Validated workflow with Formlabs Form 3B+ 3D printers

Simplant®

Manual

Simplant® Digital Guide

Manufacturer:
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www.dentsplysirona.com

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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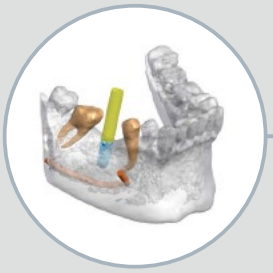
1. Product information



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

Simplant Digital Guide manufactured in your clinic: Tooth- or mucosa-supported

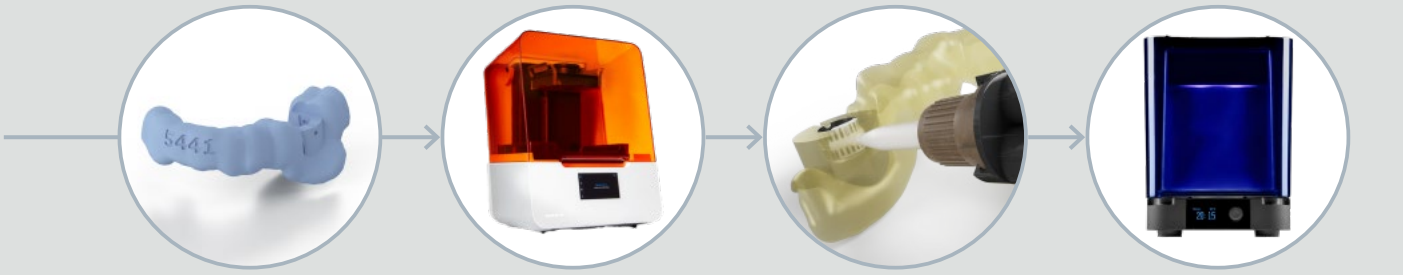
Depending on the solution, the surgical guide is always used together with other components. Make sure to check the applicable instruction for these other components.

Available solutions for the Simplant Digital Guide:

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.

  Simplant® Guide File – FT Review
  REF 37473

  (01)07392532290466

- **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.

  Simplant® Guide File – DS Design
  REF 37472

  (01)07392532290459

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 Simplant Digital 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

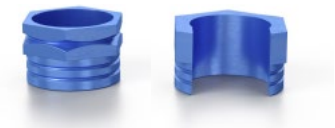
ND (A implants)

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 Simplant Digital 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

2.1 Form 3B+

The operating temperature for the Form 3B+ is 64–82 °F (18–28 °C). For optimal printing, do not exceed this range.

In chapters **“Preparation and setup”** and **“Maintenance”,** detailed instructions can be found to prepare, install and maintain the Form 3B+ printer.

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 following instructions and will be used to check the resin concentration of IPA between washes.

Before measuring the concentration make sure the hydrometer (IPA only) is calibrated. Reference the components of the hydrometer according to the following names:

A: O-ring
B: Float
C: Handle
D: Tall wings
E: Short wings
F: Weight

To calibrate the hydrometer:

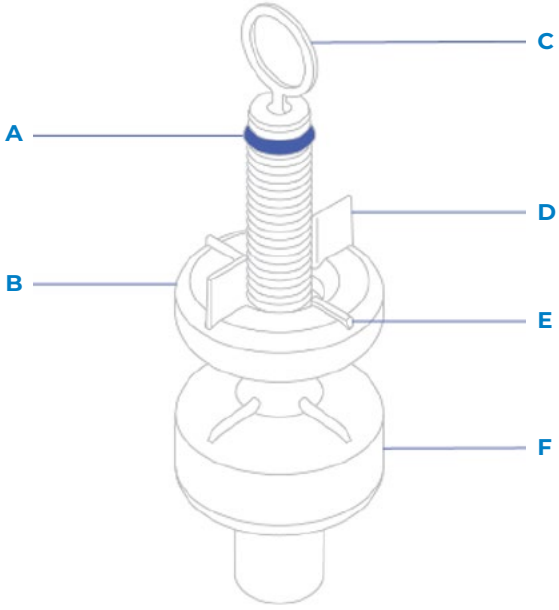
1. Hold the handle (A) and release the tool in the wash bucket’s fresh solvent.
2. Slide the O-ring (B) along the ribbed stem until the O-ring aligns with the short wings (C) at the top of the float.
3. Leave the O-ring in this position. The alignment of the wings and the O-ring is used to check the resin concentration of solvent between washes.

Store the hydrometer in the tool storage area at the back of the unit.

As the resin concentration of the IPA increases, the weight (F) on the hydrometer floats higher, and the stem and O-ring (A) on the hydrometer rise. When properly calibrated using fresh IPA, the O-ring (A) on the hydrometer should be level with the short wings (E) on the float (B). The hydrometer indicates when the resin concentration of IPA reaches 10–12%. If the O-ring (A) is higher than the tall wings (D), replace the IPA.

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.



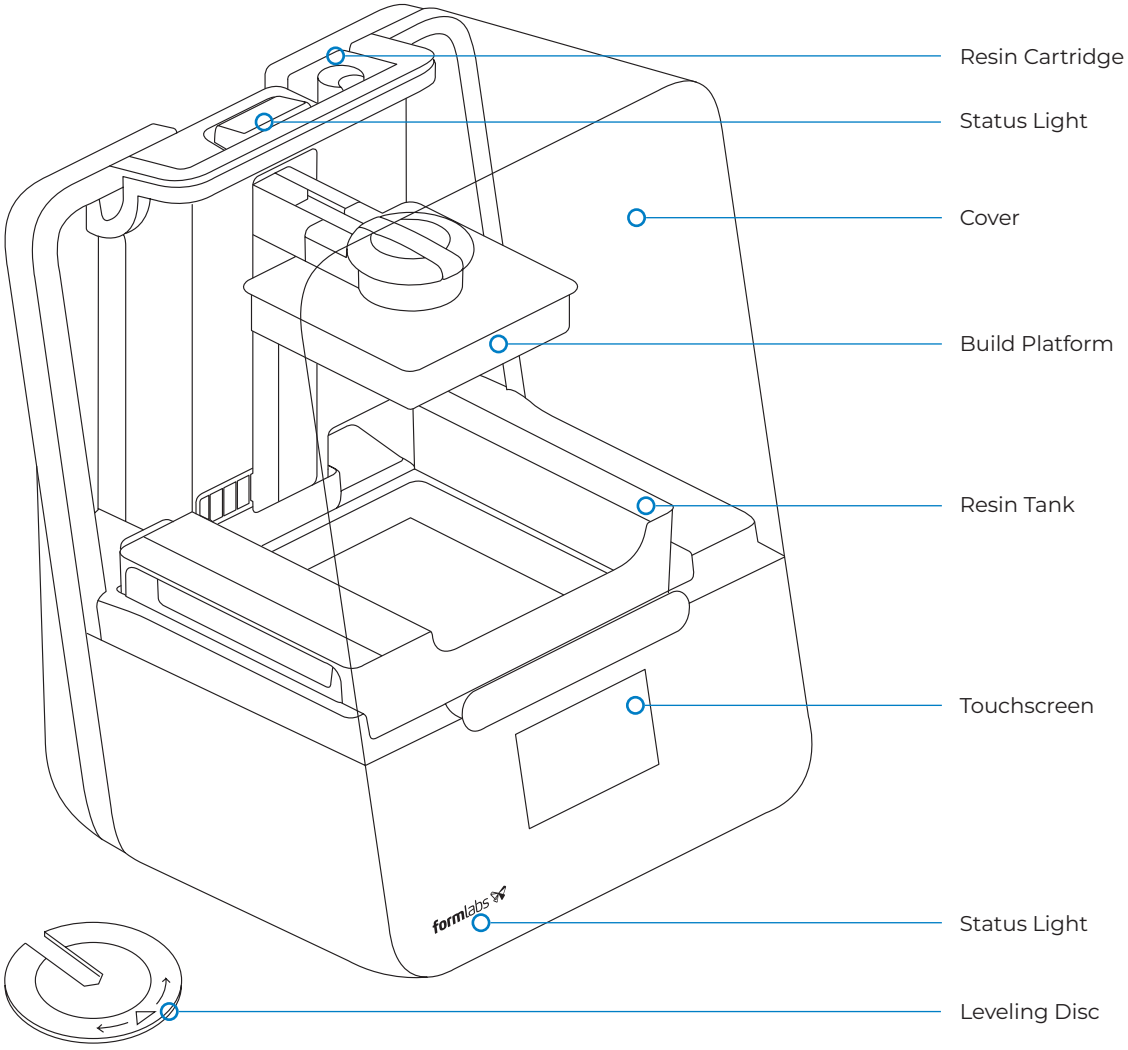
3. Form 3B+ printer introduction

3.1 Technical Specifications

	Form 3B+ Printer	Resin Cartridge	Form 3B+ Resin Tank	Form 3B+ Build Platform
Shipping Dimensions	57×51×69 cm (22.5×20×27 in)	24×20×8 cm (9.5×8×3 in)	35×30×8 cm (14×11.8×3.3 in)	18×17×8 cm (7×6.75×3 in)
Shipping Weight	22.7 kg (50 lb)	1.5 kg (3.3 lb)	1.4 kg (3.1 lb)	0.67 kg (1.5 lb)
Product Weight	17.5 kg (38.6 lb)	1.35–1.6 kg (3–3.5 lb)	0.8 kg (1.8 lb)	0.65 kg (1.4 lb)

3D Printing Technology	Low Force Stereolithography (LFS)
Minimum Dimensions for Convenient Access	Width: 40 cm (15.5 in) Depth: 53 cm (21 in) Height: 78 cm (30.5 in)
Weight	17.2 kg (37.9 lb)
Operating Temperature	Auto-heats to 35 °C (95 °F)
Temperature Control	Air heated print chamber
Power Requirements	100–240 V ~ 2.5 A 50/60 Hz 220 W
Laser Specifications	1 Light Processing Unit EN 60825-1:2014 certified Class 1 Laser Product 405 nm violet laser 250 mW laser
Laser Spot Size (FWHM)	85 microns (0.0033 in)
Radiation Information	The Form 3B+ is a Class 1 Laser product. Accessible radiation is within Class 1 limits.
Connectivity	Wi-Fi, Ethernet and USB
Ethernet Connectivity	RJ-45 Ethernet (10BASE-T/100BASE-TX/1000BASE-T) LAN Port Connect with an Ethernet cable (not included): minimum Cat5, or Cat5e or Cat6 for 1000BASE-T.
Wi-Fi Connectivity	Protocol: IEEE 802.11 b/g/n Frequency: 2.4 GHz, 5 GHz Supported security: WPA/WPA2
Sound Emission	Does not exceed 70 dB(A)
Printer Control	Interactive touchscreen
Resin Fill System	Automated
Build Volume	145×145×185 mm 5.7×5.7×7.3 in
Supports	Auto-Generated Removable

3.2 Product elements



3.3 Understanding the display

The Form 3B+ display includes a touchscreen and status lights.

The touchscreen displays print information, settings, and error messages. It serves as the user interface for the Form 3B+.

The status lights indicate the printer's state. Refer to messages on the touchscreen to understand the meaning of the status lights.

For detailed guidance and visual assistance, search on **support.formlabs.com.**

4. Form 3B+ safety warnings

WARNING

Read and understand this manual and its safety instructions before using the Form 3B+. Failure to do so can result in serious injury or death.

Supervise young or inexperienced users to ensure enjoyable and safe operation.
The instructions contain warnings and safety information, as explained below:

DANGER

Danger indicates a hazard with a high level of risk which, if not avoided, will result in death or serious injury.

WARNING

Warning indicates a hazard with a medium level of risk which, if not avoided, could result in death or serious injury.

CAUTION

Caution indicates a hazard with a low level of risk which, if not avoided, could result in minor or moderate injury.

NOTICE

Notice indicates information considered important, but not hazard-related.

Warning: The laser beam is harmful to the eyes. Avoid direct contact.

Danger: Isopropyl alcohol is a flammable chemical.

5. Form 3B+ component and subsystem safety

5.1 Laser

WARNING

Class 1 Laser Product. Only remove the shells of the printer with authorization from Formlabs or a certified service provider. Disconnect power before removing the shells.

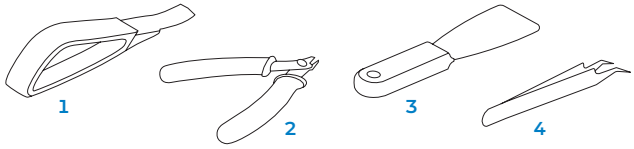
Accessible radiation is within Class 1 limits. The laser diode used inside the device has the following specifications:

Diode:
Violet (405 nm) Max Output: 250 mW

The laser beam is harmful to the eyes, so avoid direct contact. The Form 3B+ contains an interlock system to automatically shut off the laser when the cover is open. If this system is tampered with or fails, there is a risk of exposure to Class 3B+ laser light.

Laser Certification:
IEC 60825-1:2014 **EN 60825-1:2014**
FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 56, dated May 8, 2019

5.2 Sharp Tools



The accessories include sharp tools such as: a part removal tool **(1),** flush cutters **(2),** a scraper **(3),** and tweezers **(4).**

CAUTION

Cutting hazard. Using these tools on slippery surfaces (such as a resin-coated build platform) can result in sudden movement. Orient sharp tools away from yourself, especially when cutting or scraping.

5.3 Resin

Respect Formlabs resin like any household chemical. Follow standard chemical safety procedures and Formlabs resin handling instructions.

In general, Formlabs resin is not approved for use with food, drink, or medical applications on the human body. However, biocompatible resins, such as Surgical Guide Resin, are biologically safe for specific types and lengths of exposure to the human body. Refer to information about each specific resin for more detail.

WARNING

Never ingest resin in liquid or solid form. If swallowed, immediately call a poison center or medical professional.

NOTICE

Always consult the Safety Data Sheet (SDS) as the primary source of information to understand safety and handling of Formlabs materials.

5.4 Radio Interference

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to CFR Title 47, Part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at their own expense.
Changes or modifications to this product not authorized by Formlabs could void the electromagnetic compatibility (EMC) and wireless compliance and negate your authority to operate the product.

This product has demonstrated EMC compliance under conditions that included the use of compliant peripheral devices and shielded cables between system components. It is important that you use compliant peripheral devices and shielded cables between system components to reduce the possibility of causing interference to radios, televisions, and other electronic devices.

CAUTION

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

5.5 Isopropyl Alcohol (IPA)

NOTICE

Formlabs does not manufacture isopropyl alcohol. Consult the chemical manufacturer or supplier for detailed safety information. Carefully follow the safety instructions provided with the isopropyl alcohol that you purchase. Isopropyl alcohol can be flammable, even explosive, and should be kept away from heat, fire, or sparks. Any containers holding isopropyl alcohol should be kept closed or covered when not in use. We also recommend that you wear protective gloves and have good ventilation when working with IPA.

5.6 Personal Protective Equipment (PPE)

WARNING

Resin may cause skin irritation or an allergic skin reaction. Wear gloves when handling liquid resin or resin-coated surfaces. Wash skin with plenty of soap and water.

CAUTION

Some methods of support removal may cause small pieces of supports to break away. Beware of flying debris. Wear eye protection and gloves to protect the skin and eyes.

5.7 Specifications of Tools to Be Used

The Form 3B+ shall only be used with supplied accessories and additional tools recommended by Formlabs. Third-party accessories and materials may cause damage. Purchase additional supplies:

- Keep **paper towels** in stock to ensure a clean work environment for printing and finishing.
- Clean optical surfaces, including the optical window and the underside of the resin tank, with **PEC*PAD lint free wipes.**
- **Isopropyl alcohol (IPA, 90% or higher)** is the recommended solution for rinsing parts and cleaning liquid resin after each completed print.
- Connect the printer to a local area network with an **Ethernet cable.**
- Wear **disposable chemical-resistant gloves,** such as nitrile or neoprene, when handling resin or resin-coated surfaces and optics.
- Wear **safety glasses** when handling liquid resin, when removing printed parts, and when removing supports from a printed part.
- Clean the cover and outer shells with a **non-abrasive microfiber cloth** and **soapy water** or a **general purpose cleaner,** such as glass cleaner.

6. Form 3B+ preparation and setup

6.1 Arranging the workspace

Choose a stable, level workspace to install and operate the Form 3B+. Choose a location separate from any machinery or tooling that generates dust or sparks, such as wood or metal working equipment. Reserve the following minimum dimensions for the most convenient access:

Width: 40 cm (15.5 in) **Depth:** 53 cm (21 in)
Height: 78 cm (30.5 in)

Allow additional space for accessories, such as the Form 3B+ Finish Kit, Form Wash, and Form Cure.

6.2 Unboxing the Form 3B+

During unboxing, inspect the Form 3B+ for any damage or missing items. In the case of damage or missing items, contact Formlabs or the certified service provider.

6.2.1 To unbox the Form 3B+:

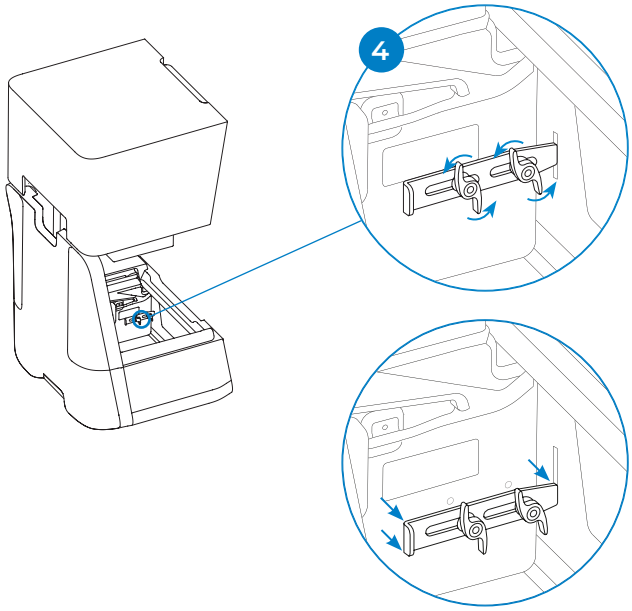
1. Open the box from the top. If the box has a side gate, fold down the side of the box.
2. Use the provided handles to lift the printer, in its carrier tray, out of the box.
3. Remove the printer from the carrier tray and set the printer in its workspace.
4. Remove any additional wrapping and packaging from the outside of the printer.

NOTICE **Remove all packaging material and release the Light Processing Unit (LPU) housing before connecting power.**

6.2.2 To release the LPU housing from its shipping position:

1. Open the printer cover.
2. Read and remove the instructional sticker wrapped around the LPU housing.
3. Locate the latch on the left side of the LPU housing.
4. Turn the thumb screws counter-clockwise by hand. Loosen and remove the two thumb screws and the latch. 4
5. Save the latch and screws along with the original printer packaging.

NOTICE **Save the Form 3B+ packaging for transporting your printer. Original packaging is required for warranty service.**



6.3 Installing the Form 3B+

6.3.1 Connect the Cables

Connect the power cable to the printer and the power supply.
Files can be uploaded via USB, Wi-Fi, or Ethernet. For USB, connect the printer to a nearby computer. For Ethernet, connect the printer to an Ethernet port.

6.3.2 Level the Printer

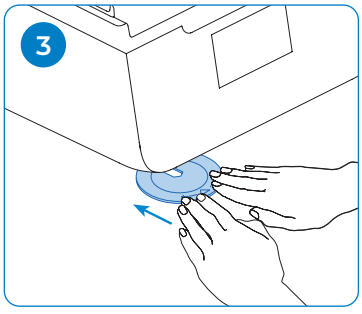
NOTICE

It is important that the printer sits level so resin does not overflow from the tank during printing. All four feet must rest on a solid surface to ensure optimal print accuracy.

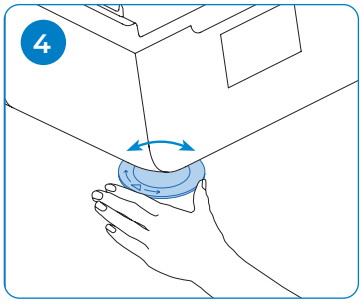
The Form 3B+ must be completely level before printing can begin. If prompted, use the leveling disc to raise or lower each foot of your printer.

6.3.3 To level the Form 3B+:

1. Connect the printer to power. If necessary, the touchscreen prompts use of the leveling disc.
   a. The initial printer setup sequence includes the leveling procedure.
2. Follow the on-screen instructions to adjust the feet under the printer.
3. Insert the round leveling disc under the designated corner. Push until the leveling disc clicks onto the foot. 3



4. Rotate the tool clockwise to raise and counter-clockwise to lower the height of the printer.
   a. The printer ships with each foot fully retracted. The height of the feet can only be raised during the initial printer setup. 4



5. Adjust the feet until the touchscreen indicates the printer is level.

6.3.4 Insert the Resin Tank and Mixer

CAUTION

Spill hazard. Resin may spill over the tank walls if the resin tank tilts more than 5-10°. Hold the resin tank level with two hands. To inspect and clean the underside of the tank, empty the resin tank and/or take care to avoid spilling resin outside the tank.

WARNING

Resin may cause skin irritation or an allergic skin reaction. Wear gloves when handling liquid resin or resin-coated surfaces. Wash skin with plenty of soap and water.

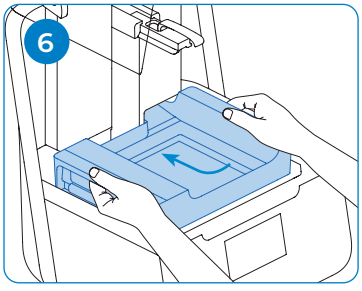
6.3.5 To install the resin tank:

1. Open the printer cover.
2. Remove the lid of the tank case.
3. Remove packaging materials from the tank.
4. Lift the resin tank with one hand on each side.

NOTICE

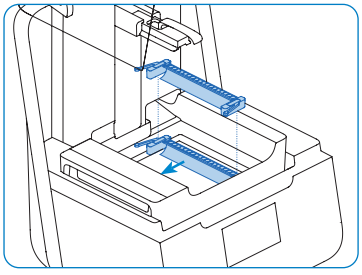
Avoid contaminating the underside of the resin tank with fingerprints or liquid resin.

5. Align the resin tank side walls with the left and right tank carrier rails.
6. Push the side handles – toward the back of the printer and downward – until the side walls lock into the rails. The resin tank clicks into place and sits firmly.
   A sensor detects the resin tank, and the status light illuminates. 6

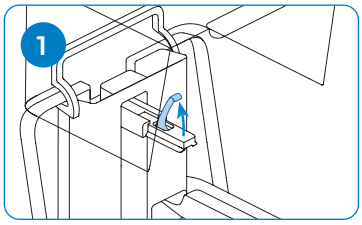


6.3.6 To insert the mixer:

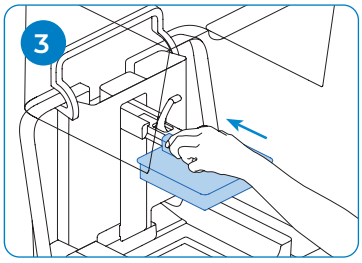
1. Orient the mixer with the flexure arms facing upward and toward the mixer case.
2. Slide the mixer to the left, into the mixer case.
   The flexure arms on each end click into place.



6.3.7 Insert the Build Platform



1. Raise the platform lock. 1
2. Align the build platform with the platform carrier.
3. Push the build platform onto the platform carrier. A sensor detects the build platform, and the status light illuminates. 3
4. Lower the platform lock to secure the build platform



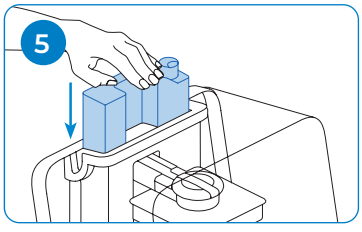
6.3.8 Insert the Resin Cartridge

1. Close the printer cover.
2. Shake the cartridge before each print to ensure the resin is mixed thoroughly. Shake the resin cartridge approximately every two weeks during storage to keep the formula well-mixed for the best print quality.
3. Remove the orange protective valve cover from the bottom of the cartridge. Consider saving the cover to protect the valve during storage.

CAUTION

Spill hazard. Do not remove the rubber valve at the bottom of the cartridge. This bite valve controls the release of the resin. Removing the rubber bite valve allows resin to continuously flow and causes extreme damage to the machine. This damage is not covered by the warranty.

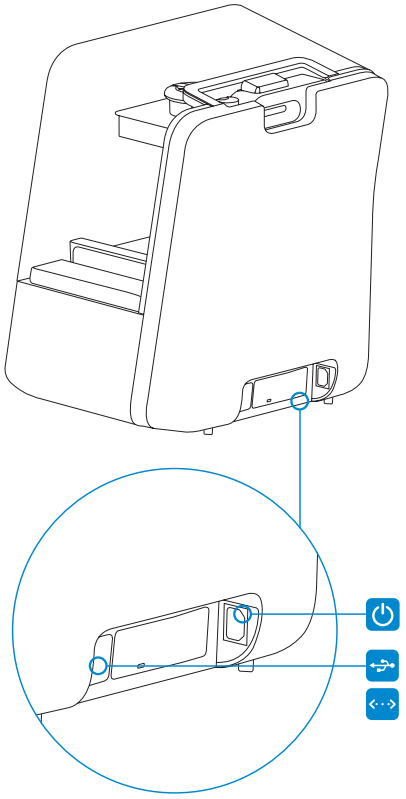
4. Align the cartridge with the opening in the back of the printer.
5. Push down on the cartridge handle until the top of the cartridge is level with the printer. A sensor detects the resin cartridge, and the status light illuminates. 5



6. Press open the vent cap, so that the resin tank fills correctly.

6.4 Connecting the Form 3B+

Connect to the Form 3B+ to upload and manage prints over Wi-Fi, USB, and Ethernet. The Form 3B+ can connect directly to a computer with a USB cable. For remote uploading and monitoring, the Form 3B+ supports both wired (Ethernet) and wireless (Wi-Fi) connections. Connect PreForm print preparation software to the same local-area network (LAN) as the printer in order to send a print job.
For a Windows operating system, after installing PreForm, check to ensure that Bonjour is properly installed. Bonjour is a piece of third-party software that is required to connect over Wi-Fi or Ethernet. See support.apple.com for assistance with Bonjour. The USB connection can still be used while the Form 3B+ is connected to a LAN. When the Form 3B+ is connected to a LAN, its current status and print progress can be monitored with Dashboard: **formlabs.com/dashboard.**



6.4.1 Connect with USB

Use the included USB cable for connecting a computer directly to the printer.

1. Plug one end of the USB cable into the back of the Form 3B+.
2. Connect the other end to a computer's USB port .

6.4.2 Connect with Ethernet

The rear of the unit is equipped with a RJ-45 Ethernet (10BASE-T/100BASE-TX/1000BASE-T) LAN Port . Connect to a LAN with an Ethernet cable (not included): minimum Cat5, or Cat5e or Cat6 for 1000BASE-T.

1. Plug one end of the Ethernet cable into the back of the Form 3B+.
2. Connect the other end to your LAN.

6.4.3 Connect with Wi-Fi

The Form 3B+'s built-in Wi-Fi (IEEE 802.11 b/g/n) supports WPA/WPA2 security. Use the Form 3B+'s touchscreen to configure a wireless network connection.

When connected to an active Ethernet connection or available Wi-Fi network, the Form 3B+ can be configured with a static IP address.

To connect with Wi-Fi using a manual IP configuration:

1. With an established Ethernet or available Wi-Fi connection, open the printer's Settings menu on the touchscreen.
   a. For Wi-Fi networks, tap Wi-Fi, then the desired wireless network.
   b. For Ethernet connections, open Ethernet from the Settings menu.
2. Toggle the Manual IP settings to "ON".
3. Input the appropriate IP Address, Subnet Mask, Default Gateway, and Name Server.

7. Form 3B+ maintenance

WARNING

- **Formlabs provides instructions to advise skilled and non-skilled persons in installing, operating, and maintaining the Form 3B+. The Form 3B+ shall only be maintained by a qualified and trained person. Do not open the Form 3B+ and/or investigate internal components unless under the guidance of Formlabs or a certified service provider. Contact Formlabs or a certified service provider for any additional guidance.**
- **Unauthorized disassembly or repair procedures may damage the printer and void the warranty.**
- **Wear personal protective equipment when performing maintenance tasks. Use tools only as described.**
- **Disconnect the power cable before maintenance. Moving parts and lead screws present crushing and tangling hazards.**

7.1 Inspecting the Product

7.1.1 Before Each Print, empty the resin tank and inspect

Inspect	Refer to	Section
Installation Environment	**Operational Environment** The operating temperature for Formlabs printers is 64–82 °F (18–28 °C). For optimal printing, do not exceed this range.	
Resin Cartridge Bite Valve	Inspect the Bite Valve	2.1
Resin Tank Interior	Maintain the Resin Tank	5.2

7.1.2 Monthly

Inspect	Refer to	Section
Resin Cartridge ID Chip and Reader	Protect the ID Chips on the Resin Tank and Resin Cartridge	3.1
Resin Tank Spring Fingers	Protect the ID Chips on the Resin Tank and Resin Cartridge	3.1
Resin Tank Exterior	Maintain the Resin Tank	5.2

7.1.3 Every 3 Months

Inspect	Refer to	Section
Cover	Inspect the Cover	4.1
Display	Inspect the Display	4.2
Drip Catcher	Inspect the Drip Catcher	4.3
Shells	Inspect the Shells	4.4
X- and Z-axis Lead Screws	Inspect and Lubricate the X- and Z-axes	4.5

7.1.4 Perform the following preventive and curative maintenance on the Form 3B+.

Inspect	Inspection	Maintenance ONLY if problems are noted:	Incidental
Optical window **Frequency:** Daily or Incidental	Inspect the optical glass for contamination, including dust, resin, spots, streaks, clouding, fingerprints, etc.	If possible, clean the glass optical window with dry photographic wipes (PEC*PADs). Over-cleaning and over-use of IPA can degrade the glass surface. If dry wipes are not sufficient, you may apply small amounts of IPA to the photographic wipe to help loosen up surface contaminants. Lay the wipe flat against the glass and wipe in a straight line from one side to the other slowly. Repeat in overlapping wipes until the surface is clean. Est. time: 0.2 hr	Perform this check after a resin spill. Perform this check when the guide sleeve does not fit the surgical guide or when the surgical guide does not fit on the model
Optics **Frequency:** Monthly or Incidental	Run an optics test print. Wash and dry once completed. Inspect each printed part for signs of optical degradation. Each of the four columns should have sharp angles and the numbers should be crisp. The center object should have crisp details in the slits and vertical rods.	If uniform optical degradation is noted, this could be an indication that the internal optical surfaces need to be cleaned. Contact Formlabs Services for assistance. Be sure to provide photos of the optics print test. Non-uniform defects indicate a problem with the optical window or resin tank. Perform checks on both systems. Est. time: 2 hr	Perform this test after resin spills or extensive cleaning procedures. Perform this check when the guide sleeve does not fit the surgical guide, when the surgical guide does not fit on the model.

For detailed instructions on how the perform the maintenance tasks, please contact support@formlabs.com.

7.2 Inspection Tasks Between Prints

7.2.1 Inspect the Bite Valve

The bite valve is located on the underside of the resin cartridge. This flexible seal regulates resin dispensing. Resin flows out of the opening in the center of the bite valve when the cartridge dispense arm squeezes the valve open.

When switching to a different resin cartridge, inspect the bite valve for any cured resin or damage.

7.2.2 Inspect the Resin Tank Interior

See ***7.5.2 Maintain the Resin Tank.***

7.3 Monthly Inspection and Maintenance Tasks

7.3.1 Protect the ID Chips on the Resin Tank and Resin Cartridge

ID (identification) chips on resin tanks and resin cartridges detect, track, and match the resin type in the tank with the proper resin cartridge. The ID chip is on the underside of each tank frame and on the bottom of the cartridge near the bite valve.

Protect the ID chips, the tank carrier, the tank spring fingers, and the cartridge spring fingers from resin contamination or damage. Cured resin or contamination prevents the printer from properly identifying a cartridge or resin tank during insertion or use. Avoid exposing the cartridge ID chip, the resin tank ID chip, the tank carrier, and the tank spring fingers to liquid resin.

7.3.2 Clean the ID Chips or Spring Fingers

To remove resin from the ID chip or spring fingers:

1. Apply a small amount of clean IPA to the tip of a cotton swab.
2. Rub the tip of the cotton swab onto the silver pads on the ID chip or onto and around the spring fingers. The cured resin or contamination dissolves.

NOTICE **Do not bend the spring fingers when cleaning. Ensure that any IPA on the ID chip dries completely before continuing printing.**

7.3.3 Inspect the Resin Tank Exterior

See ***7.5.2 Maintain the Resin Tank.***

7.4 Periodic Inspection and Maintenance Tasks

7.4.1 Inspect the Cover

Visually inspect the cover for traces of resin, cracks, or other damage.

Clean the cover with a non-abrasive microfiber cloth and soapy water or a general purpose cleaner, such as glass cleaner.
In the case of a crack that allows light to pass through the cover, replace the cover.

WARNING

All steps that involve opening the printer and/or investigating internal components should be done by skilled persons under the guidance of Formlabs or a certified service provider.

Contact Formlabs or a certified service provider to receive repair instructions and authorization, including how to disassemble or replace the cover.

7.4.2 Inspect the Display

Visually inspect the display for any traces of resin. Clean the display with a non-abrasive microfiber cloth and general purpose cleaner, such as glass cleaner.

7.4.3 Inspect the Drip Catcher

WARNING

Disconnect the power cable. Moving parts and lead screws present crushing and tangling hazards.

Remove the build platform, resin tank, and resin cartridge to access the drip catcher, which is the area below the resin tank spout or under the resin cartridge dispensing mechanism. Visually inspect the drip catcher. Clean any traces of resin or contamination with isopropyl alcohol (IPA) and paper towels.

7.4.4 Inspect the Shells

Visually inspect the rear, front, side, and top shells for traces of resin or other damage. Clean any traces of resin or contamination with soapy water and paper towels.

7.4.5 Inspect and Lubricate the X- and Z-axes

WARNING

Disconnect the power cable. Moving parts and lead screws present crushing and tangling hazards.

Wear clean gloves to handle the lead screw and lubricant.

To inspect the X-axis:

1. Manually rotate the X-axis lead screw.
2. As the LPU housing moves right and left, listen, look, and feel to check for areas that emit noise or where the carrier sticks or move less smoothly.
3. Visually inspect the X-axis to ensure that no debris or foreign objects obstruct the lead screw or path of motion.
4. Visually inspect the X-axis to ensure that lubricant covers the full length of the threads.

To inspect the Z-axis:

1. Manually rotate the Z-axis lead screw.
2. As the build platform carrier moves up and down, listen, look, and feel to check for areas that emit noise or where the carrier sticks or move less smoothly.
3 Visually inspect the Z-axis to ensure that no debris or foreign objects obstruct the lead screw or path of motion.
4. Visually inspect the Z-axis to ensure that lubricant covers the full length of the threads.

In the case that the screw is missing lubricant or if the X- or Z-axis emits intermittent noises when printing, lubricate the lead screw.

To lubricate the X- or Z-axis lead screw:

1. Remove the build platform and resin tank.
2. Place a clean low-fiber paper towel over the tank carrier and LPU housing.
3. Remove old and dirty grease from the lead screw using a paper towel.
4. Apply a light layer of lithium grease evenly along the lead screw. Apply the lubricant directly from the container or by dabbing lubricant onto the lead screw with a gloved hand.
5. Manually rotate the lead screw.
   a. Z-axis: As the build platform carrier moves up and down, listen, look, and feel to check for areas that emit noise or where the carrier sticks or moves less smoothly.
   b. X-axis: As the LPU housing moves right and left, listen, look, and feel to check for areas that emit noise or where the carrier sticks or moves less smoothly.
6. Wipe excess lubricant from the lead screw with a microfiber cloth or low-fiber paper towel.
7. Reconnect the power cable.

7.5 Planned Maintenance Procedures

For detailed guidance and visual assistance, search on **support.formlabs.com.**
Maintenance tasks shall be done according to the following plan:

Task	Frequency	Section
Update the firmware	When PreForm indicates a new firmware version is available	5.1
Replace the resin tank	Replace when wear on the film begins to affect print quality	5.2
Replace the resin cartridge	When the cartridge is empty, after 1 liter of printing	5.4
Filter the resin	When you can visually see particles in the tank	5.3

7.5.1 Update Form 3B+ Firmware

Formlabs regularly releases updated firmware to fix bugs and improve functionality. Review the PreForm and firmware release notes to learn more about the improvements that come with each version's release.

7.5.2 Maintain the Resin Tank

NOTICE

Spill hazard. Resin may spill over the tank walls if the resin tank tilts more than 5–10°. Hold the resin tank level with two hands. To inspect and clean the underside of the tank, empty the resin tank and/or take care to avoid spilling resin outside the tank. Sharp and metal tools can damage the dual-layer film in the resin tank and affect print quality. Do not use sharp or metal tools in the resin tank. Use only the tank tool to clean the inside of the resin tank.

To inspect the Resin Tank interior:

1. Use the tank tool to inspect the resin and the film. See ***7.6 Cleaning after a failed print,*** steps 1–3.
2. Check for the following issues that may lead to print failures or any excessive wear that requires replacing the tank:
   - cured resin on the film
   - debris or failed prints in the resin
   - punctures, cuts, or gouges in the film
3. Check that the mixer and float are properly installed in the tank case. See ***6.3.4 Insert the Resin Tank and Mixer.***
4. Follow cleaning instructions to remove cured resin, failed prints, debris, and settled pigment. For moderate wear or scratches on the film, use the Layout toolbar in PreForm to print outside the worn or scratched area. In the case of excessive wear or scratches on the film, replace the tank.

To inspect the Resin Tank exterior:

1. Visually inspect the film on the underside of the tank for fingerprints, dust, contamination, and scratches, which cause the laser light to diffuse and lead to print failures or inaccuracies.
2. Use cleaning instructions to remove any fingerprints, dust, or contamination on the film before printing.

To clean the Resin Tank:

- Print failures:
  – See ***7.6 Cleaning after a Failed Print.***
- Debris or contamination in the resin:
  – See ***7.5.3 Filter the Resin.***
  – Clean, debris-free resin helps avoid print failures, which may damage the tank.
- Settled pigment in the resin: Resin pigment can settle onto the film. To supplement the mixer's function, slide the tank tool against the film to remove settled pigment.
- To clean the underside of the film:
  1. Apply a small amount of clean IPA to a PEC*PAD.
  2. Wipe the surface of the film to remove contamination or resin.
- To clean the Resin Tank frame exterior:
  3. Use a paper towel to clean resin from the exterior of the tank frame.
  4. Keep the sides of the tank clean and free of resin.
  5. Avoid resin on the underside of the film, because the contamination may result in print failures and/or damage to the roller holder.

To replace the Resin Tank:

1. Remove the build platform.
2. Hold the side walls of the resin tank.
3. Gently pull - away from the printer and upward – the resin tank to release the tank from the tank carrier.
4. Store the resin tank in the tank case with the lid installed. To dispose of the resin tank, see ***7.7 Disposal of resin.***
5. To install a new resin tank, see ***6.3.4 Insert the Resin Tank and Mixer.***

7.5.3 Filter the Resin

For detailed guidance and visual assistance, search on **support.formlabs.com.**

To filter resin:

1. Suspend the paint or oil filter (with a “fine” or ~190 micron mesh size) above an opaque plastic container suitable for storing resin. Use a ring stand to reduce the risk of spilling resin.
2. Wear gloves to remove the tank and mixer. Place the mixer aside on a protected surface.
3. Hold the edge of the tank, taking care not to touch the tank’s film.
4. Tilt the resin tank with the spout aligned directly above the filter.
5. Pour the resin through the filter, into the disposable container.
6. Gently scrape the surface of the resin tank to pull resin toward the spout.
7. Once all resin passes through the filter, pour the resin back into the tank. To dispose of the used filter, see ***7.7 Disposal of resin.***

7.5.4 Remove and Replace the Cartridge

For detailed guidance and visual assistance, search on **support.formlabs.com.**

To replace the cartridge:

1. Press the vent cap closed.
2. Hold the cartridge handle.
3. Lift the cartridge out of the printer.
4. Store or dispose of the cartridge. For detailed guidance and visual assistance, search on **support.formlabs.com.**
5. To install a new resin cartridge, see ***6.3.8 Insert the Resin Cartridge.***

NOTICE

Store the cartridge upright with the valve cover installed to protect storage surfaces from resin.

7.6 Cleaning after a failed print

WARNING

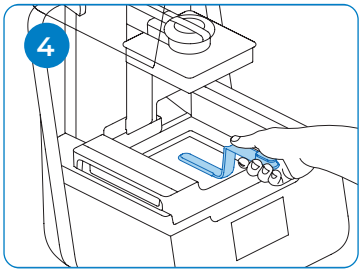
Resin may cause skin irritation or an allergic skin reaction. Wear gloves when handling liquid resin or resin-coated surfaces. Wash skin with plenty of soap and water.

NOTICE

Sharp and metal tools can damage the film in the resin tank and affect print quality. Do not use sharp or metal tools in the resin tank. Use only the tank tool to clean the inside of the resin tank.

A failed print may leave small, partially-cured pieces of resin floating in the tank or hard cured resin stuck to the film in the base of the tank. Inspect the tank after every print. Remove debris after a failed print.
Optional: Remove the resin tank from the printer.
Place the resin tank in the tank case.

1. To remove debris from the resin tank:
2. Separate the top and bottom parts of the tank tool. Place the top part aside.
3. Prepare several paper towels nearby to collect cured and uncured resin.
4. Rest the long edge of the tank tool on the film inside the resin tank. Skim the surface of the film. Search for obstructions that indicate cured resin stuck to the film.



   a. To remove cured resin:
   b. Slide the long edge of the tool under the edge of the cured resin.
   c. Pry with moderate pressure. Slide or pry from different angles or increase pressure to detach cured resin from the film’s surface. The cured resin detaches.
   d. Rest the cured resin on the blade of the tank tool.
   e. Lift the cured resin out of the resin tank.
      1. If the tank tool cannot hold the cured resin:
      2. Attach the top part of the tank tool to the bottom part.
      3. Squeeze the cured resin between the two ends.
   f. Rest the cured resin on the paper towel. 4
5. Dispose of cured resin. See ***7.7 Disposal of resin.***
6. Clean the tank tool and work area.

7.6.1 To clean the tank tool:

1. Apply clean IPA to a clean paper towel.
2. Wipe the surface of the tank tool to remove resin.
3. Allow the tank tool to air dry.

Or:

1. Rest the tank tool in the Form Wash basket.
2. Set Form Wash to clean for 5 minutes.
   Increase the time for solvent that is less fresh.
3. Allow the tank tool to air dry after washing.

7.7 Disposal of resin

Liquid resin (whether pure liquid, dissolved in alcohol, or partially cured) may be classified as hazardous waste and shall be disposed of with care.

7.7.1 Disposing of empty resin containers:

In the United States, empty resin containers are considered “RCRA empty” by EPA standards and can be thrown in the garbage as regular waste.
Optional – Triple rinse the cartridge with fresh IPA to empty the resin cartridge of traces of excess resin.
Add the resulting dirty IPA to your solvent waste stream in accordance with governmental regulations.

7.7.2 To dispose of a resin tank:

1. Remove the resin tank.
2. Transfer or dispose of the remaining resin.
3. Pour the resin from the old tank to the new tank or another container. If there is debris or cured parts in the resin, filter the resin before transferring it to a new tank.
    a. Pouring resin back into the original cartridge may risk contaminating the cartridge with cured resin pieces or debris, which can cause print failures.
4. Use a paper towel to wipe any remaining resin off the old tank.
5. Place the old tank in sunlight (a window sill is fine) or UV light to cure excess resin, and dispose of properly once cured.

7.7.3 Disposing of liquid resin:

To dispose of pure resin (resin that has not been cured or dissolved in alcohol), add this waste to your chemical disposal stream.

7.7.4 If you do not have a chemical disposal stream:

1. Pour a small amount of resin into a labeled, resin-compatible container.
2. Leave the container outside, exposed to sunlight to cure for 1–10 days. Expose resin to 405 nm light and heat for the most effective curing. The liquid resin cures to solid material when exposed to light and heat.
3. Dispose of the fully-cured resin and container in the trash.

7.7.5 Disposing of cured resin or cleaned parts:

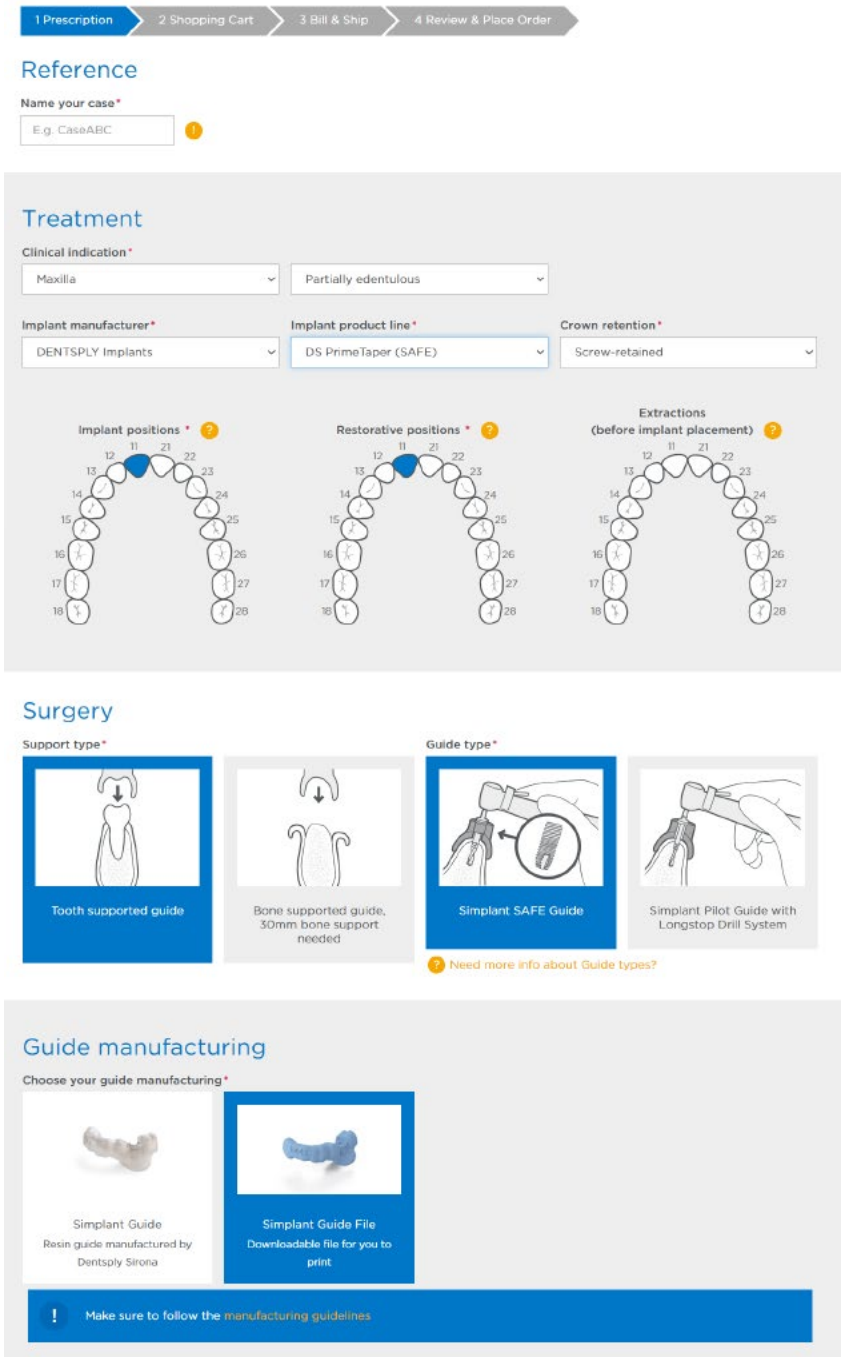
Discard cleaned parts and cured (hardened) resin with household items as trash. Cleaned
parts and cured resin cannot be recycled.

8. Creating a new Simplant® order for your case

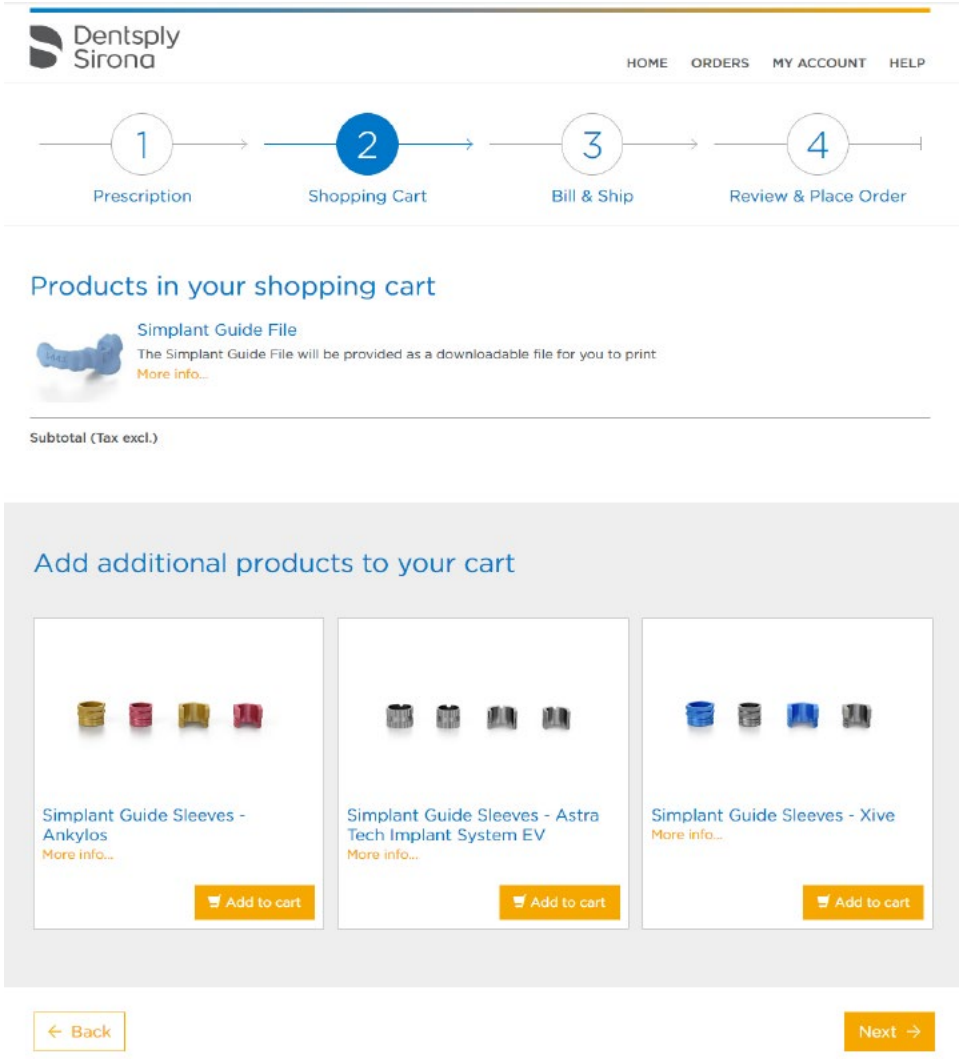
The first step in ordering a Simplant Guide File is to request a Simplant Guide for your implant planning in the Simplant Pro software or to create a Simplant Planning Service order on **www.orderdigitalsolutions.com**

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.

9. 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.

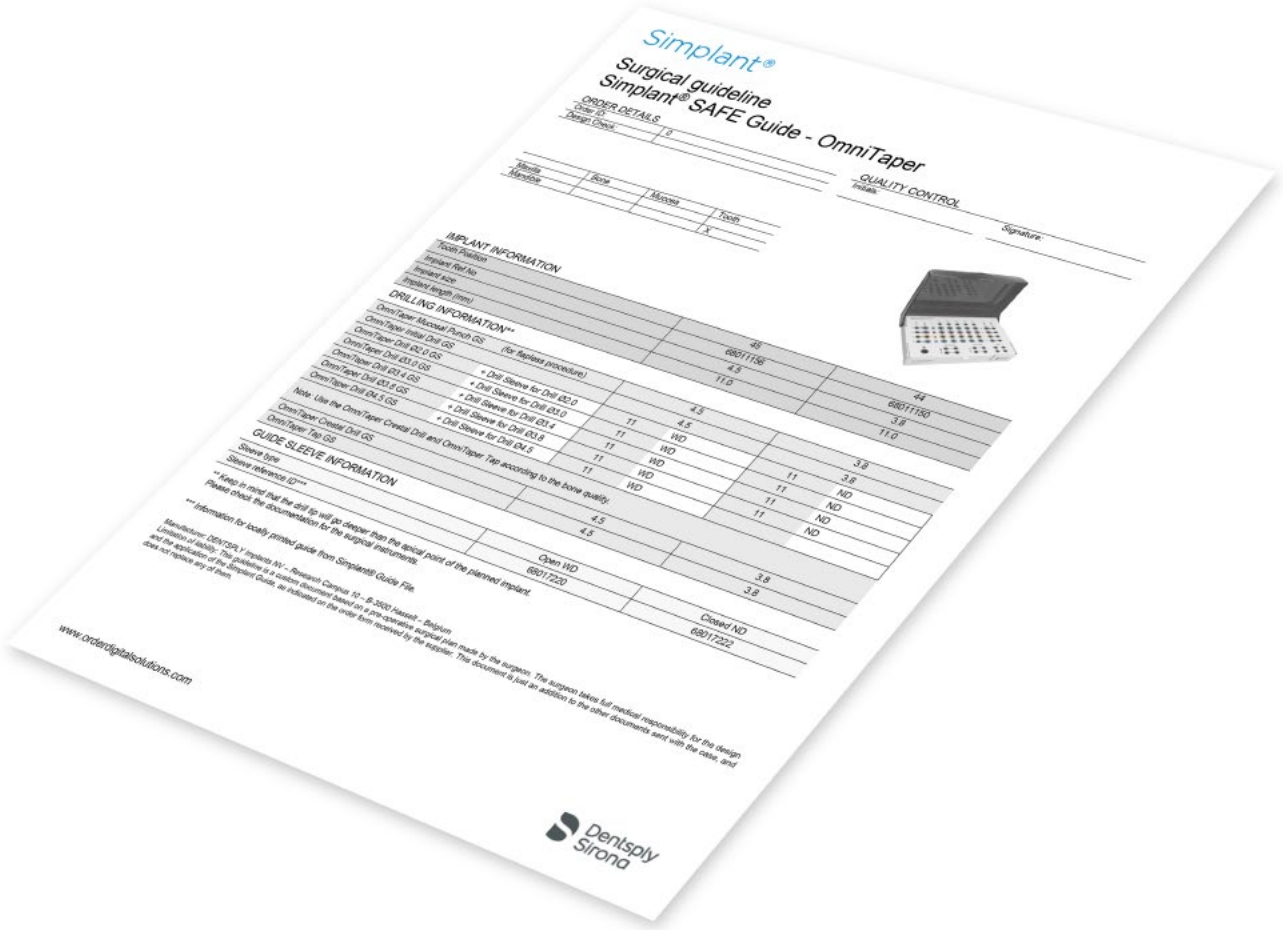
Download and save the Simplant Guide File and the surgical guideline on your computer:

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.



10. Importing Simplant® Guide File into PreForm

10.1 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.

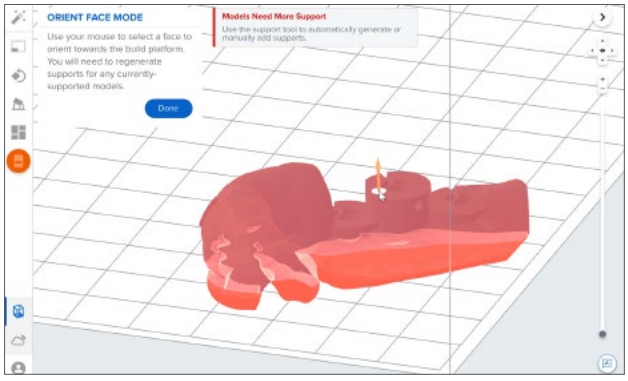
10.2 Import Model Files into PreForm

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

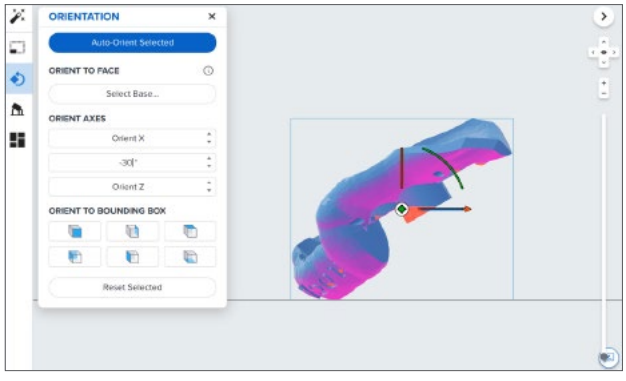
The build volume (145 × 145 × 185 mm) is displayed by the PreForm software after the printer (Form 3B+) is selected. The build volume indicated by the PreForm software can be used for placement of the Simplant Guide File.

10.3 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.

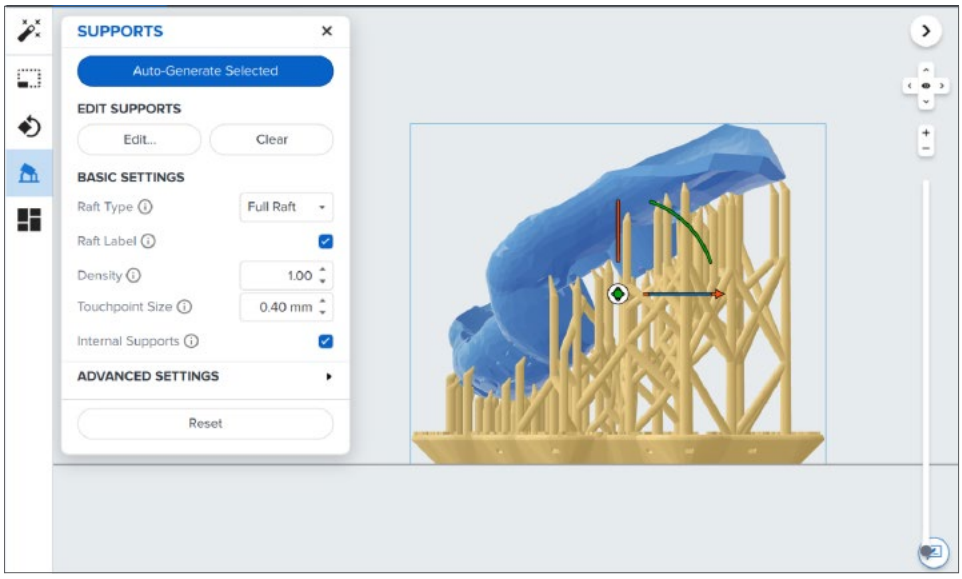


Subsequently, the face surrounding the sleeve should be oriented under an angle of + or - 30° with the build plate to optimize accuracy. The distal ends of the guide should be pointing away from the build plate, wherever applicable.



10.4 Generate Supports

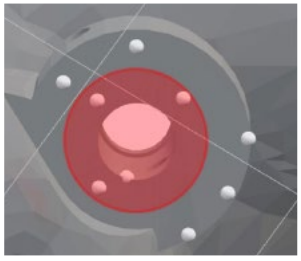
Generate supports using PreForm's auto-generation feature with the default settings.



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.

10.5 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.

10.6 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.

11. Printing the surgical guide

11.1 Print

11.1.1 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.

11.1.2 Pre-Print Checks

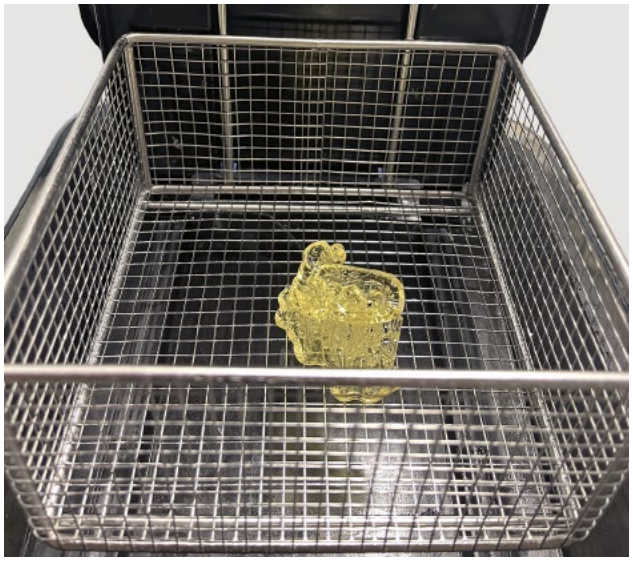
The printer checks the following before each print job:

- 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.

11.2 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. Set to wash for 20 minutes to wash all remaining liquid resin before post-curing.

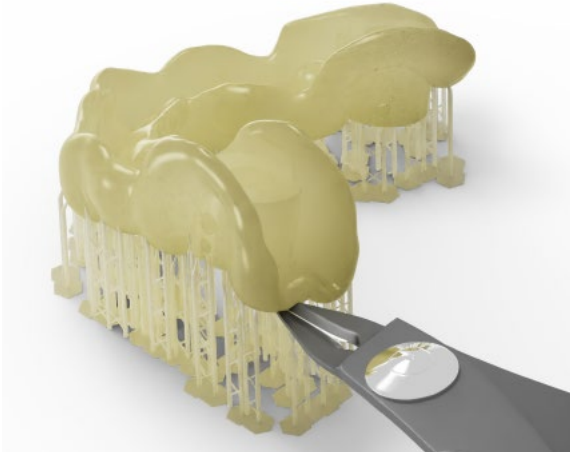


11.3 Drying

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.

11.4 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.



11.5 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:

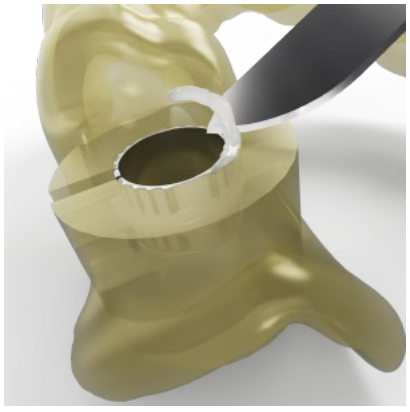
An applicable gluing tip is the Tapered Tip 20 Gage – Pink (PK50). Insert the gluing tip in the gluing channel on buccal and lingual side of the guide sleeve opening and add adhesive. Make sure the adhesive is flowing completely around the guide sleeve. Excessive adhesive that is flowing out of the gluing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



11.6 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.

11.7 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.**

11.8 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.

11.9 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).

12. 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.

The Instructions for Use – IFU – is available on the Dentsply Sirona website.

Go to: http://ifu.dentsplysirona.com

Click on “IFU – Current valid”. You can then choose “Filter Results” to search the Simplant brand or you can use “Simplant Digital Guide” in the free text search field.

12.1 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

12.2 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.

Dentsply Sirona