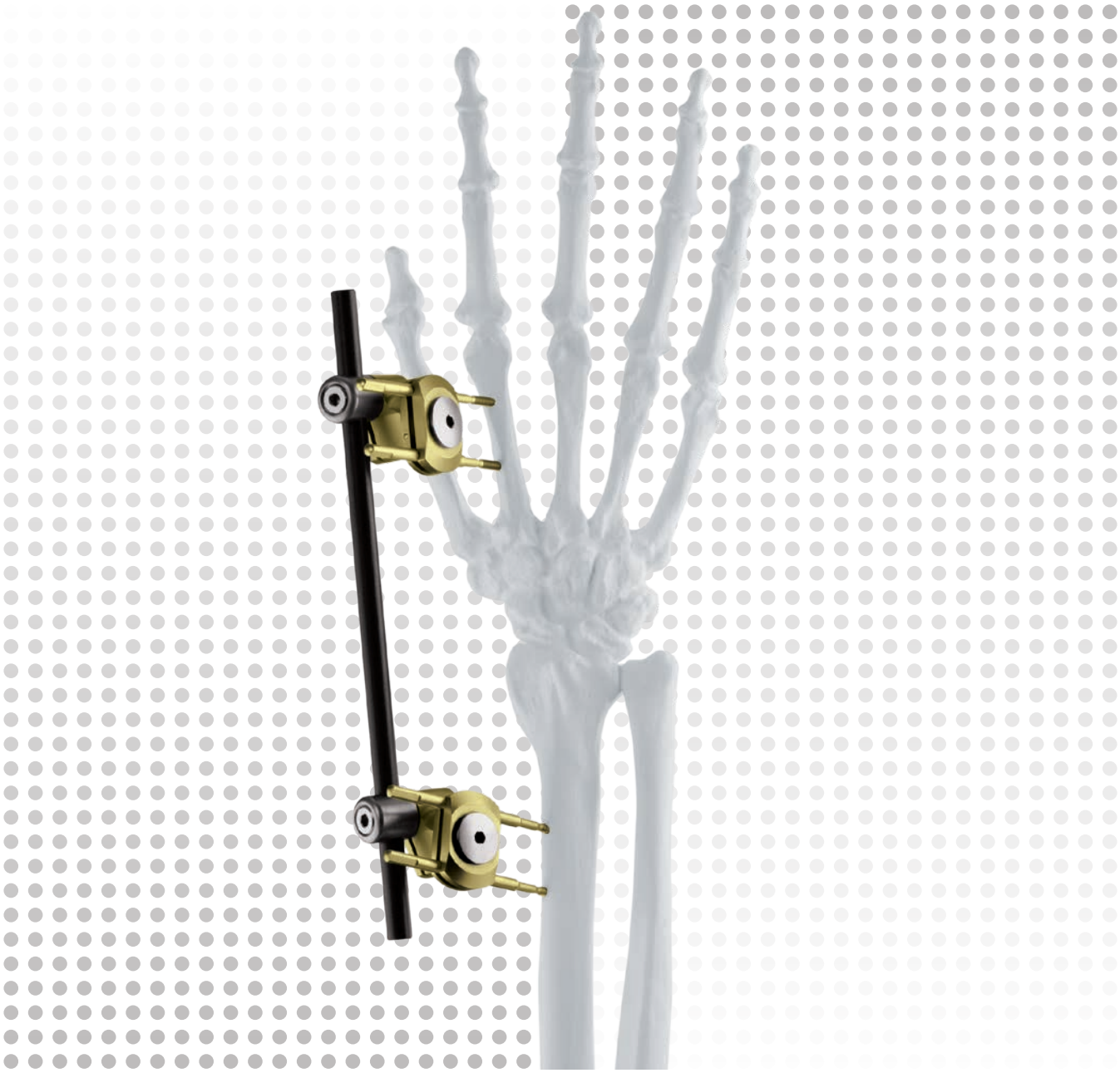
External Distal Radius Fixator

Supplement to the 8 mm Rod Fixator System

Surgical Technique



approved by AO Technical Commission

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
For general information about reprocessing, care and maintenance of DePuy Synthes reusable devices, instrument trays and cases, as well as processing of DePuy Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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External Distal Radius Fixator
Supplement to the 8 mm Rod Fixator System

- Schanz screws and carbon fibre rods can be secured individually to the clamps

Fracture visualization

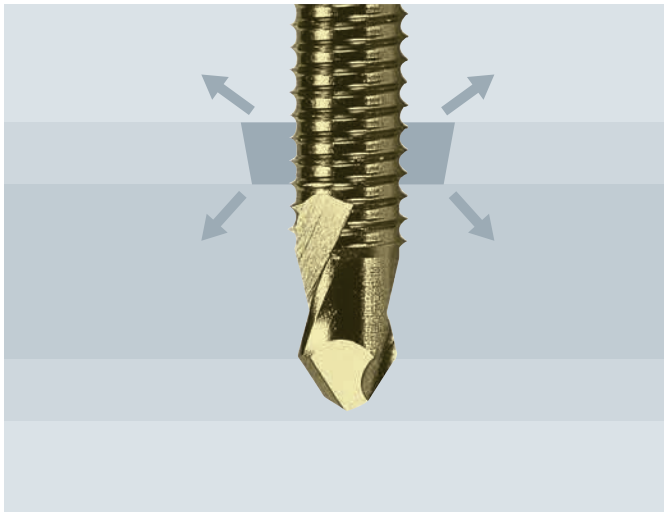
- Radiolucent carbon fibre rods ensure fracture visualization

Distraction

- Compatible with 8 mm rod systems
- Intraoperative or postoperative use of the distractor possible

Seldrill Schanz Screws

- Available in commercially pure titanium or stainless steel
- Extended range for External Distal Radius Fixator: diameters 4.0/2.5 mm, 4.0/3.0 mm or 4.0 mm



Warning

▲ WARNING:

The treating physician should make patient specific clinical judgment and decision to use External Fixation System in patients with the following conditions:

- Patients who for social and physical reasons are not suitable for an external fixator.
- Agitation.
- Patients in whom screws cannot be inserted due to a bone or soft tissue disease.

Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effect and Residual Risks. Instruction for Use are available at www.e-ifu.com and/or www.depuysynthes.com/ifu

The AO Principles of Fracture Management

Mission

The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

AO Principles[1,2]

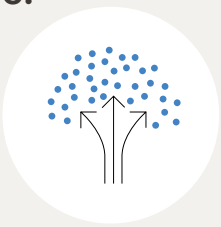
1.

Fracture reduction and fixation to restore anatomical relationships.

2.

Fracture fixation providing absolute or relative stability, as required by the "personality" of the fracture, the patient, and the injury.

3.



Preservation of the blood supply to soft-tissues and bone by gentle reduction techniques and careful handling.

4.

Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

[1] Müller ME, Allgöwer M, Schneider R, Willenegger H. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg New York: Springer 1991.
[2] Buckley RE, Moran CG, Apivatthakakul T. AO Principles of Fracture Management: 3rd ed. Vol. 1: Principles, Vol. 2: Specific fractures. Thieme; 2017.

MRI Information

Distal Radius Fixator devices used in a typical construct include clamps, rods and various attachments. A patient with a DePuy Synthes Distal Radius Fixator frame may be scanned safely after placement of the frame under the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla when the fixator frame is positioned:
  - 7 cm or less from within the outside edge of the bore of the MRI at Normal Operating Mode or
  - Completely outside of the MRI Bore in First Level Control Mode
- Highest spatial gradient magnetic field of 900 Gauss/cm or less
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg for the Normal Operating Mode and 4 W/kg for the First Level Controlled Mode for 15 minutes of scanning
- Use only whole body RF transmit coil, no other transmit coils are allowed, local receive only coils are allowed

■ Note:

In nonclinical testing, the Distal Radius Fixator frame was tested in several different configurations. This testing was conducted with the construct position 7 cm from within the outside edge of the MRI bore.
The results showed a maximum observed heating for a wrist fixator frame of 6 °C for 1.5 T and less than 1 °C for 3.0 T with a machine reported whole body averaged SAR of 2 W/kg.

▲ Precautions:

Patients may be safely scanned in the MRI chamber under the above conditions. Under such conditions, the maximum expected temperature rise is less than 6 °C. Because higher in vivo heating cannot be excluded, close patient monitoring and communication with the patient during the scan are required. Immediately abort the scan if the patient reports burning sensation or pain. To minimize heating, the scan time should be as short as possible, the SAR as low as possible and the device should be as far as possible from the edge of the bore. Temperature rise values obtained were based upon a scan time of 15 minutes.

The above field conditions should be compared with those of the user's MR system in order to determine if the item can safely be brought into the user's MR environment.

If placed in the bore of the MR scanner during scanning, DePuy Synthes Distal Radius Fixator devices may have the potential to cause artifact in the diagnostic imaging.

▲ WARNINGS:

- Only use frame components stated in the surgical technique of the Distal Radius Fixator System
- Potential complications of putting a part in the MR field are:
  - Torsional forces can cause the device to twist in MR field
  - Displacement forces can pull the device into the MR field
  - Induced currents can cause peripheral nerve stimulation
  - Radio Frequency (RF) induced currents can cause heating of the device that is implanted in the patient
- Do not place any radio frequency (RF) transmit coils over the Distal Radius Fixator frame

Artifact Information

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the DePuy Synthes Distal Radius Fixator frame. It may be necessary to optimize MR imaging parameters in order to compensate for the presence of the fixator frame.

Representative devices used to assemble a typical Distal Radius Fixator frame have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by DePuy Synthes Distal Radius Fixator System devices may present issues if the MR imaging area of interest is in or near the area where the fixator frame is located.

- For FFE sequence: scan duration 3 minutes, TR 100 ms, TE 15 ms, flip angle 15° and SE sequence: scan duration 4 minutes, TR 500 ms, TE 20 ms, flip angle 70° radio echo sequence, worst-case artifact will extend approximately 10 cm from the device.

■ Note:

For a detailed handling description of the Schanz screws and the Steinmann pin, refer to the Surgical Technique Schanz Screws and Steinmann Pins.

1. First reduction

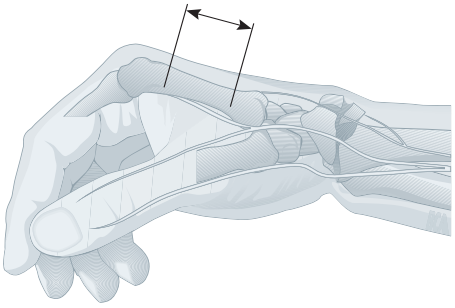
At the beginning, perform a first reduction of the hand with the fractured radius using gentle ligamentotaxis to minimize soft tissue injuries due to internal pressure.

▲ Precaution:

Select the appropriate Schanz screw for the patient's bony anatomy.

2. Recommended zones for inserting screws

Insert the Schanz screws in the shaft of the second metacarpal.



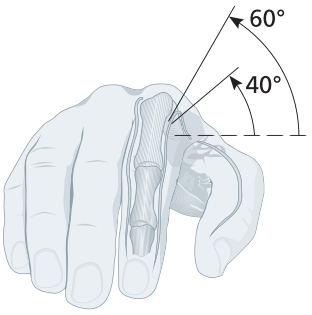
▲ Precautions:

- Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin.
- Handle devices with care and dispose worn bone cutting instruments in an approved sharps container.

3. Position of screws

Pay attention to the extensor tendons and the radiodorsal neurovascular bundle.

If the screws are placed too far laterally, they will impede the function of the thumb. For this reason, an angle between 40° and 60° to the horizontal from the orthograde view has proven useful.



4. Insert distal Schanz screws

Required instruments

Parallel drill guide ∅ 4.0 mm	395.967
Schanz screws ∅ 4.0/3.0 mm, ∅ 4.0/2.5 mm	(cf. p. 13)

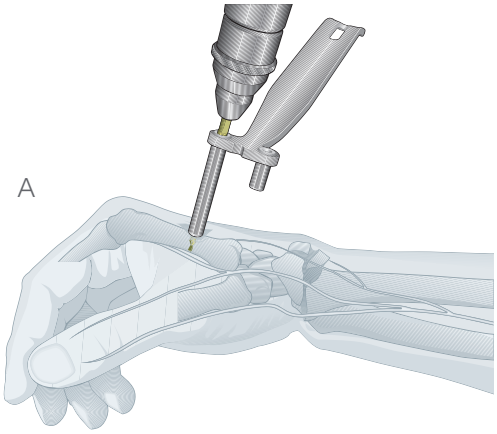
The first Schanz screws to be inserted as a pair can be placed first in the second metacarpal or radius.

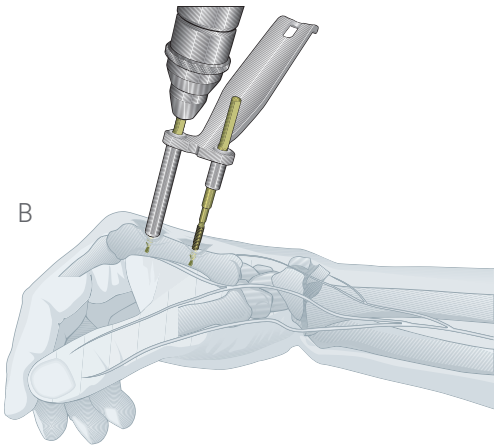
Insert the drill guide while protecting and pushing aside the tendons, vessels, and muscles in such a way that the long shaft of the drill guide is in direct contact with the bone. Place the first Schanz screw in described position through the long drill sleeve shaft (A).

Before placing the second screw, remove the drill guide and guide the short shaft over the first Schanz screw; take care here that the long shaft is again in direct contact with the bone (B).

■ Note:

Self-drilling, self-tapping Schanz Screws (Seldrill) can be inserted without predrilling.



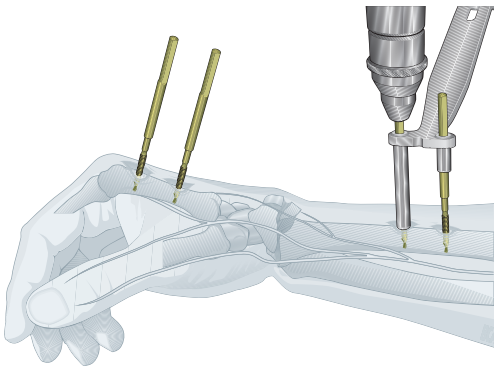


5. Insert Schanz screws in the radius shaft

Required instruments

Parallel drill guide ∅ 4.0 mm	395.967
Schanz screws ∅ 4.0 mm, ∅ 4.0/3.0 mm	(cf. p. 13)

Insert two Schanz screws obliquely in the distal to middle radius as described in step 4. Make sure that the superficial branch of the radial nerve is not damaged.



▲ Precautions:

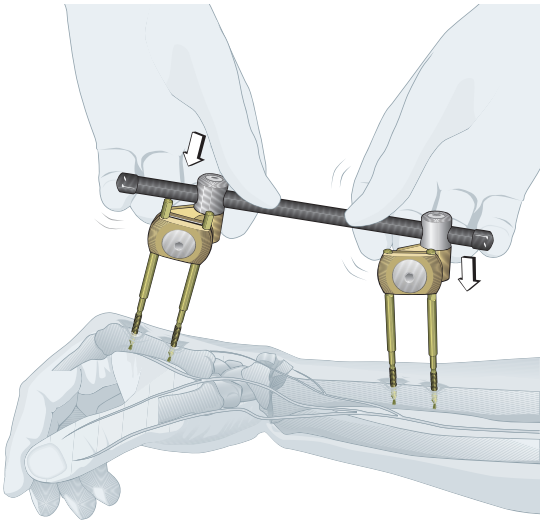
- The Seldrill Schanz Screw has been developed to minimise heat development. Nevertheless, slow insertion and additional cooling (for example with a Ringer solution) are recommended.
- The tip of the Schanz Screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability.

6. Position the frame

Required instruments	
Clamp	390.051
Protective cap for the carbon fibre rods	395.781
Carbon fibre rod	(cf. p. 13)

Loosen all screws on both clamps. Guide the carbon fibre rod of suitable length through the clamps and secure both ends of the rod with the protective caps to prevent the rod from slipping out.

Guide the fixator clamps over the Schanz screws.



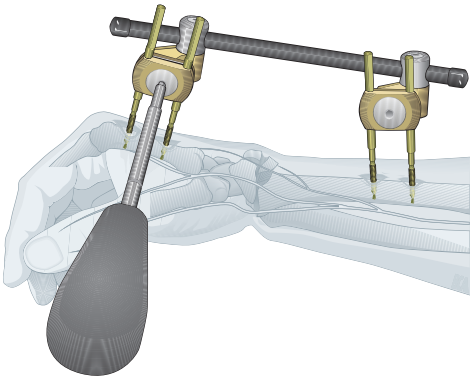
▲ Precaution:

Only when bones are osteoporotic does the Schanz Screw have to be screwed a bit further into the distant cortical bone, and it may even slightly penetrate through it since this can increase anchoring stability.

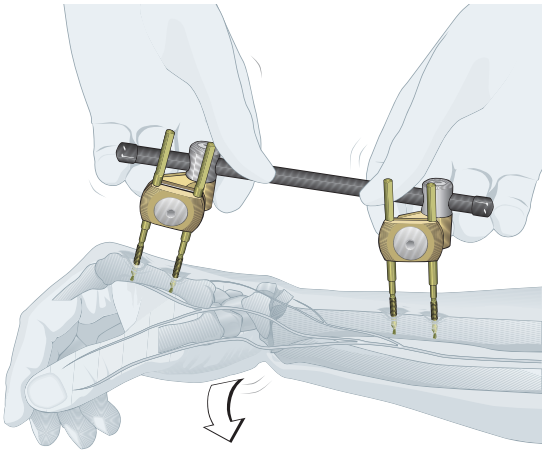
7. Tighten clamps to the screws

Required instruments	
Hexagonal screwdriver, large, ∅ 3.5 mm, with groove	314.270

Tighten the screw for fixing the clamp to the Schanz screws with the large hexagonal screwdriver.



8. Reduce the fracture

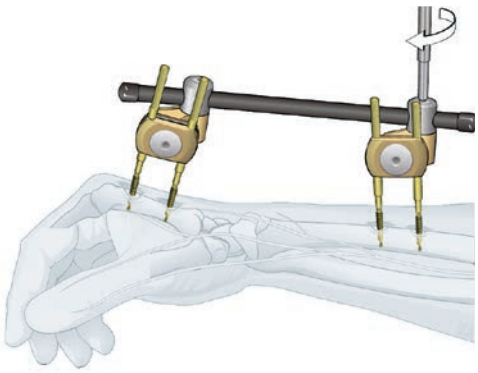


Due to the clamps, which permit independent fixation of the Schanz screws and the carbon fibre rod, the fracture can be reduced with the two Schanz screws as a lever using the modular technique.

The reduction can also be performed by conventional traction on the first and second finger (thumb and index finger) and countertraction on the forearm. Keep the two remaining set screws open here and thus allow free play of the DRF construct.

The length can also be adjusted with the distractor (see section 11 for use of the distractor), but the clamp body screws must be closed first.

9. Tighten adjusting points



After reduction, fix both axis set screws (two screws per clamp, see illustration in section 10a) jointly in a single step.

10. Axis adjustment in small subsequent corrections

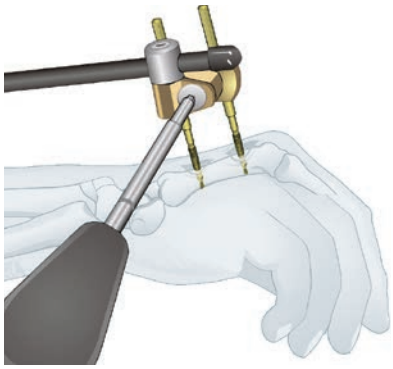
Minor axis corrections can be made after reduction if necessary.

■ Note:

Corrections in one level can lead to loss of reduction in the other levels.

10a.

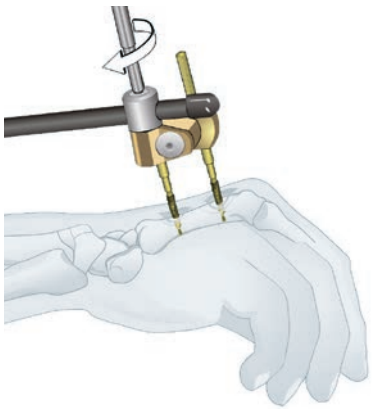
Flexion and extension, as well as radial and ulnar deviations can be corrected by loosening the screw on the main body.



10b.

The length, supination, and pronation can be corrected after the loosening of the fixing screws for the carbon fibre rod.

This manipulation can be performed primarily interoperatively or secondarily. The length adjustment can also be made by hand or with use of the distractor.



11. Use of the distractor

Use of the distractor for reduction is optional

Prepare the distractor

Required instruments	
Hexagonal screwdriver, large, ∅ 3.5 mm, with groove	314.270
Distractor	394.075

Close the distractor by turning the thumb wheel counter to the direction of the arrow “Distract”.

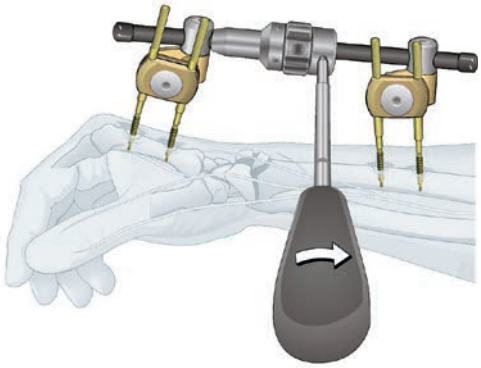
Align the thumb wheel so that a through opening forms.

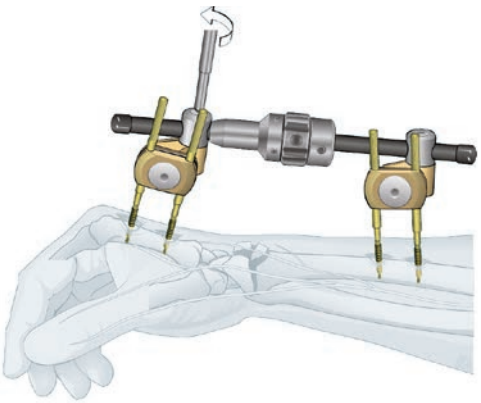
Insert the distractor

Place the distractor on the carbon fibre rod, so that the conical end of the distractor is next to the clamp for the distal radius fixator.

Secure the distractor on the carbon fibre rod by tightening the screw.

Loosen the fixator clamp in contact with the distractor by turning the rod-to-clamp screw.

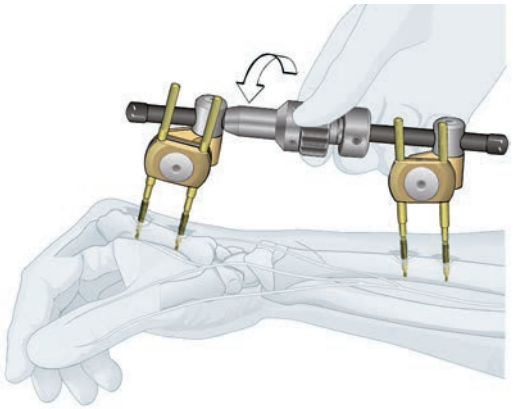




Distraction by ligamentotaxis

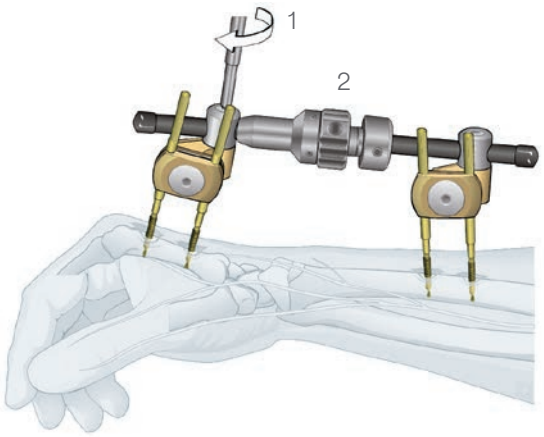
Distract the fracture by turning the thumb wheel in the direction of the arrow.

One turn corresponds to lengthening by one millimeter.



Remove the distractor

After successful distraction, tighten the screw on the clamp (1).
Remove the distractor by aligning the thumb wheel and loosening the screw on the distractor (2).



▲ Precautions:

- Implant sites should be meticulously cared to avoid pin-tract infection. Schanz screws may be surrounded with antiseptic coated foam sponges in an effort to avoid infection. An implant-site care procedure should be reviewed with the patient.
- To minimize the risk of pin tract infection the following points should be observed:
  a. Placement of Schanz screws taking anatomy into consideration (ligaments, nerves, arteries).
  b. Slow insertion and/or cooling, particularly in dense, hard bone to avoid heat necrosis.
  c. Release of skin tension at soft tissue entry point of implant.

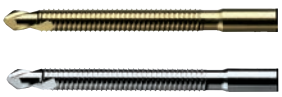
Implants and Instruments

■ Note:

For a detailed product information of the Schanz screw, refer to the Surgical Technique Schanz Screws and Steinmann Pins.

Implants

Self-drilling Schanz screws (Seldrill)



Reinforced bone anchorage

Titanium	Stainless Steel	Diameter (mm)	
	Length (mm)		
494.769	294.769	4.0/2.5	80
494.771	294.771	4.0/3.0	80
494.772	294.772	4.0/3.0	100
494.774–779	294.774–779	4.0	60–175

Self-tapping Schanz screws

Titanium	Stainless Steel	Diameter (mm)	
	Length (mm)		
494.445	294.445	4.0/2.5	80
494.300	294.300	4.0/3.0	80
494.430–460	294.430–460	4.0	60–125

Fixation Components

390.051 Clamp for the External Distal Radius Fixator
- Freely adjustable settings can be set with the large hexagonal screwdriver
- Suitable for Schanz screws ∅ 4.0 mm, 4.0/3.0 mm and 4.0/2.5 mm.

Carbon fibre rods

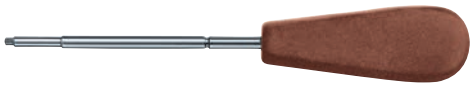
Radiolucent

Art. No.	Diameter (mm)	Length (mm)
395.782	8.0	200
395.784	8.0	220
395.786	8.0	240

395.781 Protective cap for carbon fibre rods

Instruments

314.270 Hexagonal screwdriver, large, ∅ 3.5 mm, with groove



395.967 Parallel drill guide 4.0

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Not all products are currently available in all markets.
This publication is not intended for distribution in the USA.

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