FREEPRINT® crown

ENGLISH

CAUTION STATEMENT
Caution: Federal Law restricts this device to sale by or on the order of a physician Device.

INDICATIONS FOR USE
FREEPRINT® crown is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces.
The **FREEPRINT® crown** material is used for fabricating temporary or permanent restorations such as crowns and bridges, inlays, onlays, veneers and full crown restorations. It also can be used for the fabrication of denture teeth for dental prostheses.
Fabrication with **FREEPRINT® crown** requires a computer aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer, and post-cure unit.

PATIENT TARGET GROUP
Persons being treated in the context of a dental procedure.

INTENDED USERS
Dentist, dental technician

SPECIAL MANUFACTURING REQUIREMENTS
The printing machine and post-curing unit should be set-up, validated and maintained according to their labelling and instructions for use.
FREEPRINT® crown is only intended to be used with the identified compatible equipment in Annex 1.

ENVIROMENTAL CONDITIONS
Processing temperature 23 °C ± 2 °C.

CLEANING KIT
Rinse bathtubs, flush cutter, paper towel, squeeze bottle for isopropyl alcohol, scraper

PROCESSING
- ► The use of **FREEPRINT® crown** is only approved when applied with the compatible devices mentioned in this instruction for use as oulined in Annex 1.
- ► Generate the object (STL-file) using a commercial CAD software, which is intended for dental applications.
- ► The properties of the final product depend, among other things, on post-processing. Correct post-exposure is important for biocompatibility. Therefore it must be ensured that the exposure device is in an orderly condition and that the moulds are completely cured (observe manufacturing process).
- ► After storage, the material in the bottle should be shaken intensively and homogenized with a bottle roller before use.
- ► Do not use heat-based methods for disinfection or sterilisation. This could possibly deform the workpiece.
- ► **FREEPRINT® crown** is applied for the production of permanent crowns in the anterior and posterior area, inlays, onlays, denture teeth and veneers. It is also used for long-term provisional crowns and up to 3-unit bridges with an intermediate pontic. When designing, observe the following requirements for finished restorations:

Minimum wall thickness	Connector cross-section for pontics	Layer thickness for printing
occlusal 1.5 mm circularily 1.5 mm cervical 1.0 mm	at least 16 mm²	50 µm

- ► **BONDING OF PERMANENT DENTURE TEETH**
  After removing denture base (see additional IFU FREEPRINT®denture for details) and denture teeth from the build platform and completing the cleaning process, leave the construction components in their green state (uncured). Place the printed denture teeth into the corresponding tooth sockets on the printed denture base and check teeth fitting. Apply the liquid FREEPRINT® denture into the tooth sockets by using a small brush or a syringe applicator and bond denture teeth by exposing into xenon photoflash unit (Otoflash G171) with 400 flashes under inert gas conditions (nitrogen). After assembling, post-cure the fully printed denture (base and teeth combined) into a xenon photoflash unit (Otoflash G171) with 2x1800 flashes under inert gas conditions (nitrogen).
- ► Polish the surface mechanically. Prepolish by means of rotating brushes and prepolishing paste, highgloss by means of buffing wheels and highshine polishing paste for composite.

SAFETY INFORMATION
- ► Only for the specified intended use by trained specialists.
- ► Avoid direct contact with the liquid material and the components before post-curing, especially in pregnant/ breastfeeding women. Irritating to eyes and skin (sensitization possible).
- ► Wear personal protective equipment (protective gloves, goggles) when handling the uncured material.
- ► Wear suitable personal protective equipment (protective gloves, goggles, face mask) when finishing the cured material.
- ► If resin gets into your eyes immediately rinse and consult a doctor.
- ► After contact with skin wash immediately with water and soap.
- ► Biocompatibility is only guaranteed with complete polymerisation.
- ► Refer to the relevant safety data sheet for hazard and safety information.

NOTES
- ► DETAX does not accept liability for any damage caused by misuse of the impression material.
- ► Always keep container tightly sealed, immediately close the container carefully after each use.
- ► Read and understand the safety data sheet!

MRI Safety Information
FREEPRINT® crown is MR Safe as it is composed of materials that are electrically nonconductive, nonmetallic and nonmagnetic.

STORAGE
FREEPRINT® crown is to be stored dry (at 15 °C - 28 °C) and protected from light. Minimal influence of light can already induce polymerisation.
Please cover the material vat with its lid or a glass plate to protect material from contamination.

CONTRAINDICATIONS
Contains (meth)acrylics, phosphine oxides and silanized dental glass. Overall share of inorganic fillers (particle size 1.5 µm) totals 20–40 % by mass.
Some ingredients of **FREEPRINT® crown** may cause allergic reactions in predisposed persons. In such cases refrain from using the product.
FREEPRINT® crown only insert intraorally in completely polymerised state.

ADVERSE EFFECTS
Product may cause allergic reactions.

DISPOSAL
Disposal of the contents/container must be carried out in accordance with the local/regional/national and international regulations.

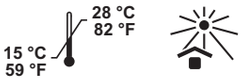
MATERIAL PROPERTIES

Colour*, **	Viscosity*
A1, A2, A3, B1, B3, C2, D3, BL	1400–2200 mPas
Flexural strength**	**Depth of cure****
≥ 100 MPa	≥ 3 mm
Water sorption**	**Water solubility****
< 40 µg/mm³	< 7.5 µg/mm³

* applies to liquid resin; **applies to cured objects

Processing:
at 23 °C ± 2 °C

Storage:



Ordering information:

FREEPRINT® crown 385

500 g	
A1	**04365**
A2	**04367**
A3	**04369**
B1	**04371**
B3	**04373**
C2	**04377**
D3	**04379**
BL	**04375**
1.000 g	
A1	**04364**
A2	**04366**
A3	**04368**
B1	**04370**
B3	**04372**
C2	**04376**
D3	**04378**
BL	**04374**

The colors A1, A2, A3, B1, B3, C2, D3, BL are similar to VITA Shade Guide.

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MANUFACTURING PROCESS

Mixing
Before filling resin into the reservoir, the material must be mixed. Use a bottle roller or mix/shake it by hand. Inadequate mixing could cause deviations of colour and print failures.

Filling of printer
Fill 3D printing resin in the reservoir of the printer. The 3D printing resin can remain in the vat for a maximum of 14 days (maximum 10 print cycles). It is not allowed to pour 3D printing resin from the reservoir of the printer back into the resin bottle.

Construction process
After storage, the material in the bottle should be shaken intensively and homogenized with a bottle roller before use. Generate a print job complying with printer and material parameters. For setting up the printer follow the instructions for use of the printer. Data preparation and fabrication of the support structure according to the instructions of the CAD software manufacturer. Remaining print resin material after printing is not allowed to be poured back into the resin bottle.

Post-processing
If possible, post-processing should commence immediately following with this construction process. After raising the platform, a drip time of approx. 10 minutes is recommended. Remove the platform from the printer and remove the construction components using appropriate device (e.g., knife or spatula). Carefully remove excess resin using a light flow of compressed air.

Cleaning
The construction components should be cleaned in two steps with isopropyl alcohol (purity ≥ 98%) using an ultrasonic bath. For additional suitable cleaning unit refer to Annex 1, item "CLEANING EQUIPMENT".

1. Clean the construction components for 1 minute in a reusable isopropyl alcohol (purity ≥ 98%) using an ultrasonic bath. Then carefully remove the construction components from the support structure.

2. The precleaned construction components must be cleaned thoroughly for 1 minute using a fresh isopropyl alcohol (purity ≥ 98%) with an ultrasonic bath. Prior to post-exposure, check the construction components for residues. Then blow off with compressed air. After cleaning the surface of the construction components must no longer be sticky (dry) and not shiny (matt).

Post-exposure
Store the washed construction components for 30 minutes at room temperature before post-exposure.
Post-exposure is performed with a suitable curing unit (See Annex 1, item„CURING LIGHT EQUIPMENT")

CAUTION: The use of **FREEPRINT® crown** is only approved when applied with the compatible devices mentioned in this instruction for use. Any unauthorized changes to the process equipment, parameters, or software may result in a device that is out of specification.

FINISHING
Finish the construction components by using conventional dental methods and instruments.

CEMENTATION OF PERMANENT RESTORATIONS
The finished permanent restorations can be attached by using self-adhesive cements (e.g., RelayX Unicem, 3M Espe) or composite cement with a primer (e.g., Variolink Esthetic DC, Ivoclar Vivadent). Please follow the instructions and indications of the corresponding suppliers.

SYMBOL EXPLANATION

Reference number and graphic	Title	Description	Reference
5.1.1	Manufacturer	Indicates the medical device manufacturer.	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
5.1.4	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
5.1.5 LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
5.1.6 REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
5.3.2	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
5.4.3	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
℞ Only	Prescription only	Requires a prescription in the United States of America Caution: In the United States of America, federal law restricts this device to sale or use by, or on the order of, a physician.	USA Code of Federal Regulations 21CFR Part 801 § 801.109 (b)(1)
MR	Magnetic resonance	The freeprint crown is MR Safe.	FDA Guidance document: Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment dated May 20, 2021.
	Caution	The uncured material is considered as hazardous subtance.	29 CFR 1910.1200 Occupational Safety and Health Standards
	This way up	This is the correct upright position of the distribution packages for transport and/or storage.	ISO 780:2015(E) Packaging-Distribution packaging- Graphical symbols for handling and storage of packages

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