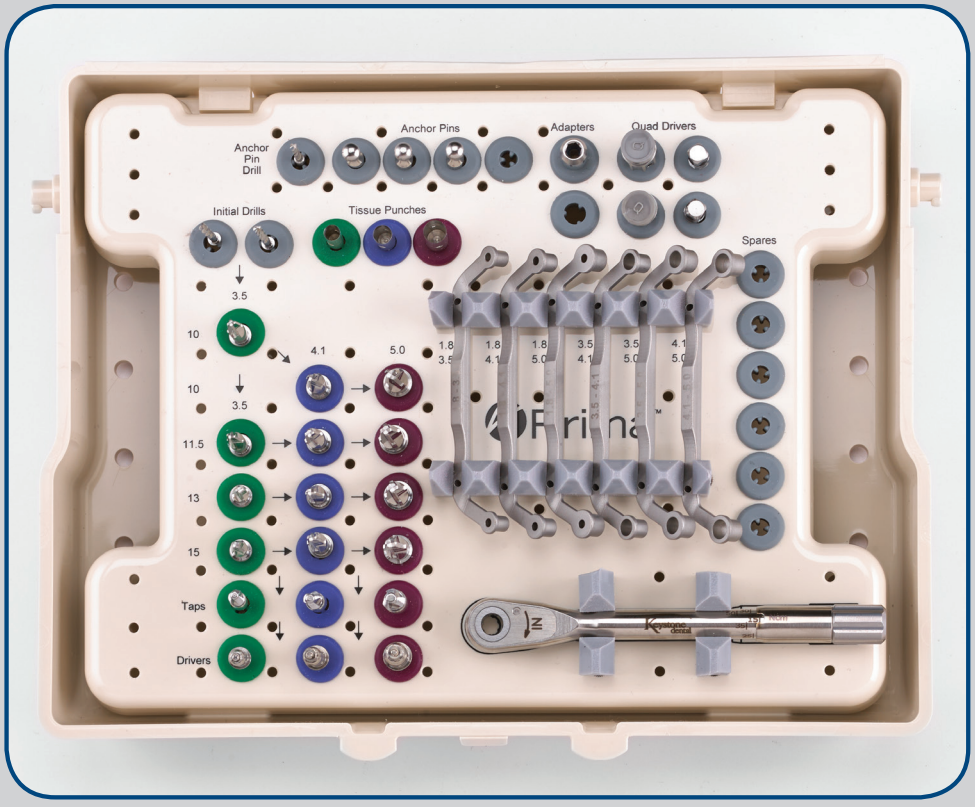
Keystone DENTAL

Smarter Thinking. Simpler Design.



Tapered Prima™ Guided Surgery Manual

TAPERED PRIMA™ GUIDED SURGERY

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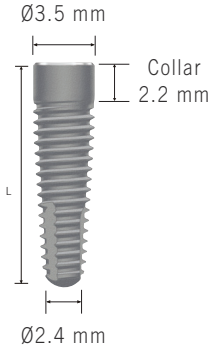
Product specifications are subject to change without notice.
Items illustrated are not to scale.

Keystone Guided Surgery Kit - 15651K

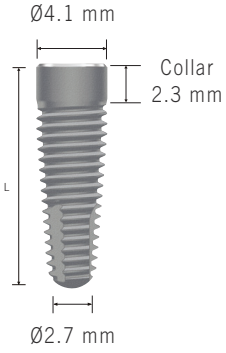
PRECISION IMPLANT PLACEMENT

The Prima Guided Surgery Kit is intended for the placement of 3.5 mm to 5.0 mm PrimaConnex Tapered Implants.

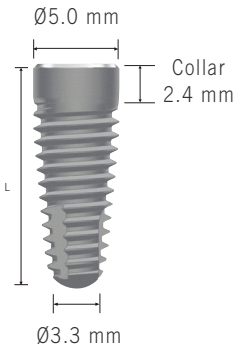
Ø3.5 mm



Ø4.1 mm



Ø5.0 mm



Getting Started

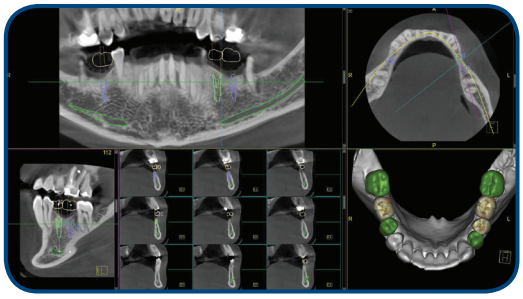
Tapered Prima Guided Surgery requires access to CT planning software, as well as a Cone Beam Scanner or CT Scanner. Software training is essential for all clinicians and technicians involved in the treatment planning process. It is recommended to fabricate a radiopaque scan template with the desired tooth/teeth position when seated intra-orally during the CT scan.

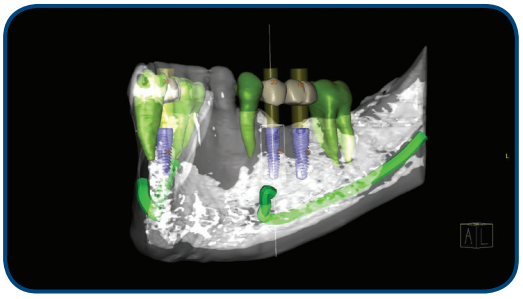
SOFTWARE COMPATIBILITY

The Tapered Prima Guided Surgery Kit is designed to place and provisionalize Tapered Prima Implants using a variety of compatible CT-planning software and surgical guides. The below software and guide manufacturers are compatible with the Tapered Prima Guided Surgery Kit:

- 360imaging - http://www.360imaging.com
- SimPlant/Materialise - http://www.materialisedental.com
- 3D Diagnostix, Inc. Dental Wings - http://www.3ddx.com/

Note: Please refer to the Keystone Dental website for additional partner updates. (www.keystonedental.com)





Guided Surgery: Surgical Progression

1. Diagnostic & Treatment Plan - Complete patient examination and master model fabrication.

2. Diagnostic tooth wax-up – fabrication and evaluation of diagnostic tooth wax-up.

3. Fabrication of scan template - Transfer of tooth set-up to radiographic guide or patient's existing denture to determine the desired tooth location in CT images.

4. CB/CT scan - Digital capture of radiographic guide and patient occlusion with scan template in place. Software suppliers scanning instructions apply.

5. 3-D diagnostics and treatment plan - Import the CB/CT scan data into the treatment planning software, followed by implant positioning based on the desired prosthetic outcome, patient anatomy and vertical space requirements.

6. Surgical Guide fabrication - The guide manufacturer fabricates the surgical guide based on the established treatment plan using Keystone Dental Guided Surgery instrumentation.

7. Guided Surgery - The implants are positioned using the surgical guide and the Tapered Prima Surgery Kit following the surgical protocol.

Instructions for Use

This manual provides guidelines for surgical, restorative clinicians and laboratory technicians for use with Keystone's Guided Surgery Kit. The success of any dental implant system depends upon proper use of components and instrumentation. This manual is not intended for use as a substitute for professional training and experience.

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.

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™ 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

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

- Multiple-part instruments must be disassembled prior to cleaning and sterilization
- 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

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 indicating tape and date of sterilization. 134˚C (~273˚F) 4 minute exposure / 40 minute drying time.

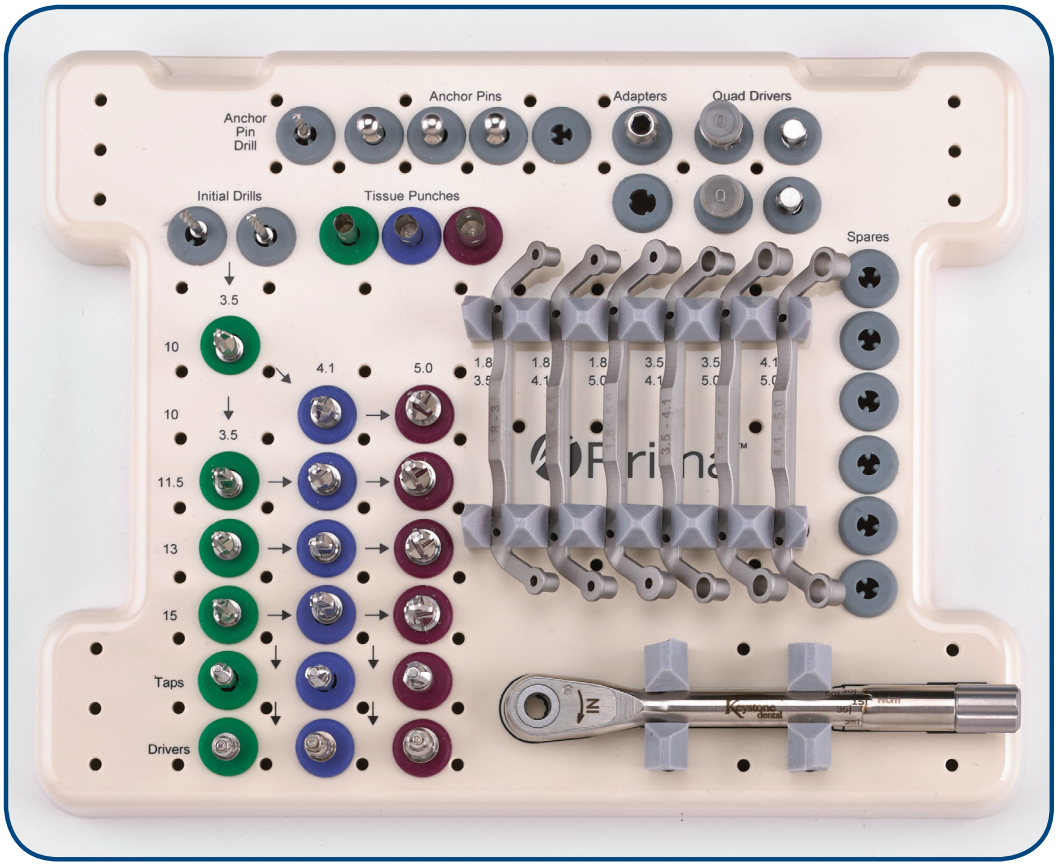
- Autoclave (pre-vacuum): 134˚C (~273˚F) 4 minute exposure / 40 minute drying time
- Autoclave (gravity cycle): 134˚C (~273˚F) 20 minute exposure / 40 minute drying time
- Always use the drying cycle

Keystone Dental does not recommend chem-clave 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.wh.com.

Surgical Kit Overview



15651K
Tapered Prima Guided Surgery Kit (with instruments) Includes the instrumentation required to place Prima Tapered implants

15650K
Guided Surgery Cassette (without instruments)

Individual Components

Anchor Pins & Anchor Pin Drill

Product Code	Description
E40100	Anchor Pins (package of 3)
E20101	Anchor Pin Drill Ø1.6 mm

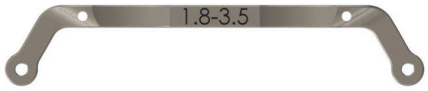
Tissue Punch

15671K	Prima Guided Tissue Punch, Ø3.5
15672K	Prima Guided Tissue Punch, Ø4.1
15673K	Prima Guided Tissue Punch, Ø5.0

Guided Surgery Drills

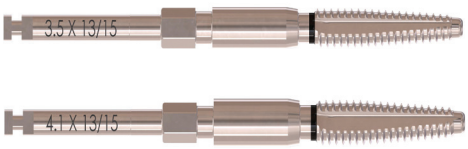
15674K	Prima Guided Initial Drill, Short
15675K	Prima Guided Initial Drill, Long
15652K	Prima Guided Surgery, Tapered Drill, Ø3.5 x 10
15653K	Prima Guided Surgery, Tapered Drill, Ø3.5 x 11.5
15654K	Prima Guided Surgery, Tapered Drill, Ø3.5 x 13
15655K	Prima Guided Surgery, Tapered Drill, Ø3.5 x 15
15656K	Prima Guided Surgery, Tapered Drill, Ø4.1 x 10
15657K	Prima Guided Surgery, Tapered Drill, Ø4.1 x 11.5
15658K	Prima Guided Surgery, Tapered Drill, Ø4.1 x 13
15659K	Prima Guided Surgery, Tapered Drill, Ø4.1 x 15
15660K	Prima Guided Surgery, Tapered Drill, Ø5.0 x 10
15661K	Prima Guided Surgery, Tapered Drill, Ø5.0 x 11.5
15662K	Prima Guided Surgery, Tapered Drill, Ø5.0 x 13
15663K	Prima Guided Surgery, Tapered Drill, Ø5.0 x 15

Drill Guides



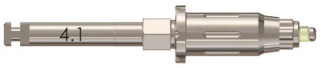
Product Code	Description
15676K	Prima Guided Drill Guide, Initial Drill, Ø3.5
15678K	Prima Guided Drill Guide, Initial Drill, Ø4.1
15679K	Prima Guided Drill Guide, Initial Drill, Ø5.0
15680K	Prima Guided Drill Guide, Ø3.5/Ø4.1
15681K	Prima Guided Drill Guide, Ø3.5/Ø5.0
15682K	Prima Guided Drill Guide, Ø4.1/Ø5.0

Guided Surgery Bone Taps



15664K	Prima Guided Bone Tap, Ø3.5, Short
15665K	Prima Guided Bone Tap, Ø3.5, Long
15667K	Prima Guided Bone Tap, Ø4.1, Short
15668K	Prima Guided Bone Tap, Ø4.1, Long
15669K	Prima Guided Bone Tap, Ø5.0, Short
15670K	Prima Guided Bone Tap, Ø5.0, Long

Guided Implant Drivers

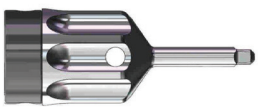


15683K	Prima Guided Implant Driver, Ø3.5
15684K	Prima Guided Implant Driver, Ø4.1
15685K	Prima Guided Implant Driver, Ø5.0

Surgical Ratchet & Ratchet Adapter

K15695	Surgical Ratchet/Torque Wrench
15686K	Ratchet Adapter

Quad Drivers

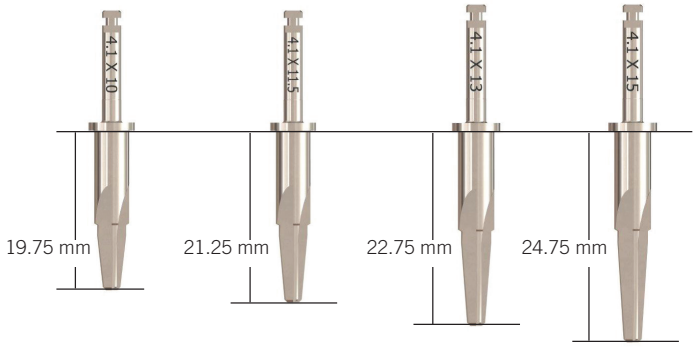


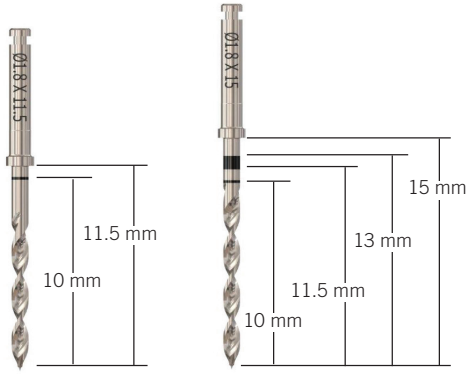
15272K	Quad Swivel, Short
15273K	Quad Swivel, Long
15276K	Quad Driver, Torque Wrench, Short
15277K	Quad Driver, Torque Wrench, Long

Drill Overview

The drill lengths are identical for all three diameters of implants and include an over drill length of 0.86 mm. Each drill is specific to a diameter and length of implant. All drills included with this system are externally irrigated and require intermittent drilling technique with steady sterile irrigation.

Example shown: Ø4.1 mm drills





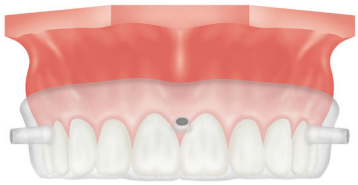
Guided Surgery Drilling Protocols

Implant Length				
10 mm	Ø1.8 mm Initial Drill, 1.8/3.5 mm Guide Tool	Ø3.5 x 10 mm Final Drill, No Guide Tool		3.5
11.5 mm	Ø1.8 mm Initial Drill, 1.8/3.5 mm Guide Tool	Ø3.5 x 10 mm Final Drill, No Guide Tool	Ø3.5 x 11.5 mm Final Drill, No Guide Tool	
13 mm	Ø1.8 mm Initial Drill, 1.8/3.5 mm Guide Tool	Ø3.5 x 10 mm Final Drill, No Guide Tool	Ø3.5 x 13 mm Final Drill, No Guide Tool	
15 mm	Ø1.8 mm Initial Drill, 1.8/3.5 mm Guide Tool	Ø3.5 x 10 mm Final Drill, No Guide Tool	Ø3.5 x 15 mm Final Drill, No Guide Tool	

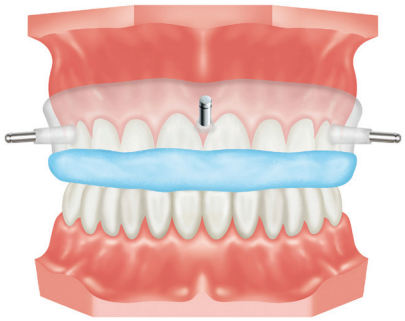
Implant Length					
10 mm	Ø1.8 mm Initial Drill, 1.8/4.1 mm Guide Tool	Ø3.5 x 10 mm Final Drill, 3.5/4.1 mm Guide Tool	Ø4.1 x 10 mm Final Drill, No Guide Tool		4.1
11.5 mm	Ø1.8 mm Initial Drill, 1.8/4.1 mm Guide Tool	Ø3.5 x 10 mm Final Drill, 3.5/4.1 mm Guide Tool	Ø3.5 x 11.5 mm Final Drill, 3.5/4.1 mm Guide Tool	Ø4.1 x 11.5 mm Final Drill, No Guide Tool	
13 mm	Ø1.8 mm Initial Drill, 1.8/4.1 mm Guide Tool	Ø3.5 x 10 mm Final Drill, 3.5/4.1 mm Guide Tool	Ø3.5 x 13 mm Final Drill, 3.5/4.1 mm Guide Tool	Ø4.1 x 13 mm Final Drill, No Guide Tool	
15 mm	Ø1.8 mm Initial Drill, 1.8/4.1 mm Guide Tool	Ø3.5 x 10 mm Final Drill, 3.5/4.1 mm Guide Tool	Ø3.5 x 15 mm Final Drill, 3.5/4.1 mm Guide Tool	Ø4.1 x 15 mm Final Drill, No Guide Tool	

Implant Length						
10 mm	Ø1.8 mm Initial Drill, 1.8/5.0 mm Guide Tool	Ø3.5 x 10 mm Final Drill, 3.5/5.0 mm Guide Tool	Ø4.1 x 10 mm Final Drill, 4.1 mm Guide Tool	Ø5.0 x 10 mm Final Drill, No Guide Tool		5.0
11.5 mm	Ø1.8 mm Initial Drill, 1.8/5.0 mm Guide Tool	Ø3.5 x 10 mm Final Drill, 3.5/5.0 mm Guide Tool	Ø3.5 x 11.5 mm Final Drill, 3.5/5.0 mm Guide Tool	Ø4.1 x 11.5 mm Final Drill, 4.1 mm Guide Tool	Ø5.0 x 11.5 mm Final Drill, No Guide Tool	
13 mm	Ø1.8 mm Initial Drill, 1.8/5.0 mm Guide Tool	Ø3.5 x 10 mm Final Drill, 3.5/5.0 mm Guide Tool	Ø3.5 x 13 mm Final Drill, 3.5/5.0 mm Guide Tool	Ø4.1 x 13 mm Final Drill, 4.1 mm Guide Tool	Ø5.0 x 13 mm Final Drill, No Guide Tool	
15 mm	Ø1.8 mm Initial Drill, 1.8/5.0 mm Guide Tool	Ø3.5 x 10 mm Final Drill, 3.5/5.0 mm Guide Tool	Ø3.5 x 15 mm Final Drill, 3.5/5.0 mm Guide Tool	Ø4.1 x 15 mm Final Drill, 4.1 mm Guide Tool	Ø5.0 x 15 mm Final Drill, No Guide Tool	

The Tapered Prima Surgical Guide is positioned and secured (if necessary) using Anchor Pins. Typically three (3) anchor Pins are placed in an edentulous mandible or maxilla with adequate cortical bone. It is recommended to create a bite index of the patient's occlusion, under light clench, with the surgical guide in place prior to fixating the Anchor Pins.



To position the Anchor Pins a Ø1.6 mm twist drill is inserted to full depth, through the soft tissue into bone at a maximum speed of 800 rpm. The Anchor Pins are inserted through the Anchor Pin Sleeve.

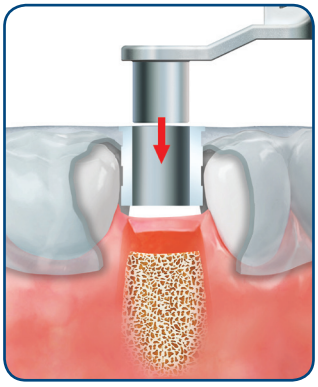


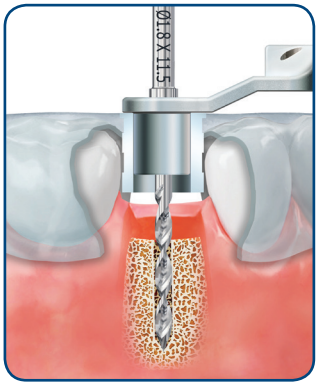
Step 1

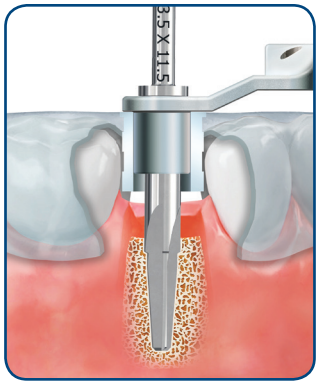
The Ø1.8 mm Initial Drill should be inserted to the required depth at a speed of no more than 800 rpm.

Note: Each template sleeve has an initial drill guide tool, marked at "1.8-3.5", "1.8-4.1" and "1.8-5.0". The appropriate guide tool is selected for the template sleeve identified in the plan.

Each tapered drill includes a drill stop and is inserted into the osteotomy to full depth. It is recommended to start drilling after the drill has entered the guide tool or template sleeve.

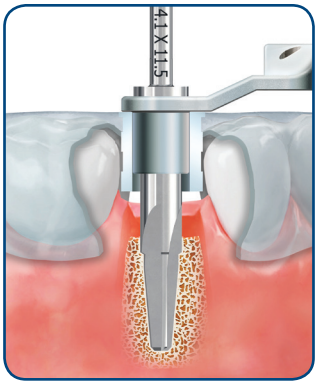






Step 2

The osteotomy is further widened with the Ø3.5 x 10 mm Tapered Drill to the required depth at 800 rpm.



Step 3

The Ø4.1 x 11.5 mm Tapered Drill is then selected, which is the final drill when placing a 4.1 mm PrimaConnex® Tapered Implant.

The osteotomy is further widened with the Ø4.1 x 11.5 mm Tapered Drill to full depth at maximum speed of 800 rpm.

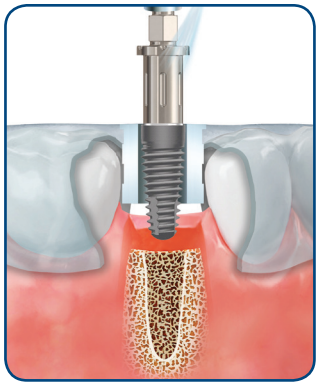
OPTIONAL

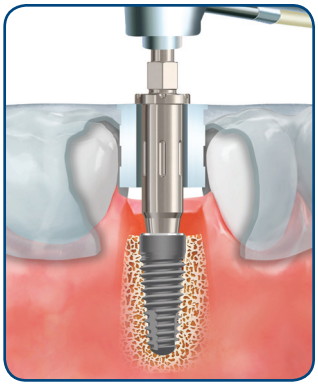
In bone quality D1 and D2, it is recommended to use Bone Taps to finalize the osteotomy. In this case, a Ø4.1 mm Surgical Bone Tap (short) is inserted into the Ø4.1 mm Template Sleeve, until the top of the hub reaches the top of the Template Sleeve. It is recommended to advance the Surgical Bone Tap as far as possible through the Template Sleeve into the osteotomy prior to rotating the Surgical Bone Tap to ensure proper guidance.

IMPLANT PLACEMENT

The Implant Driver engages into the implant assisted by a PEEK ring on the Implant Driver intended to guide the Implant Driver into place. The Implant Driver rotation at less than 20 rpm facilitates the engagement of the Driver lobes with the Tapered PrimaConnex implant lobes. A tactile and/or audible “click” may occur indicating the driver is engaged. At this point the implant is carefully removed from the vial, carried to the osteotomy.
The diameter 4.1 x 11.5 mm Tapered PrimaConnex implant is then inserted into the Template Sleeve and advances as far as possible through the Template Sleeve to ensure proper guidance. It is recommended to stop approximately 1 mm short of the depth stop to finalize the insertion of the implant by engaging the Implant Driver into the Ratchet with the Ratchet Adapter until the depth stop rests on the drill guide. No further tightening is required and might affect the correct positioning of the implant. The Implant Driver is disengaged from the implant by lightly pulling up the Implant Driver.

Note: The grooves on the Implant Driver indicate the internal lobe position of the implant.





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. 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.

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