No-Touch™ Mountless OSSEOTITE Certain Implant Delivery System

Surgical Protocol Implant Placement

Surgical Protocol Cover Screw Insertion

Surgical Manual
OSSEOTITE® Certain® Implant Systems
And OSSEOTITE External Hex Implant Systems
How To Use The Icon Key:

The icons represent the connection type of the implant system. 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 blue icon and a light blue icon are present together, the dark blue indicates which system is illustrated. When both icons are dark blue, then both systems are illustrated together.

Instructions For Use:

OSSEOTITE®, OSSEOTITE XP®, OSSEOTITE Certain®, Certain PREVAIL™, OSSEOTITE NT®, Miniplant®, Microminiplant™

This manual applies to dental implants and associated surgical components.

Description: 3i Dental Implants are manufactured from biocompatible titanium and titanium alloy. 3i Dental Implants include various surface treatments and coatings. For specific product description and net quantity refer to individual product labels.

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

In addition, when a minimum of four dental implants ≥ 10mm in length, are placed in the mandible and splinted in the anterior region, immediate loading is indicated.

Contraindications: Placement of dental implants may be precluded by patient conditions that are contraindications for surgery. 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 this manual for special storage or handling conditions.

Warnings: Excessive bone loss or breakage of dental implant may occur when an implant is loaded beyond its functional capability. Physiological and anatomic conditions may negatively affect the performance of dental implants. This should be taken into consideration when placing dental implants with the following:

- Poor bone quality
- Poor oral hygiene
- Medical conditions such as blood disorders or uncontrolled hormonal conditions
- 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 3i Dental Implants in patients with poor quality bone.

Precautions: For safe and effective use of 3i Dental Implants and other surgical dental accessories, these products or devices should only be used by trained professionals. The surgical 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 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 this 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 ART530 or this manual prior to use.

Procedural Precautions, Surgery: 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 this manual. Only sharp instruments of the highest quality should be used for any bone surgical procedure. 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.

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.
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OSSEOTITE Implants
These instructions were designed to serve as a reference guide for the dental practitioner to utilize 3i implants and surgical instruments to their maximum potential. 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.

3i’s Unique Designs enable the practitioner to place implants in edentulous or partially edentulous mandibles or maxillae in order to serve as support abutments for fixed and removable bridgework or single tooth crowns and to provide the stabilization needed for securing overdentures. 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.

General Information:
These instructions will instruct practitioners in the use of 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.

**Radiographic Marking Balls (RMB30)**

The vertical height of the bone is best 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: \((5 ÷ A) \times B = \text{amount of actual bone available.}\)

**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:**
- \(A = 6.5\)mm
- \(B = 14\)mm

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

**NOTE:** A 2mm margin of safety, from the apical end of the implant to the adjacent vital structure, should be considered.
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 ideal prosthetic platform and subsequent implant selection based on bony anatomy.

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. 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.
Surgical Precautions

Clinical Considerations
True bone contours can only be evaluated after tissue flaps have been reflected at the time of surgery. 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 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.

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 is referred to as the healing period. Healing periods 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 the 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 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.

To extend the useful life of 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.

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

<table>
<thead>
<tr>
<th>Drill Diameter</th>
<th>ITD/DTN/DT Drill Tip Length</th>
<th>ACT™ Drill Tip Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.00mm</td>
<td>0.6mm</td>
<td>0.6mm</td>
</tr>
<tr>
<td>2.30mm</td>
<td>0.7mm</td>
<td>N/A</td>
</tr>
<tr>
<td>2.75mm</td>
<td>0.8mm</td>
<td>0.9mm</td>
</tr>
<tr>
<td>3.00mm</td>
<td>0.9mm</td>
<td>0.9mm</td>
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<tr>
<td>3.15mm</td>
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<td>1.0mm</td>
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<tr>
<td>3.25mm</td>
<td>1.0mm</td>
<td>1.0mm</td>
</tr>
<tr>
<td>3.85mm</td>
<td>N/A</td>
<td>1.2mm</td>
</tr>
<tr>
<td>4.25mm</td>
<td>0.4mm</td>
<td>1.3mm</td>
</tr>
<tr>
<td>4.85mm</td>
<td>N/A</td>
<td>1.3mm</td>
</tr>
<tr>
<td>5.25mm</td>
<td>0.5mm</td>
<td>1.2mm</td>
</tr>
</tbody>
</table>

NOTE: A drill extension for areas of limited access is available.

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.

The drill depth marks do not indicate implant lengths. Rather, the marks represent the length of the implant with the 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 1mm for the cover screw plus the implant collar height. Refer to the diagram on the bottom of page 10 for more information.

**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.
3i Depth Marking System
Parallel Walled Implants

PREVAIL™, Certain®, External Hex

Drill Marks

The center of the drill’s single line depth marks and the beginning or end of the broad band indicates 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 Marks And Implants

The standard cover screws are 1mm in height for both Certain and External Hex Implants.

Regardless of the implant type, the length of the implant is the same from the top of the implant collar (platform), to the tip of the implant.

The depth marks on the drill represent implant placement where the top of the cover screw (when height of the cover screw is 1mm) is flush with the crest of the bone (subcrestal).

Types Of Twist Drills

ITD Reusable Drills
• Internal Irrigation Lumen
• All Thin Lines

DTN Disposable Drills
• Without Internal Irrigation Lumen
• Bands

ACT™ Reusable Drills
• No Hub
• Without Internal Irrigation
• Alternating Lines And Bands

Tip Dimensions

<table>
<thead>
<tr>
<th>Drill Diameter</th>
<th>ITD/DTN/DT Drill Tip Length</th>
<th>ACT Drill Tip Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.00mm</td>
<td>0.6mm</td>
<td>0.6mm</td>
</tr>
<tr>
<td>2.30mm</td>
<td>0.7mm</td>
<td>N/A</td>
</tr>
<tr>
<td>2.75mm</td>
<td>0.8mm</td>
<td>0.9mm</td>
</tr>
<tr>
<td>3.00mm</td>
<td>0.9mm</td>
<td>0.9mm</td>
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<td>3.15mm</td>
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<td>3.25mm</td>
<td>1.0mm</td>
<td>1.0mm</td>
</tr>
<tr>
<td>3.85mm</td>
<td>N/A</td>
<td>1.2mm</td>
</tr>
<tr>
<td>4.25mm</td>
<td>0.4mm</td>
<td>1.3mm</td>
</tr>
<tr>
<td>4.85mm</td>
<td>N/A</td>
<td>1.3mm</td>
</tr>
<tr>
<td>5.25mm</td>
<td>0.5mm</td>
<td>1.2mm</td>
</tr>
</tbody>
</table>
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 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 and the Ex Hex Implant Mount act as references during implant placement.

<table>
<thead>
<tr>
<th>OSSEOTITE NT* Implant Length (Label)</th>
<th>Actual OSSEOTITE NT Length</th>
<th>Parallel Walled Implant Length (Label)</th>
<th>Actual Parallel Walled Implant Length</th>
<th>Cover Screw Height</th>
<th>Actual Drill Length To Subcrestal Mark</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.5mm</td>
<td>8.1mm</td>
<td>7.0mm</td>
<td>6.6mm</td>
<td>1.0mm</td>
<td>7.8mm</td>
</tr>
<tr>
<td>10.0mm</td>
<td>9.6mm</td>
<td>10.0mm</td>
<td>9.6mm</td>
<td>1.0mm</td>
<td>10.6mm</td>
</tr>
<tr>
<td>11.5mm</td>
<td>11.1mm</td>
<td>11.5mm</td>
<td>11.1mm</td>
<td>1.0mm</td>
<td>12.1mm</td>
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<tr>
<td>13.0mm</td>
<td>12.6mm</td>
<td>13.0mm</td>
<td>12.6mm</td>
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<td>13.6mm</td>
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<tr>
<td>15.0mm</td>
<td>14.6mm</td>
<td>15.0mm</td>
<td>14.6mm</td>
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<td>15.6mm</td>
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<td>18.0mm</td>
<td>17.6mm</td>
<td>18.0mm</td>
<td>17.6mm</td>
<td>1.0mm</td>
<td>18.6mm</td>
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<tr>
<td>20.0mm</td>
<td>19.6mm</td>
<td>20.0mm</td>
<td>19.6mm</td>
<td>1.0mm</td>
<td>20.6mm</td>
</tr>
</tbody>
</table>

*From point on drill at which maximum diameter starts. (Drill depth mark is .5mm wide). Drill length listed in chart does not include drill tip.

NOTE: A 2mm margin of safety from the apical end of the implant to the adjacent vital structure should be considered.
### 3i Depth Marking System

**Parallel Walled Implants**

#### Subcrestal Placement
- The implant platform will be 1mm (or more) **below** the bone crest.
- Mostly used in the anterior region for aesthetics.

<table>
<thead>
<tr>
<th>Certain*</th>
<th>External Hex</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src=".." alt="Drill Tip" /></td>
<td><img src=".." alt="Drill Tip" /></td>
</tr>
<tr>
<td>11.5mm</td>
<td>11.5mm</td>
</tr>
<tr>
<td>10mm</td>
<td>10mm</td>
</tr>
<tr>
<td>8.5mm</td>
<td>8.5mm</td>
</tr>
<tr>
<td>7mm</td>
<td>7mm</td>
</tr>
<tr>
<td>Drill Tip max 1.3mm</td>
<td>Drill Tip max 1.3mm</td>
</tr>
<tr>
<td>11.5mm implants</td>
<td>11.5mm implants</td>
</tr>
</tbody>
</table>

For Subcrestal Certain and External Hex implant placement, Drill to the drill depth mark that corresponds to the labeled implant length.

A Countersink Drill is used when placing a 4mm diameter implant subcrestally to prepare the bone to accept the cover screw. Remember, for a 4mm diameter implant, the implant platform is 4.1mm in diameter and the cover screw flares to 4.5mm in diameter.

#### Crestal Placement
- The implant platform will be **at** the bone crest.

<table>
<thead>
<tr>
<th>Certain</th>
<th>External Hex</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src=".." alt="Drill Tip" /></td>
<td><img src=".." alt="Drill Tip" /></td>
</tr>
<tr>
<td>11.5mm</td>
<td>11.5mm</td>
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<tr>
<td>10mm</td>
<td>10mm</td>
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<tr>
<td>8.5mm</td>
<td>8.5mm</td>
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<tr>
<td>7mm</td>
<td>7mm</td>
</tr>
<tr>
<td>Drill Tip max 1.3mm</td>
<td>Drill Tip max 1.3mm</td>
</tr>
<tr>
<td>11.5mm implants</td>
<td>11.5mm implants</td>
</tr>
</tbody>
</table>

For Crestal Certain and External Hex implant placement, stop drilling **1mm before** the drill depth mark that corresponds to the labeled implant length (1mm equals cover screw height).

A Countersink Drill is generally not needed because the cover screw for the 4mm diameter implant will stay above the bone crest. It may be needed in hard bone due to the shape of the implant collar.
Supracrestal Placement

- The implant collar will be above the bone crest.
- The height of the implant platform above the bone crest varies with the implant type being placed—see diagram below.

For Supracrestal Certain implant placement, stop drilling 2.25mm before the drill depth mark that corresponds to the labeled implant length (2.25mm equals 1mm cover screw height plus 1.25mm Certain Implant collar height).

For Supracrestal External Hex implant placement, stop drilling 1.75mm before the drill depth mark that corresponds to the labeled implant length (1.75mm equals 1mm cover screw height plus 0.75mm External Hex Standard Implant collar height).

A Countersink Drill is not needed.

Implant Collar Height

- The height of the implant platform above the bone varies with the specific implant type being placed.

<table>
<thead>
<tr>
<th>Implant Type</th>
<th>Collar Height</th>
</tr>
</thead>
<tbody>
<tr>
<td>MicroMiniplant™ Implants</td>
<td>1.50mm</td>
</tr>
<tr>
<td>Certain Implants</td>
<td>1.25mm</td>
</tr>
<tr>
<td>OSSEOTITE NT® Implants</td>
<td>1.25mm</td>
</tr>
<tr>
<td>External Hex Standard Implants</td>
<td>0.75mm</td>
</tr>
<tr>
<td>External Hex Wide Implants</td>
<td>0.50mm</td>
</tr>
</tbody>
</table>
**Countersink Drill Marking System**

**Important Information Concerning Countersink Drills CD500 and CD600:**
A second depth mark has been added to the 5mm and 6mm diameter Countersink Drills (CD500 & CD600). The bottom line (closest to the apex) is positioned where the original single line has traditionally been. The top line (closest to the shank) has been added to accommodate the OSSEOTITE® Certain® Implant.

**Subcrestal Implant Placement**

**Crestal Implant Placement**

**Important Information Concerning Countersink Drills DC100, CD100, CD4500 and CD5600:**

**Subcrestal Placement**

**Crestal Placement**
Mountless Delivery Guidelines
OSSEOTITE® Certain® Implant

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

**Pick-Up And Delivery Of Cover Screw Or Healing Abutment**

The 0.048 inch tip of the Certain Implant Placement Driver 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), reduce the torque setting on the drilling unit to 10Ncm.

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

**NOTE:** Periodic O-Ring replacement is required for the Certain Driver Tips.
OSSEOTITE® Parallel Walled Implant Surgical Tray

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

The OSSEOTITE Parallel Walled Implant Surgical Tray 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 Surgical Tray illustrating numbering sequence.
Subcrestal Implant Placement Protocol - Quick Reference

Certain® PREVAIL™ 3/4/3mm Implant

- 2.0 or 2.3mm Twist Drill
- 2.75 or 3.0mm Twist Drill
- 4mm C’sink Depth Indicator
- Round Drill RD100
- Pilot Drill PD100
- C’sink Drill ICD100
- Cover Screw ICSF41
- 3/4/3mm Implant II05411

See page 21 for detailed instructions.

Certain PREVAIL 4/5/4mm Implant

- 2.0 or 2.3mm Twist Drill
- 3.0 or 3.25mm Twist Drill
- 4/5mm C’sink Depth Indicator
- Round Drill RD100
- Pilot Drill PD100
- C’sink Drill CD4550
- Cover Screw ICSF41
- 4/5/4mm Implant II054511

See page 23 for detailed instructions.
Subcrestal Implant Placement Protocol - Quick Reference

Certain® PREVAIL™ 5/6/5mm Implant

- 2.0 or 2.3mm Twist Drill
- Pilot Drill PD100
- 3.0 or 3.25mm Twist Drill
- C’sink Drill CD500
- 4.25mm Twist Drill
- 5/6mm C’sink Drill CD5600
- 5/6mm C’sink Depth Indicator CD5600
- Round Drill RD100
- Cover Screw ICSF50
- 5/6/5mm Implant IID55611

See page 25 for detailed instructions.
**OSSEOTITE® Certain® And OSSEOTITE External Hex MicroMiniplant™ 3.25mm Implant**

- 2.0 or 2.3mm Twist Drill
- 2.75 or 3.0mm Twist Drill
- Pilot Drill PD100
- Cover Screw IMMCS1
- Cover Screw MMCS1
- Round Drill RD100
- 3.25mm Implant IOSM311
- 3.25mm implant OSS311

See page 30 for detailed instructions.

**OSSEOTITE External Hex Standard 3.75mm And OSSEOTITE XP® 3/4mm Implant**

- 2.0 or 2.3mm Twist Drill
- Pilot Drill PD100
- 2.75 or 3.0mm Twist Drill
- Cover Screw CS375
- Ch’ink Drill CD100
- Round Drill RD100
- 3.75mm Implant OSS311

See page 32 for detailed instructions.
Subcrestal Implant Placement Protocol - Quick Reference

Certain® PREVAIL™ 4/3mm And OSSEOTITE® Certain 4.0mm Implant

OSSEOTITE External Hex 4.0mm Implant

See page 34 for detailed instructions.
Certain® PREVAIL™ 5/4mm And OSSEOTITE® Certain 5.0mm Implant

OSSEOTITE External Hex 5.0mm Implant

See page 36 for detailed instructions.
Subcrestal Implant Placement Protocol - Quick Reference

**OSSEOTITE® Certain® 6.0mm Implant**

- 2.0 or 2.3mm Twist Drill
- Pilot Drill PD100
- 3.0 or 3.25mm Twist Drill
- 4.25mm Twist Drill
- 6mm Pilot/C’sink Drill CD600
- 5.25mm Twist Drill
- Cover Screw ICS600

Round Drill RD100

See page 38 for detailed instructions.

**OSSEOTITE External Hex 6.0mm Implant**

- 2.0 or 2.3mm Twist Drill
- Pilot Drill PD100
- 3.0 or 3.25mm Twist Drill
- 4.25mm Twist Drill
- 6mm Pilot/C’sink Drill CD600
- 5.25mm Twist Drill
- Cover Screw CS600

Round Drill RD100

6.0mm Implant OSS611

See page 38 for detailed instructions.
OSSEOTITE XP® 4/5mm External Hex Implant

- 2.0 or 2.3mm Twist Drill
- Pilot Drill PD100
- 3.0 or 3.25mm Twist Drill
- 5mm Pilot/C’sink Drill CD4500
- Round Drill RD100
- Cover Screw CS500
- XP 4/5mm Implant OS4511

See page 23 for detailed instructions.

OSSEOTITE XP 5/6mm External Hex Implant

- 2.0 or 2.3mm Twist Drill
- Pilot Drill PD100
- 3.0 or 3.25mm Twist Drill
- 5mm Pilot/C’sink Drill CD500
- 4.25mm Twist Drill
- C’link Drill CD5600
- Round Drill RD100
- Cover Screw CS600
- XP 5/6mm Implant OS5611

See page 25 for detailed instructions.
Subcrestal Implant Placement Protocol

Certain® PREVAIL™ 3/4/3mm Diameter Implant

For a quick reference guide to implant placement, refer to page 14 for OSSEOTITE® Certain PREVAIL 3/4/3mm Implant.

1. Once the implant site has been determined, mark the site with a Round Drill and penetrate the cortical bone. The recommended drill speed is 1200–1500rpm.
   • Instruments needed:
     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.
   Continue to penetrate the bone to the desired depth. The recommended drill speed is 1200–1500rpm.
   • Instruments needed:
     2.0 or 2.3mm Twist Drill
     (ITD215, DT215, DTN215 or ACT2015)

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 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 3.0mm Twist Drill to the desired depth for implant placement in normal dense bone. Proceed with the 2.75mm Twist Drill to the desired depth for implant placement in soft Type IV Bone. The recommended drill speed is 1200–1500rpm.

- Instruments needed:
  3.0mm Twist Drill for normal dense bone (ITD315, DT315, DTN315 or ACT3015)
  2.75mm Twist Drill for soft Type IV Bone (ITD2715, DT2715, DTN2715 or ACT2715)

6. Use the Certain® Countersink Drill to shape the coronal aspect of the osteotomy. Drill to the top of the depth mark for subcrestal placement. The recommended drill speed is 1200–1500rpm.

- Instruments needed:
  Certain Countersink Drill (ICD100)

**NOTE:** Drilling to the bottom of the depth mark on the ICD100 will prepare the osteotomy for crestal placement and not subcrestal placement of implant.

7. Verify the direction and position of the preparation by inserting the Countersink Depth Indicator into the osteotomy.

- Instruments needed:
  Countersink Depth Indicator (ICD100)

Proceed to step 10a on page 28 for Certain PREVAIL™ Implant Placement.
Subcrestal Implant Placement Protocol

Certain® PREVAIL™ 4/5/4mm And OSSEOTITE XP® 4/5mm Diameter External Hex Implant

For a quick reference guide to implant placement, refer to page 14 for OSSEOTITE® Certain PREVAIL 4/5/4mm Implant and to page 20 for OSSEOTITE XP 4/5mm Implant.

1. Once the implant site has been determined, mark the site with a Round Drill and penetrate the cortical bone. The recommended drill speed is 1200–1500rpm.
   - Instruments needed: 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. Continue to penetrate the bone to the desired depth. The recommended drill speed is 1200–1500rpm.
   - Instruments needed: 2.0 or 2.3mm Twist Drill (ITD215, DT215, DTN215 or ACT2015)

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 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 for implant placement in normal dense bone. Proceed with the 3.0mm Twist Drill to the desired depth for implant placement in soft Type IV Bone. The recommended drill speed is 1200–1500rpm.

- Instruments needed:
  3.25mm Twist Drill for normal dense bone (ITD3215, ACT3215, DT3215 or DTN3215)
  3.0mm Twist Drill for soft Type IV Bone (ITD315, ACT3015, DT315 or DTN315)

6. Use the flared cutting edge on the Countersink Drill to shape the coronal aspect of the osteotomy. Drill to the top of the depth mark for subcrestal placement. The recommended drill speed is 1200–1500rpm.

- Instruments needed:
  4/5 Countersink Drill (CD4500)

**NOTE:** Drilling to the bottom of the depth mark on the CD4500 will prepare the osteotomy for crestal placement and not subcrestal placement of implant.

7. Verify the direction and position of the preparation by inserting the CDI4500 4/5 Countersink Depth Indicator into the osteotomy.

- Instruments needed:
  4/5 Countersink Depth Indicator (CDI4500)

Proceed to step 10a on page 28 for Certain® PREVAIL™ and OSSEOTITE XP® External Hex Implant Placement.
Subcrestal Implant Placement Protocol
Certain® PREVAIL™ 5/6/5mm And OSSEOTITE XP® 5/6mm Diameter External Hex Implant

For a quick reference guide to implant placement, refer to page 15 for OSSEOTITE® Certain PREVAIL 5/6/5mm Implant and to page 20 for OSSEOTITE XP 5/6mm Implant.

1. Once the implant site has been determined, mark the site with a Round Drill and penetrate the cortical bone. The recommended drill speed is 1200–1500rpm.
   - Instruments needed:
     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.
   - Instruments needed:
     2.0 or 2.3mm Twist Drill (ITD215, DT215, DTN215 or ACT2015)

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 hole to prevent accidental swallowing.
   - Instruments needed:
     Direction Indicator (DI100 or DI2310)
     Gelb Radiographic Depth Gauge (XDGXX)

At this step, a Gelb Radiographic Depth Gauge may also be used.
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 for implant placement in normal dense bone. Proceed with the 3.0mm Twist Drill to the desired depth for implant placement in soft Type IV Bone. The recommended drill speed is 1200–1500rpm.

   • Instruments needed:
     3.25mm Twist Drill for normal dense bone (ITD3215, ACT3215, DT3215 or DTN3215)
     3.0mm Twist Drill for soft Type IV Bone (ITD315, ACT3015, DT315 or DTN315)

6. Use the 5mm Countersink Drill to shape the coronal aspect of the osteotomy. Drill to the center of the top depth mark for subcrestal placement. The recommended drill speed is 1200–1500rpm.

   • Instruments needed:
     5/6/5 Countersink Drill (CD500)

   NOTE: Drilling to the center of the bottom depth mark on the CD500 will prepare the osteotomy for crestal placement and not subcrestal placement of implant.

7. Proceed with the 4.25mm Twist Drill to the desired depth for implant placement in normal dense bone. Proceed with the 3.85mm Twist Drill for implant placement in soft Type IV Bone. The recommended drill speed is 1200–1500rpm.

   • Instruments needed:
     4.25mm Twist Drill for normal dense bone (ITD423, DTN423, DT423 or ACT4213)
     3.85mm Twist Drill for soft Type IV Bone (ACT3815)
8. Use the flared cutting edge on the 5/6/5 Countersink Drill to shape the coronal aspect of the osteotomy. Drill to the top of the depth mark for subcrestal placement. The recommended drill speed is 900rpm.

- Instruments needed:
  5/6/5 Countersink Drill (CD5600)

**NOTE:** Drilling to the bottom of the depth mark on the CD5600 will prepare the osteotomy for crestal placement and not subcrestal placement of implant.

9. Verify the direction and position of the preparation by inserting the 5/6 Countersink Depth Indicator into the osteotomy.

- Instruments needed:
  5/6 Countersink Depth Indicator (CDI5600)
Subcrestal Implant Placement Protocol

Certain® PREVAIL™ And OSSEOTITE XP®
External Hex Implant Placement

**No-Touch™ Delivery System**

10a. Remove contents from the implant box.

10b. A nonsterile assistant should peel back the tray lid and drop the No-Touch Implant Tray onto the sterile drape.

10c. Place the No-Touch Implant Tray into the appropriate location on the surgical tray.

10d. Peel back the tray lid to expose the implant and cover screw.
Subcrestal Implant Placement Protocol
Certain® PREVAIL™ And OSSEOTITE XP® External Hex Implant Placement

11. Pick up the implant from the surgical tray using the Certain Implant Placement Driver Tip (IIPDTS or IIPDTL). 
   **NOTE:** The Certain MicroMiniplant™ (3.25mm dia.) requires the use of a dedicated MicroMiniplant Driver Tip (IMPDTS or IMPDTL) that is marked with a purple band on the shank. The Internal Hex configuration of the MicroMiniplant is smaller than the standard Certain Internal Hex Connection (4, 5 and 6mm dia. implants). The item numbers can be identified on the side of the driver tip.

12. Place the implant in the prepared site at approximately 15–20rpm. The ICE™ Design will allow smooth and precise implant placement without tapping in all but the most dense bone. The recommended drill torque setting for placing an implant is 40–50Ncm.

13. To remove the Certain Implant Placement Driver Tip from the implant, lift straight up and out.
   or
   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)

14. Pick up the cover screw from the surgical tray using the Certain Implant Placement Driver Tip (IIPDTS or IIPDTL) or Large Hex Driver (PHD02N) and place onto the implant.
   **NOTE:** When using the Certain Implant Placement Driver, reduce the torque setting on the drilling unit to 10Ncm.
   or
   Pick up the cover screw from the surgical tray using the Small Hex Driver (PHD00N) and place onto the implant. The Small Hex Driver may be used for all External Hex Cover Screws. Final hand-tightening of the cover screw should be done with the Small Hex Driver.
   **NOTE:** At this step, a temporary healing abutment may be placed for single-stage surgery instead of a cover screw.

15. Close tissue and suture.
Subcrestal Implant Placement Protocol
OSSEOTITE® Certain® And OSSEOTITE®
External Hex MicroMiniplant™
3.25mm Diameter Implant

Refer to page 16 for a quick reference guide to OSSEOTITE Certain and OSSEOTITE External Hex MicroMiniplant Implant Placement Protocols.

1. Once the implant site has been determined, mark the site with a Round Drill and penetrate the cortical bone. The recommended drill speed is 1200–1500rpm.
   - Instruments needed: 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.
   - Instruments needed: 2.0 or 2.3mm Twist Drill (ITD215, DT215, DTN215 or ACT2015)

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 hole to prevent accidental swallowing.
   - At this step, a Gelb Radiographic Depth Gauge may also be used.
   - Instruments needed: Direction Indicator (D1100 or DI2310)
     Gelb Radiographic Depth Gauge (XDGXX)
Subcrestal Implant Placement Protocol
OSSEOTITE® Certain® And OSSEOTITE External Hex MicroMiniplant™
3.25mm Diameter Implant

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 3.0mm Twist Drill to the desired depth for implant placement in normal dense bone. Proceed with the 2.75mm Twist Drill to the desired depth for implant placement in soft Type IV Bone. The recommended drill speed is 1200–1500rpm.

• Instruments needed:
  3.0mm Twist Drill for normal dense bone (ITD315, DT315, DTN315 or ACT3015)
  2.75mm Twist Drill for soft Type IV Bone (ITD2715, DT2715, DTN2715 or ACT2715)

Proceed to step 10a on page 41 for OSSEOTITE Certain and OSSEOTITE External Hex Implant Placement.
Subcrestal Implant Placement Protocol
OSSEOTITE® Standard 3.75mm And OSSEOTITE XP® 3/4mm Diameter External Hex Implant

For a quick reference guide to implant placement, refer to page 16 for OSSEOTITE Standard 3.75mm Implant and OSSEOTITE XP 3/4mm Implant.

1. Once the implant site has been determined, mark the site with a Round Drill and penetrate the cortical bone. The recommended drill speed is 1200–1500rpm.
   • Instruments needed: 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. Continue to penetrate the bone to the desired depth. The recommended drill speed is 1200–1500rpm.
   • Instruments needed: 2.0 or 2.3mm Twist Drill (ITD215, DT215, DTN215 or ACT2015)

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 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)
**Subcrestal Implant Placement Protocol**

*OSSEOTITE® Standard 3.75mm And OSSEOTITE XP® 3/4mm Diameter External Hex Implant*

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 3.0mm Twist Drill to the desired depth for implant placement in normal dense bone. Proceed with the 2.75mm Twist Drill to the desired depth for implant placement in soft Type IV Bone. The recommended drill speed is 1200–1500rpm.

- Instruments needed:
  - 3.0mm Twist Drill for normal dense bone (ITD315, DT315, DTN315 or ACT3015)
  - 2.75mm Twist Drill for soft Type IV Bone (ITD2715, DT2715, DTN2715 or ACT2715)

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)

Proceed to step 10a on page 41 for OSSEOTITE Certain® and OSSEOTITE XP External Hex Implant Placement.
**Subcrestal Implant Placement Protocol**

**Certain® PREVAIL™ 4/3mm, OSSEOTITE® Certain And OSSEOTITE External Hex 4.0mm Diameter Implant**

Refer to page 17 for a quick reference guide to Certain PREVAIL 4/3mm, OSSEOTITE Certain and OSSEOTITE External Hex 4.0mm Implant Placement Protocols.

1. Once the implant site has been determined, mark the site with a Round Drill and penetrate the cortical bone. The recommended drill speed is 1200–1500rpm.
   - Instruments needed:
     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. Continue to penetrate the bone to the desired depth. The recommended drill speed is 1200–1500rpm.
   - Instruments needed:
     2.0 or 2.3mm Twist Drill (ITD215, DT215, DTN215 or ACT2015)

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 hole to prevent accidental swallowing.
   - Instruments needed:
     Direction Indicator (DI100 or DI2310)
     Gelb Radiographic Depth Gauge (XDGXX)

At this step, a Gelb Radiographic Depth Gauge may also be used.
Subcrestal Implant Placement Protocol

Certain® PREVAIL™ 4/3mm, OSSEOTITE® Certain And OSSEOTITE External Hex 4.0mm Diameter Implant

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 for implant placement in normal dense bone. Proceed with the 3.0mm Twist Drill to the desired depth for implant placement in soft Type IV Bone. The recommended drill speed is 1200–1500rpm.

- Instruments needed:
  - 3.25mm Twist Drill for normal dense bone (ITD3215, ACT3215, DT3215 or DTN3215)
  - 3.0mm Twist Drill for soft Type IV Bone (ITD315, ACT3015, DT315 or DTN315)

6. Using the Countersink Drill, prepare the bone to accept the 4.5mm flared cover screw of the 4.0mm diameter implant for subcrestal placement. The recommended drill speed is 1200–1500rpm.

- Instruments needed:
  - Countersink Drill (ICD100) - Certain (Drill to the top of the laser line for subcrestal placement)
  - Countersink Drill (CD100) - External Hex (Drill to the center of the laser line for subcrestal placement)

Proceed to step 10a on page 41 for Certain PREVAIL, OSSEOTITE Certain and OSSEOTITE External Hex Implant Placement.
Subcrestal Implant Placement Protocol

Certain® PREVAIL™ 5/4mm, OSSEOTITE® Certain And OSSEOTITE External Hex 5.0mm Diameter Implant

Refer to page 18 for a quick reference guide to Certain PREVAIL 5/4mm, OSSEOTITE Certain and OSSEOTITE External Hex 5.0mm Implant Placement Protocols.

1. Once the implant site has been determined, mark the site with a Round Drill and penetrate the cortical bone. The recommended drill speed is 1200–1500rpm.
   - Instruments needed:
     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.
   Continue to penetrate the bone to the desired depth. The recommended drill speed is 1200–1500rpm.
   - Instruments needed:
     2.0 or 2.3mm Twist Drill (ITD215, DT215, DTN215 or ACT2015)

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 hole to prevent accidental swallowing.
   At this step, a Gelb Radiographic Depth Gauge may also be used.
   - Instruments needed:
     Direction Indicator (D1100 or DI2310)
     Gelb Radiographic Depth Gauge (XDGXX)
**Subcrestal Implant Placement Protocol**

*Certain® PREVAIL™ 5/4mm, OSSEOTITE® Certain And OSSEOTITE External Hex 5.0mm Diameter Implant*

4. **.tool** 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. **.tool** Once proper alignment is verified using the Direction Indicator, proceed with the 3.25mm Twist Drill to the desired depth for implant placement in normal dense bone. Proceed with the 3.0mm Twist Drill to the desired depth for implant placement in soft Type IV Bone. The recommended drill speed is 1200–1500rpm.

- Instruments needed:
  - 3.25mm Twist Drill for normal dense bone (ITD3215, ACT3215, DT3215 or DTN3215)
  - 3.0mm Twist Drill for soft Type IV Bone (ITD315, ACT3015, DT315 or DTN315)

6. **tool** Use the 5mm Countersink/Pilot Drill to shape the coronal aspect of the implant site. For subcrestal placement, drill to the center of the top depth mark for OSSEOTITE Certain Implant placement or drill to the center of the bottom depth mark for an OSSEOTITE External Hex Implant placement. The recommended drill speed is 900rpm.

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

7. **tool** Once the coronal aspect of the osteotomy has been prepared, proceed with the 4.25mm Twist Drill to the desired depth for implant placement in normal dense bone. Proceed with the 3.85mm Twist Drill to the desired depth for implant placement in soft Type IV Bone. The recommended drill speed is 1200–1500rpm.

- Instruments needed:
  - 4.25mm Twist Drill for normal dense bone (ITD423, ACT4213, DT423 or DTN423)
  - 3.85mm Twist Drill for soft Type IV Bone (ACT3815)

Proceed to step 10a on page 41 for Certain PREVAIL, OSSEOTITE Certain and OSSEOTITE External Hex Implant Placement.
Subcrestal Implant Placement Protocol
OSSEOTITE® Certain® And OSSEOTITE External Hex 6.0mm Diameter Implant

Refer to page 19 for a quick reference guide to OSSEOTITE Certain and OSSEOTITE External Hex 6.0mm Implant Placement Protocols.

1. ✂️ Once the implant site has been determined, mark the site with a Round Drill and penetrate the cortical bone. The recommended drill speed is 1200–1500rpm.
   • Instruments needed: 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.
   Continue to penetrate the bone to the desired depth. The recommended drill speed is 1200–1500rpm.
   • Instruments needed: 2.0 or 2.3mm Twist Drill (ITD215, DT215, DTN215 or ACT2015)

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 hole to prevent accidental swallowing.
   At this step, a Gelb Radiographic Depth Gauge may also be used.
   • Instruments needed: Direction Indicator (D1100 or D12310) Gelb Radiographic Depth Gauge (XDGXX)
**Subcrestal Implant Placement Protocol**

*OSSEOTITE® Certain® And OSSEOTITE External Hex 6.0mm Diameter Implant*

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 for implant placement in normal dense bone. Proceed with the 3.0mm Twist Drill to the desired depth for implant placement in soft Type IV Bone. The recommended drill speed is 1200–1500rpm.

   - Instruments needed:
     3.25mm Twist Drill for normal dense bone (ITD3215, ACT3215, DT3215 or DTN3215)
     3.0mm Twist Drill for soft Type IV Bone (ITD315, ACT3015, DT315 or DTN315)

6. Advance the 5mm Countersink/Pilot Drill to the first cutting groove to widen the coronal aspect of the osteotomy, allowing the 4.25mm Twist Drill to enter the osteotomy. The recommended drill speed is 900rpm.

   - Instrument 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 900rpm.

   - Instruments needed:
     4.25mm Twist Drill (ITD423, ACT4213, DT423 or DTN423)
8. Use the 6.0mm Countersink/Pilot Drill to shape the coronal aspect of the implant site. For subcrestal placement, drill to the center of the top depth mark for OSSEOTITE®Certain® Implant placement or drill to the center of the bottom depth mark for an OSSEOTITE External Hex Implant placement. The recommended drill speed is 900rpm.

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

9. Once the coronal aspect of the osteotomy has been prepared, proceed with the 5.25mm Twist Drill to the desired depth for implant placement in normal dense bone. Proceed with the 4.85mm Twist Drill to the desired depth for implant placement in soft Type IV Bone. The recommended drill speed is 900rpm.

- Instruments needed:
  5.25mm Twist Drill for normal dense bone
  (ITD523, ACT5213, DT523 or DTN523)
  4.85mm Twist Drill for soft Type IV Bone (ACT4813)

Proceed to step 10a on page 41 for OSSEOTITE Certain and OSSEOTITE External Hex Implant Placement.
Subcrestal Implant Placement Protocol

Certain® PREVAIL™, OSSEOTITE® Certain And OSSEOTITE External Hex Implant Placement

No-Touch™ Delivery System

10a. Remove contents from the implant box.

10b. A nonsterile assistant should peel back the tray lid and drop the No-Touch Implant Tray onto the sterile drape.

10c. Place the No-Touch Implant Tray into the appropriate location on the surgical tray.

10d. Peel back the tray lid to expose the implant and cover screw.
11. Pick up the implant from the surgical tray using the Certain® Implant Placement Driver Tip (IIPDTS or IIPDTL).

**NOTE:** The Certain MicroMiniplant™ (3.25mm dia.) requires the use of a dedicated MicroMiniplant Driver Tip (IMPDTS or IMPDTL) that is marked with a purple band on the shank. The Internal Hex configuration of the MicroMiniplant is smaller than the standard Certain Internal Hex Connection (4, 5 and 6mm dia. 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 (MDR10).

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

12. Place the implant in the prepared site at approximately 15–20rpm. The ICE™ Design will allow smooth and precise implant placement without tapping in all but the most dense bone. The recommended drill torque setting for placing an implant is 40–50Ncm.

13. To remove the Certain Implant Placement Driver Tip from the implant, lift straight up and out.

or

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)
14. Pick up the cover screw from the surgical tray using the Certain Implant Placement Driver Tip (IIPDTS or IIPDTL) or Large Hex Driver (PHD02N) and place onto the implant.

\[\text{NOTE: When using the Certain Implant Placement Driver, reduce the torque setting on the drilling unit to 10Ncm.}\]

or

\[\text{Pick up the cover screw from the surgical tray using the Small Hex Driver (PHD00N) and place onto the implant. The Small Hex Driver may be used for all External Hex Cover Screws. Final hand-tightening of the cover screw should be done with the Small Hex Driver.}\]

\[\text{NOTE: At this step, a temporary healing abutment may be placed for single-stage surgery instead of a cover screw.}\]

15. Close tissue and suture.
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 OSSEOTITE NT Depth Indicators (NTDI) were designed to confirm OSSEOTITE NT Implant position prior to seating the implant. 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 OSSEOTITE NT Implant will be positioned when properly placed. If during placement with the power drill, the OSSEOTITE NT Implant platform is higher in relation to the bone than was 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), which may result in pressure necrosis of the surrounding bone. The clinician may consider undersizing the osteotomy in extremely soft bone density (e.g. Type IV).
Quad Shaping Drill (QSD)

Introduction

The Quad Shaping Drills (QSDs) are used to prepare the osteotomy for placement of OSSEOTITE NT® Implants.

What Are the Features of the New Quad Shaping Drills?

• The depth references on the QSD Drills are ledges or steps and the hub has been eliminated. The hubless feature improves access and flow of external irrigation.

• The QSD Drills have four flutes to improve cutting efficiency and reduce drill chatter.

• The QSD Drills have end cutting capability.

• The QSD Drill design eliminates laser lines, producing a drill that is more resistant to corrosion in those areas.

• The operating speed for the QSD Drills is 1200–1500rpm to correspond to the speed of other drills used during the procedure (such as the Round Bur and Initial Twist Drill).

*Gingival Depth Marks - These depth marks are not used in the surgical procedure covered in this manual.
Quad Shaping Drill (QSD)

Key Points

**Shaping Drill Speed:**

Quad Shaping Drills should operate between 1200–1500rpm. Quad Shaping Drills cut efficiently; reducing the downward force will allow the drill to cut without 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 Quad Shaping Drill (full depth - see illustration).
- 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 full 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 out. In addition to preserving the integrity of the osteotomy site, this technique maximizes autogenous bone recovery from the shaping drill flutes.
- When placing an OSSEOTITE NT® Implant into softer Type IV Bone, the surgeon should consider undersizing the osteotomy by one shaping drill size (i.e. if placing an OSSEOTITE NT 5mm diameter X 10mm length implant in Type IV Bone, 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 59 of this manual.
- It is recommended that the clinician should tap the osteotomy when placing an OSSEOTITE NT Implant into harder Types I and II Bone.

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.

**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.
OSSEOTITE NT®
Depth Indicator (NTDI)

Introduction

The OSSEOTITE NT Depth Indicators are used to simulate the implant platform position prior to placing the implant.

When using the NTDI, verify the osteotomy is clear of bone debris.

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.

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, then final hand ratcheting of the implant into the osteotomy is required. If the surgical motor stalls prior to full placement of the implant due to insufficient torque generation, the clinician should consider hand ratcheting for final positioning.

These guidelines will help ensure good bone-to-implant contact and primary stability of the implant.
OSSEOTITE NT® Implant Taps

Introduction

When placing an OSSEOTITE NT Implant in dense (Types I and II) bone, the clinician should consider tapping the osteotomy prior to implant placement.

The OSSEOTITE NT Implant Taps are all 8.5mm in length and are designed to tap the coronal aspect of the osteotomy for all implant lengths. For both crestal and subcrestal OSSEOTITE NT Implant placement, the tap is advanced into the osteotomy until the junction of the colored mount and the tap body is level with the crest of the bone.
OSSEOTITE NT® NTDI/QSD
Surgical Tray

Coordinating The Use Of The Surgical Tray With The Surgical Manual Illustrations:
The OSSEOTITE NT NTDI/QSD Surgical Tray is numbered to indicate the appropriate steps of the implant placement protocol. The following illustrated implant placement protocol uses the same numbering sequence.
Subcrestal Implant Placement Protocol - Quick Reference

OSSEOTITE NT® Certain® And OSSEOTITE NT External Hex Implants Using Quad Shaping Drills - QSD/NTDI

2.0 or 2.3mm Twist Drill
Pilot Drill PD100
3.25mm Quad Drill QSD32XX
3.25mm NTDI
4.0mm Quad Drill QSD4XX
4.0mm NTDI
5.0mm Quad Drill QSD5XX
5.0mm NTDI
6.0mm Quad Drill QSD6XX
6.0mm NTDI

Round Drill RD190

OSSEOTITE NT Certain Implants With Cover Screws
INT32XX
INT4XX
INT5XX
INT6XX

OR

OSSEOTITE NT External Hex Implants With Cover Screws
NT32XX
NT4XX
NT5XX
NT6XX

Subcrestal Placement
Crestal Placement

See pages 51–68 for detailed instructions.
Subcrestal Implant Placement Protocol
OSSEOTITE NT® Certain® And OSSEOTITE NT External
Hex 3.25mm Diameter Implant Using QSD/NTDI

Refer to page 50 for a quick reference guide to OSSEOTITE NT Implant Placement Protocol using Quad Shaping Drills.

1. Once the implant site has been determined, mark the site with a round drill and penetrate the cortical bone. The recommended drill speed is 1200–1500rpm.
   - Instruments needed:
     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. Continue to penetrate the bone to the desired depth. Set the drill speed at approximately 1200–1500rpm.
   - Instruments needed:
     2.0 or 2.3mm Twist Drill (ITD215, DT215, DTN215 or ACT2015)

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 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. With hard cortical bone, use the Pilot Drill to shape the coronal aspect of the implant site. Drill to the depth mark for placement of an OSSEOTITE NT Implant. The apical end of a 3.25mm Shaping Drill is smaller in diameter than the osteotomy created by the 2.3mm Initial Twist Drill. The recommended drill speed is 1200–1500rpm.
   - Instruments needed:
     Pilot Drill (PD100 or DP100)
Final Shaping Drill Step For 3.25mm OSSEOTITE NT® Implant:

5a. Proceed with the 3.25mm QSD Shaping Drill that is the same length as the OSSEOTITE NT Implant to be placed. The recommended drill speed is 1200–1500rpm.

- Instruments needed:
  3.25mm QSD Shaping Drill (QSD32XX)

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

5c. Insert the tapered end of the 3.25mm NTDI Depth/Direction Indicator (purple) that corresponds to the length of the OSSEOTITE NT 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 Depth/Direction Indicator does not indicate proper osteotomy depth, adjust the depth of the osteotomy with the corresponding 3.25mm QSD Shaping Drill or consider a longer length implant if the site has been over prepared. Re-evaluate with a proper length NTDI Depth/Direction Indicator.

NOTE: If placing a 3.25mm OSSEOTITE NT Implant in Type I or Type II Bone, tapping with the NTAP32 is recommended.

Continue on for placement of 4.0, 5.0 and 6.0mm OSSEOTITE NT Implants.

Proceed to step 9a on page 56 for OSSEOTITE NT Implant Placement.
Subcrestal Implant Placement Protocol
OSSEOTITE NT® Certain® And OSSEOTITE NT External Hex 4.0mm Diameter Implant Using QSD/NTDI

Second Shaping Drill Step For Placement Of 4.0, 5.0 And 6.0mm OSSEOTITE NT Implant. Final Shaping Drill Step For 4.0mm OSSEOTITE NT Implant.

6a. Continue preparing the osteotomy with the 4.0mm QSD Shaping Drill that is the same length as the OSSEOTITE NT Implant to be placed. The recommended drill speed is 1200–1500rpm.

- Instruments needed:
  4.0mm QSD Shaping Drill (QSD4XX)

NOTE: If placing a 4.0mm OSSEOTITE NT Implant in Type IV Bone, undersizing the osteotomy by one shaping drill size (diameter) is recommended.

6b. Using suction, remove drilling debris from the osteotomy before proceeding to the NTDI.

6c. Insert the tapered end of the 4.0mm NTDI Depth/Direction Indicator (blue) that corresponds to the length of the OSSEOTITE NT 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 Depth/Direction Indicator does not indicate proper osteotomy depth, adjust the depth of the osteotomy with the corresponding 4.0mm QSD Shaping Drill or consider a longer length implant if the site has been over prepared. Re-evaluate with a proper length NTDI Depth/Direction Indicator.

NOTE: If placing a 4.0mm OSSEOTITE NT Implant in Type I or Type II Bone, tapping with the NTAP4 is recommended.

6d. 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 4.0mm diameter OSSEOTITE NT 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 4.0mm diameter OSSEOTITE NT Implant.

Continue on for placement of 5.0 and 6.0mm OSSEOTITE NT Implants.

Proceed to step 9a on page 56 for OSSEOTITE NT Implant Placement.
Subcrestal Implant Placement Protocol
OSSEOTITE NT® Certain® And OSSEOTITE NT External Hex 5.0mm Diameter Implant Using QSD/NTDI

Third Shaping Drill Step For Placement Of 5.0 And 6.0mm OSSEOTITE NT Implant. Final Shaping Drill Step For 5.0mm OSSEOTITE NT Implant.

7a. Resume preparing the osteotomy with the 5.0mm QSD Shaping Drill that is the same length as the OSSEOTITE NT Implant to be placed. The recommended drill speed is 1200–1500rpm.

- Instruments needed:
  5.0mm QSD Shaping Drill (QSD5XX)

  **NOTE:** If placing a 5.0mm OSSEOTITE NT Implant in Type IV Bone, undersizing the osteotomy by one shaping drill size (diameter) is recommended.

7b. Using suction, remove drilling debris from the osteotomy before proceeding to the NTDI.

7c. Insert the tapered end of the 5.0mm NTDI Depth/Direction Indicator (yellow) that corresponds to the length of the OSSEOTITE NT 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 Depth/Direction Indicator does not indicate proper osteotomy depth, adjust the depth of the osteotomy with the corresponding 5.0mm QSD Shaping Drill or consider a longer length implant if the site has been over prepared. Re-evaluate with a proper length NTDI Depth/Direction Indicator.

  **NOTE:** If placing a 5.0mm OSSEOTITE NT Implant in Type I or Type II Bone, tapping with the NTAP5 is recommended.

Continue on for placement of 6.0mm OSSEOTITE NT Implant.

Proceed to step 9a on page 56 for OSSEOTITE NT Implant Placement.
Final Shaping Drill Step For 6.0mm OSSEOTITE NT Implant:

8a. Resume preparing the osteotomy with the 6.0mm QSD Shaping Drill that is the same length as the OSSEOTITE NT Implant to be placed. The recommended drill speed is 1200–1500rpm.

- Instruments needed:
  6.0mm QSD Shaping Drill (QSD6XX)

**NOTE:** If placing a 6.0mm OSSEOTITE NT Implant in Type IV Bone, undersizing the osteotomy by one shaping drill size (diameter) is recommended.

8b. Using suction, remove drilling debris from the osteotomy before proceeding to the NTDI.

8c. Insert the tapered end of the 6.0mm NTDI Depth/Direction Indicator (green) that corresponds to the length of the OSSEOTITE NT 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 Depth/Direction Indicator does not indicate proper osteotomy depth, adjust the depth of the osteotomy with the corresponding 6.0mm QSD Shaping Drill or consider a longer length implant if the site has been over prepared. Re-evaluate with a proper length NTDI Depth/Direction Indicator.

**NOTE:** If placing a 6.0mm OSSEOTITE NT Implant in Type I or Type II Bone, tapping with the NTAP6 is recommended.

Proceed to step 9a on page 56 for OSSEOTITE NT Implant Placement.
Subcrestal Implant Placement Protocol

OSSEOTITE NT® Certain® And OSSEOTITE NT External Hex Implant Placement

No-Touch™ Delivery System

9a. Remove contents from the implant box.

9b. The nonsterile assistant should peel back the tray lid and drop the No-Touch Implant Tray onto the sterile drape.

9c. Place the No-Touch Implant Tray into the appropriate location on the surgical tray.

9d. Peel back the tray lid to expose the implant and cover screw.
Subcrestal Implant Placement Protocol

OSSEOTITE NT® Certain® And OSSEOTITE NT
External Hex Implant Placement

10. Pick up the implant from the surgical tray using the Certain Implant Placement Driver Tip.
   NOTE: The Certain MicroMiniplant™ (3.25mm dia.) requires the use of a dedicated MicroMiniplant Driver Tip (IMPDTS or IMPDTL) that is marked with a purple band on the shank. The Internal Hex configuration of the MicroMiniplant is smaller than the standard Certain Internal Hex Connection (4, 5 and 6mm dia. 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)
     - Handpiece Connector (MDR10)

11. 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 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 prior to implant placement.

12. 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)
     - External Hex Ratchet Extension (RE100 or RE200)
13. To remove the Certain® Implant Placement Driver Tip 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)

14. 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)

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

- Instruments needed:
  - Small Hex Driver (PHD00N)

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

16. Close the tissue and suture.
**Subcrestal Implant Placement Protocol In Soft Type IV Bone**

**OSSEOTITE NT® Certain® And OSSEOTITE NT External Hex 4.0mm Diameter Implant**

The drilling protocol for the Subcrestal Placement of the 4.0 x 11.5mm OSSEOTITE NT Certain Implant was chosen as a representative protocol to provide a detailed implant placement synopsis. For the drilling protocol specific to implant diameter and design, please refer to the Implant Placement Protocol Quick Reference section of this manual.

**NOTE:** When placing an OSSEOTITE NT Implant in soft Type IV Bone, the osteotomy should be undersized by one shaping drill size (diameter).

1. Once the implant site has been determined, mark the site with a Round Drill and penetrate the cortical bone. The recommended drill speed is 1200–1500rpm.
   - Instruments needed:
     - 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.
   - Instruments needed:
     - 2.0 or 2.3mm Twist Drill (ITD215, DT215, DTN215 or ACT2015)

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 hole to prevent accidental swallowing.
   - At this step, a Gelb Radiographic Depth Gauge may also be used.
   - Instruments needed:
     - Direction Indicator (DI100, DI2310 or NTDIXXX)
     - 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. Proceed with the 3.25 x 11.5mm Quad Shaping Drill. Drill to the top depth mark on the QSD for subcrestal placement. The recommended drill speed is 1200–1500rpm.

- Instruments needed:
  3.25mm QSD (QSD32XX)

6. Finish the osteotomy with the Countersink Drill. The recommended drill speed is 1200–1500rpm.

- Instruments needed:
  Countersink Drill (ICD100)

**IMPORTANT NOTE:** When placing a 4.0mm diameter OSSEOTITE Certain® Implant subcrestally, you must use an ICD100 Countersink Drill to prepare the ridge before placing the implant.

Proceed to step 11a on page 66 for OSSEOTITE NT® Implant Placement in soft Type IV Bone.
Subcrestal Implant Placement Protocol In Soft Type IV Bone
OSSEOTITE NT® Certain® And OSSEOTITE NT External Hex 5.0mm Diameter Implant

The drilling protocol for the Subcrestal Placement of the 5.0 x 11.5mm OSSEOTITE NT Certain Implant was chosen as a representative protocol to provide a detailed implant placement synopsis. For the drilling protocol specific to implant diameter and design, please refer to the Implant Placement Protocol Quick Reference section of this manual.

NOTE: When placing an OSSEOTITE NT Implant in soft Type IV Bone, the osteotomy should be undersized by one shaping drill size (diameter).

1. 

Once the implant site has been determined, mark the site with a Round Drill and penetrate the cortical bone. The recommended drill speed is 1200–1500rpm.

- Instruments needed:
  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.

Continue to penetrate the bone to the desired depth. The recommended drill speed is 1200–1500rpm.

- Instruments needed:
  2.0 or 2.3mm Twist Drill (ITD215, DT215, DTN215 or ACT2015)

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 hole to prevent accidental swallowing.

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

- Instruments needed:
  Direction Indicator (D1100, DI2310 or NTD1XXX)
  Gelb Radiographic Depth Gauge (XD6XX)
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. Proceed with the 3.25 × 11.5mm Quad Shaping Drill. Drill to the top depth mark on the QSD for subcrestal placement. The recommended drill speed is 1200–1500rpm.

   - Instruments needed: 3.25mm QSD (QSD32XX)

6. Continue preparing the osteotomy with the 4.0mm QSD. Drill to the top depth mark on the QSD. The recommended drill speed is 1200–1500rpm.

   - Instruments needed: 4.0mm QSD (QSD4XX)

7. Finish with a 5.0 × 8.5mm QSD. 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.

   - Instruments needed: 5.0mm QSD (QSD585)

Proceed to step 11a on page 66 for OSSEOTITE NT® Implant Placement in soft Type IV Bone.
Subcrestal Implant Placement Protocol In Soft Type IV Bone

**OSSEOTITE NT® Certain® And OSSEOTITE NT External Hex 6.0mm Diameter Implant**

The drilling protocol for the Subcrestal Placement of the 6.0 x 11.5mm OSSEOTITE NT Certain Implant was chosen as a representative protocol to provide a detailed implant placement synopsis. For the drilling protocol specific to implant diameter and design, please refer to the Implant Placement Protocol Quick Reference section of this manual.

**NOTE:** When placing an OSSEOTITE NT Implant in soft Type IV Bone, the osteotomy should be undersized by one shaping drill size (diameter).

1. Once the implant site has been determined, mark the site with a Round Drill and penetrate the cortical bone. The recommended drill speed is 1200–1500rpm.
   - Instruments needed:
     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.
   - Continue to penetrate the bone to the desired depth. The recommended drill speed is 1200–1500rpm.
   - Instruments needed:
     2.0 or 2.3mm Twist Drill (ITD215, DT215, DTN215 or ACT2015)

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 hole to prevent accidental swallowing.
   - At this step, a Gelb Radiographic Depth Gauge may also be used.
   - Instruments needed:
     Direction Indicator (DI100, DI2310 or NTD1XXX)
     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. Proceed with the 3.25 x 11.5mm Quad Shaping Drill. Drill to the top depth mark on the QSD for subcrestal placement. The recommended drill speed is 1200–1500rpm.

- Instruments needed:
  3.25mm QSD (QSD32XX)

6. Continue preparing the osteotomy with the 4.0mm QSD. Drill to the top depth mark on the QSD. The recommended drill speed is 1200–1500rpm.

- Instruments needed:
  4.0mm QSD (QSD4XX)

7. Resume preparing the osteotomy with the 5.0mm QSD that is the same length as the implant to be placed. The recommended drill speed is 1200–1500rpm.

- Instruments needed:
  5.0mm QSD (QSD5XX)
Subcrestal Implant Placement Protocol In Soft Type IV Bone

OSSEOTITE NT® Certain® And OSSEOTITE NT External Hex 6.0mm Diameter Implant

8. 🔄 Using suction, remove drilling debris from the osteotomy before proceeding to the NTDI.

9. 🔄 Insert the tapered end of the 5.0mm NTDI Depth/Direction Indicator (yellow) that corresponds to the length of the OSSEOTITE NT 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 Depth/Direction Indicator does not indicate proper osteotomy depth, adjust the depth of the osteotomy with the corresponding 5.0mm QSD or consider a longer length implant if the site has been over prepared. Re-evaluate with a proper length NTDI. The recommended drill speed is 1200–1500rpm.

10. 🔄 Finish with a 6.0 x 8.5mm Quad Shaping Drill. 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.

- Instruments needed:
  6.0mm QSD (QSD685)

Proceed to step 11a on page 66 for OSSEOTITE NT Implant Placement in soft Type IV Bone.
**Subcrestal Implant Placement Protocol In Soft Type IV Bone**

*OSSEOTITE NT*® Certain® And *OSSEOTITE NT* External Hex Implant Placement

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**No-Touch™ Delivery System**

11a. Remove contents from the implant box.

11b. The nonsterile assistant should peel back the tray lid and drop the No-Touch Implant Tray onto the sterile drape.

11c. Place the No-Touch Implant Tray into the appropriate location on the surgical tray.

11d. Peel back the tray lid to expose the implant and cover screw.
**Subcrestal Implant Placement Protocol In Soft Type IV Bone**

*OSSEOTITE NT® Certain® And OSSEOTITE NT External Hex Implant Placement*

12. Pick up the implant from the surgical tray using the Certain Implant Placement Driver Tip. *NOTE: The Certain MicroMiniplant™ (3.25mm dia.) requires the use of a dedicated MicroMiniplant Driver Tip (IMPDTS or IMPDTL) that is marked with a purple band on the shank. The Internal Hex configuration of the MicroMiniplant is smaller than the standard Certain Internal Hex Connection (4, 5 and 6mm dia. 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)
  - Handpiece Connector (MDR10)

13. 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 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 prior to implant placement.

14. 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)
  - External Hex Ratchet Extension (RE100 or RE200)
15.  To remove the Certain® Implant Placement Driver Tip 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)

16.  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)

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

- Instruments needed:
  Small Hex Driver (PHD00N)

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

18.  Close the tissue and suture.
Several advantages can be realized by 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. After the implant is fully seated in the osteotomy, remove the implant mount from the External Hex Implant.

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

**OSSEOTITE® Implants**

**EP** Healing Abutments

A Bone Profiling Pin, Bone Profilers 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.

**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.

**OSSEOTITE Certain® Two-Piece Bone Profiling Pin (IBPGP)**

The OSSEOTITE 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 hex 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 Pins.**

EP Bone Profilers correspond to sizes of EP Healing Abutments

**Bone Profiling Technique**

- EP Bone Profiler slides over the two-Piece 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.
**Surgical Indexing**

**OSSEOTITE® Implants**

**Surgeon**

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

**Surgical Indexing**

2. A surgical index may be made at stage one or stage two 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 and 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.

4. If a flapless surgery is performed or if the index is made at stage two surgery, radiograph 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.

Seated Not Seated
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 it may be included in the package to the laboratory.

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 add 1mm.