

Validated  
workflow with  
Formlabs Form2  
3D printers



Simplant®

# 3D printed surgical guides & Simplant® Guide Sleeves

Operating instructions

(not valid for USA)

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# General info

## Caution

Federal law restricts this device to sale by or on the order of a dentist. Surgical guides may only be used by dentists/ physicians who have had the appropriate education and training.

## Indications for use

The surgical guide is intended for use in assisting placement of dental implants.  
The Simplant Guide Sleeves are intended for assisting manufacturing of the surgical guide.

## Clinical application

The surgical guide can be placed on the teeth or mucosa or a combination thereof.

## 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.

## Warnings

Surgery in the oral cavity and oral rehabilitation include general risks for complications which should be known by the clinician. Possible complications associated with the use of the surgical guide include:

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.

## Precautions

To prevent personal injury and material damage, the surgical guide manufacturer should observe the warning and safety information from the 3D printing equipment provider.

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 should be used as soon as possible after the manufacturing date because clinical parameters can change over time reducing accuracy of the guided surgery.

The surgical guide is patient-specific and for single use only. Accuracy cannot be guaranteed when reused and may cause implant failure.

Start drill rotation only after having inserted the drill into the guide sleeves. Take the necessary precautions to cool the drill during the drilling. Do not use excessive force on the surgical guide during the surgery.

## Storage

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

## Expiration date

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

## Disposal

Normal clinic waste disposal.

## MRI safety

The surgical guide with Simplant Guide Sleeves has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the components in the MR environment is unknown. Scanning a patient wearing this device may result in patient injury. The surgical guide must be removed before using the MR environment.

## 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.

The manufacturer of the Simplant Guide Sleeves is Dentsply Implants GmbH, Hanau...

## Identifications of symbols used



CE Mark



Consult Instruction for Use (available in electronic format at website)



Manufacturer



Caution, warning



US Federal law restricts this device for sale by or on order of a physician or clinician



Date of manufacture



Catalogue number

# Product information

## 3D printed surgical guide

The Simplant central design delivers consistent quality and turn-around time for each patient-specific guide: whether you prefer to outsource the guide manufacturing to Dentsply Sirona for ease of mind or you prefer the flexibility of in-house printing, you benefit from the same proven Simplant design.



Centrally manufactured Simplant Guide

3D printed surgical guide

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

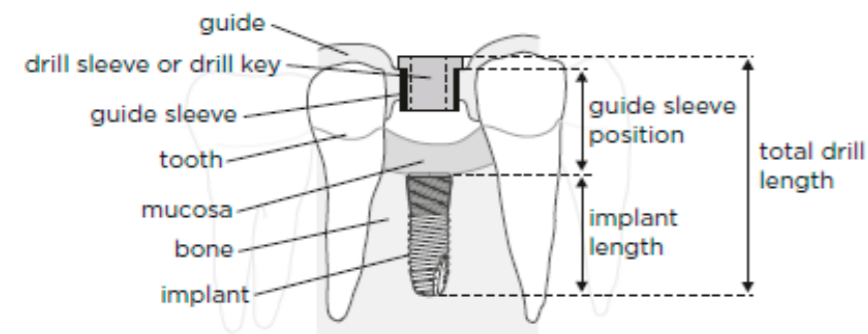
- Guided drilling only
- Drill depth control only when used in combination with Simplant LongStop drills
- Simplant Universal Drill Key set needed

### Pilot solution

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

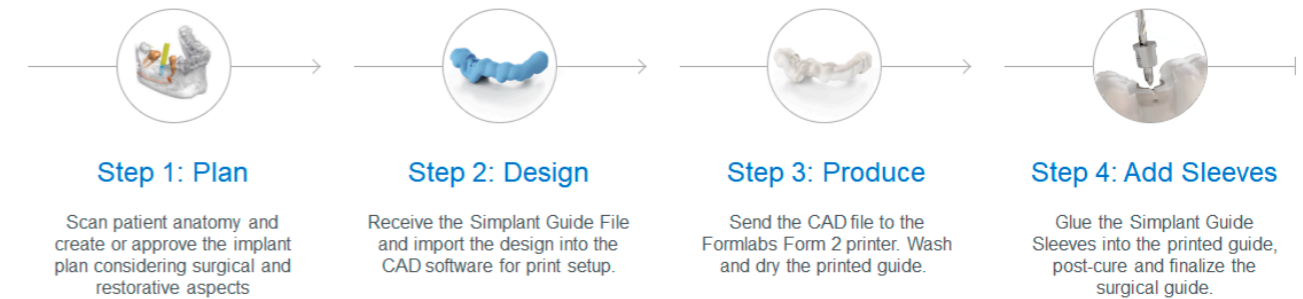
### Caution:

The Universal and the Pilot solutions 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 total drill length indicated length indicated by the manufacturer. The manufacturer receives this information on the surgical guideline delivered with the Simplant Guide File.



## 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 Simplant guide sleeve(s) in the surgical guide prior to use.

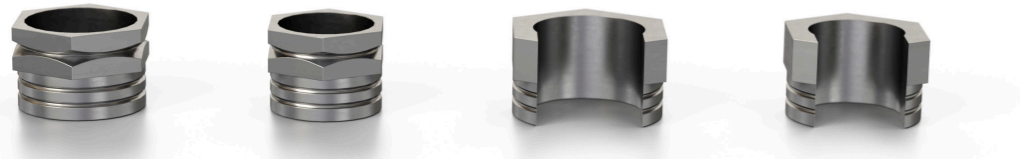


### A distinction is made between two versions of the Simplant Guide File:

- **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](http://www.orderdigitalsolutions.com) for central design review at Dentsply Sirona operations. This version of the Simplant Guide File is returned faster and incurs comparatively lower costs.
- **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 mySimplant Planning Service.

### Simplant® Guide Sleeves

The Simplant Guide Sleeves are made of stainless steel 316 L or 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 validated sterilization process for these guide sleeves as part of a locally manufactured surgical guide is described further in this document. The validated sterilization process for these guide sleeves as part of a centrally manufactured Simplant Guide is described in the Instructions for Use for Simplant Guide.

The responsibility for the sterility of the surgical guide lies with the user.

The manufacturer (dentist or dental technician) must inform the user about the required sterilization process before use in the patient's mouth.

#### 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

#### Astra Tech Implant System EV

	ND (3.6 and 4.2 implants)	WD (4.8 implants)
Guide Sleeve Type & Ø Inner	EV C/Guide-Sleeve Ø4.6 ND (10 pieces)	EV C/Guide-Sleeve Ø5.2 WD (10 pieces)
Order No.	3183 0733	3183 0735
Guide Sleeve Type & Ø Inner	EV O/Guide-Sleeve Ø4.6 ND (10 pieces)	EV O/Guide-Sleeve Ø5.2 WD (10 pieces)
Order No.	3183 0732	3183 0734

#### Xive Guide Sleeves



	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

#### 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 + Anthogyr + SIC + Thommen + Geass + Kentec
Order No.	3183 0747	
Guide Sleeve Type & Ø Inner	Simplant C/Guide-Sleeve Ø5.2 (10 pieces)	Closed sleeve for Universal Drill Keys WP + Anthogyr + SIC + Thommen + Geass + Kentec
Order No.	3183 0748	
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 Ø5.0 S (10 pieces)	Straumann guided implants
Order No.	3183 0740	
Guide Sleeve Type & Ø Inner	Simplant C/Guide-Sleeve Ø4.2 N (10 pieces)	Nobel Biocare, NP implants
Order No.	3183 0744	
Guide Sleeve Type & Ø Inner	Simplant C/Guide-Sleeve Ø5.0 N (10 pieces)	Nobel Biocare, RP implants
Order No.	3183 0745	
Guide Sleeve Type & Ø Inner	Simplant C/Guide-Sleeve Ø6.2 N (10 pieces)	Nobel, 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).

#### 3rd party guide sleeves

The Simplant Guide File is also available for guide solutions using other guide sleeves than the Simplant Guide sleeves. For these solutions, the surgical guide manufacturer must obtain the guide sleeves from the applicable implant company.

#### Validated glue and equipment

The following materials and equipment are needed for validated process of manufacturing a 3D printed surgical guide. These components are not supplied by Dentsply Sirona:

- Loctite 4304 adhesive and gluing tips
- Form2 Printer
- Form Wash
- Form Cure



# Creating a new Simplant® order

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 mySimplant planning service order on [www.orderdigitalsolutions.com](http://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.

**1** Prescription → **2** Shopping Cart → **3** Bill & Ship → **4** Review & Place Order

**Surgery**

Guide material\*

Resin guide      Digital guide

Tooth supported guide      Simplant SAFE Guide

FastTrack?      Has fixation?

✓Yes      ✗No

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.

**1** Prescription → **2** Shopping Cart → **3** Bill & Ship → **4** Review & Place Order

**Products in your shopping cart**

**Digital guide**  
The guide will be provided as a downloadable file for you to print  
[More info...](#)      \$100.00

Subtotal (Tax excl.)      \$100.00

**Add additional products to your cart**

**Astra EV RP Open sleeves**  
[More info...](#)      \$70.00      [Add to cart](#)

**Astra EV RP Closed sleeves**  
[More info...](#)      \$12.00      [Add to cart](#)

**Immediate Smile Digital**  
[More info...](#)      \$101.00      [Add to cart](#)

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



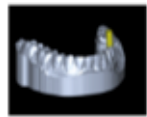
## Downloading Simplant® Guide File and surgical guideline

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

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

**▾ Implant planning and Guide design**  
Images are provided for reference purposes only. Please base your approval on the Simplant file that you can download below. Images and files are stored for 6 months after the order is placed.


Show image gallery




Download original order file



Download Simplant file



Download surgical guideline



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.



## Importing Simplant® Guide File into PreForm SW

### Select Material

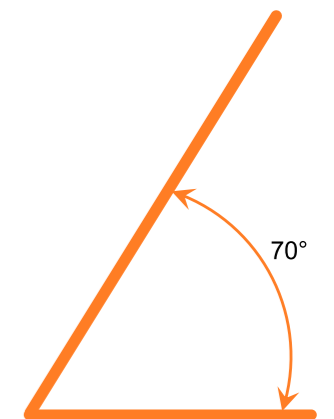
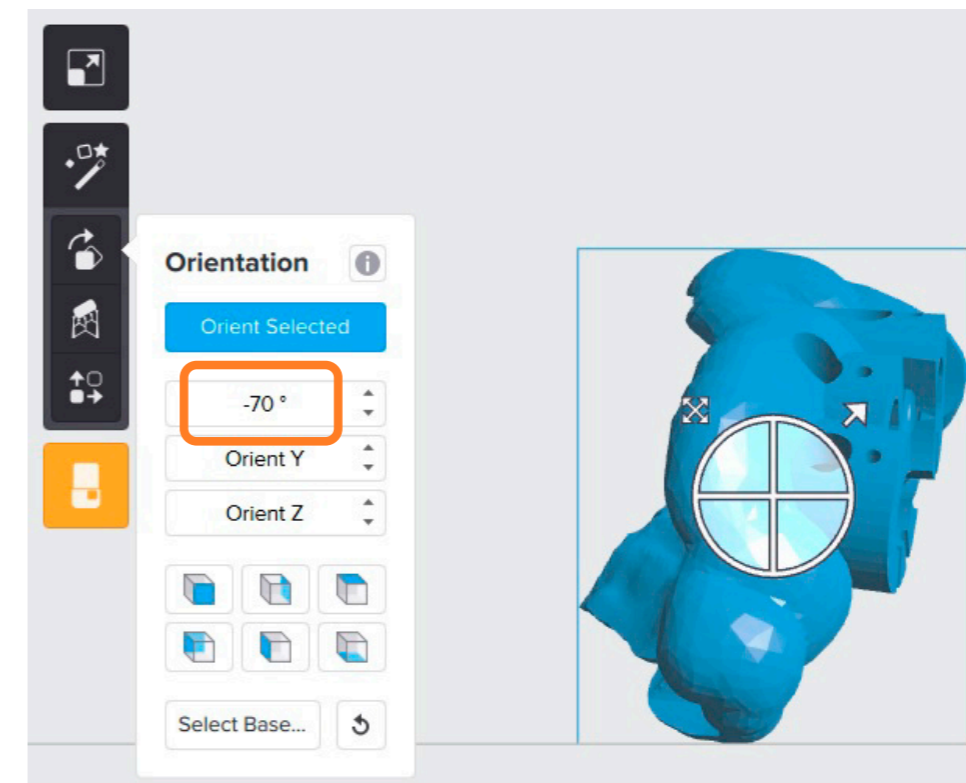
Open PreForm. Select "Dental SG" from the Material menu.

### Import Model Files into Preform

Import the Simplant Guide File into Preform

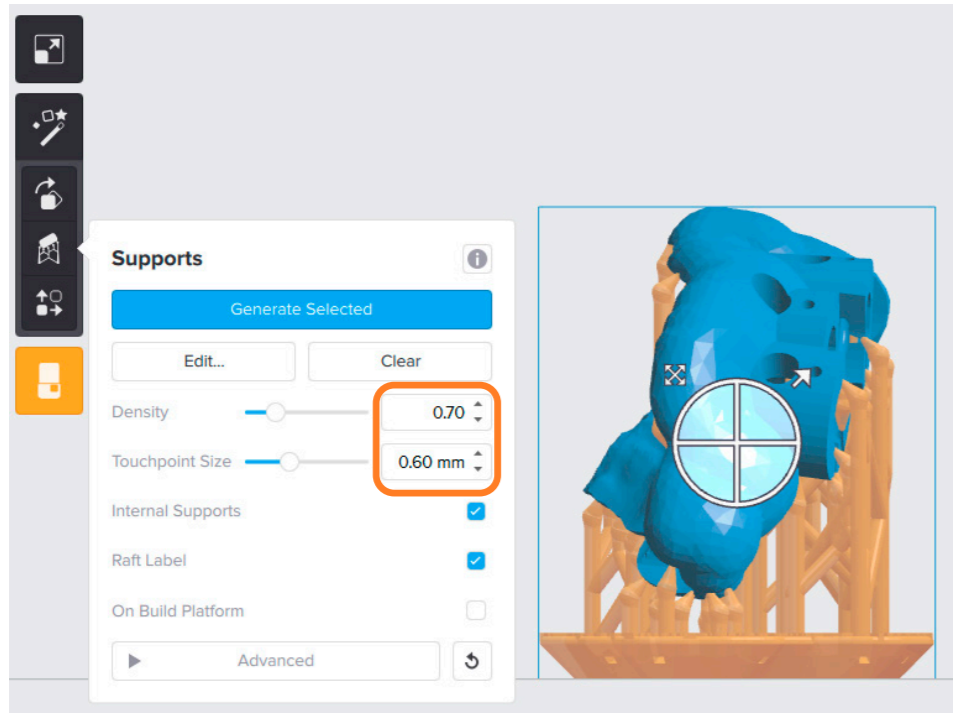
### Orient models

Orient parts under an angle of plus or minus 70° with the patient-contacting surfaces facing away from the build platform to ensure that supports will not be generated on these surfaces and orient parts such that no supports will be generated inside or near the sleeve cavities. If printing more than one surgical guide in a single print, manipulate the placement of each surgical guide on the build platform for the best fit.

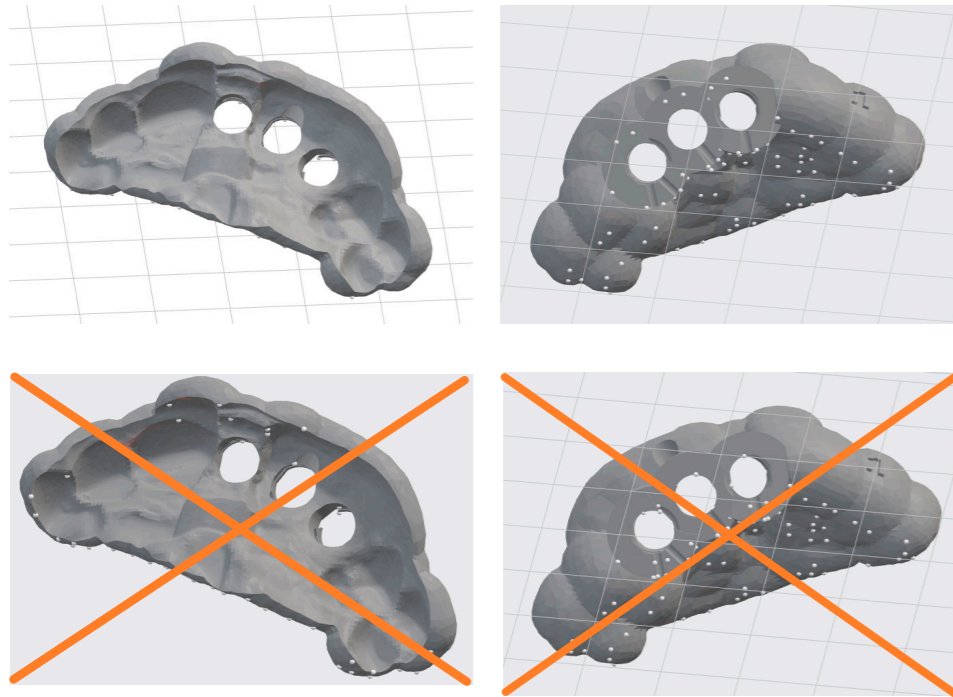


### Generate Supports

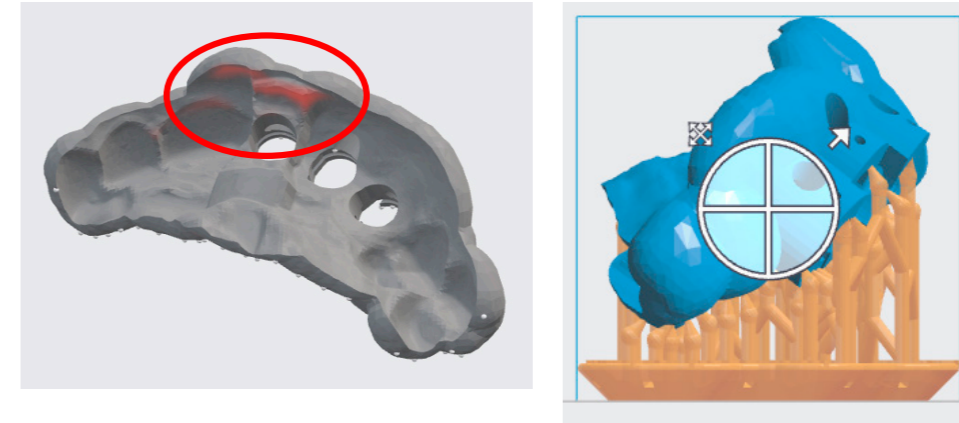
Generate supports using PreForm's auto-generation feature with the Density set to 0,7 and the Touchpoint Size to 0,6mm.



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

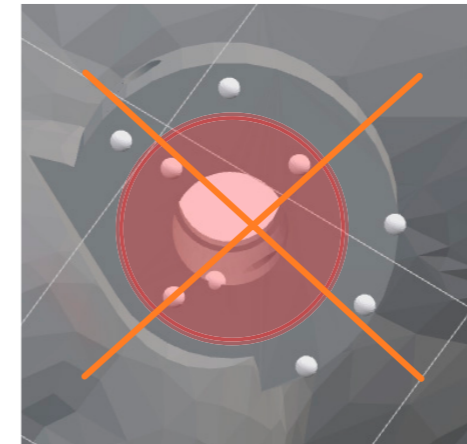


**Note:** It might be needed to orient the parts under a lower angle when no solution can be found after removing supports for the patient-contacting surface.

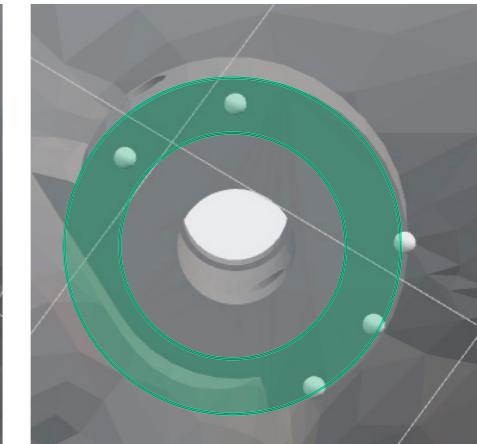


To allow for simple and precise assembly, ensure that there are no supports (white dots) on the inner side or in the inside of the guide sleeve opening. Use the manual support editing feature to closely inspect support locations and add or remove supports as needed.

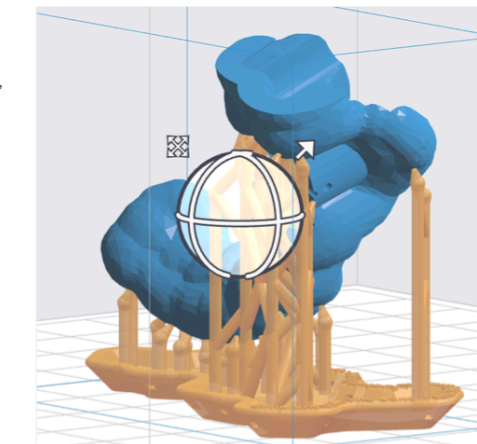
**No support attachments allowed in the red zone**



**Support attachments are allowed in the green zone**



For open guide sleeves: make sure the only gluing channel lies free of supports. To reach the gluing channel with the glue, the gluing tips should not be blocked by the printed support structures.



**Upload the print**

Send print job to the printer.



## Printing the surgical guide

Install the equipment (Form 2, Form Wash, Form Cure) according to the Formlabs online support material, taking into account the environmental requirements.

Make sure that also hygiene and personal protection instructions from the Formlabs online support material is followed.

### Prepare the printer and resin

Thoroughly agitate the resin cartridge by shaking and rotating it several times. Insert a resin tank LT, the resin cartridge, and a build platform into the Form 2 printer.

**WARNING:** For full compliance and biocompatibility, Dental SG requires a dedicated Resin Tank LT, Build Platform, and Finish Kit, which should only be used with other Formlabs biocompatible resins, such as Dental LT Clear.

### Print

Start printing by selecting print job from the print menu. Follow any prompts or dialogs shown on the printer screen. The printer will automatically complete printing.

### Wash

Place the build platform, with surgical guides still attached, in a Form Wash filled with isopropyl alcohol (IPA), 96% or higher. Set to wash for 5 minutes to wash the parts and remove liquid resin.

Remove part from the build platform with the part removal tool. For detailed techniques refer to the FormLabs online support material.



Place the part in the metal basket. Set to wash for 5 minutes to wash all remaining liquid resin before post-curing.



### Drying

Leave parts to air dry completely 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, but do not leave parts in IPA for more than 20 minutes, as this may reduce mechanical performance and cause defects in the printed parts.

### Removal of support

Remove the supporting material in front of the guide sleeve openings by using pliers.

**WARNING:** Only remove supporting structure to clear the guide sleeve openings: during post-curing the supporting structure should be attached to the guide to ensure stability.



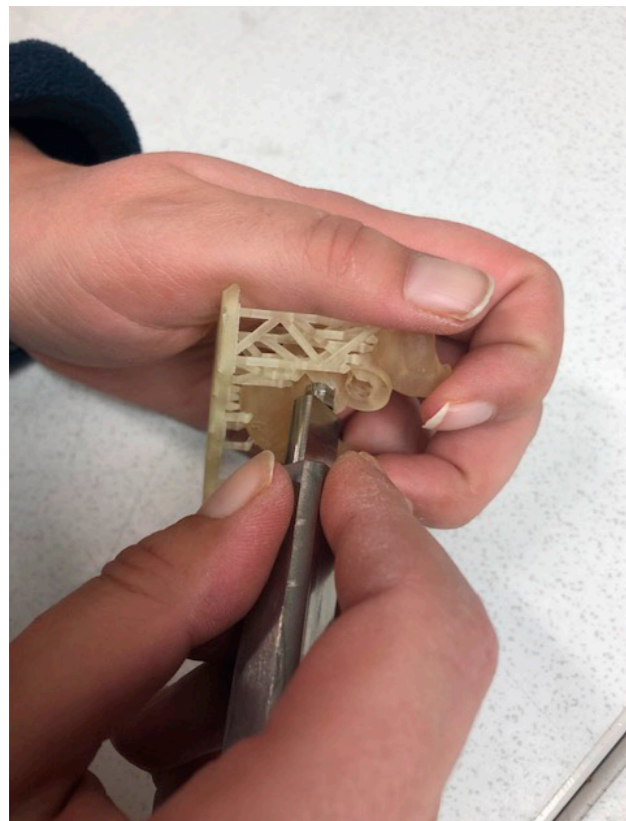


# Post-processing the surgical guide

## 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.

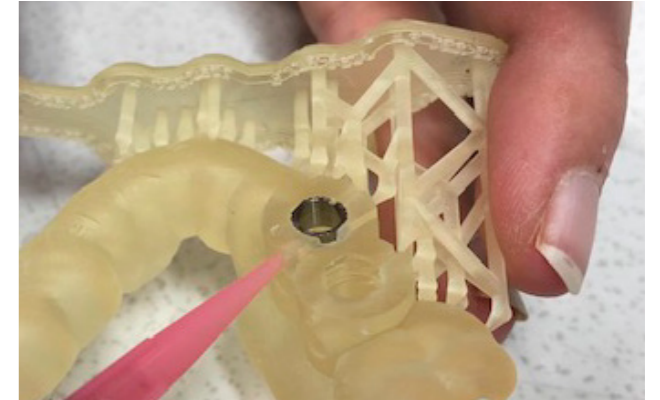
For easy insertion of the guide sleeve(s), place the guide on a flat surface facing upward and use an insertion tool slightly smaller in size than the guide sleeve diameter. Put the guide sleeve onto the insertion tool and press the sleeve into the guide. The guide sleeve(s) should fit into the guide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



There should not be any deviation in angulation between the inserted guide sleeve and the guide sleeve opening in the surgical guide (visual check). The guide sleeve should be flush with the top of the guide sleeve opening (visual check). Use magnifying aids like microscope or camera to make sure that the guide sleeve is in the correct position.

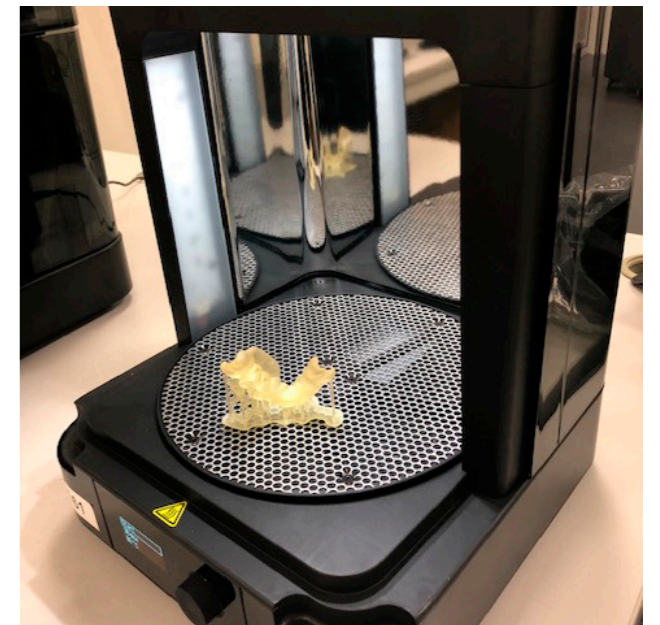


Use Loctite 4304 glue and gluing tips to attach the guide sleeves in the guide. An applicable gluing tip is the Tapered Tip 20 Gage - Pink (PK50). Insert the gluing tip in the gluing channel on buccal and lingual side of the guide sleeve opening and add adhesive. Make sure the adhesive is flowing completely around the tube. Excessive adhesive that is flowing out of the gluing channels or guide sleeve opening should be wiped off with a tissue.



## Post-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 60 °C.



A color change from translucent yellow to a uniform translucent orange will occur.



A. Printed



B. Post-cured

**WARNING:** visible-light curing will not post-cure the material.

## Removal of supports

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.

Use standard (commercially available) sandpaper to smoothen the edges and remove sharp parts on the guide.

## Finishing

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

- 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 metal sleeve sticks out of the guide and prevents a good fit of the guide on the model

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

# Additional requirements for lab-side printing

## Labeling

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

The label should contain the following information as a minimum:

- Order ID
- Expiry date (2 weeks after the production date)
- Manufacturer's address
- RxOnly (by prescription only)
- Reference to Instructions for Use
- Indication that the guide is for single use only

The guide should be accompanied by its Instructions for Use.



## Quality Control

- The borders of the surgical guide should be smooth, no sharp edges
- Guide fit:
  - 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
- 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.

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

## 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).

## Packaging and Shipping

Package the labeled guide and model together with the Siplant 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 Siplant surgical protocol. Choose packaging material that withstands the envisioned transportation method: packaging should protect the surgical guide from damage.

# Cleaning and Sterilization

Do not use in a washer-disinfector.

Clean the surgical guide in an ultrasonic bath with water for four minutes at a temperature of 30°C ± 2°C.

The surgical guide needs to be completely dry prior to the sterilization process.

Place the surgical guide in a standard steam sterilization pouch. We recommend to use a pouch with indicator. Use the sterilized components within stated time period from the sterile pouch manufacturer.

Note for US: Use a sterilization pouch that is FDA cleared for the recommended sterilization cycle.

## Use the following recommended method of sterilization:

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

Note for US: Sterilization at 275°F for 3 minutes with a dry time of 20 minutes.

These cycles have been validated to a sterility assurance level of a SAL 10<sup>-6</sup> according ISO 17665-1:2006.

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.

Check if the guide sleeves are attached firmly into the guide.

Verify the fit of the surgical guide by carefully checking its position.

Staining of the guide sleeves could occur after sterilization, this is not influencing the performance and/or safety of the guide.

# Surgical intervention

Make sure that the surgical guideline is printed before the surgery. Check that the surgical guide corresponds to the identification on the surgical guideline.

Check that drills, drill sleeves or drill keys fit easily into the surgical guide.

Do not use the guide in case it is broken or damaged.

Check that guide sleeves are attached firmly into the guide

Carefully verify the fit and stable position of the surgical guide in the patient's mouth. Evaluate the position and orientation of the guide sleeves.

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.

Make sure the guide maintains its position on the jaw, if necessary use guide fixation screws to fix the guide onto the jaw.

Hold the Siplant guide in place using finger force during the surgical procedure.

Take necessary actions to cool the drill during the drilling procedure.

## Maintenance and Servicing

Use the online support material from Formlabs to maintain and service the equipment (Form 2, Form Wash and Form Cure).

### Form 2

It is recommended to check the health of the optics of the Form 2 printer by printing the Optics test.form. the Optics test is available from the Formlabs customer support.

### 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.

### Form Cure

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

## Disclaimer

The 3D printed surgical guide has been validated for average designs of the Siplant Guide File and created in approved Siplant 3D planning and design software. If the customer chooses to design a 3D printed surgical guide with other than Siplant software, 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. To improve readability, Dentsply Sirona does not use ® or ™ in body copy. However, Dentsply Sirona does not waive any right to the trademark and nothing herein shall be interpreted to the contrary.



### About Dentsply Sirona Implants

Dentsply Sirona Implants offers comprehensive solutions for all phases of implant therapy, including Ankylos®, Astra Tech Implant System® and Xive® implant lines, digital technologies, such as Atlantis® patient-specific solutions and Simplant® guided surgery, Symbios® regenerative solutions, and professional and business development programs, such as STEPPS™. Dentsply Sirona Implants creates value for dental professionals and allows for predictable and lasting implant treatment outcomes, resulting in enhanced quality of life for patients.

### About Dentsply Sirona

Dentsply Sirona is the world's largest manufacturer of professional dental products and technologies, with a 130-year history of innovation and service to the dental industry and patients worldwide. Dentsply Sirona develops, manufactures, and markets a comprehensive solutions offering including dental and oral health products as well as other consumable medical devices under a strong portfolio of world class brands. As The Dental Solutions Company™, Dentsply Sirona's products provide innovative, high-quality and effective solutions to advance patient care and deliver better, safer and faster dentistry. Dentsply Sirona's global headquarters is located in York, Pennsylvania, and the international headquarters is based in Salzburg, Austria. The company's shares are listed in the United States on NASDAQ under the symbol XRAY.

Visit [www.dentsplysirona.com](http://www.dentsplysirona.com) for more information about Dentsply Sirona and its products.