Norian SRS Rotary Mix. Calcium phosphate bone void filler.

Technique Guide

SYNTHES® Instruments and implants approved by the AO Foundation
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*Image intensifier control*
Reactants packs for rotary mixer
Reactants packs are designed for mixing at the time of use and are composed of two components:
– Calcium phosphate powder, contained in the reactants pack
– Sodium phosphate solution, contained in the solution syringe
Reactants packs are available in 3 cc, 5 cc and 10 cc sizes, with a delivery syringe integral to the pack.

Rotary mixer
The Norian rotary mixer is electrically powered and is used outside the sterile field. Prior to starting the mixing cycle, sodium phosphate solution is manually injected into the powder compartment. When the mixing cycle begins, the mixer’s roller carriage operates to mix the powder and solution to form a paste. When mixing is complete, the reactants pack is fed through the rollers and the paste is mechanically transferred into the delivery syringe.

Delivery syringe
– Included in the sterile reactants pack
– An easy, precise way to inject the Norian SRS Rotary Mix
– Compatible with a selection of delivery needles (available in sizes to meet a variety of surgical needs)
– Single use only

Common applications include
– Tibial plateau
– Distal femur
– Proximal humerus
– Calcaneus

Features
– Hardens in a warm, wet environment, reducing the need to control moisture at the operative site
– Isothermic hardening eliminates thermal injury to surrounding soft tissue
– Gradually resorbs and is replaced with bone during the healing process
Indications and Contraindications

Norian SRS Bone Void Filler is an injectable, moldable and biocompatible material. It should be used in bone defects that have been stabilized using standard AO orthopaedic techniques and implants (i.e. external fixation, K-wires, plates, screws, etc.).

Indications
Norian SRS Bone Void Filler is intended only for bony voids or defects that are not intrinsic to the stability of the bony structure. Norian SRS Bone Void Filler is intended to be placed or injected into bony voids or gaps of the skeletal system (the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

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

Please see package insert for complete contraindications, warnings and cautions.
Norian SRS Rotary Mix is a self-setting calcium phosphate bone void filler which:

– Hardens in vivo to form carbonated apatite, closely resembling the mineral phase of bone;
– Achieves a maximum compressive strength of approximately 50 MPa (7,251 psi) within 24 hours;
– Gradually resorbs and is replaced with bone during the healing process;
– Is biocompatible and isothermic.

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. While the carbonate content of hydroxyapatite is 0%, the carbonate content of the carbonated apatite contained in bone is 4–6%. Unlike hydroxyapatite, Norian SRS Rotary Mix has a carbonate content of 5%, which closely resembles the composition of bone. The properties of bone and Norian SRS Rotary Mix are compared in Table 1.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Bone</th>
<th>Norian SRS Rotary Mix</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbonate content</td>
<td>4.0–6.0 %</td>
<td>~5.0 %</td>
</tr>
<tr>
<td>Ca/P molar ratio</td>
<td>1.33–1.73</td>
<td>1.67</td>
</tr>
<tr>
<td>Crystal order</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Perfect crystal size</td>
<td>~200 Å</td>
<td>~200 Å</td>
</tr>
<tr>
<td>Chemical make-up</td>
<td>Inorganic/organic</td>
<td>Inorganic</td>
</tr>
</tbody>
</table>

Table 1

Crystallographic analysis by powder x-ray diffraction (XRD)

Preoperative Planning

1. **Assess void**
   Assess the void or defect and plan fracture reduction and stabilization if the void is due to traumatic injury.

2. **Determine surgical approach**
   Determine the surgical approach (minimally invasive or open) and the delivery method.

3. **Void preparation**
   Irrigate and aspirate the void to clear the injection path for the bone void filler. Prepare the void by compacting the cancellous bone with a curette, elevator or similar instrument.

   **Technique tip:** The use of warm saline for irrigation can assist in returning the defect site to body temperature.

4. **Injection path**
   Preplan the injection path by inserting the delivery needle into the void and probing the depths of the cavity. It is important to be certain of the backfill injection path since the 2-minute implantation time begins as soon as the filler contacts the cavity wall.
Timing Sequence

**Time and temperature properties**
The handling properties of Norian SRS Rotary Mix 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.

<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><strong>Mixing Phase</strong></td>
<td>Approximately 70 seconds</td>
<td>Preparation for delivery</td>
<td>Implantation time 2 minutes</td>
</tr>
<tr>
<td><strong>Temperature</strong></td>
<td>18°–23°C</td>
<td>18°–23°C</td>
<td>37°C</td>
</tr>
<tr>
<td><strong>Procedure</strong></td>
<td>Mix the contents of the reactants pack using the Norian rotary mixer (70 revolutions).</td>
<td>SRS material is injectable and controllable for 5 minutes maximum at room temperature (18°–23°C/64°–73°F). Transfer the mixed Norian SRS paste into the delivery syringe and transfer the delivery syringe into the sterile field. Attach an SRS delivery needle. Insert the needle into the operative site.</td>
<td>Inject the total amount of material into the prepared bone void and manipulate as necessary. Injected SRS paste can be manipulated for 2 minutes maximum at body temperature (37°C/98.6°F).</td>
</tr>
</tbody>
</table>

**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.

**Note:** Extremities can cool to well below body temperature (37°C/98.6°F) during a lengthy open procedure where tourniquet use exceeds one hour.

**Curing time, 24 hours**
Hardened SRS material reaches full compressive strength in 24 hours.
The following steps are performed outside the sterile field.

1. **Connect power cord**
   Unwrap the power cord and connect it to a 120 VAC outlet. Once connected, the standby indicator will light.

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 it 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 Norian 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. Start with a new reactants pack and either return to Step 2 or mix using manual operation (see next page).
Follow Steps 2–5 in the Power Operation section of this technique guide, and then proceed with the following:

1. **Close mixer lid**

   Close the lid and secure by depressing the thumb latch.

2. **Operate mixer manually**

   Lift up on the manual handle on the mixer lid until locked in the upright position. Rotate the top disk 70 revolutions clockwise (approximately one revolution per second).

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

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

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

2  Load syringe

Guide the reactants pack containing the mixed Norian SRS paste into the transfer rollers by turning 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 an SRS 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.
Always use a backfill technique (see page 17). Real-time fluoroscopy should be used to visualize the material during injection. Calibration marks on the delivery syringe are in 1 cc increments.

**Inject the 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 material.

**Precaution:** 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 (1/2) turn counterclockwise to relieve pressure, then continue injection.

**Note:** If the 5-minute preparation time elapses, the remaining Norian SRS Rotary Mix that has not been implanted must be discarded, and a new reactants pack mixed if additional material is needed.
Backfill technique

a. Insert delivery needle
Use image intensification for visualization. Insert the delivery needle into the far end of the void/defect. This is the start of the 2-minute implantation time during which the material is fully injected and can be manipulated as necessary (at body temperature, 37°C/98.6°F).

b. Begin injection
Begin injection and slowly withdraw the needle as fill is achieved.

c. Fill void
Completely fill the void. Check fill with multiple views. Remove excess material.

Note: If more than one reactants pack is required, the total volume (not to exceed 40 cc) of Norian SRS Rotary Mix should be implanted within the 2-minute implantation time. Disturbing the initial Norian material after 2 minutes may damage the construct.

d. Release tourniquet and irrigate
Release the tourniquet if used, and gently irrigate with warm saline to return the operative site to core body temperature (37°C/98.6°F). Allow the Norian SRS Rotary Mix to set during the 10-minute setting time. Do not disturb the material during this time period.

Note: If the material has not set in 30 minutes, remove it and start over with a new reactants pack.

e. Allow to cure
Norian SRS Rotary Mix fully cures and reaches its ultimate compressive strength within 24 hours.

Avoiding extraosseous deposits of Norian SRS Rotary Mix
It is important to limit the amount of material that is allowed to perfuse into the soft tissues and joint space. Irritation or inflammation may be possible complications associated with large extraosseous deposits of Norian SRS Rotary Mix. If Norian SRS is implanted into a joint or soft tissue, care should be taken to remove the excess by irrigating it away from the site.
## Reactants Packs for Rotary Mixer

Norian SRS Bone Void Filler Rotary Mix

<table>
<thead>
<tr>
<th>Code</th>
<th>Volume</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SRS-003-RMS</td>
<td>3 cc</td>
<td>sterile</td>
</tr>
<tr>
<td>SRS-005-RMS</td>
<td>5 cc</td>
<td>sterile</td>
</tr>
<tr>
<td>SRS-010-RMS</td>
<td>10 cc</td>
<td>sterile</td>
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</tbody>
</table>

## Mixer

MXR-US-2000 Rotary Mixer

## Delivery Needles

Delivery Needles, sterile

<table>
<thead>
<tr>
<th>Single pack</th>
<th>5-pack</th>
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</thead>
<tbody>
<tr>
<td>DLS-7083-01S</td>
<td>DLS-7083-05S</td>
</tr>
<tr>
<td>DLS-7103-01S</td>
<td>DLS-7103-05S</td>
</tr>
<tr>
<td>—</td>
<td>DLS-7121-05S</td>
</tr>
<tr>
<td>DLS-7122-01S</td>
<td>DLS-7122-05S</td>
</tr>
<tr>
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<tr>
<td>DLS-7126-01S</td>
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</tr>
<tr>
<td>—</td>
<td>DLS-7141-05S</td>
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