OsteoMatch™ PEEK

Patient Specific Cranial Implant

Instruction for Use

DISTRIBUTED BY:

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

DESCRIPTION

MedCAD PEEK cranial implant replaces defects of 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 due to material constraints and/or the complexity of the geometry.

MedCAD PEEK patient specific cranial implant is fixed to native bone using standard 1.3 mm, 1.5 mm, 1.6 mm or 2.0 mm cranial and craniofacial plates and screws. Holes for fixing screws are drilled by the surgeon prior to fixation of the device. The fixation screw holes are to be a minimum of 7mm from the device perimeter. The edges of the PEEK implant may be minimally altered by the surgeon prior to implanting the device to overlap the neighboring native bone.

WARNING AND PRECUATIONS:

- MedCAD PEEK patient specific cranial implants are supplied **NON-STERILE.** MedCAD PEEK cranial implants have 2 mm holes throughout the implant facilitating drainage.
- This ***single use only*** device has been 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 a sub-optimal fit within the defect area.
- The MedCAD PEEK Patient Specific Cranial Implant has not been evaluated for safety and compatibility in the MR environment. The MedCAD PEEK Patient Specific Cranial Implant has not been tested for heating or migration in the MR environment.

INDICATIONS

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

STERILIZATION

This cranial implant is supplied **NON-STERILE.**

Recommended parameters for sterilization of the NON STERILE implant:

Method	Cycle	Preconditioning Pulses	Minimum Temperature	Full Cycle Time	Minimum Dry Time
Steam	Gravity Displacement (Wrapped)	N/A	132°C (270°F)	15 Minutes	30 Minutes
Steam	Pre-Vacuum (Wrapped)	3	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 Sterility Assurance Level (SAL) of 10^{-6}.

These parameters were validated with MedCAD AccuShape™ PEEK Patient Specific Cranial Implants on their own. If MedCAD AccuShape™ PEEK Patient Specific Cranial Implants are sterilized using a filtered sterilization container system, the recommended parameters may not be valid and new cycle parameters may have to be established by the user. The user is responsible for validating the process when filtered sterilization container systems are used.

The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.