

This document contains general instructions for use for Clear Acrylic ProPlan CMF Models. For case-specific instructions, refer to the case report.

DESCRIPTION

A ProPlan CMF Model is a patient-specific device and is designed to represent the patient's unique anatomy.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

INDICATIONS

ProPlan CMF Models are intended for visualization of the patient's anatomy, preparation of surgical interventions and fitting or adjustment of implants or other medical devices such as osteosynthesis plates or distractors.

ProPlan CMF Models are intended for single use only.

MATERIAL

Hybrid epoxy-acrylate polymer

CONTRAINDICATIONS

Do not use in the case of active infection of the surgical area where the surgery will be performed.

STORAGE

It is advised to store the models at room temperature in a properly cleaned, dry and dark place. Avoid exposing the models to UV-light. Only open the package right before preparing the model for surgery (i.e. before cleaning and sterilization).

WARNING

- The user should be aware of possible allergic reactions to materials used in the model. The patient should be informed on this matter by the user.
- These are patient specific, single use, disposable models.
- Do not attempt to reuse or recondition the models.
- Do not alter the models in any way.
- ProPlan CMF Models are to be used by a trained physician in the performance of surgery.
- Be aware that these patient specific models have been manufactured based of CT/MRI scans of the patient. If the patient's anatomy has changed significantly since the time of the CT/MRI scan, the models should not be used.
- The models should be properly cleaned before sterilization. Do not use if they are broken or cracked.
- The models in this package are provided non-sterile. The models in this package must be sterilized prior to use in surgery.

For customers in USA:		For customers in Canada:	
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PRECAUTIONS

- It is advised to use the model 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 model should not be used, even if the time period of 6 months is not expired.
- Do not apply excessive force on the models or place heavy objects on top.

PATIENT SPECIFIC MODEL IDENTIFIERS

A unique identifier is indicated on each model. This alphanumeric code links the model 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 model, check the unique identifier for readability and confirm that it corresponds with the case identifier.

POSSIBLE ADVERSE EFFECTS

Infection following the surgical procedure. Introduction of foreign materials can result in an inflammatory response or allergic reaction.

CLEANING AND STERILIZATION INSTRUCTIONS

ProPlan CMF Models are NOT STERILE and must be thoroughly cleaned and sterilized prior to use in surgery

- **Cleaning**

Whenever possible, a washer/disinfector (according to ISO 15883) and ultrasonic cleaning equipment should be used to clean the models. The detergents and/or enzymatic cleaner should be of neutral or near neutral pH (pH 7-9,5). The models can be cleaned using manual cleaning and/or automated cleaning in a washer/disinfector with manual pre-cleaning and ultrasonic cleaning.

Manual cleaning:

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 model manually.
3	Rinse the model thoroughly with DI or PURW.
4	Dry the model using a clean, soft, lint-free cloth or clean compressed air.

Manual pre-cleaning:

Step	Minimum Duration	Cleaning instructions
1	1 minute	Rinse the model under running cold tap water.
2	2 minutes	Manually clean the model in a newly-made enzymatic cleaner or detergent solution.
3	1 minute	Rinse the model 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 model ultrasonically per manufacturer's recommended temperature (usually 32°-60°C or 90°-140°F) 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 model using DI or PURW. Use a syringe, pipette, or water pistol to flush cylinders, slots, and other hard-to-reach areas.

Automated cleaning in a washer/disinfector:

Step	Minimum Duration	Cleaning instructions
Pre-wash	2 minutes	Cold tap water
Wash	10 minutes	Warm tap water (>40°C); use detergent
Neutralize	2 minutes	Warm tap water with neutralizer, if necessary
Rinse	2 minutes	Rinse with warm DI or PURW (>40°C)
Thermal disinfection	7 minutes	At minimum 94°C
Dry	40 minutes	At minimum 90°C

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

- **Sterilization**

Recommended sterilization specifications.

The models can be sterilized up to two (2) times prior to use. Users should conduct testing in the health care facility to ensure that conditions essential to sterilization can be achieved.

Sterilize the models using **pre-vacuum steam sterilization** before use.

During sterilization of single devices pouches may be used. Only legally marketed, FDA cleared and validated sterilization pouches should be used by the end-user for packaging the devices during sterilization. Ensure that the pouch is large enough to contain the devices without stressing the seals or tearing the pouch.

Don't exert force on the models right after autoclaving, as the models might deform during the cool-down period. After sterilization, the color of the models can change (yellow/brown), but this does not affect their properties.

Steam sterilization settings pre-vacuum cycle^{1,2}:

Minimum temperature: 132°C (269.6°F)

Maximum temperature: 135°C (275°F)

Minimum exposure time: 4 minutes

Maximum exposure time: 5 minutes

Minimum vacuum drying time: 30 minutes

1 Minimum validated steam sterilization temperature required to achieve a 10⁻⁶ sterility assurance level (SAL).

2 In the case local or national specifications for steam sterilization requirements are stricter or more conservative than those listed in this table, please contact Materialise before sterilizing and using the models.