TrueDent™–Instructions for Use (IFU)

Overview

The Stratasys® TrueDent™ biocompatible materials enable the fabrication of monolithic, high quality, functional, and aesthetic dental appliances, including removable dentures, denture teeth, denture bases, crowns, and bridges. With PolyJet™ technology and multi-material printing capabilities, TrueDent dental appliances are durable, full-color devices with gradient colors and transparencies that accurately mimic color variations of gingiva and natural teeth and offer a high level of personalization. TrueDent materials are available in 5 color materials and 1 support material: TrueDent™Cyan, TrueDent™Yellow, TrueDent™Magenta, TrueDent™White, TrueDent™Clear, TrueDent™Support. This document describes instructions for use regarding safety and environmental information, as well as manufacturing instructions and post-processing procedures for achieving optimum quality with TrueDent materials and ensuring that the dental appliances printed with TrueDent are suitable for the intended use.

Upon request, a printed copy of the IFU will be provided within 7 calendar days at no additional cost.

Indications for Use

Stratasys TrueDent is a light-curable resin indicated for the fabrication of dental appliances, including removable full and partial dentures, denture bases, denture teeth, bridges, crowns, inlays, onlays, and veneers in dental laboratories. The material is an alternative to traditional heat-curable and auto-polymerizing resins. Stratasys

TrueDent is intended exclusively for professional dental work.

Contraindications

No known contraindications. TrueDent materials should not be used for any purpose other than for 3D-printed dental appliances. Any deviation from this instruction for use may have a negative effect on the chemical and physical quality of dental appliances. In case of an allergic reaction, seek medical attention.

Warnings

Do not substitute any of the components of the system, including the TrueDent materials, 3D printer, waterjet unit, curing unit, software, and materials used in the post-printing and curing steps. Use only those specifically identified in this labeling. For compatible components, contact your Stratasys service provider.

In case of serious incident - please contact Stratasys Ltd. and the relevant authority

Precautions

The patient should be surveyed for potential anatomical changes prior to the placement of the product.

Safety Information

TrueDent materials should be used only by the specified intended users and as described in the Indications for Use above. Wear personal protective equipment (protective gloves, goggles) during post-processing. After contact with eyes rinse thoroughly with water immediately and consult a physician. After contact with skin wash immediately with water and soap. Please look at the SDS for additional information regarding the material.

Storage Conditions, Expiry Date, and Reuse of Material

Store the resin material in its original packaging at temperatures between 15°C and 27°C (60°F and 77°F), in a cool, well-ventilated, dry, and dark area away from potential sources of heat, open flames, sunlight, or other chemicals. Signs of premature polymerization in material cartridges include bulging, leaking, the emission of heat, and unusual odor. Exposure to heat can cause resin to gel in the cartridges. Store in a combustible storage area. Store in accordance with local regulations.

Before any use of the cartridge please compare the expiration date on the label with the expiration date presented in the printer.

In any case of discrepancy, please do not use the cartridge.

Please do not use expired resin. To avoid any doubt, the structure of the expiration date is YYYY-MM-DD. Printing attempts with products that have passed their expiration date will be interrupted by the printer, causing an error. DO NOT REUSE. Do not reuse empty containers.

Disposal

Dispose of the cartridges and resin according to local regulations.

In case of damaged and/or unintentionally opened packaging and/or if the packaging is exposed to environmental conditions outside of those specified – Do not use and dispose according to local regulations.

Cleaning Instructions

TrueDent dental appliances should be cleaned with nonchemical products. Dental appliances made from TrueDent cannot be sterilized.

Material Composition

Acrylates, Methyacrylates, Methacrylated oligomers and monomers, photoinitiators, colorants/dyes, fillers, and absorbers.

Manufacturing Instructions

For detailed instructions including recommendations and tips, refer to the 'TrueDent Materials Best Practice', available on the Stratasys Support Center on: support.stratasys.com

Materials and Equipment

- Source file (3MF, STL, VRML, and OBJ)
- TrueDent™ materials (colors):
  TrueDent™Cyan,
  TrueDent™Yellow,
  TrueDent™Magenta,
  TrueDent™White,
  TrueDent™Clear.
- Support Material: TrueDent™ Support
- Stratasys Printer: J5 DentaJet®

- GrabCAD™ Software
- Objet WaterJet **or** another approved alternative
- Caustic soda (2% sodium hydroxide, NaOH)
- Cure Chamber: TrueDent™ Cure **or** another approved alternative
- Glycerol (purity >99.5%)
- Container for glycerol
- Tweezers

Supported Printers

TrueDent materials can be used on Stratasys J5 DentaJet 3D printers. For detailed setup, operation, and maintenance instructions, refer to the 'Stratasys J5 Series 3D Printer User Guide', available on the Stratasys Support Center on: support.stratasys.com

Design Parameters

When designing monolithic dentures in the CAD/CAM software, make sure the base thickness is greater than 2.5mm in the final product. To compensate for material loss during polishing, it is recommended to design the upper arch denture base with a minimum thickness of 2.75mm, lower arch denture base with a minimum thickness of 3mm.

Additionally, ensure that there is no gap between the base and the teeth. The adhesive bonding stage is not applicable to TrueDent printed dentures**.**

Preparing for Printing

Follow these guidelines when preparing for printing:

- Load the J5 DentaJet printer with the TrueDent materials, including the TrueDent support material.
- Prepare the source file in a relevant format, such as 3MF, STL, etc.

  The source file should not contain sensitive and confidential patient health information to protect patients' privacy.
- Use GrabCAD Print™ to import the CAD file(s) and then select the following:
  - Select the tooth shade, as needed.
  - Select the gingiva shade, as needed.
  - Finalize tray arrangement. For optimal results, use automatic placement. In the case of manual placement, for optimum quality, orient the parts so that they are parallel to the tray. Part orientation on the Z-axis should not exceed a 45-degree tilt.
- Use a matte surface finish.
- Send the file to the printer.

Starting the Print

To start printing, follow the instructions on the printer interface screen. For more information, refer to the **'**Stratasys J5 Series 3D Printer User Guide', available on the Stratasys Support Center on: support.stratasys.com**.**

The product should not be used after the expiration date. Printing attempts with product after expiration date will be interjected by the printer causing ERROR.

Post-Print Processes

Proper support material removal and post-print treatment of the 3D printed dental appliances is important for ensuring that the dental appliances are clean, biocompatible, and suitable for the intended use.

It is recommended to start the cleaning process soon after removing the parts from the printer. TrueDent parts do not require cooling time prior to being removed from the printer.

Follow these steps for support removal and post-print treatment of TrueDent dental appliances:

1. Clean printed parts thoroughly and remove all support material using an Objet WaterJet **or** another approved alternative.
   For detailed instructions and alternative cleaning and support removal methods, refer to the Stratasys Support Center on: support.stratasys.com
2. Soak the parts in a container with a freshly prepared 2-percent solution of caustic soda (sodium hydroxide, CAS 1310-73-2), for 30 minutes at room temperature (No stirring is required).
3. Wash the parts to remove the caustic soda and any support residue.

   For detailed instructions and alternative cleaning and support removal methods, refer to the Stratasys Support Center on: support.stratasys.com
4. Visually inspect the printed parts and make sure that no support material residue remains on the part. if you recognize any support residue repeat step 3
5. Place the parts teeth facing upwards in a transparent glass container(s) with glycerol (purity >99.5%, CAS 56-81-5).
6. Place the container(s) in the TrueDent Cure chamber **or** another approved alternative
7. When using the TrueDent™ Cure - expose the parts to UV light at 80ºC (176ºF) for 60 minutes.

   When using another alternative curing system, refer to the relevant product guide, available at the Stratasys Support Center on: support.stratasys.com

   Use plastic tweezers to remove the parts from the container after the process.
8. Rinse the parts thoroughly in tap water.

Denture Cleaning Instructions for Patients

The denture can be cleaned by the patient with water and a soft brush. After cleaning, the denture should be dried and not soaked in liquid. Abrasive or whitening agents in toothpaste can damage the surface of the denture.

Disclaimer

The customer acknowledges the contents of this document and that Stratasys parts, materials, and supplies are subject to its standard terms and conditions, available on http://stratasys.com/legal/terms-and-conditions-of-sale, which are incorporatedherein by reference.

Stratasys | www.stratasys.com | info@stratasys.com

Importer:

Stratasys, Inc.

7665 Commerce Way Eden
Prairie, MN 55344
+1 888 480 3548 (US Toll-Free)
+1 952 937 3000 (Intl)

Manufacturer:

Stratasys Ltd.

1 Holtzman St.,
Science Park, PO Box 2496Rehovot 76124, Israel
+972 74 745-4000

Rx Only

© 2021 Stratasys Ltd. All rights reserved. Stratasys and Stratasys logo, PolyJet, GrabCAD Print, J5, DentaJet, and TrueDent are trademarks of Stratasys Ltd. and/or its subsidiaries or affiliates and may be registered in certain jurisdictions.All other trademarks belong to their respective owners.

Description	Symbol Title	symbol Number	Standard Number and Title	Symbol
Indicates the medical device manufacturer	Manufacturer	5.1.1	ISO 15223-1	
Indicates the date after which the medical device is not to be used	Use-by date	5.1.4	ISO 15223-1	
Indicates the manufacturer's batch code so that the batch or lot can be identified	Batch code	5.1.5	ISO 15223-1	
Indicates the manufacturer's catalogue number so that the medical device can be identified	Catalogue number	5.1.6	ISO 15223-1	
Indicates a medical device that needs protection from light sources	Keep away from sunlight	5.3.2	ISO 15223-1	
Indicates the temperature limits to which the medical device can be safely exposed	Temperature limit	5.3.7	ISO 15223-1	
Indicates a carrier that contains unique device identifier information	Unique device identifier	5.7.10	ISO 15223-1	
Indicates the entity importing the medical device into the locale	Importer	5.1.8	ISO 15223-1	
Indicates the entity distributing the medical device into the locale	Distributor	5.1.9	ISO 15223-1	
Indicates the model number or type number of a product	Model number	5.1.10	ISO 15223-1	
To identify the country of manufacture of products	Country of manufacture	5.1.11	ISO 15223-1	
Indicates a medical device that needs to be protected from moisture	Keep dry	5.3.4	ISO 15223-1	
Indicates that the original medical device information has undergone a translation which supplements or replaces the original information	Translation	5.7.8	ISO 15223-1	
Indicates a medical device that requires a prescription (or use by a physician) in the United States	Prescription device	(c)(1)(i)F	21 CFR 801.15	
Indicates that medical device may cause serious eye damage	Corrosion	GHS05	29 CFR 1910.1200	
Indicates that medical device may cause skin irritation and an allergic skin reaction	warning	GHS07	29 CFR 1910.1200	
General prohibition sign	General prohibition sign	P001	ISO 7010	
Indicates the need for the user to consult the instructions for use	Consult instructions for use or consult electronic instructions for use	5.4.3	ISO 15223-1	