Rotary Mixer Norian®.

Handling guide for
Norian SRS

The answer to
bone voids

Contents

Image intensifier control

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

Norian SRS

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		With a rigid fixation applied, patient can engage in passive range-of-motion exercise

Case example

Radiographs showing a depression fracture of the lateral tibial plateau. Reduction and fixation is made with an AO screw and the void is filled with Norian SRS.

Preoperative, lateral view

Preoperative, AP view

12-month postoperative, lateral view

12-month postoperative, AP view

System overview

Norian SRS reactants packs for Norian Rotary Mixer

Two components are needed for mixing Norian SRS:
– Calcium phosphate powder, contained in the reactants pack, designed for mixing at the time of use
– 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. When mixing is complete, the reactants pack is manually fed through the rollers and the paste is transferred into the delivery syringe.

Delivery syringe

– Integrated in the reactants pack
– Provides immediate tactile feedback while injecting
– Compatible with a selection of Norian needles available in various sizes
– Single use only

Preoperative planning

1

Assess the void

Assess the void and plan fracture reduction and stabilization.

2

Determine the surgical approach

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

3

Reduce fracture and stabilize

Reduce fracture and stabilize with necessary osteosynthetic devices.

4

Prepare the void

Irrigate and aspirate the void to clear the injection path and void from hematoma and loose bone fragments. Prepare the void by compacting the surrounding cancellous bone with a curette, elevator or similar instrument.

5

Injection path

Preplan the injection path by inserting the Norian needle into the void and probing the depths 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 void.

Timing sequence

Time and temperature properties

The handling properties of Norian SRS are governed primarily by the ambient temperature of the material as it is mixed and injected. 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: Extremities can cool below body temperature (37°C) during a lengthy open procedure where tourniquet use exceeds one hour.

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).

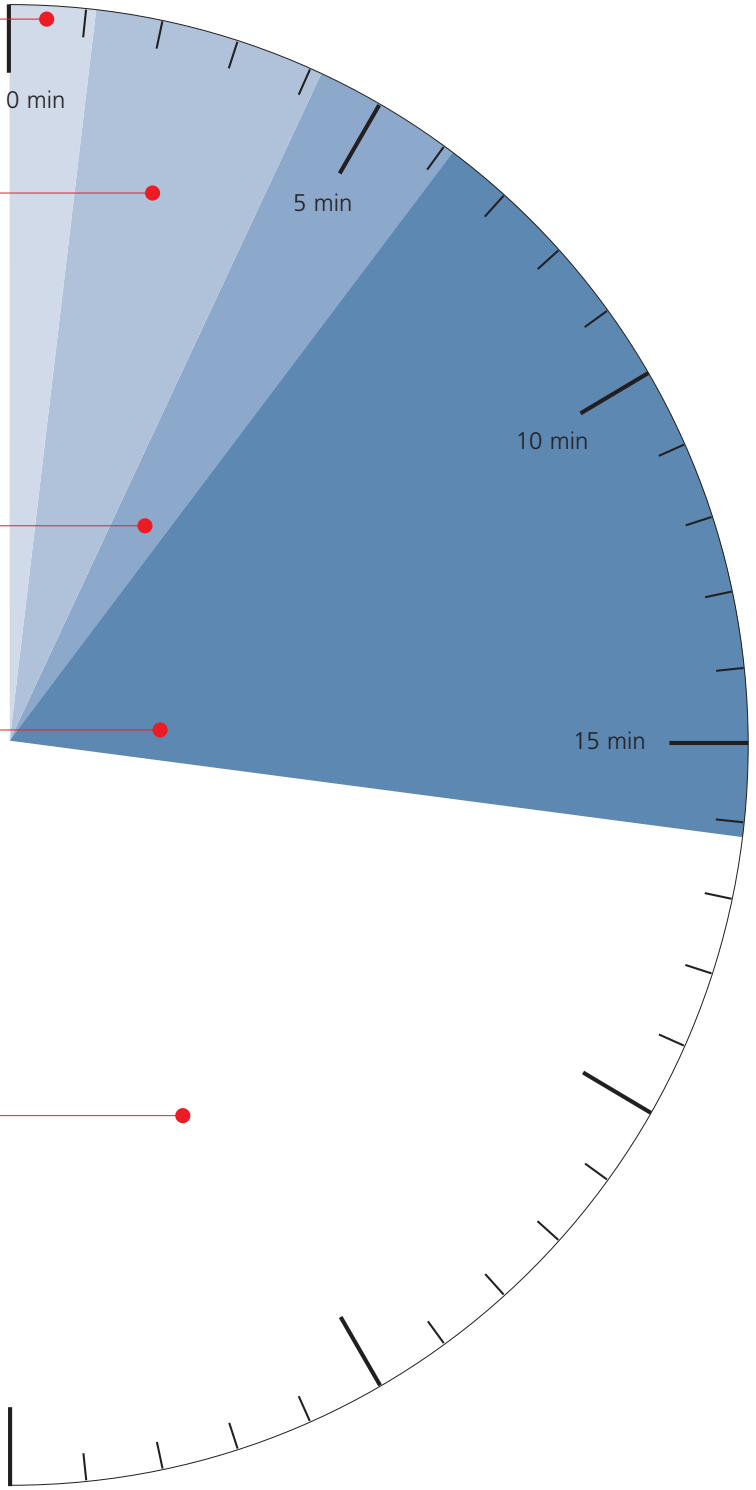
Transfer the mixed Norian SRS paste into the delivery syringe and transfer the delivery syringe into the sterile field. Attach a Norian needle. Insert the needle into the operative site and begin delivering the Norian SRS paste.

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 is 10 minutes at body temperature, 37 °C. If a tourniquet is being used, release it and lightly irrigate the exposed Norian SRS with warm saline or place warm sponges over the implant site. The 10-minute setting period begins once the site has returned to body temperature.



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 be done during the initial 24 hours.

Mixing – Powered operation

The following steps are performed outside the sterile field.

1

Connect power cord

Unwrap the power cord and connect it to a 100–240 VAC outlet. Once connected the standby indicator will light.

2

Open mixer lid

Open the mixer lid by depressing the thumb latch located at the right corner of the lid.

3

Position reactants pack

Position the reactants pack on the mixer by aligning the arrows on the reactants pack and mixer.

Press the pack over the center post of the mixer.

4

Inject solution

Remove the solution syringe from the foil pouch.

Using aseptic technique, remove the caps from the solution syringe.

Remove cap from from reactants pack 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 reactants pack the remaining steps must be completed immediately.

5

Remove pouch clip

Remove the pouch clip and unfold the reactants pack with the delivery syringe to the right.

6

Close lid and start mixer

Close the lid and secure by depressing the thumb latch.
Press the start button to begin mixing. A single, brief beep indicates the start of the mixing cycle.

Mixing is complete after 70 revolutions. A "beep" will sound and the "Complete" indicator will flash.

Caution: If the Norian Rotary Mixer fails to complete the mixing cycle, or the lid is opened before the cycle is complete, an alarm will sound and all indicators will flash. Start again with a new reactants pack and either return to step 2 of this chapter or mix using manual operation (see next page).

Mixing – Manual operation

1

Follow steps 2–5

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

Lift up on the manual handle on the mixer lid until locked in the upright position. Rotate the top disk 70 revolutions clockwise (approximately one revolution per second).

Note: The counter operates using battery power and will advance when rotating the top disc without the mixer being electrically powered.

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

Preparation

1

Open mixer lid

Open the lid and lift the reactants pack from the center post of the mixer. The 3-minute Preparation time begins at the end of the mixing cycle.

2

Transfer paste into delivery syringe

Guide the reactants pack containing the mixed Norian SRS paste into the rollers by turning the knob counterclockwise. The material will be transferred into the delivery syringe.

Remove the reactants pack by reversing this action.

The following steps are performed 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.

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.

Implantation

Inject bone void filler (two methods)

Always use a backfill technique (see next page). Image intensifier may be used to visualise the material during injection. 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 (½) turn counter clockwise to relieve the pressure; then, continue injection.

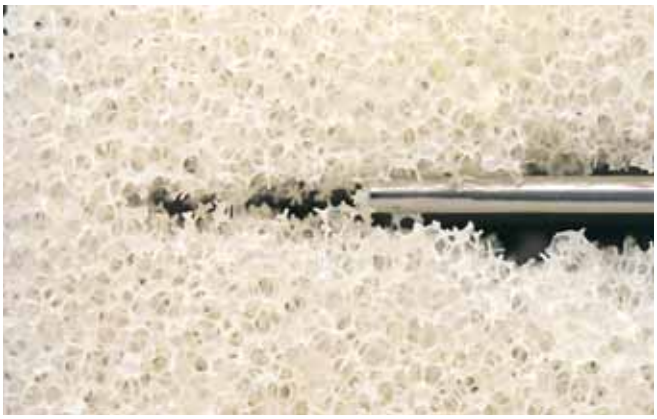
Backfill technique

1

Insert delivery needle

Use image intensifier for visualization. Insert the Norian needle into the far end of the void.

This is the start of the 2-minute Implantation time during which the material is fully injected and can be manipulated as necessary (at body temperature, 37 °C).



2

Begin injection

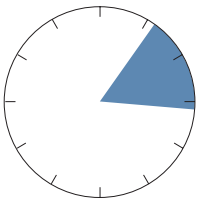
Begin injection and slowly withdraw the needle as fill is achieved. The tip of the needle should be just next to the injected material.

3

Complete injection

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

Note: If more than one reactants pack is required, the total volume (not to exceed 40 cc) of Norian SRS should be implanted within the 2-minute Implantation time. Disturbing the initial Norian material after 2 minutes may damage the construct. If this 2-minute period has elapsed, wait until the 10-minute Setting time has elapsed before starting the second injection.



Setting and curing

Setting

Release the tourniquet if used, and gently irrigate with warm saline or place warm sponges to return the operative site to body temperature (37 °C). Allow the Norian SRS to set during the 10-minute Setting Time. Do not disturb the material during this time period.

Curing

Norian SRS fully cures and reaches its ultimate compressive strength within 24 hours.

Note: 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 SRS.

If Norian SRS is injected into a joint or soft tissue, care should be taken to remove the excess by irrigating it away from the site.

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Norian® Rotary Mixer

Handling guide for Norian SRS

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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Norian Corporation
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West Chester, PA 19380
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EU authorized representative:
Synthes GmbH
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