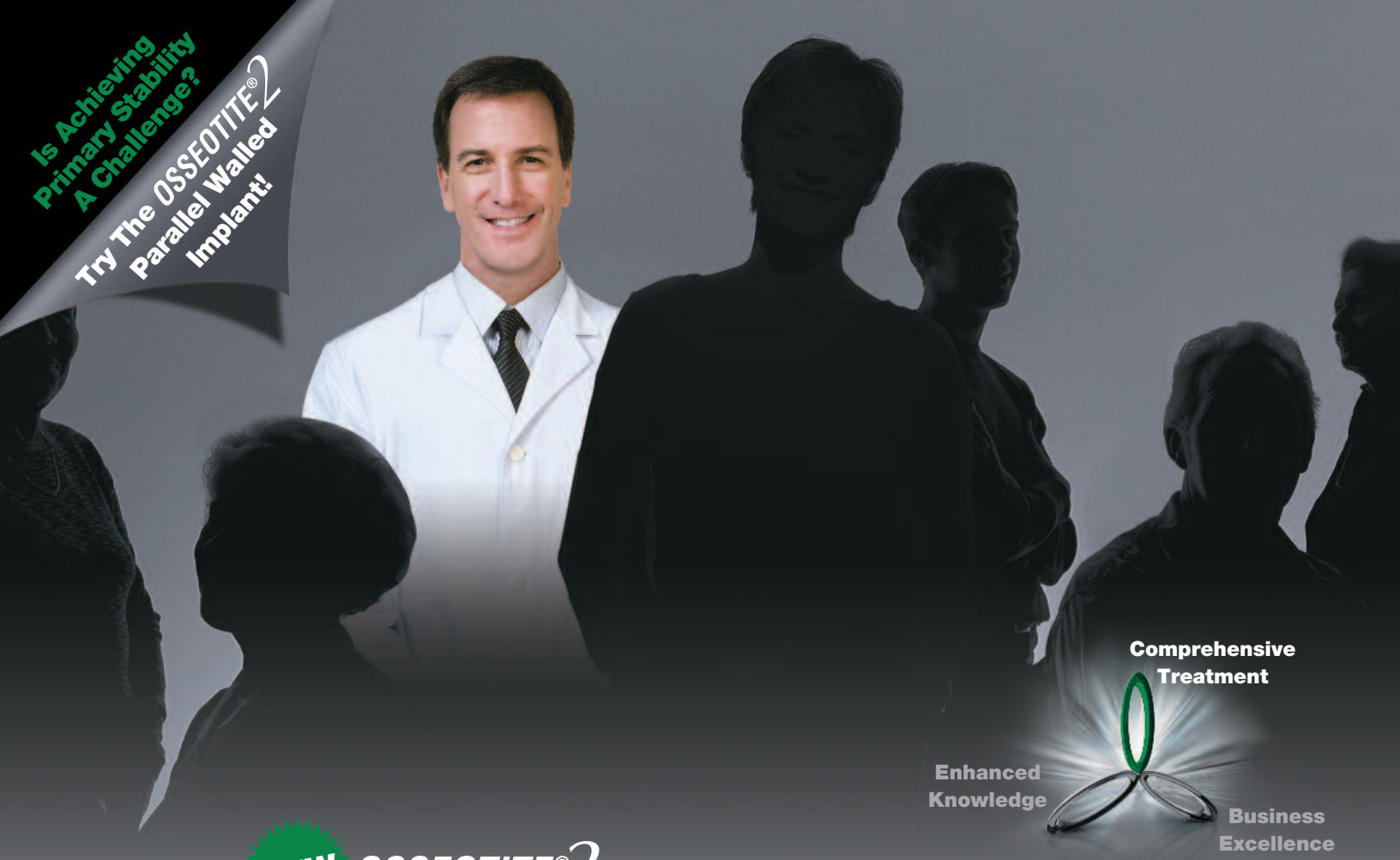
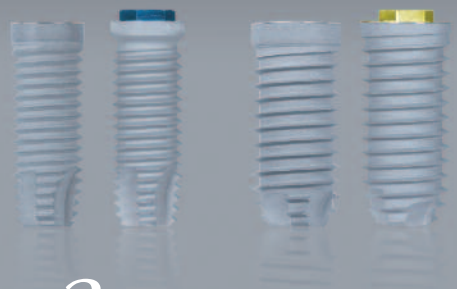


Introducing NEW OSSEOTITE® 2 Implants

The Solution Designed To Help Achieve Primary Stability With Parallel Walled Implants:

- New Design Features For A Tighter Osteotomy Fit
- Increased Lateral Threads For "Bite-In-Bone" Engagement
- New Implants Are Designed To Provide More Surface Area In Direct Contact With Bone



Providing Clinicians One Solution At A Time With OSSEOTITE® 2 Implants

- More Surface Area Than The Previous Design For Greater Immediate Bone-To-Implant Contact
- Implant Design Allows Steady Rise Of Insertional Torque Throughout Placement To Help Achieve Primary Stability

BIOMET 3i™

PROVIDING SOLUTIONS – ONE PATIENT AT A TIME™

Instructions For Use

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

Description: BIOMET ***3i*** Dental Implants are manufactured from biocompatible titanium or 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 from 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 with 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.

BIOMET ***3i*** Low Profile Abutments are intended for use as accessories to endosseous dental implants to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prosthesis can be screw or cement retained to the abutment.

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:

- Bone quality
- 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 patient's 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, coldwelding of the mount-driver interface to the implant, or stripping the walls of the osteotomy that may prevent an effective initial implant fixation.

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.

Reuse of BIOMET 3i products that are labeled for single-use may result in product contamination, patient infection and/or failure of the device to perform as intended.

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. 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

OSSEOTITE® 2 Is Pending U.S. FDA 510(k) Clearance

Introduction And Treatment Planning

These instructions were designed to serve as a reference guide for dental practitioners utilizing BIOMET 3i™ Implants and Surgical Instruments.

BIOMET ***3i***'s Designs enable the practitioner to place implants in edentulous or partially edentulous mandibles or maxillae in order to support fixed and removable bridgework or single tooth crowns and overdentures.

General Information:

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, masticatory function 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 and 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 soft 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 a 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.

Icon Key:

Certain® Internal Connection Implant System:

External Hex Connection Implant System:

Certain® Internal and External Hex Connection Implant Systems:

How To Use The Icon Key:

The icons represent the connection types of the 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 solid black icon and a light black icon are present together, the solid black indicates which system is illustrated. When both icons are solid black, then both systems are illustrated together.

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 gingiva 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 three-dimensional images. Image-guided surgical planning allows surgeons to see anatomical landmarks such as 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 treat 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 = the amount of actual bone available.

Formula Key =

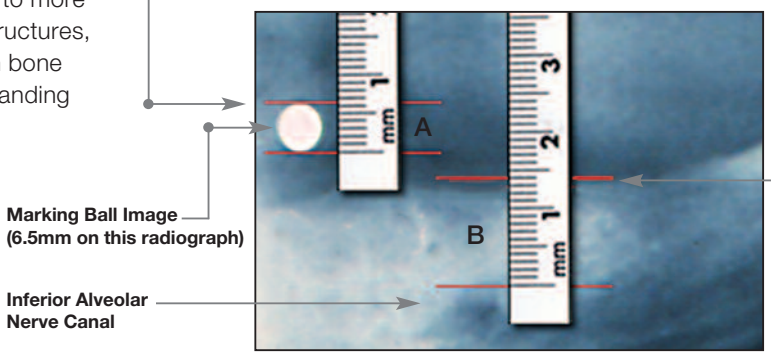
- Radiographic marking ball = 5.0mm in diameter.
- A = Size of marking ball image on radiograph.
- B = Length in millimeters on the radiograph of available bone between the crest of the ridge and the inferior alveolar canal.

Example:

A = 6.5mm
B = 14.0mm

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

NOTE: A 2.0mm margin of safety, from the apical end of the implant to the adjacent vital structure, should be considered.



Top-Down Treatment Planning

In its simplest form, top-down treatment planning refers to a protocol whereby the desired restorative result is considered first, leading to consideration of the appropriate prosthetic platform and subsequent implant selection based on bony anatomy and the size of the missing tooth.

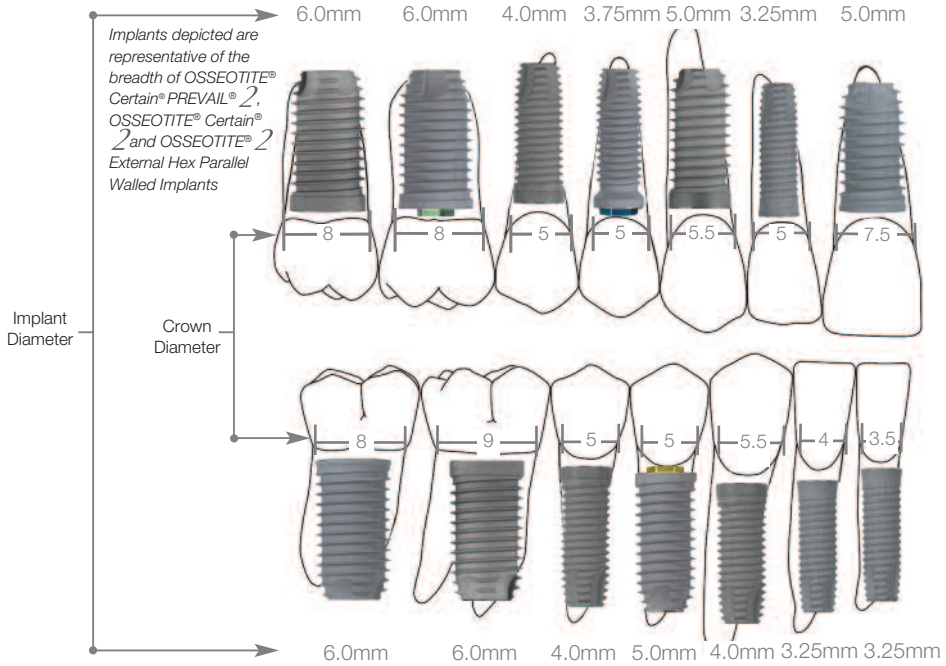
A top-down treatment planning methodology will provide maximum biomechanical stability and allow for soft tissue flaring by utilizing an implant with a prosthetic platform slightly smaller in diameter than the emergence diameter of the tooth being replaced. BIOMET 3i's wide selection of implants allows clinicians to match the size of the prosthetic platform to the restoration it will eventually support, while allowing for different bone volumes and anatomical features at the implant site. Implant and healing abutment selections are based upon the relationship of several key measurements:

- The emerging dimension of the crown in relation to the diameter of the prosthetic platform of the implant
- The height and diameter of the intended restoration at the tissue exit point
- The bone volume at the implant site in relation to the diameter of the implant body

The Emergence Profile (EP®) Healing Abutment System consists of healing abutments of various diameters and heights for shaping the soft tissue to replicate the geometry and gingival contours of natural dentition.

Implant Indications:

	Ø3.25mm	Ø3.75mm	Ø4.0mm	Ø5.0mm	Ø6.0mm	Ø4/3mm PREVAIL®	Ø5/4mm PREVAIL®	Ø6/5mm PREVAIL®
Anterior (incisor/canine)	✔	✔	✔	✔	✔	✔	✔	✔
Pre-molar	✔	✔	✔	✔	✔	✔	✔	✔
Molar			✔	✔	✔	✔	✔	✔



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 high quality CT scans. 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 interocclusal clearance - 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.

Diagnostic casts can be used preoperatively to evaluate the residual ridge and to determine the position and angulation of all implants. These casts 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 diagnostic cast.

Several software companies offer planning software that allow clinicians 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 aid in the preangulation 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.

Bone surgery utilizes a high-torque electric drilling unit that can be operated in forward and reverse modes at speeds ranging from 0 to 2000rpm, 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 definitive 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 healing period.

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 inspected 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. Reusable drills are recommended to be replaced after 15 osteotomy preparations, subject to the information below.

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, or rough or improper handling or maintenance. 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 the 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 bristle 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 sterilization method – Minimum of 20 minutes at a temperature of 270°–275°F (132°–135°C).** Pre-vacuum sterilization method – Minimum of four minutes (four pulses) 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 the 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.

**Post sterilization devices should be thoroughly dried to mitigate the risk of stainless steel corrosion (30 minutes is typical).

Twist Drill Depth Marking System

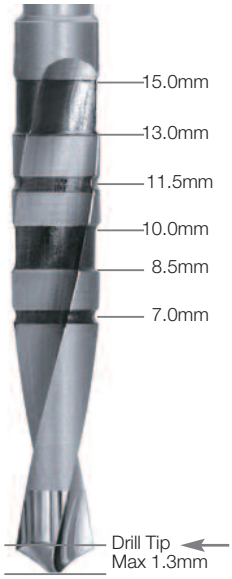
Types Of Twist Drills

ITD Reusable Drills
- Internal Irrigation Lumen
- All Thin Lines

DT & DTN Disposable Drills
- Without Internal Irrigation Lumen
- Bands
- DTN Disposable Drills Do Not Have A Hub

ACT® Reusable Drills
- Without Internal Irrigation Lumen
- Alternating Lines And Bands
- No Hub

ACT® Drill Marks



The center of the drill's single line depth marks and the beginning or end of the broad band indicate subcrestal placement for the corresponding length implant.

The length of the drill tip is not included in the depth mark measurement. The drill tip length should be considered when preparing the osteotomy.

The length of the drill tip varies with the diameter of the drill.

Drill Tip Dimensions

Drill Diameter	ITD/DTN/DT Drill Tip Length	ACT® Drill Tip Length
2.00mm	0.6mm	0.6mm
2.30mm	0.7mm	N/A
2.75mm	0.8mm	0.9mm
3.00mm	0.9mm	0.9mm
3.15mm	1.0mm	1.0mm
3.25mm	1.0mm	1.0mm
3.85mm	N/A	1.2mm
4.25mm	0.4mm	1.3mm
4.85mm	N/A	1.3mm
5.25mm	0.5mm	1.2mm

Twist Drill Depth Marking System (Continued)

The BIOMET 3i™ Depth Marks measurement system provides a mark on the drill that corresponds to the placement of the implant via well-established procedures. BIOMET ***3i***'s Original Protocol follows the principles of protecting the implant from premature loading by placing the implant **subcrestally**.

Drilling Depth

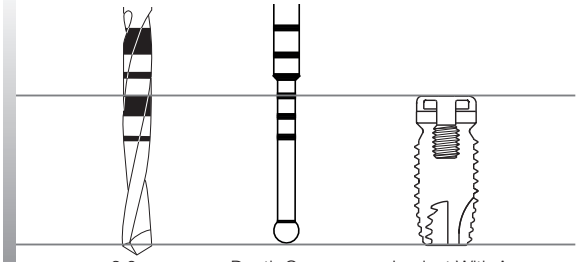
The drilling depth with the Twist Drill will vary depending on the type of placement related to the bone crest.

The depth marks are specific for **subcrestal** implant placement only. There are no specific depth marks on the drills for crestal or supracrestal placement.

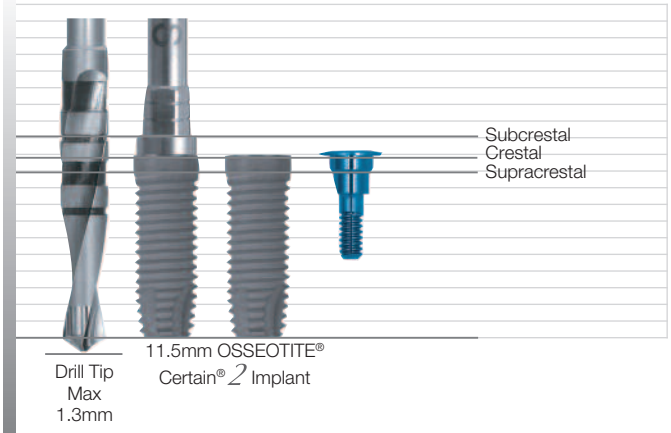
The drill depth marks do not indicate implant lengths. Rather, the drill depth marks represent the length of the implant with a standard 1.0mm cover screw in place. As a result, to place an implant and cover screw **subcrestally** requires drilling to the middle of the single line depth mark or the beginning or end of the broad band depth mark on ACT® Drills. For **crestal** placement, drill halfway before the corresponding depth mark for the implant length. For **supracrestal** placement, the drill depth mark should remain above the bone by 1.0mm for the cover screw plus the implant collar height. Refer to the diagram at the bottom of page 9 for more information on supracrestal placement.

OSSEOTITE® Certain® 2 Implants are packaged with a 0.4mm Cover Screw. However, the protocols for OSSEOTITE® Certain® 2 Implants do not differ from the protocols for BIOMET ***3i*** Implants packaged with a 1.0mm Cover Screw.

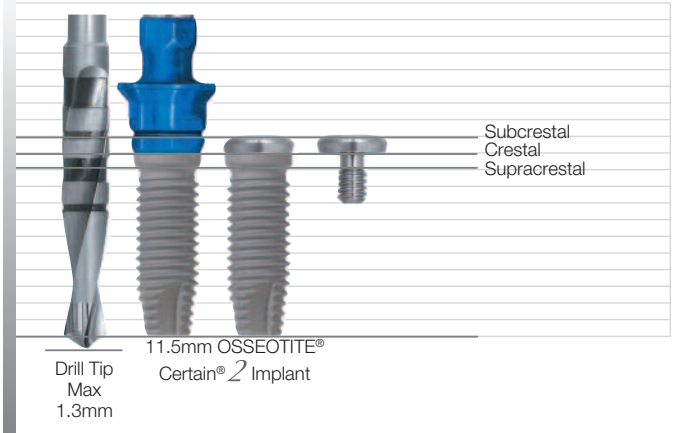
Standard Subcrestal Protocol With 1.0mm Cover Screw



Drilling Depth Comparison Certain®

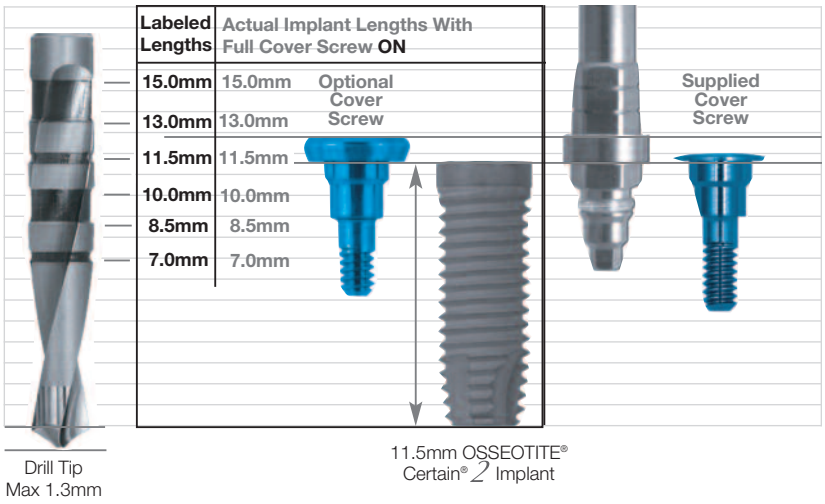


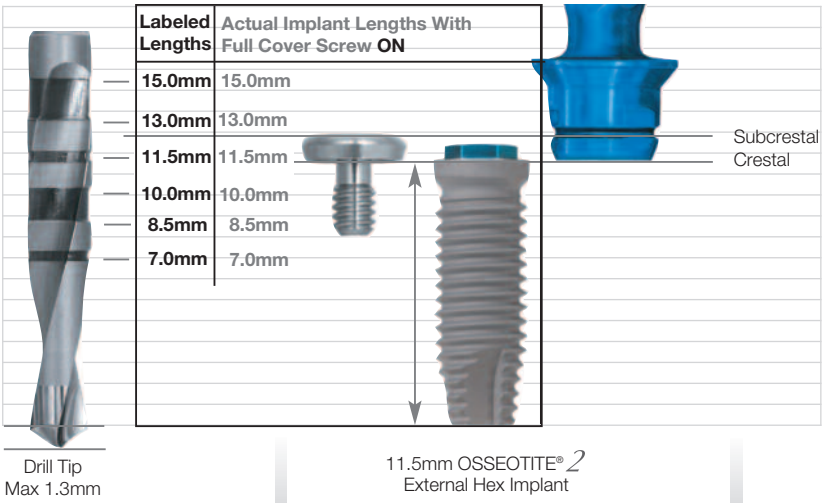
Drilling Depth Comparison External Hex



Twist Drill Depth Marking System (Continued)

Labeled vs. Actual Lengths





The center of the drill's single line depth marks and the beginning or end of the broad band indicate the length of the implant with a standard 1.0mm cover screw in place.

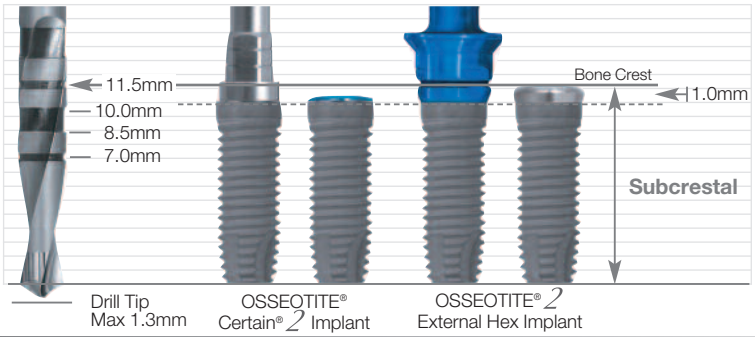
The actual implant lengths from the top of the implant collar (platform) to the tip of the implant are shorter by 0.4mm than the labeled length.

The landmarks (grooves) on the Certain® Implant Driver Tip act as references during implant placement.

Twist Drill Depth Marking System (Continued)

Subcrestal Placement

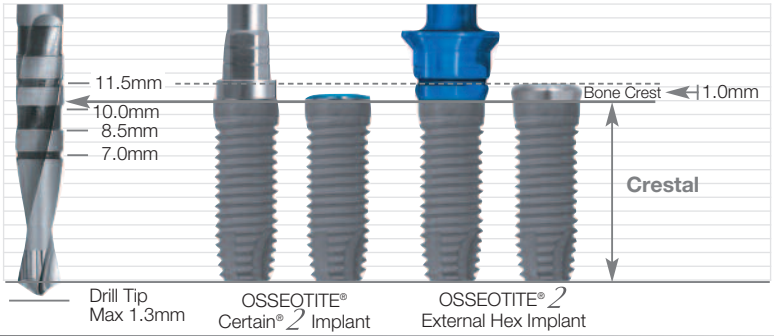
- **The implant <u>platform</u> will be 1.0mm (or more) <u>below</u> the bone crest.**
- **Mostly used in the anterior region for aesthetics.**



For subcrestal Certain® Internal Connection and External Connection Implant placement, drill to the drill depth mark that corresponds to the labeled implant length.

Crestal Placement

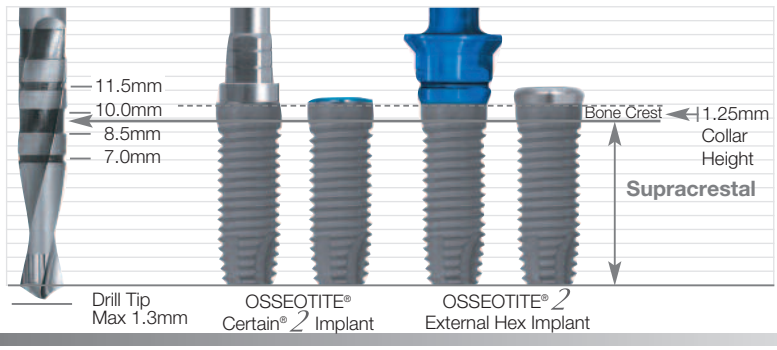
- **The implant <u>platform</u> will be <u>at</u> the bone crest.**



For crestal Certain® Internal Connection and External Connection Implant placement, stop drilling **1.0mm before** the drill depth mark that corresponds to the labeled implant length (1.0mm equals the traditional cover screw height).

Supracrestal Placement

- **The implant <u>collar</u> will be <u>above</u> the bone crest.**

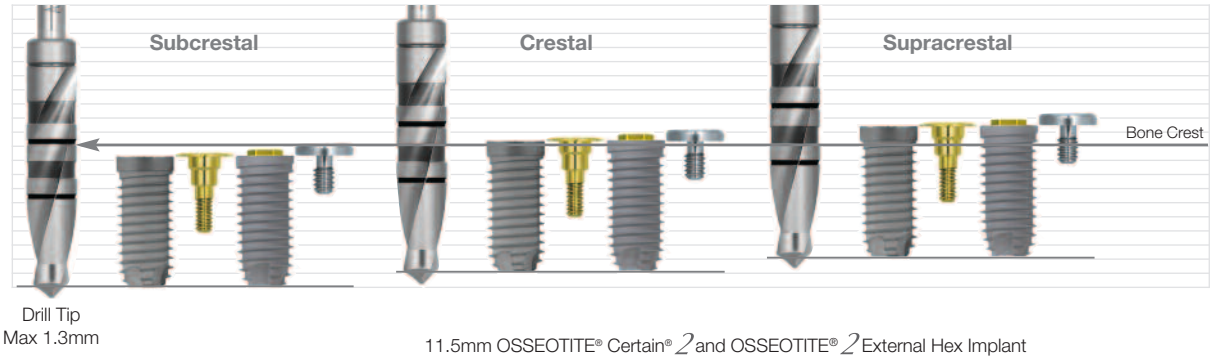


For supracrestal Certain® Internal Connection and External Connection Implant placement, stop drilling 2.25mm before the drill depth mark that corresponds to the labeled implant length (2.25mm equals the 1.0mm traditional cover screw height plus the 1.25mm Certain® Internal Connection Implant collar height).

NOTE: A Countersink Drill is not needed for internal or external connection implant supracrestal placement

Twist Drill Depth Marking System (Continued)

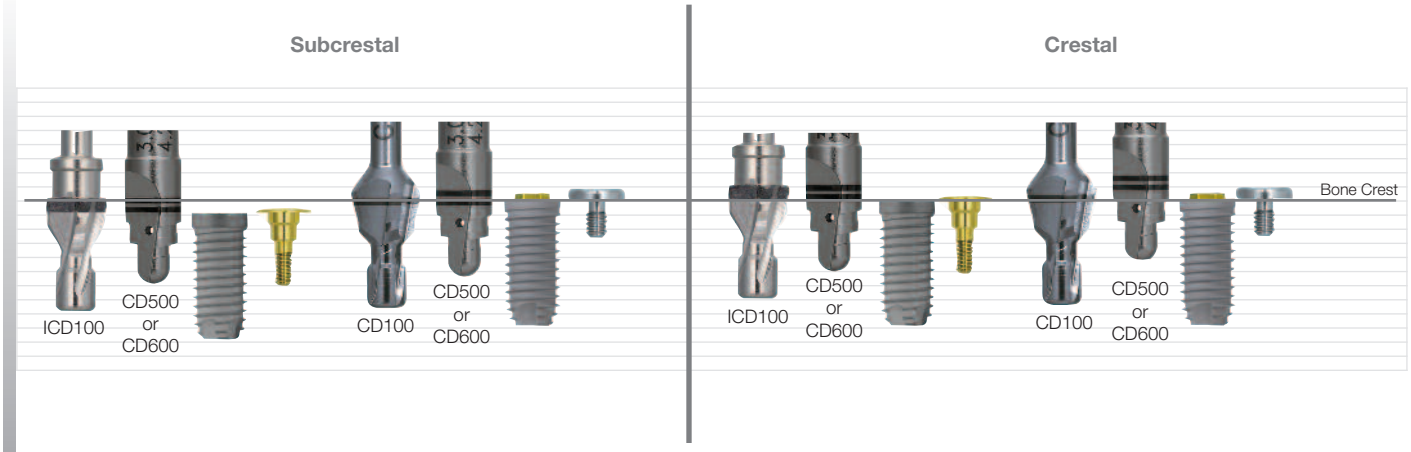
Placement Comparison Diagram



11.5mm OSSEOTITE® Certain® 2 and OSSEOTITE® 2 External Hex Implant

Countersink Drill Depth Marking System

Placement Comparison Diagram



11.5mm OSSEOTITE® Certain® 2 and OSSEOTITE® 2 External Hex Implant

A Countersink Drill is used when placing 4.0mm, 5.0mm and 6.0mm diameter implants subcrestally to prepare the bone to accept the implant collar.

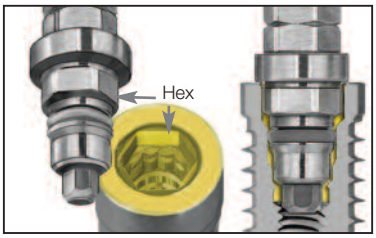
For crestal placement of the implant, a Countersink Drill may be needed in dense bone due to the shape of the implant collar.

Mountless Delivery Guidelines For OSSEOTITE® Certain® 2 Implants

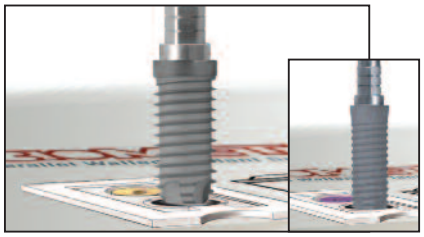
Pick-Up And Delivery Of Implant

Care must be taken when inserting the Implant Placement Driver Tip into the implant. A very low RPM must be used as you approach the internal connection of the implant with the driver tip to properly align the internal hex of the implant with the external hex of the driver. Press down firmly to engage the implant securely.

NOTE: The Certain® 3.25mm(D) and 4/3 PREVAIL® Implant requires the use of a dedicated Certain® 3.4mm(D) Driver Tip (IMPDTS or IMPDTL) that is marked with a purple band on the shank. The internal connection configuration of the Certain® 3.25mm(D) Implant is smaller than the Certain® Standard 4.0, 5.0 and 6.0mm(D) Implants. The item numbers can be identified on the side of the driver tip.



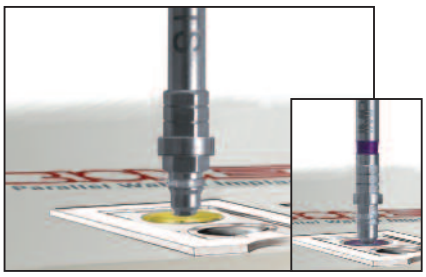
Implant And Driver Hex Design


Implant Pick-Up

Pick-Up And Delivery Of Cover Screw Or Healing Abutment

The 0.048 inch tip of the Certain® Implant Placement Driver Tip can be used to pick up and place the cover screw or the healing abutment.

NOTE: When using the Internal Connection Implant Driver (IIPDTS or IIPDTL) to place a cover screw or healing abutment, reduce the torque setting on the drilling unit to 10Ncm.


Cover Screw Pick-Up

The cover screw replica portion of the driver allows for visual verification of the standard 1.0mm cover screw position, making **subcrestal** and **crestal** placement of the implant predictable.

NOTE: Periodic O-Ring replacement is required for the Certain® Driver Tips.

Bone Density

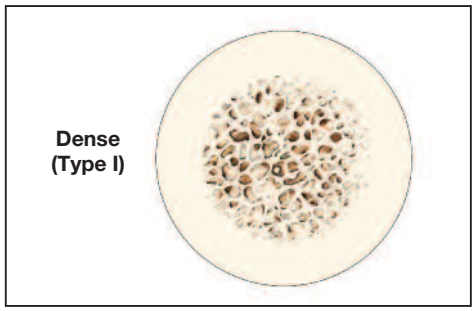
The protocols detailed in this Surgical Manual have been developed to include more specific information about drill selection when working in various bone densities. However, the clinician is responsible for assessing the bone density of the anatomy when determining the appropriate protocol.

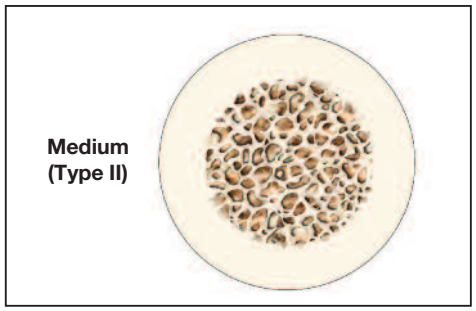
The various bone densities can be typically characterized by the following:

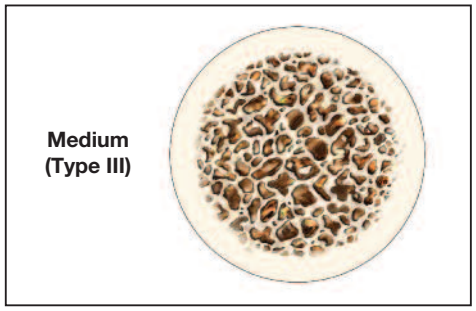
Dense (Type I) – A thick cortical layer and a very high density trabecular core

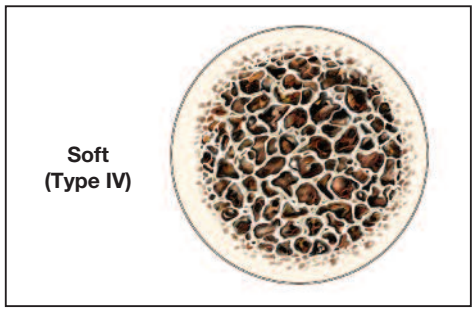
Medium (Type II & III) – A cortical layer of moderate thickness with a reasonably dense trabecular core

Soft (Type IV) – A thin cortical layer and a low density trabecular core









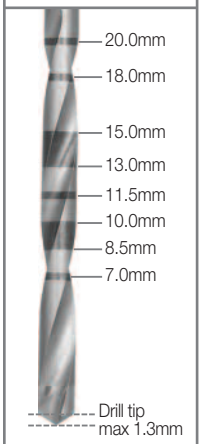
Subcrestal Placement For OSSEOTITE® Certain® PREVAIL® 2, OSSEOTITE® Certain® 2 And OSSEOTITE® 2 External Hex Parallel Walled Implants

D = Diameter
C = Collar
P = Platform
L = Length

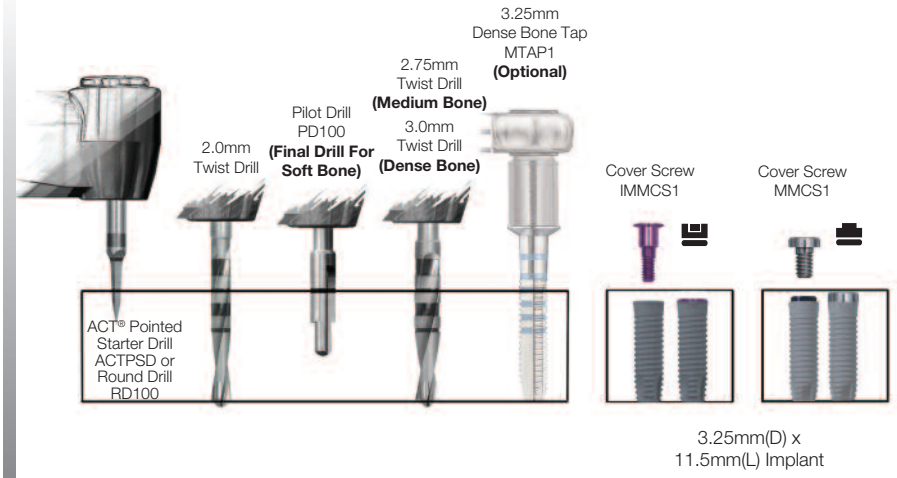
NOTE:

- The recommended drill speed for drills 3.85mm diameter or less is 1200–1500rpm.
- The recommended drill speed for drills 4.25mm diameter or greater is 900rpm.
- The implant placement torque may exceed 50Ncm.
- The recommended implant placement speed is 15–20rpm.
- Final Twist Drill selection is based on clinician evaluation of bone quality.
- Hand ratcheting may be necessary to fully seat the implant into the osteotomy.
- **Tapping is required in dense (Type I) bone for 5.0mm, 6.0mm, 5/4mm and 6/5mm diameter implants.**

ACT® Twist Drill Depth Marks

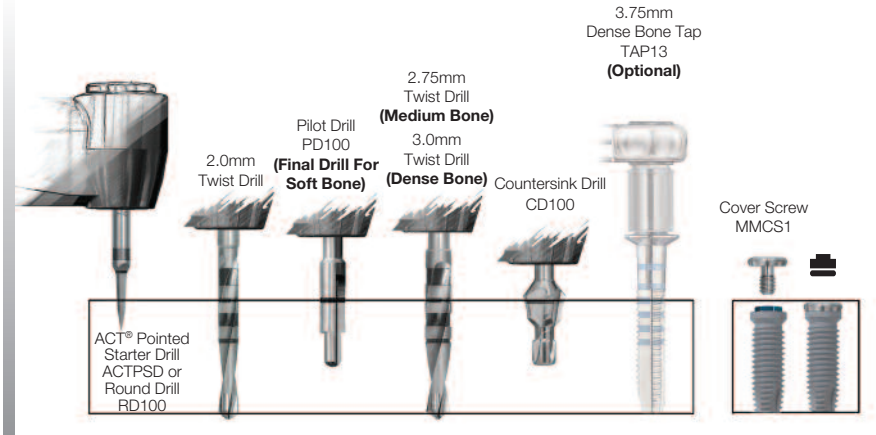


OSSEOTITE® Certain® 2 3.25mm and OSSEOTITE® 2 External Hex 3.25mm Implants



3.25mm(D) x
11.5mm(L) Implant

OSSEOTITE® 2 External Hex 3.75mm Implant



3.25mm(D) x
11.5mm(L) Implant

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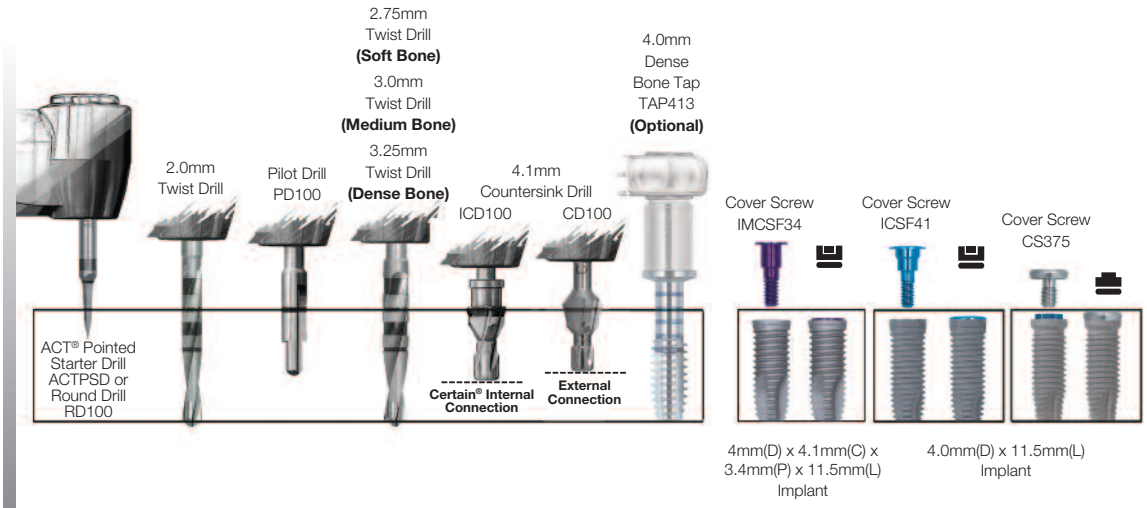
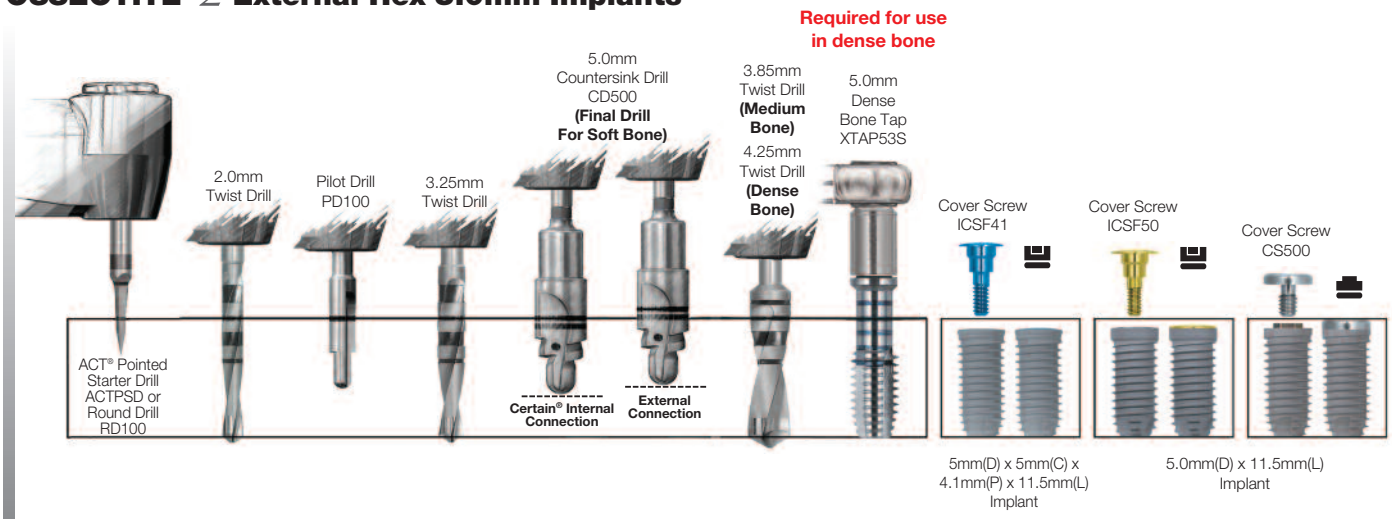
Subcrestal Placement For OSSEOTITE® Certain® PREVAIL® 2, OSSEOTITE® Certain® 2 And OSSEOTITE® 2 External Hex Parallel Walled Implants (Continued)

OSSEOTITE® Certain® PREVAIL® 2 4/3mm, OSSEOTITE® Certain® 2 4.0mm And OSSEOTITE® 2 External Hex 4.0mm Implants

D = Diameter
C = Collar
P = Platform
L = Length

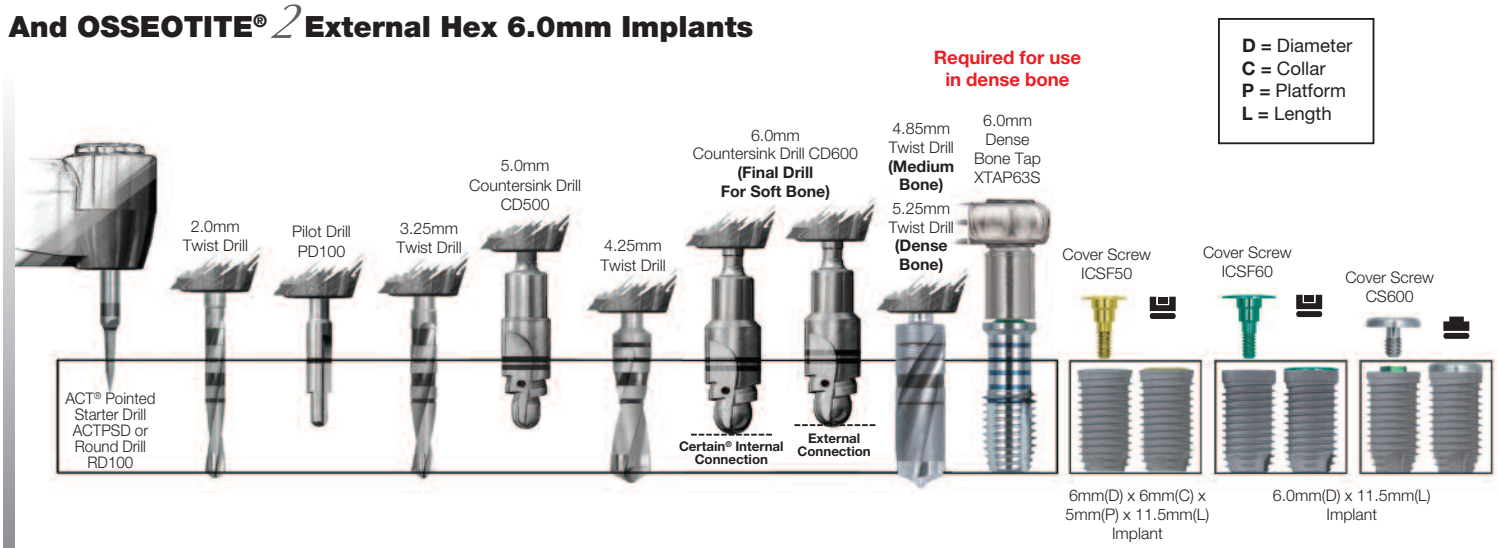


OSSEOTITE® Certain® PREVAIL® 2 5/4mm, OSSEOTITE® Certain® 2 5.0mm And OSSEOTITE® 2 External Hex 5.0mm Implants



Subcrestal Placement For OSSEOTITE® Certain® PREVAIL® 2, OSSEOTITE® Certain® 2 And OSSEOTITE® 2 External Hex Parallel Walled Implants (Continued)

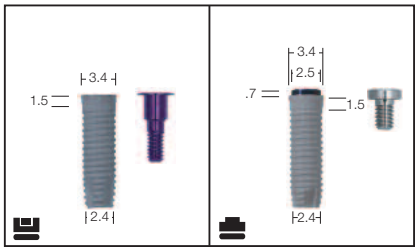
OSSEOTITE® Certain® PREVAIL® 2 6/5mm, OSSEOTITE® Certain® 2 6.0mm And OSSEOTITE® 2 External Hex 6.0mm Implants

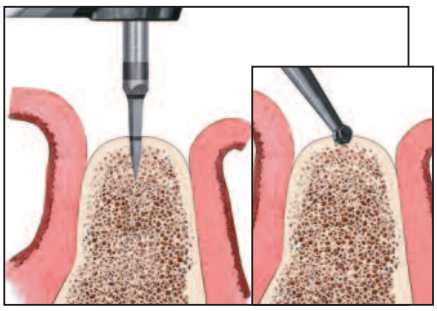


Subcrestal Surgical Protocol

OSSEOTITE® Certain® 2 And OSSEOTITE® 2 External Hex 3.25mm Diameter Implants

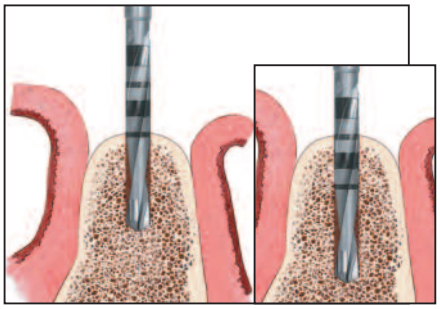
For a quick reference guide to implant placement, refer to page 13.





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.

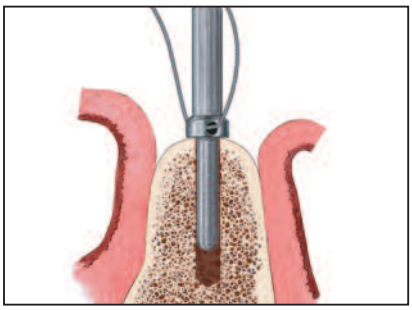
- Instruments needed:
  ACT® Pointed Starter Drill (ACTPSD)
  or
  Round Drill (RD100 or DR100)



2. Proceed with the Initial Twist Drill to approximately 7.0mm, then verify the direction with the thin portion of the Direction Indicator.

Continue to advance the drill into the osteotomy to the desired depth. The recommended drill speed is 1200 –1500rpm.

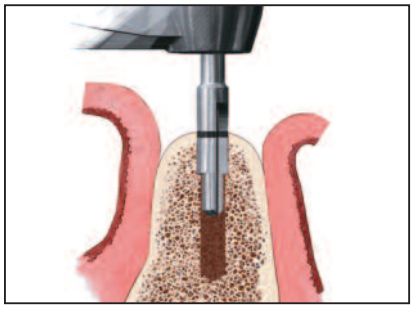
- Instruments needed:
  2.0mm Twist Drill
  Direction Indicator (DI100 or DI2310)



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

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

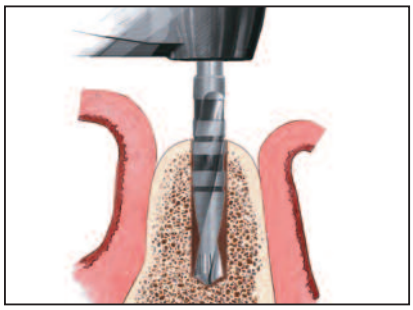
- Instruments needed:
  Direction Indicator (DI100 or DI2310)
  Gelb Radiographic Depth Gauge (XDGXX)



4. Use the Pilot Drill to shape the coronal aspect of the implant site. Drill to the depth mark.
The recommended drill speed is 1200 –1500rpm.

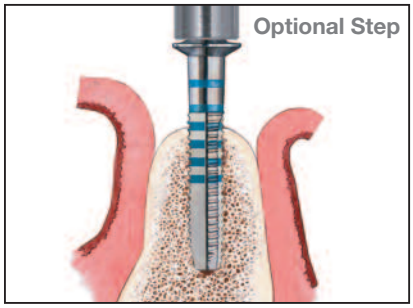
For **soft bone** (Type IV), this is the final drill. Proceed to **step 1** on **page 28** for implant placement.

- Instruments needed:
  Pilot Drill (PD100 or DP100)



5. Once proper alignment is verified using the Direction Indicator, proceed with the 2.75mm Twist Drill to the desired depth for implant placement in medium bone (Type II and III). Proceed with the 3.0mm Twist Drill to the desired depth for implant placement in dense bone (Type I). The recommended drill speed is 1200 –1500rpm.

- Instruments needed:
  2.75mm Twist Drill for medium bone (Type II and III)
  3.0mm Twist Drill for dense bone (Type I)



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

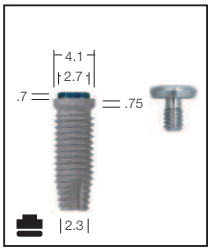
- Instruments needed:
  Bone Tap (MTAP1 or MTAP2)
  Ratchet Wrench (WR150)
  Ratchet Extension (RE100 or RE200)

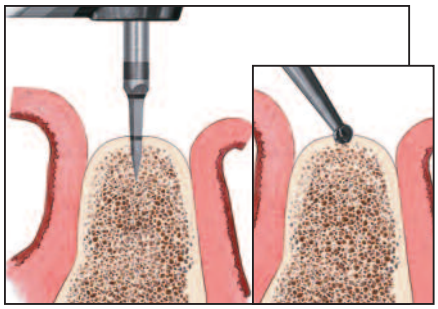
Proceed to **step 1** on **page 28** for implant pick up and placement.

For more information on various **bone densities,** please see **page 12**.

Subcrestal Surgical Protocol
OSSEOTITE® 2 External Hex
3.75mm Diameter Implant

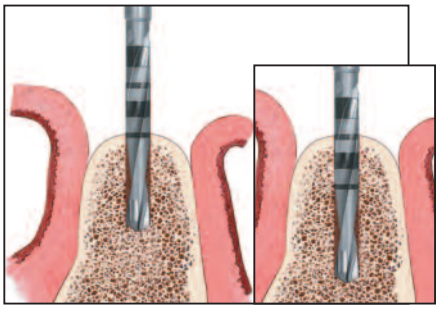
For a quick reference guide to implant placement, refer to page 13.





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.

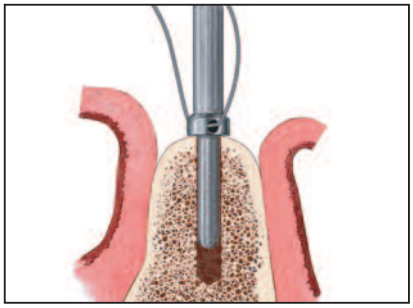
- Instruments needed:
  ACT® Pointed Starter Drill (ACTPSD)
  or
  Round Drill (RD100 or DR100)



2. Proceed with the Initial Twist Drill to approximately 7.0mm, then verify the direction with the thin portion of the Direction Indicator.

Continue to advance the drill into the osteotomy to the desired depth. The recommended drill speed is 1200 –1500rpm.

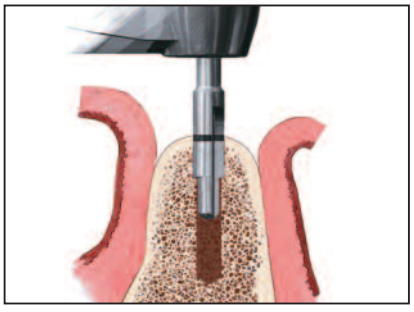
- Instruments needed:
  2.0mm Twist Drill
  Direction Indicator (DI100 or DI2310)



3. Verify the direction and position of the preparation by inserting the thin portion of the Direction Indicator into the osteotomy. Thread a suture 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)



4. Use the Pilot Drill to shape the coronal aspect of the implant site. Drill to the depth mark. The recommended drill speed is 1200 –1500rpm.

- Instruments needed:
  Pilot Drill (PD100 or DP100)

For **soft bone** (Type IV), skip **step 5** and proceed to **step 6** on **page 19**.

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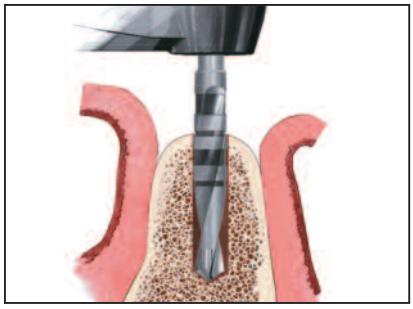
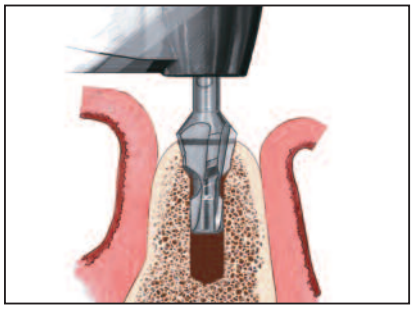


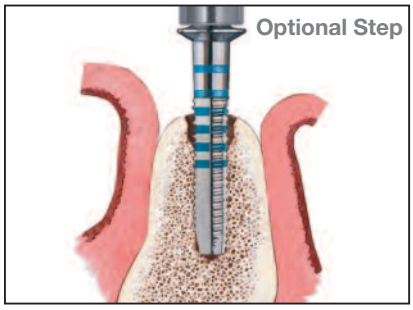
5. Once proper alignment is verified using the Direction Indicator, proceed with the 2.75mm Twist Drill to the desired depth for implant placement in medium bone (Type II and III). Proceed with the 3.0mm Twist Drill to the desired depth for implant placement in dense bone (Type I). The recommended drill speed is 1200 –1500rpm.

- Instruments needed:
  2.75mm Twist Drill for medium bone (Type II and III)
  3.0mm Twist Drill for dense bone (Type I)



6. Using the Countersink Drill, prepare the bone to accept the 4.5mm flared cover screw of the 3.75mm diameter implant for subcrestal placement. Drill to the center of the depth mark for subcrestal placement. The recommended drill speed is 1200 –1500rpm.

- Instruments needed:
  Countersink Drill (CD100)



Optional Tapping Step For Dense Bone (Type I)
If placing a 3.75mm diameter implant in dense bone (Type I), using a Bone Tap is recommended.

- Instruments needed:
  Bone Tap - 3.75mm (TAP10, TAP13 or TAP20)
  Ratchet Wrench (WR150)
  Ratchet Extension (RE100 or RE200)

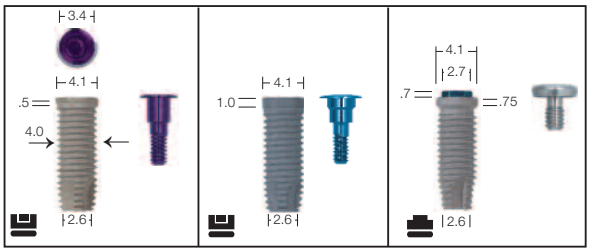
Proceed to **step 1** on **page 28** for implant pick up and placement.

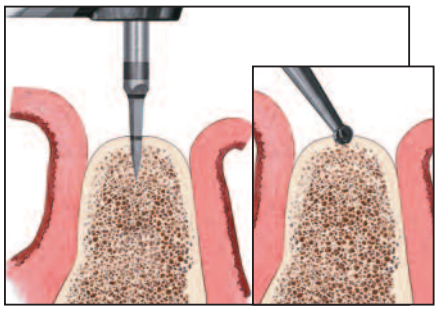
For more information on various **bone densities,** please see **page 12**.

Subcrestal Surgical Protocol

OSSEOTITE® Certain® PREVAIL® 2 4/3mm, OSSEOTITE® Certain® 2 4.0mm And OSSEOTITE® 2 External Hex 4.0mm Diameter Implants

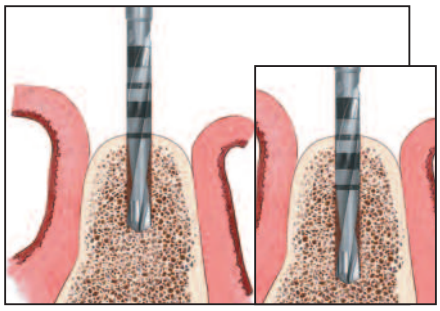
For a quick reference guide to implant placement, refer to page 14.





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.

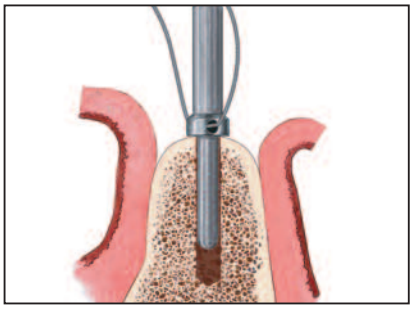
- Instruments needed:
  ACT® Pointed Starter Drill (ACTPSD)
  or
  Round Drill (RD100 or DR100)



2. Proceed with the initial Twist Drill to approximately 7.0mm, then verify the direction with the thin portion of the Direction Indicator.

Continue to advance the drill into the osteotomy to the desired depth. The recommended drill speed is 1200 –1500rpm.

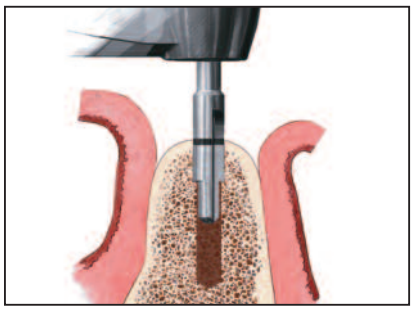
- Instruments needed:
  2.0mm Twist Drill
  Direction Indicator (DI100 or DI2310)



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

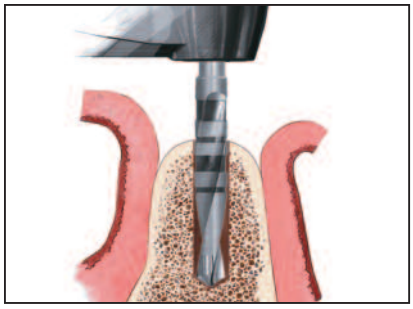
At this step, a Gelb Radiographic Depth Gauge may also be used.

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



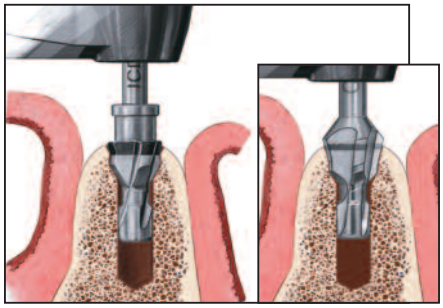
4. Use the Pilot Drill to shape the coronal aspect of the implant site. Drill to the depth mark. The recommended drill speed is 1200 –1500rpm.

- Instruments needed:
  Pilot Drill (PD100 or DP100)



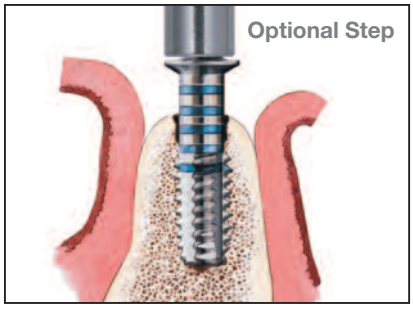
5. Once proper alignment is verified using the Direction Indicator, proceed with the 2.75mm Twist Drill to the desired depth for implant placement in soft bone (Type IV). Proceed with the 3.0mm Twist Drill to the desired depth for implant placement in medium bone (Type II and III). Proceed with the 3.25mm Twist Drill for implant placement in dense bone (Type I). The recommended drill speed is 1200 –1500rpm.

- Instruments needed:
  2.75mm Twist Drill for soft bone (Type IV)
  3.0mm Twist Drill for medium bone (Type II and III)
  3.25mm Twist Drill for dense bone (Type I)



6. Using the Countersink Drill, prepare the bone to accept a 4.0mm diameter implant. Drill to the top of the depth mark for subcrestal placement of Certain® Internal Connection Implants. Drill to the center of the depth mark for subcrestal placement of External Connection Implants.The recommended drill speed is 1200 –1500rpm.

- Instruments needed:
  Countersink Drill (ICD100)
  Countersink Drill (CD100)



Optional Tapping Step For Dense Bone (Type I)
If placing a 4.0mm diameter implant in dense bone (Type I), using a bone tap is recommended.

- Instruments needed:
  Bone Tap (TAP410, TAP413 or TAP420)
  Ratchet Wrench (WR150)
  Ratchet Extension (RE100 or RE200)

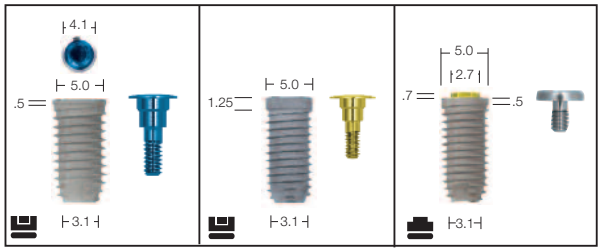
Proceed to **step 1** on **page 28** for implant pick up and placement.

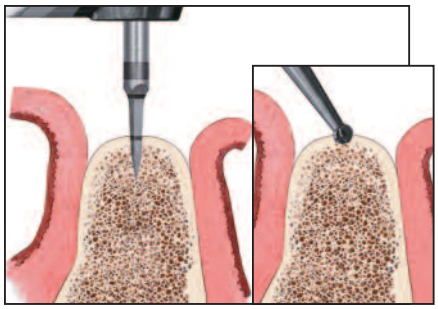
For more information on various **bone densities,** please see **page 12**.

Subcrestal Surgical Protocol

OSSEOTITE® Certain® PREVAIL®2 5/4mm, OSSEOTITE® Certain®2 5.0mm And OSSEOTITE®2 External Hex 5.0mm Diameter Implants

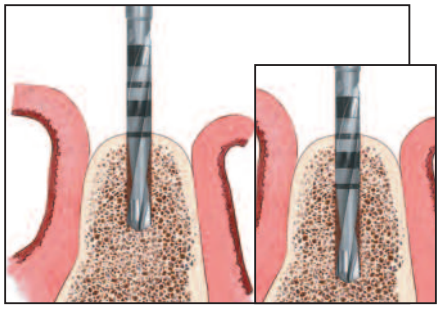
For a quick reference guide to implant placement, refer to page 14.





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.

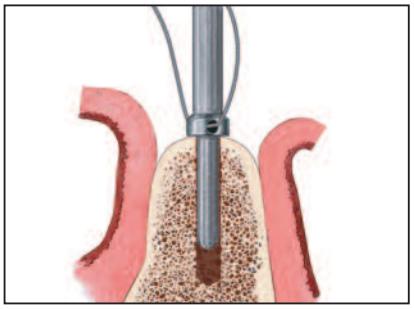
- Instruments needed:
  ACT® Pointed Starter Drill (ACTPSD)
  or
  Round Drill (RD100 or DR100)



2. Proceed with the initial Twist Drill to approximately 7.0mm, then verify the direction with the thin portion of the Direction Indicator.

Continue to advance the drill into the osteotomy to the desired depth. The recommended drill speed is 1200 –1500rpm.

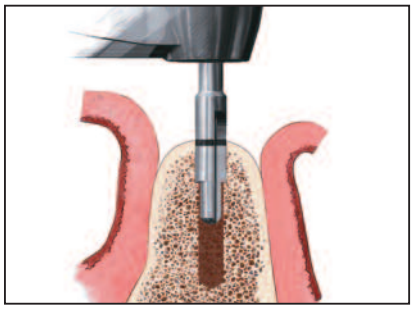
- Instruments needed:
  2.0mm Twist Drill
  Direction Indicator (DI100 or DI2310)



3. Verify the direction and position of the preparation by inserting the thin portion of the Direction Indicator into the osteotomy. Thread a suture 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)



4. Use the Pilot Drill to shape the coronal aspect of the implant site. Drill to the depth mark. The recommended drill speed is 1200 –1500rpm.

- Instruments needed:
  Pilot Drill (PD100 or DP100)

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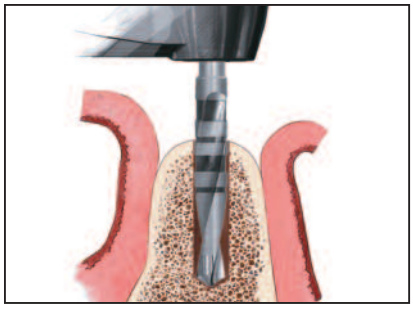
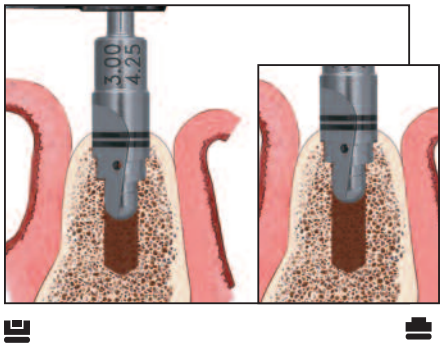


5. Once proper alignment is verified using the Direction Indicator, proceed with the 3.25mm Twist Drill to the desired depth. The recommended drill speed is 1200 –1500rpm.

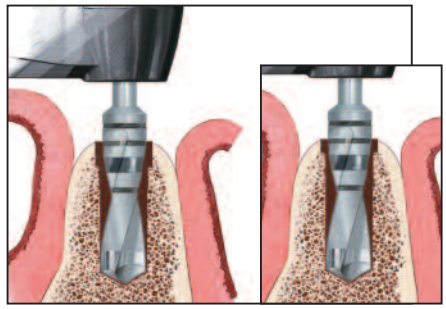
- Instruments needed:
  3.25mm Twist Drill



6. Use the 5.0mm Countersink/Pilot Drill to shape the coronal aspect of the implant site. For subcrestal placement of a Certain® Internal Connection Implant, drill to the top of the ***top*** depth mark. For subcrestal placement of an External Connection Implant, drill to the center of the ***bottom*** depth mark. The recommended drill speed is 900 –1200rpm.

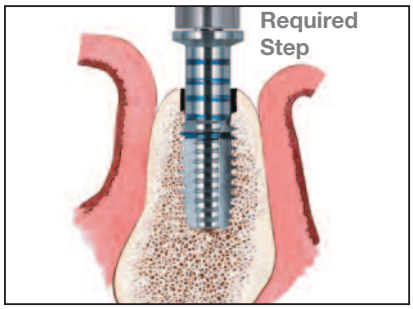
- Instruments needed:
  5.0mm Countersink/Pilot Drill (CD500)

For **soft bone** (Type IV), this is the final drill. Proceed to **step 1** on **page 28** for implant placement.



7. Once the coronal aspect of the osteotomy has been prepared, proceed with the 3.85mm Twist Drill to the desired depth for implant placement in medium bone (Type II and III). Proceed with the 4.25mm Twist Drill to the desired depth for implant placement in dense bone (Type I). The recommended drill speed is 900 –1200rpm.

- Instruments needed:
  3.85mm Twist Drill for medium bone
  (Type II and III) (ACT3815)
  4.25mm Twist Drill for dense bone (Type I)



Required Tapping Step For Dense Bone (Type I)

If placing a 5.0mm diameter implant in dense bone (Type I), using a bone tap is **required**.

- Instruments needed:
  Bone Tap (XTAP58S, XTAP53S or XTAP518S)
  Ratchet Wrench (WR150)
  Ratchet Extension (RE100 or RE200)

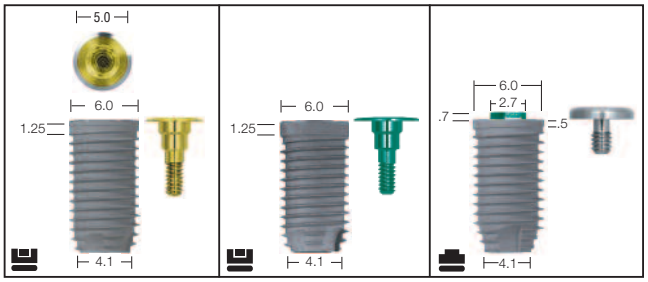
Proceed to **step 1** on **page 28** for implant pick up placement.

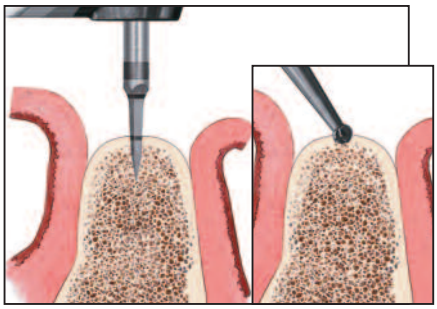
For more information on various **bone densities,** please see **page 12**.

Subcrestal Surgical Protocol

OSSEOTITE® Certain® PREVAIL® 2 6/5mm, OSSEOTITE® Certain® 2 6.0mm And OSSEOTITE® 2 External Hex 6.0mm Diameter Implants

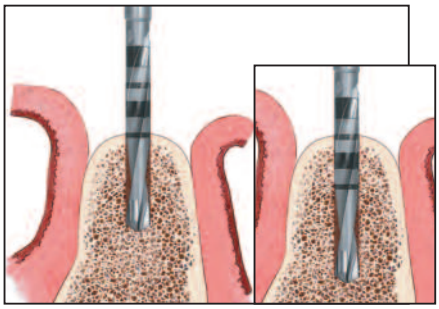
For a quick reference guide to implant placement, refer to page 15.





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.

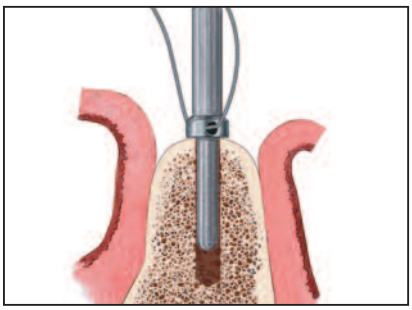
- Instruments needed:
  ACT® Pointed Starter Drill (ACTPSD)
  or
  Round Drill (RD100 or DR100)



2. Proceed with the Initial Twist Drill to approximately 7.0mm, then verify the direction with the thin portion of the Direction Indicator.

Continue to advance the drill into the osteotomy to the desired depth. The recommended drill speed is 1200 –1500rpm.

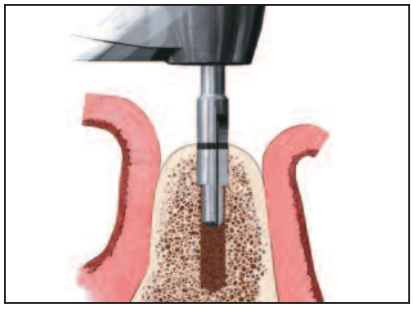
- Instruments needed:
  2.0mm Direction Indicator (DI100 or DI2310)
  2.75mm Twist Drill



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

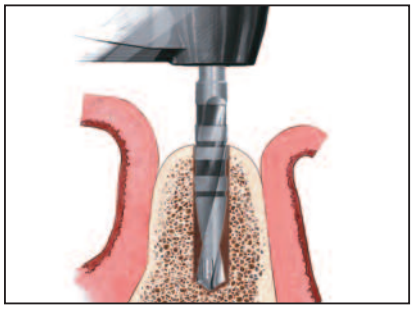
At this step, a Gelb Radiographic Depth Gauge may also be used.

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



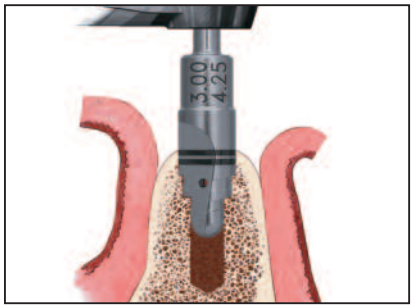
4. Use the Pilot Drill to shape the coronal aspect of the implant site. Drill to the depth mark. The recommended drill speed is 1200–1500rpm.

- Instruments needed:
  Pilot Drill (PD100 or DP100)



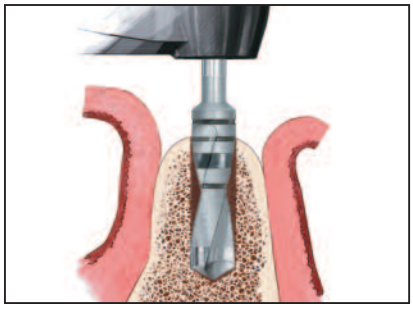
5. Once proper alignment is verified using the Direction Indicator, proceed with the 3.25mm Twist Drill to the desired depth. The recommended drill speed is 1200 –1500rpm.

- Instruments needed:
  3.25mm Twist Drill



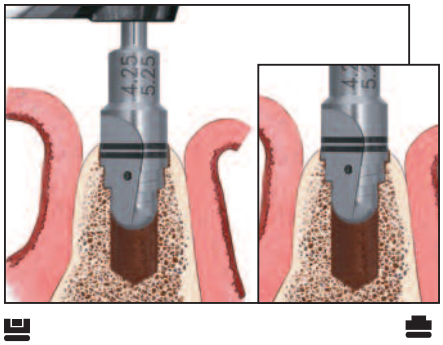
6. Advance the 5.0mm Countersink/Pilot Drill to the top of the top depth mark to widen the coronal aspect of the osteotomy, allowing the 4.25mm Twist Drill to enter the osteotomy. The recommended drill speed is 900 –1200rpm.

- Instruments needed:
  5.0mm Countersink/Pilot Drill (CD500)



7. Once the coronal aspect of the osteotomy has been prepared, proceed with the 4.25mm Twist Drill to the desired depth. The recommended drill speed is 900 –1200rpm.

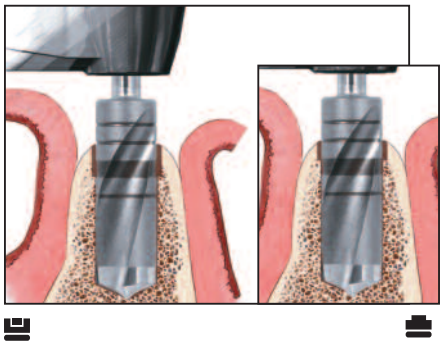
- Instruments needed:
  4.25mm Twist Drill



8. Use the 6.0mm Countersink/Pilot Drill to shape the coronal aspect of the implant site. For subcrestal placement of a Certain® Internal Connection Implant, drill to the top of the ***top*** depth mark. For subcrestal placement of an External Connection Implant, drill to the center of the ***bottom*** depth mark. The recommended drill speed is 900 –1200rpm.

- Instruments needed:
  6.0mm Countersink/Pilot Drill (CD600)

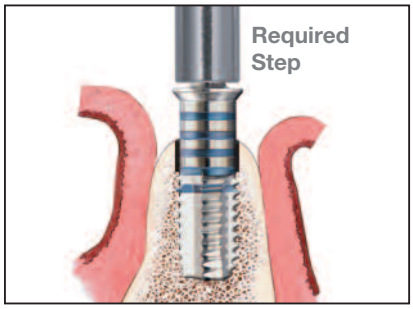
For **soft bone** (Type IV), this is the final drill. Proceed to **step 1** on **page 28** for implant placement.



9. Once the coronal aspect of the osteotomy has been prepared, proceed with the 4.85mm Twist Drill to the desired depth for implant placement in medium bone (Type II and Type III). Proceed with the 5.25mm Twist Drill to the desired depth for implant placement in dense bone (Type I). The recommended drill speed is 900 –1200rpm.

- Instruments needed:
  4.85mm Twist Drill for medium bone (Type II and III)
  5.25mm Twist Drill for dense bone (Type I)

Proceed to **step 1** on **page 28** for implant placement.



Required Tapping Step For Dense Bone (Type I)

If placing a 6.0mm diameter implant in dense bone (Type I), using a bone tap is **required**.

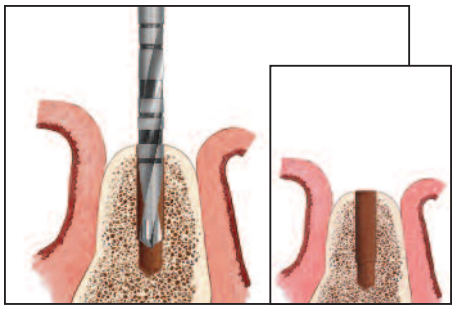
- Instruments needed:
  Bone Tap (XTAP68S, XTAP63S or XTAP618S)
  Ratchet Wrench (WR150)
  Ratchet Extension (RE100 or RE200)

Proceed to **step 1** on **page 28** for implant pick up and placement.

For more information on various **bone densities,** please see **page 12**.

Subcrestal Stepped Surgical Protocol

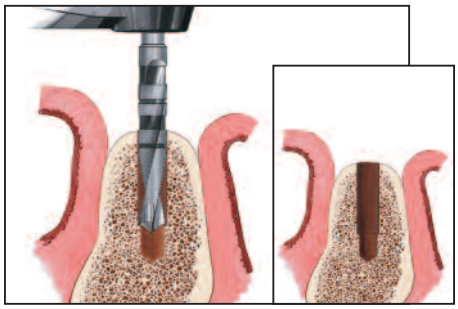
The following is an optional approach to preparing the implant site. This will result in a stepped osteotomy that is undersized at the apex to accommodate the apical taper of the implant. A stepped osteotomy can be achieved by employing the final Twist Drill 3.0mm short of the desired implant length. The following examples are for medium bone only.



OSSEOTITE® Certain® *2* 3.25mm Diameter Parallel Walled Implant In Medium Bone

1. Follow **steps 1-4** on **pages 16-17**.
2. Proceed with the 2.75mm Twist Drill to 3.0mm short of the desired depth.

   Proceed to **step 1** on **page 28** for implant placement.

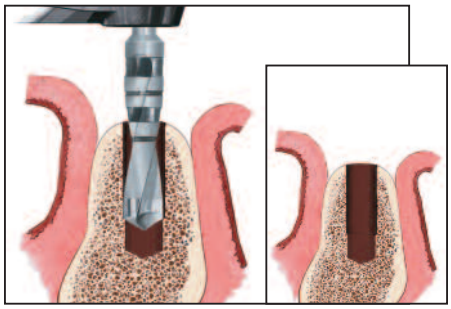


OSSEOTITE® Certain® *2* 4.0mm Diameter Parallel Walled Implant In Medium Bone

1. Follow **steps 1-4** on **page 20**.
2. Proceed with the 3.0mm Twist Drill to 3.0mm short of the desired depth.
3. Using the Countersink Drill, prepare the bone to accept the 4.5mm flared cover screw of the 4.0mm diameter implant for subcrestal placement

   • Instruments Needed:
   Certain® Internal Connection: Countersink Drill (ICD100) - (drill to the top of the laser line for subcrestal placement)
   External connection: Countersink Drill (CD100) – (drill to the center of the laser line for subcrestal placement)

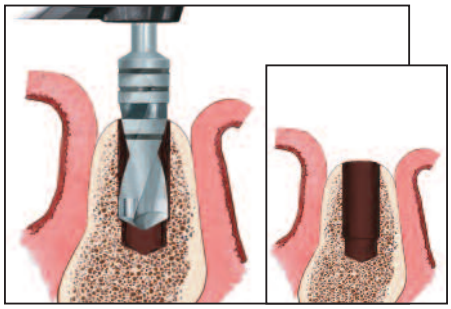
   Proceed to **step 1** on **page 28** for implant placement.



OSSEOTITE® Certain® *2* 5.0mm Diameter Parallel Walled Implant In Medium Bone

1. Follow **steps 1-6** on **pages 22-23**.
2. Proceed with the 3.85mm Twist Drill to 3.0mm short of the desired depth.

   Proceed to **step 1** on **page 28** for implant placement.



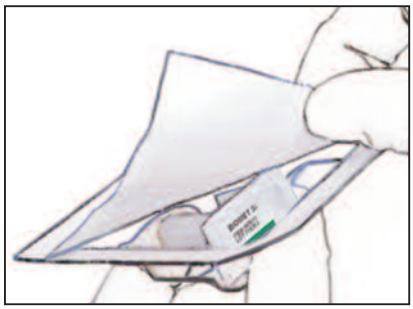
OSSEOTITE® Certain® *2* 6.0mm Diameter Parallel Walled Implant In Medium Bone

1. Follow **steps 1-8** on **pages 24-26**.
2. Proceed with the 4.85mm Twist Drill to 3.0mm short of the desired depth.

   Proceed to **step 1** on **page 28** for implant pick up and placement.

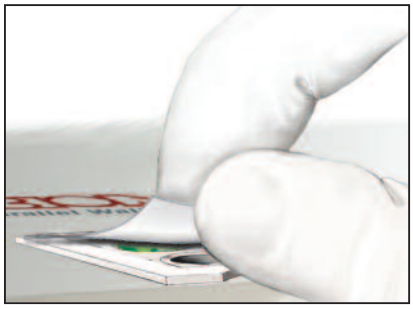
No-Touch™ Delivery System

1. Remove contents from the implant box.

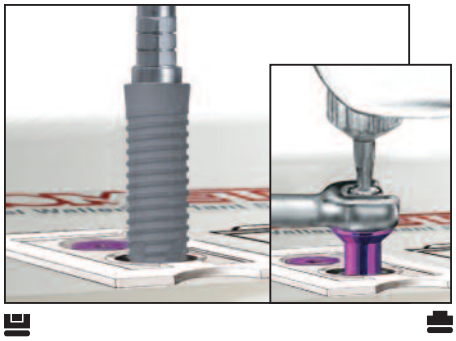


2. The nonsterile assistant should peel back the tray lid and drop the No-Touch™ Implant Tray onto the sterile drape.

3. Place the No-Touch™ Implant Tray into the appropriate location on the surgical tray.



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



Instructions Specific To 3.25mm Diameter Parallel Walled Implants

5. For the 3.25mm external hex implant, pick up the implant mount from the surgical kit using the open-end wrench. Place the mount onto the implant. Once placed on the implant, tighten the mount screw using the hex driver.

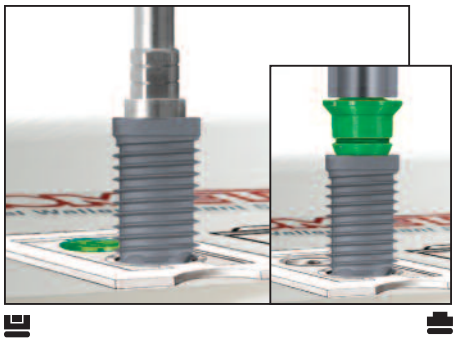
- Instruments needed:
  Open end wrench (CW100)
  Large Hex Driver (PHD02N)
  Implant Mount (MMC03 or MMC15)

For the 3.25mm Certain® Implant, pick up the implant from the surgical tray using the dedicated Certain® Implant Placement Driver Tip.

- Instruments needed:
  Dedicated Certain® 3.25mm(D) Driver Tip (IMPDTS or IMPTDL)

NOTE: The Certain® 3.25mm(D) Implant requires the use of a dedicated Certain® 3.4mm(D) Driver Tip (IMPDTS or IMPDTL) that is marked with a purple band on the shank. The internal connection configuration of the Certain® 3.25mm(D) Implant is smaller than the Certain® Standard 4.0, 5.0 and 6.0mm(D) Implants. The item numbers can be identified on the side of the driver tip.

Proceed to **step 6** on **page 30**.



Instructions Specific To 3.75mm And Larger Diameter Parallel Walled Implants

5. For the external hex implant, pick up the implant from the surgical tray using the Handpiece Connector (MDR10).

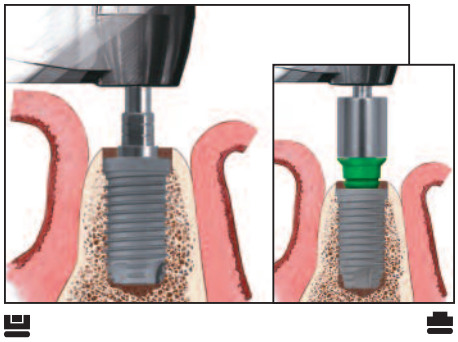
For the Certain® Implant, pick up the implant from the surgical tray using the dedicated Certain® Implant Placement Driver Tip.

For all implants, 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)

Optional Step For External Hex Implant Placement Between Or Adjacent To Teeth:

Remove the pre-attached mount and replace with the standard (long) mount from the surgical kit for the 3.75mm, 4.0mm, 5.0mm and 6.0mm implants. Fully seat the mount and tighten the mount screw using the hex driver.

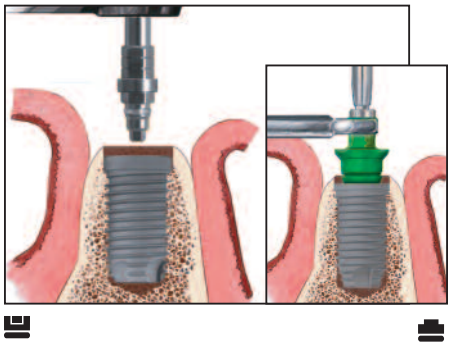


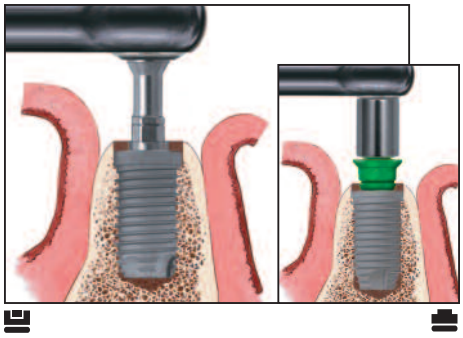
6. Place the implant in the prepared site at approximately 15–20rpm. It is not uncommon for the handpiece to stall before the implant is completely seated. In dense bone (Type I), tapping is required prior to placement for the 5.0mm, 6.0mm, 5/4mm and 6/5mm implants and is optional for the 3.25mm, 3.75mm, 4.0mm and 4/3mm implants.

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 completely loosened, rotate the Open-End Wrench counter-clockwise slightly, remove the Mount Driver tip and Open-End Wrench at the same time.

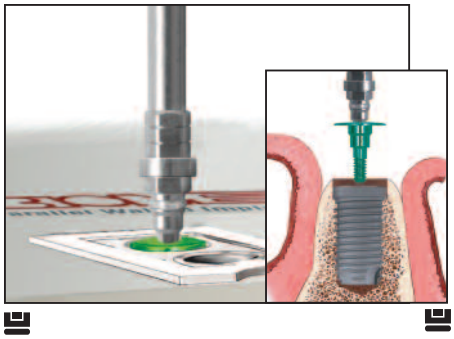
- Instruments needed:
  Open-End Wrench (CW100), Large Hex Driver Tip (RASH3) and Right-Angle Driver (CATDB with CADD1) or a Large Hex Driver (PHD02N)





7. 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
  3.4mm(D) Ratchet Extension (IMRE100 or IMRE200)
  External Connection Ratchet Extension (RE100 or RE200)

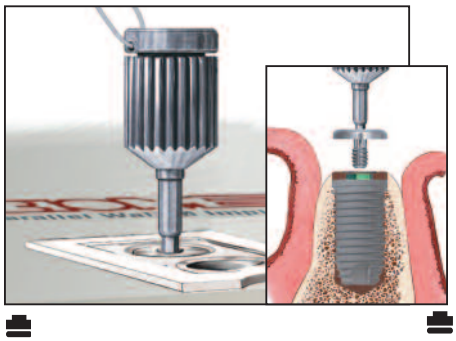


8. Pick up the Cover Screw from the No-Touch™ Implant Tray with the Implant Driver or Large Hex Driver and place onto the implant.

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

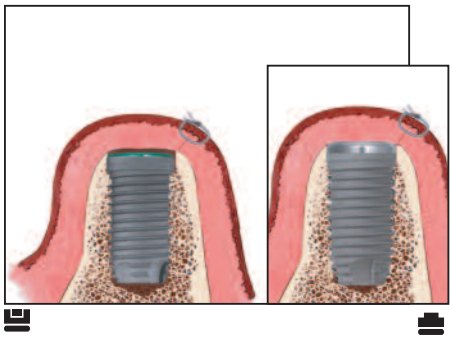
- Instruments needed:
  Implant Placement Driver Tip (IIPDTS or IIPDTL)
  Large Hex Driver (PHD02N)
- For 3.25mm implants:
  3.4mm(D) Driver Tip (IMPDTS or IMPDTL)

or



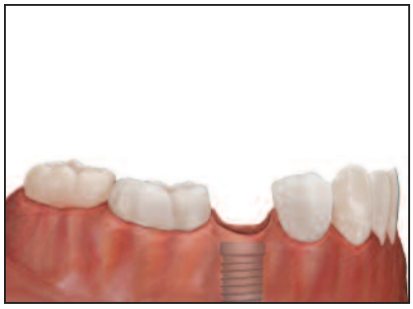
Pick up the Cover Screw from the No-Touch™ Implant Tray with the Small Hex Driver (PHD00N) and place onto the implant. Thread a suture through the hole to prevent accidental swallowing.

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



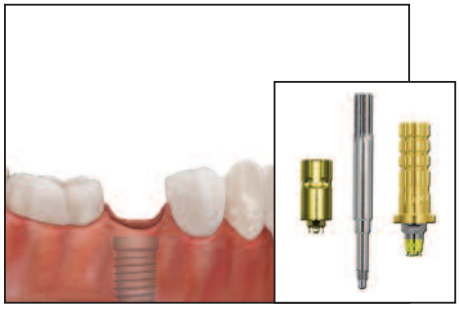
9. Close the soft-tissue flaps and secure with sutures.

Surgical Indexing



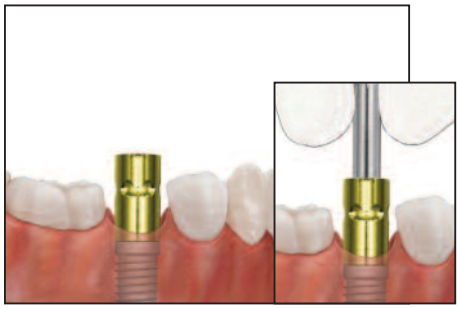
Surgeon

1. For surgical implant placement of a BIOMET 3i™ Implant, follow the normal protocol as described in the previous sections.



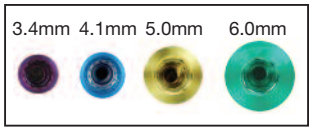
Surgical Indexing

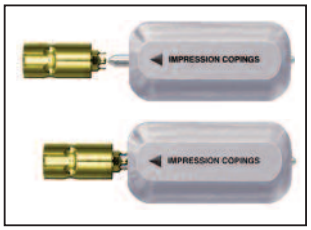
2. A surgical index may be made at stage one or stage two surgery to facilitate the fabrication of a provisional restoration. This can be accomplished by using a Pick-Up Impression Coping (or a Hexed Temporary Cylinder) with retention, a waxing screw and a medium-to-heavy body impression material.



Creating A Surgical Index

3. Select the proper Pick-Up Impression Coping by matching the diameter of the implant platform.

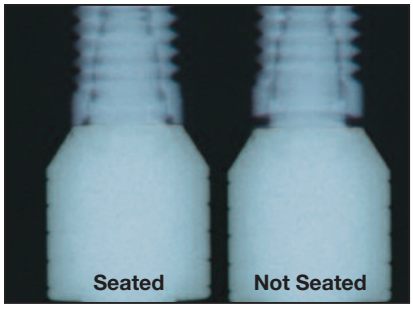




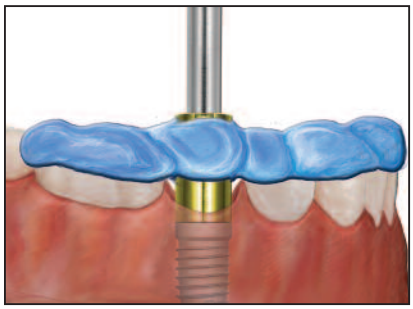
Activate the fingers using the QuickSeat® Activator Tool. Place the Pick-Up Impression Coping or the Temporary Cylinder into the implant, line up the hex and press firmly until feeling the tactile click.

Place the Pick-Up Impression Coping or the Temporary Cylinder on the implant and engage the hex.

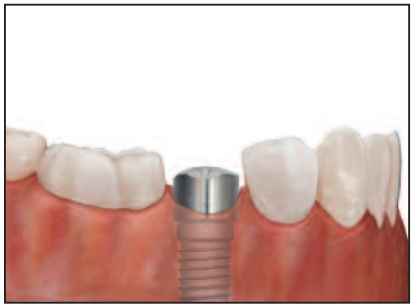
Thread the Pick-Up Impression Coping Screw or waxing screw into the implant until finger tight. Tighten the screw using the Large Hex Driver. If the Impression Coping touches the adjacent teeth, the Impression Coping may need to be modified with a bur or disc.



4. If flapless surgery is performed or if the index is made at stage two surgery, take a radiograph of the interface to verify complete seating of the coping on the implant. Place the film perpendicular to the interface of the coping on the implant.



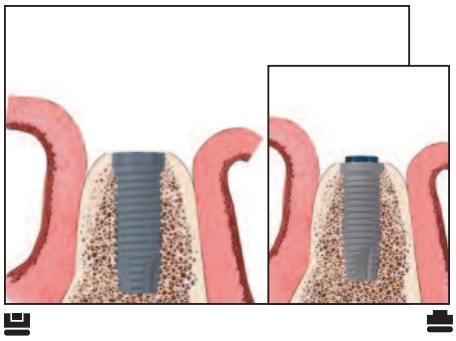
5. Syringe a medium-to-heavy body impression material around the impression coping or temporary cylinder and over the occlusal surfaces of the adjacent teeth (approximately 1.5 teeth on either side). Allow the impression material to set per the manufacturer's instructions. Once the material has set, remove the impression coping screw or waxing screw using the Large Hex Driver. Remove the surgical index from the mouth. Send the index to the restorative clinician so that it may be included in the package to the laboratory. Do not place a laboratory analog into the index.



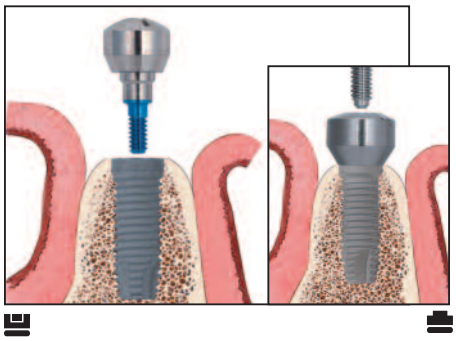
6. Select a healing abutment by matching the implant platform, preferred EP® Diameter and collar height. The collar height should be selected by measuring from the implant platform to the highest crest of the gingival tissue and adding 1.0mm.

Single-Stage Treatment

There may be several advantages in utilizing a two-stage implant system in a single-stage treatment protocol. Attaching a one-piece or two-piece healing abutment immediately following implant placement eliminates the need for a second-stage surgery. Eliminating the second surgical procedure reduces trauma and decreases treatment time, while the two-stage implant design maintains restorative flexibility.



1. Fully seat the implant. If an External Hex Implant is placed, remove the implant mount.

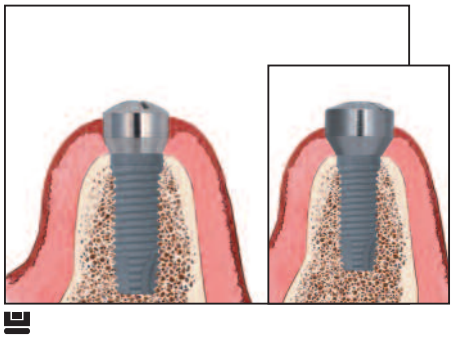


2. Select the appropriate one-piece healing abutment or Encode® Healing Abutment depending upon the implant seating surface, soft-tissue depth and desired EP® Dimension.

or

Select the appropriate one or two-piece healing abutment or Encode® Healing Abutment depending upon the implant seating surface, soft tissue depth and desired EP® Dimension.

Bone profiling of the coronal aspect of the osteotomy may be necessary to fully seat the healing abutment onto the implant.



3. Tighten the one or two-piece healing abutment screw to 20Ncm and secure the soft-tissues with intermittent sutures around the healing abutment.

Bone Profiling

Emergence Profile (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.

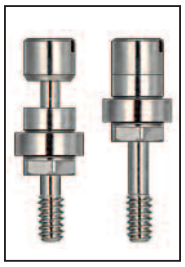
If the implant is placed subcrestally and use of an EP® Healing Abutment is indicated, the coronal aspect of the osteotomy must be prepared to receive the flare of the EP® Healing Abutment.

EP® Bone Profilers correspond to sizes of EP® Healing Abutments

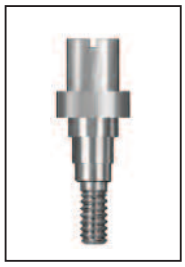
NOTE: Non-EP®, straight healing abutments and impression copings are available if bone profiling is not preferred at either stage one or stage two surgery.

Certain® Internal Two-Piece Bone Profiling Pin (IBPGP)

The Certain® Internal Connection 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.**



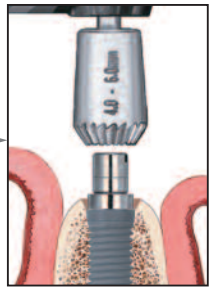
Certain®
Internal Connection
Two-Piece
Bone Profiler Pin



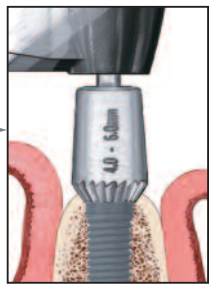
External Connection
One-Piece
Bone Profiler Pin

Bone Profiling Technique

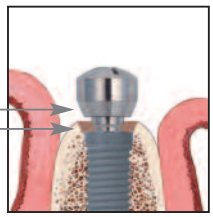
- EP® Bone Profiler slides over the Bone Profiler Pin.



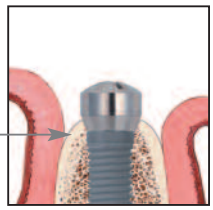
- EP® Bone Profiler creates a flare in the crest of bone.



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



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



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OSSEOTITE 2 Is Pending U.S. FDA 510(k) Clearance

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