Norian Drillable Bone Void Filler. The injectable bone void filler for drilling.

Technique Guide
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**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.

**Reprocessing, Care and Maintenance of Synthes Instruments**
For general guidelines, function control and dismantling of multi-part instruments please refer to: www.synthes.com/reprocessing
Overview

Norian Drillable Bone Void Filler is an injectable, biocompatible bone void filler. Due to its special material composition it can be drilled, tapped and screws can be placed through it at any time during or after the setting process.

Key components:
- Calcium phosphate powder
- Bioreorbable fibers
- Liquid component

Calcium phosphate has been widely used in clinical applications for decades. There are many publications\(^1\) and clinical cases available which demonstrate its safety and effectiveness to address bone regeneration.

The bioreorbable fibers are uniformly distributed within the material and provide an increase in toughness and allow the material to be drilled and tapped.

The liquid component is a pH-neutral solution to increase viscosity which leads to improved mixing and flow properties.

\(^1\) Examples:
The mixture of the key components leads to Norian Drillable, a product with unique features:

- Allows natural surgical procedure: reduce, fill, fix
- Can be drilled and tapped, and screws can be placed through it at any time during or after the setting process
- Provides partial structural support during the healing process
- Reaches a compressive strength of 35 MPa within 24 hours
- Isothermic hardening eliminates thermal injury to surrounding soft tissue
- Injectability allows minimal invasive treatment and optimal defect filling.
Basic science
Norian Drillable is a self-setting calcium phosphate bone void filler which:
- Contains resorbable polylactide/glycolide copolymer fibers which reduce crack propagation and allow the material to be drilled and tapped
- 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 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. The carbonate content of hydroxyapatite is 0%, while the carbonate content of the carbonated apatite contained in bone is 4–6%. Unlike hydroxyapatite, Norian Drillable has a carbonate content of approximately 5%, which closely resembles the composition of bone.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Bone</th>
<th>Norian Drillable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbonate content</td>
<td>4.0–6.0%</td>
<td>~5.0%</td>
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<tr>
<td>Ca/P molar ratio</td>
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<td>1.60</td>
</tr>
<tr>
<td>Crystal Order</td>
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<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>
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</table>
Indications
Norian Drillable Bone Void Filler is intended for bony voids or defects of the upper and lower extremities and pelvis. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Norian Drillable Bone Void Filler can be used as an adjunct to conventional rigid hardware fixation by supporting bone fragments during the surgical procedure. Once the material is set, it acts as a temporary support medium that provides partial structural support during the healing process and allows for early load bearing. Norian Drillable Bone Void Filler is intended to be placed into bony voids either before or after final fixation. The material can be drilled and tapped, and screws can be placed through it at any time during or after the setting process.

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

Norian Drillable Bone Void Filler is not for use in:
- Patients with traumatic open injuries that are predisposed to infection
- Full load bearing applications without the use of stabilizing hardware
- Areas where adjacent bone is avascular, or is incapable of supporting or anchoring the implanted rigid fixation hardware
- 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 are skeletally immature
- Intra-articular space (i.e., material placed into the joint

Please see package insert for complete contraindications, warnings and precautions.
Rotary pouches for rotary mixer
Rotary pouches are designed for mixing at the time of use and are composed of two components:

- Sterile powder in a rotary pouch (calcium phosphate with absorbable polylactide/glycolide copolymer fibers)
- Liquid solution in a syringe (dilute sodium phosphate with sodium hyaluronate)

Rotary pouches are available in various sizes, with a delivery syringe integrated into the rotary pouch.

Rotary mixer
The rotary mixer is electrically powered and is used outside the sterile field. Before starting the mixing cycle, the solution component is manually injected into the powder compartment. When the mixing cycle begins, the mixer’s roller carriage operates to mix the powder and solution into a paste. When mixing is complete, the rotary pouch is fed through a set of rollers and the paste is mechanically transferred into the delivery syringe.

Delivery syringe
- Included in the sterile rotary pouch
- An easy, precise way to inject the bone void filler
- Compatible with a selection of delivery needles (available in various sizes to meet a variety of surgical needs)
- Single use only
1
Assess void

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

2
Determine the surgical approach

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

3
Prepare void

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. Introduce warm saline into the defect to begin the warming process.

4
Plan injection path

Preplan the injection path by inserting the delivery needle into the void and probing the far ends 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.
Time and temperature properties

The handling properties of Norian Drillable are governed primarily by the ambient temperature of the material as it is mixed and injected. The following timing sequence refers to the specific time and temperature relationships that must be followed for the material to set properly.

Mixing, approximately 70 seconds
Mix the contents of the rotary pouch using the rotary mixer (70 revolutions).

Preparation time, 3 minutes
Three minutes maximum at room temperature (18°–23°C). Transfer the mixed Norian Drillable paste into the delivery syringe and transfer the delivery syringe into the sterile field. Attach a delivery needle. Insert the needle into the operative site and begin injection of the bone void filler.

Implantation time, 2 minutes
Two minutes maximum at body temperature (37°C). Inject the material into the prepared bone void and manipulate as necessary.

Setting time, 10 minutes
Ten minutes at body temperature (37°C). If a tourniquet is used, release it and lightly irrigate the exposed bone void filler with warm saline or place warm sponges over the implant site.

Note: Extremities can cool to well below body temperature during a lengthy open procedure when tourniquet use exceeds one hour. The 10-minute setting period begins once the site has returned to body temperature and the implantation time has expired.

Drilling and screw insertion
The material can be drilled and tapped, and screws can be placed through it at any time during or after the setting process.

Curing time, 24 hours
Twenty-four hours at body temperature (37°C). Norian Drillable reaches its full compressive strength in 24 hours.
A Mixing – Powered Operation

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, remove the cap from the syringe.

Remove cap from 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.
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 disk 70 revolutions clockwise (approximately one revolution per second).

**Note:** The counter operates on battery power and will advance when rotating the top disc, without the mixer 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 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 preformed 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 a quarter turn counterclockwise, and complete the transfer to the sterile field.

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4  
**Attach Norian needle**

Insert a Norian needle into the connector at the tip of the syringe and attach by rotating a 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.
Inject Norian Drillable bone void filler (two methods)

Always use a backfill technique (see next page). Calibration marks on the delivery syringe are spaced at 1 cc increments.

Inject the material by one of the two methods:

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

**b. 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 counter clockwise to relieve the pressure; then, continue injection.
Implant Norian Drillable either before or after final fixation

Norian Drillable remains injectable for 2 minutes at room temperature (18°–23 °C). If 2 minutes have elapsed, the remaining Norian Drillable that has not been implanted should be discarded.

Injection of the material should be performed under direct visualization or under real-time image intensification. If obstruction of the needle occurs, the needle should be discarded and replaced with a new needle.

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

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

At body temperature (37 °C), Norian Drillable begins to set approximately 2 minutes following implantation.

Avoid extraosseous deposits of Norian Drillable bone void filler

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 Drillable.

If the material is implanted into the joint or soft tissue, care should be taken to remove the excess material by irrigating it away from the site.
Drilling and Screw Insertion

The material can be drilled and tapped, and screws can be placed through it at any time after injection. Norian Drillable should not be used as a screw anchor. Screws placed through the material should be supported by bone on both sides of the material, according to proper orthopaedic reduction technique. Contouring of Norian Drillable can be done manually or with instruments, as desired.

If placing screws through fully set Norian Drillable, a hole should be predrilled to the root diameter of the screw. Do not place self-drilling screws through the material without predrilling to the root diameter.

Proceed slowly and irrigate while drilling through set Norian Drillable. Clear excess material from the flutes of the drill bit. After drilling or tapping through set material, irrigate to remove excess debris.

Placing guide wires (e.g. K-wires) through Norian Drillable bone void filler may cause the material to fracture. If guide wires are to be used, it is recommended that the guide wire is inserted into Norian Drillable bone void filler during the 2-minute implantation time or the 10-minute set time. Placing guide wires through the material after the 10-minute set time has elapsed is not recommended.

The use of cannulated screws with thread diameters greater than 5.0 mm over a guide wire is not recommended.
Release the tourniquet, if used, and gently irrigate with warm saline to return the operative site to core body temperature. At body temperature (37 °C), Norian Drillable may be considered set 10 minutes after implantation is completed.

Alternatively, to aid in the reduction of the fracture site, Norian Drillable can be allowed to set before application of final fixation materials. See chapter “Drilling and Screw Insertion”.

Norian Drillable fully cures and reaches its ultimate compressive strength within 24 hours.
Product Information

Norian Drillable Bone Void Filler Rotary Mix, sterile
- SRS-0300-FRI 3 cc
- SRS-0500-FRI 5 cc
- SRS-1000-FRI 10 cc

MXR-US-2000 Rotary Mixer

Delivery Needles, sterile

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<td>DLS-7126</td>
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<tr>
<td>DLS-7141</td>
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Also Available

Norian Drillable Fast Set Putty, sterile
- SRS-0300-FRP 3 cc
- SRS-0500-FRP 5 cc
- SRS-1000-FRP 10 cc