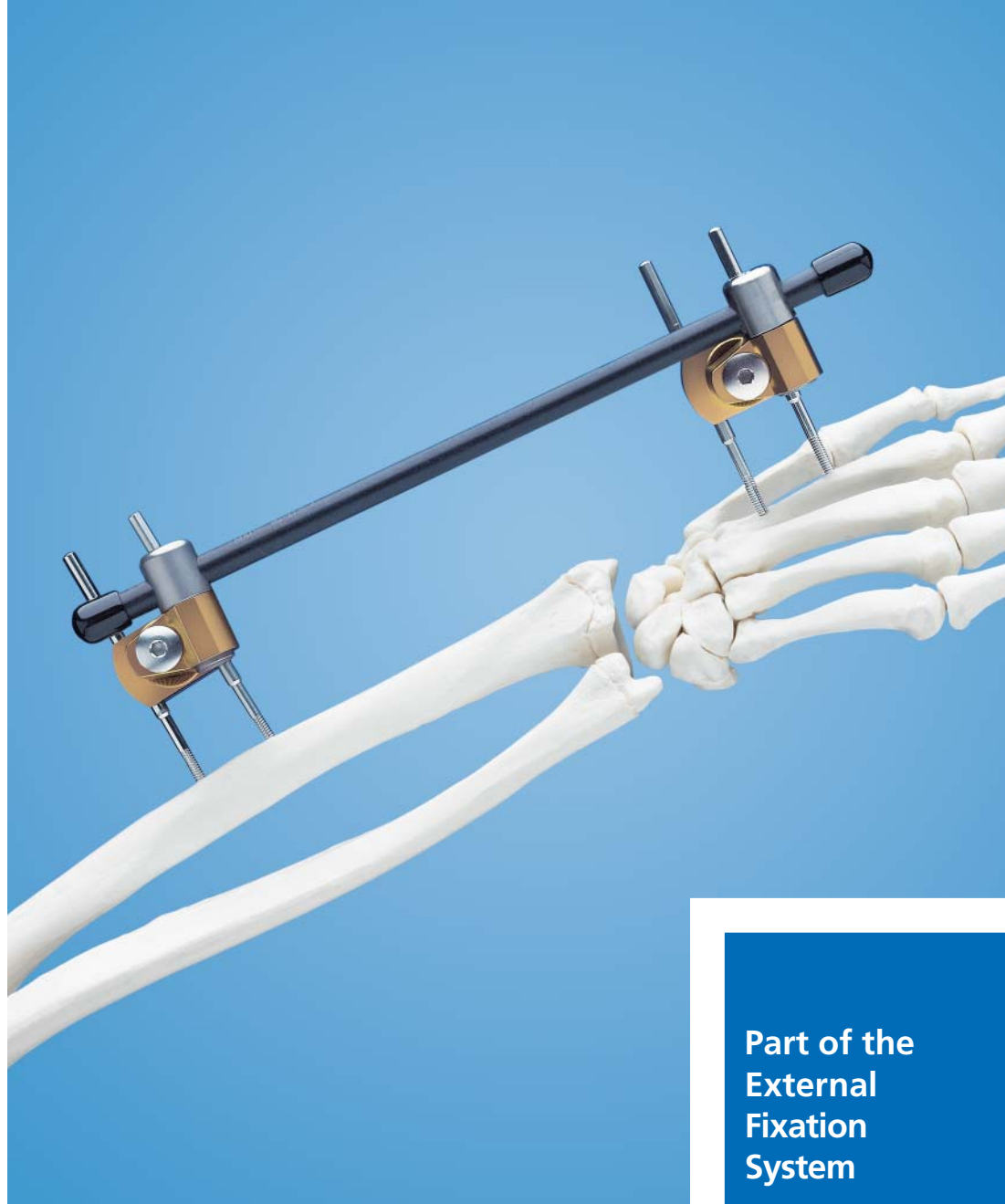


# **Distal Radius Fixator.** For stabilization of fractures of the distal radius.

## Technique Guide



**Part of the  
External  
Fixation  
System**

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# Distal Radius Fixator



## 4.0 mm Adjustable Clamp

- Independently locks to Schanz screws while allowing universal joint motion for reduction in all planes
- Allows secondary adjustment of length without loss of reduction
- Accepts 4.0 mm, 4.0 mm/3.0 mm and 4.0 mm/2.5 mm Schanz screws
- All adjustments are made with a standard 3.5 mm hexagonal screwdriver



## 4.0 mm / 3.0 mm Self-Drilling Schanz Screws

- Available in titanium and stainless steel, 20 mm thread length with 80 mm total length
- One-step insertion technique reduces operative time
- Shaft diameter is 4.0 mm and thread diameter is 3.0 mm



## 8.0 mm Carbon Fiber Rods

- Lightweight for patient comfort
- Radiolucent for improved intra- and postoperative radiographic visualization
- Multiple lengths for optimal adaptation to fracture positioning and patient needs: 200 mm, 220 mm and 240 mm

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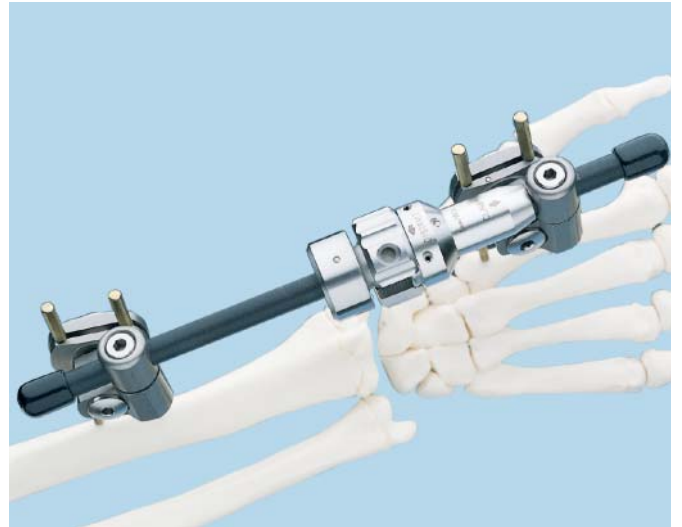
**Distractor, for Distal Radius Fixator**

- Provides controlled, measurable distraction
- Allows intraoperative application, activation and removal
- Maintains distraction during image intensification
- May be used postoperatively

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**Note:** The distractor achieves 1.0 mm distraction per revolution, with 14 mm maximum distraction.

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# MRI Information

Synthes Distal Radius Fixator devices are labeled MR Conditional according to the terminology specified in ASTM F2503-05, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

Nonclinical testing demonstrated that, when used in the specific configurations stated in Synthes labeling, Synthes Distal Radius Fixator devices are MR Conditional. Representative Synthes Distal Radius Fixator devices used in a typical construct include clamps, rods and various attachments. A patient with a Synthes Distal Radius Fixator may be scanned safely after placement of the fixator under the following conditions.

**Static magnetic field** of 1.5 Tesla when the fixation 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 Controlled Mode

**Static magnetic field** of 3.0 Tesla when the fixation 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 Controlled 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 Synthes external fixation 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 fixation frame of 6°C for the 1.5 T and less than 1°C for 3.0 T with a machine reported whole body averaged SAR of 2 W/kg.

Patients may be safely scanned in the MRI chamber at the above conditions. Under such conditions, the maximal 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 is 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, 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, Synthes MR Conditional external fixation devices may have the potential to cause artifact in the diagnostic imaging.

All components of Synthes external fixation frames must be identified as MR Conditional prior to being placed in or near an MR environment.

## 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 Synthes Distal Radius Fixator construct, and it may be necessary to optimize MR imaging parameters, to compensate for the presence of the fixation frame.

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

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

## Warning

- Do not place any radio frequency (RF) transmit coils over the external fixation frame.

# Indications

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The Synthes Distal Radius Fixator is intended for stabilization of fractures of the distal radius.

The Distractor, for Distal Radius Fixator (394.075) is an intraoperative and postoperative instrument used with the distal radius fixator to apply or release distraction.

## 1

### Insert distal Schanz screws

#### Instrument

395.965      4.0 mm Parallel Drill Guide

To avoid entrapping the extensor mechanism in extension, flex the second metacarpophalangeal joint to 90°.

Make a 25 mm longitudinal incision over the radial aspect and dissect the soft tissue.

Using the 4.0 mm parallel drill guide, insert 4.0 mm/3.0 mm self-drilling Schanz screws\* into the second metacarpal. Placement should be in the proximal and distal diaphyseal bone, 40°–60° to the frontal plane.

**Note:** The basic self-drilling Schanz screw insertion technique requires the tip to be embedded in the far cortex to resist cantilever forces. It is not necessary for the tip to penetrate through the far cortex. However, if the surgeon feels it is needed, as in osteopenic bone, the screw may be inserted so that it protrudes slightly through the far cortex.

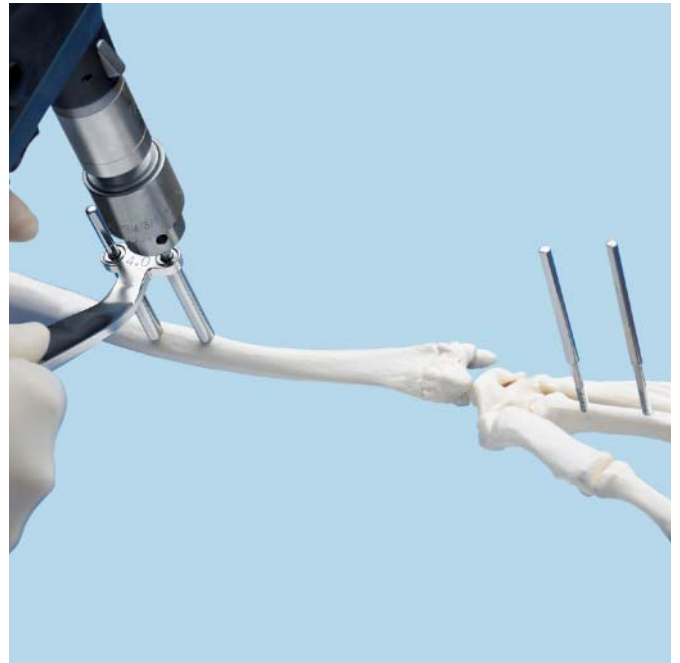


\*4.0 mm or 4.0 mm/2.5 mm self-drilling Schanz screw can be used.

## 2

### Insert proximal Schanz screws

Repeat Step 1 in the distal radius, taking care to avoid the sensory branch of the radial nerve.

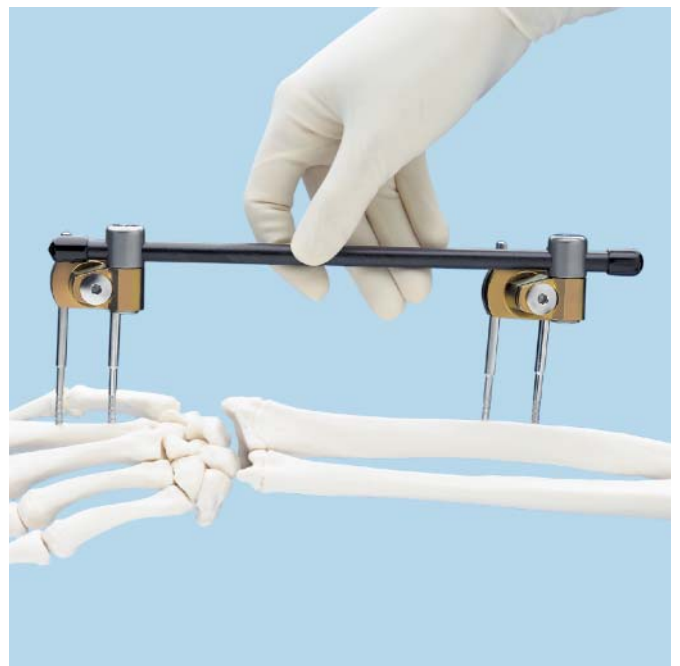


## 3

### Apply frame

With clamps loosened, place the assembled frame<sup>†</sup> over the self-drilling Schanz screws.

Clamps should always be positioned with the clamp body lying dorsal to the self-drilling Schanz screws to allow easy adjustment and clearance for the thumb.



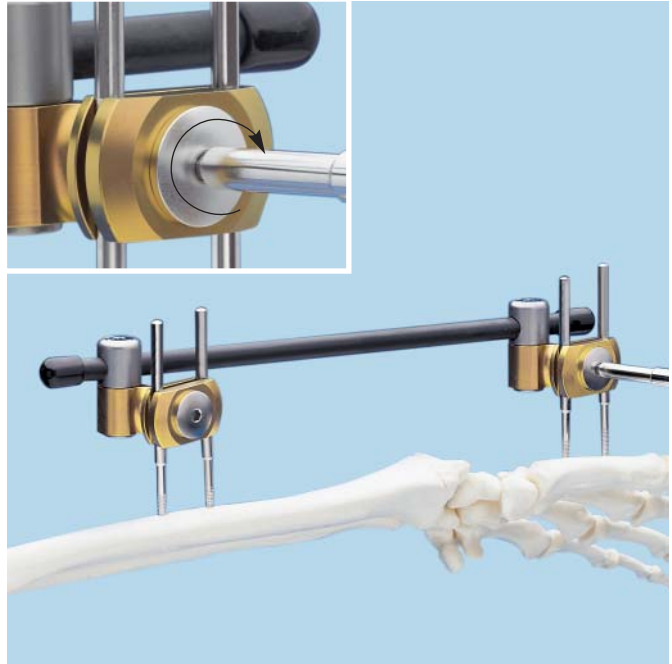
<sup>†</sup> The distal radius fixator is available in sterile-packed, preassembled frames, as well as individual, nonsterile components.



## 4

### Secure clamps on Schanz screws

Lock each vise plate to the Schanz screws using the large hexagonal screwdriver.



## 5

### Prepare distractor

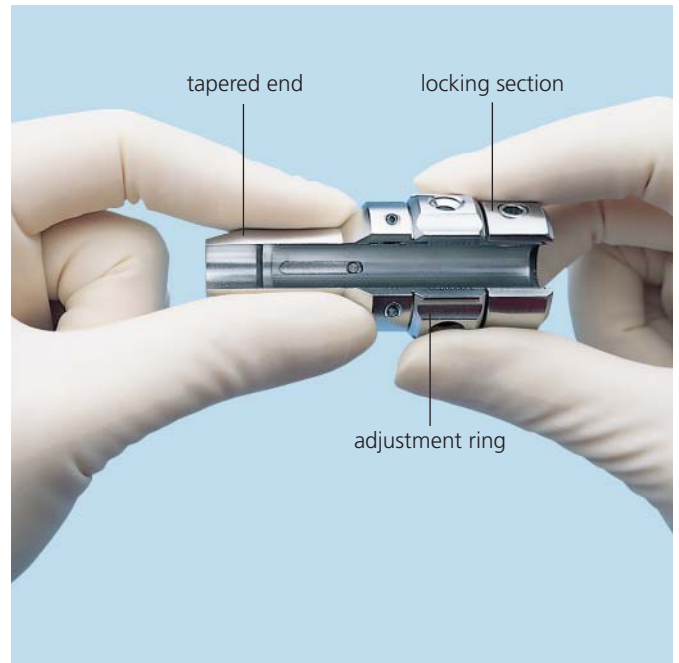
#### Instrument

394.075	Distractor, for Distal Radius Fixator
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Use the distractor to provide controlled, measurable distraction.

Close the distractor so that the adjustment ring is threaded against the locking section.

Align the openings on the distractor to form a uniform slot.



## 6

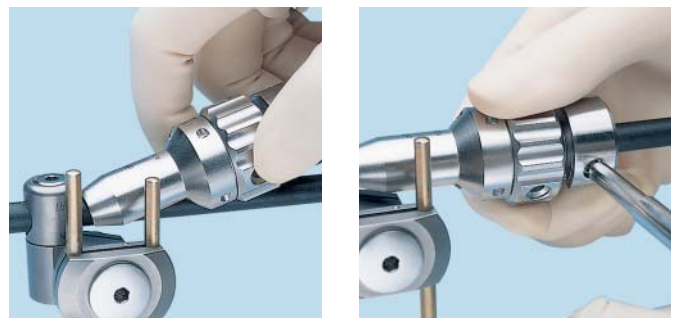
### Apply distractor

#### Instrument

314.27	Large Hexagonal Screwdriver
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Place the distractor onto the rod between the two clamps with the tapered end flush against either clamp.

Tighten the setscrew with the large hexagonal screwdriver, ensuring the locking section is fixed to the rod.



7

Loosen clamp

Loosen the distal radius fixator (DRF) clamp in contact with the distractor by loosening the clamp-to-rod adjustment screw.



8

Distract

Instrument

314.27 Large Hexagonal Screwdriver

Turn the adjustment ring in the direction of the arrow.

**Note:** 1 mm distraction per revolution.

After the desired distraction is achieved, retighten the DRF clamp.

**Note:** If additional distraction force is needed, use the large hexagonal screwdriver as a lever to turn the adjustment ring.



9

Remove distractor

Loosen the distractor setscrew.

Realign the adjustment ring to form a uniform slot.

Remove the distractor.

## 10

### Perform secondary adjustments

Supination/pronation may be adjusted by loosening the clamp on the carbon fiber rod.

Flexion/extension, and radial/ulnar deviation may be adjusted by loosening the clamp body.



# Instruments and Fixation Material

## Fixation Material, MR Conditional

390.051      4.0 mm Adjustable Clamp



394.075      Distractor, for Distal Radius Fixator



395.782      8.0 mm Carbon Fiber Rods  
395.784      200 mm  
395.786      220 mm  
395.786      240 mm



## Distal Radius Instruments, MR Unsafe\*

321.263      Offset Wrench



395.965      4.0 mm Parallel Drill Guide



\*MR Unsafe: An item that is known to pose hazards in all MR environments

## General Instruments

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311.44 T-Handle, with quick coupling



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314.27 Large Hexagonal Screwdriver



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393.101 Drive Adaptor with quick coupling,  
for 4.0 mm Schanz Screws



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395.781 Protective Caps, for 8.0 mm  
Carbon Fiber Rods



# Distal Radius Fixator Set with Self-Drilling Schanz Screws

Stainless Steel (115.953)

Titanium (115.955)

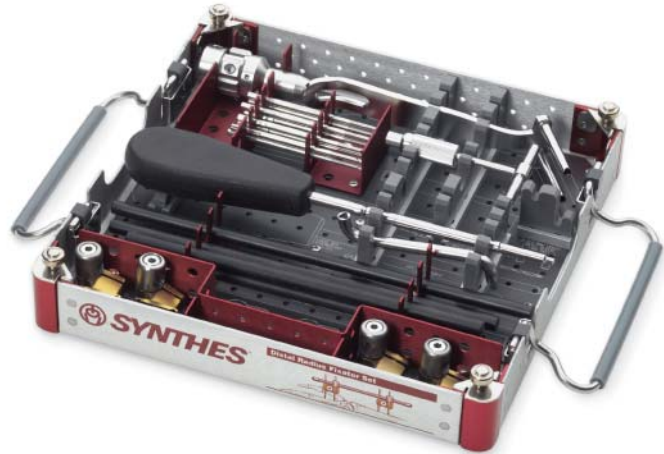
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## Graphic Case

690.388      Graphic Case, for Distal Radius Fixator

## Instruments

311.44      T-Handle, with quick coupling  
314.27      Large Hexagonal Screwdriver  
321.263      Offset Wrench  
393.101      Drive Adaptor with quick coupling,  
                 for 4.0 mm Schanz Screws  
394.075      Distractor, for Distal Radius Fixator  
395.965      4.0 mm Parallel Drill Guide



## Implants in set 115.953

294.771      4.0 mm/3.0 mm Self-Drilling Schanz Screw,  
                 80 mm, 8 ea.

## Implants in set 115.955

494.771      4.0 mm/3.0 mm Titanium Self-Drilling  
                 Schanz Screw, 80 mm, 8 ea.

## Fixation Material

390.051      4.0 mm Adjustable Clamp,  
                 for Distal Radius Fixator, 4 ea.  
395.781      Protective Caps, for 8.0 mm  
                 Carbon Fiber Rods, 2 pkgs. of 2  
                 8.0 mm Carbon Fiber Rods  
395.782      200 mm, 2 ea.  
395.784      220 mm  
395.786      240 mm

Note: For additional information, please refer to package insert.  
For detailed cleaning and sterilization instructions, please refer to  
<http://us.synthes.com/Medical+Community/Cleaning+and+Sterilization.htm>  
or to the below listed inserts, which will be included in the shipping container:  
– Processing Synthes Reusable Medical Devices—Instruments, Instrument Trays  
and Graphic Cases—DJ1305  
– Processing Non-sterile Synthes Implants—DJ1304

## Also Available

### Preassembled Frames (in sterile packaging)

- Distal Radius Fixators, with Self-Drilling Schanz Screws, sterile
- 03.390.052S with 200 mm Carbon Fiber Rod
  - 03.390.053S with 220 mm Carbon Fiber Rod
  - 03.390.054S with 240 mm Carbon Fiber Rod

- Distal Radius Fixators, with Titanium Self-Drilling Schanz Screws, sterile
- 03.390.055S with 200 mm Carbon Fiber Rod
  - 03.390.056S with 220 mm Carbon Fiber Rod
  - 03.390.057S with 240 mm Carbon Fiber Rod



### Instruments

- 310.19 2.0 mm Drill Bit, quick coupling, 100 mm
- 319.309 2.0 mm Trocar
- 394.991 Protective Caps, for 4.0 mm Fixation Pins
- 395.962 2.0 mm Parallel Insert Drill Sleeve
- 395.966 4.0 mm/2.0 mm Drill Sleeve
- 395.967 4.0 mm Short Parallel Drill Guide

### Implants

- 292.16 1.6 mm Kirschner Wire (10/pkg.)
- 292.20 2.0 mm Kirschner Wire (10/pkg.)
- 294.769 4.0 mm/2.5 mm Self-Drilling Schanz Screw, 80 mm
- 294.772 4.0 mm/3.0 mm Self-Drilling Schanz Screw, 100 mm
- 294.775 4.0 mm Self-Drilling Schanz Screw, 80 mm
- 294.776 4.0 mm Self-Drilling Schanz Screw, 100 mm
- 494.769 4.0 mm/2.5 mm Titanium Self-Drilling Schanz Screw, 80 mm
- 494.772 4.0 mm/3.0 mm Titanium Self-Drilling Schanz Screw, 100 mm
- 494.775 4.0 mm Titanium Self-Drilling Schanz Screw, 80 mm
- 494.776 4.0 mm Titanium Self-Drilling Schanz Screw, 100 mm

Note: Schanz screw bin holds any combination of these Schanz screws, maximum capacity 16.





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