



FULLY GUIDED QUICK START

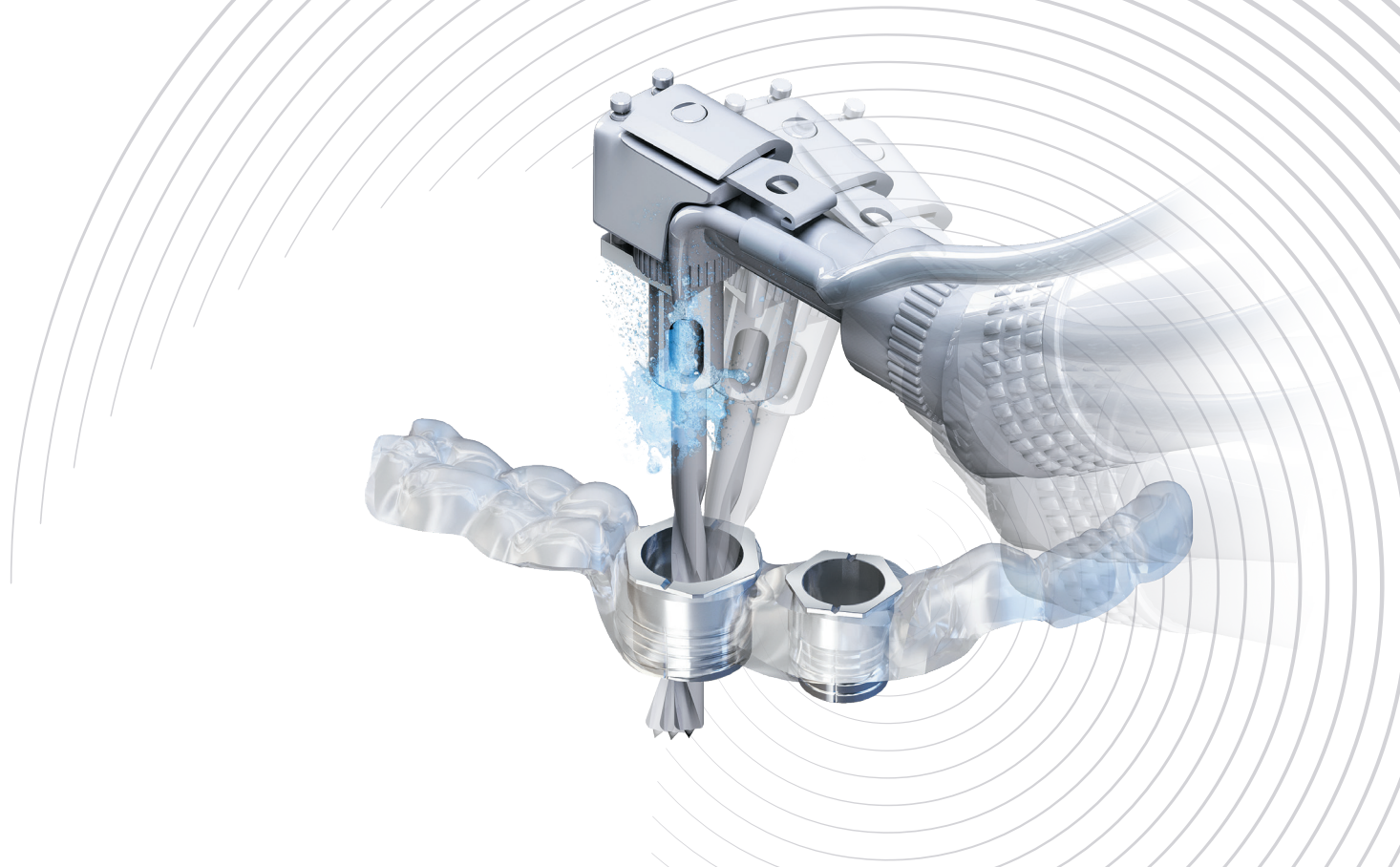


A KeystoneDentalGroup Brand

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Instructions For Use

This manual provides guidelines for surgical and restorative clinicians, as well as laboratory technicians, for use with the Paltop 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.

Implant Indications For Use

The Paltop Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Paltop Dental Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Disclaimer: Some products may not be regulatory cleared/released for sale in all markets.

Patient Evaluation and Selection

The surgical part of implant treatment must be preceded by a comprehensive patient evaluation, preoperative diagnostics and therapy planning. Inadequate treatment planning may cause implant loss.

A careful clinical and radiological examination of the patient has to be performed prior to surgery to determine the psychological and physical status of the patient. Special attention has to be given to patients who have localized or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone). In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships, reappraisal of the treatment option may be considered.

Implant Selection

The doctor selects the appropriate implant based on the individuality of the patient's condition. He/she must use his/her clinical judgment and expertise in choosing the right implant family and size.

Principal Cleaning

Best results are achieved if surgical instruments are cleaned by material type. Cleaning of the prosthetic components is performed in the dental clinic, according to the following parameters:

3.1. Ti6Al4V Eli tools:

1. Rinse and brush under free-flowing tap water
2. Soak in enzymatic solution in an ultrasonic cleaner for at least 5 minutes, following manufacturer's instructions.
3. Rinse under free-flowing distilled water.
4. Completely dry and inspect abutment for integrity and flaws.

3.2. Stainless steel tools:

Every surgical/dental instrument should be disinfected and thoroughly cleaned after each use. Proper cleaning, inspection and maintenance will help ensure correct function of the surgical instrument. Clean, inspect and test each instrument carefully. Sterilize all instruments before surgery. A good cleaning and maintenance procedure will extend the useful life of the instrument.

Special attention should be paid to slots, stops, ends hollow tubes and other highly inaccessible areas. Do not use damaged instruments. If an instrument can be disassembled, it should be cleaned in the disassembled state.

(NOTE: Keep all parts together and protected from being misplaced. Do not intermix with other or similar devices of other manufacturers.)

Cleaning and rinsing must take place immediately after each use for best effect. Failure to clean promptly may result in adherent particles or dried secretions that may resist cleaning and complicate or resist future sterilization. Instruments must be completely cleaned and rinsed of all foreign matter.

Use warm water and a commercially available instrument presoak or cleaning agent. Enzymatic cleaners should be used to remove protein deposits. Do not use corrosive cleaning agents (i.e. bleach). Cleaning solutions and rinses at or near a neutral pH (7.0) are best. Do not use abrasive cleaners. Only a soft bristle brush should be used. Rinse and maintain all parts and inaccessible areas like inside channels etc.

Ultrasonic cleaners can be used. Check and retighten any fittings that may have vibrated loose.

Can be disinfected in the washing machine up to 203°F (95°C).

Rinse thoroughly with distilled water.

Prepare for storage and / or sterilization.

After cleaning and rinsing, dry instruments completely and carefully with compressed air (Highly inaccessible areas like inside channels etc. have to be blown out).

NOTE: After cleaning and before sterilization, treat all instruments with an oil, which is considered as being physiologically safe (paraffin oil according to DAB 8 of Ph. Eur. USP XX), especially their blades, ends, stops, snaps and all movable parts.

Sterilization

The device may be delivered sterile or nonsterile. Please see indication on sticker. The device must be sterile before use. Tools may be steam-sterilized using the standard sterilization method: steam sterilization (gravity displacement) for 10 minutes at 275°F (135°C).

Surgical Motor and Handpiece

For cleaning and maintenance instructions for NSK handpieces refer to manufacturer's instructions for use. Additional information can be found at www.nskdental.com.

Software Compatibility

Paltop Guided Surgery requires access to compatible implant-planning software, cone-beam CT scan (CBCT), and intraoral scan or optical scan information. Software training is essential for clinicians, technicians, or implant-planning service providers involved in the treatment-planning process.

The Paltop Guided Surgery Kit facilitates the precise placement of Paltop implants through a custom-made surgical guide when used in conjunction with compatible guided surgery software and 3D manufacturing (milling or 3D printing). In addition, the implant-planning file may be exported to compatible prosthetic software, thus enabling the design and manufacture of provisional prosthetics prior to the surgical procedure.

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

Guided Surgery

IMPLANT PLANNING AND SURGICAL PROGRESSION

The following is the general process for implant planning and surgical guide fabrication. Follow the manufacturer's instructions for the implant planning software and other systems used in this process.

1. Patient examination, medical history, preliminary treatment protocol.
2. Collection of digital data (CBCT, intraoral scans, clinical images) completion of Rx form with patient details and requirements.
3. In partially edentulous cases, it is recommended to have intraoral scans of both jaws plus occlusal relationship in addition to the CBCT. This digital information will enable a "virtual tooth setup" in the required zone of interest without the need for a physical diagnostic setup.
4. In fully edentulous cases, it is recommended to follow the "dual scan" protocol using a radiolucent denture with scan markers.
5. Creating a 3D diagnostic treatment plan: Import the CBCT scan data into the treatment-planning software and align the intraoral scans (in partially edentulous cases) or the radiolucent denture scan (in fully edentulous cases). Special care must be taken to ensure correct alignment of digital data to DICOM. Only on completion of this step is it possible to continue with implant planning.
6. Implant planning: Following the instructions on the Rx form and in accordance with the desired prosthetic outcome/virtual tooth setup, the implant planning may be completed. Care must be taken to ensure the correct safety zone of the implants to surrounding structures (i.e., adjacent implants, root anatomy, inferior mandibular nerve,

maxillary sinus).

7. Surgical guide design: Following final approval of the implant planning by the implant surgeon, the surgical guide is designed. When designing a surgical guide using appropriate implant planning software, important factors include: Keystone Dental Group component software library for the planning software, selection of the appropriate guide sleeve and position; minimal thickness of guide to ensure proper retention of the sleeve in the guide; inspection windows to verify guide is properly seated by the clinician; and strengthening bars as needed. These parameters can be modified/added in the software by the designer.
8. Manufacturing the surgical guide: The surgical guide is manufactured using 3D printing technology. Care must be taken to follow the manufacturer's 3D printer guidelines. On completion, the guide sleeves should be introduced and luted into the surgical guide.
9. Guided surgery: The implants are positioned using the custom surgical guide and the dedicated Paltop Guided Surgery Kit, following the surgical and drilling protocols.

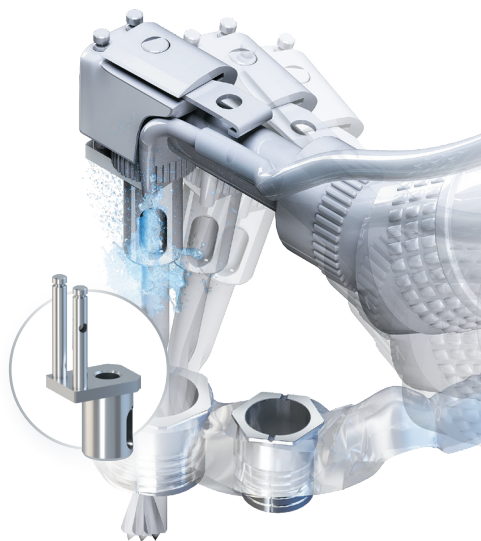
Paltop Innovative Concept

CONTRA ANGLE BASED GUIDANCE

Paltop's unique Digital Guidance Sleeve (DGS) guides the contra angle through the surgical guide to accurately position the implant drills.

Specially designed, fully guided surgical drills are sequentially inserted in the contra angle creating an accurate osteotomy, based on the virtual planning. The unique patent pending DGS offers continuous direct irrigation on the drill. This innovative feature helps to prevent overheating of the drill and improved bone quality.

The Paltop DGS system can be used even when there is minimal interarch distance, such as in the posterior maxilla and mandible. The DGS smart design facilitates angle entry of the drill into the surgical guide sleeve for easy access to the posterior segments. The drill may then be uprighted, enabling engagement of the DGS in the sleeve and activation of the drill.



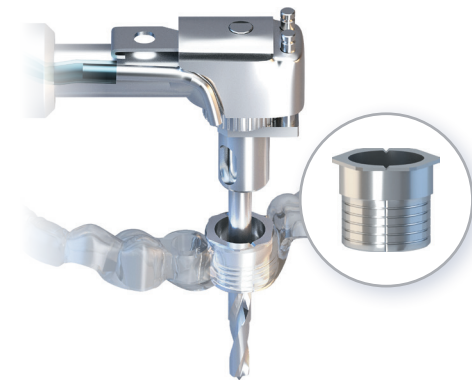
WIDE SLEEVE AND NARROW SLEEVE

The Paltop Digital Guided System uses two sleeve diameters, narrow and wide.

The narrow sleeve can be placed closer to adjacent teeth or sleeves.

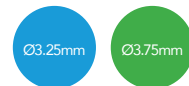
During the planning phase of the treatment the appropriate sleeve should be selected by the digital designer.

All drills: twist, spade and countersink, may be used with the wide DGS and wide sleeve. Only drills up to the diameters for the 3.75mm implant may be used with the narrow DGS/narrow sleeve.



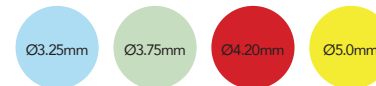
NARROW

Used for 3.25 and 3.75mm diameter implants



WIDE

Can be used for all implants. Must be used for 4.2 and 5.0mm diameter implants

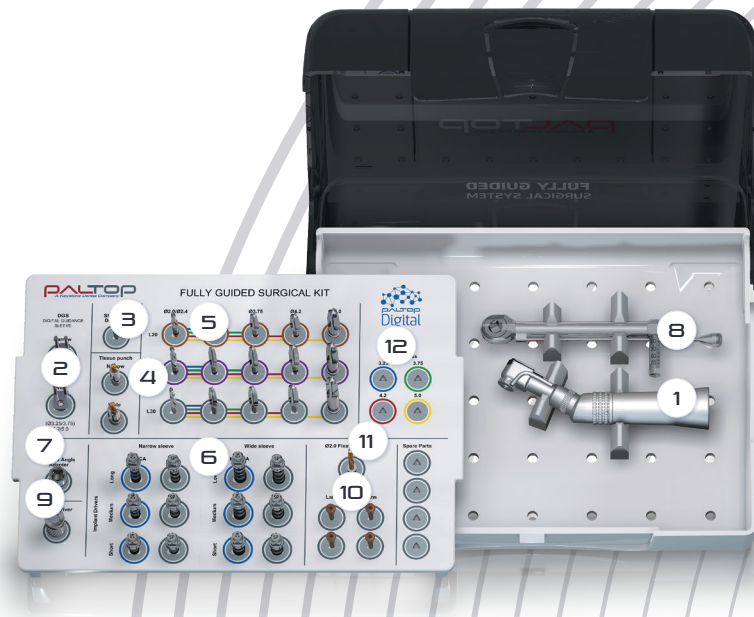


Comprehensive Surgical Kit

VIRTUAL PLANNING FOR AN IDEAL AESTHETIC RESULT

- Continuous direct irrigation on the drill
- Significantly less interarch space needed
- Use one hand, not two
- No implant drill guide keys/spoons required
- No direct contact of drilling flutes to sleeves – no metal shavings – drills last longer
- Guide sleeves available in two diameters for optimal implant distribution
- Guide sleeves in two diameters for increased flexibility in treatment planning
- Three drill lengths with fewer drills in the surgical kit
- One kit manages all Paltop implant lines
- Covers implant lengths 6mm* – 16mm
- Covers implant diameters 3.25mm – 5mm

Fully Guided System



Overview

IMAGE DESCRIPTION

1  **CONTRA ANGLE**

The contra angle included in the Paltop Fully Guided Kit is designed to connect to the Paltop narrow and wide DGS. It must be used to properly utilize the Paltop Fully Guided Kit. This contra angle may be used with most implant electric motors in use today.

IMAGE DESCRIPTION

2  **DGS (DIGITAL GUIDANCE SLEEVE) NARROW/WIDE**

The DGS connects to the dedicated contra angle and fits into the sleeve positioned in the surgical guide. Insert the appropriate DGS (narrow/wide) according to the guide sleeve diameter. The narrow DGS fits the narrow sleeve and the wide DGS fits the wide sleeve. The DGS is used with the short pilot drill and the L=20/25/30mm drills. The DGS should first be inserted into the contra angle and then all drills are placed through the DGS into the contra angle chuck. After inserting both the DGS and the indicated drill, the latch is securely closed.

IMAGE DESCRIPTION


3  **SHORT PILOT DRILL Ø 2.0MM**

The short pilot drill is used to mark and initiate the pilot osteotomy. The DGS must engage the sleeve in the guide before the drill touches bone.

4  **TISSUE PUNCH NARROW/WIDE**

The tissue punch includes a 2.0mm pilot drill and may be used instead of the short pilot drill. The narrow tissue punch will engage the narrow sleeve, and the wide tissue punch will engage the wide sleeve in the surgical guide and requires no DGS.

IMAGE DESCRIPTION

5  **FULLY GUIDED DRILLS - L=20 (BROWN) L=25 (PURPLE) L=30 (SILVER)**

The line of drills labeled L=(20/25/30) represents 20/25/30mm vertical depth as measured from the top of the sleeve in the surgical guide to the bottom of the osteotomy when used with the narrow or wide DGS. This number is indicated on the drilling report. The drills are used in sequence until the desired osteotomy diameter is obtained as indicated by the drilling protocol (3.25, 3.75, 4.2, 5.0).

Type / Size (mm) of Drill	Short Pilot Drill	Fully Guided Drills				
	2.0mm	2.0/2.4mm	3.25mm	3.75mm	4.2mm	5.0mm
Speed RPM	1200	700-900	400-850			

Overview

IMAGE DESCRIPTION



Paltop implant drivers included in the kit are available for both sleeve diameters (narrow & wide).

The kit includes three lengths of implant drivers – short, medium and long. The short drivers have an offset range of 8-10, medium drivers have an offset range of 8-14 and long drivers 8-18. For conical & narrow platforms, use the implant drivers found in the row of blue grommets. For standard platform, use the drivers found in the row of gray grommets.

IMAGE DESCRIPTION



The contra angle adapter fits into the contra angle and connects to the implant driver.



The bending beam torque ratchet provides the precision required for torquing Paltop implants and components.

- Recommended torquing of the implant is 30-50 N-cm.
- The bending beam connects directly to the implant driver and may be used in place of the contra angle with the driver adapter.

IMAGE DESCRIPTION



The included screwdriver can be used with all Paltop screws.



Lateral fixation pins may be used to provide additional guide stability when required.



The lateral fixation pin drill is used to prepare the osteotomy for the fixation pin. This drill travels through the fixation pin sleeve and has a physical stop at the brown banded drill stop.

IMAGE DESCRIPTION



A countersink may be used when there is dense cortical bone. The countersinks are labeled blue (3.25), green (3.75) red (4.2), yellow (5.0) to correspond to the final implant diameter. The countersinks should be used without the DGS. The blue (3.25) and green (3.75) countersinks are guided directly by the narrow sleeve in the surgical guide. The red (4.2) and yellow (5.0) countersinks are guided by the wide sleeve in the surgical guide. The countersink has numbers from 4-16, which refer to the offset number. Although the numbers are not visible while the countersink is spinning, the depth can be controlled by counting the appropriate number of broad black bands to the offset number.

**Not included in the kit; may be purchased separately.*

1. Planning the Surgical Guide

During the design phase of the treatment plan, the appropriate sleeve (wide/narrow) should be selected by the digital planner from the sleeve library.

Please refer to the Keystone Dental Group website for software partner updates. (www.keystonedental.com)

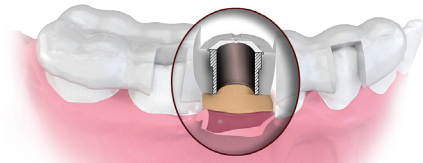


2. Seating the Surgical Guide

Seat the guide in the patient's mouth. Do so relatively passively without exerting too much force. Make sure the guide seats securely in the patient's mouth.



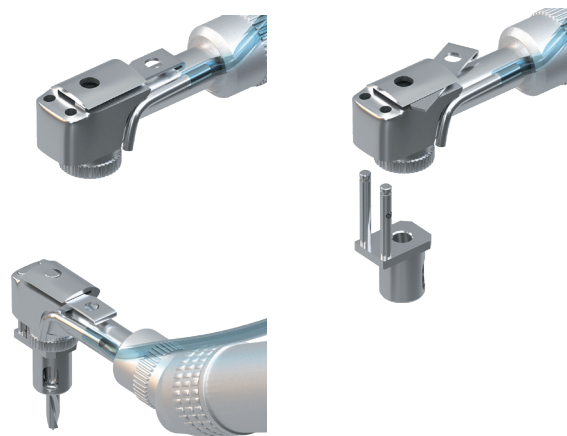
To ensure accurate seating of the guide, look through the inspection windows on the guide to make sure there is intimate contact between the windows and the teeth and/or soft tissue.



3. Attaching the DGS

The appropriate Digital Guide Sleeve (DGS) is selected and inserted into the handpiece.

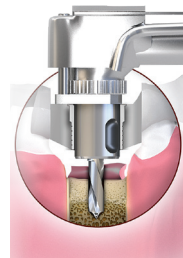
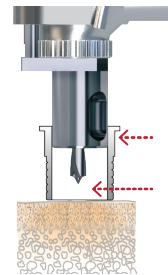
Once the DGS and appropriate drill are fully inserted into the handpiece, the latch is closed to secure and lock them both.



4a. Creating the Initial Osteotomy

After elevating a tissue flap, the osteotomy is initiated by placing the DGS with the short pilot drill into the guide sleeve.

The pilot osteotomy is complete when the DGS fully engages the sleeve. Use a drill speed of 1,200rpm.

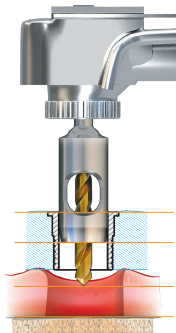


4b. Optional - Flapless Approach

Use the tissue punch to create the initial osteotomy

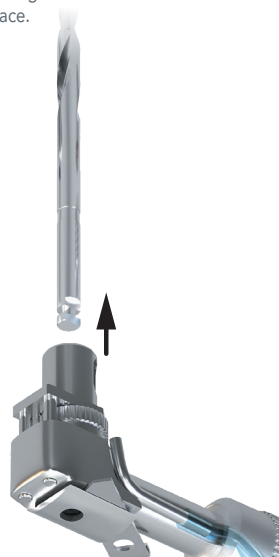


In cases where a flapless surgery technique is desired, the wide and narrow tissue punches can be used in the appropriate guide sleeve instead of the DGS and short pilot drill.



5. Short Pilot Drill Removal

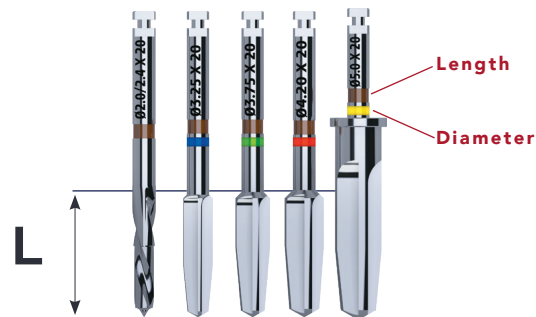
The short pilot drill is removed by opening the latch, while the DGS remains in place.



6. Drilling Protocol Review

After the short pilot osteotomy is completed, refer to the drilling report indicating the required length and diameter of drills to be used for the planned osteotomy. Drill diameters are used sequentially until the appropriate implant diameter is achieved.

The numbers on the drills indicate implant diameter and not osteotomy diameter.



7. The Final Depth Osteotomy

The initial guidance of the Ø2.0/2.4mm drill (in accordance with the length stipulated by the drilling protocol) is achieved by ensuring that the apex of the drill engages the pilot osteotomy and the DGS engages the guide sleeve.

Drilling is continued until the DGS is flush with the guide sleeve to achieve final depth. The drill can be introduced into the guide sleeves at an angle where interarch space is limited, but must not be activated until the DGS engages the sleeve.

Please Note: When 25mm is required begin with 20mm to ensure the DGS is engaged in the guide sleeve

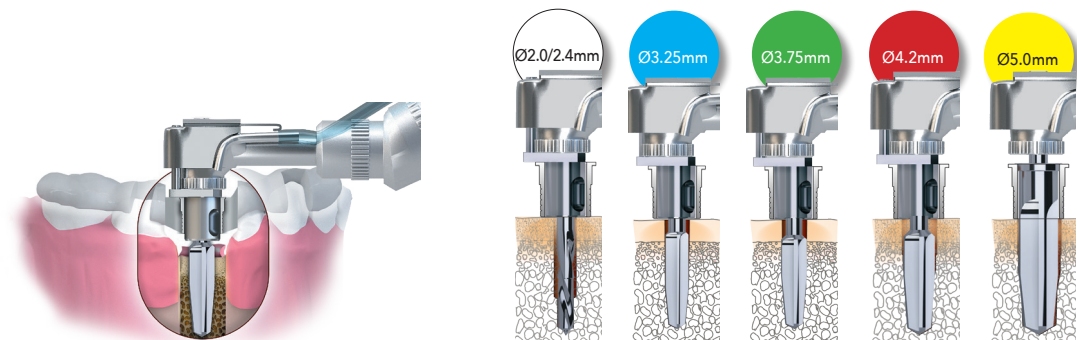


8. Expanding the Osteotomy to the Implant Diameter

Remove the pilot drill from the contra angle and insert the next diameter drill through the DGS into the contra angle. Drilling to depth is completed when the DGS bottoms out on the sleeve. All subsequent drills are used through the DGS until reaching the desired implant diameter. Each of these drills is inserted into the contra angle through the DGS.

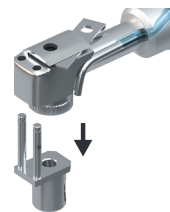
If the shaped drills are not advancing smoothly, then check to make sure that bone is not clogging the drill flutes. In hard bone, a shorter drill may be chosen to make a smaller jump in osteotomy length and then advance to the final indicated drill length.

The 5mm diameter drill is used directly through the guide sleeve (without the DGS).



9. Countersinking - Optional

Remove the DGS from the contra angle.

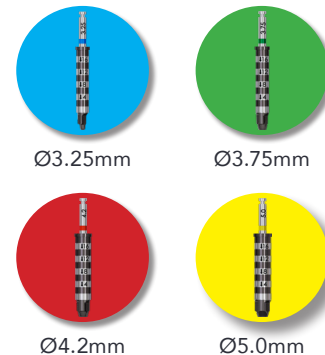
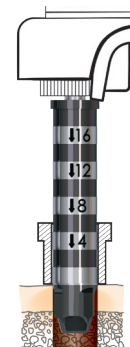


The decision to use the countersink should be made by the doctor after completing the osteotomy. The drilling report has an offset number. Drilling to this number will make a full countersink.

Optional – only required in very dense cortical bone

Choose the appropriate diameter countersink: 3.25 (blue), 3.75 (green), 4.2 (red), 5.0 (yellow) and place it into the contra angle (no DGS is used). The guidance for the countersink comes from the sleeve in the guide.

The 3.25 and 3.75 countersinks are used directly in a narrow guide sleeve, and the 4.2 and 5.0 countersinks are used directly in a wide guide sleeve.



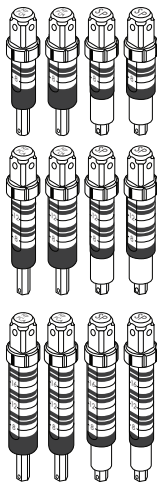
-The countersinks are not included in the kit; they may be purchased separately.

-It is possible to relieve the surgical cortical bone by using the next diameter drill to partial depth.

10. Choosing the Implant Driver

The drilling report shows you the required offset number for each implant position.

Implant information	
Implant position (FDI)	14
Manufacturer	Paltop
Type	Paltop Dynamic implant 3.75 x 13.0 mm
Order number	21-70003
Length, mm	13
Diameter (Ø), mm	3.75
Color	Green
Sleeve information	
Name	Paltop Narrow Sleeve
Type	Fully guided
Order number	30-70414
Offset, mm	12
Color	Purple
Drill information	
Length, (mm)	25



This number indicates the implant insertion depth and the countersink depth.

Two diameters of implant drivers correspond to the narrow and wide sleeves.

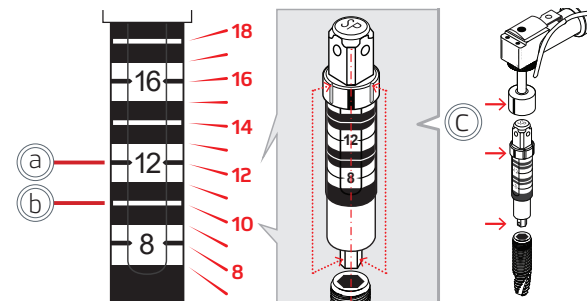
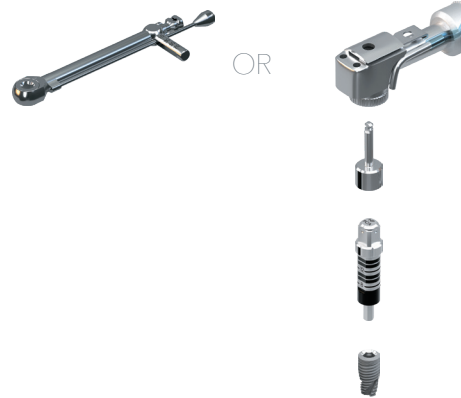
There are two connections (NP/Conical & SP) corresponding to the implant connections and three lengths of implant drivers: (short, medium and long).

For conical and narrow platforms, use the implant drivers found in the row of blue grommets.

For standard platform, use the drivers found in the row of gray grommets. Choose the shortest length implant driver that has the indicated offset number on the drilling protocol.

11. Implant Insertion

Insert the contra angle adapter into the contra angle.
Insert the implant driver into the adapter.
Remove the implant from packaging using the implant driver.
Recommended insertion torque is 30-50 N-cm.

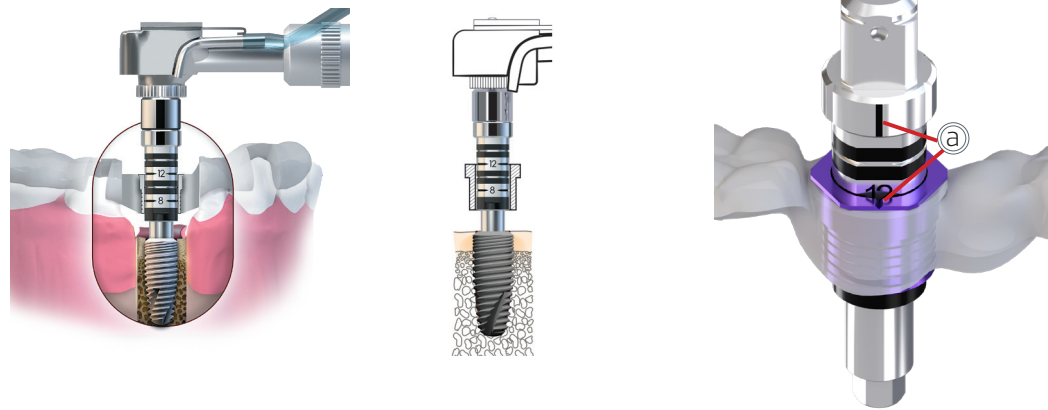


The height of the offset number (shown in the drilling report) on the driver is determined either by the line in the middle of the number (see 'a') or by the line in between the laser marking (see 'b').
The black line on the contra angle adapter should line up with the flat side of the implant driver. This will align the flat side of the implant driver with the flat side of the hex of the implant (see 'c').

12. Implant Delivery with the Implant Driver

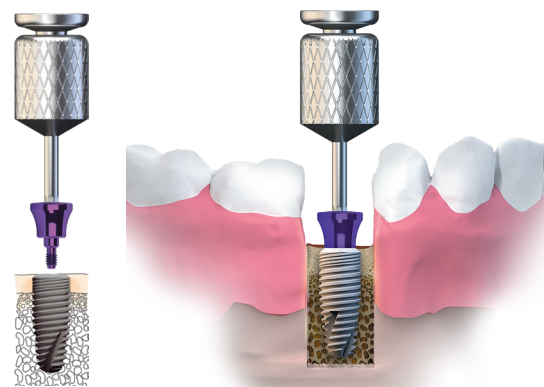
Deliver the implant with the implant driver through the guide sleeve (contra angle driven or ratchet driven) to the appropriate offset as per the drilling report. The implant motor is set to 15 rpm and 30 N-cm torque. If it torques out and the implant isn't completely seated, raise the torque gradually to 50 N-cm.

The correct implant orientation is achieved by aligning the flat side on the implant driver with the flat of the guide sleeve, and the black line on the ratchet adapter is in line with the groove on the guide (see 'a').



13. Seating of the Prosthetic Component

Once fully seated and in correct position, a cover screw, healing abutment or temporary abutment can be seated utilizing the Ø1.25mm screwdriver.



Prosthetic Components	Torque Value
Healing Cap/Multi-Unit Healing Cap Screw/Single-Unit Healing Cap	15
PEEK Abutment (used with the SP/WP, PCA or NP Abutment Screw)	10-15
Multi-Unit Abutment	30-35
Single-Unit Abutment	30-35
Equator Abutment	30-35
Ball Abutment	30-35
Multi-Unit Prosthetic Screw (80-70005 - used to attach MU/SU interface coping and MU/SU Cylinders to MU/SU)	20-25
Multi-Unit Abutment Screw for Angulated SP (80-70018 - used to attach Angulated MU/SU Abutment to the implant)	30-35
Multi-Unit Abutment Screw for Angulated NP (80-70017 - used to attach Angulated MU/SU Abutment to the implant)	25-30
Cover Screw	15
SP Abutment Screw (for Titanium/Cobalt chrome Abutment/Temporary Abutment)	30-35
NP Abutment Screw (for Titanium/Cobalt chrome Abutment/Temporary Abutment)	25-30
WP Abutment Screw (for Titanium/Cobalt chrome Abutment/Temporary Abutment)	30-35
PCA Abutment Screw (for Titanium/Cobalt chrome Abutment/Temporary Abutment)	25
Titanium Temporary Abutment, Immediate	25-30
Impression Coping Screw	15

