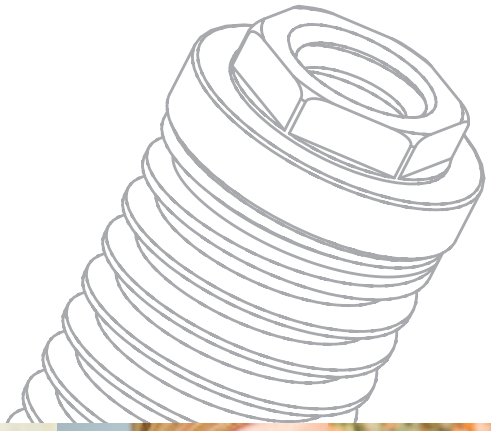
Keystone DENTAL

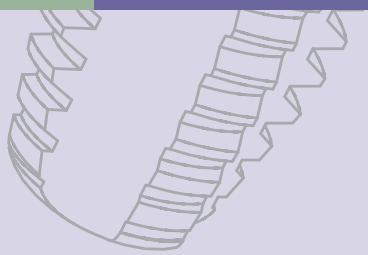


RESTORE® Implant System

Surgical Manual







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Symbols Key

= Caution = Note = Tip

Certain products may not be available in all countries.

Introduction

The RESTORE Surgical Manual is designed to aid clinicians in surgical procedures using Keystone Dental's RESTORE External Hex Implant System. Keystone Dental's RESTORE External Hex Implant System is built upon a history of clinically proven designs combined with enhancements that improve fit, function and overall ease-of-use. The External Hex Prosthetic Connection is backed by almost 40 years of successful clinical experience. Restoratively, the RESTORE System provides straightforward options for cement-retained, screw-retained and overdenture restorations. The procedures and guidelines presented in this Manual are not a substitute for formal surgical training for the clinicians and dental laboratories. It is the responsibility of the clinicians and dental laboratories to determine the final protocol and component selection.

Federal (USA) law restricts this device to sale by or on the order of a licensed dentist or physician.

Indications

The Keystone Dental RESTORE External Hex Implant System is intended for use in partially or fully edentulous areas in the maxilla and mandible in support of single or multi-unit restorations. The implants may also function as terminal or intermediate support for fixed bridgework.

PROSTHETIC CONSIDERATIONS:

- Cement-Retained Restorations (Fixed) utilizing multiple abutments
- Screw-Retained Restorations (Fixed Removable) utilizing multiple abutments
- Implant or Bar Attachment-Retained Overdenture Restorations
- Single Tooth Restorations without involvement of adjacent dentition

Contraindications

Customary general contraindications associated with elective surgery should be observed. These include, but are not limited to: significant vascular impairment to the implant site; metabolic bone disease; clotting disorders; current treatment with therapeutic agents that may have an effect on the surgical site, surrounding tissue, or normal healing responses (i.e. drug therapy, chemotherapy, radiation therapy, chronic steroid treatment, anticoagulant therapy); or other metabolic or physical disorders that interfere with bone growth, maintenance or wound healing.

POSSIBLE CONTRAINDICATIONS:

- Chronic bleeding problems
- Psychological impairment
- Treatment with chemotherapeutic agents
- Metabolic bone or connective tissue diseases
- Treatment with corticosteroids
- Certain cardiac and vascular diseases
- Diabetes (uncontrolled)
- Tobacco usage
- Chronic renal disease
- Poor patient oral hygiene
- Bruxism
- Alcoholism

TEMPORARY CONTRAINDICATIONS:

- Systemic infection
- Local oral or respiratory infection

ANATOMICAL OR PATHOLOGICAL CONTRAINDICATIONS:

- Less than 2mm of bone surrounding the implant
- Inadequate bone height where proper implant placement would encroach within 2mm of the mandibular canal, sinus floor, etc.
- Malignancies

Warnings

The implant placement procedure should be done under aseptic conditions with specifically designed sterile surgical instruments. A surgical drilling system with external or internal irrigation is recommended for drilling the surgical site. The specific drilling sequences for placement of implants should be followed. When drilling with pilot, depth and finishing drills, use an in-and-out motion. The use of surgical guides, depth gauges, and parallel pins are recommended to aid in implant placement and positioning.

Improper techniques can cause implant failure and/or bone loss. No attempt should be made to alter or modify the implant body or threaded area of the abutment. Abutments are for single use only. An opened, unused abutment should not be used in a different patient. Reduction of the abutments intraorally may transmit heat to the implant body and surrounding bone. Ample irrigation is necessary for cooling to prevent heat transfer to the bone.

The use of electro-surgical instruments or lasers around metallic implants and their abutments is discouraged due to the potential risk of electric and/or heat conductivity to the substrate metal.

Although techniques are described in the *RESTORE Surgical Manual* and the *RESTORE Prosthetic Manual*, training in the placement of implants is strongly recommended. Clinicians are encouraged to attend courses to familiarize themselves with established techniques of oral implantology.

It is very important to determine the local anatomy and suitability of the available bone prior to implant placement. Case planning with adequate radiographs, direct palpation and visual inspection of the prospective implant site are necessary prior to treatment and implant use.

Ensure that the patient has been well educated regarding implant placement and restorative procedures, home care and implant maintenance. The patient's expectations of the final result should be clearly defined.

Adverse Reactions

Some of the complications that can occur include: infection, bone loss, patient discomfort, implant mobility, local soft tissue degeneration and unfavorable implant placement or alignment.

Treatment for these reactions should follow standard dental procedures as would be indicated and applied for natural dentition. These would include pain medications, antibiotics, removal from function, removal of mobile implants and soft tissue/bone debridement and augmentation.

Implant mobility, bone loss or chronic infection may indicate implant failure. Any implant that appears to be failing should be treated as soon as possible. If the removal of the implant is necessary, any soft tissue can be curetted from the implant site and allowed to heal in the same manner as a traumatic natural tooth extraction.

Unfavorable implant placement or alignment may be treated with either pre-angled or customized abutments. If the implant is unrestorable due to alignment or positioning, either with the natural dentition or additional implants, the implant may need to be left unrestored or removed/replaced.

Sterilization

All Keystone Dental RESTORE external hex implants and select prosthetic components are provided in sterile, gamma irradiated packaging. Implants should not be used after the expiration date as sterility cannot be assured. The inner vial, cover screw and the implant body are sterile unless the outer package seal has been damaged or opened. Keystone Dental recommends storing implants in a cool, dry environment. Use only sterile, powder-free, starch-free and talcum-free gloves during the procedure.

If the implant becomes contaminated by the patient's body fluids or tissues in any way, the implant cannot be used in any other patient. The implant may not be cleaned or re-sterilized for use in another patient. Do not attempt to decontaminate the implant by any in-office method.

It is important to keep all instrumentation, the surgical handpiece and the equipment sterile to prevent the possible contamination of the components, the surgical system, and thus, the patient. Always run a system check and have back-up equipment, implants and instrumentation in case of contamination or failure of equipment or instrumentation.

Keystone Dental surgical instruments and surgical tray are non-sterile. Always remove instruments from the packaging prior to sterilization.

CLEANING PROCEDURE FOR SURGICAL TRAYS AND INSTRUMENTATION

1. Disassemble the surgical kit and wash the tray using the detergent solution. Rinse the tray with water and dry thoroughly.
2. Place the instruments in a beaker of detergent solution and sonicate for 10 minutes. Rinse thoroughly.
3. Remove any visible debris or bone fragments with a soft bristle brush. Rinse thoroughly.
4. Use a 22-gauge blunt needle connected to a syringe to flush water inside of the internally irrigated instruments. (A 22-gauge blunt needle is supplied with the surgical kit.)
5. Rinse the instruments with alcohol to remove soap residue and minerals. (This is important to help prevent corrosion.)
6. Blot the instruments with a towel and allow them to air dry completely.
7. Return the instruments to the appropriate location in the surgical tray.
8. Wrap the kit in a double layer of autoclave-approved paper.
9. Sterilize the kit according to the "Sterilization Table".

Do not remove the surgical kit from the autoclave until the dry cycle is complete.

The use of hydrogen peroxide or other oxidizing agents will cause damage to the surface of the instruments. Towel or air-dry all instrumentation before sterilization. Drills and taps should be replaced when wear, a decrease in cutting performance or signs of discoloration are noted. Keystone Dental recommends replacement after approximately 20 osteotomies depending on bone density.

Sterilization Table

1. Autoclave: 121°C (250˚F) 60 minutes exposure / 40 minute dry time / or 132°C (270˚F) 40 minutes exposure / 30 minute dry time. Do not exceed 140˚C (284˚F). Always use the dry cycle.

Do not use the original packaging in the autoclave! Autoclave re-sterilization can only be accomplished by placing the individual components in the surgical tray, a sealed autoclave bag or in a surgical towel.

2. Dry Heat: 160˚C (320˚F) 120 minutes (minimum). Do not exceed 170˚C (338˚F).

It is recommended that the proper biological indicators for the selected sterilization method accompany each load and that the appropriate sterile packaging be used to maintain sterility until use.

Keystone Dental does not recommend chemclave sterilization procedures as they may damage surgical trays and/or instruments.

Each dental office is responsible for the proper, routine sterilization of instruments. All sterilization techniques should follow the unit manufacturer's guidelines. Place all instrumentation and implants onto the sterile work field in the order they will be used. This makes for a natural progression through the case sequence. The surgical kit is set up in this fashion. Follow the drilling sequence printed on the kit and in this guide.

Surgical Guide Design and Fabrication

The implanting surgeon, the restoring dentist, and the laboratory should work together to produce diagnostic wax-ups and a surgical guide. This teamwork assists the implanting surgeon in the proper placement of the implant(s).

A surgical guide is used to indicate practical boundaries for the placement of implants and may prevent implants from being placed too buccal/lingually or mesial/distally. This process helps to ensure functional placement of implants and esthetic restorative results. A surgical guide can be made from clear, processed acrylic or vacuum-formed material produced from a duplicate stone model that replicates the shape and contour of the desired final restoration.

The laboratory may pre-drill in the surgical guide to indicate an ideal implant location and angle. This pilot drill will aid the surgeon in guiding the drilling sequence. The surgeon is ultimately responsible for the positioning and placement of the implant.

The implanting surgeon should communicate to the laboratory any conditions that may affect guide design (e.g., the type of incision that will be used, expected reflection of tissue, etc.)

FOR PARTIALLY EDENTULOUS CASES:

The surgical guide should be trimmed to avoid contact with the soft tissue areas.

FOR FULLY EDENTULOUS CASES:

Full arch surgical guides will provide a nearly complete view of all final restorations in the arch. The use of a guide for this type of restoration is crucial to ensure that the access points of the abutment screws are directed to the lingual of the anterior teeth and to the occlusal of the posterior teeth, and not through the facial, buccal or interproximal surfaces.

For stability, the laboratory should design the surgical guide to seat on the hard palate in the maxilla or the retromolar pads in the mandible.

Taking an Impression at the Time of Surgery

Taking an impression at the time of surgery is an option available if it is deemed necessary to have the laboratory fabricate a temporary restoration and have it ready to be inserted at the time of second stage surgery instead of the healing abutment(s). This allows for the tissue to heal to the natural contours of a tooth rather than to the round contours of a healing abutment. For a detailed description of this technique, please see pages 17-19.

RESTORE system information

Implant Sizing Overlays

Transparent Implant Sizing Overlays (100% and 125% magnification) are included in the RESTORE Surgical Kit. Overlays are used with radiographs to assist in the presurgical assessment and implant selection.

It is important to evaluate the general health of the mouth prior to implant placement. Special attention should be paid to the spacing of implants between the natural teeth adjacent to the proposed implant site. It is important to place the proper size implants in the area of missing teeth. Bone width and bone density play a roll in the size of the implant, as well as the interdental space. As a general guideline, there should be 2-3mm of bone between two implants and 2mm of bone between the implants and the sinus cavity, adjacent root(s), mandibular nerve canal and the outside surface of the bone structures.

X-rays should always be part of the pre-surgical treatment. The use of schematic implant overlays is helpful in determining available space for implant placement.

The charts below are guidelines for implant spacing for SD (Small Diameter), RD (Regular Diameter) and WD (Wide Diameter) single and multiple tooth replacements.

NOTE: Based on the implanting surgeon's personal preference, the spacing may be increased or decreased.

Implant Spacing

Single-Tooth Replacement	Minimum Space Requirement	
Implant Diameter	Mesio-Distal	Facio-Lingual
SD 3.3mm	6.3mm	6.3mm
RD 3.75mm	6.75mm	6.75mm
RD 4.0mm	7.0mm	7.0mm
WD 5.0mm	8.0mm	8.0mm
WD 6.0mm	9.0mm	9.0mm

Multiple-Tooth Replacement	Minimum Space Requirement	
Implant Diameter	Center-to-Center Spacing	Minimum Bone Length Required
SD 3.3mm	6.3mm	12.6mm
RD 3.75mm	6.75mm	13.5mm
RD 4.0mm	7.0mm	14.0mm
WD 5.0mm	8.0mm	16.0mm
WD 6.0mm	9.0mm	18.0mm

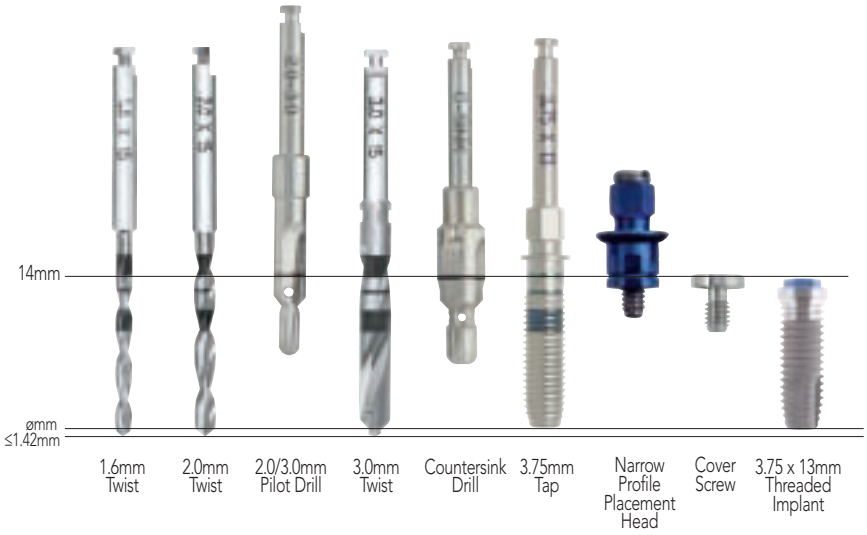
Evaluating Interproximal Space

Maxillary	Interproximal Height of Contour	Cervical Diameter M-D	Length of Crown
Central	8.5mm	7.0mm	10.5mm
Lateral	6.5mm	5.0mm	9.0mm
Cuspid	7.5mm	5.5mm	10.0mm
First Bicuspid	7.0mm	5.0mm	8.5mm
Second Bicuspid	7.0mm	5.0mm	8.5mm
First Molar	10.0mm	8.0mm	7.5mm
Second Molar	7.0mm	7.0mm	9.0mm

Mandibular	Interproximal Height of Contour	Cervical Diameter M-D	Length of Crown
Central	5.0mm	3.5mm	9.0mm
Lateral	5.5mm	4.0mm	9.5mm
Cuspid	7.0mm	5.5mm	11.0mm
First Bicuspid	7.0mm	5.0mm	8.5mm
Second Bicuspid	7.0mm	5.0mm	8.0mm
First Molar	11.0mm	9.0mm	7.5mm
Second Molar	10.5mm	8.0mm	7.0mm

Threaded Implant Placement

(3.75mm RD Implant Shown)

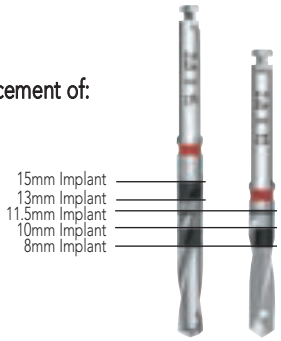


Drill bands reference the insertion depth of the corresponding implant and do not indicate actual millimeter drill length.

Depth Marking System

for Threaded Implants

For placement of:



Drill bands reference the insertion depth of the corresponding implant and do not indicate actual millimeter drill length. Refer to the Threaded Implant Placement Guide for increased length of drill tips.

Keystone Dental Drilling Sequences – Threaded Implants

Implant Diameter	Drill Sequence
3.3mm	1.6mm Twist → 2.0mm Twist → 2.8mm Twist → 3.3mm Tap
3.75mm	1.6mm Twist → 2.0mm Twist → 2.0mm/3.0mm Pilot → 3.0mm Twist → Counter-Sink → 3.75mm Tap
4.0mm	1.6mm Twist → 2.0mm Twist → 2.0mm/3.0mm Pilot → 3.0mm Twist → 3.3mm Twist → Counter-Sink (Optional) → 4.0mm Tap
5.0mm	1.6mm Twist → 2.0mm Twist → 2.0mm/3.0mm Pilot → 3.0mm Twist → 3.0mm/4.2mm Pilot → 4.2mm Twist → 5.0mm Tap
6.0mm	1.6mm Twist → 2.0mm Twist → 2.0mm/3.0mm Pilot → 3.0mm Twist → 3.0mm/4.2mm Pilot → 4.2mm Twist → 4.2mm/5.2mm Pilot → 5.2mm Twist → 6.0mm Tap

drilling and tapping procedures – threaded implants

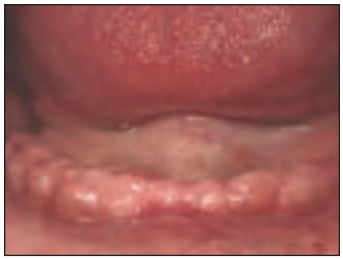
DRILL AND TAP SPEEDS

Drilling speeds of 1200-1800 rpm are recommended. When pre-tapping the bone, set the tapping speed to 25-50 rpm. All drilling and tapping procedures should be performed using copious amounts of irrigation.

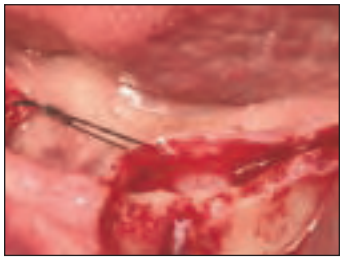
INCISIONS

Make an incision of appropriate design for elevation of a flap. When working in the anterior mandible, locate the mental foramen and where the inferior alveolar nerve exits.

Flatten any edges on the crest of the ridge if needed to create a more even plane on which to place the implant. External irrigation should be used for all modifications to the bone.



Pre-Incision



Incision

2.3mm ROUND MARKING BUR (Optional)

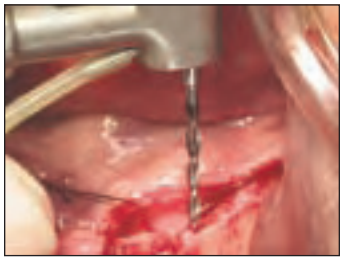
Once the implant site has been determined, either mark, dimple,or penetrate the cortical bone by utilizing a 2.3mm (8 gauge) Round Marking Bur where desired. Use of the Round Marking Bur is highly recommended for Type I and II quality bone as drills may "skitter" on hard cortical plate without an index point.

Round Marking Bur

1.6mm TWIST DRILL

Select the appropriate length 1.6mm Twist Drill (external irrigation) to begin the actual implant depth preparation. Use the laser etch depth markings on the drill that correspond to the implant that was selected. Refer to the Depth Marking Chart on page 8 for the specific markings. The proper depth will align with either the top or bottom of the etched band.

1.6 x 15mm



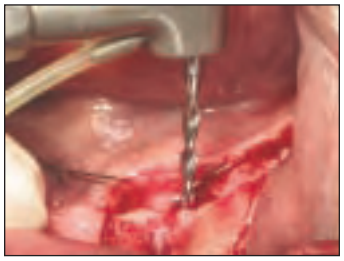
To verify the position and trajectory of the implant site relative to adjacent anatomy, a radiograph may be taken with the drill in place.

2.0mm TWIST DRILL

Use the 2.0mm Twist Drill (internal irrigation) to penetrate the bone to the appropriate depth marks on the drill. Check the orientation of the osteotomy using a Parallel Pin. When placing more than one implant, insert the Parallel Pin into the 2.0mm hole. Begin drilling the next site and align as the trajectory of the bone permits. Refer to the Depth Marking Chart on page 8 for the specific markings.

2.0 x 10mm

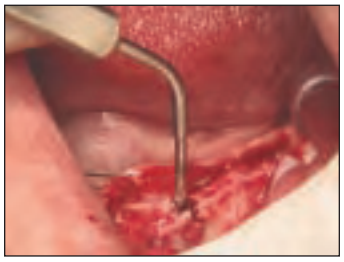
2.0 x 15mm



SURGICAL DEPTH PROBE (Optional)

The Surgical Depth Probe may be used to verify the depth of the osteotomy after the 2.0mm Twist Drill. The apical ball portion of the Surgical Depth Probe allows for tactile examination of the implant site.

Surgical Depth Probe



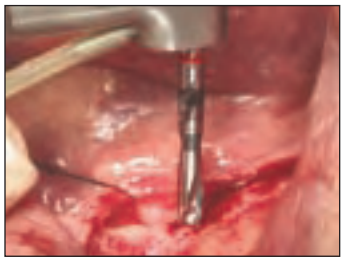
To place a 3.3mm implant, continue with the 2.8mm Twist Drill step below. Otherwise, proceed to the 2.0/3.0mm Pilot Drill Step below.

2.8mm TWIST DRILL (Final Drill for 3.3mm Implants)

Use the 2.8mm Twist Drill to expand the diameter of the site preparation. Refer to the Depth Marking Chart on page 8 for the specific markings.

2.8mm x 10mm

2.8 x 15mm

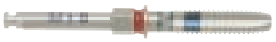


To place a 3.3mm implant, go to page 13.

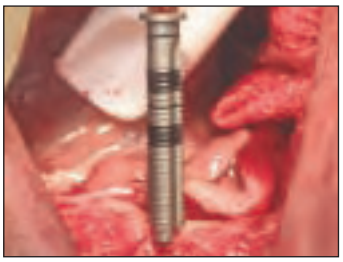
3.3mm TAP (Only for 3.3mm implants)

Use of the 3.3mm Tap is required in Type I dense bone. It is at the discretion of the surgeon whether or not to pre-tap in Type II or III bone. Pre-tapping in Type IV soft bone is not recommended.

3.3mm x13mm



3.3mm x18mm



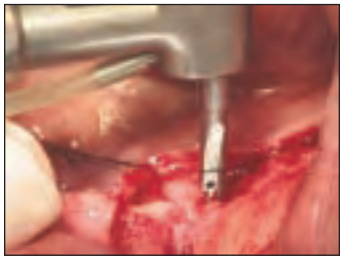
Place the Tap into the drilled implant site. Apply firm pressure and begin rotating the Tap utilizing a slow speed/high-torque handpiece (25-50 rpm maximum). When the threads begin to engage the bone, allow the Tap to feed into the site without applying additional pressure. The osteotomy should be tapped to the appropriate depth marking referenced on the Tap.

THESE ADDITIONAL STEPS ARE REQUIRED TO PLACE 3.75mm IMPLANTS

2.0/3.0mm PILOT DRILL

The 2.0/3.0mm Pilot Drill provides a smooth transition between drill diameters and ensures that implant site trajectory is maintained. To do so, drill into the site until the etched line is even with the crest of the bone.

2.0/3.0mm Pilot Drill



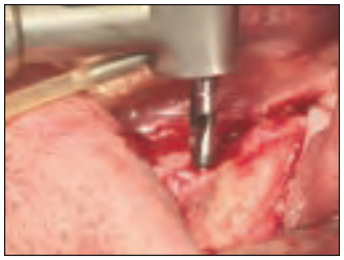
To place a 3.75mm implant, proceed with the 3.0mm Twist Drill step below. –OR–
To place a 4.0mm implant, proceed with the 3.3mm Twist Drill step on page 11. –OR–
To place a 5.0mm implant, proceed with the 3.0/4.2mm Pilot Drill step on page 11.

3.0mm TWIST DRILL (Final Drill for 3.75mm Implants)

Use the 3.0mm Twist Drill to expand the diameter of the site preparation. Refer to the Depth Marking Chart on page 8 for the specific markings. If needed, check the orientation of the osteotomy using a Parallel Pin. When placing more than one implant, insert the Parallel Pin into the 3.0mm hole. Begin drilling the next site and align as the trajectory of the bone permits.

3.0mm x 10mm

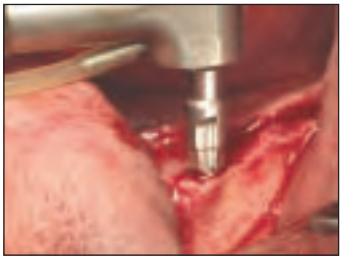
3.0mm x 15mm



COUNTERSINK DRILL (To Place 3.75mm Implants)

Prepare the superior portion of the osteotomy to accept the flared neck of the 3.75mm implant. To do so, drill down to the etched line at approximately the middle of the drill.

Countersink Drill



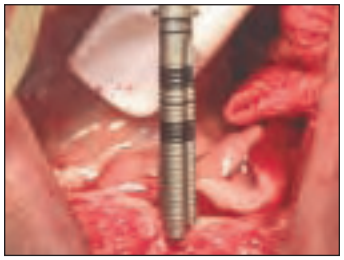
drilling and tapping procedures – threaded implants

3.75mm TAP

Use of the 3.75mm Tap is required in Type I dense bone. It is at the discretion of the surgeon whether or not to pre-tap in Type II or III bone. Pre-tapping in Type IV soft bone is not recommended.

3.75mm x 13mm

3.75mm x 18mm



Place the Tap into the drilled implant site. Apply firm pressure and begin rotating the Tap utilizing a slow speed/high-torque handpiece (25-50 rpm maximum). When the threads begin to engage the bone, allow the Tap to feed into the site without applying additional pressure. The osteotomy should be tapped to the appropriate depth marking referenced on the Tap.

To place a 3.75mm implant, go to page 13.

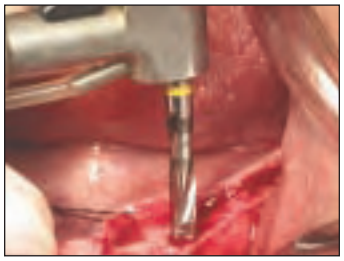
THESE ADDITIONAL STEPS ARE REQUIRED TO PLACE 4.0mm IMPLANTS

3.3mm TWIST DRILL (Final Drill for 4.0mm Implants)

Use the 3.3mm Twist Drill to expand the diameter of the site preparation. Refer to the Depth Marking Chart on page 8 for the specific markings.

3.3mm x 10mm

3.3mm x 15mm



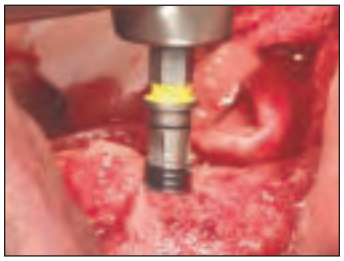
Optional: Depth Gauges are available for purchase separately. It is recommended that the surgeon thread floss through the floss-hole of the depth gauge before surgery. This will aid in transporting the depth gauge to and retrieval from the site after use.

4.0mm TAP

Use of the 4.0mm Tap is required in Type I dense bone. It is at the discretion of the surgeon whether or not to pre-tap in Type II or III bone. Pre-tapping in Type IV soft bone is not recommended.

4.0mm x 13mm

4.0mm x 18mm



Place the Tap into the drilled implant site. Apply firm pressure and begin rotating the Tap utilizing a slow speed/high-torque handpiece (25-50 rpm maximum). When the threads begin to engage the bone, allow the Tap to feed into the site without applying additional pressure. The osteotomy should be tapped to the appropriate depth marking referenced on the Tap.

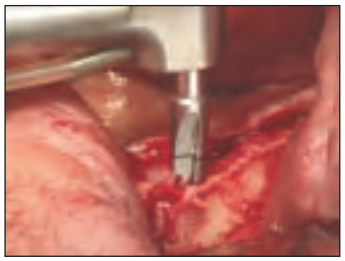
To place a 4.0mm implant, go to page 13.

THESE ADDITIONAL STEPS ARE REQUIRED TO PLACE 5.0mm IMPLANTS

3.0/4.2mm PILOT DRILL

The 3.0/4.2mm Pilot Drill provides a smooth transition between drill diameters and ensures that implant site trajectory is maintained. To do so, drill into the site until the etched line is even with the crest of the bone.

3.0/4.2mm Pilot Drill

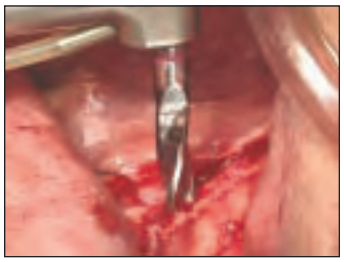


4.2mm TWIST DRILL (Final Drill for 5.0mm Implants)

Use the 4.2mm Twist Drill to expand the diameter of the site preparation. Refer to the Depth Marking Chart on page 8 for the specific markings.

4.2mm x 10mm

4.2mm x 15mm

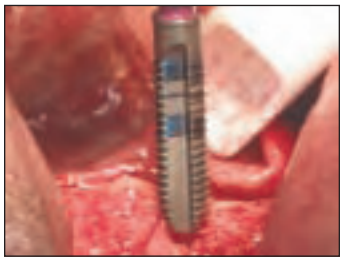


5.0mm TAP

Use of the 5.0mm Tap is required in Type I and II dense bone. It is at the discretion of the surgeon whether or not to pre-tap in Type III bone. Pre-tapping in Type IV soft bone is not recommended.

5.0mm x 13mm

5.0mm x 15mm



To place a 5.0mm implant, go to page 13.

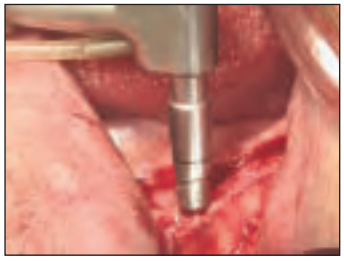
Place the Tap into the drilled implant site. Apply firm pressure and begin rotating the Tap utilizing a slow speed/high-torque handpiece (25-50 rpm maximum). When the threads begin to engage the bone, allow the Tap to feed into the site without applying additional pressure. The osteotomy should be tapped to the appropriate depth marking referenced on the Tap.

THESE ADDITIONAL STEPS ARE REQUIRED TO PLACE 6.0mm IMPLANTS

4.2/5.2mm PILOT DRILL

The 4.2/5.2mm Pilot Drill provides a smooth transition between drill diameters and ensures that implant site trajectory is maintained. To do so, drill into the site until the etched line is even with the crest of the bone.

4.2 /5.2mm Pilot Drill

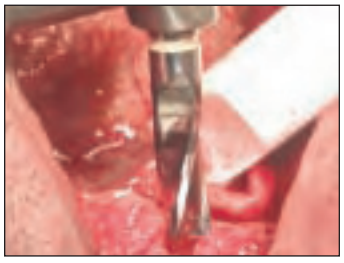


5.2mm TWIST DRILL (Final Drill for 6.0mm Implants)

Use the 5.2mm Twist Drill to expand the diameter of the site preparation. Refer to the Depth Marking Chart on page 8 for the specific markings.

5.2mm x 10mm

5.2mm x 15mm

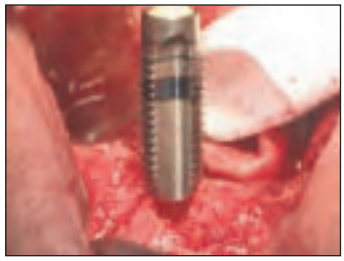


6.0mm TAP

Use of the 6.0mm Tap is required in Type I, II and III bone. It is at the discretion of the surgeon whether or not to pre-tap in Type IV soft bone.

6.0mm x 13mm

6.0mm x 15mm



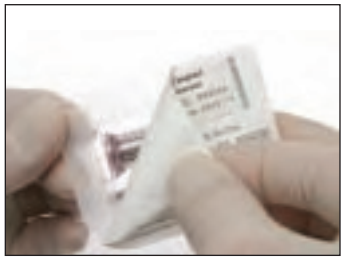
To place a 6.0mm implant, go to page 13.

Place the Tap into the drilled implant site. Apply firm pressure and begin rotating the Tap utilizing a slow speed/high-torque handpiece (25-50 rpm maximum). When the threads begin to engage the bone, allow the Tap to feed into the site without applying additional pressure. The osteotomy should be tapped to the appropriate depth marking referenced on the Tap.

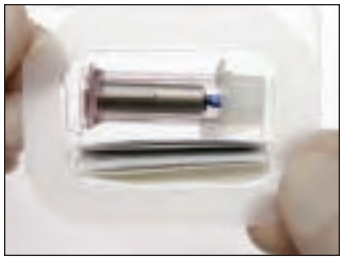
Implant Packaging

Peel back the Tyvek® lid on the outer package and place the implant vial into the sterile field. Pre-printed adhesive Patient Chart Labels are provided for use in the patient's chart.

Flip open the implant vial cap to expose the top of the implant placement head. The implant can now be removed from the implant vial and delivered to the implant site using either a handpiece with handpiece adapter, a surgical ratchet with ratchet adapter or a surgical hand driver.



Peel Back the Tyvek Lid



Implant Vial Exposed

Implant Vial Open

OPTION 1:

Motorized Implant Placement (Handpiece)

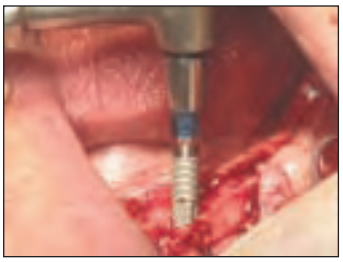
Attach the handpiece adapter to the handpiece and press it into the top of the implant placement head. Then connect the handpiece adapter onto the placement head and deliver the implant assembly to the site.

Thread the implant into the osteotomy at approximately 25-50 rpms until it is snug. Do not over tighten the implant in the site, as this could damage the threads prepared in the bone and result in less than optimal immediate fixation.

External Hex Handpiece Adapter

Connecting Handpiece Adapter onto Placement Head and Carrying the Implant

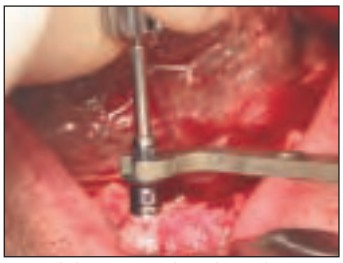
In some clinical situations, the clinician may prefer to use the surgical ratchet/ratchet adapter to manually deliver the last few rotations to fully seat the implant. This allows for a better tactile feel during seating.



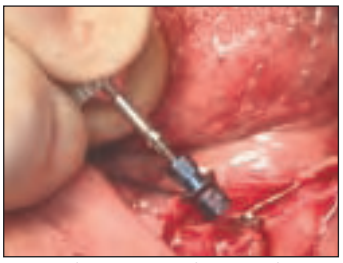
Threading Implant Using the Handpiece

PLACEMENT HEAD REMOVAL

Place either the open or closed end of the stabilizing wrench over the placement head base to provide counter-torque, while loosening the screw. Then use a .048" Hex Driver to loosen and detach the screw and placement head assembly from the implant.



Stabilizing Wrench and Handpiece



Placement Head Removed

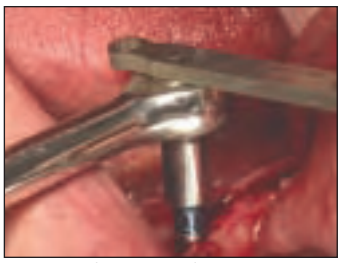
OPTION 2:
Manual Implant Placement (Surgical Ratchet)

Ratchet adapters and ratchet extenders are offered in two lengths for clinical versatility. If necessary, the ratchet extenders enable clearance of the adjacent teeth. Select the appropriate length ratchet adapter and insert it into the surgical ratchet. The directional arrow on the ratchet should point in the clockwise direction.

Removing Implant from the Vial

Surgical Ratchet

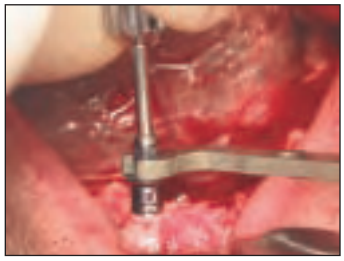
Connect the ratchet adapter or the hand adapter onto the placement head and deliver the implant assembly to the site. Thread the implant into the osteotomy until it is snug. Do not over tighten the implant in the site, as this could damage the threads prepared in the bone and result in less than optimal immediate fixation.



Tightening Implant Using the Surgical Ratchet

To improve stability of the ratchet/implant assembly during placement, insert the pin on the stabilizing wrench into the hole in the top of the ratchet adapter.

Stabilizing Wrench



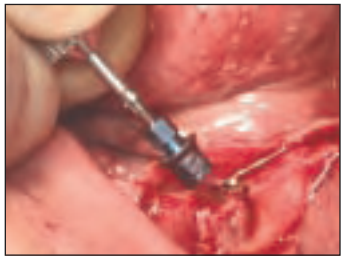
Stabilizing Wrench for Counter-Torque

Ratchet Conversion Adapter for Narrow Profile Placement Heads

Ratchet Extenders

PLACEMENT HEAD REMOVAL

Place either the open or closed end of the stabilizing wrench over the placement head base to provide counter-torque, while loosening the screw. Use a .048" Hex Driver to loosen and detach the screw and placement head assembly from the implant.

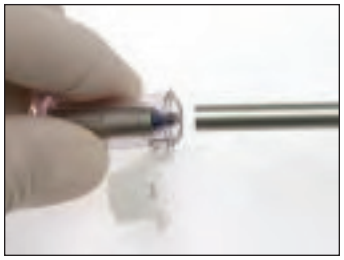


Turn Counter Clockwise to Remove Placement Head Screw

OPTION 3:

Manual Implant Placement (Surgical Hand Driver)

The Keystone Dental Surgical Hand Driver is used to provide a hand-delivery option for implant placement in the anterior region of the mouth. It provides a more tactile feel when placing implants. Open the flip-top lid of the implant vial and connect the surgical hand driver to the implant placement head. Remove the implant assembly from the vial and deliver to the implant site. Thread the implant by hand clockwise into the osteotomy until it is snug.



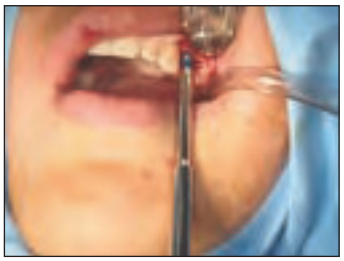
Surgical Hand Driver Carries the Implant

External Hex Surgical Hand Driver

Stabilizing Wrench

PLACEMENT HEAD REMOVAL

Place either the open or closed end of the stabilizing wrench over the placement head base to provide counter-torque, while loosening the screw. Then use a .048" Hex Driver to loosen and detach the screw and placement head assembly from the implant.



Threading Implant Using
the Surgical Hand Driver

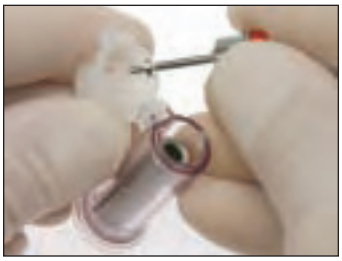
Cover Screw Placement

Use the .035" Hex Driver to unthread the cover screw from the underside of the implant vial cap. Carry the cover screw to the implant site and thread it into the implant using finger pressure.


Straight Cover Screw

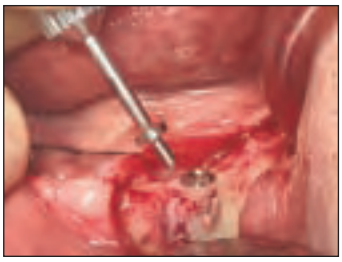

Flared Cover Screw


Headless Cover Screw


Unthreading the Cover Screw from Vial Cap

Closure and Suturing

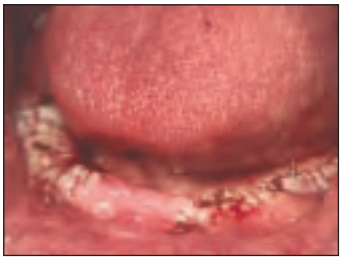
Remove the retaining sutures on the reflected tissue flaps, if applicable. Close and suture the tissue flap utilizing the desired technique. Take a radiograph to be used as a baseline for future diagnosis.


Placing the Cover Screw

Second Stage Uncovery

With a scalpel, make a small incision to expose the implant/cover screw. A tissue punch may also be used as an alternative. Use a .035" Hex Driver to remove the cover screw. Then with a .048" Hex Driver, place the appropriate height and diameter of healing abutment.

If bone prevents the healing abutment from fully seating on the implant, use the Bone Profiler to clean up the interface. Doing so will help to create the proper bone contours.


Final Suturing

Post-Operative Procedures

A period of no less than three months unloaded healing time in the mandible and four months unloaded healing time in the maxilla is strongly recommended. This is dependent on individual patient healing rates. Each case should be independently evaluated. This unloaded healing period allows for the integration between the bone and implant surface.

The patient must be instructed to follow a routine post-surgical regimen including ice or cold packs for 24 hours post-implantation and to consume a soft, high nutrient diet, if possible. According to individual surgical practice, consideration should also be given to dietary supplements with high protein, high vitamin and high mineral content for up to a month as well. Anti-edema steroid therapy may be initiated prior to surgery and continued for a period of 24 hours to one week post-surgery. Antibiotic treatment may be initiated one day pre-op and up to one week post-op as the patient's condition dictates. Sutures should be removed after approximately 10 days or as an individual's soft tissue healing dictates; chromic resorbable sutures will typically resorb within 7 to 10 days.

If a removable prosthesis is used during this initial healing phase, it is recommended that the underside of the prosthesis be relieved. This area may be relined with a soft tissue conditioner to prevent pressure on the surgical site(s). The patient should be examined periodically using radiographic evaluations to monitor healing of the soft tissues and bone.


Bone Profiler

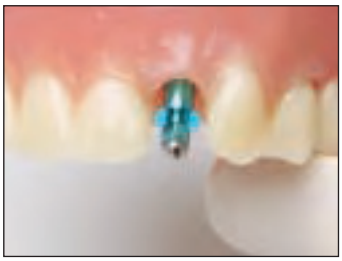
impression taking procedures – at the time of surgery (threaded implants only)

CLINICAL PROCEDURE
Immediate Impressioning

The lab will need full-arch impressions/models of the upper and lower jaw in order to fabricate the restoration. These can be alginate impressions taken before surgery.

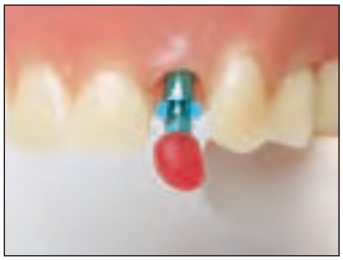
Step 1: Without removing the placement head, place the implant following normal protocol.

Depending on how the height of the placement head relates to the adjacent teeth, a taller placement head may have to be installed.


Implant Placed

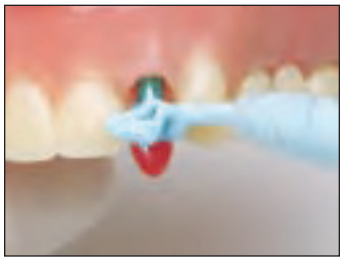
Step 2: Place a 3-4mm tall "ball" of rope wax on the top of the placement head. This will allow for easy access to the screw later.

Do not apply any rope wax to the hex portion of the placement head.


Ball of Rope Wax on Placement Head

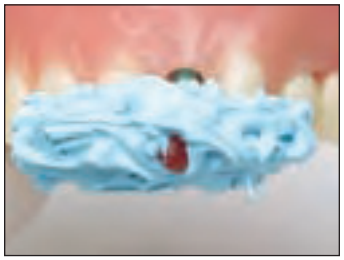
Step 3: Use a vinyl polysiloxane occlusal registration material around the hex of the head and over the incisal 1/3 of the adjacent teeth, mesial and distal to the implant.

Do not allow the material to engage any undercuts of the adjacent teeth.


Occlusal Registration Material Syringed

Step 4: Wipe off the excess occlusal registration material to expose the top of the screw prior to the material setting. Once the material has set, remove the wax to expose the screw for the placement head.

Step 5: Utilizing a .048" Hex Driver, disengage the placement head screw from the implant. Remove the jig, which includes the placement head locked in position.


Top of the Screw Exposed

If the assembly does not remove fairly easily, it may be engaging an undercut.

Step 6: Send this assembly to the laboratory for fabrication of a final or temporary abutment and a temporary restoration.

Step 7: Place the cover screw utilizing a .035" Hex Driver, close the flap and suture the tissue.


Placement Head Screw Removed


Placement Head and Jig Removed

LABORATORY PROCEDURE
Fabrication of the Abutment and Temporary Crown

Step 1: Attach an implant analog to the placement head.

Implant Analog Attached
to Placement Head

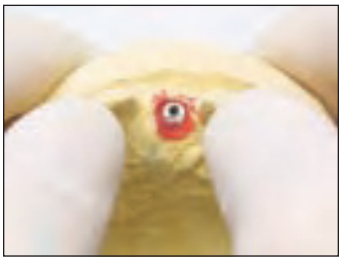
Step 2: Drill a hole in the pre-op model to accommodate placement of the implant analog into the model.

Hole Drilled in Model

Step 3: After drilling the hole, place the jig/placement head/implant analog onto the diagnostic model.

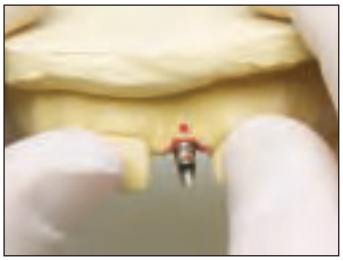
Jig/Placement Head/Implant Analog
Placed on Model

Step 4: Use acrylic or stone to secure the implant analog into the stone model.



Analog in Stone Model

Step 5: Modify the final/temporary abutment and fabricate the temporary crown.



Abutment Modified and
Temporary Crown Fabricated

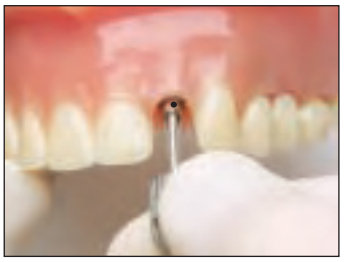
impression taking procedures – at the time surgery (threaded implants only)

CLINICAL PROCEDURE
Uncovery

Step 1: Uncover the implant following normal protocol. Then remove the cover screw.

Step 2: Remove the abutment from the model and seat it onto the implant.

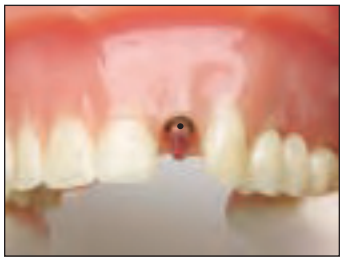
The abutment's rotational position must be in the same position in the mouth as it was on the model.



COC Abutment Seated in Mouth

Step 3: Tighten the abutment screw by hand and use an x-ray to verify that it is seated.

Step 4: Plug the screw access hole with wax or a cotton pellet.



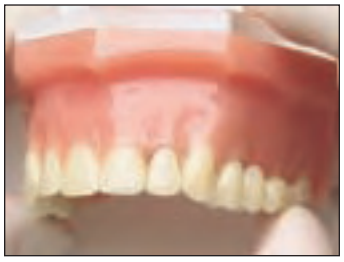
Screw Access Hole Plugged with Wax

Step 5: Try in the crown to confirm proximal contacts and occlusion. The floss should "snap" through the proximal contacts. Keep the crown slightly out of occlusion.

Try in the Crown

Step 6: Place a small amount of temporary cement into the crown. Then seat the crown. Be sure to remove any excess cement.

Step 7: Suture the tissue around the temporary crown. If needed, instruct the patient to return to the restorative doctor for adjustments to the crown.



Crown Seated

notes

notes

notes

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CE 0086 Caution, consult accompanying documents

The products described herein are covered by one or more of the following patents:
US 5,996,779, US 6,142,296, US 7,249,949, and applicable international patents.
Additional patents are pending.

 MK40040 Rev. C 02/2018