TESCAN MEDICAL
TESCAN ORSAY HOLDING

BoneForm - Instructions

Description

The BoneForm Cranial System is a custom-made class I medical device that is used to precise moulding of methyl-methacrylate-resin cranial bone cement to correct cranial defects. It comprises a two-piece moulding form. The moulding form has been patient-tailored out of certified plastic material. Data obtained by a diagnostic CT scan of the patient is the basis for the form geometrical design. The volume of the resulting substitute is given on the bottom of the form and on the opposite side of this instructions.

Cranial bone substitute moulding and hardening takes only place in the attached moulding form, completely independently of the patient in sterile conditions in the operating room. The patient comes in contact with a completely finished and fully hardened cranial bone substitute during the implantation process.

The list of supplied aids and the graphical representation of their use are on the opposite side of this instructions.

Indication

The BoneForm Cranial System has been designed to correct loss cranial defects where the cranium bone plate has been removed for therapeutic reasons.

Contraindication

Do not use the BoneForm Cranial in case of active infection. The BoneForm Cranial should not be used with patients who are hypersensitive to methyl-methacrylate, depending on the use of resin.

Sterilization

The moulding form **is supplied in a non-sterile condition**. Recommended sterilization methods are **Cold plasma and Autoclave 134 ºC** including the Pre-sterilization preparation (cleaning and disinfection). The form can be sterilized repeatedly, maximally 10 times. The pre-sterilization preparation (cleaning and disinfection) is carried out according to the customary practice and internal regulations of applied hospital.

Storing

There are no special requirements for storing in respect of the BoneForm Cranial moulding form. Length guarantees the mold declared by the manufacturer is 24 months from date of declaration of conformity to a particular product.

Medical device classification

The BoneForm Cranial System is a **Custom-made class I medical device**. It is non-invasive, inactive and without a measurement function. It is supplied as non-sterile.

Warning

- Patient Identifier (PID) is created by composition of first three letters from surname and first three letters from name. Example: Surname: Novak, Name: Karel -> PID: NOVKAR
- **Before use make sure** that Case ID (BFCxyz) and Patient Identifier (PID) on the supplied moulding form with the data on the individual Declaration of Conformity match.
- The moulding form **is supplied in a non-sterile condition**. Both parts of the moulding form must be disinfected and sterilized prior to surgery as recommended in this instructions. Sterilize individual parts separately.
- The BoneForm Cranial System is a custom-made medical device. The supplied moulding form is intended only for the specific patient and can be used repeatedly.

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