Keystone DENTAL

STAGE-1® Implant System

Surgical Manual

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Symbols Key

= Caution = Note = Tip

Introduction

The STAGE-1 Surgical Manual is designed to aid clinicians in surgical procedures using Keystone Dental's STAGE-1 Single Stage Implant System. The Keystone Dental STAGE-1 Single Stage Implant System is designed to simplify the implant procedure for both the patient and the clinician. Surgically, it eliminates the second stage surgery resulting in reduced trauma to the patient and reduced chairtime for the patient and the surgeon. Restoratively, the STAGE-1 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.

Morse Taper Prosthetic Connection

- Mechanically locking friction fit between the implant and abutment virtually eliminates loosening.
- Superior strength and prosthetic stability.
- Automatically centers abutments in the implant during seating.

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

Indications

The Keystone Dental STAGE-1 Single Stage Implant System is intended for use in partially or fully edentulous maxillae and mandibles, 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:

- Insufficient alveolar bone width and height to surround the implant with at least 1mm of bone.
- 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 and depth gauges is 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 *STAGE-1 Surgical Manual and the STAGE-1 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 is 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 patients 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 STAGE-1 Single Stage 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 ensure all instrumentation, surgical handpieces, and equipment have been sterilized to prevent the possible contamination of the components, the surgical system, and thus the patient. Always remove instrumentation from its packaging prior to sterilization.

Always run a system check to ensure that the surgical motor and its components are functioning properly. Backup equipment, implants and instrumentation are recommended in case of contamination or failure of equipment or instrumentation. Surgical drills eventually become dull with use and require replacement.

CLEANING PROCEDURE FOR SURGICAL TRAYS AND INSTRUMENTATION

1. Disassemble the surgical kit and wash the tray using a detergent solution. Rinse the tray with water and dry thoroughly.
2. Place the instruments in a beaker of detergent solution and sonicate for approximately 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.

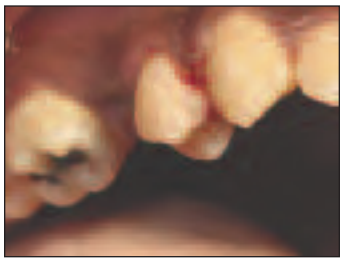
The surgical guide is often vital in determining the access point for an abutment screw through the surface of a crown or bridge. This is particularly important when the removal of anterior restorations are indicated.

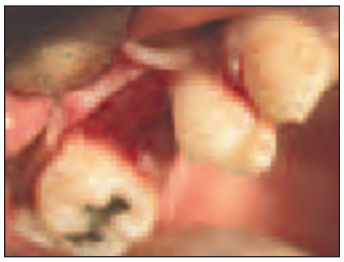
Implant Sizing Overlays

Transparent Implant Sizing Overlays (100% and 125% magnification) are included in the STAGE-1 Surgical Kit. Overlays are used with radiographs to assist in the presurgical assessment and implant selection.

Incisions

Due to the extension of the STAGE-1 Single Stage Implant System Cover Screw through the tissue, a standard "flap" type of reflection is contraindicated. Instead, use a surgical blade to place the incision directly over the center of the implant site. 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


Implant Site Exposed

Preparation of the Osteotomy

The Round Marking Bur included in the surgical kit can be used to smooth and/or flatten the crestal bone at the intended implant site to create a more even plane in which to place the implant. External irrigation should be used on all bone modifications and preparations. Please refer to the Drill Sequence Charts for the specific depth markings and diameters.


Round Marking Bur

Depth Marking System

KEYSTONE DENTAL STAGE-1 SINGLE STAGE DEPTH MARKING SYSTEM FOR DRILLS & TAPS

FOR 2.8mm DIAMETER DRILLS: Drill tip adds an additional 0.20mm to the actual total depth of the osteotomy.

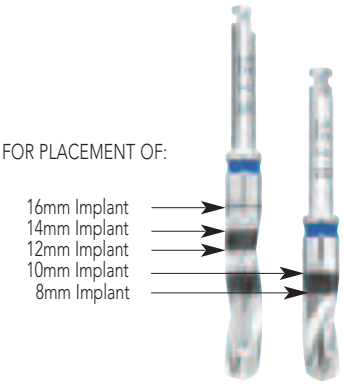
Drill bands reference the insertion depth of the corresponding implant and do not indicate actual millimeter drill length.

FOR 3.5mm DIAMETER DRILLS: Drill tip adds an additional 0.25mm to the actual total depth of the osteotomy.

FOR 4.2mm DIAMETER DRILLS: Drill tip adds an additional 0.33mm to the actual total depth of the osteotomy.

FOR 4.8mm DIAMETER DRILLS: Drill tip adds an additional 0.33mm to the actual total depth of the osteotomy.

FOR 5.5mm DIAMETER DRILLS: Drill tip adds an additional 0.33mm to the actual total depth of the osteotomy.

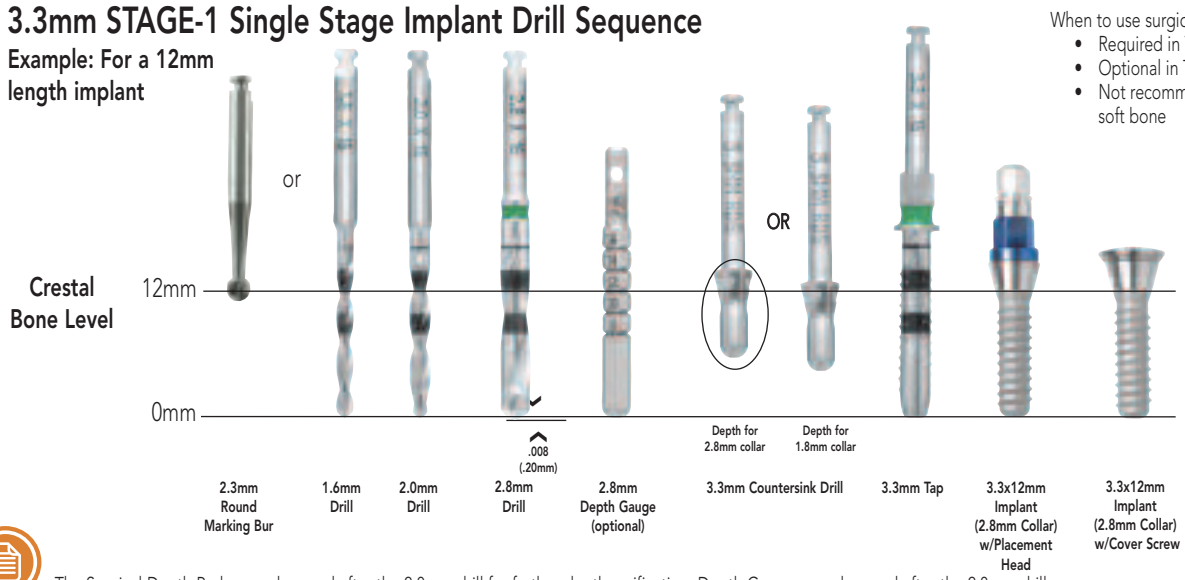


Example: When a 2.8mm diameter drill is used to prepare an osteotomy to the drill's 10mm band, the actual total depth is 10.20mm (including the drill tip).

3.3mm STAGE-1 Single Stage Implant Drill Sequence

Example: For a 12mm length implant

When to use surgical taps:
- Required in Type I dense bone
- Optional in Type II and III bone
- Not recommended in Type IV soft bone

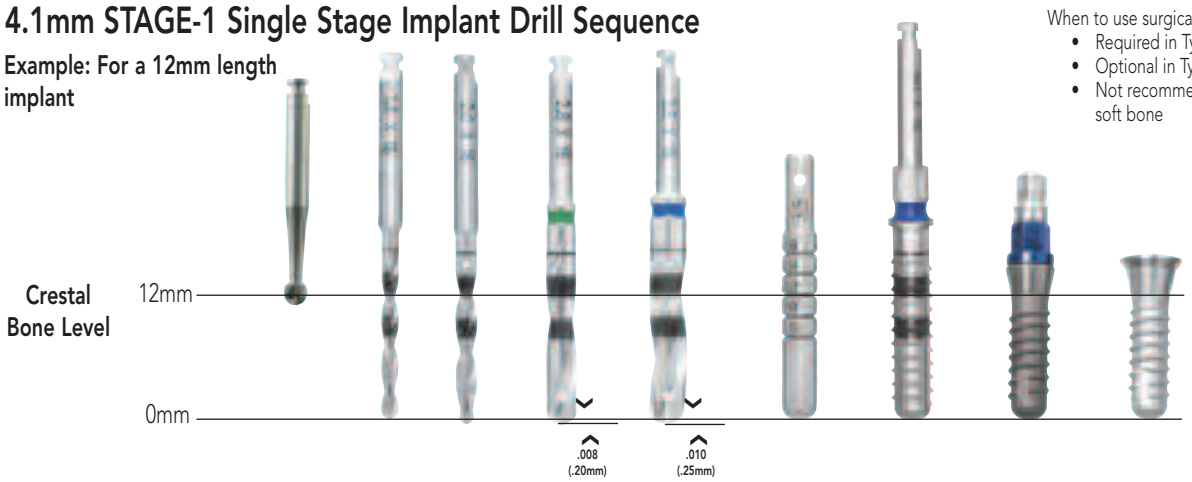


The Surgical Depth Probe may be used after the 2.0mm drill for further depth verification. Depth Gauges may be used after the 2.8mm drill.

4.1mm STAGE-1 Single Stage Implant Drill Sequence

Example: For a 12mm length implant

When to use surgical taps:
- Required in Type I dense bone
- Optional in Type II and III bone
- Not recommended in Type IV soft bone

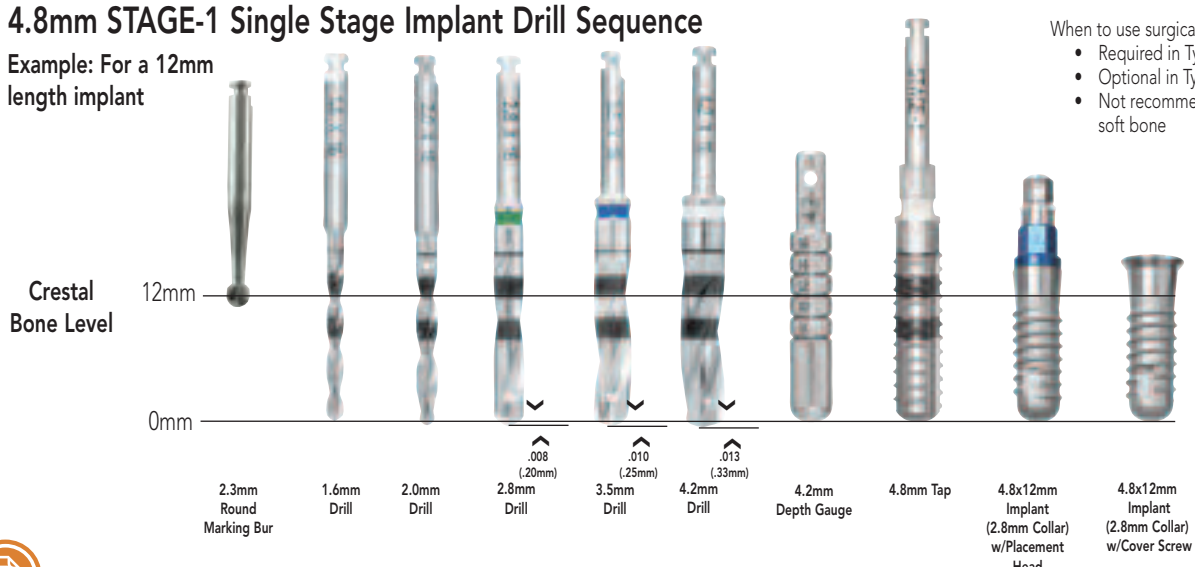


The Surgical Depth Probe may be used after the 2.0mm drill for further depth verification. Depth Gauges may be used after the 2.8mm drill.

4.8mm STAGE-1 Single Stage Implant Drill Sequence

Example: For a 12mm length implant

When to use surgical taps:
- Required in Type I dense bone
- Optional in Type II and III bone
- Not recommended in Type IV soft bone



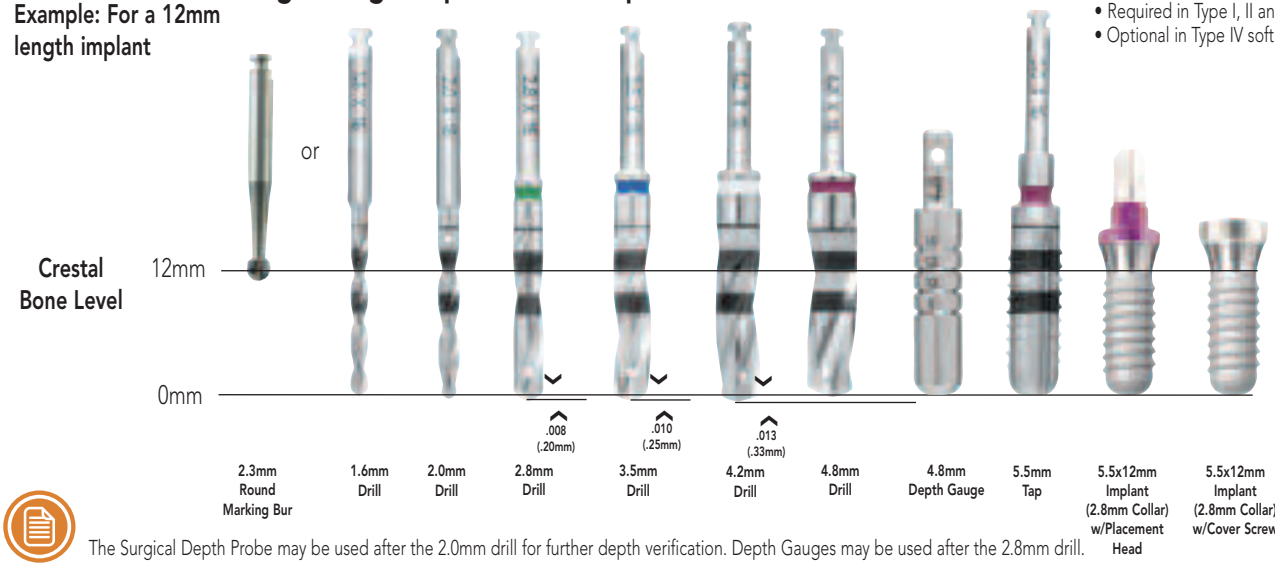
The Surgical Depth Probe may be used after the 2.0mm drill for further depth verification. Depth Gauges may be used after the 2.8mm drill.

drill sequence charts

5.5mm STAGE-1 Single Stage Implant Drill Sequence

Example: For a 12mm length implant

When to use surgical taps:
- Required in Type I, II and III bone
- Optional in Type IV soft bone

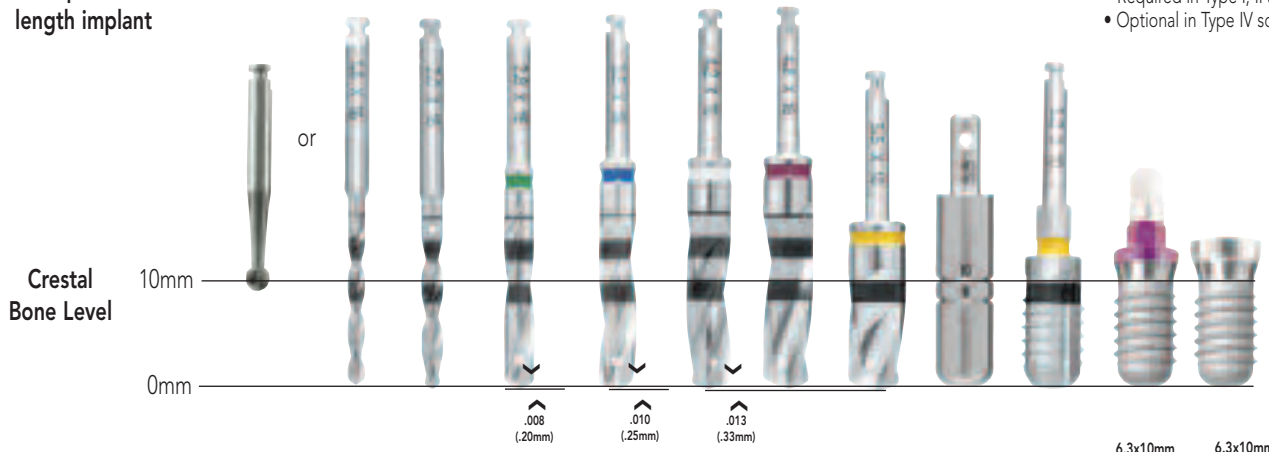


The Surgical Depth Probe may be used after the 2.0mm drill for further depth verification. Depth Gauges may be used after the 2.8mm drill.

6.3mm STAGE-1 Single Stage Implant Drill Sequence

Example: For a 10mm length implant

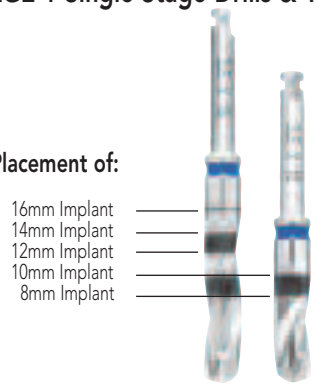
When to use surgical taps:
- Required in Type I, II and III bone
- Optional in Type IV soft bone



The Surgical Depth Probe may be used after the 2.0mm drill for further depth verification. Depth Gauges may be used after the 2.8mm drill.

Depth Marking System

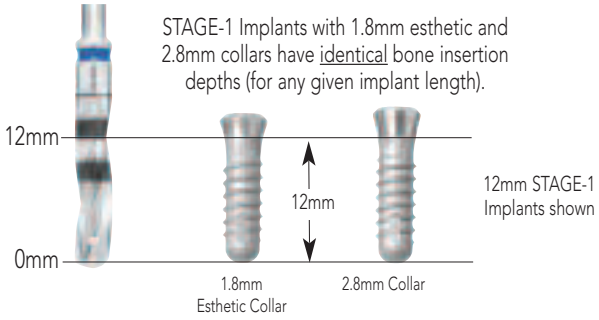
for STAGE-1 Single Stage Drills & Taps



Drill bands reference the insertion depth of the corresponding implant and do not indicate actual millimeter drill length. Refer to the Drill Sequence Chart for increased length of the drill tips.

Implant Measurement Guide

STAGE-1 Implants with 1.8mm esthetic and 2.8mm collars have identical bone insertion depths (for any given implant length).



- Stated implant length refers to the implant's actual insertion depth. For example, when placing a 12mm implant (regardless of whether it is a 1.8mm esthetic or 2.8mm collar) the site should be drilled to the corresponding 12mm drill band.

Preliminary Steps for Placing 3.3mm - 6.3mm Implants

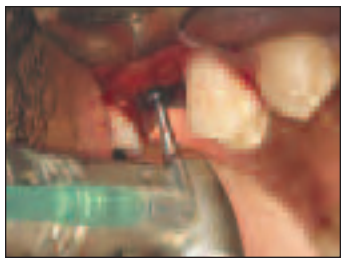
DRILL AND TAP SPEEDS

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.

2.3mm ROUND MARKING BUR

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

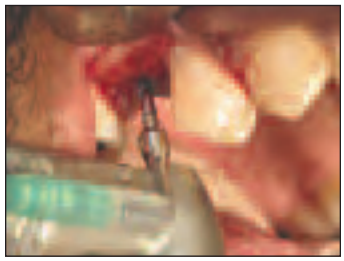


1.6mm TWIST DRILL
(Option for hard cortical bone)

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 graphic on the top of the Surgical Tray or the chart on page 9 for the specific markings.
The proper depth will align with either the top or bottom of the etched band.

1.6mm x 10mm

1.6mm x 16mm



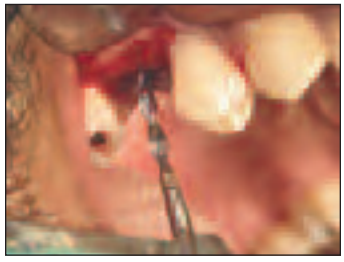
To verify position and trajectory of the implant site relative to adjacent anatomy, a radiograph may be taken with one drill in place.

2.0mm TWIST DRILL

Use the 2.0mm Twist Drill (internal irrigation) to penetrate the bone to the appropriate depth marks on the drill. Refer to the depth marking graphic on the top of the Surgical Tray or the chart on page 9 for the specific markings.

2.0mm x 10mm

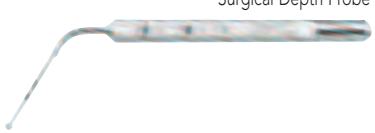
2.0mm x 16mm

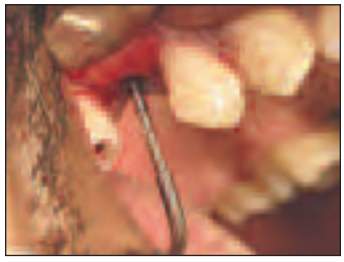


SURGICAL DEPTH PROBE (Optional)

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

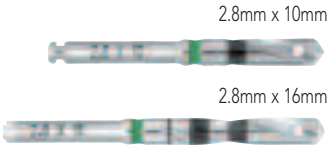


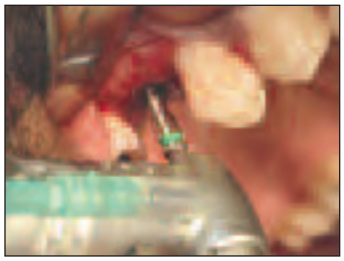


drilling and tapping procedures

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

The 2.8mm Twist Drill is then utilized to drill to the proper depth marking on the drill and expand the diameter of the site preparation. Refer to the depth marking graphic on the top of the Surgical Tray or the chart on page 9 for the specific markings. Use copious amounts of irrigation.

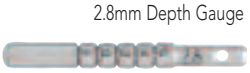


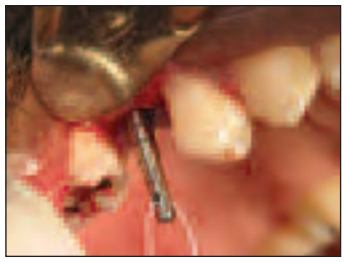


When placing 3.3mm diameter implants, the 2.8mm Twist Drill is the final drill followed by the 3.3mm Countersink Drill and 3.3mm Tap if needed.

2.8mm DEPTH GAUGE (Optional)

Use the 2.8mm Depth Gauge to verify the correct angulation and depth preparation of the implant site. If necessary, the 2.8mm Depth Gauge may be left in the preparation site for x-ray verification. Adjustments to the trajectory and depth can be made to the preparation site during the remaining drilling sequence.

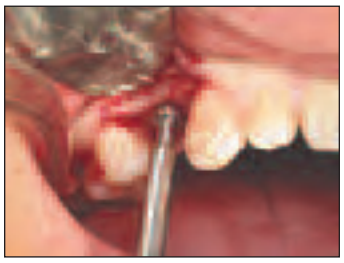




Depth Gauges feature a hole through which floss or suture can be threaded for added security during handling.

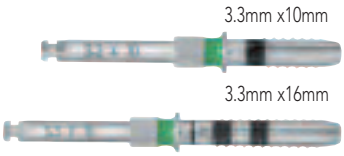
3.3mm COUNTERSINK DRILL (Only for 3.3mm Implants)

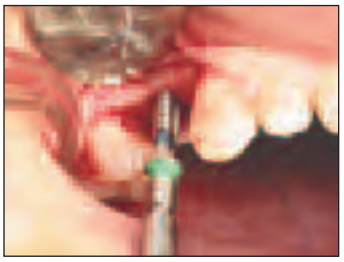
Use the 3.3mm Countersink Drill to the corresponding 1.8/2.8mm collar markings. Please see the Drill Sequence Chart on page 8 for more information on depth markings.



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.





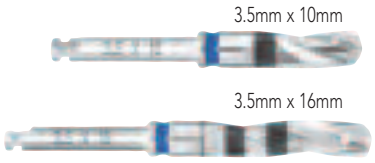
Place the Tap into the drilled implant site. Apply firm pressure and begin rotating the Tap utilizing a slow speed/high-torque handpiece (25-50 rpm maximum). When the threads begin to engage the bone, allow the Tap to feed into the site without applying additional pressure. The osteotomy should be tapped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

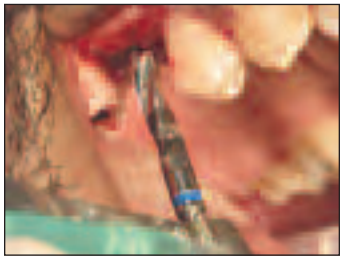
To place a 3.3mm implant, go to pages 15-17.

THESE ADDITIONAL STEPS ARE REQUIRED TO PLACE 4.1mm IMPLANTS

3.5mm TWIST DRILL (Final Drill for 4.1mm Implants)

Apply the 3.5mm Twist Drill to the depth consistent with the implant to be placed by using the etched bands on the drill. If additional depth or angulation changes are needed, they need to be done at this time. Refer to the depth marking graphic on the top of the Surgical Tray or the chart on page 9 for the specific markings. Use copious amounts of irrigation.





3.5mm DEPTH GAUGE (Optional)

Use the 3.5mm Depth Gauge to verify the correct angulation and depth preparation of the implant site. If necessary, the 3.5mm Depth Gauge may be left in the preparation site for x-ray verification.

3.5mm Depth Gauge

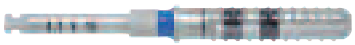
Depth Gauges feature a hole through which floss or suture can be threaded for added security during handling.

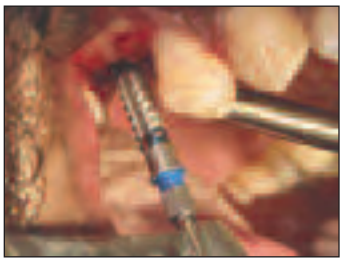
4.1mm TAP

Use of the 4.1mm 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.

4.1mm x 10mm

4.1mm x 16mm





To place a 4.1mm implant, go to pages 15-17.

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.

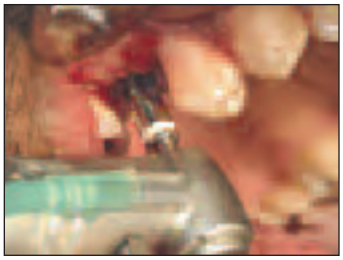
THESE ADDITIONAL STEPS ARE REQUIRED TO PLACE 4.8mm IMPLANTS.

4.2mm TWIST DRILL (Final Drill for 4.8mm Implants)

The 4.2mm Twist Drill is used to complete the drilling sequence for the 4.8mm Implants. Drill to the proper depth marking on the drill. Refer to the depth marking graphic on the top of the Surgical Tray or the chart on page 9 for the specific markings. Use copious amounts of irrigation.

4.2mm x 10mm

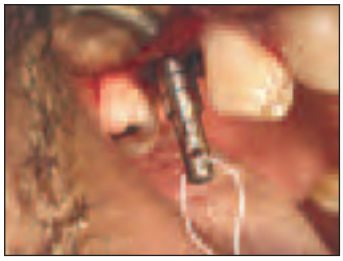
4.2mm x 16mm



4.2mm DEPTH GAUGE (Optional)

Use the 4.2mm Depth Gauge to verify the correct angulation and depth preparation of the implant site. If necessary, the 4.2mm Depth Gauge may be left in the preparation site for x-ray verification.

4.2mm Depth Gauge



Depth Gauges feature a hole through which floss or suture can be threaded for added security during handling.

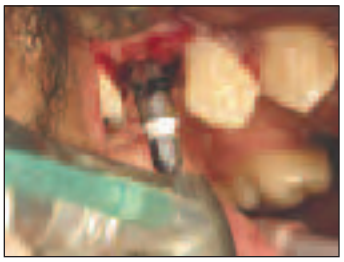
drilling and tapping procedures

4.8mm TAP

Use of the 4.8mm 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.

4.8mm x 10mm

4.8mm x 16mm



To place a 4.8mm implant, go to pages 15-17.

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.

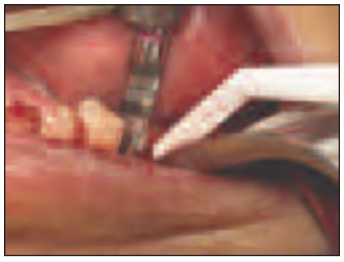
THESE ADDITIONAL STEPS ARE REQUIRED TO PLACE 5.5mm IMPLANTS

4.8mm TWIST DRILL (Final Drill for 5.5mm Implants)

The 4.8mm Twist Drill is used to complete the drilling sequence for the 5.5mm Implants. Drill to the proper depth marking on the drill. Refer to the depth marking graphic on the top of the Surgical Tray or the chart on page 9 for the specific markings. Use copious amounts of irrigation.

4.8mm x 10mm

4.8mm x 16mm



4.8mm DEPTH GAUGE (Optional)

Use the 4.8mm Depth Gauge to verify the correct angulation and depth preparation of the implant site. If necessary, the 4.8mm Depth Gauge may be left in the prepared site for x-ray verification.

4.8mm Depth Gauge

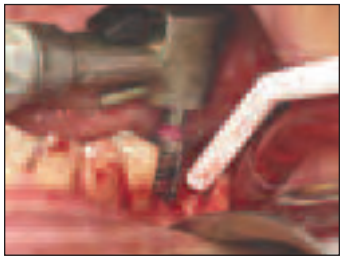
Depth Gauges feature a hole through which floss or suture can be threaded for added security during handling.

5.5mm TAP

Use of the 5.5mm 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.

5.5mm x 10mm

5.5mm x 16mm



To place a 5.5mm implant, go to pages 15-17.

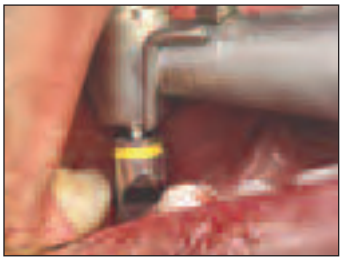
Place the Tap into the drilled implant site. Apply firm pressure and begin rotating the Tap utilizing a slow speed/high-torque handpiece (25-50 rpm maximum). When the threads begin to engage the bone, allow the Tap to feed into the site without applying additional pressure. The osteotomy **must** be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

THESE ADDITIONAL STEPS ARE REQUIRED TO PLACE 6.3mm IMPLANTS.

5.5mm TWIST DRILL (Final Drill for 6.3mm Implants)

The 5.5mm Twist Drill is used to complete the drilling sequence for the 6.3mm Implants. Drill to the proper depth marking on the drill. Refer to the depth marking graphic on the top of the Surgical Tray or the chart on page 9 for the specific markings. Use copious amounts of irrigation.

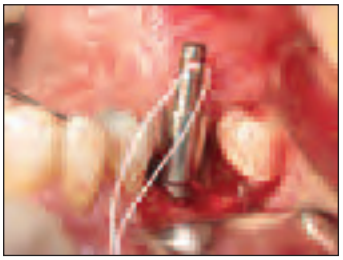
5.5mm x 10mm



5.5mm DEPTH GAUGE (Optional)

Use the 5.5mm Depth Gauge to verify the correct angulation and depth preparation of the implant site. If necessary, the 5.5mm Depth Gauge may be left in the prepared site for x-ray verification.

5.5mm Depth Gauge

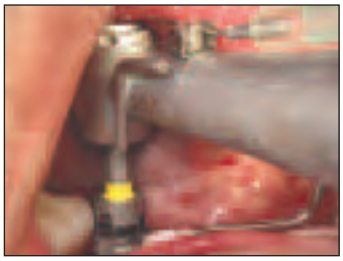


Depth Gauges feature a hole through which floss or suture can be threaded for added security during handling.

6.3mm TAP

Use of the 6.3mm 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.

6.3mm x 10mm



To place a 6.3mm implant, go to pages 15-17.

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 **must** 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.


Peeling Back the Tyvek Lid

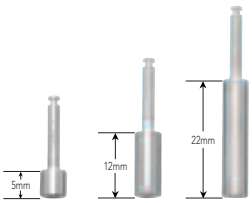

Implant Vial Exposed


Implant Vial Open

OPTION 1:

Motorized Implant Placement (Handpiece)

Latch-type Handpiece Adapters are offered in three lengths for clinical versatility. Select the appropriate length Handpiece Adapter and insert it into the handpiece.



STAGE-1 Handpiece Adapters

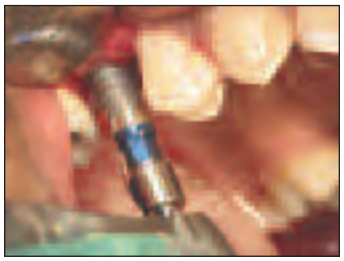
Connect the Handpiece Adapter onto the Placement Head and deliver the implant assembly to the site.


Connecting Handpiece Adapter onto Placement Head


Carrying the Implant

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.

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 may allow 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. Using the Handpiece Adapter in reverse direction, loosen the placement head screw from the implant. Remove the Placement Head assembly from the implant.

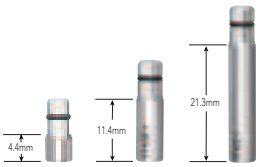

Stabilizing Wrench and Handpiece


Placement Head Removed

OPTION 2:

Manual Implant Placement (Surgical Ratchet)

Ratchet Adapters are offered in three lengths for clinical versatility. 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.



STAGE-1 Ratchet Adapters

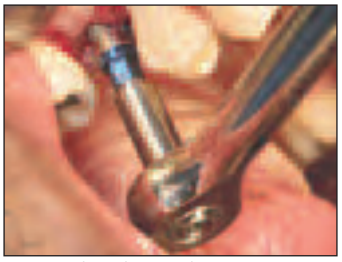
Surgical Ratchet

Connect the Ratchet 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.

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.

STAGE-1 Stabilizing Wrench

Removing Implant from the Vial



Threading Implant Using the Surgical Ratchet

Stabilizing Wrench for Counter-Torque

PLACEMENT HEAD REMOVAL

After placement, remove the Ratchet Adapter from the Surgical Ratchet and insert it into the opposite side of the Surgical Ratchet so that the directional arrow points in the counter clockwise direction.

Place either the open or closed end of the Stabilizing Wrench over the Placement Head base to provide counter-torque, while using the Ratchet to loosen the screw. Remove the Placement Head assembly from the implant.

Turn Counter Clockwise to Remove Placement Head Screw

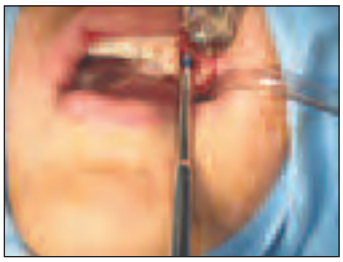
OPTION 3:

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

STAGE-1 Surgical Hand Driver



Threading Implant Using the Surgical Hand Driver

STAGE-1 Stabilizing Wrench

PLACEMENT HEAD REMOVAL

After placement, place either the closed or open end of the Stabilizing Wrench over the Placement Head base to provide counter-torque while loosening the screw. Then attach the Surgical Hand Driver and turn counter clockwise to loosen and remove the Placement Head.

Implant Depth Adjustment/Removal
(At the Time of Surgery)

OPTION 1:

If at the time of surgery, if it becomes necessary to partially or fully unthread an implant from the site, the following procedure can be used.

1. Insert the STAGE-1 Placement Head Assembly into the Ratchet Adapter and use finger pressure to thread the screw into the implant, until snug.

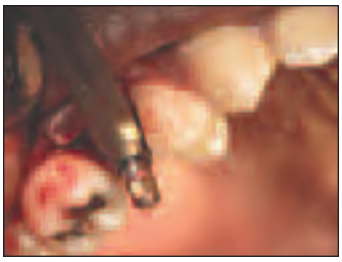
2. Insert the Ratchet Adapter into the Surgical Ratchet for operation in the clockwise (tightening) direction.

3. Place either the closed or open end of the Stabilizing Wrench over the Placement Head base. If the open end is used, be sure that it is fully engaged onto the Placement Head.

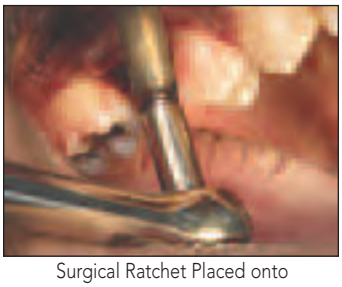
4. Place the Surgical Ratchet with Ratchet Adapter onto the Placement Head Screw. While securely holding the Stabilizing Wrench on the Placement Head base to provide counter-torque, use the Surgical Ratchet to tighten the Placement Head Screw. DO NOT EXCEED MORE THAN 1/4 TURN (90 degrees). Be very careful to not over tighten the screw.

5. When the Placement Head Screw is tightened, remove the Stabilizing Wrench and Surgical Ratchet with the Ratchet Adapter from the Placement Head.

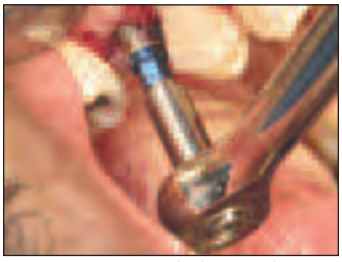
6. Remove the Ratchet Adapter from the Surgical Ratchet and insert it into the opposite side of the Ratchet so the directional arrow points in the counter clockwise direction. Place the Surgical Ratchet with Ratchet Adapter onto the Placement Head Screw and slowly unthread the implant from the site to the desired position.



Stabilizing Wrench Placed on Base of Placement Head



Surgical Ratchet Placed onto Placement Head Screw



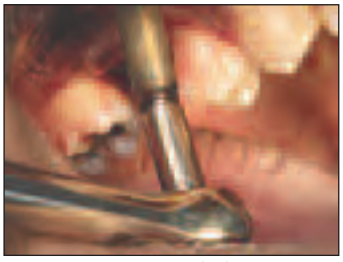
Turn Counter Clockwise with Surgical Ratchet and Ratchet Adapter

OPTION 2:

1. Attach a new Placement Head as directed above. Remember not to exceed 1/4 turn when tightening the Placement Head Screw.

2. Engage the colored portion of the Placement Head with the closed end of the Stabilizing Wrench.

3. Use the Stabilizing Wrench to unscrew the implant in a counter clockwise direction. **At the same time**, apply light tightening pressure (clockwise) to the silver Placement Head Screw using the Ratchet Adapter or Conversion Handle. (Apply pressure only. Do not physically turn the screw clockwise.) This clockwise pressure prevents the Placement Head Screw from loosening when the implant is being removed.

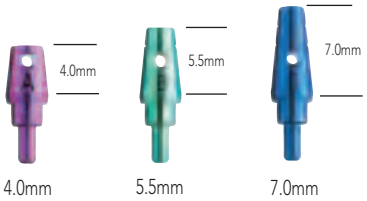


Turn Counter Clockwise with Stabilizing Wrench

To remove the Placement Head from the implant, follow the Placement Head Removal procedure outlined on page 16.

COC Abutment Try-in (Optional)

If a cementable restoration is desired, the following procedure will save the clinician valuable chairtime. This is accomplished by using the COC Abutment Try-ins at the time of surgery.



RDS COC Abutment Try-ins

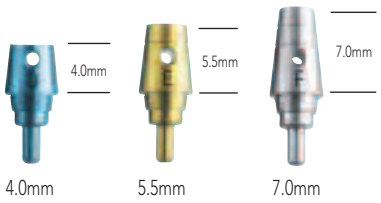
Selection and Placement of the Appropriate Height COC Abutment Try-in:

1. Place the appropriate Try-in. Seat the pin fully into the implant and twist slightly. The Try-in pin can then engage the implant. Gently close the patient's jaw.

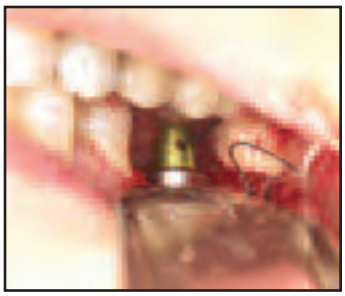
2. Check the interocclusal space. There should be approximately 2mm of occlusal clearance for the metal and porcelain.

3. Check the buccal/lingual position and verify clearance in lateral/protrusive movements.

4. Once the appropriate Try-in size has been selected, this can be color-matched to the required COC Abutment components.



WDS COC Abutment Try-ins

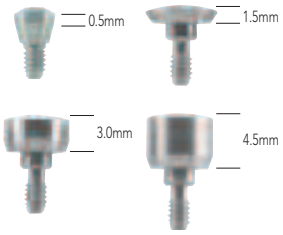

COC Abutment Try-in Placed Too Tall


COC Abutment Try-in Placed Correct Height

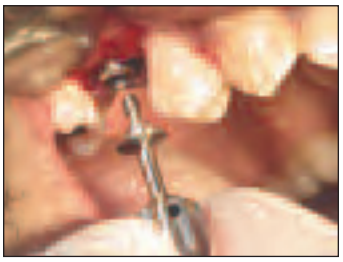
Try-in pins feature a hole through which floss can be threaded for added security during handling.

Cover Screw Placement

Use the .048" 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.



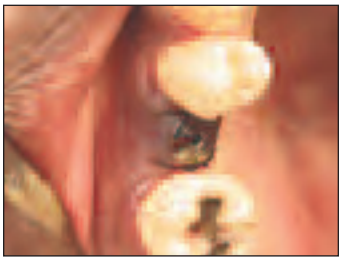
RDS Cover Screws Require .048" Hex Driver


Placing the Cover Screw

RDS STAGE-1 Implants include the 1.5mm Cover Screw. WDS Implants include the 3.0mm Cover Screw. Additional sizes may be ordered separately.

Closure and Suturing

Remove the retaining sutures on the reflected tissue flaps, if applicable. Close the tissue and suture around the extending implant cuff and Cover Screw using traditional suturing methods. Do not attempt to obtain primary closure or cover the implant and Cover Screw. The implant and Cover Screw should extend through the tissue as shown.


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.

notes

notes

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CE 0086 Rx 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.

 MK40042 Rev. C 02/2018