

Instructions for Use

OsteoMatch Patient-Specific Cranial Implant

Nonsterile

Sterilize using Ethylene Oxide (EtO) sterilization. See *Cleaning and Sterilization*

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

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Indications/Intended Use: The OsteoMatch Patient Specific Cranial Implants are designed individually for each patient to correct defects in craniofacial bone.

The Skull Model is provided to demonstrate the fit of the Cranial Implant.

Contraindications:

- Patients with active infections
- Patients with PMMA allergy or foreign body sensitivity
- Fractures of severely atrophic bone

Warnings and Precautions:

- The Cranial Implant is supplied nonsterile.
- Handle the Cranial Implant with care.
- Do not implant the Cranial Implant in the presence of significant swelling.
- Do not reuse the Cranial Implant.

Cleaning and Sterilization:

- The Cranial Implant and Skull Model are supplied non-sterile.
- Inspect the Cranial Implant and remove any packaging debris that may be visible.
- Clean the Cranial Implant by scrubbing using a soft-bristled brush and distilled water.
- The Cranial Implant and Skull Model are intended to be sterilized using 100% Ethylene Oxide (EtO).
 - EtO Concentration: 725 mg/L
 - Temperature: 55° C (130 ° F)
 - Relative Humidity: 30 to 80%
 - Exposure Time: 60 minutes (minimum)
 - Aeration time: 12 hours
- ***Do not sterilize implant more than twice***
- ***Do not autoclave***

Recommendations for Use:

- Handle the Cranial Implant with care.
- At least three points of fixation are recommended.
- Use commercially available, non-biodegradable fixation screws and plates. ***Do not use self-drilling screws.***
- Screw holes must be predrilled away from the surgical site.
- Screw holes should be 6-10mm from edge of Cranial Implant.
- Screws should not protrude past the underside of the implant to avoid tissue damage.
- Perform thorough soft tissue excision. ***Do not force the device into the defect/void.***
- The Cranial Implant may be modified as necessary by burring. ***Perform away from the surgical site.***