Cranios Reinforced Rotary Mix.
The tougher bone cement.
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Cranios Reinforced Rotary Mix is an injectable, biocompatible calcium phosphate bone cement with reinforcing fibers added for increased toughness* that sets at body temperature.

Due to its special composition, the reinforced cement resists cracking during the setting process. The addition of sodium hyaluronate solution provides excellent mixing and handling properties.

Cranios Reinforced Rotary Mix is an injectable option suitable for bony defects positioned at difficult angles, and sets in a wet environment. When 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 Synthes, mechanical test FRN Test 132.
Calcium phosphate powder 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.1,2

**Calcium phosphate powder**

The bioresorbable fibers are randomly oriented and uniformly distributed throughout 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.

**Bioresorbable fibers**

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

**Sodium hyaluronate solution**

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*Toughness is defined as a measure of a material’s resistance to fracture when stressed. Data on file with Synthes, mechanical test FRN Test 132.
Cranios Reinforced Rotary Mix is a two-component, self-setting calcium phosphate bone cement used to fill defects in the restoration or augmentation of the cranial skeleton. Cranios Reinforced Rotary Mix is provided in a rotary pouch and prepared with an auto-mixer. The powder component contains soluble salts of calcium, calcium carbonate and 3% resorbable reinforcing fibers. Fibers are composed of 82:18 Poly (lactide:glycolide) copolymer. The liquid component is a pH-neutral solution of sodium phosphate salts with sodium hyaluronate added to increase viscosity and improve mixing and flow properties.

Once Cranios Reinforced is fully cured, the resulting biomineral formed is carbonated apatite which has a crystallographic characteristic and chemical composition similar to bone, as demonstrated in Table 1. The carbonate content of carbonated apatite distinguishes Cranios Reinforced from hydroxyapatite. Hydroxyapatite does not contain any carbonate; however the carbonate content of Cranios Reinforced is 4.0–5.0%, which more closely resembles the composition of bone as demonstrated in Table 2.

### Properties of Bone vs. Cranios Reinforced Rotary Mix

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Bone</th>
<th>Cranios Reinforced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbonate content</td>
<td>4.0 – 6.0%</td>
<td>4.0 – 5.0%</td>
</tr>
<tr>
<td>Ca/P molar ratio</td>
<td>1.33 – 1.73</td>
<td>1.60</td>
</tr>
<tr>
<td>Crystal order</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Optimal crystal size</td>
<td>~200 Å</td>
<td>~200 Å</td>
</tr>
<tr>
<td>Chemical make-up</td>
<td>Inorganic/organic</td>
<td>Inorganic/organic</td>
</tr>
</tbody>
</table>

Table 1

Crystalllographic analysis by powder x-ray diffraction (XRD)

![Graphs showing crystallographic analysis](image)

Table 2

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Indications and Contraindications

Indications
Cranios Reinforced Rotary Mix is indicated for repairing or filling cranial defects and craniotomy cuts with a surface area no larger than 25 cm². Cranios Reinforced Rotary Mix is 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.

Clinical applications include:
– Cranioplasty
– Cranial recontouring
– Cranial flap augmentation
– Skull base defect repair
– Onlay grafting

Contraindications
Cranios Reinforced Rotary Mix is not intended for use in the spine and should not be used in the presence of active or suspected infection.

Cranios Reinforced Rotary Mix is not for use in:
– patients with traumatic open injuries that are predisposed to infection
– stress-bearing applications, such as the temporomandibular joint or anchoring of endosseous implants
– 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 and facial growth is essentially complete

Please refer to package insert for complete indications, contraindications, warnings and precautions.
# Timing Sequence

## Time and temperature properties

The handling properties of Cranios Reinforced Rotary Mix are governed primarily by the ambient temperature of the material as it is mixed and injected into the surgical site. The following timing sequence refers to the specific time and temperature relationships that must be followed for the material to set properly.

<table>
<thead>
<tr>
<th>Timing Sequence</th>
<th>Mixing</th>
<th>Preparation and Implantation Time**</th>
<th>Setting Time</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Approximately 70 seconds</strong></td>
<td>3 minutes maximum</td>
<td>2 minutes maximum</td>
<td>10 minutes at body temperature</td>
</tr>
<tr>
<td><strong>Temperature</strong></td>
<td>18–23°C / 64°–73°F</td>
<td>18–23°C / 64°–73°F</td>
<td>37°C / 98°F</td>
</tr>
<tr>
<td><strong>Procedure</strong></td>
<td>Mix the contents of the rotary pouch using the rotary mixer (70 revolutions).</td>
<td>Transfer the mixed Cranios Reinforced Rotary Mix paste into the delivery syringe and transfer the delivery syringe into the sterile field.</td>
<td>Inject the material into the prepared bone void and manipulate as necessary. Product should only be manipulated during this two-minute window. <strong>Layering precaution:</strong> If more than one pack is required, the total volume of Cranios Reinforced Rotary Mix should be implanted within the two-minute implantation time.</td>
</tr>
</tbody>
</table>

** The preparation and implantation phases should be completed simultaneously.
The following steps are performed outside the sterile field

1. **Connect power cord**

Unwrap the power cord and connect to an appropriate hospital-grade outlet. Once connected, the "Standby" indicator will illuminate, indicating that the unit is ready for operation.
2  
Open mixer lid

Open the lid by depressing the thumb latch on the right corner of the lid.

3  
Position rotary pouch

Position the rotary pouch on the mixer by aligning the arrows on the rotary pouch and mixer. Press the pouch over the center post of the mixer.
4
Inject solution

Remove the syringe from the tray.

Using aseptic technique, unscrew the cap from the syringe.

Remove the cap from the rotary pouch injection port.

Connect the solution syringe to the injection port by turning clockwise.

Inject the entire contents of the solution syringe. Remove the solution syringe after injection is complete.

Note: Once the solution has been injected into the rotary pouch, the remaining steps must be completed immediately.
5
Remove pouch clip

Remove the pouch clip from the rotary pouch and unfold with the delivery syringe to the right.

6
Close lid and start mixer

Close the lid and secure it by depressing the thumb latch.

Depress the “Start” button. A single brief beep will be heard, the “Standby” indicator will turn off, and the “Mixing” indicator will illuminate.

After 70 revolutions, the mixing cycle is complete. An extended beep will be heard and the “Complete” indicator will slowly flash. The rotary mixer will continue to beep every five seconds until the lid is opened.

Caution: If the rotary mixer fails to complete the mixing cycle, or the lid is opened before the cycle is complete, an audible alarm will sound and all function indicators will flash. Using a new rotary pouch, return to Step 2, or mix using manual operation.
Rotary Mixer Manual Operation

1
Initial steps

Follow Steps 2–5 in the powered operation section.

2
Close mixer lid

Close the lid and secure by depressing the thumb latch.

3
Operate mixer manually

To operate the mixer manually, lift up on the handle located on the mixer lid until it locks in the upright position. Rotate the top disc 70 revolutions clockwise (approximately one revolution per second).

Note: The counter operates on battery power and will advance when rotating the top disc.

When mixing is complete, lower the handle on the mixer lid by pulling it up and pushing it to the side.
The five minute preparation and implantation time sequence begins at the end of the mixing cycle. There is a three minute maximum at room temperature (18-23°C/64-74°F) before implantation must begin. This allows time to transfer the mixed Cranios Reinforced Rotary Mix paste into the delivery syringe and transfer the delivery syringe into the sterile field.

1
Open mixer lid

Open the lid and lift the mixed rotary pouch from the center post.

2
Transfer paste into delivery syringe

Guide the pouch and turn the knob counterclockwise to feed the rotary pouch into the transfer rollers. The material will be expelled from the mixing chamber into the delivery syringe.

Once the material is completely transferred, turn the transfer knob clockwise to remove the rotary pouch.
The following steps are performed inside the sterile field

3 Transfer delivery syringe to sterile field

Using aseptic technique, peel back the outer pouch to expose the sterile delivery syringe. A sterile person should detach the delivery syringe with one-quarter turn of the syringe counterclockwise, and complete the transfer to the sterile field.

4 Attach delivery needle

Insert a delivery needle into the connector at the tip of the syringe and attach by rotating one-quarter turn clockwise to lock in place.

Remove the clip from the plunger. Slowly depress the plunger to evacuate air from the syringe until a small amount of paste is ejected.

The material is now ready for implantation.
5
Prepare implant site

Using lavage and/or suction instruments, remove blood clots and tissue debris while controlling active bleeding.

**Note:** If bone wax or gelfoam is used, it should be removed prior to implanting Cranios Reinforced Rotary Mix.

Cranios Reinforced Rotary Mix is not intended for use in defects with a surface area larger than 25 cm².

**Precaution:** Not recommended for use in sinus obliteration or near an open sinus.

6
Implant and contour material

Calibration marks on the delivery syringe are spaced at 1 cc increments.

Inject the material by one of the two methods:

1. **Standard injection**
   Slowly push the plunger. Every click corresponds to approximately 0.5 cc of injected material.

2. **Injection under resistance**
   If you encounter resistance to injection before satisfactory defect filling is achieved, additional injection pressure can be applied by slowly turning the plunger knob clockwise. One full rotation of the knob injects 0.5 cc of material.

**Note:** At no time during injection should excessive pressure or force be used because this may result in occlusion of the needle or syringe. If resistance is encountered, pull the syringe back slightly and rotate the knob one-half turn counterclockwise to relieve the pressure; then, continue injection.
Implant and contour material continued

Cranios Reinforced Rotary Mix remains injectable for 2 minutes at room temperature (18°–23°C / 64°–73°F). If 2 minutes have elapsed, the remaining material that has not been implanted should be discarded.

Start filling the defect at one side and completely fill the void. Remove excess material and move smoothly across the defect. Ensure that the material is completely contained within the defect.

Layering precaution: Layering of Cranios Reinforced Rotary Mix is not recommended. Should additional material be required, apply during the two-minute implantation time (see Time and temperature properties, pg 6).

Warning: If Cranios Reinforced Rotary Mix is applied against the dura, the use of Synthes Titanium mesh is recommended as an underlay to protect the cement from potential micro-fracture caused by dural pulsation.
8 Setting

Cranios Reinforced Rotary Mix sets within 10 minutes at normal body temperature (37°C/98.6°F). Once the material begins to harden, it must be left undisturbed to set properly.

Cranios Reinforced Rotary Mix should be kept moist during the setting process. It is recommended to gently cover it with a warm, wet lap sponge and carefully irrigate it with warm saline (approximately 37°C/98.6°F) twice per minute. Care should be taken not to disturb the cement. Do not tap or touch the material during setting.

Cranios Reinforced Rotary Mix fully cures and reaches its ultimate compressive strength of approximately 35 MPa in 24 hours.

**Note:** Once the cement begins to harden it must be left undisturbed to set properly. Additional time may be required if the operative site is not at body temperature.

Discard any unused material.
Product Information

Cranios Reinforced Rotary Mix, sterile
616.03.01S 3 cc (6 grams)
616.05.01S 5 cc (9 grams)
616.10.01S 10 cc (17 grams)

MXR-US-200 Rotary Mixer

Delivery Needles, sterile

<table>
<thead>
<tr>
<th>Single Pack</th>
<th>5 Pack</th>
</tr>
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<tbody>
<tr>
<td>612.40.01S</td>
<td>n/a</td>
</tr>
<tr>
<td>612.41.01S</td>
<td>612.41.05S</td>
</tr>
<tr>
<td>612.42.01S</td>
<td>n/a</td>
</tr>
</tbody>
</table>