CRANIOS REINFORCED®
BONE VOID FILLER

The tougher bone cement
CRANIOS REINFORCED® Bone Void Filler is a biocompatible, self-setting calcium phosphate cement intended to fill defects in the restoration or augmentation of the cranial skeleton.

It contains reinforcing fibers that impart an increase in toughness* to reduce crack propagation during the setting process.

CRANIOS REINFORCED Bone Void Filler also incorporates a sodium hyaluronate solution to enhance viscosity, and improve handling and injection properties.

When the cement is fully cured, the composition closely approximates the mineral phase of bone. It is gradually resorbed and replaced with bone during the healing process.

*Toughness is defined as a measure of a material’s resistance to fracture when stressed. Data on file with DePuy Synthes Companies, mechanical test number FRN test 132.
Indications
CRANIOS REINFORCED Fast Set Putty and CRANIOS REINFORCED Rotary Mix are indicated for repairing or filling cranial defects and craniotomy cuts with a surface area no larger than 25 cm². CRANIOS REINFORCED Fast Set Putty and CRANIOS REINFORCED Rotary Mix are also indicated for the restoration or augmentation of bony contours of the cranial skeleton (including fronto-orbital areas), such as burr hole voids and other cranial defects.

Contraindications
CRANIOS REINFORCED Fast Set Putty and CRANIOS REINFORCED Rotary Mix are not intended for use in the spine and should not be used in the presence of active or suspected infection. CRANIOS REINFORCED Fast Set Putty and CRANIOS REINFORCED Rotary Mix are not for use in:
- patients with traumatic open injuries that are predisposed to infection
- stress-bearing applications, such as the temporomandibular joint
- areas where adjacent bone is avascular, or is incapable of supporting or anchoring the implant
- patients with compromised health (e.g., abnormal calcium metabolism, metabolic bone disease, a recent local untreated infection, vascular or severe neurological disease, infection, immunologic deficiencies, or systemic disorders) that result in poor wound healing or will result in tissue deterioration over the implant site
- patients who have not reached an age at which skull/facial growth is essentially complete
- defects contiguous with any of the paranasal sinuses
- defects greater than 25 cm²
- CRANIOS REINFORCED is not intended for use in the spine

Please see Directions for Use for full prescribing indications, contraindications, precautions and warnings.
CHEMICAL PROPERTIES

Sodium Hyaluronate Solution
Sodium hyaluronate solution is a pH-neutral viscous solution that provides enhanced mixing and flow properties for a smooth and easy application.

Bioresorbable Fibers
The bioresorbable poly(lactide co-glycolide) polymer fibers are randomly oriented and uniformly distributed in the material to impart an increase in toughness.* This incorporation of fibers into the matrix increases the material’s resistance to cracking during the setting process.

Calcium Phosphate
Calcium phosphate has been widely used in clinical applications for decades. There are a number of publications and clinical cases available which demonstrate its safety and effectiveness to address bone regeneration.¹²

*Toughness is defined as a measure of a material’s resistance to fracture when stressed.
Mechanical test data on file with DePuy Synthes Companies, mechanical test number FRN test 132.
Mechanical test results may not necessarily be indicative of clinical results.

¹ DePuy Synthes Companies CRANIOS REINFORCED® Bone Void Filler Technical Monograph
Approximation to Bone
Once CRANIOS REINFORCED Bone Void Filler is fully cured, the resulting biomaterial formed is carbonated apatite, which has a crystallographic characteristic and chemical composition similar to bone.

The carbonate content of carbonated apatite distinguishes CRANIOS REINFORCED Bone Void Filler from hydroxyapatite. Hydroxyapatite does not contain any carbonate; however the carbonate content of CRANIOS REINFORCED Bone Void Filler is 4.0–5.0%, which more closely resembles the composition of bone (Figure 1).

![Figure 1](image-url)
MECHANICAL PROPERTIES

Performance in a Physiological Environment
In order to set properly, CRANIOS REINFORCED Bone Void Filler requires a warm, wet environment which reduces the need to limit moisture at the operative site. The setting reaction of CRANIOS REINFORCED Bone Void Filler is isothermic, which does not cause thermal damage to the surrounding tissue.

Compressive Strength
As the carbonated apatite forms, the compressive strength of the material increases. In approximately 24 hours, CRANIOS REINFORCED Bone Void Filler has achieved its full compressive strength (Figure 2).

<table>
<thead>
<tr>
<th>Compressive Strength</th>
<th>CRANIOS REINFORCED Rotary Mix</th>
<th>CRANIOS REINFORCED Fast Set Putty</th>
<th>Bone³</th>
</tr>
</thead>
<tbody>
<tr>
<td>~35MPa</td>
<td>~25MPa</td>
<td>Cancellous Bone 5–7 MPa</td>
<td></td>
</tr>
</tbody>
</table>
FIBERS INCREASE THE MATERIAL’S RESISTANCE TO CRACKING

**Toughness***

Three-point bend testing confirms CRANIOS REINFORCED Bone Void Filler to be the tougher* bone cement with an increased ability to resist cracking.

Ceramic materials are brittle in flexural loading; however, the incorporation of biodegradable fibers into CRANIOS REINFORCED Bone Void Filler increases the material's resistance to fracture during flexural loading when compared to calcium phosphate cements without reinforcing fibers (Figure 3).

CRANIOS REINFORCED Bone Void Filler also displayed a high Work of Fracture, which is directly related to the toughness* of the material (Figure 4).

---

*Toughness is defined as a measure of a material’s resistance to fracture when stressed.
Mechanical test data on file with DePuy Synthes Companies, mechanical test number FRN test 132.
Mechanical test results may not necessarily be indicative of clinical results.
CRANIOS REINFORCED Bone Void Filler
The tougher bone cement

ADDITIONAL TOUGHNESS* FOR SEVERAL MONTHS

CRANIOS REINFORCED Bone Void Filler has an increased toughness* imparted by the reinforcing fibers that is sustained over a period of several months (Figure 5). When the fibers degrade, the material is equivalent in strength to the previous, Norian CRS Bone Void Filler product.

**Duration of Increased Toughness**

* Toughness is defined as a measure of a material’s resistance to fracture when stressed.

Mechanical test data on file with DePuy Synthes Biomaterials, mechanical test number FRN test 132. Mechanical test results may not necessarily be indicative of clinical results.

FIBERS ARE SIGNIFICANTLY RESORBED IN 12 MONTHS

**Fiber Resorption**

Over time, the reinforcing fibers begin to degrade through hydrolysis (Figure 6). The relationship between Work of Fracture and the fiber molecular weight test was determined to be directly proportional.

**Fiber Degradation**
EASIER TO INJECT

Injection
For ergonomic reasons, the amount of load required to inject the material out of a syringe should be minimized. An elevated injection force may make it difficult to successfully implant the biomaterial. Each material was injected through a 12 gauge, 10 cm delivery needle (available through DePuy Synthes Companies) during the material’s working time. The results of the injection test showed the amount of force required to inject both CRANIOS REINFORCED Rotary Mix and Norian CRS Rotary Mix to be comparable. While, in contrast, HydroSet (Stryker) required more than twice the injection force to inject (Figure 7).

Injection Test–Peak Load

![Injection Test–Peak Load](Figure 7)
### CRANIOS REINFORCED Fast Set Putty, sterile

<table>
<thead>
<tr>
<th>Code</th>
<th>Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>615.03.01S</td>
<td>3 cc</td>
</tr>
<tr>
<td>615.05.01S</td>
<td>5 cc</td>
</tr>
<tr>
<td>615.10.01S</td>
<td>10 cc</td>
</tr>
</tbody>
</table>

### CRANIOS REINFORCED Rotary Mix, sterile

<table>
<thead>
<tr>
<th>Code</th>
<th>Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>616.03.01S</td>
<td>3 cc</td>
</tr>
<tr>
<td>616.05.01S</td>
<td>5 cc</td>
</tr>
<tr>
<td>616.10.01S</td>
<td>10 cc</td>
</tr>
</tbody>
</table>

### Delivery Needles, sterile

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>612.40.01S</td>
<td>8 gauge x 10 cm, 1/pkg.</td>
</tr>
<tr>
<td>612.41.01S</td>
<td>10 gauge x 10 cm, 1/pkg.</td>
</tr>
<tr>
<td>612.41.05S</td>
<td>10 gauge x 10 cm, 5/pkg.</td>
</tr>
<tr>
<td>612.42.01S</td>
<td>12 gauge x 10 cm, 1/pkg.</td>
</tr>
</tbody>
</table>

### MXR-US-2000

Rotary Mixer


Limited Warranty and Disclaimer: DePuy Synthes Biomaterials products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

Not all products are currently available in all markets.