

# restor3d

## Instructions for Use and Important Medical Information – Anatomic Bone Models.

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.

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For Symbols Glossary, please refer to: <https://restor3d.com/resources/instructions-for-use>



**Rx only**



For an electronic version of this IFU, please refer to [www.restor3d.com](http://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 Anatomic Models are intended to replicate the patient's anatomy.

Such devices are manufactured on a case-by-case basis on the explicit order of a physician to represent the unique anatomy 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 Anatomic Bone Models are intended to replicate the patient's anatomy. The devices are only to be used for the patient specified on the labeling.

**Contraindications:** Anatomic Bone Models are not intended to represent anyone other than the individual identified in the surgical plan or label nor are they intended for use by anyone except the prescribing surgeon. All other contraindications are physician specified.

**Warnings:** The surgeon is responsible for understanding the proper use of the Anatomic Bone Model.

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

**Materials:** restor3d Anatomic Bone Models are manufactured according to the material in the table below.

Abbreviation	Material
MED610/ MED615	Biocompatible Rigid Thermoset Polymer
Radiopaque Polymer	Biocompatible Radiopaque Formlabs Thermoset Polymer

**Storage and Handling:** restor3d bone models should be stored in original packaging in a dry place at room temperature.

Before removing parts from packaging inspect for possible damage to the device or packaging.

All devices should be handled using powder-free gloves. Care should be taken to ensure that parts do not contact hard surfaces that may cause damage.

Devices that can no longer be used should be returned to the manufacturer. Following completion

of use, devices should be returned to the manufacturer or destroyed.

**Non-Sterile Devices:** restor3d Anatomic Bone models are packaged in a clean, but unsterilized condition. The packaging of the non-sterile components is 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 any devices 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 Anatomic Bone Models are provided non-sterile and have undergone cleaning via a validated process compliant with ISO 19227 and ASTM F3127-16. 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. **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

Sterilization of Anatomic Bone Models for immediate use may be performed using only the Prevacuum cycle described above without dry, open door, or cool down time. Anatomic Bone Models are made of polymeric material and should not be rapidly cooled.

<b>Immediate use Steam Sterilization</b>		
	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<sup>-6</sup>. Due to variations in environment and equipment, the above cycle and conditions must be demonstrated to produce sterility in your environment.

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