

Norian® SRS®. Trochanteric fractures in combination with DHS®.

Surgical Technique

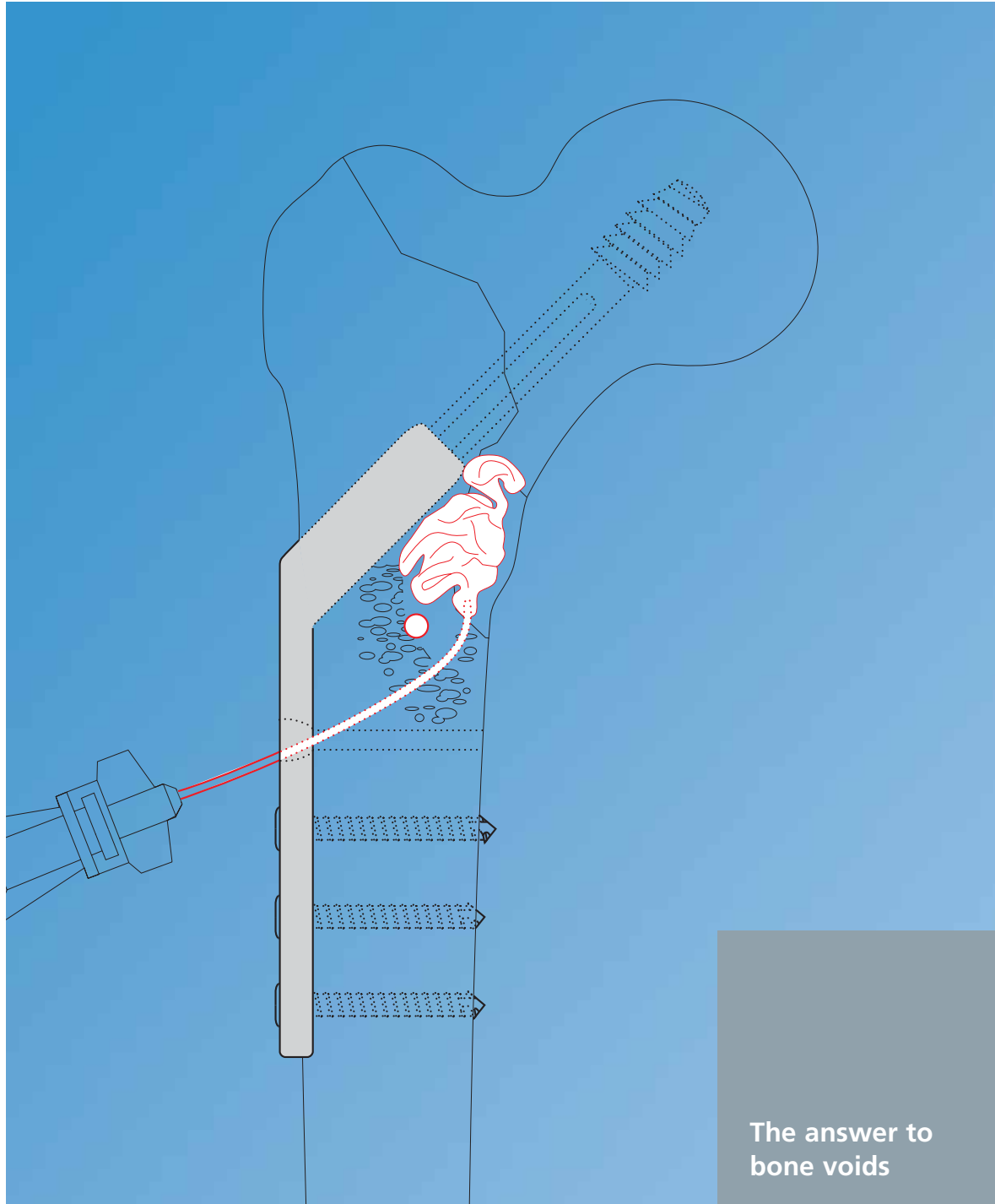


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 Image intensifier control

Warning

This description is not sufficient for immediate application of the device. Instruction by a surgeon experienced in handling this device is highly recommended.

Introduction

Description

Norian SRS (Skeletal Repair System) is an injectable, moldable and biocompatible calcium phosphate that sets at body temperature into carbonated apatite. It has a compressive strength of approximately 50 MPa, which is 4–10 times greater than the average 5–15 MPa of cancellous bone. Norian SRS closely resembles the mineral phase of bone and gradually remodels to bone via osteoclastic resorption and osteoblastic new bone formation.

Clinical applications

Norian SRS should be used in bony voids, which have been stabilized using standard AO ASIF orthopedic techniques and implants, i.e. external fixation, K-wires, plates and screws. These bony voids may be created surgically or result from traumatic injury.

Clinical applications include:

- Fractures of distal radius
- Fractures of proximal and distal tibia
- Fractures of calcaneus
- Fractures of proximal and distal femur
- Fractures of proximal humerus
- Fractures of acetabulum
- Filling of cystic lesions
- Augmentation of screws

Features and benefits

AO ASIF Principle	Norian SRS Design Feature	Clinical Importance
Anatomic reduction	Flows into bone void	Fills cancellous bone between fragments of a reduced fracture
Preservation of blood supply	Injectable paste, cures physiologically, gradually resorbs and is replaced with bone	Can be injected percutaneously, no harm to surrounding tissue
Stable fixation	Forms dense crystalline structure with compressive strength 4–10 times greater than cancellous bone	Completely hardens in the defect within 24 hours
Early mobilization		Given stable fixation, the patient can do early, passive motion exercises

System overview

Norian SRS reactants packs for Norian Rotary Mixer

Two components are needed for mixing Norian SRS:

- Calcium phosphate powder in cement packages
- Sodium phosphate solution, contained in the solution syringe. The solution is injected into the reactants pack.

Norian SRS reactants packs for Norian Rotary Mixer are available in 3 cc, 5 cc and 10 cc sizes, with a delivery syringe integrated in the pack.



Norian Rotary Mixer

The Norian Rotary Mixer is electrically powered and is used outside the sterile field. Prior to starting the mixing cycle, sodium phosphate solution is manually injected into the powder compartment of the reactants pack. When the mixing cycle begins, the mixer's roller carriage operates to mix the powder and solution to form a paste. At the end of mixing, the cement package is manually guided through the rollers, and the paste is injected into the application syringe (see "Norian Rotary Mixer, Handling guide for Norian SRS" (036.000.600), p. 8).



Delivery syringe

- Integrated in the reactants pack
- Provides immediate tactile feedback while injecting
- Compatible with a selection of Norian needles available in various sizes (not included)
- Single use only



Schedule

Time and temperature properties

The handling of the Norian SRS is strongly affected by the temperature of the material while mixing and injecting. The following timing sequence references the specific time and temperature relationships that must be followed for the material to obtain full strength. All steps have to be followed consecutively.

Note: During a long, open operation with the blood supply arrested for more than one hour, the extremities can easily cool below body temperature (37 °C). This can lengthen the setting time.

Mixing 70 revolutions

Mix the reactants pack using the Norian Rotary Mixer (70 revolutions).

Preparation, 3 minutes

The preparation time is 3 minutes maximum at room temperature (18–23 °C).

Transfer the mixed Norian SRS paste into the delivery syringe and transfer the delivery syringe into the sterile field. Attach a Norian needle. Insert the needle into the operative site and begin delivering the Norian SRS paste.

Implantation, 2 minutes

The implantation time is 2 minutes maximum at 37 °C. Inject the Norian SRS paste into the prepared bone void and manipulate as necessary.

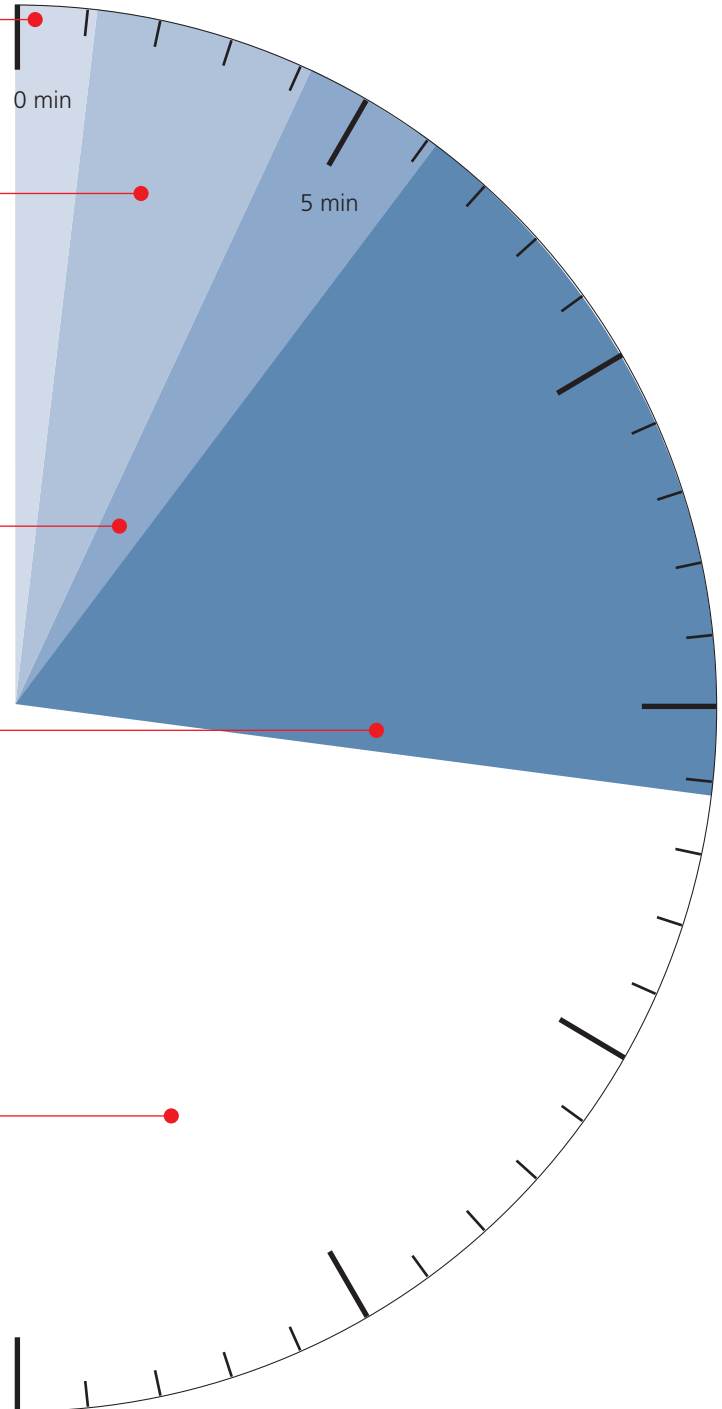
Setting, 10 minutes

The setting time at body temperature (37 °C) is 10 minutes. Reweave blood flow and lightly irrigate the exposed Norian SRS with warm saline solution, or cover the application site with warm gauze pads.

Curing

The curing time is 24 hours at body temperature, 37 °C. Hardened Norian SRS reaches full compressive strength (50 MPa) within 24 hours.

Note: Do not disturb the material during the setting or curing period. Manipulation of the fracture or removal of K-wires embedded in Norian SRS must not be done during the initial 24 hours.



Surgical technique

Norian SRS is intended for the structural augmentation of areas of compromised cancellous bone in unstable 3- and 4-part trochanteric hip fractures in conjunction with the DHS Dynamic Hip Screw System.

For the treatment of trochanteric hip fractures with the DHS Dynamic Hip Screw please refer to the DHS/DCS System surgical technique.

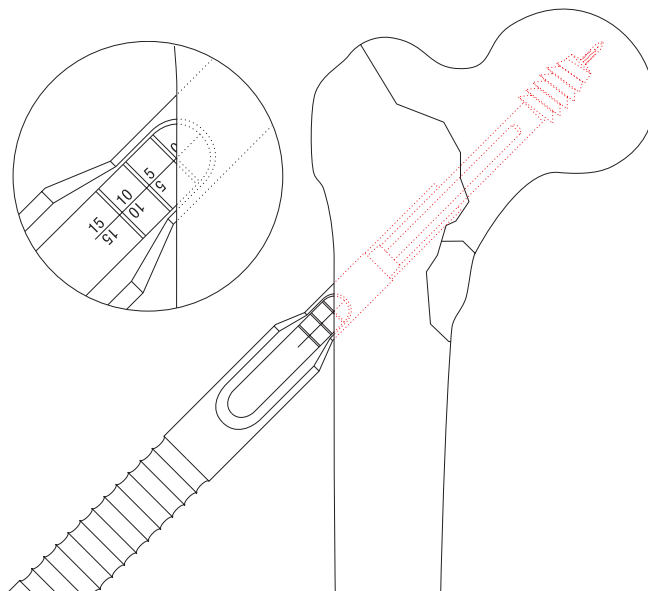
For detailed information on how to use the Norian SRS please refer to the brochure "Norian Rotary Mixer, Handling guide for Norian SRS" (036.000.600).

1

Insert DHS screw

Using the insertion instrument slide the DHS Screw over the guide wire and insert the centering sleeve into the drill hole. Continue inserting the screw until the 0-mark on the wrench reaches the lateral cortex. In osteoporotic bone insert the screw 5 mm deeper.

Remove the DHS/DCS wrench and the DHS/DCS centering sleeve.

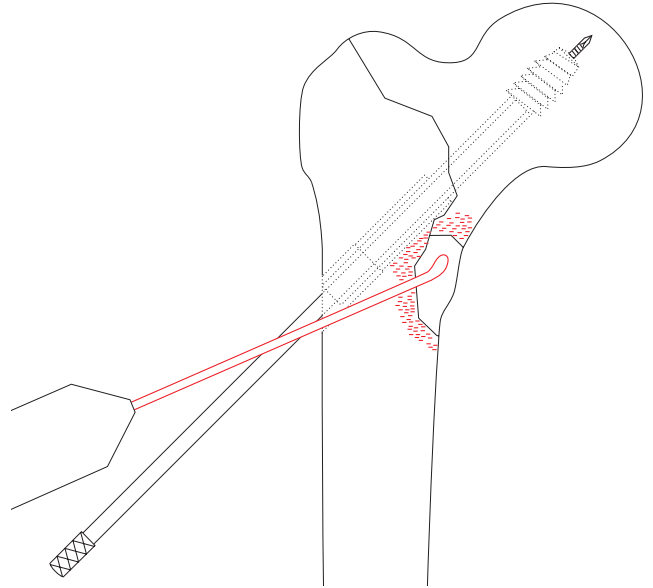


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Prepare fracture void

Prepare the fracture void with a curette before sliding the DHS plate over the coupling screw. Concentrate on the inferior-medial region as well as the superior-medial region. Irrigate and aspirate the void to remove blood clots or other organised tissue and loose bone debris to allow an optimal fill.

- ① Explore the prepared cavity with a needle under image intensifier to visualize the dimension of the prepared void.



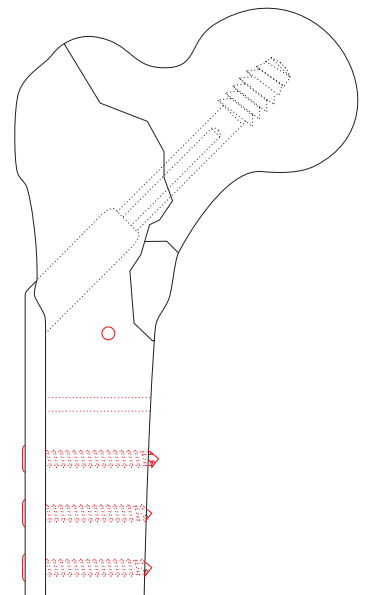
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Drill screw and injection holes

Slide the DHS plate over the coupling screw onto the femoral shaft. Use the DCP Hip Drill Guide 4.5 (322.430) and the Drill Bit \varnothing 3.2 mm (310.310) to drill holes through the plate holes in neutral position.

Drill an additional hole for cement injection in the anterolateral cortex at the level of the side plate angle.

Omitting the most proximal plate hole, insert 4.5 mm cortex screws of appropriate lengths to attach the side plate. The Norian SRS will be injected through this plate hole.



4

Mix and prepare Norian SRS

Once the operative site is fully prepared for injection, start mixing Norian SRS as described in the Norian Rotary Mixer, Handling guide for Norian SRS (036.000.600), page 8.

Select the curved needle (DLS-7126) for better void access.

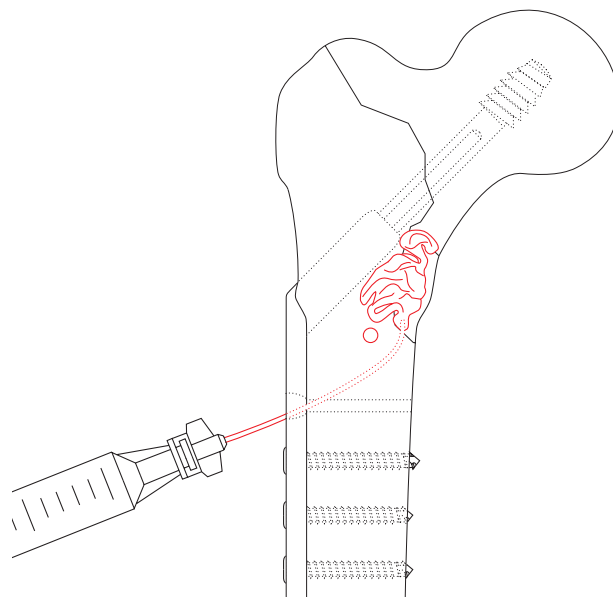
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Inject Norian SRS

1 Insert the needle through the proximal plate hole and slowly inject Norian SRS in a retrograde fashion under image intensifier control. During injection the needle tip should be just next to Norian SRS. Over-advancing the needle can cause occlusion of the needle. Ensure that all areas are filled with Norian SRS.

For correct injection technique, please refer to the Norian Rotary Mixer, Handling guide for Norian SRS (036.000.600), page 16.

Insert the proximal screw into the side plate observing the 2-minute implantation time.

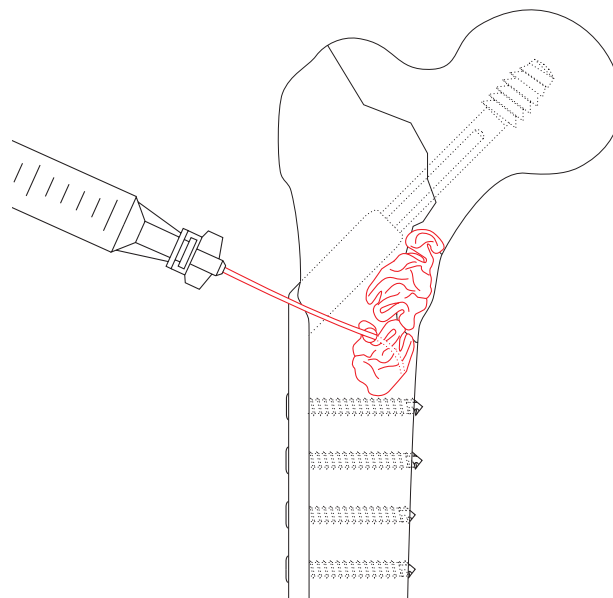


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Additional injection (optional)

In areas where inadequate fill may occur (e.g. inferior-medial), use another Norian SRS pack and inject through the antero-medial hole to support the calcar.

Before continuing with the surgery wait for the 10-minute setting period to elapse. Once the Norian SRS has set, follow the surgical procedure as described in the DHS/DCS-System DHS Dynamic Hip Screw.



Case study

The clinical utility of Norian SRS is to augment unstable trochanteric hip fractures, to assist in stabilising the posterior medial buttress and thus minimising fracture collapse without interfering with the biological fracture healing process.



Unstable 3-part trochanteric fracture



Immediately postoperative: Norian SRS injected into the posteromedial calcar region to strengthen the buttress and retain anatomic fracture reduction. The patient was allowed full weight-bearing immediately after surgery.



6 months postoperative: United trochanteric fracture with unchanged Dynamic Hip Screw position due to improved postoperative stability by augmentation with Norian SRS.

Literature: trochanteric fractures

Goodman SB, Bauer TW, Carter D, Casteleyn PP, Goldstein SA, Kyle RF, Larsson S, Stankewich CJ et al (1998) Norian SRS cement augmentation in hip fracture treatment. *Clinical Orthopaedics and Related Research*, 348: 42–50

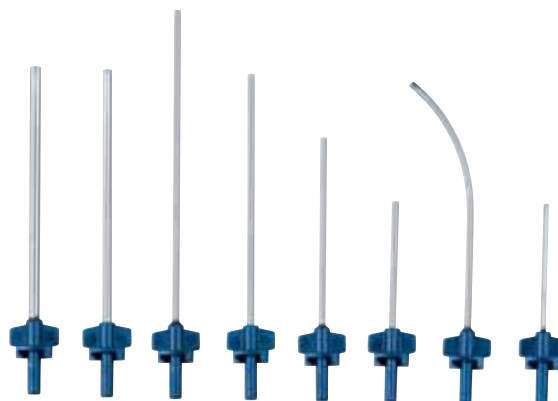
Mattson P, Alberts A, Dahlberg G, Sohlman M, Hyldahl HL, Larsson S: Resorbable cement for the augmentation of internally-fixed unstable trochanteric fractures. *The Journal of Bone and Joint Surgery* Vol. 87-B, No. 9, September 2005

Ordering information



Reactants Packs for Rotary Mixer

SRS-0300-RMS	Norian® SRS® Reactants Pack for Norian® Rotary Mixer, 3 cc
SRS-0500-RMS	Norian® SRS® Reactants Pack for Norian® Rotary Mixer, 5 cc
SRS-1000-RMS	Norian® SRS® Reactants Pack for Norian® Rotary Mixer, 10 cc



Delivery Needles

Single Pack	Five Pack	SRS® Delivery Needles, sterile
	DLS-7083	8 gauge × 10 cm
DLS-7103-01	DLS-7103	10 gauge × 10 cm
	DLS-7121	12 gauge × 5 cm
DLS-7122-01	DLS-7122	12 gauge × 7.5 cm
DLS-7123-01	DLS-7123	12 gauge × 10 cm
DLS-7124-01	DLS-7124	12 gauge × 12.5 cm
DLS-7126-01	DLS-7126	12 gauge × 10 cm, curved
	DLS-7141	14 gauge × 5 cm



Mixer

MXR-US-2000	Norian® Rotary Mixer
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Presented by:



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