Recommendations for the Sterilization of restor3d Non-Sterile Implantable Custom Devices and Instrumentation

Description
Custom devices and products manufactured by restor3d fall under the Food and Drug Administration (FDA) custom device exemption contained in Section 520(b) of the Food, Drug and Cosmetic Act. Such custom devices will be provided clean but NON-STERILE. Non-sterile products MUST undergo a sterilization process by the health care provider in order to render the device STERILE prior to implantation.

Custom devices are intended to treat a unique pathology or physiological condition for which no other domestically available device exists. Such devices are assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of the patient. As such, the patient-specificity of the design can result in unpredictable risks due to the potential variability in the design, size, and strength of the device. Sound and ethical surgical practices must be employed in each case. The device type selected by the surgeon, including all design features, must be appropriate for the desired treatment. It is required that the patient is made aware of all risks. Before surgery, it is required that the surgeon become aware of the design features of the implant, the surgical technique required for its placement, and any instrumentation used during implantation.

Materials
Ti6Al4V
Co28Cr6Mo
Stainless Steel Alloy per ASTM F899
Thermoset Polymer (Instrumentation and models)

Note: Interfacing third party hardware may be composed of titanium, titanium alloys, nickel-titanium alloys, cobalt chrome, cobalt chrome alloys, stainless steel alloys, polyethylene, as well as all suture and cement materials.

Indications
restor3d custom devices are specifically manufactured based on a physician's prescription. The devices are intended to be used for the individual patient identified in the prescription and on the device labeling. The devices are to only be used for the indications identified by the surgeon.

Contraindications
restor3d custom devices are not intended for use on those other than the individual identified in the physician's prescription, nor are they intended for use by anyone except the prescribing surgeon. All other contraindications are physician specified.

Warnings
Incorrect placement, alignment, or fixation of restor3d custom devices can lead to unintended loading or conditions that shorten the service life of the implant. The surgeon is responsible for understanding the proper use, placement, alignment, and fixation of the custom device and

should confer with a restor3d representative if they have any questions or concerns.

Polymeric devices MUST NOT be submerged or exposed for extended periods of time in alcohol or any other cleaning solution as it may cause degradation of the material.

Disclaimer

Health care personnel bear the ultimate responsibility for ensuring that any particular packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in a particular health care facility. Testing should be conducted in the health care facility to ensure that requirements and conditions essential to sterilization can be achieved.

In the event that health care personnel fail to properly sterilize the device as required, restor3d does not accept responsibility or liability for any damages or otherwise arising from a lack of sterility of an implantable device supplied in a clean but non-sterile condition.

Cleaning and Decontamination

restor3d custom devices are provided clean, in clean packing products, but not sterile. No further cleaning other than sterilization is required. The integrity of the device may be jeopardized if care is not employed when handling the device, including removal of the implant from its packaging.

If the healthcare facility desires to perform an additional cleaning step prior to sterilization, the following procedure must be followed:

1. Remove the devices from their original packaging using gloved hands. The integrity of the device may be jeopardized if care is not employed when handling the device, including removal of the implant from its packaging.

   Note: All handling must take place with gloved hands in a controlled/clean environment. Take care not to drop devices.
2. Clean the devices as follows:
   - 2.1. Metallic Implants/Instruments (cobalt chrome, titanium alloy, stainless steel)

     Completely submerge the devices for 5 minutes in isopropyl alcohol (minimum 99% concentration). Remove devices and shake off all excess alcohol being sure to remove alcohol as best as possible from crevices and porous regions. Clean compressed air may be utilized if necessary. Allow devices to dry for a minimum of 2 hours prior to sterilization.
   - 2.2. Polymeric Devices (thermoset polymers)

     Generously spray device surfaces with isopropyl alcohol (minimum 99% concentration) and immediately wipe off using a lint free cloth if accessible. For cannulas and other hard to reach areas, shake off excess alcohol or use clean compressed air. Allow devices to dry for a minimum of 2 hours prior to sterilization.

     Note: Polymeric devices MUST NOT be submerged in alcohol or exposed for extended periods of time as it may cause degradation of the material.

Responsibilities of the User
The ultimate responsibility for use of the correct methods suitable for use in sterilization processing lies with the health care personnel. THE PROVIDED PACKAGING MATERIALS ARE NOT TO BE USED DURING STERILIZATION PROCESSING.

The health care facility is responsible for validating and maintaining an environment appropriate for steam sterilization processing and in which sterilization can be achieved. This environment, including the details on the topics of personnel, processing recommendations, care of sterilizers, quality control, and quality process improvement, must abide by the guidelines set forth in ANSI/AAMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities as well as amendments A1, A2, A3 and A4.

The end-user is responsible for selecting permanent interfacing hardware components that are comprised of the compatible materials listed in the “Materials” Section above.

All custom devices are provided complete and in their final form. Therefore, modification to either implants or instrumentation whether it be via drilling, cutting, or otherwise is prohibited.

Storage and Shelf Life
Implantable devices that have been wrapped to maintain sterility must be stored in a constant, well-regulated environment for temperature and humidity and handling must be done in a way that prevents any damage to sterile barrier. Care must be taken to prevent subjecting the devices to any environmental extremes, including both temperature and moisture. Based on the recommendations of the sterile wrap manufacturer, the health care facility should develop an appropriate shelf life for wrapped devices.

Sterility
Custom devices manufactured and supplied by restor3d are provided CLEAN but NON-STERILE. Unless otherwise indicated, these devices MUST be sterilized prior to use and are single use only. Do not reuse. Do not use any component from an opened or damaged package.

The health care facility is responsible for sterilizing and validating sterility of the restor3d custom devices.

restor3d custom devices can be steam autoclaved, and repeated autoclaving will not adversely affect them, unless otherwise noted on the label.

Implants and instruments may be autoclaved using a full cycle. Detailed below is a recommended minimum cycle for steam sterilization of wrapped goods:

- Use a validated, properly maintained and calibrated steam sterilizer following the manufacturer’s recommendations to ensure that the maximum load is not exceeded.
- Effective steam sterilization can be achieved using the following protocol:
    - Sterilizer type: prevacuum
    - Preconditioning pulses: 4

- Temperature: 132°C
- Full cycle time: 4 minutes
- Dry time: 70 minutes
- Open Door time: 30 minutes
- Cool-down time: 30 minutes
    - Note: Cool-down phase should be completed outside of the chamber on a wire-rack.
    - Do not rapidly cool polymeric instruments.

- Store sterile packaged instruments in a manner that provides protection from dust, moisture, insects, vermin, and extremes of temperature and humidity.

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