RADTEC MEDICAL DEVICES, INC.
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DISINFECTION AND STERILIZATION INSTRUCTIONS

Each IPD is finished as a non-sterile product. The manufacturing process includes disinfection using a germicidal solution prior to packaging. Follow the instructions below to sterilize each device prior to use.

Each IPD is intended to be used for no more that a total of 24 hours mucosal membrane contact, this is cumulative time in a patient's mouth, over the course of treatment. Each IPD is intended solely to be used by one patient for the duration of treatment. Upon completion of the treatment, discard the used IPD following all relevant local and state regulations.

Clean the IPD after each use: rinse with clean water, removing any debris and saliva, before drying thoroughly.

An ethanol based cleaner may also be used, following the manufactures instructions for use, making sure to rinse the IPD thoroughly in clean water ensuring that no cleaning solution is left on the device prior to drying and storage.

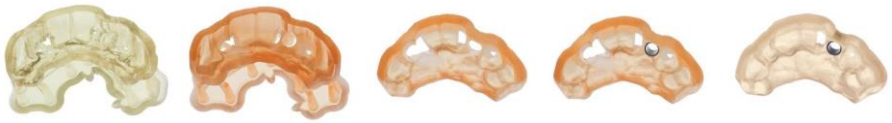
Store in a cool dry place. Avoid excess exposure to light, specifically in the UV spectrum.

- The IPD is to be placed in the patient's mouth for the planning of radiotherapy procedures.
- The same IPD is then to be used through-out the duration of the prescribed treatment regime.
- The IPD is intended for single patient use only.
- A single device is not intended for use across multiple patients.
- Devices are pending FDA market clearance

Prior to first use sterilize and/ or disinfect the IPD in accordance with all hospital and facility requirements.
The following Sterilization and Disinfection methods are recommended.

Sterilization: Steam sterilization in an autoclave can be done with the printed guide in a pouch. Recommended autoclave cycle is: **132°C for 4 minutes prevacuum.**
Disinfecting: Clean with non-chemical products. If chemical disinfection methods are necessary, an ethanol solution is recommended. Follow disinfecting instruction provided by cleaning solution manufacturer. Rinse thoroughly with clean water after cleaning and prior to use. Dry thoroughly prior to storage.

During autoclave sterilization a color change from translucent yellow to translucent orange will occur. Stages from left to right: Printed, Post-cured, Finished,, Sterilized.



Unfinished Cured Finished Sterilized

Raw Material Certifications

The raw material 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.

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

The rad material has been tested on biocompatibility according to the ISO 10993-1:2009 at NAMSA, Chasse sur Rhônein France. Devices printed with *The Material* on a 3D 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.

*More information about *The raw material* is available upon request
**The material* is a generalized name for the actual material used