KeystoneDentalGroup

Surgical
Manual

MOLARIS™

MOLARIS
A KeystoneDentalGroup Brand

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Warning

The guidelines presented herein are not adequate to allow inexperienced clinicians to administer professional implant treatment or prosthetic dentistry and are not intended to be a substitute for formal clinical or laboratory training. These devices should only be used by individuals with training and experience specific to their clinically accepted application.

1 Characteristics

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1.1 Specifications

Introduction

This manual outlines the appropriate procedures for using the I-HEXMRT™ and TILOBEMAXX® Implant System in the process of restoring endosseous dental implants with a common range of prosthetic solutions, such as single- or multiple-unit crowns and bridges (cementable or screw-retained), fixed-removable full-arch prostheses, or attachments for securing removable implant overdentures. Keystone Dental Group is not liable for damages resulting from treatment outside of its control. Responsibility rests with the provider.

CAUTION: US Federal law restricts this device to sale by, or on the order of, a licensed dentist or physician.

TILOBEMAXX®			
Diameter	**Ø 7.0**	**Ø 8.0**	**Ø 9.0**
Length	7.0 mm 9.0 mm 11.0 mm	7.0 mm 9.0 mm 11.0 mm	7.0 mm 9.0 mm 11.0 mm
Maximum Outside Diameter	7.0 mm	8.0 mm	9.0 mm
Neck Diameter	6.0 mm	7.0 mm	8.0 mm
Platform Diameter	5.7 mm	6.5 mm	7.5 mm
Connection Diameter		4.34 mm	
Bevel Height	0.15 mm	0.25 mm	0.25 mm
Apical Diameter	4.44 mm	3.94 mm	4.94 mm

I-HEXMRT™			
Diameter	**Ø 7.0**	**Ø 8.0**	**Ø 9.0**
Length	7.0 mm 9.0 mm 11.0 mm	7.0 mm 9.0 mm 11.0 mm	7.0 mm 9.0 mm 11.0 mm
Maximum Outside Diameter	7.0 mm	8.0 mm	9.0 mm
Neck Diameter	6.0 mm	7.0 mm	8.0 mm
Platform Diameter	5.7 mm	6.5 mm	7.5 mm
Connection Diameter		5.57 mm	
Bevel Height	0.15 mm	0.25 mm	0.25 mm
Apical Diameter	4.44 mm	3.94 mm	4.94 mm

1.2 Design

Features

The I-HEXMRT™ and TILOBEMAXX® Implant Systems includes implants, abutments, and associated surgical, restorative, and dental laboratory components. The I-HEXMRT™ and TILOBEMAXX® external geometry is larger-than-conventional diameter to replace the root structure of a molar site, ultimately achieving primary stability by engaging the perimeter of the bony wall. The Implants have a tapered body, an enhanced surface and is designed to fit the natural shape of a molar socket. I-HEXMRT™ and TILOBEMAXX® provides an optimal fit in the multi-rooted immediate extraction site, minimizing bone loss and reduces treatment time.
There are no medicinal substances or human blood derivatives found in I-HEXMRT™ and TILOBEMAXX® Implant System implants, abutments, and associated surgical, restorative, and dental laboratory components.

I-HEXMRT™ and TILOBEMAXX® abutments & other restorative prosthetic and laboratory components are manufactured from Ti6AL-4V ELI titanium. Other restorative prosthetic or laboratory components are made from POM (polyoxymethylene), and/or PEEK.

2 Considerations

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2.1 Indications

Indications for Use

The I-HEXMRT™ and TILOBEMAXX® Implant Systems are intended for implantation in the maxillary or mandibular molar region where sufficient bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability or increased surgical procedures leading to complications. The I-HEXMRT™ and TILOBEMAXX® implants provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

Patient Population

Implant placement is not recommended until the end of jawbone growth is completed.

Directions for Use

The implantation drilling sequence procedure should be performed under aseptic conditions using only sterile I-HEXMRT™ and TILOBEMAXX® Implant Systems surgical instruments. A drilling protocol with copious irrigation is recommended for implant placement in the surgical site. The use of the I-HEXMRT™ and TILOBEMAXX® Implant System Surgical Manual and surgical instruments are recommended to aid in implant placement.

Following site preparation, attach the surgical ratchet and/or handpiece adapter to the implant driver. To maintain the sterility of the implant, remove the implant and screw from the vial as follows:

The implant is packaged in an outer vial with shrink-wrap. This outer vial holds an inner sleeve/cap with the implant and cover screw. The surgical assistant opens the outer vial and removes the vial cap, without touching

the inner sleeve/cap and tips the contents into the sterile field. The clinician holds the sterile inner sleeve/cap to remove the implant and cover screw with the appropriate sterile drivers.

Thread the implant into the prepared site in a clockwise direction, seating the implant at bone level, as indicated in the Surgical Manual. Place the cover screw*/healing abutment onto the implant and hand tighten. Close and suture the tissue.

*All implants are provided with a cover screw found in the cap of the implant vial.

NOTE: Refer to the Molaris™ I-HEXMRT™ and TILOBEMAXX® Implant System Prosthetic Manual for detailed explanation of restorative procedures. Available upon request from Keystone Dental.

NOTE: Improper treatment planning and/or implant placement might result in implant failure and potential loss of surrounding bone.

Contraindications

- Contraindications include: (1) cases where the remaining jaw bone is too diminished to allow implant installation, (2) patients allergic or hypersensitive to chemical ingredients of the following materials including but not limited to: titanium, titanium alloy, stainless steel, (3) patients with insufficient mental health precluding patient cooperation, (4) patients who abuse drugs or alcohol, (5) patients who have conditions such as but not limited to myocardial infarct within the last year, oral infections, or malignancies, (6) patients who have uncontrolled diabetes or blood disorders.

Caution

- Dental implant surgery and restoration are not without risks. It is the obligation of the clinician to inform the patient about risks associated with these procedures.
- Pre-operative evaluation of the patient is necessary to determine factors that may either cause risk to the patient or affect the healing process of the bone and/or soft tissue.
- Care should be taken that the patient does not swallow or aspirate components. It is recommended to use a rubber dam to prevent swallowing or aspiration of small parts during the surgical and restorative phases.
- Implant failure or fracture can occur during routine function.
- It is important that the clinician use an appropriate number, length, and diameter of implants to provide adequate support and properly distribute load between abutments, to minimize the potential for implant failure or fracture.
- The use of electro-surgical instruments or lasers around metallic implants and their abutments may cause electric and/or heat conductivity.
- Implant mobility, bone loss, or chronic infection may result in implant failure.
- Implants should not be used if their surface is damaged.

- Single-use devices shall not be reused. Re-use of device may lead to infection of tissue, infectious diseases, and/or failure of the device to perform as intended.
- Restorative components are intended for single use only.
- Do not alter implants.

Warning

For the safe and effective use of dental implants, it is strongly suggested that specialized training be undertaken, including hands on training to learn proper technique, biomechanical requirements and radiographic evaluations. THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING. Responsibility for proper patient selection, adequate training, experience in the placement of implants, and providing appropriate information for informed consent rests with the practitioner. Improper technique can result in implant failure and/or loss of supporting bone. Keystone Dental, Inc. will not accept liability for damage caused by improper implant treatment.

Precautions

- Proper clinical and radiographic evaluation of the patient should be performed prior to implant placement.
- Determine local anatomy and suitability of the available bone prior to implant placement. Adequate radiographs, direct palpation, and visual inspection of the implant site are necessary prior to treatment.
- Products are intended for use only in the applications defined in the Molaris™ I-HEXMRT™ and TILOBEMAXX® Implant System Surgical and/or Prosthetic Manual.

Procedural Precautions

- All implant drilling and placement procedures should be done at speeds recommended in the I-HEXMRT™ and TILOBEMAXX® Implant Surgical Manual.
- Drilling procedures require the use of specifically designed I-HEXMRT™ and TILOBEMAXX® instruments.
- All drills must be sharp prior to use. Keystone Dental recommends a maximum of 20 uses and sterilization cycles.
- All drilling should be done using intermittent drilling action with minimal pressure and continuous irrigation using ample chilled sterile saline.
- Do not open sterile packaging until the correct implant size has been determined and the operative site has been prepared.
- Excessive insertion torque above 100 Ncm can cause damage to the implant and surrounding bone.
- Clean and dry the inside of the internal connection of the implant beforehand tightening the Healing Abutment or Cover Screw.
- Application of excessive force to the implant area should be avoided, especially during the healing period.
- After implant surgery, the clinician should evaluate patient bone quality and implant stability to determine when implants may be loaded.
- Proper occlusion should be evaluated, and restorations should have a passive fit to the abutments.

Healing Period

Any inadvertent loading of the implant should be avoided, especially during the first 6 weeks of healing to achieve optimal osseointegration.

Immediate Restoration

I-HEXMRT™ and TILOBEMAXX® Implants may be immediately temporized on a single or splinted multiple unit restorations when excellent primary stability is achieved and with appropriate occlusal loading. Whenever possible these restorations should be out of occlusion in both centric and eccentric positions. The patient should adhere to a soft diet and place minimal forces on these restorations for 6 to 8 weeks.

Delayed Restoration

The healing period is generally 3-4 months in the mandible and 4-6 months in the maxilla, however, healing periods for each patient vary. After the appropriate healing period the Cover Screw is removed, the Healing

Abutment is placed, and the gingiva is slightly sutured around. In some cases, sutures might not be necessary. The Healing Abutment remains in place for approximately 2 weeks. Impressions can then be taken, and the prosthetic protocol may proceed.

For additional information, please consult the Molaris™ I-HEXMRT™ and TILOBEMAXX® Implant System Prosthetic Manual.

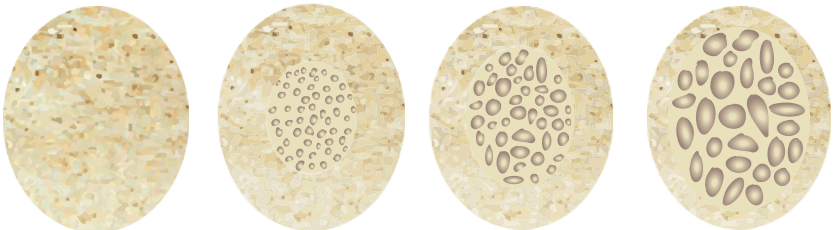
Soft-Tissue Healing and Temporization

- Following the placement of a I-HEXMRT™ or TILOBEMAXX® implant, soft tissue can be contoured using a titanium Healing Abutment or a custom-fabricated Temporary Abutment.
- A Titanium Temporary Abutment can be placed when good primary stability has been established for immediate temporization. The abutment relies on mechanical retention of the acrylic to the Temporary Abutment.
- The PEEK Cap of the Titanium Temporary Abutment, Immediate bonds with dental composite/acrylic allowing for custom aesthetic contouring.
- All temporary restorations should be kept out of occlusion and excursive movements.

Patient Evaluation and Selection

Implant selection should be made with the final restorative result as the primary consideration. Selecting implants in this manner aids in maximizing biomechanical stability and proper contouring of the soft tissue. The final implant position is at the discretion of the surgeon. Each case should be evaluated based on placement, protocol and type of implant prior to osteotomy preparation. Choosing an implant with a slightly smaller platform than the emergence of the tooth being replaced will provide support of the soft tissue and optimize the aesthetic result. Implant placement and Healing Abutment selections should be based on the following:

- Emergence profile of the restoration in relation to the prosthetic platform diameter.
- Height and diameter of the crown as it emerges through the tissue.
- General medical history
- Oral hygiene
- Patient's expectations
- General dentistry and product indications and contraindications
- Anatomical landmarks related to implant positioning.
- Interocclusal clearance (the space available between alveolar crest and opposing dentition).
- Ridge width in relation to the implant diameter



D1 Bone
Cortical bone

D2 Bone
Cortical bone/
trabecular

D3 Bone
Cortical bone/
trabecular

D4 Bone
Cortical bone/
trabecular

Bone Quality

While one method of classifying bone density is shown in the images above, different combinations of cortical and trabecular bone varying in thicknesses and densities can occur. These typically differ by jaw location. The clinician is responsible for assessing bone density of the surgical site and choosing the appropriate protocol.

Surgical Kit

The Surgical Kit must be cleaned and sterilized prior to use. The Surgical Kit instruments are provided non-sterile and must be cleaned and sterilized prior to use. All drills are non-irrigated and require external irrigation when preparing the osteotomy. Instruments should be inspected, cleaned separately, and discarded if damaged. Surgical instruments are susceptible to damage and wear and should be inspected before use. It is recommended to inspect the latch-lock shank after each use. The number of uses per drill will vary and depends on a variety of factors including bone density, proper handling, and cleaning. It is recommended to replace drills after 20 osteotomies, as repeated sterilizations and use may affect cutting efficiency and color appearance.

Surgical Kit Layout

Pre-Cleaning

- Used tools should be soaked immediately in instrument cleaning solution to avoid the drying of blood, saliva, and tissue residue.
- Used surgical trays must be cleaned with a suitable disinfectant.
- Multiple-part instruments must be disassembled prior to cleaning and sterilization.
- Internal debris/residue of instruments must be removed with a soft brush.
- Instruments should be inspected, cleaned separately, and discarded if damaged.

Principle Cleaning

- Best results are achieved if surgical tools are cleaned by material type.
- Rinse and brush under free-flowing tap water.
- Soak in enzymatic solution in an ultrasonic cleaner for at least five minutes following manufacturer's instructions.
- Rinse under free-flowing distilled water.
- Tools and non-sterile or modified abutments with their corresponding screws must be sterilized by the clinician prior to placement in a surgical

site. Instructions are provided in the Molaris I-HEXMRT™ and TILOBEMAXX® Implant System Prosthetic Manual.

Sterilization Guide

Description - Abutments	Sterilization Procedure
Custom Abutments, ANGLEBase®, Pre-mills, and all Prosthetic Tools	See reference table found in Sterilization Section
Cover Screws	Delivered Sterile: Sterilization required if modified.
Healing Abutments	
Multi-Unit Abutment Healing Caps	
Impression Posts	
Titanium Temporary Abutments, Immediate	
Titanium Temporary Abutments	
Titanium Abutments	
Straight and Angled Multi-Unit Abutments	
Abutment Screws in sterile package	

*It is recommended that non-sterile abutments from the dental laboratory or milling center be sterilized according to sterilization procedures listed above prior to final insertion.

Sterilization

Sterilization of non-sterile components is performed in the dental clinic setting by steam autoclave sterilization as detailed in the Instructions for Use according to the following parameters.

Sterilization Method	Steam, Pre-vacuum method
Preconditioning Pulses	4
Cycle Time	273°F (134°C) for 4 minutes
Dry Time	40 minutes
Packaging	510(k)-cleared sterilization pouch
Sterility Assurance Level	$\leq 10^{-6}$

NOTE: Products labeled as sterile should be considered sterile until the indicated “use by” date on the label or unless the package has been opened or damaged.

Surgical Motor and Handpiece

Cleaning and maintenance instructions for W&H motors and handpieces can be found on www.wh.com.

Implant Packaging

I-HEXMRT™ and TILOBEMAXX® implants are delivered sterile. The intact sterile packaging protects the gamma-sterilized implant from outside influences and, if stored correctly, ensures sterility up to the expiration date. When removing the implant from the sterile packaging, the rules of asepsis must be observed. The sterile packaging must not be opened until immediately prior to insertion of the implant. Implants with damaged sterile packaging must not be used due to the risk of contamination. It is recommended to have a replacement implant on hand.

Implant Delivery

The implant may be delivered to the osteotomy with the specific I-HEXMRT™ or TILOBEMAXX® Implant Driver in the options below.

The Implant Driver/Latch-Type can be used with a surgical handpiece or a Surgical Ratchet.

Following site preparation, attach the surgical ratchet and/or handpiece adapter to the implant driver. To maintain the sterility of the implant, remove the implant and Cover Screw from the vial as follows:

The implant is packaged in an outer vial with shrink-wrap. This outer vial holds an inner sleeve/cap with the implant and Cover Screw. The surgical assistant opens the outer vial and removes the vial cap, without touching the inner sleeve/cap and tips the contents into the sterile field. The clinician holds the sterile inner sleeve/cap to remove the implant and Cover Screw with the appropriate sterile drivers.

While holding the inner sleeve, align the Implant Driver of choice with the

implant. Rotate the Implant Driver to find the perfect seating between the Implant Driver and the internal connection of the implant.

Implant Placement

The final implant position is at the discretion of the surgeon. Each case should be evaluated based on placement, protocol, and type of implant prior to osteotomy preparation. It is recommended to place a I-HEXMRT™ or TILOBEMAXX® implant 2.0 mm subcrestal relative to the lowest part of the crest on the buccal and 2.0 mm off the buccal plate.

- Once the implant is seated to the final desired depth, with a recommended minimum torque of 30 Ncm and maximum torque of 100 Ncm, the Implant Driver is removed in a straight up motion to disengage the Implant Driver from the implant. Special care should be taken in very soft bone to not disrupt primary stability.

CAUTION: Corrections of the vertical positioning through reverse rotations during the surgery may lead to a decrease of initial/mechanical stability.

3 Sequence

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3.1 Surgical Sequence

Ø 8.0 x 9.0 mm Implant

(for demonstration purposes only)

Prosthetic Reminder

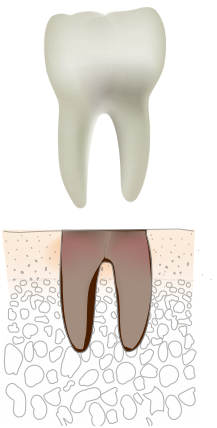
I-HEXMRT™ and TILOBEMAXX® Ø 7.0 mm Implants feature a Ø 5.7 mm prosthetic platform. Abutments are available in a flare of 6.0 and 7.0 mm.

I-HEXMRT™ and TILOBEMAXX® Ø 8.0 mm Implants feature a Ø 6.5 mm prosthetic platform. Abutments are available in a flare of 7.0 and 8.0 mm.

I-HEXMRT™ and TILOBEMAXX® Ø 9.0 mm Implants feature a Ø 7.5 mm prosthetic platform. Abutments are available in a flare of 8.0 and 9.0 mm.

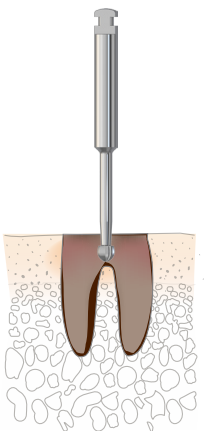
Step 1

The tooth is removed atraumatically ensuring the structural integrity of the extraction socket. The buccal plate and the sinus (maxilla) must be intact, and no major grafting should be required.



Step 2 (Optional)

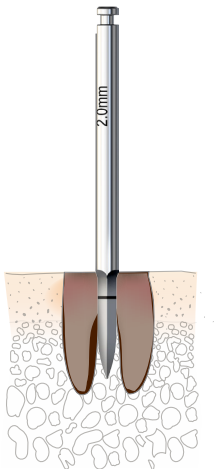
Utilizing a Round Bur, the osteotomy is initiated by drilling in the center of the remaining intra-radicular bone.

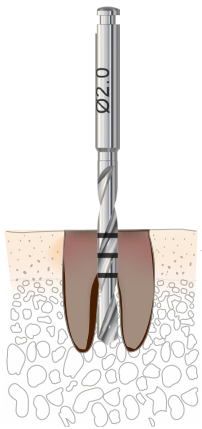


Step 3

Utilizing the Ø 2.0 mm Spade Drill, the osteotomy is initiated by drilling through the remaining intra-radicular bone.

NOTE: In bone types I/II it is recommended to progressively widen the osteotomy with an intermediate Ø 2.0 mm drill.



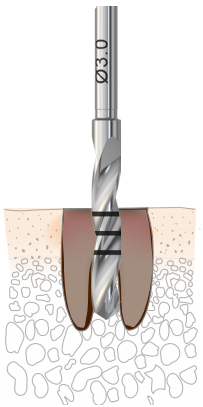


Step 4

The osteotomy is widened with a Ø 3.0 mm Twist Drill to the required depth at 1000-2000 rpm.

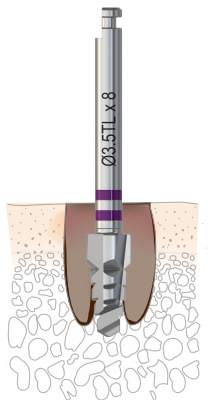
Surgical Pointers for bone type I/II:

- Properly align the latch-type instrument within the drill extension and/or handpiece.
- Only use drill extension when absolutely necessary.
- Rotate the latch-type instrument when engaging into W&H handpiece to ensure proper seating.



Step 5

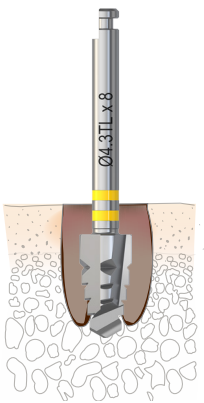
The osteotomy site is further widened utilizing a Ø 3.5 mm x 8 mm Tapered Drill to the full depth of the drill at approximately 500-800 rpm.



Step 6

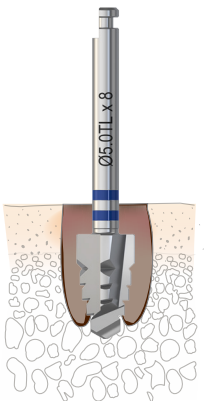
The osteotomy site is further widened utilizing a Ø 4.3 mm x 8 mm Tapered Drill to the full depth of the drill at approximately 500-800 rpm.

NOTE: Care must be taken to maintain the integrity of the buccal plate while widening the osteotomy. It is important to maintain a 2 mm clearance between the I-HEXMRT™ and TILOBEMAXX® implant and the buccal plate.



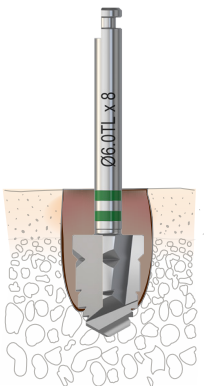
Step 7

The osteotomy site is further widened utilizing a Ø 5.0 mm x 8.0 mm Tapered Drill to the full depth of the drill at approximately 500-800 rpm.



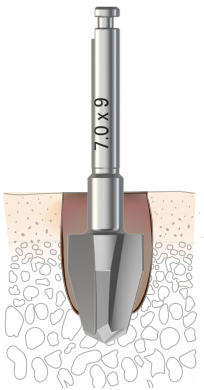
Step 8

The osteotomy site is further widened utilizing a Ø 6.0 mm x 8.0 mm Tapered Drill at approximately 500-800 rpm.



Step 9

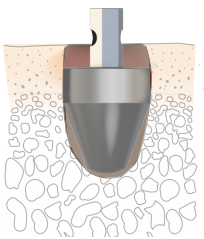
The osteotomy site is further widened utilizing a Ø 7.0 mm x 9.0 mm Tapered Drill at approximately 300-500 rpm.



Step 10

It is recommended to use a Ø 7.0 mm x 9 mm Profile Gauge to determine the proper site preparation prior to implant placement.

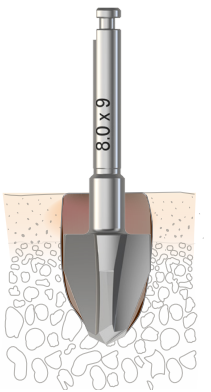
NOTE: It is recommended to thread floss through the opening of the Profile Gauge to ensure retrieval if dislodged.



Step 11

The final Ø 8.0 mm x 9.0 mm Tapered Drill, is inserted to the required depth at approximately 300-500 rpm to provide the final osteotomy shape.

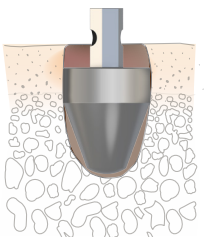
NOTE: It is recommended that the I-HEXMRT™ and TILOBEMAXX® be seated 2.0 mm sub-crestal, relative to the lowest part of the crest on the buccal.



Step 12

It is recommended to use a Ø 8.0 mm x 9 mm Profile Gauge to determine the proper site preparation prior to implant placement. A radiograph should be taken to verify the final seating of the implant placed checking both the apical and coronal depth.

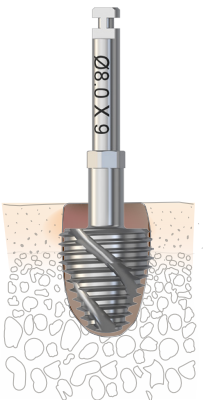
NOTE: It is recommended to thread floss through the opening of the Profile Gauge to ensure retrieval if dislodged.



Step 13

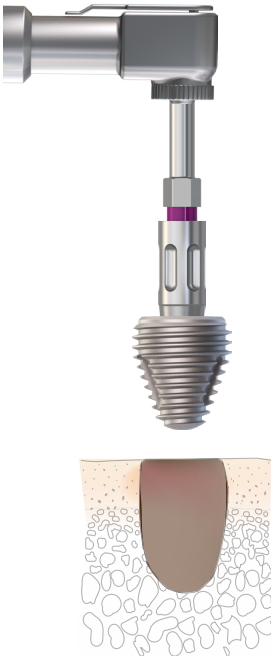
A dedicated Bone Tap can be used in addition to the Tapered Drill, or as a replacement to finalize the osteotomy (depending on bone quality). The Bone Tap is inserted at 15-20 rpm.

NOTE: For torques over 60 Ncm, the Bone Tap should be utilized with the Surgical Ratchet to tap the bone by using the Ratchet Adapter.



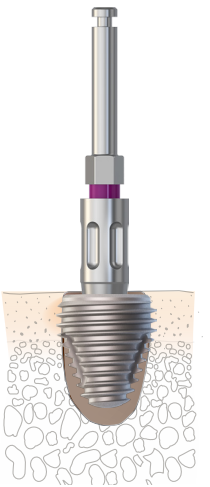
Step 14

The I-HEXMRT™ or TILOBEMAXX® Implant is carefully removed from its sterile vial utilizing the proper Implant Driver pre- attached to the handpiece and is carried to the osteotomy site.



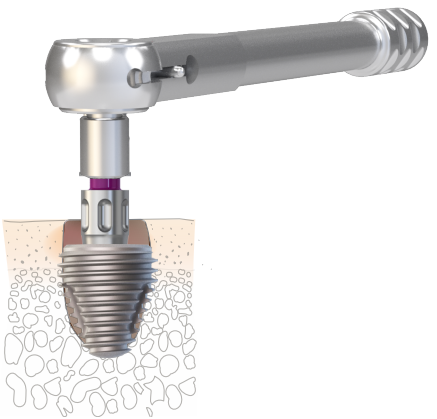
Step 15

Insert the implant into the osteotomy at 15-20 rpm and approximately 45 Ncm (depending on bone quality). The Implant Driver is disengaged from the handpiece and remains joined to the implant



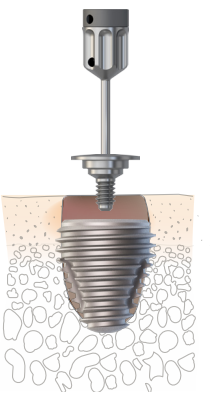
Step 16

Once the implant is placed, the Surgical Ratchet is used to fully seat the implant. The Ratchet Adapter is inserted into the Surgical Ratchet to engage the Implant Driver.



Step 17

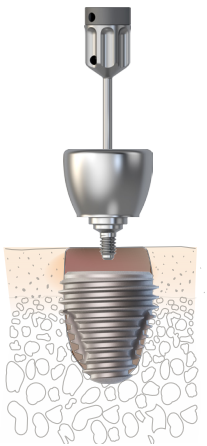
The I-HEXMRT™ or TILOBEMAXX® Cover Screw or Healing Abutment is placed with the appropriate prosthetic driver. NOTE: Healing Abutments are packaged separately.

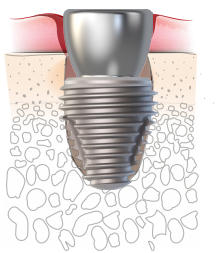


Step 18

The flap margins are positioned around the Healing Abutment and sutured in a tension-free manner. In some cases, sutures might not be necessary.

NOTE: It is recommended to take an x-ray to ensure correct seating of the Healing Abutment.



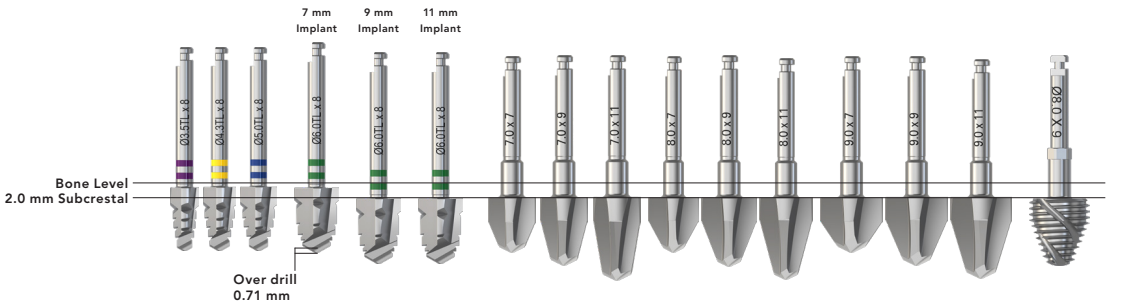


4 Markings

4.1 Depth Markings 47

4.1 Depth Markings

Drill Depth Markings



Over Drill Lengths

Drill	Over Drill Depth
Ø 3.5, Ø 4.3, Ø 5.0	No over drill
Ø6.0	.71 mm
Ø 7.0 x 7 mm & Ø 8.0 x 7 mm	.44 mm
Ø 7.0 x 9, Ø 7.0 x 11, Ø 8.0 x 9, and Ø 8.0 x 11	.28 mm
Ø 9.0 x 7 mm	0.5mm
Ø 9.0 x 9 mm	.35 mm
Ø 9.0 x 11 mm	.28 mm

5 Protocols

5.1	Manual Drilling Protocol	52
5.2	Torque Reference Table	53

5.1 Manual Drilling Protocol

Diameter	Length	Round Burr	Spade Drill	Ø 2.0 Twist Drill	Ø 3.0 Twist Drill	Ø 3.5 Tapered Drill	Ø 4.3 Tapered Drill	Ø 5.0 Tapered Drill	Ø 6.0 Tapered Drill	Ø 7.0 Tapered Drill	Ø 7.0 Profile Gauge	Ø 7.0 Bone Tap
Ø 7.0	7.0 mm	(Optional)	•	7.0 mm	7.0 mm	8.0 mm	8.0 mm	8.0 mm	8.0 mm	7.0 mm	7.0 mm	7.0 mm
	9.0 mm	(Optional)	•	9.0 mm	9.0 mm	8.0 mm	8.0 mm	8.0 mm	8.0 mm	9.0 mm	9.0 mm	9.0 mm
	11.0 mm	(Optional)	•	11.0 mm	11.0 mm	8.0 mm	8.0 mm	8.0 mm	8.0 mm	11.0 mm	11.0 mm	11.0 mm

Diameter	Length	Round Burr	Spade Drill	Ø 2.0 Twist Drill	Ø 3.0 Twist Drill	Ø 3.5 Tapered Drill	Ø 4.3 Tapered Drill	Ø 5.0 Tapered Drill	Ø 6.0 Tapered Drill	Ø 7.0 Tapered Drill	Ø 7.0 Profile Gauge	Ø 8.0 Tapered Drill	Ø 8.0 Profile Gauge	Ø 8.0 Bone Tap
Ø 8.0	7.0 mm	(Optional)	•	7.0 mm	7.0 mm	8.0 mm	8.0 mm	8.0 mm	8.0 mm	7.0 mm	7.0 mm	7.0 mm	7.0 mm	7.0 mm
	9.0 mm	(Optional)	•	9.0 mm	9.0 mm	8.0 mm	8.0 mm	8.0 mm	8.0 mm	9.0 mm	9.0 mm	9.0 mm	9.0 mm	9.0 mm
	11.0 mm	(Optional)	•	11.0 mm	11.0 mm	8.0 mm	8.0 mm	8.0 mm	8.0 mm	11.0 mm	11.0 mm	11.0 mm	11.0 mm	11.0 mm

Diameter	Length	Round Burr	Spade Drill	Ø 2.0 Twist Drill	Ø 3.0 Twist Drill	Ø 3.5 Tapered Drill	Ø 4.3 Tapered Drill	Ø 5.0 Tapered Drill	Ø 6.0 Tapered Drill	Ø 7.0 Tapered Drill	Ø 7.0 Profile Gauge	Ø 8.0 Tapered Drill	Ø 8.0 Profile Gauge	Ø 9.0 Tapered Drill	Ø 9.0 Profile Gauge	Ø 9.0 Bone Tap
Ø 9.0	7.0 mm	(Optional)	•	7.0 mm	7.0 mm	8.0 mm	8.0 mm	8.0 mm	8.0 mm	7.0 mm	7.0 mm	7.0 mm	7.0 mm	7.0 mm	7.0 mm	7.0 mm
	9.0 mm	(Optional)	•	9.0 mm	9.0 mm	8.0 mm	8.0 mm	8.0 mm	8.0 mm	9.0 mm	9.0 mm	9.0 mm	9.0 mm	9.0 mm	9.0 mm	9.0 mm
	11.0 mm	(Optional)	•	11.0 mm	11.0 mm	8.0 mm	8.0 mm	8.0 mm	8.0 mm	11.0 mm	11.0 mm	11.0 mm	11.0 mm	11.0 mm	11.0 mm	11.0 mm

5.2 Torque Reference Table

Prosthetic Component	**Torque (Ncm)**
Cover Screw, Healing Abutment* Multi-Unit Abutment Healing Caps* Intra-Oral Scan Abutments* Laboratory Screws**	15
Impression Post	20
Ti Temporary Abutment, Immediate*** Temporary Abutment*** Titanium Abutment Multi-Unit Prosthetic Screw, RP/WP** Multi-Unit Temporary Abutments RP/WP** Castable Abutment** Torx® Screw for ANGLEBase® Gold/Plastic UCLA Abutment Quick Abutment Straight & Angulated Multi-unit Abutments** Titanium Blanks Ti-Base Abutments Final Abutment Screws	30

* Recommended not to exceed 20 Ncm
** Clinician should use best clinical judgment when lowering the recommended torque value for any temporary abutment/cylinder placed at time of implant placement.

NOTE: It is recommended that the PEEK Concave Temporary Abutment be kept out of occlusion and excursive movements.

6 References

6.1	MR Safety - MR Conditional	56
6.2	Symbol Definitions	58

6.1 MR Safety - MR Conditional

WARNING: The RF safety of the device has not been tested. The patient may only be imaged by landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the RF coil.

A patient with a Keystone Dental Implant System device can be scanned safely in an MR system under the following conditions found on the next page.

For MR patient safety card please visit KeystoneDental.com/pages/mr

MRI Safety Information - MR Conditional

Device Name	Keystone Dental Implant System
Static Magnetic Field Strength (B0)	≤ 3.0T
Maximum Spatial Field Gradient	20 T/m (2000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	For body transmit coil, landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the coil. Extremity T/R coils permitted. Excludes Head T/R coil.
Operating Mode	Normal Operating Mode in the allowed imaging zone.
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	Not evaluated for head landmark.
Scan Duration	No specific constraints due to implant heating.

6.2 Symbol Definitions

	Catalog number		Non-Sterile
	Batch Code		Single Sterile Barrier System
	Medical Device		Do not use if package is damaged
	Caution, consult accompanying documents		Sterilized using gamma radiation
	Do not reuse		By Prescription Only

	Use by date
	Do not resterilize
	Manufacturer
	Date of Manufacturer
	MR Conditional

	Keep away from sunlight
	Consult Instructions for Use

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