CRANIOPLASTY MOULD
Surgical technique

Proper surgical procedures and techniques are the responsibility of the medical professional.

The intended purpose of the Craniotomy Kit is to serve as a tool to assist the surgeon in obtaining a desired surgical outcome. The Craniotomy Kit does not replace or reduce the responsibility of the surgeon to execute professional judgment during full course of executing the surgery. The following guidelines are furnished for information purposes only. It remains the sole responsibility of the surgeon to make sure that he/she is satisfied, and deem it safe, to use the instrumentation and to ensure that the final implant placement is acceptable.

Overview

The Cranioplasty mould is a patient-specific mould that is used intra-operatively to produce a PMMA (poly methyl methacrylate) cranioplasty prosthesis.

This document will illustrate to the surgeon how to use the Cranioplasty Mould.

Cranioplasty Mould

Step 1: Prosthesis Casting

Propriety prepare the bone cement according to the instructions for use of the respective bone cement.

Gently pour the liquid bone cement into the cavity of the mould.

Slowly insert the inner part of the mould into the cavity ensuring correct orientation of the inner part.

Carefully push the inner part of the mould down until the surface of the inner part is flush with the surface of the mould. Excess bone cement will exit the mould through its sprue(s). Allow the prosthesis to cool down and harden.

Step 2: Prosthesis Preparation

Confirm that the prosthesis has properly hardened by inspecting the hardness of the excess bone cement. Once the prosthesis has hardened, take out the inner part of the mould.

Remove the prosthesis from the inner part of the mould. This may require breaking off the unwanted pieces still attached to the prosthesis either by hand or by using a clamping tool.

Step 3: Prosthesis Placement and Fixation

Place the prosthesis in the defect/resected area and fasten to the existing bone using your preferred method.

Symbols Used On Labelling

- Single Use
- Manufacturing Date
- Case Number
- Attention, See Instructions for Use
- Keep Dry
- Manufacturer: CranioTech
- Patient Specific for each device as prescribed
- Supplied Non-Sterile

Warnings & Precautions

Proper surgical procedures and techniques are the responsibility of the medical professional.

The intended purpose of the Cutting guide and Cranioplasty mould is to serve as a tool to assist the surgeon in obtaining a desired surgical outcome. The cutting guide and cranioplasty mould does not replace or reduce the responsibility of the surgeon to execute professional judgment during full course of executing the surgery. These guidelines are furnished for information purposes only. It remains the sole responsibility of the surgeon to make sure that he/she is satisfied, and deem it safe, to use the instrumentation and to ensure that the final implant placement is acceptable.

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