

Fiber Reinforced Calcium Phosphate Bone Void Filler

# Norian<sup>®</sup> Drillable Inject

Surgical Technique



# INDICATIONS AND CONTRAINDICATIONS\*

---

## Indications

Norian® Drillable Inject 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 Inject 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 Inject 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 Inject should not be used in the presence of active or suspected infection.

Norian Drillable Inject is not for screw augmentation.

Norian Drillable Inject 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 (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.

# TABLE OF CONTENTS

INTRODUCTION	Norian Drillable Inject	2
	System Overview	5
SURGICAL TECHNIQUE*	Timing Sequence	6
	Preoperative Planning	7
	Mixing – Powered Operation	8
	Mixing – Manual Operation	12
	Preparation	13
	Implantation	15
	Drilling and Screw Insertion	17
	Setting and Curing	18
PRODUCT INFORMATION	Implants and Instruments	19
	Warnings and Precautions	20

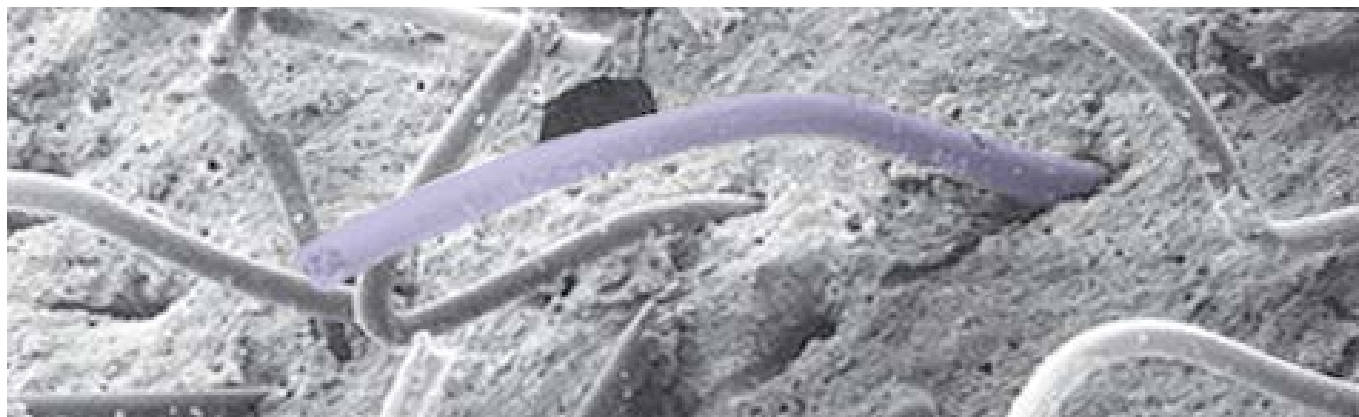
\* This technique guide is intended for instructions for Norian Drillable Inject, only. Please refer to the manufacturer's information or instruction for use of other products depicted in the images in this technique guide (eg, rigid fixation hardware).

 Image intensifier control

# NORIAN DRILLABLE INJECT

## Fiber reinforced calcium phosphate bone void filler

**Material Composition.** Three key components:



### Calcium phosphate powder

The calcium phosphate powders that make up Norian® Drillable Inject convert *in vivo* to form carbonated apatite, closely resembling the mineral phase of bone. Norian Drillable Inject 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.<sup>1</sup>



### Bioresorbable fibers

Bioresorbable 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 (FRN Test 65).

1. Bajammal S, Zlowodzki M, Lelwica A, et al. The use of calcium phosphate bone cement in fracture treatment. A meta-analysis of randomized trials. *J Bone Joint Surg Am.* 2008;90(6):1186–96.

# NORIAN DRILLABLE INJECT

## Overview

Norian Drillable Inject 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.



## Features

Drillable

Reinforcing fibers

Flexibility of application

Sets in a warm, wet environment

Compressive strength

Isothermic hardening

Closely resembles mineral phase of bone

Injectable

## Benefits

Cleared to be drilled, tapped, and have screws placed through the material at any time during or after the setting process

Enhance structural integrity by providing added toughness,\* allowing for drillability and increasing the material's resistance to cracking

Material can be implanted either before or after final fixation

Reduces need to limit moisture at the operative site

Reaches a maximum compressive strength of 35 MPa within 24 hours, which is greater than that of cancellous bone (~5-7 MPa)<sup>2</sup>

Eliminates thermal injury to surrounding soft tissue

Gradually resorbed and replaced with bone during the natural healing process

Allowing for minimally invasive treatment and optimal defect filling

\* Toughness is defined as a measure of the material's resistance to fracture when stressed (FRN Test 65).

2. Cowin, S.C., ed. *Bone Mechanics Handbook*. 2nd ed. New York, NY: CRC Press, 2001. 16-3. Print.

# NORIAN DRILLABLE INJECT

## Basic Science

Norian Drillable Inject 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 resorbed and replaced with bone during the healing process
- 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 Inject has a carbonate content of approximately 4.5%, more closely resembling the mineral phase of bone. The properties of bone and Norian Drillable Inject are compared in the adjacent table.

Once Norian Drillable Inject 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 Inject

Characteristic	Bone <sup>3</sup>	Norian Drillable Inject
Carbonate content	4.0–6.0%	4.5%
Ca/P molar ratio	1.33–1.73	1.60
Crystal order	Low	Low
Optimal crystal size	~200 Å	~200 Å
Chemical make-up	Inorganic/ organic	Inorganic/ organic

Table 1

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

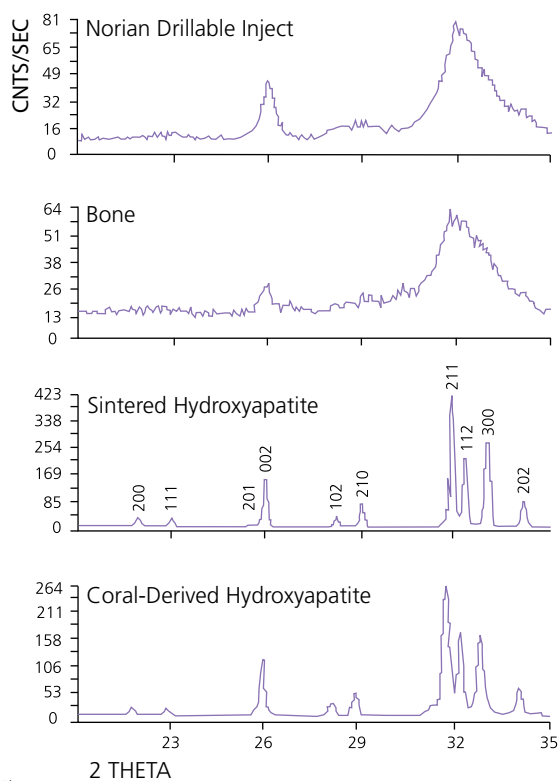


Figure 1

3. Constantz B, Ison IC, Fulmer MT, et al. Skeletal repair by in situ formation of the mineral phase of bone. *Science*. 1995;267(5205):1796–9.

# SYSTEM OVERVIEW

## Norian Drillable Inject

Designed for use with the Rotary Mixer and contains two components:

- Rotary Pouch: calcium phosphate with bioresorbable polylactide/glycolide copolymer fibers
- Solution Syringe: dilute sodium phosphate with sodium hyaluronate

Norian Drillable Inject is available in 3 cc, 5 cc, and 10 cc offerings. Includes an integrated, sterile Delivery Syringe.



## 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 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

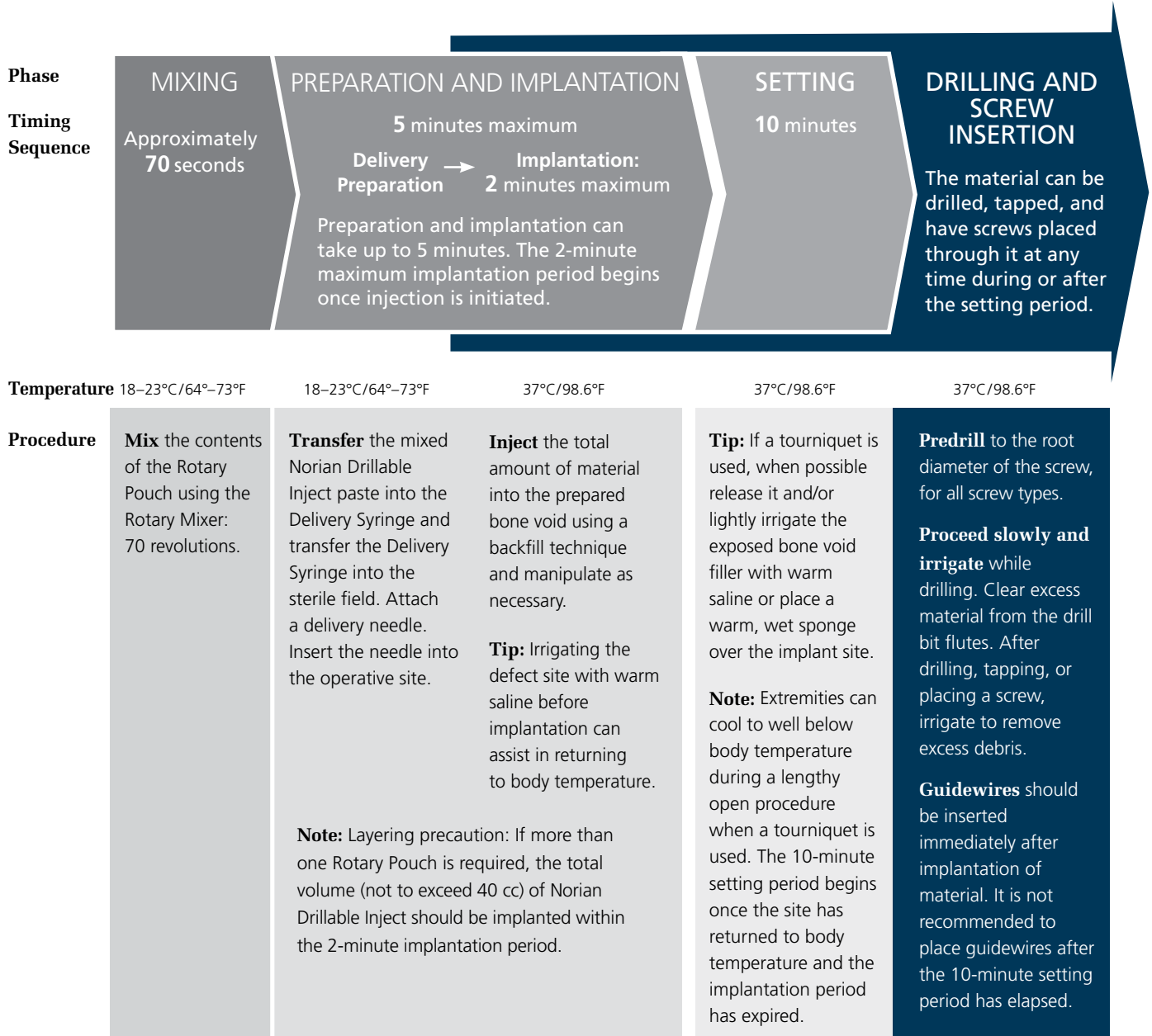


# NORIAN DRILLABLE INJECT TIMING SEQUENCE

## Time and temperature properties

The handling properties of Norian Drillable Inject are governed primarily by the ambient 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.



## Curing Time, 24 hours

Norian Drillable Inject reaches its full compressive strength after 24 hours at body temperature (37°C/98.6°F).



# 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 (minimally invasive or open) 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 injection path by inserting the delivery needle into the void and probing the far end of the cavity. It is important to be certain of the backfill injection path since the 2-minute implantation period begins immediately after the mixing period. See page 6 for timing sequence overview.

**Note:** Norian Drillable Inject can be implanted before or after final fixation. This technique illustrates the implantation of Norian Drillable Inject prior to final fixation.

# ROTARY MIXER POWERED OPERATION

**Note:** The following steps are performed outside the sterile field.

## 1 Connect the 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 Rotary 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 solution syringe from the tray.

Using aseptic technique, remove the cap from the solution syringe by turning the gray silicone cap counter-clockwise.



Using aseptic technique, remove the cap from the 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 the Delivery Syringe to the right of the Rotary Mixer.



**6**

**Close lid and start the Rotary 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.**



# ROTARY MIXER MANUAL OPERATION

---

**Note:** The following steps are performed outside the sterile field.

---

## 1

### Initial steps

Follow Steps 2–5 in the Rotary Mixer Powered Operation section.

---

## 2

### Close the Rotary Mixer lid

Close the lid and secure by depressing the thumb latch.



## 3

### Operate Rotary Mixer manually

To operate the Rotary 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 Rotary Mixer plugged in.

When mixing is complete, lower the handle on the Rotary Mix lid by pulling it up and pushing the handle to the side.



# PREPARATION

**1**

## **Open Rotary Mixer lid**

Open the lid and lift the mixed Rotary Pouch from the center post.



**2**

## **Transfer paste into Delivery Syringe**

Guide the Rotary Pouch and turn the knob counterclockwise to feed the Rotary Pouch into the transfer roller. The material will be expelled from Rotary Pouch into the Delivery Syringe.



Once the material is completely transferred, turn the transfer knob clockwise to remove the Rotary Pouch.



---

**Note:** The following steps are performed inside the sterile field.

---

**3**  
**Transfer Delivery Syringe into the sterile field**

Using aseptic technique, peel back the outer pouch to expose the sterile Delivery Syringe. A sterile person should grasp the handle of the Delivery Syringe and detach the Syringe with one-quarter turn counterclockwise, and complete the transfer to the sterile field.



**4**  
**Attach Delivery Needle**

Insert a Delivery Needle into the connection port at the tip of the Delivery Syringe and attach by rotating one-quarter turn clockwise to lock in place.



**5**  
**Remove clip from plunger**

Remove the clip from the plunger. Slowly depress the plunger to evacuate air from the Delivery Syringe barrel until a small amount of paste is ejected.

The material is now ready for implantation.





# IMPLANTATION

## 1

### Select injection method

Using one of the following methods, implant Norian Drillable Inject:

#### a. Standard injection

Slowly push the plunger. Every click corresponds to approximately 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 rotation of the knob injects 0.5 cc of material.

#### Notes:

- **At no time during injection should excessive pressure or force be used because this may result in a blockage of the Needle or Syringe.**
- **Norian Drillable Inject is temperature sensitive. Minimize contact with the barrel of the Delivery Syringe.**

## 2

### Implant Norian Drillable Inject before or after final fixation

Immediately implant the Norian Drillable Inject into the defect site using a backfill technique and slowly withdraw the Needle as fill is achieved. Once injection is initiated, the material remains injectable during the 2-minute implantation period at room temperature (18°–23°C/64–73°F).

- The size or nature of the void or defect may require more than one package of Norian Drillable Inject. 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 injected. Disturbing the first Norian Drillable Inject implanted after 2 minutes may damage the construct. Completely fill the void. Check the fill with multiple views.



**Notes:**

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

- 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.

**3**

**Remove extraosseous deposits of material**

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

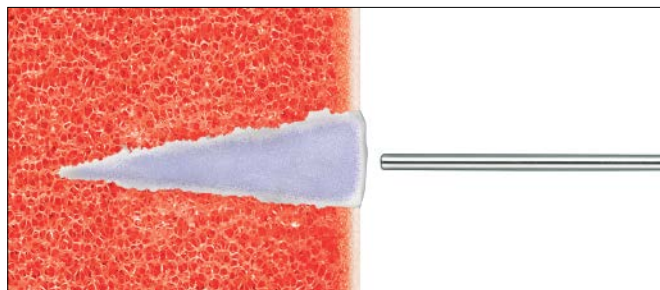
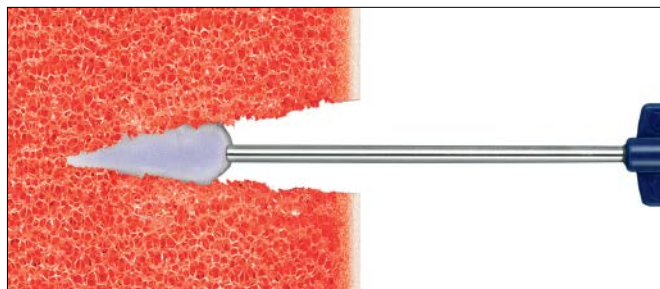
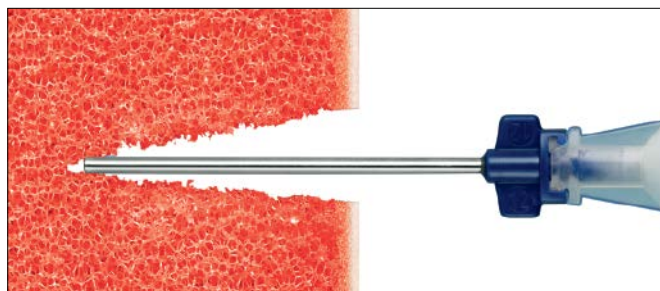
It is important to limit the amount of material that is allowed to perfuse into the soft tissues and joint space. Irritation or inflammation may be possible complications associated with large extraosseous deposits of Norian Drillable Inject.

**4**

**Discard unused material**

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

**Technique tip:** Norian Drillable Inject may be implanted before or after final fixation.



# DRILLING AND SCREW INSERTION

Norian Drillable Inject 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 Inject, 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 Inject. Remove excess material from the flutes of the drill bit.

**Precaution\*:** Placing guide wires (eg, K-wires) through Norian Drillable Inject 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 Inject during the 2-minute implantation period or the 10-minute setting period. Placing guide wires through the material after the 10-minute setting period has elapsed is not recommended.

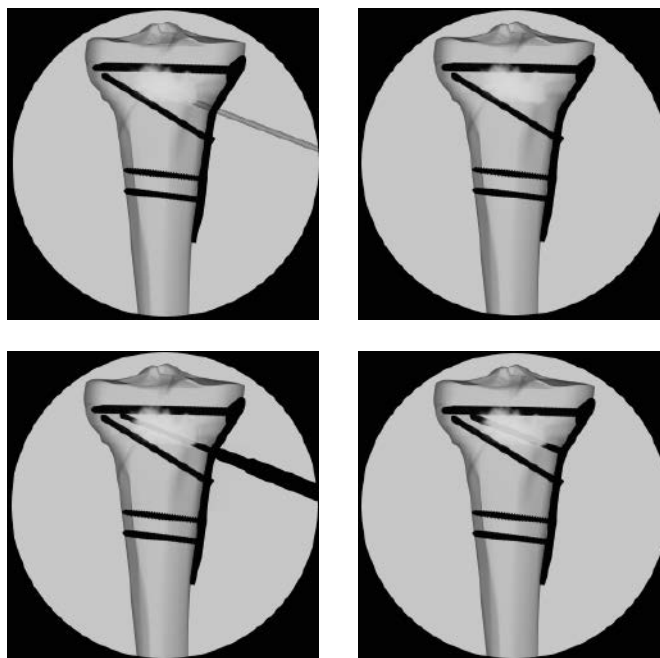
### Precautions:

- Do not place self-drilling screws through the material without predrilling to the root diameter.
- Norian Drillable Inject 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.



This technique guide is intended for instructions for Norian Drillable Inject, only. Please refer to the manufacturer's information or instruction for use of other products depicted in the images (eg, rigid fixation hardware).

\*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 Inject with warm, sterile saline to return the operative site to core body temperature.

## 2

### **Norian Drillable Inject sets in 10 minutes**

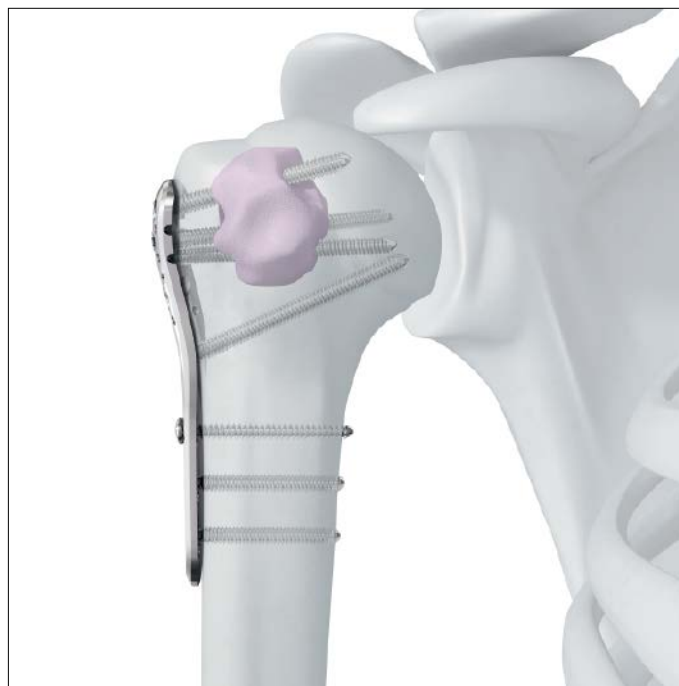
At body temperature (37°C/98.6°F), Norian Drillable Inject can be considered set in 10 minutes after the 2-minute implantation period.

**Note:** To aid in the reduction of the fracture site, Norian Drillable Inject may be allowed to set before application of final fixation hardware. See [Drilling and Screw Insertion](#).

## 3

### **Norian Drillable Inject cures in 24 hours**

Norian Drillable Inject fully cures and reaches its ultimate compressive strength of 35 MPa within 24 hours.



# PRODUCT INFORMATION

## Norian Drillable Inject, sterile

07.704.003S	3 cc
07.704.005S	5 cc
07.704.010S	10 cc

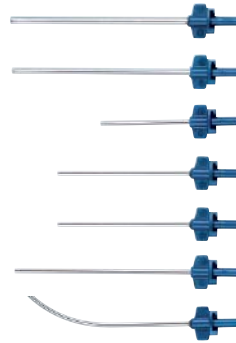


## MXR-US-2000 Rotary Mixer



## Delivery Needles, sterile

Single Pack	5 Pack	
DLS-7083-01S	DLS-7083-05S	8 gauge x 10 cm
DLS-7103-01S	DLS-7103-05S	10 gauge x 10 cm
n/a	DLS-7121-05S	12 gauge x 5 cm
DLS-7122-01S	DLS-7122-05S	12 gauge x 7.5 cm
DLS-7123-01S	DLS-7123-05S	12 gauge x 10 cm
n/a	DLS-7124-05S	12 gauge x 12.5 cm
DLS-7126-01S	DLS-7126-05S	12 gauge x 10 cm, curved



## Also Available

### Norian Drillable Fast Set Putty, sterile

07.704.103S	3 cc
07.704.105S	5 cc
07.704.110S	10 cc



Note: For additional information, please refer to the package insert or [www.eifu.com](http://www.eifu.com).

For detailed cleaning and sterilization instructions, please refer to [www.depuy-synthes.com/hcp/cleaning-sterilization](http://www.depuy-synthes.com/hcp/cleaning-sterilization) or sterilization instructions, if provided in the instructions for use.

# WARNINGS AND PRECAUTIONS

---

## Warnings

- Norian Drillable Inject is for single use only, and should not be resterilized.
- Remove excess material in adjacent soft tissue.
- Norian Drillable Inject is provided sterile. If integrity of the package is compromised, the product must be assumed to be non-sterile and appropriately discarded.
- Norian Drillable Inject should be implanted within 5 minutes after mixing. Discard any unused material.
- The safety and effectiveness of Norian Drillable Inject 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 Inject 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 Inject is not known.
- Do not mix Norian Drillable Inject 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 Inject 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, 10 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, injection technique, Preparation Time, Implantation Time, Setting Time, and Cure Time are required prior to treatment.
- The Norian Drillable Inject Rotary Pouch and Rotary Mixer should be equilibrated to 18°-23°C/64°-73°F prior to mixing.
- If more than one Rotary Pouch is required, the total volume (not to exceed 40 cc) of Norian Drillable Inject should be implanted within the 2-minute Implantation Time.
- Due to the radiopacity of the material, anomalies may not be detected.
- Norian Drillable Inject attains physiologic pH after components are mixed. In the unlikely event that the seal of the Rotary Pouch is breached during mixing, 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 Inject 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.
- Unused Norian Drillable Inject should be discarded. Before disposal of a Rotary Pouch, mix according to the Directions for Use to render the contents pH neutral.

---

**Precautions** continued

- The recommended application of Norian Drillable Inject is to fill bone defects that have been stabilized using standard orthopaedic reduction techniques and fixation protocol, i.e., external fixation pins, K-wires, plates, screws, etc.
- If the Preparation Time (5 minutes from end of mixing process) elapses, the remaining Norian Drillable Inject that has not been implanted must be discarded and a new Rotary Pouch mixed.
- Because Norian Drillable Inject must be placed in the void within 5 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 Inject 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 Inject (i.e. into the intra-articular space), injection of the material should be performed under direct visualization or under real-time image intensification.
- The long term effects of extraosseous Norian Drillable Inject or intra-articular Norian Drillable Inject (material injected into the joint space) are unknown. Irritation or inflammation may be possible complications associated with large extraosseous deposits of Norian Drillable Inject. 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 Inject.
- Fractures with intra-articular involvement should be properly reduced according to ORIF technique prior to injecting Norian Drillable Inject. Extra care must be taken to ensure Norian Drillable Inject has not entered the joint space when the bone void being filled is adjacent to the articular surface.
- Fractured articular surfaces where Norian Drillable Inject can communicate with the joint should be sealed prior to injection of Norian Drillable Inject. This can be accomplished by utilizing a sequential injection technique wherein Norian Drillable Inject is first implanted in the subchondral area without application of pressure on the material. After allowing the material to partially set, additional Norian Drillable Inject can be implanted to fill the remaining bone void.
- 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 Inject 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 Inject 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 Inject 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. 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 Inject. 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 Inject may cause the Bone Void Filler 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.

Norian is a registered trademark of DSM Biomedical or its affiliates

Limited Warranty and Disclaimer: DePuy Synthes 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.

Please also refer to the package insert(s) or other labeling associated with the devices identified in this surgical technique for additional information.

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

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.

Not all products may currently be available in all markets.



*Manufactured or distributed by:*

**Synthes USA Products, LLC**  
1302 Wrights Lane East  
West Chester, PA 19380

**Synthes USA, LLC**  
1101 Synthes Avenue  
Monument, CO 80132

**Synthes GmbH**  
Luzernstrasse 21  
4528 Zuchwil, Switzerland

To order (USA): 800-523-0322

To order (Canada): 844-243-4321

*Note: For recognized manufacturer, refer to the product label.*

[www.depuysynthes.com](http://www.depuysynthes.com)