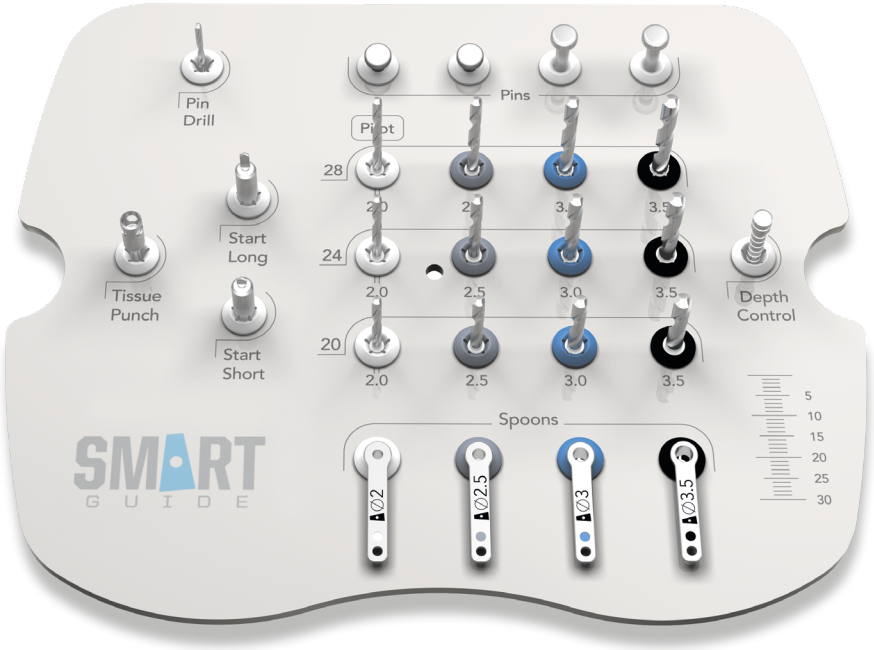
SMART KIT
SURGICAL KIT FOR DENTAL IMPLANTATION
USER'S MANUAL



SMART
GUIDE

CONTENTS

INTRODUCTION

INTENDED USE:

The smarT Kit surgical kit for dental implantation(henceforth: SMART Kit) is intended to be usedaccording to the surgical protocol generated from the surgical plan prepared in SMART Guidesurgicalplanningsoftwarefordentalimplantation(henceforth:SMARTGuideplanning software). SMART Kit is intended to be used with SMART Guide surgical template for dental implantation (henceforth: SMART Guide surgical template) for the preparation of the bone for freehand implant insertion.

INDICATIONS:

SMART Guide should be used only by professionals legally authorized to perform dental implant surgery in patients with complete or partial edentulousness, in combination with a SMART Guide surgical template manufactured according to plans prepared in SMART Guide planning software.

CONTRAINDICATIONS:

The contraindications of the use of SMART Kit are the same as the contraindications of dental implant surgery in general. No further or specific contraindications are known.

WARNING:

The user must adhere to the instructions of this manual and the surgical protocol. The manufacturer is not liable for any damage or injury that stems from failure to adhere to the instructions of this manual and the surgical protocol.

CONNECTION:

The mounts of the drills have standardized RA-type connections.

MANUFACTURER INFORMATION

SMART KIT IS MANUFACTURED BY:

dicomLaB Dental, Ltd.
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MARKINGS ON THE SURGICAL KIT

CE marked products of dicomLAB Dental,Ltd. meet the requirements of the directive 93/42/EEC on medical devices.

Read user's manual for instructions.

LOT number, individual identifier.

Implantation device

REF Model No.

Manufacturer

Fragile

NON STERILE Non-sterile

134 °C Autoclavable at 134 °C / 273 °F

5°C 40°C Store between 5°C/41°F and 40°C/104°F

BEFORE THE SURGERY

THE SMART GUIDE SURGICAL TEMPLATE PACKAGE CONTAINS:

- Instructions for use
- Surgical protocol
- SMART Guide surgical template

CHECKLIST:

- Make sure that the packaging and the template are intact.
- Make sure that the individual identifier on the template matches those on the surgical protocol and the surgical plan.
- Make sure that the metal guiding sleeves are intact and allow access.

STERILIZING THE SURGICAL TEMPLATE:

The surgical guide is not sterile, please sterilize according to sterilization instructions before use.

Attention! Use of a non-sterile device may lead to tissue infection or infectious disease.

Caution! SMART Guide surgical guide is a disposable product, it is strictly forbidden to reuse. The surgical guide was personalized based on the CBCT scan of the patient. Reusing the guide can lead to loss of mechanical, chemical and/or biological features and can cause cross-contamination.

NextDentTM 3D-printing material should be cleaned with non chemical products. If disinfecting before intended use is required, an ethanol solution can be used. NextDent™ SG can be sterilized by making use of an autoclave or using gamma-ray sterilisation. Do not use a dishwasher or thermal disinfector. NextDent recommends the following method of sterilization:

· Place the surgical guide in a standard sterilization pouch
· Apply sterilization by placing the pouch containing the guide in an autoclave for 15 minutes at 121°C (249,8 °F) or 3 minutes at 134°C (280,4 °C). Make sure no mechanical forces are applied to the guide during sterilization.
· Let the guide cool down to room temperature before using the guide. Make sure no mechanical forces are applied to the guide during cooling down.
· The heat changes the color of material which does not affect its quality.
· Please do not deviate from the recommended sterilization, it may cause deformation of the guide.

FIT CHECK:

Before use, check that the template properly fits on the patient's dentition!
This may be done in the following ways:

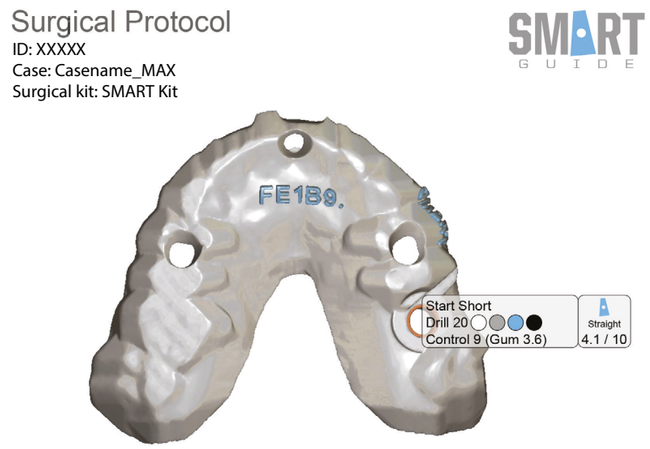
- Under pressure, the gingiva turns white. In cases of complete edentulousness, this is visible through the material of the template.
- In partial edentulousness, use the fit-check windows on the template.

SURGICAL PROTOCOL:

The sugical protocol helps you and your assistance to prepare for the surgery, and it contains detailed instructions for the preparation of the implant's bony bed. The surgical protocol is automatically ge ne rate d from your surgical plan and is also uploaded to SMART Cloud so that it is accessible during the surgery also in a digital format. The use of the surgical protocol ensures that the surgery is carried out in a simple and safe manner.

THE SURGICAL PROTOCOL SHOWS:

- the name and identifier of the patient (case)
- the name of the treating physician
- an image of the surgical template
- instructions on what tools of the SMART Kit should be used and in what sequence
- type and dimensions of the planned implants
- summary of the surgical plan in a table format



Implant information

ID: XXXXX
Doctor: Dr. XY

Implant	Length	Diam.	Piece
Straight	10.0	4.1	1

BEFORE THE SURGERY

STORAGE:

• The SMART Guide surgical template should be shipped and stored only in its original packaging.
• Store the template in a dry and dark place and do not expose it to direct sunlight.

Note: If necessary, material may be removed from the material of the body of the template, as long as this does not affect the integrity and fit of the template.

NEVER modify the metal guiding sleeves in any way.

QUALITY:

All SMART Guide surgical templates are manufactured solely in the manufacturing center of dicomLAB Dental. Both digital planning and manufacturing are subject to strict standards and the procedures are continuously audited.

• SMART Guide surgical templates are shipped in non-sterile packaging.
• Exposure to ultraviolet light or fluids may lead to changes in the material characteristics of the SMART Guide surgical template.

WATER COOLING:

The drilling pieces of SMART Kit are intended to be used with external water cooling. Ample application of cooled water contributes to a longer lifespan of the pieces and a safer, more predictable treatment.

ROTATIONAL SPEED:

The manufacturer recommends that the drill pieces of SMART KIT be used at no higher speeds than 800 rPm.

COMPATIBLE IMPLANTS:

SMART Guide, used in partial sequence, supports most implant types and sizes. The compatibility range spans 2.0 mm to 6.0 mm in diameter and 6.0 mm to 16.0 mm in length.

Both root-form and cylindrical implants are supported.

SMART KIT allows the preparation of a bony socket up to 3.5 mm in diameter, with straight drill pieces. It is recommended that the drilling be finished with the last drill piece (and other tools) of the given implant system before inserting the implant.

THE LIFESPAN OF THE DRILL PIECES- RECOMMENDATION:

According to our research results,* drill pieces of the SMART Kit may be used safely up to 50 sterilizations. Please make sure before each surgery that your pieces have not reached this limit.

*Barrak I, joob-Fancsaly a, Braunitzer G, Varga E, jr., Boa K, Piffko j. Intraosseous heat Generation During Osteotomy Performed Freehand and Through Template With an Integrated metal Guide sleeve: an In Vitro study. Implant dentistry. 2018;27(3):342-50.

SURGICAL TOOLS

PRODUCT CODE	NAME	DIAMETER (MM)	CUTTING DEPTH(MM)	MAX. U/MIN	MATERIAL
F1-15-20-01	PIN DRILL	1.5	20	800	WNR: 1.4197 Ø5,0X3000 BAR STOCK

PIN DRILL

A drill piece to prepare the bony socket for the fixation pin. A vertical stop prevents drilling deeper than intended.The pin drill is applied through a special guiding sleeve built into the SMART Guide surgical template.

INDICATIONS OF USE:
Use this piece only if your surgical plan contained fixation pins for the stabilization of the SMART Guide surgical template.

WARNING:
Do not use this piece if your surgical plan does not contain fixation pins.

PRODUCT CODE	NAME	DIAMETER (MM)	CUTTING DEPTH(MM)	MATERIAL
R1-15-26-01	FIXATION PIN 26 MM	1.5	20	WNR: 3.7035 BAR STOCK Ø6MM
R1-15-35-01	FIXATION PIN 35 MM	1.5	20	WNR: 3.7035 BAR STOCK Ø6MM

FIXATION PINS

Short/long

Pins to fasten and stabilize the SMART Guide surgical template. The short variant allows application in the molar region and other regions of limited accessibility.

INDICATIONS OF USE:
Fasten and stabilize the SMART Guide surgical template for the duration of the surgery with these pins, if they are part of the surgical plan.

WARNING:
Do not use this piece if your surgical plan does not contain fixation pins.

SURGICAL TOOLS

PRODUCT CODE	NAME	DIAMETER (MM)	CUTTING DEPTH(MM)	MAX. U/MIN	MATERIAL
K1-45-24-01	TISSUE PUNCH	3.8	10	15-25	WNR: 1.4197 Ø5,0X3000 BAR STOCK

TISSUE PUNCH

The tissue punch is used for access preparation when a flapless implant surgery is performed to remove a cylindrical piece of gingiva, thus providing access to the underlying bone. The tissue punch is used through the guiding sleeves of the SMART Guide surgical template.

Being technically a soft tissue trephine, the tissue punch is unable to cut into the bone, and thus overpenetration is impossible .

INDICATIONS OF USE:
Transgingival access preparation.

WARNING:
Do not use the tissue punch for a flap surgery.

PRODUCT CODE	NAME	DIAMETER (MM)	CUTTING DEPTH(MM)	MAX. U/MIN	MATERIAL
F1-15-30-01	START SHORT	4.5	3.0	800	WNR: 1.4197 Ø5,0X3000 BAR STOCK
F1-15-60-01	START LONG	4.5	6.0	800	WNR: 1.4197 Ø5,0X3000 BAR STOCK

START DRILLS

Short/long

Used to prepare an initial guiding pit into the cortical bone. The start drills are used through the guiding sleeves of the SMART Guide surgical template.

The shape of these drills exclude the possibility of overpenetration.

INDICATIONS OF USE:
Preparation of a cortical guiding pit before the application of the first surgical drill.

SURGICAL TOOLS

PRODUCT CODE	NAME	INNER DIAMETER (MM)	COLOR CODE	MATERIAL
P1-20-45-01	NARROWING SLEEVE 2.0 MM	2.0		WNR: 3.7035 LV: 6MM
P1-25-45-01	NARROWING SLEEVE 2.5 MM	2.5		WNR: 3.7035 LV: 6MM
P1-30-45-01	NARROWING SLEEVE 3.0 MM	3.0		WNR: 3.7035 LV: 6MM
P1-35-45-01	NARROWING SLEEVE 3.5 MM	3.5		WNR: 3.7035 LV: 6MM

NARROWING SLEEVES

These adaptor sleeves fit into the default sleeve of the SMART Guide surgical template and serve to guide surgical drills that are narrower than the diameter of the default sleeve.

INDICATIONS OF USE:
Drilling through the SMART Guide surgical template. Use according to the surgical protocol, with a drill of the same color code.

WARNING:
Do not use these adaptors with non color-coded drills of the kit. Before use, make sure that the color code of the drill and the narrowing sleeve match.

PRODUCT CODE	NAME	DIAMETER (MM)	CUTTING DEPTH (MM)	MAX. U/MIN	COLOR CODE	MATERIAL
F1-20-20-01	SURGICAL DRILL	2.0	20	800		WNR:1.4197 Ø5,0X3000 BAR STOCK
F1-25-20-01	SURGICAL DRILL	2.5	20	800		WNR:1.4197 Ø5,0X3000 BAR STOCK
F1-30-20-01	SURGICAL DRILL	3.0	20	800		WNR:1.4197 Ø5,0X3000 BAR STOCK
F1-35-20-01	SURGICAL DRILL	3.5	20	800		WNR:1.4197 Ø5,0X3000 BAR STOCK
F1-20-24-01	SURGICAL DRILL	2.0	24	800		WNR:1.4197 Ø5,0X3000 BAR STOCK
F1-25-24-01	SURGICAL DRILL	2.5	24	800		WNR:1.4197 Ø5,0X3000 BAR STOCK
F1-30-24-01	SURGICAL DRILL	3.0	24	800		WNR:1.4197 Ø5,0X3000 BAR STOCK
F1-35-24-01	SURGICAL DRILL	3.5	24	800		WNR:1.4197 Ø5,0X3000 BAR STOCK
F1-20-28-01	SURGICAL DRILL	2.0	28	800		WNR:1.4197 Ø5,0X3000 BAR STOCK
F1-25-28-01	SURGICAL DRILL	2.5	28	800		WNR:1.4197 Ø5,0X3000 BAR STOCK
F1-30-28-01	SURGICAL DRILL	3.0	28	800		WNR:1.4197 Ø5,0X3000 BAR STOCK
F1-35-28-01	SURGICAL DRILL	3.5	28	800		WNR:1.4197 Ø5,0X3000 BAR STOCK

SURGICAL DRILLS

Color-coded bone drills for the preparation of the bony socket for the implant. They are applied through the proper narrowing sleeves inserted into the default sleeve of the SMART Guide surgical template. Surgical drills have a vertical stop to prevent overpenetration.

INDICATIONS OF USE:
Preparation of the bony socket for the implant through the SMART Guide surgical template.

SURGICAL TOOLS

PRODUCT CODE	NAME	DIAMETER (MM)	LENGTH (MM)	MATERIAL
ME1-30-30-01	DEPTH CONTROL PEG	3.0 and 4.0	30	WNR: 3.7035 Ø5MM BAR STOCK

DEPTH CONTROL PEG

A mesauring tool to check the vertical position of the inserted implant. The engraved markings are 2mm apart. The reference of measurement is value of the surgical protocol.

INDICATIONS OF USE:
Control the vertical position of the inserted implant by applying the peg through the sleeve of the SMART Guide surgical template .

CLEANING, STERILIZATION, STORAGE

THE SURGICAL KIT IS NOT STERILE WHEN DELIVERED. PLEASE STERILIZE BEFORE USE ACCORDING TO THE INSTRUCTIONS.

WARNING: The use of a non-sterile instrument may cause infection and disease.

MANUAL DEBRIDEMENT AND CLEANSING

1. Remove debris by ample rinsing in lukewarm water (<40 °C / 104 ° F). Keep the instruments damp until the next step.

2. Immerse the instrument in a cleansing solution made with lukewarm tap water and an enzymatic agent (pH 7 to 10). Never ecxeed 40 ° C / 104 ° F. Regarding dilution and the duration of immersion, follow the instructions of the enzymatic agent's manufacturer.

3. Carefully rub the surface of the instruments with a soft bristle brush under cold running water until all visible debris and contamination is removed. Pay special attention to difficult-to-reach areas.

4. Rinse amply with cleaned or sterile water to remove the cleansing solution.

5. Check if any contamination has remained on the surface of the instrument, and repeat steps 1 to 4 if necessary.

6. Filtered compressed air may be used for drying if necessary.

Never use abrasive agents or agressive solvents when cleaning the instruments of the SMART KIT surgical kits, as these may damage the labeling.

Do not soak the plastic casing and inner plate of the SMART KIT surgical kits in enzymatic solution, clean it with a disinfectant (Soak in Gigasept 3% solution (3ml/L) for a maximum of 15 minutes).

STERILIZATION

7. Put the surgical kit with the instruments into a sterlization puch, and put the pouch into the autoclave. The recommended sterilization time, temperature and pressure are: 3 minutes (minimally), 134°C (270 –273.2 °F), 206 kPa (2.1 bar). Drying time: 20 minutes.

INSPECTION AND MAINTENANCE

The surgical instruments of SMART KIT are intended to be used multiple times. Replacement is necessary if reduced efficiency is experienced. Worn or damaged drills must be replaced.

1. Inspect every instrument (piece) before sterilization. Concentrate on the following questions:

- Is there visible contamination on the instrument?
- Are the cutting edges worn?
- Is the instrument deformed?
- Is the instrument broken?
- Is there visible corrosion on the surface of the instrument?

Pay special attention to recessed parts, such as grooves. Perform fit check where necessary.

Note:
- Regarding all instuments in both the SMART KIT, dicomLAB Dental provides support up to 50 surgeries (50 ordered guides), which includes the maintenance, repair and replacement of instruments free of charge.

DISCLAIMER: dicomLAB Dental does not take responsibility if the instrument is lost, destroyed or damaged due to improper use. In case of debate, the user has to prove proper use.

- Individual replacement of instruments is possible according to the price list in effect (see General Terms and Conditions at https://www.dicomlab.com/documents/documents.php)

CLEANING, STERILIZATION, STORAGE

STERILIZATION PACKAGING

The single-use sterilization packaging must be steam permeable (heat resistance at least 138 °C / 280 °F).

STORAGE

Following sterilization, keep the instruments in a dry, dust-free and dark place in their packaging. Store between 5°C/41°F and 40°C/104°F.

NOTE:
- dicomLAB Dental does not recommend any specific brand of cleansing agent for the cleansing of its instruments. Regardless of what agent is chosen:
- Keep the instructions of the manufacturer of the cleansing agent at all times.
- Before using any cleaning agent, the user must make sure that the chosen agent is suitable for the cleaning of medical devices.

WASTE MANAGEMENT

All instruments covered in this manual qualify as hazardous medical waste. Regarding these instruments, it is the sole and full responsibility of the user to comply with the effective hazardous medical waste management regulations of the geographical area where the instruments are used.

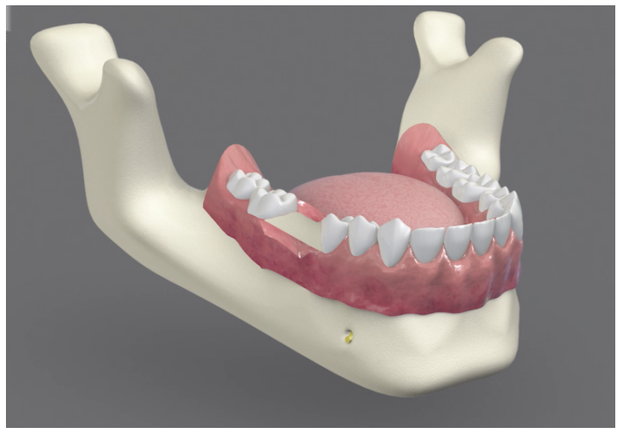
STEPS OF THE SURGERY

1. Soft tissue preparation/access preparation
2. Positioning and fastening of the surgical template
3. Preparation of the implant bed
4. Finalizing the preparation
5. Insertion of the implant
6. Checking the vertical position
7. Wound closure

THE SURGERY

1/A RAISING A FLAP

Fig.1:In partially edentulous cases, raise the flap before placing the surgical template. As a result, the surface of the bone becomes visible.



In complete edentulousness, place the surgical template, mark the entry points, remove the template, and make short incisions at the implant positions.

THE SURGERY

1/B TRANSGINGIVAL ACCESS

Fig.1: As a first step, place the surgical guide on the patient's dentition without fastening.

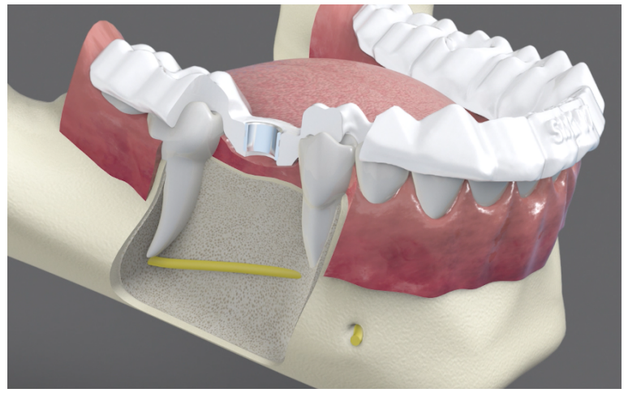


Fig. 2: Insert the tissue punch into the default sleeve of the surgical template. The tissue punch should not rotate while being inserted. Once inserted, start the hand instrument so that the tissue punch is rotating. Push the rotating tissue punch downwards until contacting the bone.

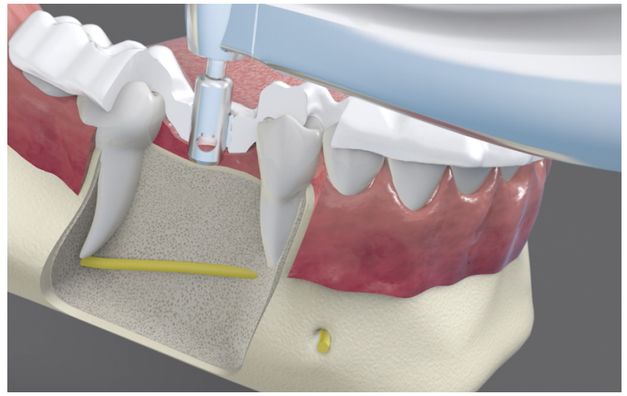
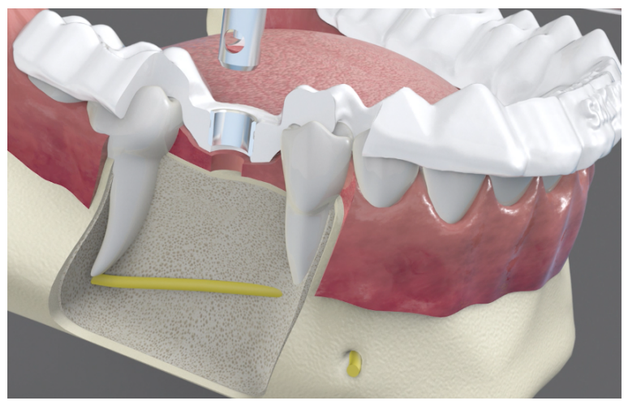


Fig. 3:Remove the tissue punch and check if the soft tissue has been removed properly. If necessary, the tissue punch may be applied once again without the template.



2 PLACE AND FASTEN THE SURGICAL GUIDE

1. Place the SMART Guide surgical template and check if it fits properly.

2. Keep the template in its place manually, applying bilateral pressure or insert fixation pins in the following manner:

3. Insert the pin drill into the pin drill sleeve. The pin drill should not be rotating while being inserted.

4. Push the rotating pin drill into the bone until it is stopped by the sleeve.

5. Remove the pin drill while still rotating.

6. Insert a fixation pin through the sleeve.

3 PREPARATION OF THE IMPLANT BED

1.Insert the start drill (long or short, as written in the protocol) into the default sleeve of the template. The start drill should not be rotating.

2. Push the rotating start drill until, its working end is entirely in the cortical bone.

3.Remove the start drill while it is still rotating.

4.Choose the proper narrowing sleeve and insert it into the default sleeve of the template. Choose the corresponding surgical drill and insert it through the narrowing sleeve. The drill should not be rotating.

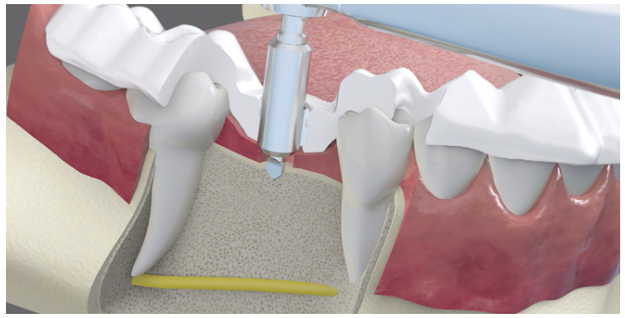
5. Start drilling with the rotating drill. Apply a pumping movement. Drill until the vertical stop prevents further drilling.

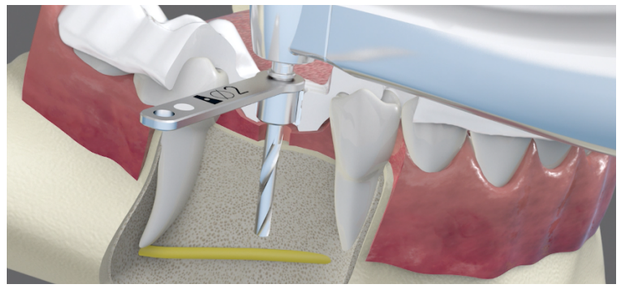
NOTE: you may need to remove the drill during the process to remove debris from the surface of the drill.

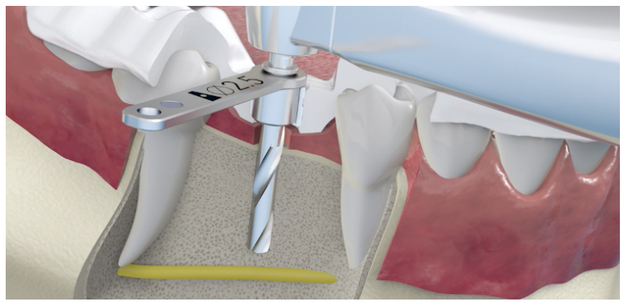
6. Remove the drill while still rotating.

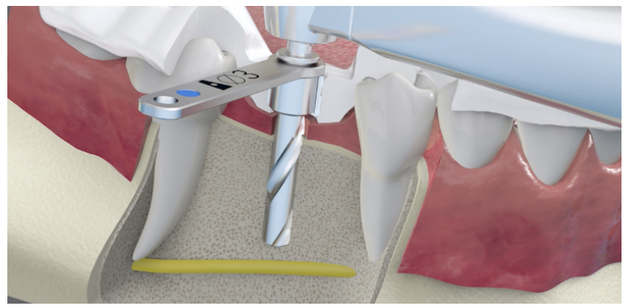
7.Repeat from 4. for all drill diameters that appear in the protocol.

Warning: always perform all the steps of the surgical protocol! There are no optional steps.









4 FINALIZING THE PREPARATION

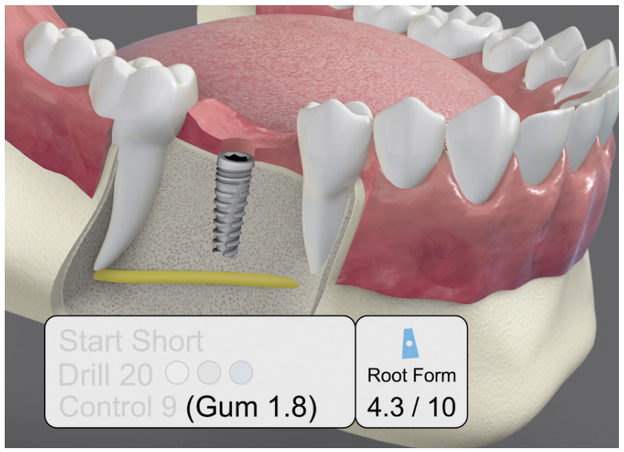
The tools of the SMART Kit allow implant bed preparation for the following range of implant dimensions: 2.0 mm to 6.0 mm in diameter and 6.0 mm to 16.0 mm in length. Modifications beyond this range are possible without the SMART Guide surgical template.It may be necessary to use the tools and protocol of the chosen implant system to finalize the shape and dimensions of the implant bed.

5 INSERTION OF THE IMPLANT

Insert the implant without the surgical template (freehand insertion).

The “Gum” value of the surgical protocol helps the determination of the appropriate depth.

This value is the distance between the platform of the implant and the external surface of the gingiva in millimeters.



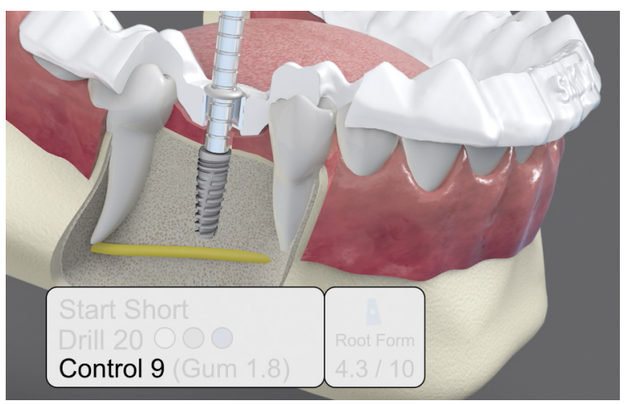
6 CHECKING THE VERTICAL POSITION

The “Gum” and “Control” values of the protocol help you to achieve the planned vertical position (depth).

“Control” is the distance between the platform of the implant and the bottom rim of the default sleeve in millimeters.

After having inserted an implant, always check its vertical position.

1.Place the template back in the patient’s mouth.



2. Check the “Control”value in the protocol.

3. Insert the depth control peg through the default sleeve so that its end rests on the implant’s platform.

4. Check if the actual depth of the implant matches the “Control” value shown in the protocol. The narrower end of the peg can be used for narrower implants and the wider end for wider implants.

7 WOUND CLOSURE

Close the wound as appropriate in the given situation.

The surgical template may be useful for the exact location of the implant or implants when it comes to suture removal .

MAN-SMG-03-EN
Updated: 02/21/2020