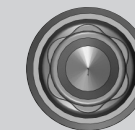


Prima Plus™

Surgical Manual



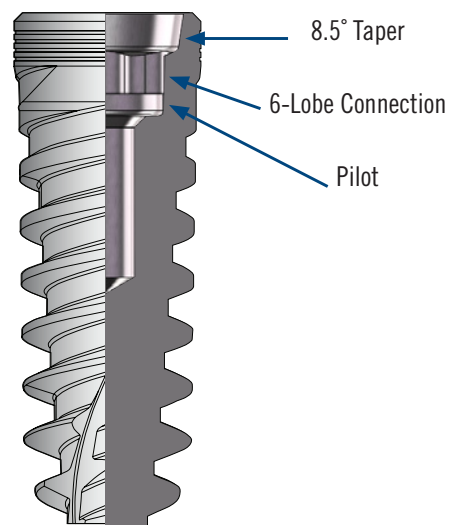
PRIMA PLUS™ IMPLANT SURGICAL MANUAL

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Product specifications are subject to change without notice.
Items illustrated are not to scale.

Design Features

The Prima Plus™ dental implant features the Ti-Lobe connection. This internal 6-lobe connection combines the benefits of a platform switch, internal lobed design, and integrated pilot (self-alignment feature), providing a secure implant/abutment connection. This design allows for one screw for all platform diameters.



Dimensions

- The Ø3.5 mm Prima Plus™ implants can be restored with either 4.0 mm or 5.0 mm prosthetic components.
- The Ø4.1 mm Prima Plus™ implants can be restored with either 5.0 mm or 6.0 mm prosthetic components.
- The Ø5.0/6.0 mm Prima Plus™ implants share the same connection and can be restored with either a 6.0 mm prosthetic component or a Ø7.0 and Ø8.0 mm Healing Abutment.

3.5 The Ø3.5 mm Prima Plus™ implants are available in 8.0, 10.0, 11.5, 13, 15 mm lengths.

4.1 The Ø4.1 mm Prima Plus™ implants are available in 8.0, 10.0, 11.5, 13, 15 mm lengths.

5.0 The Ø5.0 mm Prima Plus™ implants are available in 8.0, 10.0, 11.5, 13, 15 mm lengths.

6.0 The Ø6.0 mm Prima Plus™ implants are available in 8.0, 10.0, 11.5, and 13 mm lengths.

Considerations

INDICATIONS

Keystone Dental Prima Plus™ 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

Prima Plus™ 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.

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 corticosteroids, 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 Plus™ Implant Instructions for Use*.

SOFT TISSUE HEALING AND TEMPORIZATION

Following the placement of a Prima Plus™ 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.

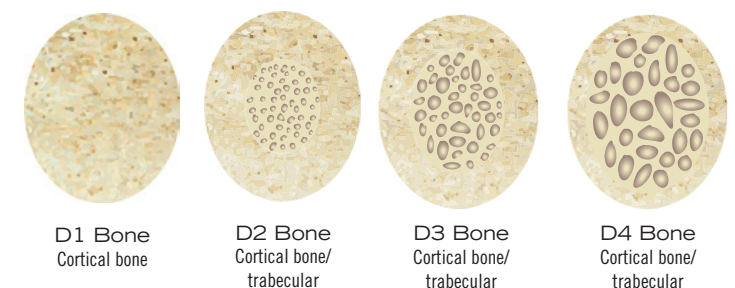
PATIENT EVALUATION AND SELECTION

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.



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.

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

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 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.

- Steam Sterilization Gravity Cycle: 134°C (~273°F)
20 minute exposure / 40 minute dry time
- Steam Sterilization Pre Vacuum Cycle: 134°C (~273°F)
4 minute exposure / 40 minute dry time

SURGICAL MOTOR AND HANDPIECE

Cleaning and maintenance instructions for W&H handpieces and motors can be found on www.wh.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 Plus™ drills are externally irrigated and require external irrigation when preparing the osteotomy.
- All drills must be inspected for signs of wear, damage or discoloration.

The drills are labeled with a diameter to 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 depth marking appearance.

Drilling and Tapping Procedures

Soft bone considerations: The end-cutting capabilities of Prima Plus™ allows it to be inserted into sites that have been prepared with a reduced diameter drill (see drilling protocol on page 12). When the implant is inserted, the end-cutting features will aid in guiding the implant to the final depth.

Dense bone considerations: Utilizing the end-cutting feature to seat the implant should not be attempted in dense bone. Surgical taps should be used when the recommended surgical protocol (see drilling protocol on page 12) is not sufficient to fully seat the implant or insertion torques are higher than 70Ncm.

- 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 Twist Step drills, it is recommended to use an in-and-out technique when preparing the site. Recommended drill speeds are 1200 - 1500 rpm.
- When tapping, the top of the tap should correspond to the height of the implant platform, regardless of implant length.



Implant Packaging

Each Prima Plus™ 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 Plus™ implant.

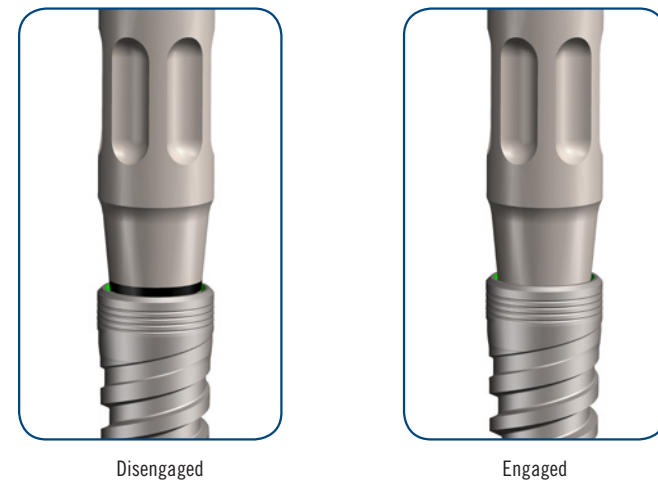
The implant may now be removed from the vial, delivered to the site and placed using one of the following options.

Implant Delivery

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

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.

NOTE: When correctly seated, the laser mark on the driver should be below the platform of the implant and not visible.



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 Prima Plus™ implant at bone level.

Surgical Sequence – Prima Plus™ Ø4.1 mm x 11.5 mm (For demonstration purposes)

For additional drilling protocols by bone density please see page 12.

Soft Bone				
				NOTE: Drill dimensions in brackets denote that widening of the crestal bone for insertion torques above 70Ncm is recommended.
1.8 mm Initial Drill x 11.5 mm Drill Speed 1200-1500 rpm	Parallel Pin/Depth Gauge 11.5 mm	2.2/2.6 mm Twist Step Drill Drill Speed 1200-1500 rpm	(2.6/2.9) mm Twist Step Drill Drill Speed 1200-1500 rpm (It is not recommended to drill to full depth).	
Medium Bone				
1.8 mm Initial Drill x 11.5 mm Drill Speed 1200-1500 rpm	Parallel Pin/Depth Gauge 11.5 mm	2.2/2.6 mm Twist Step Drill Drill Speed 1200-1500 rpm	2.9/3.3 mm Twist Step Drill Drill Speed 1200-1500 rpm	
Dense Bone				
1.8 mm Initial Drill x 11.5 mm Drill Speed 1200-1500 rpm	Parallel Pin/Depth Gauge 11.5 mm	2.2/2.6 mm Twist Step Drill Drill Speed 1200-1500 rpm	2.9/3.3 mm Twist Step Drill Drill Speed 1200-1500 rpm	
			(3.4/3.9 mm) Twist Step Drill Drill Speed 1200-1500 rpm (It is not recommended to drill to full depth).	

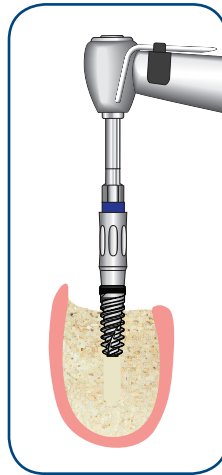
PRIMA PLUS™ IMPLANT POSITIONING

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

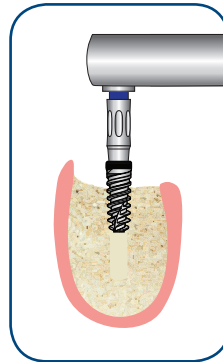
Handpiece Insertion - Prima Plus™

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 - Prima Plus™

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.

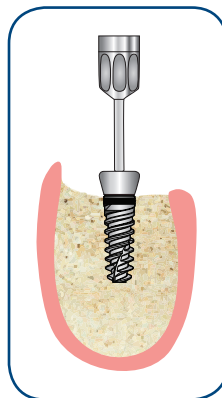


NOTE: Depending on bone quality and osteotomy preparation, the insertion torque may vary from 20-70 Ncm.

Step 7

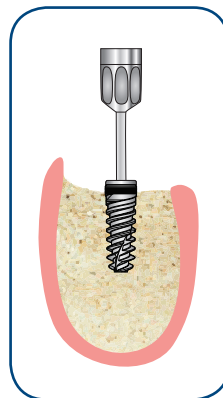
Single-Stage Surgery

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.

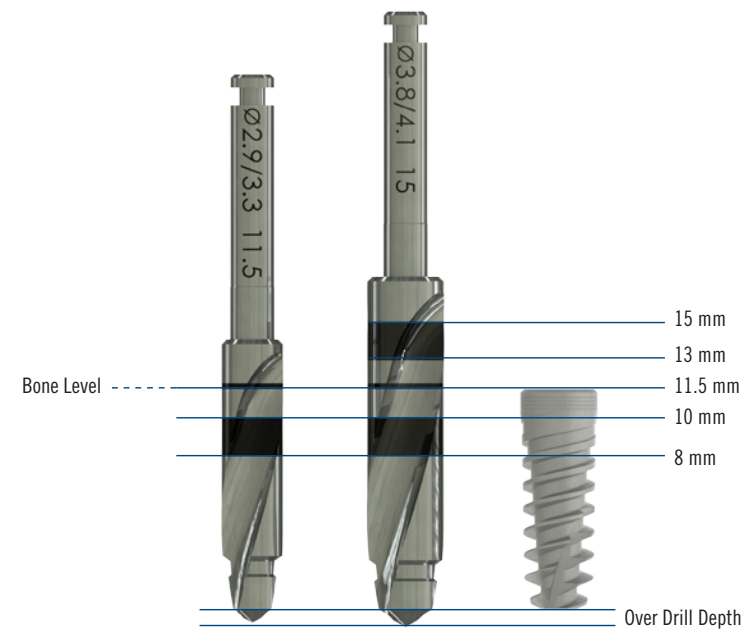
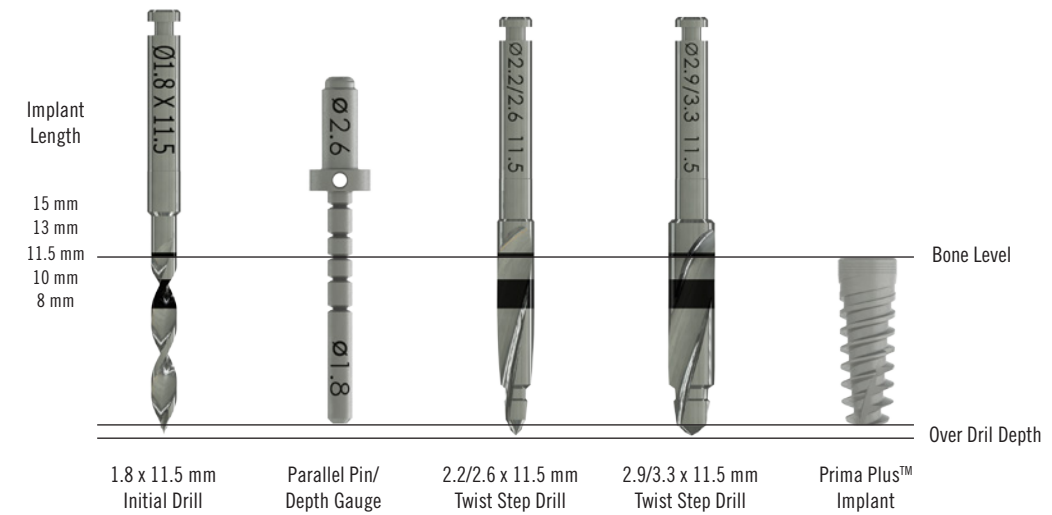


Prima Plus™ Drilling Sequence - 4.1 x 11.5 mm in Medium Bone

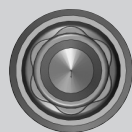
The Prima Plus™ Twist Step drills feature the following laser markings:

- Laser mark represents implant length + over drill length
- Diameter and length of drill is identified on the shaft

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



Twist Step Drills	Over Drill Depth
Ø3.5 mm	0.88 mm
Ø4.1 mm	0.83 mm
Ø5.0 mm	1.03 mm
Ø6.0 mm	1.13 mm



Drill protocols are based on bone quality. Drill dimensions in brackets denote that widening of the crestal bone for insertion torques above 70Ncm is recommended.

Implant Ø (mm)	Soft Bone Type IV	Medium Bone Type II - III	Dense Bone Type I
SD 3.5	1.8	1.8	1.8
	(2.2/2.6)	2.2/2.6	2.2/2.6
		(2.6/2.9)	2.6/2.9
			(2.9/3.3)
RD 4.1	1.8	1.8	1.8
	2.2/2.6	2.2/2.6	2.2/2.6
	(2.6/2.9)	2.9/3.3	2.9/3.3
			(3.4/3.9)
WD 5.0	1.8	1.8	1.8
	2.2/2.6	2.2/2.6	2.2/2.6
	2.9/3.3	2.9/3.3	2.9/3.3
	3.4/3.9	3.8/4.1	3.8/4.1
			(4.4/4.8)
WD 6.0	1.8	1.8	1.8
	2.2/2.6	2.2/2.6	2.2/2.6
	2.9/3.3	2.9/3.3	2.9/3.3
	3.4/3.9	3.4/3.9	3.8/4.1
	(4.6/5.3)	4.4/4.8	4.4/4.8
		(4.6/5.3)	4.6/5.3
			(5.3/5.7)

Implant Ø (mm)	Soft Bone Type IV	Medium Bone Type II - III	Dense Bone Type I
SD 3.5	1+(2)	1+2+(3)	1+2+3+(4)
RD 4.1	1+2+(3)	1+2+4	1+2+4+(5)
WD 5.0	1+2+4+5	1+2+4+6	1+2+4+6+(7)
WD 6.0	1+2+4+5+(8)	1+2+4+5+7+(8)	1+2+4+6+7+8+(9)

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Caution, consult accompanying documents

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