INCLUSIVE®
DENTAL IMPLANT SYSTEM

Surgical Manual
December 2018

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GLIDEWELL DIRECT
CLINICAL AND LABORATORY PRODUCTS

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

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 702124**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design and manufacturing of dental restorative products. Design and development, manufacture and distribution of software used with milling systems for dental restorations.

For and on behalf of BSI:

Carlos Pitanga, Chief Operating Officer Assurance – Americas

Original Registration Date: 2011-09-02
Latest Revision Date: 2018-10-16

Effective Date: 2018-10-16
Expiry Date: 2019-08-02

...making excellence a habit.™

Introducing the Inclusive® Dental Implant System

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. From cementable or screw-retained single-tooth replacement to full-arch reconstruction with removable or fixed-removable prostheses, the Inclusive Dental Implant System can provide a predictable foundation for clinical success.

About the Manufacturer

Prismatik Dentalcraft was established in 2006 with the mission of making implant dentistry the standard of care for edentulous patients across the economic spectrum. To realize this goal, we carefully assembled a team of experts with decades of combined experience in the design, engineering, and manufacture of dental implants. With a support staff of highly respected researchers, material scientists, clinical specialists, and dental technicians, Prismatik is dedicated to advancing implant therapies by combining proven treatment protocols with progressive materials, technologies, and techniques.

Expert Personnel

Our team of experts have decades of combined experience in the design and manufacture of dental implants.

State-of-the-Art Equipment

Our Swiss-type lathes and multi-axis milling machines are ideal for implants and prosthetics requiring extreme precision.

Made in the U.S.A.

Our ISO-certified facility in Irvine, Calif. operates under FDA Current Good Manufacturing Practices (CGMPs).

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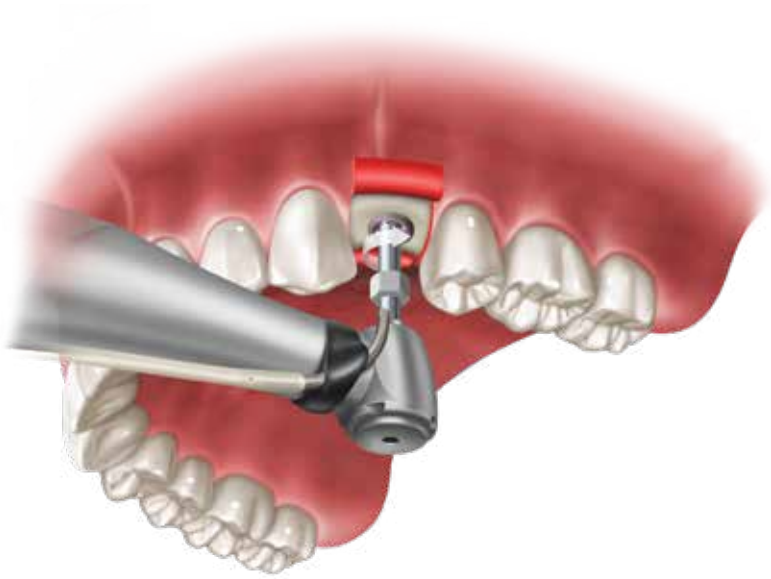
INCLUSIVE®
TAPERED IMPLANT SYSTEM

SURGICAL PROCEDURES



Surgical Considerations

Scope

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

The procedures and guidelines presented herein are not adequate to allow inexperienced clinicians to administer professional implant treatment or prosthetic dentistry, and are not intended to substitute for formal clinical or laboratory training. Inclusive devices should only be used by individuals with training and experience specific to their clinically accepted application. Prismatik Dentalcraft, Inc. is not liable for damages resulting from treatment outside of its control. The responsibility rests with the provider.

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

Intended Use

Inclusive Tapered Implants are intended 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

Inclusive Tapered Implants should not be placed in patients discovered to be medically unfit for the intended treatment. Prior to clinical intervention, prospective patients must be thoroughly evaluated for all known risk factors and conditions related to oral surgical procedures and subsequent healing. 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.

Treatment of children is not recommended until growth is finished and epiphyseal closure has occurred.

Warnings

Do not reuse Inclusive Tapered Implants. The reuse of such device on another patient is not recommended due to the risks of cross-contamination or infection.

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 intended 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, surgical instruments, and restorative 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.

Surgical Considerations

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.

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.

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 2000 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.

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.

Prior to surgery, ensure that the needed components, instruments and ancillary materials are complete, functional and available in the correct quantities.

MRI

The Inclusive Tapered Implant System has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Inclusive Tapered Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Sterility

Inclusive Tapered Implants are shipped sterile. They should not be resterilized. They are for single use only, prior to the expiration date. Do not use implants if the packaging has been compromised or previously opened.

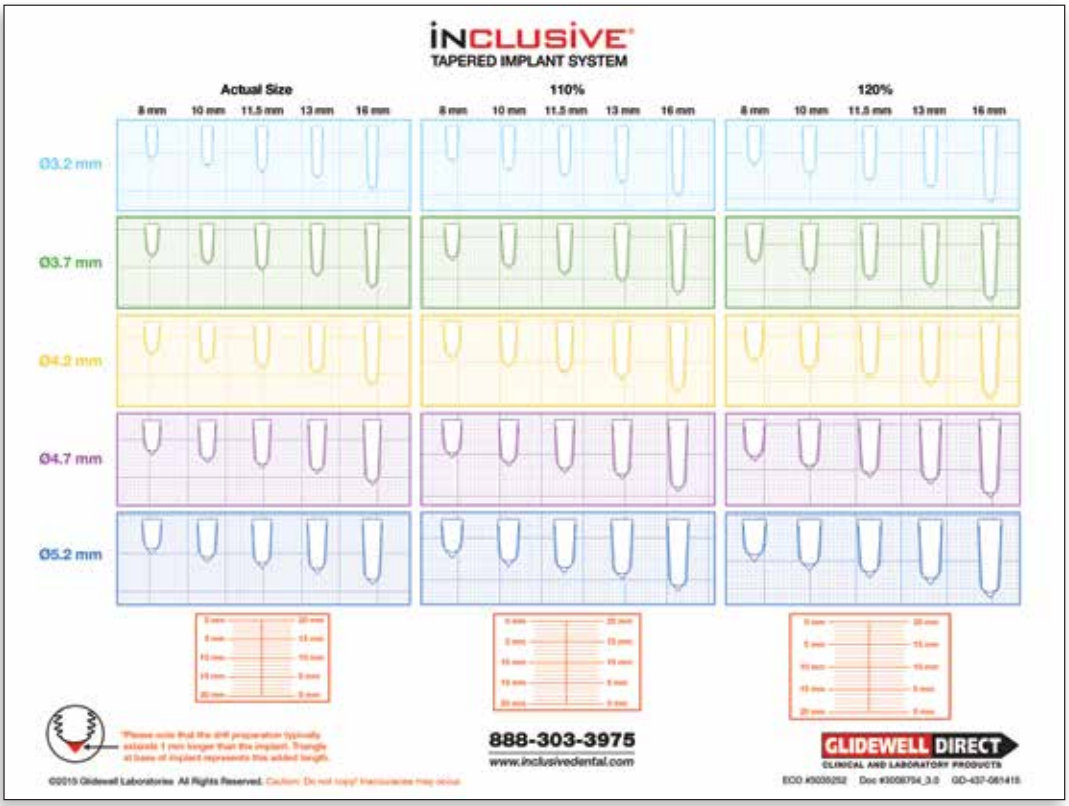
Storage and Handling

Inclusive Tapered Implants must be stored in a dry location (30% to 85% relative humidity) at room temperature (20°C to 25°C), in their original packaging. Inclusive Tapered Implants are packaged sterile. Do not handle implant surfaces directly. Users are advised to visually inspect packaging to ensure seals and contents are intact prior to use. Please refer to the individual product label for all relevant product information and cautions.

Surgical Considerations

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.

Color Coding

The Inclusive Tapered Implant System utilizes color-coding for easy component identification. Colors may be found across system articles such as surgical tray, radiographic template, screw taps, and the implant carrier included in each sterile package, reflecting either the prosthetic platform or implant diameter, as indicated in the legend below:

Implant Body	Ø3.2 mm	Ø3.7 mm	Ø4.2 mm	Ø4.7 mm	Ø5.2 mm
Implant Icon					
Prosthetic Platform	Ø3.0 mm	Ø3.5 mm	Ø3.5 mm	Ø4.5 mm	Ø4.5 mm
Prosthetic Icon	3.0	3.5	3.5	4.5	4.5

Surgical Considerations

Implant Selection

Inclusive Tapered Implants are available in five diameters (3.2 mm, 3.7 mm, 4.2 mm, 4.7 mm, 5.2 mm), each of which is available in up to five lengths (8 mm, 10 mm, 11.5 mm, 13 mm, 16 mm). Three standard prosthetic platform sizes (3.0 mm, 3.5 mm, 4.5 mm) serve to minimize the number of system components and simplify the restorative process.

Ø3.2 mm	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
Ø3.2 x 11.5 mm 70-1070-IMP0032	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
Ø3.2 x 13 mm 70-1070-IMP0033	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
Ø3.2 x 16 mm 70-1070-IMP0034	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

Surgical Instrumentation

All instrumentation is manufactured in the U.S.A. or Switzerland. For specific country of origin, please refer to the individual product label.

Instruments are shipped non-sterile. All instruments should be cleaned, disinfected, and sterilized according to a validated method prior to use in the oral environment.

- ***Cleaning:*** Wash using a broad spectrum cleaning solution, followed by thorough rinsing and drying. The recommended disinfection process is based on ANSI/AAMI ST79 guidelines, as follows:

- ***Disinfection:*** Immerse abutments in disinfectant,[1] rinse with distilled water, and dry.

Surgical Instrumentation

The recommended sterilization process is based on the ANSI/AAMI/ISO 17665-1 and ANSI/AAMI ST79 guidelines, as follows:

- ***Sterilization:*** Gravity-fed sterilizers: Autoclave in sterilization pouch for fifteen (15) minutes at 132°C (270°F). Allow sterilized components to dry for at least thirty (30) minutes.

[1] Oral disinfectant containing Chlorhexidine is recommended. Refer to the disinfectant manufacturer's instructions.

NOTE: The validated procedures require the use of FDA-cleared sterilization trays, wraps, biological indicators, chemical indicators, and other sterilization accessories labeled for the sterilization cycle recommended. The healthcare facility should monitor the sterilizer for the facility according to an FDA-recognized sterility assurance standard such as ANSI/AAMI ST79.

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.
- Dry promptly and completely to avoid oxidation.

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, 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 (level with the crest of the ridge).

Ø2.3/2.0 mm
Pilot Drill

Ø2.8/2.3 mm
Shaping Drill

Ø3.4/2.8 mm
Shaping Drill

Ø3.8/3.4 mm
Shaping Drill

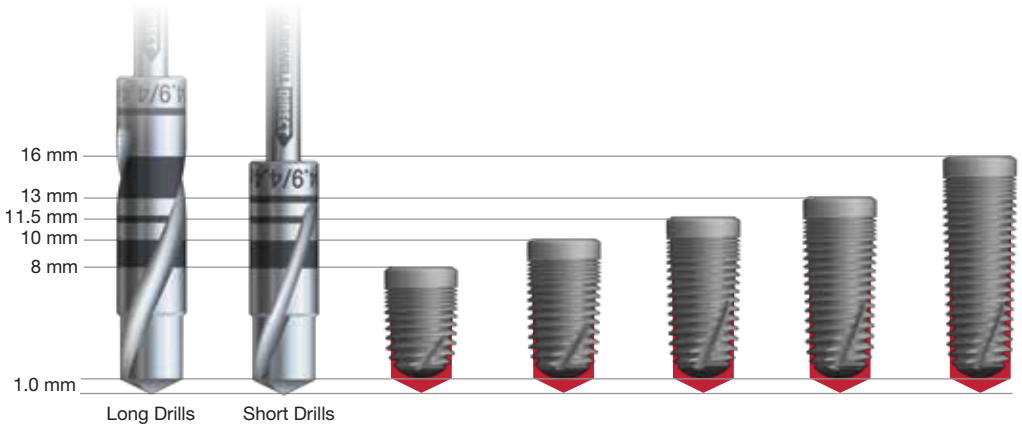
Ø4.4/3.8 mm
Shaping Drill

Ø4.9/4.4 mm
Shaping Drill

Surgical Instrumentation

Depth Markings

The illustration below demonstrates the correlation 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.



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 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
Ø3.2 mm Screw Tap

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

Bone Profilers *(Optional for subcrestal implant placement)*

When Inclusive Tapered Implants are placed subcrestal to the surrounding alveolar ridge, a profiler may be used to remove excess bone around the implant platform. This is to aid in the proper seating of any abutment wider than the implant platform. Profiling may be performed immediately following implant placement, or following successful osseointegration. Bone profilers are categorized by implant platform size, and are intended for manual use.

Ø3.0 mm Bone Profiler

Ø3.5 mm Bone Profiler

Ø4.5 mm Bone Profiler

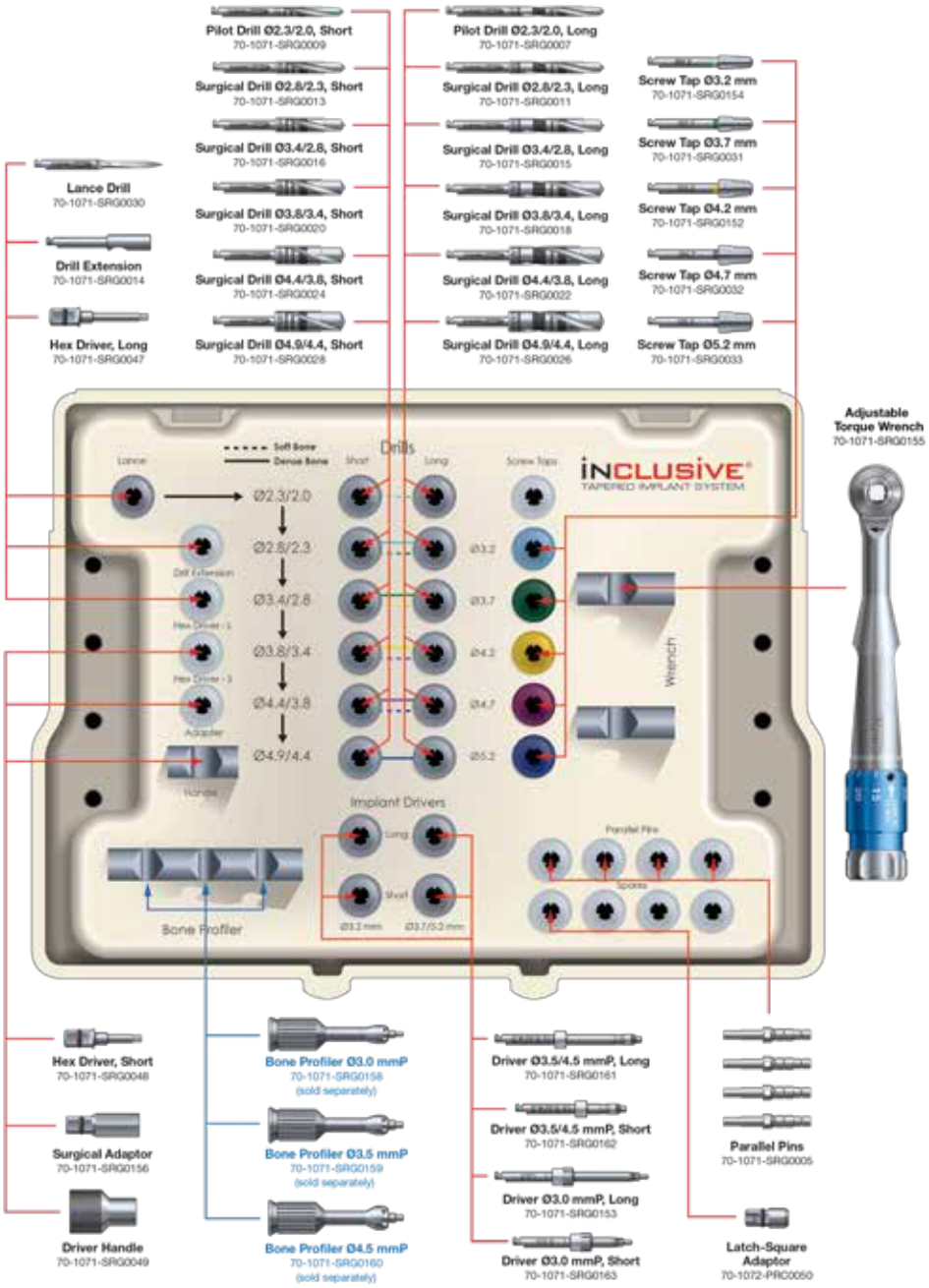
Surgical Instrumentation

All instruments associated with the Inclusive Tapered Implant System are machined from corrosion-resistant, surgical stainless steel, and feature standard connectivity. All instrumentation is manufactured in the U.S.A. or Switzerland. For specific country of origin, please refer to the individual product label.

NOTE: Instruments are shipped non-sterile. Steam sterilize the surgical tray and its contents for fifteen (15) minutes at 132°C/270°F. Allow sterilized components to dry for at least thirty (30) minutes.

Surgical Kit

The surgical kit allows the clinician to easily organize, store and transport the components of the Inclusive Tapered Implant System. Drills are arranged from top to bottom in order of increasing diameter, following the recommended drilling sequence. Color-coded fields indicate the corresponding diameter of Inclusive Tapered Implant.

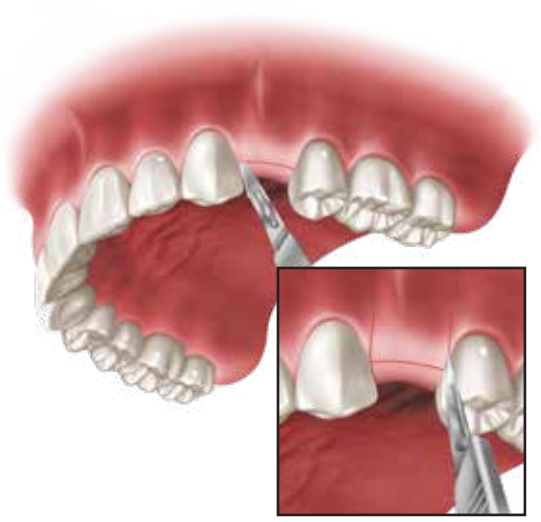


Surgical Protocol

■ Soft Tissue Reflection

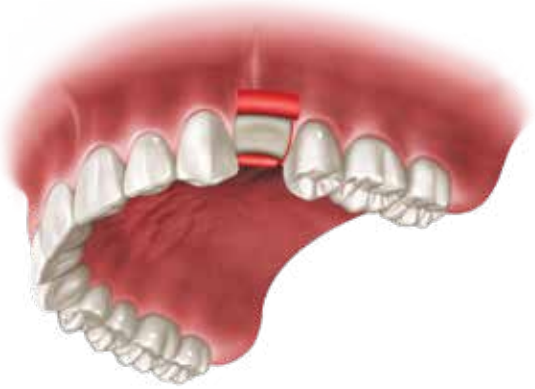
Following administration of anesthesia, make an incision designed for elevation of a flap.

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.

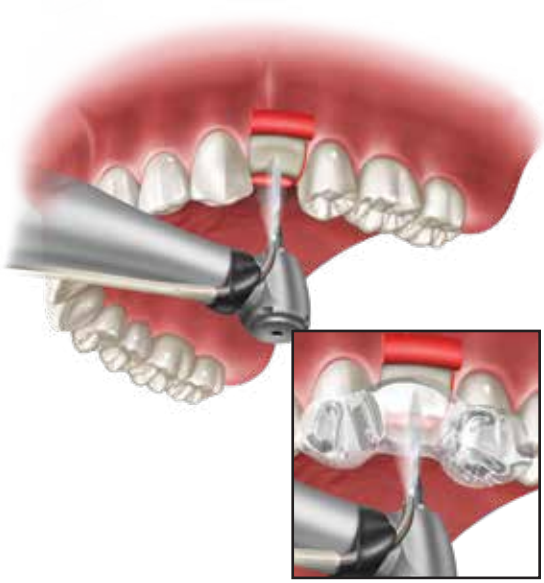


■ Osteotomy Site Preparation

Step 1: Lance Drill

With copious irrigation, perforate the alveolar crest. Utilize a surgical guide, if necessary, as a reference for proper positioning.

Ø1.5 mm Lance Drill

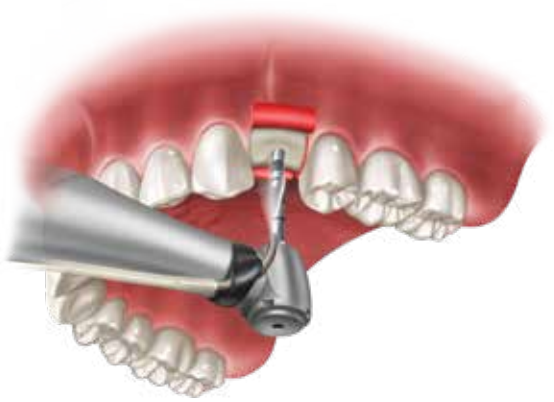


Surgical Protocol

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 copious irrigation, drill a pilot hole to the appropriate depth marking on the drill.

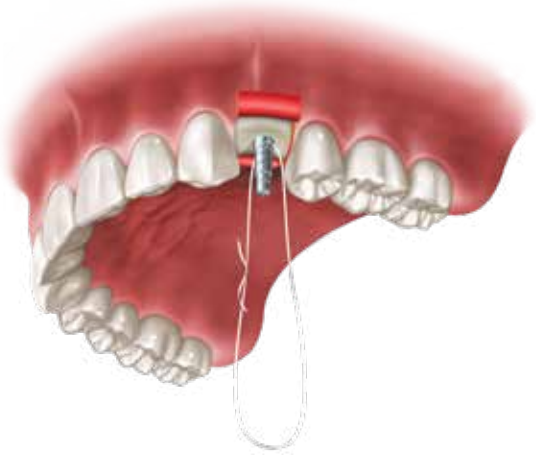
Ø2.3/2.0 mm Pilot Drill



NOTE: Depth markings are calculated to place the implant level with the ridge crest. If supracrestal placement is desired, do not drill to full depth.

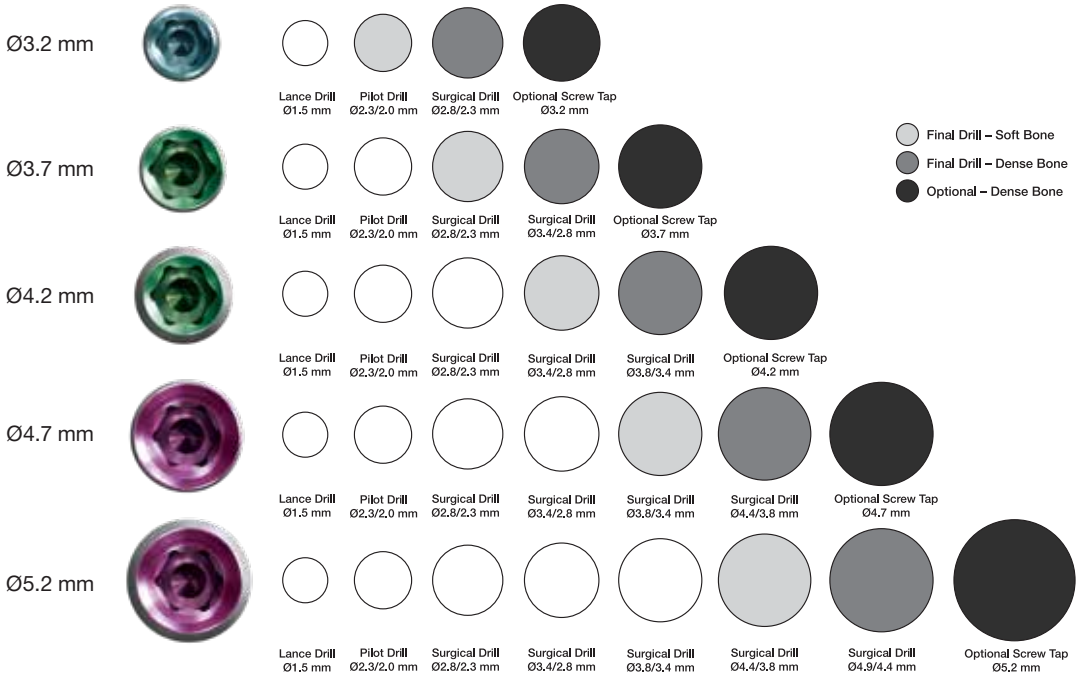
Check the orientation of the initial osteotomy using a Parallel Pin. If placing more than one implant and parallelism is desired, begin drilling the next site and align as the trajectory of the bone permits.

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 copious 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 20 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 Screw 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.

Ø3.2 mm Screw Tap

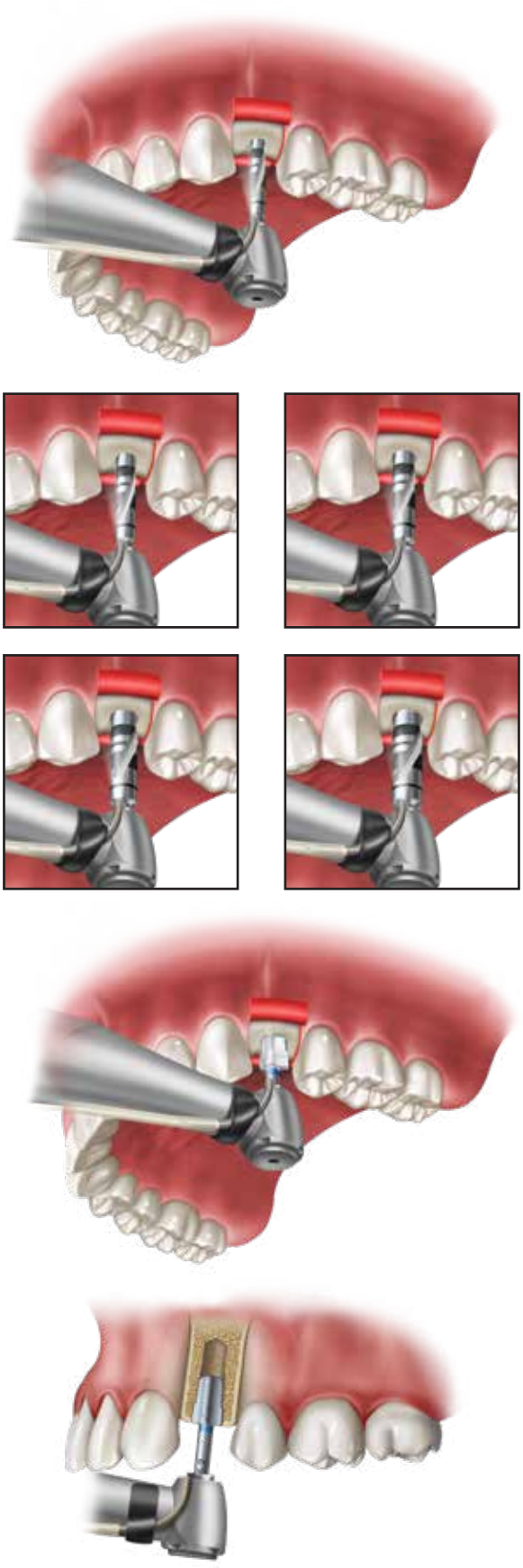
Ø3.7 mm Screw Tap

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.



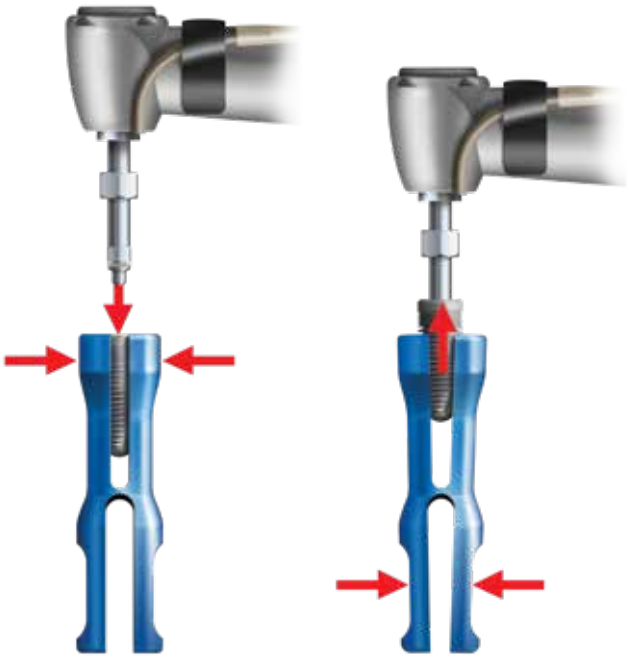
Surgical Protocol

■ Implant Placement

Step 1: Implant Selection

Remove the titanium implant holder from its packaging and place it onto a sterile field.

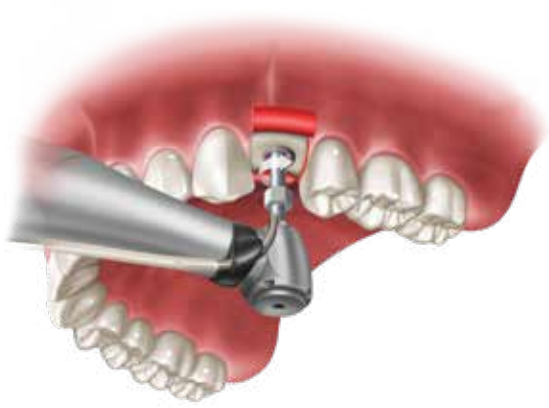
⚠ NOTE: The plastic tray contains a Cover Screw, for use when following a two-stage surgical protocol. Do not discard the Cover Screw upon removal of the implant.



Step 2: Initial Placement

Use slight finger pressure to pinch the occlusal end of the implant in its holder while inserting the appropriate Implant Driver. Gently rotate implant and holder, allowing the driver to engage the implant connection. With the driver securely attached to the implant, squeeze the opposing end of the holder to disengage the implant from the holder. Transport the implant to the prepared site, and insert into the osteotomy. Rotate clockwise with applied pressure to engage the self-tapping grooves. Avoid lateral forces, which can affect the angulation and final alignment of the implant.

⚠ NOTE: Apply pressure to ensure the driver is fully engaged with the implant prior to disengaging the titanium holder.



Step 3: Advancement and Final Seating

Continue threading the implant into the osteotomy site using the preferred placement method. A minimum torque value of 35 Ncm upon final seating indicates good primary stability.

■ Methods of Implant Placement

Option 1: Handpiece Implant Placement

Place the appropriate 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.

Surgical Protocol

Option 2: Manual Implant Placement

Assemble the Adjustable Torque Wrench with the Surgical Adaptor and appropriate Implant 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.

Adjustable Torque Wrench

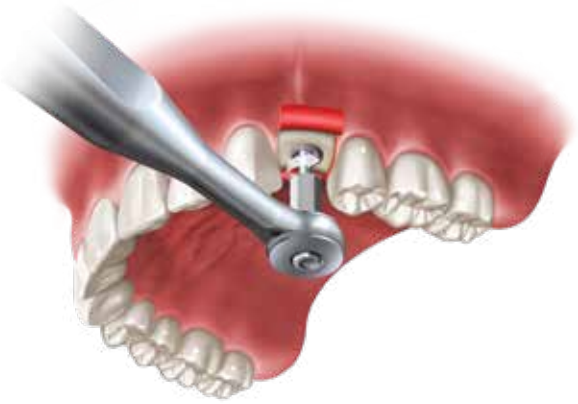
Surgical Adaptor

Driver Ø3.5/4.5 mmP, Long

Driver Ø3.5/4.5 mmP, Short

Driver Ø3.0 mmP, Long

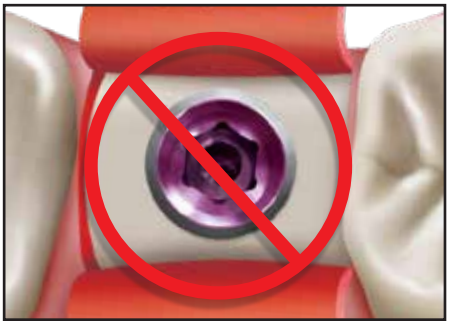
Driver Ø3.0 mmP, Short



■ 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.

NOTE: Implant may be placed level with the ridge crest, or supracrestal, in accordance with the desired treatment plan.



Surgical Protocol

■ Bone Profiling

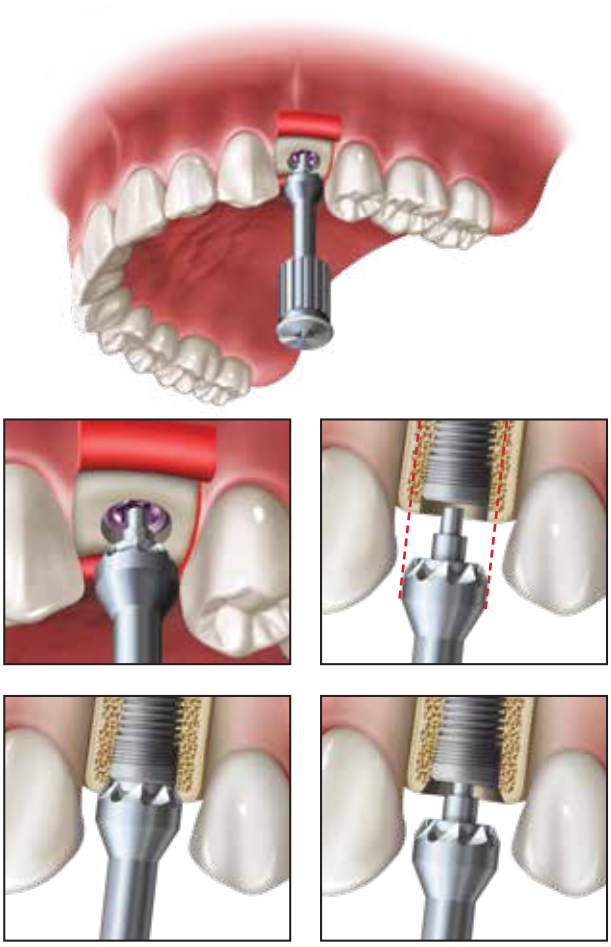
If indicated by subcrestal placement of the implant or excess bone around the restorative platform, select the appropriate Bone Profiler based on the implant's platform size. Insert the tip of the profiler into the implant's connection interface, taking care to ensure a parallel orientation with the implant. Using finger pressure, maintain parallelism while gently rotating the profiler clockwise until the profiler reaches a stop against the implant platform (progressing no farther with continued rotation). Remove the profiler when finished. With suction, irrigate site to ensure removal of bone debris.

NOTE: Failing to maintain parallelism between the profiler and the implant may result in damage to the implant interface, or lead to incorrect profiling of the bone.

Ø3.0 mm Bone Profiler

Ø3.5 mm Bone Profiler

Ø4.5 mm Bone Profiler



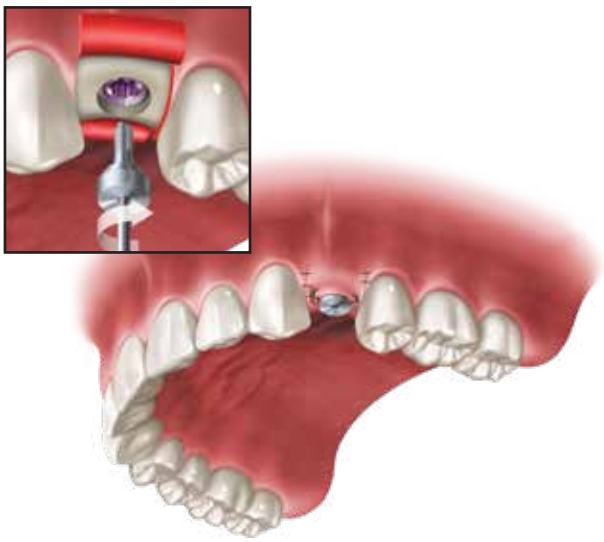
■ Healing Component Placement

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 (Single-Stage Surgical Protocol)

If observing a single-stage surgical protocol, select a Healing Abutment of the appropriate height and diameter. Thread the Healing Abutment into place atop the implant. Hand-tighten with the appropriate Prosthetic Driver.

Healing Abutment

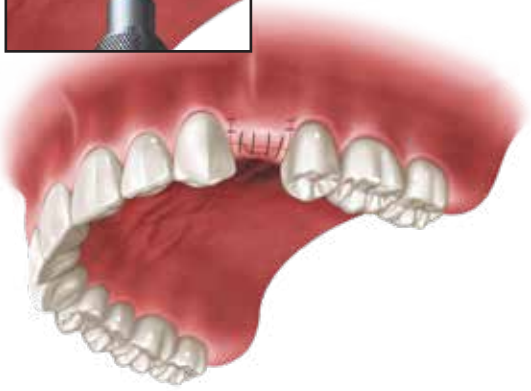


Surgical Protocol

Option 2: Cover Screw
(Two-Stage Surgical Protocol)

If observing a two-stage surgical protocol, thread the Cover Screw into place atop the implant. Hand-tighten with the appropriate Prosthetic Driver.

Cover Screw

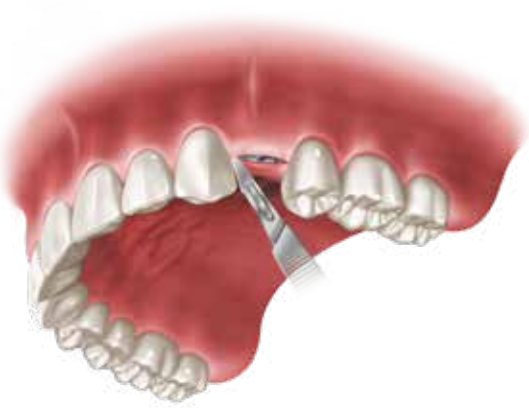


■ Closure and Suturing

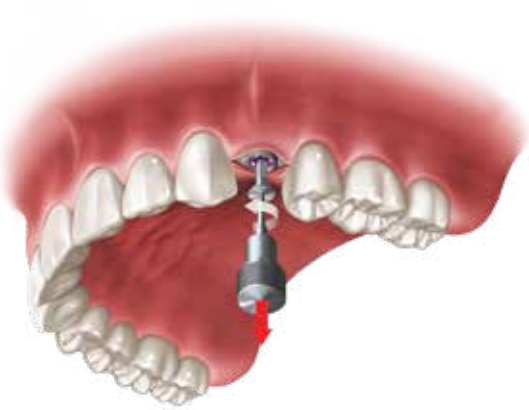
If the soft tissue was reflected, close and suture the flap utilizing the desired technique. Take a postoperative radiograph to use as a baseline, and advise the patient as to the recommended postoperative procedures.

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

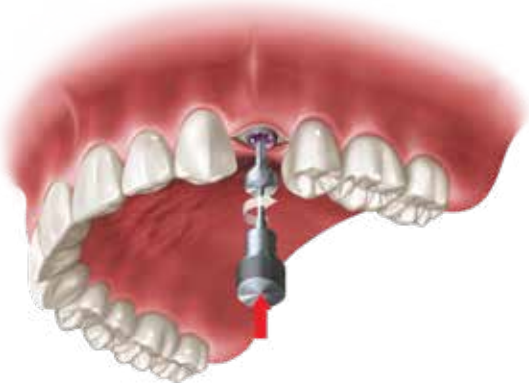
Following the appropriate healing period, make a small incision in the gingiva over the implant site to expose the Cover Screw. Using the Prosthetic Driver, remove the Cover Screw and place a Healing Abutment or Temporary Abutment of the appropriate height and diameter.



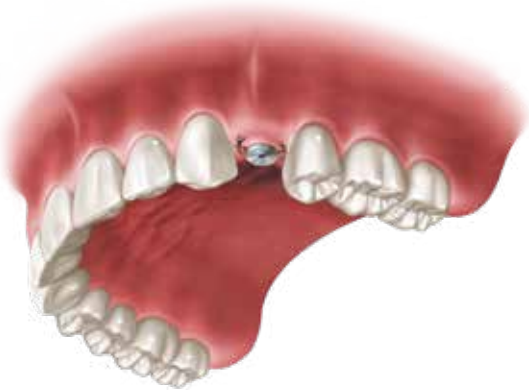
Step 1: Expose the Cover Screw



Step 2: Remove the Cover Screw



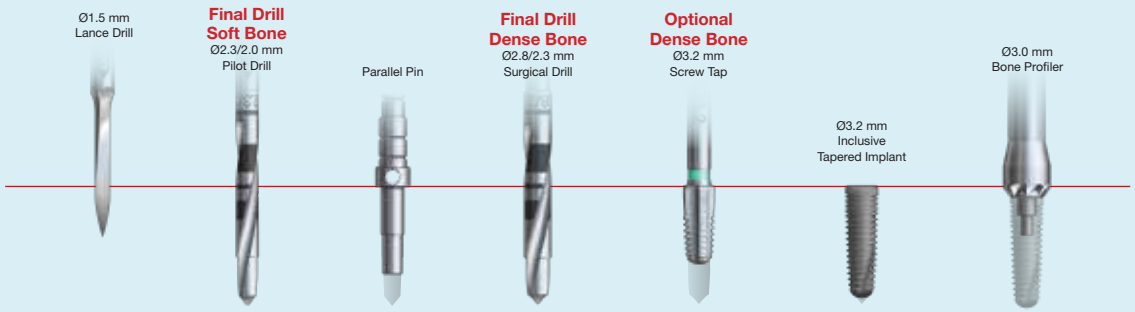
Step 3: Place Healing Abutment



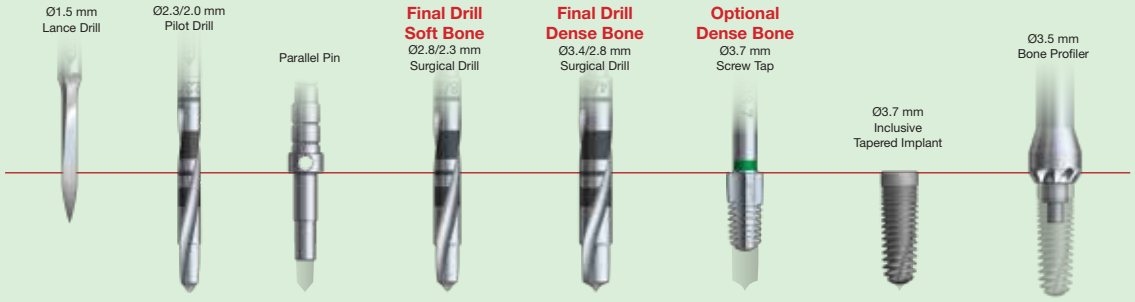
Step 4: Close and suture

Drilling Sequences

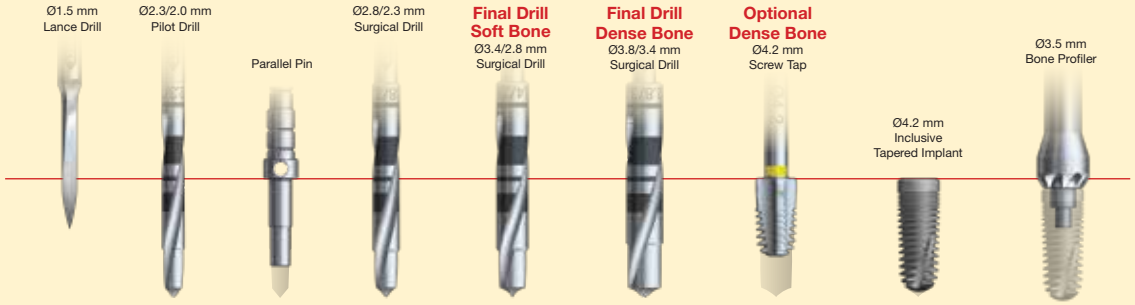
Ø3.2 mm Inclusive Tapered Implant



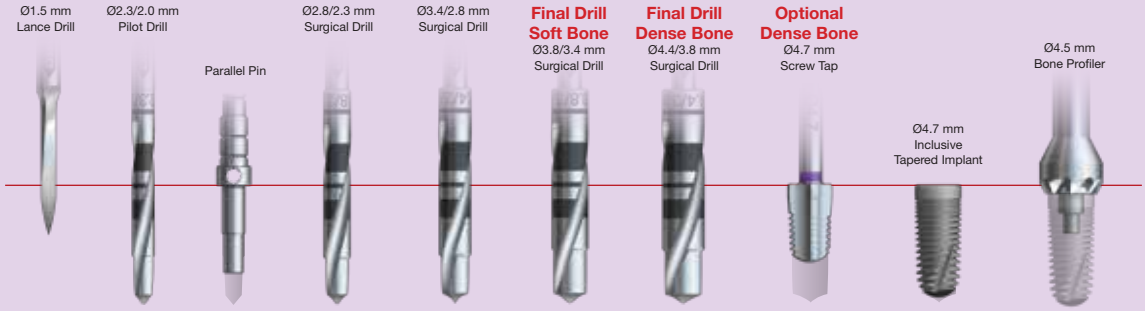
Ø3.7 mm Inclusive Tapered Implant



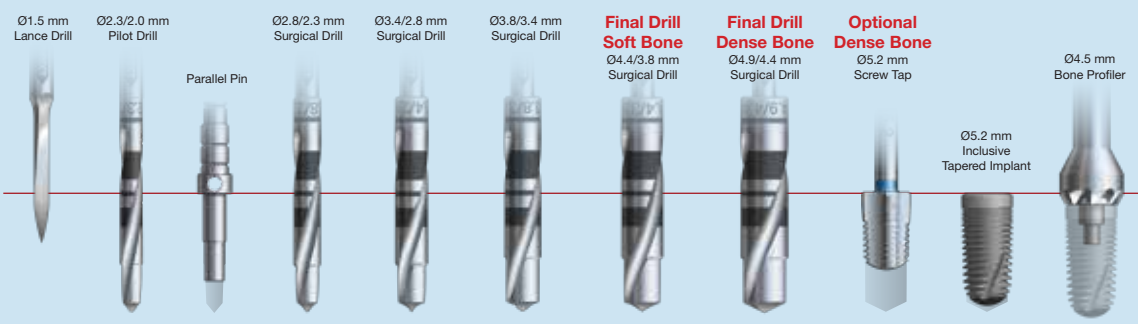
Ø4.2 mm Inclusive Tapered Implant



Ø4.7 mm Inclusive Tapered Implant

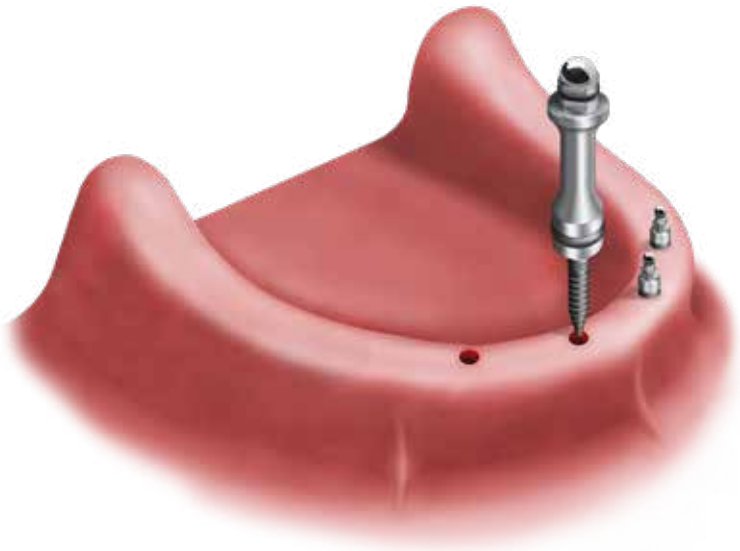


Ø5.2 mm Inclusive Tapered Implant



INCLUSIVE®
MINI IMPLANT SYSTEM

SURGICAL & PROSTHETIC PROCEDURES



Surgical Considerations

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.

The procedures and guidelines presented herein are not adequate to allow inexperienced clinicians to administer professional implant treatment or prosthetic dentistry, and are not intended to substitute for formal clinical or laboratory training. Inclusive devices should only be used by individuals with training and experience specific to their clinically accepted application. Prismatik Dentalcraft, Inc. is not liable for damages resulting from treatment outside of its control. The responsibility rests with the provider.

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

Intended Use

Inclusive Mini Implants are self-tapping threaded titanium implants designed for long-term or provisional applications. The implants are to be used for immediate loading only in the presence of adequate primary stability and appropriate occlusal loading.

Contraindications

Inclusive Mini Implants should not be placed in patients discovered to be medically unfit for the intended treatment. Prior to clinical intervention, prospective patients must be thoroughly evaluated for all known risk factors and conditions related to oral surgical procedures and subsequent healing. 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.

Treatment of children is not recommended until growth is finished and epiphyseal closure has occurred. Inclusive Mini Implants are not indicated for abutment or crown restorations.

Warnings

Do not reuse Inclusive Mini Implants. The reuse of such device on another patient is not recommended due to the risks of cross-contamination or infection.

Inclusive Mini 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 intended use are not clearly specified, treatment should be suspended until these considerations have been clarified.

Inclusive Mini Implants are not recommended for the posterior region of the mouth.

The following instructions are not sufficient to allow inexperienced clinicians to administer professional prosthetic dentistry. Inclusive Mini Implants, surgical instruments, and restorative components must only be used by dentists and surgeons with training/experience with oral surgery and prosthetics.

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.

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. Biomechanical overloading may lead to loss of osseointegration after delivery of the prosthetic restoration.

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 2000 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. 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.

Prior to surgery, ensure that the needed components, instruments and ancillary materials are complete, functional and available in the correct quantities.

Sterility

Mini Implants

Inclusive Mini Implants are shipped sterile. They should not be resterilized. They are for single use only, prior to the expiration date. Do not use implants if the packaging has been compromised or previously opened.

Surgical Instruments

Surgical instruments are shipped non-sterile. Surgical tray and instruments must be cleaned, disinfected, and sterilized prior to clinical use, according to a validated method.

Prosthetic Components

Inclusive Mini Implant prosthetic components are shipped non-sterile. Non-sterile components must be cleaned, disinfected, and sterilized prior to clinical use, according to a validated method.

Surgical Considerations

■ ***Cleaning:*** Wash using a broad spectrum cleaning solution, followed by thorough rinsing and drying.

The recommended disinfection process is based on ANSI/AAMI ST79 guidelines, as follows:

■ ***Disinfection:*** Immerse in disinfectant[1], rinse with distilled water and dry.

The recommended sterilization process is based on the ANSI/AAMI/ISO 17665-1 and ANSI/AAMI ST79 guidelines, as follows:

■ ***Sterilization of Surgical Instruments:*** Gravity-fed sterilizers: Autoclave in sterilization pouch for 20 minutes at 132°C (270°F). Devices are to be used immediately after sterilization.

■ ***Sterilization of Prosthetic Components:*** Gravity-fed sterilizers: Autoclave in sterilization pouch for 30 minutes at 121°C (250°F). Devices are to be used immediately after sterilization.

[1]Oral disinfectant containing Chlorhexidine is recommended; refer to the disinfectant manufacturer's instructions.

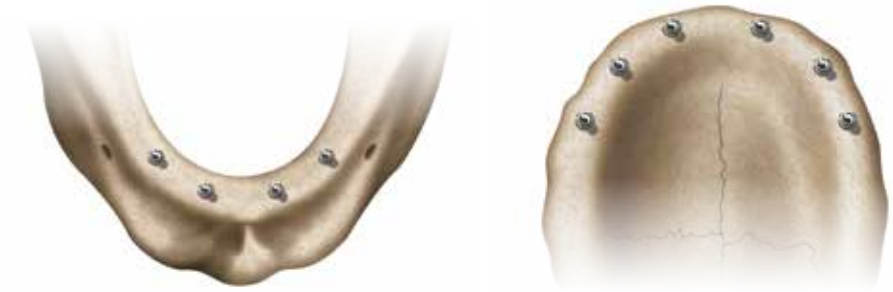
NOTE: The validated procedures require the use of FDA-cleared sterilization trays, wraps, biological indicators, chemical indicators, and other sterilization accessories labeled for the sterilization cycle recommended. The healthcare facility should monitor the sterilizer for the facility according to an FDA-recognized sterility assurance standard such as ANSI/AAMI ST79.

Storage and Handling

Inclusive Mini Implants must be stored in a dry location (30% to 85% relative humidity) at room temperature (20°C to 25°C), in their original packaging. Inclusive Mini Implants are packaged sterile. Do not handle implant surfaces directly. Users are advised to visually inspect packaging to ensure seals and contents are intact prior to use. Please refer to the individual product label for all relevant product information and cautions.

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 (center-to-center), 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.



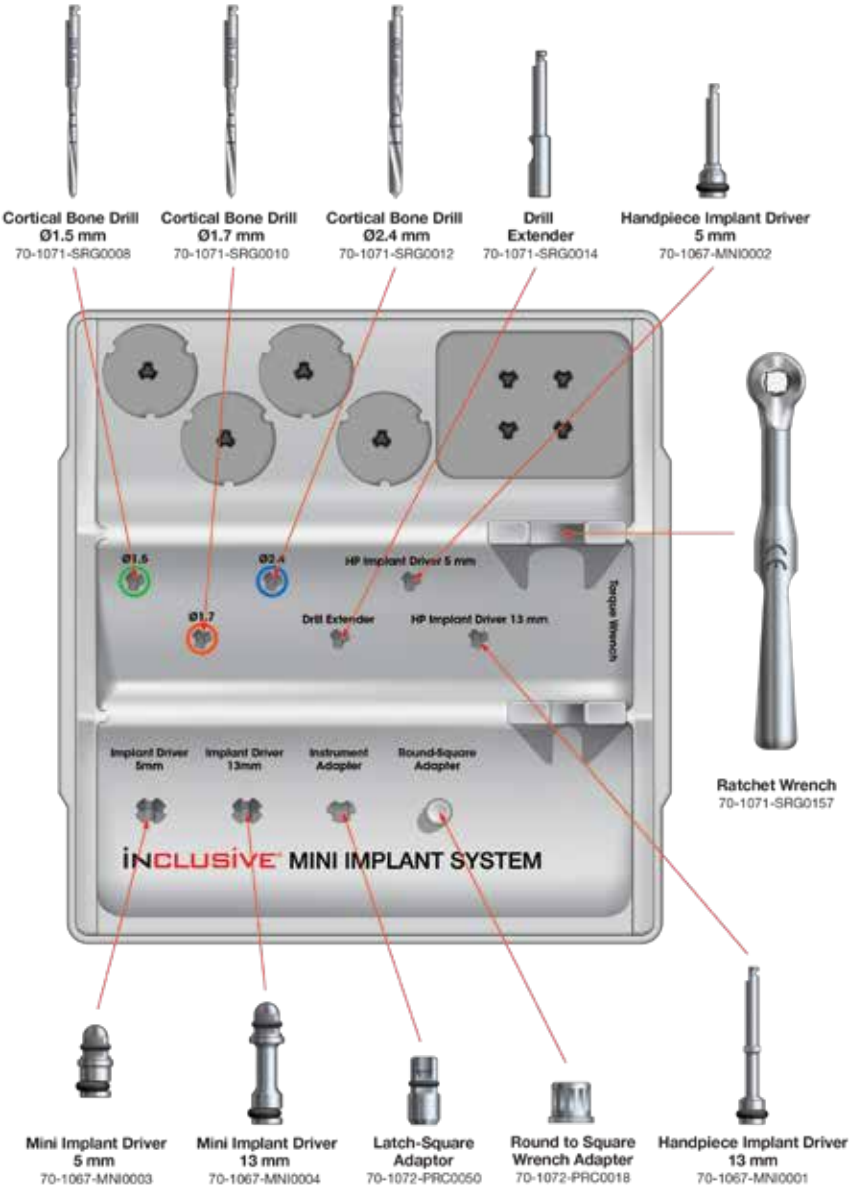
Surgical Instrumentation

Surgical Kit

The Mini Implant Surgical Instrumentation Kit allows the clinician to easily organize, store and transport the components of the Inclusive Mini Implant System. It has been designed for ease of use, with 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, with color-coded fields to indicate the corresponding diameter of Inclusive Mini Implant.

⚠ NOTE: Instruments are shipped non-sterile. Steam sterilize the surgical tray and its contents for twenty (20) minutes at 132°C (270°F). Devices are to be used immediately after sterilization.



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.

Surgical Instrumentation

Cortical Bone Drills

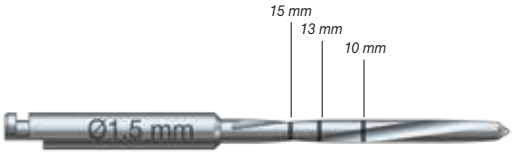
Proper treatment planning should be used to determine the appropriate-sized drill for each implant site. In standard cases, the appropriate drill diameter is associated with one of the available Inclusive Mini Implant diameters, as follows:

- 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



Surgical Procedures

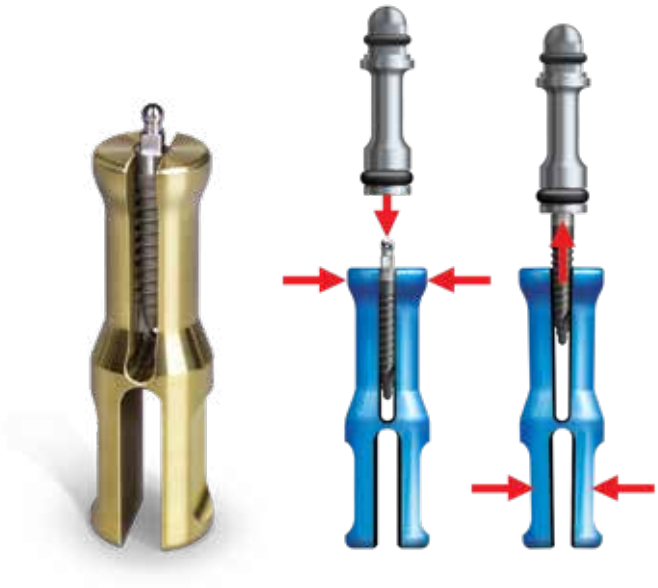
■ Drilling Protocol

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

Remove the titanium implant holder from its packaging and place it onto a sterile field.

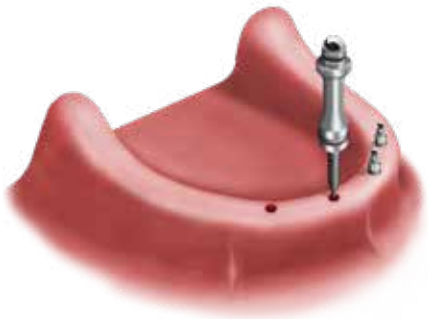
Use slight finger pressure to pinch the occlusal end of the implant in its holder while inserting the appropriate Mini Implant Driver. Gently rotate implant and holder, allowing the driver to engage the implant connection. With the driver securely attached to the implant, squeeze the opposing end of the holder to disengage the implant from the holder. Transport the implant to the prepared site, and insert into the osteotomy. 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.



⚠ **NOTE: Apply pressure to ensure the driver is fully engaged with the implant prior to disengaging the titanium holder.**

■ Final Insertion

With the implant threaded securely in its proper site, slide the Ratchet Wrench fully into place over the mini implant driver. 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.**

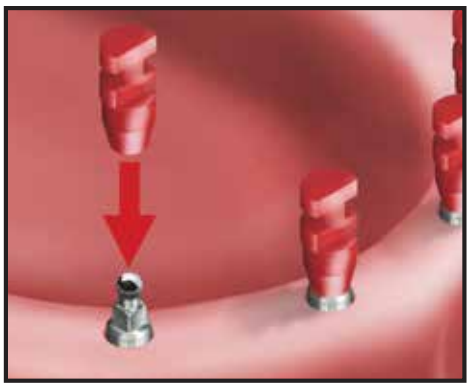
Prosthetic Procedures

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.

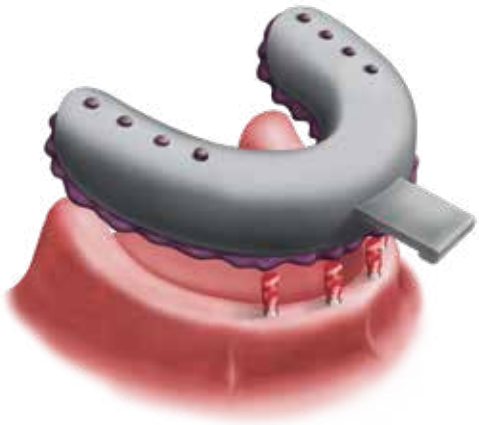


■ Seating the Copings

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

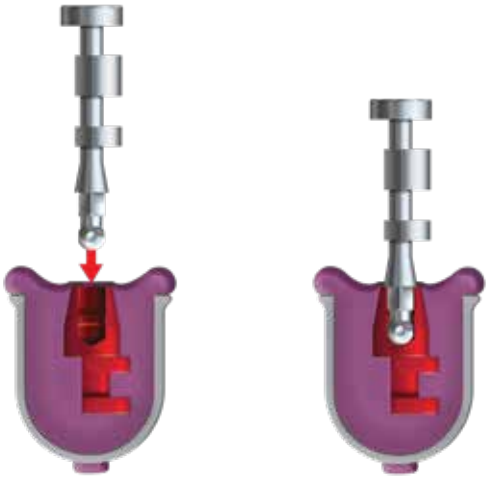
Once the impression has fully set, carefully remove the tray from the patient's mouth and verify that all impression copings have been captured accurately in the impression.

■ 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 procedures 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 tissue-facing 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.

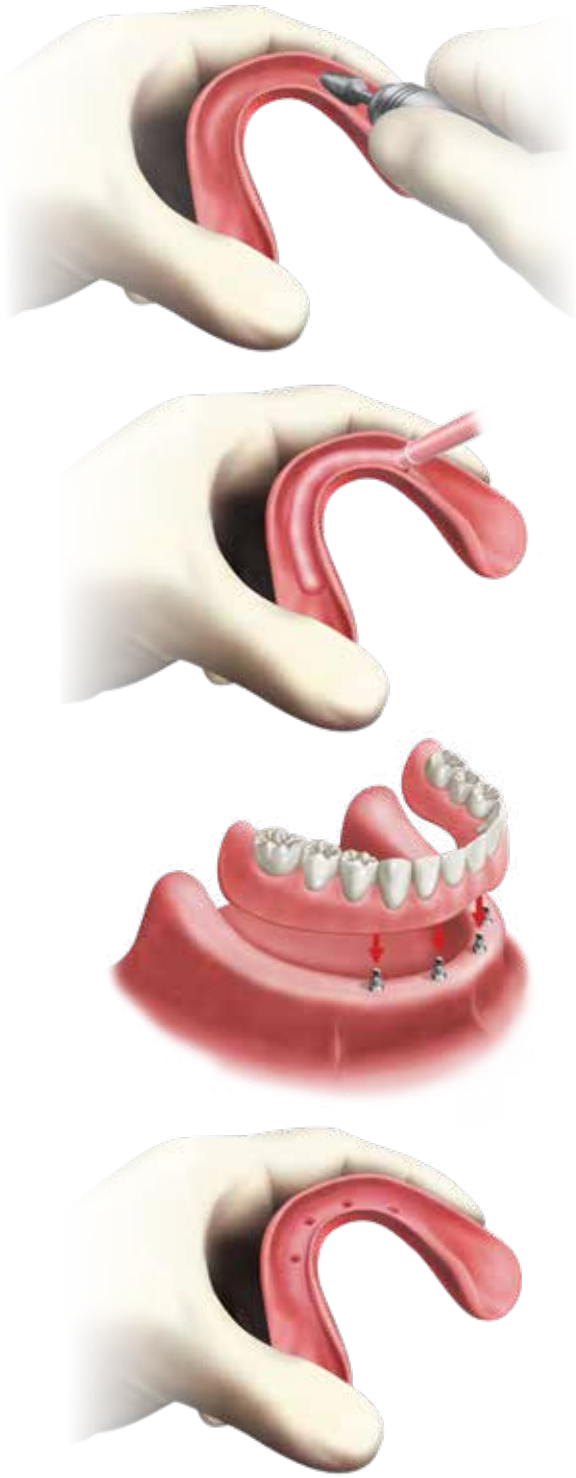
b) Seat the denture in the patient's mouth. Instruct the patient to close with normal pressure into centric occlusion.

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.



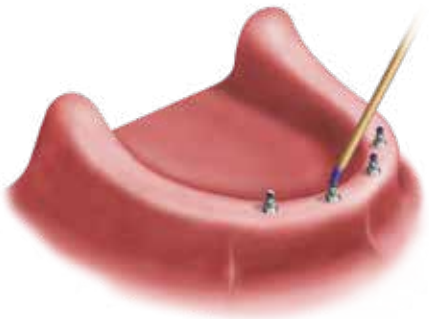
Hard Denture Reline

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 tissue-facing 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.

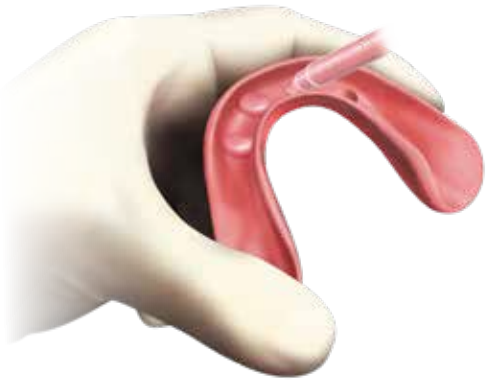
■ Lining the Denture

a) Apply a thin layer of adhesive on the tissue-facing 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.

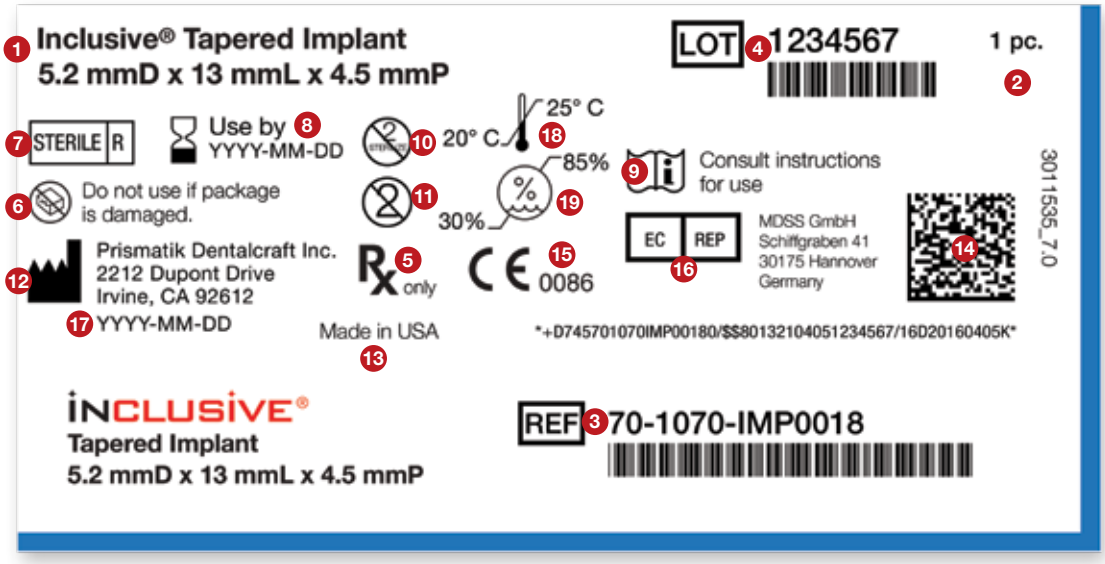
b) Instruct the patient to keep the denture in place for the first 48 hours following implant placement, to prevent gingival overgrowth.

Implant Packaging

Inclusive Implants are shipped sterile, and should not be resterilized. They are for single-use only, prior to the expiration date. Do not use implants if packaging has been compromised or previously opened. Do not handle implant surfaces directly. Users are advised to visually inspect packaging to ensure seals and contents are intact prior to use. Please refer to the individual product label for all relevant product information and cautions.

Explanation of Label Codes:

1. Official product description
2. Quantity
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. Country of origin
14. FDA Unique Device Identification (UDI)
15. Notified body number
16. European Authorized Representative
17. Date of manufacture
18. Store at room temperature
19. Store at 30% to 85% relative humidity



Ordering Information

Order at glidewelldirect.com or call Glidewell Direct at 888-303-3975. Our product specialists are committed to answering questions in a timely fashion to ensure your ordering is easy and efficient. We are available Monday—Friday from 6 a.m.—5 p.m. (PST).

Shipping Policy

- Orders placed after 3 p.m. (PST) will be processed on the following business day. Business days do not include Saturdays, Sundays, or U.S. holidays.
- Online shopping cart available to U.S. customers only.

Terms

All accounts are payable within 30 days of invoice date. Accounts not paid within the stated terms will be subject to COD status and a late charge of 2 percent of the unpaid balance. We accept American Express, Visa, MasterCard, and Discover. All prices are subject to change without notice.

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"). Prismatik and Glidewell Direct hereinafter are referred to collectively as Glidewell. 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"), Glidewell 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.

Glidewell 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 Glidewell'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 Glidewell Direct, 18651 Von Karman Ave, Irvine, CA 92612.

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DENTAL IMPLANT SYSTEM

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by

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