1. IDENTIFICATION AND INDICATIONS FOR USE

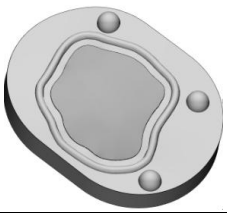
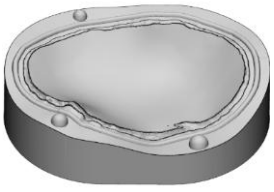
Fastmold is intended for molding the bone cement chosen by the surgeon for cranial reconstruction. The mold is indicated as an aid in shaping the bone cement, allowing the implant to be modeled according to the patient's anatomy during procedures in the craniofacial region.

Note: Fastmold is not supplied with bone cement. For instructions on the use of the bone cement, consult the cement manufacturer.

2. MODELS

Fastmold, an auxiliary mold for Bone Cement, is a patient-specific device indicated for molding and shaping bone cement at the time of cranioplasty surgery or in the immediate preoperative period, facilitating the shaping of the bone cement and the modeling of the implant according to the patient's anatomy. The models are made of silicone and defined according to their maximum dimensions.

Table 1: Codes, Models and dimensions.

CODE	NAME	ILLUSTRATIVE IMAGE
E200.013-P	FASTMOLD SMALL	
E200.013-M	FASTMOLD MEDIUM	
E200.013-G	FASTMOLD LARGE	

E200.013-GG	FASTMOLD EXTRA LARGE	

3. STORAGE, PRESERVATION AND TRANSPORT

All models are supplied sterile. Fastmold must be stored and transported in a cool, dry place, at room temperature, without direct exposure to light. The product must be transported in its original packaging, kept at room temperature and in places free from sunlight and humidity.

4. WARNING

- Fastmold must only be used by specialized professionals.
- Product manufactured exclusively for molding bone cement. Follow the manufacturer's guidance for handling the bone cement.
- Do not use the product if it shows apparent damage or if its packaging has been opened or damaged.
- The manufacturer recommends single use.

5. ASSOCIATED RISKS

Fastmold is contraindicated for patients who are allergic or sensitive to any component of the bone cement.

6. SURGICAL TECHNIQUE

The healthcare professional must be adequately trained in the surgical procedures commonly used in craniofacial reconstruction. The packaging must be opened manually, in an appropriate surgical environment, by pulling the surgical-grade paper from the side. It must be opened only during the surgical procedure, in order to avoid contamination of the product, and by specialized personnel.

It is recommended to test the fit between the base and the lid of the Fastmold, using the holes in the base and the projections on the lid for guidance. Check that they are correctly aligned to ensure a matching fit. Before application, moisten the inner part of the mold that will come into contact with the bone cement using saline solution. Prepare the bone cement according to the manufacturer's instructions and apply it evenly over the entire inner surface of the mold. Then place the lid of the mold on the base, ensuring that the cavities of the base (or holes in the base) and the projections on the lid are aligned. Apply uniform pressure to the lid and wait for the material to dry completely, according to the manufacturer's guidance. After molding, remove the bone cement and trim the excess from the edges.

Note: the bone cement molding time may differ between manufacturers; the more solid the cement, the more accurate the finish after removal of the excess.

After use, Fastmold must be discarded. CPMH recommends single use. For disposal, it is recommended that the products be mechanically deformed and then clearly and visibly identified as unfit for use. Dispose of them in appropriate places, avoiding contamination of the environment and of other people.

It is advisable to follow local regulations for the disposal of potentially contaminating products.

7. STERILISATION METHOD

CPMH recommends **SINGLE USE** of Fastmold. **Sterile product**. All models are sterilized with Ethylene Oxide.

8. DISPOSAL

Disposal must begin by rendering the product unusable. Arrange disposal in accordance with the standards for hospital waste; the product must be placed in a suitable container bearing the indication that it is contaminated waste. The healthcare institution must in turn arrange final disposal in accordance with the legislation in force.

9. EXPIRY DATE/LOT

The date of manufacture, expiry date and lot are stated on the product packaging. CPMH Fastmold has a shelf life of 1 year from its date of manufacture.

10. COMMERCIAL PRESENTATION

Fastmold is supplied sterile, in surgical-grade primary packaging. The product comes with an identification label with guidance for obtaining the instructions for use in non-printed format and the corresponding version.

11. CUSTOMER SERVICE

These instructions for use are made available in non-printed format and can be accessed at cpmh.com.br/instrucoes.

Compliments, Suggestions or Complaints may be made directly to CPMH by telephone (61) 3028-8883, or by e-mail qualidade@fixhealth.com.br or on our website by filling in the Customer Service (SAC) form at the web address: https://www.cpmh.com.br/sac/.

NOTE: For information on the date of manufacture, expiry date, lot and reference, see the label.

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