



Indirect Bonding Trays

Using MED625FLX

The indirect bonding (IDB) tray vastly improves speed and precision in the bracket installation process. It replaces the traditional tooth-by-tooth method which necessitates an hour or more of discomfort for the patient and a high level of skill and precision. With IDB trays, the orthodontist prints the tray, fixes the brackets on the tray all at once ahead of time. This efficient installation process reduces the time patients spend in the chair to as little as 15 minutes.

Stratasys MED625FLX™ is a flexible, clear, biocompatible material. Printed on Stratasys 3D printers it enables orthodontists to work digitally, ensure faster production times, and optimize placement and bonding. 3D printed IDB tray eliminate steps like molding, thermoforming, and manual installation along with the corresponding opportunities for human error.

To ensure that the IDB tray parts printed with MED625FLX are biocompatible, make sure that you follow the instructions in the Biocompatibility Requirements document.

The following section describes recommendations and tips for achieving optimum quality and mechanical properties with MED625FLX.



1. Traditional Treatment

Dental braces (also known as braces, orthodontic cases, or cases) are devices used in orthodontics to align and straighten teeth and help position them precisely to a person's bite, while also aiming to improve dental health.

Traditionally, the dental brackets are manually applied tooth by tooth by the orthodontist, making it highly dependent on the dentist's expertise and precision.

2. Manually Produced IDB Tray

Due to recent advancements in this area, a relatively new application was invented called an Indirect Bonding (IDB) tray.

This new dental orthodontic appliance is used for bracket installation and aims to improve the procedure's efficiency, precision and the overall workflow.

The technique optimizes fixed appliance installation at the orthodontic clinic, ensuring precise bracket positioning.



3. Semi-Digitally Manufactured IDB Tray

The availability of 3D printing means IDB tray producers now have a means of partially digitizing the workflow of IDB tray production. Using CAD software, the clinic/lab can design a set-up arch, which includes digitally placed brackets. The technician digitally places brackets on the digital arch. Once printed, the technician can thermoform the IDB as in the manual IDB tray process above.



4. Direct-Printed 3D Printed IDB Tray

With Stratasys's new MED625FLX material and CAD design software, it is now possible to design a digital IDB tray, 3D print it, and then use it in the clinic/lab. This digital IDB tray process enables much faster production times by omitting many of the necessary steps required in traditional or regular IDB production.

Both manually produced and 3D printed IDB trays are used similarly during the actual treatment, resulting in reduced chair time from upwards of an hour to as little as 15 minutes.

The 3D printed IDB tray delivers a highly accurate transfer system to hold the brackets in the exact position needed for the most accurate bond possible. The optimal placement is planned digitally and incorporated into the IDB tray and human error is minimized as the brackets are held in place during bonding.

IDB Tray Production

1. The traditional manually produced (non-3D printed) IDB tray production is a multi-phase process with many different steps that involves different tools to create an accurate appliance. It begins with creating a stone model of the patient's teeth, usually done by a dental impression.



This is followed by meticulously positioning each bracket on the model precisely where it should go on each tooth.



This entire process is completed by several thermoforming steps.

2. The 3D printed IDB tray process is much faster and more accurate. If the orthodontist has an intraoral scanner, there is no need to create a mold. This removes error that can be introduced during scanning. Bracket placement is done digitally, rather than manually. The labor- intensive thermoforming process is removed altogether. The IDB tray can be 3D printed directly from the digital file.

Supported Printers and Software

| | |
|------------------------------|---|
| Printer | Objet260 Dental , Objet260 Dental Selection , Objet500 Dental Selection |
| Printer Software | 29.2.0.25308 D46, 58.2.0.25310 D48 |
| Printing Mode | HS, DM (HQ is not supported.) |
| Objet Studio Software | Version 9.2.11.6831 and above |
| Support Material | SUP705™ |

Design Considerations

When printing IDB tray parts from MED625FLX, part height along the Z-axis must not exceed the following measurements:

- in HS (high speed) mode: 40 millimeters.
- in DM (digital material) mode: 18 millimeters

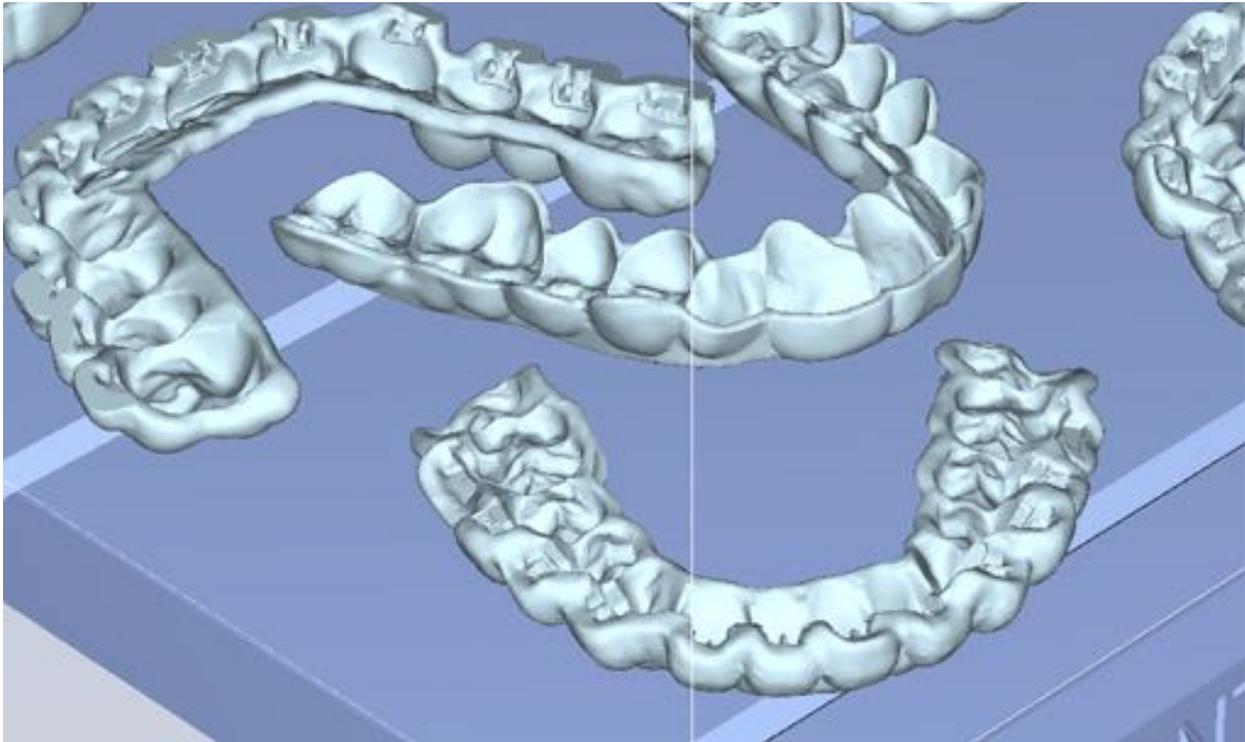
This limitation is applicable to MED625FLX parts only. Therefore, whenever there are MED625FLX parts on the tray that exceed the measurements listed above, a warning message appears, and the print job is stopped.

In DM mode, if the tray contains MED625FLX parts that are within the limitation and other parts (such as MED620) that are higher than 18 millimeters, the print job is not stopped.

Preparing Trays for Printing

The arrangement of the IDB trays on the build tray and other factors affect the duration of printing and the quality of the printed part. Follow these instructions for best efficiency and utilization of the tray.

- In Objet Studio™, insert the STL files one by one until the tray is filled. After placing all the IDB parts on the build tray, use the **Automatic Placement** feature for optimal tray arrangement and part positioning.
- Position the parts so that teeth are facing downwards, and the hollow area is facing upwards, as shown below.



Teeth facing downwards.

Technical Specifications

Software Requirements:

1. IDB Tray Design

- a. The 3Shape Indirect Bonding Module software is one of the most common options used by orthodontists to digitally design an IDB tray.



Image courtesy of 3Shape.

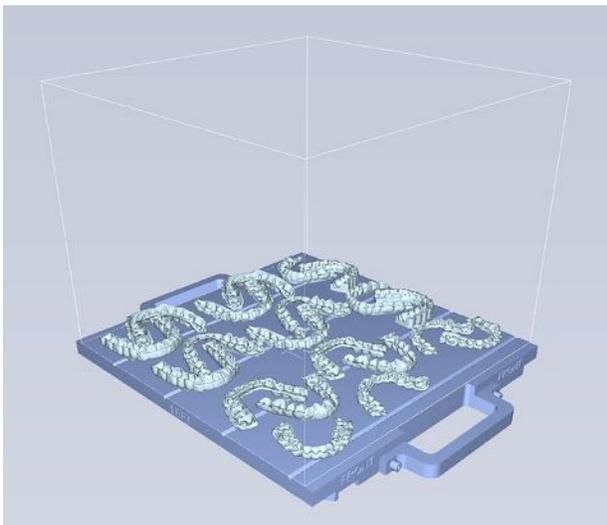
The software allows automated bracket and wire placement, all done digitally on the scanned model. Once completed, the final IDB tray file can be exported as an STL file format.

- b. Besides 3Shape's solution, there are other IDB tray design solutions, such as CAD BRACE SOFTWARE by FABDENT, ArcadLab by by ARCAD and others.

NOTE: As with manually produced IDB trays, most designers will print the tray in three sections or a full arch and then separate the arch into sections. This facilitates bonding operations, as working with a complete arch can be cumbersome and difficult to manage.

2. Automatic Optimized 3D Print Tray Arrangement

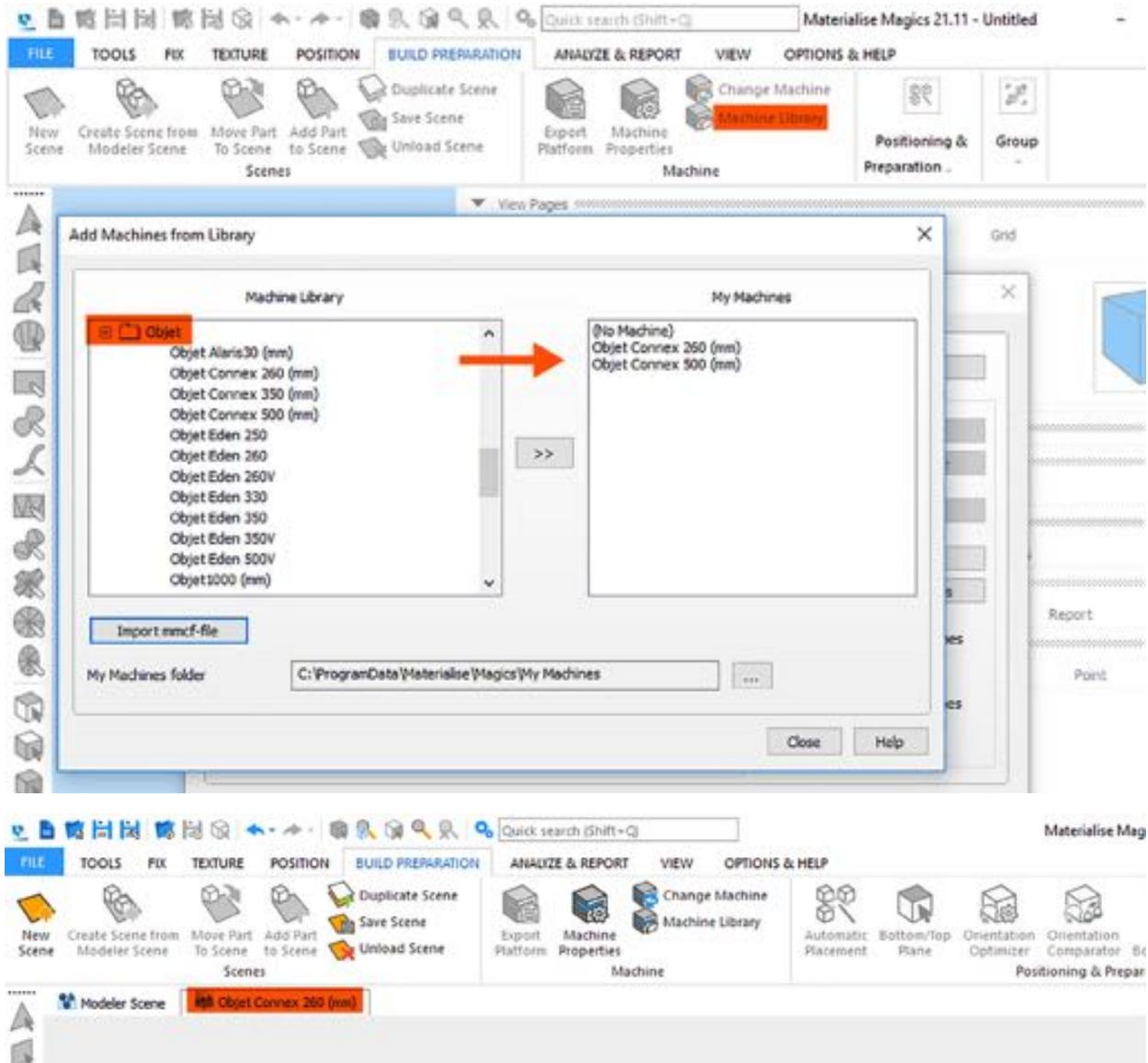
- a. Materialize Magics 3D Print Suite can be used in order to maximize tray utilization, so a maximum number of parts can be printed all at once.



An Example for Optimal Objet260 Dental / Dental Selection Tray

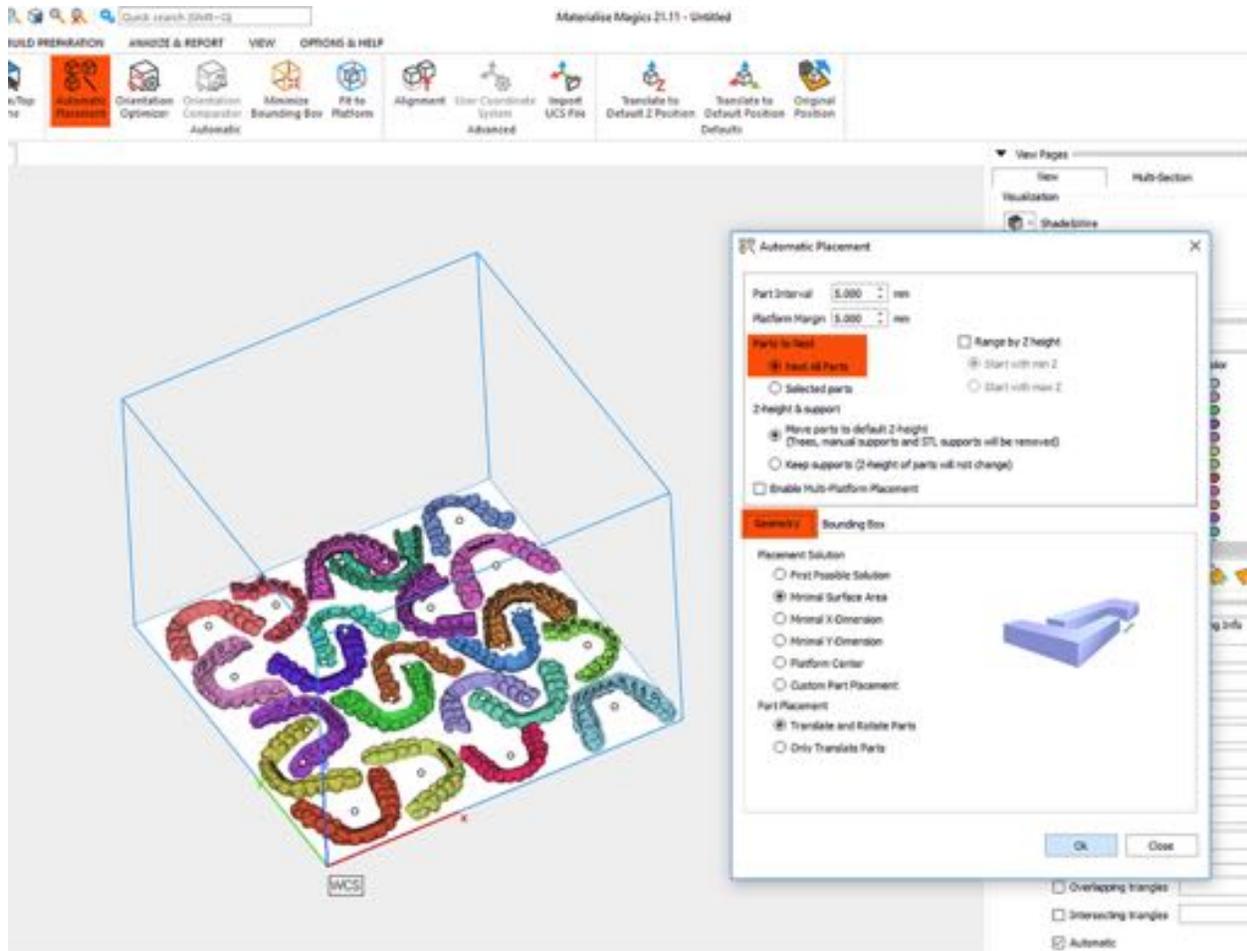
Magics software can nest the parts using the **Build Preparations** tab.

In this section the user can add Strasys (Objet) printers by clicking on the **Machine Library** and choosing the Objet Connex 260/500 (mm) printer.



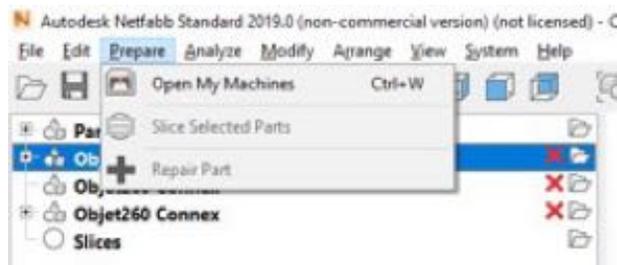
Once the printer is added, all STL files can be loaded and efficiently placed on the tray using the **Automatic Placement** → **Geometry tab** → **Nest All Parts**. The user can modify **Part Interval** and **Platform Margin** to try and utilize the tray.

Once the printer is added, all STL files can be loaded and efficiently placed on the tray using the **Automatic Placement** → **Geometry tab** → **Nest All Parts**. The user can modify **Part Interval** and **Platform Margin** to try and utilize the tray.



Using this method, the Objet 260/500 tray can be utilized to provide on average up to 23/60 IDB trays respectively, on a single tray, depending on the part sizes.

- b. Netfabb® additive manufacturing can also provide automatic placement with even better nesting capabilities. Similar to Magics, the user can load Stratasys (Objet) printers by clicking on **Open My Machines** -



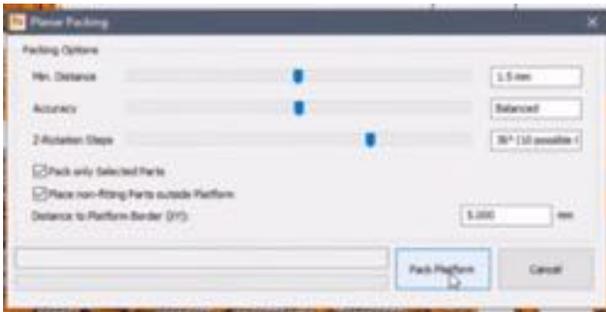
And selecting **Objet260/500 Connex** from the **Stratasys** category -



Once all parts are loaded to the tray, the user can click on **Planar Packing** button -

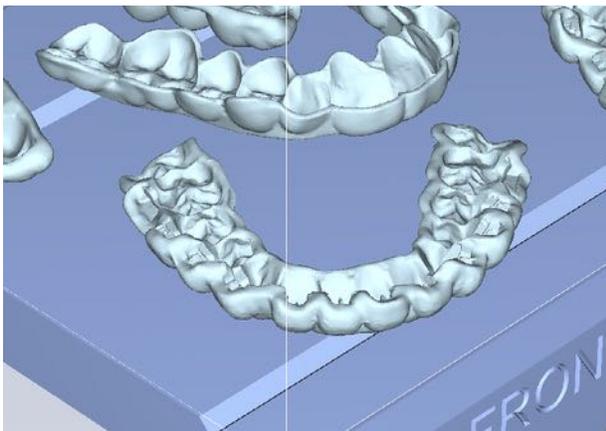


And then on **Pack Platform** to nest all parts efficiently -



c. Comments

- Regardless of the nesting method performed, it is important to note that for minimal support consumption, it is best to orient the IDB tray with teeth facing down as shown here:



- Once the trays are properly nested, it is best to save the tray as a single STL file (and not as separated STLs). That will allow for easy import process on the Stratasys Objet260 Dental, Objet260 Dental Selection or Objet500 Dental Selection printers.

Material Requirements

MED625FLX is the recommended material for printing IDB trays due to its mechanical and biocompatible properties. It is a clear material with flexible mechanical properties.

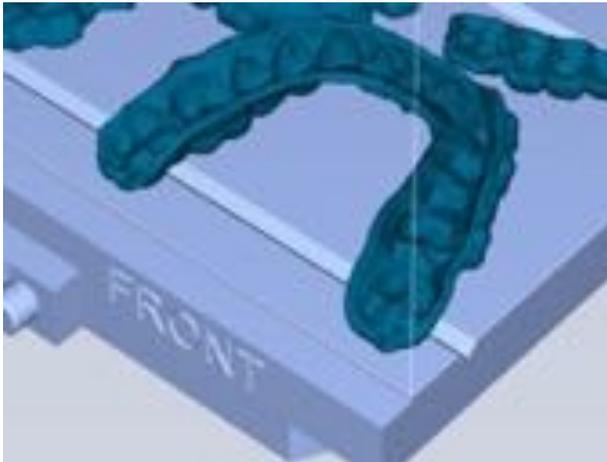
Biocompatibility Requirements

MED625FLX is a biocompatible material like MED610™ and MED620, hence is suitable for prolonged skin contact (more than 30 days) and short-term mucosal-membrane contact (up to 24 hours).

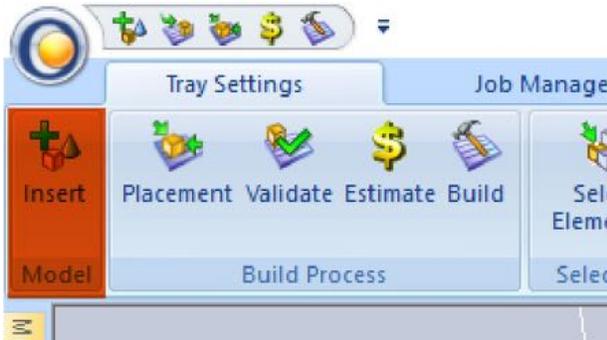
Please follow the same steps in the 'Printing Biocompatible Parts on PolyJet™ 3D Printers with MED625FLX guide.

Stratasys Printer Modes

1. Objet260 Dental, Objet260 Dental Selection and Objet500 Dental Selection Printers can support IDB tray printing with the new MED625FLX material.
 - a. MED625FLX is a flexible material which is compatible with 28µm layer thickness only, which means that HS and DM are the available modes.
 - b. HS mode can be considered when assigning a printer to print just IDB trays to have a better throughput, whereas DM should be used when printing mixed trays (parts from different materials on the same tray/job).
 - c. Support material compatible with MED625FLX is SUP705. For minimal support consumption, it is best to print the IDB trays with teeth facing down as shown here:



2. Once the nested tray is prepared, after saving a single STL file, the user can simply load it using the Insert button.
 - a. MED625FLX is a flexible material which is compatible with 28 μ m layer thickness only, which means that HS and DM are the available modes.
 - b. HS mode can be considered when assigning a printer to print just IDB trays to have a better throughput, whereas DM should be used when printing mixed trays (parts from different materials on the same tray/job).
 - c. Support material compatible with MED625FLX is SUP705. For minimal support consumption, it is best to print the IDB trays with teeth facing down as shown here:



Then the tray can be printed immediately and there is no need for any further modifications with the Objet Studio software.

Printing Preferences

Use the following printing mode as applicable:

- HS mode – use this mode when printing trays with only MED625FLX parts for better throughput.
- DM mode – use this mode when printing mixed trays (trays that contain parts made of MED625FLX and other materials).

Removing the Support Material

Proper handling of IDB tray parts printed with MED625FLX is required to ensure that the parts are not damaged when cleaning them in the waterjet.

To avoid tears and damage to the IDB tray parts:

- Hold the jet nozzle at approximately 20 centimeters (7.8 inches) when using standard water pressure (750 PSI/50 bar). If the pressure is less than the standard, you can hold the nozzle closer to the part.
- Do not apply pressure for too long to any area of the part.

Furthermore, follow the Support Removal instructions detailed in the Biocompatibility Requirements document to ensure that the parts are biocompatible.

Comments

The MED625FLX material is limited in its Z height when printing in DM/HS mode to 18mm / 40mm respectively. Upon tray preparation, a message to the user will be presented indicating this limitation. Nevertheless, in case the user ignores it and tries to build a tray higher than the compatible Z heights indicated, the print job will not continue and an error message will appear on the screen.

Note: this limitation will only impact parts planned to be printed with MED625FLX. When using DM mode, if other parts planned to be printed on the same print job/tray from different materials (e.g., MED620) are higher than 18mm, the print job will not be stopped in any way, making it relevant to MED625FLX parts only.

Post Process

1. Water Jet

- a. The MED625FLX is a flexible material which is more sensitive to tearing than regular Vero materials.

In general, the IDB tray geometry is delicate and therefore extra caution is required when removing support with a high-pressure outlet such as a waterjet device.

- We recommend soaking the parts in a container with tap water for 2-3 hours before using the waterjet device. The soak decreases the force needed to remove any SUP705 residue and provides a well-cleaned part. It is important to verify the part is fully cleaned (verification can be done by visual inspection) to enable its biocompatibility properties (support material is not bio-compatible).
- It is best to hold the waterjet nozzle a safe distance from the model – approximately 20cm is considered safe when using a standard water pressure of 750 Psi/50 Bar. If the water pressure used is less than the standard (i.e., due to infrastructure limitations), the safe distance should be decreased accordingly. It is also recommended to move the nozzle with quick movements (not fixed on a single location for more than 2 seconds), to avoid tearing and/or other damage due to high water-model impact.

2. Effegi Brega (Automated support cleaning machine, available in Europe)

- a. The Effegi Brega (EB) machine can provide automatic support removal.

Once the parts are printed, the user can load them to the EB and click on the **Double cycle running** option (8 mins. runtime). More current versions of the EB system include a timer system that can be used instead of **Double cycle running**.

| Colour combinations and meaning of led signals | | | | |
|--|-------|-------|-------|---|
| No. | LED A | LED B | LED C | Machine status / alarm |
| 1 | ● | ○ | ○ | Machine ready for use |
| 2 | ○ | ● | ○ | Single cycle running |
| 3 | ○ | ● | ● | Double cycle running |
| 4 | ● | ● | ● | Triple cycle running |
| 5 | ● | ● | ○ | Lid open |
| 6 | ● | ● | ● | Warning: service required within 30 hours |
| 7 | ● | ● | ● | Alarm: call technical service |

Once the cycle is over, the IDB trays should be unloaded from the EB machine and be inspected for any support residue, especially in the bracket locations. In the event there is residue remaining, the waterjet device can be used to quickly remove them.

Placing Brackets into the IDB Tray

IDB trays built from MED625FLX are flexible enough to allow easy placement of the brackets into the tray while firm enough to retain the brackets during transportation. Place each bracket into its predesigned slot. The brackets will be held in the IDB tray until the dentist places them on the patient's teeth.

A model of the patient's mouth can be printed simultaneously on the same tray as the IDB tray using Stratasys multi-material printing capability. This model can be used to confirm the fit and easy application of the IDB onto the patient's mouth prior to shipping the IDB tray to the patient. The combined IDB tray and model can be shipped together to further ensure that the brackets do not come out of the IDB tray.

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Biocompatible Clear MED610



MED610 is a transparent, biocompatible PolyJet™ material medically approved for bodily contact. The material is designed for both medical and dental applications and is approved for permanent skin contact (more than 30 days) and limited mucosal membrane contact (up to 24 hours).

MED610 has been evaluated and deemed acceptable for the following biological risks

| Test | Standard |
|-------------------------------|----------------------|
| Cytotoxicity | EN ISO 10993-5:2009 |
| Irritation | EN ISO 10993-10:2013 |
| Delayed-type hypersensitivity | EN ISO 10993-10:2013 |
| Genotoxicity | EN ISO 10993-3:2014 |
| Chemical characterization | EN ISO 10993-18:2009 |
| USP Plastic Class VI | USP 34 <88> |

| Property | Standard / Procedure | Value |
|-------------------------|-----------------------|--|
| Tensile Strength | D-638-03 | 50 – 65 MPa (7,252 – 9,427 psi) |
| Elongation at Break | D-638-05 | 10 – 25% |
| Modulus of Elasticity | D-638-04 | 2,000 – 3,000 MPa (290.1 – 435.1 ksi) |
| Flexural Strength | D-790-03 | 75 – 110 MPa (10,878 – 15,954 psi) |
| Flexural Modulus | D-790-04 | 2,200 – 3,200 MPa (319.1 – 464.1 ksi) |
| HDT @ 0.45 MPa | D-648-06 | 45 – 50 °C (113 – 122 °F) |
| HDT @ 1.82 MPa | D-648-07 | 45 – 50 J/m (113 – 122 °F) |
| Izod Notched Impact | D-256-06 | 20 – 30 (0.37 – 0.56 ft-lb/in) |
| Water Absorption | D-570-98 24HR | 1.1 – 1.5% |
| Tg | DMA E | 52 – 54 °C (126 – 130 °F) |
| Shore Hardness | Scale D | 83 – 86 D |
| Rockwell Hardness Scale | Scale M | 73 – 76 M |
| Polymerized Density | ASTM D792 | 1.17 – 1.18 (g/cm ³) (0.676 – 0.682 oz/in ³) |
| Biocompatibility | prEN ISO 10993-1:2017 | Skin contact – permanent (>30 days) Mucous membrane – short term (up to 24 hrs) |
| Sterilization Methods | --- | Gamma sterilization ¹ using a dose of 25–50 kGy Steam sterilization ² for four (4) minutes at 132 °C (270 °F) with fractionated pre-vacuum |
| Support Removal Type | --- | WaterJet or soluble |

Biocompatible Clear MED610



| System Availability | Minimum Layer Thickness Capability | Support Structure | Available Colors |
|-----------------------------------|---|---|------------------|
| Objet30 Prime™ | 16 microns (0.0006 in.) | SUP705 (WaterJet removable) SUP706 (soluble) | Transparent |
| Objet30 Dental Prime™ | 16 microns (0.0006 in.) | SUP705 (WaterJet removable) SUP706 (soluble) | Transparent |
| Objet260 Dental™ | 16 microns (0.0006 in.) | SUP705 (WaterJet removable) SUP706 (soluble) | Transparent |
| Objet Eden260VS™ | 16 microns (0.0006 in.) | SUP705 (WaterJet removable) | Transparent |
| Objet Eden260VS Dental Advantage™ | 16 microns (0.0006 in.) | SUP705 (WaterJet removable) | Transparent |
| Objet260/500™ Connex1 | 16 microns (0.0006 in.) | SUP705 (WaterJet removable) SUP706 (soluble) | Transparent |
| Objet260/500 Dental Selection™ | 16 microns (0.0006 in.) (high quality) | SUP705 (WaterJet removable) SUP706 (soluble) | Transparent |
| Objet260/350/500™ Connex3 | 16 microns (0.0006 in.) | SUP705 (WaterJet removable) SUP706 (soluble) | Transparent |

All data provided herein, which is related to consumables, was collected from specific specimens and test conditions and is provided for information only. Characteristics may vary if different specimens and test conditions are applied. Unless expressly provided in writing, no warranties are made and warranties of merchantability or fitness for a particular purpose are expressly disclaimed.

¹ Gamma radiation may result in color change in the part.

² Allow the parts to cool down to room temperature before removing them from the autoclave. Flash autoclave may result in part deformations and changes to the flexural strength.

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Vero™ ContactClear

Vero™ContactClear is a transparent, biocompatible PolyJet™ material medically approved for bodily contact. The material is designed for both medical and dental applications and is approved for permanent skin contact (more than 30 days) and limited mucosal membrane contact (up to 24 hours).

Vero™ContactClear has been evaluated and deemed acceptable for the following uses:

| Test | Standard | | |
|---|-------------------------------|--|--|
| Cytotoxicity | EN ISO 10993-5:2009 | | |
| Irritation | EN ISO 10993-10:2013 | | |
| Delayed-type hypersensitivity | EN ISO 10993-10:2013 | | |
| Genotoxicity | EN ISO 10993-3:2014 | | |
| Chemical characterization | EN ISO 10993-18:2009 | | |
| USP Plastic Class VI | USP 34 <88> | | |
| Property | Standard / Procedure | J8 Series Value | J55/35 Value |
| Tensile Strength | D-638-03 | 50 – 65 MPa (7,252 – 9,427 psi) | 40 – 55 MPa (5,800 – 8,000 psi) |
| Elongation at Break | D-638-05 | 10 – 25% | 5 – 20% |
| Modulus of Elasticity | D-638-04 | 2,000 – 3,000 MPa (290.1 – 435.1 ksi) | 2,200 – 3,000 MPa (320,000 – 435,000 psi) |
| Flexural Strength | D-790-03 | 75 – 110 Mpa (10,878 – 15,954 psi) | 70 – 85 MPa (10,000 – 16,000 psi) |
| Flexural Modulus | D-790-04 | 2,200 – 3,200 Mpa (319.1 – 464.1 ksi) | 2,000 – 2,500 MPa (290,000 – 365,000 psi) |
| HDT @ 0.45 MPa | D-648-06 | 45 – 50 °C (113 – 122 °F) | 45 – 50 °C (113 – 122 °F) |
| HDT @ 1.82 MPa | D-648-07 | 45 – 50 J/m (113 – 122 °F) | 45 – 50 °C (113 – 122 °F) |
| Izod Notched Impact | D-256-06 | 20 – 30 (0.37 – 0.56 ft-lb/in) | 20 – 30 J/m (0.375 – 0.562 ft-lb/in) |
| Water Absorption | D-570-98 24HR | 1.1 – 1.5% | 1.1 – 1.5% |
| Tg | DMA E | 52 – 54 °C (126 – 130 °F) | 52 – 54 °C (126 – 129 °F) |
| Shore Hardness | Scale D | 83 – 86 D | 83 – 86 (Scale D) |
| Polymerized Density | ASTM D792 | 1.17 – 1.18 (g/cm ³) (0.676 – 0.682 oz/in ³) | 1.17 – 1.18 g/cm ³ |
| Biocompatibility and Sterilization | | | |
| Biocompatibility | ISO 10993-1:2018 | <ul style="list-style-type: none"> • “Surface device” with “long term” (> 30 days) contact to “intact skin” • “Surface device” with “limited” (≤ 24 hours) contact to “mucosal membranes” • “Surface device” with “limited” (≤ 24 hours) contact to “breached or compromised surfaces” • “External communicating device with “limited” (≤ 24 hours) contact to “tissue/bone/dentin” • “Implant device” with “limited” (≤ 24 hours) contact to “tissue/bone”. | |
| Sterilization Methods | USP <88> USP Plastic Class VI | Gamma sterilization ¹ using a dose of 25–50 kGy Steam sterilization ² for four (4) minutes at 132 °C (270 °F) with fractionated pre-vacuum | |

Vero™ ContactClear

| System Availability | Minimum Layer Thickness Capability | Support Structure | Available Color |
|---------------------|--|---|--------------------------------------|
| J8 Series | Min High speed Mode: 14 microns (0.00055 in.) Super High Speed mode 55 microns (0.002 in.) | SUP705 (water jet removable) SUP706B (soluble) | <input type="checkbox"/> Transparent |
| J55™ Prime | 18 microns (0.0001 in.) | SUP710 (WaterJet removable) | <input type="checkbox"/> Transparent |
| J35™ Pro | 18 microns (0.0001 in.) | SUP710 (WaterJet removable) | <input type="checkbox"/> Transparent |

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