INSTRUCTIONS FOR USE
AccuShape® PEEK Patient-Specific Cranial Implant

DESCRIPTION:

The AccuShape® PEEK Patient-Specific Cranial Implant replaces defects and bony voids in the patient's cranial skeleton. The implant is shaped and sized to fit the individual defect of the specific patient. The implant is made of PEEK (polyetheretherketone) and is supplied as one or as multiple parts.

The AccuShape® PEEK Patient-Specific Cranial Implant is attached to native bone using standard implant-grade titanium and titanium alloy cranial and craniofacial plates and screws measuring 1.3 mm, 1.5 mm, 1.6 mm, or 2.0 mm. Holes for fixation are to be drilled prior to sterilization. Place fixation holes a minimum of 7 mm from the device perimeter. The edges of the implant may be minimally altered by the surgeon prior to implantation using high-speed surgical instruments away from the surgical site. Thoroughly rinse the implant with sterile saline after drilling or alteration to remove any loose particles.

Caution: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS:

- The MedCAD AccuShape® PEEK Patient Specific Implant is designed individually for each patient and intended to correct defects / replace bony voids in the cranial skeleton.

CONTRAINDICATIONS:

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

WARNINGS:

- The AccuShape® PEEK Patient-Specific Cranial Implant is supplied **NON-STERILE** and must be sterilized prior to use according to the sterilization instructions provided herein.
- Do not apply fixation prior to sterilization.
- This SINGLE USE ONLY device is designed to fit the defect existing at the time of the patient's CT/MRI scan. Changes in the patient's anatomy occurring after the scan as well as the use of the implant after such changes may result in sub-optimal fit within the defect area.
- The AccuShape® PEEK Patient-Specific Cranial Implant has not been evaluated for safety and compatibility in the magnetic resonance environment or for heating or migration in the MR environment.
- Use on pediatric patients may result in dehiscence of the incision, prominence or disfigurement at the implant site, or related complications due to growth of the patient's skull.

STORAGE:

- Store implant in a dry, clean environment, protected from direct sunlight, pests and extremes of temperature and humidity.

STERILIZATION INSTRUCTIONS:

1. Remove implant from protective pouch only when ready to sterilize. Discard pouch. This protective pouch is NOT sterilizable.
2. Inspect implant before sterilization. Remove any loose materials that are not part of the implant prior to sterilization.
3. Wrap implant in two layers of 1-ply FDA-cleared sterilization wrap (such as Kimguard KC-600) using sequential wrapping techniques OR individually in a self-sealed sterilization pouch (such as Cardinal Health 92510)
4. Sterilize by steam autoclave using one of the following methods and the parameters listed.

Method	Gravity Displacement (Wrapped)	Pre-Vacuum (Wrapped)
Preconditioning Pulses	N/A	3
Minimum Temperature	132 °C (270 °F)	132 °C (270 °F)
Cycle Time	15 minutes	4 minutes
Minimum Dry Time	30 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}. Sterilization equipment must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm the inactivation of all viable microorganisms.

SYMBOLS GLOSSARY:

Symbol	Symbol Name	Definition
ISO 15223-1 - Symbols to be used with medical device labels, labelling and information to be supplied		
LOT	Batch code (ISO 7000-2492)	To identify the manufacturer's batch or lot code.
REF	Catalogue number (ISO 7000-2493)	To identify the manufacturer's catalogue number.
SN	Serial number (ISO 7000-2498)	To identify the manufacturer's serial number.
	Operator's manual; operating instructions (ISO 7000-1641)	To indicate that the operating instructions should be considered when operating the device.
	Do not re-use (ISO 7000-1051)	To indicate that the item is for single use only and must not be used more than once.
	Caution (ISO 7000-0434A)	To indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
Other		
℞ Only	21 CFR 801.109	Caution: Fedeal law restricts this device to sale by or on the order of a physician.
QTY	Quantity	"QTY" refers to the quantity of device(s) contained within the packaging.

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