

Intra-articular Distal Tibia Frame

The Distraction Osteogenesis Ring System

Surgical Technique

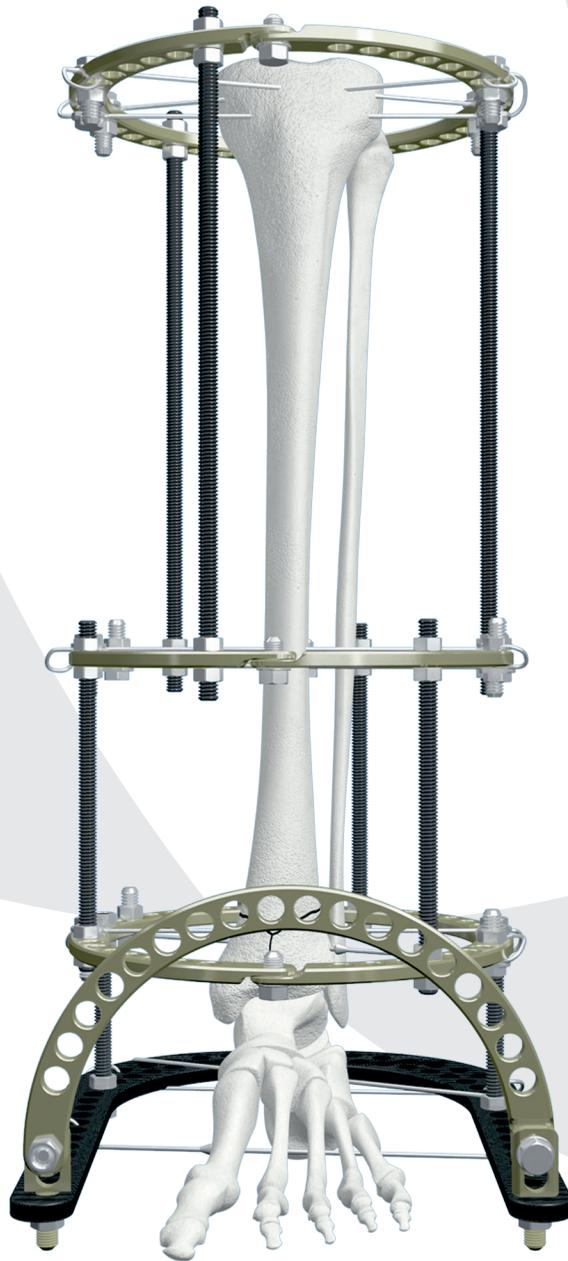


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The Distraction Osteogenesis Ring System

Features

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 modular nature of a ring fixation frame allows multiple frame options. A ring fixation frame can be customized by the surgeon to address the individual characteristics of each case. Ring fixators are most commonly applied to the tibia, but also can be applied to the femur, the humerus, the foot, the hand and the forearm.

Ring fixators offer versatility and viable alternatives for deformity corrections in addition to fracture management. Special components included in the system assist in angular corrections, lengthening and compression. Ring fixation systems allow generation of bone through distraction and/or compression.

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 to address a wide variety of applications.



Additional features

- The Distraction Osteogenesis Ring System is considered MR Conditional
- 8 mm threaded rods allow 3 rods to be used in each ring block, saving time and cost
- Compatible with the DePuy Synthes medium external fixator, allowing use of that system's clamps, for more freedom in Schanz screw placement and versatility in frame design

- The 1.5 mm, 1.8 mm and 2.0 mm smooth and reduction wires are available with a new drill point tip (half-point tip and spade-point wires are also available)
- A wide variety of components are available for compression, distraction, angulation and translation of bone segments
- Lightweight titanium alloy or carbon fiber rings are available



Reduction wire



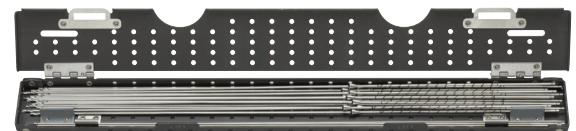
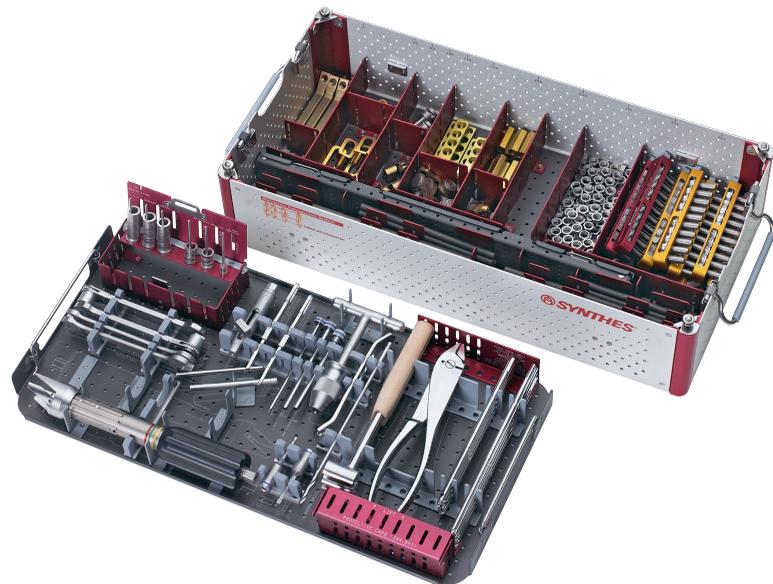
Reduction wire, half point tip



Linear distractor

Graphic cases and removable modules

- Two graphic cases contain all components and instruments required for surgery: a ring case and the implant and instrument graphic case
- The implant and instrument graphic case has adjustable bins and label sheets so only the desired components need to be stored
- Removable modules included in the implant and instrument graphic case hold wires, wire bolts, connection bolts and nuts



MRI Information

DePuy Synthes Distraction Osteogenesis System 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 DePuy Synthes labeling, DePuy Synthes Distraction Osteogenesis Fixation devices are MR Conditional. Representative Synthes Distraction Osteogenesis Fixation devices used in a typical construct include clamps, rods and various attachments. A patient with a DePuy Synthes Distraction Osteogenesis External Fixation frame may be scanned safely after placement of the frame 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 DePuy 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 the distraction osteogenesis 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, DePuy Synthes MR Conditional external fixation devices may have the potential to cause artifact in the diagnostic imaging.

All components of DePuy 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 DePuy Synthes Distraction Osteogenesis Fixation 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 DePuy Synthes Distraction Osteogenesis Fixation frame have been evaluated in the MRI chamber and worst-case artifact information is provided below. Overall, artifacts created by DePuy Synthes Distraction Osteogenesis Fixation 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.
- Do not place the device across the growth plate in pediatric patients.

AO Principles

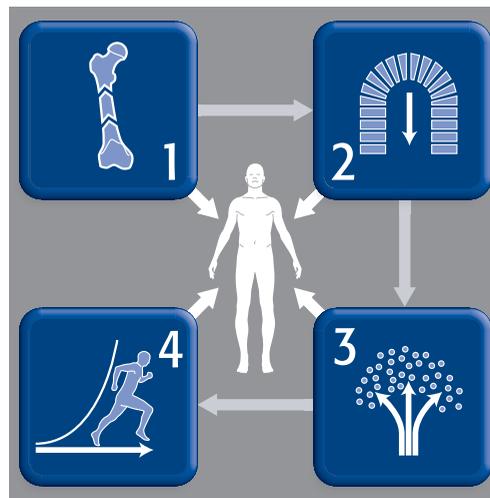
In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.^{1,2}

Anatomic reduction

Fracture reduction and fixation to restore anatomical relationships.

Early, active mobilization

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



Stable fixation

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

Preservation of blood supply

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

1. Müller ME, Allgöwer M, Schneider R, Willenegger H. *Manual of Internal Fixation*. 3rd ed. Berlin, Heidelberg, New York: Springer-Verlag; 1991.
2. Rüedi TP, RE Buckley, CG Moran. *AO Principles of Fracture Management*. 2nd ed. Stuttgart New York: Thieme; 2007.

Indications

The Synthes Distraction Osteogenesis Ring System, MR Conditional is intended to provide treatment for long bone fractures (open and closed) of adult and pediatric patients that require external fixation.

Specifically, the components can be used for:

- Pseudoarthrosis or nonunions of long bones
- Limb lengthening by epiphyseal or metaphyseal distraction
- Correction of bony or soft tissue deformities
- Correction of segmental bony or soft tissue defects



Preparation

Required set

01.311.000 Distraction Osteogenesis System Implant and Instrument Set

Required components and instruments

03.311.308– Titanium Half Rings,
03.311.324 (80 mm–240 mm diameter)

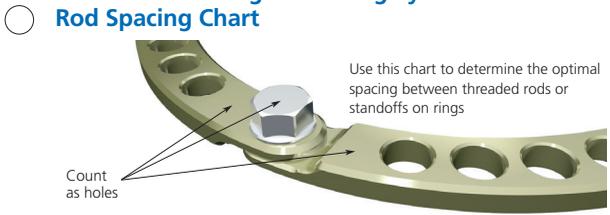
511.791 Quick Coupling, for K-wires

530.100 Power Drive

Threaded rod spacing chart

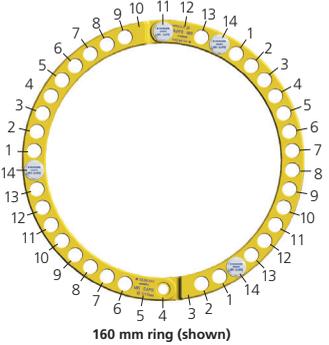
The threaded rod spacing chart is an aid for determining where threaded rods should be placed on the rings for maximum stability, for the different ring sizes. Use the chart during preoperative planning or when constructing a frame to determine optimal spacing of the threaded rods.

Distraction Osteogenesis Ring System Threaded Rod Spacing Chart



Use this chart to determine the optimal spacing between threaded rods or standoffs on rings

Ring Diameter	Place Threaded Rod in Hole #
80 mm	7*
100 mm	9*
110 mm	10
120 mm	10*
130 mm	12
140 mm	12*
150 mm	13*
160 mm	14
180 mm	16
200 mm	17*
220 mm	14*
240 mm	15*



160 mm ring (shown)

*One interval will be longer for these diameters due to the fact that the total number of holes is not divisible by 3 (or 4 for the 220 mm and 240 mm rings)

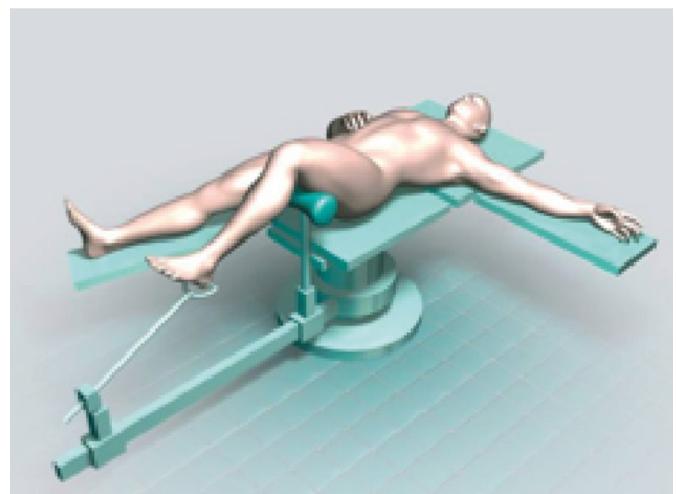
SYNTHES

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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.

Note: 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 page 28 for further information on applying a prebuilt frame.



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 where rings will be applied). Any anticipated swelling of the limb must also be taken into consideration.

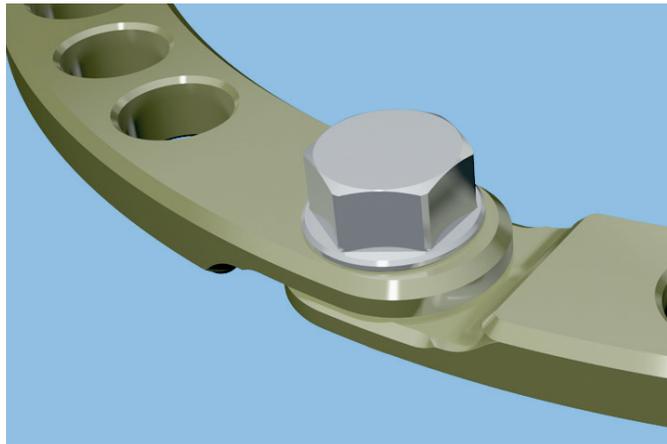
2

Assemble rings

Instrument

03.311.007 8 mm/11 mm Wrench

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 nonthreaded 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 nonthreaded holes into the threaded holes from the marked side of the rings. Tighten the bolts with the wrench.



3

Assemble two more rings

Repeat Steps 1 and 2 two more times so that there is a total of 3 assembled rings of the same diameter.

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 of worn bone cutting instruments in an approved sharps container.
-

Frame Construction

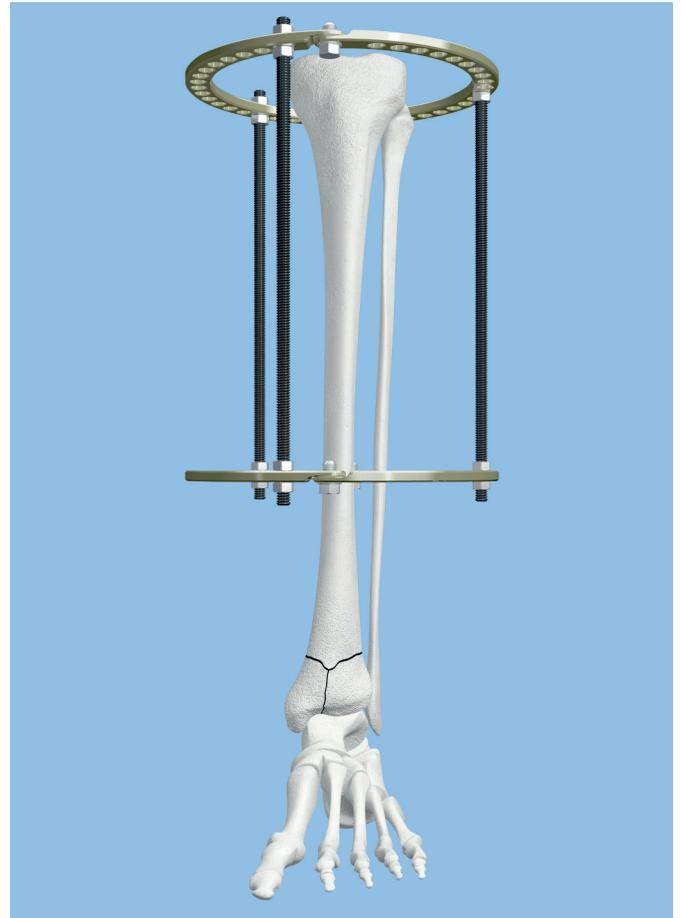
1

Connect proximal rings

Instrument

03.311.007 8 mm/11 mm Wrench

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 mm–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 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. Be sure that the rings remain parallel to each other after they are connected.



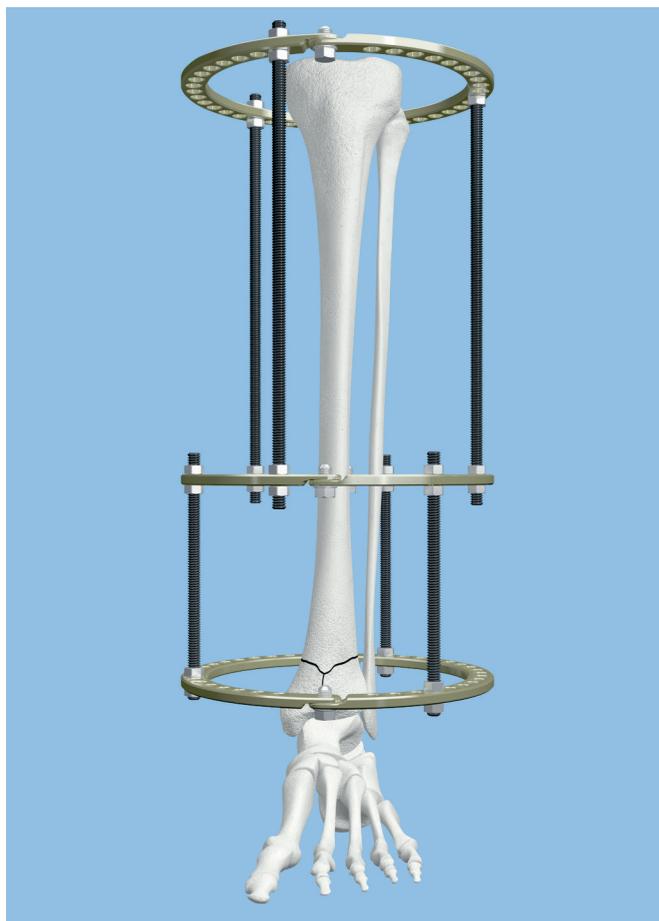
2

Attach third ring to frame

Instrument

03.311.007 8 mm/11 mm Wrench

Position the third assembled ring at the metaphysis of the distal tibia, no closer than 10 mm to the joint, 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, position these threaded rods as equally as possible between the threaded rods from the previous ring (see picture). Be sure that the rings remain parallel to each other after they are connected.



3

Attach foot ring to frame

Instrument

03.311.007 8 mm/11 mm Wrench

Position the foot ring at the foot of the affected limb. Position the foot ring so that wires that will be placed in the calcaneus and metatarsals can be easily attached to it. Use threaded rods and nuts to connect this ring to the previous rings. For maximum stability, place the threaded rods as far apart from each other as possible. Be sure 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.

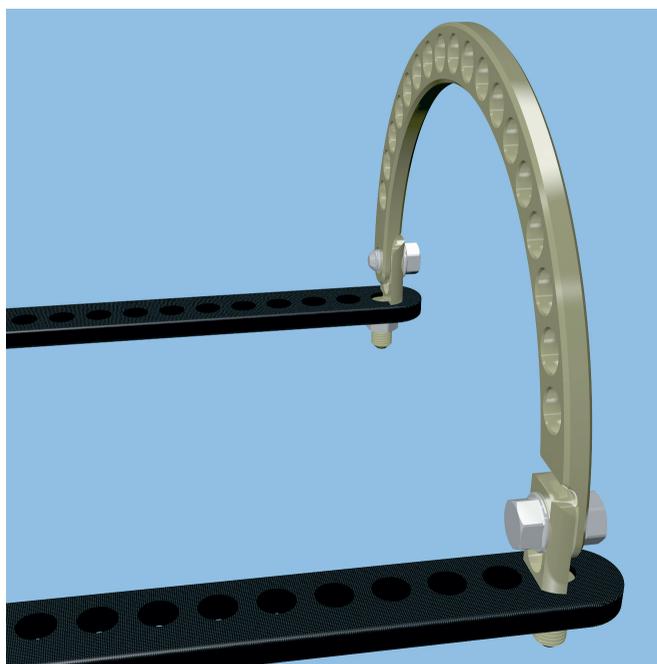


Note: When holes in the rings do not line up properly (such as when different diameter rings are used), spherical washer couples, locking hinges or connecting plates may be used to connect the threaded rods to adjacent rings.



4 Close foot ring

The opening in a foot ring can be closed by attaching a half ring of the same diameter. Two standoffs can be used to place the half ring in the same plane as the foot ring or short wire posts can be used to place the half ring 90° to the foot ring arching over the foot (see picture). Large stature patients may require the connection of the closing half ring to the frame above for stability.



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 or foot. Surgeon preference determines whether smooth wires or reduction wires are used.

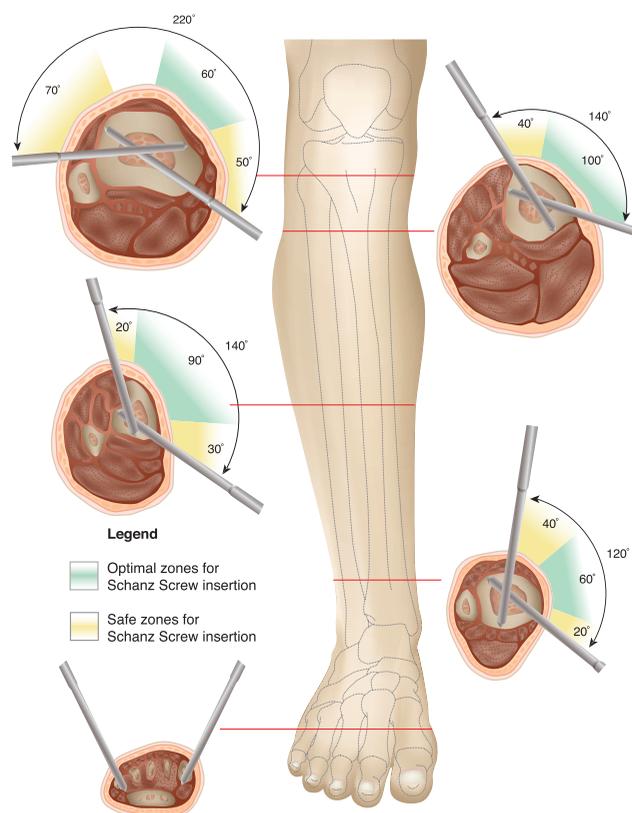
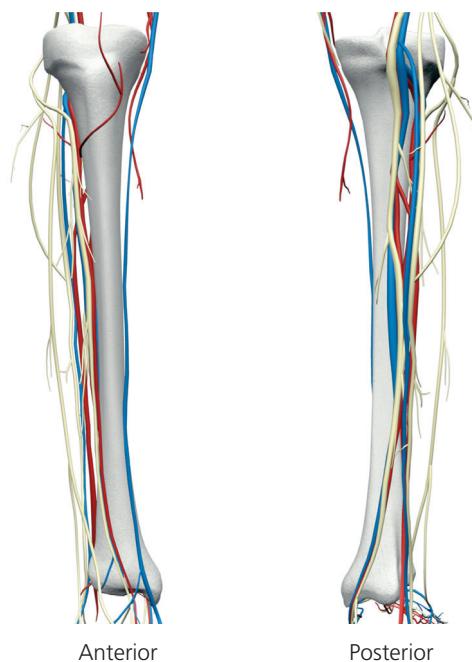
2

Wire insertion

Instruments

391.962	Bending/Cutting Pliers
511.791	Quick Coupling, for K-wires
530.100	Power Drive

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.

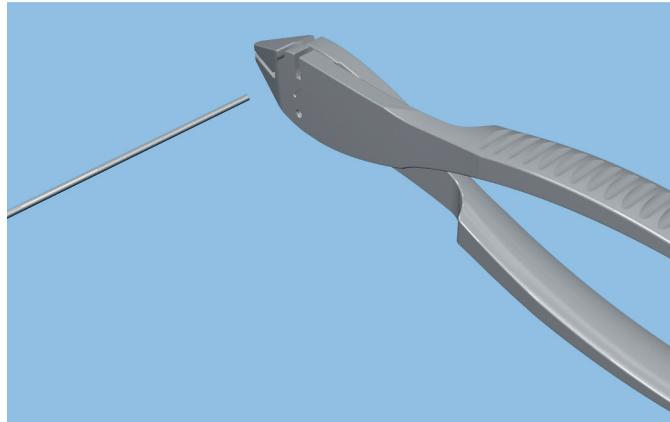


Tibial safe zones ²

2. A. Fernández. "External Fixation." *AO Principles of Fracture Management*. T. Rüedi and W. Murphy, ed. Dübendorf, Switzerland; AO Publishing. 2000. 239. Illustration modified and used with permission.

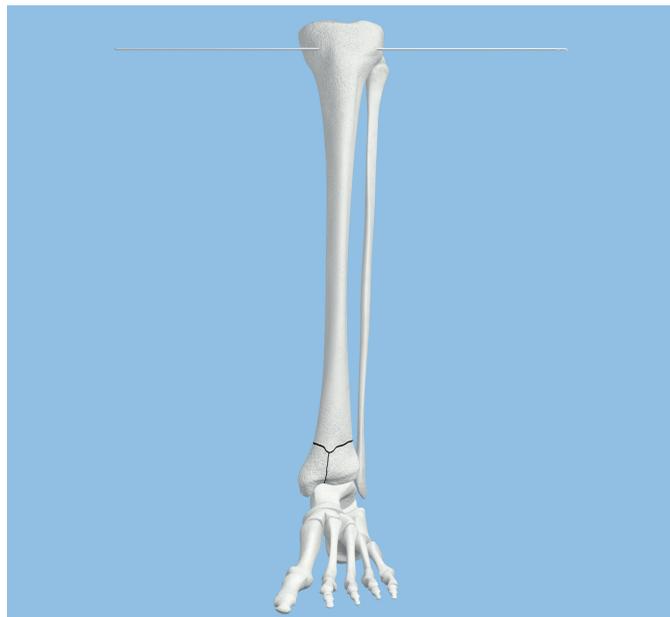
Once the wire protrudes from the far cortex of the bone, tap it through the tissue on the far side. The flat side of the bending/cutting pliers may be used to tap the wire through the tissue. Once the wire is through, cut off the tip to prevent injury.

Insert a smooth wire in the proximal tibia, perpendicular to the long axis of the bone. 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 instruments

03.311.004	Ratchet Wrench, 11 mm
03.311.005	Split Tissue Protection Sleeve, 2.5 mm
399.41– 399.43	Hammers, 350–700 grams
399.50	Hammer, 100 grams



Alternative techniques

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.

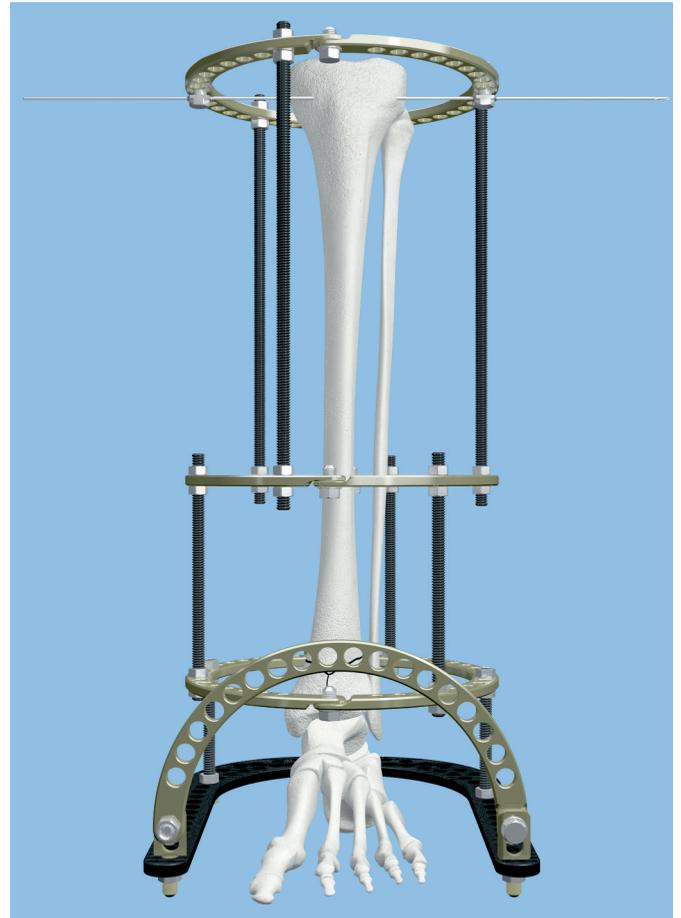
Use the flat side of the ratchet wrench or a hammer to tap the wire through the soft tissue.



3

Position frame on 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 with the rings perpendicular to the long axis of the bone. If the frame is not properly aligned with the bone, reposition the wire.



Wire Fixation

1

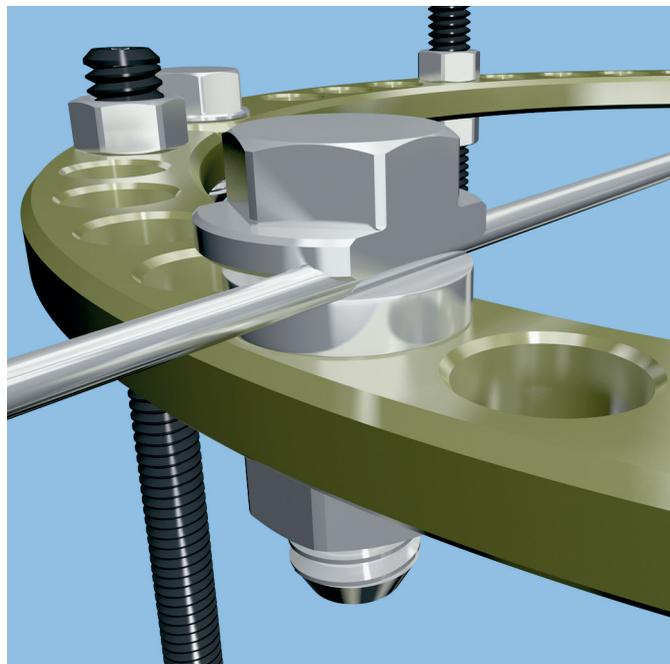
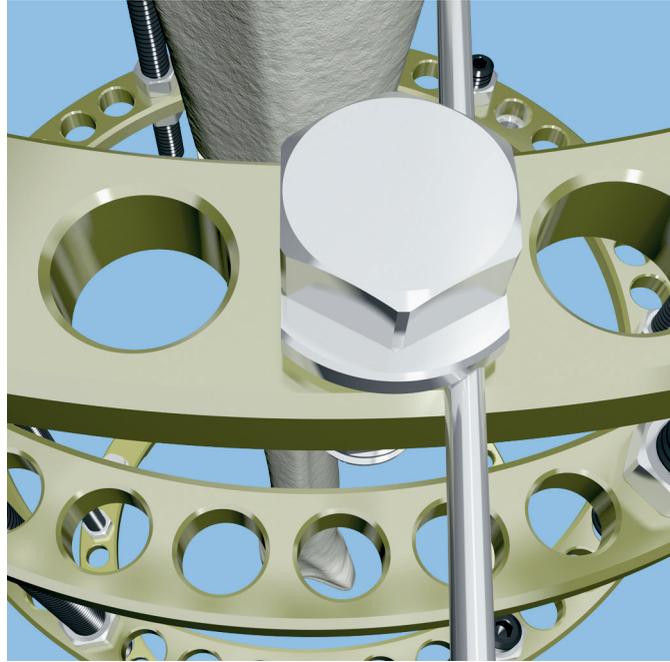
Attach wire to ring

Instrument

03.311.007 8 mm/11 mm Wrench

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 easily repositioned on the wire.



Insertion of Wire in Calcaneus

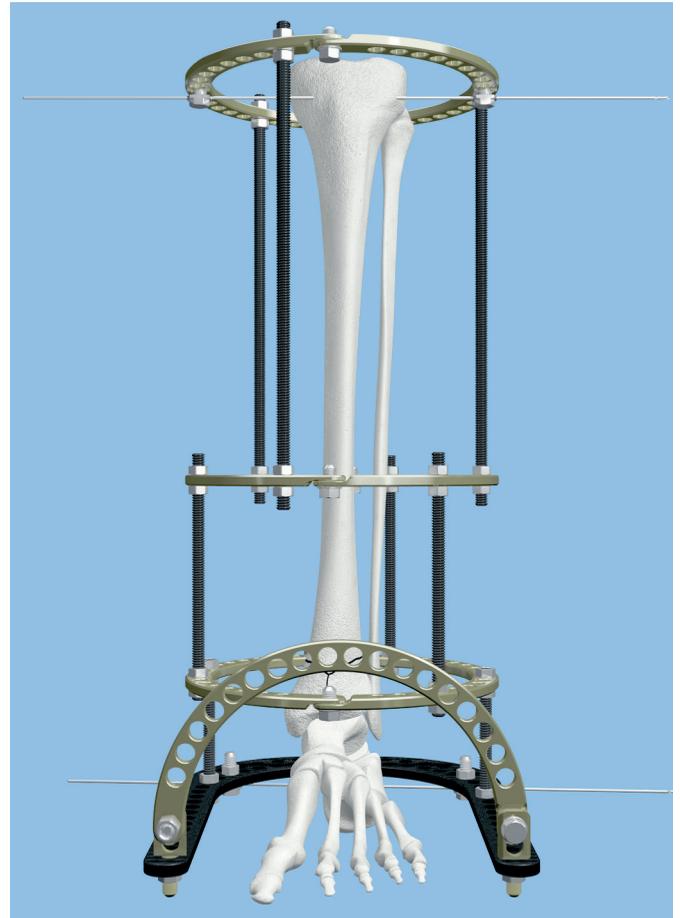
1

Repeat wire insertion in calcaneus

Instruments

03.311.007	8 mm/11 mm Wrench
391.962	Bending/Cutting Pliers
511.791	Quick Coupling, for K-Wires
530.100	Power Drive

Insert a transverse wire in the calcaneus. Confirm that the frame sits with the rings perpendicular to the long axis of the bone. If the frame is not properly aligned with the bone, reposition the wire.



2

Attach wire to foot ring

Use wire bolts and nuts to attach the wire to the ring taking care not to bend the wire. Use wire posts or spacing washers if the wire is positioned off the ring.

Wire Tensioning

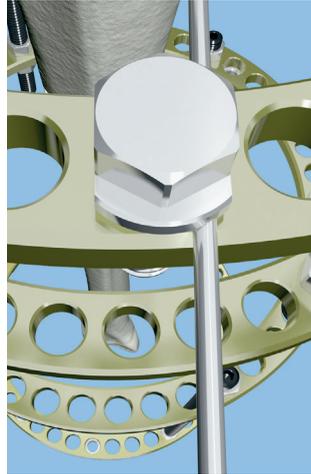
1

Tighten one wire bolt and nut at proximal ring

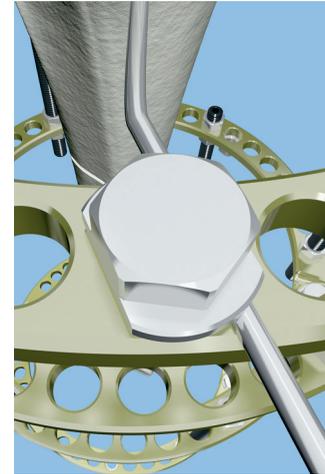
Instrument

03.311.007 8 mm/11 mm Wrench

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 prevent bending the wire.



Correct



Incorrect

2

Position tensioner on wire

Instruments

03.311.001 Tensioner

03.311.220– Standoffs

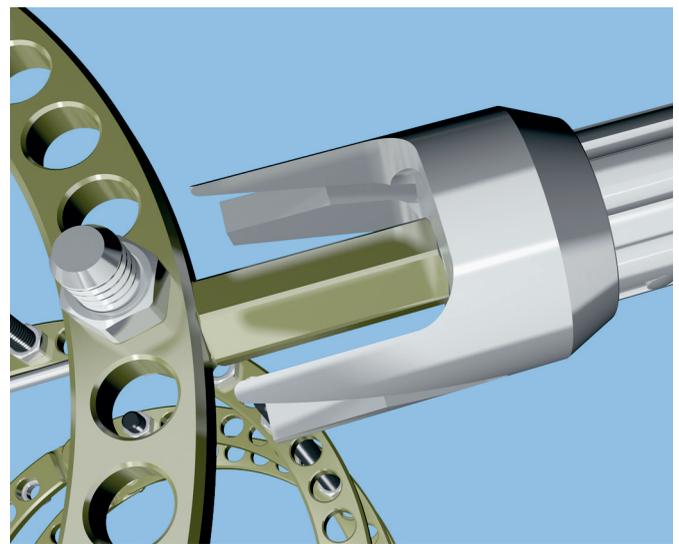
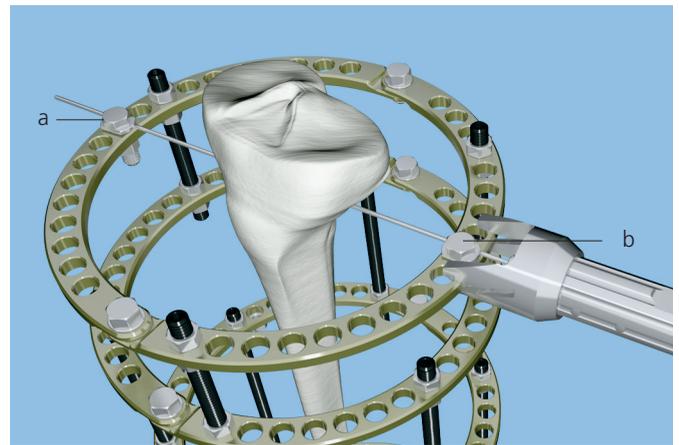
03.311.250

From the tensioning side of the ring, pass the wire into the cannulation of the tensioner. The tensioner 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 tensioner.

Tighten offset bolt (a) opposite the tensioner before tensioning.

Leave offset bolt (b) loose when tensioning. Tighten after the wire is tensioned.

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



3

Apply tension to wire

Instruments

03.311.001 Tensioner

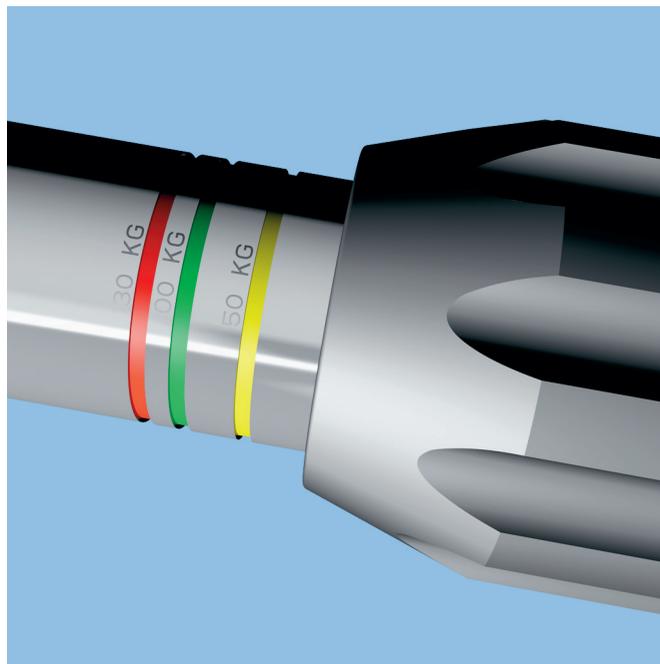
03.311.004 Ratchet Wrench, 11 mm

Turn the tensioner 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 small stature 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 tensioner to make turning the handle quicker.



4

Tighten wire bolt and nut

Instruments

03.311.002 Slotted Socket Wrench, 11 mm

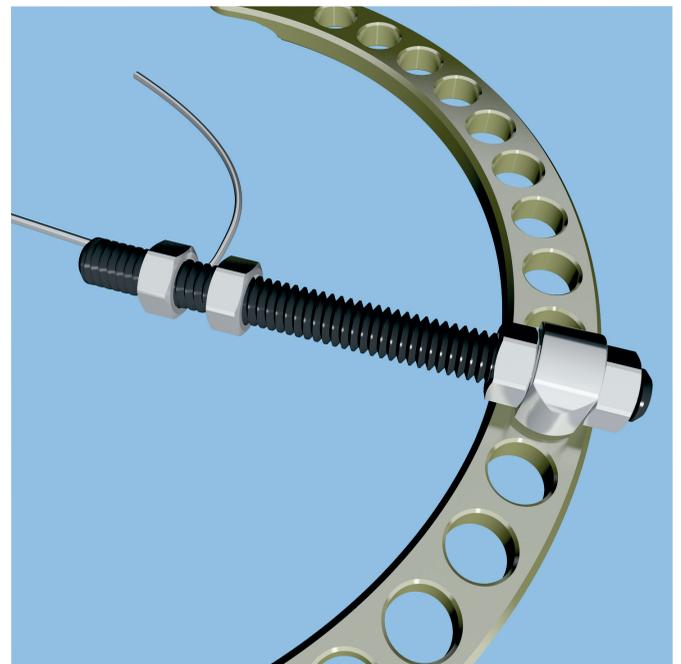
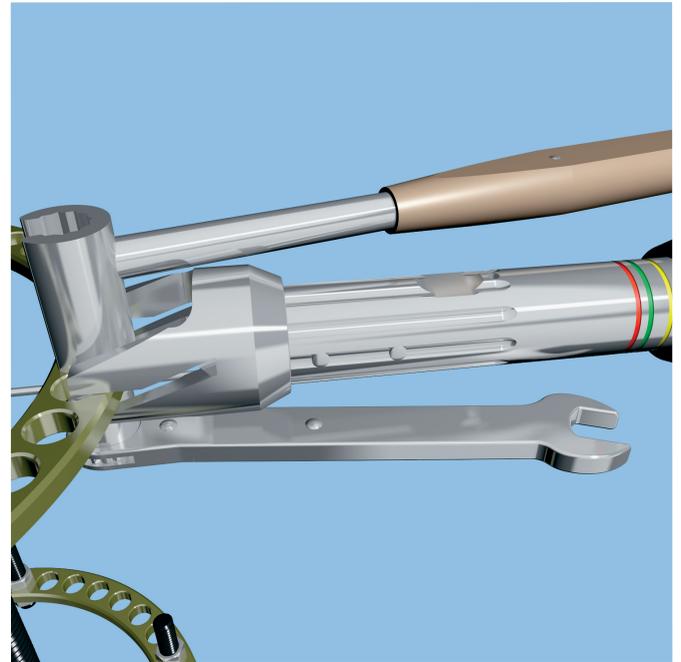
03.311.004 Ratchet Wrench, 11 mm

When the wire is fully tensioned, tighten the wire bolt near the tensioner. A slotted 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 best frame stability, with minimal deformation of the rings. 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 best 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.



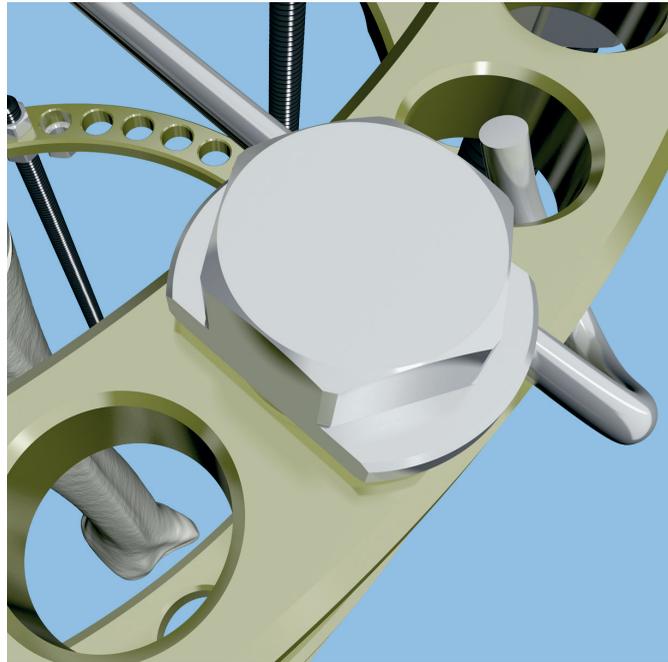
5

Cut ends of wire

Instruments

391.962 Bending/Cutting Pliers

After tensioning, cut the ends of the wire. 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 bending/cutting pliers.



6

Tension wire at foot ring

Tension, tighten and cut the wire at the foot ring, as described on pages 18–22.

Insertion of Additional Wires at First Ring

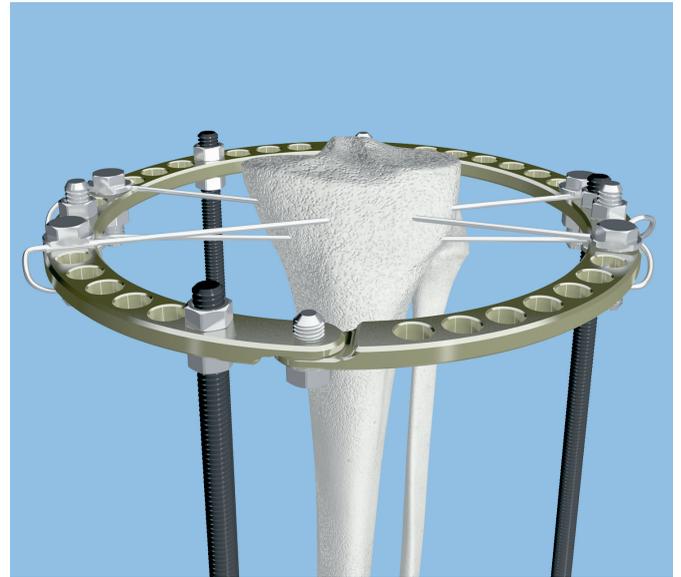
1

Insert two additional wires at first ring

Instruments

391.962	Bending/Cutting Pliers
511.791	Quick Coupling for K-Wires
530.100	Power Drive

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 maximum stability. Counter-opposing reduction (olive) wires can help stabilize this bone segment.



2

Attach wires to ring

Instrument

03.311.007	8 mm/11 mm Wrench
------------	-------------------

Use wire bolts and nuts to attach the wires to the ring taking care not to bend the wires. Use wire posts or spacing washers if a wire is positioned off the ring.

3

Tension wires

Tension, tighten and cut both wires as described on pages 17–21.

Insertion of Additional Wire in Calcaneus

1

Insert second wire in calcaneus

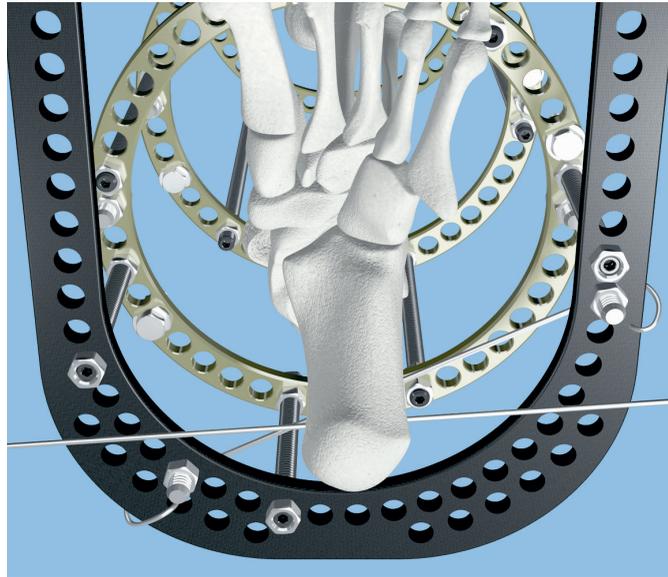
Instruments

391.962 Bending/Cutting Pliers

511.791 Quick Coupling, for K-Wires

530.100 Power Drive

Insert a second wire in the calcaneus. A reduction wire is often used to aid in controlling the position of the foot. 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 maximum stability.



2

Attach wire to foot ring

Instrument

03.311.007 8 mm/11 mm Wrench

Use wire bolts and nuts to attach the wire to the ring taking care not to bend the wire. Use wire posts or spacing washers if a wire is positioned off the ring.

3

Tension wire

Tension, tighten and cut the wire as described on pages 18–22.

Insertion of Wires in Distal Tibia

1

Insert reduction wires to maintain reduction

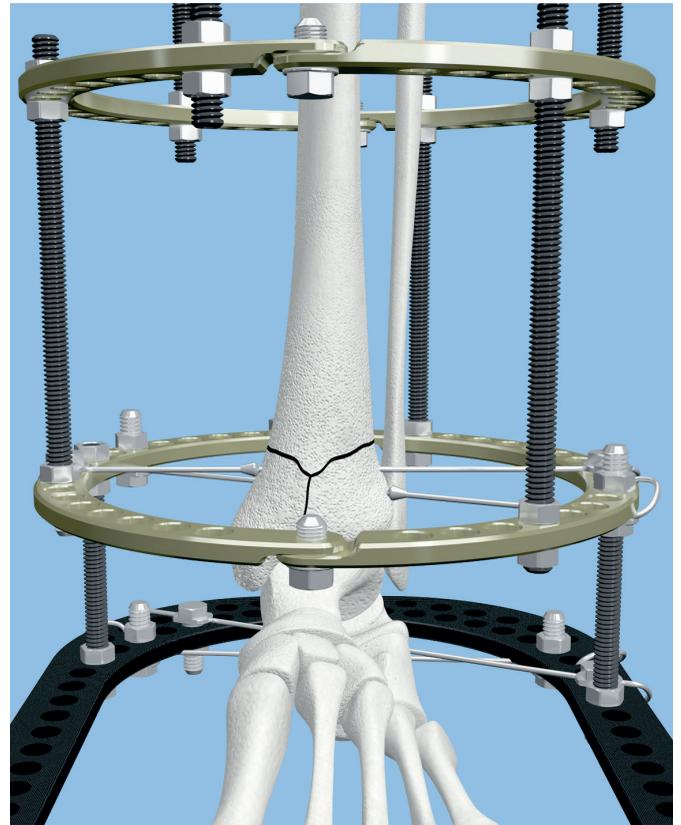
Instruments

391.962	Bending/Cutting Pliers
511.791	Quick Coupling, for K-Wires
530.100	Power Drive

Insert a minimum of 2 wires in the metaphysis of the distal tibia to maintain reduction, no closer than 10 mm to the joint surface. Position the stoppers of the reduction wires on opposite sides of the bone.

Alternative technique

Cannulated screws are sometimes used in conjunction with wires at the distal tibia to help maintain reduction.



2

Attach wires to ring

Instrument

03.311.007	8 mm/11 mm Wrench
------------	-------------------

Use wire bolts and nuts to attach the wires to the ring taking care not to bend the wire. Use wire posts or spacing washers if a wire is positioned off the ring.

3

Tension wires

Tension, tighten and cut the wires as described on pages 18–22.

Insertion of Wires in Diaphysis of Tibia

1

Insert wire in diaphysis of tibia

Instruments

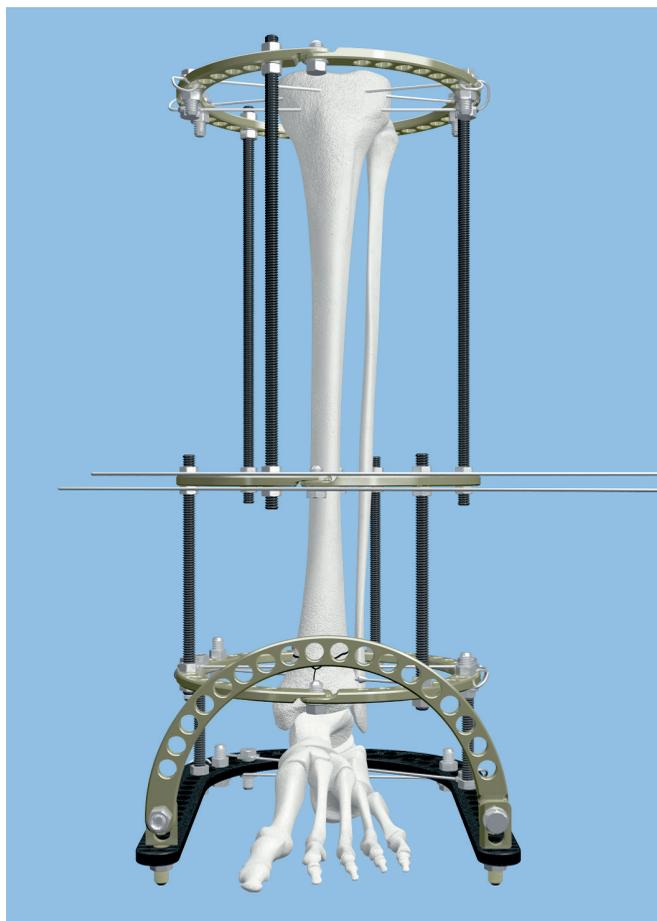
03.311.007 8 mm/11 mm Wrench

391.962 Bending/Cutting Pliers

511.791 Quick Coupling, for K-Wires

530.100 Power Drive

Insert a wire at the ring that is 30 mm–50 mm proximal to the affected area. Attach the wire to the ring as described on page 16.



2

Insert second wire in diaphysis of tibia

Insert a second wire at the ring that is 30 mm–50 mm proximal to the affected area. 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. Attach this wire to the ring as described on page 16.

3

Tension wire

Tension, tighten and cut the wire as described on pages 18–22.

Insertion of Wire in Metatarsals

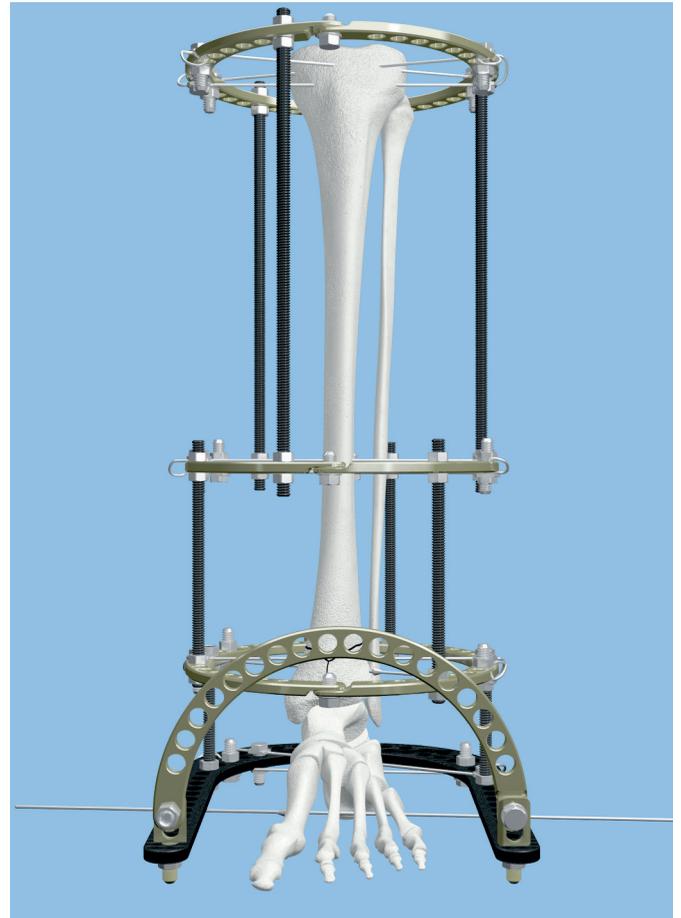
1

Insert wire through metatarsals

Instruments

03.311.007	8 mm/11 mm Wrench
391.962	Bending/Cutting Pliers
511.791	Quick Coupling, for K-Wires
530.100	Power Drive

Insert a wire through the first, second and third metatarsals, tissue condition and anatomy permitting.



2

Attach and tension wire

Attach the wire to the foot ring and tension it as described on pages 18–22.

3

Check wires and connections

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

Notes and Alternative Technique

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 wire and pin-site care procedure should be reviewed with the patient.
- To help minimize the risk of pin-tract infection, the following points should be observed:
 - Placement of Schanz screws taking anatomy into consideration (ligaments, nerves, arteries).
 - Slow insertion and/or cooling, particularly in dense, hard bone to avoid heat necrosis.
 - 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). Hydroxyapatite-coated Schanz screws are also available and may also be used with the system. The Distraction Osteogenesis Ring System contains a variety of clamps and bolts that can be used to attach Schanz screws to the frame. The medium open adjustable clamp (390.035), the medium combination clamp (390.031) and the 8.0 mm/11.0 mm combination clamp (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.

Warnings:

- DePuy Synthes hydroxyapatite (HA)-coated Schanz screws are only available sterile packed. Do not attempt to re-sterilize.
- DePuy Synthes self-drilling, self-tapping, hydroxyapatite-coated Schanz screws are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Precautions:

- Select the appropriate Schanz screw (self-tapping, self-drilling, hydroxyapatite) or Steinmann pin for the patient's bony anatomy.
- The self-drilling Schanz screw has been developed to minimize heat development. Nevertheless, slow insertion and additional cooling (for example with a Ringer solution) are recommended.
- The tip of the self-drilling Schanz screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability.
- Only when bones are osteoporotic does the self-drilling 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.
- The tip of the self-tapping Schanz screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability.

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. Insert a wire in the proximal tibia, no closer than 20 mm to the joint. Attach the frame to the wire using wire bolts and nuts. Insert a transverse wire through the calcaneus at the foot ring. Attach this wire to the frame with wire bolts and nuts. Tension, tighten and cut both wires as described on pages 18–22. Insert additional wires at the proximal ring and foot ring as described on pages 23–24. Insert reduction wires at the metaphysis of the tibia as described on page 25 and insert wires in the diaphysis as described on page 26. Insert a wire through the metatarsals as described on page 27. Check all wires for tension and all connections for tightness.

Implants and Fixation Material, MR Conditional

219.98 Washer, 7.0 mm



5.0 mm Self-Drilling Schanz Screws

294.785 175 mm

294.786 200 mm



03.311.010 Schanz Screw Bolt

03.311.015* Schanz Screw Bolt, 2 piece



03.311.011 Pivot Schanz Screw Clamp



03.311.012 Locking Hinge



Smooth Wires

03.311.031* 1.5 mm diameter, 400 mm long

03.311.032 1.8 mm diameter, 400 mm long

03.311.033* 2.0 mm diameter, 400 mm long



Reduction Wires

03.311.041* 1.5 mm diameter, 400 mm long

03.311.042 1.8 mm diameter, 400 mm long

03.311.043* 2.0 mm diameter, 400 mm long



*Also available

	Wire Bolts	
03.311.050	Slotted	
03.311.051	Offset	
03.311.054	Offset, short	
03.311.055	Connection Bolt	
03.311.060	Square Nut	
03.311.061	Nut	
	Wire Posts	
03.311.070	Short	
03.311.071	Tall	
03.311.171*	1 hole	
03.311.172*	2 hole	
03.311.173*	3 hole	
03.311.174*	4 hole	
03.311.175*	5 hole	
	Spacing Washers	
03.311.081	1 mm	
03.311.082	2 mm	
03.311.084	4 mm	
03.311.090	Spherical Washer Couple	

*Also available

03.311.091 Oblique Support



03.311.092 Eye Bolt



Threaded Rods

03.311.106 60 mm long, slotted
03.311.108 80 mm long, slotted
03.311.110 100 mm long, slotted
03.311.112 120 mm long
03.311.115 150 mm long
03.311.120 200 mm long
03.311.125 250 mm long
03.311.130 300 mm long
03.311.135 350 mm long
03.311.140* 400 mm long



Connecting Plates, 90° offset*

03.311.022 2 hole
03.311.023 3 hole
03.311.024 4 hole
03.311.025 5 hole

Connecting Plates

03.311.201* 1 hole
03.311.202* 2 holes
03.311.203 3 holes
03.311.204 4 holes
03.311.205* 5 holes



Connecting Plates, threaded*

03.311.212 2 hole
03.311.213 3 hole
03.311.214 4 hole
03.311.215 5 hole

*Also available

	Standoffs	
03.311.220*	20 mm	
03.311.230	30 mm	
03.311.240	40 mm	
03.311.250*	50 mm	
03.311.450	Angular Distractor	
03.311.451	Angular Distractor Pivot	
394.993	Protective Caps, for 5.0 mm Fixation Pins	
Also Available		
03.311.013	Schanz Screw Bolt, post mount	
03.311.020	Universal Hinge	
	Smooth Wires	
03.311.036	1.5 mm diameter, half point tip	
03.311.037	1.8 mm diameter, half point tip	
03.311.038	2.0 mm diameter, half point tip	
	Reduction Wires	
03.311.046	1.5 mm diameter, half point tip	
03.311.047	1.8 mm diameter, half point tip	
03.311.048	2.0 mm diameter, half point tip	

03.311.056 Connection Bolt, long



03.311.058 Schanz Screw Bolt, Cannulated Ring Mount



03.311.059 Schanz Screw Bolt, Cannulated Post Mount



03.311.062 Speed Nut



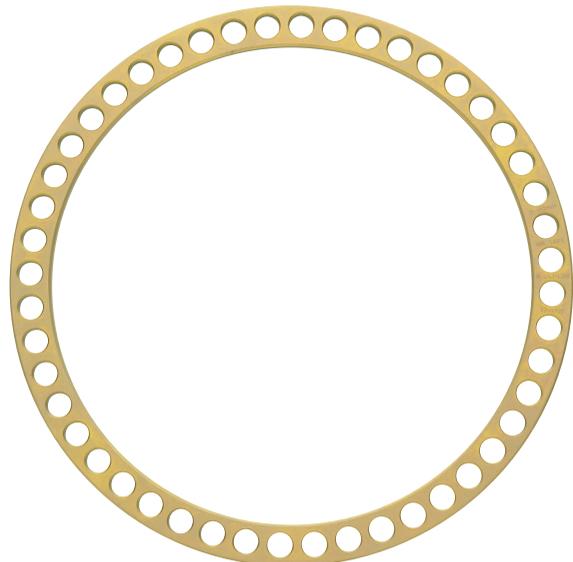
Titanium Half Rings

- 03.311.308 80 mm diameter
- 03.311.310 100 mm diameter
- 03.311.311 110 mm diameter
- 03.311.312 120 mm diameter
- 03.311.313 130 mm diameter
- 03.311.314 140 mm diameter
- 03.311.315 150 mm diameter
- 03.311.316 160 mm diameter
- 03.311.318 180 mm diameter
- 03.311.320 200 mm diameter
- 03.311.322 220 mm diameter
- 03.311.324 240 mm diameter



Titanium Full Rings

- 03.311.344 140 mm diameter
- 03.311.346 160 mm diameter
- 03.311.348 180 mm diameter
- 03.311.350 200 mm diameter



-
- Titanium 5/8 Rings
- 03.311.373 130 mm diameter
 - 03.311.375 150 mm diameter
 - 03.311.376 160 mm diameter
 - 03.311.378 180 mm diameter
 - 03.311.380 200 mm diameter



-
- Titanium Femoral Arch Plate
- 03.311.391 180 mm diameter, 90°
 - 03.311.392 180 mm diameter, 120°
 - 03.311.396 240 mm diameter, 90°
 - 03.311.397 240 mm diameter, 120°



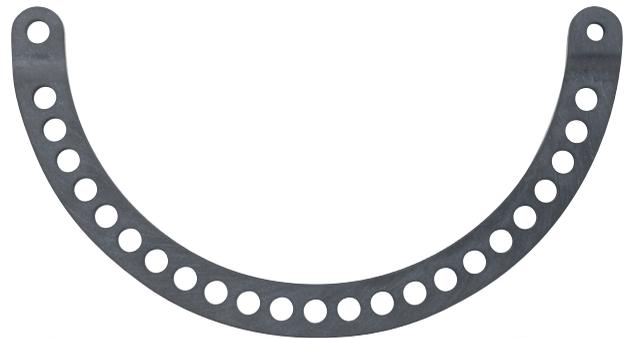
-
- Titanium Foot Rings
- 03.311.960 100 mm, short
 - 03.311.964 140 mm, short
 - 03.311.966 160 mm, short
 - 03.311.968 180 mm, short
 - 03.311.970 200 mm, short
 - 03.311.980 100 mm, long
 - 03.311.984 140 mm, long
 - 03.311.986 160 mm, long
 - 03.311.988 180 mm, long
 - 03.311.990 200 mm, long



-
- Linear Distractors
- 03.311.406 60 mm long, 25 mm travel
 - 03.311.412 120 mm long, 85 mm travel
 - 03.311.418 180 mm long, 145 mm travel
 - 03.311.425 250 mm long, 215 mm travel



Carbon Fiber Half Rings	
03.311.810	100 mm diameter
03.311.812	120 mm diameter
03.311.814	140 mm diameter
03.311.816	160 mm diameter
03.311.818	180 mm diameter
03.311.820	200 mm diameter



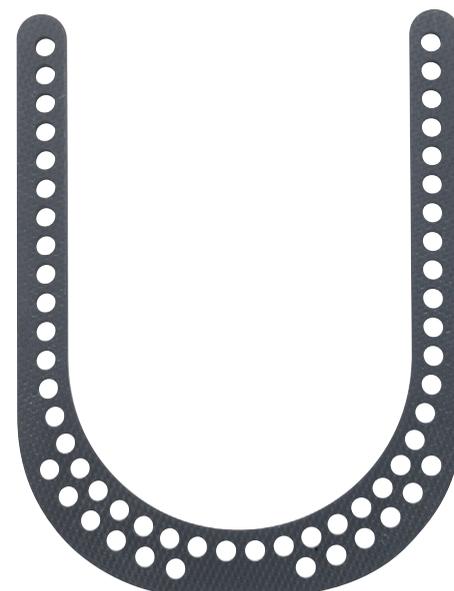
Carbon Fiber 5/8 Rings	
03.311.874	140 mm diameter
03.311.876	160 mm diameter
03.311.878	180 mm diameter
03.311.880	200 mm diameter



Carbon Fiber Femoral Arch Plates	
03.311.891	180 mm diameter, 90°
03.311.892	180 mm diameter, 120°
03.311.896	240 mm diameter, 90°
03.311.897	240 mm diameter, 120°



Carbon Fiber Foot Rings	
03.311.910	100 mm diameter, short
03.311.914	140 mm diameter, short
03.311.916	160 mm diameter, short
03.311.918	180 mm diameter, short
03.311.940	100 mm diameter, long
03.311.944	140 mm diameter, long
03.311.946	160 mm diameter, long
03.311.948	180 mm diameter, long



DO Instruments, MR Unsafe*

03.311.001 Tensioner



03.311.002 Slotted Socket Wrench, 11 mm



03.311.004 Ratchet Wrench, 11 mm



03.311.005 Split Tissue Protection Sleeve, 2.5 mm



03.311.006 Split Tissue Protection Sleeve, 5 mm



03.311.007 8 mm/11 mm Wrench



03.311.008 Backup Tensioner



*MR Unsafe: An item that is known to pose hazards in all MR environments, per ASTM F2503-08 definition.

03.311.003* Patient Wrench, 8 mm/11 mm



General Instruments

310.37 3.5 mm Drill Bit, quick coupling, 195 mm



391.962 Bending/Cutting Pliers



393.103 Drive Adaptor with quick coupling, for 5.0 mm Schanz screws



393.105 Small Universal Chuck with T-Handle



394.182 3.5 mm Trocar, 118 mm (long)



395.911 Drill Sleeve Handle



*Also available

395.913 5.0 mm/3.5 mm Drill Sleeve, 107 mm (long) 

395.923 6.0 mm/5.0 mm Threaded Drill Sleeve, 98 mm (long) 

Also Available

393.101 Drive Adaptors with quick coupling
For 4.0 mm Schanz screws

393.102 For 4.5 mm Schanz screws

393.104 For 6.0 mm Schanz screws



Hammers

399.41 350 grams

399.42 500 grams

399.43 700 grams

399.50 100 grams



The Distraction Osteogenesis Ring System Implant and Instrument Set (01.311.000)

Graphic Case

- 690.454 Distraction Osteogenesis System Implants and Instruments Graphic Case
- 690.822 Label Sheet, for Distraction Osteogenesis Components
- 690.829 Label Sheet, for Distraction Osteogenesis Threaded Rods

Instruments

- 03.311.001 Tensioner
- 03.311.002 Slotted Socket Wrench, 11 mm, 2 ea.
- 03.311.004 Ratchet Wrench, 11 mm, 2 ea.
- 03.311.005 Split Tissue Protection Sleeve, 2.5 mm
- 03.311.006 Split Tissue Protection Sleeve, 5 mm
- 03.311.007 8 mm/11 mm Wrench, 2 ea.
- 03.311.008 Backup Tensioner
- 310.37 3.5 mm Drill Bit, quick coupling, 195 mm
- 391.962 Bending/Cutting Pliers
- 393.103 Drive Adaptor with quick coupling, for 5.0 mm Schanz Screws, 2 ea.
- 393.105 Small Universal Chuck with T-handle
- 394.182 3.5 mm Trocar, 118 mm (long)
- 395.911 Drill Sleeve Handle
- 395.913 5.0 mm/3.5 mm Drill Sleeve, 107 mm (long)
- 395.923 6.0 mm/5.0 mm Threaded Drill Sleeve, 98 mm (long)

Implants and Fixation Material

- 219.98 Washer, 7.0 mm, 12 ea.
- 294.785 5.0 mm Self-Drilling, 175 mm, 8 ea.
- 294.786 5.0 mm Self-Drilling, 200 mm, 8 ea.
- 03.311.010 Schanz Screw Bolt, 3 ea.
- 03.311.011 Pivot Schanz Screw Clamp, 2 ea.
- 03.311.012 Locking Hinge, 4 ea.
- 03.311.032 Smooth Wire, 1.8 mm diameter, 400 mm long, 20 ea.
- 03.311.042 Reduction Wire, 1.8 mm diameter, 400 mm long, 20 ea.



Note: For additional information, please refer to the package insert or www.e-ifu.com.

For detailed cleaning and sterilization instructions, please refer to www.depuy-synthes.com/hcp/cleaning-sterilization or sterilization instructions, if provided in the instructions for use.

Implants and Fixation Material

03.311.050	Wire Bolt, slotted, 20 ea.
03.311.051	Wire Bolt, offset, 60 ea.
03.311.055	Connection Bolt, 40 ea.
03.311.060	Square Nut, 6 ea.
03.311.061.10	Nut, 12 pkgs. of 10
03.311.070	Wire Post, short, 4 ea.
03.311.071	Wire Post, tall, 2 ea.
03.311.081	Spacing Washer, 1 mm, 40 ea.
03.311.082	Spacing Washer, 2 mm, 20 ea.
03.311.084	Spacing Washer, 4 mm, 10 ea.
03.311.090	Spherical Washer Couple, 8 ea.
03.311.091	Oblique Support, 4 ea.
03.311.092	Eye Bolt, 2 ea.
	Threaded Rods
03.311.106	60 mm length, slotted, 6 ea.
03.311.108	80 mm length, slotted, 6 ea.
03.311.110	100 mm length, slotted, 6 ea.
03.311.112	120 mm length, 6 ea.
03.311.115	150 mm length, 6 ea.
03.311.120	200 mm length, 6 ea.
03.311.125	250 mm length, 6 ea.
03.311.130	300 mm length, 3 ea.
03.311.135	350 mm length, 3 ea.
03.311.203	Connecting Plate, 3 holes, 3 ea.
03.311.204	Connecting Plate, 4 holes, 3 ea.
03.311.230	Standoff, 30 mm, 6 ea.
03.311.240	Standoff, 40 mm, 6 ea.
03.311.450	Angular Distractor, 2 ea.
03.311.451	Angular Distractor Pivot, 2 ea.
394.993	Protective Caps, for 5.0 mm Fixation Pins, 1 pkg. of 10

Also Available

Instruments		03.311.062	Speed Nut
03.311.003	Patient Wrench, 8 mm/11 mm	03.311.140	Threaded Rod, 400 mm long
	Drive Adaptors with quick coupling		Wire Posts
393.101	For 4.0 mm Schanz screws	03.311.171	1 hole
393.102	For 4.5 mm Schanz screws	03.311.172	2 hole
393.104	For 6.0 mm Schanz screws	03.311.173	3 hole
	Hammers	03.311.174	4 hole
399.41	350 grams	03.311.175	5 hole
399.42	500 grams		Connecting Plates, for Carbon Fiber Rings
399.43	700 grams	03.311.200	1 hole
399.50	100 grams	03.311.201	1 hole
511.791	Quick Coupling, for K-wires	03.311.202	2 holes
530.100	Power Drive	03.311.205	5 holes
			Connecting Plates, threaded
		03.311.212	2 hole
03.311.013	Schanz Screw Bolt, post mount	03.311.213	3 hole
03.311.015	Schanz Screw Bolt, 2 piece	03.311.214	4 hole
03.311.020	Universal Hinge	03.311.215	5 hole
	Connecting Plates, 90° offset	03.311.220	Standoff, 20 mm
03.311.022	2 hole	03.311.250	Standoff, 50 mm
03.311.023	3 hole		Titanium Half Rings
03.311.024	4 hole	03.311.308	80 mm diameter
03.311.025	5 hole	03.311.310	100 mm diameter
	Smooth Wires	03.311.311	110 mm diameter
03.311.031	1.5 mm diameter, 400 mm length	03.311.312	120 mm diameter
03.311.033	2.0 mm diameter, 400 mm length	03.311.313	130 mm diameter
03.311.036	1.5 mm diameter, half point tip	03.311.314	140 mm diameter
03.311.037	1.8 mm diameter, half point tip	03.311.315	150 mm diameter
03.311.038	2.0 mm diameter, half point tip	03.311.316	160 mm diameter
	Reduction Wires	03.311.318	180 mm diameter
03.311.041	1.5 mm diameter, 400 mm length	03.311.320	200 mm diameter
03.311.043	2.0 mm diameter, 400 mm length	03.311.322	220 mm diameter
03.311.046	1.5 mm diameter, half point tip	03.311.324	240 mm diameter
03.311.047	1.8 mm diameter, half point tip		Titanium Full Rings
03.311.048	2.0 mm diameter, half point tip	03.311.344	140 mm diameter
03.311.054	Wire Bolt, offset, short	03.311.346	160 mm diameter
03.311.056	Connection Bolt, long	03.311.348	180 mm diameter
03.311.058	Schanz Screw Bolt, Cannulated Ring Mount	03.311.350	200 mm diameter
03.311.059	Schanz Screw Bolt, Cannulated Post Mount		

	Titanium 5/8 Rings		Carbon Fiber Foot Rings
03.311.373	130 mm diameter	03.311.910	100 mm diameter, short
03.311.375	150 mm diameter	03.311.914	140 mm diameter, short
03.311.376	160 mm diameter	03.311.916	160 mm diameter, short
03.311.378	180 mm diameter	03.311.918	180 mm diameter, short
03.311.380	200 mm diameter	03.311.940	100 mm diameter, long
	Titanium Femoral Arch Plates	03.311.944	140 mm diameter, long
03.311.391	180 mm diameter, 90°	03.311.946	160 mm diameter, long
03.311.392	180 mm diameter, 120°	03.311.948	180 mm diameter, long
03.311.396	240 mm diameter, 90°		Titanium Foot Rings
03.311.397	240 mm diameter, 120°	03.311.960	100 mm, short
	Linear Distractors	03.311.964	140 mm, short
03.311.406	60 mm long, 25 mm travel	03.311.966	160 mm, short
03.311.412	120 mm long, 85 mm travel	03.311.968	180 mm, short
03.311.418	180 mm long, 145 mm travel	03.311.970	200 mm, short
03.311.425	250 mm long, 215 mm travel	03.311.980	100 mm, long
	Carbon Fiber Half Rings	03.311.984	140 mm, long
03.311.810	100 mm diameter	03.311.986	160 mm, long
03.311.812	120 mm diameter	03.311.988	180 mm, long
03.311.814	140 mm diameter	03.311.990	200 mm, long
03.311.816	160 mm diameter		Clamps
03.311.818	180 mm diameter	390.031	Medium Combination Clamp
03.311.820	200 mm diameter	390.035	Medium Open Adjustable Clamp
	Carbon Fiber Full Rings	390.037	8.0 mm/11.0 mm Combination Clamp
03.311.844	140 mm diameter		
03.311.846	160 mm diameter		
03.311.848	180 mm diameter		
03.311.850	200 mm diameter		
	Carbon Fiber 5/8 Rings		
03.311.874	140 mm diameter		
03.311.876	160 mm diameter		
03.311.878	180 mm diameter		
03.311.880	200 mm diameter		
	Carbon Fiber Femoral Arch Plates		
03.311.891	180 mm diameter, 90°		
03.311.892	180 mm diameter, 120°		
03.311.896	240 mm diameter, 90°		
03.311.897	240 mm diameter, 120°		

Graphic Case Replacement Parts

304.454	Offset Bolt Rack
304.455	Slotted Bolt Rack
304.456	Connection Bolt Rack
304.457	Wire Box
304.458	Stopper for Bolt Racks
304.459	Long Connection Bolt Rack
690.455	Ring Rack for Distraction Osteogenesis System Ring Case
690.458	Ring Rack for Graphic Case, for Distraction Osteogenesis Carbon Fiber Rings
690.821	Label Sheet, for Distraction Osteogenesis Rings
690.822	Label Sheet, for Distraction Osteogenesis Components
690.829	Label Sheet, for Distraction Osteogenesis Threaded Rods

Graphic Cases for Distraction Osteogenesis Rings

690.452	Full Case
690.453	Half Case
690.456	Stacked Case
690.457	For Carbon Fiber Rings

Limited Warranty and Disclaimer: DePuy Synthes products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

Please also refer to the package insert(s) or other labeling associated with the devices identified in this surgical technique for additional information.

CAUTION: Federal Law restricts these devices to sale by or on the order of a physician.

Some devices listed in this technique guide may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.

Not all products may currently be available in all markets.



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To order (USA): 800-523-0322

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Note: For recognized manufacturer, refer to the product label.

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