MAXFRAME™

Multi-Axial Correction System

Computer Assisted Circular Ring Fixation System for the Treatment of Limb Deformity Correction

Surgical Technique

DePuy Synthes

PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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MAXFRAME™ Multi-Axial Correction System

The MAXFRAME™ Multi-Axial Correction System is a computer-assisted circular ring fixation system. The circular 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 struts to create a frame.

The nature of a circular ring fixation system allows surgical flexibility in creating treatment options. A circular ring fixation frame can be customized by the surgeon to address the individual characteristics of each case.

The MAXFRAME System offers alternatives for fracture management and deformity correction.

The main components of the system are transfixion wires (smooth and reduction or "olive"), Schanz screws (Standard and Variable Thread Length), rings, plates (full rings, 5/8 rings, and foot plates), and struts (Quick Adjust, Standard, Linear, and Polyaxial). Other available components include wire posts, spacing washers, connecting plates, and Schanz screw clamps.

The MAXFRAME System hardware is coupled with the MAXFRAME Software for creation of preoperative and treatment planning. MAXFRAME Software can be accessed at MAXFRAME3d.com. Previously, the MAXFRAME3d.com site brought the user directly to the MAXFRAME 3D software application. With the introduction of a newer software version, MAXFRAME 3D II, the website MAXFRAME3d.com becomes a landing page where the user has the ability to select either MAXFRAME 3D or MAXFRAME 3D II, depending on regulatory availability in their country. Refer to the corresponding Software User's Manual (SUM) for a full description of MAXFRAME 3D and/or MAXFRAME 3D II. For the remainder of this document, "MAXFRAME Software" refers to both MAXFRAME 3D MAXFRAME 3D II.

Additional resources for Healthcare Professionals can be found at www.MAXFRAMEsystem.com.

The MAXFRAME Patient Care Program offers materials for patients, such as helpful information on strut adjustments, at www.maxframepatients.com.

The AO Principles of Fracture Management

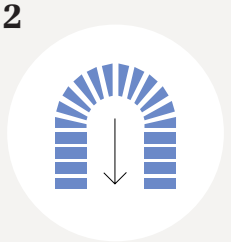
Mission
The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

AO Principles [1,2]

1

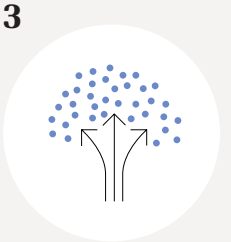
Fracture reduction and fixation to restore anatomical relationships.

2



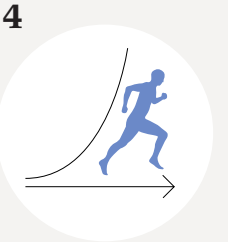
Fracture fixation providing absolute or relative stability, as required by the "personality" of the fracture, the patient, and the injury.

3



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

4



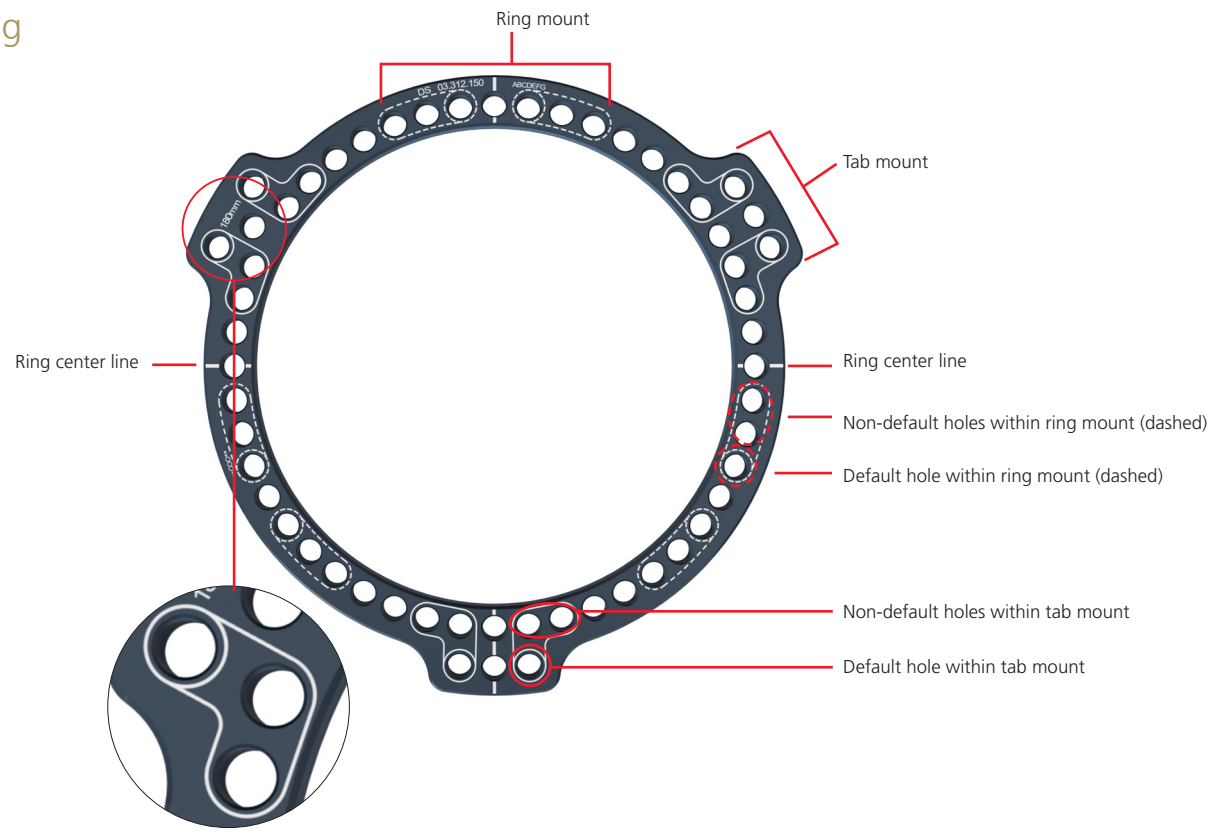
Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

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

Product Description

Hardware Description

Ring



The **tab mount** locations are designated by a solid line and are located on the physical tabs of the ring.

The **ring mount** locations are designated by a dashed line and are located between the physical tabs on the ring.

Default hole locations are designated by a circle (solid or dashed line) and are the strut locations that the software will choose by default.

Non-default hole locations are inclusive of the remaining holes enclosed by the solid or dashed line (depending on ring mount or tab mount). The MAXFRAME Software has settings to account for choosing a non-default hole location.

Struts can be connected to the plates via holes with dashed or solid lines only.

Notes:

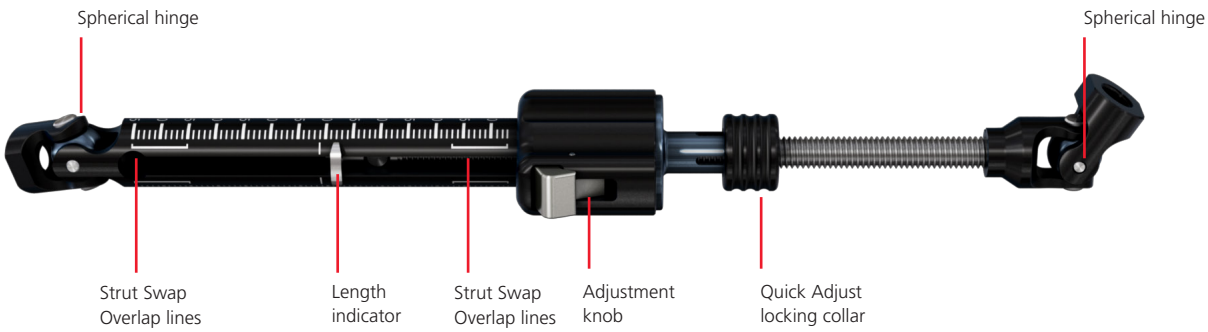
(1) Do not place struts in the unmarked holes as the software will be unable to locate them.

(2) For 90 mm and 120 mm full and 5/8 rings, do not use more than 2 non-default holes on a single ring.

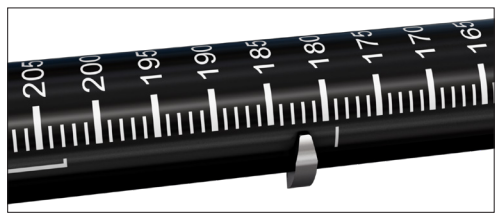
Hardware Description

Quick Adjust Strut

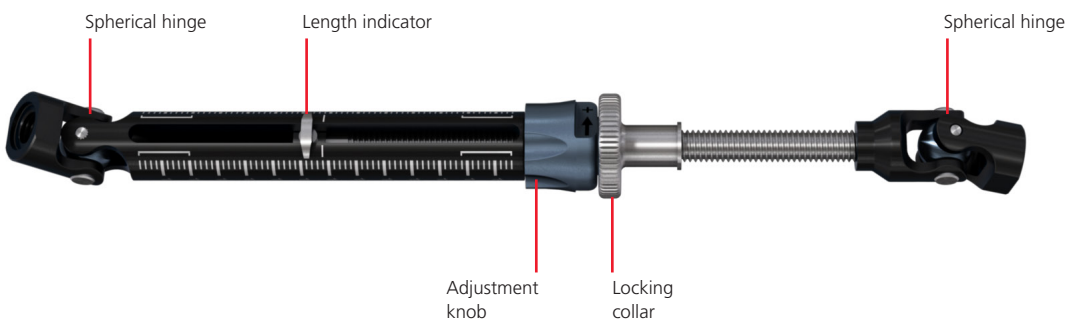
Provides an audible "click" every 1 mm of rotation to support patients and caregivers during strut adjustments.



The image on the right shows the length indicator on the Quick Adjust strut at 182 mm.



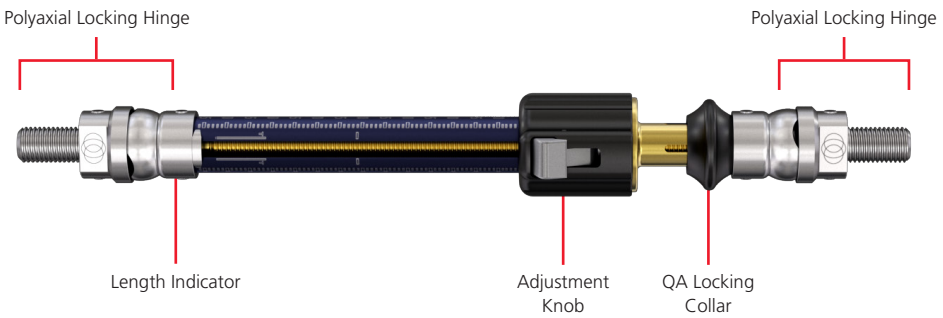
Standard Strut



Polyaxial Strut – Gross Adjust

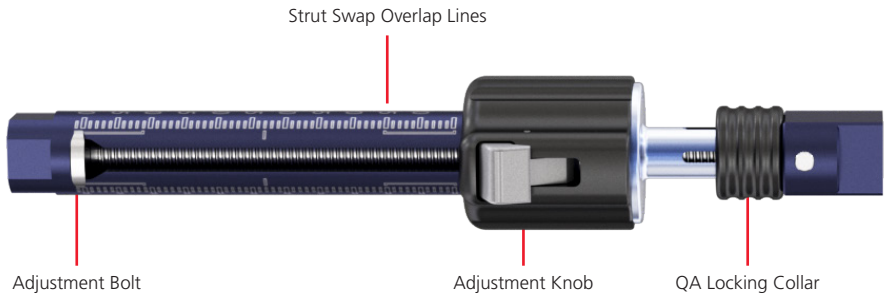
Polyaxial Strut – Fine and Gross Adjust

Polyaxial struts adjust 1/4 mm per adjustment click.



Linear Strut

Linear struts adjust 1/4 mm per adjustment click.



MAXFRAME Quick Adjust Struts

03.312.813	Long (203-329 mm)
03.312.812	Medium (145-213 mm)
03.312.811	Short (116-155 mm)
03.312.810	X-Short (101-126 mm)

MAXFRAME Standard Struts

03.312.818	Long (184-309 mm)
03.312.817	Medium (126-193 mm)
03.312.816	Short (97-135 mm)
03.312.815	X-Short (81-103 mm)
03.312.814	XX-Short (65-82 mm)

MAXFRAME Polyaxial Struts – Gross Adjust

03.313.877	Long (173-310 mm)
03.313.876	Medium (109-181 mm)
03.313.875	Short (77-117 mm)
03.313.874	X-Short (60-84 mm)
03.313.873	XX-Short (48-60 mm)

MAXFRAME Polyaxial Struts – Fine and Gross Adjust

03.313.881	Long (199-323 mm)
03.313.880	Medium (144-214 mm)
03.313.879	Short (117-159 mm)
03.313.878	X-Short (103-132 mm)

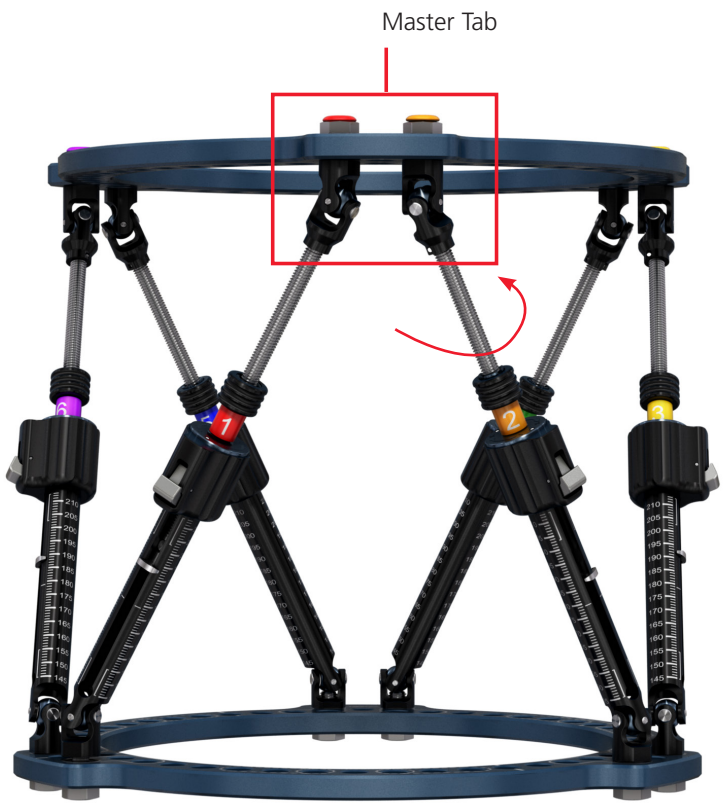
MAXFRAME Linear Struts

03.313.872	Long (175-277 mm)
03.313.871	Medium (129-185 mm)
03.313.870	Short (107-139 mm)

The end of the strut (Standard and QA) with the threaded rod will freely rotate while the opposite end remains static in the frame.

The linear and polyaxial struts lock on each end.

The **master tab** is the ring location in which struts 1 and 2 are adjacent to each other. This defines the reference ring and reference bone segment (proximal or distal).



Software Description

MAXFRAME Software is required for treatment planning in the application of the MAXFRAME System, accessible at www.MAXFRAME3d.com. MAXFRAME Software can be accessed at MAXFRAME3d.com. Previously, the MAXFRAME3d.com site brought the user directly to the MAXFRAME 3D software application. With the introduction of a newer software version, MAXFRAME 3D II, the website MAXFRAME3d.com becomes a landing page where the user has the ability to select either MAXFRAME 3D or MAXFRAME 3D II, depending on regulatory availability in their country. Refer to the corresponding Software User's Manual (SUM) for a full description of MAXFRAME 3D and/or MAXFRAME 3D II. For the remainder of this document, "MAXFRAME Software" refers to both MAXFRAME 3D MAXFRAME 3D II.

Warnings:

- **Do not use the MAXFRAME Hardware with any software program other than MAXFRAME Software as it could result in an incomplete or incorrect treatment plan.**
- **Linear and polyaxial struts are not intended for use with the MAXFRAME Software.**
- **MAXFRAME Half and Third Rings are not intended for use with the MAXFRAME Software.**

Indications and Contraindications

Intended Use

The DePuy Synthes MAXFRAME™ Multi-Axial Correction System is intended for external fixation of fracture long bones and bones of the foot, limb lengthening, and deformity correction in adult, children* (3-12), and adolescent* (12-21) patient populations. The DePuy Synthes MAXFRAME Multi-Axial Correction System utilizes software for assisting surgeons in treatment planning.

*In which the growth plates have fused or will not be crossed.

Indications

The DePuy Synthes MAXFRAME System is indicated for the following treatments in adults and in both children (3-12) and adolescents (12-21) in which the growth plates have fused or will not be crossed with hardware:

- fracture fixation (open and closed)
- pseudoarthrosis of long bones
- limb lengthening (epiphyseal or metaphyseal distraction)
- joint arthrodesis
- infected fractures or nonunions
- correction of bony or soft tissue deformities
- correction of segmental defects

Contraindications

MAXFRAME is not intended for use in the spine.

MRI Information

MRI Safety Information

Non-clinical testing has demonstrated that the DePuy Synthes MAXFRAME is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T or 3.0 T
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) or 4 W/kg (First Level Controlled Mode)
- The entire MAXFRAME construct must remain outside of the bore of the MR system
- All components of the MAXFRAME construct must be identified as MR Conditional prior to entering the MR environment

Under the scan conditions defined above, the DePuy Synthes MAXFRAME is expected to produce a maximum temperature rise of less than 6°C after 15 minutes of continuous scanning.

Preparation

Required Set

01.312.000	MAXFRAME/DO System Set

The modular nature of the MAXFRAME Multi-Axial Correction System allows for multiple frame configurations dependent on patient anatomical need. These frames can be customized by the surgeon to address the individual characteristics of each case within the system's indications for use.

The technique outlined below describes building a frame on the patient using Quick Adjust struts, wires and Schanz screws for the treatment of a proximal tibia fracture.

This technique can also be applied using standard, linear, and polyaxial struts.

Ring Selection

Select rings that allow for at least 2 cm of clearance between the skin and the 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.

Precaution: Do not combine MAXFRAME Rings with Distraction Osteogenesis rings for construction of the frame with one exception: Distraction Osteogenesis half rings (03.311.312, 315, 318, 320) can be used to close off the MAXFRAME Foot Plates. The MAXFRAME Software cannot create a treatment plan using Distraction Osteogenesis rings.

Please refer to page 80 for the surgical technique of building a foot frame.

Note: Instruments and implants in images may vary depending on technique used.

Frame Assembly – On Patient

Placement and Mounting of Proximal Ring

Wire Insertion

Instruments	
391.962	Bending/Cutting Pliers
Optional Instruments	
03.311.005	Split Tissue Protection Sleeve, 2.5 mm
03.311.004	Ratchet Wrench 11 mm
399.41	Hammer, 350 grams

1. Position the proximal ring.

Position the proximal ring on the affected limb based on the clinical plan at least 5 to 6 cm proximal to the fracture, orthogonal to the long axis of the bone. Slide the ring above the knee to allow for insertion of the first wire. If using the MAXFRAME Software, it is recommended that a tab mount be located directly anterior for ease of use.

If the fracture is close to a joint the distance between ring and fracture should be adjusted accordingly. Distance between mounted rings must accommodate existing strut sizes.

Note: If the Standard planning method is used within the MAXFRAME Software the reference ring should be placed orthogonal to the reference bone.

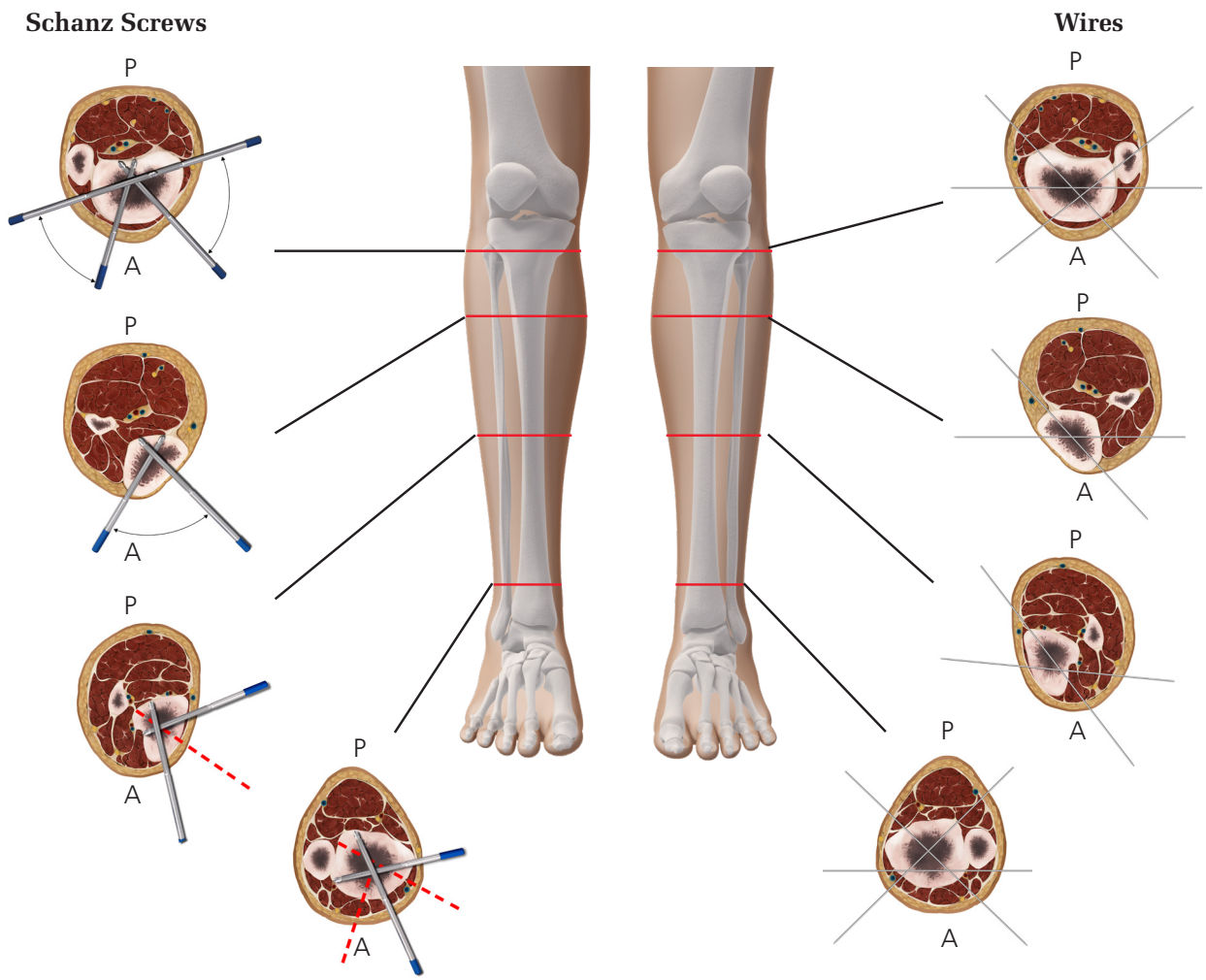
Note: Instruments and implants in images may vary depending on technique used.

2. Select appropriate size wire.

Available wire sizes include 2.0 mm, 1.8 mm and 1.5 mm. The 1.8 mm and 2.0 mm wires are commonly used for adult patients while 1.5 mm wires are often used for pediatric patients. Surgeon preference determines whether smooth wires or reduction wires (olive wires – which are used to create interfragmentary compression) are used.

3. Select appropriate location.

Maintain awareness of the safe zones in pertinent anatomy when inserting fixation points. The example below shows safe zones in a tibia.



4. Insert the wire.

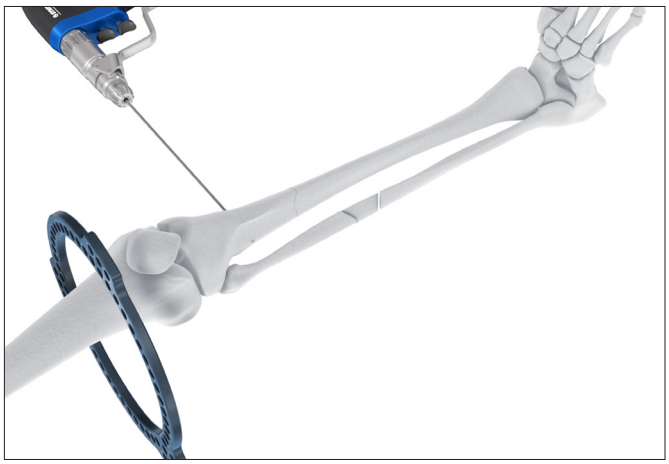
Using power, insert the wire perpendicular to the long axis of the bone.

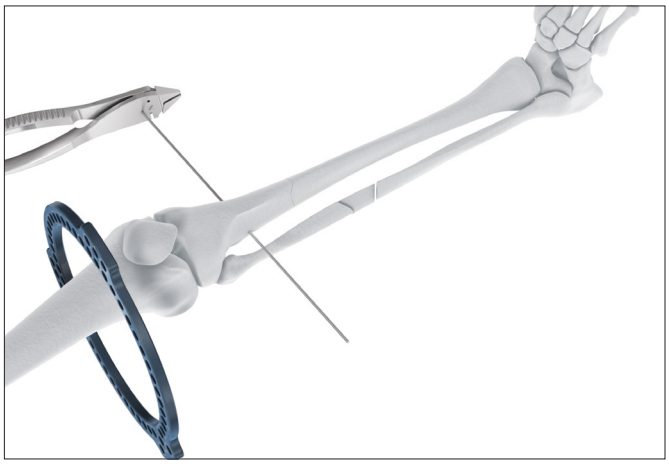
Do not start the drill until the wire tip makes contact with the bone and stop drilling as soon as the tip protrudes from the far cortex of the bone.

Care should be taken to ensure that diaphyseal wires are bicortical. A unicortical wire (that is so far anterior that it does not cross the intramedullary canal) can generate excessive heat during insertion and create stress risers in the bone.

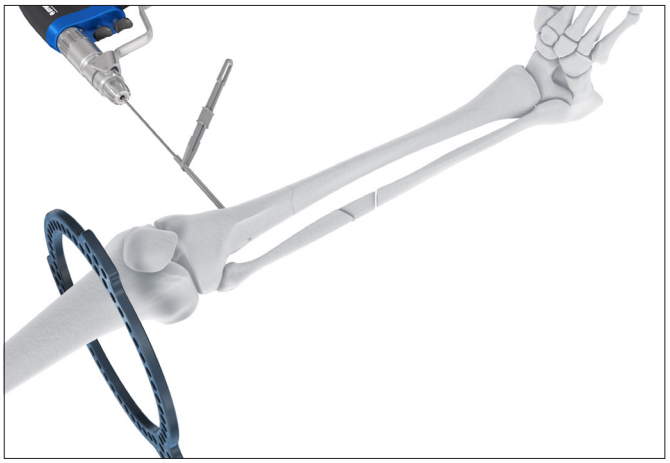
Once the wire protrudes from the far cortex of the bone, tap it through the tissue on the far side. The flat side of the bending/cutting pliers or a hammer may be used to tap the wire through the tissue. Once the wire is through, cut off the tip to prevent injury.

Care should be taken to avoid violation of the joint space (15-20 mm from subchondral bone in proximal tibia).





Alternative Technique:
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.



Note: Instruments and implants in images may vary depending on technique used.

5. Move the ring into the proper position along the wire to allow for maximum soft tissue clearance.

Identify the locations on the ring where you intend to place the struts, preferably in the default hole locations. Select appropriate location on the ring for connection of the first wire. Be sure not to occupy the planned location of struts.

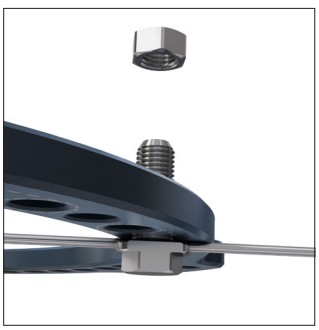
As a reminder, if using the MAXFRAME Software, it is recommended that a tab mount be located directly anterior.

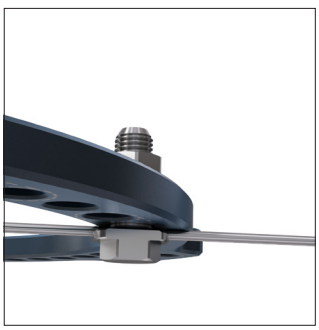
Note: Instruments and implants in images may vary depending on technique used.

6. Connect the wire to the ring with wire bolts and tighten with nuts.

- Wire should be positioned between bolt head and ring
- Wire can be placed above or below ring
- Type of wire bolt utilized is dependent upon the position of the wire in relationship to the ring hole. Select the wire bolt that results in the least amount of wire deformation. **Do not bend wires to attach them to the ring.**
- If needed, choose either offset wire bolts (03.311.051, 03.311.054) or slotted wire bolts (03.311.050, 03.313.885, 03.311.054), depending on the position of the wire in relation to the holes in the ring. Select the wire bolt that results in the least amount of wire deformation.

Precaution: Do not bend wires to attach them to the ring as this could increase the risk of wire breakage. See the next page for offset fixation options.



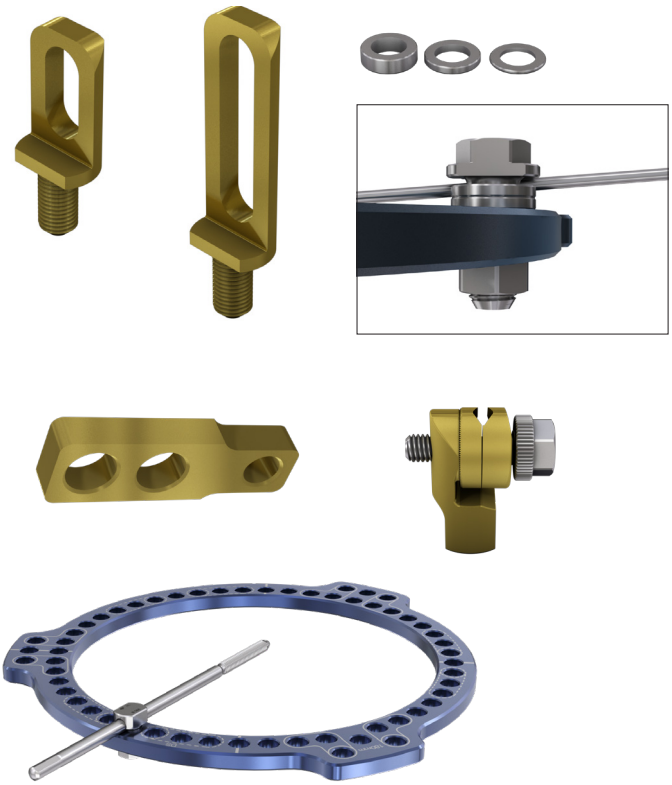


Additional Fixation Options

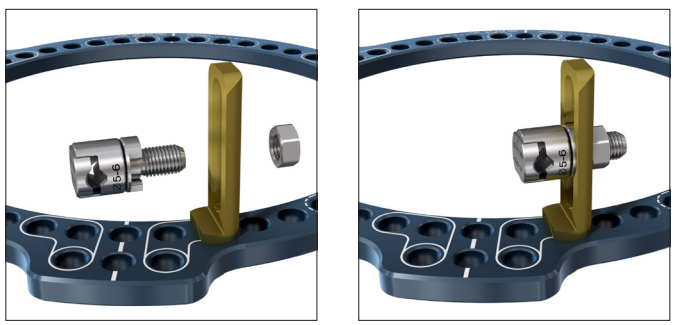
There are a variety of items that can be used in conjunction with Schanz screws and wires when there is a need to position them in locations offset from the ring's surface. For example:

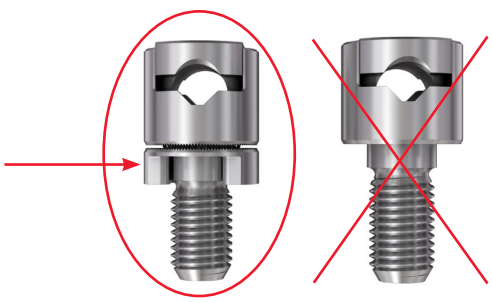
- Wire posts*
- Spacing washers
- Connecting plates
- Pivot Schanz screw clamps**

**The Pivot Schanz screw clamp (03.311.011) requires the Connection Bolt, long (03.311.056) in order to connect to the ring.



*Precaution: **To maintain proper alignment of the Schanz screw, you must use the Schanz screw bolt, cannulated post mount (03.311.059) to connect the wire post to the Schanz screw. Do not use the Schanz screw bolt, cannulated ring mount (03.311.058).**





03.311.059 03.311.058

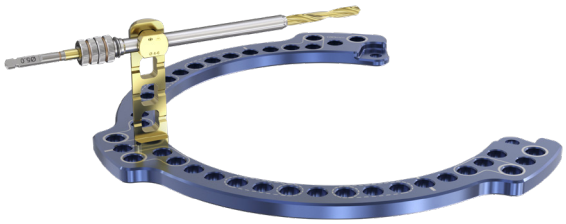
Multiparallel Pin Mount – See page 119 for part numbers

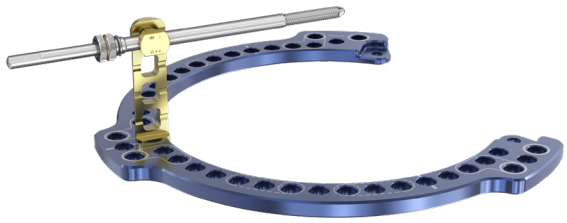
Steps

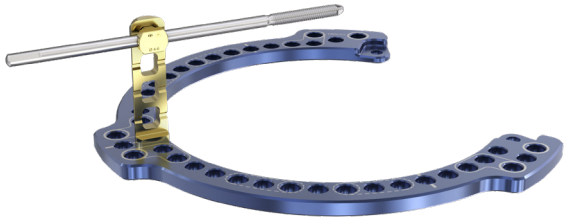
1. Attach Multiparallel Pin Mount Post to ring with a 11 mm nut (03.311.061).
2. Select the mounting hole on the Multiparallel Pin Mount Post that is needed.
3. Attach the Multiparallel Pin Mount Bolt to the mounting hole using an 11 mm nut (03.311.061).

Optional: Clamp the drill sleeve in device for soft tissue protection

4. Drill hole.
5. Remove drill sleeve.
6. Insert implant along guided path.



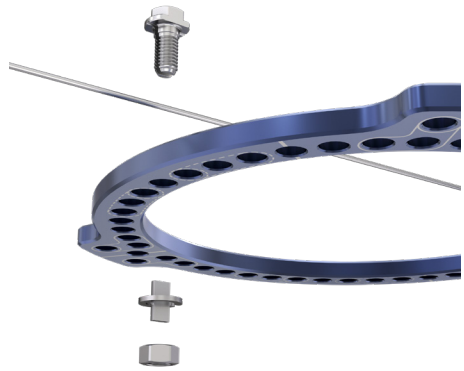




Tabbed Washer

Steps

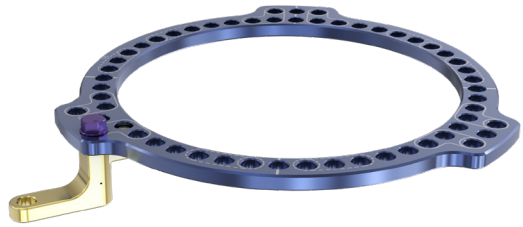
1. Implant the wire in the desired location.
2. Place the wire bolt, short-slotted (03.313.885) through the ring and around the wire.
3. Place the Tabbed Washer, 03.313.867 on the opposite side of the ring
4. Use a 11 mm nut (03.311.061) to clamp it together.



Right-angled Post

Steps

1. Orient the right-angled post (03.313.869) on the ring.
2. Use the connection bolt, long (03.311.056) to attach the right-angled post to the ring.



Tension Wire

Instruments	
03.311.007	8 mm/11 mm Wrench
03.312.001	Wire Tensioner
391.962	Bending/Cutting Pliers
Optional Instruments	
03.311.004	Ratchet Wrench 11 mm
03.311.002	Slotted Socket Wrench

1. Use one wrench to stabilize the wire bolt head while using a second to tighten the nut at the location opposite from where tension will be applied.

Note: When reduction wires (olive wires) are used, tighten the nut and the bolt on the same side as the stopper.

Precaution: Take care to keep the wire bolt head aligned, to prevent bending the wire.

Correct

Incorrect

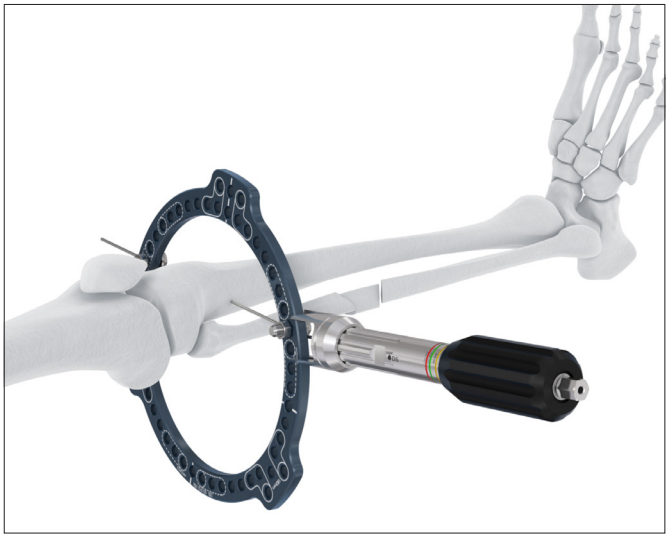
Note: Instruments and implants in images may vary depending on technique used.

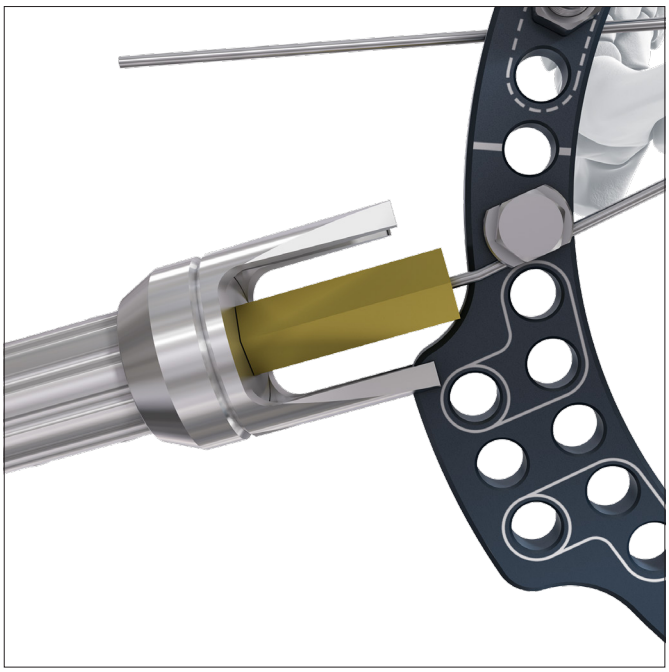
2. Position tensioner on wire.

From the tensioning side of the ring, opposite to the tightened nut and wire bolt, pass the wire into the cannulation of the tensioner. The tensioner should be fully open (the black handle turned counterclockwise until it makes an audible click) and the jaws 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 jaws of the tensioner.

Note: When reduction wires are used, the tensioner should be placed on the side of the bone opposite the stopper to ensure the stopper provides compression during tensioning.

Alternative Technique:
If other features prevent the jaws from sitting on the ring, place a standoff on the tensioner between the tensioner and the ring. The threaded tip of the standoff allows it to be threaded onto the tensioner.



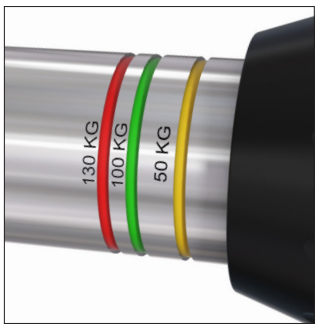


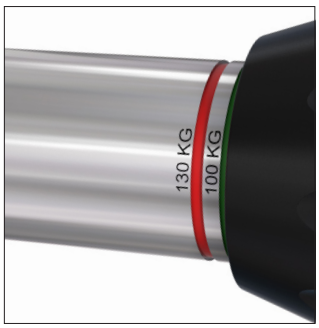
Note: Instruments and implants in images may vary depending on technique used.

3. Apply tension to wire.

Leave the wire bolt that is near the tensioner loose when tensioning.

Turn the tensioner handle clockwise until the desired tension is attained.





Alternative technique: A ratchet wrench can be used on the external hex nut at the back of the tensioner to make turning the handle quicker.

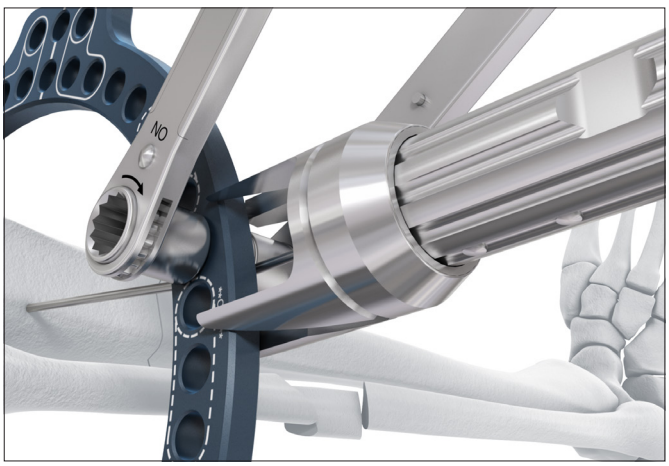
Note: Instruments and implants in images may vary depending on technique used.

4. Tighten wire bolt and nut.

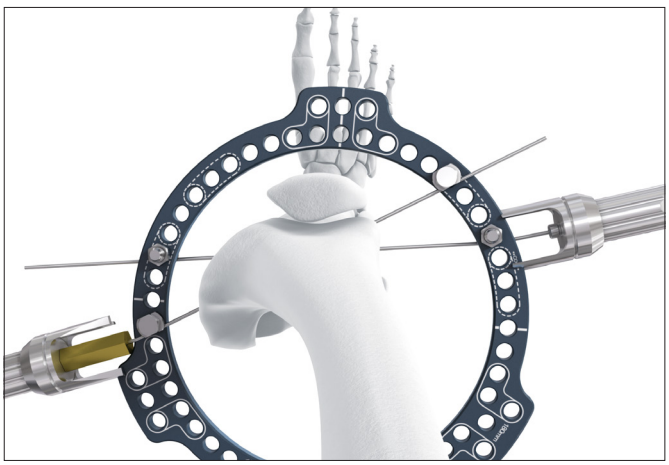
When the wire is fully tensioned, tighten the wire bolt near the tensioner. A ratchet wrench can be used to hold the wire bolt head stationary while a second ratchet wrench is used to tighten the nut (or two ratchet wrenches may be used).

Double check tightness of connections.

If placing additional wires, after initial tensioning, consider re-tensioning all wires on the ring in the same sequence in which they were inserted 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 technique:
Use two tensioners from opposite sides to simultaneously tension two wires until the desired tension is achieved.



Note: Instruments and implants in images may vary depending on technique used.

5. Cut ends of wire.

After tensioning, cut the ends of the wire. Leave at least 60 mm (approximately 3 finger widths) of wire past the wire bolts in the event that additional tension needs to be applied to wire.

Curl the end of the wire using the bending/cutting pliers to minimize injury risk.

Precaution: If it is determined that a wire must be removed because of sub-optimal placement, the recommended technique is to cut wire inside of ring and remove by pulling away from bone to reduce the chance of introducing debris into soft tissue.

Do not pull any portion of a wire that has been bolted to a ring through soft tissue to reduce the chance of debris being introduced to the patient.

Do not reinsert the same wire. Use a new wire.

At this point, manipulate the location of the ring until desired alignment is achieved. Before applying second fixation element, adjust the ring for optimal position by tilting or translating along the wire.

Note: Instruments and implants in images may vary depending on technique used.

Insert first Schanz screw

If using Variable Thread Length Schanz Screws follow technique starting on page 35.

Instruments	
03.311.007	8 mm/11 mm Wrench
03.312.953	7.0 mm/6.0 mm Drill sleeve/Long
355.87	3.5 mm Trocar
395.913	5.0 mm/3.5 mm Drill Sleeve
395.923	6.0 mm/5.0 mm Threaded Drill Sleeve
Optional Instruments	
03.312.950	Ø 3.5 mm Drill Bit
03.312.954	7.0 mm/6.0 mm Drill sleeve/Extra Long
393.105	Small Universal Chuck with T-handle
355.88	5.0 mm/3.5 mm Drill Sleeve
355.89	6.0 mm/5.0 mm Drill Sleeve

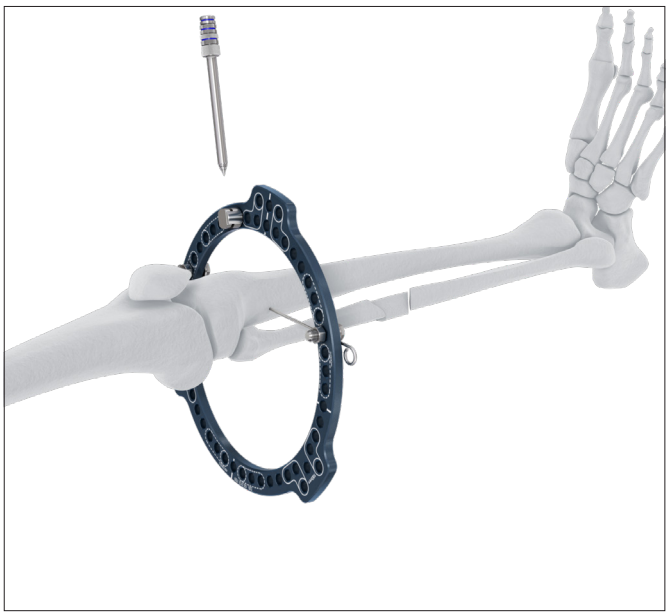
1. Select appropriate size Schanz screw.

If using Variable Thread Length Schanz Screws follow technique starting on page 35.

2. Select appropriate location on the ring for insertion of the first Schanz screw.

See page 16 to review safe zones.

Maintain an awareness of the planned strut locations, so as to not block them.



3. Use a nut to loosely attach Schanz screw bolt to proximal ring in line with the planned location of the Schanz screw insertion.

4. Insert the drill sleeve assembly through the Schanz screw bolt and finger tighten the nut.

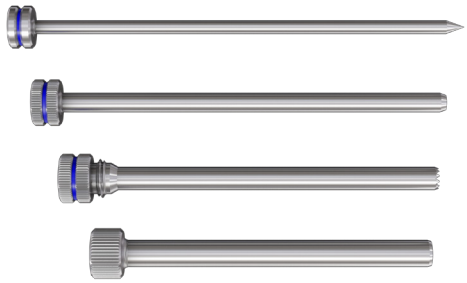
For insertion of a 4.0 mm Schanz screw use:

Long (Yellow bands)
4.0 mm Threaded Drill Sleeve-Long (395.931)
4.0 mm/2.5 mm Drill Sleeve-Long (392.956)
2.5 mm Trocar-Long (394.184)

For insertion of a 5.0 mm Schanz screw use:

Long (Blue bands)
6.0 mm/5.0 mm Threaded Drill Sleeve-Long (395.923)
5.0 mm/3.5 mm Drill Sleeve-Long (395.913)
3.5 mm Trocar-Long (394.182)

Extra Long
6.0 mm/5.0 mm Drill Sleeve (355.89)
5.0 mm/3.5 mm Drill Sleeve (355.88)
3.5 mm Trocar (355.87)



For insertion of a 6.0 mm Schanz screw use:

Long (Blue bands)
7.0 mm/6.0 mm Drill Sleeve Long (03.312.953 – no blue band)
6.0 mm/5.0 mm Threaded Drill Sleeve-Long (395.923)
5.0 mm/3.5 mm Drill Sleeve-Long (395.913)
3.5 mm Trocar-Long (394.182)

Extra Long
7.0 mm/6.0 mm Drill Sleeve Extra Long (03.312.954)
6.0 mm/5.0 mm Drill Sleeve (355.89)
5.0 mm/3.5 mm Drill Sleeve (355.88)
3.5 mm Trocar (355.87)

Remove trocar.

Note: Instruments listed on page 35 can also be used with the self drilling standard thread length schanz screws. Due to the necessary drill bit size, the standard length blunted trocar point and spade point schanz screws require the instruments listed above.

5. Make a skin incision ensuring the incision is large enough to allow insertion of drill sleeve assembly.

6. Pre-drill for the appropriate size Schanz screw.

For non-self drilling Schanz screws:
- 5.0 mm and 6.0 mm require a 3.5 mm drill bit
- 4.0 mm requires a 2.0 mm drill bit

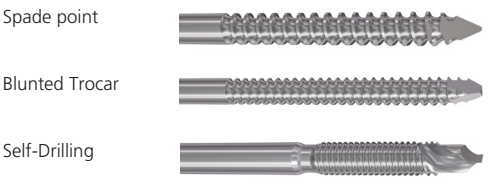
Precaution: Pre-drilling for self-drilling screws is recommended for dense or thick cortical bone to avoid bone necrosis. Consider cooling the drill with saline.

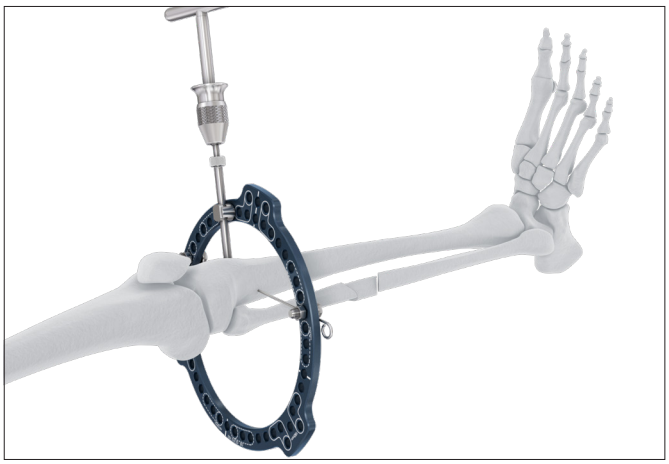
Care should be taken to ensure that diaphyseal Schanz screws are bicortical. A unicortical Schanz screw (that is so far anterior or posterior that it does not cross the intramedullary canal) can generate excessive heat during pre-drilling and create stress risers in the bone.

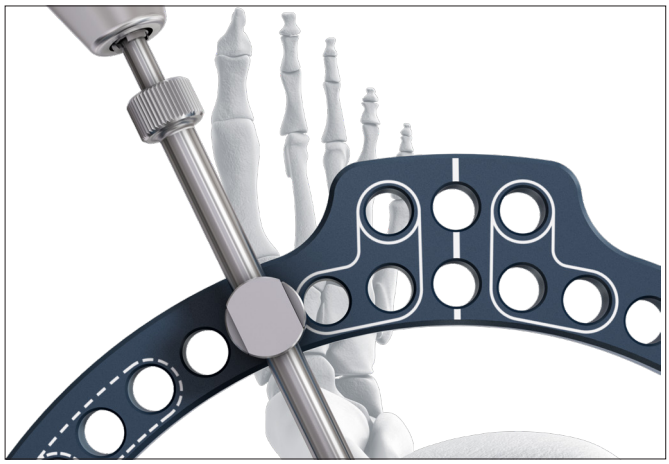
Insert the Schanz screw manually through the drill sleeve using a T-handle chuck until properly inserted.

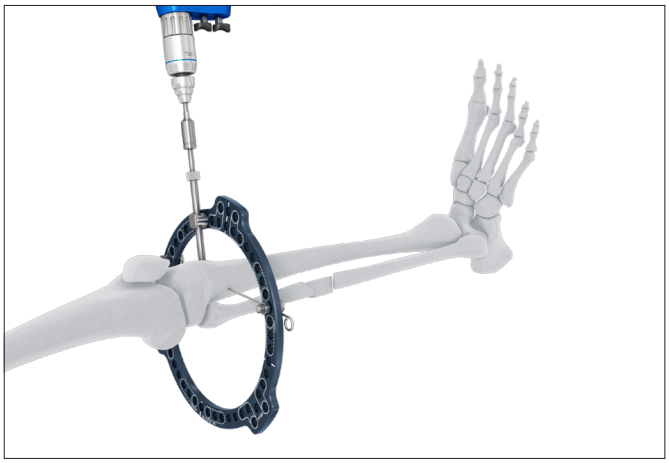
Ensure that the Schanz screw is properly in line with the opening in the Schanz screw bolt. When using non-cannulated Schanz screw bolts, do not bend the Schanz screw to meet the Schanz screw bolt to avoid unintentional side loading.

Alternate Technique: Insert Schanz screw using power with the appropriate drill sleeve through the near cortex.

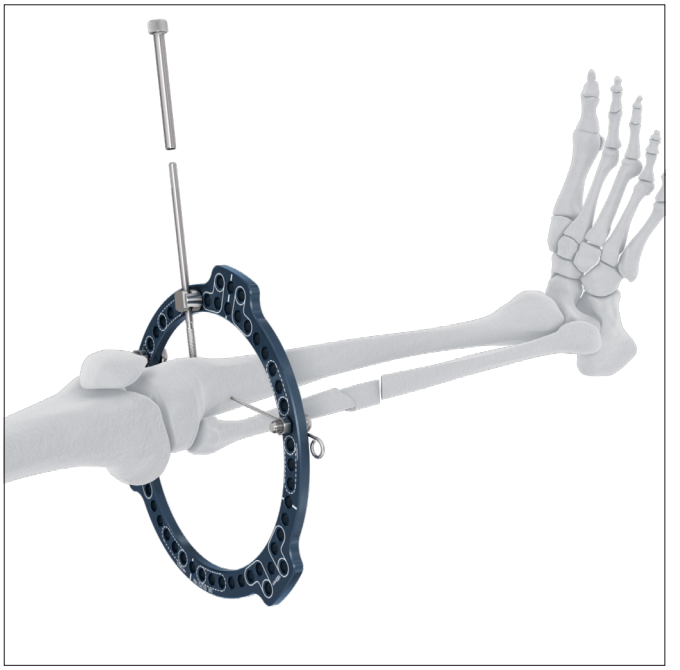








7. Remove the drill sleeve assembly.

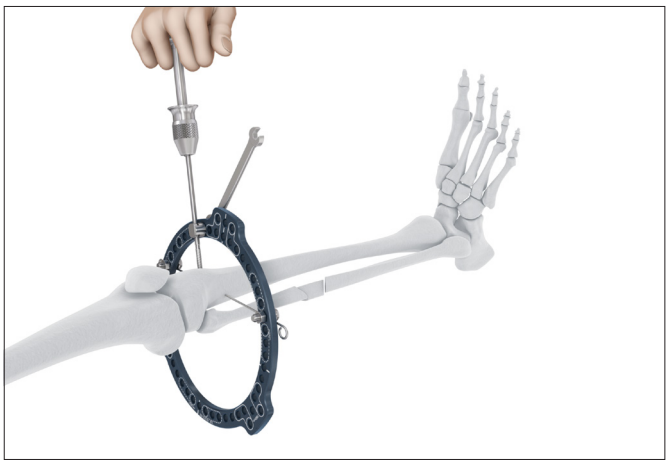


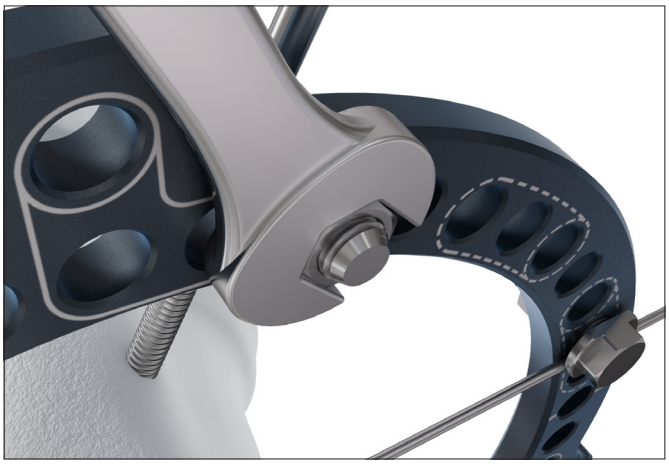
8. Perform final tightening of the Schanz screw bolt to ring using the 8 mm/11 mm wrench.

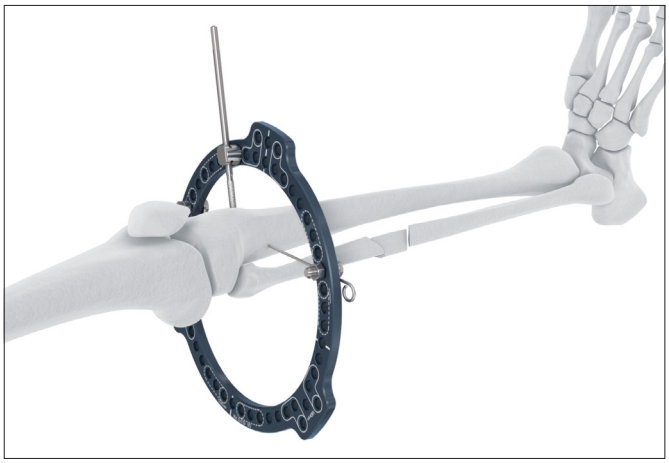
Ensure the Schanz screw is properly seated within the Schanz screw bolt.

Provide counter-torque to the Schanz screw when tightening.

Double check tightness of the connections.



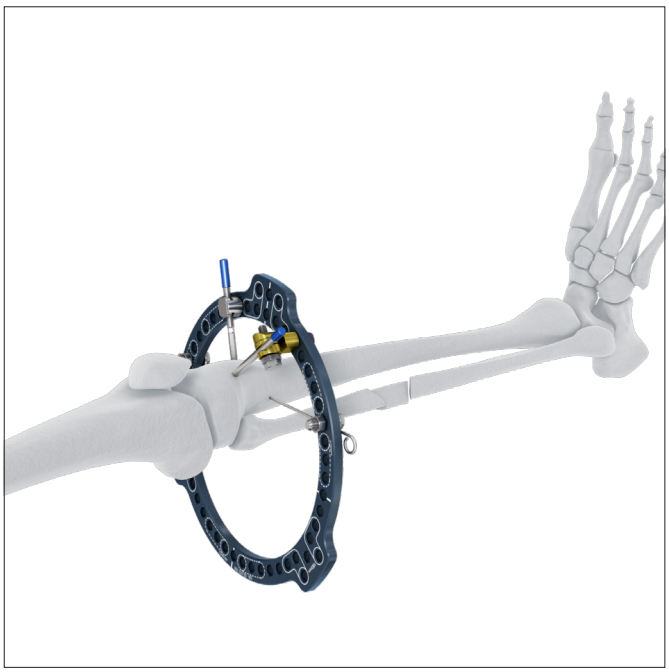




Note: Instruments and implants in images may vary depending on technique used.

9. Insert second Schanz screw divergent to the location of the first Schanz screw following the same steps as previously described starting on page 27.

Double check tightness of the connections.



Insertion of Additional Points of Fixation
If needed, insert additional Schanz screws and/or wires at the proximal ring until a stable construct has been achieved. Avoid planned location of struts.

A minimum of three points of fixation is recommended.

If you choose to cut pins, utilize a cap.

Once all Schanz Screws are placed move to page 43 for Placement and Mounting of Distal Ring.

Technique for Variable Thread Length Schanz Screws

If using standard thread length Schanz screws follow steps on page 27.

For 4.0 mm Variable Thread Length Schanz Screw	
03.313.700	3.2 mm Drill Bit, Long/Calibrated
03.313.700S	3.2 mm Drill Bit, Long/Calibrated/Sterile
03.313.720	4.0 mm Drill Sleeve, Long/Outer
03.313.721	4.0 mm Drill Sleeve, Long/Inner
03.313.730	3.2 mm Trocar, Long

For 5.0 mm Variable Thread Length Schanz Screw	
Long	
03.313.701	4.3 mm Drill Bit, Long/Calibrated
03.313.701S	4.3 mm Drill Bit, Long/Calibrated/Sterile
03.313.722	5.0 mm Drill Sleeve, Long/Outer
03.313.723	5.0 mm Drill Sleeve, Long/Inner
03.313.731	4.3 mm Trocar, Long
Extra Long	
03.313.702	4.3 mm Drill Bit, Extra Long/Calibrated
03.313.702S	4.3 mm Drill Bit, Extra Long/Calibrated/ Sterile
03.313.724	5.0 mm Drill Sleeve, Extra Long/Outer
03.313.725	5.0 mm Drill Sleeve, Extra Long/Inner
03.313.732	4.3 mm Trocar, Extra Long

For 6.0 mm Variable Thread Length Schanz Screw	
Long	
03.313.703	5.0 mm Drill Bit, Long/Calibrated
03.313.703S	5.0 mm Drill Bit, Long/Calibrated/Sterile
03.313.726	6.0 mm Drill Sleeve, Long/Outer
03.313.727	6.0 mm Drill Sleeve, Long/Inner
03.313.733	5.0 mm Trocar, Long
Extra Long	
03.313.704	5.0 mm Drill Bit, Extra Long/Calibrated
03.313.704S	5.0 mm Drill Bit, Extra Long/Calibrated/ Sterile
03.313.728	6.0 mm Drill Sleeve, Extra Long/Outer
03.313.729	6.0 mm Drill Sleeve, Extra Long/Outer
03.313.734	5.0 mm Trocar, Extra Long

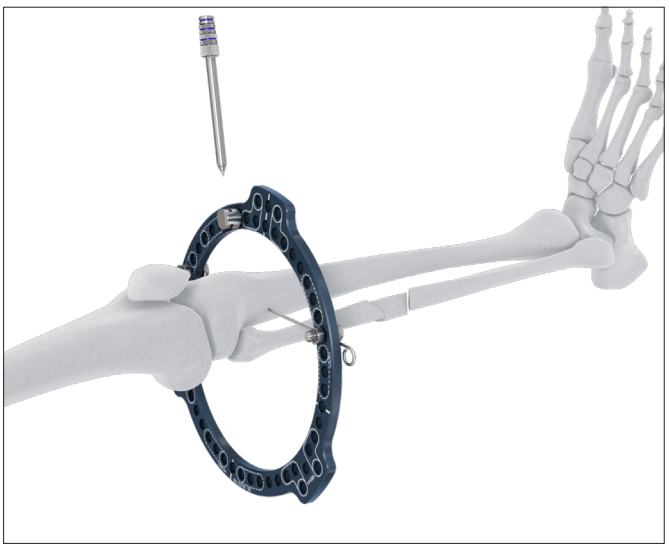
Note: Instruments listed above can also be used with the self drilling standard thread length schanz screws. Due to the necessary drill bit size, the standard length blunted trocar point and spade point schanz screws require the instruments listed on page 29.

1. Select appropriate diameter (4.0 mm, 5.0 mm, 6.0 mm) Schanz screw.

2. Select appropriate location on the ring for insertion of the first Schanz screw.

See page 16 to review safe zones.

Maintain an awareness of the planned strut locations, so as to not block them.



3. Use a nut to loosely attach Clamping Bolt for Schanz screw to proximal ring in line with the planned location of the Schanz screw insertion.

4. Insert the drill sleeve assembly through the Clamping Bolt for Schanz screw and finger tighten the nut.

For 4.0 mm Variable Thread Length Schanz Screw	
Long (Green bands)	
03.313.720	4.0 mm Drill Sleeve, Long/Outer
03.313.721	4.0 mm Drill Sleeve, Long/Inner
03.313.730	3.2 mm Trocar, Long

For 5.0 mm Variable Thread Length Schanz Screw	
Long (Red bands)	
03.313.722	5.0 mm Drill Sleeve, Long/Outer
03.313.723	5.0 mm Drill Sleeve, Long/Inner
03.313.731	4.3 mm Trocar, Long
Extra Long (Black bands)	
03.313.724	5.0 mm Drill Sleeve, Extra Long/Outer
03.313.725	5.0 mm Drill Sleeve, Extra Long/Inner
03.313.732	4.3 mm Trocar, Extra Long

For 6.0 mm Variable Thread Length Schanz Screw	
Long (Brown bands)	
03.313.726	6.0 mm Drill Sleeve, Long/Outer
03.313.727	6.0 mm Drill Sleeve, Long/Inner
03.313.733	5.0 mm Trocar, Long
Extra Long (White bands)	
03.313.728	6.0 mm Drill Sleeve, Extra Long/Outer
03.313.729	6.0 mm Drill Sleeve, Extra Long/Outer
03.313.734	5.0 mm Trocar, Extra Long


03.313.720


03.313.721


03.313.730

Remove trocar.

5. Make a skin incision ensuring the incision is large enough to allow insertion of drill sleeve assembly.

Note: Instruments and implants in images may vary depending on technique used.

6. Pre-drill and measure for the appropriate thread length Schanz screw.

- 4.0 mm Variable Thread Length Schanz screw requires a 3.2 mm drill bit
- 5.0 mm Variable Thread Length Schanz Screw requires a 4.3 mm drill bit
- 6.0 mm Variable Thread Length Schanz Screw requires a 5.0 mm drill bit

Precaution: Pre-drilling for self-drilling screws is recommended for dense or thick cortical bone to avoid bone necrosis. Consider cooling the drill with saline.

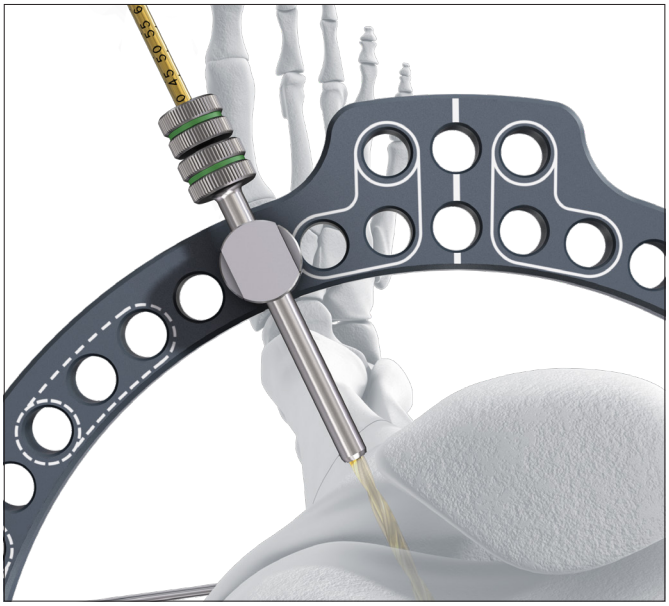
To use calibrated drill guides to measure for the appropriate thread length, pre-drilling is required.

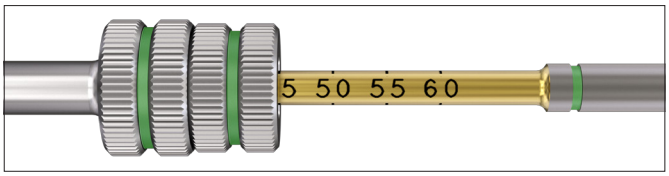
Care should be taken to ensure that diaphyseal Schanz screws are bicortical. A unicortical Schanz screw (that is so far anterior or posterior that it does not cross the intramedullary canal) can generate excessive heat during pre-drilling and create stress risers in the bone.

To Measure
1. Insert the calibrated drill bit through the drill sleeve assembly.
2. Drill to the appropriate depth.
3. Check to ensure the drill bit tip is in proper location—confirm not over inserted.
4. Read the measurement off the calibrated drill bit to determine the appropriate thread length Schanz screw. See example to the right for clarification.

Insert the Schanz screw manually through the drill sleeve using a T-handle chuck until properly inserted.

Ensure that the Schanz screw is properly in line with the opening in the Clamping Bolt for Schanz screw. When using non-cannulated Clamping Bolts for Schanz screw, do not bend the Schanz screw to meet the Clamping Bolt for Schanz screw to avoid unintentional side loading.





Drill bits are calibrated so that depth measurements can be read directly from the drill bit. For example, the above shows a minimum thread length of 45 mm is needed.

Alternate technique: Insert Schanz screw using power with the appropriate drill sleeve through the near cortex.

Blunted Point

Self-Drilling

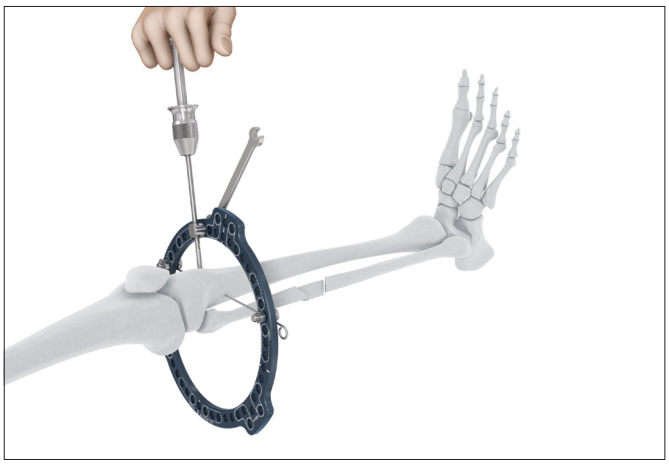
7. Remove the drill sleeve assembly.

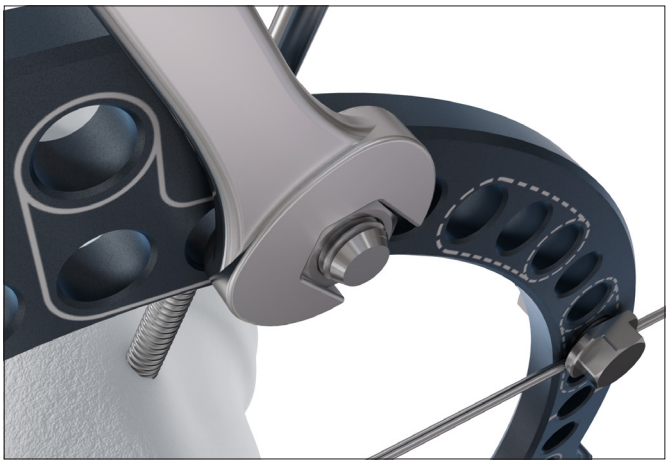
8. Perform final tightening of the Clamping Bolt for Schanz screw to ring using the Wrench Ø 8.0/11.0 mm.

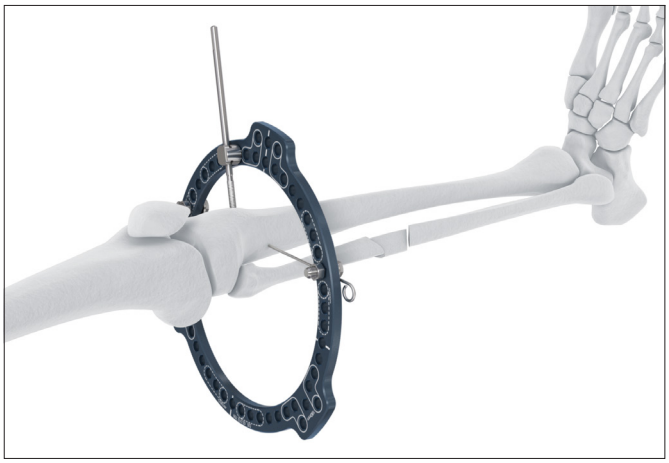
Ensure the Schanz screw is properly seated within the Clamping Bolt for Schanz screw.

Provide counter-torque to the Schanz screw when tightening.

Double check tightness of the connections.



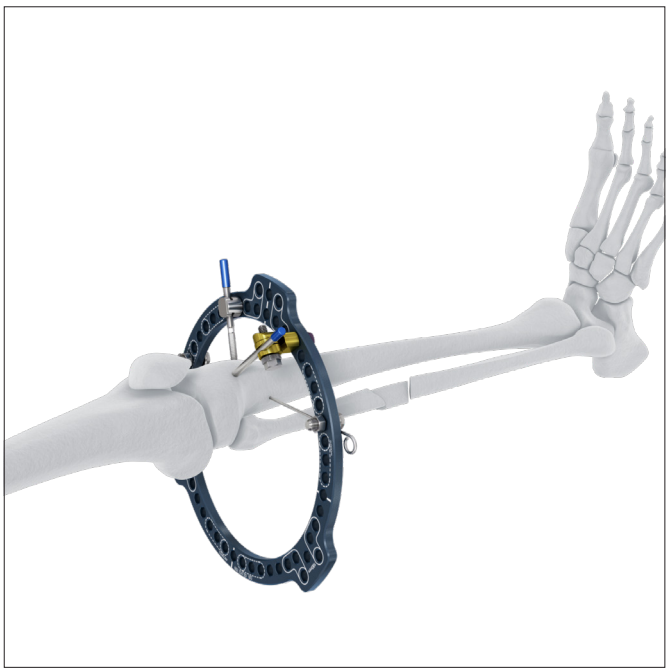




Note: Instruments and implants in images may vary depending on technique used.

9. Insert second Schanz screw divergent to the location of the first Schanz screw following the same steps as previously described starting on page 35.

Double check tightness of the connections.



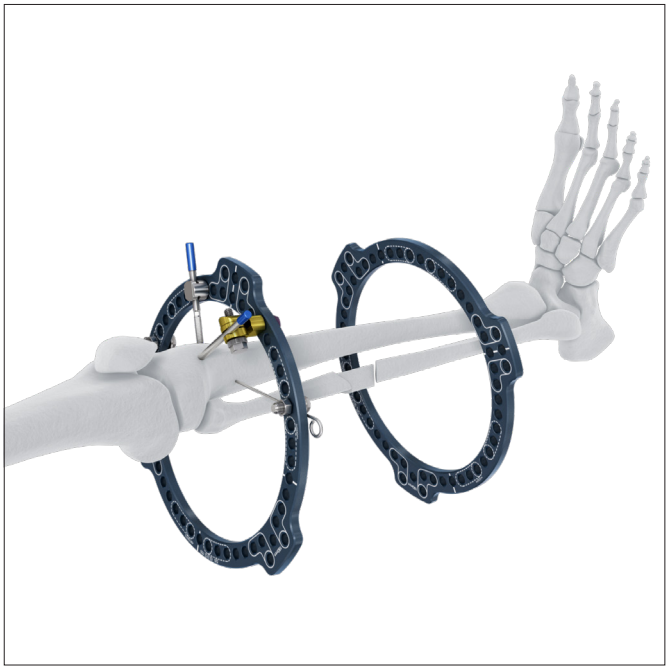
Insertion of Additional Points of Fixation
If needed, insert additional Schanz screws and/or wires at the proximal ring until a stable construct has been achieved. Avoid planned location of struts.

A minimum of three points of fixation is recommended.

If you choose to cut pins, utilize a cap.

Placement and Mounting of Distal Ring

Instruments	
03.312.953	7.0 mm/6.0 mm Drill sleeve/Long
03.311.007	8 mm/11 mm Wrench
Optional Instruments	
03.312.950	Ø 3.5 mm Drill Bit
03.312.954	7.0 mm/6.0 mm Drill sleeve/Extra Long
393.105	Small Universal Chuck with T-handle



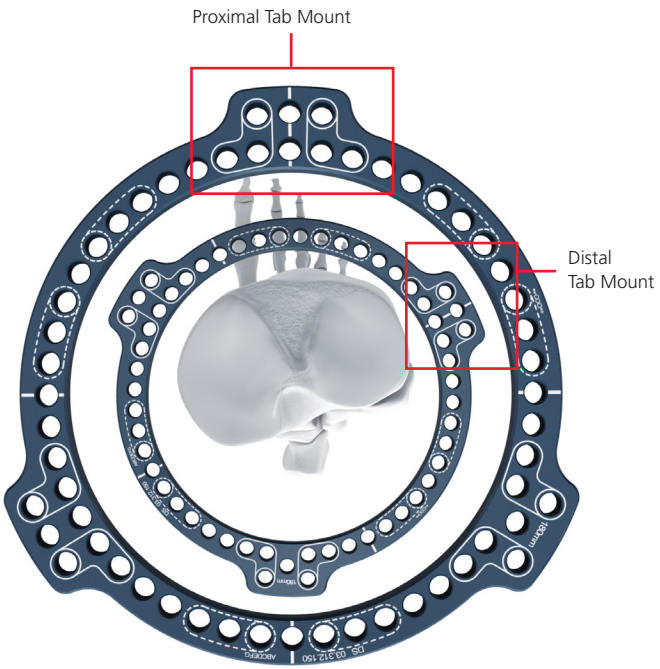
1. Position the distal ring on the affected limb based on the clinical plan.

If placing the struts from a tab mount (default) in the proximal ring to a tab mount (default) in the distal ring, rotate the distal ring 60° to ensure the struts align appropriately. (Only applicable when utilizing the MAXFRAME software.)

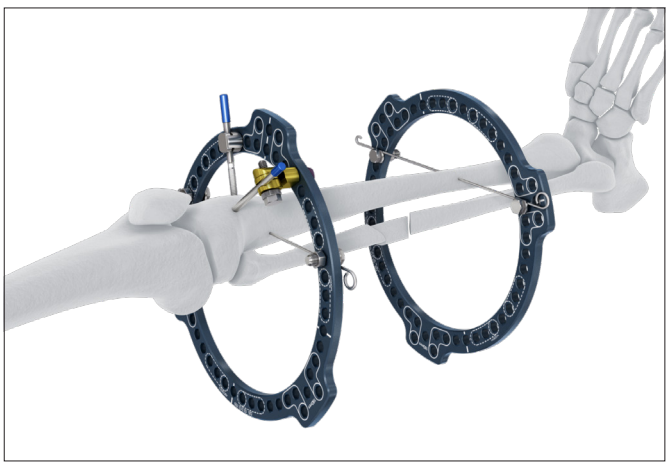
If placing the struts from a tab mount in the proximal ring to a ring mount on the distal ring, ensure that the tabs are directly in line with one another.

Notes:

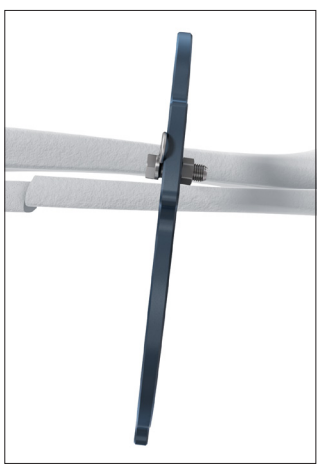
- **A frame must not use rings that are more than 2 sizes apart.**
- **Only one ring (proximal or distal) per frame should have struts mounted on ring mount holes between the tabs. The MAXFRAME Software will not allow you to choose ring mount holes on both rings.**



2. Insert a wire following the steps outlined above starting on page 15.

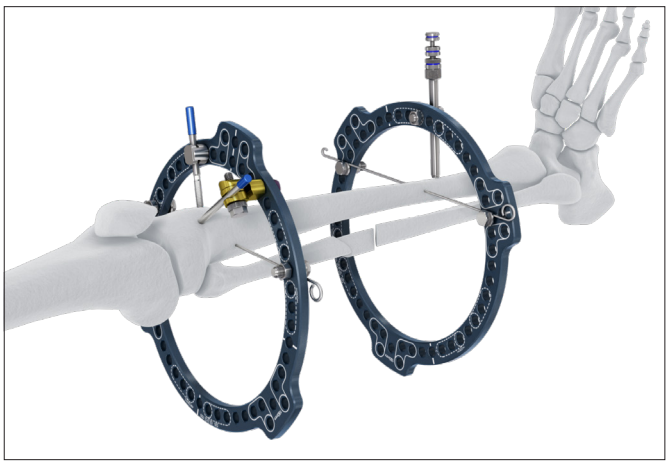


At this point, manipulate the orientation of the ring until desired alignment is achieved, generally perpendicular to the bone segment.

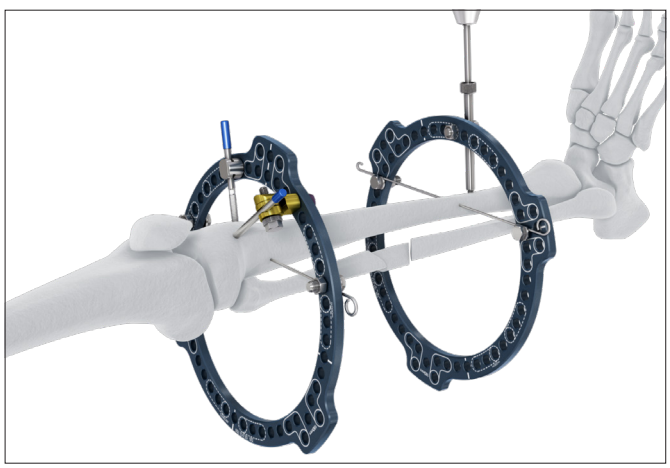


3. Select appropriate size Schanz screw.

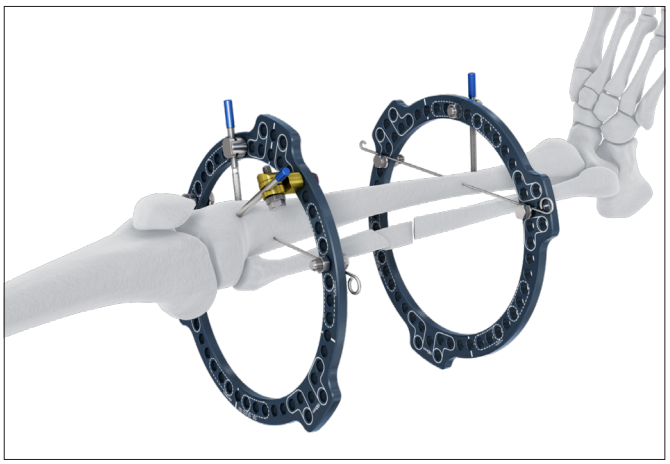
4. Select appropriate location on the ring for insertion of the first Schanz screw.

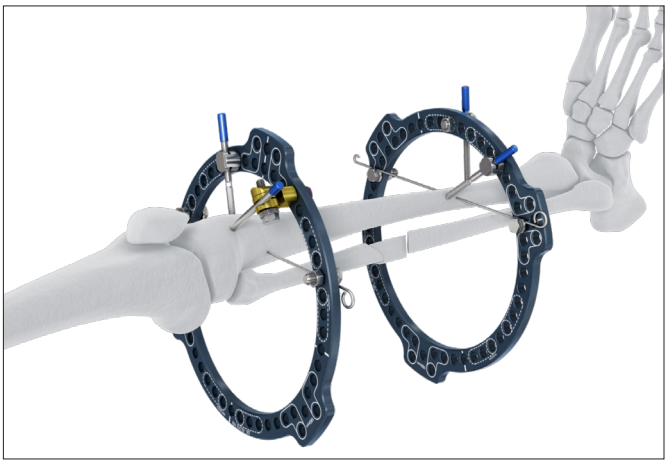


5. Insert the first Schanz screw following the same steps outlined above starting on page 27 or on page 35 for Variable Thread Length Schanz Screws.



6. Insert a second Schanz screw in appropriate hole locations in the same manner.





7. Double-check tightness of all connections.

Insertion of Additional Points of Fixation
If needed, insert additional Schanz screws and/or wires at the distal ring until a stable construct has been achieved.

A minimum of three points of fixation is recommended.

Maintain an awareness of the planned strut locations, so as to not block them. Alternatively, additional fixation points can be added after the struts are installed.

Attach Struts

Instruments	
03.311.007	8 mm/11 mm Wrench
03.312.851	10 Nm Torque Wrench

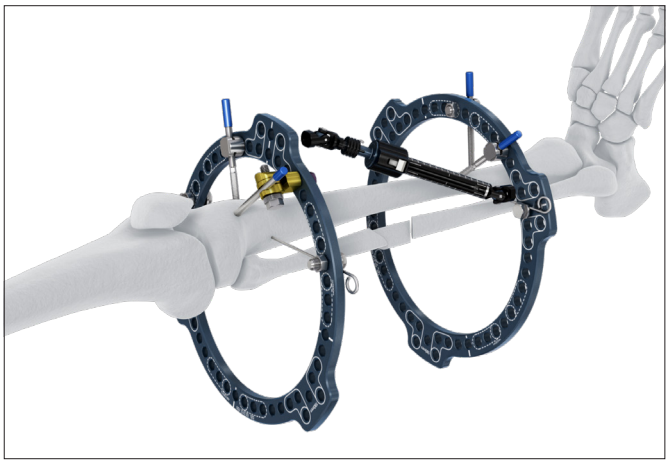
1. Choose an appropriate strut type and length.

The use of Quick Adjust (QA) struts is outlined below. See page 61 for information on the use of Standard Struts, page 65 for the use of Linear Struts, and page 72 for the use of polyaxial struts.

Note: Make sure to consider the strut swap overlap lines when determining the appropriate length strut.

2. Orient the QA strut so that the length indicator is visible to the patient when attaching a strut.

It is recommended to place all struts in the same orientation (e.g. all of the adjustment knobs toward the distal ring) for ease of strut adjustments postoperatively.



3. Attach the QA strut to the proximal ring.

Align the QA strut with the intended hole on the proximal ring.

It is recommended to place struts in default holes when adjacent hardware allows. This will simplify the MAXFRAME Software workflow.

Thread the shoulder bolt into the QA strut through the hole in the ring.

Note: QA and Standard struts are only compatible with MAXFRAME shoulder bolts.

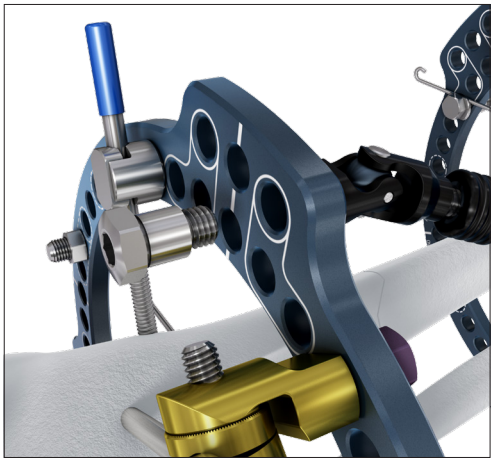
Place the 11 mm end of the 8 mm/11 mm wrench on the flats at the end of the spherical hinge to provide counter-torque.

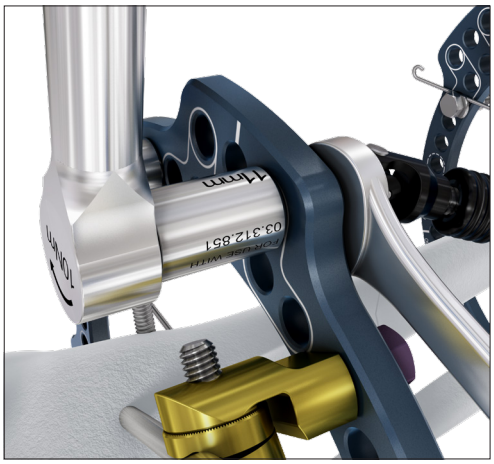
Precaution: If counter-torque is not provided the force of the 10 Nm Torque Wrench could damage the strut.

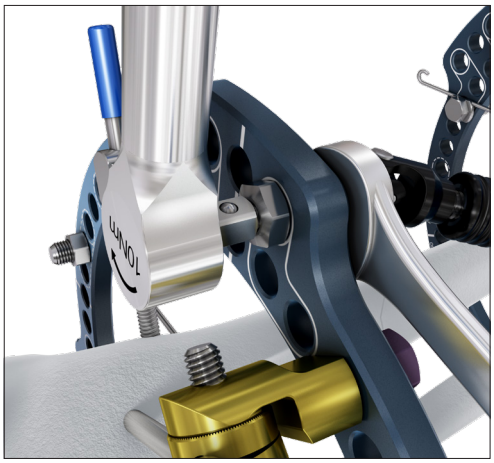
Using the 10 Nm Torque Wrench, tighten the shoulder bolt until you feel the wrench slip, indicating it has reached the appropriate torque. Ensure that the wrench is fully seated.

Notes:

- **If there is not enough room to place the 11 mm socket of the 10 Nm Torque Wrench, remove the socket on the torque wrench to expose a 5 mm hex that mates with the internal recess on the head of the shoulder bolt.**
- **Remember that the end of the strut with the threaded rod will rotate freely, while the other end will remain locked.**



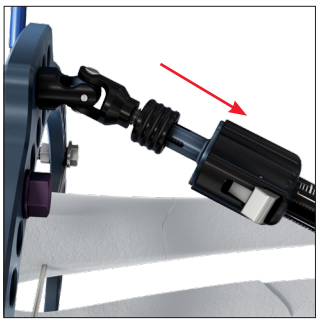


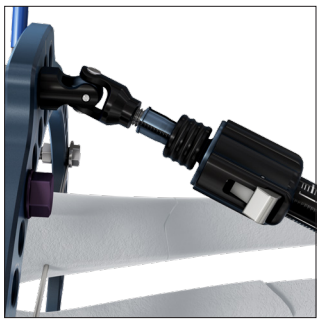


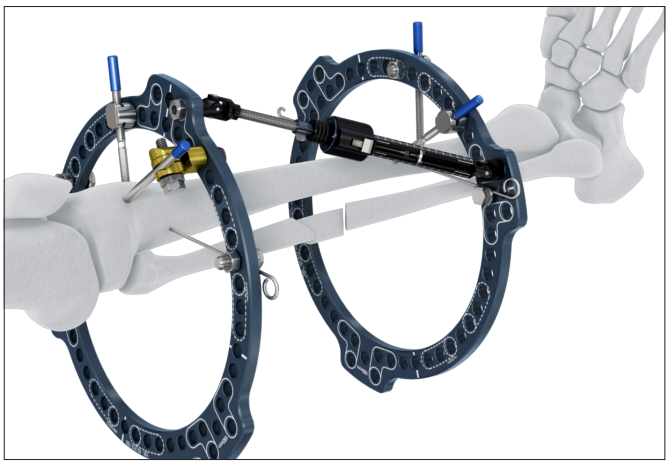
4. Adjust strut length to reach distal ring.

To unlock the strut, pull the QA locking collar until it hits the adjustment knob. The QA strut will telescope freely in this position.

Pull body of QA strut until the strut reaches the distal ring.

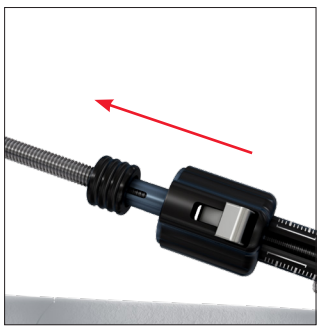






5. Attach QA strut to appropriate hole in the distal ring using a shoulder bolt and finger tighten.

6. Push the QA locking collar to lock the QA strut to length.

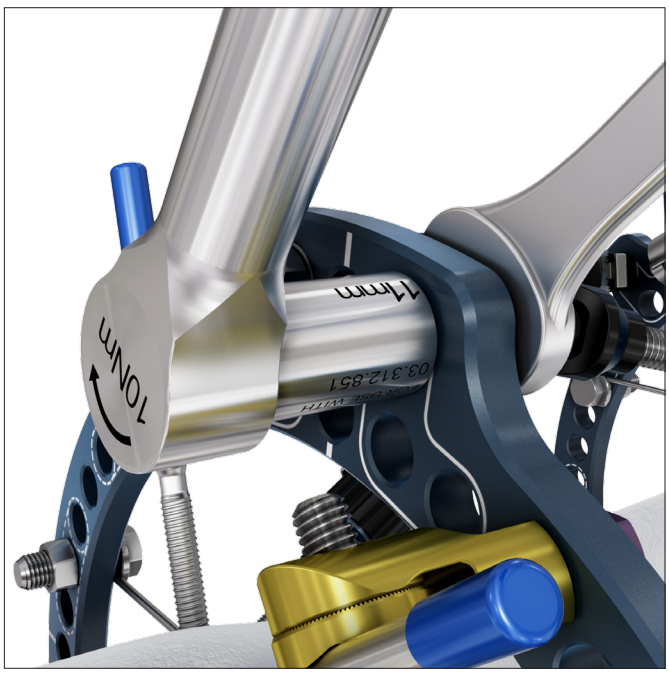


7. Repeat the process of attachment to the ring by way of the shoulder bolts for the remaining five struts.

Record strut lengths.

Note: The Surgeon Planning Worksheet can be utilized to capture this information. See page 57 for more information on the Surgeon Planning Worksheet.

8. Perform final tightening of all shoulder bolts on the proximal ring.



Place the 11 mm end of the 8 mm/11 mm wrench on the flats provided on the end of the spherical hinge to provide counter-torque.

Precaution: If counter-torque is not provided the force of the 10 Nm Torque Wrench could damage the strut.

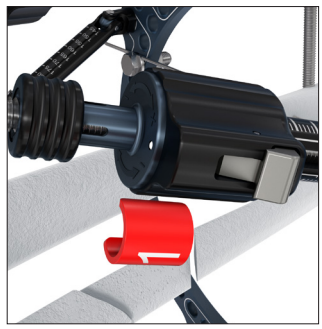
Using the 10 Nm torque wrench, tighten the shoulder bolt until you feel the wrench slip, indicating it has reached the appropriate torque.

Install ID Bands and Plugs

ID Bands and Plugs help a patient and surgeon identify each strut for ease in carrying out the treatment plan developed by the MAXFRAME Software.

Designate the master tab on the reference ring by placing struts 1 and 2 in that location (ring mount or tab mount) with strut 1 on the left from a surgeon's perspective. Continue the numbering scheme counter-clockwise, looking at the frame from proximal to distal. See example on the next page.

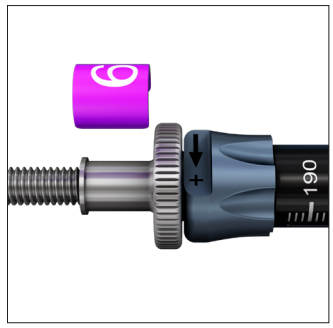
When **ID Bands** are used on QA struts they are placed between the adjustment knob and the Quick Adjust locking collar.

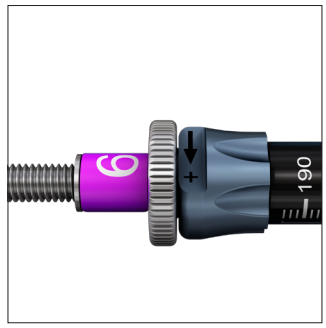


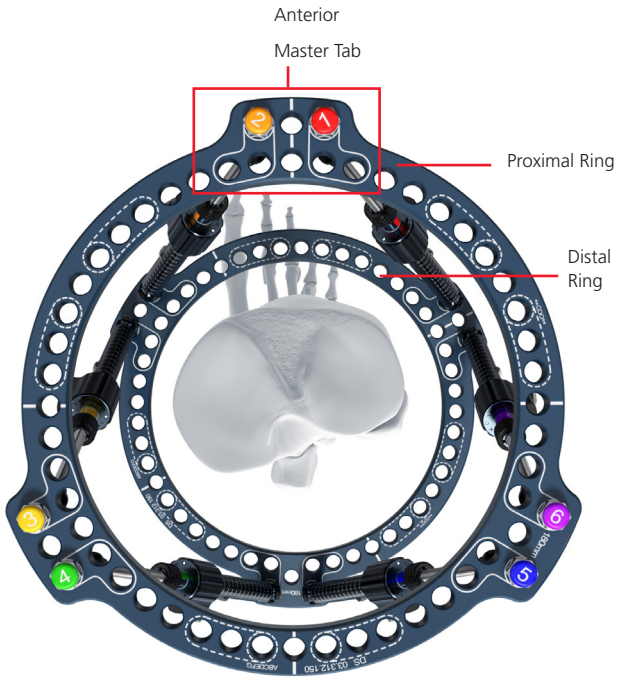
Warning: If using the Quick Adjust struts, you must use the ID Bands to prevent inadvertent unlocking of the Quick Adjust locking collar.

When ID Bands are used on Standard Struts, they are placed above the locking collar.

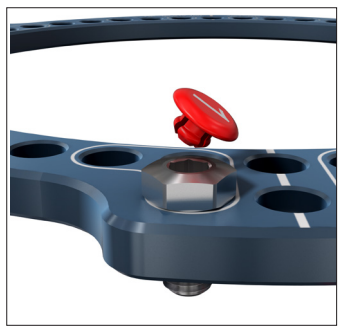
Press until fully wrapped around the strut.





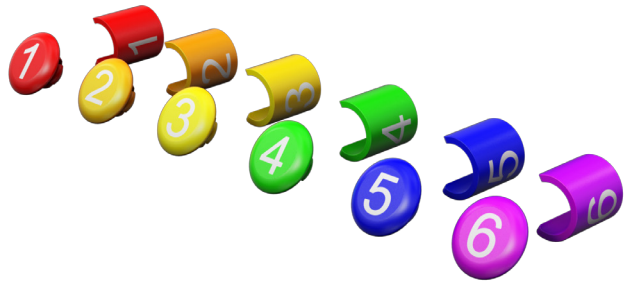


Optional: Insert the **ID Plug** into the hex recess of the shoulder bolt on the proximal ring, for ease of visualization by the patient. Ensure that the ID plug is pressed fully into hex recess of shoulder bolt.



Notes:

- **You are able to use the ID Plugs in addition to the ID Bands if desired.**
- **There is no accommodation for ID bands on the MAXFRAME Standard Strut XX Short (03.312.814). Only ID Plugs are used to identify this strut.**

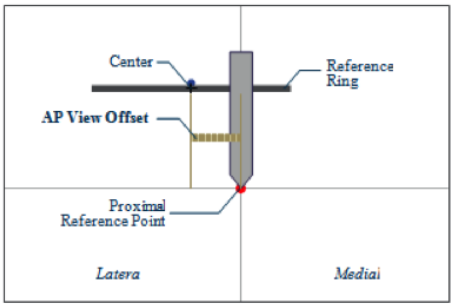


Imaging

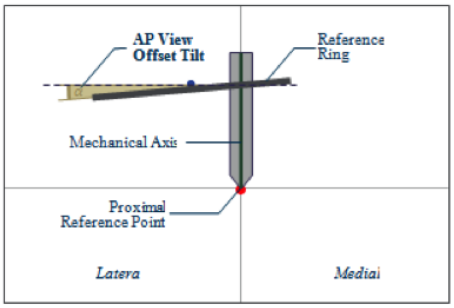
- Postoperative images are required.
- When utilizing the Standard Planning Method in the MAXFRAME Software, AP and lateral images of the reference ring on edge are required to calculate mounting parameters.
- When utilizing the Perspective Frame Matching Planning Method in the MAXFRAME Software, the calculation of mounting parameters is not necessary.

The Mounting Parameters describe the position of the frame with respect to the Proximal Reference Point. The following six Mounting Parameters will be used in the MAXFRAME Software.

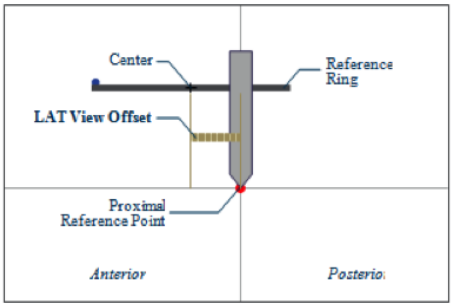
1) AP View Offset



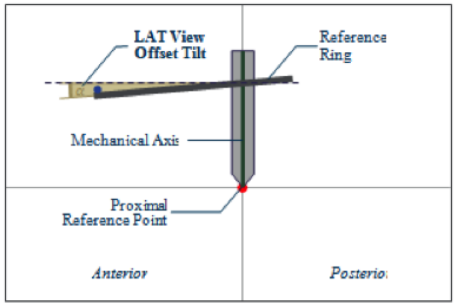
2) AP View Offset – Tilted



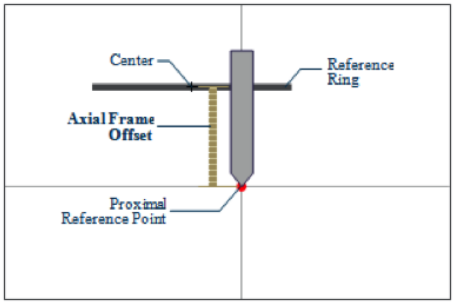
3) LAT View Offset



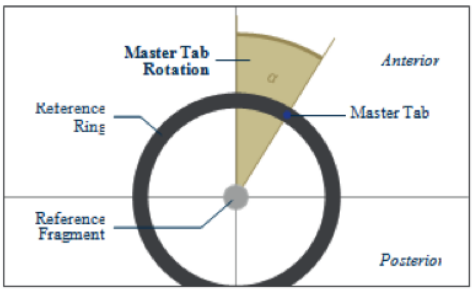
4) LAT View Offset – Tilted



5) LAT View – Axial Offset



6) LAT View Offset – Master Tab Rotation



Please see the Software User's Manual for additional details and description.

Radiographic Markers

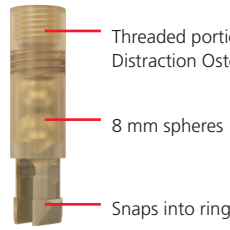
Radiographic markers are used to aid the surgeon in calculation of Mounting Parameters in the Standard Method. They radiographically identify the center of the reference ring for purposes of measuring the six Mounting Parameters listed on the previous page.

Use the radiographic markers in pairs. Insert them directly opposite one another, in the appropriate holes of the ring or foot plate to indicate the center (depending on the AP or lateral view).

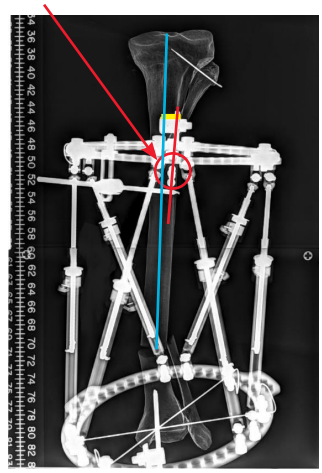
The x-ray is taken with the radiographic markers aligned vertically in the image to properly facilitate measurements. On the right, see an example of measuring the AP View Offset and the LAT View Offset using the Radiographic Markers.

Notes:

- **The top portion of the radiographic marker accepts threads. This allows placement of the radiographic marker onto any Distraction Osteogenesis hardware that has threads exposed.**
- **Radiographic markers are single use only. The radiographic markers have been evaluated for use after being subjected to 20 clinical reprocessing cycles.**

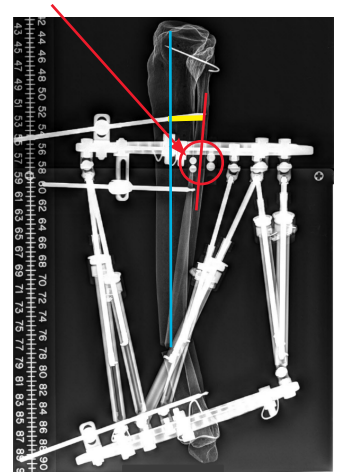


Radiographic marker



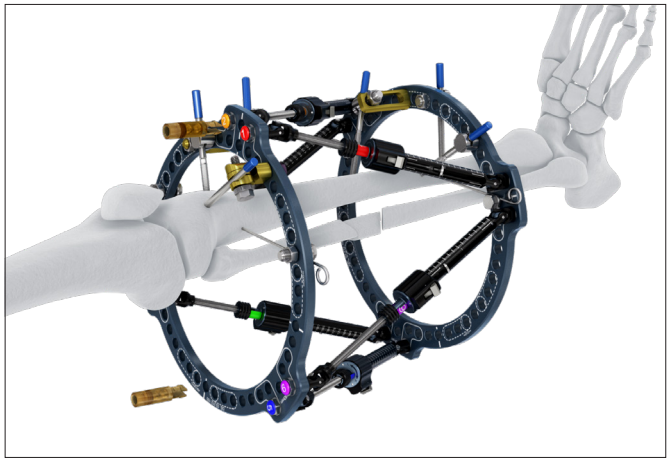
AP View Offset (yellow)

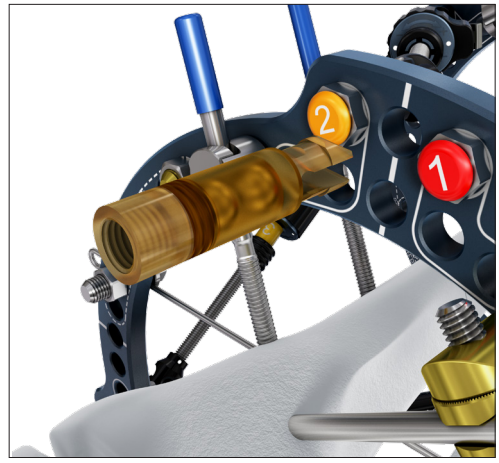
Radiographic marker



LAT View Offset (yellow)

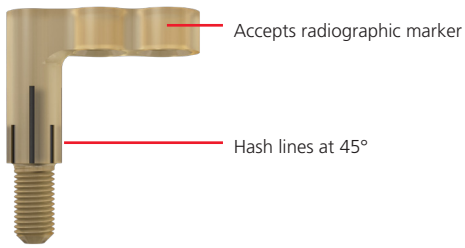
Please see the Software User's Manual for additional details and description.





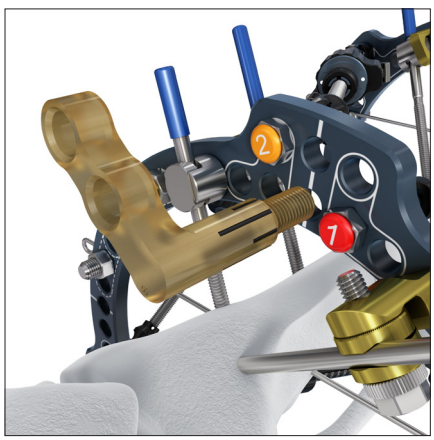
Vertical Mount for Radiographic Marker

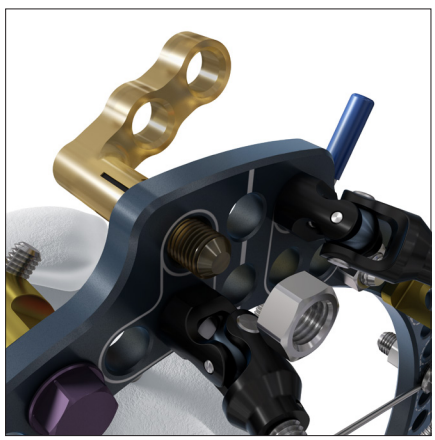
There are instances when MAXFRAME Hardware already occupies the hole to be marked on the reference ring, preventing placement of a radiographic marker. In those instances, place a vertical mount for radiographic marker into an adjacent hole on the ring. Thread a nut on the opposite side of the ring and finger tighten.

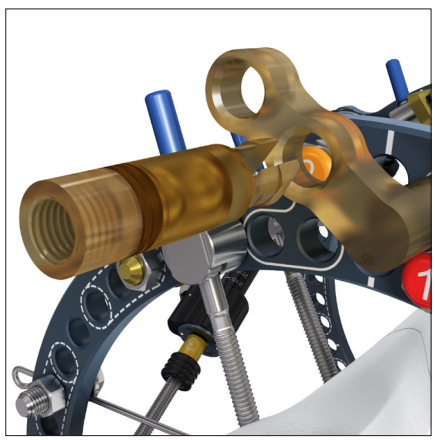


Next, place a radiographic marker in one of the holes in the top portion of the vertical mount for radiographic marker. The vertical mount for radiographic marker can fully rotate to gain proper alignment of the radiographic marker.

Note: Vertical mounts for radiographic markers are single use only.







Surgeon Planning Worksheet

The Surgeon Planning Worksheet can be utilized to keep track of the necessary inputs for use in the MAXFRAME Software. See the Software User's Manual for full instructions on the use of the software.

DePuy Synthes

Surgeon:

PATIENT INFORMATION:

Patient ID

Treatment Plan Title

Surgery Date

CASE INFORMATION:

PFM Operating Bone

Standard Left Right

AID Reference Ring /Master Tab on

Proximal Distal

DEFORMITY PARAMETERS:

AP VIEW:
Translation mm
Lateral Medial
Coronal Angulation deg
Valgus Varus

LAT VIEW:
Translation mm
Anterior Posterior
Sagittal Angulation deg
Apex-Anterior Apex-Posterior

Bone Length mm
Too Long Too Short
Clinical Rotation Deformity deg
Internal External

RING CONFIGURATION:

Proximal Ring:
Full 5/8
Proximal Ring Diameter mm
If applicable, Ring Opening between:
Strut AND Strut

Distal Ring:
Full 5/8 Footplate-S / L
Distal Ring Diameter mm
If applicable, Ring Opening between:
Strut AND Strut

Ring Types and Diameters:
Full: 90, 120, 150, 180, 210, 240, 270mm
5/8: 90, 120, 150, 180, 210, 240mm
Foot plate: 120, 150, 180, 210mm
Short and Long

STRUT CONFIGURATION:

	Strut Type Quick Adjust/ Standard	Strut Size Std: XXS/XS/S/M/L QA: XS/S/M/L	Initial Strut Length	Final Strut Length (AID)	Proximal and Distal Non-Default Mounting Points
Strut 1:	QA Std		mm	mm	*Please Refer to the Other Side of this Worksheet to Mark Non-Default Mounting Points*
Strut 2:	QA Std		mm	mm	
Strut 3:	QA Std		mm	mm	
Strut 4:	QA Std		mm	mm	
Strut 5:	QA Std		mm	mm	
Strut 6:	QA Std		mm	mm	

MOUNTING PARAMETERS:

The Center of the Reference Ring is:

AP VIEW OFFSET:
mm Lateral Medial
- to Reference Point
Tilted deg
Lateral Side Tilted:
Proximal Distal

LAT VIEW OFFSET:
mm Anterior Posterior
- to Reference Point
Tilted deg
Anterior Side Tilted:
Proximal Distal

AXIAL OFFSET:
mm Proximal Distal
- to Reference Point
Master Tab Rotation deg
Internal External

LOCATION OF CONCERN:

AP View Offset mm
Lateral Medial
LAT View Offset mm
Anterior Posterior
Axial Offset is mm
Proximal Distal
- to the Reference Point

IMAGES:

AP Image Taken From:
Anterior Posterior
LAT Image Taken From:
Lateral Medial
Image Info:

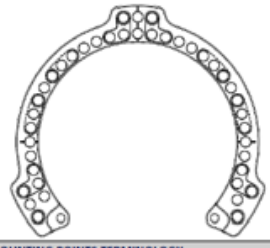
NOTES:

Please Mark the Non-Default Mounting Points

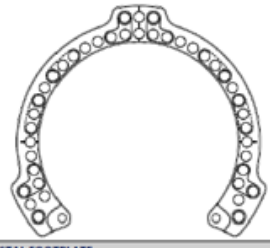
PROXIMAL FULL RING:

DISTAL FULL RING:

PROXIMAL 5/8 RING:



DISTAL 5/8 RING:



MOUNTING POINTS TERMINOLOGY:

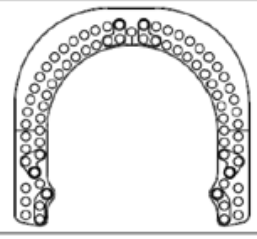
Standard Default Mounting Points: Holes identified by a solid circle *on the tabs*.

Standard Non-Default Mounting Points: Holes identified within a solid line perimeter, one or two holes away from Standard Default.

Non-Standard Default Mounting Points: Holes identified by a dashed circle *between the tabs*.

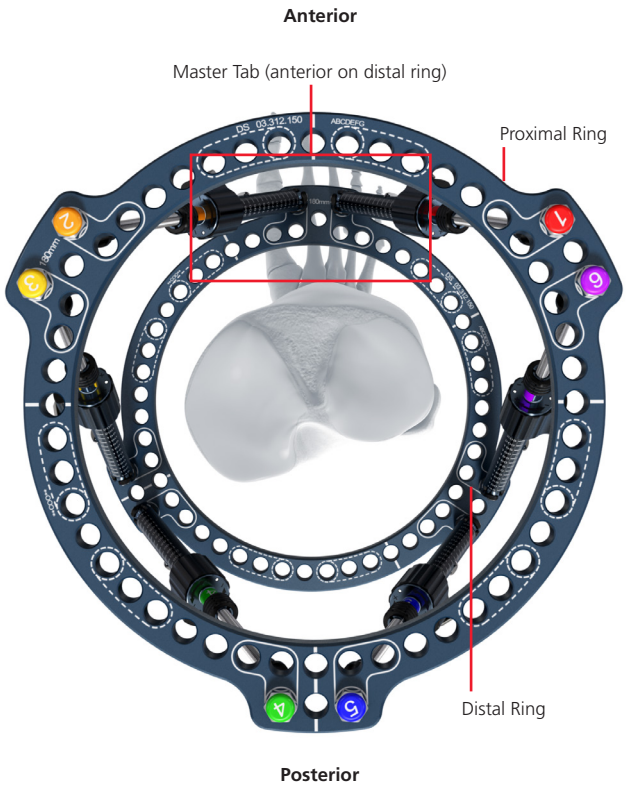
Non-Standard Non-Default Mounting Points: Holes identified within a dashed line perimeter, one or two holes away from Non-Standard Default.

DISTAL FOOTPLATE:



Distal Referencing

There are clinical situations when it will be necessary to have a distal reference ring, such as with a distal tibia fracture. In the situation below, the master tab is the anterior hole location (tab mount) on the distal ring. Strut 1 is always designated as the one on the left from a surgeon's perspective. The numbering scheme continues counter-clockwise when looking at the frame from proximal to distal.



Converting Reference Rings Postoperatively

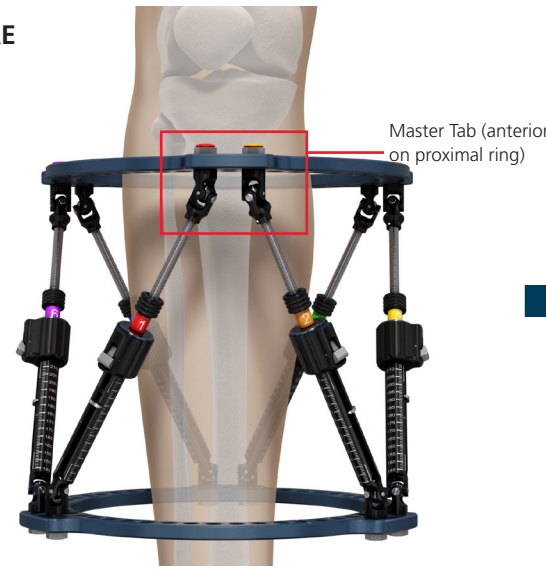
If a frame has been mounted with a proximal reference ring, but a need arises postoperatively to convert it to a distal reference ring in the MAXFRAME Software, you are required to re-label the struts.

Note: Physical movement of the struts is not required.

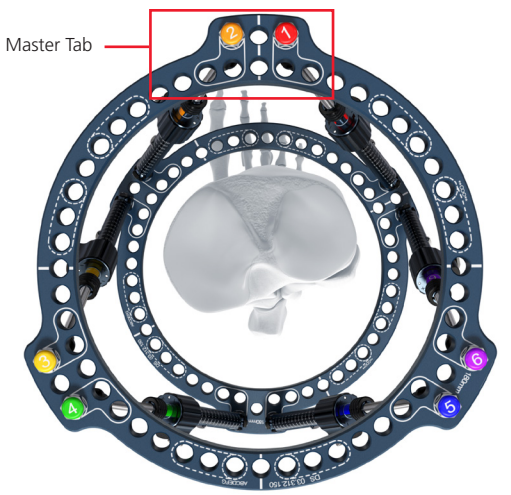
Remove the ID Bands and/or ID Plugs. Choose a ring location (ring mount or tab mount) to designate the master tab on the new reference ring.

One option is to use the tab mount located directly posterior, for ease of conversion in the software, because the master tab rotation in the MAXFRAME Software will then be 180° (with no directionality). Replace the ID Bands and/or ID Plugs following the numbering scheme shown below.

BEFORE

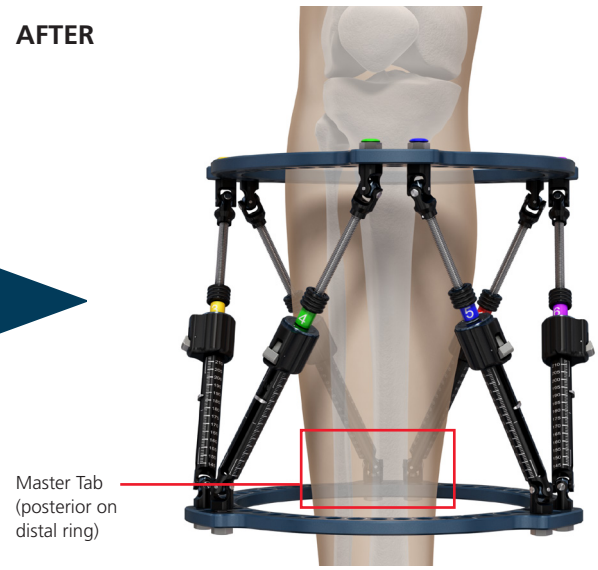


Anterior

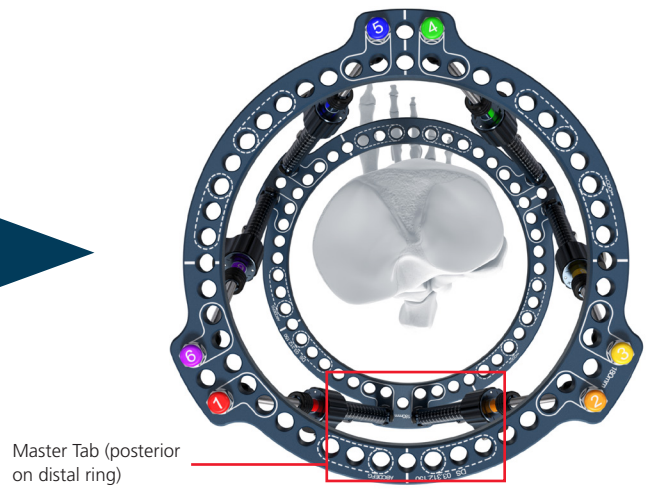


Posterior

AFTER



Anterior

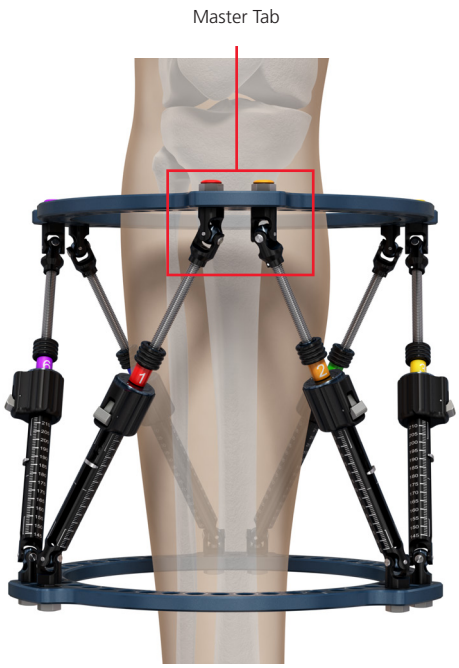


Posterior

Common Strut Configurations

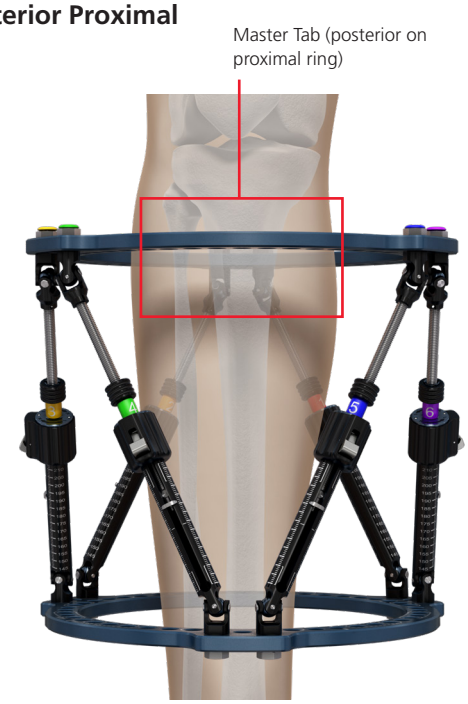
Below see some common strut numbering conventions.

Anterior Proximal

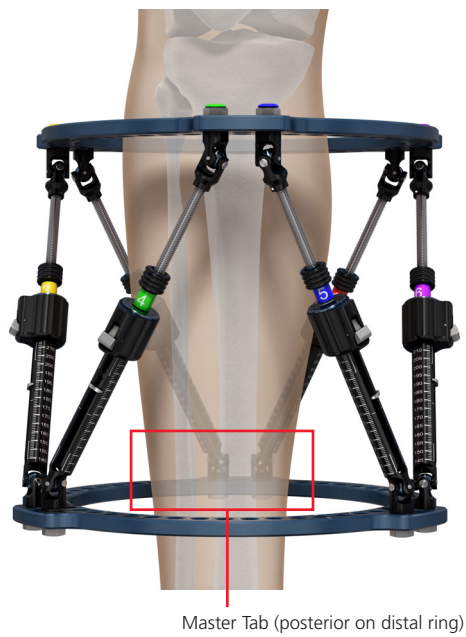


Anterior Distal

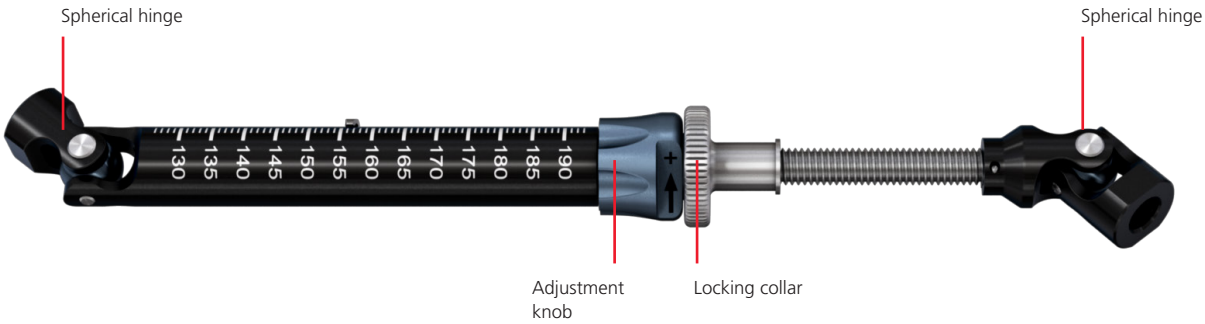
Posterior Proximal



Posterior Distal



Standard Strut



A surgeon could choose to use the Standard Strut instead of a Quick Adjust strut to connect the rings. Additionally, a frame could be built that uses both Standard and Quick Adjust struts. Orient all struts so that the length indicator is visible to the patient when attaching a strut.

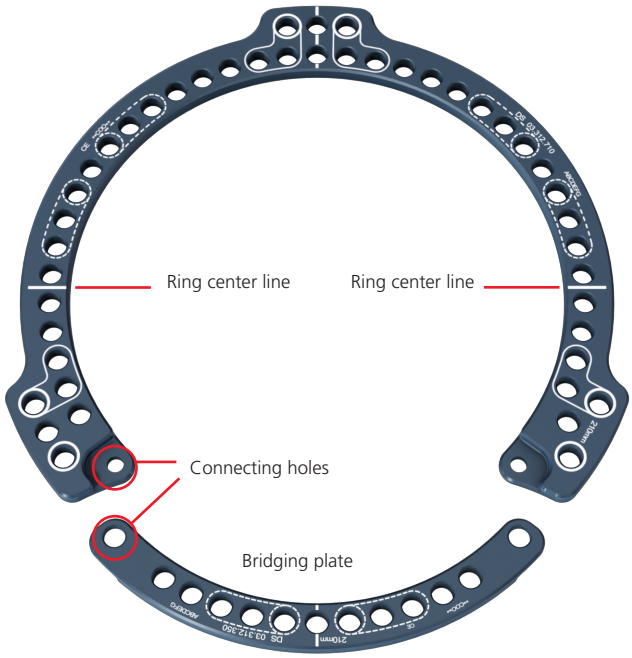
To adjust the length of the Standard Strut, turn the locking collar until it reaches the top of the threaded portion of the strut, or is sufficiently out of the way.

Next, turn the adjustment knob in the appropriate direction until the desired length of the strut is reached. To lock the Standard Strut to length, turn the locking collar until it is in direct contact with the adjustment knob.

5/8 Ring and Bridging Plate

Certain clinical situations will call for the use of a 5/8 ring. The 5/8 rings can be utilized with or without the bridging plate. If using a bridging plate, select the appropriate size to match the 5/8 ring.

Note: The 90 mm and 120 mm 5/8 rings do not have corresponding bridging plates. In those situations, surgeons can choose to utilize threaded rods and wire posts to close off the 5/8 ring.



Connecting holes.
Use only for connecting the bridging plate to 5/8 ring. Do not place struts in connecting holes.

To connect the 5/8 ring to the bridging plate, align the connecting holes on the end of the bridging plate with the corresponding connecting holes on the 5/8 ring and attach with connecting bolts (03.311.055). The bridging plate should sit flat within the shallow pockets on the 5/8 ring.

Tighten the connecting bolts with the 8 mm/11 mm or ratchet wrench.

Note: If using a bridging plate to close the 5/8 ring, ensure the connecting holes are free of interfering hardware.

Precaution: If using a bridging plate to close a 5/8 rings, do not tension any wires until after the 5/8 ring and bridging plate have been connected, otherwise the tension can deform the ring such that the bridging plate will no longer fit.

Once complete double check tightness of all connections.

Frame Assembly – Off-Patient

In situations of highly complex deformities it may be helpful to pre-assemble the frame on the back table of the OR. Frame pre-assembly may help with postoperative care of the patient by potentially minimizing strut changes during the treatment phase.

It is recommended to lock the struts while attaching to rings during assembly of the frame off the patient.

Once constructed, the struts can be placed in the unlocked position in order to optimize position on the patient.

Tips

Implant Site Care

Implant sites should be cared for meticulously to avoid infection. Consideration should be given to release of the skin at the conclusion of the procedure. An implant site care program should be reviewed with the patient.

Preparation

Required Set	
01.312.000	MAXFRAME™ System Complete Set
01.313.000	MAXFRAME™ Static/Linear Complete Set

The modular nature of the MAXFRAME Multi-Axial Correction System allows for surgeons to build and mount frames in a variety of ways. The technique outlined below describes one method of building a frame off the patient using linear struts. If building the frame on a patient, please refer to page 16 for the surgical technique of building a Proximal Tibia frame or page 80 for the surgical technique of building a foot frame.

Warning: The linear struts are not intended for use with the MAXFRAME Software.

Ring Selection

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

Note: The contralateral limb may be used for measurement purposes in instances where the affected limb is inaccessible.

Attach Struts

Part Numbers	
03.313.872	MAXFRAME Linear Strut/Long (175-277 mm)
03.313.871	MAXFRAME Linear Strut/Medium (129-185 mm)
03.313.870	MAXFRAME Linear Strut/Short (107-139 mm)

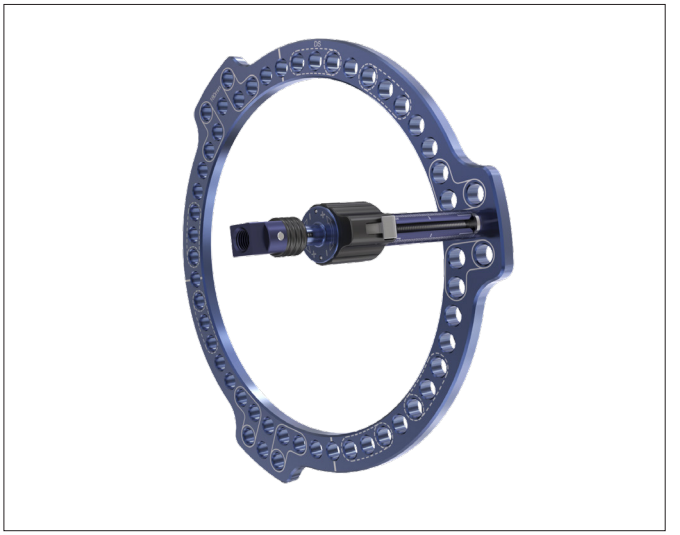
1. Choose appropriate strut type and length

The use of Linear Struts is outlined below. See page 47 for information on the use of Quick Adjust (QA) struts and page 61 for information on the use of Standard Struts and page 72 for information on the use of Polyaxial struts.

A minimum of 4 linear struts must be used per frame.

2. Orient the strut so that the length indicator is visible to the patient when attaching a strut.

It is recommended to place all struts in the same orientation (e.g., all of the adjustment knobs toward the distal ring) for ease of strut adjustments postoperatively.



3. Attach the Struts to Rings

Part Numbers	
03.311.056	Connection Bolt, Long
03.311.004	Ratchet wrench 11 mm
Optional Instruments	
03.313.884	MAXFRAME Linear Strut Bolt
03.311.090	Spherical Washer Couple
03.311.007	8 mm/11 mm wrench
03.312.851	10 Nm torque wrench

Align the linear strut with the intended hole on the proximal ring. Linear struts can be installed on any hole in the ring to create a stable construct.

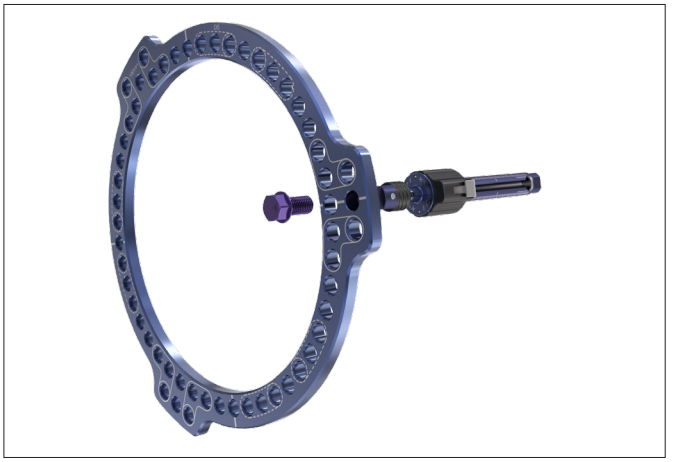
Thread the long connection bolt into the Linear strut through the hole in the ring.

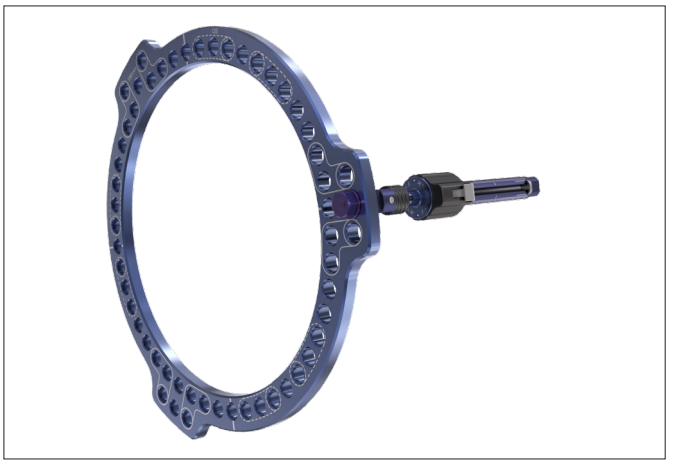
Note: If using the spherical washer couple, use the Linear Strut Bolt.

Place an 11 mm wrench on the flats at the end of the strut to provide counter-torque.

Precaution: If counter-torque is not provided, the torque could damage the strut.

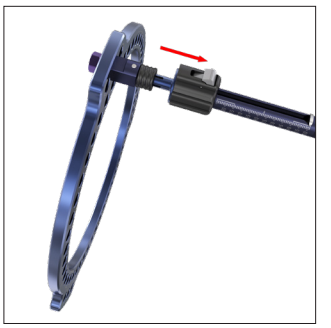
Using the 10 Nm torque wrench, tighten the bolt.

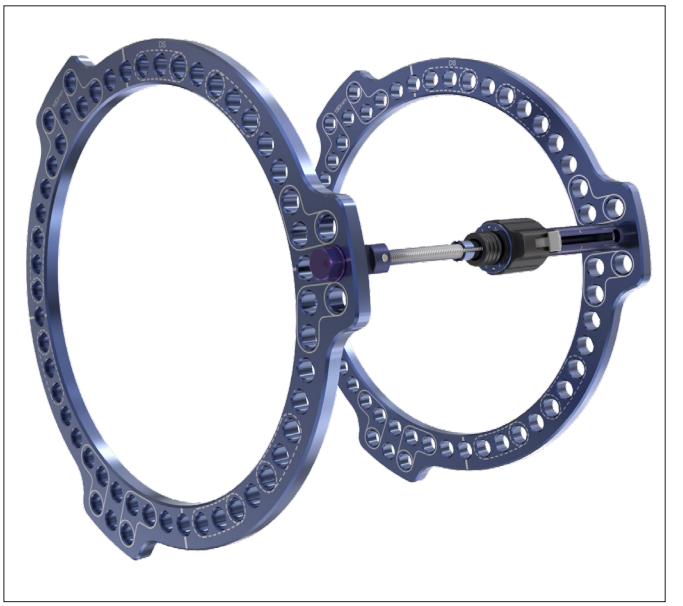




4. Adjust the strut length to reach the distal ring.

To unlock the strut, pull the locking collar until it hits the adjustment knob. The strut will telescope freely in this position. Pull body of the strut until the strut reaches the distal ring. The distance between the mounted rings must

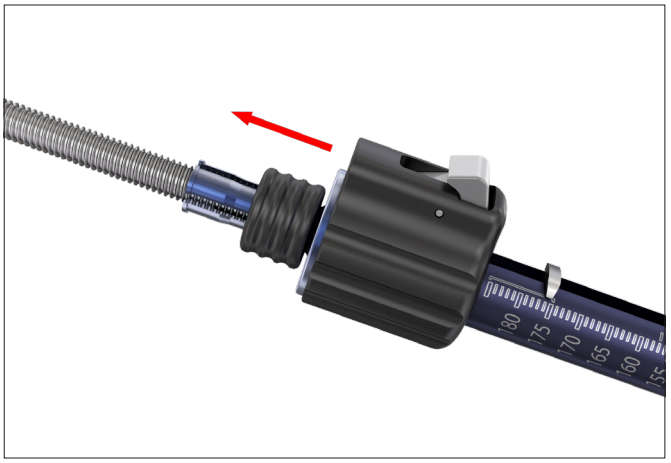




accommodate the strut sizes used.

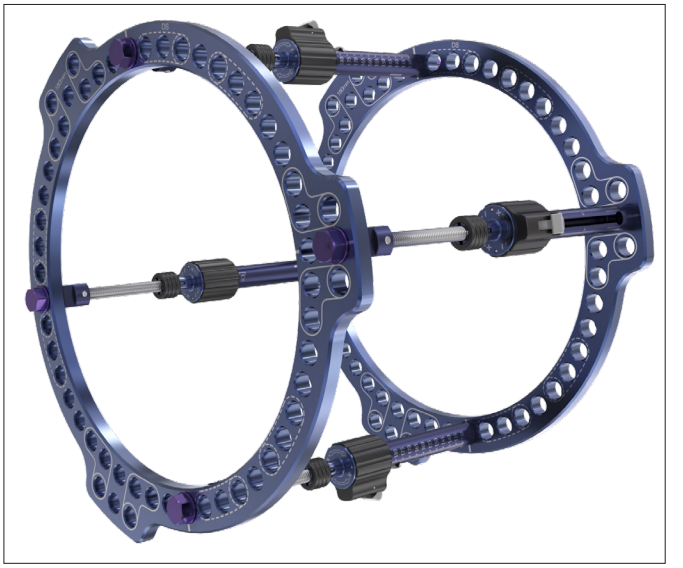
5. Attach the linear strut to the appropriate hole in the distal ring using a long connection bolt, 03.311.056, and finger tighten.

6. Push the locking collar to lock the strut to length.



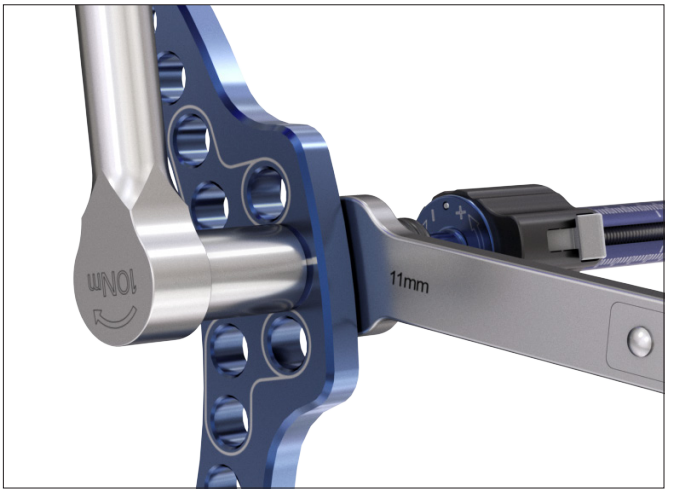
7. Repeat the process of attachment to the ring for the remaining 3 struts (4 total struts).

Struts should be distributed as evenly as possible around the circumference of the ring to create a stable construct.



8. Perform final tightening of all bolts on the proximal ring.

Prior to completing frame construction, confirm construct is stable.



9. If prebuilding the frame, place on patient.

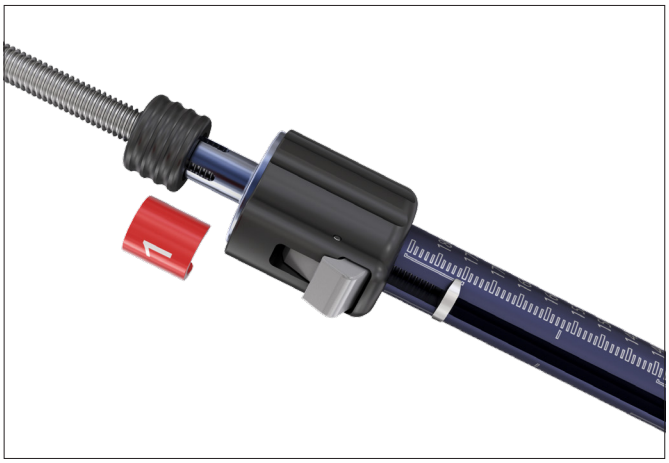
If needed, utilize the outlined technique starting on page 15 as a guide.

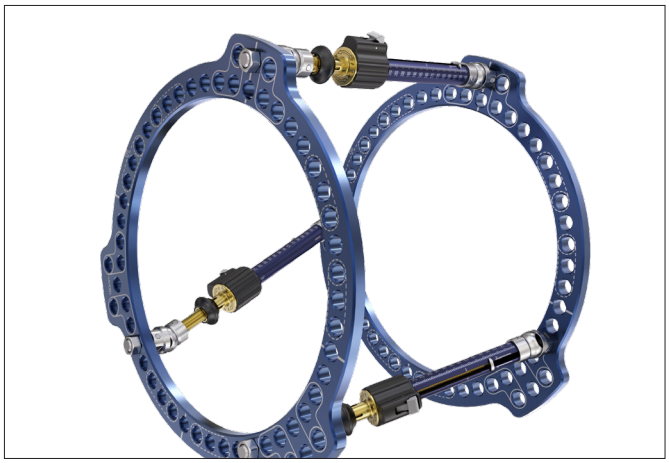
Linear struts move ¼ mm per adjustment click.

10. Install ID Bands to prevent the locking collar from moving postoperatively.

Part Numbers	
03.312.820	MAXFRAME™ Strut ID band set

See page 52 for more information on ID Bands.





Preparation

Required Set	
01.312.000	MAXFRAME™ System Complete Set
01.313.000	MAXFRAME™ System Static/Linear Complete Set

The modular nature of the MAXFRAME Multi-Axial Correction System allows for surgeons to build and mount frames in a variety of ways. The technique outlined below describes one method of building a frame off the patient using polyaxial struts. If building the frame on a patient, please refer to page 16 for the surgical technique of building a Proximal Tibia frame or page 80 for the surgical technique of building a foot frame.

Warning: The polyaxial struts are not intended for use with the MAXFRAME Software.

Ring Selection

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

Note: The contralateral limb may be used for measurement purposes in instances where the affected limb is inaccessible.

Attach Struts

Part Numbers	
MAXFRAME Polyaxial Struts Gross Adjust	
03.313.877	Polyaxial Struts Gross Adjust/Long (173-310 mm) 137 mm travel
03.313.876	Polyaxial Struts Gross Adjust/Medium (109-181 mm) 72 mm travel
03.313.875	Polyaxial Struts Gross Adjust/Short (77-117 mm) 40 mm travel
03.313.874	Polyaxial Struts Gross Adjust/X-Short (60-84 mm) 24 mm travel
03.313.873	Polyaxial Struts Gross Adjust/XX-Short (48-60 mm) 12 mm travel
MaxFrame Polyaxial Struts Fine and Gross Adjust	
03.313.881	Polyaxial Struts Fine and Gross Adjust/Long (199-323 mm) 124 mm travel
03.313.880	Polyaxial Struts Fine and Gross Adjust/Long Medium (144-214 mm) 70 mm travel
03.313.879	Polyaxial Struts Fine and Gross Adjust/Long Short (117-159 mm) 42 mm travel
03.313.878	Polyaxial Struts Fine and Gross Adjust / Long X-Short (103-132 mm) 29 mm travel

1. Choose appropriate strut type and length.

The use of polyaxial struts is outlined below. See page 47 for information on the use of Quick Adjust (QA) struts, page 61 for information on the use of Standard Struts and page 65 for the use of linear struts.

A minimum of 3 polyaxial struts must be used per frame.

2. Attach the Struts to Rings

Part Numbers	
03.311.061	11 mm Nut
03.311.004	Ratchet wrench 11 mm
Optional Instruments	
03.311.090	Spherical Washer Couple
03.311.007	8 mm/11 mm wrench
03.312.851	10 Nm torque wrench

Align the polyaxial strut with the intended hole on the proximal ring. Polyaxial struts can be installed on any hole in the ring to create a stable construct.

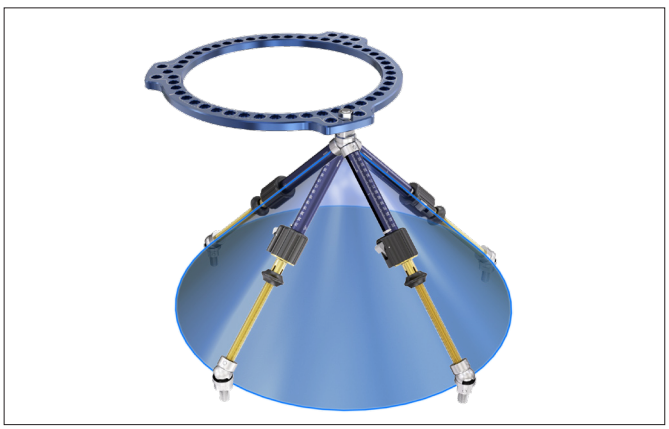
Use an 11 mm nut, 03.311.061, to attach the polyaxial strut to the ring.

Place an 11 mm wrench on the flats at the end of the strut to provide counter-torque.

Precaution: If counter-torque is not provided the torque could damage the strut.

Using an 11 mm wrench, tighten the nut.

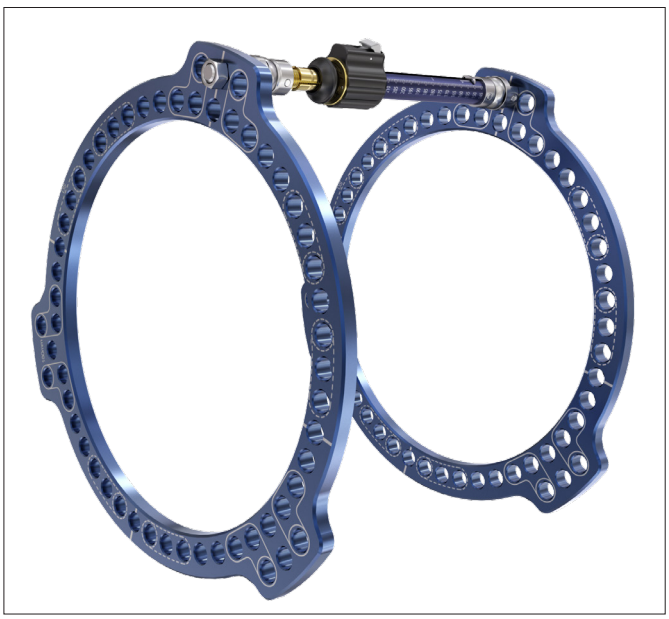
If more than 45 degree angulation is desired, the strut can be attached to a wire post.



3. Adjust the strut length to reach the distal ring.

To unlock the fine and gross adjust strut, pull the locking collar until it hits the adjustment knob. The fine and gross adjust strut will telescope freely in this position. Pull body of the strut until the strut reaches the distal ring.

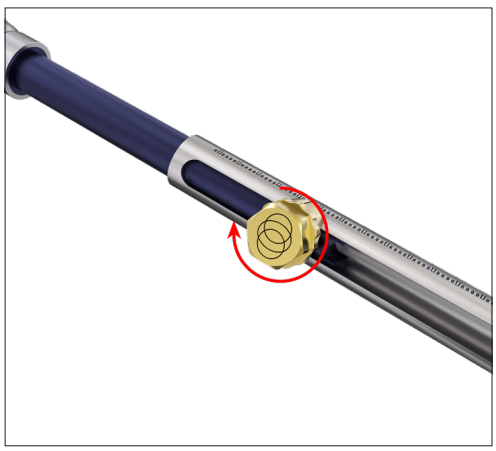
To unlock the gross adjust strut, twist the adjustment bolt open and the strut will telescope freely in this position. Pull the body of the strut until the strut reaches the distal ring.



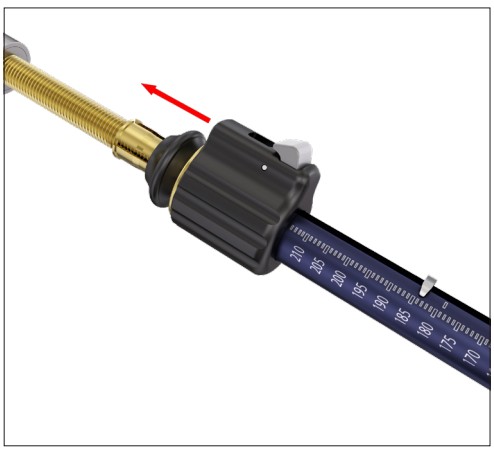
4. Attach the polyaxial strut to the appropriate hole in the distal ring using an 11 mm nut, 03.311.061, and finger tighten.

5. Lock the strut to length.

For gross adjust-struts, tighten the adjustment bolt to lock the strut length. For fine and gross adjust struts, push the locking collar to lock the strut to length.



Gross Adjust



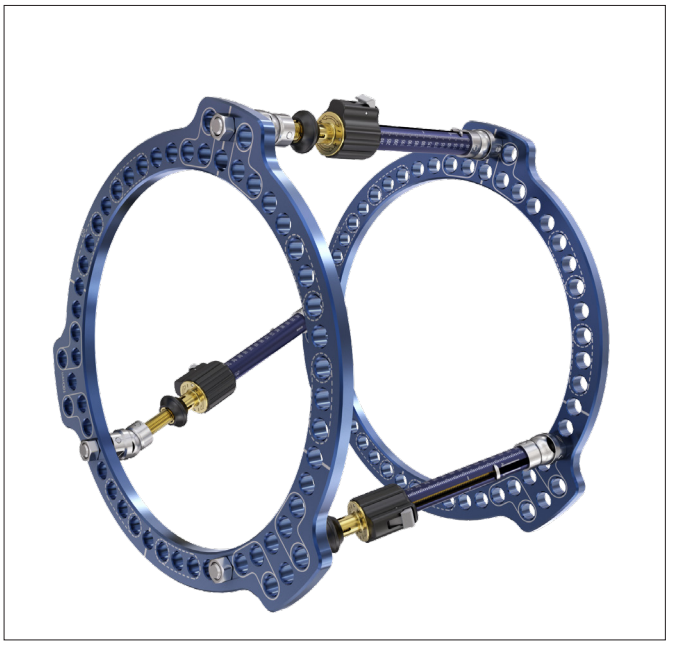
Fine and Gross Adjust

6. Repeat the process of attachment to the ring for the remaining 2 struts (3 total struts minimum based on construct stability).

Struts should be distributed as evenly as possible around the circumference of the ring to create a stable construct. Additional Struts may be used, as needed, to create a stable construct.

7. Perform final tightening of all nuts on the proximal ring.

Prior to completing frame construction, confirm construct is stable.



8. If prebuilding the frame, place on patient.

If needed, utilize the technique outlined starting on page 15 as a guide.

Polyaxial struts move ¼ mm per adjustment click, with fine adjustment.

9. Install ID Bands on the fine and gross adjust struts to prevent the locking collar from moving postoperatively.

Part Numbers	
03.312.820	MAXFRAME™ Strut ID band set

See page 52 for more information on ID Bands.

Surgical Technique – Foot Frame

Required Set

01.312.000	MAXFRAME/DO System Set

The modular nature of the MAXFRAME Multi-Axial Correction System allows for surgeons to build and mount frames in a variety of ways. The technique outlined below describes one method of building and mounting a foot frame using Quick Adjust struts and wires.

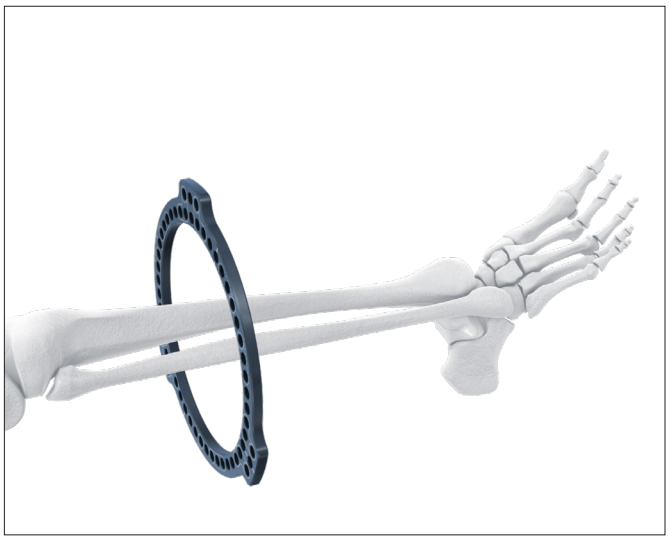
Foot Plate

Instruments

03.312.953	7.0 mm/6.0 mm Drill sleeve / Long
03.311.007	8 mm/11 mm Wrench

Optional Instruments

03.312.954	7.0 mm/6.0 mm Drill sleeve / Extra Long
03.312.950	Ø 3.5 mm Drill Bit
393.105	Small Universal Chuck with T-handle



1. Slide the proximal ring over the affected limb.

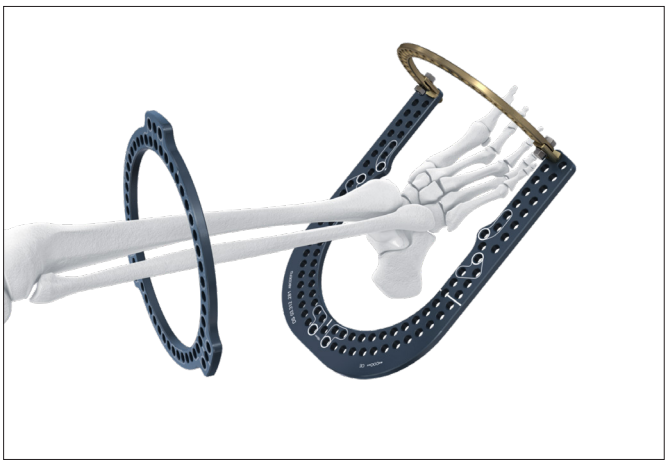
2. Select appropriate size foot plate that allows for at least 2 cm of clearance between the skin and the foot plate.

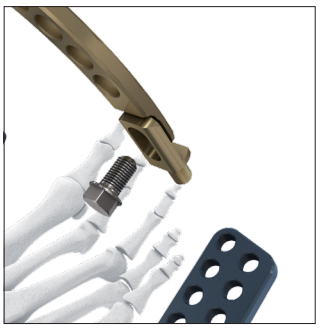
Select corresponding Distraction Osteogenesis half ring (03.311.312, 315, 318, 320) for the chosen foot plate.

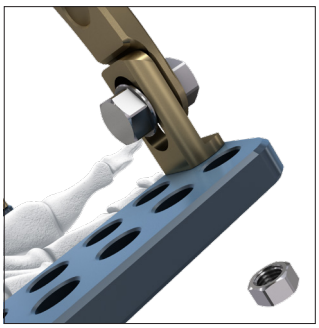
3. Connect the DO half ring to the foot plate with a wire bolt, offset, and nut so that the DO half ring is perpendicular to the foot plate.

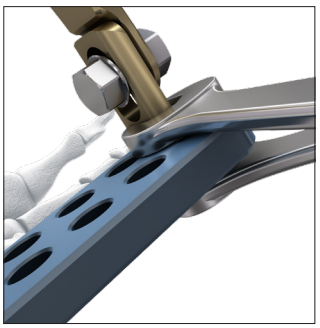
Tighten the wire bolt, offset, and nut with the wrench.

You must use a DO half ring to close off the foot plate prior to insertion and tensioning of wires.



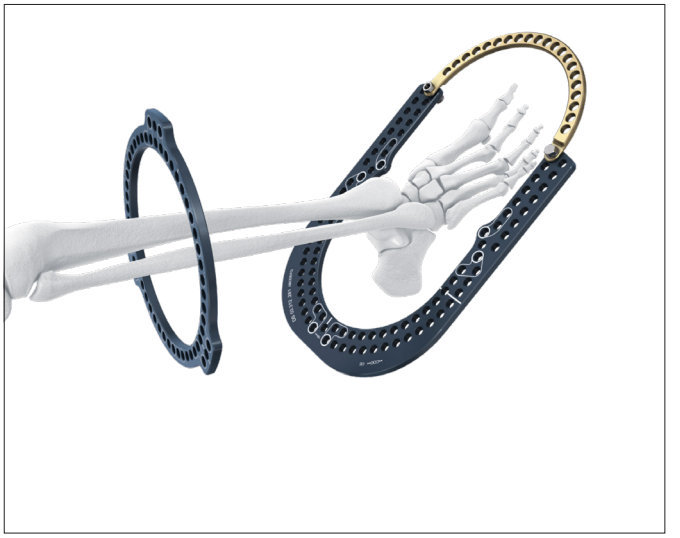






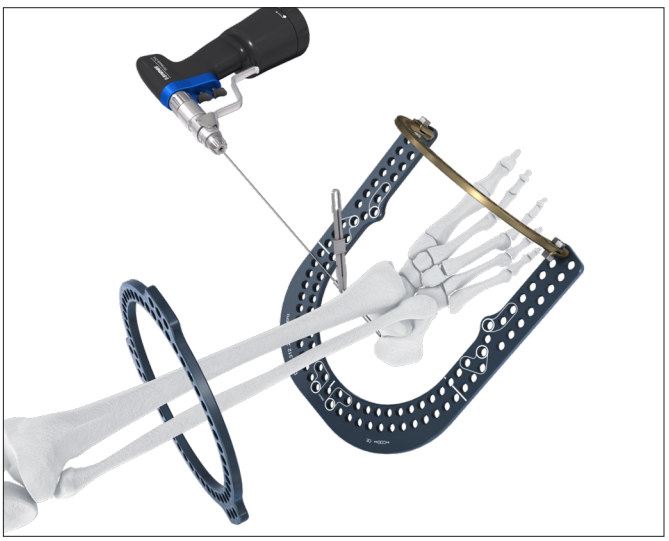
Alternative Technique: Connect the DO half ring to the foot plate using two connecting bolts, long (03.311.056) so that the DO half ring is in the same plane as the foot plate.

Tighten the connection bolts, long with the wrench.

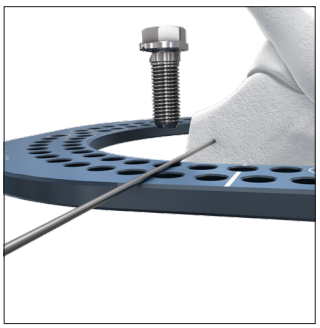
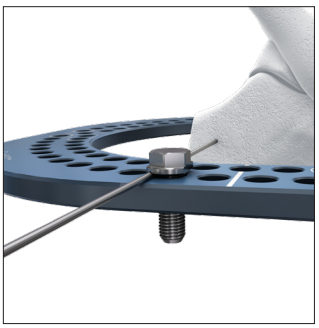
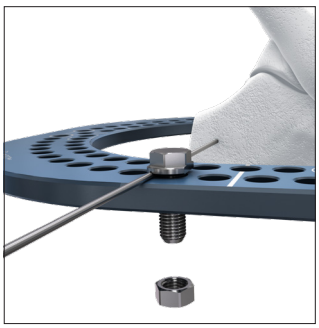
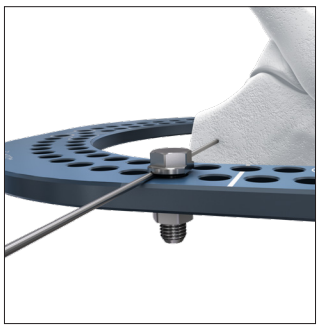


4. Position the foot plate parallel to the plane of the foot, keeping the foot centered.

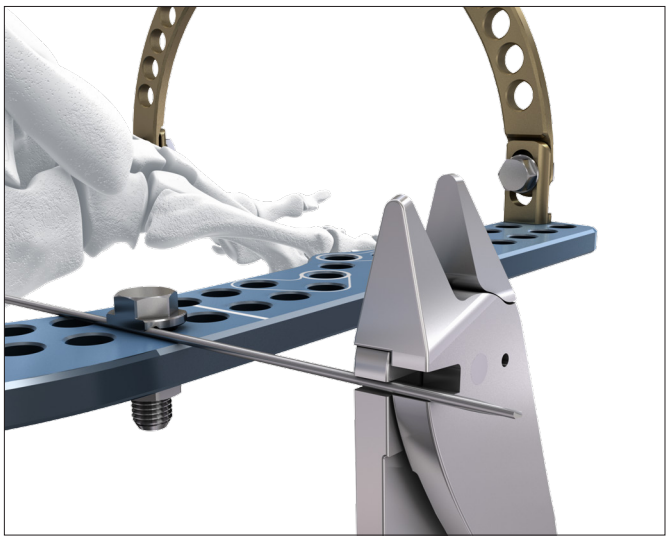
5. Insert wire through the calcaneus in line with the foot plate.

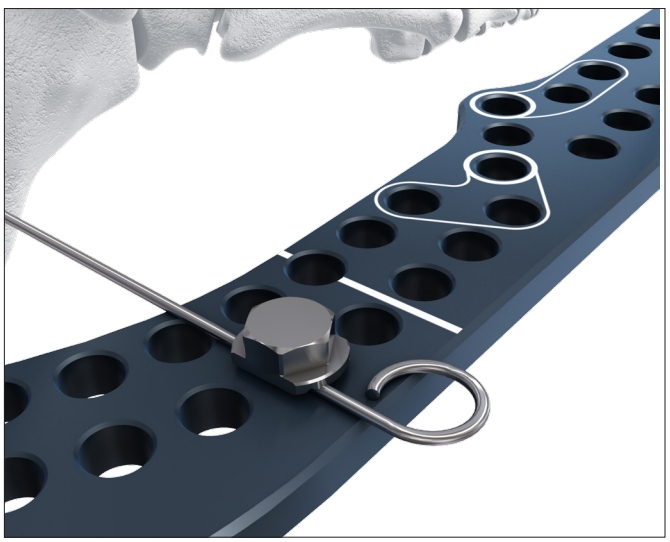


6. Connect the foot plate to the wire using wire bolts and nuts.

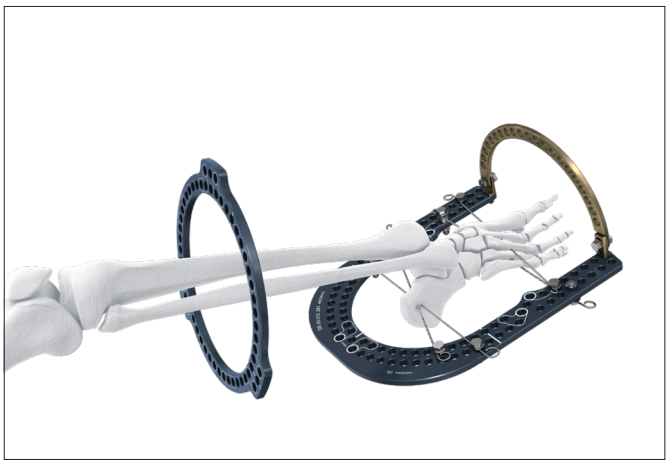






7. Tension, tighten, and cut the wire as previously described starting on page 24.



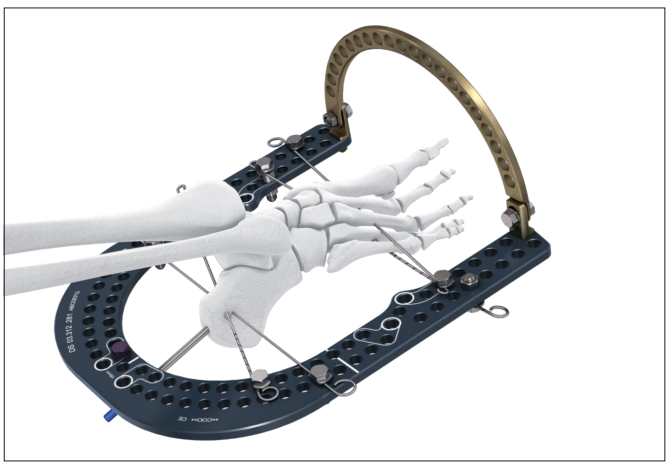


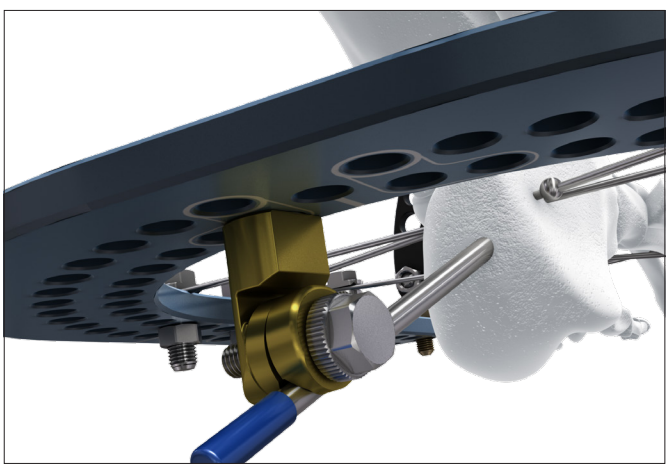
8. Insert additional points of fixation into calcaneus and metatarsals, in the same manner as the first, until a stable construct has been achieved.



Depending on the clinical plan, a Schanz screw in the calcaneus may be indicated.

Consider the use of reduction wires in the foot to prevent translational movement.





Attach Initial Struts

Instruments	
03.311.007	8 mm/11 mm Wrench
03.312.851	10 Nm Torque Wrench

1. Select the longest and shortest strut needed for the construction of the foot frame.

This will help determine the final location of the proximal ring.

2. Attach the longest and shortest struts to the foot plate and the tibia ring following the steps outlined starting on page 47.

Tibia Ring

Instruments	
03.312.953	7.0 mm/6.0 mm Drill sleeve/Long
03.311.007	8 mm/11 mm Wrench
Optional Instruments	
03.312.950	Ø 3.5 mm Drill Bit
03.312.954	7.0 mm/6.0 mm Drill sleeve/Extra Long
393.105	Small Universal Chuck with T-handle

1. Position the tibia ring on the affected limb to a level that can be easily connected to the foot plate according to available strut lengths.

2. Mount the tibia ring to the bone using wires and/or Schanz screws as previously described starting on page 15.

A minimum of three points of fixation is required.

Attach Remaining Struts

Instruments

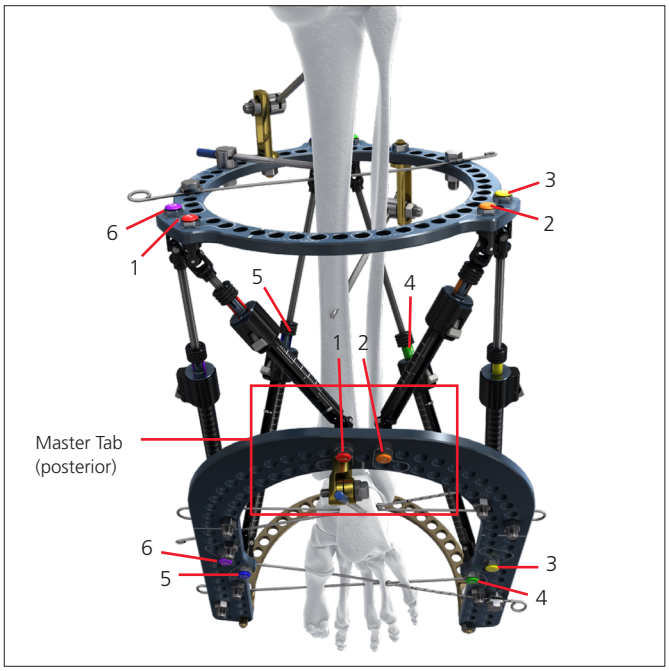
03.311.007	8 mm/11 mm Wrench
03.312.851	10 Nm Torque Wrench

1. Attach remaining struts to both the foot plate and the tibia ring following the steps outlined above.

2. Attach ID Bands and/or ID plugs.

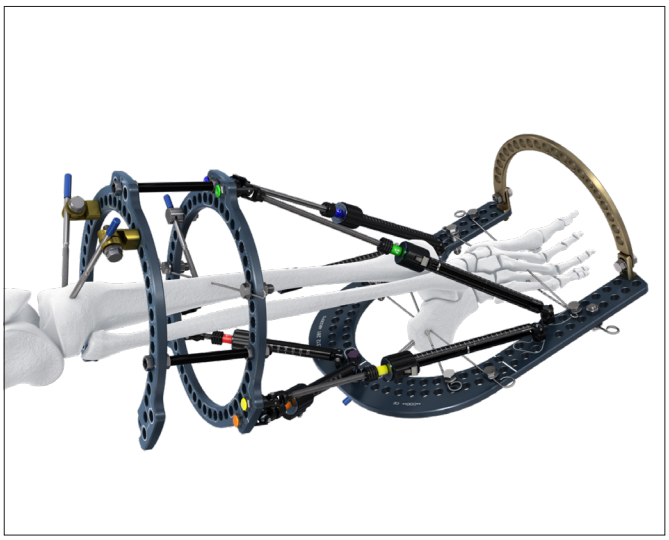
Designate the master tab on the reference ring (commonly the foot plate) by placing struts 1 and 2 in that location (ring mount or tab mount) with strut 1 on the left from a surgeon's perspective. Continue the numbering scheme clockwise, from the surgeon's perspective looking from distal to proximal.

Should the master tab be placed on the foot plate, this is an example of distal referencing. Please see page 58 for more information on distal referencing.



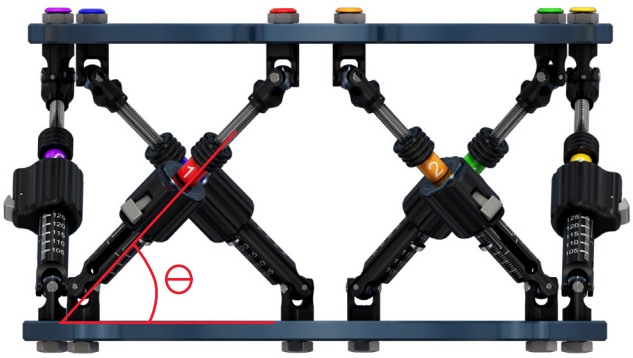
3. If necessary, consider mounting a second level of fixation to provide increased mechanical stability.

Use threaded rods, nuts and the 8 mm/11 mm wrench to connect the rings. Typically only three threaded rods are necessary. Be sure that the rings remain parallel to each other after they are connected.



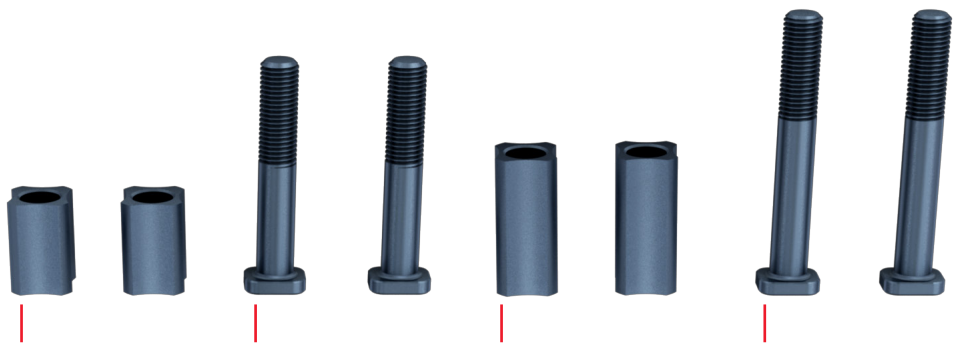
Postoperative Surgical Techniques

The MAXFRAME System has been tested to assure a construct's ability to sustain full weight-bearing of a patient throughout the entire treatment plan. Caution should be taken to limit full weight bearing until the frame is adjusted into a more stable configuration of 30° or greater ring to strut angle.



Foot Plate Support Kit

There is a left and a right foot plate support within the foot plate support kit. Both should be utilized in conjunction with a single foot plate. These items are for single use and not designed to be clinically reprocessed.



Foot plate support

Instruments

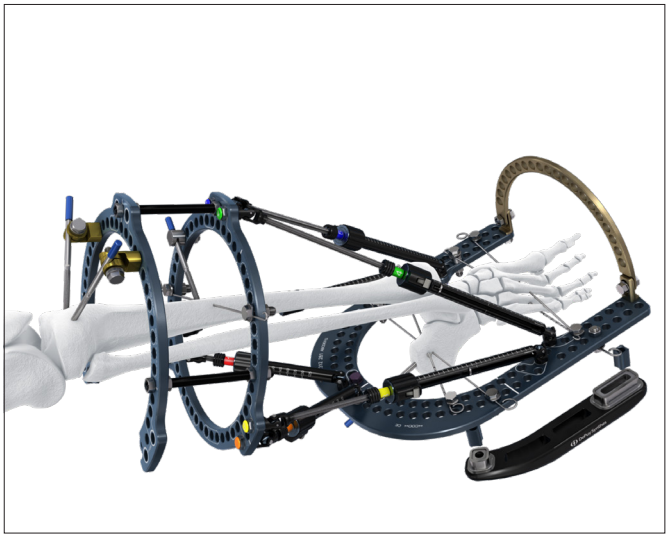
03.311.007	8 mm/11 mm Wrench

1. Determine correct standoff height sleeve and T bolt for the foot plate.

Two heights are provided to accommodate patient anatomy. Choose the corresponding T bolt height based on the standoff height sleeve chosen. Place the standoff height sleeve in the foot plate support slot.

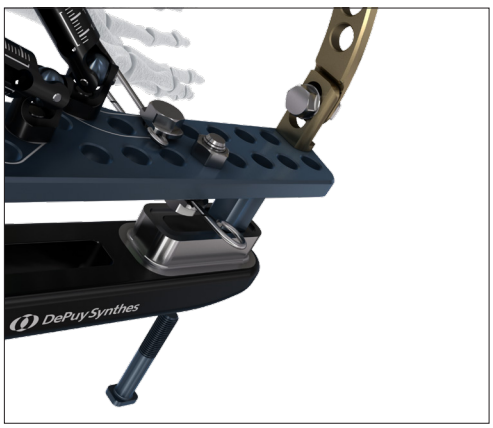
Ensure the standoff height sleeve is fully seated.

Note: The anterior slot for the standoff height sleeve has adjustability in the anterior/posterior direction for situations where adjacent hardware is in a desired assembly hole in the foot plate.

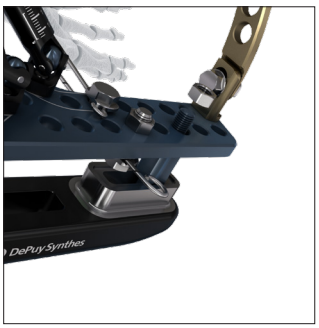


2. Insert the T-bolt from the bottom of the foot plate support through the standoff height sleeve.

Ensure the head of the T-bolt is fully seated.

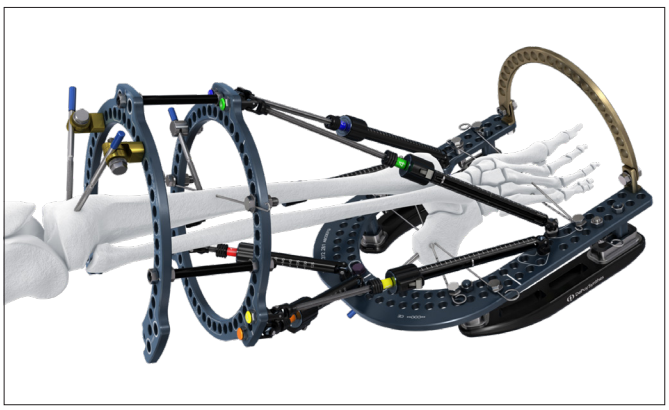


3. Attach the foot plate support by inserting the exposed portion of the T-bolt into an available hole in the foot plate and tightening with a nut using the 8 mm/11 mm wrench.



4. Repeat the process for the second foot plate support on the alternate side.

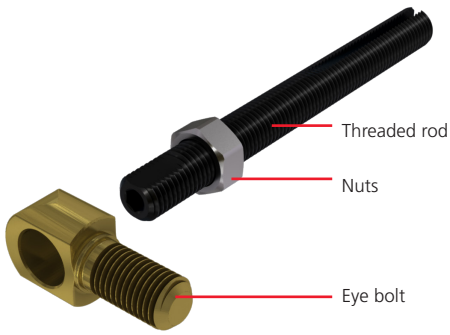
Double check tightness of all connections.



Strut Swaps

During the course of a treatment plan, a surgeon may need to perform a strut swap. It is necessary to support this area of the frame with a strut swap assembly prior to the strut swap being performed. This temporary support will allow the strut to be changed without loss of construct stability.

Failure to do so will result in an unstable construct, loss of correction, and potential patient discomfort/pain.



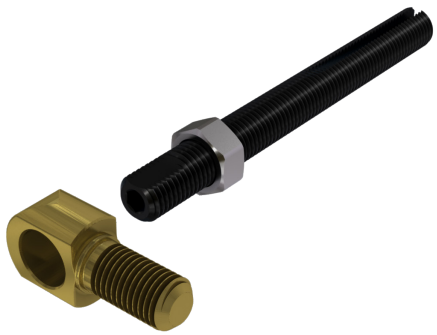
Required Set	
01.312.012	Strut Swap Kit

Strut Swap Assembly

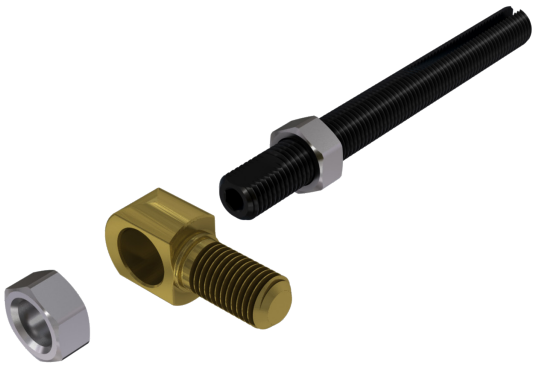
Components	
03.311.108	Threaded Rod, 80 mm lg, slotted
03.311.092	Eye Bolt
03.311.061	Nut
03.311.007	8 mm/11 mm Wrench

1. Thread one nut onto the threaded rod until it is approximately 3 cm from the end.

2. Slide one eye bolt on the short end of the threaded rod until it meets the nut.



3. Thread a second nut onto the threaded rod to secure the eye bolt in place.



4. Use two wrenches to provide counter-torque on one nut while completing full tightening of the other.

5. Repeat the steps above to create two strut swap assemblies.

Perform Strut Swap

Instruments	
03.311.007	8 mm/11 mm Wrench
03.312.851	10 Nm Torque Wrench

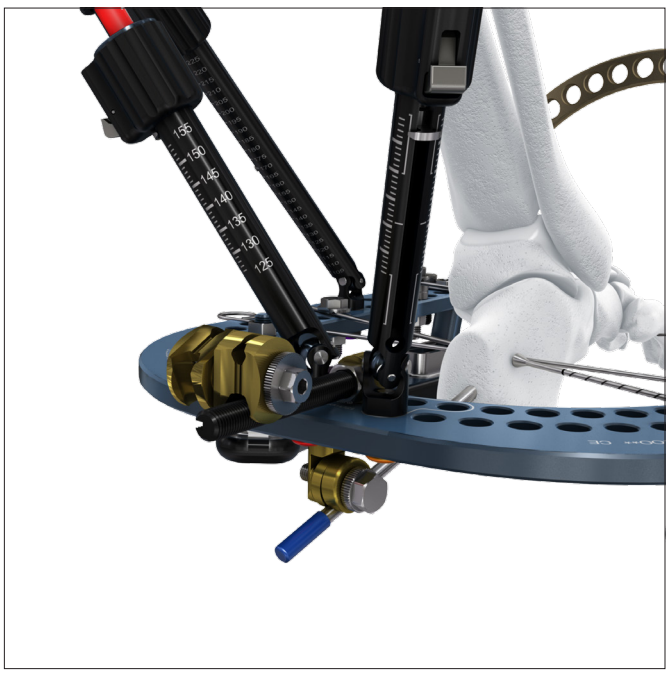
1. Insert the eye bolt of a strut swap assembly through the proximal ring in an open hole on either side of the strut being swapped.

Thread a nut onto the eye bolt on the opposite side of the ring and finger-tighten.

Insert a second eye bolt in the same manner on the distal ring in line with the first eye bolt.

2. Loosely connect two medium ex-fix combination clamps to the threaded rod portion of each strut swap assembly.

It is recommended to place the neural nut of each medium ex-fix combination clamp on the same side for ease in tightening.



3. Use the long threaded rod to connect each of the medium ex-fix combination clamps and tighten with the 8 mm/11 mm wrench.

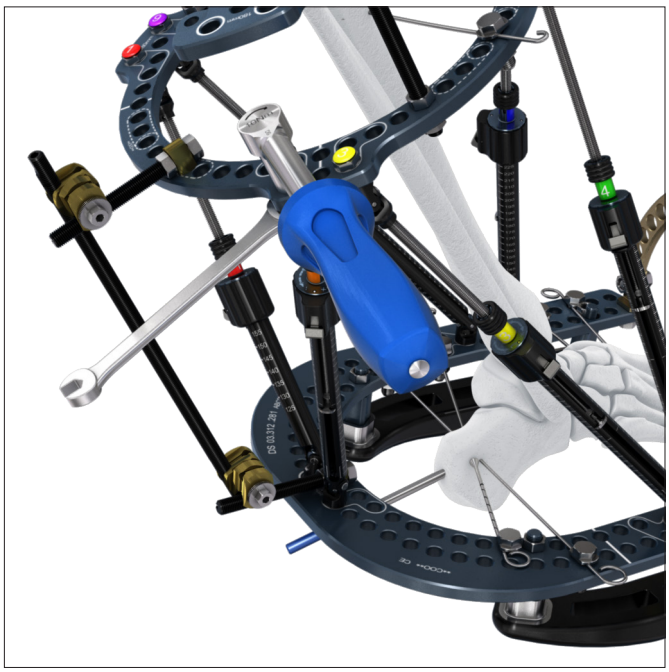
4. Loosen the shoulder bolt on both ends of the affected strut to be swapped using the 8 mm/11 mm wrench. Provide counter-torque.

Precaution: Do not use the 10 Nm Torque Wrench for loosening as it may damage the torque wrench. The 10 Nm Torque Wrench is calibrated for one direction only.

5. Remove the initial strut, place the new strut in the same location, and connect with shoulder bolts.

Transfer the ID band and plug to the new strut.

6. Perform final tightening of the shoulder bolts using the 10 Nm wrench while providing counter-torque.



7. Remove the long threaded rod, medium ex fix clamps and strut swap assemblies.

Hardware Removal

Instruments	
03.311.007	8 mm/11 mm Wrench
393.105	Small Universal Chuck with T-Handle
391.962	Bending/Cutting Pliers

1. Using the 8 mm/11 mm wrench, loosen the nuts on all Schanz screw bolts.

Precaution: Do not use the 10 Nm Torque Wrench for loosening as it may damage the torque wrench. The 10 Nm Torque Wrench is calibrated for one direction only.

2. Remove all Schanz screws using the Small Universal Chuck with T-Handle.

The Schanz Pin Removal Tool (SD393.107) can be utilized if needed.

3. Cut all wires on both sides about 2-3 cm from the skin edge inside the ring.

Remove wire remnants attached to the frame, or curl the ends of the wire connected to the frame to prevent inadvertent abrasions to the skin. Prepare the wire on the side of the skin that will be pulled through the soft tissue and bone.

Precaution: It is important to cut the wires inside of ring, close to the skin before pulling through bone to reduce the chance of debris being introduced to the patient.

4. Slide the intact frame off of the affected limb.

If necessary, unlock the struts to facilitate removal of the frame.

5. Remove all wires. Ensure all wires are straight prior to removal.

Note: If a reduction (olive) wire has been used, consider performing a releasing incision at the skin level on the side with the stopper prior to removal.

Precaution: Do not pull the stopper on the reduction wire through bone. Pull on the side with the spiral markings.

Care and Maintenance

After each use, all instruments should be cleaned. Instruments with removable parts should be dismantled prior to cleaning. Steel brushes must not be used to clean the instruments. Cannulated instruments must be thoroughly cleaned and opened prior to washing and disinfection.

Prior to autoclaving, instruments should be inspected for cleanliness. Instruments with moving parts must be lubricated with Synthes Autoclavable Oil (519.97).

Important: Prior to use, and while cleaning, visually inspect the instrument. Do not use the instrument if damaged. Examples of damage include, but are not limited to, corrosion (rust, pitting), discoloration, excessive scratches, flaking, cracks and wear.

Please refer to www.depuysynthes.com/hcp/cleaning-sterilization for a full list of recommendations for processing DePuy Synthes reusable medical devices.

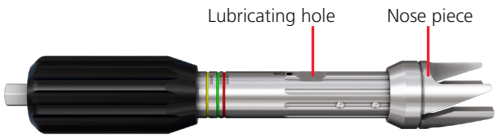
10 Nm Torque Wrench

Milk Bath
After hand washing, and prior to sterilization, clean the 10 Nm Torque Wrench according to the recommendations outlined on www.depuysynthes.com/hcp/cleaning-sterilization. This instrument requires immersion in a milk bath. After cleaning and rinsing, fully immerse the 10 Nm Torque Wrench hand piece in instrument milk (non-silicone based medical lubricant) prepared according to the lubricant manufacturer at room temperature in a suitable container and agitate for 30-45 seconds.

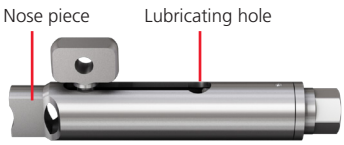
Calibration
Every six months the 10 Nm Torque Wrench must be returned to the Service Department for re-calibration.

Wire Tensioners

Wire Tensioner (03.312.001)



Backup Tensioner (03.311.008)



Clean and sterilize the wire tensioners according to www.depuysynthes.com/hcp/cleaning-sterilization.
Lubricate the tensioners according to instruction below.

Maintenance Instructions
To lubricate the tensioners prior to sterilization:
1. Apply 4-6 drops of Autoclavable Oil (519.97):
- Into each lubricating hole;
- Into the cannulation at the back end of the instrument, with the tensioner in a vertical position; and
- Into the cannulation of the nosepieces, with the tensioner in a vertical position

2. Spread the oil throughout the mechanism by rotating the knob through several full turns.

Note: Failure to clean and lubricate the tensioner after each use may result in poor performance and reduced operating life of the instrument.

Struts and Rings

MAXFRAME Quick Adjust Struts*

03.312.810	X-Short
03.312.811	Short
03.312.812	Medium
03.312.813	Long

MAXFRAME Standard Struts*

03.312.814	XX-Short
03.312.815	X-Short
03.312.816	Short
03.312.817	Medium
03.312.818	Long

MAXFRAME™ Linear Struts◊*

03.313.870	Short
03.313.871	Medium
03.313.872	Long

MAXFRAME™ Polyaxial Struts – Gross Adjust◊*

03.313.873	XX-Short
03.313.874	X-Short
03.313.875	Short
03.313.876	Medium
03.313.877	Long

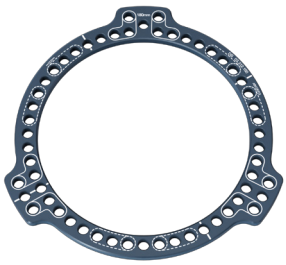
MAXFRAME™ Polyaxial Struts – Fine and Gross Adjust◊*

03.313.878	X-Short
03.313.879	Short
03.313.880	Medium
03.313.881	Long

◊Indicates product is not intended for use with the MAXFRAME Software.
*Indicates MR Conditional.

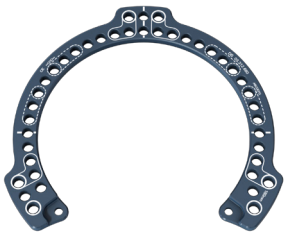
MAXFRAME Full Rings*

03.312.090	90 mm, Aluminum
03.312.120	120 mm, Aluminum
03.312.150	150 mm, Aluminum
03.312.180	180 mm, Aluminum
03.312.210	210 mm, Aluminum
03.312.240	240 mm, Aluminum†
03.312.270	270 mm, Aluminum†



MAXFRAME 5/8 Rings*

03.312.590	90 mm, Aluminum
03.312.620	120 mm, Aluminum
03.312.650	150 mm, Aluminum
03.312.680	180 mm, Aluminum
03.312.710	210 mm, Aluminum
03.312.740	240 mm, Aluminum†



MAXFRAME Bridging Plates for 5/8 Ring*

03.312.350	150 mm, Aluminum
03.312.380	180 mm, Aluminum
03.312.410	210 mm, Aluminum
03.312.440	240 mm, Aluminum†

MAXFRAME Foot Plate, short*

03.312.141	120 mm, Aluminum
03.312.161	150 mm, Aluminum
03.312.181	180 mm, Aluminum
03.312.201	210 mm, Aluminum

MAXFRAME Foot Plate, long*

03.312.241	120 mm, Aluminum
03.312.261	150 mm, Aluminum
03.312.281	180 mm, Aluminum
03.312.301	210 mm, Aluminum

*Indicates MR Conditional.
**Indicates MR Unsafe.
†Additionally available.

MAXFRAME™ Half Ring◊*

03.313.121	120 mm, Aluminum
03.313.151	150 mm, Aluminum
03.313.181	180 mm, Aluminum
03.313.211	210 mm, Aluminum

MAXFRAME™ Third Ring◊*

03.313.321	120 mm, Aluminum
03.313.351	150 mm, Aluminum
03.313.381	180 mm, Aluminum
03.313.411	210 mm, Aluminum

◊Indicates product is not intended for use with the MAXFRAME Software.
*Indicates MR Conditional.

Standard Thread Length Schanz Screws

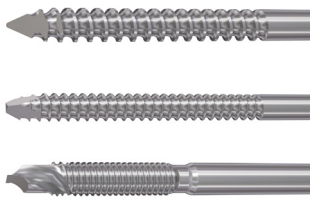
Schanz Screws*

Non-Self Drilling

294.48	4.0 mm Schanz Screw Spade Point, 150 mm
294.56	5.0 mm Schanz Screw Blunted Trocar Point, 200 mm‡
294.68	6.0 mm Schanz Screw Spade Point, 190 mm‡

Self-Drilling

294.785	5.0 mm Self-Drilling Schanz Screw, 175 mm‡
294.786	5.0 mm Self-Drilling Schanz Screw, 200 mm‡



Additionally Available Schanz Screws*

Non-Self Drilling

294.43-46	4.0 mm Schanz Screw Spade Point, 60-120 mm‡
294.52-55	5.0 mm Schanz Screw Blunted Trocar Point, 100-170 mm‡
294.57	5.0 mm Schanz Screw Blunted Trocar Point, 250 mm‡
294.65-66	6.0 mm Schanz Screw Spade Point, 100-130 mm
294.67	6.0 mm Schanz Screw Spade Point, 160 mm‡

*Indicates MR Conditional
**Indicates MR Unsafe
†Additionally available
‡Available HA Coated Sterile

*Self-Drilling**

294.774	4.0 mm Self-Drilling Schanz Screw, 60 mm
294.775-779	4.0 mm Self-Drilling Schanz Screw, 80-175 mm‡
494.774-779	4.0 mm Ti Self-Drilling Schanz Screw, 60-175 mm
294.782-784	5.0 mm Self-Drilling Schanz Screw, 100-150 mm‡
294.788	5.0 mm Self-Drilling Schanz Screw, 250 mm
494.782	5.0 mm Ti Self-Drilling Schanz Screw, 100 mm
494.784-786	5.0 mm Ti Self-Drilling Schanz Screw, 150-200 mm‡
494.788	5.0 mm Ti Self-Drilling Schanz Screw, 250 mm
294.792-798	6.0 mm Self-Drilling Schanz Screw, 100-250 mm‡
494.792-798	6.0 mm Ti Self-Drilling Schanz Screw, 100-250 mm

Wires*

Smooth

03.311.032	1.8 mm Diameter, 400 mm Long

Reduction

03.311.042	1.8 mm Diameter, 400 mm Long

Additionally Available Wires*

Smooth

03.311.031	1.5 mm Diameter, 400 mm Long
03.311.033	2.0 mm Diameter, 400 mm Long
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

03.311.041	1.5 mm Diameter, 400 mm Long
03.311.043	2.0 mm Diameter, 400 mm Long
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

*Indicates MR Conditional.
**Indicates MR Unsafe.
†Additionally available.
‡Available HA Coated Sterile.

Instruments for Standard Thread Length Schanz Screws

Drill Sleeve Assemblies

For a 4.0 mm Schanz screw:

Long

395.931	4.0 mm Threaded Drill Sleeve-Long
392.956	4.0 mm/2.5 mm Drill Sleeve-Long
394.184	2.5 mm Trocar-Long

For a 5.0 mm Schanz screw:

Long

395.923	6.0 mm/5.0 mm Threaded Drill Sleeve-Long
395.913	5.0 mm/3.5 mm Drill Sleeve-Long
394.182	3.5 mm Trocar-Long

Extra-Long

355.89	6.0 mm/5.0 mm Drill Sleeve
355.88	5.0 mm/3.5 mm Drill Sleeve
355.87	3.5 mm Trocar

For a 6.0 mm Schanz screw:

Long

03.312.953	7.0 mm/6.0 mm Drill Sleeve Long
395.923	6.0 mm/5.0 mm Threaded Drill Sleeve-Long
395.913	5.0 mm/3.5 mm Drill Sleeve-Long
394.182	3.5 mm Trocar-Long

Extra-Long

03.312.954	7.0 mm/6.0 mm Drill Sleeve Extra Long
355.89	6.0 mm/5.0 mm Drill Sleeve
355.88	5.0 mm/3.5 mm Drill Sleeve
355.87	3.5 mm Trocar

Variable Thread Length Schanz Screws

Implants included in Set

Blunted Point Variable Thread Length Schanz Screws*◊

02.152.420	4.0 mm, 20 mm Thread, 150 mm
02.172.530	5.0 mm, 30 mm Thread, 175 mm
02.172.535	5.0 mm, 35 mm Thread, 175 mm
02.172.540	5.0 mm, 40 mm Thread, 175 mm
02.252.540	5.0 mm, 40 mm Thread, 250 mm
02.252.555	5.0 mm, 55 mm Thread, 250 mm
02.172.625	6.0 mm, 25 mm Thread, 175 mm
02.172.630	6.0 mm, 30 mm Thread, 175 mm
02.172.635	6.0 mm, 35 mm Thread, 175 mm
02.172.640	6.0 mm, 40 mm Thread, 175 mm

Sterile HA-Coated, Blunted Point Variable Thread Length Schanz Screws*‡

02.152.420SHA	4.0 mm, 20 mm Thread, 150mm
02.172.525SHA	5.0 mm, 25 mm Thread, 175 mm
02.172.530SHA	5.0 mm, 30 mm Thread, 175 mm
02.172.535SHA	5.0 mm, 35 mm Thread, 175 mm
02.172.540SHA	5.0 mm, 40 mm Thread, 175 mm
02.252.555SHA	5.0 mm, 55 mm Thread, 250 mm
02.252.570SHA	5.0 mm, 70 mm Thread, 250 mm
02.252.585SHA	5.0 mm, 85 mm Thread, 250 mm
02.172.625SHA	6.0 mm, 25 mm Thread, 175 mm
02.172.630SHA	6.0 mm, 30 mm Thread, 175 mm
02.172.635SHA	6.0 mm, 35 mm Thread, 175 mm
02.172.640SHA	6.0 mm, 40 mm Thread, 175 mm
02.252.655SHA	6.0 mm, 55 mm Thread, 250 mm
02.252.670SHA	6.0 mm, 70 mm Thread, 250 mm

X= 2 Stainless Steel.
X= 4 Titanium.
*Indicates MR Conditional.
†Additionally Available.
◊Available Sterile.
‡Available HA Coated.

Additionally Available

Please check with your local sales consultant for the availability of the below schanz screws. Some schanz screws may not be immediately available.

Blunted Point Variable Thread Length Schanz Screws*◊

0X.152.415	4.0 mm, 15 mm Thread, 150 mm
0X.152.420	4.0 mm, 20 mm Thread, 150 mm
0X.152.425	4.0 mm, 25 mm Thread, 150 mm
0X.152.430	4.0 mm, 30 mm Thread, 150 mm
0X.152.435	4.0 mm, 35 mm Thread, 150 mm
0X.152.440	4.0 mm, 40 mm Thread, 150 mm
0X.152.445	4.0 mm, 45 mm Thread, 150 mm
0X.152.450	4.0 mm, 50 mm Thread, 150 mm
0X.152.455	4.0 mm, 55 mm Thread, 150 mm
0X.152.460	4.0 mm, 60 mm Thread, 150 mm
0X.172.525	5.0 mm, 25 mm Thread, 175 mm
0X.172.530	5.0 mm, 30 mm Thread, 175 mm
0X.172.535	5.0 mm, 35 mm Thread, 175 mm
0X.172.540	5.0 mm, 40 mm Thread, 175 mm
0X.252.540	5.0 mm, 40 mm Thread, 250 mm
0X.172.555	5.0 mm, 55 mm Thread, 250 mm
0X.172.570	5.0 mm, 70 mm Thread, 250 mm
0X.172.585	5.0 mm, 85 mm Thread, 250 mm
0X.172.625	6.0 mm, 25 mm Thread, 175 mm
0X.172.630	6.0 mm, 30 mm Thread, 175 mm
0X.172.635	6.0 mm, 35 mm Thread, 175 mm
0X.172.640	6.0 mm, 40 mm Thread, 175 mm
0X.252.640	6.0 mm, 40 mm Thread, 250 mm
0X.252.655	6.0 mm, 55 mm Thread, 250 mm
0X.252.670	6.0 mm, 70 mm Thread, 250 mm
0X.252.685	6.0 mm, 85 mm Thread, 250 mm

Self-Drilling Variable Thread Length Schanz Screws*◊

0X.150.415	4.0 mm, 15 mm Thread, 150 mm
0X.150.420	4.0 mm, 20 mm Thread, 150 mm
0X.150.425	4.0 mm, 25 mm Thread, 150 mm
0X.150.430	4.0 mm, 30 mm Thread, 150 mm
0X.150.435	4.0 mm, 35 mm Thread, 150 mm
0X.150.440	4.0 mm, 40 mm Thread, 150 mm
0X.150.445	4.0 mm, 45 mm Thread, 150 mm
0X.150.450	4.0 mm, 50 mm Thread, 150 mm
0X.150.455	4.0 mm, 55 mm Thread, 150 mm
0X.150.460	4.0 mm, 60 mm Thread, 150 mm
0X.170.525	5.0 mm, 25 mm Thread, 175 mm
0X.170.530	5.0 mm, 30 mm Thread, 175 mm
0X.170.535	5.0 mm, 35 mm Thread, 175 mm
0X.170.540	5.0 mm, 40 mm Thread, 175 mm
0X.250.540	5.0 mm, 40 mm Thread, 250 mm
0X.250.555	5.0 mm, 55 mm Thread, 250 mm
0X.250.570	5.0 mm, 70 mm Thread, 250 mm
0X.250.585	5.0 mm, 85 mm Thread, 250 mm
0X.170.625	6.0 mm, 25 mm Thread, 175 mm
0X.170.630	6.0 mm, 30 mm Thread, 175 mm
0X.170.635	6.0 mm, 35 mm Thread, 175 mm
0X.170.640	6.0 mm, 40 mm Thread, 175 mm
0X.250.640	6.0 mm, 40 mm Thread, 250 mm
0X.250.655	6.0 mm, 55 mm Thread, 250 mm
0X.250.670	6.0 mm, 70 mm Thread, 250 mm
0X.250.685	6.0 mm, 85 mm Thread, 250 mm

X= 2 Stainless Steel.
X= 4 Titanium.
*Indicates MR Conditional.
†Additionally Available.
◊Available Sterile.
‡Available HA Coated.

Sterile HA Coated, Blunted Point Variable Thread Length Schanz Screws*‡

0X.152.415SHA	4.0 mm, 15 mm Thread, 150 mm
0X.152.420SHA	4.0 mm, 20 mm Thread, 150 mm
0X.152.425SHA	4.0 mm, 25 mm Thread, 150 mm
0X.152.430SHA	4.0 mm, 30 mm Thread, 150 mm
0X.152.435SHA	4.0 mm, 35 mm Thread, 150 mm
0X.152.440SHA	4.0 mm, 40 mm Thread, 150 mm
0X.152.445SHA	4.0 mm, 45 mm Thread, 150 mm
0X.152.450SHA	4.0 mm, 50 mm Thread, 150 mm
0X.152.455SHA	4.0 mm, 55 mm Thread, 150 mm
0X.152.460SHA	4.0 mm, 60 mm Thread, 150 mm
0X.172.525SHA	5.0 mm, 25 mm Thread, 175 mm
0X.172.530SHA	5.0 mm, 30 mm Thread, 175 mm
0X.172.535SHA	5.0 mm, 35 mm Thread, 175 mm
0X.172.540SHA	5.0 mm, 40 mm Thread, 175 mm
0X.252.540SHA	5.0 mm, 40 mm Thread, 250 mm
0X.252.555SHA	5.0 mm, 55 mm Thread, 250 mm
0X.252.570SHA	5.0 mm, 70 mm Thread, 250 mm
0X.252.585SHA	5.0 mm, 85 mm Thread, 250 mm
0X.172.625SHA	6.0 mm, 25 mm Thread, 175 mm
0X.172.630SHA	6.0 mm, 30 mm Thread, 175 mm
0X.172.635SHA	6.0 mm, 35 mm Thread, 175 mm
0X.172.640SHA	6.0 mm, 40 mm Thread, 175 mm
0X.252.640SHA	6.0 mm, 40 mm Thread, 250 mm
0X.252.655SHA	6.0 mm, 55 mm Thread, 250 mm
0X.252.670SHA	6.0 mm, 70 mm Thread, 250 mm
0X.252.685SHA	6.0 mm, 85 mm Thread, 250 mm

HA Coated, Self-Drilling Variable Thread Length Schanz Screws*‡

0X.150.415SHA	4.0 mm, 15 mm Thread, 150 mm
0X.150.420SHA	4.0 mm, 20 mm Thread, 150 mm
0X.150.425SHA	4.0 mm, 25 mm Thread, 150 mm
0X.150.430SHA	4.0 mm, 30 mm Thread, 150 mm
0X.150.435SHA	4.0 mm, 35 mm Thread, 150 mm
0X.150.440SHA	4.0 mm, 40 mm Thread, 150 mm
0X.150.445SHA	4.0 mm, 45 mm Thread, 150 mm
0X.150.450SHA	4.0 mm, 50 mm Thread, 150 mm
0X.150.455SHA	4.0 mm, 55 mm Thread, 150 mm
0X.150.460SHA	4.0 mm, 60 mm Thread, 150 mm
0X.170.525SHA	5.0 mm, 25 mm Thread, 175 mm
0X.170.530SHA	5.0 mm, 30 mm Thread, 175 mm
0X.170.535SHA	5.0 mm, 35 mm Thread, 175 mm
0X.170.540SHA	5.0 mm, 40 mm Thread, 175 mm
0X.250.540SHA	5.0 mm, 40 mm Thread, 250 mm
0X.250.555SHA	5.0 mm, 55 mm Thread, 250 mm
0X.250.570SHA	5.0 mm, 70 mm Thread, 250 mm
0X.250.585SHA	5.0 mm, 85 mm Thread, 250 mm
0X.170.625SHA	6.0 mm, 25 mm Thread, 175 mm
0X.170.630SHA	6.0 mm, 30 mm Thread, 175 mm
0X.170.635SHA	6.0 mm, 35 mm Thread, 175 mm
0X.170.640SHA	6.0 mm, 40 mm Thread, 175 mm
0X.250.640SHA	6.0 mm, 40 mm Thread, 250 mm
0X.250.655SHA	6.0 mm, 55 mm Thread, 250 mm
0X.250.670SHA	6.0 mm, 70 mm Thread, 250 mm
0X.250.685SHA	6.0 mm, 85 mm Thread, 250 mm

X= 2 Stainless Steel.
X= 4 Titanium.
*Indicates MR Conditional.
†Additionally Available.
◊Available Sterile.
‡Available HA Coated.

Instruments for Variable Thread Length Schanz Screws

For 4.0 mm Variable Thread Length Schanz Screw

03.313.700	3.2 mm Drill Bit, Long/Calibrated◊
03.313.720	4.0 mm Drill Sleeve, Long/outer
03.313.721	4.0 mm Drill Sleeve, Long/inner
03.313.730	3.2 mm Trocar, long

For 5.0 mm Variable Thread Length Schanz Screw

Long

03.313.701	4.3 mm Drill Bit, Long/Calibrated◊
03.313.722	5.0 mm Drill Sleeve, Long/Outer
03.313.723	5.0 mm Drill Sleeve, Long/Inner
03.313.731	4.3 mm Trocar, Long

Extra-Long

03.313.702	4.3 mm Drill Bit, Extra Long/Calibrated◊
03.313.724	5.0 mm Drill Sleeve, Extra Long/Outer
03.313.725	5.0 mm Drill Sleeve, Extra Long/Inner
03.313.732	4.3 mm Trocar, Extra Long

For 6.0 mm Variable Thread Length Schanz Screw

Long

03.313.703	5.0 mm Drill Bit, Long/Calibrated◊
03.313.726	6.0 mm Drill Sleeve, Long/outer
03.313.727	6.0 mm Drill Sleeve, Long/inner
03.313.733	5.0 mm Trocar, Long

Extra-Long

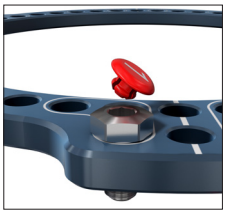
03.313.704	5.0 mm Drill Bit, Extra Long/Calibrated◊
03.313.728	6.0 mm Drill Sleeve, Extra Long/outer
03.313.729	6.0 mm Drill Sleeve, Extra Long/outer
03.313.734	5.0 mm Trocar, Extra Long

Note: Instruments listed above can also be used with the self drilling standard thread length schanz screws. Due to the necessary drill bit size, the standard length blunted trocar point and spade point schanz screws require the instruments for standard thread length schanz screws listed on page 111.

◊Available Sterile.

Implants and Instruments

292.41	2.0 mm Spade-Point Reduction Wire 400 mm*†
294.950	6.0 mm Transfixation Pin 225 mm*†
ID-Bands and Plugs	
03.312.820	MAXFRAME™ Strut ID band set
03.312.821	MAXFRAME™ Strut ID plug set
03.312.830	MAXFRAME™ Shoulder Bolt for 8mm Rings*
03.311.010	Schanz Screw Bolt*
03.311.013	Schanz Screw Bolt Post Mount*†
03.311.015	Schanz Screw Bolt 2 Piece*†
03.311.011	Pivot Schanz Screw Clamp*
03.311.012	Locking Hinge*
03.311.020	Universal Hinge*†
Connecting Plates*	
03.311.022	90° Offset, 2 holes†
03.311.023	90° Offset, 3 holes
03.311.024	90° Offset, 4 holes
03.311.025	90° Offset, 5 holes†
03.311.070	Wire Post, Short*
03.311.071	Wire Post, Tall*



*Indicates MR Conditional.
**Indicates MR Unsafe.
†Additionally available.
‡Available HA Coated Sterile.

Wire Posts*	
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†
03.311.058	Schanz Screw Bolt Cannulated Ring Mount*
03.311.059	Schanz Screw Bolt Cannulated Post*
03.311.050	Wire Bolt, slotted*
03.311.051	Wire Bolt, offset*
03.311.054	Wire Bolt, short, offset*†
03.313.885	MAXFRAME™ Wire Bolt Short Slotted*
03.313.867	MAXFRAME™ Tabbed Washer* Note: For use with 03.313.885 or 03.311.050.
03.311.055	Connection Bolt*
03.311.056	Connection Bolt, long*
03.311.060	Square Nut*
03.311.061	Nut*
03.311.062	Speed Nut*†
219.98	Washer 7.0 mm*†
Spacing Washers*	
03.311.081	1 mm
03.311.082	2 mm
03.311.084	4 mm



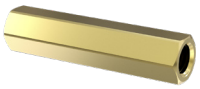
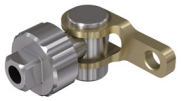








*Indicates MR Conditional.
**Indicates MR Unsafe.
†Additionally available.
‡Available HA Coated Sterile.

03.311.090	Spherical Washer Couple*	
03.311.091	Oblique Support*	
03.311.092	Eye Bolt*	
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†	
Standoff*		
03.311.220	20 mm long†	
03.311.230	30 mm long	
03.311.240	40 mm long	
03.311.250	50 mm long†	
MAXFRAME™ Standoff*		
03.313.864	65 mm	
03.313.865	80 mm	
03.313.866	100 mm	
03.311.450	Angular Distractor*	
03.311.451	Angular Distractor Pivot*	

*Indicates MR Conditional.
**Indicates MR Unsafe.
†Additionally available.
‡Available HA Coated Sterile.

MAXFRAME Ring Mount*

03.313.855	For 4-5 mm
03.313.856	For 5-6 mm

MAXFRAME™ Multiparallel Pin Mount Post*

03.313.857	1 High
03.313.858	2 High
03.313.859	3 High
03.313.860	4 High
03.313.861	5 High
03.313.862	6 High

03.313.863	MAXFRAME™ Multiparallel Pin Mount Bolt*	
03.313.868	MAXFRAME™ Slotted Washer*	
03.313.869	MAXFRAME™ Right Angle Post*	
03.313.884	MAXFRAME™ Linear Strut Bolt*	
03.313.886	MAXFRAME™ Retention Band* Note: For use with polyaxial struts.	

Threaded Rods*

Standard

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†

*Indicates MR Conditional.
**Indicates MR Unsafe.
†Additionally available.
‡Available HA Coated Sterile.

Threaded Rods*	
Slotted	
03.311.106	60 mm long
03.311.108	80 mm long
03.311.110	100 mm long
	Ti Half Rings*
03.311.312	120 mm Diameter
03.311.315	150 mm Diameter
03.311.318	180 mm Diameter
03.311.320	200 mm Diameter

Carbon Fiber Half Rings*†	
03.311.812	120 mm Diameter
03.311.818	180 mm Diameter
03.311.820	200 mm Diameter

390.031	Medium Combination Clamp*

390.035	Medium Open Adjustable Clamp*†

390.005	Large Ex-Fix Combination Clamp*

390.037	8.0 mm/11.0 mm Combination Clamp*†

Protective Caps	
394.991	for 4.0 mm Fixation Pins
394.993	for 5.0 mm Fixation Pins
394.994	for 6.0 mm Fixation Pins

Foot Plate Support Kit*†	
03.312.010	MAXFRAME™ Foot Plate Support Kit

03.312.840	MAXFRAME™ Radiographic Marker**

*Indicates MR Conditional.
**Indicates MR Unsafe.
†Additionally available.
‡Available HA Coated Sterile.

03.312.841	MAXFRAME™ Vertical Mount for Radiographic Marker

03.312.851	10N*m Torque Wrench
395.911	Drill Sleeve Handle
03.311.005	Split Tissue Protection Sleeve 2.5 mm**
03.311.006	Split Tissue Protection Sleeve 5 mm**

Standard Thread Length Drill Bits

310.21	2.0 mm Drill Bit/QC/125 mm
310.37	3.5 mm Drill Bit/QC/195 mm
03.312.950	ø 3.5mm Drill Bit

Variable Thread Length Drill Bits

03.313.700	3.2 mm Drill Bit, Long/Calibrated‡
03.313.701	4.3mm Drill Bit, Long/Calibrated‡
03.313.702	4.3 mm Drill Bit, Extra Long/Calibrated‡
03.313.703	5.0 mm Drill Bit, Long/Calibrated‡
03.313.704	5.0 mm Drill bit, Extra Long/Calibrated‡

391.962	Bending/Cutting Pliers

Hammers†

399.41	350 grams
399.42	500 grams
399.43	700 grams

03.312.001	Wire Tensioner**
03.311.008	Backup Tensioner**†

Drive Adaptors with QC

393.101	for 4.0 mm Schanz Screws
393.103	for 5.0 mm Schanz Screws
393.104	for 6.0 mm Schanz Screws

*Indicates MR Conditional.
**Indicates MR Unsafe.
†Additionally available.
‡Available HA Coated Sterile.

393.105	Small Universal Chuck with T-Handle
03.311.002	Slotted Socket Wrench 11 mm**
03.311.004	Ratchet Wrench 11 mm**
03.311.007	8 mm/11 mm Wrench**
03.311.003	Patient Wrench 8 mm/11 mm**†
SD393.107	Schanz Pin Removal Tool†

Strut Swap Kit (01.312.012)

03.311.108	Threaded Rod, 80 mm long, slotted*
03.311.092	Eye Bolt*
03.311.061.10	Nut (10 pack)*
390.031	Medium Combination Clamp*
03.311.125	Threaded Rod, 250mm long, slotted*
03.311.007	8 mm/11 mm Wrench**
03.312.851	10N*m Torque Wrench
61.312.010	MAXFRAME™ Strut Swap Kit Case

*Indicates MR Conditional.
**Indicates MR Unsafe.
†Additionally available.

Graphic Cases

Graphic Cases

61.312.001	MAXFRAME™ Implants/ Instruments Case 1
61.312.002	MAXFRAME™ Implants/ Instruments Case 2
61.312.003	MAXFRAME™ Implants/ Quick Adjust Struts
61.312.004	MAXFRAME™ Implants/ Standard Struts
61.312.005	MAXFRAME™ Rings 90 mm, 120 mm
61.312.006	MAXFRAME™ Full Rings 150 mm, 180 mm, 210 mm
61.312.007	MAXFRAME™ Implants/ Instruments Case 3
61.312.008	MAXFRAME™ 5/8 & Bridging Plates 150 mm, 180 mm, 210 mm
61.312.010	MAXFRAME™ Strut Swap Kit Case
61.312.011	MAXFRAME™ Label Sheet
61.312.012	MAXFRAME™ Foot Plates Long 120 mm, 150 mm, 180 mm, 210 mm
61.312.013	MAXFRAME™ Foot Plates Short 120 mm, 150 mm, 180 mm, 210 mm
61.312.014	MAXFRAME™ Shoulder Bolt Rack
61.313.001	MAXFRAME™ Implants/Linear Struts & Hardware
61.313.002	MAXFRAME™ Implants/Polyaxial Struts with Gross Adjustment
61.313.003	MAXFRAME™ Schanz Screw Instruments and Drill Bits
61.313.004	MAXFRAME™ Connecting Element
61.313.005	MAXFRAME™ Half and Third Rings 120 mm/150 mm/180 mm/210 mm
61.313.006	MAXFRAME™ Bolt Rack For Linear Strut Bolt
61.313.007	MAXFRAME™ Implants/Polyaxial Struts with Fine/Gross Adjust
61.313.008	MAXFRAME™ Connecting Element 2
61.313.009	MAXFRAME™ Connecting Element 3

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†

*Indicates MR Conditional.
**Indicates MR Unsafe.
†Additionally available.

Sets

01.312.000	MAXFRAME™ System Complete Set
01.313.000	MAXFRAME™ System Static/Linear Complete Set
01.313.001	MAXFRAME™ Additional
01.313.100	MAXFRAME™ Variable Thread Length Schanz Screw Set

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 surgical technique 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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