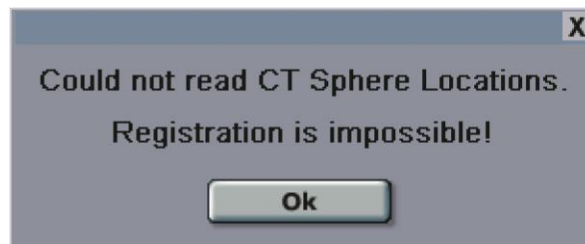
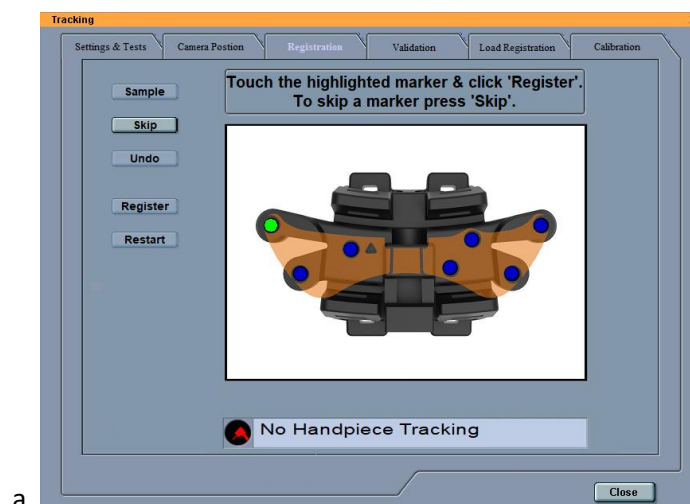


Figure 77: Registration is Impossible Message

To perform a registration:

- Insert the registration bur into the handpiece.
- On the **Tracking** window, click the **Registration** tab.
- The Registration tab opens.





b.

Figure 78: Registration Tab (a. Mandible; b. Maxilla)

- The first marker to be registered is colored green on the **Registration** tab.
- Hold the CRD with your left hand, and the handpiece with your right hand.
- Gently place the registration bur at 90 degrees over the first silicon nitride marker to be registered. Try to hold the handpiece at an optimal angle towards the camera. See **Figure 78: Performing the Registration** on page 125.



Warning: Do not apply any pressure to the silicon nitride marker. The contact must be very light to avoid distortion of the Fixation device.



Figure 79: Performing the Registration

- A green light coupled with a message of **Tracking Operating** indicates that the system is tracking both the Handpiece Tracker and the Patient Tracker.
- Any problem with tracking, either with the Handpiece Tracker or the Patient Tracker, is indicated with a red light together with an error message.

Make sure that the:

- Correct serial numbers for both trackers have been selected.
- Camera is set in its optimal position with both trackers within the work sphere of the camera.

- With the registration bur steady on the silicon nitride marker and the tracking operational, register the first silicon nitride marker by clicking **Sample**.

Important: The system will not register the marker if it is unable to track the Handpiece Tracker or the Patient Tracker.

If the registration bur was not steady on a silicon nitride marker during registration, cancel the last sampled marker by clicking **Undo**. Sample it again.

- If one of the silicon nitride markers is missing or corrupted, omit this marker by clicking **Skip**.

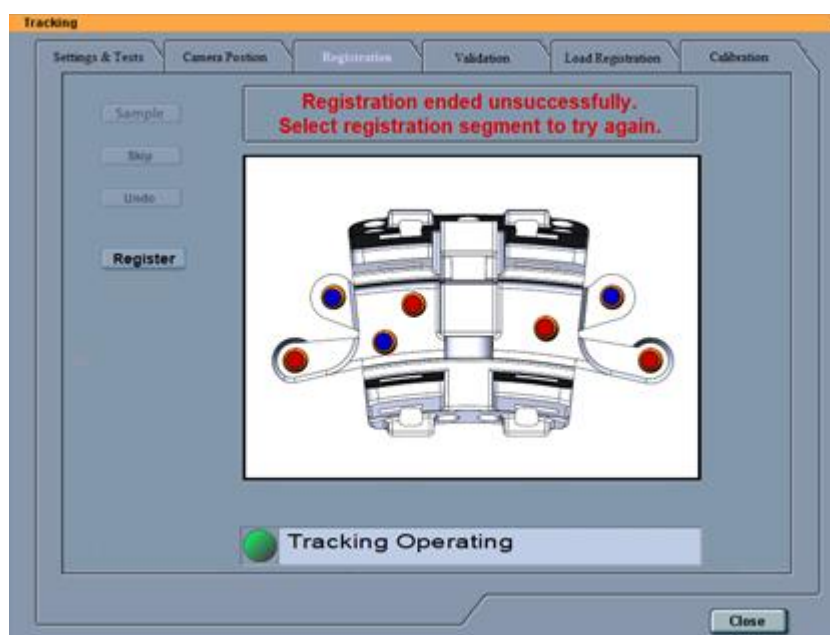


Figure 80: Red X on an Ignored Silicon Nitride Marker

- Proceed to the next green marker and follow the above procedure. Repeat until you have sampled 5 silicon nitride markers.
- On completion of the registration process, click **Register**.
- A message indicates the success or failure of the registration

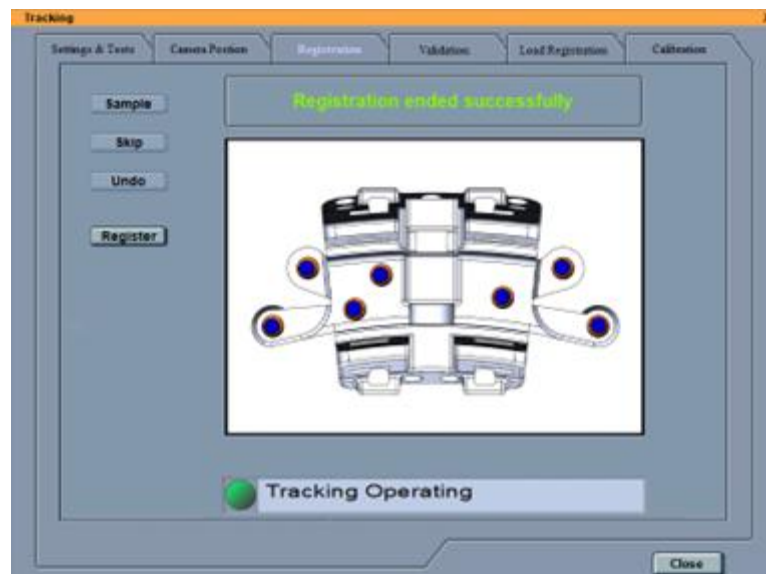


Figure 81: Registration Ended Successfully

- If registration ends successfully: Click Close.
- The registration is loaded and you may proceed to the next stage, see **Implantation Procedure**, on page **128**

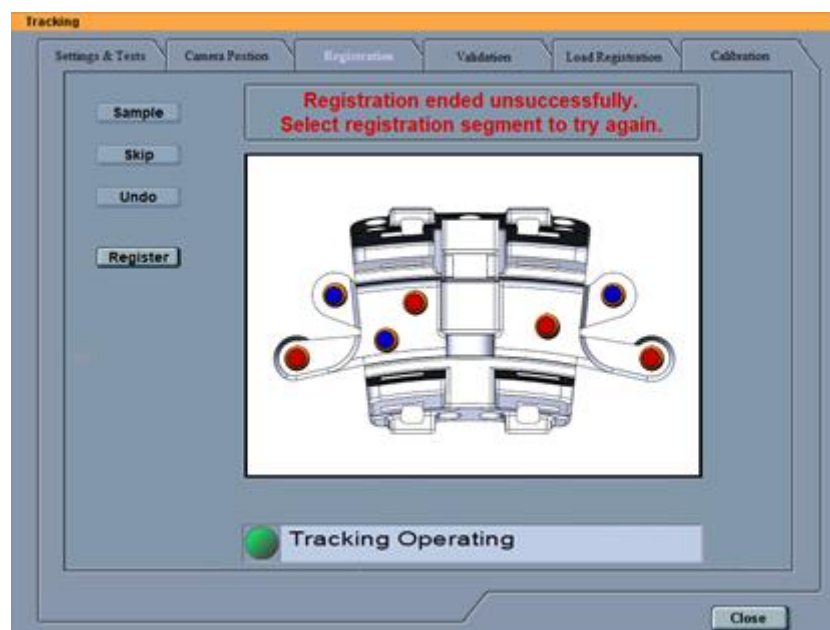


Figure 82: Registration Ended Unsuccessfully

If registration ends unsuccessfully:

- The problematic markers are colored red.
- Repeat the registration process, and make sure that:
- Correct serial numbers for both trackers are selected.

- Handpiece is optimally angled towards the camera.
- Bur is steady on the markers while registering, without applying any pressure.

b. Loading the Registration

The last registration file that you have performed (for each implantation segment) is saved and you can load it before and during the implantation procedure.

Note: Only the **last** successful registration is saved and available for loading.

1. On the *Tracking* window, select the *Load Registration* tab



Figure 83: Load Registration Tab

- Prior to surgery, select Load registration.
- Select the registration type. By default, for fiducial registration, Middle is selected. Then Click **Close**.
- The selected registration is loaded.

E. Implantation Procedure

Follow the instructions below to perform the implantation procedure.

1. **Positioning the CRD**

Before drilling, the dental surgeon performs all necessary preparatory procedures (i.e., anesthesia, flap elevation, extractions etc.). During these procedures, the CRD is kept out of the mouth to allow visibility and accessibility.



Warning: Premature CRD positioning may lead to distortion while surgical forces are applied.



Warning: It is crucial that the Fixation Device is stable and maintains the exact same position during the implantation procedure.

Fiducial Registration

The CRD is placed in its position when the dental surgeon is ready to proceed with IGI tracked drilling.

- a. Place the CRD *carefully* in the patient's mouth to avoid distortion.
- b. Minilock™ tray: Place the correct wedge in place, a *click* should be heard to indicate that the wedge is firmly in place. If the largest planned wedge doesn't fit, try the next smaller size wedge.
- c. Make sure that the Minilock™ Device is stable and that there is no rocking movement.
- d. Minilock™ tray: If any kind of movement occurs, use one of the two methods described below. Before using the below methods, use the 3-way syringe to blow air on the internal part of the Minilock™ tray to remove any interfering particles.
 - Place 2 thin lines of Build-It™ internally on the occlusal surface of the registered teeth. Replace and fully seat the Minilock™ tray on the teeth. Place and fully seat (hear the click) the wedge in place. Wait until the Build-It has set before proceeding.
 - Place a bead of GC Universal Flo™ (a flowable composite) in three to four places externally to bond the LuxaBite® to the teeth. Use light to cure the flowable composite. Other flowable composite materials were not tested.



Warning: If Build-It is used, all composites and crowns must be first covered with glycerin.



Warning: It is crucial that the Fixation Device is stable and maintains its position throughout the entire procedure. Any dislodgement or movement of the Fixation Device from its place will have a dramatic negative effect on the system's accuracy.

 **Warning:** If the Fixation Device is not stable, do not perform the implantation using the IGI system.

Anatomic Registration

Prepare the CRD as written on page **69**, *IGI Kit for Partially Edentulous Jaw Implantation*.

There are 3 kits provided, 2 Fixation kits (anterior and posterior Minilock) and a pole kit. Below are charts which list the components of each.

Table 3: Minilock™ Kits (a. posterior, b. anterior)

a.	1 Individual Posterior Minilock™ Tray
	3 wedges for each tray (S, M, L)
	1 Hex screw
b.	1 Individual Anterior Minilock™ Tray
	3 wedges for each tray (S, M, L)
	1 Hex screw

Table 4: Poles Kit

7 Poles
Rubber Dam Forceps as Posterior TRI
Posterior TRI
Anterior TRI
Allen Wrench
4 Thumb Screws
Pole Removal Device

Preparing the CRD

2. Positioning the Camera before Implantation

- With the CRD positioned in the patient's mouth and the handpiece in the drilling position, reposition the camera.
- Using the handpiece, simulate the different angles you expect to use during implantation to ensure an optimal tracking range.
- Make sure that the camera view is not obstructed by the surgeon's

or dental assistant's head and hands.

- To position the camera using the indicators:

Follow the general instructions, see ***Positioning the Camera before Implantation***, on page **130**. However, make sure to select the *relevant implantation segment*: **Right, Middle** or **Left** see ***Figure 67: Selecting a Segment for Camera Positioning***, on page **117**.



Figure 84: Surgery Simulation for Camera Re-positioning

3. Guidelines for Camera Positioning:

- Place the dental chair at the expected position for surgery.
- For procedures in quadrants mandibular right, mandibular middle, maxillary right, maxillary middle, position the camera directly above the patient's shoulders and perpendicular to the patient chair (6:00 position on a clock), see ***Figure 84: Set-Up for mandibular right, middle, and maxillary right and middle implantations***, on page **131**.
- For procedures in the quadrants of mandibular left, and maxillary left Implantations position the camera above the assistant (3:00 position on a clock), see ***Figure 85: Set-Up for maxillary and mandibular left implantations***, on page **132**.

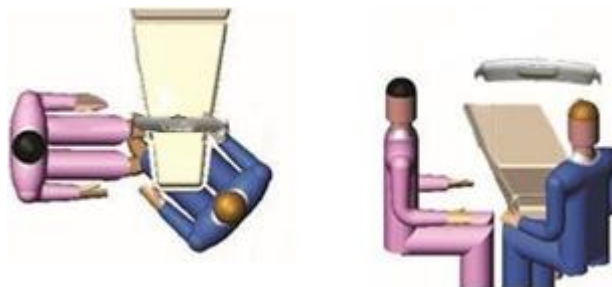


Figure 85: Set-Up for mandibular right, middle, and maxillary right and middle implantations

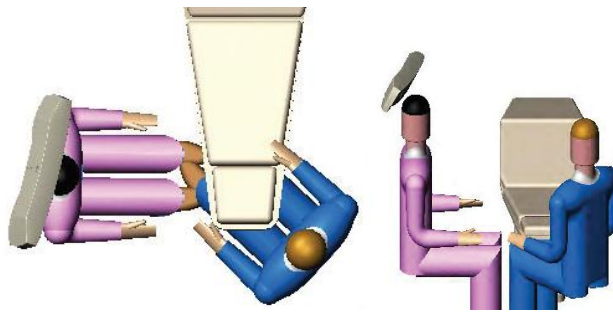


Figure 86: Set-Up for maxillary and mandibular left implantations

- Place the CRD in the patient's mouth and use the handpiece to simulate the implantation procedure.
- The Handpiece Tracker and the Patient Tracker must be within the work area of the camera. The IR emitters (LEDs) of both trackers must face the camera.
- When Fiducial Registration is used, skip to step 6 Drilling Procedure.
- Camera position can be checked during surgery by pressing the camera position tool button, number 4 on Figure 13: IGI Procedure Screen, on page 50. For instructions on its use, see below.

Camera Positioning Tool Button

The Camera Positioning Tool button labeled number 4 in **Figure 13: IGI Procedure Screen**, on page 50. This tool can be used in real time on demand or left open and moved to a convenient place on the screen. Once opened, the LEDs of both patient tracker and the handpiece 2C are visible and show the location of the tools within the working sphere, each in a different color, see **Figure 87: Camera positioning Tool** on page 133. The line underneath shows the distance of the tools from the camera. For accurate tracking, one must keep this distance within the green part of the line. The red parts of the line indicate that the objects (one or both objects), are too far away and not seen well by the cameras.

This camera positioning tool uses only one camera to track the handpiece and patient tracker. One can choose between the right and left cameras by clicking on the word camera in the top orange box, see **Figure 87a**. If the cameras can't see the tools, "No tracking" will be shown below the sphere, see **Figure 87b**. See pictures below.

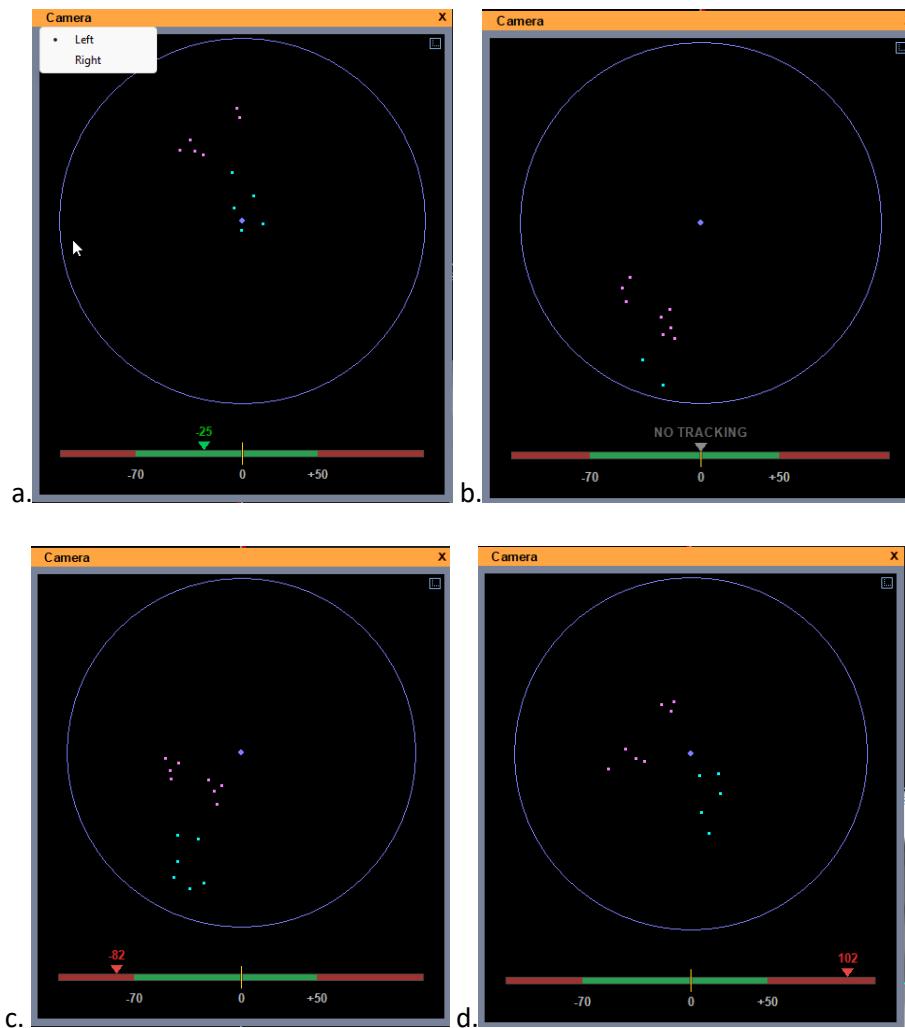


Figure 87: Camera positioning Tool

Correct distance, b. No tracking, c. Camera too far, d. Camera too close

4. Anatomic Registration

After performing all pre-surgical steps mentioned on page **111 Pre-Surgical Preparations**, you are ready for registration. Registration of the teeth creates an interface between the CT image and the actual jaw of the patient.

a. Performing the Registration

If possible, registration is performed on the segment of the planned implants to ensure optimal accuracy.

For this method, the patient must have an additional 2 cumulative linear cm of teeth (without artifacts) within a maximum gap of 2 molars (approximately 2 cm) from the implant sites or 3 cumulative linear cm of teeth if the gap is larger, besides the 3 teeth needed for the Fixation device. Anatomic registration must be done on teeth that have no artifacts on the CT scan.



Warning: Anatomic registration on teeth that aren't periodontally sound (stable and rigid), may result in unsuccessful registration and/or injury to the patient.



Warning: Anatomic registration on less than the recommended area (3 cumulative linear cm of teeth without artifacts on the CT scan, or 2 cumulative linear cm of teeth within 2 cm of the implant site), may cause distortions in the pairing of the CT to the live patient. This can lead to patient injury.

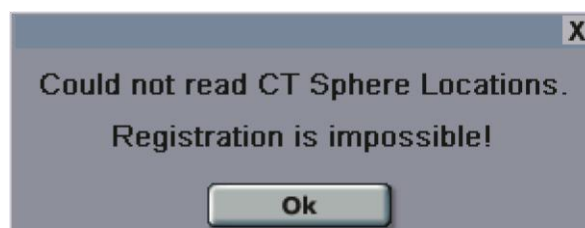


Figure 88: Registration is Impossible Message

To perform a registration:

1. Take the tracing bur from the handpiece tools kit.
2. Check that the O-ring is attached to the tracing bur. If the O-ring is attached, go to step 3. If it isn't, see below.

Replacing the O-ring:

Use the cone jig for O-ring when replacing the O-ring. See **Figure 87: Replacing the O-ring of the Tracing below.**

- Put the cone on the back part of the tracing bur (the part that goes into the drill).
- Place the O-ring on the cone jig for O-ring.
- Slide the O-ring onto the tracing bur and into place at the top of the neck.



Figure 89: Replacing the O-ring of the Tracing Bur

3. **Important:** After replacing the O-ring, the tracing bur must be sterilized before use. See section *XIV B 4 TRI's, Poles, Cone Jig for O-Ring, Pole Removal Device, IGI Burs and Thumb Screws*.
4. Insert and lock the tracing bur in the handpiece.
5. On the **Tracking** window, click the **Registration** tab. The Registration tab opens.

Important: When registering with CT (and not STL), the opacity threshold used in the planning, will be used here

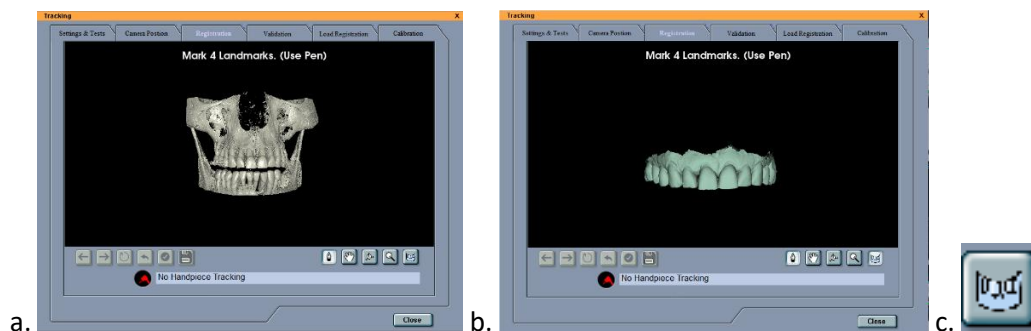


Figure 90: Anatomic Registration

a. CT, b. STL or PLY, c. CT/ STL Button

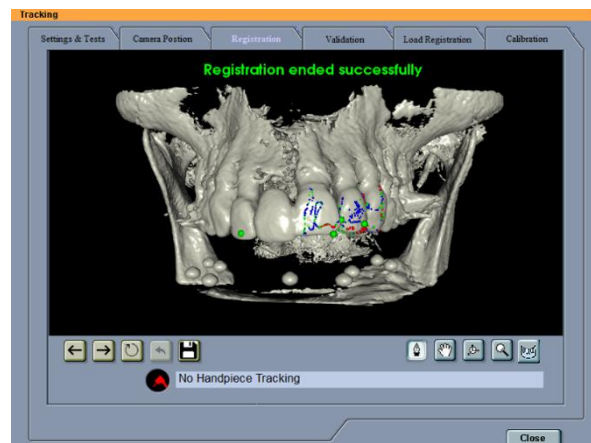
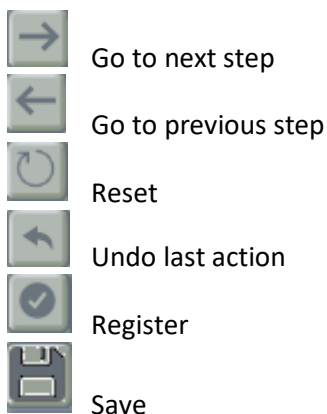


Figure 91: Registration Tab Successful Registration

The buttons on the bottom left from left to right are:



On the lower far right side there is a new button



Figure 92: Registration Tab Buttons

6. When the CT/STL isn't pressed, the registration is done with the CT. When the CT/STL button is pressed, the registration is done with the STL.

Note: The software always records the registration points on the CT

7. Mark 4 landmarks on the teeth in the CT scan that are easily reproduced on the patient. The landmarks chosen are designated by yellow circles with numbers indicating the order they were chosen.
8. After choosing the landmarks, the software changes the first point to red.
9. With the tracing bur in the handpiece, use the bur to touch each landmark in the patient's mouth (and in the same order) and wait until prompted by the software to continue. After indicating each point, the color of the circle will turn orange, and a blue ball will appear on the screen, where the software records the course registration.

The previous marking can be cancelled by clicking the **Undo** button. Register it again.

A green light coupled with a message of **Tracking Operating** indicates that the system is tracking both the Handpiece Tracker and the Patient Tracker.

Any problem with tracking, either with the Handpiece Tracker or the Patient Tracker, is indicated with a red light together with an error message.

Make sure of the following:

- The correct bur is in the handpiece.
- The correct serial numbers for both trackers have been selected.
- The handpiece Tracker is attached to the correct slot in the handpiece (maxilla, mandible).
- The camera is set in its optimal position with both trackers within the work sphere of the camera.

Important: The system will not register the marker if it is unable to track the Handpiece Tracker or the Patient Tracker.

If the course registration is successful, the computer will prompt you to start tracing (step 8).

10. If the registration is unsuccessful, press the previous step button and then the reset button. Start from step 5.
11. If the registration is still unsuccessful, press the previous step button twice and then the reset button. Start from step 3, marking 4 landmarks. Choose new landmarks that are easier to duplicate in the mouth.

Note: *If anatomic registration is unsuccessful after trying the above, it may be that the CT scan is distorted.*

-
12. To start tracing, place the drill on a tooth and hold still for 2 seconds while touching a tooth. The software will prompt with a bell to start the tracing process. Trace all available sides of the teeth without removing the drill from the teeth surfaces. While tracing a drum sound is heard. Tracing points are either red, blue or green. The green points are the closest to the teeth, while the red points are the furthest away from the teeth.
 13. The software will indicate when there are enough tracing points for registration by changing the sound from a drum to a raindrop. However, the software is not aware of how many teeth or sides of teeth were registered. Therefore, it is up to the dentist to decide when enough tracing points are registered before continuing.

Important: The buccal, occlusal/ incisal, and lingual sides must be traced for accurate registration.

Note: *It is better to have more registration points spread out on more teeth all, than concentrated on fewer teeth.*

14. If the drill must be removed from the tooth surface (i.e. if there is a gap between teeth), the software must be notified in a specific manner. Hold the drill still for 2 seconds, and when the bell rings 3 times, move the drill to the next starting point.
15. At the next starting point, hold the drill still for 2 seconds (hear the bell), and continue tracing as before.
16. When enough tracing points have been registered, hold the drill still for 2 seconds for the software to recognize that tracing stopped (bell rings 3 times).
17. Remove the drill from the camera tracking area.

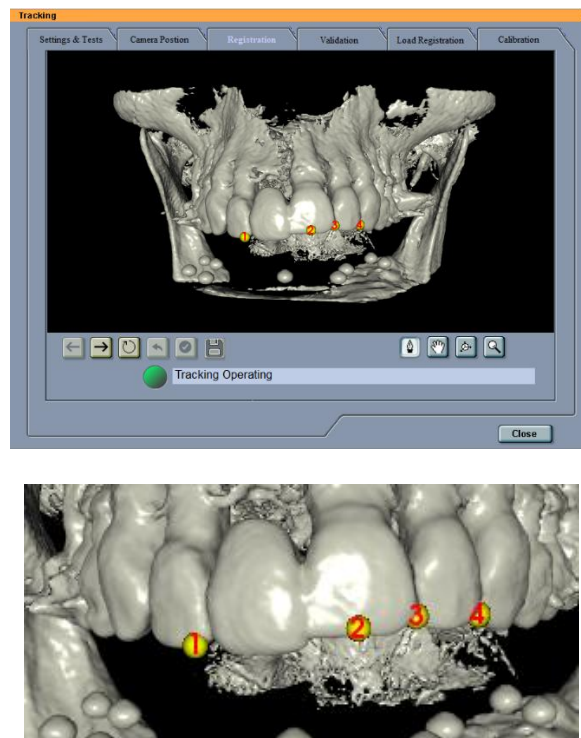


Figure 93: Anatomic Registration: 4 landmarks chosen

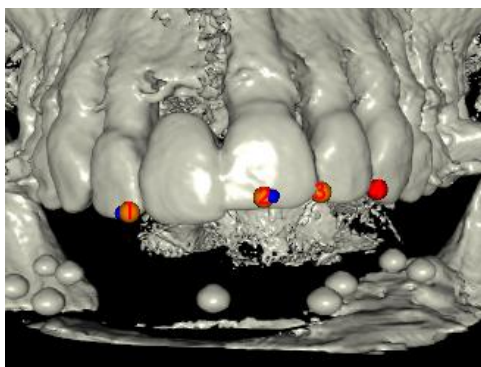
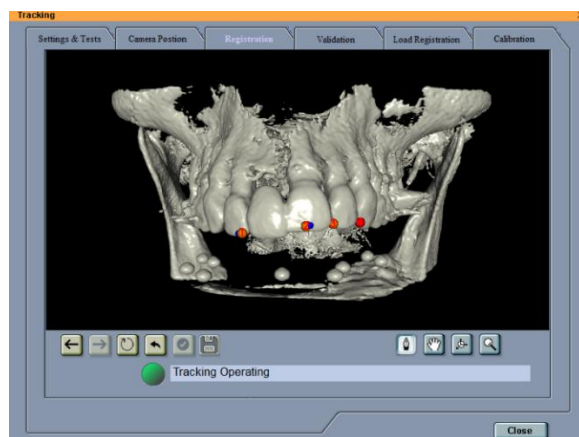


Figure 94: Anatomic Registration: First 3 landmarks, identified in the mouth

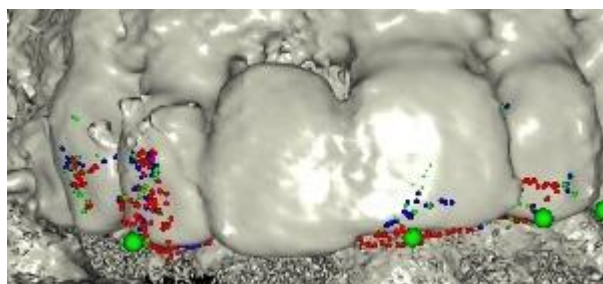
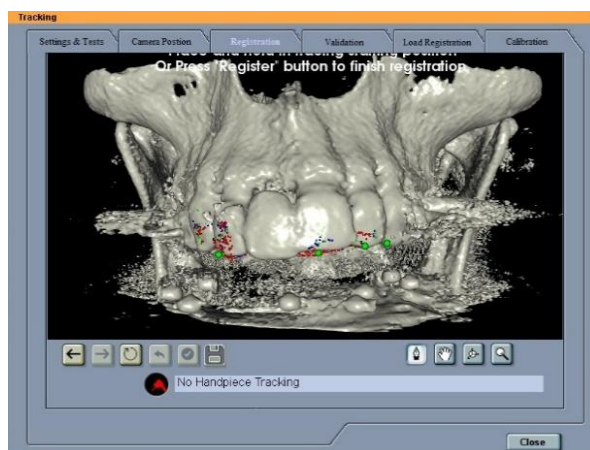


Figure 95: Anatomic Registration: Tracing

18. Press the Register button  (check sign).

A message indicates the success or failure of the registration

19. If **"Registration ended successfully"** appears on the screen, save the registration by pressing the save button, see **Figure 93: Registration Ended Successfully** on page **141**. Go to step 19 Validation.

20. If the registration is unsuccessful, press the reset step button and try tracing again (step 6).

21. If the registration is still unsuccessful, press the previous step button, then press the reset button, and start from coarse registration (step 5).

22. On the same **Tracking** window, click the **Validation** tab. There are two options for Validation.

- Keep the drill steady on a tooth until a large dot is visible on the screen. Continue with this method to check various points close to the implantation site to validate the anatomic registration.
- Tracing as before and checking the close approximation to the teeth on the CT scan to validate the anatomic registration.

The **Validate** button should only be pressed once the surgeon is satisfied with the accuracy of anatomic registration



Warning: It is the surgeon's responsibility to validate the registration results.



Warning: Do not apply pressure to the teeth. The contact of the tracing bur on the tooth surface should be light to avoid removing the drill bit tip from the teeth surfaces.

Note: *Unsuccessful registration can occur if the drill tip comes off the tooth surface during registration.*

Note: *If anatomic registration is unsuccessful after trying all of above, it may be that the CT scan is distorted.*

Note: *The undo button can't undo part of the tracing.*

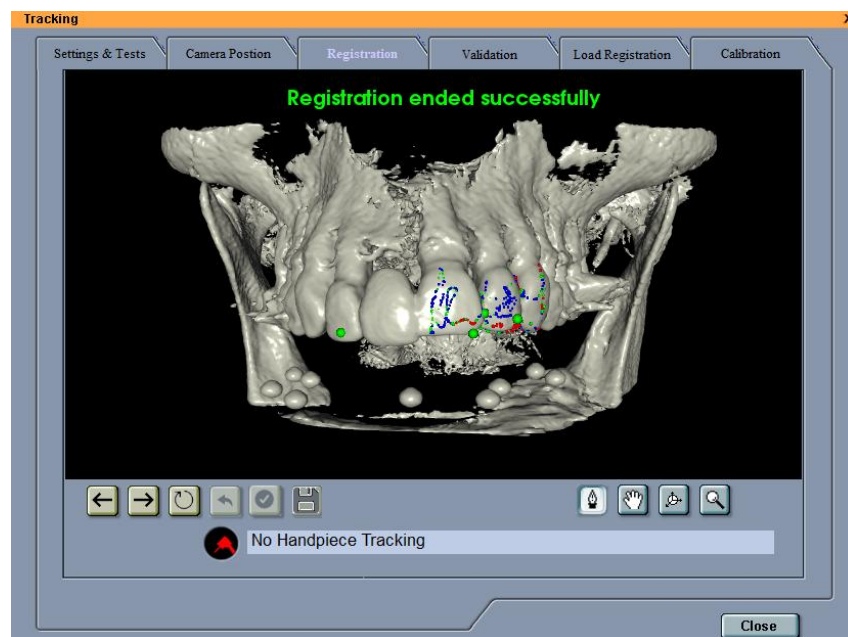


Figure 96: Registration Ended Successfully

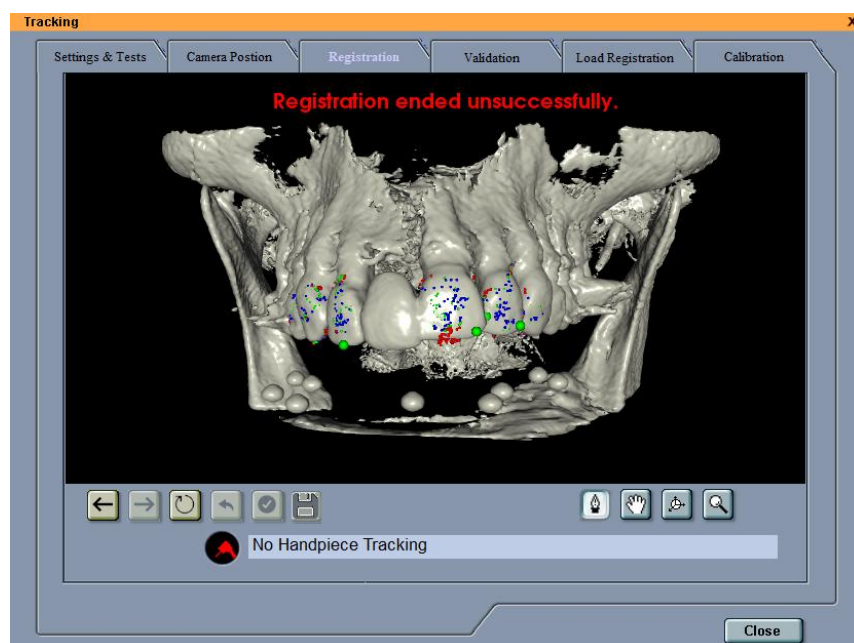


Figure 97: Registration Ended Unsuccessfully

b. Loading the Registration

The last registration file that you have performed (for each implantation segment) is saved and you can load it before and during the implantation procedure.

1. On the *Tracking* window, select the *Load Registration* tab

see Figure **82: Load Registration Tab** on page **128**.

2. Prior to surgery, select the appropriate saved **CLOUD** registration, to be loaded.
3. Click **Close**.
The selected registration is loaded.

5. Drilling Procedure

During the drilling procedure, the system simulates the handpiece position in relation to the CT scan.

a. Drilling Autostop Box (DAB) connection (optional)

When using the DAB, connect the DAB to the motor footswitch per instructions in **Appendix Two: DAB (Drilling Autostop Box) For Aseptico User Manual** on page **192**.



Warning: The surgeon should first try to drill in an area where the indicators are red, verify that the DAB is on and working properly.

b. Handpiece Activation

Connect the sterile handpiece to the motor. Then, connect the motor to the physio- dispenser unit. Connect the water tube to the handpiece and to a sterile saline bag.

c. Accuracy Validation

After registration, as well as after changing each bur, when choosing a bur from the bur menu, a window will prompt you to perform an accuracy validation test (see **Figure 95: Accuracy validation window**, on page **143**). Before continuing, verify that the Minilock™ device is fully seated (every time the drill is used).

Note: This test must be performed just before starting surgery.

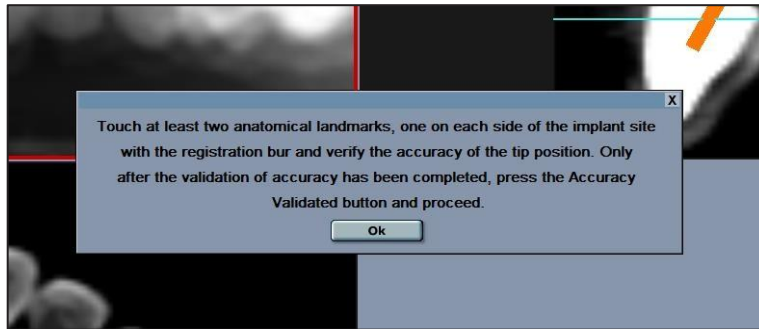


Figure 98: Accuracy validation window

To perform the accuracy check:

1. **Choose a bur and define it in IGI** (see *Defining the Bur*, on page 146).
2. Click the **Autopage** button. This option enables you to follow the handpiece movements on screen during the accuracy check.
3. Position the tip of the bur (not its side) on the buccal surface of a tooth, which is adjacent to the implantation area. Then, move it gently and continuously over the buccal, occlusal and lingual surfaces of the tooth, while following the handpiece movements on the Cross-Section View and Axial View. See, **Figure 96: Accuracy Check on Buccal Surface of Adjacent Tooth**, **Figure 97: Accuracy Check on Occlusal Surface of Adjacent Tooth**, and **Figure 98: Accuracy Check on Lingual Surface of Adjacent Tooth** **Figure 99: Accuracy Check on Mesial & Distal**, on page 144).
4. Make sure that the virtual bur tip location on the screen corresponds to the actual bur tip location.
5. Repeat this check on other adjacent teeth. This must be checked in more than 1 place to avoid false negatives.



Warning: Do not continue with surgery If the virtual bur tip location on screen doesn't match the actual bur tip location. Surgery in this case can lead to patient injury. See #8 for troubleshooting this problem.

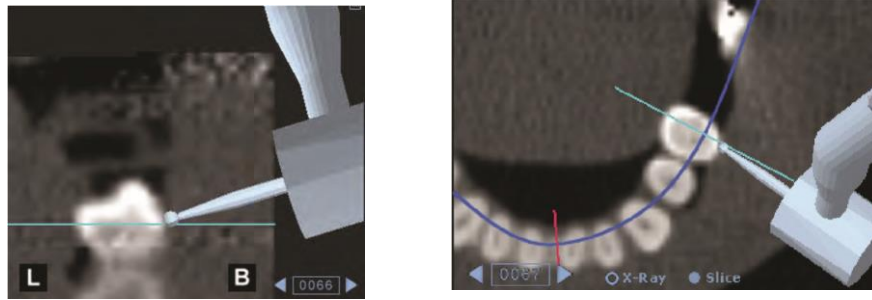


**Figure 99: Accuracy Check on Buccal Surface of Adjacent Tooth
(Cross Section and Axial Views)**

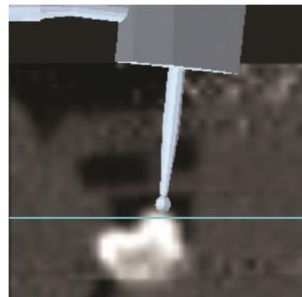


**Figure 100: Accuracy Check on Occlusal Surface of Adjacent
(Cross Section View)**

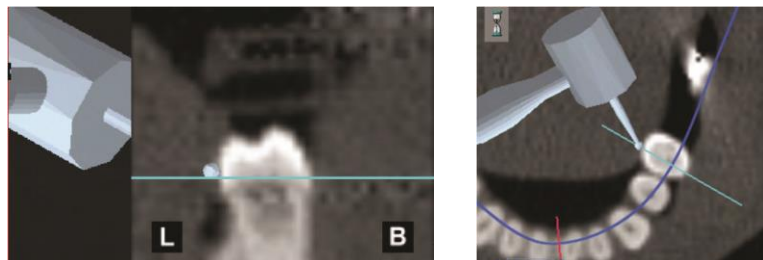


**Figure 101: Accuracy Check on Lingual Surface of Adjacent Tooth
(Cross Section and Axial Views)**

6. If possible, perform this check also over the *mesial* and *distal* surfaces of the adjacent teeth.

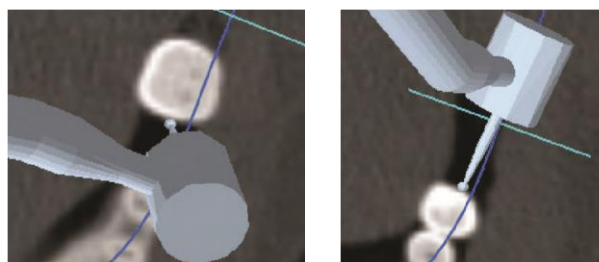


**Figure 102: Accuracy Check on Mesial & Distal
(Axial View)**

7. If a **flap** is elevated, perform an *additional* accuracy check over the buccal, occlusal and lingual surfaces of the exposed **bone** in the implantation area.

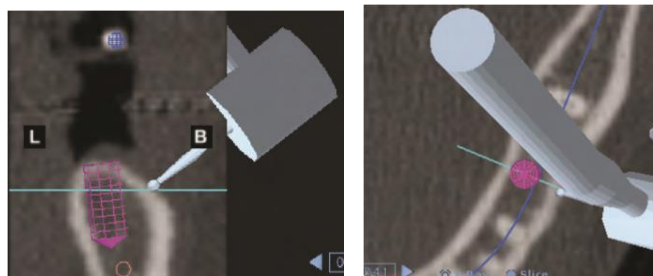


Figure 103: Accuracy Check on Buccal surface of Bone
(Cross Section and Axial Views)

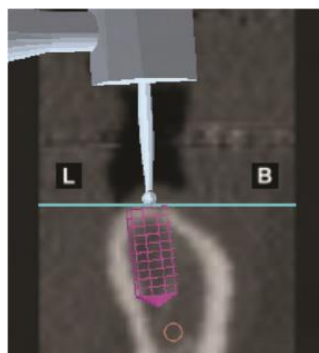


Figure 104: Accuracy Check on Occlusal Surface of Bone
(Cross Section View)

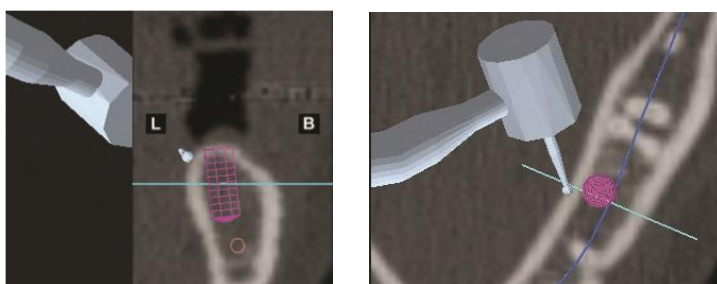


Figure 105: Accuracy Check on Lingual Surface of Bone
(Cross Section and Axial Views)

Only when you approve of the accuracy, press the Accuracy Validated button found in the lower right part of the screen. (See **Figure 103: Accuracy Validation button**, on page **146**).

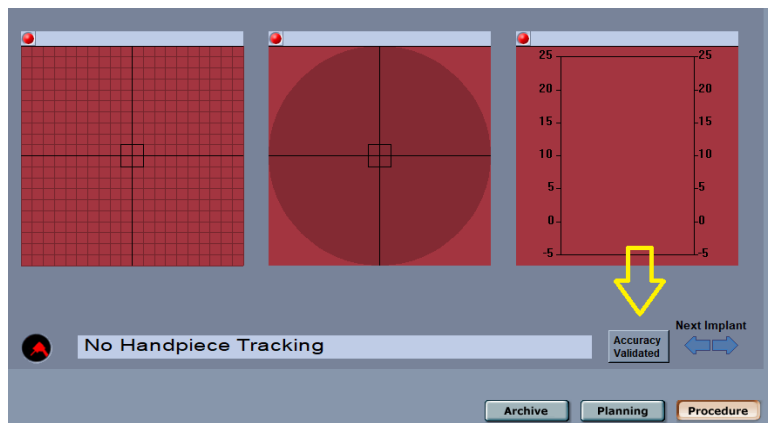


Figure 106: Accuracy Validation button

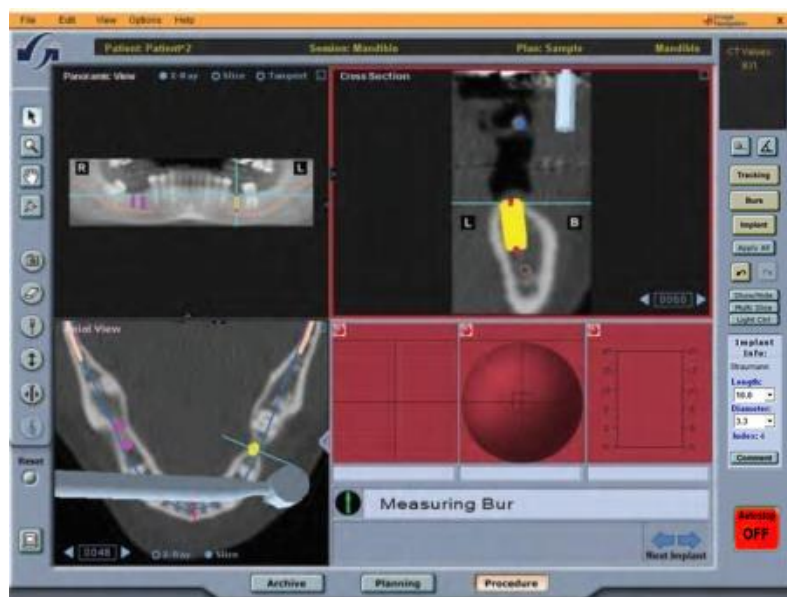
8. If you aren't satisfied with the accuracy, check the following:
 - If the Fixation Device with patient tracker moved.
 - The chosen bur and its length are correct in IGI.
 - The patient tracker is screwed on tight and has no independent movement from the CRD.
 - The handpiece tracker is screwed tight and has no independent movement from the handpiece.
 - If the above doesn't help, redo functionality test.
- d. **Defining the Bur**

During the drilling procedure, you use different burs. Be sure to define the bur in the IGI system to match the bur that is used for drilling. Each time you replace a bur in the handpiece, you must define it in the IGI system. You may use either the Automatic Bur Measuring or the Bur Menu.
1. Automatic Bur Measuring
 - After inserting the bur into the handpiece, place the bur tip on the **Bur Point**, which is the round elevated plane on the pole.



Figure 107: Bur Measuring

- Hold the bur tip at 90 degrees and keep it steady for few seconds. The system automatically measures and updates the bur length. A confirmation message is then displayed.



a.



Figure 108: Bur Measuring Messages

(a. Measuring Bur; b. Bur was Measured Successfully)

Note: The automatic bur measuring is enabled through the Options menu, refer to **Figure 106: Options Menu**, on page 149. The automatic bur measuring option works only if a bur measuring point is defined in Settings & Tests tab first, refer to **Bur Point** on page 122.

If an extension is used, place the bur with the extension on the bur point. The bur is displayed as a twist bur with a constant diameter (only the bur length changes).

2. Bur Menu

All burs (besides Image Navigation burs) are placed into the database by the user. After burs are placed in the database, they can be chosen directly from the Bur Menu or the Mini Menu. (See **Creating a Drilling Burs Mini Menu**, on page 105).

- On the **Procedure** Screen, click the **Burs** button.
- The **Bur Menu** opens together with the **Mini Menu**
- Select the relevant bur and extension.
- Close the Bur Menu. The Mini Menu stays open for next bur selection



Warning: If the bur defined in the IGI system does not match the bur used for

drilling, the guidance will be incorrect and there will be an error in drilling, which may lead to patient injury.

 **Warning:** Accuracy validation must be done every time a different bur is chosen (see page **142**).

e. **Selecting the Implant**

You may use either the **automatic** implant selection or the **manual** implant selection.

Important: The indicators always refer to the selected implant which is colored yellow. Be sure to select the implant that you are about to place.

1. Automatic Implant Selection

- a) Decide on the first implant to be placed and place the tip of the handpiece around the planned implant area on the bone ridge.
The implant which is closest to the tip of the drill is automatically selected and colored yellow.
- b) To select a different implant, move the handpiece tip accordingly.

Note: The Automatic Implant Selection is enabled through the **Options menu**.

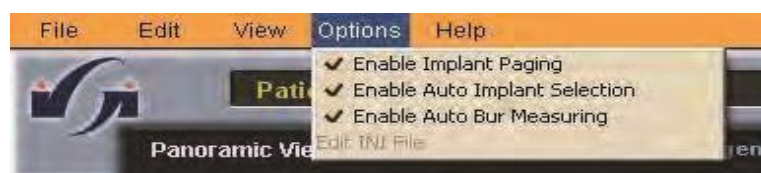


Figure 109: Options Menu

2. Manual Implant Selection

On the Procedure Screen, click the desired implant.

- a) The selected implant is colored yellow.
- b) There is an option to select implants according to their index number. Use the arrows in the Indicators View to select the next or previous implant.

Note: The index number refers to the order when the implants were planned in IGI, not the next implant to the right or left.

Once you select an implant, you may use the **Implant Paging** option. All views automatically display the CT slices in the selected implant area. The implant paging option is enabled through the **Options menu**, see **Figure 106: Options Menu** on page 149.

f. Drilling According to IGI Indicators

Before drilling, verify that the Minilock™ device is fully seated (every time the drill is used).

The Indicators View appears automatically after loading a registration, and they are available only when tracking is operating and after accuracy has been validated (see page 142). The IGI indicators guide you to place the implants in the planned positions. While drilling, note the following:

- Red background of the Indicators View – **Indicators are not active**, and an appropriate message is displayed, such as:
No Tracking, No Handpiece Tracking, No Patient Tracking, No Bur was Measured, No Implant Selected or Handpiece is not in implant area.
- The red line above the indicators signals that the DAB will not allow drilling.

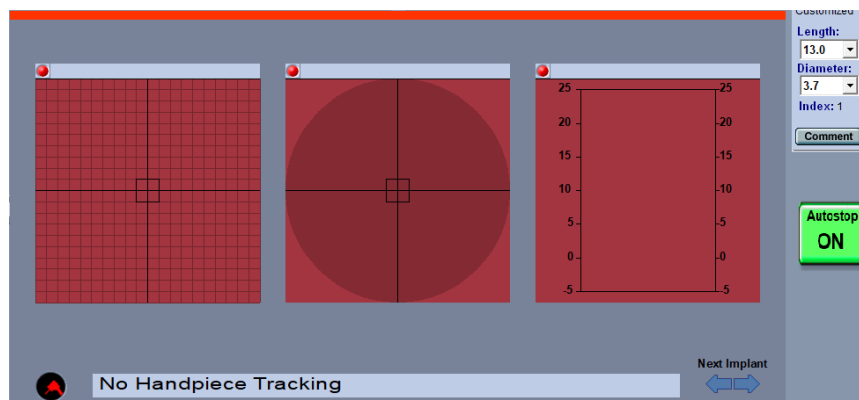


Figure 110: Disabled Indicators

- When the handpiece tip is close to the selected implant, indicators become **active**:
- Green and red lines indicate the handpiece tip position.
- A distinctive sound is heard.
- The green or red line above the indicators signals that the DAB will or won't allow drilling. See **Figure 107: Disabled Indicators above**, and **Figure 108: Enabled Indicators below**.

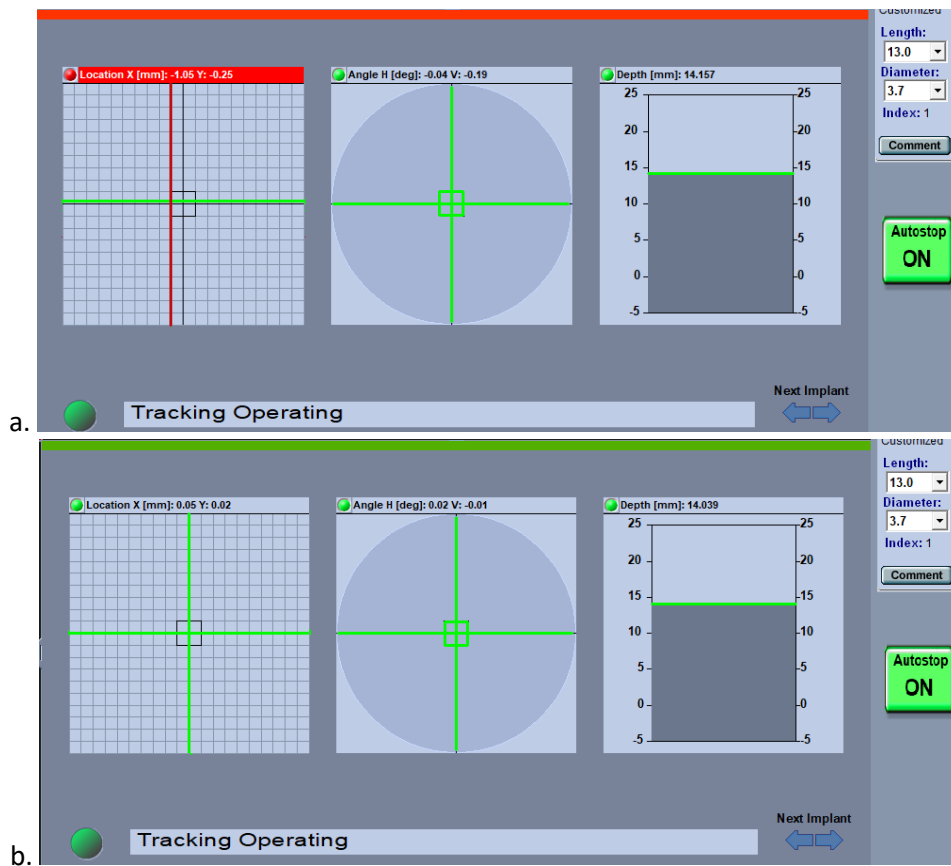


Figure 111: Enabled Indicators

- If tracking is not operating, you are alerted by:
- A warning *message* with red indicators.
- A warning *sound*.



Warning: Do not proceed with drilling until the system resumes tracking.

Three indicators are available:

Location Indicator:

- Displays the deviation of the bur tip location from the planned implant location.
- Each gray square of the grid represents 1 mm.
- The latero-lateral deviation (X-axis) and antero-posterior deviation (Y-axis) are displayed in millimeters (see header of indicator field).

Angle Indicator:

- Displays the angle of deviation of the bur tip from the planned implant. The horizontal (H) angle of deviation and vertical (V) angle of deviation are

displayed in degrees (see header of indicator field).

Depth Indicator:

- Displays the depth deviation of the bur tip from the planned implant bottom.
- The depth is displayed in millimeters (see header of indicator field).

Note: Visualization of the indicators in relation to surgeon's sitting position can be changed from the default position. See **Appendix Five: Indicators in Relation to Surgeon's Sitting Position** on page 218.

Drilling Autostop Box (DAB)

The autostop button is found on the lower right side of the procedure screen.

If the DAB is disconnected, on the lower right side of the procedure screen, a Disconnected sign will be shown, see **Figure 109: Disconnected DAB below**.

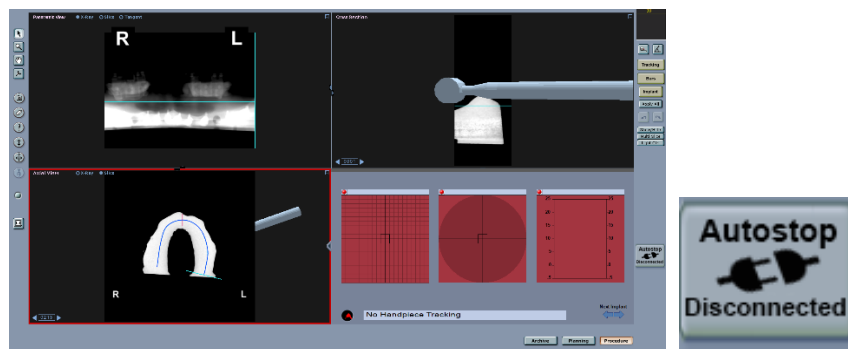


Figure 112: Disconnected DAB

If the autostop is connected, but turned off, the autostop button will be red and the line above the indicators will be dark grey, see **Figure 110: DAB Connected but Turned Off below**.

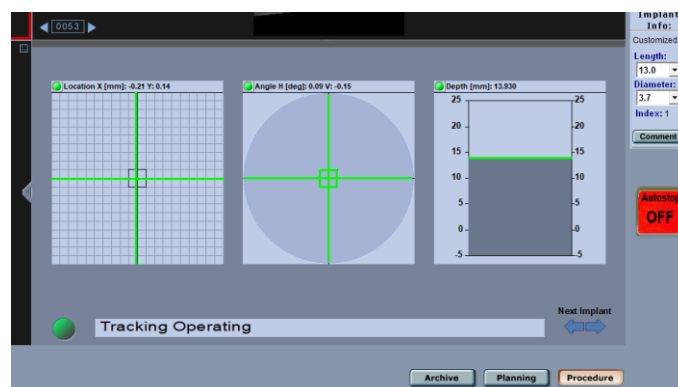


Figure 113: DAB Connected but Turned Off

The Autostop button is either green (on) or red (off). When it is on, there is a green line above the indicators. When it is off, there is red line above the indicators. see **(a procedure screen, b with indicators)** on page 153. and **(a- procedure screen, b- with indicators, c- with all indicators green)** on page 154.

When using the optional DAB:

- Verify that the Autostop button is on, not off, or disconnected.
- If the indicator is red and the DAB is attached, click the button to change it on (green).
- When all the indicators are green, the line above the indicators is green.
- When the DAB is attached but turned off, the line above the indicators is dark gray.

Important: Before drilling, try activating the drill close to but not in the correct location or angle, to verify that the DAB system is on. When the autostop is activated (green), the drill bur should not rotate due to the incorrect position (location and/or angle) of the drill.

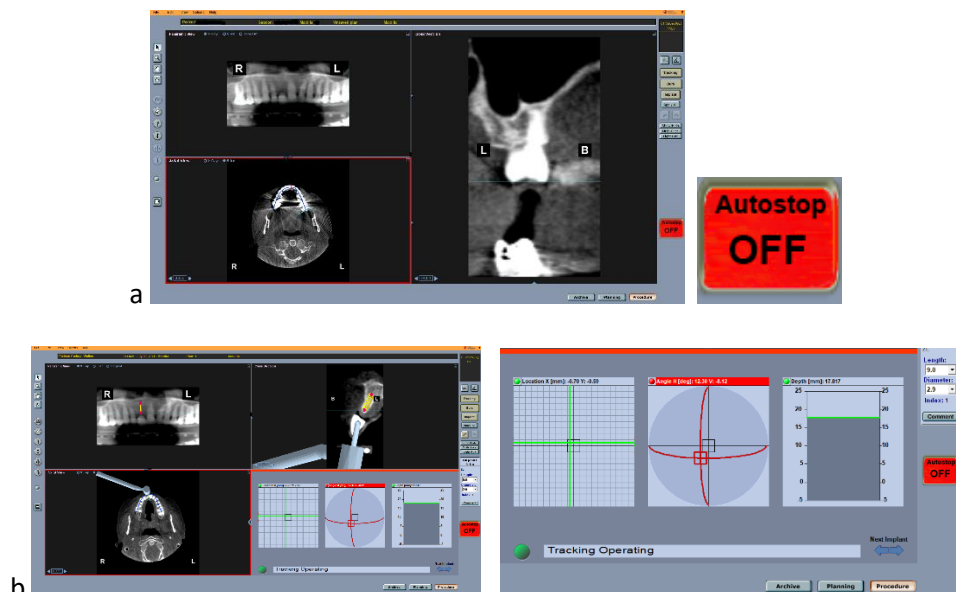


Figure 114: DAB, Autostop On-Off Indicator-Off
(a procedure screen, b with indicators)

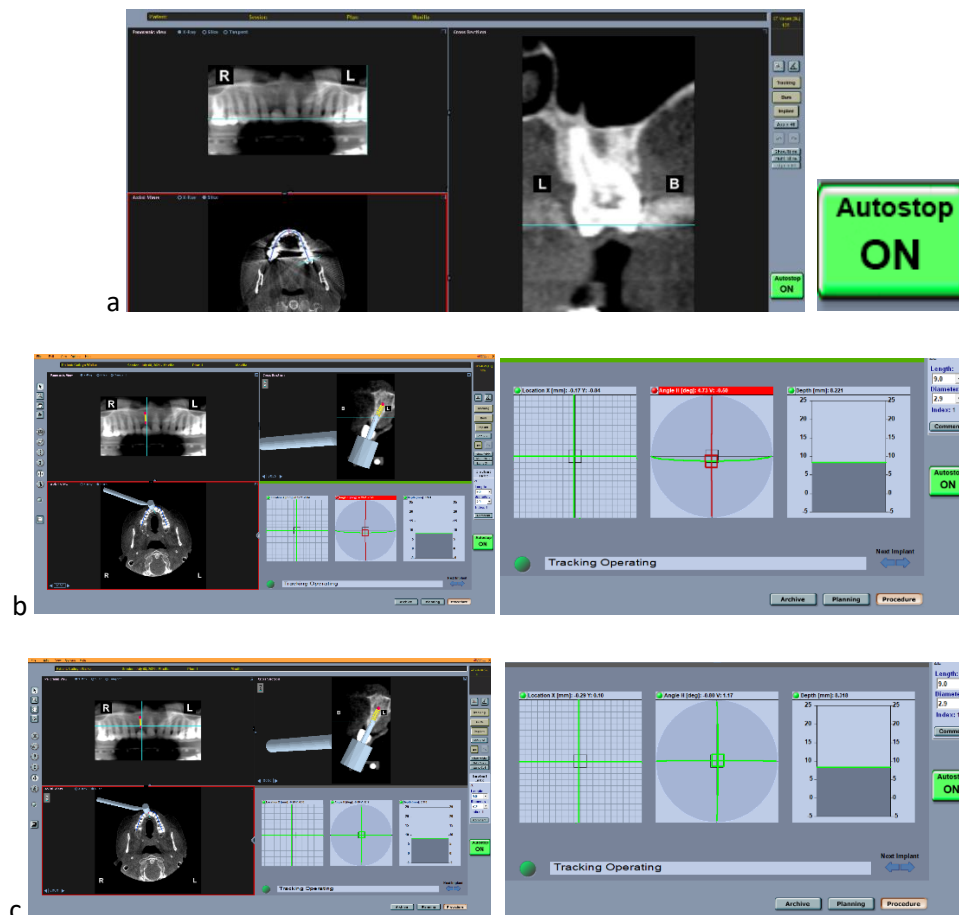


Figure 115: DAB, Autostop On-Off Indicator-On

(a- procedure screen, b- with indicators, c- with all indicators, green)

To perform drilling:

1. Mark the primary location for the implant with a round bur. Follow the Location Indicator to place the primary mark according to the pre-operative plan. While following the Location Indicator, a beeping and ticking sound is heard until you reach the precise location.

Note: When using the DAB, the drill will not work unless the drill is held at the correct angle. When not using the DAB, the angle indicator can be ignored when marking the primary location.



Figure 116: Drilling the Implant According to IGI Indicators

2. After drilling the primary mark, change the bur in the handpiece and define the bur in the IGI system.
3. Begin the drilling procedure by following the **Angle Indicator** to orient the drilling to the planned angle. While following the Angle Indicator, a different beeping sound without ticking, is heard until you reach the precise angle.
4. Follow the **Depth Indicator** to orient the drilling to the planned depth. While following the Depth Indicator, a long continuous sound is heard. If drilling is too deep, a distinctive warning sound is heard, and the Depth Indicator becomes red. When using the optional DAB, the drill will stop when the indicators become red.

 **Warning:** The optional DAB is only an adjunct for the surgeon. It is the surgeon's responsibility to decide when to activate and deactivate the drill by proper use of the foot pedal.

 **Warning:** Critical anatomical structures should be avoided by at least 1.5 mm.

 **Warning:** Any inadvertent pressure placed on the pole or the patient tracker, may cause an inaccuracy in tracking leading to patient injury.



Figure 117: Over Drilling

5. After drilling the first implant bore, select the next one (automatically or manually) and repeat the steps mentioned above.
6. Place the implants in the prepared bores.
7. After drilling is completed for all implants, you may remove the CRD. Follow the instructions **Removal of the** on page 73.
8. After placing all the implants, perform final suturing of the flap.



Warning: If another implant will be placed at another visit using the same CRD, a new registration is mandatory.

6. Intra-Operative Modifications of Implants Position

In certain cases, there is a discrepancy between the planned position of the implant, and the surgeon's clinical judgment at the time of surgery. In such cases, you may intra-operatively modify the implant planned position, using the **On the Fly** mode.

Note: The **On the Fly** button is disabled when there is no tracking

- a. Select the planned implant to be modified.
- b. Define a bur.
- c. Click the **On the Fly** button.

The implant image is automatically attached to the drill tip

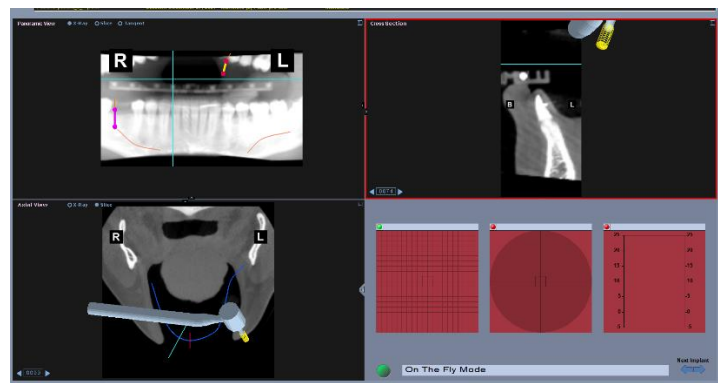


Figure 118: On the Fly Mode

- d. Place the drill on the bone ridge in the implant's desired position. The modified position of the implant is displayed.
- e. Evaluate the modified implant position in relation to the alveolar bone, critical anatomical structures and occlusion.
- f. Click **On the Fly** again to set the implant in the modified position. The implant is set in the new position and the indicators are reset accordingly
- g. If needed, adjust the implant position on screen using the mouse.
- h. Drill the implant according to the reset indicators.

Note: The **On the Fly** mode can be used for *On the Spot* planning.

6. Snapshot of Implantation

There is an option to record the drill in the bone by taking a snapshot. This is usually done for comparing the planned osteotomy to the actual preparation made at the time of surgery, and for analysis needs.

- a. Once the osteotomy is completed, hold the bur steady in the drilled bone and click the **Snapshot** button.
A small implant image appears in the drilled bone. The image is colored yellow when selected and grey when not.

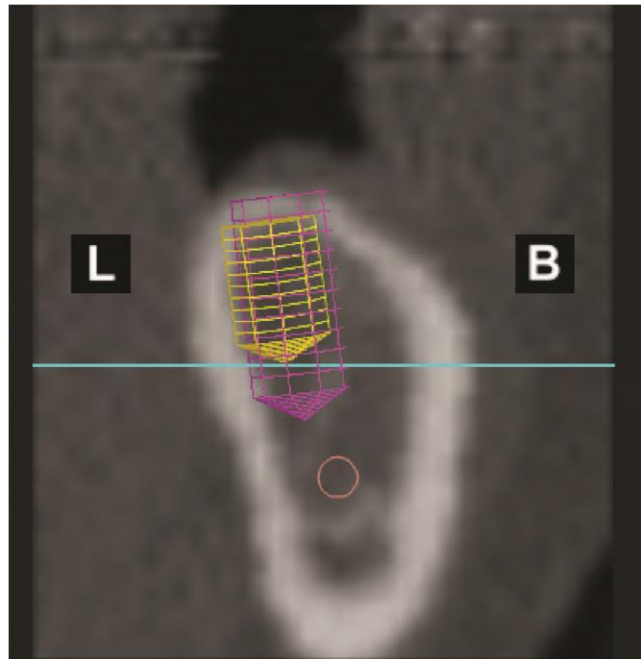


**Figure 119: Snapshot of the Drill in the Bone
(Yellow Image)**

- b. To save the snapshot from the **File** menu, select **Save** (see **Figure 55: File Menu** on page 107).

7. General Guidelines

Throughout the implantation procedure:

- Make sure that the system is tracking the Handpiece Tracker and Patient Tracker.
- Avoid obstructing the camera view of both the Handpiece Tracker and the Patient Tracker by any instrument or by any person.
- Avoid applying pressure to the Fixation Device, pole or Patient Tracker by any instrument or by any person.
- Make sure that the Fixation Device is in place and that the Patient Tracker is not distorted by the patient's chest, chin, nose or glasses, etc.

8. Surgery Report

At the end of the procedure, fill in a Surgery Report.

Site	Type	Diameter	Length
	Friadent, FRIALIT-2, Stepped cylinder	3.80	13.00
	Nobel Biocare	3.75	8.50
	Nobel Biocare	3.75	10.00

Figure 120: Surgery Report

- a. Exit the **Procedure** Screen, clicking the **Planning** button or the **Archive** button. The surgery report opens. All known fields are automatically filled: **Patient Initials**, **Surgeon Name** (the plan creator), **Date**, **Time** and a detailed list of **Implants**.

Note: The surgery report appears automatically only if drilling has been performed.

- b. You may use the *On Screen Keyboard* to enter any relevant information to the **Comment** field, or to edit other fields (apart from the Date and Time fields).
- c. To reset the surgery report, click **Reset**.
- d. To print the surgery report, click **Print**.
- e. To save the surgery report, click **OK**.

9. Closing IGI

To close IGI, click on the File tab, and click exit.

10. Pole Removal and Fixation Disposal

At this point the Minilock™ device is out of the mouth and without a wedge.

a. Removal of Posterior Minilock™ Device

Place the Pole removal device on the Minilock™ tray with the U shape vertical part over the pole, and the vertical wall in the slot of the Minilock™ tray, see **Figure 118: Pole Removal Jig on Posterior Minilock™ Tray below**.



Figure 121: Pole Removal Jig on Posterior Minilock™ Tray

Unscrew the pole using the allen wrench provided by Image Navigation. See **Figure 119: Allen Wrench in Pole Removal Jig on Posterior Tray, below**



Figure 122: Allen Wrench in Pole Removal Jig on Posterior Tray

When the Fixation device isn't needed anymore, dispose as medical waste. See **Section III C Maintenance and Component Disposal** on page 29.

b. Removal of Anterior Minilock™ Device

Place the Pole removal device on the Minilock™ tray with the U shape vertical part in between the wings holding the fiducials, and the vertical wall outside the Minilock™ tray (NOT in the slot). See **Figure 120:: Pole Removal Jig on Anterior Minilock™ Tray, below.**



Figure 123:: Pole Removal Jig on Anterior Minilock™ Tray

Unscrew the pole using the allen wrench provided by Image Navigation. See **Figure 121: Allen wrench in Pole Removal Jig on Anterior tray, below.**



Figure 124: Allen wrench in Pole Removal Jig on Anterior tray

When the Fixation device isn't needed anymore, dispose as medical waste. See **Section III C Maintenance and Component Disposal** on page 29 .

XII. Operating Instructions for Implantation in a Fully Edentulous Jaw (optional kit)

A. Introduction

The use of the IGI system for the treatment of a **fully edentulous** jaw requires the use of unique hardware and changes to the workflow described for a **partially edentulous** jaw implantation. This section is intended to provide all the additional information required for the successful use of the IGI system, to guide the placement of implants in a fully edentulous jaw when using the unique hardware.



Warning: The user should be fully proficient in the use of IGI before using the system for the treatment of fully edentulous jaws.

B. Overview

1. General Description

In patients with a fully edentulous jaw use a different CRD, to attach the fiducials and Patient Tracker in a stable position to the fully edentulous jaw. The Minilock™ Device is replaced by a titanium framework with retentive caps attachments. The retentive caps are supported over standard bone screws placed in the jaw a few days prior to the implantation surgery. A horseshoe with fiducials is attached to the titanium framework.



Figure 125: Bone screws Placed in Jaw Model

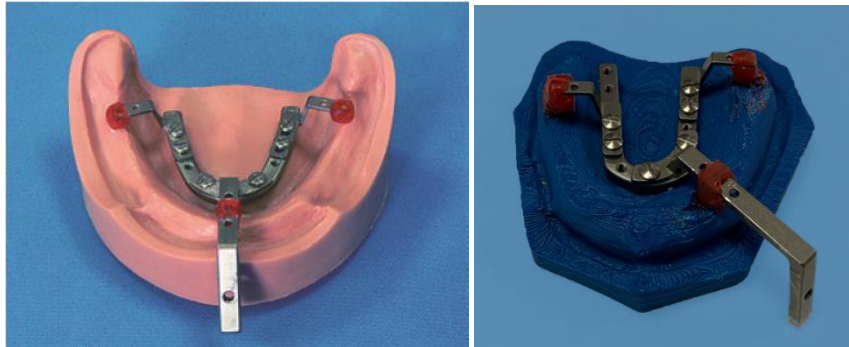


Figure 127: Titanium Framework over Implants



Figure 126: Bone screw (Center) & Retentive Cap over Bone screw Upper Right)



Figure 128: Retentive Cap

The Mini Dental Implants are used as implants to support the titanium framework with the retentive caps. The coronal end of the implant is spherical and allows positioning of the retentive cap by means of a simple ball attachment mechanism. The implants are removed immediately after surgery.



Warning: The lag time between placing the bone screws and implant surgery **should not exceed 1 week**. Longer lag time may result in unstable implants and inability to perform surgery using the IGI system.

2. IGI Kit for Fully Edentulous Jaw Implantation (optional)

The optional IGI kit for fully edentulous jaw implantation consists of a kit which has parts for the dental laboratory as well as for the IGI clinic. Additional items are not supplied by Image Navigation and should be purchased from the manufacturer. The elements of IGI kit for fully edentulous jaw implantation are listed in Tables 5-6 below.

Table 6: Clinic's components of Kit for Fully Edentulous Jaw

Item	No. of Units
Maxilla Patient Tracker pole	1 unit
Mandible Patient Tracker pole	1 unit
Short thumb screws for connecting the pole to: Patient Tracker Anterior Connector	4 units
Screwdriver	1 unit
Horseshoe (single patient use)	10 units

The horseshoe is a single patient use product. It must be discarded after use. Additional horseshoe units may be purchased through your distributor or Image Navigation.



Figure 129: Mandible (1) & Maxilla (2) Patient Tracker Poles & Thumb Screw (3)

Note: A specially customized clinic's kit is available for a **left-handed surgeon**, see **IGI Kit**, on page **185**.

Table 7: Dental Laboratory's components of Kit for Fully Edentulous Jaw

Item	Item Description
Maxilla Framework	Palatal Bar Anterior Connector Left Connector Right Connector Screws
Mandible Framework	Lingual Bar Anterior Connector Left Connector Right Connector Screws
Extra screws	4 units

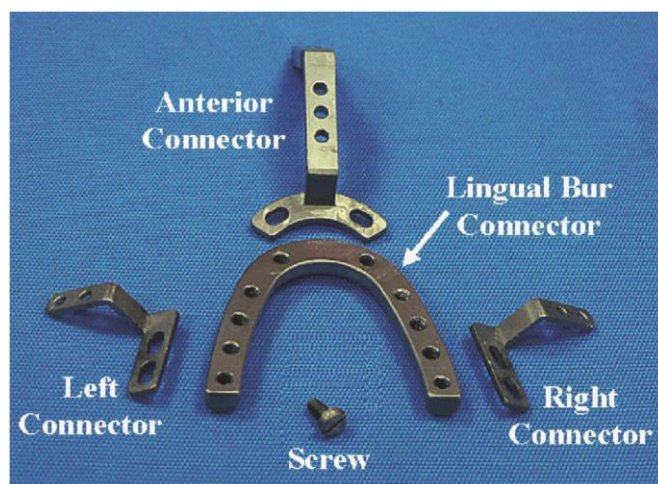


Figure 130: Framework Parts

Table 8: Additional Recommended Items for Fully Edentulous Jaw

Item
Bone screws with ball attachment
Impression caps
Surgical drill 1.1 mm
Winged thumb wrench
Finger driver
Ratchet wrench
Ratchet wrench extension — length 16 mm “¼

Table 9: Dental Laboratory’s Additional Recommended Items for Fully Edentulous Jaw

Item
Retentive CRD caps
Implant analogs

C. Workflow

Chart 3: General Workflow of Fully Edentulous Jaw Implantation

Selecting the Patient & Taking Study Impressions
 Casting Study Models & Preparing Temporary Base and Rim (by dental lab)
 Adjusting the Temporary Base and Rim
 & Recording a Bite Registration and Vertical Dimension
 Set-Up of Radio-Opaque Teeth & Initial Assembling of Framework (by dental lab)
 Try-In & Adjustment of Teeth Set-Up
 Try-In of Framework & Placing Bone screws Accordingly
 Taking Pick-Up Impressions
 Fabricating the CRD (by dental lab)
 Try-In & Evaluating the CRD
 CT Scan
 Planning the Implants' Position
 Pre-Surgical Preparations
(Details as in Chart 1: General Workflow of Partially Edentulous Jaw Implantation page 64)
 Accuracy Validation
 Drilling Procedure
 Removing the Bone screws

Note: It is recommended to follow the workflow as described here. However, the

*surgeon might choose to work according to an alternative, shorter workflow, described in **Short Workflow (Optional)** on page 181.*

1. Selecting the Patient & Taking Study Impressions

The fully edentulous patient requiring dental implants, as part of the treatment plan, is clinically evaluated. X-rays and study impressions are taken.

- a. Evaluate the fully edentulous patient clinically and radiographically to ensure adequate bone volume is available to accommodate the implants.
- b. Evaluate the bone height at the posterior region on both sides to ensure the insertion of the bone screws is possible.

Note: A minimum of 5 mm bone height must be available in the posterior region on both sides, to allow insertion of the bone screws.



Warning: Low bone density, may affect the bone screws' position between the CT and actual surgery, which can cause inaccurate implant placement.

- c. Take upper and lower study impressions and send them to the dental lab for fabrication of temporary base and rim.

Note: In complex, non-fully edentulous cases, characterized by periodontally compromised teeth or separate scattered teeth, the surgeon may consider the use of the fully edentulous kit. This approach may be beneficial in cases in which the Minilock™ Device may not be securely held by available teeth.

2. Adjusting the Temporary Base & Rim and Recording a Bite Registration & Vertical Dimension

The temporary base and rim are adjusted to record the desired facial vertical dimension and patient's occlusion.

- Position the temporary base and rim in the patient's mouth and ensure its passive seat.
- Adjust the wax rim to record the facial vertical dimension and plane of occlusion.
- Record a bite registration.
- Take an impression of the antagonist dental arch. If the patient wears a denture in the antagonist jaw, then take an impression with the denture.

Note: The temporary base is used in the next stage as a custom tray to take an impression of the placed implants. In addition, the adjusted base and rim are used to mount the patient's models in an articulator.

- Send the adjusted base and rim, as well as the bite registration to the dental lab for setting up **radio-opaque simulation teeth** over the temporary base (according to the antagonist dental arch). The wax-up should reflect the desired position for the final restoration so that it can guide the digital treatment planning.
- In this same session, ask the dental lab to prepare an initial assembly of the **titanium framework**. This can be done based on study models of the patient and existing denture.

3. Try-In & Adjustment of Teeth Set-Up

- Try-in the teeth set-up in the patient's mouth.
- Confirm that teeth articulate in the desired final position and make fine adjustments as required.

4. Framework Try-In & Placing the Bone Screws Accordingly

The surgeon places the bone screws and takes an impression.

- Evaluate the patient's radiographs to decide on the possible position and length of the bone screws according to the following guidelines:
 - The bone screws should be placed into reasonably dense bone to be stable.
 - An appropriate length of the bone screws should be selected to avoid damage to critical anatomical structures (e.g. mandibular nerve canal, maxillary sinus).

Note: If the available bone height to accommodate the min- implant is less than 10 mm, you may shorten the mini-implant up to 5 mm.



Warning: Using bone screws that are too long may cause damage to critical anatomical structures.



Warning: Using bone screws that are too short may prevent proper stability of the splint and cause inaccurate tracking.

- Try the titanium framework in the patient's mouth with the patient tracker pole

attached to it.

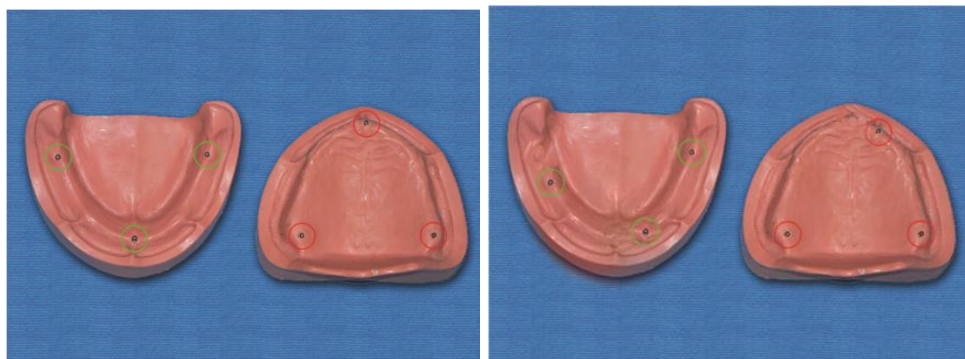
- Ensure the pole does not contact the patient's nose or chin.
- Use the titanium framework as a guide to position the most anterior bone screw.



Warning: It is critical that the most anterior bone screw is positioned such that the pole does not touch the patient's face or glasses.

c. Plan the bone screws' position according to the following guidelines:

- The three bone screws should form a wide triangle to effectively support the titanium framework.
- The first bone screw should be placed anteriorly at or near the midline.
- The second and third bone screws should be placed posteriorly, on both sides of the dental arch, either distal to the most posterior planned permanent implant (normally distal to the approximate position of the first molar), or distally in areas where no implants will be placed and form a wide triangle to allow for the stability of the titanium framework. See below and **Figure 125** on page 162.
- An effort should be made to place all 3 bone screws parallel to each other.



(Maxilla & Mandible)

Note: Do not place a bone screw where its surface is closer than 5mm on either side of a planned permanent implant. The retentive caps and titanium framework will take up more space than the implant itself, interfering with surgical implant placement.

- d. Use local anesthesia to anesthetize the area at the planned position of all three-bone screws.
- e. Drill the entry bores in the planned bone screws' position according to the following guidelines:

Figure 131: Three Bone screws in Place, Forming a Wide Triangular Base

- Use the 1.1 mm surgical drill with sterile water-cooling.
- Drill through the gingiva and bone cortex to make the entry bore.
- Extend the drilling to 1/3 - 1/2 of the threaded length. In extremely dense bone, extended penetration might be necessary.



Warning: The bone screws must achieve high primary stability; thus, the entry bore should be minimized.

- f. Place the bone screws through the drilled entry bores into the alveolar crest according to the following guidelines:
 - 1) Use the winged thumb wrench to place the bone screws in the alveolar bone. If high bone resistance is encountered, you may use the ratchet wrench to drive the bone screw in place.
 - 2) The bone screws should be placed vertically into the alveolar crest.
 - 3) The spherical head of the bone screws should extend 2 mm above the gingiva to avoid coverage.
 - 4) Make sure that the bone screws are stable and not mobile.



Figure 132: Bone screws Positioned in the Patient's Mouth

Note: Bear in mind that you will not be able to drill in the bone screw area using the IGI navigation.

5. Taking a Pick-Up Impression

The impression is taken immediately after placing the bone screws.

- a. Use the “try-in” (the adjusted base and rim with the radio-opaque teeth) as a customized tray to take an impression of the implants position:
 - Apply a marking paste to the spherical head of each one of the bone screws.
 - Position the temporary base gently in the patient's mouth to achieve contact with the bone screws.

- Remove acrylic on the resultant marks which should appear on the tissue surface of the base. Make sure to release about 6 mm of acrylic around the marked area.
- Position impression caps on the bone screws.
- Position the base in the patient's mouth again and ensure its passive seat without any contact with the impression caps on the bone screws.
- Apply low viscosity impression material (wash) in the mouth around each impression cap and onto the tissue surface of the try-in, then use it to take an impression.



Figure 133: Maxillary "Try-in" with Radio-Opaque Teeth, Used as a Custom Tray for Pick-up Impression

(impression material shown in blue).

A Subsequent Bite Registration is also taken (shown in green)

- Evaluate the impression and make sure that the impression caps on all 3 bone screws have been accurately copied.
- If the impression caps remain on the bone screws, remove them from the patient mouth and insert them into their corresponding spaces in the impression.



Figure 134: Pick-Up Impression with Yellow Impression Caps Inside

- If you have not already done so, take an impression of the antagonist dental arch. If the patient wears a denture in the antagonist jaw, then take an impression with the denture.
- Take a bite registration.

-
- f. Forward the adjusted temporary base and rim with the impression to the dental lab for fabricating the CRD.
-



Warning: Avoid any pressure on the bone screws until the implant surgery and instruct the patient accordingly. If the patient wears an existing denture, relieve the denture around the bone screws. If the patient does not wear a denture, ensure no occlusal forces will be applied to the bone screws. Any force may jeopardize the stability of the bone screws and the subsequent surgery.

Note: Bone screw caps protect the gingiva from overgrowing. These are especially useful in mandibular cases where no lower denture is worn.

6. CRD Preparation

At this stage, the CRD is fabricated in the dental as described below:

- a. Each connector of the titanium framework is attached to the corresponding bone screw cap with self-curing acrylic (for example: Pattern Resin®). These caps are attached to the implants' analogs in the working model and to the implants in the patient's mouth, by a ball attachment mechanism.

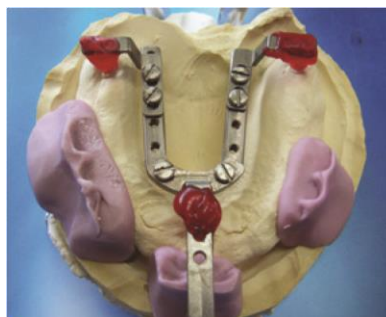


Figure 135: Titanium Connectors Attached to Retentive Caps with Self Curing Acrylic

- b. The radio-opaque simulation teeth are repositioned on the patient's model.



Figure 136: Radio-Opaque Teeth are Repositioned on Patient's Model

- c. The horseshoe is attached to the titanium framework, over the occlusal aspect of the titanium connectors with self-curing acrylic (for example: Pattern Resin®).



Figure 137: Horseshoe Attached to Connectors with Self-Curing Acrylic

- d. The horseshoe is attached to the radio-opaque simulation teeth with self-curing acrylic.

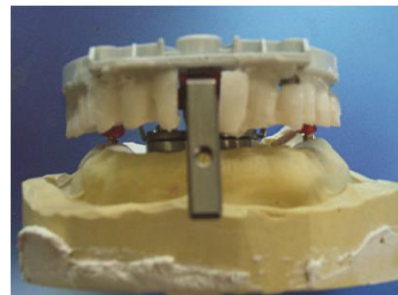


Figure 138: Horseshoe Attached to Connectors and to Simulation Teeth with Self Curing Acrylic

- e. The CRD is now ready for try-in and evaluation before CT scan.



Figure 139: CRD Ready for Evaluation before CT Scan

7. Saving the CRD

After disinfection, see

Fully Edentulous CRD (Titanium Framework, Retentive Caps & Horseshoe) on page 187, the CRD should be saved in the packaging provided. The patient's name, ID number as well as the date should be written on the individual package in the appropriate places. The symbols are:

 for the patient's name;  for the patient's ID number; and  for the date.

8. Evaluating the CRD at Try-In

The surgeon evaluates the CRD in the patient's mouth to ensure it is stable and retentive, before referring the patient for the CT scan.

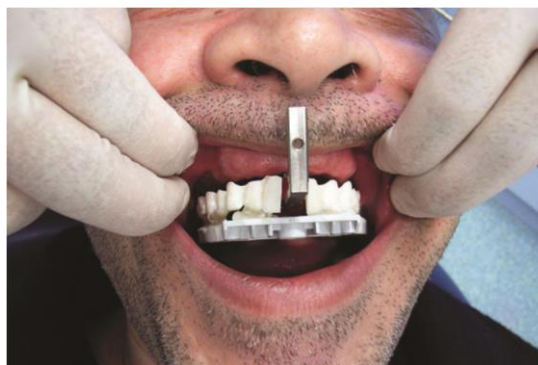


Figure 140: Edentulous CRD Tried in the Patient's Mouth

- a. On the day of the CT scan, evaluate the implants and make sure they are stable within the bone.
- b. Before positioning the CRD in the patient's mouth, make sure that:
 - All the connectors' screws are fully tightened.
 - The horseshoe is stable without any rocking movement relative to the

framework.

- The radio-opaque simulation teeth are separated from the titanium framework and from the retentive caps.
- c. Position the CRD over the implants. An audible click is heard as each retentive cap engages its corresponding bone screw .
 - d. Make sure the CRD is retentive and stable.



Warning: If any of the bone screws are mobile, they must be replaced with stable ones and modify the CRD accordingly (either chair-side or in the lab). You must NOT proceed with the CT scan if one of the bone screws is mobile.

- e. Make sure that there is a separation between the simulation teeth and the gingiva when the CRD is positioned.
- f. Make sure that the Anterior Connector is not touching the facial soft tissue.
- g. Remove the CRD from the patient's mouth. Connect the relevant Patient Tracker Pole (upper or lower) to the Anterior Connector, then connect the Patient Tracker to the pole.
- h. Reposition the CRD in the patient's mouth. Make sure that the pole and Patient tracker are not in contact with the facial soft tissue such as chin, nose, forehead or glasses.
- i. Remove the CRD from the patient's mouth and disconnect the pole.
- j. Ensure the horseshoe contains all nine silicon nitride markers. If any silicon nitride marker is missing or corrupt, the horseshoe must be replaced before performing the CT scan.

9. CT Scan

The CT scan is performed with the CRD in the patient's mouth. Perform the CT scan only after verifying that the preparative steps have been successfully completed. Be sure to follow the instructions detailed below and to guide the CT technician accordingly, to ensure the CT scan complies with IGI implantation procedure requirements.

Note: Only DICOM standard CT scans are readable by IGI software.

- a. Ensure that the horseshoe contains all nine silicon nitride markers. If any silicon nitride marker is missing or corrupted, the horseshoe must be replaced before performing the CT scan.
- b. Position the CRD in its place and "click" it over the bone screws. Make sure it is stable and in its place. If the CRD does not sit correctly, the CT technician should consult the dental surgeon. Do not perform the CT scan if there is any question

regarding correct CRD seat.

Place three cotton rolls, or folded gauze, over the part of the horseshoe that is supported by each bone screw . See **Figure 138: Patient Bites on Cotton Rolls & CT is Lined Up with Horseshoe** on page 176 (In certain cases, it may be more convenient to place two cotton rolls on the anterior bone screw , instead of one).

- c. Ask the patient to bite gently on the cotton rolls or gauze. In maxilla cases, if it is difficult for the patient to close his/her mouth, the patient's mouth may be left open.



Warning: Do not scan a mandible with an open mouth.

- d. Make sure that the CRD is retained in place, and that the horseshoe is separated from the antagonist teeth and not distorted.
- e. The CT scan is performed parallel to the horseshoe plane (rather than to the lower border of the mandible, in a mandible case), to get all the silicon nitride markers' images in the CT scan, by any metal restorations present in the patient's mouth. See **Figure 138: Patient Bites on Cotton Rolls & CT is Lined Up with Horseshoe** on page 176.
- f. Refer to **CT scan** on page 77 for the appropriate scanning parameters.
- g. Save the CT scan. This digital data is used to create patient's sessions in the IGI software application.



Figure 141: Patient Bites on Cotton Rolls & CT is Lined Up with Horseshoe

10. Planning the Implants' Positions

Follow the standard planning protocol to create the pre-surgical plan. Avoid

positioning implants with their surface less than 5 mm from the bone screws.



Warning: Difficulty in drilling may occur for implants that are planned too close to the bone screws due to obstruction by the titanium connectors and acrylic.

Pre-Surgical Preparations

During the pre-surgical preparations, the CRD is assembled with the Patient Tracker, the horse- shoe is registered and is detached from the CRD, together with the radio-opaque teeth.

Important: Before pre-surgical preparations, you should sterilize/disinfect all the elements of the IGI kit. (See *Disinfecting and Sterilizing the IGI Kit Elements*, on page 186). Therefore, handling these elements at this stage should be done according to accepted dental implant protocol.

- a. Assemble the Patient Tracker with the CRD:
 - Connect the Patient Tracker to the pole (upper or lower, corresponding to the implant arch) and secure it with a metal thumb screw.
 - Connect the pole to the Anterior Connector and secure it with a metal thumb screw.

Important: Strongly tighten the thumb screw to avoid any movement of the Patient Tracker.

- b. Perform the following preparation procedures:
 - Perform *camera positioning* and *functionality test* of Patient Tracker and Handpiece, in the usual manner.

Note: With a fully edentulous mandibular implant, the camera may have to be positioned to the left of the patient as opposed to directly above them (parallel to the patient tracker).

Define a *bur point* to enable using the Automatic Bur Measurement throughout the surgery. The bur point is defined on the anterior end of the Anterior Connector. There is no round elevated plane on the pole.

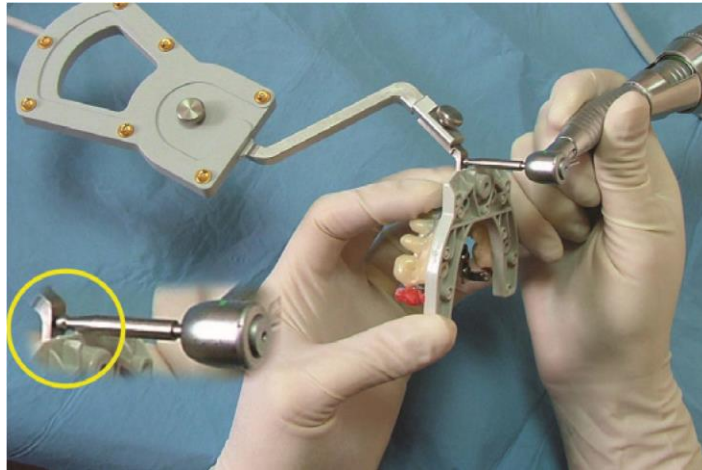


Figure 142: Defining a Bur Point on the Anterior End of Anterior Connector

- c. Perform a Registration:
 - Follow the standard protocol to perform the registration. Perform two sets of registrations (left and right). Each registration should include 5 silicon nitride markers (overlap at the midline).
- d. Detach the horseshoe from the three framework connectors.

Note: It is preferable to ensure the bone screws are stable prior to severing the horseshoe from the framework.

- Once registration is successful and accurate for both sites, use a low-speed metal disc to sever the horseshoe from the three titanium connectors.

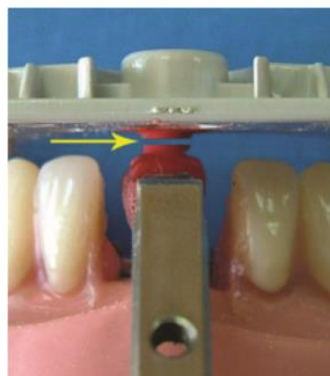


Figure 143: Site of Severing Horseshoe

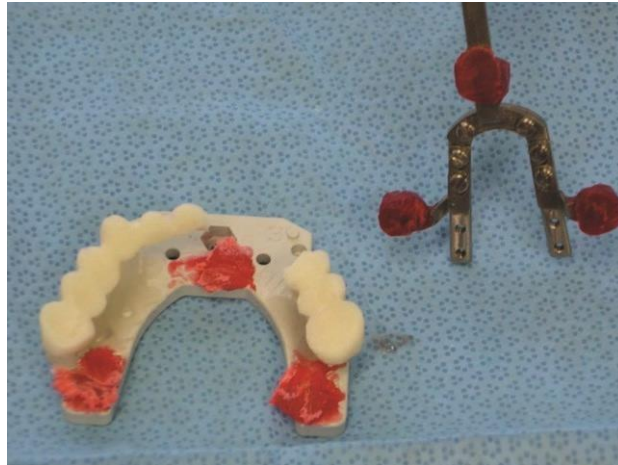


Figure 144: Horseshoe Detached from Titanium Connectors

Caution: Detaching the horseshoe is irreversible. You must not detach the horseshoe until the two registrations are successfully completed. Avoid detaching the retentive caps from the titanium connectors.



Figure 145: Pole & Patient Tracker Assembled with Framework

D. Drilling Procedure

After detaching the horseshoe and performing local anesthesia and flap elevation, the CRD is positioned in the patient's mouth, and the osteotomies are drilled for the implants. **Right** before the implant surgery, you **must verify** that all three bone screws are stable.



Warning: You must not proceed with the image guided implant surgery if one of the bone screws is not stable. It is preferable to ensure the bone screws are stable prior to severing the horseshoe from the framework.

1. After anesthetizing and elevating a flap, if required, position the CRD over the implants. An audible click should be heard
2. Ensure that the CRD is stable and retained in place.

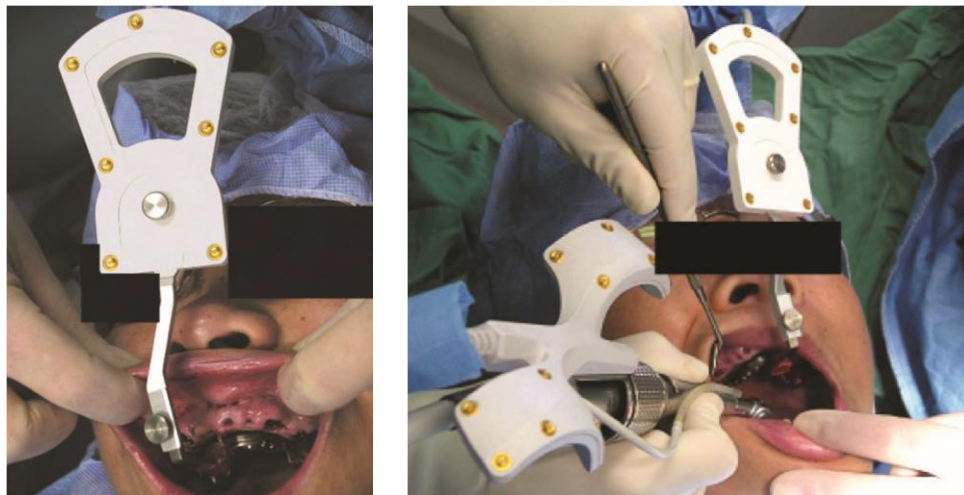


Figure 146: Framework is Attached to Implants at Implantation Stage

Select the correct registration file that corresponds to the site of drilling (e.g. right registration file for drilling on the right side).



Warning: Remember to load the appropriate registration file before drilling in the contra-lateral side.

3. Check the system's accuracy, see **Accuracy Validation**, on page **142**.
 - In *Autopage* mode, move the round bur over the **bone screws** area, and ensure the virtual position of the implants on the screen matches the position as seen clinically. This critical step ensures the implants' position has remained stable since the CT scan, and that the system is accurate.
 - If a **flap** is elevated - check the system's accuracy over the exposed **bone** in the implantation area.
4. Follow the standard protocol for drilling using the IGI guidance, see **Drilling According to IGI Indicators**, found in section **Drilling Procedure** which starts on page **142**.

Before drilling, always verify the position precision visually (every time the drill is used).

5. Once the implant surgery is completed, remove the bone screws from the patient's mouth.

E. Short Workflow (Optional)

It is recommended to follow the workflow as described above, see **Workflow**, on page **166**. However, the surgeon might choose to work according to an alternative shorter workflow, which does not include these two stages:

- Try-in & adjustment of teeth set-up
- Framework try-in before placing the bone screws

Chart 4: Short Workflow of Fully Edentulous Jaw Implantation

Selecting the Patient & Taking Study Impressions
Casting Study Models & Preparing Temporary Base and Rim (by dental lab)
Adjusting the Temporary Base and Rim & Recording a Bite Registration and Vertical Dimension
Placing Bone screws
Taking Pick-Up Impressions
Fabricating the CRD (by dental lab)
Try-In & Evaluating the CRD
CT Scan
Planning the Implants' Position
Pre-Surgical Preparations
(Details as in **Chart 1: General Workflow of Partially Edentulous Jaw Implantation using Anatomic Registration** on page 62)
Accuracy Validation
Drilling Procedure
Removing the Bone screws

F. Sterilizing the CRD

The **fully edentulous CRD** and other IGI elements — **Handpiece Tracker, Patient Tracker, handpiece, poles, thumb screws** and **screwdriver** — are sterilized as described in Chapter XII Section B: **Disinfecting and Sterilizing the IGI Kit Elements**, on page **186**.

G. Disinfecting the DAB

See *Cleaning, Disinfecting and Sterilizing* on page 185.

H. Fabrication of the Titanium Framework by the Dental Laboratory

The edentulous patient kit comprises of the three acrylic screw caps connected to the titanium framework.

1. Cast the working model from the adjusted temporary base and rim that were used to take an impression of the bone screws position.
 - a. Place three o-ball prosthetic head analogs into the impression at the corresponding negatives of the 3 bone screws spherical head.
 - b. Block the spherical head of the analogs (if exposed) with wax.
 - c. Cast the impression.
2. Mount the patient's models in an articulator using the bite registration and the temporary base and rim.
 - a. If the patient is using a denture on the antagonist jaw, then mount a cast of an impression that was taken with the denture.
3. Fabricating the titanium framework:
 - a. Use the upper palatal titanium bar for a maxillary case or the lower lingual titanium bar for a mandibular case.
 - b. Place the acrylic screw caps over the spherical head of the analogs.
 - c. Position the titanium bar palatal / lingual to the alveolar crest.
 - d. Relate the titanium left and right joints to the position of the screw caps and secure to the titanium bar with the titanium screws.
 - e. Use titanium screws to connect the upper or lower patient tracker connector (corresponding to the target jaw) to the anterior part of the palatal / lingual bar. See **Figure 144: The three titanium joints connected to the titanium bar below**).

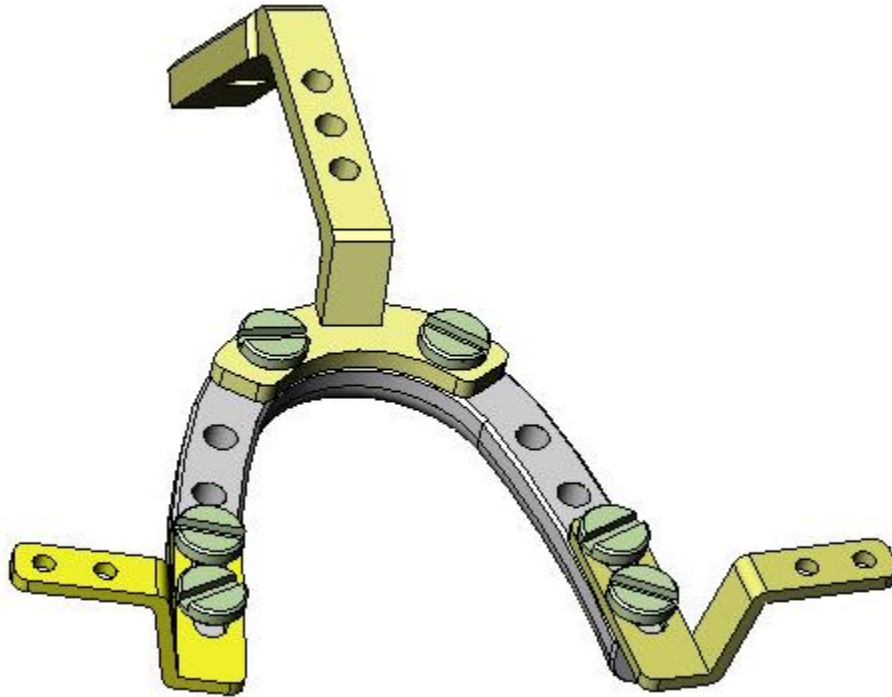


Figure 147: The three titanium joints connected to the titanium bar

- f. Relate the titanium framework to the screw caps. Make sure that the lingual/palatal bar is positioned anteriorly to the greatest extent possible. Attach the titanium joints to the caps using self-curing acrylic. The titanium framework should be separated from the soft tissue with minimum of a 2mm gap. The acrylic should be locked into holes within the joints.
- g. It is highly recommended to wax-up radio-opaque artificial teeth over the edentulous ridge to guide the digital treatment planning.

- 1) Dismount the titanium framework.
- 2) In the articulator, follow the antagonist dental arch to wax-up artificial radio-opaque teeth on the edentulous ridge.

The wax-up should reflect the desired position for the final crowns.

- 3) Remove the two central incisors and expose the spherical head of all 3 analogs.
- 4) Mount the titanium framework in place.



Figure 148: The horseshoe connected to the titanium joints

- h. Attach the horseshoe to the upper aspect of the titanium joints using self-curing acrylic (**Figure 145: The horseshoe connected to the titanium joints above**). Extend the acrylic vertically by 3mm to allow future detachment of the horseshoe (following registration) by means of a low-speed metal disc.
- i. If you are using artificial teeth then use self-curing acrylic to attach the teeth to the horseshoe. Avoid attaching the artificial teeth to the titanium bar or joints.
- j. Dismount the final CRD (Customized Registration Device) and remove the wax.



Important: The artificial teeth should be completely separated from the titanium framework and from the gingiva.

XIII. IGI Implantation by a Left- Handed Surgeon

IGI implantation can be performed also by a left-handed surgeon. A special customization is required for this.

A. IGI Cart Location

The IGI cart is positioned at the *right* side of the dental chair.

Note: Camera positioning is performed as usual.

B. IGI Kit

1. A specially customized **set of poles** for partially edentulous jaw implantation is used. Each pole is marked "**LH**" (Left-Handed).
2. A specially customized **IGI kit for fully edentulous jaw implantation** is used. The upper and lower poles of the kit are marked "**LH**" (Left-Handed).
3. A special **IGI handpiece** is used. The attachment of the Handpiece Tracker to the handpiece is customized for a left-handed surgeon. Both Handpiece and Handpiece Tracker are marked "**LH**" (Left-Handed).
4. For **implantation in the anterior segment** of the dental arch, a **right posterior Minilock™ Device** is preferred (instead of left posterior) for better accessibility (left side approach).

XIV. Cleaning, Disinfecting and Sterilizing

Autoclave is sterilization, Zeta 2 Sporex™™ is high-level disinfection, Mediwipes® is mid-level disinfection.

Instructions for cleaning and disinfecting the DAB for Aseptico, can be found at the section: **Cleaning**, on page **200**.

A. Cleaning

All external parts of the system, such as keyboard, mouse cart and DAB, are cleaned by wiping with cotton pads or a soft cloth fully dampened with a cleaning and disinfecting agent or presoaked cleaning and disinfecting wipes approved for use in a dental practice such as Mediwipes®². Any excess cleaning liquid should be wiped off with a soft cloth.



² Mediwipes is a registered trademark of Farla Medical Int LTD Limited Liability Company UK.

Warning: Before cleaning, verify the DAB is not in use and IGI is OFF.

Caution: Avoid spilling liquids into the interior of the system during cleaning and/or disinfecting it. This may cause damage to the device.

B. Disinfecting and Sterilizing the IGI Kit Elements

Instructions for disinfecting and sterilizing the IGI kit elements are detailed below and summarized in **Table 10: Disinfecting & Sterilizing the IGI Kit Elements** on page **188** and in **Table 1: Disposable IGI Elements - must be discarded after single patient use**, page **30**. Instructions for cleaning and disinfecting the DAB for Aseptico, can be found at **Cleaning**, on page **200**.

1. Handpiece

The handpiece is dismantled from the Handpiece Tracker and sterilized by autoclave after cleaning any debris.

Preliminary cleaning must be carried out prior to sterilization by autoclave. For directions relevant to the IGI handpiece, download the Instructions For Use (IFU) for model # SURGmatic S201XL Pro at <https://www.kavo.com/en-us/download-center>.

Steam sterilization conditions are:

- Temperature – 134°C
- Time – 4 minutes

2. Handpiece Tracker

The Handpiece Tracker is disinfected by wiping 3 times with Mediwipes® or equivalent, after cleaning any debris. After reassembling the Handpiece Tracker back on the handpiece, a functionality test is performed (prior to surgery). Mediwipes® is used as a mid-level disinfection.

3. Patient Tracker

The Patient Tracker is disinfected by wiping 3 times with Mediwipes® or equivalent, after first cleaning any debris. Mediwipes® is a mid-level disinfection.

4. TRI's, Poles, Cone Jig for O-Ring, Pole Removal Device, IGI Burs and Thumb Screws

The poles, IGI burs (tracing bur, registration bur, long bur, short bur, and the thumb screws are dismantled from the Patient Tracker and sterilized by autoclave. The anterior and posterior TRI's, the cone jig for O-ring and the pole removal device are also sterilized by autoclave. The tracing bur is sterilized with the O-ring attached.

Steam sterilization conditions are:

- Temperature – 134°C
- Time – 4 minutes

5. Screwdriver and Allen Wrench

The screwdriver is cleaned and then sterilized by using a cold disinfection bath of Zeta 2 Sporex™™ (high-level disinfection):

- a. Submerge the screwdriver or allen wrench in a cold sterilization solution, while shaking it, to abolish air voids.
- b. Submerge for 10 minutes.
- c. After submersion rinse with sterile or 0.2 µm filtered water.

6. Partially Edentulous CRD (Minilock™ tray & wedge)

- a. Submerge the for 10 minutes a cold disinfection bath of Zeta 2 Sporex™ (high-level disinfection).
- b. After submersion rinse with sterile or 0.2 µm filtered water.
- c. After Implantation: Minilock™ tray and wedge are discarded.

7. Fully Edentulous CRD (Titanium Framework, Retentive Caps & Horseshoe)

- a. **Before Implantation:**
The CRD (titanium framework attached to the retentive caps and horseshoe) is cleaned and then submerged in a cold disinfection bath of Zeta 2 Sporex™ (high-level disinfection).
 1. Submerge the titanium framework, retentive caps and horseshoe in a cold disinfection solution of Zeta 2 Sporex™, while shaking it, to abolish air voids.
 2. Submerge the titanium framework, retentive caps and horseshoe for 10 minutes.
 3. After submersion, rinse with a sterile or 0.2 µm filtered water.
 4. Dry with dry cloth.
- b. **After Implantation:**
All used retentive caps and horseshoe are disposed of. Bone screws are also disposed of after being removed.

After removing remaining acrylic and any other debris, the titanium bar,

joints, pole connector and titanium screws are sterilized with an autoclave before reusing.

Steam sterilization conditions are:

- Temperature – 134°C
- Time – 4 minutes

Note: After sterilization, all **titanium items** are sent back to the dental lab for next use.



Warning: Failure to use the sterilization instructions provided for each product as indicated, may result in cross infection.

Table 10: Disinfecting & Sterilizing the IGI Kit Elements

Element	Autoclave	Soaking	Wiping	Remarks
Handpiece	+			
Handpiece Tracker			+	
Patient Tracker			+	
Poles	+			
Thumb Screws	+			
TRI's	+			
IGI Burs (tracing bur, registration bur. long bur, short bur)	+			
Screwdriver	+			
Allen Wench	+			
Cone Jig for O-Ring	+			
Pole Removal Device	+			
Fully Edentulous CRD: (Before implantation) Titanium Framework Retentive Caps Horseshoe		+		Discarded after implantation, apart from the titanium framework

Element	Autoclave	Soaking	Wiping	Remarks
Titanium Framework: (After implantation) Titanium Bar Titanium Joints Pole Connector Titanium Screws	+			Sent back to dental lab after sterilization



Warning: Reusing the items listed in table 10 may result in biocontamination, degraded performance, mechanical/material failure, or loss of functionality. These items are not designed or validated to be used on more than one patient.

XV. Glossary

CRD- Customized Registration Device

DAB- Drilling Autostop Box

TRI- Tray (and wedge) Removal Instrument

XVI. Appendix One

A. IGI Device and Accessories Unique Device Identification (UDI)

Table 11: IGI components table and UDI

DESCRIPTION	UDI	PART NUMBER	Partially/ Fully edentulous	Reusable / Single patient multiple use	Comments
IGI Device	01-0729001685510 4	AIG0005-V2	All types		
IGI Anterior Minilock™ Kit	01-0729001685541 8	AIG45020	Partially Edentulous	Single patient multiple use	IGI Accessory. 10 kits are supplied with the IGI Device
IGI Posterior Minilock™ Kit	01-0729001685540 1	AIG45010	Partially Edentulous	Single patient multiple use	IGI Accessory. 10 kits supplied with the IGI Device
IGI Fully Edentulous Kit	01-0729001685503 6	AIG3610	Fully Edentulous	Reusable. The horseshoes only are single patient multiple use	Include the below listed components UDI's applicable for FDA only
Edentulous Framework Lower	01-072900168526 5	AIG3620	Fully Edentulous	Reusable.	IGI Fully Edentulous Kit Component – UDI's applicable for FDA only
Edentulous Framework Upper	01-072900168527 2	AIG3640	Fully Edentulous	Reusable	IGI Fully Edentulous Kit Component -UDI's applicable for FDA only
IGI Horseshoe	01-0729001685506 7	AIG3650	Fully Edentulous	Single patient multiple use	Accessory of the Fully Edentulous Kit. 10 Kits supplied with IGI Device.

B. Medical System Applied Parts

Table 12: Applied Parts

Part Name
IGI Handpiece
IGI Poles
IGI burs (Registration bur, tracing bur, long bur, short bur, cone jig for O-ring)

XVII. Appendix Two: DAB (Drilling Autostop Box) For Aseptico User Manual

Information concerning the accuracy and precision of this product may be obtained upon request by contacting Image Navigation Ltd.

A. Introduction & Intended Use/ Purpose

The DAB (Drilling Autostop Box) (referenced A-IG-40760) for Aseptico is an IGI component which can be purchased separately and used with Aseptico drilling motor only. The DAB (drilling auto-stop box) for Aseptico shall be used only with the Aseptico Implant Dental System AEU 6000. The DAB is connected between the Aseptico foot pedal and the Aseptico electronic control console. Using USB cable, the DAB is connected to the IGI Cart.

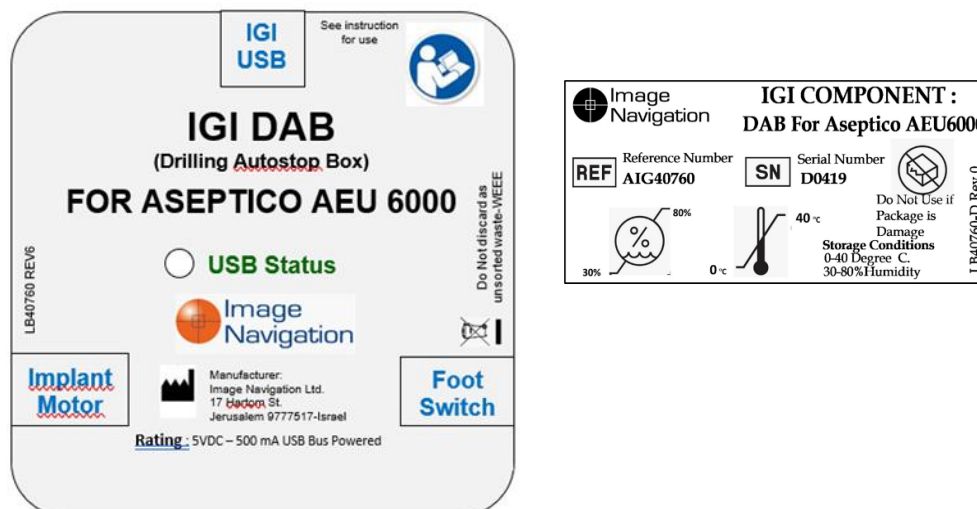
The DAB is controlled by the IGI system to provide the surgeon with additional assistance and security during the surgical (intra-operative) phase of the dental implantation procedure. The DAB is an extra safety feature which, when attached to IGI, prevents drilling when the drill is not in the correct location, angle or within the allocated depth according to the preapproved plan.



Figure 149: The a-ig-40760 Aseptico DAB

B. Device Classification

- Ordinary Equipment - degree of protection against ingress of water
- Not suitable for use in the presence of flammable anesthetics or substances, explosive substances or substances which could cause combustion.
- Labels on the DAB box and on the packing:



C. DAB Features

- Bus Powered, no external Power Supply or Battery required
- High Retention USB Connector
- Bi-color LED Status Indicator
- Plug & Play Functionality

D. Safety Precautions

This equipment meets all the requirements for safety (iec60601-1 ed.3.1) and performance, related to electromagnetic compatibility standard (iec60601-1-2 ed.4).

Image Navigation Ltd. accept no liability for direct or consequential injury or damage resulting from improper use, arising through the non-observance of the User Manual, or improper preparation and maintenance of this product.



Warning: The USB cable of the DAB shall be connected only to the IGI system manufactured by Image Navigation.



Warning: Before using this product, make sure that you have read and understand the present User Manual and the Aseptico Motor Manual.



Warning: Use this product for intended use/ purposes only.



Warning: DAB for Aseptico is to be installed in a clinic and used only with the IGI System.

Caution: This device is restricted for dentist's use with the Aseptico surgical Motor exclusively. Use of other dental accessories or sub-assemblies from third-party manufacturers is the sole responsibility of the user.



Warning: Do not install where there is a risk of an explosion. The product is not intended for operation in the presence of flammable anesthetics or substances, explosive substances or substances which could cause combustion.

Caution: All repairs are to be performed by authorized Image Navigation Service technician only.



Warning: Do not disassemble or alter the DAB. Do not disassemble or alter the System motor, console, cart or foot switch.



Warning: Portable RF communication Equipment should be used no closer than 30 cm (12 inches) to the DAB.



Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could negatively affect EMC performance and immunity of this equipment, and result in improper operation.



Warning: The DAB, as the other signals from the IGI software, is only an adjunct to assist the implantologist. It is the surgeon's responsibility to decide when to activate and when to stop drilling.



Warning: It is the surgeon's responsibility to decide, select and activate the right motor speed for drilling.



Warning: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Explanation of safety signs and symbols marked on this equipment can be found under the heading **Explanation of Warning Symbols** on page **15**

NOTE: Any malfunction or deterioration in the characteristics and/or performance of this device – this information shall be reported immediately to Image Navigation Ltd.

NOTE: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

E. DAB Status

The DAB Status USB connection can be identified using the bi-color (Red/Green) LED indicator.

The LED modes are:

- RED** DAB powered but there is no communication with the IGI System (or Computer).
- GREEN** DAB powered and controlled by IGI System (or Computer)
- OFF** DAB disconnected from USB Bus or IGI Computer under Sleep mode or any suspended mode.

Using the IGI SW interface, the dentist can choose to activate the DAB during the drilling through the DAB indicator button on the screen (ON/OFF). During the drilling, when the DAB is ON and giving assistance to the dentist, the IGI positioning indicators are flickering when the DAB is activated.

F. Setting Up the DAB

1. Before proceeding to the following steps, turn the power off of the connected devices.
2. Unpack the DAB
3. Connect 10' USB Cable A Plug to USB A Receptacle on the Connector plate of IGI Main Pole: The USB cable of the DAB shall be connected to the IGI (REF AIG0005-V2) manufactured by Image Navigation only".

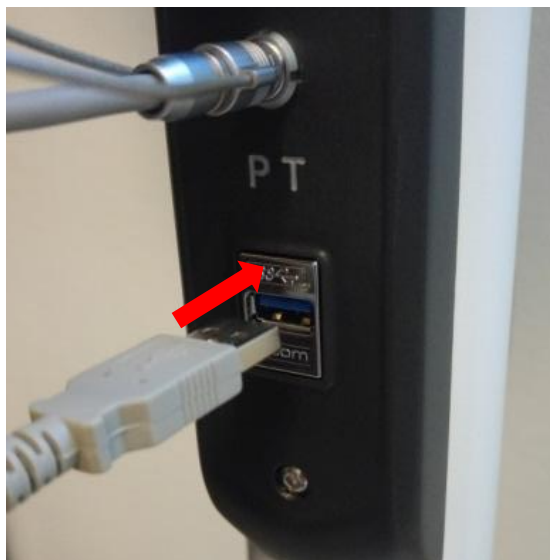


Figure 150: 2: 10' USB Cable A connection

4. Connect 10' USB Cable B Plug to USB B Receptacle of the DAB:



Figure 151: 10' USB Cable B connection

5. Connect DAB "Implant Motor" Cable to "FOOTSWITCH" Connector on the back panel of Aseptico Electronic Control Console (Note keyway on Connector, turn Locking Sleeve clockwise to secure cable to Connector).



Figure 152: Implant Motor Cable connected to Foot Pedal Connector

6. Connect Aseptico Foot Control Cable to Foot Pedal Connector on the DAB (Note keyway on Connector, turn Locking Sleeve clockwise to secure cable to Connector):



Figure 153: Aseptico Foot Control Cable Connected to DAB

7. Set Up Aseptico Electronic Control Console accordance with Aseptico "OPERATION AND MAINTENANCE INSTRUCTION MANUAL"
8. Set Up IGI System accordance with "IGI USER MANUAL".
9. Switch on Aseptico Electronic Control Console and IGI System.

G. Implant Mode Operation

Important Notice: Before drilling, try activating the drill close to but not in the correct location or angle, to verify that the DAB system is on.

Perform this Implant Operation Mode in accordance with "IGI USER MANUAL" Chapter "DRILLING AUTOSTOP BOX".

H. Test Mode Operation (for trained technicians only)

1. Click on the "ON/OFF Simulator" icon on IGI Monitor Desktop.



Figure 154: ON/OFF Simulator icon

The “ON/OFF Simulator” Virtual Button will appear with the OFF Position:



Figure 155: Virtual Button OFF Position

2. Press on the Aseptico Foot Control Pedal. The Motor should not be activated at this stage.

Click on “ON/OFF Simulator” Virtual Button using the Left Button of the Mouse. The icon should change to the ON Position and The Motor should be activated.

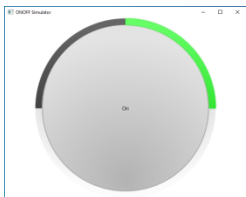


Figure 156: Virtual Button ON Position

3. Click on the “ON/OFF Simulator” Virtual Button few times to start/stop Motor.
4. Make sure the system works properly and accordance with the table below.

Aseptico	“ON/OFF Simulator”	Aseptico Motor
----------	--------------------	-----------------------

Foot Control Pedal 	on IGI Monitor Desktop 	
Released	OFF	OFF
Released	ON	OFF
Depressed	OFF	OFF
Depressed	ON	ON

5. Release ASEPTICO Foot Control Pedal. Close “ON/OFF Simulator” Soft.

I. Cleaning



Warning: Before cleaning or normal maintenance, verify the DAB is not in use and IGI is OFF.



Caution: Cleaning and disinfection of the Aseptico motor, handpiece, console and foot pedal is described in the Aseptico motor User Manual.



Caution: Avoid spilling liquids into the interior of the system during cleaning and/or disinfecting it. This may cause damage to the system.



Caution: Use of other cleaning or disinfecting solutions may damage the console and may void the warranty.

It is recommended to clean the DAB exterior surface by wiping with cotton pads or a soft cloth fully dampened with a cleaning and disinfecting agent or presoaked cleaning and disinfecting wipes approved for use in a dental practice such as Mediwipes®. Any excess cleaning liquid should be wiped off with a soft cloth.

J. Environment &

Maintenance

Product Name	DAB (Drilling Autostop Box) for Aseptico
Part Number	AI640760
Supply Voltage	5 Vdc, 500 mA, (USB Powered)
USB connection	USB B Receptacle
Operating Temperature/Humidity	10°C to +28°C/10% to 80%
Atmospheric pressure:	50 kPa to 106 kPa
Dimensions (not include Cables)	130X100X30 mm
Weight (include "Implant Motor Cable and USB Cable)	334 g
Safety Approval	IEC60601-1 Ed.3.1
EMC Approval	IEC60601-1-2 Ed.4

K. Electromagnetic and RF Declarations

DECLARATION – ELECTROMAGNETIC EMISSIONS		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group1 Class A	The DAB for Aseptico AEU 6000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	The DAB for ASEP Aseptico TICO AEU 6000 is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the DAB for Aseptico AEU 6000 or shielding the location.
Voltage Fluctuations And Flicker IEC 61000-3-3:2013	Complies	

DECLARATION – ELECTROMAGNETIC IMMUNITY			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	1 kV line(s) to line(s) 2 kV line(s) to earth N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	0% UT; 0.5cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DAB for Aseptico AEU 6000 requires continued operation during power mains interruptions, it is recommended that the DAB for Aseptico AEU 6000 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

DECLARATION – ELECTROMAGNETIC IMMUNITY			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance

Conducted RF IEC 61000-4-6	3V, 6V	3Vrms, 6V	Portable and mobile RF communications equipment should be used no closer to any part of the DAB for Aseptico AEU 6000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{12}{V_2} \right] \sqrt{P}$ $d = \left[\frac{12}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{23}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. D Interference may occur in the vicinity of equipment marked with the following symbol: 
	3V/m	3V/m	
	3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz	3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz	
	3V/m from 80MHz to 2.7GHz	3V/m from 80MHz to 2.7GHz	

Recommended separation distances between portable and mobile RF communications equipment and the DAB for Aseptico AEU 6000				
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM bands $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = \left[\frac{12}{V_2} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{12}{E_1} \right] \sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{23}{E_1} \right] \sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment							
Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	Immunity Test level (V/m)	Compliance level (V/m)
385	380 – 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28	28
1720 1845 1970	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28	28
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28	28
5240 5500 5785	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9	9
^{a)} For some services, only the uplink frequencies are included. ^{b)} The carrier shall be modulated using a 50 % duty cycle square wave signal. ^{c)} As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.							

L. Troubleshooting

PROBLEM	CORRECTION
DAB LED is OFF	Check USB Cable and connection to IGI Computer.

DAB LED is RED	Check IGI system connection and IGI is in operating.
DAB LED is GREEN, but Aseptico Motor is not activated	Perform the Test Mode Operation. If during test mode the aseptic is working, turn to Image Navigation Support. If the Test Mode Operation cannot activate the motor, verify the connections of the: ASEP Aseptico TICO Electronic Control Console, Aseptico Foot Control Pedal or Aseptico cables.



Warning: In event of any defect on the product or malfunction, do not use the product.

Do not open the DAB box. Immediately notify support@image-navigation.com.

M. Warranty

Image Navigation Ltd. Company warrants this product against defects for a period of one year, from date of original invoice.



Warning: The safety, reliability and performance of the equipment can be assured only if: Maintenance, modifications and service are performed by an IGI authorized technician only.

For technical support please contact manufacturer at: Image Navigation Ltd.
17 Hartom Street Jerusalem, Israel Postal Code 9777517
P.O. Box 45345
Phone: +972-2-6417748
Fax: +972-2-6426901
Email: support@image-navigation.com
Website: www.image-navigation.com

XVIII. Appendix Three: IGI Error Messages Explanation and Basic Trouble Shooting:

ERROR MESSAGE	TROUBLE SHOOTING STEPS
1. "Warning - Resources Limit"	reset IGI
2. "Another DenX application is running!"	Check only tracking and IGI are running. (IGI was open twice or Dxdtd program is running in parallel).
3. "Couldn't open ini file : %s .\ please specify an existing ini file!":	Check ini file is under c:\image-navigation\IGI directory. If persists, Contact Support
4. "Cannot open IGI_DB. Application Error!"	Contact Support
5. "Could not examine the disks"	If disk on key that you need is visible continue if the needed disk is not visible try to use another disk on key If persists, Contact Support
6. "CT files are missing or folder does not exist. Can't edit session." 7. "Error in opening file " + fileName + " for reading"; 8. "Error in reading session file"	When opening an existing session and the session cannot be open by the system. It can be due to changes in versions of IGI after SW update. If you can recreate the session based on the CT, try to do so. If not Contact Support.
9. "Error in writing session file"	Check if the hard disk is full or this place is write-protected

10. "Error in opening session file: " + sessionFileName + " for writing"; 11. "Could not write session files" 12. "Error Occurred during writing balls centers" 13. "Error opening output file." 14. "Error opening the record file for writing."	If cleaning the disk and remove the protected doesn't help Contact support.
15. "The Study Data file is missing. You need to import the session again." 16. "Could not read initial CT bed position. You need to import the session again." 17. "The Study Data file is missing. You need to import the session again."	Import the session again If persists, Contact Support
18. "Cannot accept this type of non-homogeneous intervals between CT slices"	Export of the CT has been done from the CT machine with inhomogeneous slices interval distance. The export has to be done again from the machine with same slices interval distance. This CT slices are not usable by IGI.
19. "Warning - Found slices with gap that is too small" 20. "Warning - Found slices with gap that is too small" 21. "Warning - Found slices with gap that is too small"	Export of the CT has been done from the CT machine with small slices interval distance. The export has to be done again from the machine with same slices interval distance bigger than 0.01mm. This CT slices are not usable by IGI.
22. "Failed to read %s. Import is denied!"	IGI SW cannot read the format. Retry export by the CT machine.

	If persist contact support.
23. "place drill in validation hall and press OK to validate bar Length\nor press CANCEL and reselect a bar."	NA
24. "problem in study normalization"	Re-import the CT, make sure that the CT loaded fit to the correct study in the CT dicom. If persist Contact support
25. "No nerve canal/jaw curve was plotted. Cannot enable planning!"	Go back to Jaw curve marking page and proceed again.
26. "Error opening file!" 27. "Cannot load planning from newer IGI version." 28. "The Plan was created by older version of IGI. It cannot be saved as is. Please choose "Save As" to update it."	Plan version do not correspond to SW version. Replan using the current SW version.
29. "error - cannot delete the file!"	Or file has already been deleted or it is write protected. If not Contact support
30. "Drill Samples can't be written, you might want to delete some drillPosSample*.txt files!!!" 31. "Drill Samples can't be written, you might want to delete some drillPosSample*.txt files!!!"	Technician window: disk is full. Empty hard disk.
32. "NO SAMPLE WAS TAKEN!!!"	In Technician window take samples before saving.
33. "Can't Grab Snapshot!"	On the fly use is only for implant and not for implant snapshot.
34. "GL: Invalid num", 35. "GL: Invalid value", 36. "GL: Invalid operation", 37. "GL: Stack overflow", 38. "GL: Stack underflow", 39. "GL: Out of memory"	Reset IGI If persists, Contact Support

40. "OpenGL inactive: no rendering context", "CheckRC:" 41. "Can't plot more than 20 points." 42. "Attempt to play with GL before valid RC creation!!" 43. "Attempt to play with GL before valid RC creation!!"	
44. "Undefined session path."	Technician function: handpiece motion tracking has been recorded on a session that does not exist anymore.
45. "Error opening the record file for reading."	Format of the file is not the right one.
46. "Error opening file"	File is from a different SW version or corrupted. Replan or use another file.
47. "WARNING: Duplicated Led in File"	Contact support (tool file is invalid)
48. "Could not read CT Sphere Locations. Registration is impossible!" 49. "Failed to locate spheres in the CT.\n"	Do session again and mark the CT sphere points. Or you will have to use only anatomical registration. If you can't do the anatomical registration contact support.
50. "Failed to read 3 metal spheres ground points.\n Cannot use sphere auto-locating\n"	Mark more spheres and try to be more accurate. If persists, contact support
51. "images %d and %d have same bed position\nunmark one of them"	Check you chose the correct study. If persists, try to export the CT again. If persists, Contact support
52. "Overlap Rejection: The slice thickness is %3.2fmm while the slice gap is %3.2fmm.\n The scan is rejected due to severe inaccuracies." 53. "Overlap Warning: The slice thickness is %3.2fmm while the slice gap is %3.2fmm.\n Use of this scan can cause inaccurate results."	When exporting the CT, the format requested by IGI was not respected. Re-export the CT with the correct format or re-scan.

54. "Cannot save value. One of the fields is probably empty or access to file is denied"	In the Ini file, one of the field values is missing.
55. "fail in creation of dialog"	Contact support
56. "DataBase Error!"	Contact support
57. "Procedure will be very inaccurate due to severe CT distortion.\n Continue?"	Contact support
58. "DB Fail"	Contact support
59. "fail to create window!"	Reset the computer If persists, Contact Support
60. "Non standard safety margins. Continue ?"	Contact support (Ini file - indicators)
61. "Invalid creator name."	You cannot modify plan from another creator only save the plan under your creator name.
62. "Invalid password."	NA
63. "Failed to initialize the printer"	NA
64. "Failed to start a page on the printer"	NA
65. "The printer could not be found"	NA

IGI errors related to Tracking	Hardcoded Tracking errors related: (not visible by the user- available in LOG file.)	Explanation	Trouble Shooting Steps
"Tracking system problem, please reset the tracking system"	"Initialization of Ws2_32.dll failed" "Invalid socket" "The MT system is not available"	Motion Tracking System is not available due to system error (not related to tools).	Reset Motion tracking from IGI button: "reset 7D"

"The MT system is not available" "Tracking system problem, please reset the tracking system" "No Motion Tracking." "Motion Tracking control window creation failed!\The motion tracking driver is disabled."	"Socket initialization failed" "Set socket to non blocking mode failed" "Set socket to blocking mode failed" "Invalid host name" "Failed to get host address" "Create socket failed" "Connection to socket failed" "Failed to accept socket" "Failed to read from socket" "Failed to write to socket" "Connection closed by client" "Operation is timed out" "Invalid communication socket" "Invalid version" "Invalid header identifier" "Undefined command id" "Invalid data"		If persist close IGI and Tracking and restart tracking, restart IGI. If persists, restart computer. If persists, turn to service.
"No Handpiece Tracking"	"Frame spotless"	The HP is not seen by the system.	Check camera position and tools

	"Frame includes more spots than expected" "Frame 2d locations were not triangulated (check cameras calibration files validity)" "Led events" "Led obscured" "Led not seen" "Led disabled" "Bad camera led angle - led ignored" "Led too close to some other led" "Tool events" "Tool unlighted" "Not enough leds seen for tool identification" "Tool geometry error"		are easily visible on the camera Reset tracking system. If functionality test failed, need calibration
"No Patient Tracking"	"Reference Frame Frame spotless" "Reference Frame Frame includes more spots than expected" "Reference Frame Frame 2d locations were not triangulated (check cameras calibration files validity)" "Reference Frame Led events" "Reference Frame Led obscured"	Tracking system don't see the PT	Check camera position and tools are easily visible on the camera Reset tracking system. If functionality test failed, need calibration

	"Reference Frame Led not seen" "Reference Frame Led disabled" "Reference Frame Bad camera led angle - led ignored" "Reference Frame Led too close to some other led" "Reference Frame Tool events" "Reference Frame Tool unlighted" "Reference Frame Not enough leds seen for tool identification" "Reference Frame Tool geometry error" "Reference Frame Identification in process"		
"No Tracking"	"Algorithm result does not exist" "System has not been Initiated: all commands aborted."	Usually related to tools pb.	Check camera position and tools are easily visible on the camera Reset Motion tracking from IGI button:" reset 7D" If persists, close IGI and Tracking and restart tracking. Restart IGI.

			If persist restart computer. If persist turn to service.
--	--	--	--

XIX. Appendix Four: Import Planning from Exocad

IGI allows the user to import implant planning that was created on approved third party software. Check with your distributor regarding which software versions are currently approved.

Important: if during the planning phase in Exocad "continue **with** accepted alignment" is selected, IGI will provide the option to register the patient to either the model or the CT using anatomic registration.

Important: Only use the 3D model for registration if you are sure of its alignment to the CT.

If the "continue **without** accepted alignment" option is selected during planning in Exocad, IGI will only provide the option to register the patient to the CT using anatomic registration.

On the Archive Screen, click Import and then click the Exocad root directory

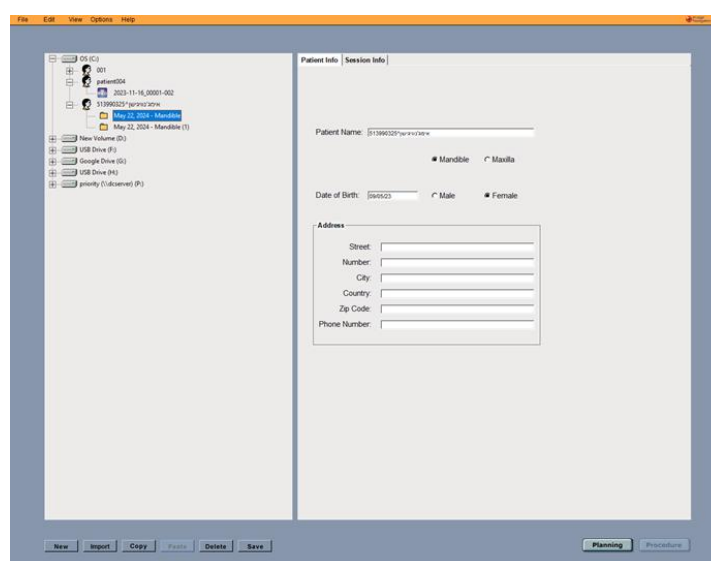


Figure 157: Import Button

The system automatically creates a named patient folder. In this folder, there are

numbered Exocad folders. In the Exocad folders, there are study folders with CT axial slices.

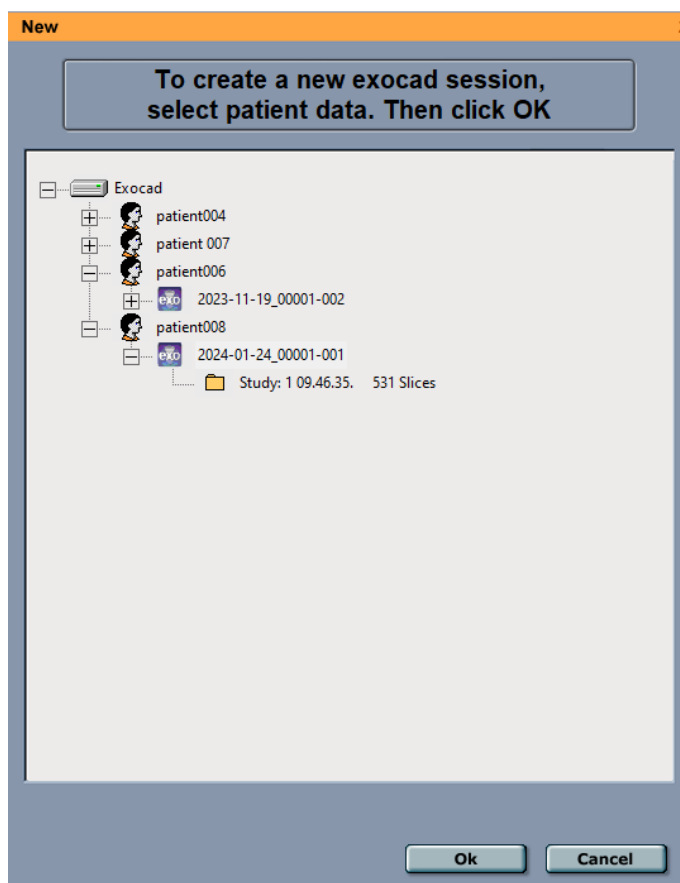
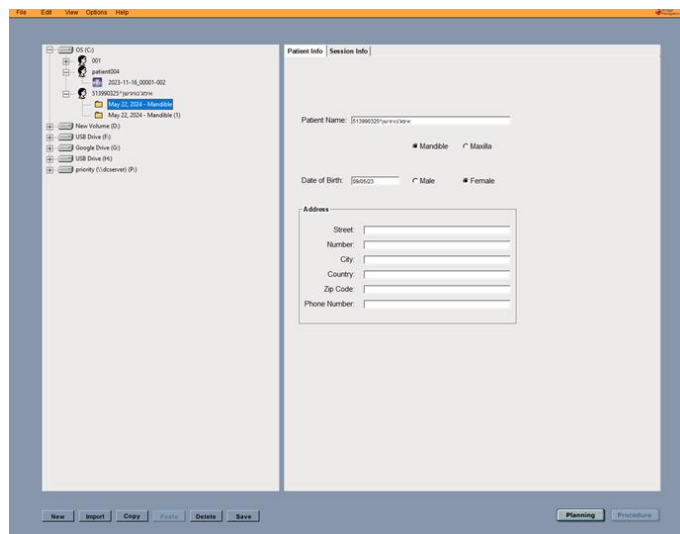


Figure 158: Archive Screen with Imported cases from Exocad

Note: If the drive contains data of two or more patients, IGI arranges the data in separate patient folders (one for each patient)

- **Double-click the name of the relevant patient.**
The patient's Exocad folder opens
- **Double-click the relevant patient Exocad folder.**
The patient study folder opens
- **Select the patient study folder and click OK.**
The Import Screen with the CT axial slices opens. The IGI automatically arranges the patient's axial slices from top to bottom and displays the slices according to their serial number.

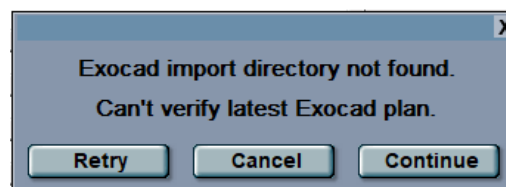


Figure 159: Import CT

Make sure that all slices are present and that the interval between the slices is consistent.

Important: The drive with the CT digital data may contain additional files other than axial slices. The system arranges these additional files in a different serial folder in the patient's main folder. In such a case, select the serial file that contains the axial slices.

IGI verifies that the chosen plan is the most current created in Exocad. If IGI can't find the plan on the computer, the following message is displayed.



The user chooses to retry, continue or cancel the import.

After the CT is imported, on the planning screen, the following warning will appear:

Warning: Final implant planning should be done in IGI.

When proceeding with final planning in IGI, the cross-section, axial, and 3D views should be used to verify the implant position.

Jaw Curve: The imported jaw curve is displayed in IGI. The surgeon must check it, if necessary, change it, then press the complete button on the lower right of the screen.

Nerve Canal: If working on the mandible, the imported jaw curve will be displayed. The surgeon must check it, if necessary, change it, then press the complete button on the lower right of the screen.

Implant Plan: The imported implant plan will be show on the screen. The surgeon must check it, if necessary, change it, then press the complete button on the lower right of the screen. **The procedure button is only active after the completed button on the planning screen has been pressed.**

Note: Imported plans, once changed in IGI, can't be exported back to the original 3rd party software.

If the user makes changes to the plan in the 3rd party software, the plan must be reimported into IGI by pressing the "Reload" button.

Warning: Updated plans from the 3rd party software will not be imported into IGI unless the "Reload" button is pressed.

Importing Plan with CT and STL 3D Models

Follow the above directions. When the import includes a 3D model (STL, PLY), there is an extra orange slide regulator which controls the opacity of the STL in the 3D window. See **Figure 11: Light Control Aid** on page 49.

When a 3D model is imported, it can be seen in the 3D view. Its outline can be seen in the cross-section view, the axial view, and the panoramic slice view. It isn't available in the panoramic x-ray view.

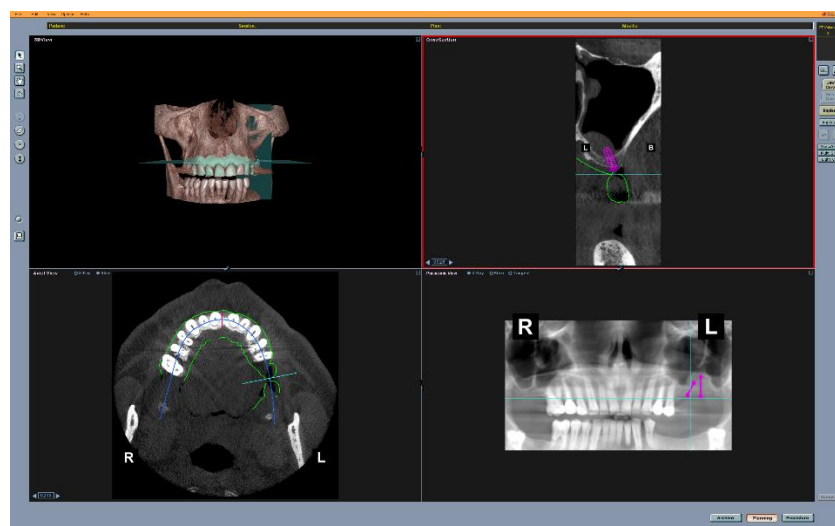


Figure 160: Planning screen with CT and 3D Model

Reload

If the user decides to make a new plan in the external third-party software, it should be reloaded on the planning screen (on the bottom) or imported as a new session using

the import button found on the archive screen. If either of these options aren't used, the planning will not be updated.

Note: If IGI didn't find the original session in an Exoplan folder, there won't be a Reload button to push.

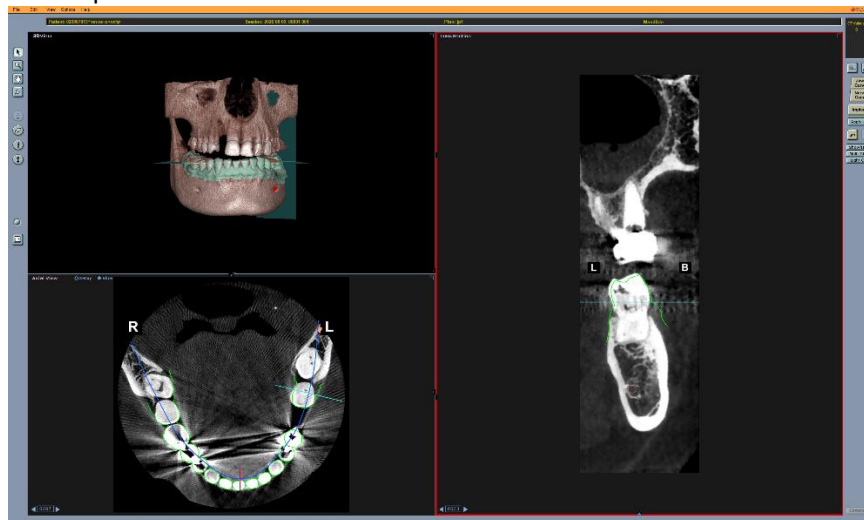


Figure 161: Reload Button

When the reload button is pressed, the following warning will appear:

Warning: Reload will cause all modifications made in IGI to be lost. Continue?

Continue planning according to the instructions: **Planning Implant Placement**, on page 90.

XX. Appendix Five: Indicators in Relation to Surgeon's Sitting Position

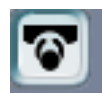
On the procedure screen, above the indicators, there are 5 icons depicting different sitting positions of the surgeon. They are pictured with their tool tip explanations below.



3 O'clock



1:30



12 O'clock



10:30



9 O'clock

Figure 162: Surgeon's Sitting Indicators

The surgeon's sitting position dictates the directions used, when showing the position of the handpiece in relation to the planned implant.

Press the button which corresponds to the sitting position that will be used during implantation for the current implant. If placing multiple implants, choose the sitting position (button) for each implant prior to implant placement.

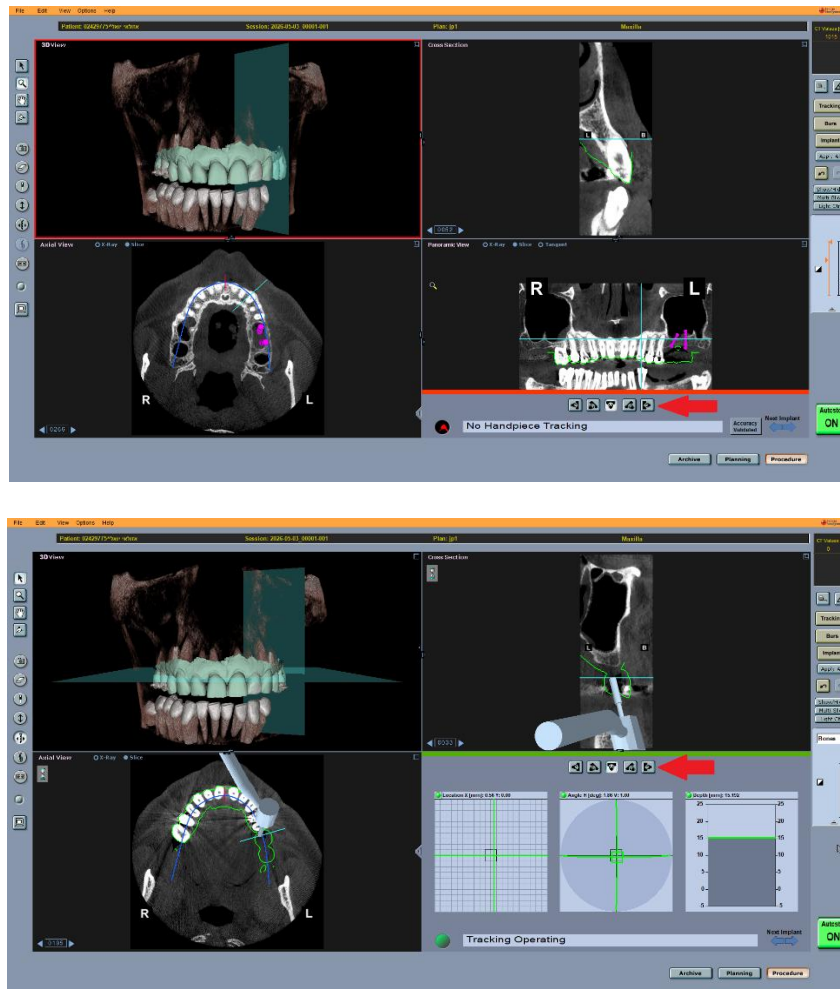


Figure 163: Placement of Sitting Indicators on Procedure Screen

When using the correct sitting position button, the indicators will show the drill moving away from you or towards you, right or left, always compared to the chosen sitting position. The default position is always the 12 O'clock position. In this position, the indicators are in line with the patient when the patient is looking straight up at the ceiling. In this position, moving the handpiece from the posterior to the anterior teeth, the handpiece will move up on the screen. For example, when in the 9 O'clock position (and the correct button is pressed), moving the handpiece from the posterior to the anterior teeth, the handpiece will move to the right. After changing the sitting position, the corresponding button should be chosen.

Important: If the sitting position is changed without pressing the button of the new position, the indicators will continue showing the handpiece position relative to the original sitting position.

