

English Instructions for Use (US)

Plaster ProPlan CMF Models

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

DESCRIPTION

Plaster ProPlan CMF Models are custom-made models designed to represent the patient's anatomy. They are intended for visual inspection, discussing surgical treatment approaches or model surgery.

MATERIAL

Plaster

WARNING

- Plaster ProPlan CMF Models do not qualify as medical devices and as such cannot be used during surgery.
- Plaster ProPlan CMF Models are provided non-sterile and are **not suited for sterilization** with sterilization techniques involving heat or humidity.
- ProPlan CMF Models are fragile. Store and handle the models with care.
- Be aware that the models have been manufactured based on CT/MRI scans of the patient. If the patient's anatomy has changed significantly since the CT/MRI scan, the models should not be used for surgery preparation.

PATIENT SPECIFIC SPLINT IDENTIFIERS

A unique identifier is indicated on each model. This alphanumeric code corresponds to 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 model.

Before using the model, check the unique identifier for readability and confirm that it corresponds with the case identifier.

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