
Handling Technique
Warning
This description is not sufficient for immediate application of the instrumentation. Instruction by a surgeon experienced in handling this instrumentation is highly recommended.
Norian Craniofacial Repair System (CRS) Fast Set Putty is a mouldable, biocompatible bone substitute that sets at body temperature. The ingredients for mixing the putty are provided separately. One container contains the sterile powder (calcium phosphate) and a vial contains a sterile aqueous solution (sodium phosphate).

Mixing the components produces a mouldable putty, which is suitable for augmentation and restoration of the craniofacial skeleton. When fully cured, Fast Set Putty closely resembles the mineral phase of bone. It gradually remodels to bone via osteoclastic resorption and new bone formation.

**Indications**

Norian CRS Fast Set Putty is used for repairing or filling craniofacial defects and craniotomy cuts. It is also indicated for the restoration or augmentation of bony contours of the craniofacial skeleton, including the fronto-orbital, malar and mental areas.

Clinical applications include:

- Cranioplasty
- Cranial recontouring (e.g. atrophy of temporal bone)
- Cranial flap augmentation
- Augmentation genioplasty
- Skull base defect repair

**Restrictions**

Norian CRS Fast Set Putty is not suitable for the restoration of craniofacial continuity defects with a surface area greater than 25 cm².

**Contraindications**

See package insert.
Properties

- Easily shaped: Highly suitable for implantation into defects and for onlay applications
- Hardens in a warm, moist environment: There is no need to monitor moisture at the operative site
- Isothermal hardening prevents thermal injury to surrounding soft tissue
- Fast setting time (3–6 minutes): Shorter operative times
- Maximum compressive strength of approximately 30 Mpa (4350 psi) within 24 hours: This is 2–6 times greater than the compressive strength of cancellous bone
- Gradual remodeling to bone via osteoclastic resorption and new bone formation

Basic science

- Self-setting calcium phosphate bone substitute
- Hardens isothermally in vivo to form carbonated apatite. This material closely resembles the mineral phase of bone.
- Fast Set Putty is biocompatible

Carbonated apatite (carbonate content 4–6%) comprises 60–70% of the bone dry weight. With a carbonated content of 5%, Norian CRS Fast Set Putty therefore closely resembles the composition of bone. Hydroxylapatite, which is usually regarded as the mineral phase of bone, in contrast has no carbonate content. The properties of bone and Fast Set Putty are compared in Table 1.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Bone¹</th>
<th>Norian CRS Fast Set Putty</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
Properties of Norian CRS Fast Set Putty vs. bone

### Estimating cement volume*

- Burr hole filling: 3 cc
- Cranial defect: 10–25 cc
- Temporal bone augmentation: 25 cc
- Suboccipital cranioplasty: 5–10 cc
- Genioplasty: 5 cc
- Orbital rim: 5 cc

*Volumes are approximate

### Timing sequence

The flow chart represents the changes in the material over time and the related surgical procedure.

<table>
<thead>
<tr>
<th>Timing sequence</th>
<th>Mixing phase</th>
<th>Working phase</th>
<th>Hardening/Setting phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>18–23°C</td>
<td>37°C</td>
<td>37°C</td>
</tr>
<tr>
<td>CRS properties</td>
<td>Beginning of the chemical reaction</td>
<td>Body temperature triggers curing</td>
<td>Material starts curing, crystalline structure starts to develop</td>
</tr>
<tr>
<td>Surgical procedure</td>
<td>Mix until both of the components are fully integrated to produce a homogeneous putty</td>
<td>Apply CRS into surgical site Contour CRS</td>
<td>Do not manipulate the material after 2 minutes of contact with body to prevent disruption of the crystallisation process Keep the material moist</td>
</tr>
</tbody>
</table>
1. **Prepare implant site**

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

*Note:* Remove excessive bone wax or collagen prior to implanting Norian CRS Fast Set Putty.

2. **Open cup**

When the site is ready for implantation, prepare materials for mixing. Remove the cup from the tray, tap the cup on a hard surface and slowly peel back the lid to expose the powder. Take care not to spill any powder.

3. **Add liquid**

Remove the vial from the tray and pour the liquid onto the powder.

4. **Mix components (45–90 seconds)**

Using the spatula provided, mix the powder and liquid components together for 45–90 seconds depending on volume. Use a sweeping motion along the sides of the cup to incorporate all powder into the mix. Ensure that the components are fully integrated to produce a homogeneous putty.
Implant and contour material (within 2 minutes)
Immediately apply the Norian CRS Fast Set Putty to the defect site with the spatula or by hand. Contour the putty manually, using a wet gloved finger or a surgical instrument. Complete all contouring within 2 minutes of implantation.

Note: If Fast Set Putty 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 adhesion of the cement to the bone.
Allow Fast Set Putty to harden (3–6 minutes)

The putty will set within 3–6 minutes at normal body temperature (37°C). Once the putty begins to harden, it must be left undisturbed to set properly.

The Fast Set Putty should be kept moist by covering it with the skin flap or by gently drip irrigating the cement with warm saline (approximately 37°C) twice per minute.

**Note:** Once the cement has hardened, an abrasive may be used to modify the contour, taking care not to chip the hardened material. Do not drill into the cement because this could shatter the implant.

Norian CRS Fast Set Putty fully cures and reaches its ultimate compressive strength in 24 hours.

**Important:** If more Fast Set Putty is needed to fill the defect, another kit may be mixed and added during the 2-minute implant period. If the 2-minute implant period has elapsed, wait 6 minutes for the putty to completely harden before adding more material. If adding a second layer after the 6-minute set time do not keep the cement moist by covering it with the skin flap, use the drip irrigation method. To increase mechanical bonding between layers, ensure the hardened putty is free of blood.

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Ordering information
Norian CRS Fast Set Putty

<table>
<thead>
<tr>
<th>Art. No.</th>
<th>Volume</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSP-03-01</td>
<td>3 cc (6 grams), sterile</td>
<td></td>
</tr>
<tr>
<td>FSP-05-01</td>
<td>5 cc (9 grams), sterile</td>
<td></td>
</tr>
<tr>
<td>FSP-10-01</td>
<td>10 cc (17 grams), sterile</td>
<td></td>
</tr>
<tr>
<td>FSP-15-01</td>
<td>15 cc (25 grams), sterile</td>
<td></td>
</tr>
</tbody>
</table>

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A Company of Synthes-Stratec, Inc.

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