MEDPRIN

INSTRUCTIONS FOR USE

Recranio™

Customized Cranio-Maxillofacial Repair System

Symbols used on labeling

	Do not re-use		Consult instructions for use or consult electronic instruction for use
	Caution		Fragile, handle with care
	Keep dry		Keep away from sunlight
LOT	Batch code		Do not use if package is damaged and consult instruction for use
SN	Serial number		Use-by date
REF	Catalogue number		Date of Manufacture
NON STERILE	Non-sterile	EC REP	Authorized representative in the European Community
MR	MR Safe	MD	Medical Device
UDI	Unique device identifier		

Any serious incident related to this device, please report to the manufacturer (Email: ae@medprin.com) and the competent authority of the Member State.

The Link of Summary of Safety and Clinical Performance:The link has not yet been generated until the SSCP is uploaded to EUDAMAD.

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Recranio™ Customized Cranio-Maxillofacial Repair System

【Description】

Recranio™ Customized Cranio-Maxillofacial Repair System allows for replacement of bony voids in the patient's craniofacial skeleton. The implant is shaped and sized to fit the individual anatomy of the specific patient. The implant is designed with CAD software after receiving the patient's CT scan and made of polyetheretherketone (PEEK), which has been used in clinic for nearly 20 years and is supplied as a single piece or multiple pieces. Recranio™ Customized Cranio-Maxillofacial Repair System is attached to native bone with the plates by themselves and fixed using standard cranial and craniofacial fixation systems or using standard titanium screws. All patient specific craniofacial implants are supplied non-sterile in a sealed Nylon bag.

【Indications】

Customized Cranio-Maxillofacial Repair System is designed individually for each patient and intended to correct defects or replace bony voids in the craniofacial skeleton.

【Instructions for Surgical Implantation】

- ○ Fully expose defects of bone window.
- ○ Place Recranio™ Customized Cranio-Maxillofacial Repair System on the defect skeleton and adjust the position to the right place.
- ○ Thorough hemostasia.
- ○ Tighten screw into the plate to fix the implant.
- ○ Put a drainage tube under or on the Customized Cranio-Maxillofacial Repair System.

【Contraindications】

1. Infected or with high risk of infection
2. Local surgical infection
3. Fever or abnormal leukocytes
4. Mentally disordered
5. Anatomic abnormality of the skull
6. Patient that do not follow surgeon's instructions

【Sterilization Instructions】

WARNING: The cranial implant is supplied NON-STERILE and is intended for single use.

Recommended parameters for sterilization of the NON-STERILE implant:

Method	Temperature	Time
Steam	121°C	30 minutes
	134°C	4 minutes

【Warnings】

- ○ Customized Cranio-Maxillofacial Repair System is supplied NON-STERILE and must be sterilized prior to use according to the sterilization instructions provided herein.
- ○ Customized Cranio-Maxillofacial Repair System is single use only devices to be used on a single patient and in a single surgical case shortly after the patient's CT scan is provided. 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.
- ○ Use on pediatric patients is not recommended. Rapid growth of the pediatric skull may cause dehiscence of the incision, prominence or disfigurement at the implant site, or related complications that may necessitate removal of the implant.

【Storage】

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