Norian CRS Rotary Mix. Injectable calcium phosphate bone cement.
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Norian CRS Craniofacial Repair System is self-setting calcium phosphate bone cement used to fill defects in the restoration or augmentation of the craniofacial skeleton. Cured CRS material closely resembles the mineral phase of bone and is gradually resorbed and replaced with bone during the healing process.

Common applications include but are not limited to:
- Cranioplasty
- Cranial recontouring
- Cranial flap augmentation
- Augmentation genioplasty
- Onlay grafting
- Skull base defect repair

Features
- Injectable and moldable for remote, deep and onlay applications
- Hardens in a warm, wet environment, reducing the need to control moisture at the operative site
- Isothermic hardening prevents thermal injury to surrounding soft tissue
- Approximate ten-minute setting period minimizes procedure time
- Achieves maximum compressive strength of approximately 50 MPa (7,250 psi) within 24 hours
- Gradually resorbs and is replaced by bone during the healing process
Indications and Contraindications

Indications
Norian CRS bone cement is intended for filling craniofacial defects in the restoration or augmentation of bony contours of the craniofacial skeleton (including fronto-orbital, malar, and mental areas), such as burr hole voids and other craniofacial defects with a surface area no larger than 25 cm².

Contraindications
Norian CRS is not intended for use in the spine and should not be used in the presence of active or suspected infection.

Caution: Norian CRS is not recommended for use in sinus obliteration or near an open sinus.

Please see package insert for complete contraindications, warnings and precautions.
Norian CRS Bone Cement is a self-setting calcium phosphate cement which:
– Hardens in vivo to form carbonated apatite, closely resembling the mineral phase of bone;
– Gradually resorbs and is replaced with bone during the healing process;
– Is biocompatible;
– Is isothermic during setting

Although hydroxyapatite is commonly thought of as the mineral phase of bone, carbonated apatite actually constitutes 60–70% of total dry bone weight. The main distinction between hydroxyapatite and carbonated apatite is the presence of carbonate. The carbonate content of hydroxyapatite is 0%, while the carbonate content of the carbonated apatite contained in bone is 4–6%. Norian CRS has a carbonate content of approximately 5%, which closely resembles the composition of bone.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Properties of Bone vs. Norian CRS Bone Cement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Characteristic</strong></td>
<td><strong>Bone</strong></td>
</tr>
<tr>
<td>Ca/P Molar Ratio</td>
<td>1.33–1.73</td>
</tr>
<tr>
<td>Inorganic carbonate content (% by wt.)</td>
<td>4.0–6.0</td>
</tr>
<tr>
<td>Crystal Order</td>
<td>Low</td>
</tr>
<tr>
<td>Perfect Crystal Size</td>
<td>~200 Å</td>
</tr>
<tr>
<td>Chemical Make-up composite</td>
<td>Inorganic/organic</td>
</tr>
</tbody>
</table>

Norian CRS Rotary Mix System Overview

**Norian CRS Reactants Packs for Rotary Mixer**
- Designed for mixing at the time of use
- Contain premeasured amounts of sodium phosphate solution in a syringe and calcium phosphate powder in the mixing pouch
- Integrated with a delivery syringe for transferring cement to the operative site
- Available in 3 cc, 5 cc, and 10 cc sizes

**Norian Rotary Mixer**
- Electric powered—120 VAC
- Used outside the sterile field
- Sodium phosphate solution is manually injected into the powder compartment before the mixing cycle is started
- Roller carriage operation mixes the powder and solution to form a paste
- When mixing is complete, the reactants pack is fed through the rollers to transfer the paste into the delivery syringe

**Norian CRS Delivery Syringe and Needles**
- Syringe included in the sterile reactants pack
- Allow easy, precise injection of Norian CRS bone cement
- Provide tactile feedback while injecting
- Each syringe compatible with a selection of delivery needles
- Delivery needles available in sizes to meet a variety of surgical needs
- Single use only
Estimate the amount of Norian CRS bone cement required for surgery using the diagram shown. Large void volumes may be calculated by multiplying the length, width, and depth of the defect in centimeters for an approximate volume requirement (e.g. 2 cm long x 5 cm wide x 1 cm deep = 10 cc of Norian CRS bone cement).

Note: Volumes are approximate.
Preoperative Planning

Timing sequence
The handling properties of Norian CRS bone cement are governed primarily by the ambient temperature of the material as it is mixed and injected. The following timing sequence references the specific time and temperature relationships that must be followed for the material to obtain full strength.

The flow chart represents the changes in the material over time.

<table>
<thead>
<tr>
<th>Timing Sequence</th>
<th>Mixing Phase</th>
<th>Preparation and Implantation Phase**</th>
<th>Hardening/Setting Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>Approximately 70 seconds</td>
<td>Preparation for delivery</td>
<td>2 minutes maximum</td>
</tr>
<tr>
<td>Temperature</td>
<td>18°–23°C</td>
<td>18°–23°C</td>
<td>37°C</td>
</tr>
<tr>
<td>Procedure</td>
<td>Automatically prepared in the Norian rotary mixer.</td>
<td>Preparation time begins upon completion of mixing.</td>
<td>Inject cement into surgical site. Implantation time begins immediately at the start of injection of material at the implant site. Complete all contouring within two minutes of implantation.</td>
</tr>
</tbody>
</table>

** The preparation and implantation phases should be completed simultaneously.

**Caution:** If an insufficient amount of cement has been mixed to fill the defect, another pack may be mixed and applied during the two-minute implantation period. Once the putty begins to harden, it must be left undisturbed to set properly.

Curing time, 24 hours
Hardened CRS material reaches full compressive strength in 24 hours.
**Rotary Mixer Power Operation**

1. **Connect power cord**

   Unwrap the power cord and connect it 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 mixer lid by depressing the thumb latch located at the right corner of the lid.

3. **Position reactants pack**

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

Remove the solution syringe from the foil pouch. Using aseptic technique, remove the caps from the syringe and the reactants pack injection port. Connect the syringe to the injection port by turning clockwise and 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 reactants pack, the remaining steps must be completed immediately.
5

Remove pouch clip

Remove the pouch clip and unfold the reactants pack with the delivery syringe to the right.

6

Close lid and start mixer

Close the lid and secure by depressing the thumb latch. Press the start button to begin mixing. A single, brief beep indicates the start of the mixing cycle. Mixing is complete after 70 revolutions. An extended “beep” will sound and the “Complete” indicator will flash.

Caution: If the rotary mixer fails to complete the mixing cycle, or if the lid is opened before the cycle is complete, an audible alarm will sound and all function indicators will flash. Start with a new reactants pack and either return to Step 2 or mix using manual operation (see next page).
1
Follow Steps 2–5
Follow Steps 2–5 in the Power Operation section of this technique guide.

2
Close mixer lid
Close the lid and secure by depressing the thumb latch.

3
Operate mixer manually
Lift up on the handle on the mixer lid until it locks in the upright position. Rotate the top disk 70 revolutions clockwise (approximately one revolution per second).

When mixing is complete, lower the handle on the mixer lid by pulling it up and pushing it to the side.

Note: The counter operates using battery power and will advance when rotating the top disc without the mixer being plugged in.
Preparation for Delivery

1
Open mixer lid
Open the lid and lift the reactants pack from the center post of the mixer. The 5-minute preparation and implantation phase begins at the end of the mixing cycle.

2
Load delivery syringe
Guide the reactants pack containing the mixed Norian CRS bone cement into the transfer rollers and turn the knob counterclockwise. The material will be transferred into the delivery syringe.
Remove the reactants pack by reversing this action.

3
Transfer syringe to sterile field
Using aseptic technique, peel back the outer pouch to expose the delivery syringe. A sterile person should disengage the syringe with a quarter-turn counterclockwise, and complete the transfer to the sterile field.
4

Attach needle

Insert a delivery needle into the connector at the tip of the syringe and engage by rotating a quarter-turn clockwise to lock in place. Remove the clip from the plunger and prime the needle.

The material is now ready for implantation.
Inject material by one of two methods:

**Method 1**
Slowly push the plunger. For every “click,” 0.5 cc of material will be injected.

**Method 2**
For additional injection pressure and control, slowly turn the plunger knob clockwise. One full rotation of the knob injects 0.5 cc of CRS bone cement.

Calibration marks on the delivery syringe are in 1 cc increments.

**Caution:** 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 plunger back slightly and rotate the knob one-half (½) turn counterclockwise to relieve the pressure, then continue injection.

**Notes:** Discard any unused material after the 5-minute preparation and implantation phase.
Technique for Implantation

1

**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 before implanting the cement.

2

**Apply Norian CRS bone cement to implant site**

Using the delivery syringe, deliver the cement into the implant site, starting at one edge of the implant site and moving smoothly across the defect, making certain to fill the entire void.

For defects greater than 4 cm², reinforcement with Synthes titanium mesh is recommended.

**Important:** The cement should fill the entire defect, but stop precisely at the edge of the defect; it should not be “feathered” over the adjacent bone.

**Caution:** If Norian CRS bone cement is applied against the dura, the use of Synthes titanium mesh is recommended as an underlay to protect the cement from potential microfracture caused by dural pulsation.
3

Contour cement

Use a spatula or moistened fingertips to contour the cement. At normal body temperature there is a period of approximately two minutes after injection of the cement into the defect for contouring the cement.

**Technique tip:** If Norian CRS bone cement is used as an onlay, the perimeter of the defect site should be cut or burred down so that the cement is fully contained. Ridges should also be created on the implant site to improve the mechanical bond of the cement to the bone.

**Note:** If the patient's body temperature is lower than 37°C, the cement will stay moldable for more than two minutes. Conversely, if body temperature is higher than 37°C, the cement will stay moldable for less than two minutes. Fill the entire void and contour the cement within two minutes.

**Important:** If insufficient cement has been mixed to fill the defect, another reactants pack may be mixed and added during the two-minute implantation period. However, if the two-minute implantation period has elapsed and the cement has hardened, additional material should not be applied.

4

Allow cement to harden

Once the desired contour has been achieved, the cement must remain undisturbed for ten minutes at normal body temperature.

**Technique tip:** During this ten-minute setting period, it is recommended that the Norian CRS bone cement be kept moist, by gently covering it with a moist lap sponge and carefully irrigating the cement with warm saline (approximately 37°C) twice per minute. Care should be taken not to disturb the cement. Do not tap or touch the material during set-up.
Product Information

CRS Rotary Mixer Cement, sterile
614.03.01S 3 cc
614.05.01S 5 cc
614.10.01S 10 cc

MXR-US-2000 Rotary Mixer

Delivery Needles, sterile

<table>
<thead>
<tr>
<th>Single Pack</th>
<th>5-Pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>612.40.01S</td>
<td>612.40.05S 8 gauge x 10 cm</td>
</tr>
<tr>
<td>612.41.01S</td>
<td>612.41.05S 10 gauge x 10 cm</td>
</tr>
<tr>
<td>612.42.01S</td>
<td>612.42.05S 12 gauge x 10 cm</td>
</tr>
<tr>
<td>612.43.01S</td>
<td>612.43.05S 12 gauge x 10 cm, curved</td>
</tr>
<tr>
<td>612.44.01S</td>
<td>612.44.05S 12 gauge x 5 cm</td>
</tr>
<tr>
<td>612.45.01S</td>
<td>612.45.05S 14 gauge x 5 cm</td>
</tr>
<tr>
<td>612.46.01S</td>
<td>612.46.05S 12 gauge x 12.5 cm</td>
</tr>
</tbody>
</table>

Also Available

CRS Fast Set Putty, sterile
613.03.01S 3 cc
613.05.01S 5 cc
613.10.01S 10 cc
613.15.01S 15 cc