The TRU® and PUR® Implant System Keyless Guided Surgery

The true value, pure performance dental implant system provides a guided surgical option for placing these reliable implants, integrating seamlessly into your digital workflow.

Sterngold® GUIDED SURGERY

The Affordable, Simple, and Keyless Guided Surgery System

Sterngold® provides you all you need:

- ✓ Simple, keyless guided surgery protocol
- ✓ Predictable surgical outcomes
- ✓ Quality, affordable solution

Sterngold® GUIDED SURGERY

THE STERNGOLD GUIDED SURGERY KIT

The Guided Surgery Kit is a fully heat/steam sterilizable polymer tray containing the TRU® and PUR® guided surgery instruments for the 3.2mm, 3.5mm, 4.3mm, and 5.0mm TRU® and PUR® implants. Optional mount drivers are sold separately.

905812

Guided Surgery for TRU® and PUR® Implant System

Sterngold Guided Surgery is based on and intended to be used solely with Sterngold TRU® and PUR® implants, adding value to both implant lines. Enjoy all of the existing benefits of TRU® and PUR® including ease of use, precision, and highest quality manufacturing with all complementary surgical and prosthetic components. The Guided Surgery kit can be used with the TRU® 3.5mm narrow platform and the 4.3mm and 5.0mm regular diameter, as well as the PUR® 3.2mm, 3.5mm, 4.3mm, and the 5.0mm diameter implants. This Guided Surgery solution encompassing the kit, protocol, software, implants and proprietary tools and drills, make up the TRU® and PUR® digital workflow. Note: TRU® and PUR® 6.0mm implants are not compatible with the guided surgery system.

Sterngold® GUIDED SURGERY

TRU® Internal Conical Hex

Prosthetic connection substantially equivalent to Nobel Biocare® NobelActive® Conical

Nobel Biocare® is a registered trademark of Nobel Biocare®

TRU®			
Body Diameter	3.5mm	4.3mm	5.0mm
Prosthetic Connection	NP 3.5mm	RP 4.5mm	RP 4.5mm
Apical Diameter	2.6mm	2.6mm	2.6mm
8.0mm Length	901340	901344	901348
10.0mm Length	901341	901345	901349
12.0mm Length	901342	901346	901350
14.0mm Length	901343	901347	---

NP= Narrow Platform= 3.5mm RP= Regular Platform= 4.5mm

PUR® Internal Hex

Internal prosthetic connection substantially equivalent to the Zimmer® Tapered Screw-Vent® hex connection

Zimmer® Screw-Vent® is a registered trademark of ZimVie (formerly Zimmer Biomet)

PUR®				
Body Diameter	3.2mm	3.5mm	4.3mm	5.0mm
Prosthetic Connection	NP 3.5mm	NP 3.5mm	NP 3.5mm	RP 4.5mm
Apical Diameter	2.6mm	2.6mm	2.6mm	2.6mm
8.0mm Length	901382	901356	901360	901365
10.0mm Length	901383	901357	901361	901366
12.0mm Length	901390	901358	901362	901367
14.0mm Length	901391	901359	901363	---

NP= Narrow Platform= 3.5mm RP= Regular Platform= 4.5mm

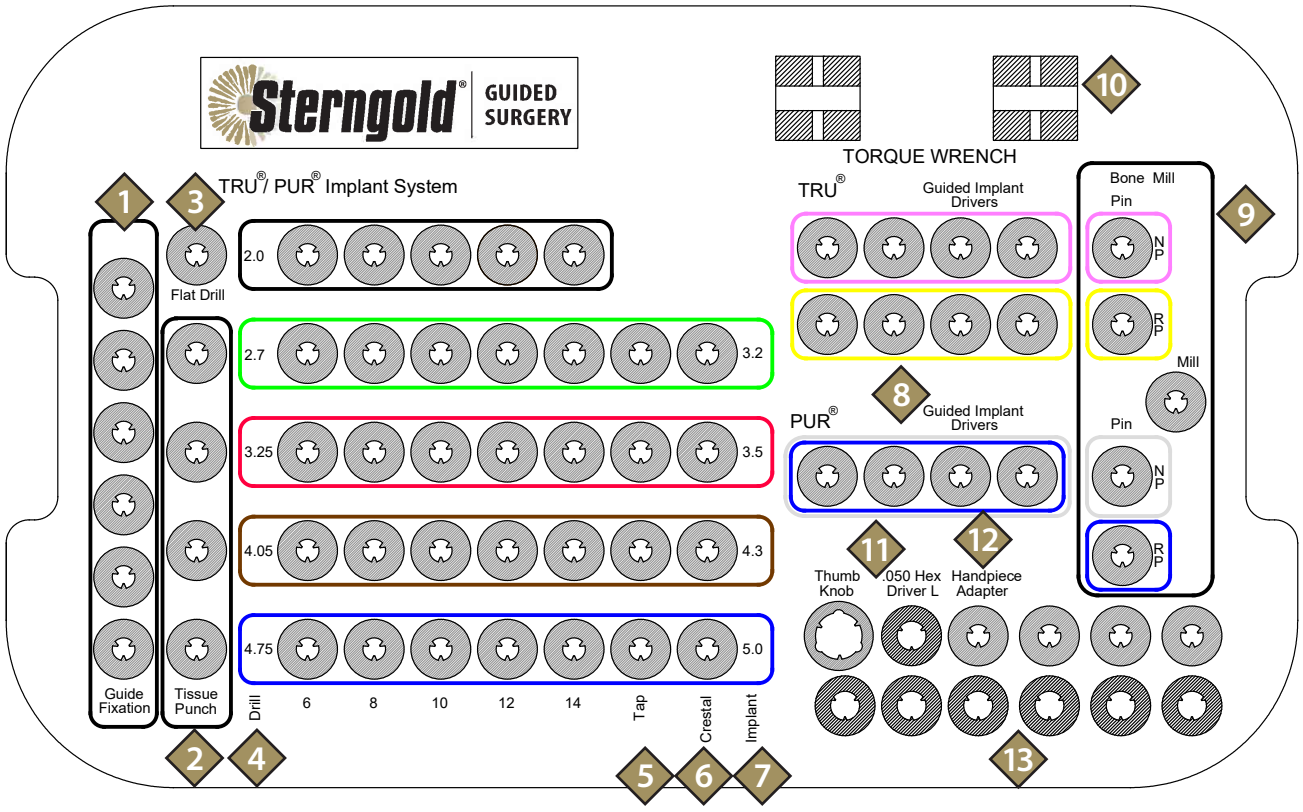
STRAIGHTFORWARD PROTOCOL

While many guided surgery systems can be complex, Sterngold Guided Surgery with TRU® and PUR® implants is designed to be a simple surgical protocol that ensures precise implant placement with perfect fit and increases the predictability of the surgical restorative outcomes. The Guided Surgery kit includes the instruments to be used for fully guided and partially guided procedures, with 3D planning software through CBCT imaging. The kit utilizes a keyless design to prepare the osteotomy site and placement of the 3.2mm, 3.5mm, 4.3mm, and 5.0mm TRU® and PUR® implants in coordination with a surgical guide prepared with Sterngold surgical sleeves.

Sterngold Dental's keyless guided surgery system (without handles), is for single implant, full arch fixed-hybrid cases, and implant supported overdenture cases and ensures ease of use for the clinician through a simple yet comprehensive kit. This keyless system includes a series of drills with drill stops to be used through a guide sleeve affixed into a surgical guide. This allows for complete control of the position and final drill depth of the osteotomy according to the surgical plan. Eliminating the need for keys with handles offers more ease of use, increased control, and predictability to guided surgery.

Sterngold® GUIDED SURGERY

One simple, color coded Guided Surgery Kit for TRU® and PUR® implants

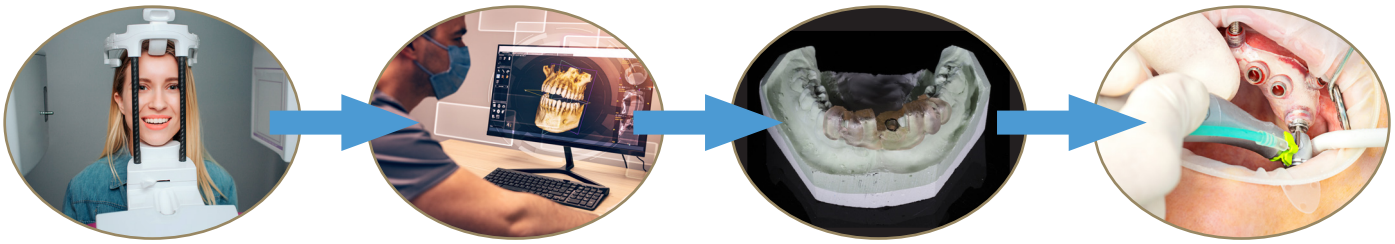


1. Guide Fixation
2. Tissue Punch
3. Flat Drill – Used as a "pilot" drill
4. Drill Diameters 2.0mm – 4.75mm
5. Drill Tap – For dense bone
6. Cortical Bone Drill – For dense bone
7. Implant Body Diameters 3.2/3.5/4.3/5.0mm
8. Guided Implant Drivers
9. Bone Mill with Guide Pin
10. Torque Wrench
11. Thumb Knob + .050 Hex Driver
12. Handpiece Adapter
13. Extra Slots

Sterngold® GUIDED SURGERY

GUIDED SURGERY OVERVIEW

Data Acquisition | 3D Treatment Planning | Surgical Guide Fabrication | Surgical Procedure



1. Data Acquisition

Using patient's CBCT data along with scanned reference materials and records will ensure precision in the preparation for the surgical guide and final placement of the implants.

2. 3D Treatment Planning

Careful and accurate patient selection, diagnosis, and treatment planning form the foundation of a successful dental implant surgical procedure. 3D treatment planning software using acquired scan data, allows the clinician to correctly assess the quality and amount of bone, vertical space needed, and precise plan for selection and the positioning of the implants based on the clinical and prosthetics requirements for the case. TRU® and PUR® implant libraries and Sterngold Guided Surgery surgical components are available in most popular implant planning and surgical guide software systems. Finally, a patient specific surgical protocol is generated indicating proper drilling sequence of each implant site using the Guided Surgery Kit instrumentation.

3. Surgical Guide Fabrication

Based on the surgical plan, the guide is fabricated with Sterngold Surgical sleeves. Depending on the protocol, the surgical guide may be tooth supported, mucosa supported, or bone supported, with optional guide fixation screws.

4. Surgical Procedure

Using the surgical guide and generated drilling protocol, the clinician places the TRU® and PUR® implants using the Sterngold Guided Surgery Kit.

Compatible software platforms include:

RealGUIDE™ UNIVERSAL OPEN SYSTEM

exoplan 3.0 Galway

RealGUIDE™ Universal Open System is the software platform brand of RealGUIDE Empowered Labs.

exoplan is a trademark for the implant planning and surgical guide design software of exocad.

Sterngold® GUIDED SURGERY

INDIVIDUAL COMPONENTS

GUIDE FIXATION SCREW

GS1920

TISSUE PUNCH

905813

905814

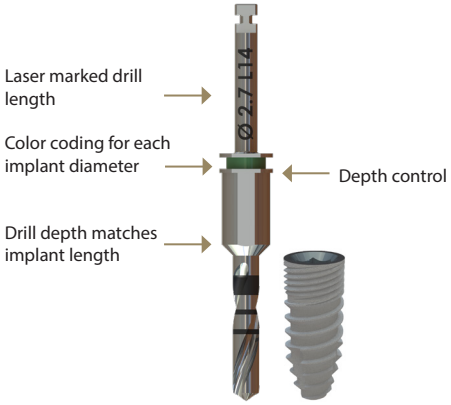
FLAT DRILL

905783

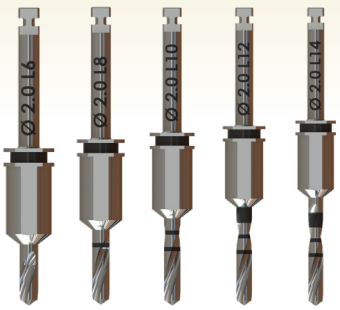
DRILLS 2.0mm – 4.75mm

SIMPLE DRILL DESIGN

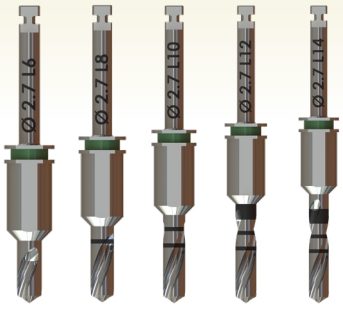
All Sterngold guided surgical drills are conveniently arranged, color coded, and laser engraved for easy identification. All have precise guidance and depth control stops that are used with the guide sleeves. There are five 2mm diameter pilot drills from 6mm to 14mm long and four different diameter drills ranging from 2.7mm to 4.75mm, all with lengths from 6mm to 14mm, which directly correspond to the TRU® and PUR® implants. Note: The TRU® and PUR® drills are not true-to -depth, the drill tip should not be included in determining the final depth of the osteotomy in coordination with indicator lines on each drill.



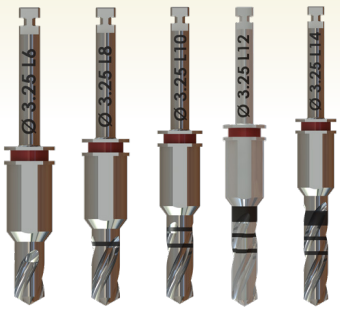
2.0mm



2.7mm



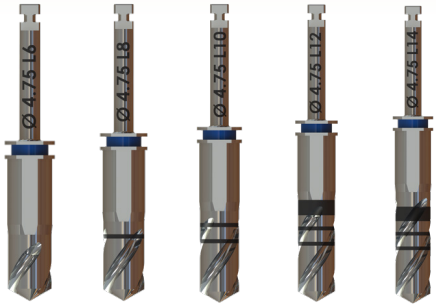
3.25mm



Sterngold® GUIDED SURGERY

4.05mm

4.75mm

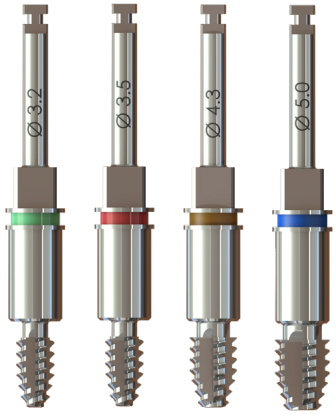


Diameter

Length	2.0mm	2.7mm	3.25mm	4.05mm	4.75mm
6mm	905758	905763	905768	905773	905778
8mm	905759	905764	905769	905774	905779
10mm	905760	905765	905770	905775	905780
12mm	905761	905766	905771	905776	905781
14mm	905762	905767	905772	905777	N/A

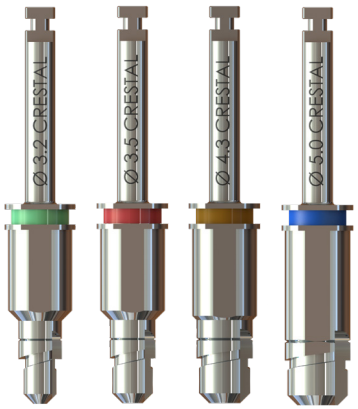
Sterngold® GUIDED SURGERY

BONE TAP



3.2mm diameter	905789
3.5mm diameter	905790
4.3mm diameter	905791
5.0mm diameter	905792

CRESTAL BONE DRILL



3.2mm diameter	905785
3.5mm diameter	905786
4.3mm diameter	905787
5.0mm diameter	905788

GUIDED IMPLANT DRIVERS

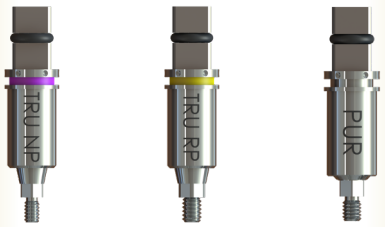
GUIDED LATCH

905793 905794 905795

GUIDED WRENCH

905802 905801 905796

GUIDED MOUNT DRIVER
(optional)



905803 905799 905797

Sterngold® GUIDED SURGERY

BONE MILL & GUIDE PINS

905806	905810	905809	905808	905807
		BONE MILL GUIDE PIN		
BONE MILL	TRU RP	TRU NP	PUR RP	PUR NP

GRADUATED TORQUE WRENCH

905738

.050mm HEX DRIVER

905229

THUMB KNOB

905213

LATCH TO SQUARE DRIVER ADAPTER

905260

Sterngold® GUIDED SURGERY

SURGICAL MANUAL

IMPORTANT

This surgical manual serves as a reference for using the Sterngold Guided Surgery Kit. It is only intended to provide instructions on the use of Sterngold TRU® & PUR® implants and its complementary products. It is not intended to describe the methods or procedures for diagnosis, treatment planning, or placement of implants, nor does it replace clinical training or a clinician's best judgment regarding the needs of each patient. Sterngold strongly recommends appropriate training as a prerequisite for the placement of dental implants and associated treatment. The procedures described within this manual reflect idealized patient presentations with adequate bone and soft tissue to accommodate implant placement. No attempt has been made to cover the wide range of actual patient conditions that may adversely affect surgical and prosthetic outcomes. Clinician judgment as related to any specific case must always supersede any recommendations made in this or any Sterngold literature.

Before beginning any dental implant surgical procedure using the Sterngold Guided Surgery Kit:

- Carefully select patient after thorough clinical evaluation of medical and dental history.
- Read and understand the Instructions for Use that accompany TRU® & PUR® dental implants and its complementary implant products.
- Clean and sterilize the surgical tray and instruments following the Instructions for Use.
- Become thoroughly familiar with all the instruments within the kit as well as complimentary instruments not included in the kit, and their uses.
- Design a surgical treatment plan to satisfy the prosthetic requirements of the case.

INDICATIONS

The Sterngold TRU® & PUR® Keyless Fully Guided Surgery Kit is to be used solely with Sterngold TRU® & PUR® implants. The kit is intended to be used for dental implant applications including oral rehabilitation of edentulous and partially dentate patients in the maxilla and mandible to support single unit, and multiple unit restorations. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures. TRU® & PUR® implants are intended for delayed or immediate loading when adequate primary stability appropriate occlusal loading is achieved clinically. Patient selection should be such that there are no compromising health conditions, disease, or medications that would interfere with the complete integration of the implants into the bone. Adequate bone quality and quantity should be assessed as well as available vertical opening to allow for kit instruments to be used.

PRE-OPERATORY TREATMENT PLANNING, DIAGNOSIS, AND DATA GATHERING

A thorough clinical examination and assessment of the patient's complete medical and dental history should be performed to assess whether the patient is a good implant and guided surgery candidate.

Assess the restorative site using CBCT scans and/or radiographs for assessing bone volume and density, anatomy of the residual ridge, maxillary sinus, nasal cavities, inferior alveolar nerve, mental foramen, natural tooth positions, jaw relationship, and surrounding anatomic features that may affect implant placement.

Determine the type of restoration, load type, number of implants, esthetic, and functional factors.

Ensure communication and planning between each clinician and laboratory technician who is involved in the treatment plan along with utilization of surgical planning software of choice, to determine the precise digital plan for accurate implant installation.

3D SURGICAL PLANNING AND SURGICAL GUIDE DESIGN

Import data set (DICOM files) into the surgical planning software of choice. Sterngold has approved partnerships with several virtual planning companies and all available implants, complementary parts, and surgical instrument libraries available to design a Sterngold TRU® & PUR® guided surgery case.

Determine precise digital plan for accurate implant installation and combine with patient .STL data.

According to the patient's clinical condition as previously assessed, precisely position the implants in the design software for the desired anatomical, functional, and esthetic goals.

ANESTHESIA

Administer anesthesia as indicated in preparation for dental surgery.

ATTACHING AND ANCHORING THE SURGICAL GUIDE

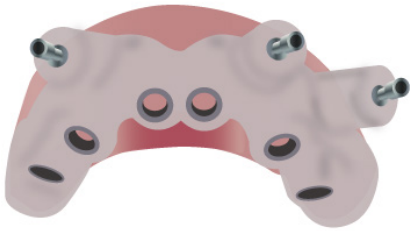
Tooth Supported

Single/multiple unit, minimally invasive, tooth fixated.

Secure guide onto arch. According to the surgical and sequence report, use appointed surgical components and drills to penetrate mucosa to create osteotomy.

Mucosa-Supported
Rests on mucosa, fully edentulous, no flap, anchor screw fixation.

Anchor surgical guide into place using guide anchor screw drill and guide anchor screws. According to surgical and sequence report, use appointed surgical components and drills to penetrate mucosa and create osteotomy.



Bone Supported
Rests on exposed alveolar bone, fully edentulous.

Gain access to the surgical site by making an incision through the mucosa and attached gingiva along the crest of the ridge. Reflect a full thickness mucoperiosteal flap both lingually (palatally) and facially. Expand the operative site to identify the neurovascular bundles of the mental foramen in the mandible. In the maxilla, the borders of the maxillary sinus should also be identified. Examine the anatomy, quality, and quantity of available bone at the site. Alterations to the predetermined "ideal" position should be made based upon the clinical findings, prior discussions with the restorative clinician and laboratory technician, and all diagnostic information. Anchor surgical guide into place using guide anchor screw drill and guide anchor screws. Reduce bone as indicated by the surgical report and guide. According to surgical and sequence report, use appointed surgical components and drills to create osteotomy.

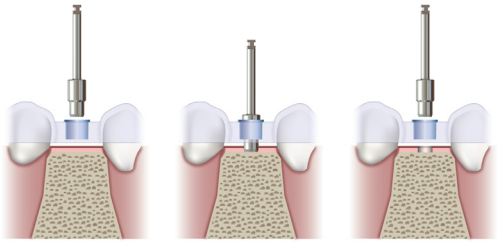
DRILLING SEQUENCE

The graduated drilling sequence and specific size of each surgical component for each osteotomy will be indicated in the surgical and sequence report provided with the surgical guide.

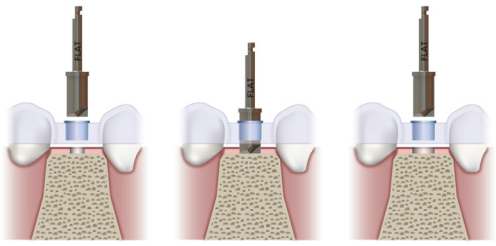
Note: Drilling speeds must be performed at speeds between 1500 - 2000 rpm for D1 and D2 bone and 1000 rpm for D3 and D4 (unless otherwise indicated) with copious irrigation of refrigerated sterile saline (0.9%NaCl). The TRU® and PUR® drills are not true-to -depth, the drill tip should not be included in determining the final depth of the osteotomy in coordination with indicator lines on each drill.

This is a keyless surgical system; all components and drills will be advanced completely until they the stop inside the surgical guide sleeves. The stops are built into the components and drills which are considered during the planning. All components and drills are color coded according to size and the surgical kit box. The general sequence of components and drills follow the order below:

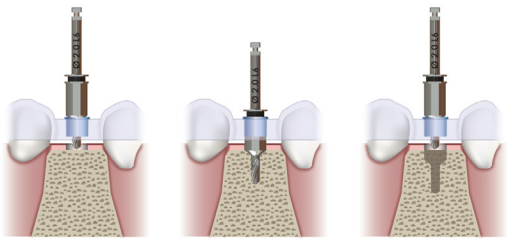
1. Tissue Punch, for tooth and mucosa supported surgical guides not requiring flap technique allows for minimally invasive implant placement while preserving the adjacent tissue. (Recommended Speed 600 RPM)



2. Flat Drill, model and flatten the cortical bone at the implant site preparatory. (Recommended Speed 650 - 900 RPM)



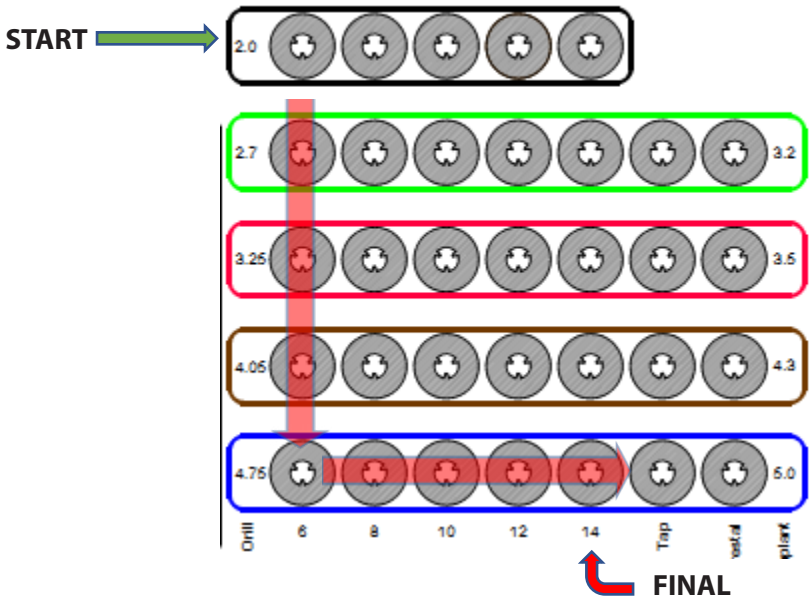
3. 2.0mm x 6.0mm (pilot) drill. This will be the initial penetration of the cortical plate.



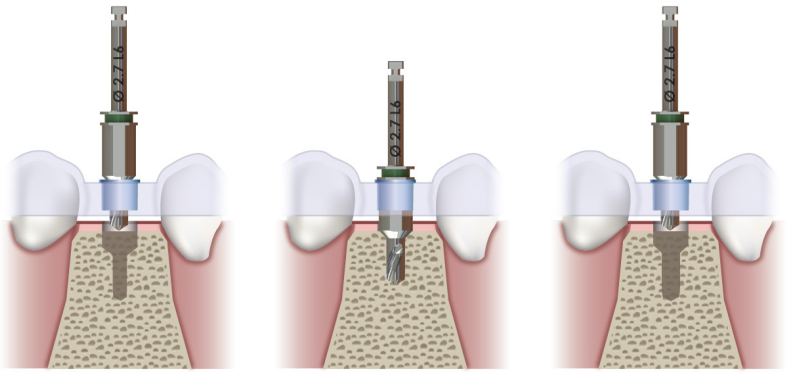
Suggested Drilling Sequence

Establish final width beginning with 2.0mm X 6mm, then sequentially increase diameter until the final diameter is reached. Then proceed, increasing the length of the osteotomy using each sequential drill, until the final depth is reached. Continue advancing each drill until the stop on the drill contacts the guide sleeve.

Example of placing a 5.0mm x 14mm implant:

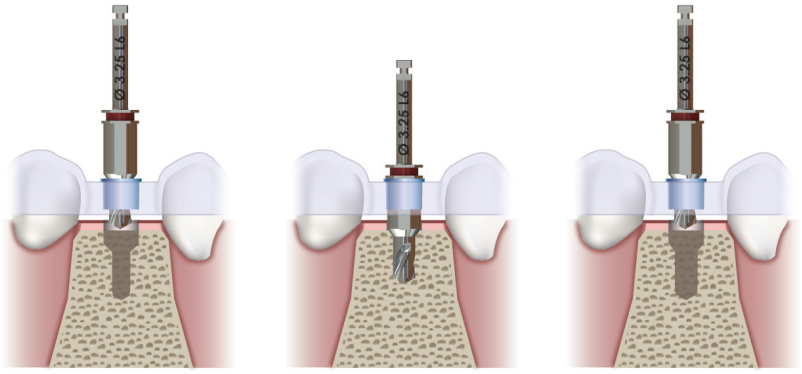


4.



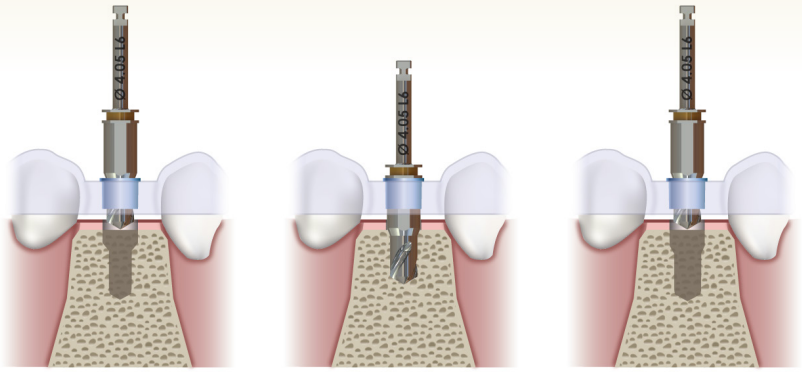
2.7mm

5.



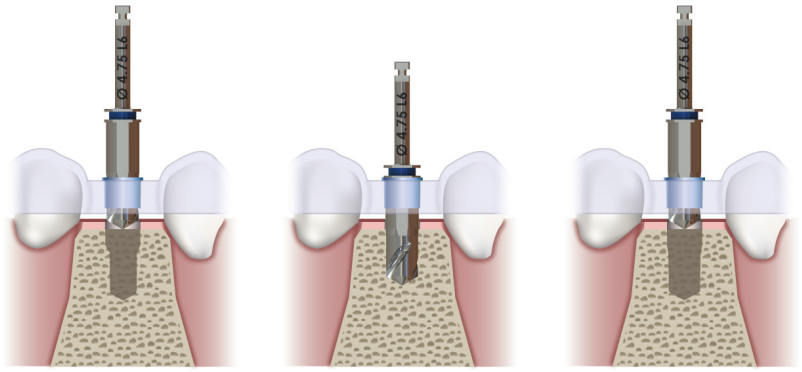
3.25mm

6.



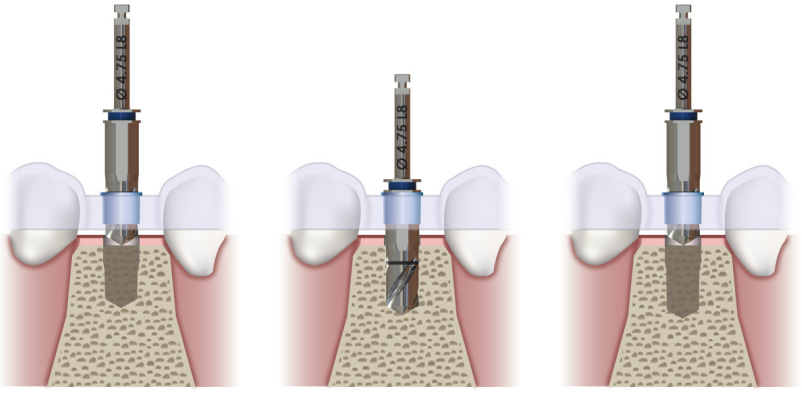
4.05mm

7.



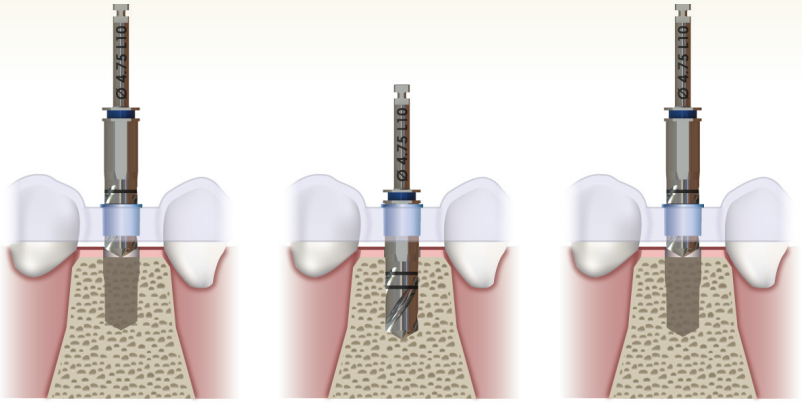
4.75mm

8.



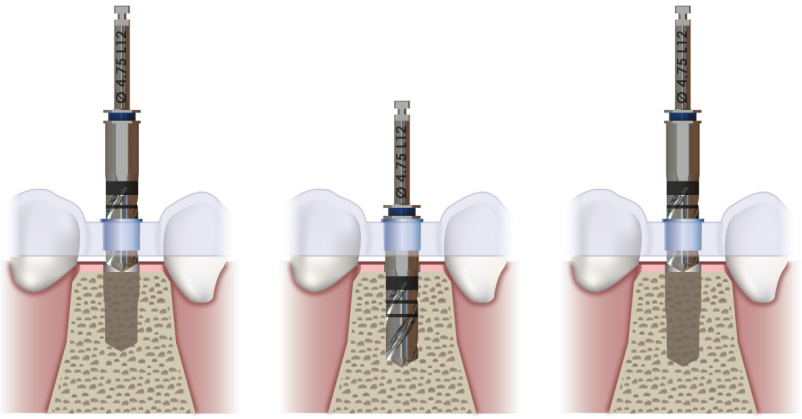
4.75mm - 8mm

9.



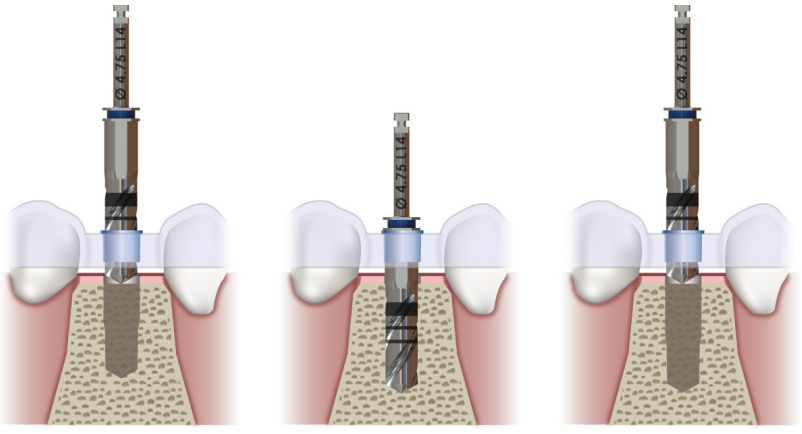
4.75mm - 10mm

10.



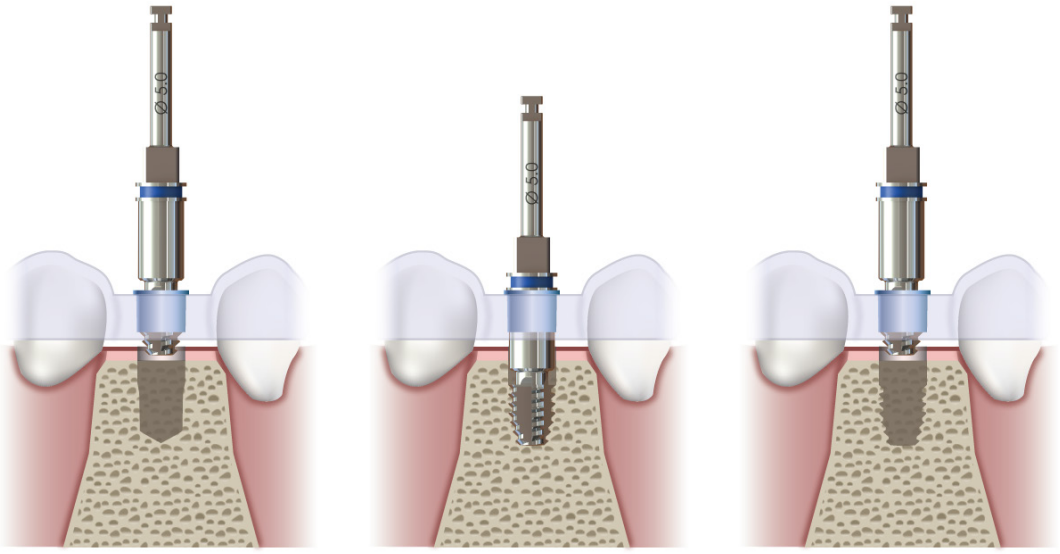
4.75mm - 12mm

11.

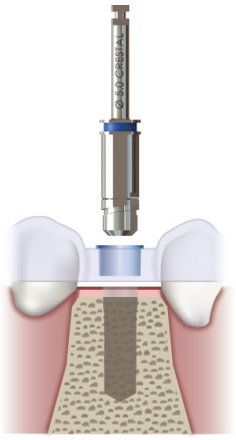


4.75mm - 14mm

12. Bone Tap, use the final appointed tap to create the threads for the implant. (Recommended speed 15 – 30 RPM). This step is optional based on your treatment plan.

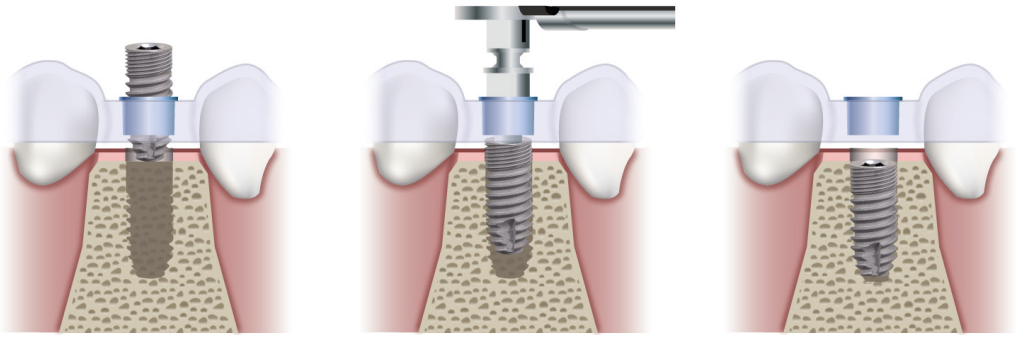


13. Crestal Drill, use the appointed crestal drill for areas of high bone density to relieve the final diameter of the osteotomy in the cortical region. (Recommended speed 200 – 600 RPM.)

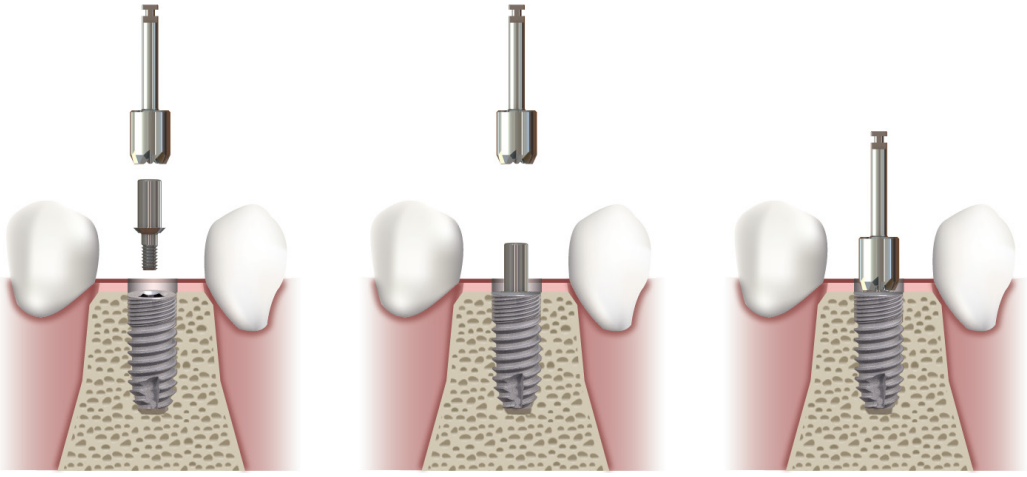


IMPLANT INSERTION

1. Using the guided driver of choice from the Sterngold Guided Surgery kit (Guided Latch, Guided Wrench, or Guided Mount Driver), install the TRU® & PUR® implants through surgical guide into the prepared osteotomy until the stop on the carrier/mount bottoms out. Recommended speed 15 – 30 RPM. It is important to stop rotating the implant once the stop contacts the guide sleeve to avoid stripping the bone and any loss in primary stability. Using the graduated torque wrench, confirm primary stability of 35 N-cm, not to exceed 55 N-cm. (Insertion Torque Value should be at 45 N-cm and Reverse Torque Value should be at 50 N-cm.

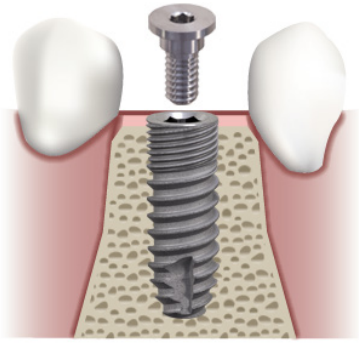


2. Use the Bone Mill with Guide Pins to profile and prepare restorative platform area of implant site. (Recommended speed 200 RPM.)

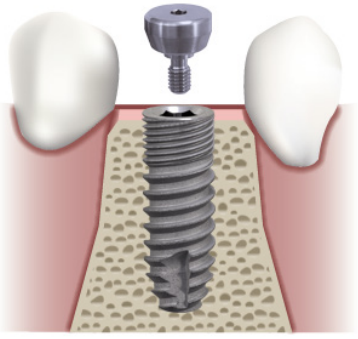


3. Proceed to healing or restoration phase based on treatment plan.

COVER SCREW



HEALING ABUTMENT



Sterngold® GUIDED SURGERY

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