NORIAN REINFORCED FAST SET PUTTY BONE VOID FILLER

Calcium phosphate bone cement with added reinforcing fibers

Instruments and implants approved by the AO Foundation.
This publication is not intended for distribution in the USA.
# Image intensifier control

**Warning**
This description alone does not provide sufficient background for direct use of the product. Instruction by a surgeon experienced in handling this product is highly recommended.
Calcium phosphate bone cement with added reinforcing fibers.

Overview

Norian Reinforced Fast Set Putty Bone Void Filler is a moldable, biocompatible bone void filler with added reinforcing fibers and a sodium hyaluronate based solution.

Due to its special composition the reinforced cement resists cracking during the setting process and shows excellent mixing and handling properties.

Once the components are mixed together, the putty is suitable for augmentation and restoration of the craniofacial skeleton.
Features and Benefits

<table>
<thead>
<tr>
<th>Features</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Addition of sodium hyaluronate</td>
<td>Enhanced mixing, handling, and flow properties</td>
</tr>
<tr>
<td>Addition of reinforcing fibers</td>
<td>Material resists cracking during setting process</td>
</tr>
<tr>
<td>Easily shapeable and moldable</td>
<td>Allows for customization of implant</td>
</tr>
<tr>
<td>Isothermal hardening</td>
<td>Eliminate thermal injury to surrounding soft tissue</td>
</tr>
<tr>
<td>Fast setting time (6 minutes)</td>
<td>Minimizes procedure time</td>
</tr>
<tr>
<td>Maximum compressive strength of approx. 25 MPa within 24 hours</td>
<td>Compressive strength is 2–6 times higher than compressive strength of cancellous bone¹</td>
</tr>
<tr>
<td>Resembles mineral phase of bone</td>
<td>Gradual resorption and replacement with bone during the healing process</td>
</tr>
</tbody>
</table>

Calcium phosphate powder

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.²,³

Bioresorbable fibers

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

Sodium hyaluronate solution

Sodium hyaluronate is a pH-neutral solution that increases viscosity, which leads to enhanced mixing and flow properties.

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* Mechanical test data on file at Synthes. Mechanical test results may not necessarily be indicative of clinical performance.
Norian Reinforced is a two-component self-setting calcium phosphate bone cement. The powder component contains soluble salts of calcium phosphate and calcium carbonate and also 3% resorbable reinforcing fibers. Fibers are composed of 82:18 polylactide: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.

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%, the carbonate content of carbonated apatite contained in bone is 4–6%. Unlike hydroxyapatite, Norian Reinforced Fast Set Putty Bone Void Filler has a carbonate content of 5%, which closely resembles the composition of bone.

**Properties of Bone vs. Norian Reinforced**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Bone</th>
<th>Norian Reinforced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ca/P molar ratio</td>
<td>1.33–1.73</td>
<td>1.67</td>
</tr>
<tr>
<td>Inorganic carbonate content (% by wt.)</td>
<td>4.0–6.0%</td>
<td>~5.0%</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>

Indications and Contraindications

Indications
Norian Reinforced Fast Set Putty Bone Void Filler is indicated for repairing or filling craniofacial defects and craniotomy cuts with a surface area no larger than 25 cm². Norian Reinforced Fast Set Putty Bone Void Filler 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
- Cranial flap augmentation
- Augmentation genioplasty
- Skull base defect repair

Contraindications
Norian Reinforced Fast Set Putty Bone Void Filler is contraindicated for use in spinal applications. Norian Reinforced Fast Set Putty Bone Void Filler should not be used in the presence of active or suspected infection.

Norian Reinforced Fast Set Putty Bone Void Filler 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 facial growth is essentially complete
- Sinus obliteration
Warnings and Precautions

Warnings
– Do not manipulate site during the six-minute setting time at body temperature (37 °C).
– Remove excess material in adjacent soft tissue.
– Norian Reinforced Fast Set Putty Bone Void Filler is provided sterile and is a single use only device. If integrity of the package is compromised, the product must be assumed non-sterile and appropriately discarded.
– Norian Reinforced Fast Set Putty Bone Void Filler should be implanted within two minutes after mixing. Discard any unused material.
– If the 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.
– Mix materials into a homogeneous putty prior to implantation.
– Do not attempt to re-sterilize the unused contents of an opened pack, but dispose of such remnants. Re-sterilizing of Norian Reinforced Fast Set Putty Bone Void Filler can result in product not being sterile, and/or not meeting mechanical properties.
– Norian Reinforced Fast Set Putty Bone Void Filler attains a physiological pH after components are mixed, but the mixing cup, spatula and syringe components may be independent irritants. Proper eye protection and surgical gloves should be worn when cleaning up the components. Seek medical attention if the components are ingested or inhaled. If skin or eye contact occurs, do the following and seek medical attention if irritation occurs:
  – Skin exposure: Wash area with soap and water.
  – Eye exposure: Rinse thoroughly with running water.
– Unused Norian Reinforced Fast Set Putty Bone Void Filler should be discarded. Before disposal of the material, mix according to the Instructions for Use to render the contents pH neutral.
– A successful result is not achieved in every surgical case. If reoperation is required, the device should be removed and the surrounding bone should be reevaluated to make sure it is still viable.
– In defects equal to or larger than 4 cm², closed suction or drainage is recommended to prevent wound fluid accumulation in the immediate post-operative period.
– Excess fluids could result in device malfunction (e.g. washing away prior to setting).
– When using Norian Reinforced Fast Set Putty Bone Void Filler, some of the material may extrude into the surrounding facial soft tissues. The surgeon should minimize extrusion by observing the implantation of Norian Reinforced Fast Set Putty Bone Void Filler, and remove the extruded cement when possible. The effect of extrusion in craniofacial applications is not yet established.

Precautions
– Norian Reinforced Fast Set Putty Bone Void Filler must not be used in combination with hydrophilic materials.
– Familiarity with the use of bone substitutes for filling defects in bone, and the use of Norian Reinforced Fast Set Putty Bone Void Filler are required prior to treatment.
– The size or nature of the void or defect may require more than one package. If so, the total volume of Norian Reinforced Fast Set Putty Bone Void Filler implanted in that void or defect must be implanted within the two minute period commencing at the moment when the Norian Reinforced Fast Set Putty from the first package begins to be implanted. Disturbing the first Norian Reinforced Fast Set Putty Bone Void Filler implanted after that two minute period may damage the construct.
– Due to the radiopacity of the materials, anomalies may not be detected.
Timing Sequence

Time and temperature properties
The handling properties of Norian Reinforced Fast Set Putty Bone Void Filler are governed primarily by the room temperature of the material as it is mixed and delivered to 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>Implantation time</th>
<th>Setting time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixing</td>
<td>45–90 seconds</td>
<td>2 minutes maximum</td>
</tr>
<tr>
<td>Temperature</td>
<td>18–23 °C/64°–73 °F</td>
<td>37 °C/98.6 °F</td>
</tr>
<tr>
<td>Procedure</td>
<td>Mix the contents of the package for 45–90 seconds until a cohesive putty is formed. Mixing time is dependent on the size of the package being applied.</td>
<td>Deliver the material either with the spatula or by hand into the prepared bone void and contour as necessary. If more than 1 pack is required, the total volume of Norian Reinforced Fast Set Putty Bone Void Filler should be implanted within the same 2-minute implantation time.</td>
</tr>
</tbody>
</table>

Curing time: 24 hours at body temperature (37 °C). Norian Reinforced Fast Set Putty Bone Void Filler reaches its full compressive strength in 24 hours.
Surgical Technique

1

Prepare implant site

Using lavage and/or suction instruments, remove blood clots and tissue debris while controlling active bleeding. Prepare the void by compacting the cancellous bone with a curette elevator or similar instrument.

If bone wax or gelfoam is used, it should be removed prior to implanting Norian Reinforced Fast Set Putty Bone Void Filler.

Norian Reinforced Fast Set Putty Bone Void Filler is indicated for repairing or filling craniofacial defects and craniotomy cuts with a surface area no larger than 25 cm².
2

Mix components

Transfer the tray containing the mixing cup and the tray containing the solution syringe to the sterile field using aseptic technique.

When the site is ready for implantation, prepare materials for mixing.
- Remove the cup containing powder from the tray.
- Tap the cup on a hard surface to insure all powder is at the bottom of the cup.
- Slowly and gently peel back the lid to expose the powder, making sure not to spill any powder.

The tray and syringe package containing product cannot be stored once the outer pouches have been opened.
- Remove the syringe from the blister tray.
- Pull off the syringe cap and unthread the inner cap.
- Deliver the liquid onto the powder, ensuring that all liquid is dispensed from the syringe.

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.
3

Implant and contour material

Immediately apply Norian Reinforced Fast Set Putty Bone Void Filler 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 two minutes of implantation.

Norian Reinforced Fast Set Putty Bone Void Filler remains moldable for 2 minutes at room temperature (18–23 °C). If two minutes have elapsed, the remaining putty that has not been implanted should be discarded.

Implantation of the material should be performed under direct visualization or under real-time image intensification.

Completely fill the void. Check the fill with multiple view. Remove excess material.

If the 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.
Hardening

The putty will set within six minutes at normal body temperature (37 °C). Once the putty begins to harden, it must be left undisturbed to avoid cracking and/or crumbling.

The Norian Reinforced Fast Set Putty Bone Void Filler should be kept moist by gently covering it with a wet warm 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 the material during set-up.

Norian Reinforced Fast Set Putty Bone Void Filler fully cures and reaches its ultimate compressive strength by 24 hours.

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

### Norian Reinforced Fast Set Putty (Bone Void Filler)

<table>
<thead>
<tr>
<th>Code</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRS-0300-FRP</td>
<td>3 cc (6 grams)</td>
</tr>
<tr>
<td>CRS-0500-FRP</td>
<td>5 cc (9 grams)</td>
</tr>
<tr>
<td>CRS-1000-FRP</td>
<td>10 cc (17 grams)</td>
</tr>
</tbody>
</table>