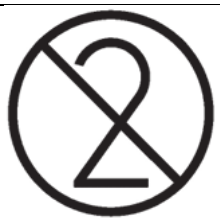
Instructions for Use and Important Medical Information – Custom and Compassionate Use Implantable Products, Instrumentation and Accessories.

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN LICENSED BY THE LAW OF THE STATE IN WHICH THE PRACTITIONER PRACTICES TO USE OR ORDER THE USE OF THE DEVICE.

For Symbols Glossary, please refer to: https://restor3d.com/resources/instructions	
	
	For an electronic version of this IFU, please refer to www.restor3d.com For a print copy or to have an electronic copy emailed to you contact the manufacturer.
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Description: restor3d's custom and compassionate use implants, instrumentation, and accessories are intended for patients with conditions that, in the prescribing surgeons' expert opinion, cannot be treated using products cleared for use by the FDA that are currently domestically available on the market.

Custom implants, instrumentation, and accessories fall under the Food and Drug Administration (FDA) custom device exemption contained in Section 520(b) of the Food, Drug and Cosmetic Act. Compassionate use implants, instrumentation and accessories fall under the FDA investigational device exemption contained in section 520(g).

Such devices are manufactured on a case-by-case basis on the explicit order of a physician to accommodate the unique needs of the patient. It is required that the prescribing physician make the patient aware of all risks. For specific details related to an individual case please refer to the provided case-specific surgical plan.

Indications: restor3d custom and compassionate use devices are specifically manufactured for an individual patient on the order of a physician. The indication for use can be found on the device labeling, specifically the case-specific surgical plan. The devices are only to be used for the indications identified by the surgeon for the patient specified on the labeling.

Contraindications: restor3d custom and compassionate use 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, or for use other than the intended use shown in the Surgical Plan of restor3d custom and compassionate use 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.

All restor3d custom devices MUST NOT be used for any other patient. Patient identity should be verified using the device labeling provided.

Materials: restor3d custom implants may be manufactured from a variety of materials listed below. Materials are selected based on patient need, implant design specifications and indication.

Abbreviation	Material
Ti6Al4V	Titanium Alloy (ASTM F2924-14)
CoCr	Cobalt Chrome Alloy (ASTM F3213-17, F1537-20)
SS	Stainless Steel (ASTM F899-20)
iPoly	UHMWPE (ASTM F648-21)
iPoly XE	UHMWPE (with Vitamin E) (ASTM F2695-12)
MED610/ MED615	Biocompatible Rigid Thermoset Polymer
Nylon 12	DuraForm Polyamide Thermoplastic
Radiopaque Polymer	Radiopaque Formlabs Thermoset Polymer

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 suture and cement materials.

Storage and Handling: restor3d custom implants, instruments, and accessories should be stored in a dry place at room temperature.

Before removing parts from packaging inspect for possible damage to the device or packaging. If an expiration date for sterility of the product is provided it must be observed.

All implants, instruments, and accessories should be handled using powder-free gloves. Care should be taken to ensure that parts do not contact hard surfaces that may damage the parts.

Implants, instruments, and accessories that can no longer be used should be returned to the manufacturer. Following surgery, any unused implants should be returned to the manufacturer.

Sterile Devices: restor3d custom implants, instruments, and accessories may be supplied and packaged sterile. The packaging of sterile components will be labeled with one of the following to indicate that the component has been sterilized prior to arrival at the surgical facility:

STERILE EO STERILE VHP

The packaging is labeled with the patient information and this information should be verified prior to opening the components. Open the sterile barrier using standard aseptic techniques.

DO NOT USE the device or any components and contact the manufacturer if the patient information is incorrect.

DO NOT USE if the sterile barrier appears to be compromised or the package is damaged.

DO NOT resterilize components manufactured using iPoly or iPoly XE or if the packaging is labeled with the following:

Non-Sterile Devices: restor3d custom implants, instruments, and accessories may be supplied and packaged in a clean, but unsterilized condition. The packaging of the non-sterile components will be labeled with the following to indicate that the component requires sterilization prior to use:

The packaging is labeled with the patient information and this information should be verified prior to opening the components

DO NOT USE the device or any components and contact the manufacturer if the patient information is incorrect.

CONTACT MANUFACTURER if the inner packaging appears damaged for instructions on how to proceed.

Sterilization: restor3d implants, instruments, and accessories that are provided non-sterile have undergone cleaning via a validated process compliant with ISO 19227 and ASTM3127-16 prior to packaging. Components are designed for steam sterilization via autoclave.

1. Open packaging using standard clean technique. Remove all parts from packaging and place parts in a validated tray for sterilization. Discard packaging materials. All parts should be handled using powder-free gloves and care should be taken to avoid contact with hard objects that may damage the parts.

   Additional cleaning of parts is not required or recommended prior to sterilization.
2. Double wrap the tray in an FDA-cleared CSR wrap or similar type non-woven medical grade wrapping material.
3. Autoclave according to the following parameters:

Steam Sterilization		
	Parameter	Minimum Set Point
Prevacuum Cycle 270°F (132°C)	Exposure Temperature	270°F (132°C)
	Exposure Time	4 minutes
	Dry Time	70 minutes
	Open Door Time	30 minutes
	Cool Down Time	30 minutes

Sterile packaged implants, instruments, and accessories should be stored in a manner that provides protection from dust, moisture, insects, vermin, and extremes of temperature and humidity.

Sterilization of implants, instruments, and accessories for immediate use may be performed using only the Prevacuum cycle described above without dry, open door, or cool down time. Polymeric instrumentation should not be rapidly cooled.

Immediate use Steam Sterilization		
	Parameter	Minimum Set Point
Prevacuum Cycle 270°F (132°C)	Exposure Temperature	270°F (132°C)
	Exposure Time	4 minutes

These recommendations are consistent with ANSI/AAMI ST79 guidelines and have been developed and validated using specific equipment for a SAL of 10^{-6}. Due to variations in environment and equipment, the above cycle and conditions must be demonstrated to produce sterility in your environment.