NORIAN® DRILLABLE

Fiber reinforced calcium phosphate bone void filler
Indications
Norian Drillable is intended for bony voids or defects of the extremities and pelvis that are not intrinsic to the stability of the bony structure. 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. Norian Drillable can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure. Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process. Norian Drillable is intended to be placed into bony voids either before or after final fixation.

Contraindications
The safety and effectiveness of this device for use in the spine has not been established. Use of this device is contraindicated in the spine, including use in the pedicle, as this could be associated with leakage of the device material into the bloodstream, which could cause serious adverse events, including death. Norian Drillable should not be used in the presence of active or suspected infection. Norian Drillable is not for screw augmentation. Norian Drillable is not for use in:
- Patients with traumatic open injuries that are predisposed to infection
- Stress-bearing applications
- 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
- Vertebral compression fractures
- Intra-articular space (i.e., material injected into the joint space)

Please refer to the instructions for use for a complete list of indications, contraindications, warnings, and precautions.
**Norian Drillable** is a biocompatible, fiber reinforced, calcium phosphate, bone void filler that can be implanted either before or after final fixation, allowing flexibility of application.

The reinforcing fibers enhance the material's structural integrity by providing added material toughness,* allowing for drillability, and increasing the material's resistance to cracking. Due to its unique material composition, when set, it closely resembles the mineral phase of bone and is gradually resorbed and replaced with bone during the natural bone healing process.

---

**Key Components**

**Sodium Hyaluronate**
The liquid component is a pH-neutral solution that increases viscosity, leading to improved mixing and handling.

**Bioresorbable Fibers**
Bioresorbable poly(lactide co-glycolide) (PLGA) fibers are uniformly distributed and randomly oriented within the material. These fibers provide added toughness, which reduces crack propagation and allows for the material to be drilled and tapped.

**Calcium Phosphate Powder**
The calcium phosphate powder that makes up Norian Drillable converts *in vivo* to form carbonated apatite, closely resembling the mineral phase of bone. It is gradually resorbed and replaced with bone during the natural bone healing process. Calcium phosphate has been widely used in clinical applications for decades, resulting in the availability of many publications and clinical cases demonstrating its safety and efficacy to address bone regeneration.1

---

* Toughness is defined as a measure of a material's resistance to fracture when stressed.

Data on file with DePuy Synthes.

---

Once Norian Drillable is fully set, the resulting biomaterial formed is carbonated apatite which has a crystallographic characteristic and chemical composition similar to bone, as demonstrated in Figure 1.

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. Hydroxyapatite does not contain any carbonate, however the carbonate content of Norian Drillable is approximately 4.5%, which more closely resembles the mineral phase of bone, 4–6% (Figure 2).

**Figure 1. Crystallographic analysis by Powder X-ray Diffraction (XRD)**

**Figure 2. Properties of Bone vs. Norian Drillable**

<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>4.5%</td>
</tr>
<tr>
<td>Ca/P molar ratio</td>
<td>1.33 –1.73</td>
<td>1.60</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/organic</td>
</tr>
</tbody>
</table>

Mechanical test results are not necessarily indicative of clinical performance.

For ergonomic reasons, the amount of load required to inject material from a syringe should be minimized as elevated injection forces may make it difficult to successfully implant the biomaterial.

One of the distinguishing features of Norian Drillable is that it sets in a moist environment. A warm, wet environment ensures that the material can fully convert to carbonatedapatite. In contrast, if the material is exposed to a dry environment during the setting process, it would become brittle and chalky. Therefore, in order to set properly and attain full compressive strength, Norian Drillable requires a wet, 37°C environment.

**Figure 3. Injection Test***
*Norian Drillable, Norian SRS®, and Stryker® Hydroset™

**EASIER TO INJECT**

*Mechanical test results are not necessarily indicative of clinical performance.*
A TOUGHER MATERIAL

Reinforcing fibers increase the material’s toughness.

Ceramic materials are brittle in flexural loading. However, the incorporation of bioresorbable fibers in Norian Drillable increases its material toughness compared to other ceramics. It is the addition of these fibers that provides improved handling and resistance to cracking as well as allows the material to be drilled, tapped and screws placed through it at any time during or after the setting process.

Three Point Bend Test
A three point bend test measures the flexural strength of a material. From the flexural test, the material’s toughness can also be established. Work of fracture is a quantitative way of expressing a material’s toughness, or the ability of a material to resist crack propagation. To determine the work of fracture, a stress-strain curve is generated during the three point bend test. From this curve, the material’s toughness or work of fracture is calculated.

Norian Drillable has a higher average work of fracture compared to Norian SRS and Hydroset, as demonstrated by the results of the three point bend test (Figure 4). This difference is directly related to the toughness of the material, as graphically shown by the stress-strain curve (Figure 5).

Figure 4. Three Point Bend Test*

Figure 5. Comparison of Material Toughness

*Mechanical test results are not necessarily indicative of clinical performance.
Norian Drillable's reinforcing fibers are present during the setting process to allow for drilling. Over time, these reinforcing fibers begin to degrade through hydrolysis. To demonstrate the relationship between the fiber degradation and the material’s work of fracture, three point bend tests were conducted at time points throughout the course of a year on samples that experienced simulated body conditions. The testing verified that Norian Drillable has an increased toughness over a period of several months. As the reinforcing fibers degrade, the material toughness of Norian Drillable reduces to levels comparable to Norian SRS.
As Norian Drillable sets, it begins to form carbonated apatite. The micro-structural development occurs as bridges form between adjacent particles. The scanning electron microscope (SEM) images on the adjacent page illustrate the structure of the material as it sets. As the carbonated apatite is formed, the compressive strength of the material increases. At 24 hours, the Norian Drillable Inject has reached its maximum compressive strength of approximately 35 MPa, which is greater than that of cancellous bone.³

Figure 8. Compression Test*

*N Mechanical test results are not necessarily indicative of clinical performance.

Figure 8. Norian Drillable Microstructural Development (SEM Images)

<table>
<thead>
<tr>
<th></th>
<th>Norian Drillable</th>
<th>Norian SRS</th>
<th>Cancellous Bone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compressive Strength</td>
<td>Inject: ~35MPa</td>
<td>Inject: ~50MPa</td>
<td>~5–7MPa³</td>
</tr>
<tr>
<td></td>
<td>FSP: ~25MPa</td>
<td>FSP: ~30MPa</td>
<td></td>
</tr>
</tbody>
</table>

Start of Mix | Post Mix | 10 minutes at 37°C | 24 hours
**PRODUCT INFORMATION**

<table>
<thead>
<tr>
<th>07.704.103S</th>
<th>07.704.105S</th>
<th>07.704.110S</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 cc</td>
<td>5 cc</td>
<td>10 cc</td>
</tr>
</tbody>
</table>

**Norian Drillable Fast Set Putty, sterile**

<table>
<thead>
<tr>
<th>07.704.003S</th>
<th>07.704.005S</th>
<th>07.704.010S</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 cc</td>
<td>5 cc</td>
<td>10 cc</td>
</tr>
</tbody>
</table>

**Norian Drillable Inject, sterile**

**Also Available**

**Delivery Needles, sterile**

<table>
<thead>
<tr>
<th>Single Pack</th>
<th>5 Pack</th>
<th>8 gauge x 10 cm</th>
<th>10 gauge x 10 cm</th>
<th>12 gauge x 5 cm</th>
<th>12 gauge x 7.5 cm</th>
<th>12 gauge x 10 cm</th>
<th>12 gauge x 12.5 cm</th>
<th>12 gauge x 10 cm, curved</th>
</tr>
</thead>
<tbody>
<tr>
<td>DLS-7083-01S</td>
<td>DLS-7083-05S</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DLS-7103-01S</td>
<td>DLS-7103-05S</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n/a</td>
<td>DLS-7121-05S</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DLS-7122-01S</td>
<td>DLS-7122-05S</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DLS-7123-01S</td>
<td>DLS-7123-05S</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n/a</td>
<td>DLS-7124-05S</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DLS-7126-01S</td>
<td>DLS-7126-05S</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**MXR-US-2000 Rotary Mixer**
Limited Warranty and Disclaimer: DePuy Synthes Biomaterials products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA law restricts these devices to sale by or on the order of a physician.

Not all products are currently available in all markets.