CranioTech
PATIENT-SPECIFIC SOLUTIONS

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.

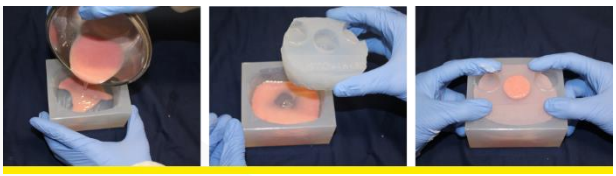
Overview

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

This document will illustrate to the surgeon how to use the cutting guide and the cranioplasty mould.

Cranioplasty Mould

Step 1: Prosthesis Casting



Properly 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.

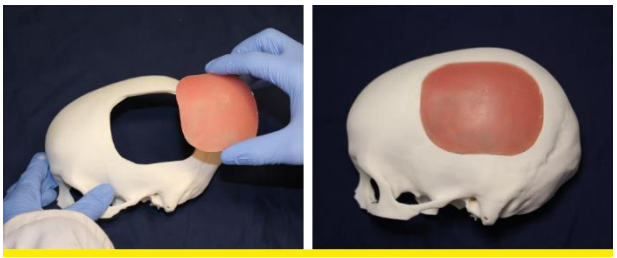
Carefully push the inner part of the mould down until the top surface of the inner part is flush with the top surface of the mould. Excess bone cement will exit the mould through its sprue(s). Allow the prosthesis to cool down and harden.

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 & Fixation



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

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Terms & Conditions

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Warranty & Limitations of Liability

Craniotech guarantees that each of its products is treated with utmost care in development, selection of material, manufacture and final inspection before release for distribution. Through inexpert storing, handling and other manipulation, the fixation system can be damaged, and its operability can be restricted.

Craniotech accepts no liability or warranty for malfunctioning, breakdown and potential medical complications for patient and hospital staff, or for resulting damages arising from inexpert handling, operation, storing, from acts of God or from other external influences or manipulation.

Craniotech will replace any device, which, in its opinion, was defective at the time of shipment and if defects that were caused during manufacturing or packaging are immediately brought to the attention of Craniotech or its distributors. This warranty is exclusive and in lieu of all other warranties, whether expressed or implied, written or oral, including, but not limited to, any implied warranties of merchantability of fitness.

As a result of biological differences in individuals, no product is 100% effective under all circumstances. Craniotech has no control over the operation, inspection, maintenance, or use of its products after sale, and has no control over the selection of patients. Therefore, Craniotech and its distributors do not guarantee either for a good effect or against a poor result following use. Craniotech and its distributors shall not be liable for any incidental or consequential loss, damage or expense arising directly or indirectly from the use of the device or from ineffective sterilisation processes or re-use of the product(s).

Important Use Information

℞ Only SAHPRA guidelines restricts this product to sale by or on the order of a surgeon.

Indications for Use: Craniotech's patient-specific solutions are intended for use as implants, anatomical models and surgical guides.

Contraindications: The cranioplasty mould should not be used if any of the following occur:

1. Patient has an active infection.
2. Significant changes to patient's anatomy have occurred since the medical scan used for product definition was obtained.

Warnings & Precautions

1. To avoid potentially serious allergic reactions, ensure that the patient is not allergic to the materials used in the surgical guides.
2. To avoid mix-ups and associated serious injury, patient identification on models and guides must be verified and confirmed against patient identification prior to use.
3. Products are single-use only and designed for use with a specific patient only. To avoid risk of infection and serious injury, do not attempt to re-clean or re-sterilise or in any way re-use the products.
4. Prior to use of any of Craniotech's patient-specific products, the user must thoroughly review the instructions for use and all other labelling provided with the devices.

1. Craniotech products are provided in a non-sterilised state. To avoid possibility of infection, open, clean and sterilise per provided instructions.
2. To ensure that damage has not occurred during shipping and handling, inspect all products prior to use. Do not use if the these are broken, cracked or otherwise damaged.
3. Handle anatomical models with delicate anatomy cautiously to avoid damage.
4. To avoid material toxicity reactions, contact time for each material should be limited to the time shown below:

Material	Device	Contact Duration	Body Contact
Platinum-based Silicone	Mould	N/A	N/A

Material Applicability Table

The following table defines the basic methods that must be used for cleaning and sterilisation of the moulds:

Material	Cleaning	Sterilisation
Platinum-based Silicone	Hand Cleaning / Auto Cleaning	Steam

Cleaning & Sterilisation

Cranioplasty moulds are provided in a non-sterile condition. Cleaning and sterilisation are required prior to use.

Hand Cleaning:

1. Prepare the detergent per manufacturer's instructions using sterile water.
2. Immerse parts in the solution and agitate until all surface bubbles have been removed and slots and holes are in contact with the solution. Use a small syringe (60cc) or soft bristle brush (e.g. nylon bristle M-16) to flush solution into small areas when necessary.
3. Soak one (1) minute.
4. While immersed, use a soft wipe (such as a cleanroom wiper or a 4x4 lap sponge), a soft bristle brush (e.g. nylon bristle M-16)) or 6mm pipe cleaner (as appropriate) to gently wipe or brush all surfaces, including the small openings for a minimum of one (1) minute.
5. Rinse each part under running filtered tap water which is less than 25°C for a minimum of one (1) minute. After the rinse, use a 60cc syringe filled with sterile water for injection which is less than 25°C to aspirate water through channels, slots, small openings or crevices to remove the enzyme detergent solution.
6. Soak each part in sterile water for injection for a minimum of one (1) minute and then agitate sample for 30 seconds in the rinse water to ensure complete rinsing, repeat two (2) more times.
7. Visually inspect surfaces prior to drying, re-rinse if residues and soils are found.
8. Wipe dry with sterilised cloth or wipes.

Auto Cleaning (according to ISO 15883):

1. Place the parts in the disinfectant that is aldehyde-free with a proven efficacy and that is suitable and compatible for disinfecting instruments for at least five (5) minutes. Ensure they are immersed properly. Do not allow the parts to touch each other.
2. Run the cleaning cycle in accordance with ISO 15883.

Steam Sterilisation (according to ISO 17665-1):

1. Wrap the instruments in a porous pack and place chemical indicator strips in tray and pouches as well as on outside of pack. Write expiry date on the tape. Load pack.
2. Pre-condition: Vacuum pump removes air from chamber.
3. Sterilisation: After air removal, steam is injected in chamber at 132°C and 240kPa for at least four (4) minutes. The upper control limit being equal to sterilization temperature plus 3°C, with no deviation exceeding 1°C, and temperature difference of any 2 points inferior to 2°C.
4. Drying: The pack is dried by the vacuum pump that will draw vacuum to sufficiently remove moisture from the packs. Eight (8) minutes of vacuum is normally enough.
5. Vacuum break: Sterile air to be filtered into chamber to break the vacuum.
6. Removal and cool down: Remove and place in special cooling rack. Avoid touching the hot pack by hand as hot packs can absorb moisture and bacteria from hands.
7. Place pack in a sterile storage area. Please observe expiry dates and re-sterilise if necessary.

Symbol Legend


Warning

Non-sterile


Caution


Manufacturer


Date of Manufacture


Do Not Re-Use

Prescription Only


Consult Instruction for Use

Communication

In the case of product complaint, an appropriate complaint protocol is to be obtained from Craniotech and returned, together with the product(s), to Craniotech.

Comments or questions regarding the use of this device can be directed to:

Craniotech (Pty) Ltd
4 Oewerpark, Rokewood Road
Die Boord, Stellenbosch
South Africa, 7613
Email: info@craniotech.com