




















3. 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.
4. Before sterilization, the packaging should be removed.

[Storage]

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

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
	Batch code		Do not use if package is damaged and consult instructions for use
	Serial number		Use-by date
	Catalogue number		Date of manufacture
	Non-sterile		Authorized representative in the European Community
	MR Safe		Medical Device
	Unique device identifier		Importer
	Manufacturer		

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.

 **Medprin Regenerative Medical Technologies Co., Ltd.**
 3/F & 7/F, Zone E; Room 207, 2/F, Zone E; Room 717-720, 7/F, Zone D; 80 Lanyue Road, Science City, New High-Tech Ind. Park, Guangzhou Guangdong 510663 China.
 Room 104, No 8 Lianhuayan Road, Huangpu District Guangzhou Guangdong 510663 China.

FAX:+86-20-32296128 TEL:+86-20-32296118



Medprin Biotech GmbH

Gutleutstraße 163-167, 60327 Frankfurt am Main, Germany

Tel: + 49-69-580059970 Fax: + 49-69-580059971

Issue Date:2017.06.08

Revision Date:2022.10.11

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INSTRUCTIONS FOR USE

Recranio™

Customized Cranio-Maxillofacial Repair System

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.

【Performance Characteristics】

According to equivalent products and clinical demands, after the product is implanted in defects position of the cranio-maxillofacial bone, the product is fixed in autogenous bone by skull fixed system. The incomplete anatomical structure in local defects shall be recovered; the soft tissue should be protected in bone after the bone protection structure is formed again. And the nice-looking of defects position shall be recovered, and the unwell symptoms resulting from bone defects should be eliminated. The product will not degrade or result in toxic effects after implantation. It is firmly fixed in implanted parts in the long time to permanently and safely replace bone defects.

【Intended Use】

The product is suitable for repairing cranio-maxillofacial defects with cranio-maxillofacial internal fixation system.

【Indications】

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

【Intended Patient Population】

Patients who need craniofacial repair.

【Intended User& Environment】

The product must be used by clinicians, and they must carefully read the instruction before use. Operation in surgery room with professional health care facilities. Normative and local regulations must be observed.

【Instructions for Surgical Implantation】

1. Fully expose defects of bone window.
2. Place Recranio™ Customized Cranio-Maxillofacial Repair System on the defect skeleton and adjust the position to the right place.

3. Thorough hemostasia.
4. Tighten screw into the plate to fix the implant.
5. 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

【Adverse Effects】

Possible complications that may occur with Recranio™ Customized Cranio-Maxillofacial Repair System include pain, discomfort or paresthesia, infection, aseptic inflammation, and implants loosed, displaced, or fall out.

【Expected Clinical Benefits】

The data support that the benefits of using Recranio™ Customized Cranio-Maxillofacial Repair System outweigh the risks when the device is used as indicated and in accordance with the direction for use.

【Material and Substances】

Recranio™ is made of PEEK.

【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	Sterilization Equipment	Temperature	Time
Steam	Vertical pressure steam sterilizer	121°C	30 minutes
		134°C	4 minutes
	Pulsating vacuum sterilizer	134°C	5 minutes

【Warnings】

1. Customized Cranio-Maxillofacial Repair System is supplied NON-STERILE and must be sterilized prior to use according to the sterilization instructions provided herein.
2. 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.