# The Distraction Osteogenesis Ring System

**Nonarticular Tibia Frame** 

# **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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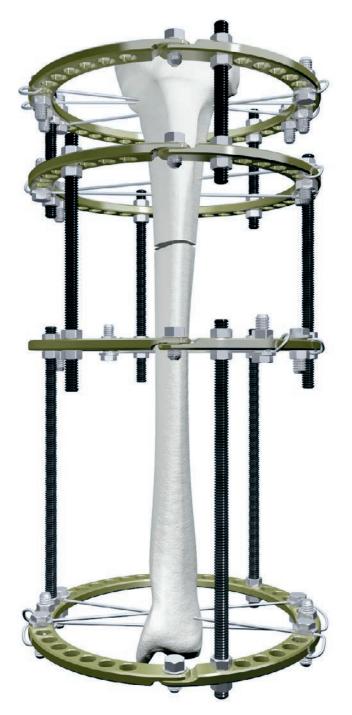
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# The Distraction Osteogenesis Ring System

Nonarticular Tibia Frame

The Distraction Osteogenesis Ring System is a ring fixation system. The ring fixation technique is based on the use of transfixion wires and external fixation pins attached to rings that encircle the affected limb. These rings are then attached to each other with components such as threaded rods and nuts to create a frame.

The main components of the system are transfixion wires (smooth and reduction or "olive"), rings (half rings, full rings, 5/8 rings, femoral arches, and foot rings), threaded rods, nuts, connection bolts and wire bolts. Other components available include standoffs, locking hinges, angular distractors, linear distractors, clamps, connecting plates, speed nuts, supports, washers and Schanz screws. These components can be used to create many frame configurations.



## **Additional features**

- 8 mm threaded rods allow 3 rods to be used in each ring block.
- Compatible with the DePuy Synthes Medium External Fixator.
- The 1.5 mm, 1.8 mm and 2.0 mm smooth and reduction wires are available with a drill point tip (half-point tip and spade-point wires are also available).
- A variety of components are available for compression, distraction, angulation and translation of bone segments.
- Lightweight titanium alloy or carbon fiber rings are available.

## Vario Cases and removable modules

- Two Vario Cases contain all components and instruments required for surgery: a ring case (standard or optional) and the implant and instrument Vario Case.
- The implant and instrument Varion Case has labeled bins so only the desired components need to be stored.
- Removable modules included in the implant and instrument Vario Case hold washers and spacing washers.

Reduction wire

Reduction wire, half point tip



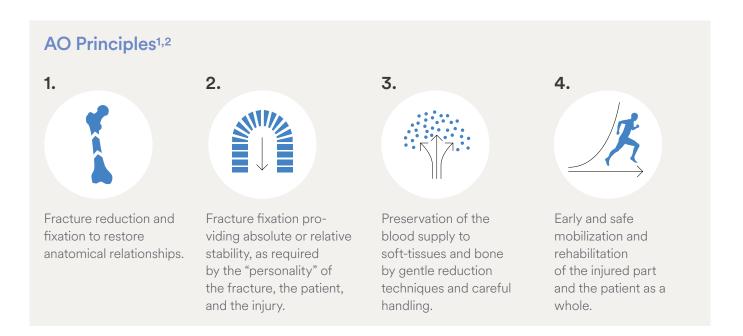
Linear distractor

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.



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

## **MRI Information**

Distraction Osteogenesis Ring devices used in a typical construct include clamps, rods and various attachments. A patient with a DePuy Synthes Distraction Osteogenesis Ring frame may be scanned 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 Distraction Osteogenesis Ring System 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 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 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 be brought into the user's MR environment.

• If placed in the bore of the MR scanner during scanning, DePuy Synthes Distraction Osteogenesis Ring devices may have the potential to cause artifact in the diagnostic imaging.

#### **WARNINGS:**

- Only use frame components stated in the surgical technique of the Distraction Osteogenesis Ring 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 Distraction Osteogenesis Ring 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 Distraction Osteogenesis Ring frame. It may be necessary to optimize MR imaging parameters in order to compensate for the presence of the frame.

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

## **Required Set**

01.311.000 Set Distraction Osteogenesis

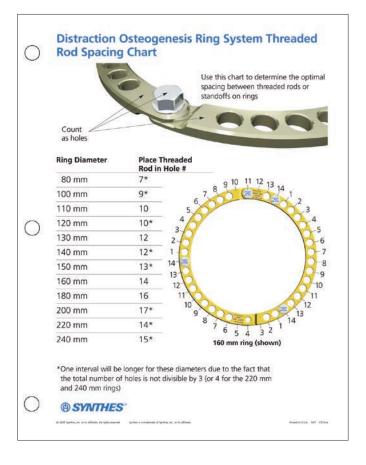
#### **Required Components and Instruments**

 03.311.308−
 Half-Ring Ø 80 mm−240 mm,

 03.311.324
 Titanium Alloy

## **Threaded Rod Spacing Chart**

The Threaded Rod Spacing Chart is an aid for determining where threaded rods should be placed on the rings for maximum stability, for the different ring sizes. Use the chart during preoperative planning or when constructing a frame to determine optimal spacing of the threaded rods.

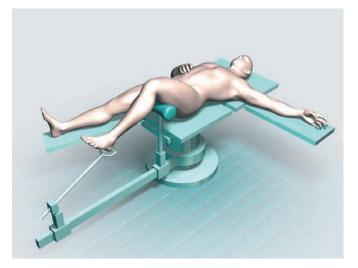


## **Patient Positioning**

Position the patient supine on a radiolucent table with the affected limb elevated to provide access for the Distraction Osteogenesis Ring System frame, wires, and Schanz screws.

#### Notes:

- This technique describes building the frame on the patient. It is possible to build the frame using the same construction techniques before placement on the patient, in which case, the wires and Schanz screws are inserted after frame construction and application. See "Alternative Technique" for further information on applying a prebuilt frame.
- For a detailed handling description of the Schanz screws, refer to the surgical technique Schanz Screws and Steinmann Pins.



## **Ring Selection and Assembly**

### 1. Select half rings

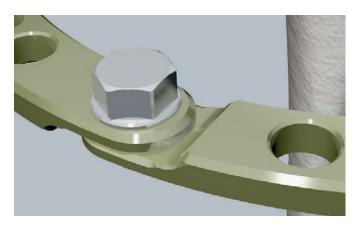
Select two half rings (of the same size) that allow at least 2 cm of clearance between the limb and ring (take care to measure at the thickest portion of the affected limb). Any anticipated swelling of the limb must also be taken into consideration.

### 2. Assemble half rings

#### Instrument

03.311.007 Wrench Ø 8.0/11.0 mm

Place the two half rings around the limb. Connect the half rings using two connection bolts. Take care to align a threaded hole of one half ring with a non-threaded hole of the other. The number markings near the connection holes on the half rings serve as guides and should be visible when assembling the half rings. Thread the connection bolts through the non-threaded holes into the threaded holes from the marked side of the rings. Tighten the bolts with the wrench.



### 3. Assemble three more rings

Repeat steps 1 and 2 three more times so that there are a total of 4 assembled rings of the same diameter.

#### A 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.

## **Frame Construction**

## 1. Connect the two proximal rings

Instrument	t
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03.311.007 Wrench Ø 8.0/11.0 mm

Position the rings so that the most proximal ring is near the joint, but no closer than 20 mm, tissue condition and anatomy permitting. Position the next ring so that it is approximately 30–50 mm proximal to the affected area, tissue condition and anatomy permitting. Align the connection bolts/joints of the half rings. Use threaded rods and nuts and the 8 mm/11 mm wrench to connect the rings. Typically, only three threaded rods are necessary between each pair of rings (4 rods should be used between pairs of 220 mm and 240 mm rings). See the Threaded Rod Spacing Chart for the recommended number of holes between threaded rods for each ring size. Ensure that the rings remain parallel to each other after they are connected.



## 2. Attach the third ring to the frame

Position the third assembled ring approximately 30–50 mm distal to the affected area, tissue condition and anatomy permitting. Align the connection bolts/joints of the half rings with those of the previously connected rings and use threaded rods and nuts to connect this ring to them. For maximum stability, these threaded rods should be placed as close to equally between the threaded rods from the previous ring as possible (see picture). Be sure that the rings remain parallel to each other after they are connected.



## 3. Attach the fourth ring to the frame

#### Instrument

03.311.007 Wrench Ø 8.0/11.0 mm

Position the fourth assembled ring near the distal joint, but no closer than 20 mm, tissue condition and anatomy permitting. Align the connection bolts/joints of the half rings with those of the previously connected rings and use threaded rods and nuts to connect this ring to them. For maximum stability, these threaded rods should be placed as close to equally between the threaded rods from the previous ring as possible (see picture). Ensure that the rings remain parallel to each other after they are connected.

#### Note:

During the construction of a frame, it may be helpful to insert a long threaded rod through all of the rings to help keep them aligned.



#### Note:

When holes in the rings do not line up properly (such as when different diameter rings are used), spherical washer couples, locking hinges or connecting plates may be used to connect the threaded rods to adjacent rings.



## Wire Insertion

### 1. Wire selection

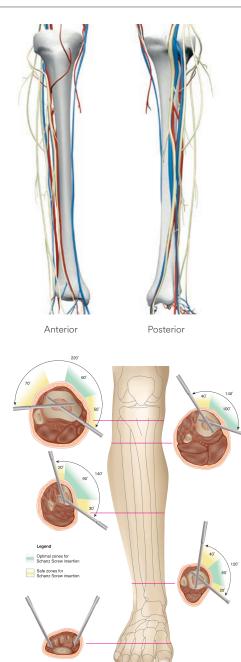
Select wires of appropriate size. The 1.8 mm and 2.0 mm wires are commonly used for adult patients while 1.5 mm wires are often used for small stature patients or in the hand and foot. Surgeon preference determines whether smooth wires or reduction wires are used.

### 2. Wire insertion

#### Instrument

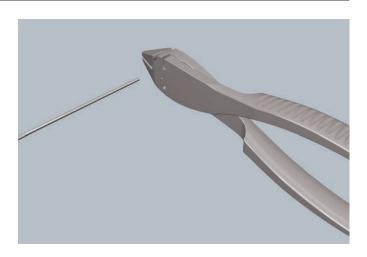
391.962 Bending/Cutting Pliers

An alcohol-soaked 4"x 4" sponge helps guide and cool the wire. Do not start the drill until the wire tip makes contact with the bone and stop drilling as soon as the tip protrudes from the far cortex of the bone. Insert wires perpendicular to the longitudinal axis of the affected limb, from the side with the most vulnerable anatomy.



Tibial safe zones

Once the wire protrudes from the far cortex of the bone, tap it through the tissue on the far side. The flat side of the bending/cutting pliers may be used to tap the wire through the tissue. Once the wire is through, cut off the tip to prevent injury.



Insert a smooth wire near the joint that is furthest from the injury site, perpendicular to the long axis of the bone and parallel to the joint. Insert the wire from the side of the limb with the most vulnerable anatomy. The wire should be no closer than 20 mm to the joint surface. Place the limb in longitudinal traction to aid in restoring length and reduction.

## **Alternative Techniques**

Instruments	
03.311.004	Ratchet Wrench 11.0 mm
03.311.005	Protection Sleeve, slotted, $\varnothing$ 2.5 mm
399.410- 399.430	Hammer 300–700 g
399.500	Hammer 100 g

The 2.5 mm split tissue protection sleeve may be used to hold the wire near the bone and aid in protecting the soft tissue.

Use the flat side of the ratchet wrench or a hammer to tap the wire through the soft tissue.





## 3. Position the frame on the wire

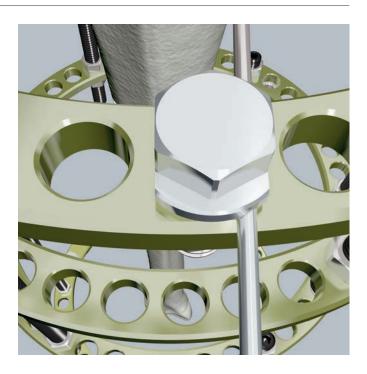
Move the frame into the proper position along the wire. Position the half ring joints over anatomy features that would prevent wire insertion (there are fewer holes near the half ring joint). In the tibia, this places the connection bolts over the tibial crest or just lateral to it. Confirm that the frame sits so that the rings are perpendicular to the long axis of the bone. If the frame is not properly aligned with the bone, reposition the wire.



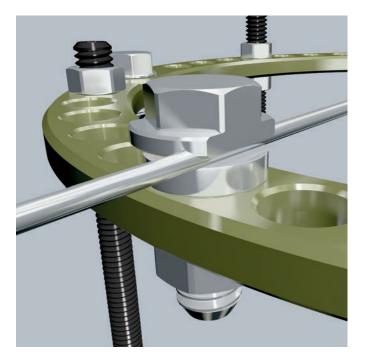
# Wire Fixation

## 1. Attach the wire to the ring

Use wire bolts to connect the wire to the ring. Choose either offset wire bolts or slotted wire bolts, depending on the position of the wire in relation to the holes in the ring. The wire should remain in a neutral position. Thread the bolts from below or above the ring, depending on where the wire sits. The wire should be between the bolt head and the ring.



Use spacing washers between the bolt head and the ring or use wire posts if the wire does not contact the ring without bending. Do not bend wires to attach them to the ring (unless more advanced reduction techniques are being used). Fasten the bolts with nuts (standard or square). Tighten the nuts onto the bolts by hand; leave them loose enough to allow the rings to be repositioned on the wire.



## Insertion of Wire at the Opposite Bone End

# 1. Repeat wire insertion at the opposite end of the bone

Instruments	
03.311.004	Ratchet Wrench 11.0 mm
03.311.007	Wrench Ø 8.0/11.0 mm

Insert a wire in the opposite end of the affected bone as was done at the first ring. Use wire bolts and nuts to attach this wire to the ring.



# Wire Tensioning

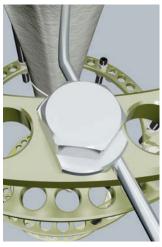
# 1. Tighten one wire bolt and nut opposite from tensioning side

Instrument	
03.311.007	Wrench $\varnothing$

Wrench  $\varnothing$  8.0/11.0 mm

Use two wrenches to tighten the nut and wire bolt opposite from where tension will be applied. When reduction wires are used, tighten the side with the stopper. Take care to keep the wire bolt head aligned, to reduce risk of bending of the wire.





Correct

Incorrect

## 2. Position tensioner on wire

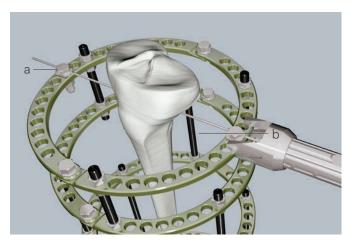
#### Instruments

03.311.001	Wire Tightener
03.311.220- 03.311.250	Standoff, hexagonal, length 20–50 mm

From the tensioning side of the ring, pass the wire into the cannulation of the wire tightener. The wire tightener should be fully open (the black handle turned counterclockwise until it stops) and the teeth on the front of the device seated securely against the ring, to ensure proper tensioning of the wire. Center the wire bolt and nut between the teeth of the wire tightener.

- a Tighten offset bolt opposite wire tightener before tensioning.
- b Leave offset bolt loose when tensioning. Tighten after wire is tensioned.

If other features prevent the teeth from sitting on the ring, place a standoff on the wire between the wire tightener and the ring. The threaded tip allows the standoff to be threaded onto the wire tightener.





## 3. Apply tension to the wire

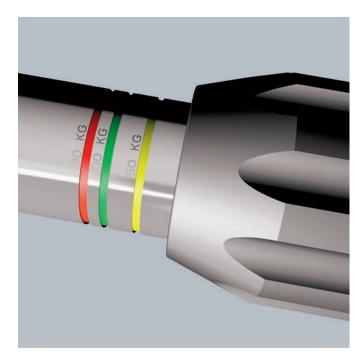
Instruments	
03.311.001	Wire Tightener
03.311.004	Ratchet Wrench 11.0 mm

Turn the wire tightener handle clockwise until the desired tension is attained. Typical wire tensions used are:

- When attached to a ring: 130 kg
- When attached to a ring on a young patient: 100 kg
- When positioned off of a ring: 50 kg–75 kg
- When positioned in the hand or foot: 50 kg-75 kg

#### **Optional technique**

A ratchet wrench can be used on the external hex nut at the back of the wire tightener to make turning the handle quicker.



## 4. Tighten the wire bolt and nut

#### Instruments

03.311.002	Socket Wrench, slotted
03.311.004	Ratchet Wrench 11.0 mm

When the wire is fully tensioned, tighten the wire bolt near the wire tightener. A socket wrench can be used to hold the wire bolt head straight while a ratchet wrench is used to tighten the nut onto the bolt (or two ratchet wrenches may be used). Repeat this process for the remaining wire(s). After tensioning all the wires on a ring, retension them in the same sequence to maintain appropriate tension and obtain the frame stability. After all wires have been tensioned, all nuts and bolts should be checked for tightness.

#### **Alternative Techniques:**

- Use two tensioners from opposite sides to simultaneously tension two wires to maintain appropriate tension and obtain the frame stability.
- Reduction wires are not always tensioned, as when they are used to reduce a fracture by transporting a segment over time. In this case, the end of the wire with the stopper is not secured to the ring. The opposite end may be held in a slotted threaded rod with two nuts and inserted through an eye bolt. The threaded rod can be pulled through the eye bolt using another nut, thereby moving the wire and the bone fragment that is held by the stopper.

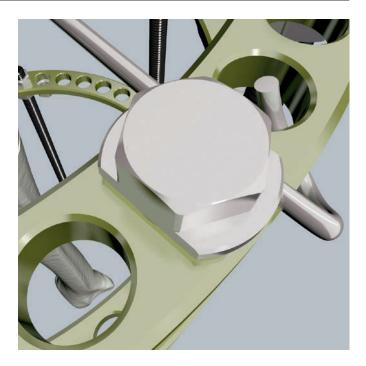




## 5. Cut the ends of the wires

Instrument	
391.962	Bending/Cutting Pliers

After tensioning, cut the ends of the wires. Leave at least 60 mm (approximately 3 finger widths) of wire past the wire bolt so that there is sufficient wire to grab if the wire needs tightening. Curl the end of the wire using the bend-ing/cutting pliers.



## 6. Tension the wire at the distal ring

Repeat the tensioning process on the wire that is attached to the distal ring.

## **Insertion of Additional Wires at First Ring**

### 1. Insert two additional wires at first ring

Place two more wires in the tibia at the first ring, perpendicular to the long axis of the bone. One wire should be above the ring and one below with the third wire inserted diagonally starting below the ring and ending above it on the opposite side. The third wire may also be inserted a few millimeters above or below the rings. These techniques help prevent the wires from hitting each other inside the bone or tissue. A wire may be weakened if it is contacted by the tip of another wire as it is inserted. Insert the wires so that they cross in the bone at as large an angle as the anatomy permits to prevent the bone from moving along the wires and provide stability. Counter-opposing reduction (olive) wires can help stabilize this bone segment.



### 2. Attach the wires to the ring

Instrument		
03.311.007	Wrench Ø 8.0/11.0 mm	

Use wire bolts and nuts to attach the wires to the ring, taking care not to bend the wires.

#### 3. Tension the wires

Tension, tighten and cut both wires as described under "Wire Tensioning".

## Insertion of Additional Wires at the Opposite Bone End

# 1. Repeat wire insertion at the opposite end of the bone

Insert two more wires in the opposite end of the affected bone as was done at the first ring. Refer to step 1 "Repeat wire insertion at the opposite end of the bone".



### 2. Attach the wires to the ring

Use wire bolts and nuts to attach the wires to the ring taking care not to bend the wires.

#### 3. Tension the wires

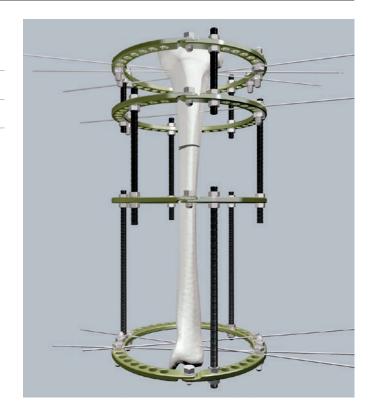
Tension, tighten and cut both wires as described under "Wire Tensioning".

# **Insertion of Remaining Wires**

# 1. Insert a wire in the proximal segment near the affected area

Instrument	
03.311.007	Wrench $\varnothing$ 8.0/11.0 mm

Insert a wire at the ring that is 30–50 mm proximal to the affected area. Connect the wire to the ring as described under "Wire Fixation".

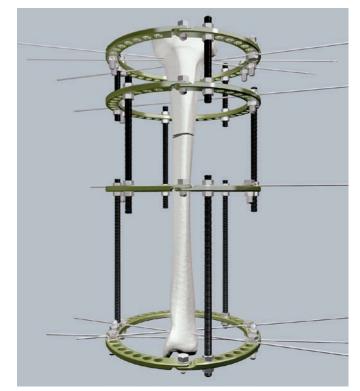


# 2. Insert a wire in the distal segment near the affected area

Insert a wire at the ring that is 30–50 mm distal to the affected area. Connect the wire to the ring as described under "Wire Fixation".

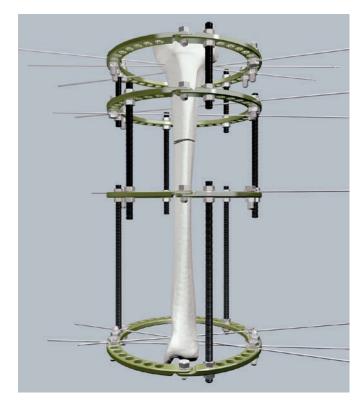
#### Alternative Technique

Reduction wires may be used instead of smooth wires to aid in reduction. If reduction wires are used, they are placed with the stoppers on opposite sides of the bone to help hold the segments together.



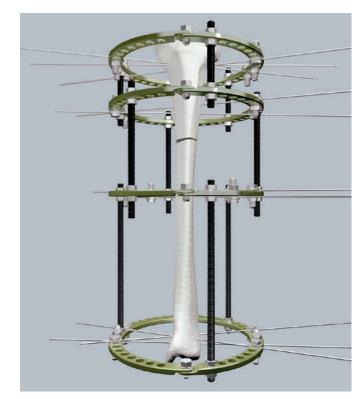
# 3. Insert a second wire in the proximal segment near the affected area

Insert a second wire at the ring that is just proximal to the fracture. Insert this wire on the opposite face of the ring from the first wire to prevent the wires from contacting and damaging each other. Insert this wire so that the angle between it and the previously inserted wire is as large as possible.



# 4. Insert a second wire in the distal segment near the affected area

Insert a second wire at the ring that is just distal to the fracture. Insert this wire on the opposite face of the ring from the first wire, to prevent the wires from contacting and damaging each other. Insert this wire so that the angle between it and the previously inserted wire is as large as possible.



# 5. Attach and tension the remaining wires

Instruments	
03.311.001	Wire Tightener
03.311.002	Socket Wrench, slotted
03.311.004	Ratchet Wrench 11.0 mm
03.311.007	Wrench Ø 8.0/11.0 mm
391.962	Bending/Cutting Pliers

Attach the wires to the middle two rings with wire bolts as before and tension, tighten and cut them as described under "Wire Tensioning".

#### **Alternative Technique**

If reduction wires are used to help reduce a fragment, they are usually not tightened on the opposite side of the wire tightener until the fragment is pulled into the desired position by the wire tightener. Then the opposite wire bolt can be tightened and the wire tensioned.

### 6. Check the wires and connections

Check all of the wires for tension and all connections for tightness.

#### Note:

Do not overtighten the screws.

### 7. Implant Removal

Implants can be removed by using general surgical instruments.



#### A Precautions:

- Wire sites and pin sites should be cared for meticulously to avoid wire-tract and pin-tract infection. Wires and Schanz screws may be surrounded with antiseptic coated foam sponges in an effort to avoid infection.
- A wireand pin-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.

#### **Use of Schanz screws**

Schanz screws may be used in the place of wires, or with wires (usually one Schanz screw in the place of one wire on a ring). The Distraction Osteogenesis Ring System contains a variety of clamps and bolts that can be used to attach Schanz screws to the frame. The Clamp, medium, clip-on, self-holding, (390.035), the Combination Clamp, medium, clip-on, self-holding, (390.031) and the Combination Clamp 8.0/11.0, clip-on, self-holding, (390.037) can also be used to fix Schanz screws to threaded rods. Various drill sleeves are available that can be inserted in the clamps and bolts to aid in Schanz screw insertion.

#### Note:

For a detailed handling description of the Schanz screws, refer to the surgical technique Schanz Screws and Steinmann Pins.

#### **Limb positioning**

Surgeons often use suction tubing and clamps to suspend the limb in the rings when applying the frame. Bumps or stands may also be used.

#### **Alternative Technique**

#### Prebuilding a frame

Prebuild the Distraction Osteogenesis Ring System frame and apply it in the operating room. Preoperative planning is required for construction of the appropriate frame. X-rays of 1:1 scale can be helpful when constructing such frames. The frame may also be constructed in the operating room off the patient. Once the frame is constructed, the connection bolts may be loosened on the rings to allow the frame to open up and be placed around the limb. Insert a wire in the tibia near the joint most distal to the affected area, no closer than 20 mm to the joint. Attach the frame to the wire using wire bolts and nuts. Insert a wire near the other joint, using the preconstructed frame as a reference. This wire should be no closer than 20 mm to that joint. Attach this wire to the frame with wire bolts and nuts. Tension both wires. Place additional wires at the proximal ring and distal ring. Insert wires at the middle two rings as described under "Insertion of Remaining Wires" using the rings as references when placing the wires. Tension and tighten all the wires.

# **Implants and Fixation Material**

03.311.010	Clamping Bolt for Schanz Screw	
		46
03.311.011	Clamp, adjustable, for Schanz Screw	
03.311.012	Locking Hinge	
03.311.013	Clamping Bolt for Schanz Screws, for Post	
03.311.020	Universal Hinge	
03.311.031*	Wire Ø 1.5 mm, length 400 mm	· · · · / · · · · · · · · · · · · · · ·
03.311.032	Wire Ø 1.8 mm, length 400 mm	
03.311.033*	Wire Ø 2.0 mm, length 400 mm	
Smooth Wire	25	
03.311.036	Wire $\varnothing$ 1.5 mm with Half Point Tip	/
03.311.037	Wire $\varnothing$ 1.8 mm with Half Point Tip	

03.011.038 Wire  $\emptyset$  2.0 mm with Half Point Tip

03.311.041*	Reduction Wire $\oslash$ 1.5 mm, length 400 mm	
03.311.042	Reduction Wire $\varnothing$ 1.8 mm, length 400 mm	
03.311.043*	Reduction Wire $\varnothing$ 2.0 mm, length 400 mm	
Reduction W	ïres	
03.311.046	Reduction Wire $\varnothing$ 1.5 mm with Half Point Tip	
03.311.047	Reduction Wire $\varnothing$ 1.8 mm with Half Point Tip	
03.011.048	Reduction Wire $\varnothing$ 2.0 mm with Half Point Tip	
03.311.050	Wire Bolt, slotted	
03.311.051	Wire Bolt, Offset	
03.311.055	Connecting Bolt	
03.311.056	Connecting Bolt, long	
03.311.058	Clamping Bolt, cannulated, for Schanz Screws, for Rings	
03.311.059	Clamping Bolt, cannulated, for Schanz Screws, for Post	

\* Also sterile available

03.311.060	Square Nut	3
03.311.061	Nut, hexagonal	
03.311.062	Speed Nut	
03.311.070	Wire Post, short	
03.311.071	Wire Post, long	
03.311.081	Spacing Washer, 1.0 mm	
03.311.082	Spacing Washer, 2.0 mm	
03.311.084	Spacing Washer, 4.0 mm	
03.311.090	Spherical Washer, (Pair)	00
03.311.091	Support, oblique	
03.311.092	Eye Bolt	

#### Threaded Rod, slotted

Art. No.	Length (mm)
03.311.106	60
03.311.108	80
03.311.110	100

 $\circ$ 

#### Threaded Rod

Art. No.	Length (mm)
03.311.112	120
03.311.115	150
03.311.120	200
03.311.125	250
03.311.130	300
03.311.135	350
03.311.140*	400

#### **Connecting Plate**

Art. No.	Holes
03.311.201*	1
03.311.202*	2
03.311.203	3
03.311.204	4
03.311.205*	5

#### Standoff, hexagonal

Art. No.	Length (mm)	
03.311.220*	20	
03.311.230	30	-
03.311.240	40	-
03.311.250*	50	-

\* Also sterile available

03.311.450 Distractor for Angular Correction



03.311.451 Angular Distractor Pivot for AngularCorrection



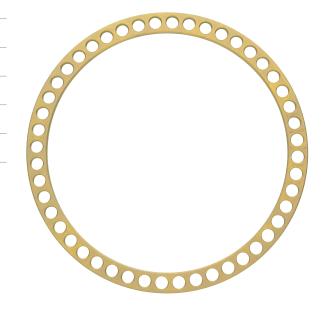
#### Half-Ring, Titanium Alloy

Art. No.	Diameter (mm)
03.311.308	80
03.311.310	100
03.311.311	110
03.311.312	120
03.311.313	130
03.311.314	140
03.311.315	150
03.311.316	160
03.311.318	180
03.311.320	200
03.311.322	220
03.311.324	240



#### Full Ring, Titanium Alloy

Art. No.	Diameter (mm)
03.311.344	140
03.311.346	160
03.311.348	180
03.311.350	200



## 5/8 Ring, Titanium Alloy

Art. No.	Diameter (mm)
03.311.373	130
03.311.375	150
03.311.376	160
03.311.378	180
03.311.380	200

# Femoral Arch Plate, Titanium Alloy

Art. No.	Angle	Diameter (mm)
03.311.391	90°	180
03.311.392	120°	180
03.311.396	90°	240
03.311.397	120°	240

# Linear Distractor

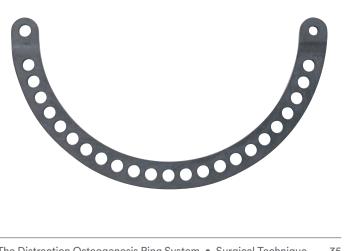
Art. No.	Length (mm)	Distraction width (mm)	
03.311.406	60	25	
03.311.412	120	85	
03.311.418	180	145	
03.311.425	250	215	

## Half-Ring, Carbon Fibre

Art. No.	Diameter (mm)
03.311.810	100
03.311.812	120
03.311.814	140
03.311.816	160
03.311.818	180
03.311.820	200







## 5/8 Ring, Carbon Fibre

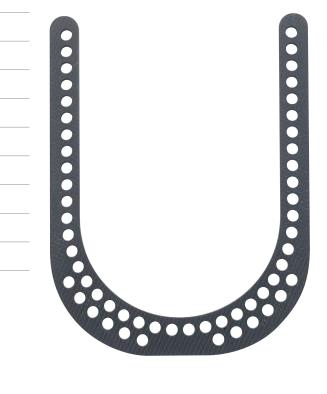
Art. No.	Diameter (mm)	
03.311.874	140	
03.311.876	160	
03.311.878	180	
03.311.880	200	

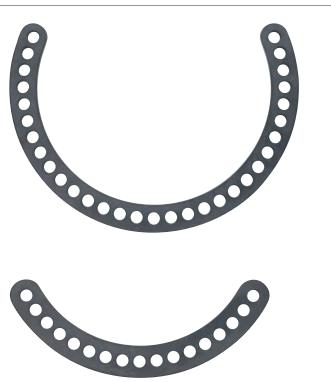
#### Femoral Arch Plate, Carbon Fibre

Art. No.	Angle	Diameter (mm)
03.311.891	90°	180
03.311.892	120°	180
03.311.896	90°	240
03.311.897	120°	240

# Foot Plate, Carbon Fibre

Art. No.	Description	Diameter (mm)
03.311.910	short	100
03.311.914	short	140
03.311.916	short	160
03.311.918	short	180
03.311.940	long	100
03.311.944	long	140
03.311.946	long	160
03.311.948	long	180





Foot	Plate,	Titanium	Alloy
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Art. No.	Description	Diameter (mm)
03.311.960	short	100
03.311.964	short	140
03.311.966	short	160
03.311.968	short	180
03.311.970	short	200
03.311.984	long	140
03.311.986	long	160
03.311.988	long	180



# Instruments

03.311.001	Wire Tightener	
03.311.002	Socket Wrench, slotted	
03.311.004	Ratchet Wrench 11.0 mm	
03.311.005	Protection Sleeve, slotted, Ø 2.5 mm	
03.311.006	Protection Sleeve, slotted, Ø 5.0 mm	
03.311.007	Wrench Ø 8.0/11.0 mm	⇒ TE ∞C
03.311.008	Back-up Wire Tightener	

310.370	Drill Bit Ø 3.5 mm, length 195/170 mm, 2-flute, for Quick Coupling	
391.962	Bending/Cutting Pliers	
393.103	Adapter for Seldrill Schanz Screw Ø 5.0 mm	Ø5.0
393.105	Universal Chuck, small, with T-Handle	
394.182	Trocar Ø 3.5 mm, long	
395.911	Handle for Drill Sleeve	

 395.913
 Drill Sleeve 5.0/3.5, long

 395.923
 Drill Sleeve 6.0/5.0, long, with thread

Ø5.0

#### Also Available

03.311.003	Wrench $\varnothing$ 8.0/11.0 mm, for Patient		-	~
		5	_	00

## **Drive Adaptors with Quick Coupling**

393.101	Schanz Screw $\varnothing$ 4.0 mm	9
393.102	Schanz Screw Ø 4.5 mm	
393.103	Schanz Screw Ø 5.0 mm	
393.104	Schanz Screw Ø 6.0 mm	

#### Hammers

399.410	350 g	
399.420	500 g	
399.430	700 g	
399.500	100 g	

# Set (01.311.000)

#### Vario Case

68.311.000	Vario Case for Distraction Osteogenesis (Implants and Instruments)
68.311.001	Vario Case for Distraction Osteogenesis (standard ring components)
68.311.002	Vario Case for Distraction Osteogenesis (optional ring components)

#### Instruments

Art. No.	Description	Units
03.311.001	Wire Tightener	1
03.311.002	Socket Wrench, slotted	2
03.311.004	Ratchet Wrench 11.0 mm	2
03.311.005	Protection Sleeve, slotted, $\emptyset$ 2.5 mm	n 1
03.311.006	Protection Sleeve, slotted, $\varnothing$ 5.0 mm	n 1
03.311.007	Wrench $\varnothing$ 8.0/11.0 mm	2
03.311.008	Back-up Wire Tightener	1
310.370	Drill Bit Ø 3.5 mm, length 195/170 m 2-flute, for Quick Coupling	m, 1
391.962	Bending/Cutting Pliers	1
393.103	Adapter for Seldrill Schanz Screw Ø 5.0 mm	2
393.105	Universal Chuck, small, with T-Hand	le 1
394.182	Trocar Ø 3.5 mm, long	1
395.911	Handle for Drill Sleeve	1
395.913	Drill Sleeve 5.0/3.5, long	1
395.923	Drill Sleeve 6.0/5.0, long, with threa	d 1

#### Implants and Fixation Material

Art. No.	Description	Units
219.980	Washer $\emptyset$ 7.0/3.6 mm, for Screws $\emptyset$ 2.7 to 4.0 mm, Stainless Steel	1
294.785	Seldrill Schanz Screw ∅ 5.0 mm, length 175/60 mm, Stainless Steel	8
294.786	Seldrill Schanz Screw ∅ 5.0 mm, length 175/60 mm, Stainless Steel	8
03.311.010	Seldrill Schanz Screw Ø 5.0 mm, length 200/80 mm, Stainless Steel Clamping Bolt for Schanz Screw	3
03.311.011	Clamp, adjustable, for Schanz Screv	N 2
03.311.012	Locking Hinge	4
03.311.032	Wire Ø 1.8 mm, length 400 mm	20
03.311.042	Reduction Wire $\varnothing$ 1.8 mm, length 400 mm	20
03.311.050	Wire Bolt, slotted	20
03.311.051	Wire Bolt, Offset	60
03.311.055	Connecting Bolt	40
03.311.060	Square Nut	6
03.311.061.10	Nut, hexagonal, pack of	10
03.311.070	Wire Post, short	4
03.311.071	Wire Post, long	2
03.311.081	Spacing Washer, 1.0 mm	40
03.311.082	Spacing Washer, 2.0 mm	20
03.311.084	Spacing Washer, 4.0 mm	10
03.311.090	Spherical Washer (Pair)	8
03.311.091	Support, oblique	4
03.311.092	Eye Bolt	2

Threaded Rod		
Art. No.	Length (mm)	Units
03.311.106	60, slotted	6
03.311.108	80, slotted	6
03.311.110	100, slotted	6
03.311.112	120	6
03.311.115	150	6
03.311.120	200	6
03.311.125	250	6
03.311.130	300	3
03.311.135	350	3

03.311.203	Connecting Plate, 3 holes		
03.311.204	Connecting Plate, 4 holes		
03.311.230	Standoff, hexagonal, length 30 mm		
03.311.240	Standoff, hexagonal, length 40 mm		
03.311.450	Distractor for Angular Correction		
03.311.451	Angular Distractor Pivot for Angular Correction	2	
393.420	Protective Cap, for Schanz Screws ar Steinmann Pins $\varnothing$ 5.0 mm pack of	nd 10	

#### Note:

For a detailed product information of the Schanz screws, refer to the surgical technique Schanz Screws and Steinmann Pins.

03.311.003

Wire, *half spade tip			
Art. No.	Diameter (mm)	Length (mm)	Description
03.311.031	1.5	400	
03.311.033	2.0	400	
03.311.036	1.5	400	*
03.311.037	1.8	400	*
03.311.038	2.0	400	*

Wrench  $\oslash$  8.0/11.0 mm, for Patient

Half-Ring, Titanium Alloy		
Art. No.	Diameter (mm)	
03.311.308	80	
03.311.310	100	
03.311.311	110	
03.311.312	120	
03.311.313	130	
03.311.314	140	
03.311.315	150	
03.311.316	160	
03.311.318	180	
03.311.320	200	
03.311.322	220	
03.311.324	240	

Reduction Wire, *hal	fs	spade	tip
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Art. No.	Diameter (mm)	Length (mm)	Description
03.311.041	1.5	400	
03.311.043	2.0	400	
03.311.046	1.5	400	*
03.311.047	1.8	400	*
03.311.048	2.0	400	*

03.311.140	Threaded Rod, length 400 mm
03.311.202	Connecting Plate, 2 holes
03.311.205	Connecting Plate, 5 holes
03.311.220	Standoff, hexagonal, length 20 mm
03.311.250	Standoff, hexagonal, length 50 mm

## Full Ring, Titanium Alloy

Art. No.	Diameter (mm)
03.311.344	140
03.311.346	160
03.311.348	180
03.311.350	200

#### Linear Distractor

Art. No.	Length (mm)	Distraction width (mm)
03.311.406	60	25
03.311.412	120	85
03.311.418	180	145
03.311.425	250	215

# 5/8 Ring, Titanium Alloy

Art. No.	Diameter (mm)
03.311.373	130
03.311.375	150
03.311.376	160
03.311.378	180
03.311.380	200

Half-Ring, Carbon Fibre		
Art. No.	Diameter (mm)	
03.311.810	100	
03.311.812	120	
03.311.814	140	
03.311.816	160	
03.311.818	180	
03.311.820	200	

# Femoral Arch Plate, Titanium Alloy

Art. No.	Angle	Diameter (mm)	
03.311.391	90°	180	
03.311.392	120°	180	
03.311.396	90°	240	
03.311.397	120°	240	

#### Full Ring, Carbon Fibre

Art. No.	Diameter (mm)
03.311.844	140
03.311.846	160
03.311.848	180
03.311.850	200

## 5/8 Ring, Carbon Fibre

Art. No.	Diameter (mm)
03.311.874	140
03.311.876	160
03.311.878	180
03.311.880	200

#### Femoral Arch Plate, Carbon Fibre

Art. No.	Angle	Diameter (mm)
03.311.891	90°	180
03.311.892	120°	180
03.311.896	90°	240
03.311.897	120°	240

## Foot Plate, Carbon Fibre

Art. No.	Description	Diameter (mm)
03.311.910	short	100
03.311.914	short	140
03.311.916	short	160
03.311.918	short	180
03.311.940	long	100
03.311.944	long	140
03.311.946	long	160
03.311.948	long	180

## Clamps

390.031	Combination Clamp, medium, clip-on, self-holding
390.035	Clamp, medium, clip-on, self-holding
390.037	Combination Clamp 8.0/11.0, clip-on, self-holding

# Drive Adaptors with Quick Coupling

393.101	Schanz Screw Ø 4.0 mm
393.102	Schanz Screw Ø 4.5 mm
393.104	Schanz Screw Ø 6.0 mm

#### Hammers

399.410	350 g
399.420	500 g
399.430	700 g
399.500	100 g

# Vario Case Additional Components

304.454	Rack for Offset Bolts
304.455	Rack for Slotted Bolts
304.456	Rack for Connection Bolts

Instruments	
391.962	Bending/Cutting Pliers
393.436	Ring-to-Rod Clamp, for Hybrid Ring Fixator
393.464	Wire/Pin-to-Ring Clamp
393.721	Full Ring, internal diameter 205 mm
393.722	Three-quarter Ring, internal diameter 205 mm
393.730	Double Clamp with Angled Piece
393.731	Full Ring, internal diameter 115 mm
393.732	Three-quarter Ring, internal diameter 115 mm
393.734	Three-quarter Ring, internal diameter 140 mm
393.735	Full Ring, internal diameter 165 mm
393.736	Three-quarter Ring, internal diameter 165 mm
393.737	Quarter Ring, internal diameter 165 mm
393.742	Wire Tightener
393.745	Protection Sleeve, slotted, for Wires $\varnothing$ 1.8 to 2.0 mm
393.746	Protection Sleeve, slotted, for Schanz Screws up to $\varnothing$ 5.0 mm

# Cases/Accessories/Non-Devices

676.200	SynCase for Hybrid Ring Fixator, without Contents
676.201	Lower Tray, for Rings, for No. 676.200
676.202	Tray, medium, for Clamps and Wires, for No. 676.200
676.203	Upper Tray, for Instruments, for No. 676.200
676.204	Lid Hybrid Ring Fixator, for No. 676.200
686.200	Vario Case™ for Upgrade Set for Hybrid Ring Fixator, without Lid, without Contents
686.210	Vario Case™ for Hybrid Ring Fixator Set, without Lid, without Contents
107.971	Hybrid Ring Fixator in Sterilization Tray
117.971	Upgrade Set Hybrid Ring Fixator in Sterilization Tray
186.200	Upgrade Set for Hybrid Ring Fixator in Vario Case™
186.210	Hybrid Ring Fixator Set in Vario Case™
308.972	Insert, size 1/1, for No. 300.971

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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