

Acrylic ProPlan CMF Orthognathic Splints

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

DESCRIPTION

ProPlan CMF Orthognathic Splints 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.

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

INDICATIONS

ProPlan CMF Orthognathic Splints are intended to be used as surgical tools to transfer a pre-operative plan to surgery. ProPlan CMF Orthognathic Splints are intended to guide the alignment of the maxilla and/or mandible in orthognathic surgical procedures.

ProPlan CMF Orthognathic Splints 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 splints at room temperature in a properly cleaned, dry and dark place. Avoid exposing the splints to UV-light. Only open the package right before preparing the splint for surgery (i.e. before cleaning and sterilization).

WARNING

- The user should be aware of possible allergic reactions to materials used in the splint. The patient should be informed on this matter by the user.
- These are patient specific, single use, disposable splints.
- Do not attempt to reuse or recondition the splints.
- Do not alter the splints in any way.
- The splints are to be used by a trained physician in the performance of surgery.
- Be aware that these patient specific splints have been manufactured based on CT/MRI scans of the patient patient and plaster models of the patient's teeth. If the patient's anatomy has changed significantly since the time of the CT/MRI scan or the moment patient's tooth impressions were taken, the splints should not be used. This includes teeth movement due to ongoing orthodontic treatment.
- The splints should be properly cleaned before sterilization. Do not use if they are broken, cracked, or are visibly contaminated.
- The splints in this package are provided non-sterile.

For customers in USA:		For customers in Canada:	
Distributed by: Synthes Inc. 1101 Synthes Avenue Monument, CO 80132	Manufactured in USA by: Materialise LLC 44650 Helm Court Plymouth, MI 48170	Imported by: Synthes (Canada) Ltd. 2566 Meadowpine Boulevard Mississauga, Ontario Canada L5N6P9	Manufactured in USA by: Materialise LLC for Materialise NV Technologielaan 15 3001 Leuven Belgium

PRECAUTIONS

- The splints are intended to be used during the surgery only. If, for any reason, it is decided to keep a splint in the patient's mouth for a longer period, this should never be longer than 24 hours.
- It is advised to use the splints 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 splints should not be used, even if the time period of 6 months has not expired.
- Do not apply excessive force on the splints, or place heavy objects on top.
- Markings on the splints 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 SPLINT IDENTIFIERS

A unique identifier is indicated on each splint. This alphanumeric code corresponds to the last 6 digits of the case identifier. The case report shipped with each patient case details the link between the case identifier and the patient's identity and the shipped instruments.

Before using the splint, 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.

INSTRUCTIONS FOR USE

- Fitting of the splint
 - The splint is designed to fit the patients' anatomy. The supporting surface (teeth, mucosa) should be completely freed to assure proper fit of the splint.
 - Limit the forces on the splint to 20N (i.e. 4.5 lb(f)).
 - Take enough time to fit the splint on the patient. Try different positions and check whether or not the splint stays in place. Choose the most stable position, i.e. the position in which the least movement of the splint is possible. Don't push the splint down too hard to avoid breaking the splint.
If it is not possible to place the splint on the patient in a unique and stable position, the splint does not guarantee an accurate transfer of the pre-operative planning.
 - Do not alter the splint before use. Small particles might come off, which could contaminate the operating region. In addition, altering the size of the splint may result in an inadequate fit to the patient's anatomy or reduced mechanical strength of the splint. Therefore, it is the responsibility of the user if the splint is altered in any way prior to, or during, surgery.
- During splint use
 - Make sure the splint maintains its position between maxilla and mandible during surgery.
 - In case a sequence of multiple splints is provided, start with the splint whose label ends in the number '01'. Work your way up from there, using splints with increasing label numbers until you've used all the splints.

ProPlan CMF Orthognathic Splints are provided NON-STERILE

- Cleaning instructions

The splint is provided clean of residual manufacturing materials. If additional cleaning is required prior to sterilization please consult hospital or office standard protocol for cleaning.

- Sterilization instructions

The splints are provided NON-STERILE. The splints have been manufactured in materials that meet biocompatibility requirements for limited in-vivo exposure (less than 24 hours). The recommended and validated sterilization method is the STERRAD[®] 100S method (Hydrogen Peroxide Gas Plasma).

Instructions: Wrap the splint with the manufacturer's recommended sterilization wrap or place it in a pouch. Place in STERRAD[®] unit and depress start button. Follow all STERRAD[®] unit manufacturer's requirements.