ATTENTION: PLEASE READ THE FOLLOWING INFORMATION PRIOR TO USE OF ANATOMIC MODELS

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ACCURA® CLEARVUE™ ANATOMIC MODELS

DESCRIPTION:
This anatomic model is produced from a photopolymer material that is hard plastic in nature. The model is designed using the patient's medical scan data and is intended for visualization of patient anatomy.

MATERIALS:
The materials used to manufacture the models are acrylic and epoxy photopolymers. Selective coloration within Accura ClearVue models may darken during sterilization.

⚠ WARNINGS:
1. Models are not intended to contact the patient or be implanted.
2. Models are single use only and designed for use with a specific patient only. To avoid risk of infection and serious injury, do not attempt to re-clean or re-sterilize or in any way re-use the models.
3. Prior to use of anatomic model, the user must thoroughly review this instruction for use and all other labeling provided with the devices.
4. Models are shipped in a non-sterilized state. To avoid possibility of infection, open, clean and sterilize per provided instructions before intraoperative use.

⚠ PRECAUTIONS:
1. Handle models with delicate anatomy cautiously to avoid damage.
2. Image processing and model fabrication are not to be construed as supplying a medical diagnosis.
3. Anatomic models are to be used by trained professionals only.
4. Anatomic models are created from patient data therefore anatomy may change between manufacture of device and surgery date. Do not use if surgery date is more than 6 months from scan date. For pediatric patients, discretion must be used as anatomy can change more rapidly.
5. Clinician is responsible for ensuring the anatomic model correctly references the patient under care.

MATERIAL APPLICABILITY TABLE:
The following table defines the basic methods that must be used for cleaning and sterilization of anatomic models:

Material	Cleaning	Sterilization
Accura ClearVue	Manual	Steam

CLEANING & STERILIZATION:
Anatomic models are provided in a non-sterile condition. Cleaning and sterilization is required prior to intraoperative use.

Manual Cleaning Method:
1. Prepare enzymatic cleaner (neutral pH) in a clean container per manufacturer's instructions using tap water. Ensure that enough solution is prepared to completely submerge all devices.
2. Immerse all devices in the prepared enzymatic cleaning solution and agitate until all surface bubbles have been removed. Verify that all slots and holes are in contact with the solution by using a small syringe to flush solution into small areas as necessary. Soak for a minimum of one (1) minute.
3. While immersed, use a soft wipe or sponge to gently wipe surfaces.
4. Remove all devices from the prepared enzymatic cleaning solution.
5. Rinse the devices under running lukewarm tap water for a minimum of one (1) minute.
6. Use a syringe filled with lukewarm tap water to flush all channels, slots, small openings, and crevices to remove remaining enzymatic cleaning solution.
7. Immerse each device in RO/DI water for a minimum of one (1) minute. After immersion agitate the device in the RO/DI water for thirty (30) seconds to ensure complete rinsing.
8. Repeat step 7 in a fresh bath of RO/DI water. (2nd RO/DI rinse)
9. Repeat step 7 in a fresh bath of RO/DI water. (3rd RO/DI rinse)
10. Dry the device with clean, low-linting wipes or sterilized cloth.

Automated Cleaning Method:
Not Recommended.

Sterilization Method / Instructions:
1. **Packaging:** Wrap parts using an FDA cleared sterilization wrap
2. **Cycle Type**: Dynamic-Air-Removal Sterilization (Pre-Vacuum / Steam)
3. **Cycle Temperature:** 132°C
4. **Cycle Time:** 4 minutes

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5. **Dry Time:** 60 minutes (NOTE: open sterilization chamber and let cool prior to removal from chamber)
6. **Storage in Sterile State:** Product is intended for use immediately after sterilization only. Do Not Unwrap until ready for use.

Note: Sterilization must be performed using a validated steam sterilization process in accordance with relevant AAMI/ASTM/ISO standards, such as ANSI/AAMI ST79-2017.

Comments or questions regarding the use of this device can be directed to Attn:

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Symbol Legend

Warning
Symbol indicates a potentially hazardous situation, which if not avoided could result in death or serious injury to the user.

Caution
Symbol indicates a situation that the user must take into consideration to ensure the safe and effective operation of the equipment and associated accessories.

Manufacturer

Date of Manufacture

Non-Sterile

Do Not Re-Use

Catalog Number

Batch Code

Consult Instructions for Use