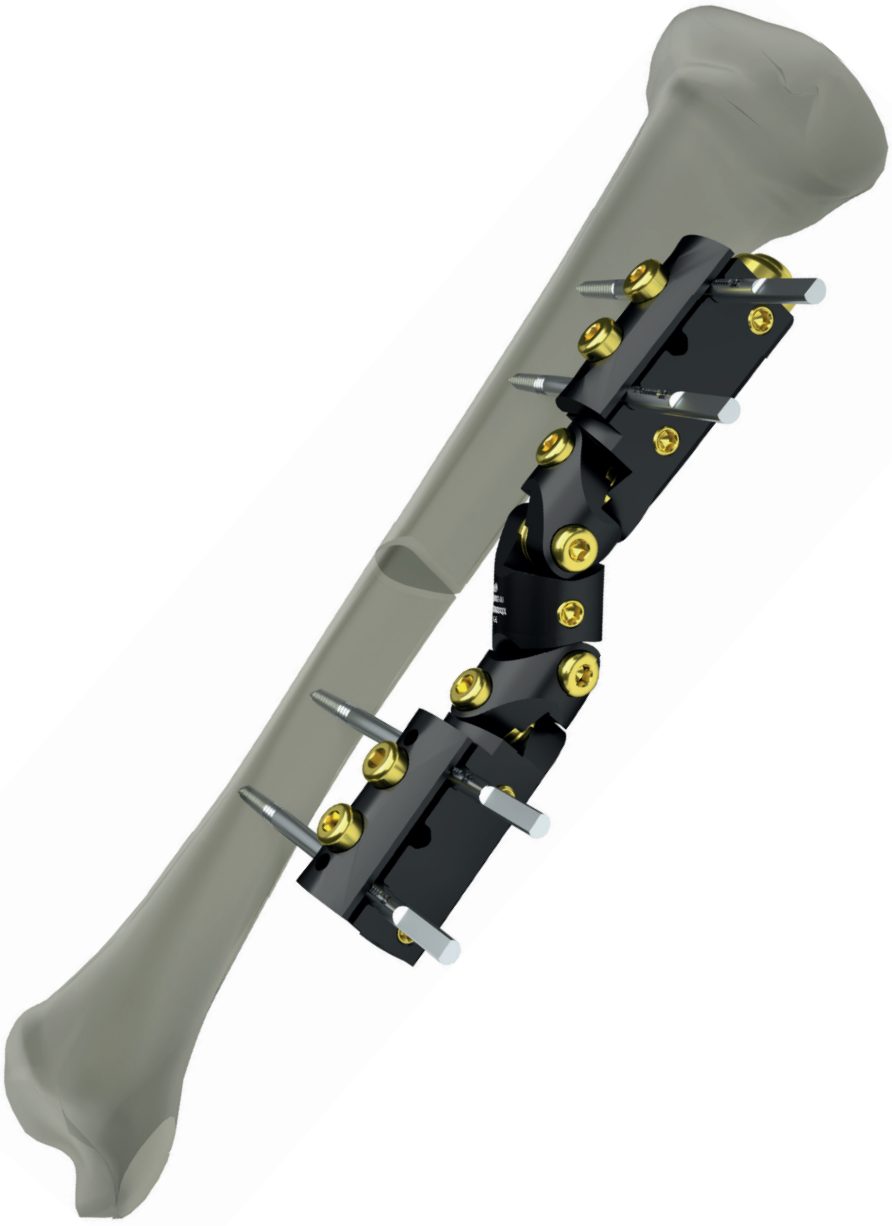
unix

Standard & Hybrid Fixator



RESPONSE™ ORTHO

A WishBone Medical Company

Response Ortho is a global
orthopaedic trauma solutions manufacturer
offering premium products
created under its founding principles of
innovation, excellence by design
and functional superiority

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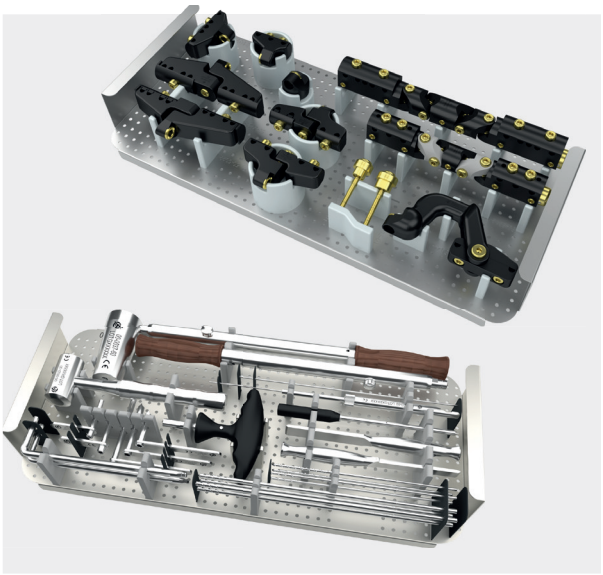

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Introductions

The Response Ortho® UniX Standard and Hybrid Fixator System is designed for the stabilization of diaphyseal, intra and periarticular fractures.

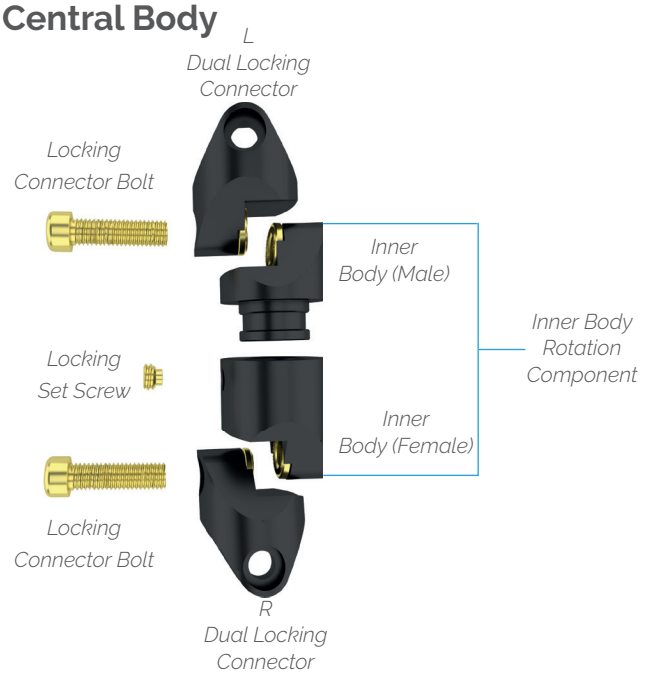
The system includes 1/2, 2/3 and full ring options with necessary components for half pin and/or wire fixation for hybrid application for fixation of metaphyseal humeral, femoral and tibial applications.

Indications

UniX Bar Fixator System is proposed to be used for open or closed fracture fixation, Second and third degree open fractures, Immobilization of closed fractures with severe soft tissue trauma, distracted fractures, longe bone pseudoarthrosis, bony or soft tissue deformity corrections, arthrodesis of joint and comminuted intra-articular fracture of distal radius management, certain injuries to the pelvic ring, and selected fractures in children.

Component And Instruments

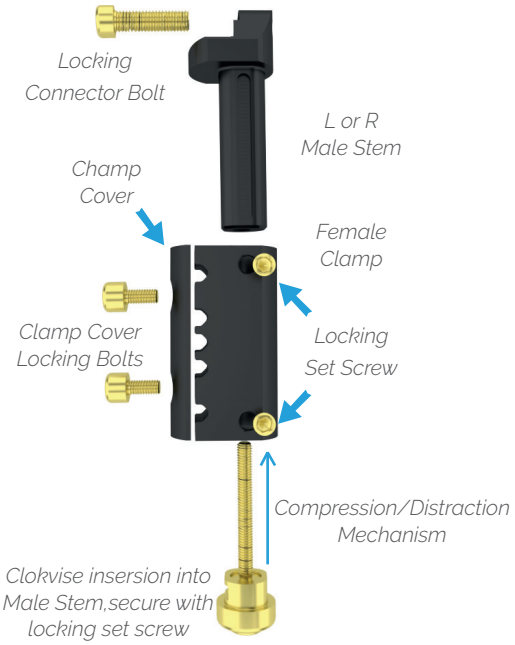
a. Central Body



The inner body rotation component is comprised of two portions: inner body male and inner body female. When male and female portions are joined care should be taken to insure that serrated discs and locking set screw are in line. Assembly is then correct and set screw is tightened. This component allows 360˚ of rotation about the axis of the fixator.

Dual locking connectors provide serrated discs at 90˚ angles relative to one another. The serrated discs interface with the serrated discs of the inner body rotation component and the telescoping fixator arm. These components are assembled and secured by means of the locking connector bolts. The outer-most serrated discs of the dual locking connectors are identified by L or R. When correctly assembled, the telescoping fixator arms marked L and R should correspond to the L and R of the dual locking connectors.

b. Straight Clamp with C/D Unit



Modular compression/distraction mechanism provides incremental excursion (compression/distraction) capability to the telescoping fixator arm component. The modular C/D mechanism is turned clockwise into the threaded hole in the end of the male stem. It is then positioned such that the flat side of the mechanism faces the locking set screw. The locking set screw is then secured.

Note: Clamp locking set screw must be loosened prior to operation of the compression/distraction mechanism.

The compression/distraction mechanism is available in lengths corresponding to the lengths of the telescoping fixator arms. In diaphyseal applications where two 0-5 cm telescoping fixator arms are employed there is a total distraction capability of 10 cm. In metaphyseal applications, where one telescoping fixator arm is employed, there is a total distraction capability of 5 cm. In those cases where extreme shortening exists, it is recommended that the longer 0-8 cm telescoping fixator arm be employed.

c. T-Clamp

T-Clamp may be substituted for a telescoping fixator arm component where horizontal bone screw placement is desired. The T-Clamp is attached at the dual locking connector by means of a locking connector bolt.

d. Convergent T Clamp

A

e. Ankle Clamp

Assembly for the left ankle requires removal of the R telescoping fixator arm and the R dual locking connector.

Assembly for the right ankle requires removal of the L telescoping fixator arm and the L dual locking connector.

The ankle clamp is then secured to the inner body rotation component by means of a locking connector bolt. The modular compression/distraction mechanism is utilized in the remaining telescoping fixator arm to obtain length.

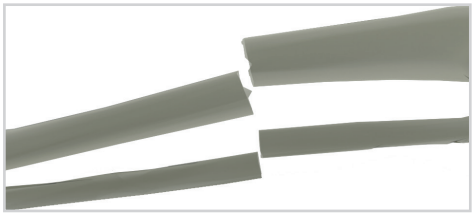
Locking of the hinge of the ankle clamp is in the direction of the arrow etched on the clamp.

f. Hybrid Ring Connector

The Hybrid Ring Connector Assembly is used to connect Smart Correction® rings to the Rods to build a Hybrid Construct. The Ring Connector Assembly is secured to the Ring with two locking bolts. A 10/10 combination of the clampsis utilized with this assembly to attach to the body of the fixator.

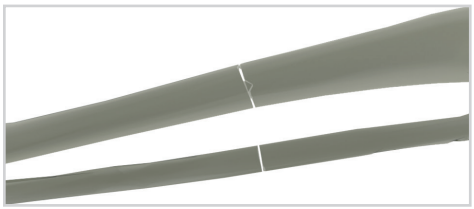
Screw Insertion

1



Pre-operative planning is recommended prior to the application of this device. Assess potential screw site location based on available bone stock and soft tissue considerations. Additional modules may be utilized for horizontal screw placement or fracture specific applications. Selected screw sites must accommodate the length of the central body component. All constructs should include at least one telescoping fixator arm. The telescoping fixator arm should be positioned such that it is parallel to the long axis of the bone to which it is to be secured. Axial alignment of the telescoping fixator arm helps assure free excursion (compression/ distraction). Fixator components are used as templates. Prep and drape in routine fashion.

2



Obtaining a preliminary reduction is recommended. A 1 cm incision is made and blunt dissection continued to bone. The first bone screw is generally inserted in the shortest or most difficult fragment. Assess available bone stock for desired screw position. When possible, allow 4 cm of distance between fracture site and first bone screw.

3

The trocar and appropriate length soft tissue guide are then utilized to identify the center of the bone and to establish the orientation of the screw tract to be pre-drilled. The orientation of the insertion of the bone screws should be perpendicular to the long axis of the bone.

4

Once the screw site is selected use gentle pressure to maintain contact between the soft tissue guide and the cortex of the bone. Extract the trocar.

The soft tissue guide is tapped with a mallet to engage the soft tissue guide with bone.

5

Insert appropriate drill guide into the soft tissue guide.

Drill Guide	Drill Bit	Screw
4.8 mm	4.8 mm	6/5 mm Cortical
3.2 mm	3.2 mm	6/5 mm Cancellous
3.2 mm	3.2 mm	4.5/3.5 mm Cortical

(Bone screw diameter should not exceed 1/3 diameter of bone)

6

Insert drill bit into the drill guide and drill both near and far cortexes. Be sure pre-drilled screw tract is perpendicular to the long axis of the bone.

7

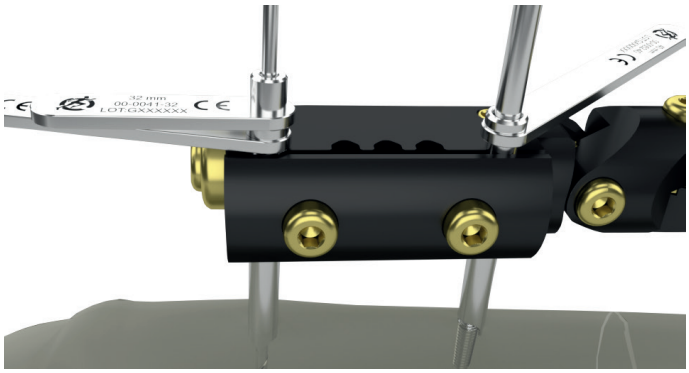
After bi-cortical penetration of the drill, the drill bit and drill guide are withdrawn. Maintain contact and position of the soft tissue guide.

8

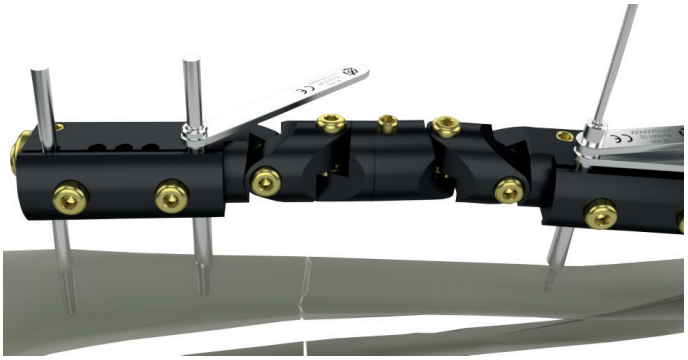
The appropriate length screw is then inserted through the soft tissue guide. The bone screw T-wrench is used to advance the screw into bone.

To obtain optimal purchase, all bone screws must be bi-cortical with no less than 2 mm protruding from the far cortex and about 5 mm remaining outside the near cortex. Image intensification is utilized to confirm depth of penetration.
Note: Care must be taken to avoid over-penetration. Due to the tapered design bone screws must not be backed out or they will lose purchase.

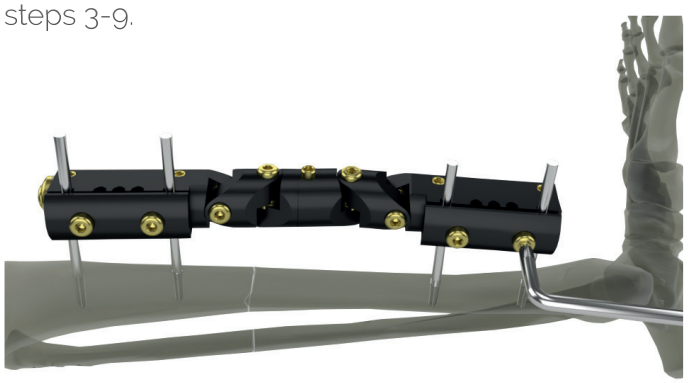
Standard Fixator Application



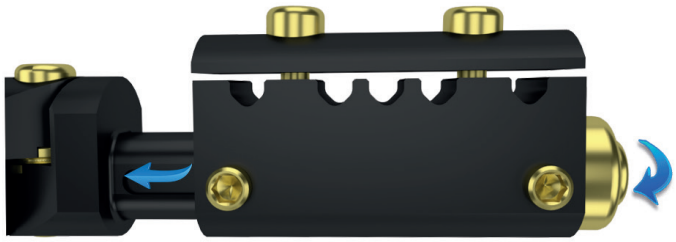
Loosen the clamp cover locking bolts of the telescoping fixator arm such that the soft tissue guide and existing bone screw are accommodated. At this point a second bone screw may be introduced into the same female clamp to insure a parallel relationship of the telescoping fixator arm to bone. Repeat steps 3-9 making sure to snug down the female clamp cover locking bolts to prevent toggle of the soft tissue guides within the clamp. This helps maintain proper bone screw alignment.



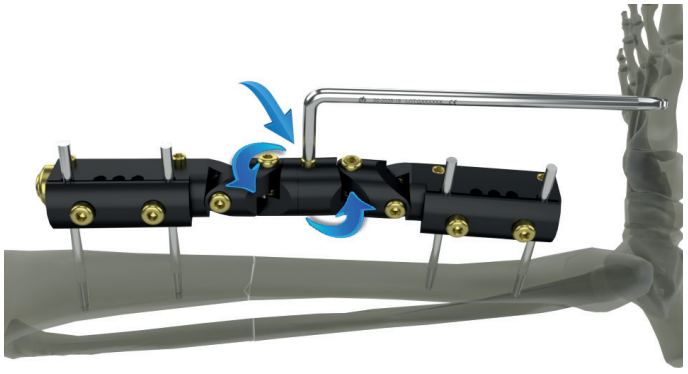
It is also possible at this point to address the opposing bone screw cluster. The locking connector bolts of the central body component are tentatively tightened. Leave approximately 1 cm of distance in the telescoping fixator arms for subsequent excursion. Proceed to opposite telescoping fixator arm. Identify and secure screw placement following steps 3-9. Align telescoping fixator arms such that they are parallel to the long axis of the bone. Insert soft tissue guide and trocar, snug down clamp cover locking bolts, and proceed with subsequent bone screw insertion steps 3-9.



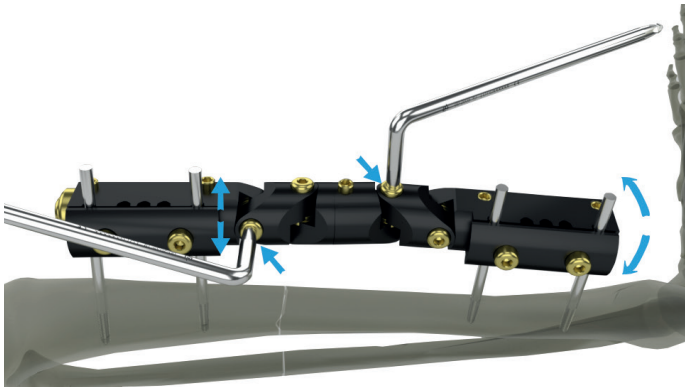
Remove soft tissue guides and tighten clamp cover locking bolts providing at least 3 cm clearance between fixator body and skin surface.



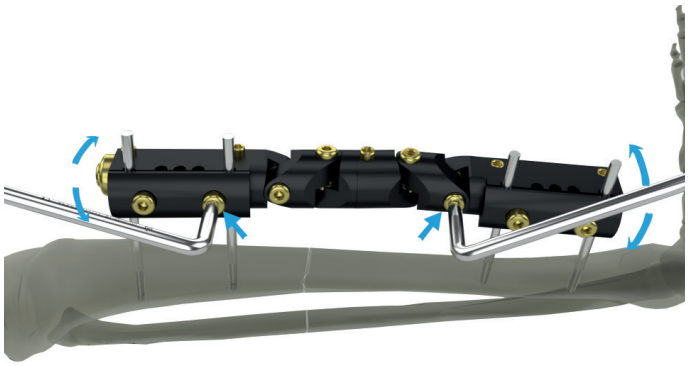
Final reduction may be addressed systematically. Length is accomplished by the distraction (manually or incrementally) of the telescoping fixator arms.



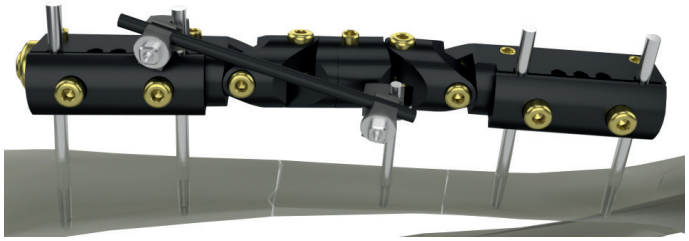
Rotation about the axis of the fixator may be achieved by releasing the set screw of the inner body rotation component.



Each dual locking connector will provide angular adjustments in two planes relative to fixator position as applied to the bone. Utilize the dual locking connector most adjacent to fracture for angular corrections.

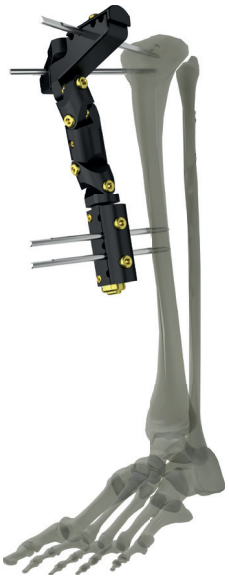


Translational adjustments are performed by releasing two opposing dual locking connectors in the same plane as desired correction.



Supplemental fixation may be employed when off plane or additional single screw placement is required utilizing the supplemental bone screw clamp. A bone screw shank is secured to another bone screw shank within the proximal or distal bone screw cluster by means of a 6 mm connecting rod.

T-Clamp Application



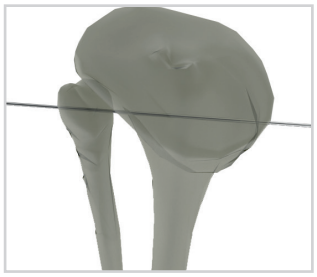
When horizontal screw placement is desired a T-clamp is added to the fixator construct. The position of the T-clamp and the corresponding axial alignment and length of the fixator must be considered when selecting screw site location. The T-Clamp should be applied first repeating steps 3-9. Attach fixator T-clamp to fixator at the dual locking connector. Assess selected diaphyseal screw sites to assure a parallel relationship between telescoping fixator arm and the bone. Insert diaphyseal bone screws following steps 3-9. Obtain reduction and definitively tighten all fixator locking bolts.

1/3 Ring Application

When horizontal screw placement is desired a 1/3 ring is added to the fixator construct with the Hybrid Ring Connector. The position of the 1/3 Ring and the corresponding axial alignment and length of the fixator must be considered when selecting screw site location. The 1/3 Ring should be applied first repeating steps 3-9. Attach 1/3 Ring and Hybrid Connector to fixator at the dual locking connector. Assess selected diaphyseal screw sites to assure a parallel relationship between telescoping fixator arm and the bone. Insert diaphyseal bone screws following steps 3-9. Obtain reduction and definitively tighten all fixator locking bolts.

Hybrid Fixator Application

Reduction of Articular Surface



For fractures with intra-articular involvement and displacement, articular fragments should be aligned and bone grafted (if necessary) to restore anatomic alignment of the articular surface. When possible, percutaneous lag screw fixation is recommended to provide interfragmentary compression of the articular fragments. As with all fractures, a provisional reduction of the major fracture components should be carried out prior to wire introduction. The use of a fluoroscope is recommended.

Wire Introduction

Wires should be positioned distal to the capsular attachments of the knee joint or roughly 15mm inferior to the joint line. Olive wires should be used in cases where additional interfragmentary compression is desired. Appropriate length and

diameter wires are chosen based on anatomic considerations and available bone stock.

To obtain maximum fixation, a minimum of three wires or a combination of two wires and a bone screw should be utilized. The first wire is introduced into the fibular head and guided to allow for an anteromedial exit through the far cortex. If introduction through the fibular head is not desireable, the reference wire can be introduced just anterior to the fibular head.

Care should be taken to ensure a parallel relationship to the joint line.

Once the wire has passed through the far cortex it should be removed from the drill and tapped with a mallet until an equal amount of wire is present on the exit side. If olive wires are used, insertion should continue until the olive engages the near cortex. washer is available to facilitate small fragment positioning in osteopenic bone. Once the first wire has been inserted, a variable wire carriage may then be attached to the wire shanks. When loosening the variable wire carriage locking bolt, maintain orientation of the key to allow for free passage of the wire into the carriage. Once in place, the locking bolt should be provisionally tightened to allow for attachment to the ring.

Ring Selection

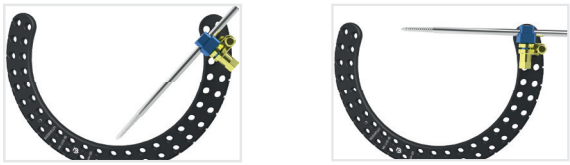
The appropriate size ring should allow for at least two finger space from the inside of the ring to the anteromedial and lateral soft tissue borders. If there are less than two finger breadths, the surgeon should opt to utilize the next largest diameter. Between 135mm and 150mm rings may be appropriate for distal tibial, elbow and smaller patients. Between 180mm and 225mm rings are more appropriately used in tibial and femoral fractures in larger patients.

Application of Advanced Screw & Wire Clamps

Height Adjustment

Vertical Angle of the Screw

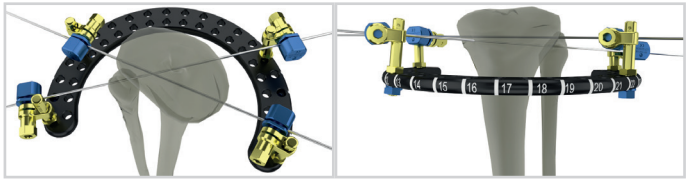
Horizontal Angle of the Screw



Application of Advanced Wire Clamps

Once provisionally tighten the wire clamp to the wire. Clamp may now be attached to the ring. In cases where a full ring is not used, 2/3 ring should be positioned so that the open portion is oriented posteriorly to allow for range of motion of the knee.

Once the wire clamp has been attached and the spatial relationship between the wire and the ring has been established, threaded portion of the clamp or rail part of the Advanced Wire Clamp is definitively secure using a 10 mm standard nut.



A second wire is then inserted from posteromedial to anterolateral allowing for a maximum

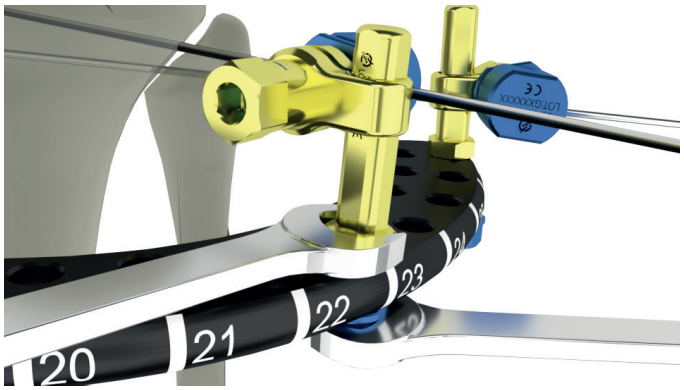
convergence between the reference wire. Care should be taken to avoid contact with the reference wire and can be prevented by adjusting the height of the additional wire to be introduced. The identical technique should be used for wire insertion and if a second olive wire is chosen, the olive should be oriented to engage the opposite cortex from the first olive wire.

After the second wire has been inserted, a standard or advanced wire clamp may then be attached to the wire.

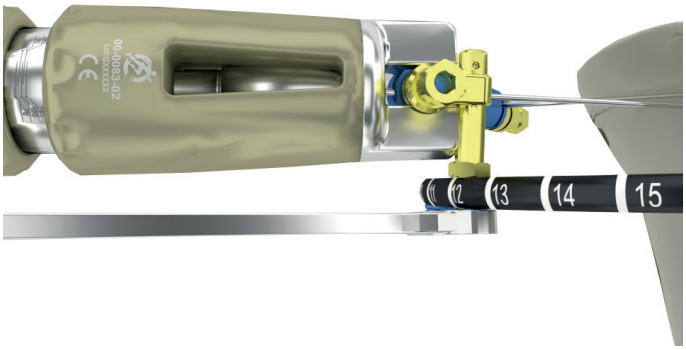
An additional wire or bone screw will enhance the stability of fragment fixation. If a bone screw is chosen, please refer to the section pertaining to supplemental fixation. If a third wire is desireable, introduction and attachment to the ring should follow identical technique for the previous two wires. The third wire may be inserted distal to the ring. Care should be taken to avoid contact between the respective wires and can be prevented by adjusting the height of the additional wires to be introduced.

Tensioning Wires

Prior to wire tensioning, the wire to advanced wire clamp should be examined to make sure that wires are not prestressed or bent in any fashion. If bowing of the wires exists, the rail and locking bolt of the advanced wire clamps should be loosened and re-positioned to ensure straight wire positioning.



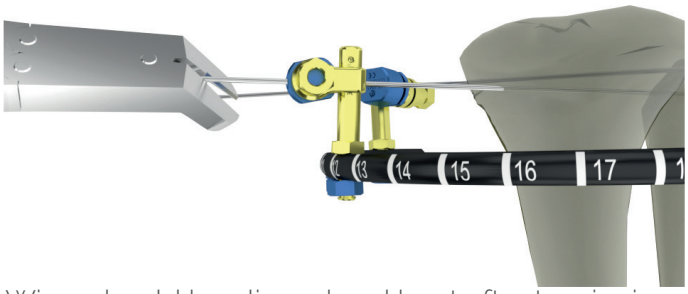
Making sure the opposite variable wire carriage has been definitively tightened. If using olive wires, the wire locking bolt on the olive side of the wire should be definitively tightened.



Loosen the wire locking bolt. Proper tensioning should commence from the side opposite to the olive.

Attach tensioner to the wire. The wire carriage locking bolt on the side to be tensioned should be loosened prior to definitive tensioning. The tensioner should then be locked onto the wire by securing the tensioner bolt.

Wire tension should range from 70kg to 100kg for a 2/3 ring, and 100kg to 130kg for a full ring depending on the quality of the bone. Once adequate tension has been achieved, definitively lock the wire carriage locking bolt with a wrench prior to removing the tensioning device.



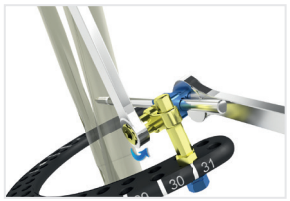
Wires should be clipped and bent after tensioning.

NOTE: The tensioner position must be reset after tensioning. Tension the remaining wires as previously described.

Supplemental Fixation

All of the adjustment of the angulation and also fixation of the screw to the clamp is facilitated through a single locking nut mechanism located on the gold end of the horizontal portion of the Advanced Screw Clamp as highlighted below.

The ideal position of the bone screw is chosen by the Surgeon, the bone drilled and the screw introduce.



The locking nut on the locking mechanism of the clamp is loosened using the 10mm spanner. (Care should be taken not to over loosen the mechanism).

The Advanced Clamp is then slide onto the bone screw and lightly tightened. The threaded portion of the Advanced Clamp is then passed through one of the holes in the ring and secured using a 10mm standard nut.

Alternatively if the ring is already in position slide the Advanced Screw Clamp onto the bone screw. Keeping the locking mechanism loose, pass the threaded portion of the Advanced Locking Clamp into the ring and secure using a 10 mm standard nut.

Attachment of Ring Fixator

A ring to fixator connector is then attached to a standard UniX® fixator. Removal of a telescoping component is necessary to complete the frame. For left proximal tibias, the left telescoping arm is removed and replaced by a ring to fixator connector. For right proximal tibias, the right telescoping arm is replaced by a ring to fixator connector. Once this has been achieved, the two locking bolts of the ring to fixator connector are inserted through the ring and tightened into the fixator construct and placed in an anteromedial fashion.

Ankle Clamp Application

After achieving a preliminary preop reduction, the first screw to be introduced should be positioned medially in the talar neck such that it is parallel to the dome of the talus following steps 3-9 of standard operative technique.

After bi-cortical penetration, release the 3.2 mm drill bit and evaluate its position fluoroscopically to confirm a parallel relationship to the talar dome. Re-attach drill to drill bit and extract the drill bit. Repeat step 9 of standard operative technique.

Attach the ankle clamp onto the talar bone screw and screw guide with the window of the device positioned medially and anterior to facilitate lateral radiographic evaluation. Clamp cover locking

bolts of the ankle clamp must be facing distally for access.

Using the ankle clamp as a template select second screw position in the calcaneus allowing for desired plantar/dorsi flexion. Repeating steps 3-9 of standard operative technique, insert second bone screw. Confirm bone screw position and depth of penetration utilizing image intensification.

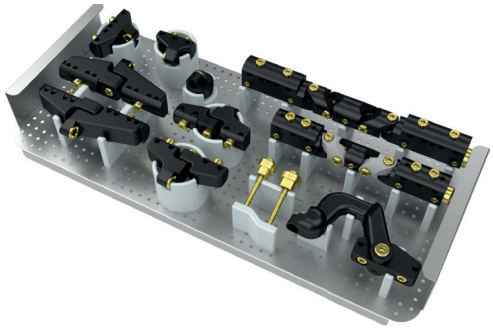
Attach fixator body to ankle clamp at the inner body rotation component by means of a locking connector bolt.

Note: Assembly for left ankle application requires removal of the R telescoping fixator arm and R dual locking connector. For right ankle application, remove L telescoping fixator arm and L dual locking connector.

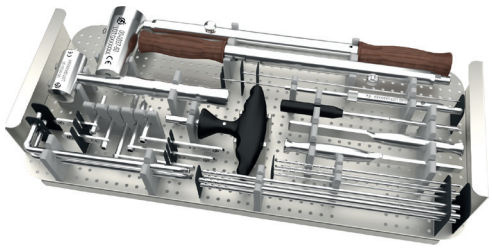
Spacially relocate the talus under the tibia and position remaining bone screws through the telescoping fixator arm in the tibial diaphysis perpendicular to the long axis of the tibia. Secure clamp locking bolts. Reduction is maintained by locking all fixator fittings. The hinge of the ankle clamp is tightened in the direction of the arrow etched on the clamp.

Screw Site Care

At the conclusion of fixator application and fracture reduction, wounds are dressed in routine sterile fashion. Care should be taken to insure all fixator fittings are securely tightened. Dry sterile gauze is wrapped around the shanks of the bone screws to prevent pistoning of the soft tissues on the bone screws. Once wounds have healed and sutures are removed, routine postoperative screw site care is recommended. Screw sites should be monitored during subsequent clinic visits. All fixator fittings should be evaluated for tightness during subsequent clinic visits.

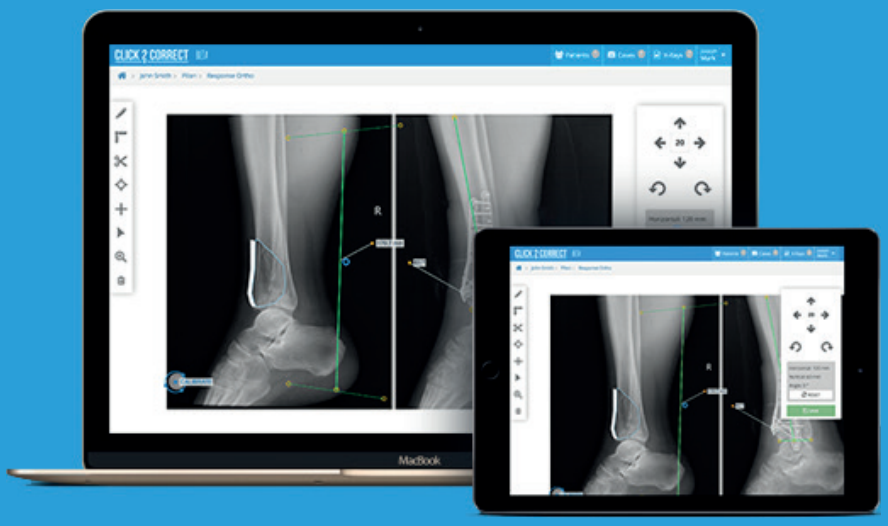


00-9069-08	UniX Std&Small Fixator Set	1
00-8109-08	UniX Std&Small Fixator Case	1
50-5012-00	Unix Multijoint External Fixator, Small	1
50-5012-01	Unix Multijoint Small C/D Unit	1
50-5013-00	Unix Multijoint External Fixator, Large	1
50-5013-01	Unix Multijoint Large C/D Unit	1
50-5021-00	Unix Large Convergent T-Clamp, Offset	1
50-5022-00	Unix Large Convergent T-Clamp, Parallel	1
50-5023-00	Unix Large T-Clamp, Standard	1
50-5021-01	Unix Small Convergent T-Clamp, Offset	1
50-5022-01	Unix Small Convergent T-Clamp, Parallel	1
50-5023-01	Unix Small T-Clamp, Standard	1
50-5028-00	Unix Ring Adapter	1
50-5024-00	Unix Ankle Clamp	1



00-8109-00	External Fixator General Instrument Case	1
00-0022-00	Hammer (Light)	1
00-3321-20	Quick Release Drill, 3.2mm Ø, 200mm Length	2
00-3323-20	Quick Release Drill, 3.2mm Ø, 200mm Length, Cannulated	1
00-3481-03	Quick Release Drill, 4.8mm Ø, 280mm Length	2
00-3483-28	Quick Release Drill, 4.8mm Ø, 280mm Length, Cannulated	1
00-0041-32	Drill Guide 3.2mm	2
00-0041-48	Drill Guide 4.8mm	2
00-0052-40	Soft Tissue Guide, 40mm	2
00-0052-60	Soft Tissue Guide, 60mm	2
00-0050-00	Trocar	1
00-2035-19	Alien Wrench, 5mm/190mm	2
00-2036-00	T-Wrench for Bone Screws	1
00-0130-13	Osteotome, 13mm Wide Blade	1
00-0130-19	Osteotome, 19mm Wide Blade	1
00-7057-00	2.0mm X 250mm Non-Threaded Guide Wire	4
00-0013-90	Depth Gauge, 4.5/6.0mm Range, 90mm length	1
00-0037-60	Low Profile Rod Cutter, 6mm (modular handle)	1

CLICK 2 CORRECT



Click2Correct™ Web App

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