NORIAN® DRILLABLE FAST SET PUTTY
Fiber reinforced calcium phosphate bone void filler
INDICATIONS AND CONTRAINDICATIONS*

Indications
Norian® Drillable Fast Set Putty 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 Fast Set Putty 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 Fast Set Putty 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 Fast Set Putty should not be used in the presence of active or suspected infection.

Norian Drillable Fast Set Putty is not for screw augmentation.

Norian Drillable Fast Set Putty 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 (eg, 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 (ie, material injected into the joint space)

*Please refer to the instructions for use for a complete list of indications, contraindications, warnings, and precautions.
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* This technique guide is intended for instructions for Norian Drillable Fast Set Putty, only. Please refer to the manufacturer’s information or instruction for use of other products depicted in the images in this technique guide (e.g., rigid fixation hardware).
NORIAN DRILLABLE FAST SET PUTTY
Fiber reinforced calcium phosphate bone void filler

Material Composition. 3 key components:

- **Calcium phosphate powder**
  The calcium phosphate powders that make up Norian Drillable Fast Set Putty convert in vivo to form carbonated apatite, closely resembling the mineral phase of bone. Norian Drillable Fast Set Putty is gradually resorbed and replaced with bone during the natural 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

- **Bioresorbable fibers**
  Biodegradable polylactide/glycolide copolymer 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, tapped, and have screws placed through it.*

- **Sodium hyaluronate solution**
  The liquid component is a pH-neutral solution that increases viscosity, which leads to improved mixing and handling properties.

* Toughness is defined as a material's resistance to fracture when stressed. Data on file at DePuy Synthes Companies of Johnson & Johnson.

Norian Drillable Fast Set Putty is a biocompatible, fiber-reinforced, calcium phosphate bone void filler that is intended to be placed into bony voids either before or after final fixation. When fully cured, it closely approximates the mineral phase of bone.

<table>
<thead>
<tr>
<th>Features</th>
<th>Benefits</th>
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<tr>
<td>Drillable</td>
<td>Cleared to be drilled, tapped, and have screws placed through the material at any time during or after the setting process</td>
</tr>
<tr>
<td>Reinforcing fibers</td>
<td>Enhance structural integrity by providing added toughness,* allowing for drillability and increasing the material’s resistance to cracking</td>
</tr>
<tr>
<td>Flexibility of application</td>
<td>Material can be implanted either before or after final fixation</td>
</tr>
<tr>
<td>Sets in a warm, wet environment</td>
<td>Reduces need to limit moisture at the operative site</td>
</tr>
<tr>
<td>Compressive strength</td>
<td>Reaches a maximum compressive strength of 25 MPa within 24 hours, which is greater than that of cancellous bone (~5–7 MPa)²</td>
</tr>
<tr>
<td>Sets in 3–6 minutes</td>
<td>Reduces operating room time</td>
</tr>
<tr>
<td>Isothermic hardening</td>
<td>Eliminates thermal injury to surrounding soft tissue</td>
</tr>
<tr>
<td>Closely resembles mineral phase of bone</td>
<td>Gradually resorbed and replaced with bone during the natural healing process</td>
</tr>
<tr>
<td>Manual delivery</td>
<td>Easily shaped and molded to the contour of the defect site</td>
</tr>
</tbody>
</table>

* Toughness is defined as a measure of the material’s resistance to fracture when stressed. Data on file at DePuy Synthes Companies of Johnson & Johnson.

Basic science
Norian Drillable Fast Set Putty 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, tapped, and have screws placed through it
- 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. Hydroxyapatite does not contain any carbonate. In contrast, Norian Drillable Fast Set Putty has a carbonate content of approximately 4.5%, more closely resembling the mineral phase of bone. The properties of bone and Norian Drillable Fast Set Putty are compared in the adjacent table.

Once Norian Drillable Fast Set Putty is fully set, it has a crystallographic characteristic and chemical composition similar to bone, as demonstrated in Figure 1.

### Properties of Bone vs. Norian Drillable Fast Set Putty

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Bone</th>
<th>Norian Drillable Fast Set Putty</th>
</tr>
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<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>Optimal 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>

Table 1

### Crystallographic Analysis by Powder X-ray Diffraction (XRD)

Figure 1
**Time and temperature properties**

The handling properties of Norian Drillable Fast Set Putty are governed primarily by the mixing technique and ambient temperature of the material as it is prepared 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.

### NORIAN DRILLABLE FAST SET PUTTY TIMING SEQUENCE

<table>
<thead>
<tr>
<th>Phase</th>
<th>Timing Sequence</th>
<th>Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mixing</strong></td>
<td>45–90 seconds</td>
<td>18°–23°C/64°–73°F</td>
</tr>
<tr>
<td><strong>Preparation and Implantation</strong></td>
<td>2 minutes</td>
<td>37°C/98.6°F</td>
</tr>
<tr>
<td><strong>Setting</strong></td>
<td>3–6 minutes</td>
<td>37°C/98.6°F</td>
</tr>
</tbody>
</table>

### Procedure

- **Mix** until both of the components are fully integrated to produce a cohesive putty.

**Deliver** the material either by hand or surgical instrument into the prepared bone void and manipulate as necessary.

**Tip:** Irrigating with warm saline before implantation can assist in returning the defect site to body temperature.

**Note:** Layering precaution: If more than 1 package is required, the total volume (not to exceed 40 cc) of Norian Drillable Fast Set Putty should be implanted within the 2-minute preparation and implantation period.

**Tip:** If a tourniquet is used, when possible, release it and/or lightly irrigate the exposed bone void filler with warm saline or place a warm, wet sponge over the implant site.

**Note:** Extremities can cool to well below body temperature during a lengthy open procedure when tourniquet use exceeds 1 hour. The 3–6-minute setting period begins once the site has returned to body temperature and the preparation and implantation period has expired.

**Predrill** to the root diameter of the screw, for all screw types.

**Proceed slowly and irrigate** while drilling. Clear excess material from the drill bit flutes. After drilling, tapping, or placing a screw, irrigate to remove excess debris.

**Guidewires** should be inserted immediately after implantation of material. It is not recommended to place guidewires after the 3–6-minute setting period has elapsed.

### Curing Time, 24 hours

Norian Drillable Fast Set Putty reaches its full compressive strength after 24 hours at body temperature (37°C/98.6°F).
MANUAL APPLICATION

Mix Norian Drillable Fast Set Putty and apply the material by hand or with surgical instruments. Ideal for voids with clear visualization that may require material contouring.
MANUAL APPLICATION OF
NORIAN DRILLABLE FAST SET PUTTY

PREOPERATIVE PLANNING

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

2
Determine the surgical approach
Determine the surgical approach and the delivery method.

3
Prepare the implant site
Remove blood clots and tissue debris using lavage and/or suction instruments. Control active bleeding.

Prepare the void by compacting the cancellous bone with a curette elevator or similar instrument.

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

4
Plan delivery of material
Plan the method in which the material will be delivered; by hand or with surgical instruments. It is important to be familiar with the delivery of Norian Drillable Fast Set Putty since the 2-minute implantation period begins immediately after the mixing period. See page 5 for timing sequence overview.

**Note:** Norian Drillable Fast Set Putty can be implanted before or after final fixation. This technique illustrates the implantation of Norian Drillable Fast Set Putty prior to final fixation.
1 Transfer components to sterile field

Open the outer pouch containing the Norian Drillable Fast Set Putty tray and aseptically transfer the tray containing the cup and spatula to the sterile field. Open the outer tray containing the solution and aseptically transfer the inner tray to the sterile field.

Note: The trays containing the mixing cup and the solution cannot be stored once the seal on the outer packaging has been removed.

2 Prepare components for mixing

When the site is ready for implantation, prepare materials for mixing. Remove the cup, spatula, and solution from the inner trays.

3 Remove the lid of the Norian Drillable Fast Set Putty cup

Tap the cup on a hard surface and slowly peel back the lid to expose the powder. Take care not to spill any powder.
4

Mix components (45–90 seconds)

Remove the cap from the solution syringe by turning the gray silicone cap counterclockwise. Carefully deliver the liquid onto the powder in the cup, ensuring that all liquid is expelled from the syringe.

Using the spatula provided, mix the powder and liquid components together for 45–90 seconds, depending on volume. Using a sweeping motion at first, slowly mix the components until the liquid and powder components are incorporated.

Once the powder and solution mimic a putty material, begin to vigorously mix the putty in a circular motion, using the spatula and side of the cup to apply shear force to the material.

At the completion of the mixing period the components should be fully integrated as a homogenous putty.

**Technique tip:** Mix Norian Drillable Fast Set Putty in a circular motion against the side of the cup. The shear force created from this technique will increase compressive strength and improve material handling.
1 Implant Norian Drillable Fast Set Putty

Immediately apply the Norian Drillable Fast Set Putty to the defect site using the provided spatula or by hand. Contour the putty manually, using a wet gloved finger or surgical instrument. Complete all implantation and contouring within the 2-minute implantation period.

Precaution: The size or nature of the void or defect may require more than 1 package of Norian Drillable Fast Set Putty. If so, the total volume of material placed in a void must be implanted within the 2-minute implantation period commencing when the first package is implanted. Disturbing the first Norian Drillable Fast Set Putty implant after the 2-minute period may damage the construct. Completely fill the void. Check the fill with multiple views.

Notes:
• The effect of layering packages of Norian Drillable Fast Set Putty after the 2-minute implantation period is unknown.
• It is not recommended to mix Norian Drillable Fast Set Putty with other versions of the Norian product line, including Norian Drillable Inject.

Implantation of the material should be performed under direct visualization or under real-time image intensification.
Material Implantation (2 minutes at body temperature, 37°C/98.6°F)

2

Remove extraosseous deposits of material

If Norian Drillable Fast Set Putty is implanted into the joint or soft tissue, care should be taken to remove the excess material through irrigation.

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 Fast Set Putty.

3

Discard unused material

Norian Drillable Fast Set Putty remains moldable during the 2-minute implantation period at room temperature. If 2 minutes have elapsed, the remaining Norian Drillable Fast Set Putty that has not been implanted should be discarded in accordance with hospital regulations.

**Technique tip:** Norian Drillable Fast Set Putty may be implanted before or after final fixation.
Norian Drillable Fast Set Putty can be drilled, tapped, and have screws placed through it at any time after implantation.

1
Insert final fixation hardware
When placing screws into Norian Drillable Fast Set Putty, it is recommended that a drill hole be predrilled to the root diameter of the screw. Proceed slowly and irrigate while drilling through set Norian Drillable Fast Set Putty. Remove excess material from the flutes of the drill bit.

Precautions*:
• Placing guide wires (eg, K-wires) through Norian Drillable Fast Set Putty may cause the material to fracture. If guide wires are to be used, it is recommended that the guide wire be inserted into Norian Drillable Fast Set Putty during the 2-minute implantation period or the 3–6 minute setting period. Placing guide wires through the material after the 3–6 minute setting period has elapsed is not recommended.
• Do not place self-drilling screws through the material without predrilling to the root diameter.
• Norian Drillable Fast Set Putty 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.

2
Irrigate to remove excess material
After drilling, tapping, or placing a screw through the setting material, irrigate to remove excess debris.

*The complete list of Warnings and Precautions can be found in the back of the Technique Guide.
SETTING AND CURING

1

**Restore operative site to body temperature**

If possible, release the tourniquet and/or gently irrigate the Norian Drillable Fast Set Putty with warm, sterile saline to return the operative site to core body temperature.

2

**Norian Drillable Fast Set Putty sets in 3–6 minutes**

At body temperature (37°C/98.6°F), Norian Drillable Fast Set Putty can be considered set in 3–6 minutes after the 2-minute implantation period.

**Note:** To aid in the reduction of the fracture site, Norian Drillable Fast Set Putty may be allowed to set before application of final fixation hardware. See Drilling and Screw Insertion.

3

**Norian Drillable Fast Set Putty cures in 24 hours**

Norian Drillable Fast Set Putty fully cures and reaches its ultimate compressive strength of 25MPa within 24 hours.
**IMPLANTS AND INSTRUMENTS**

**Norian Drillable Fast Set Putty, sterile**
- 07.704.103S 3 cc
- 07.704.105S 5 cc
- 07.704.110S 10 cc

**Also Available**
**Norian Drillable Inject, sterile**
- 07.704.003S 3 cc
- 07.704.005S 5 cc
- 07.704.010S 10 cc

**Delivery Needles, sterile**

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

**MXR-US-2000**  Rotary Mixer
WARNINGS AND PRECAUTIONS

**Warnings**

- Mix materials into a homogeneous putty prior to implantation.
- Norian Drillable Fast Set Putty is for single use only, and should not be resterilized.
- Remove excess material in adjacent soft tissue.
- Norian Drillable Fast Set Putty is provided sterile. If integrity of the package is compromised, the product must be assumed to be nonsterile and appropriately discarded.
- Norian Drillable Fast Set Putty should be implanted within 2 minutes after mixing. Discard any unused material.
- The safety and effectiveness of Norian Drillable Fast Set Putty when used in patients having received or to receive chemotherapy or radiation therapy at or near the implant site are not known.
- The safety and effectiveness of Norian Drillable Fast Set Putty when combined with autograft, allograft, muscle grafts, dura, fascia, abdominal fat, acrylic, silicone, or polymer are not yet established.
- The effect of layering Norian Drillable Fast Set Putty is not known.
- Do not mix Norian Drillable Fast Set Putty with any other substance, as this may alter the safety and effectiveness of the material and could prevent the material from setting.
- Highly pressurized application of Norian Drillable Fast Set Putty into a tightly confined space with ready venous or arterial access is not recommended, as the potential for formation of emboli is unknown.
- Limit manipulation of the surgical site during the setting time, 3-6 minutes at body temperature (37°C/98.6°F), to drilling, tapping, or inserting fixation hardware.
- Do not overfill the defect site.
- Do not remove any hardware until after the device has cured for 24 hours.
- Do not use if temperature indicator has been activated (as shown by indicator dot turning black).

**Precautions**

- The medical professional is responsible for using his/her best medical judgment prior to using this or any other medical device. In particular, familiarity with the use of bone void fillers for filling defects in bone, mixing instructions, instrumentation, implantation technique, Preparation Time, Implantation Time, Setting Time, and Cure Time are required prior to treatment.
- The Norian Drillable Fast Set Putty package should be equilibrated to 18°-23°C/64°-73°F prior to mixing.
- If more than 1 package is required, the total volume (not to exceed 40 cc) of Norian Drillable Fast Set Putty should be implanted within the 2-minute Implantation Time.
- Due to the radiopacity of the material, anomalies may not be detected.
- Norian Drillable Fast Set Putty attains physiologic pH after components are mixed. 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**: Flush thoroughly with running water.
- The effect of Norian Drillable Fast Set Putty on patients with the following conditions is not known:
  - Individuals who will not or cannot follow a prescribed rehabilitation course such as with alcohol or drug abusers
  - Defects due to congenital malformation or metabolic disease
  - Documented renal disease
  - Pregnancy and/or nursing women
  - Cardiovascular disease precluding elective surgery
  - Osteoporosis
- 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 re-evaluated to make sure it is still viable.
Precautions continued

- Unused Norian Drillable Fast Set Putty should be discarded. Before disposal, mix according to the Directions for Use to render the contents pH neutral.

- The recommended application of Norian Drillable Fast Set Putty is to fill bone defects that have been stabilized using standard orthopaedic reduction techniques and fixation protocol, ie, external fixation pins, K-wires, plates, screws, etc.

- If the Implantation Time (2 minutes from end of mixing process) elapses, the remaining Norian Drillable Fast Set Putty that has not been implanted must be discarded and a new package mixed.

- Because Norian Drillable Fast Set Putty must be placed in the void within 2 minutes from the end of mixing, the surgeon should develop a preoperative plan. This requires understanding the method, sequence, and estimated volume of Norian Drillable Fast Set Putty needed to fill the void. The plan should be confirmed intraoperatively by direct visualization or under real-time image intensification.

- Excess fluids could result in device malfunction (eg, washing away prior to setting)

- To avoid inadvertent delivery of Norian Drillable Fast Set Putty (ie, into the intra-articular space), placement of the material should be performed under direct visualization or under real-time image intensification.

- The long-term effects of extraosseous Norian Drillable Fast Set Putty or intra-articular Norian Drillable Fast Set Putty (material implanted into the joint space) are unknown. Irritation or inflammation may be possible complications associated with large extraosseous deposits of Norian Drillable Fast Set Putty. 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.

- Arthritis may be a possible complication of intra-articular Norian Drillable Fast Set Putty.

- Fractures with intra-articular involvement should be properly reduced according to ORIF technique prior to implanting Norian Drillable Fast Set Putty. Extra care must be taken to ensure Norian Drillable Fast Set Putty has not entered the joint space when the bone void being filled is adjacent to the articular surface.

- Over-pressurizing the device may lead to extrusion of the device beyond the site of its intended application and damage to the surrounding tissues.

- Over-pressurizing the defect site may lead to fat embolization or embolization of the device material into the bloodstream.

- Norian Drillable Fast Set Putty 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 orthopedic reduction technique.

- Placing guide wires (eg, K-wires) through Norian Drillable Fast Set Putty 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 Fast Set Putty during the 2-minute implantation time or the 3-6 minute set time. Placing guide wires through the material after the 3–6 minute set time has elapsed is not recommended. Monitor the K-wire position when over drilling to ensure the K-wire does not advance with the drill.

- The use of self drilling screws is not recommended with Norian Drillable Fast Set Putty. If self drilling screws are to be used, it is recommended that the material is pre-drilled to the root diameter of the screw.

- As with most materials, placing screws near the edge of the implanted Norian Drillable Fast Set Putty may cause the Norian Drillable Fast Set Putty to fracture.

- The use of cannulated screws with thread diameters greater than 5.0 mm over a guide wire is not recommended.
Store at room temperature (5°C–25°C). Avoid excessive heat or humidity. Maximum shipping exposure 43°C.

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Limited Warranty and Disclaimer: DePuy Synthes Companies 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.

Some devices listed in this Technique Guide may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.