Synthes ProPlan CMF

English Instructions for Use (US)

Polyamide ProPlan CMF Guides and Models

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

DESCRIPTION

ProPlan CMF Guides and Models are patient-specific devices designed to fit, or represent, the patient's anatomy. They are intended for improving and simplifying the performance of surgical interventions, the placement of implants or other medical devices such as osteosynthesis plates or distractors.

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

INDICATIONS

ProPlan CMF Guides and Models are intended to be used as surgical tools to transfer a pre-operative plan to surgery. ProPlan CMF Guides are intended to guide the marking of bone and/or guide surgical instruments in mandibular and maxillofacial surgical procedures.
ProPlan CMF Guides and Models are intended for single use only.

MATERIAL

Polyamide

CONTRAINDICATIONS

Do not use in the case of active infection of the surgical area.

STORAGE

Since the guides and models are made of porous material, it is advised to store them in a properly cleaned and dry place. Only open the package right before preparing the guide or model for surgery (i.e. before cleaning and sterilization).

WARNING

- The user should be aware of possible allergic reactions to materials used in the guide or model. The patient should be informed on this matter by the user.
- These are patient specific, single use, disposable guides or models.
- Do not attempt to reuse or recondition the guides or models.
- We do not recommend altering of the surgical guides. Altering the size of the guide may result in an inadequate fit to the patient's anatomy. It is the sole responsibility of the surgeon if the guide is altered in any way prior to, or during, surgery. If modifications to the guides are made, it is advised to restrict the modifications to a strict minimum and avoid the functional areas of the guide (cutting slots, drill cylinders). The guides can be modified with a high speed burr. It is suggested that the guides be modified and rinsed in a saline solution away from the surgical site to avoid infiltration of particulate debris in the surgical site.
- ProPlan CMF Guides are to be used by a trained physician in the performance of surgery.
- Be aware that these patient specific guides and 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 guides or models should not be used.
- The guides and models should be properly cleaned before sterilization. Do not use if they are broken, cracked, or are visibly contaminated.
- The guides and models in this package are provided non-sterile. The guides and models in this package must be sterilized prior to use in surgery.

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PRECAUTIONS

- It is advised to use the guide or model within 6 months of 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 guide or model should not be used, even if the time period of 6 months has not expired.
- Do not apply excessive force on the guides or models, or place heavy objects on top.
- Markings on guides used to indicate anatomical references and case information must be legible. These include lines indicating anatomical directions, identifiers with case information such as implant size, and the unique case identifier (see below). Notify your representative if the markings are not legible or if the identifiers do not correspond to the intended patient or surgeon.

PATIENT SPECIFIC GUIDE IDENTIFIERS

A unique identifier is indicated on each guide and model. This alphanumeric code links the guide or 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 guide or model, check the unique identifier for readability and confirm that it corresponds with the case identifier.
If the guide contains an external tag with the unique identifier, this tag can be removed before coming in contact with the patient.

POSSIBLE ADVERSE EFFECTS

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

INSTRUCTIONS FOR USE

- <u>Fitting of the guide</u>
  - The guide is designed to fit the patients' anatomy. The supporting surface (bone, cartilage, teeth, soft tissue) should be completely freed to assure proper fit of the guide.
    Take enough time to fit the guide on the patient. The case report shipped with every guide indicates the position of the guide relative to the surrounding anatomy. Try different positions and check whether or not the guide stays in place. Choose the most stable position, i.e., the position in which the least pressure must be exerted in order to keep the guide in place. Don't push the guide down too hard. Make sure critical anatomical structures are not damaged during fitting. Anatomical models can be ordered together with the guide. As such, fitting the guide can be tried on the anatomical models before surgery.
  - When a stable position for the guide is obtained, fixate the guide by means of fixation pins or screws (if present). Make sure fixation holes are correctly identified, and not mixed with holes for drilling for implant positioning (if present).
  - If it is not possible to place the guide on the patient in a unique and stable position, the guide does not guarantee an accurate transfer of the pre-operative planning.
    Even in a stable position, it is possible that the guide may not make contact with the bone over its full length, since it is not always possible to resolve all of the undercuts. The undercuts depend on the shape of the patient's anatomy. During the design of the guide the amount of undercut is kept to a minimum in order to ensure maximal contact between bone surface and the guide.
- <u>During cutting and drilling</u>
  - Make sure the guide maintains its position on the contact surface during cutting and/or drilling.
  - All necessary measures should be taken to avoid excessive heat generation during cutting and/or drilling. Please consult the procedures outlined by the manufacturer of the cutting and/or drilling equipment on this matter.
  - Do not try to use a sawing blade that is thicker than the indicated thickness of the cutting slot (if present).
  - Do not try to use a drill that is larger than the indicated diameter of the drill hole. The case report shipped together with the guide lists the drill diameters to be used.
  - Make sure the sawing blade follows the cutting surface or slot to obtain a correct osteotomy and to avoid cutting into the guide's cutting surface or slot.
  - Since the inner diameters of the drill holes are larger than the diameter of the drill (0.1 to 0.2 mm), try to drill along the centerline of the drill holes to obtain a correct hole and to avoid drilling into the inner wall of the drill hole.

CLEANING AND STERILIZATION INSTRUCTIONS

ProPlan CMF Guides and 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 guides and models. The detergents and/or enzymatic cleaner should be of neutral or near neutral pH (pH 7-9,5). The guides and 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 guide or model manually.
3	Rinse the guide or model thoroughly with DI or PURW.
4	Dry the guide or 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 guide or model under running cold tap water.
2	2 minutes	Manually clean the guide or model in a newly-made enzymatic cleaner or detergent solution.
3	1 minute	Rinse the guide or 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 guide or 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 guide or 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 guides 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 guides or 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.

  Steam sterilization settings pre-vacuum cycle[1,2]:

  Minimum temperature: 132°C (269.6°F)

  Minimum exposure time: 4 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.