

Smarter Thinking. Simpler Design.



PrimaTM
Surgical Manual

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PRIMA™ IMPLANT SURGICAL MANUAL

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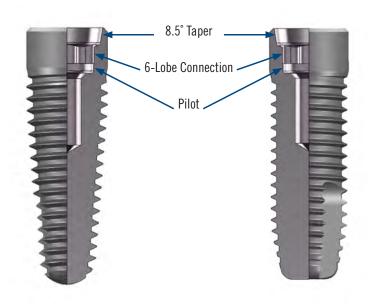
Product specifications are subject to change without notice.

Items illustrated are not to scale.

Certain products may not be available in all countries.

Design Features

The $PrimaConnex^{\circledcirc}$ dental implant is available in tapered as well as straight designs and features a Ti-Lobe[™] connection. This internal 6-lobe connection combines the benefits of a tapered, internal lobed design and integrated pilot (self-aligning feature), providing a secure implant/abutment connection. The same Abutment Screw can be used for all implant diameters.



The **PrimaSolo**® dental implant is a tapered, one-piece implant with an integrated, gold-colored abutment. The implant is placed in a single-stage surgery and is intended to support a cement-retained restoration. The 3.0 mm narrow PrimaSolo® implant is recommended for replacement of missing maxillary/mandibular lateral incisors as well as mandibular central incisors.



Dimensions

- The ø3.5 mm PrimaConnex® can be restored with either 4.0 mm or 5.0 mm prosthetic components.
- The Ø4.1 mm PrimaConnex® can be restored with either 5.0 mm or 6.0 mm prosthetic components.
- The Ø5.0 mm PrimaConnex® can be restored with either 5.0 mm or 6.0 mm prosthetic components.



The $\emptyset 3.0$ mm PrimaSolo® is available in 13 and 15 mm lengths.



The Ø3.5 mm tapered Prima[™] (PrimaConnex® and PrimaSolo®) are available in 10, 11.5, 13 and 15 mm lengths.



The $\emptyset 3.3$ mm straight PrimaConnex® is available in 10, 11.5, 13 and 15 mm lengths.

All ø3.5 mm tapered and ø3.3 mm straight PrimaConnex® are available with a 1.0 mm machined collar or Total Coverage (TC).



The $\emptyset 4.1~\text{mm}$ tapered Prima $^{\text{TM}}$ (PrimaConnex® and PrimaSolo®) are available in 10, 11.5, 13 and 15 mm lengths.



The $\emptyset 4.0$ mm straight PrimaConnex® is available in 8, 10, 11.5, 13 and 15 mm lengths.



All Ø4.1 mm tapered and Ø4.0 mm straight PrimaConnex® are available with a 1.0 mm machined collar or Total Coverage (TC).



The $\emptyset 5.0$ mm tapered Prima $^{\text{TM}}$ (PrimaConnex $^{\text{@}}$ and PrimaSolo $^{\text{@}}$) are available in 10, 11.5, 13, and 15 mm lengths.



The \emptyset 5.0 mm straight PrimaConnex® is available in 8, 10, 11.5, and 13 mm lengths.

5.0

All ø5.0 mm tapered and straight PrimaConnex® are available with a 1.0 mm machined collar or Total Coverage (TC).



Considerations

INDICATIONS

Keystone Dental Prima[™] implants are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including cement-retained, screw-retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.

SPECIFIC INTENDED USES

PrimaConnex® Internal Connection Implants are threaded, internal connection implants intended for immediate placement and can be restored with a temporary prosthesis in single-tooth and multiple-tooth applications with good quality bone.

PrimaSolo® One-Piece Implants are threaded implants with an integrated abutment designed for a single-stage surgical procedure and cemented restoration. PrimaSolo® 3.5, 4.1, and 5.0 mm implants are intended for immediate placement and can be restored with a temporary prosthesis in single-tooth and multiple-tooth applications with good quality bone. PrimaSolo® 3.0 mm implants are indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. Mandibular central and lateral incisors must be splinted if using two or more 3.0 mm implants adjacent to one another.

CONTRAINDICATIONS

- General contraindications associated with elective surgery should be observed
- Possible contraindications: chronic bleeding problems, psychological impairment, metabolic bone or connective tissue diseases, treatment with corticosteriods, certain cardiac and vascular diseases, tobacco usage, diabetes (uncontrolled), treatment with chemotherapeutic agents, chronic renal disease, poor patient oral hygiene, bruxing, alcoholism
- Temporary contraindications: systemic infection; local oral or respiratory infection
- Anatomical or pathological contraindications: insufficient alveolar bone width and height to surround the implant with at least one millimeter of bone, both buccally and lingually to the most superior aspect of the implant body; inadequate bone height where proper implant placement would encroach on the mandibular canal; malignancies

For additional information, please consult the Keystone Dental Prima™ Implant Instructions for Use.

SOFT TISSUE HEALING AND TEMPORIZATION

Following the placement of a PrimaConnex® implant, soft tissue can be contoured using a titanium Healing Abutment or a custom fabricated temporary abutment.

A Temporary Abutment can be placed at this time for immediate temporization. The acrylic portion of the Temporary Abutment bonds with dental composite/acrylic allowing for custom esthetic contouring directly to the Temporary Abutment.

PATIENT EVALUATION AND SELECTION

Successful implant treatment requires the coordinated efforts of the implanting surgeon, the restorative dentist, and the dental laboratory technician. Proper patient selection is important for long-term function of a dental implant. The following factors should be considered prior to implant surgery:

- General medical history
- Oral hygiene
- Patient's expectations
- General dentistry and product indications and contraindications
- Anatomical landmarks related to implant positioning
- Inter-occlusal clearance (the space available between alveolar crest and opposing dentition)
- Ridge width in relation to the implant diameter
- Emergence profile of the restoration in relation to prosthetic platform diameters

BONE QUALITY

While one method of classifying bone density is shown in the images below, different combinations of cortical and trabecular bone in varying thicknesses and densities can occur. These typically differ by jaw location. The clinician is responsible for assessing bone density of the surgical site and choosing the appropriate protocol.



D1 Bone Cortical bone



D2 Bone Cortical bone/



D3 Bone Cortical bone/ trahecular trahecular



Cortical bone/ trahecular



Surgical Guide

Available planning software provides both clinicians and technicians the ability to plan implant placement three-dimensionally in conjunction with CT scans. A surgical guide could aid in the site preparation and placement of implants.

NOTE: PrimaSolo®: The use of a surgical guide is always recommended. The maximum angle for PrimaSolo® 3.5, 4.1 and 5.0 mm Implants is 15° (30° divergence between implants). For PrimaSolo® 3.0 mm Implants, the maximum angle is 10° (20° divergence between implants).

Implant Selection

Implant selection should be made with the final restorative result as the primary consideration.

Selecting implants in this manner aids in maximizing biomechanical stability and proper contouring of the soft tissue. Choosing an implant with a slightly smaller platform than the emergence of the tooth being replaced will provide support of the soft tissue and optimize the esthetic result.

Implant placement and healing abutment selections should be based on the following:

- Emergence profile of the restoration in relation to the prosthetic platform diameter
- Height and diameter of the crown as it emerges through the tissue

Implant selection can also be completed with the use of sizing overlays. Transparent implant sizing overlays (100% and 125% magnification) are available.

Instrument Care

Instruments must be cleaned and sterilized prior to first and after each use based on established procedures. Proper instrument care is an important part of successful implant dentistry.

PRE-CLEANING

- Used instruments should be soaked immediately in instrument cleaning solution to avoid the drying of blood, saliva and tissue residue.
- Used surgical trays including grommets must be cleaned with a suitable disinfectant.

- Multiple-part instruments must be disassembled prior to cleaning and sterilization.
- Internal debris/residue of instruments must be removed with a soft brush.
- Instruments should be inspected, cleaned separately and discarded if damaged.

PRINCIPAL CLEANING

- Best results are achieved if surgical instruments are cleaned by material type.
- Instruments and trays can be cleaned and disinfected in a dedicated dishwasher or alternatively by hand, followed by an ultrasonic bath with a detergent appropriate for surgical instruments.
- Instruments and trays must be rinsed and dried thoroughly.

STERILIZATION

Instruments and surgical tray should be autoclaved with a sufficient drying cycle to avoid instrument corrosion. Instruments should be placed in the tray and wrapped in sterilization paper or sterilization packs featuring indicating tape and date of sterilization.

- Autoclave: 121 124°C (~250°F) 60 minute exposure / 40 minute drying time or 132 135°C (~270°F) 40 minute exposure / 30 minute drying time. Do not exceed 140°C (284°F). Always use the drying cycle.
- Dry Heat: 160°C (320°F) 120 minute exposure (minimum). Do not exceed 170°C (338°F).

Keystone Dental does not recommend chemclave sterilization procedures as they may damage surgical trays and/or instruments.

SURGICAL MOTOR AND HANDPIECE

Cleaning and maintenance instructions for W&H handpieces and motors can be found on www.w&h.com.

Surgical Kit

The Surgical Kit must be cleaned and sterilized prior to use. For further information, please consult Keystone Dental's *Instructions for Use*.

- All surgical instruments are provided non-sterile.
- All Prima[™] drills and taps are internally irrigated, except for the 1.5 and 1.8 mm drills which require external irrigation when preparing the osteotomy.
- All drills must be inspected for signs of wear, damage or discoloration.

The drill markings and color-coding facilitate proper instrument selection. It is recommended to inspect the latch-lock shank after each use. The number of uses per drill will vary and depends on a variety of factors including bone density, proper handling and cleaning. It is recommended to replace drills after 20 osteotomies, as repeated sterilizations and use may affect cutting efficiency and color appearance.

Drilling and Tapping Procedures

The Final Drills are designed to collect bone. During surgery, it is recommended to remove the collected bone from the drill before proceeding to the final depth marking. This will reduce the downward force applied to the handpiece.

- In certain instances, tapping is required (see Tapered Surgical Sequence, Step 5 or Straight Surgical Sequence, Step 8).
 Depending on bone density, a maximum tapping speed of 20 rpm is recommended.
- It is recommended to avoid lateral pressure during drilling and tapping procedures as the resulting osteotomy may be oversized and/or redirected.
- When using the tapered Final Drills, it is not recommended to use an in-and-out technique as this may inadvertently enlarge the site.





Implant Packaging

Each Prima™ implant is packaged in a vial, sealed in a tray with a Tyvek® lid and gamma-sterilized. The flip-open lid on the vial contains a cover screw. The sealed tray contains a label identifying the implant type, diameter and length, as well as other important device information. Inside, pre-printed patient labels with product data and the lot number are provided. These are adhesive labels that should be affixed to the patient's chart.

Opening instructions:

- 1. The Tyvek lid on the tray is peeled back and placed into the sterile field.
- 2. The patient labels are affixed to the patient's chart.
- 3. The implant lid is flipped open to gain access to the selected $Prima^{TM}$ implant.

The implant may now be removed from the vial, delivered to the site and placed using one of the following options.

Implant Delivery

Prima[™] implants are delivered to the osteotomy with an Implant Driver.

PRIMACONNEX®:

- The Implant Driver is aligned with the implant. While pressure
 is applied, the Implant Driver is rotated at a speed less than 20
 rpm until the lobes of the Implant Driver engage the implant
 lobes. A tactile and/or audible click may occur indicating the
 Implant Driver is engaged. The implant is lifted out of the vial
 and placed into the osteotomy.
- The Implant Driver is pulled straight up to disengage the Implant Driver from the implant. Special care should be taken in very soft bone to not disrupt primary stability.

Depending on the clinical situation and accessibility, two different Implant Drivers are available for placing PrimaConnex® implants. The Implant Driver/latch type can be used with a surgical motor, a Surgical Ratchet or a Surgical Hand Driver. For limited inter-occlusal clearance, a direct-to-ratchet Implant Driver is available.

PRIMASOLO®:

- Align the internal flat of the driver with the flat on the abutment portion of the implant and press firmly. (An identifying mark on the Implant Driver identifies the internal flat.) The implant is lifted out of the vial and placed into the osteotomy.
- The Implant Driver is pulled straight up to disengage the Implant Driver from the implant. Special care should be taken in very soft bone to not disrupt primary stability.

Implant Placement

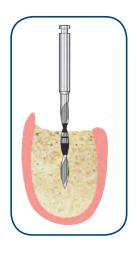
The final implant position is at the discretion of the surgeon. Each case should be evaluated on the basis of placement, protocol and type of implant prior to osteotomy preparation. It is recommended to place a PrimaConnex® implant at bone level. A PrimaSolo® implant should be placed so that the junction of the gold-colored abutment portion and the machined titanium collar is level with the bone crest.

Surgical Sequence - PrimaConnex $^{\rm B}$ Tapered ø4.1 mm x 13 mm

(For demonstration purposes)

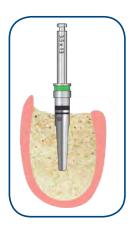
Step 1

An incision of the appropriate design is made and the flap elevated. The Ø1.8 mm Initial Drill has markings at lengths of 8, 10, 11.5, 13 and 15 mm and should be inserted to the required depth at 1,200-1,500 rpm.



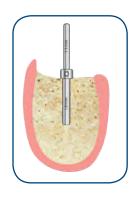
Step 3

The osteotomy is further widened with the $\emptyset 3.5 \times 13$ mm Tapered Drill to the required depth at 800 rpm.



Step 2

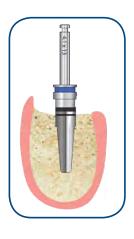
The Prima $^{\text{TM}}$ Ø1.5/1.8 mm Parallel Pins are dual ended. The proper position of the osteotomy is verified with the 1.8 mm end of the Parallel Pin. It is recommended to thread floss through the opening in the center of the Parallel Pin to allow for retrievability.



Step 4

Then the Ø4.1 x 13 mm Tapered Drill is selected, which is the final drill when placing a 4.1 x 13 mm PrimaConnex® Tapered Implant.

The osteotomy is further widened with the $\emptyset 4.1 \times 13$ mm Tapered Drill to the required depth at 800 rpm.



DRILL STOPS FOR PRIMA™ TAPERED DRILLS

An optional Drill Stop is available for Tapered Drills. The position of the Drill Stop is calculated to align the implant with the crest of the bone and fully seat the implant.

The Drill Stops are color-coded to match the drills.

The Drill Stop is slipped over the drill with the fins facing the drill shank (latch). It is important to firmly press the fins of the Drill Stop over the drill hub to ensure proper positioning. Drill Stops add approximately 1 mm of additional width to each side of the drill.



Step 5

In bone quality D1 and D2, it is recommended to use a Surgical Tap to finalize the osteotomy.

In this case, a $\emptyset 4.1 \times 13/15$ mm Surgical Tap is inserted into the osteotomy with slight pressure at 20 rpm to the appropriate depth. The Surgical Tap is then removed by reversing the rotation.



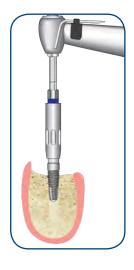
PRIMACONNEX® IMPLANT POSITIONING

If the treatment plan includes using anatomically-shaped abutments such as the angled or straight Esthetic Contour Abutments, the rotational position of the implant can be adjusted at the time of placement to ensure optimal positioning of the final abutment. This will allow the restoring clinician to take full advantage of the anatomical abutment contours and minimize the need for abutment prepping. If the clinical situation allows, adjust the final position of the implant so that any one of the six internal connection lobes faces the buccal or facial aspect.

Step 6

Handpiece Insertion - PrimaConnex®

With the Implant Driver connected to the handpiece, the internal lobes are fully engaged by the Implant Driver and carefully removed from the vial. It is then carried to the osteotomy and inserted at 15-20 rpm.



Ratchet Insertion - PrimaConnex®

The Surgical Ratchet can be used in addition to or instead of a handpiece to finalize the insertion of the implant by engaging the Implant Driver into the Ratchet with the Ratchet Adapter.

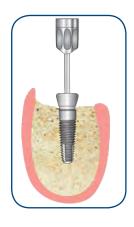




NOTE: Depending on bone quality and osteotomy preparation, the insertion torque may vary from 20-60 Ncm.

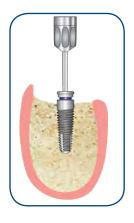
Step 7 Single-Stage Surgery

In a single-stage surgery, the healing abutment is placed with a Quad Driver to help contour the soft tissue during the healing phase. The flap margins are positioned around the Healing Abutment and sutured in a tension-free manner. A radiograph is recommended for use as a baseline of implant-to-bone contact for future diagnosis.



Two-Stage Surgery

In a two-stage surgery, the Cover Screw is placed with a Quad Driver and the flap margins are repositioned and sutured in a tension-free manner. A radiograph is recommended for use as a baseline of implant-to-bone contact for future diagnosis.

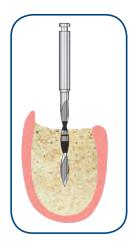


Surgical Sequence - PrimaConnex® Straight ø4.0 mm x 13 mm

(For demonstration purposes)

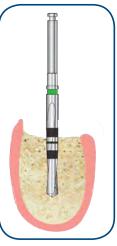
Step 1

An incision of the appropriate design is made and the flap elevated. The $\emptyset 1.8$ mm Initial Drill has markings at lengths of 8, 10, 11.5, 13 and 15 mm and should be inserted to the required depth at 1,200-1,500 rpm.



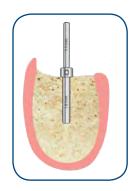
Step 4

The osteotomy is further widened with the $\emptyset 2.8$ mm Straight Drill to the required depth at 1,200-1,800 rpm.



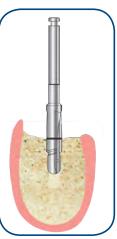
Step 2

The $\operatorname{Prima}^{^{\intercal}}$ $\emptyset 1.5/1.8$ mm Parallel Pins are dual ended. The proper position of the osteotomy is verified with the 1.8 mm end of the Parallel Pin. It is recommended to thread floss through the opening in the center of the Parallel Pin to allow for retrievability.



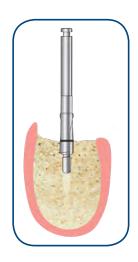
Step 5

The $\emptyset 2.8/3.3$ mm Step Drill is used to open the site to 3.3 mm at 1,200-1,800 rpm to prepare the osteotomy for the $\emptyset 3.3$ mm Straight Drill.



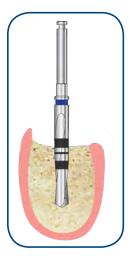
Step 3

The $\emptyset 1.8/2.8$ mm Step Drill is used to enlarge the initial osteotomy site to 2.8 mm at 1,200-1,800 rpm. This preparation guides the $\emptyset 2.8$ mm Straight Drill to ensure proper osteotomy width.



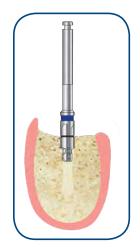
Step 6

The osteotomy is further widened with the ø3.3 mm Straight Drill to the required depth at 1,200-1,800 rpm.



Step 7

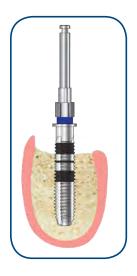
The Countersink Drill is inserted to the laser mark at 1,200-1,800 rpm to prepare the coronal area. Over-preparation of the osteotomy with the Countersink Drill must be avoided. It is not recommended to countersink in soft bone.



Step 8

In bone quality D1 and D2, it is recommended to use a Surgical Tap to finalize the osteotomy.

In this case, a $\emptyset4.0 \times 15$ mm Surgical Tap is inserted into the osteotomy with slight pressure at 20 rpm to the appropriate depth. The Surgical Tap is then removed by reversing the rotation.



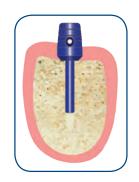
The surgical sequence for the PrimaSolo® Implant is the same as for the PrimaConnex® Tapered Implant, as shown on pages 9 and 10.

If a flapless surgical procedure is indicated, preparation of the osteotomy starts with the Ø1.5 mm Initial Drill.

The \emptyset 1.5 mm Initial Drill has markings at lengths of 8, 10, 11.5, 13 and 15 mm and should be inserted through the tissue to the required depth at 1,200-1,500 rpm.

The $Prima^{™}$ Ø1.5/1.8 mm Parallel Pins are dual ended. The proper position of the osteotomy is verified with the 1.5 mm end of the Parallel Pin. It is recommended to thread floss through the opening in the center of the Parallel Pin to allow for retrievability.

The appropriate color-coded Tissue Punch Guide is seated in the osteotomy. The Tissue Punch is connected to the handpiece and placed over the Tissue Punch Guide to remove the tissue at 600-800 rpm).

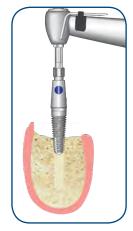


Proceed to Step 3 of the Prima™ Tapered Surgical Sequence on page 9.

PRIMASOLO® IMPLANT PLACEMENT

The internal flat (identified by the colorcoded dot) of the PrimaSolo® Implant Driver attaches directly to the flat of the integrated abutment portion of the implant. The implant is carefully removed from the vial by pressing the Driver firmly onto the implant. It is then carried to the osteotomy and inserted at 15-20 rpm.

The Surgical Ratchet can be used in addition to or instead of a handpiece to finalize the insertion of the implant by engaging the Implant Driver into the Ratchet with the Ratchet Adapter.



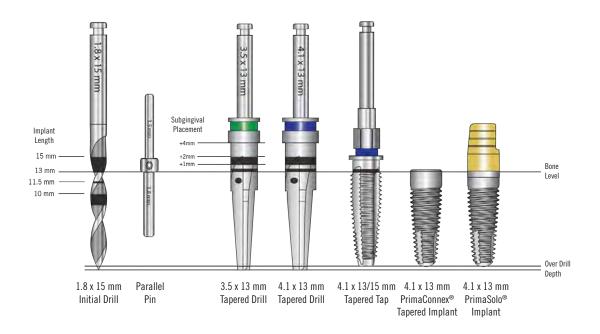


Depth Markings - Prima™ Tapered Drilling Sequence Ø4.1 x 13 mm

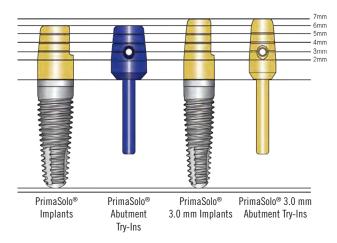
*The Prima™ tapered drills feature the following laser markings:

- Thin laser mark represents implant length
- Bottom of thick laser mark represents implant length + 1 mm sub-crestal
- Top of thick laser mark represents implant length + 2 mm sub-crestal

The actual drill tip is not included in the designated drill length and must be considered when preparing the osteotomy.



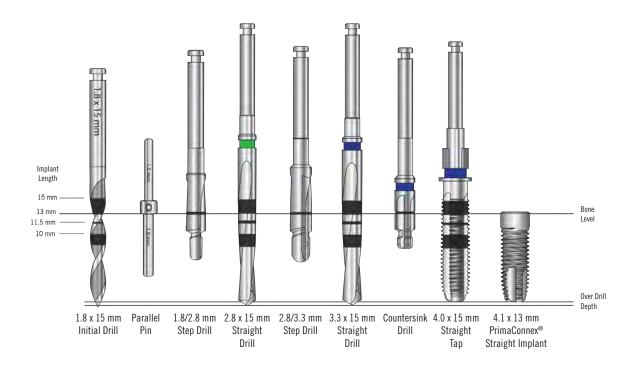
Depth Markings for PrimaSolo® Implants and Abutment Try-Ins



Depth Markings - Prima™ Straight Drilling Sequence Ø4.0 x 13 mm

*The Prima $^{\text{TM}}$ straight drills feature laser markings at lengths of 8, 10, 11.5, 13 and 15 mm.

The actual drill tip is not included in the designated drill length and must be considered when preparing the osteotomy.



Implant Length	ø3.0 Tapered Drilling Sequence					
13 mm	1.8 mm Initial Drill	Parallel –	3.0 x 13 mm — Tapered Drill	3.0 mm Tap		
15 mm	1.8 mm Initial Drill	Parallel –	3.0 x 15 mm – Tapered Drill	3.0 mm Tap		

Implant Length	ø3.5 Tapered Drilling Sequence					
10 mm	1.8 mm Initial Drill	Parallel –	3.5 x 10 mm Tapered Drill	3.5 x 10/11.5 mm Tap		
11.5 mm	1.8 mm Initial Drill	Parallel –	3.5 x 11.5 mm Tapered Drill	3.5 x 10/11.5 mm Tap		
13 mm	1.8 mm Initial Drill	Parallel _ Pin	3.5 x 13 mm Tapered Drill	3.5 x 13/15 mm Tap		
15 mm	1.8 mm Initial Drill	Parallel _ Pin	3.5 x 15 mm Tapered Drill	3.5 x 13/15 mm Tap		

Implant Length	ø4.1 Tapered Drilling Sequence					
10 mm	1.8 mm Initial Drill	Parallel –	3.5 x 10 mm Tapered Drill	4.1 x 10 mm Tapered Drill -	4.1 x 10/11.5 mm Tap	
11.5 mm	1.8 mm Initial Drill	Parallel –	3.5 x 11.5 mm Tapered Drill	4.1 x 11.5 mm Tapered Drill	4.1 x 10/11.5 mm Tap	
13 mm	1.8 mm Initial Drill	Parallel _ Pin	3.5 x 13 mm Tapered Drill	4.1 x 13 mm — Tapered Drill	4.1 x 13/15 mm Tap	
15 mm	1.8 mm Initial Drill	Parallel _ Pin	3.5 x 15 mm Tapered Drill	4.1 x 15 mm — Tapered Drill	4.1 x 13/15 mm Tap	

Implant Length	ø5.0 Tapered Drilling Sequence						
10 mm	1.8 mm Initial Drill	Parallel –	3.5 x 10 mm Tapered Drill	4.1 x 10 mm Tapered Drill	5.0 x 10 mm Tapered Drill	5.0 x 10/11.5 mm Tap	
11.5 mm	1.8 mm Initial Drill	Parallel Pin –	3.5 x 11.5 mm Tapered Drill	4.1 x 11.5 mm Tapered Drill	5.0 x 11.5 mm Tapered Drill	5.0 x 10/11.5 mm Tap	
13 mm	1.8 mm Initial Drill	Parallel Pin –	3.5 x 13 mm Tapered Drill	4.1 x 13 mm Tapered Drill	5.0 x 13 mm Tapered Drill	5.0 x 13/15 mm Tap	
15 mm	1.8 mm Initial Drill	Parallel –	3.5 x 15 mm Tapered Drill	4.1 x 15 mm Tapered Drill	5.0 x 15 mm Tapered Drill	5.0 x 13/15 mm Tap	

Implant Length	ø3.3 Straight Drilling Sequence					
all	1.8 mm Initial — Drill	Parallel_ Pin	1.8/2.8 mm Step Drill	2.8 mm ►Straight— Drill	3.3 mm Countersink	3.3 mm Tap

Implant Length	ø4.0 Straight Drilling Sequence							
all	1.8 mm Initial — Drill	Parallel_ Pin	1.8/2.8 mm Step Drill	2.8 mm ►Straight— Drill	2.8/3.3 mm_ Step Drill	3.3 mm ►Straight— Drill	4.0 mm _ Countersink	4.0 mm Tap

Implant Length		ø5.0 Straight Drilling Sequence								
all	1.8 mm Initial— Drill	Parallel_ Pin	1.8/2.8 mm Step Drill	2.8 mm ►Straight— Drill	2.8/3.3 mm_ Step Drill	3.3 mm ►Straight— Drill	3.3/4.2 mm Step Drill	4.2 mm ►Straight— Drill	5.0 mm Countersink	5.0 mm Tap

Tap Protocol:

 ${\rm D1~\&~D2-Required}$

D3 - Clinicians Discretion

 ${\sf D4-Not}$ recommended



Smarter Thinking. Simpler Design.

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