

STERILIZATION:

Patient Specific Anatomical Models (Biomodels) can be sterilized once prior to use. Biomodels are intended for single use only and should only be used once. Medical professionals should conduct testing in the health care facility to ensure that conditions essential to sterilization can be achieved.

Sterilize the Biomodel using pre-vacuum steam sterilization before surgical use. During sterilization of single devices pouches may be used. Only standard medical grade steam sterilization polyethylene or Tyvek pouches should be used. Ensure that the pouch is large enough to contain the devices without stressing the seals or tearing the pouch.

Use one of the following standard steam sterilization settings:

1. Pre-vacuum Cycle UK, NL1,2:

Minimum temperature: 134°C
 Minimum exposure time: 3 minutes
 Minimum vacuum drying time: 30 minutes

2. World Health Organization Pre-Vacuum Cycle 2,3:

Minimum temperature: 134°C (273.2°F)
 Minimum exposure time: 18 minutes
 Minimum vacuum drying time: 30 minutes

Contact Information

For any questions or concerns, please contact your local Lyka Smith Health Services representative or Customer Service directly at:

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Instructions For Use

Patient Specific Anatomical Models [PSAM]

This document contains general instructions for use for the Lyka Smith Patient Specific Anatomical Models [PSAM] (Biomodels)

For case-specific instructions, refer to the corresponding case specific Virtual Surgical Planning Report.

DESCRIPTION:

Lyka Smith Patient Specific Anatomical Models [PSAM] “Biomodels” are custom-made devices designed to represent an individual’s patient anatomy. They are beneficial for patient education, medical staff training, pre-surgical planning as well as operating as a reference during surgical procedures. They facilitate collaborative surgical planning, allow for simplification & preparation of surgical procedures and improve both surgical procedure times & performance. They are particularly useful for surgical intervention & placement of implants.

INDICATIONS FOR USE:

Lyka Smith Patient Specific Anatomical Models [PSAM] “Biomodels” are intended to be used as surgical tools to transfer a pre-operative plan to surgery.

MATERIAL:

Nylon or Med610

WARNING:

1. These are patient-specific, single use, disposable Biomodels.
2. Do not attempt to reuse or recondition the Bio models.
3. Do not alter the Biomodels in anyway.
4. Biomodels are to be used by a trained physician in the performance of surgery.
5. Be aware that these patient-specific Biomodels have been manufactured based on CT/MRI scans of the patient. If the patient’s anatomy has changed significantly since the time of the CT/MRI scan, the Biomodels should not be used.
6. The Biomodels should be properly cleaned before sterilization. Do not use if the Biomodels are broken, cracked, or are visibly contaminated.
7. The Biomodels in this package are provided non-sterile. The Biomodels in this package must be sterilized prior to use.

PRECAUTIONS:

1. It is advised to use the Biomodel within 6 months after performing the CT/MRI scans on which they are based. If the patient’s anatomy has changed significantly since the time of the CT/MRI-scan, the Biomodel should not be used, even if the period of 6 months is not expired.
2. Do not apply excessive force on the Biomodels or place heavy objects on top.
3. Markings on Biomodels used for indicating anatomical references and case information must be legible, if they are not, contact Lyka Smith Health Services. The factors which should be legible include, but are not limited to, anatomical directions and identifiers with case information, such as patient details.

PATIENT SPECIFIC BIOMODEL IDENTIFIERS:

A unique identifier is indicated on each Biomodel. This alphanumeric code links the Biomodel unambiguously to the patient case. The last two characters of the unique identifier are a part identifier that uniquely identifies the part within the patient case. A list of all unique identifiers is present in the case report shipped with each patient case. Before using the Biomodel, check the unique identifier for readability and confirm that it corresponds with the patient’s identity. If the Biomodel contains an external tag with the unique identifier, this tag can be removed before coming in contact with the patient.

INSTRUCTIONS FOR USE:

The Biomodel is designed to represent the patient anatomy in a 3D physical form and case be used for surgical planning and studying purposes.

DISPOSAL:

Treat used Biomodels as biohazard material and dispose of in accordance with hospital regulations.

CLEANING AND STERILIZATION INSTRUCTIONS:

Lyka Smith Biomodels are NOT STERILE and must be thoroughly cleaned and sterilized following the stated procedure, if sterilization need occur.

CLEANING:

Whenever possible, a washer/disinfectant (according to ISO 15883) and ultrasonic cleaning equipment should be used to clean the Biomodel. The detergents and/or enzymatic cleaner should be of neutral or near neutral pH (pH7-9,5). The Bio model can be cleaned using manual cleaning and/or automated cleaning in a washer/disinfectant with manual pre-cleaning and ultrasonic cleaning.

**AUTOMATED CLEANING INSTRUCTIONS:
WASHER/DISINFECTOR:**

Step	Minimum Duration	Cleaning Instructions
Pre-Wash	2 Minutes	Cold tap water
Wash	10 Minutes	Warm tap water (>40°C); use detergent
Neutralise	2 Minutes	Warm tap water with neutralizer, if necessary
Rinse	2 Minutes	Rinse with warm Deionized or purified water (>40°C)
Thermal Disinfectant	7 Minutes	At minimum 94°C
Dry	40 Minutes	At minimum 90°C

MANUAL CLEANING INSTRUCTIONS:**Option 1:**

Step	Cleaning Instructions
1	Prepare a fresh, newly-made solution using warm de-ionized (DI) or purified water (PURW) and enzymatic cleaner or detergent.
2	Carefully wash the Biomodel manually
3	Rinse the Biomodel thoroughly with DI or PURW.
4	Dry the Biomodel using a clean, soft, lint-free cloth or clean compressed air.

Option 2:

Step	Minimum Duration	Cleaning Instructions
1	1 Minute	Rinse the Biomodel under running cold tap water.
2	2 Minutes	Manually clean the Biomodel in a newly-made enzymatic cleaner or detergent solution.
3	1 Minute	Rinse the Biomodel using cool to lukewarm running tap water. Use a syringe, pipette or water pistol to flush cylinders, slots, and other hard-to-reach areas.
4	15 Minutes	Clean the Biomodel ultrasonically per manufacturer’s recommended temperature (usually 32°-60°C) and specially formulated detergents. Follow manufacturer’s recommendations for proper cleaning solution formulated specifically for ultrasonic cleaners and medical equipment.
5	2 Minutes	Rinse the Biomodel using DI or PURW. Use a syringe, pipette, or water pistol to flush cylinders, slots, and other hard-to-reach areas.

Before the cleaned products are sterilized, carefully examine them to see if they are clean and undamaged.