Validated workflow with Formlabs Form 3B+ 3D printers

Simplant®

Manual

Simplant® Guide File

Dentsply Sirona

The 3D printed surgical guide has been validated for average designs of the Simplant Guide File and created in approved Simplant 3D planning and design software. If the customer chooses to design a 3D printed surgical guide with other than Simplant software, Dentsply Sirona cannot give any guarantee, and does not assume any liability for the performance of the surgical guide. If the customer chooses to use Simplant Guide Sleeves in a surgical guide printed from a different design than the Simplant Guide File, Dentsply Sirona cannot give any guarantee, and does not assume any liability for the performance of the surgical guide.

All products may not be regulatory cleared/released/licensed in all markets. Please contact the local Dentsply Sirona sales office for current product assortment and availability. Product illustrations are not to scale.

Simplant®

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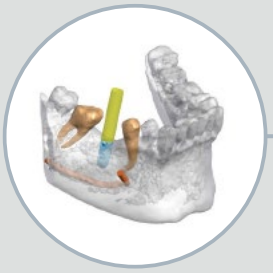
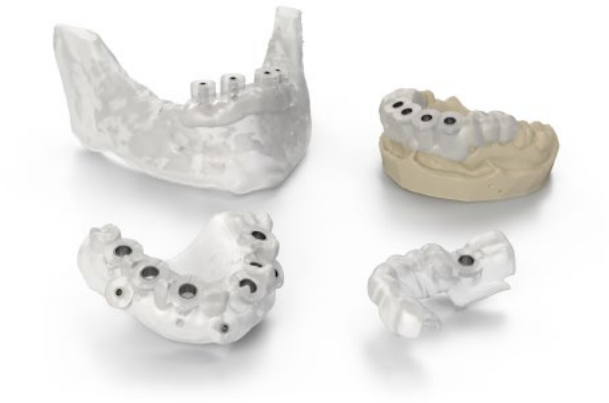
1. Product information



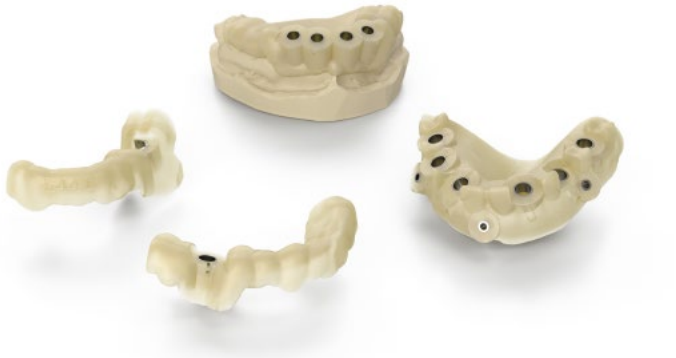
Step 1: Plan
Scan patient anatomy and create or approve the implant plan considering surgical and restorative aspects.

1.1 3D printed surgical guide

Using Simplant Pro software or Simplant Planning Service, you can order Simplant Guides directly from Dentsply Sirona or for desktop 3D printing in your own clinic. Whatever your implant workflow preferences, you benefit from the same expert Simplant Guide design.



Simplant Guide manufactured at Dentsply Sirona:
Tooth-, mucosa- or bone-supported



Surgical guide manufactured in your clinic:
Tooth- or mucosa-supported

Depending on the solution, the surgical guide is always used together with other components. Make sure to check the applicable instruction for these other components.

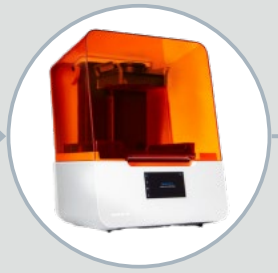
Available solutions for the Simplant Guide File:

SAFE solution
- Guided drilling and guided implant placement
- Brand specific guided surgery kit needed – Immediate temporization possible

Universal solution
- Guided drilling only
- Drill depth control only when used in combination with Simplant LongStop drills
- Simplant Universal Drill Key set needed

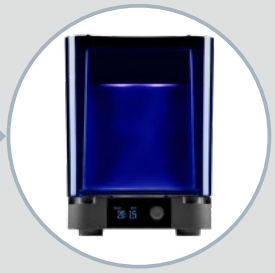
Pilot solution
- Guided drilling of the initial pilot drill only
- Drill depth control only when used in combination with Simplant LongStop drills

Step 2: Design
Receive the Simplant Guide File and import into the preparation software for printing.



Step 3: Print & Wash
Send the prepared Simplant Guide File to the Formlabs Form 3B+ printer.

Step 4: Add Sleeves
Remove the supports and insert and glue the Simplant Guide Sleeves into the printed guide.



Step 5: Cure
Post-cure the guide with the Guide Sleeves glued in. Then finalize the surgical guide.

1.2 Simplant® Guide File

Simplant Guide File is a digital representation of the Simplant Guide design. It enables specialist dentists or dental technicians to manufacture a surgical guide for dental implants. The manufacturing process requires gluing of the applicable guide sleeve(s) in the surgical guide prior to use.

A distinction is made between two versions of the Simplant Guide File:

- **The Design Review version** is the Simplant Guide File that is designed by the specialist dentist or dental technician with the FastTrack design option in Simplant Pro software. The FastTrack design is submitted via www.orderdigitalsolutions.com for central design review at Dentsply Sirona operations. This version of the Simplant Guide File is returned faster.

- **The Full Design version** is the Simplant Guide File that is designed centrally at Dentsply Sirona operations based on your planning in Simplant Pro software. Alternatively, this version of the Simplant Guide File can be designed centrally at Dentsply Sirona operations as part of a Simplant Planning Service.

1.3 Simplant® Guide Sleeves

The Simplant Guide Sleeves are made of titanium alloy and are available in different models.
The Simplant Guide Sleeves are indicated for single use and delivered non-sterile in sets of 10.

The responsibility for sterility of the surgical guide (including its guide sleeves) lies with the end-user. For instructions, see the Instruction For Use.

1.3.1 Closed Guide Sleeves for the EV implant family

	Description	Used for...
Guide Sleeve Type & Ø Inner	C/Guide-Sleeve Ø3.4 XND PrimeTaper (10 pieces)	Closed sleeve XND for DS PrimeTaper Implant System D3.0 implants
Order No.	6801 7305	
Guide Sleeve Type & Ø Inner	C/Guide-Sleeve Ø4.5 ND OmniTaper (10 pieces)	Closed sleeve ND for DS OmniTaper Implant System D3.0, D3.4 and D3.8 implants
Order No.	6801 7222	
Guide Sleeve Type & Ø Inner	C/Guide-Sleeve Ø4.6 ND PrimeTaper/AstraTech Implant EV (10 pieces)	Closed sleeve ND for DS PrimeTaper Implant System and Astra Tech Implant System EV, D3.6 and D4.2 implants
Order No.	6801 7219	
Guide Sleeve Type & Ø Inner	C/Guide-Sleeve Ø5.2 WD PrimeTaper/OmniTaper/ AstraTech Implant EV (10 pieces)	Closed sleeve WD for DS PrimeTaper Implant System and Astra Tech Implant System EV, D4.8 implants Closed sleeve WD for DS OmniTaper Implant System D4.5 implants
Order No.	6801 7221	

1.3.2 Open Guide Sleeves for the EV implant family

	Description	Used for...
Guide Sleeve Type & Ø Inner	O/Guide-Sleeve Ø4.5 ND OmniTaper (10 pieces)	Open sleeve ND for DS OmniTaper Implant System D3.0, D3.4 and D3.8 implants
Order No.	6801 7223	
Guide Sleeve Type & Ø Inner	O/Guide-Sleeve Ø4.6 ND PrimeTaper/AstraTech Implant EV (10 pieces)	Open sleeve ND for DS PrimeTaper Implant System and Astra Tech Implant System EV, D3.6 and D4.2 implants
Order No.	6801 7218	
Guide Sleeve Type & Ø Inner	O/Guide-Sleeve Ø5.2 WD PrimeTaper/OmniTaper/ AstraTech Implant EV (10 pieces)	Open sleeve WD for DS PrimeTaper Implant System and Astra Tech Implant System EV, D4.8 implants Open sleeve WD for DS OmniTaper Implant System D4.5 implants
Order No.	6801 7220	

1.3.3 Guide Sleeves for Ankylos

ND (A implants)

WD (B implants)

Guide Sleeve Type & Ø Inner	Ankylos C/Guide-Sleeve Ø4.5 ND (10 pieces)	Ankylos C/Guide-Sleeve Ø4.9 WD (10 pieces)
Order No.	3183 0729	3183 0731
Guide Sleeve Type & Ø Inner	Ankylos O/Guide-Sleeve Ø4.5 ND (10 pieces)	Ankylos O/Guide-Sleeve Ø4.9 WD (10 pieces)
Order No.	3183 0728	3183 0730

1.3.4 Guide Sleeves for Xive

ND (3.0, 3.4 and 3.8 implants)

WD (4.5 implants)

Guide Sleeve Type & Ø Inner	Xive C/Guide-Sleeve Ø4.5 ND (10 pieces)	Xive C/Guide-Sleeve Ø5.2 WD (10 pieces)
Order No.	3183 0737	3183 0739
Guide Sleeve Type & Ø Inner	Xive O/Guide-Sleeve Ø4.5 ND (10 pieces)	Xive O/Guide-Sleeve Ø5.2 WD (10 pieces)
Order No.	3183 0736	3183 0738

1.3.5 Guide Sleeves for other implants

	Description	Used for...
Guide Sleeve Type & Ø Inner	Simplant C/Guide-Sleeve Ø2.0 (10 pieces)	Simplant LongStop Drills Ø1.95
Order No.	3183 0743	
Guide Sleeve Type & Ø Inner	Simplant C/Guide-Sleeve Ø2.1 (10 pieces)	EV Guide Fixation Screw
Order No.	3183 0751	
Guide Sleeve Type & Ø Inner	Simplant C/Guide-Sleeve Ø4.2 (10 pieces)	Closed sleeve for Universal Drill Keys RP
Order No.	3183 0747	
Guide Sleeve Type & Ø Inner	Simplant C/Guide-Sleeve Ø5.2 (10 pieces)	Closed sleeve for Universal Drill Keys WP Closed sleeve for Straumann BLX implants, with VeloDrill self-locking drill key
Order No.	3183 0748	
Guide Sleeve Type & Ø Inner	Simplant C/Guide-Sleeve Ø5.0 S (10 pieces)	Closed sleeve for Straumann guided implants
Order No.	3183 0740	
Guide Sleeve Type & Ø Inner	Simplant O/Guide-Sleeve Ø4.2 (10 pieces)	Open sleeve for Universal Drill Keys RP
Order No.	3183 0749	
Guide Sleeve Type & Ø Inner	Simplant O/Guide-Sleeve Ø5.2 (10 pieces)	Open sleeve for Universal Drill Keys WP
Order No.	3183 0750	
Guide Sleeve Type & Ø Inner	Simplant C/Guide-Sleeve Ø4.2 N (10 pieces)	Closed sleeve for Nobel Biocare NP implants
Order No.	3183 0744	
Guide Sleeve Type & Ø Inner	Simplant C/Guide-Sleeve Ø5.0 N (10 pieces)	Closed sleeve for Nobel Biocare RP implants
Order No.	3183 0745	
Guide Sleeve Type & Ø Inner	Simplant C/Guide-Sleeve Ø6.2 N (10 pieces)	Closed sleeve for Nobel Biocare WP implants
Order No.	3183 0746	

For the design features of Simplant Pilot Guide – LongStop drill system and the design features of Simplant Universal Guide, please refer to the appropriate manual (the Simplant LongStop Concept).

	Description	Used for...
Guide Sleeve Type & Ø Inner	Simplant Guide-Sleeve Ø3.3 CG (10 pieces)	Closed sleeve for Camlog Gray, D3.3 implants
Order No.	6801 7210	
Guide Sleeve Type & Ø Inner	Simplant Guide-Sleeve Ø3.8 CY (10 pieces)	Closed sleeve for Camlog Yellow, D3.8 implants
Order No.	6801 7207	
Guide Sleeve Type & Ø Inner	Simplant Guide-Sleeve Ø4.3 CP (10 pieces)	Closed sleeve for Camlog Red, D4.3 implants
Order No.	6801 7208	
Guide Sleeve Type & Ø Inner	Simplant Guide-Sleeve Ø4.2 Z (10 pieces)	Closed sleeve for Zimmer Size A Drill Key
Order No.	6801 7211	
Guide Sleeve Type & Ø Inner	Simplant Guide-Sleeve Ø5.3 Z (10 pieces)	Closed sleeve for Zimmer Size B Drill Key
Order No.	6801 7212	
Guide Sleeve Type & Ø Inner	Simplant Guide-Sleeve Ø4.3 BY (10 pieces)	Closed sleeve for Biohorizons Yellow Drill Key
Order No.	6801 7213	
Guide Sleeve Type & Ø Inner	Simplant Guide-Sleeve Ø5.1 BG (10 pieces)	Closed sleeve for Biohorizons Green Drill Key
Order No.	6801 7214	
Guide Sleeve Type & Ø Inner	Simplant Guide-Sleeve Ø6.3 BB (10 pieces)	Closed sleeve for Biohorizons Blue Drill Key
Order No.	6801 7215	
Guide Sleeve Type & Ø Inner	Simplant Guide-Sleeve RP 3i (10 pieces)	Closed sleeve for Biomet 3i D4.0 Blue
Order No.	6801 7216	
Guide Sleeve Type & Ø Inner	Simplant Guide-Sleeve WP 3i (10 pieces)	Closed sleeve for Biomet 3i D5.0 Yellow
Order No.	6801 7217	

For the design features of Simplant Pilot Guide – LongStop drill system and the design features of Simplant Universal Guide, please refer to the appropriate manual (the Simplant LongStop Concept).

2. Validated equipment and components

The following materials and equipment are needed for validated process of manufacturing a 3D printed surgical guide. Except for Calibra Universal adhesive, these components are not supplied by Dentsply Sirona:

- Calibra Universal adhesive or Loctite 4310 adhesive and gluing tips
- Form 3B+ printer
- Surgical Guide resin
- Resin Tank LT
- Preform software version 3.29.0 or newer
- Form Wash
- Form Cure

Consult Formlabs documentation provided with the equipment for any topic that is not included in this document.

Use the online support material from Formlabs to maintain and service the equipment (Form 3B+, Form Wash and Form Cure).

2.1 Form 3B+

It is recommended to check the health of the optics of the printer by printing the Optics test.form. the Optics test is available from the Formlabs customer support.

2.2 Form Wash

It is recommended to verify the washing solvent, IPA, with the hydrometer that comes with the Form Wash equipment. The hydrometer is calibrated according to the Formlabs online support material and will be used to check the resin concentration of IPA between washes.

2.3 Form Cure

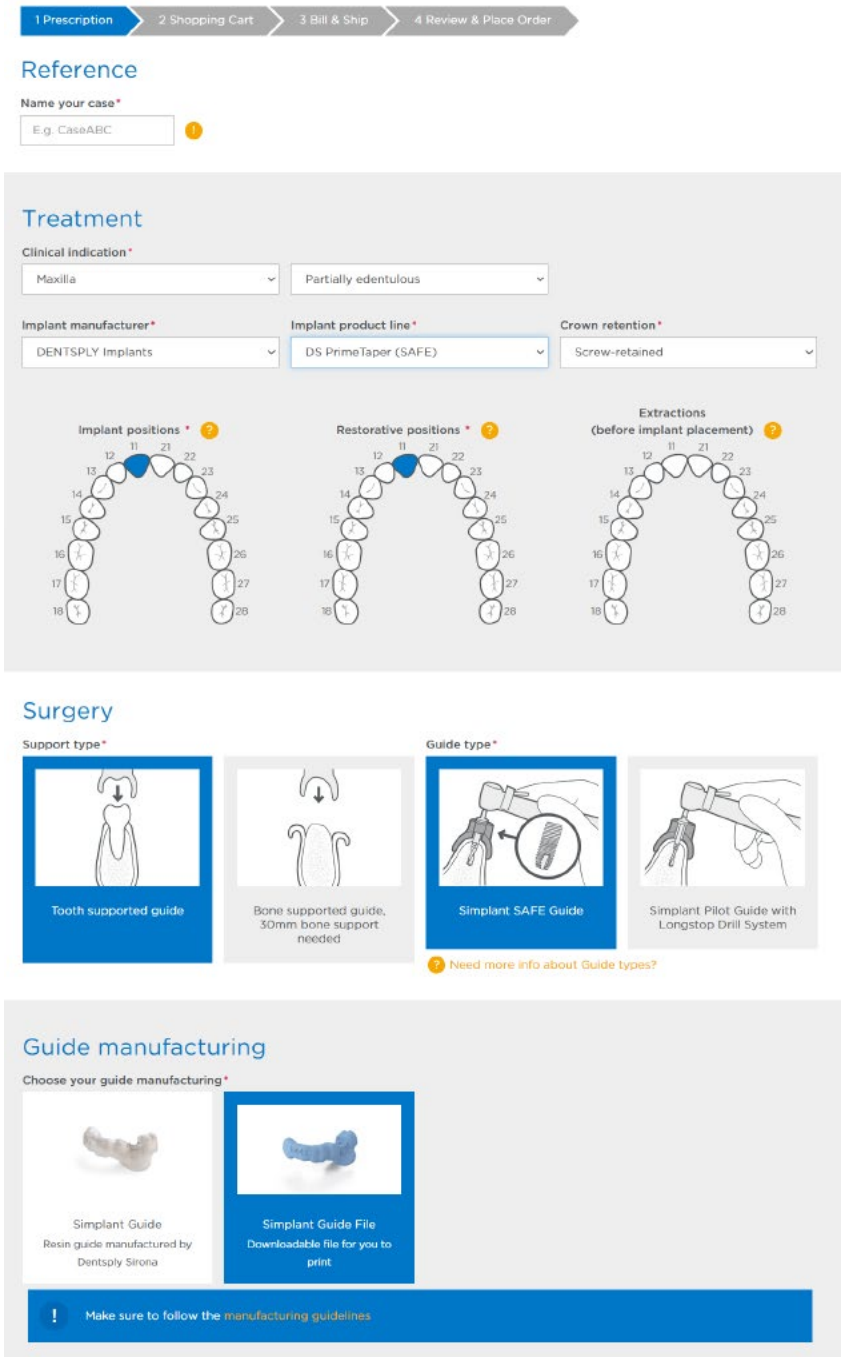
It is recommended to verify that the LED's of the Form Cure are ignited after starting the post-curing operation.

3. Creating a new Simplant® order for your case

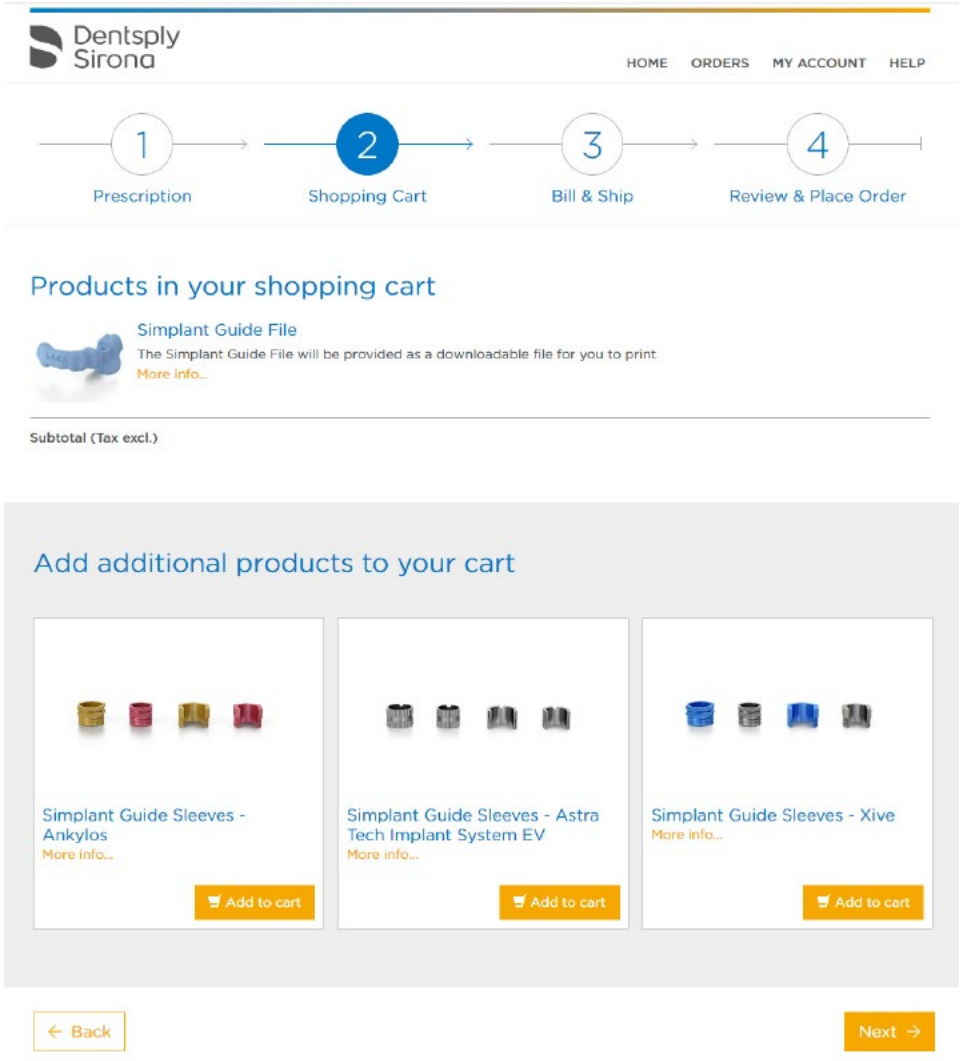
The first step in ordering a Simplant Guide File is to request a Simplant Guide for your implant planning in the Simplant Pro software or to create a Simplant Planning Service order on **www.orderdigitalsolutions.com**

For more flexible design and ordering options, as well as a faster turnaround of the Simplant Guide File, it is recommended to use the Simplant Pro software.

On the “Prescription” page, specify the options for your order and select “Simplant Guide File” as the manufacturing choice.



If you do not have the applicable guide sleeves in stock yet, you can add 1 or more sets of Simplant Guide Sleeves before submitting the order.



Simplant Guide Sleeves can also be ordered separate from the Simplant case planning via the Dentsply Sirona sales rep or web shop.

4. Downloading Simplant® Guide File and surgical guideline

A notification will be sent when the Simplant Guide File is available for your order. Follow the link in the notification email to the order details page.

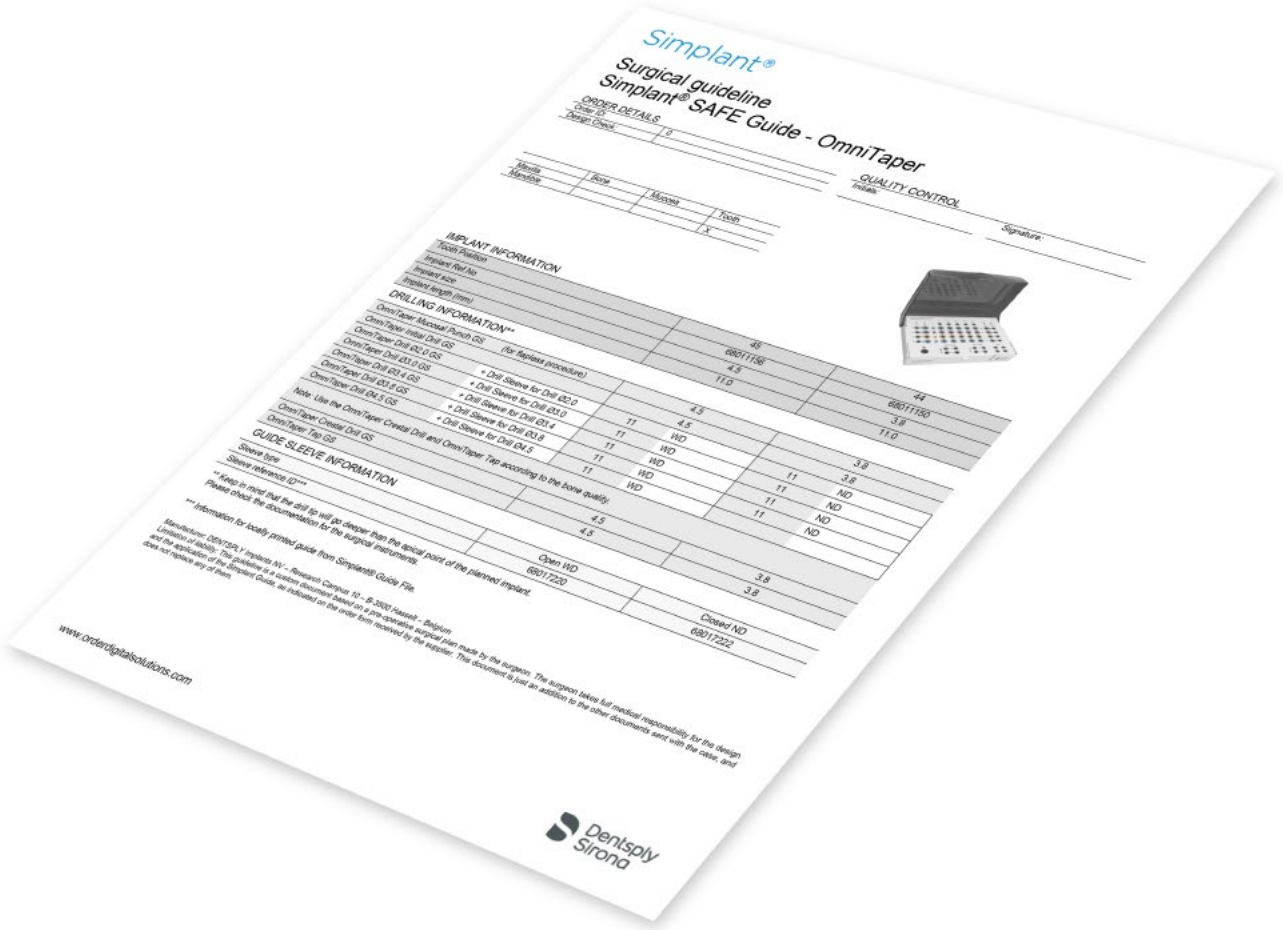
Download and save the Simplant Guide File and the surgical guideline on your computer:

Before proceeding, note down the Order ID of your planning and verify that all case files display the same Order ID:

- The Simplant Guide File name starts with the correct Order ID
- Open the surgical guideline and verify the Order ID in the top left section matches the Order ID of your planning
- Open the Simplant Guide File and verify that the ID print on the guide design matches the last 4 digits of the Order ID of your planning

Use the Simplant Guide File for further pre-processing and manufacturing of the surgical guide.

Use the surgical guideline to verify guide sleeve information for the different implant positions when manufacturing the surgical guide. In addition, this surgical guideline includes the steps to follow for the case-specific drilling sequence and is an important document to accompany the surgical guide for the surgical intervention.



5. Importing Simplant® Guide File into PreForm

5.1 Select Material

Open PreForm.

Opening PreForm, you will see the boundaries of the build volume and the build platform, which is inverted from the print direction. Select “Surgical Guide” from the Material menu and set the layer thickness to 0.05mm before configuring the model.

A layer thickness of 0.05mm results in optimal print quality.

NOTICE

The selection of Surgical Guide material will define the build path used for printing the Simplant Guide File.

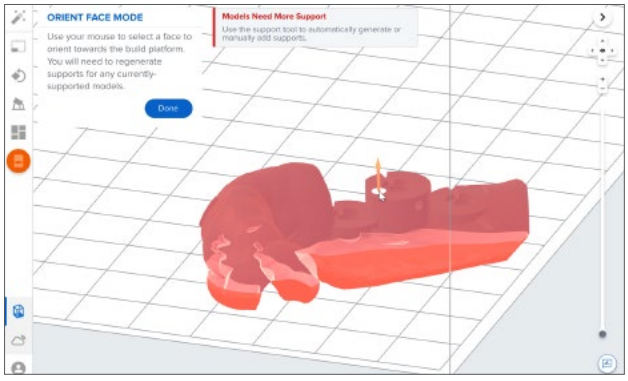
5.2 Import Model Files into PreForm

Import the Simplant Guide File (STL file) into Preform.

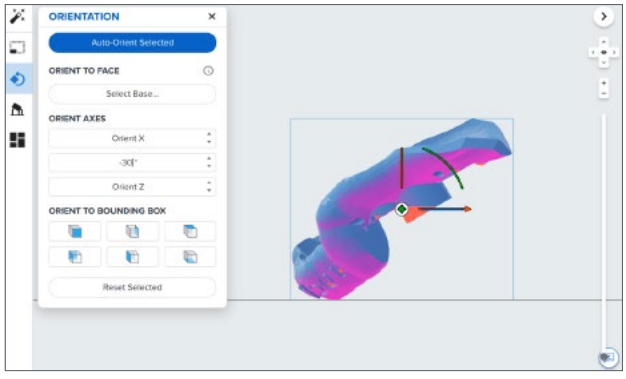
The build volume (145 × 145 × 185 mm) is displayed by the PreForm software after the printer (Form 3B+) is selected. The build volume indicated by the PreForm software can be used for placement of the Simplant Guide File.

5.3 Orient models

The Simplant Guide File should be oriented with Select Base menu, the face surrounding the sleeve should be selected as a base to be oriented towards the build platform.

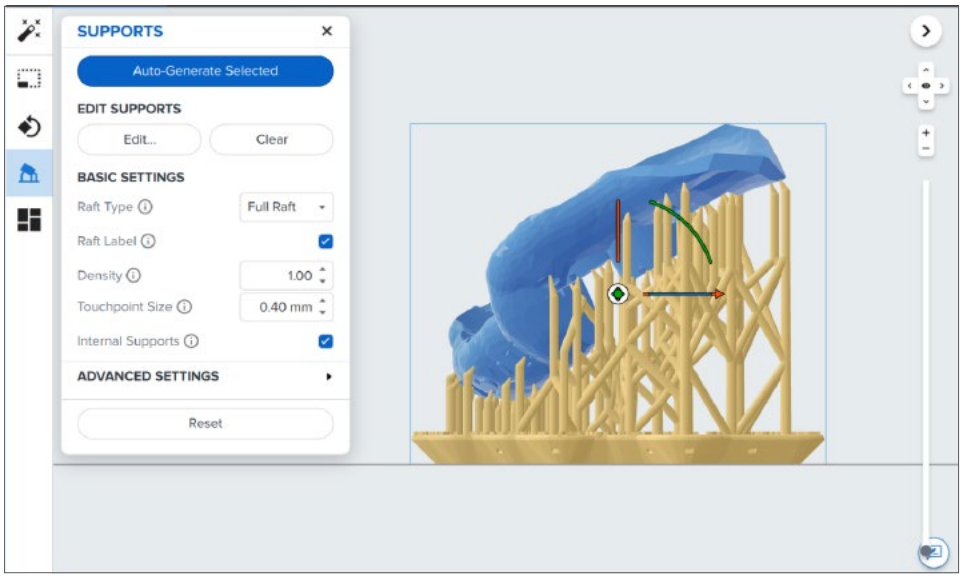


Subsequently, the face surrounding the sleeve should be oriented under an angle of + or - 30° with the build plate to optimize accuracy. The distal ends of the guide should be pointing away from the build plate, wherever applicable.



5.4 Generate Supports

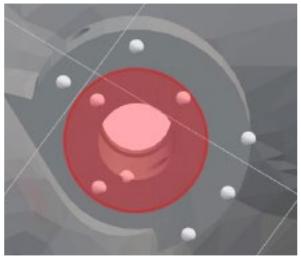
Generate supports using PreForm's auto-generation feature with the default settings.



To allow for simple and precise assembly, ensure that there are no supports (white dots) on the patient-contacting surfaces. Use the manual support editing feature to closely inspect support locations and add or remove supports as needed.

To allow for simple and precise assembly, ensure that there are no supports on the inner side or in the inside of the guide sleeve opening. Use the manual support editing feature to closely inspect support locations and add or remove supports as needed.

No support attachments allowed in the red zone



Support attachments are allowed in the green zone

NOTICE

Avoiding Supports on the patient contacting surface and the inside of the guide sleeve openings will eliminate the need for postprocessing and ensure a smooth and untouched surface where needed.

Areas in need of support are highlighted in red on your model. If some parts of a model are highlighted in red as undersupported, add individual supports.

5.5 Layout

When bundling several parts on the build plate, move the supported prints to their final location on the build plate. The full build area can be used for positioning the parts. Ensure a minimum distance of 0.5 mm between parts.

5.6 Upload the print

When the printability indicator is changed to a check mark, save the print as a FORM file and send the print job to the printer. Select which printer to upload the file to from the printer dialogue.

6. Manufacturing the surgical guide

6.1 Print

6.1.1 Confirm Print on Printer

1. From the home or print queue view, the Form 3B+'s touchscreen displays the FORM file's upload in progress.
2. Select the file name.
3. Select Print.
4. Confirm the print by pushing the button.
5. Follow the onscreen prompts. The Form 3B+ automatically fills and warms the tank. The print starts automatically.

6.1.2 Pre-Print Checks

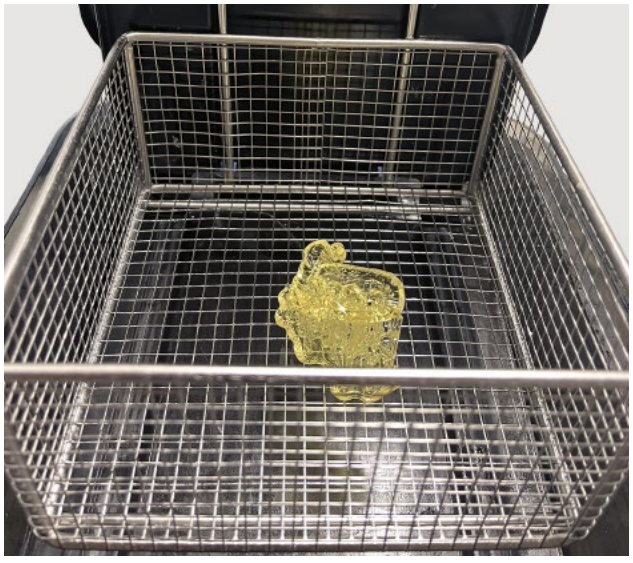
The printer checks the following before each print job:

- Accessories – Sensors check for the proper installation of the resin tank, build platform, and resin cartridge.
- Temperature – The print chamber and resin heat to around 35 °C. A heating fan blows air across the heater into the resin tank to heat the resin.
- Resin – Resin flows from the cartridge into the tank when the cartridge dispense arm squeezes the valve open. The Form 3B+ regulates the volume of resin in the tank through a sensor called the LevelSense board, which is located behind the resin tank. The printer begins to fill the resin tank once a print starts and maintains the level of resin in the tank during the print. Printing begins automatically when LevelSense detects the proper amount of resin.

6.2 Wash

Remove part from the build platform with the part removal tool or by detaching the part instantly from the platform with Quick Release Technology. Verify that the parts are hard to ensure that the correct print parameters have been used.

Place the part in the metal basket of the Form Wash, filled with 99% isopropyl alcohol (IPA). Set to wash for 20 minutes to wash all remaining liquid resin before post-curing.

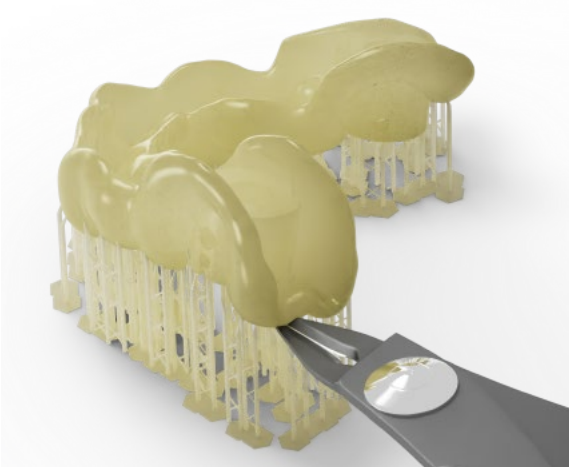


6.3 Drying

Leave parts to air dry completely for 30 minutes or use a compressed air hose to blow IPA away from surfaces. Inspect parts closely to ensure all uncured resin has been removed. Ensure that parts are clean and dry, with no residual stickiness. Repeat wash if necessary.

6.4 Removal of support

Use flush cutters (included in the Formlabs Finish Kit) to carefully cut the supports at the points where they attach to the part. Use caution when cutting the supports, as the post-cured material may be brittle. Safety goggles are recommended. Supports can also be removed using other specialized appliances, such as cutting disks or round cutting instruments like carbide burs.



6.5 Adding the Guide Sleeve(s)

The guide sleeve(s) according to the case-specific guide design are inserted in the surgical guide. For each planned implant position, consult the guide sleeve information in your planning or on the Simplant surgical guideline if applicable.

For easy insertion of the guide sleeve(s), place the guide on a flat surface coronal side facing upward and use an insertion tool slightly smaller in size than the guide sleeve diameter. Put the guide sleeve onto the insertion tool and press the sleeve into the guide. The guide sleeve(s) should fit into the guide without excessive force.

Use magnifying aids like microscope or camera to make sure that the guide sleeve is in the correct position. Visually inspect that the coronal surface of the guide sleeve is flush and level with the surface of the guide sleeve opening, which confirms correct depth and angulation of the guide sleeve.

Use Calibra Universal or Loctite 4310 adhesive and gluing tips to attach the guide sleeves in the guide.

1. Loctite 4310:

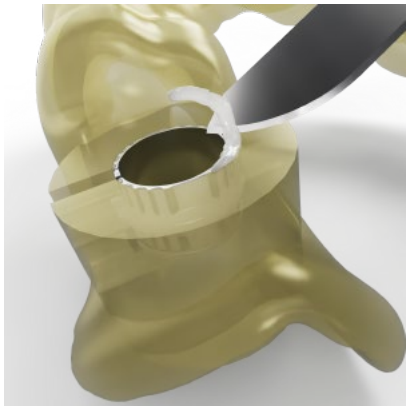
An applicable gluing tip is the Tapered Tip 20 Gage – Pink (PK50). Insert the gluing tip in the gluing channel on buccal and lingual side of the guide sleeve opening and add adhesive. Make sure the adhesive is flowing completely around the guide sleeve. Excessive adhesive that is flowing out of the gluing channels or guide sleeve opening should be wiped off with a tissue.

2. Calibra Universal:

Use Calibra Universal adhesive and mixing tips to attach the guide sleeves in the guide.

The guide design provides multiple inlets that can be used to inject adhesive around the guide sleeve. Choose an injection location (or locations) that minimizing the amount of excess adhesive spilling out via an irrigation window or indexing notch. Inject slowly and allow the adhesive to flow completely around the guide sleeve.

Excessive adhesive should be removed in gel-state. Gel-state is achieved with light curing the excess adhesive for a few seconds. Conventional powered quartz tungsten halogen or LED lights producing only one peak wavelength around 470 nm are recommended. The illumination time depends on the amount of excess adhesive. On average a good illumination time to start with is 4 seconds. The adhesive is also reaching gel-state by self-curing for a few minutes. Adhesive in gel-state can be easily removed with an instrument. Thin layered adhesive is fully cured after 6 minutes of self-curing. Adhesive cannot be easily removed anymore after it reaches a fully cured state.



6.6 Cure with Form Cure

Parts must be fully post-cured by exposure to UV light and heat for biocompatibility and optimal mechanical properties. Place the printed guide(s) inside Form Cure. Post-cure for 30minutes at 70 °C.

6.7 Finishing

Use cutting tools, such as carbide burrs, for finishing the guide and the model:

- removal of sharp edges.
- reducing the guide dimension to support only on ½ of last teeth for better visibility of the fit of the guide on the model.
- removal of material on the guide that results from extraction wounds.
- removal of interdental material, at the same time making sure that tightness of the guide on the model is maintained.
- removal of material on the model in case the guide sleeve sticks out of the guide and prevents a good fit of the guide on the model.
  - the same flap will be required in surgery, mark and communicate this guide sleeve stick-out clearly to the clinician for a good fit in the patient's mouth.

WARNING **Apart from the finishing procedure mentioned above, do not alter the patient-specific contacting surface of the guide.**

6.8 Quality Control

As a final quality control the guide should be fitted onto the physical model.

- Use the intended instruments to check that excess adhesive has been removed in the critical areas:
  - on top of the guide sleeve and top resin plane which serves as a physical stop for the instrument to be guided.
  - on the inside of the guide sleeve, obstructing the guiding path for the instrument to be guided.
- Guide should allow the handpiece to be used up to the correct depth. Verify there is no blockage of the drill head by neighbouring teeth.
- Guide should be hard, not flexible or soft (fully cured).
- Guide should not be fragile by design or overcuring (increases brittleness).
- Guide surface should appear smooth, without 'steps' by shifted layers in its contours.
- Guide's unique ID (4 digits) should be readable.
- Guide's resin surface around the guide sleeve should be free from support remainders (flat), as this area acts as a reference in case a drill key is used.
- Verify if important anatomical parts are not missing by chipped resin parts.
- The borders of the surgical guide should be smooth, no sharp edges.
- Finally, check the guide fit on the physical model.
  - no space visible by the naked eye between the guide and the model (illumination level of 750 lux minimum at the inspection surface).
  - guide doesn't wobble on the model.

If the guide does not meet the above criteria, the guide cannot be used and it is recommended to reprint or redesign.

6.9 Steam Clean

Steam clean the surgical guide for 25 seconds. The surgical guide must be clean (without dust or other particles) as visibly seen with the naked eye (illumination level of 750 lux minimum at the inspection surface).

7. Additional requirements for lab-side printing

It is the responsibility of the local guide manufacturer that the guide is properly labeled, documented (Instructions for Use - IFU) and packaged for delivery to the end user.

Proposed content for the label and IFU is listed below.

7.1 Labeling

Label the guide according to the applicable regulation for medical devices.

The label should contain the following information as a minimum, in the appropriate language:

- Order ID
- Expiry date (2 weeks after the production date)
- Manufacturer's address
- Reference to Instructions for Use
- Single Use
- Non sterile
- Keep away from sunlight
- Keep dry

7.2 Packaging and Shipping

Package the labeled guide and model together with the Simplant surgical guideline and Instructions for Use and send to the clinician. Verify that the order ID printed on the guide corresponds to the order ID on the Simplant surgical guideline. Package the guide in a sealable PE bag and choose an outer packaging that offers sunlight and humidity protection and packaging that is validated for ASTM D4169 DC13 transport test or equivalent.

8. Surgical intervention – Information for the end user of the guide

It is the responsibility of the manufacturer of the guide, that the end user of the guide is provided with required information. This chapter contains proposal of information to be provided to the end user of the the locally manufactured guide. The information in this chapter does not relate to the Simplant Guide File.

8.1 Indications for use

The surgical guide is intended for use in assisting placement of dental implants.

8.2 Clinical application

This product is intended to be used to help the surgeon prepare an osteotomy for dental implants and/or place dental implants. Depending on the type of support, the guide can be placed onto the teeth, mucosa or a combination thereof.

8.3 Description of the product

Depending on the solution, the surgical guide is always used together with other components. Make sure to check the applicable instruction for these other components.

SAFE solution

- Guided drilling and guided implant placement
- Brand specific guided surgery kit needed – Immediate temporization possible

Universal solution

- Guided drilling only
- Drill depth control only when used in combination with Simplant LongStop drills
- Simplant Universal Drill Key set needed

Pilot solution

- Guided drilling of the initial pilot drill only
- Drill depth control only when used in combination with Simplant LongStop drills

8.4 Contraindications

Allergy against or hypersensitivity to used materials (check with the surgical guide manufacturer). In case the patient is allergic or hypersensitive to any of the materials, the surgery should be continued without the surgical guide. All contraindications for implant surgery are also applicable to the surgical guide.

8.5 Warnings

Surgery in the oral cavity and oral rehabilitation include general risks for complications:

- Components that accidentally are dropped in the patient's mouth may be swallowed or aspirated which can result in suffocation or physical injury. Care must be taken to have control over small parts.
- Damaging of the implant site because of overheating. It is important to correctly take into account the instructions for use applicable to the surgical instrument set used to avoid excessive temperature generation during surgical drilling. Furthermore, instruments that are excessively worn should be disposed of as these can contribute to overheating.

8.6 Precautions

- The accuracy of the surgery depends on many different factors such as the quality of the (CB) CT scan, the quality of the impression, and the complexity of the surgery.
- The surgical guide must be used as soon as possible after the manufacturing date (within 2 weeks).
- The surgical guide must not be altered (cutting, further finishing, clipping...) as it can lead to incorrect seating of the guide.
- The surgical guide is patient-specific and for single use only. Accuracy cannot be guaranteed when reused and may cause implant failure.
- Position the patient so that the danger of aspiration of components is minimized.
- Start drill rotation only after having inserted the drill into the guide sleeves.
  Take the necessary precautions to cool the drill during the drilling.
- Drill guidance can be compromised when the drills/drills with drill sleeves/drill keys are not adequately inserted into the guide sleeves. Special attention needs to be given to open guide sleeves.
- Do not use excessive force on the surgical guide during the surgery.

- It is important to correctly take into account the precautions, instructions and cleaning and sterilization instructions outlined in this document in order to avoid excessive force on the guide or to avoid structural weakening of the guide, as this can result in fracturing of the guide. In case of fracture, the guide should be disposed of and the surgery should not be performed with the guide.
- The surgical guide with Universal solution and Pilot solution are used with the Simplant LongStop Drill System instruments to obtain a vertical stop during drilling. When using other surgical instruments with these guides, drill depth control has to be obtained visually, taking into account the drill length indicated on the surgical guideline delivered with the Simplant Guide File (Figure 1).
- The drill length indicated on the surgical guideline for LongStop Drills does not take the drill tip into account. The LongStop drill's actual length includes a drill tip offset (Figure 1).

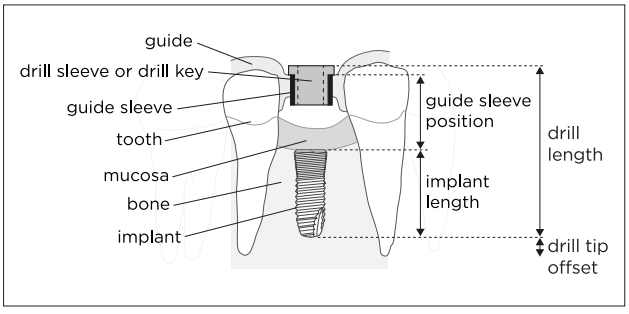


Figure 1

8.7 Adverse reactions

Adverse reactions during or after implant treatment can be:

- perforation of the maxillary sinus, inferior border, lingual plate, labial plate,
- inferior alveolar canal, gingiva or tooth
- damage to the implant site because of overheating
- temporary local swelling
- edema
- haematoma
- temporary anaesthesia/masticatory impediment
- allergy or hypersensitivity to used materials.

8.8 Step-by-step instructions

1. Print the surgical guideline before the surgery. Check that the surgical guide ID corresponds to the identification on the surgical guideline.
2. Check that drills, drill sleeves or drill keys fit easily into the surgical guide.
3. Clean and sterilize the surgical guide according to the instructions in the 'Cleaning and sterilization' section.
4. Do not use the guide in case it is broken or damaged.
5. Check that guide sleeves are attached firmly into the guide.
6. Verify the fit and stable position of the surgical guide in the patient's mouth. Evaluate the position and orientation of the guide sleeves.
7. Check if the depth of the osteotomies to be created is realistic compared to your planned implant length and make sure that the drills have the correct length according to the surgical guideline.
8. Make sure the guide maintains its position on the jaw, if necessary, and use guide fixation screws to fix the guide onto the jaw.
9. Hold the surgical guide in place using finger force during the surgical procedure.
10. Take necessary actions to cool the drill during the drilling procedure.

8.9 Cleaning and sterilization

Use the following recommended method of cleaning:

1. Do not clean in a washer-disinfector.
2. While rinsing under running room temperature tap water, brush the device using a soft-bristled, nylon brush of suitable size until visually clean (minimum 1 minute) before ultrasonic cleaning.
3. Clean the guide in an ultrasonic bath with tap water for four minutes at a temperature of 30°C ± 2°C and at a frequency of 40kHz.
4. While rinsing under running room temperature tap water, brush the device using a fresh/clean, soft-bristled, nylon brush of suitable size until visually clean (minimum 1 minute).
5. Allow the guide to dry for 30 minutes prior to the sterilization process.

Use the following recommended method of sterilization:

1. Place the surgical guide in a standard steam sterilization pouch. It is recommended to use a pouch with indicator.
2. Place the surgical guide in a dynamic air removal sterilizer for steam.
3. Make sure to put one part per tray in the sterilizer and that no mechanical forces are applied to the surgical guide during sterilization.
4. Sterilization at 134°C for 4 minutes with a dry time of 20 minutes.

   NOTE: Exposure times are calculated after the temperature of the sterilizer has reached the indicated temperature.
5. Let the surgical guide cool down to room temperature for 30 minutes in the pouch before using the surgical guide. Make sure no mechanical forces are applied to the surgical guide during cooling down.
6. Use the sterilized components within the stated period from the sterile bag manufacturer.
7. Check if the guide sleeves are attached firmly to the guide.
8. Verify the fit of the surgical guide by carefully checking its position.
9. Staining of the guide sleeves could occur after sterilization; this does not influence the performance and/or safety of the guide."

8.10 Storage

Store at room temperature for no longer than 2 weeks after the manufacturing date. Do not expose to UV-light and moisture.

8.11 Expiration date

The surgical guide has an expiration date of 2 weeks after the manufacturing date.

8.12 Disposal

Normal clinic waste disposal.

8.13 MRI safety

Not applicable for the surgical guide.

8.14 Manufacturer

The manufacturer of the surgical guide is the dentist or dental technician who uses the Simplant Guide Sleeves and the Simplant Guide File to manufacture the surgical guide according to the described validated workflow.

Dentsply Sirona