

Mini External Fixator

Assembly and Surgical Technique

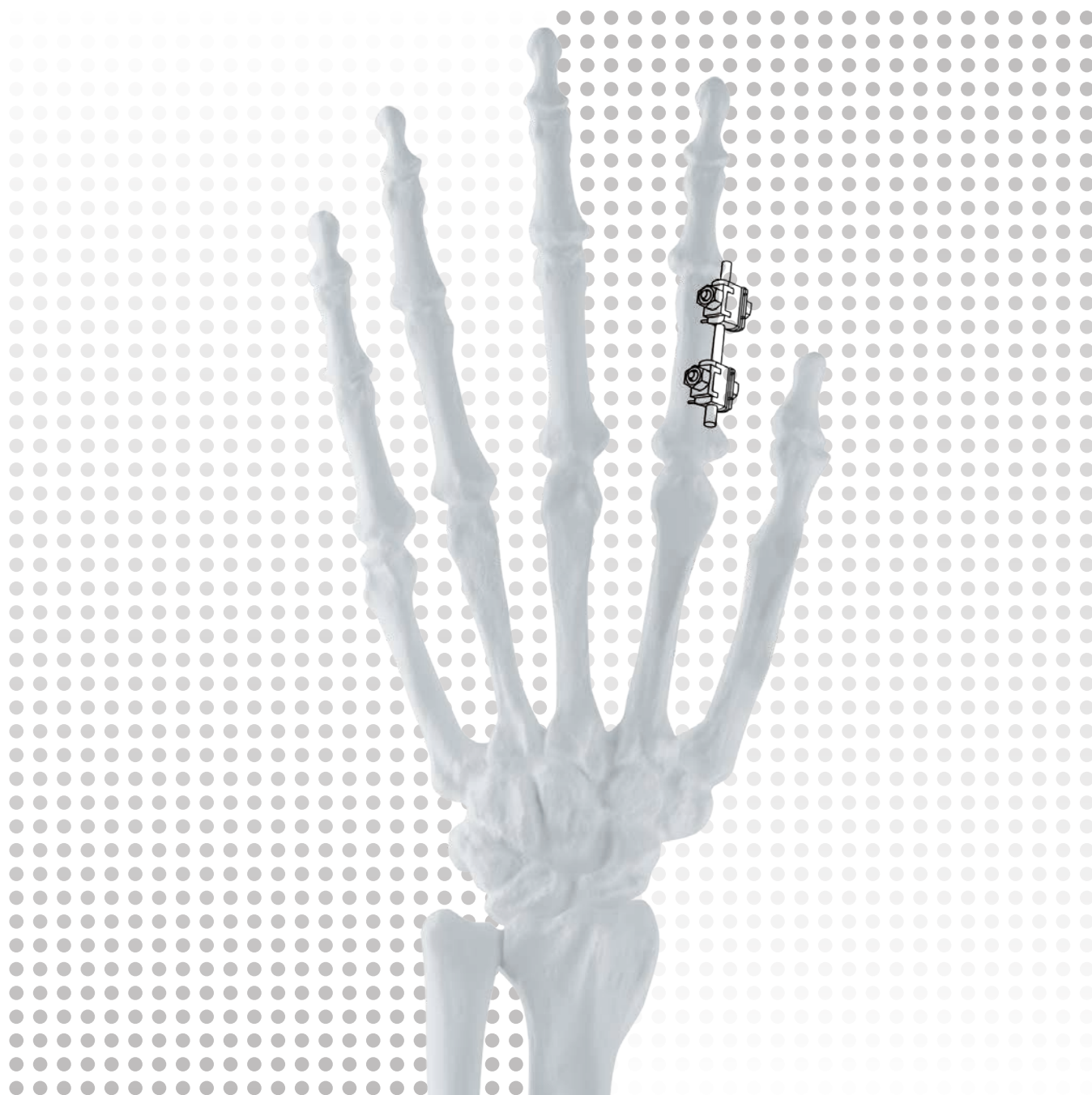


 Image intensifier control

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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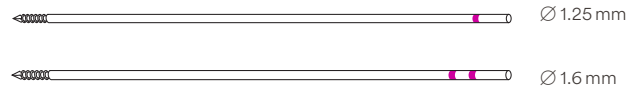
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Mini External Fixator

Kirschner Wires

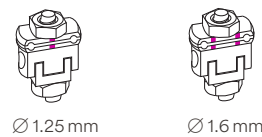
(specially designed for Mini External Fixator)

- diameter 1.25 mm (292.600S or 292.600.01) or 1.6 mm (292.708.01)
- length 100 mm
- threaded tip
- stainless steel



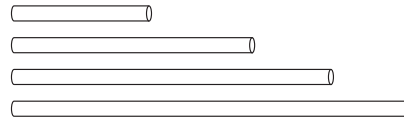
Holding Clamps

- for two Kirschner Wires $\varnothing 1.25$ mm (395.125) or $\varnothing 1.6$ mm (395.126)
- swivelling
- stainless steel



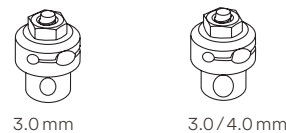
Connecting Carbon Fibre Rods

- diameter 3.0 mm
- lengths 25 mm (395.105), 45 mm (395.107), 60 mm (395.109), or 75 mm (395.111)
- radiolucent carbon fibre composite (CFK)



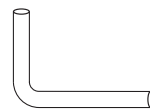
Connecting Clamps

- clamp 3.0 mm (395.133) for two $\varnothing 3.0$ mm rods
- clamp 3.0/4.0 mm (395.134) to connect the $\varnothing 3.0$ mm rods of the Mini External Fixator to the $\varnothing 4.0$ mm rods of the Small External Fixator
- stainless steel



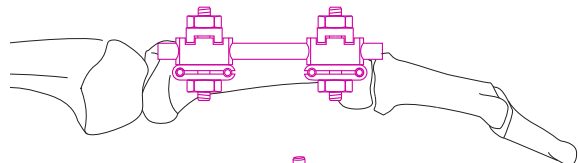
Connecting Rod, angled (395.103)

- diameter 3.0 mm
- length of limbs 18 and 26 mm, respectively
- stainless steel



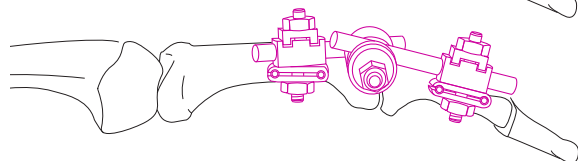
Single rod assembly

- holding clamps
- connecting rod



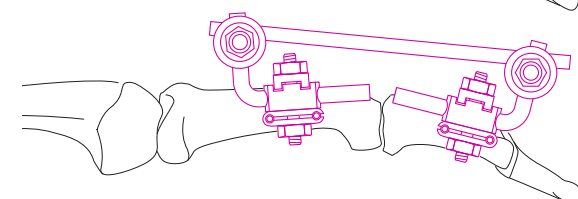
Double rod assembly

- holding clamps
- connecting rods
- connecting clamp



Assembly with angled connecting rods

- holding clamps
- angled connecting rods
- connecting clamps
- connecting rod



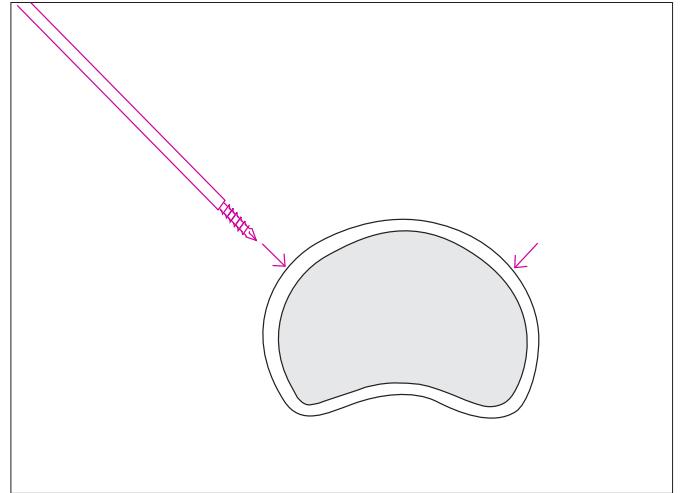
Positioning of Kirschner wires

The anatomical situation of ligaments and tendons of the hand requires particular surgical caution. As a rule, the Kirschner wires are inserted into the metacarpals and phalanges using a dorso-radial or a dorso-ulnar approach.

The Kirschner wires can be introduced laterally into the metacarpals I, II and V, the distal third of the proximal phalanges, as well as into the middle and end phalanges.

To place the Kirschner wires in the proximal part of the first phalanges, the extensor hood is incised in the direction of the movement of the tendon.

With the exception of the single rod assembly, the pairs of Kirschner wires can be placed freely and independently of each other in any position or angle required. In the configuration of a double rod assembly, for instance, the components of the Mini External Fixator allow an individual three-dimensional frame assembly.



▲ 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.
- Implant sites should be meticulously cared to avoid pin tract infection. Wires 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 Kirschner wires 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.

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

Single Rod Assembly

■ Note:

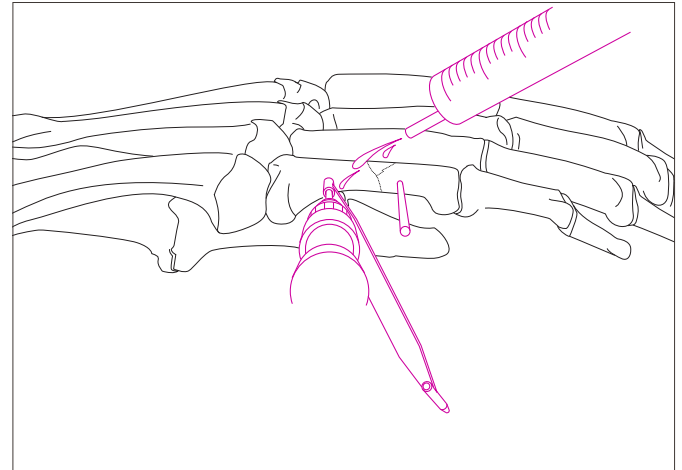
For a detailed handling description of the Kirschner wires, refer to the surgical technique Kirschner Wires and Cerclage Wires.

1. Insertion of primary Kirschner wires

Instruments

292.600.01	Kirschner wire Ø 1.25 mm with threaded tip, 100 mm
or	
292.600S	Kirschner wire Ø 1.25 mm with threaded tip, 100 mm Sterile
292.708.01	Kirschner wire Ø 1.6 mm with threaded tip, 100 mm

- ① The skin and the subjacent soft tissue are incised and one Kirschner wire each is inserted proximally and distally to the fracture. Using the Double Drill Sleeve 1.25/1.6 (395.902) the Kirschner wires are inserted until their tips are anchored in the far cortical bone. They must not, however, penetrate the cortical bone. Make sure the Kirschner wires are aligned in one plane.



When using a drill, the Kirschner wires should be inserted at low speed so as to avoid heat development. During the drilling process cool the Kirschner wires with a saline or Ringer's solution. In proximity to joints Kirschner wires can also be inserted using the Handle for Kirschner Wires Ø 0.6 to 1.6 mm (392.040).

■ Note:

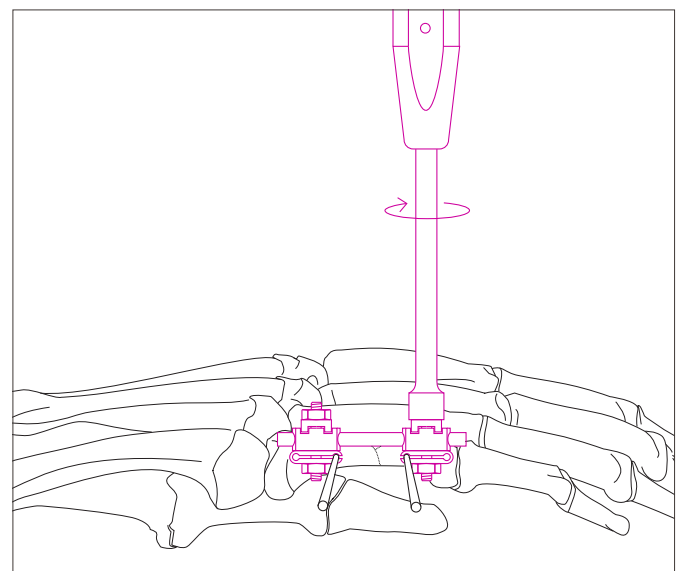
Use Kirschner wires 292.600.01 or 292.708.01 exclusively.

2. Rod connection assembly

Slide a Holding Clamp (395.125 or 395.126) on each Kirschner wire by its slotted opening and slightly tighten the screw nut by hand.

In order to determine the entry points of the secondary Kirschner wires introduce a Kirschner wire into the vacant openings of the clamps, mark and incise the skin and the subjacent soft tissue. Remove the Kirschner wire used for marking.

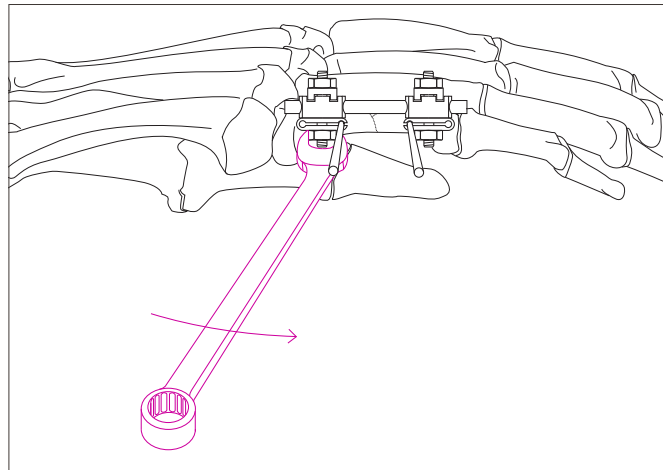
Slide a Connecting Rod (395.105/107/109/111) through both holding clamps and tighten it to one of them using the Socket Wrench Ø 5.5 mm (395.304).



3. Fracture reduction and fixation

- 1 Reduce the fracture and fix the reduction by slightly tightening the screw nut for the Kirschner wires with the Combination Wrench \varnothing 5.5 mm (395.302). Tighten the nut only as much as necessary to fix the reduction, making sure the vacant opening is still wide enough so that the parallel secondary Kirschner wire can be introduced later.

Securely tighten the screw nuts for the connecting rod.



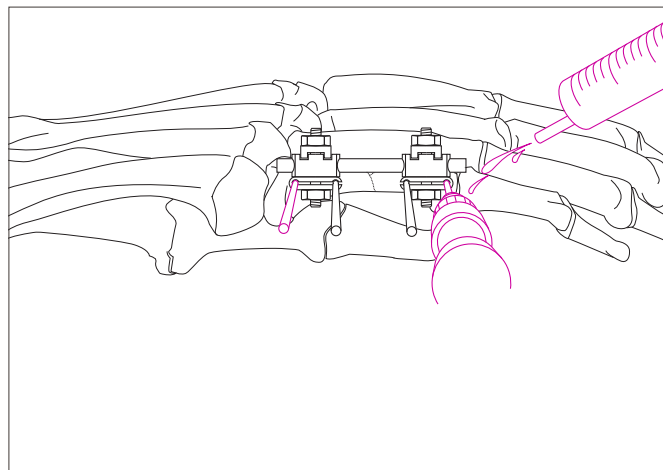
4. Insertion of the secondary Kirschner wires

Retract the soft tissue along the incision with small bone hooks and insert the secondary Kirschner wires through the vacant openings of the holding clamps while cooling the wire and the clamps.

- 1 the vacant openings of the holding clamps while cooling the wire and the clamps.

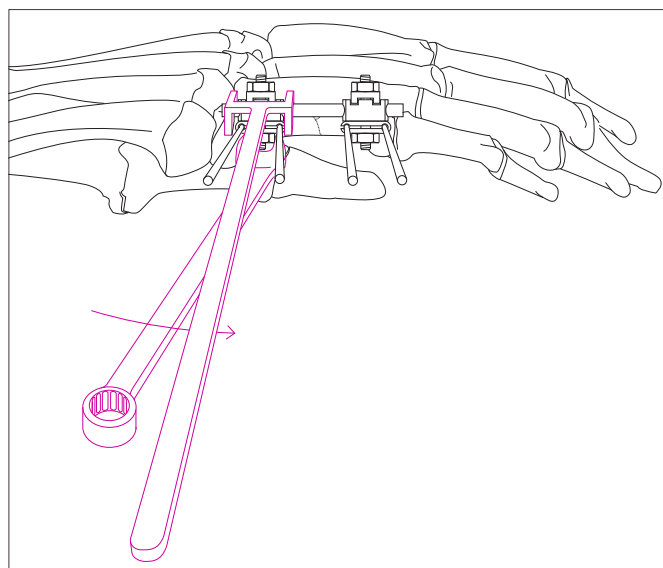
■ Note:

Make sure to always occupy both openings of the holding clamps with a Kirschner wire to ensure proper functioning of the clamps.



5. Tightening the screw nuts

Tighten the screw nuts for the Kirschner wires and simultaneously hold the connecting rod with the Clamp Holder (395.139) to counteract torque. Cut the Kirschner wires using a Wire Cutter (391.930).



Double Rod Assembly

1. Assembly of holding clamps

Instruments

292.600.01	Kirschner wire Ø 1.25 mm with threaded tip, 100 mm
or	
292.600S	Kirschner wire Ø 1.25 mm with threaded tip, 100 mm Sterile
292.708.01	Kirschner wire Ø 1.6 mm with threaded tip, 100 mm

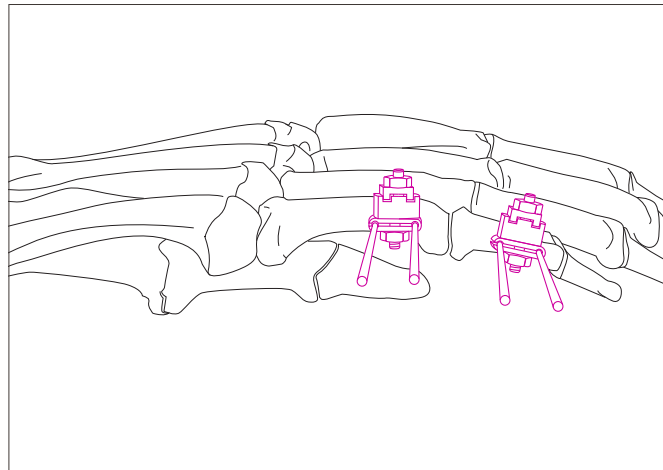
Incise skin and soft tissue and introduce a Kirschner wire through the double drill sleeve 1.25/1.6 (395.902) into the bone proximally to the fracture until its tip is anchored in the far cortical bone without penetrating it. Slide a Holding Clamp (395.125 or 395.126) onto the wire and introduce a Kirschner wire into the vacant opening of the clamp in order to determine the entry point of the secondary Kirschner wire. Mark the skin and make an incision. Position the holding clamp closely to the body and insert the secondary Kirschner wire.

Repeat this process for the second holding clamp.

When using a drill, Kirschner wires should be inserted at low speed so as to avoid heat development. During the drilling process cool the Kirschner wire with a saline or Ringer's solution. In proximity to joints Kirschner wires can also be inserted using the Handle for Kirschner Wires Ø 0.6 to 1.6 mm (392.040).

■ Note:

Use Kirschner wires 292.600.01 or 292.708.01 exclusively.

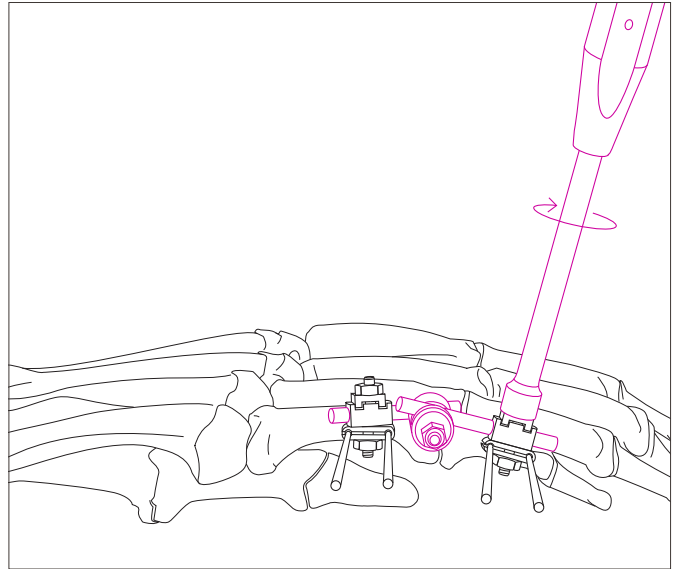


2. Frame assembly

Slide a Connecting Rod (395.105/107/109/111) through each holding clamp and mount the Connecting Clamp (395.133) (do not tighten the screw nut). Tighten the screw nut for the connecting rod of the distal holding clamp using the Socket Wrench \varnothing 5.5 mm (395.304).

Alternative:

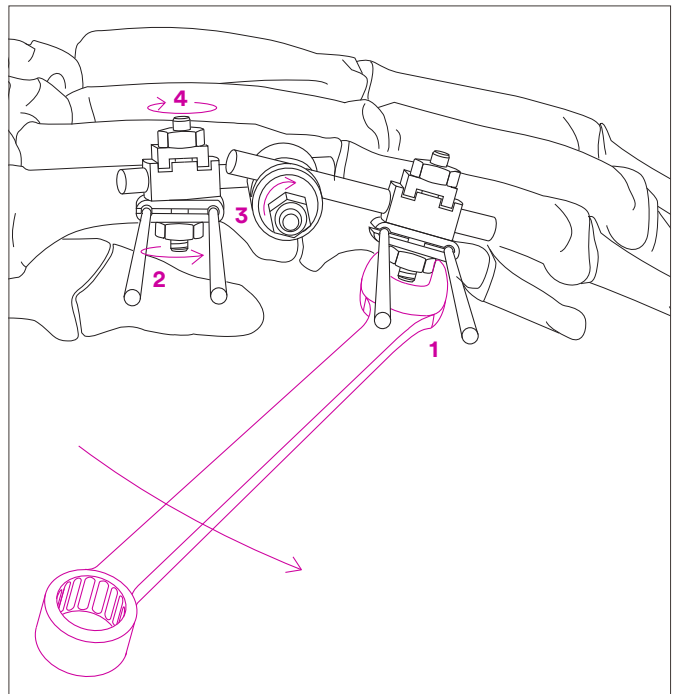
The use of the assembly with angled connecting rods increases the assembly freedom.



3. Fracture reduction and fixation

- Reduce the fracture and fix the reduction by tightening the screw nuts of the holding clamps and of the connecting clamp with the Combination Wrench \varnothing 5.5 mm (395.302). Sequence for tightening the screw nuts: 1, 2, 3, 4.

Cut the Kirschner wires using a Wire Cutter (391.930).



Removal

Dismount connecting rods and holding clamps. If the holding clamps cannot be removed from the Kirschner wires, the clamping plate can easily be opened on the slotted side with a chisel for instance. Unscrew the Kirschner wires anticlockwise with the Handle for Kirschner Wires \varnothing 0.6 to 1.6 mm (392.040), Wire Bending Pliers (391.820) or flat-nosed Pliers (391.850).

MRI Information

The “Mini External Fixator” is MR unsafe. Do not use this device in any MR environment. This device is known to pose hazards in all MR environments.

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

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