Surgical bone cement

FIX 1 medium viscosity

FIX 3 low viscosity

groupe l'épine
A SAFER PRODUCT RANGE THAT MEETS ALL INDICATIONS

FIX 1 and FIX 3 radiopaque surgical bone cements are designed to provide rapid and stable fixation of implants in hemi- or total hip/knee arthroplasty and other joint reconstructions. Selection of FIX 1 or FIX 3 depends on the surgeon’s preferences and type of joint:

➜ FIX 1: medium viscosity, for digital application
➜ FIX 3: low viscosity, for syringe application.

A VALIDATED FORMULATION

The N,N-dimethyl-p-toluidine (DMPT) contained in the liquid acts as an accelerator. Some authors2 suspected this basic component of any acrylic cement of having a residual toxicity. By limiting its content to less than 1.5% (p/p) and by controlling the amount released in vitro - concentration is undetectable 30 minutes after initiation of the reaction3 - one dramatically reduces the cytotoxic risks associated with bone cement.

<table>
<thead>
<tr>
<th>Chemistry</th>
<th>FIX 1</th>
<th>FIX 3</th>
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</thead>
<tbody>
<tr>
<td>methymethacrylate</td>
<td>85.3%</td>
<td>85.3%</td>
</tr>
<tr>
<td>butylmethacrylate</td>
<td>13.2%</td>
<td>13.2%</td>
</tr>
<tr>
<td>N,N-dimethyl-p-toluidine</td>
<td>1.5% max.</td>
<td>1.5% max.</td>
</tr>
<tr>
<td>hydroquinone</td>
<td>20 ppm</td>
<td>20 ppm</td>
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PACKAGING

Ampule
MONOMER (liquid)

Bottle
POLYMER (powder)

CONTROLLED MAXIMAL TEMPERATURE

Under the conditions defined by the applicable standard1, the maximal polymerization temperature for Fix bone cements is close to 57±5° (well within the limit of 90° defined by the standard). This temperature has been measured on a cylinder of bone cement of about 25 g. Furthermore, placement of thermocouples within the cement mantle both proximally and distally allowed plotting of the variations that occur during polymerization and better reflect the normal conditions of use.

1: ISO 5833 - Implants for surgery - Acrylic resin cements
3: CRITT Report N° B 00.02.43 N, 03/14/2000
The FIX range offers the highest level of safety for the patient, and has been developed in strict compliance with the applicable standard for acrylic resin cements.

**PACKAGING THAT MEETS ALL ASEPTIC TECHNIQUE REQUIREMENTS**

Each dose consists of:
- one self-breaking ampule of liquid (monomer),
- one glass bottle with a sealed cap that contains polymer grains.

The ampule and bottle are delivered in a double tray with Tyvek® peel off covers. The double tray is packaged in a protective outer box.

**OPTIMAL STERILIZATION METHOD**

The liquid is sterilized by ultrafiltration.

The powder is gamma sterilized in its glass bottle by a minimum of 25 kGy. The double blister pack is sterilized by ethylene oxide (EtO).
A controlled setting time
To comply with standard requirements (ISO 5833 : Implants for surgery - Acrylic resin cements), the setting times must be measured at 23°C. Setting times for Fix 1 and Fix 3 are:
- Fix 1: 7 ± 1 minute
- Fix 3: 9 ± 1 minute
Polymerization of acrylic cement is highly influenced by the O.R. temperature. At temperatures above 23°C, the resting, mixing and setting times will decrease. Conversely, they will increase at a lower room temperature. Although these variations remain within an acceptable range, they should not be ignored. The following curves will help optimize the use of cement.