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INSTRUCTIONS FOR USE

PATIENT-SPECIFIC DEVICE

AccuShape® PEEK patient-specific implant and accessories.

CAUTION: R_X ONLY. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

DESCRIPTION:

MedCAD AccuShape® PEEK patient-specific implants and accessories allow for replacement of bony voids in the patient's skeleton. The implant is shaped and sized to fit the individual anatomy of the specific patient. The implant is made of PEEK (polyetheretherketone) and is supplied as one or as multiple parts. Accessories are supplied to support the surgery.

MedCAD AccuShape® PEEK patient-specific implants are attached to native bone using standard implant grade titanium and titanium alloy 1.3 mm, 1.5 mm, 1.6 mm or 2.0 mm cranial and craniofacial plates and screws.

MedCAD AccuShape® PEEK patient-specific implants are supplied **NON-STERILE** in a sealed polyethylene bag**.**

MedCAD AccuShape® PEEK patient-specific implants are ***single patient use only*** devices to be used on a single patient.

INDICATIONS:

The MedCAD AccuShape® PEEK patient-specific implant is designed individually for each patient and intended to replace bony voids in the skeleton.

CONTRAINDICATIONS:

DO NOT USE in an area with an active or latent local infection.

WARNINGS AND PRECAUTIONS:

- MedCAD AccuShape® PEEK patient-specific implants are supplied **NON-STERILE and must be sterilized prior to use according to the sterilization instructions provided herein.**
- MedCAD AccuShape® PEEK patient-specific implants are ***single patient use only*** devices to be used on a single patient. Changes over time in the patient's anatomy may result in an inaccurate fit not meeting intended specifications and may require a new CT scan and implant.
- The MedCAD AccuShape® PEEK patient-specific implant has not been evaluated for safety and compatibility in the magnetic resonance environment or for heating or migration in the MR environment.
- Re-shaping, re-sizing or contouring of the implant by the surgeon is best achieved using high-speed, rotary instruments, away from the surgical site prior to implantation. **Care should be taken to remove any loose particles with sterile saline rinse**.
- Use on pediatric patients, due to growth of the patient skull, may result in dehiscence of the incision, prominence or disfigurement at the implant site, or related complications.

STORAGE:

Packaged products should be stored in a dry, clean environment, protected from direct sunlight and extremes of temperature and humidity.

STERILIZATION INSTRUCTIONS FOR PEEK IMPLANTS:

All items should be inspected before processing. Any loose materials that are not part of the implant should be removed before processing. PEEK implants are to be sterile processed as follows:

IMPORTANT: Remove from shipping package prior to sterilizing. Wrap implant in two layers of 1-ply polypropylene wrap (Kimguard KC600-510(k) K082554, or equivalent) using sequential wrapping techniques or place implant in sterilization pouch 5.5 inch by 10 inch Cardinal Health catalog number 92510 – 510k K062704 or utilize an equivalent sterilization pouch. STEAM STERILIZE as indicated in the chart below.

Recommended parameters for steam sterilization and recommended dry times of the PEEK implant supplied as **NON-STERILE**:

Steam Autoclave Cycle	Minimum Temp °C (°F)	Minimum Exposure Time (minutes)	Minimum Dry Time (minutes)
Gravity Displacement	132°C (270°F)	15 minutes	30 minutes
Pre-Vacuum 4 Pulses Preconditioning	132°C (270°F)	4 minutes	30 minutes

The validated method of sterilization follows ANSI/AAMI/ISO 17665-1:2006 and ANSI/AAMI ST79 guidelines for steam sterilization to provide a minimum Sterility Assurance Level (SAL) of 10^{-6}.

The sterilizers must be properly installed, maintained, and calibrated.

FOR NON-AUTOCLAVABLE ACCESSORIES

WARNING: Models are supplied non-sterile and are not intended for use in the sterile field. DO NOT AUTOCLAVE. The following sterilization methods may be used.

Suggested methods:

Method	Temperature °C (°F)	Minimum Cycle Time (minutes)
Sterrad (Hydrogen Peroxide)	45-50 °C (113 °F-122 °F)	45 minutes
Steris	50-56 °C (122 °F -133 °F)	12 minutes
Cidex® OPA	Room temperature	12 minutes
Gluteraldehyde (Cidex Plus® and Cidex®)	Room temperature	20 minutes