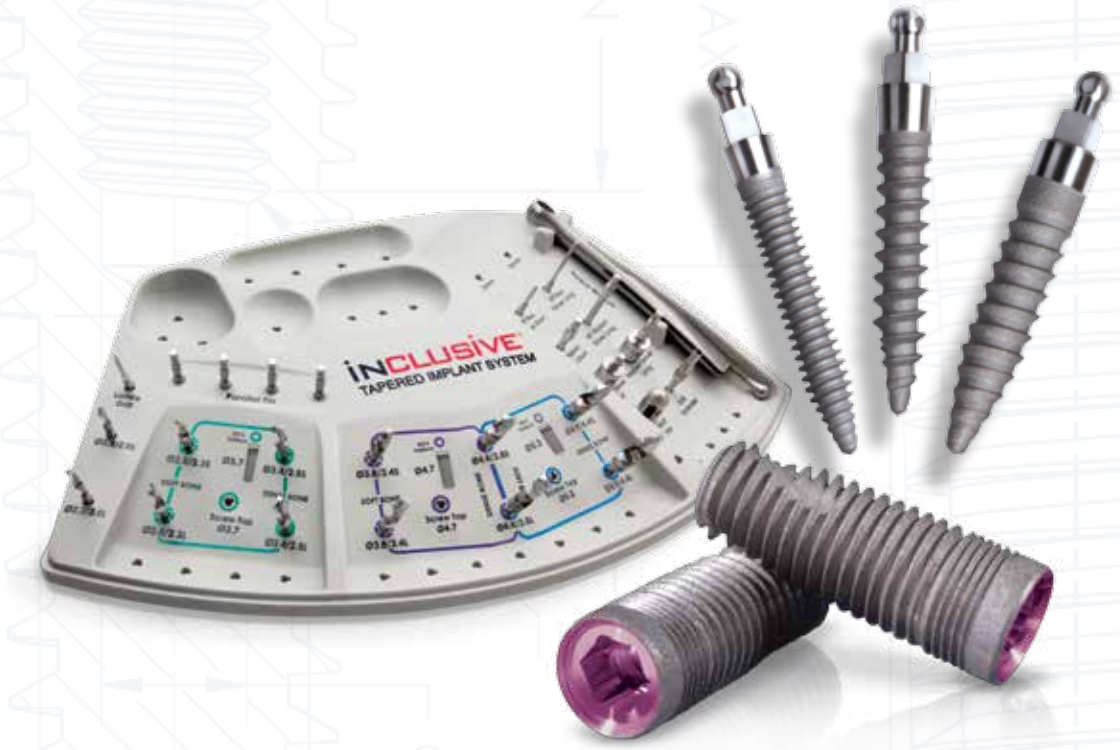
INCLUSIVE®
DENTAL IMPLANT SYSTEM

Surgical Manual

May 2015



bsi.

Certificate of Registration

By Royal Charter

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

Prismatik Dentalcraft, Inc.
a wholly owned subsidiary of
Glidewell Laboratories
2212 Dupont Drive
Irvine
California
92612
USA

Holds Certificate No: **FM 573328**

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

Design and manufacturing of dental restorative products.

The above scope of registration includes activities at:
2181 Dupont Drive, Irvine CA
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For and on behalf of BSI:

VP Regulatory Affairs, BSI Group America Inc.

Originally registered: 09/02/2011 Effective Date: 08/25/2014 Expiry Date: 08/24/2017

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Introducing the Inclusive® Dental Implant System

Founded in 2006 with the goal of expanding the availability of comprehensive dental implant therapy to patients across the economic spectrum, Prismatik Dentalcraft reduces the component and restorative cost of treatment while maintaining the highest standard of quality. Having assembled a diverse team of experts with decades of combined experience in the design, engineering, and manufacture of dental implants, along with a staff of highly respected researchers, material scientists, clinical specialists, restorative doctors, and dental technicians, we at Prismatik are dedicated to advancing implant dentistry by combining proven treatment protocols with cutting-edge materials, technologies, and techniques.

The Inclusive® Dental Implant System is the result of an expansive effort to offer clinicians and their patients a simple, convenient, affordable way to restore missing dentition. Choose between conventional-diameter or small-diameter implant assortments, supported by a wide array of restorative options, and discover a system streamlined for ease of use, yet versatile enough to address almost any clinical indication. In keeping with our commitment to quality, Inclusive implant components are precision-machined to tight tolerances in an ISO 13485 certified environment in Irvine, California, operating under the U.S. Food and Drug Administration Current Good Manufacturing Practices (CGMPs).

From its beginnings until today, Prismatik Dentalcraft has experienced an ever-growing demand in support of its vision to make dental implant therapy more accessible to patients around the globe. This growth has enabled the company to consistently expand and improve its offerings even in a time of widespread economic challenge. The Inclusive brand has quickly established itself as a trusted name within the industry, and Prismatik Dentalcraft as a manufacturer at the forefront of dental technology.

Thank you for choosing Prismatik. You can place your trust in us.

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No representations as to the completeness or accuracy of this information is given, and no representations or warranties, either expressed or implied, of merchantability, fitness for a particular purpose or of any other nature are made here under with respect to the information or the product to which information refers.

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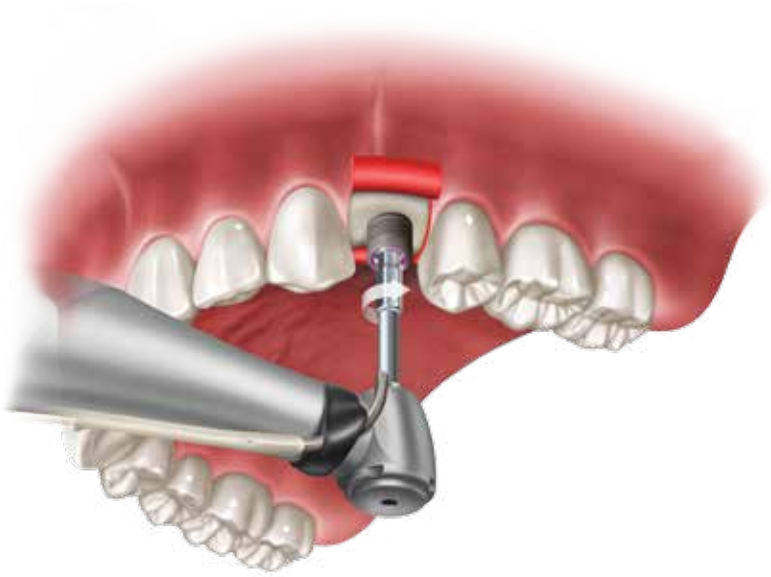
INCLUSIVE®
TAPERED IMPLANT SYSTEM

SURGICAL PROCEDURES



Surgical Consideration

Scope

This manual outlines the appropriate procedures for placing Inclusive® Tapered Implants.

The procedures and guidelines presented herein are not intended to be a substitute for formal implant training. It is the responsibility of the clinician and laboratory technician to determine the final protocol and component selection.

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

Indications for Use

The Inclusive Dental Implant System implants are indicated for use in maxillary and mandibular partially or fully edentulous cases, to support single, multiple unit, and overdenture restorations. The implants are to be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.

Contraindications

Patients should be evaluated before the time of surgery for factors that put them at risk from the implant placement procedure, or that may affect healing of bone or surrounding soft tissue. Contraindications include but are not limited to: vascular conditions, uncontrolled diabetes, clotting disorders, anticoagulant therapy, metabolic bone disease, chemotherapy or radiation therapy, chronic periodontal inflammation, insufficient soft tissue coverage, metabolic or systemic disorders associated with wound and/or bone healing, use of pharmaceuticals that inhibit or alter natural bone remodeling, any disorders which inhibit a patient's ability to maintain adequate daily oral hygiene, uncontrolled parafunctional habits, insufficient height and/or width of bone, and insufficient interarch space. Do not reuse Inclusive Dental Implants. Reuse of Inclusive Dental Implants carries the risk of pathogenic patient cross-contamination.

Warning

Inclusive Tapered Implants may only be used for their intended purpose in accordance with general rules for dental/surgical treatment, occupational safety and accident prevention. They must only be used for dental procedures with the restorative components they were designed for. If the indications and use are not clearly specified, treatment should be suspended until these considerations have been clarified.

The following instructions are not sufficient to allow inexperienced clinicians to administer professional prosthetic dentistry. Inclusive Tapered Implants and related components must only be used by dentists and surgeons with training/experience with oral surgery, prosthetics and biomechanical requirements, as well as diagnosis and preoperative planning.

The implant site should be inspected for adequate bone by radiographs, palpations and visual examination. Determine the location of nerves and other vital structures and their proximity to the implant site before any drilling to avoid potential injury, such as permanent numbness to the lower lip and chin. Prior to surgery, ensure that the needed components, instruments and help materials are complete, functional and available in the correct amounts. Treatment of children is not recommended until growth is finished and epiphyseal closure has occurred.

Surgical Consideration

Absolute success cannot be guaranteed. Factors such as infection, disease and inadequate bone quality and/or quantity can result in osseointegration failures following surgery or initial osseointegration. Inclusive Dental Implants have not been evaluated for safety and compatibility in the MR environment. Inclusive Dental Implants have not been tested for heating or migration in the MR environment. Inclusive Dental Implants can distort images obtained via magnetic resonance imaging (MRI). Prismatik Dentalcraft, Inc. is not liable for damages resulting from treatment outside of our control. The responsibility rests with the provider.

Surgical Procedure Precautions

Minimizing tissue damage is crucial to successful implant osseointegration. In particular, care should be taken to eliminate sources of infection, contaminants, surgical and thermal trauma. Risk of osseointegration failure increases as tissue trauma increases. All drilling procedures should be performed at 1200 RPM or less under continual and copious irrigation. All surgical instruments used must be in good condition and should be used carefully to avoid damage to implants or other components. Implants should be placed with sufficient stability; however, excessive insertion torque may result in implant fracture, or fracture or necrosis of the implant site. The proper surgical protocol should be strictly adhered to. Since implant components and their instruments are very small, precautions should be taken to ensure that they are not swallowed or aspirated by the patient.

Sterilization

Inclusive Tapered Implants are packaged sterile by gamma irradiation, suspended in sterile vials, and are intended for single-use only. They are considered sterile for five (5) years from the date of initial sterilization. Expiration dates are noted on implant packaging. They should not be resterilized.

Inclusive Tapered Implants should be stored in a dry location at room temperature, in their original packaging. Do not use implants if the packaging has been compromised or previously opened. Do not handle implant surfaces directly.

Instruments are shipped non-sterile. It is recommended that the Surgical Tray and its contents be steam-sterilized for twenty (20) minutes at 132°C/270°F minimum.

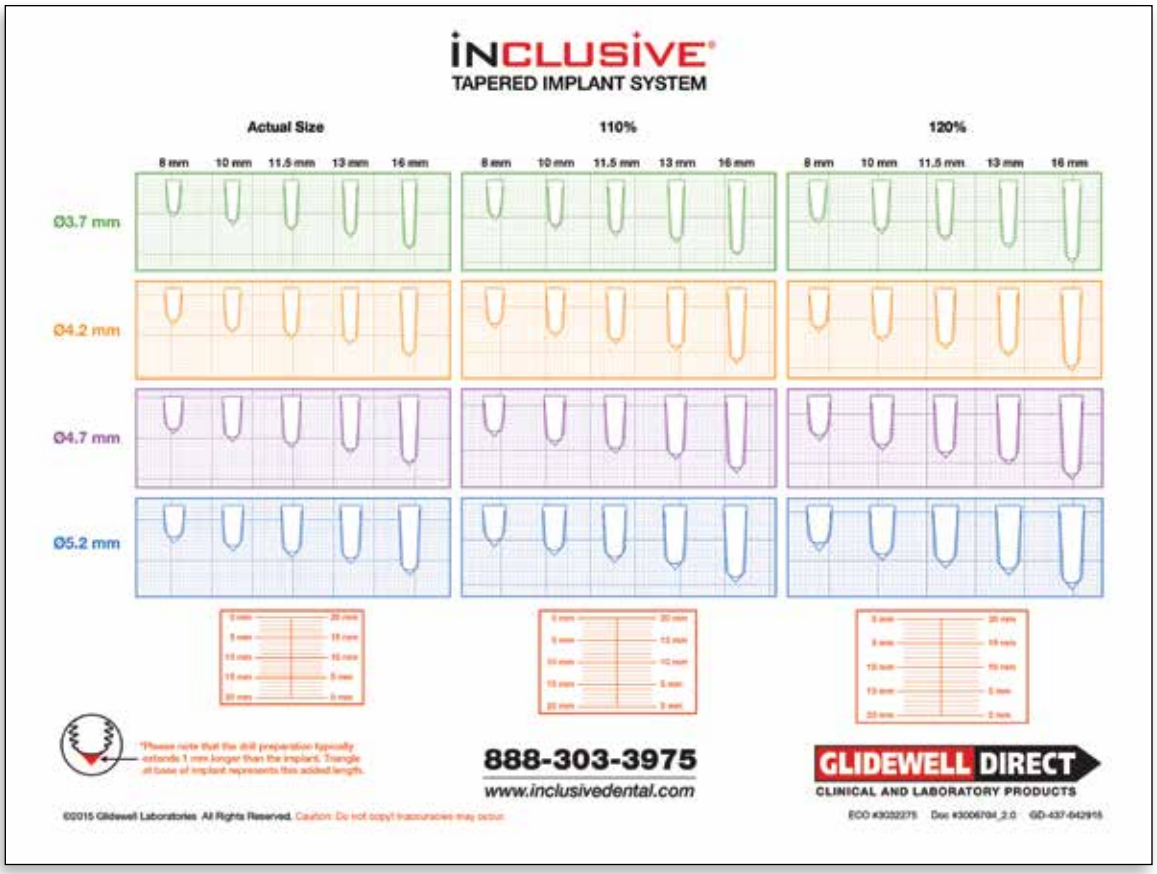
General Cleaning Tips:

- Observe universal precautions for the handling of contaminated or biohazardous materials.
- Clean promptly after each use, to prevent biological fluids and tissues from drying on the instruments.
- When applicable, disassemble parts and instruments prior to cleaning.
- Do not rely solely on automatic cleaning. Thorough manual cleaning is recommended.
- Preliminary cleaning should consist of wiping parts, soaking them in a lukewarm enzymatic solution for a minimum of twenty (20) minutes, and rinsing them with running water.
- Routine cleaning should consist of (a) washing parts using a broad spectrum cleaning solution, followed by thorough rinsing and drying; and (b) sonicating parts fully submerged in cleaning solution for at least ten (10) minutes, preferably at 45-50 kHz, followed by thorough rinsing and drying.

Surgical Consideration

Radiographic Template

A radiographic template is available to clinicians who place Inclusive Tapered Implants. This transparency is to be used as a diagnostic tool in selecting an implant of the appropriate size.



⚠ NOTE: This image is for illustrative purposes only, and is not intended for clinical use.

Surgical Consideration

Implant Selection

Inclusive Tapered Implants are available in three diameters (3.7 mm, 4.2 mm, 4.7 mm, 5.2 mm) and five lengths (8 mm, 10 mm, 11.5 mm, 13 mm, 16 mm). All 4.7 mm and 5.2 mm diameter Inclusive Tapered Implants share the same 4.5 mm prosthetic platform.

Ø3.7 mm	Ø4.2 mm	Ø4.7 mm	Ø5.2 mm
Ø3.7 x 8 mm 70-1070-IMP0005	Ø4.2 x 8 mm 70-1070-IMP0026	Ø4.7 x 8 mm 70-1070-IMP0010	Ø5.2 x 8 mm 70-1070-IMP0015
Ø3.7 x 10 mm 70-1070-IMP0006	Ø4.2 x 10 mm 70-1070-IMP0027	Ø4.7 x 10 mm 70-1070-IMP0011	Ø5.2 x 10 mm 70-1070-IMP0016
Ø3.7 x 11.5 mm 70-1070-IMP0007	Ø4.2 x 11.5 mm 70-1070-IMP0028	Ø4.7 x 11.5 mm 70-1070-IMP0012	Ø5.2 x 11.5 mm 70-1070-IMP0017
Ø3.7 x 13 mm 70-1070-IMP0008	Ø4.2 x 13 mm 70-1070-IMP0029	Ø4.7 x 13 mm 70-1070-IMP0013	Ø5.2 x 13 mm 70-1070-IMP0018
Ø3.7 x 16 mm 70-1070-IMP0009	Ø4.2 x 16 mm 70-1070-IMP0030	Ø4.7 x 16 mm 70-1070-IMP0014	Ø5.2 x 16 mm 70-1070-IMP0019

Color Coding

The Inclusive Tapered Implant System utilizes color-coding for easy component identification. Color-coding is featured consistently across system articles such as surgical tray, radiographic template, screw taps, and the implant carrier included in each sterile vial, with colors reflecting either the prosthetic platform or implant diameter, as indicated in the legend below:

Implant Body	Implant Icon	Prosthetic Platform	Prosthetic Icon
Ø3.7 mm		Ø3.5 mm	
Ø4.2 mm		Ø3.5 mm	
Ø4.7 mm		Ø4.5 mm	
Ø5.2 mm		Ø4.5 mm	

Surgical Instrumentation

All instruments associated with the Inclusive Tapered Implant system are machined from high-quality, corrosion-resistant, surgical stainless steel, and feature standard ISO latch connectivity.

NOTE: Instruments are shipped non-sterile. Steam sterilize the surgical tray and its contents for twenty (20) minutes at 132°C/270°F minimum.

Surgical Kit

The surgical kit allows the clinician to easily organize, store and transport the components of the Inclusive Tapered Implant System. The tray features component markings and angled rows for easy identification and to help maximize space. The durable, synthetic material is autoclavable and provides a snug, secure fit.

Drills are arranged from left to right in order of increasing diameter, following the recommended drilling sequence. Color-coded fields indicate the corresponding diameter of Inclusive Tapered Implant.

Surgical Drills

The Inclusive Tapered Implant System features a full range of surgical drills, with each diameter available in long and short sizes. All are designed to achieve maximum cutting efficiency while effectively removing bone from the osteotomy. Drills may be used for up to five preparations, depending on bone density. For best results, replace regularly.

The drills are stepped to accommodate the tapered design of the implant, and feature wide-band, easy-to-see, laser-etched depth markings. The position of each marking is calculated to indicate where the top of the implant will reside when fully seated to that depth.

Ø1.5 mm Lance Drill | Ø2.3/2.0 mm Pilot Drill | Ø2.8/2.3 mm Surgical Drill | Ø3.4/2.8 mm Surgical Drill | Ø3.8/3.4 mm Surgical Drill | Ø4.4/3.8 mm Surgical Drill | Ø4.9/4.4 mm Surgical Drill

Surgical Instrumentation

Screw Taps *(Optional for Dense Bone)*

For the placement of Inclusive Tapered Implants in extremely dense bone, it may be necessary to utilize a screw tap (sold separately) corresponding to the diameter of the implant body. Due to the tap design and implant cutting efficiency, one tap is used for multiple implant lengths. The coronal head of each screw tap is slightly flared, resulting in a gentle expansion of the cortical plate for receiving the wider neck of the implant.

Optional Dense Bone
Ø3.7 mm Screw Tap

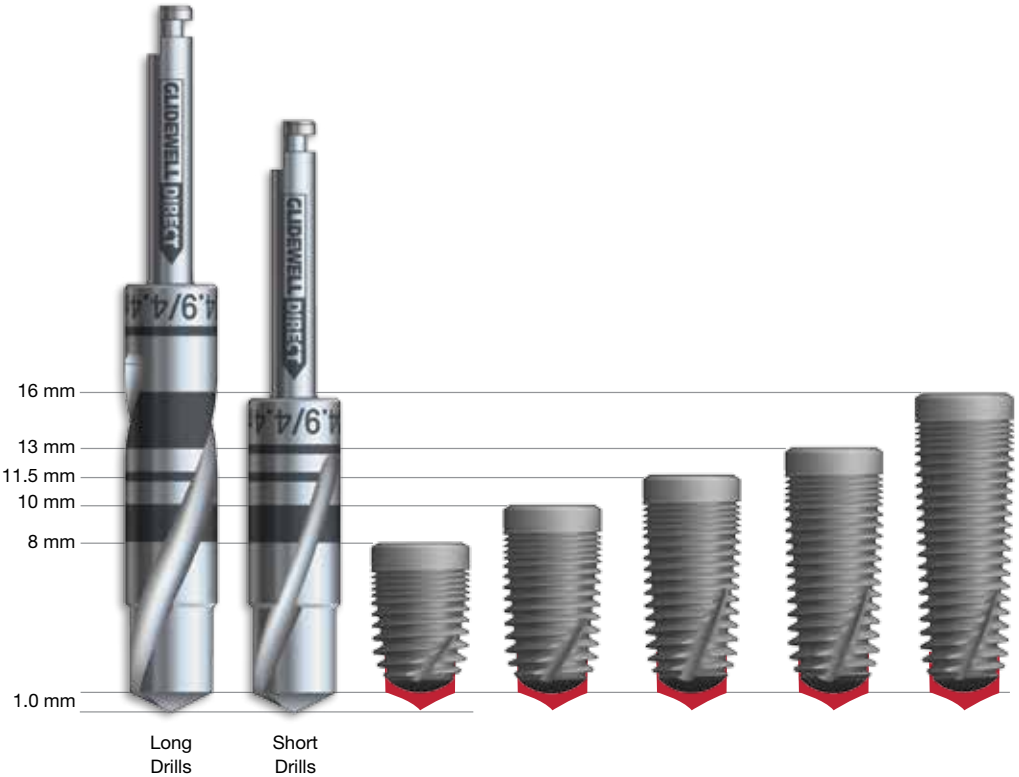
Optional Dense Bone
Ø4.2 mm Screw Tap

Optional Dense Bone
Ø4.7 mm Screw Tap

Optional Dense Bone
Ø5.2 mm Screw Tap

Depth Markings

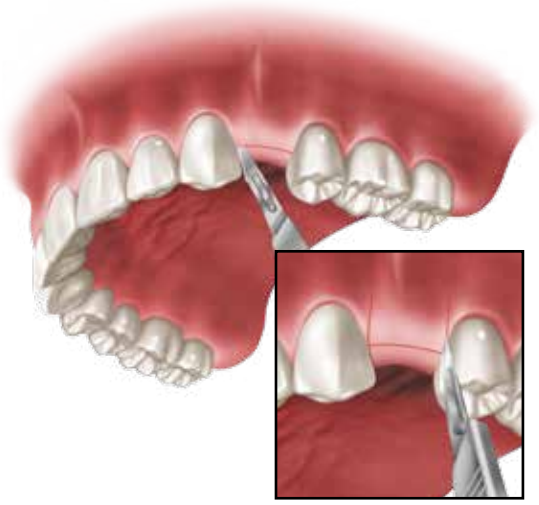
The illustration below demonstrates the corrolation between laser-etched depth markings on each drill and the corresponding implant length. Please note that, due to the cutting tip, the osteotomy preparation typically extends 1 mm longer than the stated length of the implant. This added length must be taken into account when planning the case.



Surgical Protocol

■ Soft Tissue Reflection

Following administration of appropriate anesthesia, make an incision of appropriate design for elevation of a flap.



Perform alveoloplasty on the crest of the ridge, if needed, to create a more even plane in which to place the implant. Irrigation should be used for all modifications of the bone.

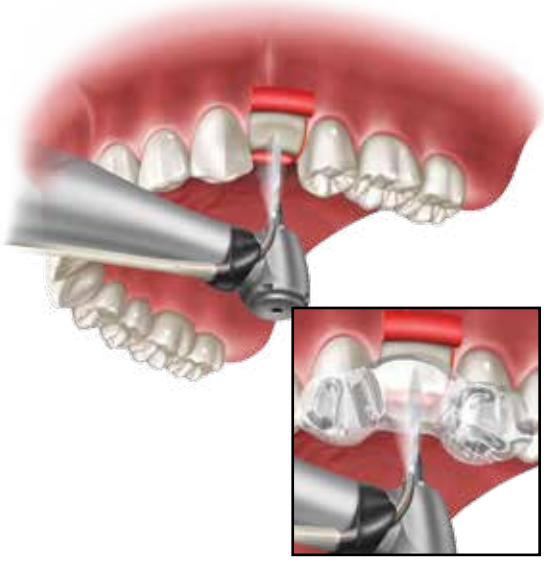
■ General Drilling Guidelines

- A speed of 800–1200 RPM is recommended when using the Pilot Drills or Surgical Drills.
- Screw Tap speed should be no greater than 25 RPM.
- All drilling and tapping procedures should be performed using copious, sterile irrigation.
- Do not apply lateral pressure during drilling and tapping procedures.
- Drill the osteotomy using light pressure along the long axis of the osteotomy.

■ Osteotomy Site Preparation

Step 1: Lance Drill

With proper irrigation, perforate the alveolar crest using a surgical stent, if necessary, as a reference for proper positioning.



Ø1.5 mm
Lance Drill

Surgical Protocol

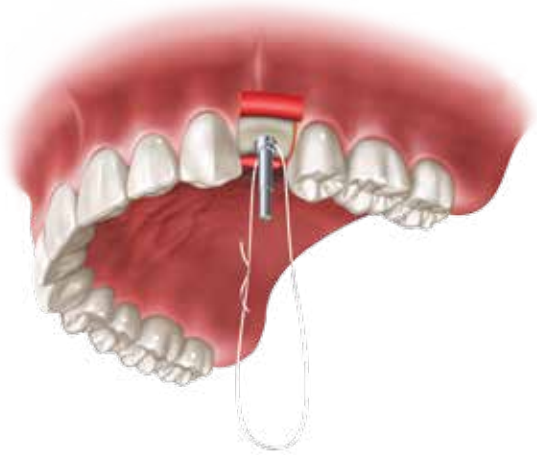
Step 2: Pilot Drill

Select the 2.3/2.0 mm Pilot Drill (Long or Short, depending on vertical clearance). If any change is needed in trajectory, it may be corrected at this time. With proper irrigation, drill a pilot hole to the appropriate depth marking on the drill.

Ø2.3/2.0 mm
Pilot Drill

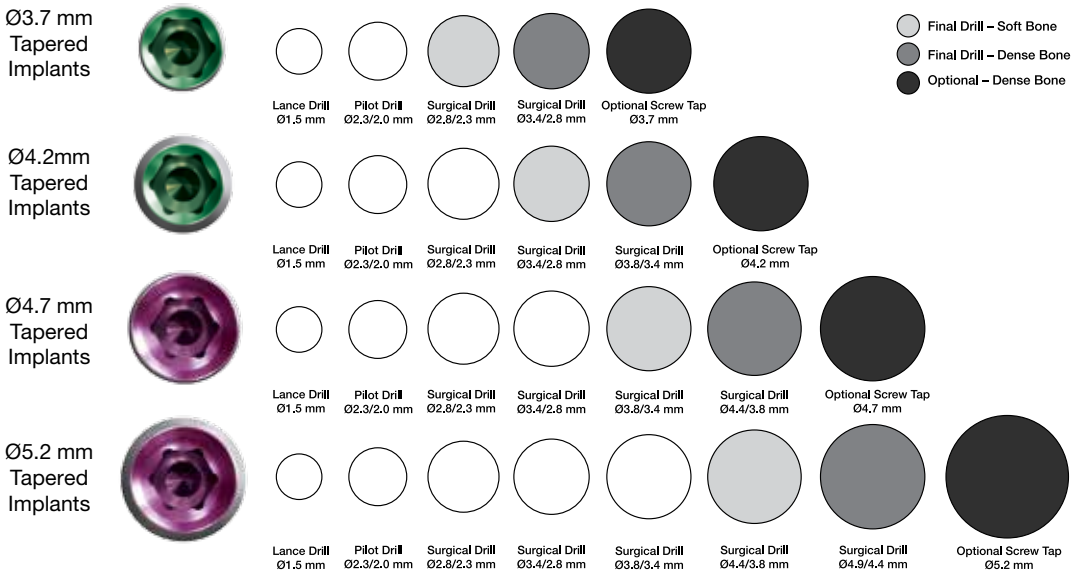
Check the orientation of the initial osteotomy using a Parallel Pin. If placing more than one implant and parallelism is desired, begin drilling the next site and align as the trajectory of the bone permits.

Parallel Pin



Step 3: Surgical Drills

Depending on implant diameter and the density of bone at the osteotomy site, it may be necessary to utilize one or more of the Surgical Drills to widen the osteotomy. To avoid over-preparation, widening drill diameters should be used only as necessary, and in proper succession.



Surgical Protocol

Select the desired Surgical Drill, accounting for the density of bone at the osteotomy site and the diameter of the implant to be placed. With proper irrigation, drill to the appropriate depth marking on the drill.

The final drill for each implant diameter should be based on the density of the bone. The goal is to achieve high primary stability upon implant placement. The specific drill sequence charts on page 19 illustrate the final drills for soft and dense bone.

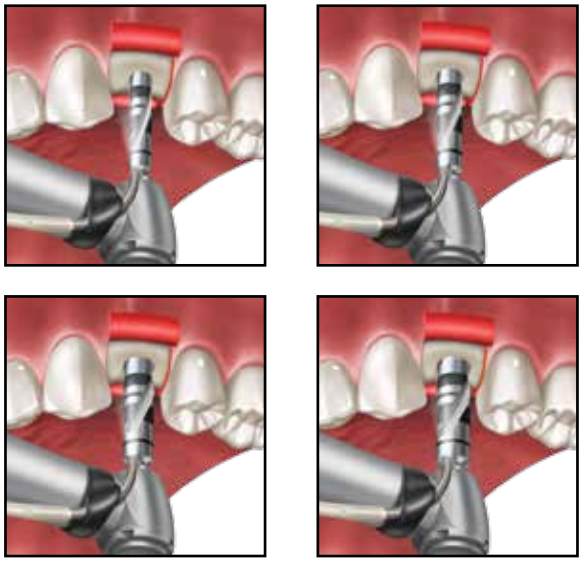
Ø2.8/2.3 mm Surgical Drill

Ø3.4/2.8 mm Surgical Drill

Ø3.8/3.4 mm Surgical Drill

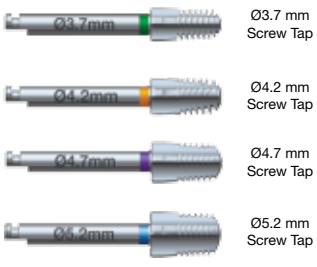
Ø4.4/3.8 mm Surgical Drill

Ø4.9/4.4 mm Surgical Drill



Step 4: Optional Dense Bone Tap (25 RPM)

If indicated by the presence of dense bone, select the Screw Tap with a diameter matching that of the implant. Place the tap into the prepared implant site. Apply firm pressure and begin slowly rotating the tap (25 RPM maximum). When the threads begin engaging the bone, allow the tap to feed into the site without applying additional pressure. The osteotomy should be tapped through the cortical bone. Reverse the tap out of the site.

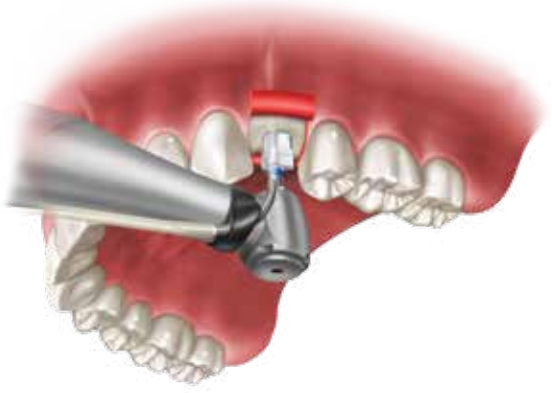


Ø3.7 mm Screw Tap

Ø4.2 mm Screw Tap

Ø4.7 mm Screw Tap

Ø5.2 mm Screw Tap



Do not over-tighten the tap in the site, as this might damage the threads prepared in the bone and result in less than optimal primary stability.

Surgical Protocol

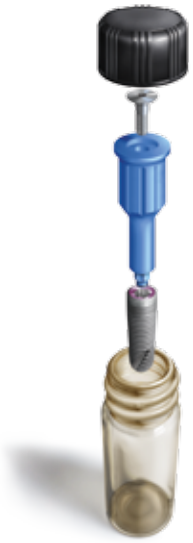
■ Implant Placement

Step 1: Implant Selection

Remove the sterile vial from its tamper-proof pouch and place it onto a sterile field.

Step 2: Initial Placement

Remove the implant from the vial by its plastic carrier, taking care not to touch the implant body. Transport the implant to the prepared site, and insert into the osteotomy. Rotate clockwise with applied pressure to engage the self-tapping groove. Avoid lateral forces, which can affect the angulation and final alignment of the implant. The plastic carrier will separate from the implant head upon reaching a torque threshold of approximately 15 Ncm.



NOTE: The plastic carrier contains a Cover Screw, for use when following a two-stage surgical protocol. Do not discard the Cover Screw upon removal of the plastic carrier.

Step 3: Advancement and Final Seating

Continue advancing the implant in place using an appropriate implant driver with either a handpiece or torque wrench. A minimum torque value of 35 Ncm upon final seating indicates good primary stability.

■ Methods of Implant Placement

Inclusive Tapered Implants are threaded into the osteotomy utilizing drivers that engage the internal connection of the implant. As all Inclusive Tapered Implants share the same internal connection dimensions, the same driver can be used, regardless of implant size. The plastic carrier contained in the implant vial can be used to deliver the implant from the vial to the implant site.

Surgical Protocol

Option 1: Handpiece Implant Placement

Place the Handpiece Implant Driver into the handpiece. Seat the driver into the internal hex connection of the implant, and press firmly to fully engage the connection. Thread the implant into the osteotomy at approximately 25 RPM until fully seated.

⚠ **NOTE: The Handpiece Implant Driver is not recommended for manual implant placement. For manual seating, use the one-piece Implant Driver.**

Handpiece Implant Driver

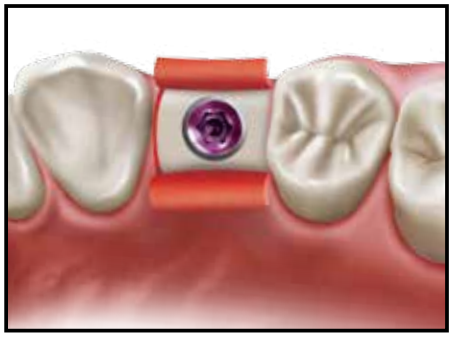
Option 2: Manual Implant Placement

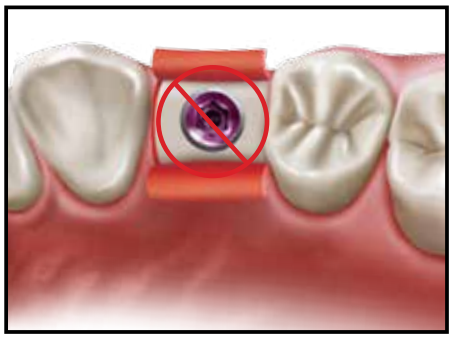
Select the Torque/Ratchet Wrench and assemble it with the Implant Driver. (The Implant Driver may also be used separately as a hand driver.) With the implant threaded securely in its site, seat the driver into the internal hex connection of the implant, and press firmly to fully engage the connection. Turn the wrench clockwise in increments of approximately 90 degrees. Avoid lateral forces, which can affect the final alignment of the implant.

Implant Driver

■ Implant Positioning

The implant should be rotated at the time of placement to ensure optimal positioning of the internal hex connection. This will allow the restoring clinician to take full advantage of the anatomical abutment contours and minimize the need for abutment preparation. Adjust the final position of the implant so that any one of the six flats of the internal hex connection is oriented toward the facial.





Surgical Protocol

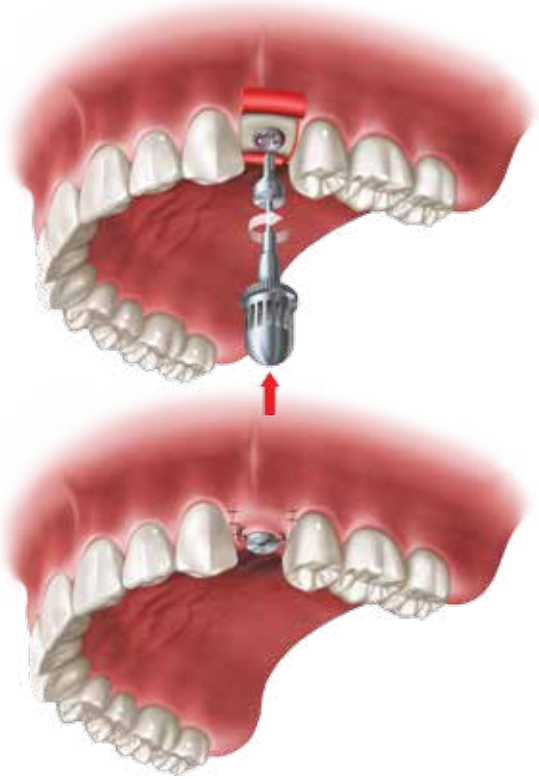
■ Healing Component Placement

Following implant placement, prepare the site for healing by placing either a Healing Abutment (single-stage surgical protocol) or the Cover Screw (two-stage surgical protocol).

Option 1: Healing Abutment

If observing a single-stage surgical protocol, select a Healing Abutment of the appropriate height and diameter. Thread the abutment into place atop the implant. To secure the abutment, assemble the Handpiece Hex Driver with the Instrument Adaptor and use this combination driver to hand-tighten.

Healing Abutment

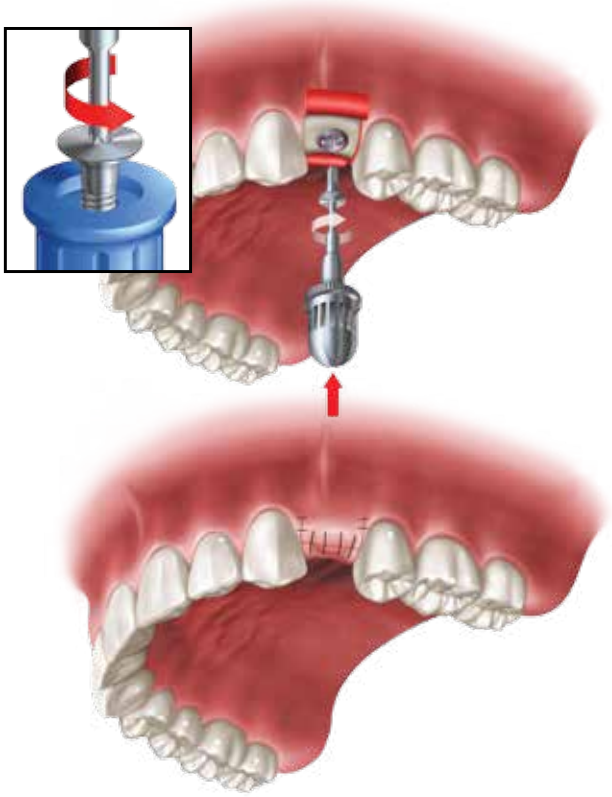


Single-Stage Surgical Protocol

Option 2: Cover Screw

If observing a two-stage surgical protocol, assemble the Handpiece Hex Driver with the Instrument Adaptor. Use this combination driver to unthread the Cover Screw from the plastic carrier contained in the sterile vial. Carry the Cover Screw to the implant and hand-tighten.

Cover Screw



Two-Stage Surgical Protocol

■ Closure and Suturing

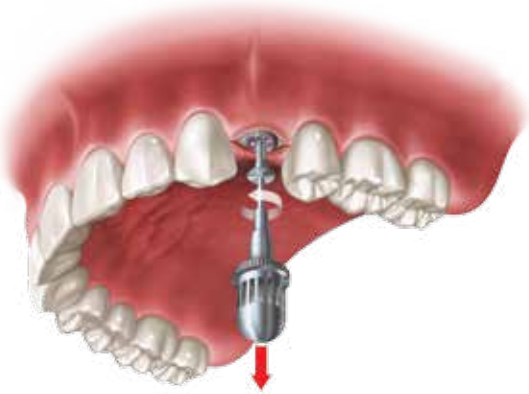
If the soft tissue was reflected, close and suture the flap utilizing the desired technique. Take a postoperative radiograph to use as a baseline, and advise the patient as to the recommended postoperative procedures.

Surgical Protocol

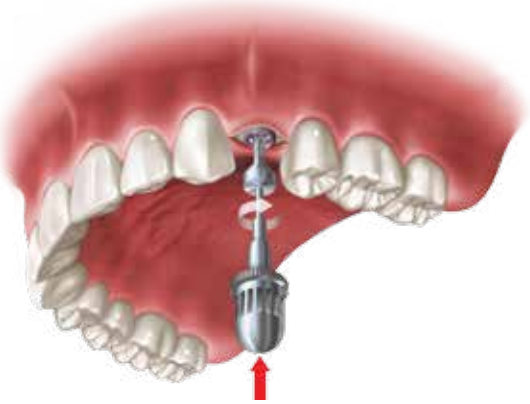
■ Second-Stage Uncovery (Two-Stage Surgical Protocol)

If observing a two-stage surgical protocol, allow for an appropriate healing period before proceeding with second-stage uncovery. During the uncovery appointment, make a small incision with a scalpel to expose the Cover Screw. Use the Hex Driver to remove the Cover Screw and place a Healing Abutment or Temporary Abutment of the appropriate height and diameter.

Step 1: Expose the Cover Screw



Step 2: Remove the Cover Screw

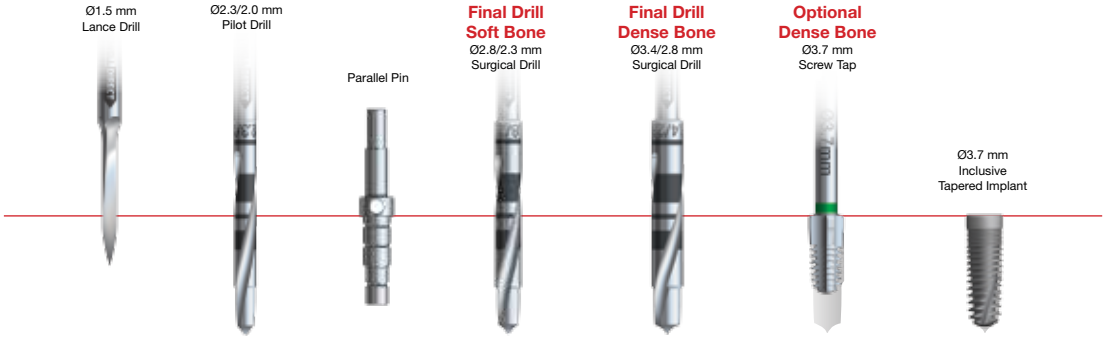


Step 3: Place Healing Abutment

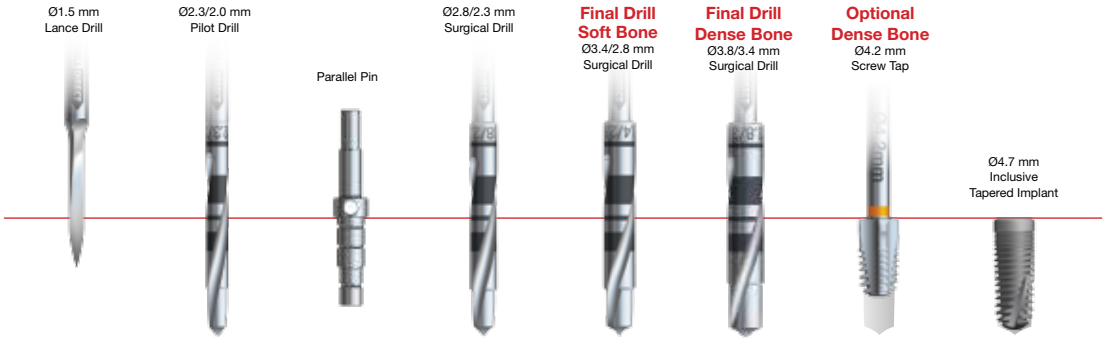
Step 4: Close and suture

Drilling Sequences

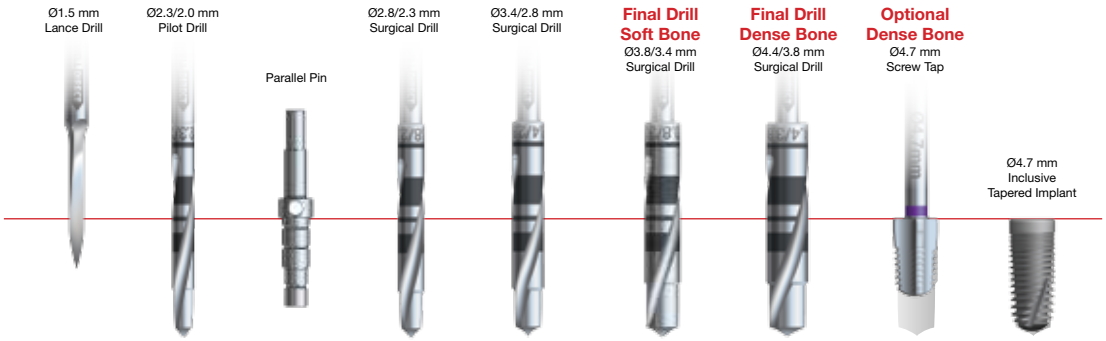
Ø3.7 mm Inclusive Tapered Implant



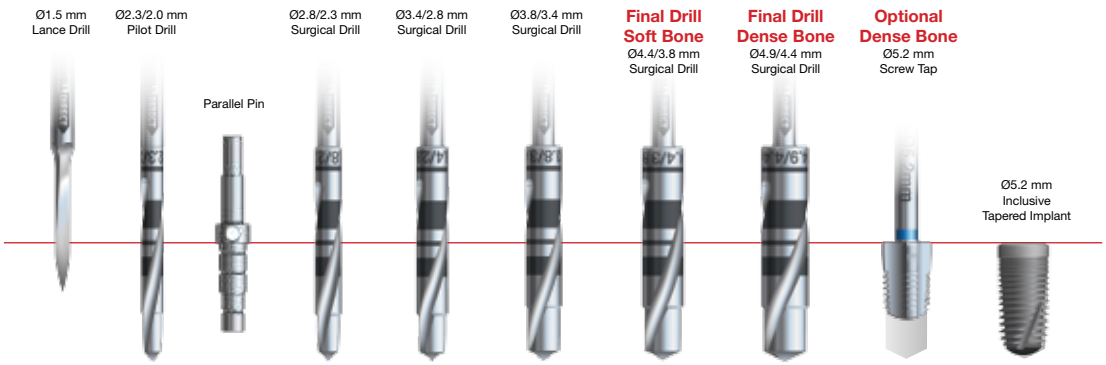
Ø4.2 mm Inclusive Tapered Implant



Ø4.7 mm Inclusive Tapered Implant

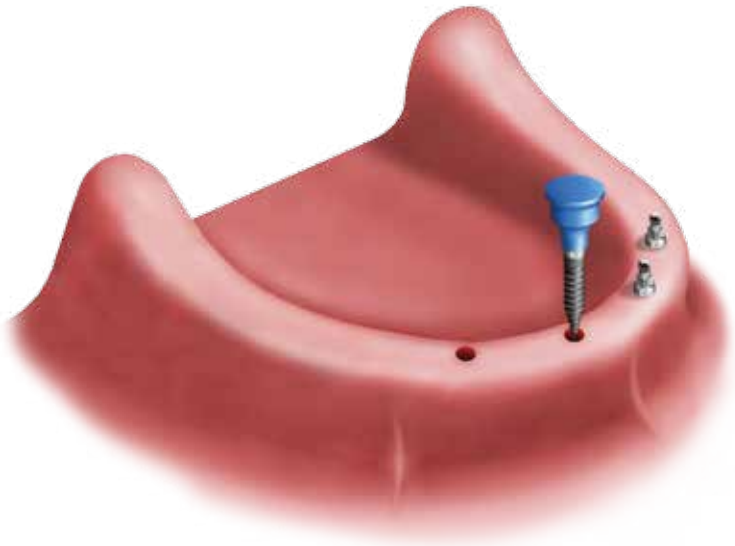


Ø5.2 mm Inclusive Tapered Implant



INCLUSIVE®
MINI IMPLANT SYSTEM

SURGICAL & PROSTHETIC PROCEDURES



Surgical Procedures

Introduction

The insertion protocol for Inclusive Mini Implants is considered minimally invasive, and should be strictly adhered to. Using the correct insertion protocol will allow Inclusive Mini Implants to be immediately loaded after placement, provided primary stability and appropriate occlusal loading are assured.

Precautions

Minimizing tissue damage is crucial to successful implant osseointegration. In particular, care should be taken to eliminate sources of infection, contaminants, surgical and thermal trauma. Risk of osseointegration failure increases as tissue trauma increases. All drilling procedures should be performed at 1200 RPM or less under continual, copious irrigation. All surgical instruments used must be in good condition, and should be used carefully to avoid damage to implants or other components. Inclusive Mini Implants are for single use only, prior to the expiration date. Do not use implants if the packaging has been compromised or previously opened. Implants should be placed with sufficient stability (35 Ncm recommended); however, insertion torque greater than 45 Ncm may result in implant fracture, or fracture or necrosis of the implant site. The proper surgical protocol should be strictly adhered to. Since implant components and instruments are very small, precautions should be taken to ensure that they are not swallowed or aspirated by the patient.

Case Planning

Prescribed implant length and diameter should take into account crestal width, cortical thickness, bone density, and any other relevant clinical factors. Use appropriate radiography in mandibular cases to identify the location of the inferior alveolar nerve, including a possible anterior loop. Use appropriate radiography in maxillary cases to identify the location of the sinuses. When patient evaluation is complete, establish the number of Inclusive Mini Implants required for denture stabilization and identify the appropriate implant sites. In mandibular cases, it is recommended that four (4) mini implants be placed within the symphysis area with as wide an anterior-posterior spread as possible while still ensuring an adequate margin of safety from the nerve. In maxillary cases, it is recommended that six (6) mini implants be placed anterior to the sinuses. Wider implants are often preferred for softer bone types. Mini implants should be placed with a minimum of 7 mm between implants, to accommodate the size of the O-ring housings. The housings can accommodate up to 30 degrees of angular divergence between mini implants. However, implants should be placed as parallel to one another as possible to provide ideal prosthetic fit and to avoid excessive wearing of the O-rings. There should be at least 8 mm of vertical space from the top of the implant collar to allow for adequate thickness of the prosthesis. The denture teeth would be in addition to this space.

Mini Implant Radiographic Template

A radiographic template is available to clinicians who place Inclusive Mini Implants. This transparency is to be used as a diagnostic tool in selecting an implant of the appropriate size.

NOTE: This image is for illustrative purposes only, and is not intended for clinical use.

Cortical Bone Drills

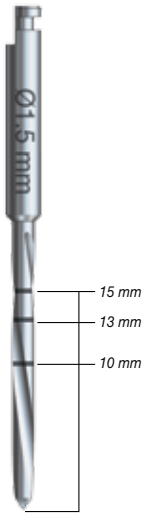
Proper treatment planning should be used to determine the appropriate-sized drill for each implant site. In standard cases, the appropriate drill diameter is associated with one of the available Inclusive Mini Implant diameters, as follows:

- Ø1.5 mm (for use with the Ø2.2 mm Inclusive Mini Implant; dependent on bone density)
- Ø1.7 mm (for use with the Ø2.5 mm Inclusive Mini Implant; dependent on bone density)
- Ø2.4 mm (for use with the Ø3.0 mm Inclusive Mini Implant; dependent on bone density)

Each drill includes laser-etched depth marks at 10 mm, 13 mm, and 15 mm, measured from the apical tip. Procedural depth is determined by clinical factors such as bone height and density. As a general guideline, the formula used to determine approximate drilling depth is one-half (1/2) the length of the implant, plus tissue depth.

Example:
Implant Length = 13 mm
Tissue Depth = 2 mm
(13 x ½) + 2 = 8.5

Approx. Drilling Depth = 8.5 mm



■ Drilling Protocol

Mark each implant site on the patient's tissue. Select the appropriate Cortical Bone Drill (1.5 mm, 1.7 mm, or 2.4 mm), as determined by the patient's bone density and the diameter of the implant to be placed. Carefully place the drill directly above the implant site and gently drill through the tissue and alveolar crest using an in-and-out motion and profuse, sterile irrigation to a depth of one-third (1/3) to one-half (1/2) the length of the implant threads. If placing 3.0 mm diameter Inclusive Mini Implants, continue drilling to a depth of at least two-thirds (2/3) the length of the implant threads. For the majority of implant sites, this is the extent of the drilling that is required. However, in dense bone, the drilling depth may need to be greater. The goal is to achieve high primary stability with an insertion torque of approximately 35 Ncm, taking care not to exceed the recommended maximum of 45 Ncm.

■ Implant Placement

Open the Inclusive Mini Implant vial. Grasping the plastic carrier, remove the implant from the vial, taking care not to touch the sterilized implant body. Transport the implant to the implant site, and insert into the pilot hole. Rotate clockwise with applied pressure to engage the self-tapping threads. Avoid lateral forces, which can affect the angulation and final alignment of the implant. The plastic carrier will separate from the implant head upon reaching a torque threshold of approximately 15 Ncm. Alternately, locking titanium forceps may be used to hold the implant body while the plastic carrier is removed and the implant driver is securely attached to the implant head. The forceps may then be removed and the implant placed in its site using the implant driver.

■ Final Insertion

With the implant threaded securely in its proper site, slide the Torque/Ratchet Wrench fully into place over the implant driver (utilizing the Round-Square Wrench Adaptor, if necessary). Turn the wrench clockwise in small increments of approximately 90 degrees, pausing between rotations to allow the bone to expand. Avoid lateral forces, which can affect the final angulation of the implant. Optimal final insertion of the implant leaves the implant head fully exposed, while the collar is embedded in the gingiva with no threads visible. For immediate loading of the implant, final torque at seating should be 30–35 Ncm minimum. Exceeding 45 Ncm torque during implant placement is not recommended.

⚠ NOTE: If the implant cannot be fully seated using the recommended torque, it may be necessary to reverse the implant from the site and drill again to increase the depth of the osteotomy. For positive long-term prognosis, solid resistance must be met during final insertion. Inadequate resistance contraindicates primary stability and loading. In such instances, a larger implant should be placed, or a new implant site determined.

Prosthetic Procedures

Precautions

Following successful placement of Inclusive Mini Implants, verify primary stability and appropriate occlusal loading before proceeding with the placement of a permanent or provisional prosthesis. All components that are used intraorally should be secured to prevent aspiration or swallowing. Distribution of stress is an important consideration. Care should be taken to avoid excessive loads significantly transverse to the implant axes.

Impression Procedure

An impression procedure is required whenever a new removable prosthesis is going to be fabricated. Based on the clinician's preference, the O-ring housings can be processed into the denture, or space made and the housings picked up chairside.

■ Seating the Copings

Snap a Mini Implant Impression Coping onto the head of each Inclusive Mini Implant. If gingival tissue prevents full engagement of a coping onto an implant, take an impression of the mini implant without the use of impression copings, or trim the tissue.

■ Seating the Impression

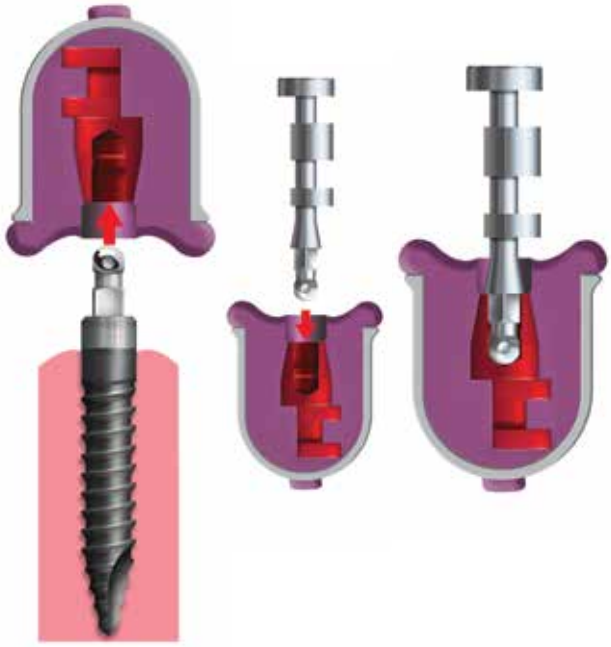
Standard impression techniques are used to pick up the impression copings, recording each implant's position easily and accurately.

■ Removing the Impression

Once the impression has fully set, carefully remove the tray from the patient's mouth and verify that all impression copings have been captured accurately in the impression.

■ Inserting the Replicas

This step can be performed in the clinic or at the dental laboratory. Align the squared neck of a Mini Implant Replica with the squared opening at the base of the impression coping. Press the replica into the coping until it snaps into proper position. Insert a replica into each coping and prepare the impression to be used to fabricate a stone model.



■ Fabrication of the Model

Use standard laboratory procedure to fabricate a soft tissue model.

Soft Denture Reline

A soft denture reline procedure is used when immediate loading with the O-rings is contraindicated, as in the case of a transitional prosthesis, or whenever the Inclusive Mini Implants are placed in soft bone (such as the maxilla or a Type III mandible). Following an appropriate healing period, the soft inner liner can be replaced with a hard pick-up of the O-ring housings to increase the level of retention.

■ Preparing the Denture

a) Relieve the patient's existing denture to make room for the implant heads. The positions of the implants can be identified using a color transfer applicator, or by lining the intaglio surface of the denture with impression or bite registration material. An acrylic bur can then be used to relieve the denture.

NOTE: The denture must be sufficiently relieved to seat passively, without resting on or against the implant heads.

b) Lightly roughen the tissue-facing surface of the denture with an acrylic bur, and degrease the surface with isopropyl alcohol.

■ Lining the Denture

a) Apply the selected soft reline material onto the tissue-facing surface of the denture.

b) Seat the denture in the patient's mouth. Instruct the patient to close with normal pressure into centric occlusion.

c) Allow the soft reline material to set.

■ Final Preparation

a) Remove the denture from the patient's mouth and trim excess material with fine scissors or a surgical blade. Do not remove the palate of a maxillary denture during this stage.

b) Instruct the patient to keep the denture in place for the first 48 hours following placement, to prevent gingival overgrowth.

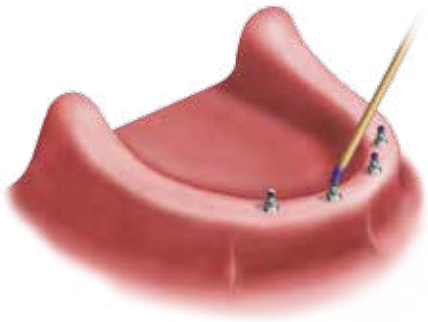
Hard Denture Reline

A hard denture reline procedure is used to incorporate the retention caps (O-ring Housings) that cover the Inclusive Mini Implants in the patient's final prosthesis. This loading procedure can typically be performed immediately after placement of the Inclusive Mini Implants, provided primary stability and appropriate occlusal loading are assured. Primary stability is generally indicated when 35 Ncm of torque resistance is achieved, with implants seated at the appropriate gingival depth.

■ Preparing the Denture

a) Mark the location of the implants on the intaglio surface of the patient's existing denture. This can be done using a color transfer applicator, or by lining the intaglio surface of the denture with impression or bite registration material.

b) Relieve the denture to make room for the O-ring housings. This can be done by creating a space for each housing where marked (or by burring a full trough).



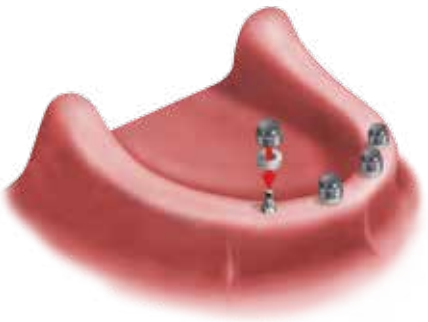
⚠ **NOTE: The denture must be sufficiently relieved to seat passively, without resting on or against the O-ring housings.**

■ Blocking Out the Implant Heads

a) Use a rubber dam or trim the Blockout Shims to the appropriate length in order to completely mask the exposed neck of each implant beneath the O-ball head. This is critical to prevent pick-up material from flowing under the O-ball.

b) Place an O-ring housing on each mini implant, checking for passive fit over the blockout shims.

c) Place the denture in the patient's mouth, checking for passive fit over implants and housings.



■ Lining the Denture

a) Apply a thin layer of adhesive on the intaglio surface of the denture.

b) Place hard pick-up material directly onto the O-ring housings and into the housing spaces (or trough) in the denture.

c) Seat the denture in the patient's mouth. Instruct the patient to close with normal pressure into centric occlusion.

d) Allow the hard pick-up material to set.

■ Final Preparation

a) Remove the denture and all blockout shims. Trim and polish.

b) Instruct the patient to keep the denture in place for the first 48 hours following implant placement, to prevent gingival overgrowth.

Implant Packaging

Inclusive Implants are packaged sterile by gamma irradiation, and are intended for single-use only, prior to the expiration date. Do not use implants if packaging has been compromised or previously opened. Packaging consists of a shrink-wrapped vial inside a robust heat-sealed plastic pouch. Please refer to the individual product label for all relevant product information and cautions. Printed label includes convenient peel-off stickers for individual case records.

Explanation of Label Codes:

1. Official product description

2. Product image silhouette

3. Reference number (product code)

4. Lot number

5. By prescription only

6. Do not use if tampered with

7. Gamma sterilization symbol

8. Expiration date

9. Consult Instructions for Use (IFU)

10. Do not re-sterilize

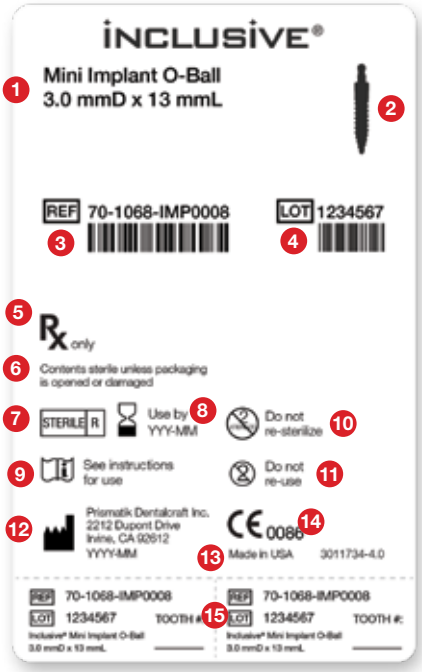
11. For single-use only

12. Manufacturer

13. Guaranteed Made in USA

14. CE 0086

15. Peel-off case labels



Policies and Warranty

Product Return Policy

Products may be returned at the customer's expense for credit within 30 days of invoice date. All returned products must meet the following conditions:

- A copy of the original invoice must accompany the products.
- Products must be packaged to arrive at the seller's facility undamaged.
- Discontinued, obsolete, expired, damaged, or opened items will not be accepted for return.
- Amount credited will be based on invoice price, less 15 percent for restocking fee.
- Shipping charges are the responsibility of the customer and will not be credited.

Product & Pricing Changes

Because products and equipment are continually undergoing refinement in design and manufacturing methods, we reserve the right to improve, modify, or discontinue products and equipment or change pricing at any time without incurring any obligation and without prior notice.

Warranty

Limited Warranty—Prismatik Dentalcraft, Inc.

Prismatik Dentalcraft, Inc. ("Prismatik") is the manufacturer of dental products (the "product"), including Inclusive® Dental Implants ("implants"). For a period from the original purchase date of seven (7) years for implants and six (6) months for ceramic blanks and any other product ("the warranty period"), Prismatik will at its option replace or refund the purchase price of any product, to the original purchaser ("user"), that is returned due to defects in material and manufacture.

NO GUARANTEE OR WARRANTY IS IMPLIED OTHER THAN EXPRESSLY STATED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Prismatik shall not be liable for any incidental or consequential damages, whether foreseeable or not, caused by defects in the product or dental devices produced using said product. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, user's exclusive remedy and Prismatik's sole obligation shall be replacement or refund of the purchase price of the product. For replacement or refund under this warranty, the original purchaser shall send the product at its own expense, postage prepaid, to the seller.

INCLUSIVE®
DENTAL IMPLANT SYSTEM

Designed & Manufactured in the USA
by

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