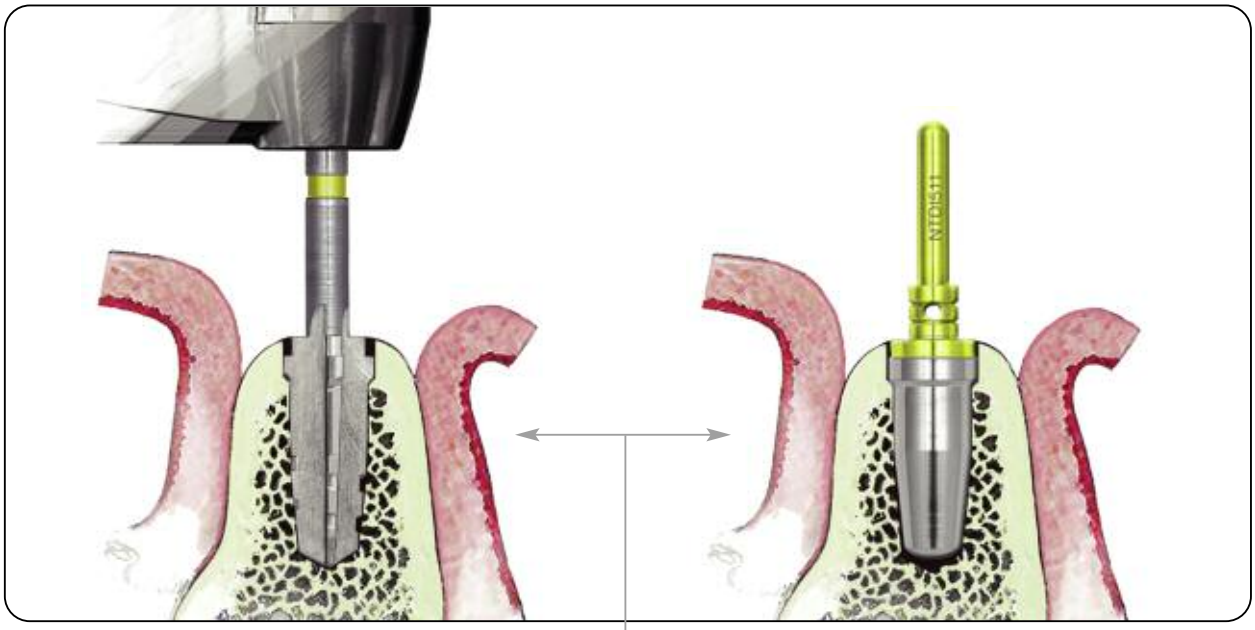


Tapered Implant Surgical Manual

Implant Placement With Tapered Implants Using Quad Shaping Drills And Tapered Implant Depth/Direction Indicators

How To Use The Icon Key:

The icons represent the connection types of the BIOMET ***3i*** Implant System and both internal and external connection types are represented in this manual. In the fully illustrated protocols, each icon is present by each step. When a dark burgundy icon and a light burgundy icon are present together, the dark burgundy indicates which system is illustrated. When both icons are dark burgundy, then both systems are illustrated together.

Icon Key:

Certain® Internal Connection Implant System:

External Connection Implant System:

Certain Internal Connection and External Connection Implant System:

Instructions For Use:

OSSEOTITE®, OSSEOTITE XP®, Certain®, PREVAIL®, OSSEOTITE NT®, Encode®, IOL®, Miniplant®, Microminiplant™, GingiHue®, Gold-Tite®, Provide®, STA®, ZiReal®, CAM StructSURE®, NanoTite™, PreFormance®, QuickBridge™

This document applies to dental implants, abutments, overdenture bars and associated surgical, restorative and dental laboratory components.

For detailed information on the specific procedure for the product you are using, please refer to the individual product labels and/or the appropriate manual:

Product Catalog - **CATALOG:** Listing of all products
Surgical Manual - **CATSM:** Dental implant placement, surgical protocol and cover screw insertion
Restorative Manual - **CATRM:** Abutment placement, provisional and final restoration protocols
Additional Restorative Manuals:
CAM StructSURE Manual - **ART868**
DIEM™ Guidelines - **ART860**
Encode Restorative Manual - **ART924**
QuickBridge Manual - **ART1016**

Description: BIOMET ***3i*** Dental Implants are manufactured from biocompatible titanium and titanium alloy and abutments from titanium, titanium alloy, gold alloy and ceramic material. BIOMET ***3i*** Dental Implants and Abutments include various surface treatments and coatings. Other restorative components are manufactured with titanium, titanium alloy, gold alloy, stainless steel and a variety of polymers.

For specific product description and net quantity refer to individual product labels.

Indications for Use: BIOMET ***3i*** Dental Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework and to retain overdentures.

BIOMET ***3i*** OSSEOTITE and NanoTite Dental Implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.

Additional Indications: BIOMET ***3i*** Dental Abutments and Overdenture Bars are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or edentulous patient. These are intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prostheses can be screw or cement-retained to the abutment.

PEEK Abutment Posts and Temporary Cylinders are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or fully edentulous patient. These are intended for use to support single and multiple unit prostheses in the mandible or maxilla for up to 180 days during endosseous and gingival healing and are for non-occlusal loading of single and multiple unit provisional restorations. The prostheses can be screw and/or cement-retained to the abutment. These Temporary Posts and Cylinders require a minimum interarch space of 6mm and a maximum angulation of 15°. These also allow for occlusal loading of single and multiple unit restorations of integrated implants for guided soft tissue healing.

The QuickBridge Provisional Components are intended to be mated with BIOMET ***3i*** Conical Abutments for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or fully edentulous patient. The QuickBridge Provisional Components are intended to support multiple unit prostheses in the mandible or maxilla for up to 180 days during endosseous and gingival healing.

Contraindications: Placement of dental implants may be precluded by patient conditions that are contraindications for surgery. BIOMET ***3i*** Dental Implants should not be placed in patients where the remaining jaw bone is too diminished to provide adequate implant stability.

Storage and Handling: Devices should be stored at room temperature. Refer to individual product labels and the Surgical Manual for special storage or handling conditions.

Warnings: Excessive bone loss or breakage of a dental implant or restorative device may occur when an implant or abutment is loaded beyond its functional capability. Physiological and anatomic conditions may negatively affect the performance of dental implants.

The following should be taken into consideration when placing dental implants:
- Poor bone quality
- Poor oral hygiene
- Medical conditions such as blood disorders or uncontrolled hormonal conditions

It is recommended that small diameter implants not be restored with angled abutments in the molar region.

Mishandling of small components inside the patients mouth carries a risk of aspiration and/or swallowing.

Forcing the implant into the osteotomy deeper than the depth established by the drills can result in: stripping the driver hex interface inside the implant, stripping the driver, cold-welding of the mount-driver interface to the implant or stripping the walls of the osteotomy that may prevent an effective initial implant fixation.

Clinical data have demonstrated enhanced performance of OSSEOTITE Implants as compared to other BIOMET *3i* Dental Implants in patients with poor quality bone.

Precautions: For safe and effective use of BIOMET ***3i*** Dental Implants, abutments and other surgical and restorative dental accessories, these products or devices should only be used by trained professionals. The surgical and restorative techniques required to properly utilize these devices are highly specialized and complex procedures. Improper technique can lead to implant failure, loss of supporting bone, restoration fracture, screw loosening and aspiration.

Sterility: All dental implants and some abutments are supplied sterile and are sterilized by an appropriate validated method. Refer to individual product labels for sterilization information; all sterile products are labeled **'STERILE.'** All products sold sterile are for single use before the expiration date printed on the product label. Do not use sterile products if the packaging has been damaged or previously opened. Do not re-sterilize or autoclave except where instructions to do so are provided on the product label, in the Surgical Manual, in the Restorative Manual or in any additional marketing literature for that product. Products provided non-sterile must be cleaned and sterilized according to the directions found in **ART630** or the Surgical Manual prior to use.

Procedural Precautions, Surgery: *For a detailed explanation of the procedural precautions refer to the Surgical Manual.* During the planning phase, it is important to determine the vertical dimension, the actual space available between the alveolar crest and the opposing dentition, in order to confirm that the available space will accommodate the proposed abutment and the final crown restoration. This information varies with each patient and abutment; therefore it should be carefully evaluated before placing any dental implant. The final prosthesis should be designed prior to the placement of the dental implant. Utilize continuous irrigation with a cool, sterile irrigating solution to avoid excessive damage to the surrounding tissue and to prevent compromising osseointegration. This is mandatory during all procedures. Avoid excessive pressure during preparation of the bone site. As the drilling speed varies based on the instrument and the surgical procedure, recommendations for speed can be found in the Surgical Manual. Only sharp instruments of the highest quality should be used for any surgical procedure involving bone. Minimizing trauma to the bone and surrounding tissue enhances the potential for successful osseointegration. In order to eliminate contaminants and other sources of infection, all non-sterile devices should be cleaned and/or sterilized prior to use, per the instructions on the individual product labels.

Procedural Precautions, Restoration: The healing period varies depending on the quality of the bone at the implantation site, the tissue response to the implanted device and the surgeon's evaluation of the patient's bone density at the time of the surgical procedure. Excessive force applied to the dental implant should be avoided during the healing period. Proper occlusion should be evaluated on the implant restoration to avoid excessive force.

Potential Adverse Events: Potential adverse events associated with the use of dental implants may include:

- Failure to integrate
- Loss of integration
- Dehiscence requiring bone grafting
- Perforation of the maxillary sinus, inferior border, lingual plate, labial plate, inferior alveolar canal, gingiva
- Infection as reported by: abscess, fistula, suppuration, inflammation, radiolucency
- Persistent pain, numbness, paresthesia
- Hyperplasia
- Excessive bone loss requiring intervention
- Implant breakage or fracture
- Systemic infection
- Nerve injury

Caution: U.S. Federal Law restricts this device to sale by or on the order of a licensed dentist or physician.

Table Of Contents

Introduction And Treatment Planning 1
Preoperative Planning 2
Surgical Precautions 3
Cleaning And Sterilization 4
Quad Shaping Drill (QSD) 5
The BIOMET *3i* Tapered Implant System: Why Tapered Implants Are Different 6
Tapered Implant Surgical Tray (QNTSK) 7
Tapered Implant Bone Taps And Bone Tap Kit (NTAPK) 8
Tapered Implant Depth/Direction Indicator (NTDI) 9

Subcrestal Implant Placement Protocol

Certain® And External Connection Tapered 3.25mm, 4mm, 5mm and 6mm Diameter Implants Using QSD/NTDI 10
Certan And External Connection Tapered Implant Placement 15

Soft Bone (Type IV) Subcrestal Implant Placement Protocol

Certain And External Connection Tapered 4mm, 5mm and 6mm Diameter Implants 18
Bone Profiling: BIOMET *3i* Implants 19

Introduction And Treatment Planning

These instructions were designed to serve as a reference guide for the dental practitioner to utilize BIOMET 3i Implants and surgical instruments to their maximum potential. BIOMET 3i's Implant System was developed to meet the diverse needs of the patient and to offer the practitioner a choice of surgical techniques customized to meet each patient's individual requirements.

BIOMET ***3i***'s Unique Designs enable the practitioner to place implants in edentulous or partially edentulous mandibles or maxillae in order to serve as support for fixed and removable bridgework or single tooth crowns and to provide the stabilization needed for securing overdentures. BIOMET ***3i***'s System uses proven surgical procedures to properly secure the implant in the osseous tissue, thus achieving the physiological phenomenon referred to as osseointegration.

With NanoTite™ Implants, the combined microtopography of the OSSEOTITE® Implant with the nanometer-scale architecture created with the NanoTite Surface treatment renders the surface Bone Bonding™ by the interlocking of the newly formed cement line matrix of bone with the implant surface.

General Information:

These instructions will instruct practitioners in the use of BIOMET ***3i***'s Implant Systems. The success of any dental implant system depends upon proper use of the components and instrumentation. This manual is not intended for use as a substitute for professional training and experience.

Treatment Planning:

Patient Evaluation And Selection

Several important factors must be considered when evaluating a patient prior to implant surgery. The presurgical evaluation must include a cautious and detailed assessment of the patient's general health, current medical status, medical history, oral hygiene, motivation and expectations. Factors such as heavy tobacco use, chewing patterns and alcohol consumption should also be considered. In addition, the clinician should determine if the case presents an acceptable anatomical basis conducive to implant placement. An extensive intraoral examination should be undertaken to evaluate the oral cavity for any potential bone or soft-tissue pathology. The examiner should also determine the periodontal status of the remaining teeth, the health of the soft tissue, or the presence of occlusal abnormalities such as bruxism or crossbite. The presence of other conditions that could adversely affect any existing natural dentition or healthy tissue surrounding the implant should also be evaluated.

Diseases of the mucous membrane and connective tissues, pathologic bone disease and severe malocclusion could affect the determination of whether the patient is a suitable implant candidate.

The use of anticoagulants and the existence of metabolic diseases, such as diabetes, allergies, chronic renal or cardiac disease and blood dyscrasia could significantly influence the patient's ability to successfully undergo implant procedures.

If the patient's medical history reveals an existing condition or signals a potential problem that may compromise treatment and/or the patient's well-being, consultation with a physician is recommended.

Preoperative Planning

Preoperative Planning:

Proper treatment planning, as well as the selection of the proper implant length and diameter, are crucial to the long-term success of the implant and restoration. Before an implant can be selected, the anatomical foundation available to receive the implant must be carefully assessed. Several steps should be taken to complete the evaluation:

1. Clinical examination of the oral cavity can provide important information about the health of the soft tissue at the proposed implant site. Tissue tone and the state of the superficial tissues should be evaluated. In addition, the patient should demonstrate an adequate dimension of attached mucosa or keratinized tissue at the site selected for implantation. In partially edentulous cases, the periodontal status of the remaining dentition should be assessed and interaction between the implant restoration and the adjacent natural dentition should be considered.

2. The bony foundation and ridge need to be clinically analyzed to ensure the presence of proper dimensions and the amount of bone for implant placement. At least one millimeter of bone should be present at the buccal and lingual aspects of the implant following placement. During the planning state, it is useful to measure the existing bone foundation.

CT Scans:

Computed tomography (CT) scans help surgeons view parts of the body with the help of three-dimensional images. Image-guided surgical planning allows surgeons to see anatomical landmarks like nerves, sinus cavities and bony structures in order to plan for the placement of dental implants and prostheses.

Through the use of CT scans, clinicians are able to more precisely measure the locations of anatomical structures, dimensions of the underlying bone and ascertain bone densities in order to plan and perform clinically demanding cases.

Radiographic Marking Balls (RMB30)

The vertical height of the bone can be determined radiographically. Accurate measurement of the vertical dimension on the radiograph facilitates the selection of the appropriate implant length. This helps to avoid implant placement into the maxillary sinus, the floor of the nose or the mandibular canal and prevents perforation of the inferior aspect of the mandible. Measurements can be made directly on the panoramic radiograph using a millimeter ruler. Corrections should be made for the degree of enlargement produced by the particular radiographic equipment.

Radiographic marking balls of a known dimension can be embedded in a plastic template prior to radiographic examination. Once the radiograph is taken and the metal marking balls are visible on the image, measurements can be taken to determine the amount of bone available for implant placement.

To calculate the distortion factor, a simple formula can be utilized: (5 ÷ A) x B = amount of actual bone available.

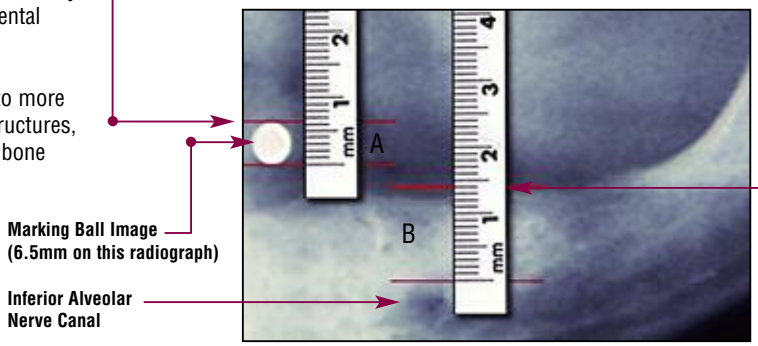
Formula Key =

- Radiographic marking ball = 5mm in diameter.
- A = Size of marking ball image on radiograph.
- B = Length in millimeters on the radiograph of available bone between the crest of the ridge and the inferior alveolar nerve canal.

Example:

A = 6.5mm
B = 14mm
Therefore: (5 ÷ 6.5) x 14 = 10.76mm actual bone available

NOTE: **A 2mm margin of safety, from the apical end of the implant to the adjacent vital structure, should be considered.**



Surgical Precautions

Clinical Considerations

True bone contours can only be evaluated after tissue flaps have been reflected at the time of surgery or via preoperative CT scans of sufficient quality. Even if bone dimensions are painstakingly measured prior to surgery, the doctor and patient must accept the possibility that inadequate bone anatomy might be discovered during surgery and preclude implant placement.

During the presurgical planning phase, it is important to determine the vertical dimension - the actual space available between the alveolar crest and the opposing dentition - to confirm that the available space will accommodate the proposed abutment and the final crown restoration. The height required by the abutment may vary with the type of abutment; therefore, the surgeon and restorative dentist should carefully evaluate the abutment size. The final prosthesis should be conceptually designed prior to the placement of the implant.

Study models should be used preoperatively to evaluate the residual ridge and to determine the position and angulation of all implants. These models allow the clinician to evaluate the opposing dentition and its effect on the implant position. A surgical guide stent, which is critical for determining the precise position and angulation of the implant, can be constructed on the study model.

Several software companies offer planning software that allows clinicians the ability to plan implant placement three dimensionally in conjunction with the CT scans. From plans created in these software packages, surgical guides can be made to aide in the preparation and placement of implants.

To prevent damage to the bone tissue and to prevent compromising osseointegration, abundant and continuous irrigation with a cool, sterile, irrigating solution is mandatory during all drilling procedures. The application of excessive pressure during preparation of the bone site must be avoided.

Bone surgery utilizes a high-torque electric drilling unit that can be operated in forward and reverse modes at speeds ranging from 0 to 1500rpm, depending on the surgical requirements. Sharp instruments of the highest quality should be utilized during implant site preparation to reduce possible overheating and trauma to the bone. Minimizing trauma enhances the potential for successful osseointegration.

The time elapsed between surgical placement of the implant and final abutment placement can vary or be modified, depending on the quality of the bone at the implantation site, bony response to the implant surface and other implanted materials and the surgeon's assessment of the patient's bone density at the time of the surgical procedure. Extreme care must be taken to avoid excessive force being applied to the implant during this time.

Cleaning And Sterilization

Single use drills/burs are supplied sterile and should be properly disposed of after each procedure. Reusable drills/burs and instrumentation are supplied nonsterile and must be sterilized prior to use. Nonsterile items must be removed from the packaging before sterilization.

Multiple sterilizations may affect the flow of fluid through internally irrigated drills. The drills should be checked following each sterilization cycle to determine if fluid flows through the irrigation ports. Although the surgical drills are constructed of stainless steel, these should be adequately dried prior to packaging for sterilization and again after the sterilization cycle.

The end of life for surgical instruments is normally determined by wear and damage. Surgical instruments and instrument cases are susceptible to damage for a variety of reasons including prolonged use, misuse, rough or improper handling. Care must be taken to avoid compromising the intended performance of the instrument.

Visually inspect each instrument before and after each use for damage and/or wear.

To extend the useful life of BIOMET ***3i***'s Instruments, certain procedures should always be followed:

Cleaning:

1. After use, place drills into a beaker of plain water, mild soap or specialized cleaning solution.
2. Rinse with tap water for a minimum of two minutes while brushing with a soft bristled brush to remove visible debris. Clean the interior lumen with a thin wire to remove any remaining debris.
3. Place instruments in an ultrasonic bath containing enzymatic detergent for five minutes.* Scrub the instruments again with a soft bristled brush and ream interior lumen to remove any remaining debris.
4. Rinse and flush the instruments for one minute using tap water.
5. Inspect visually for any remaining bone fragments or debris and scrub as necessary.

Sterilization:

6. Remove the bur block from the surgical tray. Scrub the surgical tray and block with a soft bristled brush and mild soap. Rinse thoroughly.
7. Place the components into the surgical tray and pour ethyl alcohol (do not use rubbing alcohol) over the burs and tray to remove soap residue and minerals from the water. This step is important to help prevent corrosion and spotting. Let the components dry before wrapping.
8. Wrap the surgical tray in paper or autoclave-approved bags twice to prevent a tear of the outer packaging from contaminated instruments.
9. Steam gravity sterilize for forty minutes at a temperature of 270˚–275˚F (132˚–135˚C).
10. Dry for 30 minutes. Drying times may vary according to load size.

Notes:

1. Multiple sterilizations may affect the flow of fluid through internally irrigated burs. After each use, ream the burs individually with wire to remove any bone fragments or debris that will prevent the flow of water. **This is done prior to the sterilization cycle.**
2. Do not remove drills, instrumentation or surgical tray from the autoclave until the “dry cycle” is complete. **Very Important!**
3. These guidelines **DO NOT** apply to the cleaning and sterilization of your powered instrumentation. Please follow your powered instrumentation manufacturer’s instructions.

Please refer to ART630 for complete instructions on the sterilization and care of stainless steel.

*ENZOL enzymatic detergent was used to validate this process, per the manufacturer’s dilution recommendation.

Quad Shaping Drill (QSD)

The Quad Shaping Drills (QSDs) are used to prepare the osteotomy for placement of BIOMET ***3i*** Tapered Implants.

The BIOMET ***3i*** Depth Measurement System includes drill depth marks on the ACT® Twist Drill that correspond to the placement of the implant via a well-established procedure. BIOMET ***3i***s Protocol follows the principles of protecting the implant from premature loading by placing the implant subcrestally.

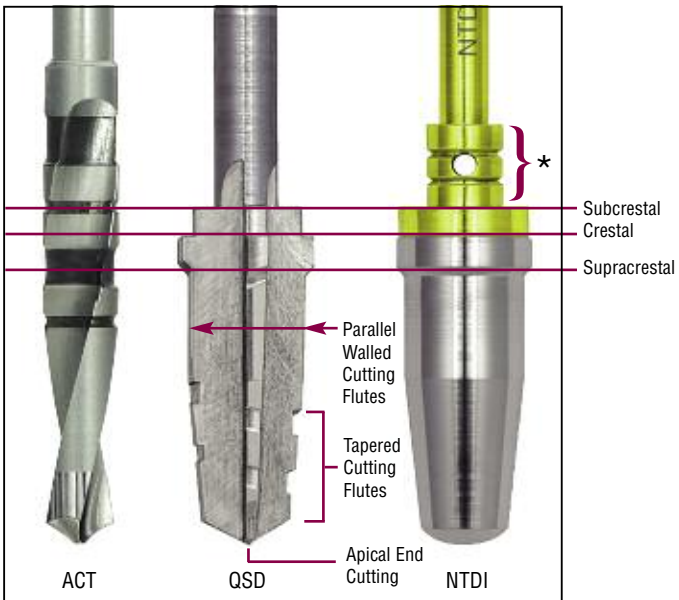
The Quad Shaping Drills have been designed with geometrical depth landmarks to assess proper depth rather than laser etched markings. The clinician should become familiar with these depth landmarks to prevent over or under preparation of the osteotomy site.

Shaping Drill Speed:
QSDs should operate between 1200–1500rpm.

QSDs cut efficiently; reducing the downward force will allow the drill to cut without detectable chatter.

Shaping Drill Technique:
- For either crestal or subcrestal implant placement, drill to the top of either the crestal or subcrestal depth landmarks on the QSD (full depth - see illustration to the right).
- Do not pump the shaping drill as you might pump a twist drill when creating the osteotomy. The shaping drill should be advanced once to full depth, then be removed without any pumping action.
- Once the shaping drill has reached desired depth, pull it out of the site without running the drill. If the drill does not pull out easily, tap the foot pedal while pulling drill out. In addition to preserving the integrity of the osteotomy site, this technique maximizes autogenous bone recovery from the shaping drill flutes.
- When placing a tapered implant in soft bone (Type IV), the surgeon should consider undersizing the osteotomy by one shaping drill size (i.e. if placing a tapered 5mm diameter X 10mm length implant in soft bone (Type IV), stop at the 4mm diameter X 10mm length shaping drill and directly place the implant). For more detailed information on implant placement in soft bone, please refer to page 18 of this manual.
- It is recommended that the clinician should tap the osteotomy when placing a tapered implant in dense bone (Type I and II). For more detailed information on implant placement in dense bone, please refer to pages 10-17 of this manual.

NOTE: During preparation of the osteotomy, the shaping drill should advance into the osteotomy using light pressure. The need to push heavily on the shaping drill may indicate the need to replace the shaping drill, the need to tap or that the previous drill depth was inadequate.



Depth landmarks on the QSD versus corresponding depth landmarks on the NTDI and depth marks on the ACT Drill for an 11.5mm length tapered implant.

*Gingival Depth Marks - These depth marks are not used in the surgical procedure covered in this manual.

The BIOMET 3i Tapered Implant System

Why Tapered Implants Are Different

Due to the geometrical differences that exist between a tapered and a parallel walled implant, there are several important technique adjustments that are required.

In all tapered implant placement procedures, **the surgeon should determine the appropriate vertical position of the implant (supracrestal, crestal or subcrestal) at the time of osteotomy preparation.** The surgeon should prepare the tapered osteotomy so that when the implant is fully seated, the implant seating surface is at the desired position. The Tapered Implant Depth/Direction Indicator (NTDI) was designed to simulate the tapered implant position prior to placement. After preparation of the osteotomy with the final shaping drill, suction out the osteotomy to remove debris. Select the corresponding NTDI and place the tapered end into the osteotomy. Check the platform position (crestal or subcrestal) of the NTDI in relation to the adjacent bone. This position locates where the platform of the tapered implant will be positioned when properly placed. If during placement with the power drill, the tapered implant platform is higher in relation to the bone than was demonstrated with the NTDI platform, the clinician should consider using a hand ratchet to complete the implant placement so that the tapered portion of the implant body conforms correctly with the tapered portion of the osteotomy (Figure 1. Proper Subcrestal Placement).

Over Preparing the osteotomy depth and then placing the implant at a crestal level may result in a conical space around the apical and coronal aspects of the tapered implant with minimal thread engagement (Figure 2. Over Prepared Subcrestal Placement). This placement position may result in decreased implant to osteotomy contact, with contact occurring only along the parallel coronal portion of the implant, resulting in decreased stability of the implant.

Under Preparing the osteotomy depth and then placing the implant more apical relative to the prepared depth may result in increased pressure along the tapered portion of the osteotomy and on the collar contact areas of the implant profile (Figure 3. Under Prepared Subcrestal Placement). This may result in the implant spinning and losing rotational resistance.

The clinician may consider undersizing the osteotomy in soft bone (Type IV). For more detailed information on implant placement in soft bone, please refer to page 18 of this manual.

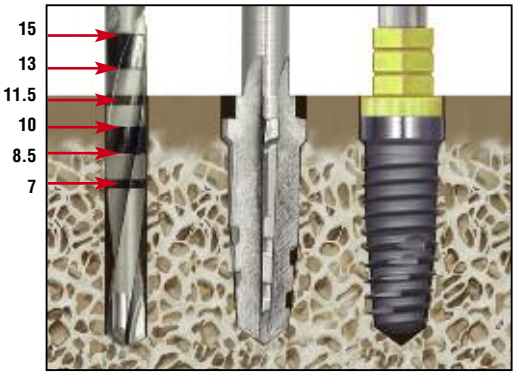


Figure 1
Proper Subcrestal Placement Of 11.5mm Implant

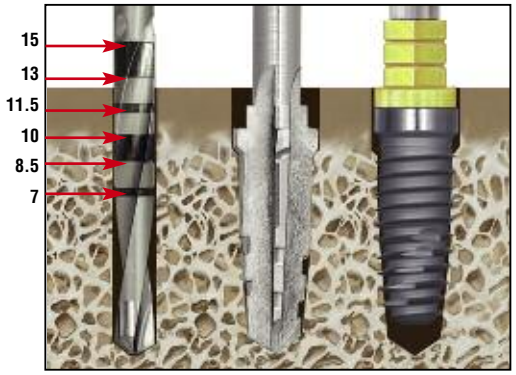


Figure 2
Over Prepared Subcrestal Placement Of 11.5mm Implant

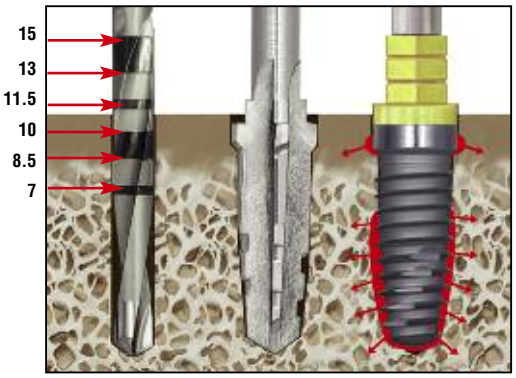
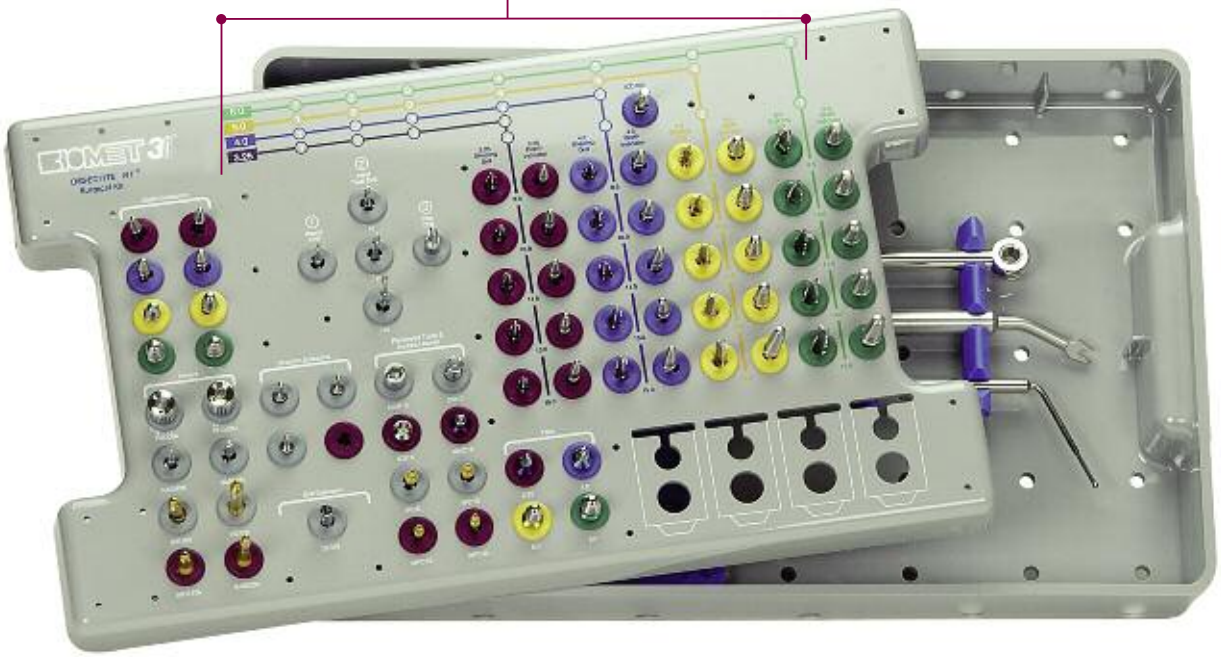


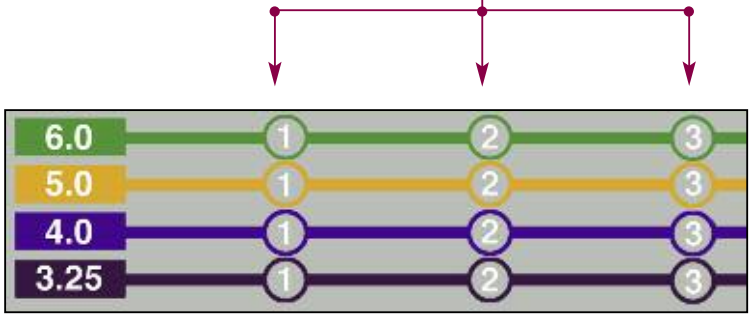
Figure 3
Under Prepared Subcrestal Placement Of 11.5mm Implant

Tapered Implant Surgical Tray (QNTSK)



Coordinating The Use Of The Surgical Tray With The Surgical Manual Illustrations:

The Surgical Tray (QNTSK) for tapered implants is numbered to indicate the appropriate steps of the implant placement protocol. The following illustrated implant placement protocol uses the same numbering sequence.



Close-up view of the Surgical Tray illustrating numbering sequence.

NOTE: Future editions of the Tapered Implant Surgical Tray will replace the Round Drill with a Pointed Starter Drill and will eliminate the Pilot Drill from the surgical protocol.

Tapered Implant Bone Taps And Bone Tap Kit (NTAPK)

Standard Bone Taps

Previously available Standard Tapered Bone Taps (Figure 1), were all 8.5mm in length and were designed to tap the coronal aspect of the osteotomy for all implant lengths. For both crestal and subcrestal tapered implant placement, the tap is advanced to the platform of the tap body, where the tap mount and stem converge, which should be level with the crest of the bone. These taps have been discontinued and have been replaced by the Dense Bone Taps.

Dense Bone Taps

When placing a tapered implant in dense bone (Type I and II), the clinician should consider tapping the osteotomy prior to implant placement (Figure 2).

Dense Bone Taps are available to fully thread the entire osteotomy. These Dense Bone Taps are both length and diameter specific to correspond to each tapered implant (Figure 3).

Tapered Implant Tap Kit (NTAPK) For Use With Tapered Implants In Dense Bone

When placing a tapered implant, the need to tap the osteotomy may arise, especially in dense bone. The Dense Bone Tap Kit has a specific tap that matches each tapered implant, which then facilitates site specific preparation to aid in final implant placement.

Figure 1

Figure 2

Figure 3

Tapered Implant Depth/Direction Indicator (NTDI)

The Tapered Implant Depth/Direction Indicator is used to simulate the implant platform position prior to placing the implant.

STEP 1

When using the NTDI and after preparation of the osteotomy with the final shaping drill, suction out the osteotomy to verify the osteotomy is clear of bone debris. (Figure 1)

STEP 2

Verify the NTDI platform position in reference to the crest of the bone. This also verifies the depth of the osteotomy that has been created. The NTDI platform should be at the level you desire the implant platform to attain. If the NTDI platform is too high versus the desired position, then re-drilling to the appropriate depth is required. If the NTDI platform is too deep versus the desired position, this indicates some degree of osteotomy over preparation has taken place. To ensure proper engagement of the implant, it must be seated to the depth demonstrated by the NTDI. A longer implant can be considered. The clinician may consider verifying the position of the NTDI with a radiograph. (Figure 2)

STEP 3

When placing the implant, the implant platform should reach the same position that the NTDI platform previously attained. If the implant platform is positioned higher in relation to the crest of the bone than the platform of the NTDI previously demonstrated, or if the surgical motor stalls prior to full placement of the implant due to insufficient torque, then hand ratcheting is recommended to achieve the proper final implant seating position. (Figure 3)

These guidelines will help ensure good bone-to-implant contact and primary stability of the implant.

Figure 1

Figure 2

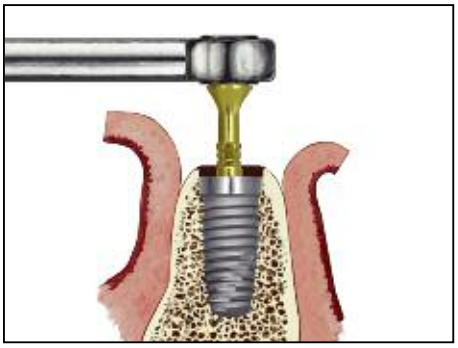
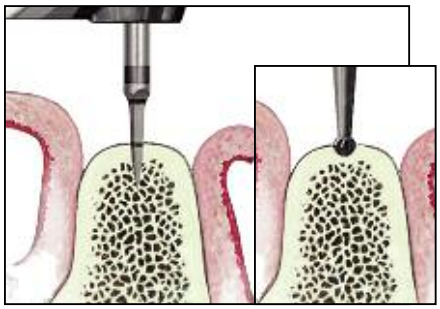


Figure 3

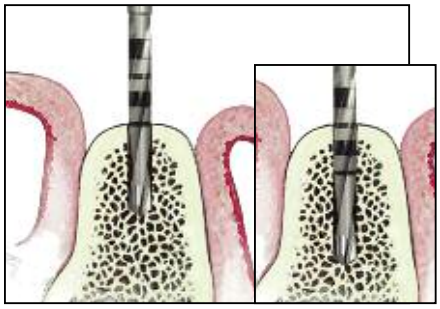
Subcrestal Implant Placement Protocol

Certain® And External Connection Tapered
3.25mm, 4mm, 5mm and 6mm Diameter Implants
Using QSD/NTDI



1. Once the implant site has been determined, mark the site with the ACT® Pointed Starter Drill or Round Drill and penetrate the cortical bone. The recommended drill speed is 1200–1500rpm.

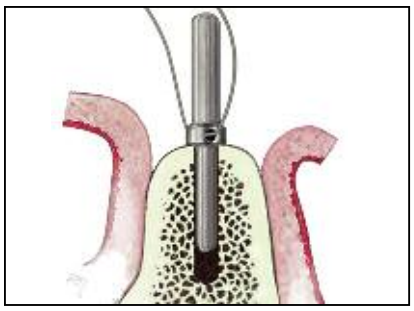
- Instruments needed:
  ACT Pointed Starter Drill (ACTPSD)
  Round Drill (RD100 or DR100)



2. Proceed with the Initial Twist Drill to approximately 7mm, then verify the direction with the thin portion of the Direction Indicator. Thread floss through the hole to prevent accidental swallowing.

Continue to penetrate the bone to the desired depth. Set the drill speed at approximately 1200–1500rpm.

- Instruments needed:
  2mm or 2.3mm Twist Drill
  (See our Product Catalog for a complete listing of applicable Twist Drills.)



3. Verify the direction and position of the preparation by inserting the thin portion of the Direction Indicator into the osteotomy. Thread dental floss through the hole to prevent accidental swallowing.

At this step, a Gelb Radiographic Depth Gauge may also be used.

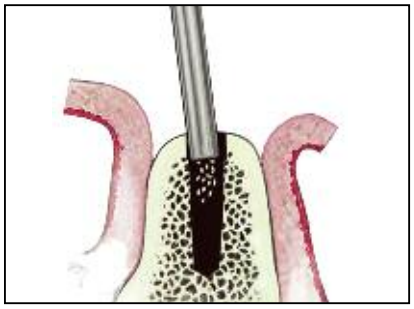
- Instruments needed:
  Direction Indicator (DI100 or DI2310)
  Gelb Radiographic Depth Gauge (XDGXX)

Final Shaping Drill Step For 3.25mm Tapered Implant.

4a. Proceed with the 3.25mm Quad Shaping Drill (QSD32XX) that is the same length as the implant to be placed. The recommended drill speed is 1200–1500rpm.

Subcrestal Implant Placement Protocol

Certain® And External Connection Tapered 3.25mm, 4mm, 5mm and 6mm Diameter Implants Using QSD/NTDI



Preparation For Placement Of 3.25mm Tapered Implant.

4b. Using suction, remove drilling debris from the osteotomy before proceeding with the Depth/Direction Indicator (NTDI).

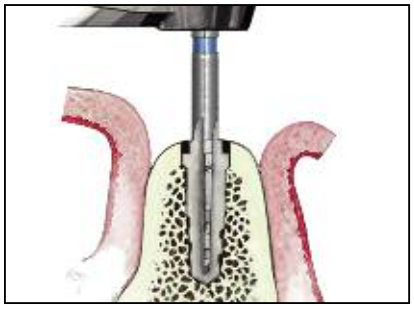
4c. Insert the tapered end of the 3.25mm (purple) NTDI that corresponds to the length of the implant to be placed. This will simulate the position of the implant platform in relation to the crest of the bone. If the position of the NTDI does not indicate proper osteotomy depth, adjust the depth of the osteotomy with the corresponding 3.25mm Quad Shaping Drill or consider a longer length implant if the site has been over prepared. Re-evaluate with a proper length NTDI.

Optional Tapping Step For Dense Bone (Type I and II).
If placing a 3.25mm implant in dense bone (Type I and II), tapping with a Dense Bone Tap is recommended.

- Instruments needed:
  Dense Bone Tap (NTAP32XX)
  Ratchet Wrench (WR100)
  Ratchet Extension (RE100 or RE200)

Proceed to **step 8a** on page 15 for implant placement.

Second Shaping Drill Step For Placement Of 5 And 6mm Implants. Final Shaping Drill Step For 4mm Tapered Implant.



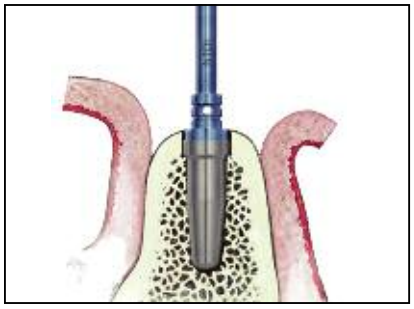
5a. Resume preparing the osteotomy with the 4mm Quad Shaping Drill (QSD4XX) that is the same length as the implant to be placed. The recommended drill speed is 1200–1500rpm.

Subcrestal Implant Placement Protocol

Certain® And External Connection Tapered
3.25mm, 4mm, 5mm and 6mm Diameter Implants
Using QSD/NTDI

Preparation For Placement Of 4mm Tapered Implant.

5b. Using suction, remove drilling debris from the osteotomy before proceeding to the Depth/Direction Indicator (NTDI).



5c. Insert the tapered end of the 4mm (blue) NTDI that corresponds to the length of the implant to be placed. This will simulate the position of the implant platform in relation to the crest of the bone. If the position of the NTDI does not indicate proper osteotomy depth, adjust the depth of the osteotomy with the corresponding 4mm Quad Shaping Drill or consider a longer length implant if the site has been over prepared. Re-evaluate with a proper length NTDI.

5d. Countersink the osteotomy with an ICD100 to accommodate the cover screw for the 4mm implant. The recommended drill speed is 1200–1500rpm.

***IMPORTANT NOTE:* When placing a 4mm diameter implant subcrestally, you must use an ICD100 Countersink Drill to prepare the ridge before placing the implant. The ICD100 is not required for crestal and supracrestal placement of a 4mm diameter implant.**

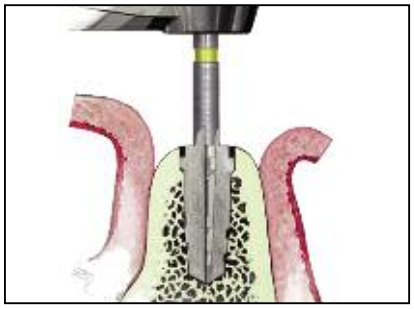
Optional Tapping Step For Dense Bone (Type I and II).
If placing a 4mm implant in dense bone (Type I and II), tapping with a Dense Bone Tap is recommended.

- Instruments needed:
  Dense Bone Tap (NTAP4XX)
  Ratchet Wrench (WR100)
  Ratchet Extension (RE100 or RE200)

Proceed to **step 8a** on page 15 for implant placement.

Subcrestal Implant Placement Protocol

Certain® And External Connection Tapered 3.25mm, 4mm, 5mm and 6mm Diameter Implants Using QSD/NTDI



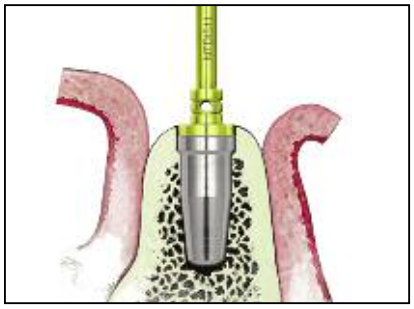
Third Shaping Drill Step For Placement Of 6mm Implant. Final Shaping Drill Step For 5mm Tapered Implant.

6a. Resume preparing the osteotomy with the 5mm Quad Shaping Drill (QSD5XX) that is the same length as the implant to be placed. The recommended drill speed is 1200–1500rpm.

Proceed to **step 8a** on page 15 for implant placement.

Preparation For Placement Of 5mm Tapered Implant.

6b. Using suction, remove drilling debris from the osteotomy before proceeding to the Depth/Direction Indicator (NTDI).

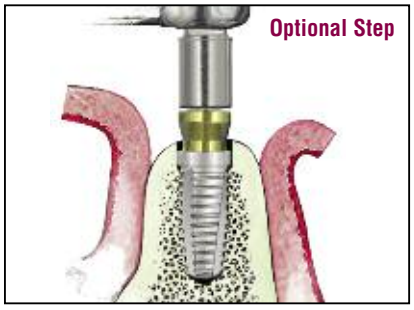


6c. Insert the tapered end of the 5mm (yellow) NTDI that corresponds to the length of the implant to be placed. This will simulate the position of the implant platform in relation to the crest of the bone. If the position of the NTDI does not indicate proper osteotomy depth, adjust the depth of the osteotomy with the corresponding 5mm Quad Shaping Drill or consider a longer length implant if the site has been over prepared. Re-evaluate with a proper length NTDI.

Optional Tapping Step For Dense Bone (Type I and II).
If placing a 5mm implant in dense bone (Type I and II), tapping with a Dense Bone Tap is recommended.

- Instruments needed:
  Dense Bone Tap (NTAP5XX)
  Ratchet Wrench (WR100)
  Ratchet Extension (RE100 or RE200)

Proceed to **step 8a** on page 15 for implant placement.



Subcrestal Implant Placement Protocol

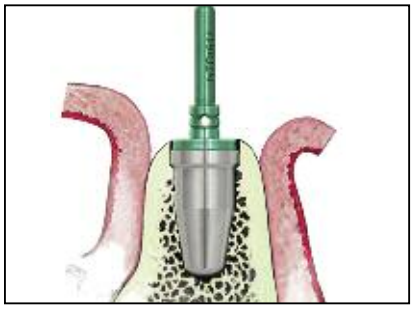
Certain® And External Connection Tapered
3.25mm, 4mm, 5mm and 6mm Diameter Implants
Using QSD/NTDI

Final Shaping Drill Step For 6mm Tapered Implant.

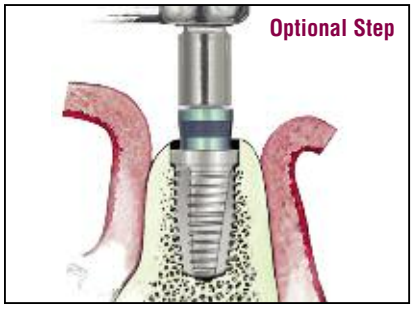
7a. Resume preparing the osteotomy with the 6mm Quad Shaping Drill (QSD6XX) that is the same length as the implant to be placed. The recommended drill speed is 1200–1500rpm.

Preparation For Placement Of 6mm Tapered Implant.

7b. Using suction, remove drilling debris from the osteotomy before proceeding to the Depth/Direction Indicator (NTDI).



7c. Insert the tapered end of the 6mm (green) NTDI that corresponds to the length of the implant to be placed. This will simulate the position of the implant platform in relation to the crest of the bone. If the position of the NTDI does not indicate proper osteotomy depth, adjust the depth of the osteotomy with the corresponding 6mm Quad Shaping Drill or consider a longer length implant if the site has been over prepared. Re-evaluate with a proper length NTDI.



Optional Tapping Step For Dense Bone (Type I and II).
If placing a 6mm implant in dense bone (Type I and II), tapping with a Dense Bone Tap is recommended.

- Instruments needed:
  Dense Bone Tap (NTAP6XX)
  Ratchet Wrench (WR100)
  Ratchet Extension (RE100 or RE200)

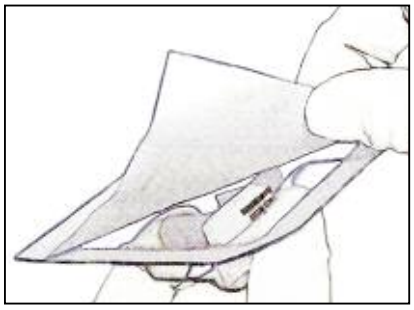
Proceed to **step 8a** on page 15 for implant placement.

Subcrestal Implant Placement Protocol

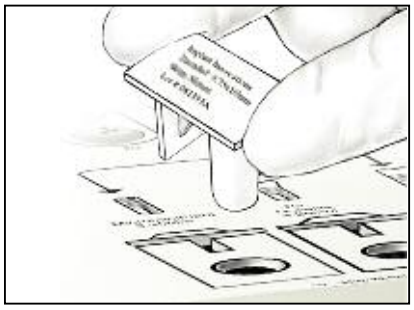
Certain® And External Connection
Tapered Implant Placement

No-Touch™ Delivery System

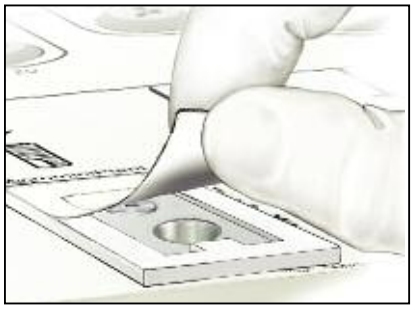
8a. Remove contents from the implant box.



8b. The nonsterile assistant should peel back the tray lid and drop the No-Touch Implant Tray onto the sterile drape.



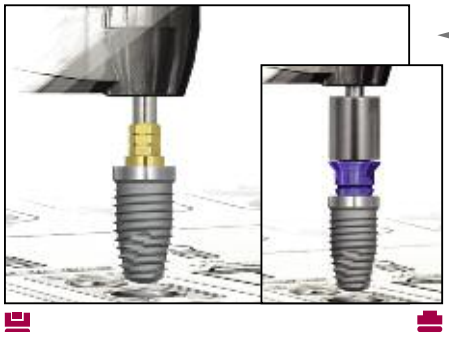
8c. Place the No-Touch Implant Tray into the appropriate location on the surgical tray.



8d. Peel back the tray lid to expose the implant and cover screw.

Subcrestal Implant Placement Protocol

Certain® And External Connection Tapered Implant Placement



9. Pick up the implant from the surgical tray using the Certain Implant Placement Driver Tip.

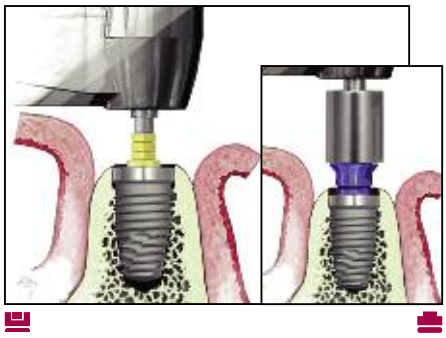
NOTE: The Certain MicroMiniplant™ 3.25mm Implant requires the use of a dedicated MicroMiniplant Driver Tip (IMPDTS or IMPDTL) that is marked with a purple band on the shank. The internal connection configuration of the MicroMiniplant is smaller than the standard Certain Internal Connection (4, 5 and 6mm implants). The item numbers can be identified on the side of the driver tip.

or

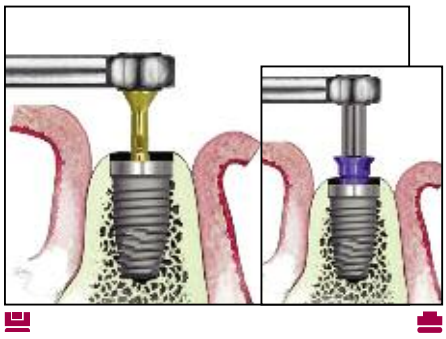
Pick up the implant from the surgical tray using the Handpiece Connector.

Carry the implant to the mouth facing upward to prevent accidental dislodging.

- Instruments needed:
  Implant Placement Driver Tip (IIPDTS or IIPDTL) or Handpiece Connector (MDR10)

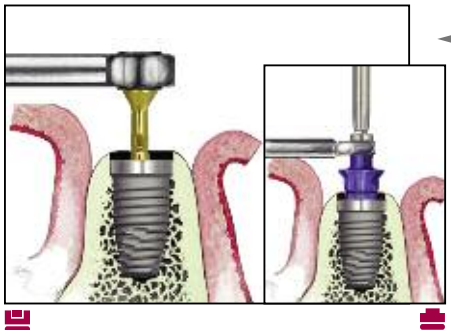


10. Place the implant in the prepared site at approximately 15–20rpm. It is not uncommon for the handpiece to stall before the implant is completely seated. The implant position must match what was simulated with the Depth/Direction Indicator (NTDI) or there is a risk of a poor fit between the implant and osteotomy. In dense bone, it is recommended to tap the site with a Dense Bone Tap prior to implant placement.



11. Final seating of the implant may require the use of the Ratchet Extension and the Ratchet Wrench.

- Instruments needed:
  Ratchet Wrench (WR150)
  Certain Ratchet Extension (IRE100 or IRE200) or MicroMiniplant Ratchet Extension (IMRE100 or IMRE200)
  External Connection Ratchet Extension (RE100 or RE200)



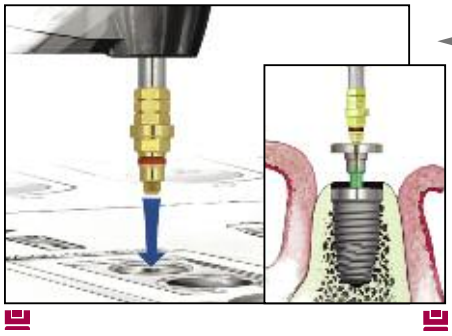
12. To remove the Certain Ratchet Extension from the implant, lift straight up and out.

To remove the implant mount, place the Open-End Wrench onto the mount. Loosen the screw at the top of the mount with a Large Hex Driver or the Large Hex Driver Tip inserted into the Right-Angle Driver and rotate counter-clockwise. After the screw is loosened, rotate the Open-End Wrench counter-clockwise slightly before removing the mount. The mount may be carried from the mouth with the Open-End Wrench.

- Instruments needed:
  Open-End Wrench (CW100), Large Hex Driver Tip (RASH3) and Right-Angle Driver (CATDB with CADD1) or a Large Hex Driver (PHD02N)

Subcrestal Implant Placement Protocol

Certain® And External Connection Tapered Implant Placement

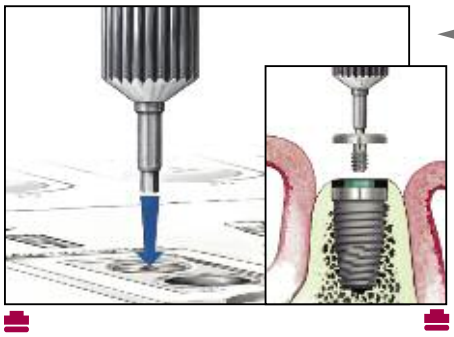


13. Pick up the Cover Screw from the No-Touch™ Implant Tray with the Implant Driver or Large Hex Driver and place onto the implant.

NOTE: When using the Certain Implant Placement Driver, reduce the torque setting on the drilling unit to 10Ncm.

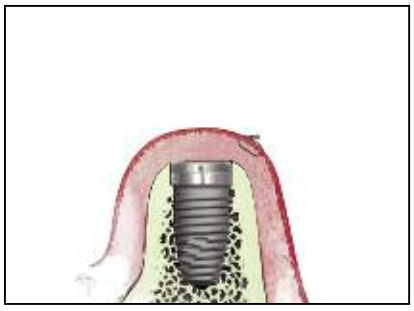
- Instruments needed:
  Implant Placement Driver Tip (IIPDTS or IIPDTL)
  Large Hex Driver (PHD02N)

or



Pick up the Cover Screw from the No-Touch Implant Tray with the Small Hex Driver (PHD00N) and place onto the implant.

NOTE: At this step, a temporary healing abutment may be placed for single-stage surgery instead of a cover screw.



14. Close the tissue and suture.

Soft Bone (Type IV) Subcrestal Implant Placement Protocol

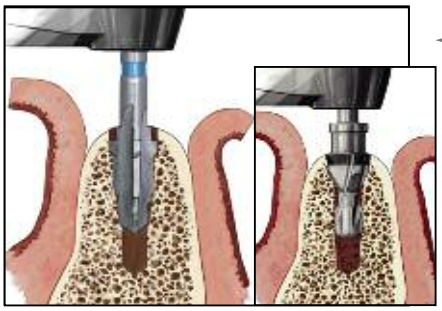
Certain® And External Connection
Tapered 4mm, 5mm and 6mm
Diameter Implants

If planning to place a tapered implant in soft bone, undersizing the osteotomy by one Quad Shaping Drill (QSD) diameter, is recommended. For example, if planning to place a:

- 4x13mm tapered implant, the 3.25x13mm QSD would be the final drill
- 5x13mm tapered implant, the 4x13mm QSD would be the final drill
- 6x13mm tapered implant, the 5x13mm QSD would be the final drill

Soft Bone (Type IV) With Dense Cortical Bone

In soft bone situations where dense cortical bone is present it may be necessary to prepare the coronal aspect of the osteotomy as illustrated below.



4mm Tapered Implants In Soft Bone With Dense Cortical Bone

1. After preparing the osteotomy with the appropriate length 3.25mm QSD, finish with a 4mm x 8.5mm QSD (QSD485). This will create an osteotomy of proper dimension in the dense cortical bone to receive the implant, but will slightly undersize the osteotomy in the cancellous region to allow for some compression. The recommended drill speed is 1200–1500rpm.

2. Finish by countersinking the osteotomy with an ICD100 to accommodate the cover screw for the 4mm implant. The recommended drill speed is 1200–1500rpm.

IMPORTANT NOTE: ***When placing a 4mm diameter implant subcrestally, you must use an ICD100 Countersink Drill to prepare the ridge before placing the implant. The ICD100 is not required for crestal and supracrestal placement of a 4mm diameter implant.***

See **step 8a** on page 15 for implant placement.

5mm Tapered Implants In Soft Bone With Dense Cortical Bone

1. After preparing the osteotomy with the appropriate length 4mm QSD, finish with a 5mm x 8.5mm Quad Shaping Drill (QSD585). This will create an osteotomy of proper dimension in the dense cortical bone to receive the implant, but will slightly undersize the osteotomy in the cancellous region to allow for some compression. The recommended drill speed is 1200–1500rpm.

See **step 8a** on page 15 for implant placement.

6mm Tapered Implants In Soft Bone With Dense Cortical Bone

1. After preparing the osteotomy with the appropriate length 5mm QSD, finish with a 6mm x 8.5mm Quad Shaping Drill (QSD685). This will create an osteotomy of proper dimension in the dense cortical bone to receive the implant, but will slightly undersize the osteotomy in the cancellous region to allow for some compression. The recommended drill speed is 1200–1500rpm.

See **step 8a** on page 15 for implant placement.

Bone Profiling

*BIOMET **3i** Implants*

EP® Healing Abutments

Bone Profiling Pins and corresponding EP Bone Profilers are available to contour the bone that is to receive the EP Healing Abutment. These tools are especially helpful in a single-stage surgical protocol when the implant is placed subcrestally.

If the implant is placed subcrestally and use of an EP Healing Abutment is indicated, the coronal aspect of the osteotomy must be prepared to receive the flare of the EP Healing Abutment.

EP Bone Profilers correspond to sizes of EP Healing Abutments

NOTE: Non-EP, straight healing abutments and impression copings are available if bone profiling is not preferred at either stage one or stage two surgery.

Certain® Two-Piece Bone Profiling Pin (IBPGP)

The Certain Implant requires a dedicated Bone Profiling Pin, which is used with the existing EP Bone Profilers. This new two-piece design allows the pin to engage the internal connection of the implant. The hex engagement prevents the pin from tightening into the implant during profiling, making it easy to remove. **Lubricating the top of the pin with an appropriate lubricant, such as tetracycline ointment, is recommended. Do not exceed 50rpm when using Bone Profilers.**

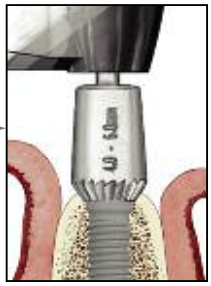
Certain Two-Piece
Bone Profiler Pin

External Connection
One-Piece
Bone Profiler Pin

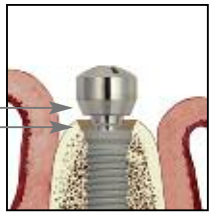
Bone Profiling Technique

- EP Bone Profiler slides over the Bone Profiler Pin.

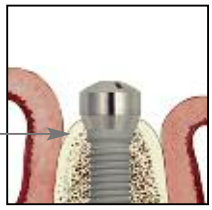
- EP Bone Profiler creates a flare in the crest of bone.



- Flare of EP Abutment matches the flare of the corresponding EP Bone Profiler.



- EP Healing Abutment seated properly onto the implant in subcrestal placement.



NOTES

Global Headquarters
4555 Riverside Drive
Palm Beach Gardens, FL 33410
1-800-342-5454
Outside The U.S.: +1-561-776-6700
Fax: +1-561-776-1272
www.biomet3i.com

Sign Up For BIOMET 3i's Electronic Newsletter "BIOMET 3innovations."
Simply Go Online To www.biomet3i.com/signup

ART939
REV B 11/07

SUBSIDIARIES

AUSTRALIA
Phone: +61-2-9855-4444
Fax: +61-2-9888-9900

BELGIUM
Phone: +32-2-5410290
Fax: +32-2-5410291

BRAZIL
Phone: +55-11-5081-4405
Fax: +55-11-5081-7484

CANADA
Phone: +514-956-9843
Fax: +514-956-9844

FRANCE
Phone: +33-1-41054343
Fax: +33-1-41054340

GERMANY
Phone: +49-721-255177-10
Fax: +49-721-255177-73

IRELAND
Phone: +35-31-477-3925
Fax: +35-31-402-9590

MEXICO
Phone: +52-55-5679-1619
Fax: +52-55-5684-8098

THE NETHERLANDS
Phone: +31-(0)78-629-2800
Fax: +31-(0)78-629-2801

NEW ZEALAND
Phone: +64-508-122-221
Fax: +64-508-133-331

NORDIC REGION
Phone: +46-40-17-6090
Fax: +46-40-17-6099

PORTUGAL
Phone: +351-21-000-1645
Fax: +351-21-000-1675

SPAIN
Phone: +34-93-470-59-50
Fax: +34-93-372-11-25

SWITZERLAND
Phone: +41-44-380-46-46
Fax: +41-44-383-46 55

U.K.
Phone: +44-1628-829314
Fax: +44-1628-820182

DISTRIBUTORS

ARGENTINA
Dentalmax, SA
Phone: +541-1482-71001
Fax: +541-1482-67373

AUSTRIA
Wieladent
Phone: +43-7672-93901
Fax: +43-7672-93903

CHILE
Cybel, SA
Phone: +56-2-2321883
Fax: +56-2-2330176

CHINA
Atek Inc.
Phone: +86-21-6329-1265
Fax: +86-21-6329-1620

COLOMBIA
3i Colombia
Phone: +571-612-9362
Fax: +571-620-6412

COSTA RICA
Implantec S.A.
Phone: +506-2-256411
Fax: +506-2-247620

EL SALVADOR
Dentimerc SA de CV
Phone: +503-263-6350
Fax: +503-263-6676

GREECE
Kostas Kornisorlis and Co.
Phone: +30-2310-501-651
Fax: +30-2310-522-417

HONG KONG
Ositek Inc., Ltd.
Phone: +852-8121-6601
Fax: +852-3747-3754

ISRAEL
H.A. Systems
Phone: +972-3-6138777
Fax: +972-3-6138778

ITALY
Biomax, srl.
Phone: +39-0444-913410
Fax: +39-0444-913695

JAPAN
Implant Innovations Japan
Phone: +81-66-868-3012
Fax: +81-66-868-2444

KOREA
Jungsan Biomed Corp.
Phone: +82-2-516-1808
Fax: +82-2-514-9434

LEBANON
3i MENA s.a.l.
Middle East And North Africa
Phone: +961-1-694000
Fax: +961-1-694222

PARAGUAY
Andres H. Arce y Cia SRL
Phone: +595-21-208185
Fax: +595-21-496291

POLAND
Dental Depot
Phone: +48-71-341-3091
Fax: +48-71-343-6560

RUSSIA
Com-Dental
Phone: +7-495-797-6686
Fax: +7-499-242-9567

SINGAPORE
Asia Implant Support & Services
Phone: +65-6223-2229
Fax: +65-6220-3538

SOUTH AFRICA
Selective Surgical CC
Phone: +27-11-991-7007
Fax: +27-11-672-1391

TAIWAN
Kuo Hwa Dental Suppliers Co., Ltd.
Phone: +886-2-2226-1770
Fax: +886-2-2226-8747

THAILAND
3i (Thailand) Co., LTD.
Phone: +662-252-6685
Fax: +662-252-6686

UKRAINE
Com-Dental
Phone: +38-067-7007667
Fax: +38-044-5017117

URUGUAY
Pro3implant S.R.L.
Phone: +598-2-4034163
Fax: +598-2-4034163