iCMF PEEK

Custom made craniomaxillofacial implant in PEEK

The use of the *iCMF PEEK* custom made medical device should only be performed by a qualified clinician, with deep knowledge and complete mastery of specific surgical techniques for craniomaxillofacial implant and prosthesis procedures. Before using a BoneEasy branded product (Resdevmed Lda.), the responsible surgeon/physician must carefully review all information provided by the manufacturer, including indications, contraindications, warnings, instructions and other information, and respect them. Resdevmed Lda. recommends participating in practical training courses in the use of BoneEasy brand products. Detailed instructions in addition to those contained in this document can be obtained by contacting the manufacturer or its representative.

iCMF PEEK should be used at the discretion of the clinician, who has an obligation to determine whether the product is suitable for the patient and to assess all relevant circumstances. The clinician is responsible for any direct, indirect complications or harmful situations that may result from an erroneous indication or surgical technique, improper use of the material, overload, lack of asepsis, or failure to observe the explicit safety instructions in the instructions for use. The manufacturer or representative of Resdevmed Lda cannot be held responsible for complications associated with the use by the doctor, as described above, or to the patient, including the patient's general anatomy and habits. Resdevmed, Lda declines any responsibility, express or implied. It is also the responsibility of the surgeon/doctor to adequately inform the patient about the function and necessary care, as well as the known risks associated with the product in question.

Description

iCMF PEEK is a custom made craniomaxillofacial implant consisting of Polyether ether ketone (PEEK).It is developed based on files from a computed tomography, using segmentation software and computer aided design and manufactured by Fused Deposition modelling (FDM). The *iCMF PEEK* medical device must be stabilized with fixing screws, not included with this device.

Indications

iCMF PEEK is a long-term, custom made medical device to be used in rehabilitation and/or replacement procedures in craniomaxillofacial areas.

Contraindications

iCMF PEEK should only be used if the volume of cortical bone allows the implant to stabilize. Poor bone quality, difficulty in anchoring screws, systemic diseases (diabetes, etc.), reduced immunity, alcoholism, drug addiction and psychological instability are factors that can contribute to the lack of integration and/or subsequent failure of the implant. Misuse of these implants or poor fixation can lead to relaxation of the screw, fractures and/or failure of the implant. Exposure to radiation and chemotherapy can affect the functionality of the implant.

Warnings

Wrong surgical techniques can result in bone loss, damage to the patient, pain and partial or total failure of the medical device.

Treatments with steroids or anticoagulants can affect the surgery site and have an impact on the patient's ability to integrate.

Exposure or prolonged use of bisphosphonate-based drugs, especially with chemotherapy, can have a negative impact on the functionality of the implant. A detailed study of the patient's history is recommended, including consultation with the attending physician, before opting for any solution proposed by Resdevmed, Lda.

Mobility, bone loss or infection may be indications of implant failure. The decision on the best course of action must be carefully evaluated by the doctor. If removal of the implant is necessary, you should seek for closure by first intention.

Precautions

Proper clinical case planning is crucial to the long-term success of the medical device.

During surgery, asepsis rules must be respected. Direct handling of the medical device should be avoided.

iCMF PEEK can not be used in load situations. Micromovements may lead to bone resorption, so proper fixation with osteosynthesis screws is essential.

iCMF PEEK is a medical device made to measure for a particular patient, so it should not be used on a patient other than the one on which it is based.

iCMF PEEK was developed for single use. It must not be reused, reprocessed or resterilized. Failure to follow these instructions can compromise the structural integrity of the device and/or lead to its failure, with consequent damage to the patient.

The patient's clinical situation should be carefully monitored.

Do not use the medical device if its original packaging is open, damaged or showing signs of deterioration.

See also Contraindications.

Requirements

iCMF PEEK is a medical device designed on a tomography where three-dimensional volume reconstruction is performed. For a good adaptation of the device, the quality of the tomography is essential. For this, the presence of metals that can cause effects and that do not allow to reconstruct the volume correctly must be checked. The removal of metallic elements that interfere with the three-dimensional reconstruction may be necessary prior to the examination. When requesting to the radiology center, the order should short include cuts (about 2 mm) unless the volume is very large and causes a harmful exposure to the patient, this being a clinical criterion that must be evaluated by the doctor.

Recommendations

During the first week, at least one visit is recommended for patient monitoring and professional prophylaxis.

X-rays may be taken four months after surgery to assess the condition of the tissues and the medical device, unless due to complications resulting from the implantation, advance evaluation tests are necessary.

Possible adverse effects

Complications that can occur with the use of the implant include (but are not limited to): pain, discomfort, delayed healing, paraesthesia, hyperesthesia, edema, hemorrhage, hematoma, infection, inflammation, need for additional surgery or removal, lack of integration, mechanical failure, exposure, bone loss and implant loss. Other adverse effects can also occur as a result of iatrogenic factors or the patient's response.

The removal of the implant should be considered whenever the location where it was placed shows signs of being compromised in such a way that it cannot be controlled by postoperative treatments.

Report to the manufacturer, any adverse situation recorded and not presented in this document.

Technical information

iCMF PEEK is an implantable medical device that requires proper planning. The incisions and detachments that allow an intimate contact with the bone must be previously planned, it must be evaluated if the added volume is able to be contained by the soft tissues and the complementary surgical techniques that may be necessary to complement the procedure, such as microvascularized flaps, grafts or the previous use of tissue-distending balloons.

Excessive torques on the screws must be avoided, either because they can create opposing vector forces on the screws, leading to their loosening, or due to the mechanical limits of the implant, which can lead to fracture.

Sterilization

iCMFPEEK is sterilized by ethylene oxide. The packaging will serve as a sterilization barrier until the expiration date shown on the box. This medical device has been developed for single use, so it should not be re-sterilized.

Single use

iCMF PEEK must not be reused. The reuse of a single-use medical device that has been in contact with blood, bone, tissues, body fluids or other contaminants can lead to damage to the user. Possible risks associated with the reuse of a single-use device include, but are not limited to, mechanical failure and transmission of infectious agents. *iCMF PEEK* is a medical device made to measure for a particular patient, so it should not be used on a patient other than the one on which it is based.

Packaging

iCMF PEEK was cleaned and packed in a controlled environment. It is supplied in multipack. The outer label contains information about the batch number that must be recorded on the patient's medical record to ensure complete product traceability. The manufacturer also provides extra labels on the packaging that can be placed on the clinical record for the same purpose.

Storage

iCMF PEEK must be stored at room temperature and protected from external damage.

If contaminated with blood or other fluids, it must be disposed of according to rules for biological contamination residues. If not, it can be normally disposed, as plastic residue.

Patient information

It is the responsibility of the surgeon/doctor to adequately inform the patient about the function and necessary care, as well as the known risks associated with the product in question.

Manufactured and Distributed by:

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Symbology information used:

	Batch Code
	Use by
	Do not reuse
	Manufacturer
	Sterilized using ethilene oxide

	Date of Manufacture
	**Caution**
	Do not resterilize
	Do not use if package is damaged
	The law restricts the sale of this device to a doctor or under his demand