RadTec Medical Device, Inc.

Improving Patient Care One Patient at a Time

Lollipop BiteBlock™ Disinfection and Sterilization Instructions With Material Spec Sheets

170 Glenn Way #5, San Carlos CA, 94070

1(844) Rad-Tec1 RadTecMD.com

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Disinfection and Sterilization Instructions

*This product is a Non-Sterile item. It has been disinfected using a germicidal solution in a clean environment however, it is not certified as Sterile. Follow the sterilization instructions below to sterilize each device prior to use.

Each device is certified for a total of 24 hours mucosal membrane contact, this is time in contact added up over the course of treatment. Each device is intended solely to be used by one patient for the duration of their treatment. Following use, discard the device following all local and state regulations.

Disinfect thoroughly before use in accordance with all hospital and facility requirements.

Clean after each use: Rinse the device in warm water with mild soap as needed, do not leave to soak for extended periods of time. Remove any debris, saliva, and other particulates. Once clean, rinse with warm water and allow to dry prior to storage, autoclave sterilization, or gamma-ray sterilization.

Sterilization: steam sterilization in autoclave, or gamma-ray sterilization. Steam sterilization in an autoclave can be done with the printed guide in a pouch. Recommended autoclave cycles are 15 minutes at 121 °C or 3 minutes at 138 °C.

Disinfecting: Clean with non-chemical products. If chemical disinfection methods are necessary, ethanol solution is recommended.

- The device is to be placed in the mouth during planning and treatment for radiographic procedures as well as radiotherapy treatments
- Not intended for use across multiple patients
- Materials are FDA certified
- Devices are pending FDA approval 510(K) exempt
- Each device may be autoclaved multiple times as needed

Dental SG 3D printing material has been tested on biocompatibility according to the ISO 10993-1:2009 at NAMSA, Chasse sur Rhönein France. Devices printed with Dental SG on a Formlabsprinter and post-cured according to the instructions for use, meet the applicable requirements of ISO 10993-1 and USP Class VI, and are biologically safe.

- Cytotoxicity test Testreport 177178
- Sanitization Testreport 168884
- Irritation Testreport 168883
- Systemic toxicity (acute toxicity) Testreport 168888
- Genotoxocity Testreport 170296

Dental SG is tested at NAMSA, Chasse sur Rhône in France, and is certified biocompatible per EN-ISO 109931:2009/AC:2010:

- Non-mutagenic.
- Non-cytotoxic.
- Not induce any erythema oredema reactions.
- Not a sensitizer.
- Not cause systemic toxicity.

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Certificate of Biocompatibility

We,

Vertex-Dental B.V.
Centurionbaan 190
3769 AV Soesterberg,
The Netherlands

Hereby declare under our sole responsibility that the CE marked product to which this declaration relates,

Formlabs Dental SG
3D printing material

has been tested on biocompatibility according to the ISO 10993-1:2009 at NAMSA, Chasse sur Rhône in France. Devices printed with Dental SG on a Formlabs printer and post-cured according to the instructions for use, meet the applicable requirements of ISO 10993-1 and USP Class VI, and are biologically safe.

The product were tested on:

- Cytotoxicity test	Testreport 177178
- Sensitization	Testreport 168884
- Irritation	Testreport 168883
- Systemic toxicity (acute toxicity)	Testreport 168888
- Genotoxocity	Testreport 170296

The results in these tests show that the product meets the requirements of ISO 10993-1:2009 Biological Evaluation of Medical Devices.

Zeist, April 14, 2016

Rik Jacobs
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Material Spec sheet

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	Postcured	
Flexural Properties		
Flexural Strength	≥ 50 MPa	ISO 20795-1:2013
Flexural Modulus	≥ 1500 Mpa	ISO 20795-1:2013
Hardness Properties		
Hardness Shore D	≥ 80D	per ISO 868:2003
Impact Properties		
Charpy Impact Strength Unnotched	12 – 14 kg/m^2	ISO 179:2010

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Sterilization: Recommended — steam sterilization in autoclave, or gamma-ray sterilization. Steam sterilization in an autoclave can be done with the printed guide in a pouch. Recommended autoclave cycles are 15 minutes at 121 °C or 3 minutes at 138 °C.