

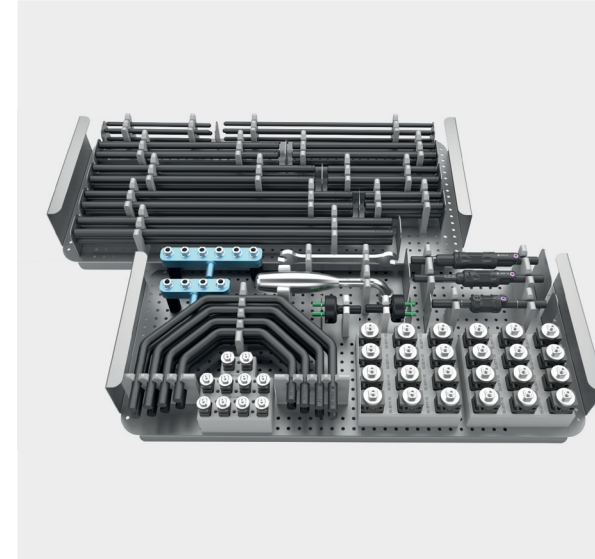


Bar Fixator





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



CONTENTS

- 3 Introductions
- 4 Surgical Technique
- 5 Bone Screw Insertion
- 6 Pelvic Fractures Fixation
- 7 Knee Spanning
- 7 Long Bone Fixation
- 8 Metaphyseal Hybrid Fixation
- 9 Ankle Spanning
- 10 Humeral and Elbow Bridging
- 10 Wrist Fractures Fixation
- 11 Fixator Removal
- 12 Ordering Information
- 14 Bone Screws

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Introductions

The Response Ortho® UniX Bar Fixator System is a complete solution for primary and definitive fracture care with carbon fiber external bar fixator system for fixation of lower and upper limb fractures.

The Bar Fixator system can be used in conjunction with existing UniX (Rail, Hybrid, Standard, Ankle and Elbow fixators) and Smart Correction solutions.

Indications

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

Components

Clamp



- Connects two bars or a bar to a bone screw
- 6mm and 10mm options are available.
- Serrated structure between the clamp jaws prevents loosening of the bars.

Carbon Fiber Bar



- 6mm and 10mm diameter options
- Fully radiolucent carbon fiber containing a radiopaque marker

Compression Distraction Unit



- Compression/Distraction Unit allows small adjustments for controlled fracture alignment

Hybrid Ring Connector



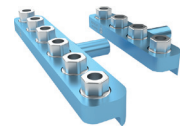
- Compatible with 1/3, 2/3 and full rings
- Locks to the ring using two locking bolts
- Connects with 10mm component of 6/10/10 clamps

Metaphyseal Bar



- Available only for peri-articular fracture fixation with Bone Screws. (not for tensioned wire fixation)
- Utilize with 10mm part of 6/10/10 clamps
- Allows enhanced radiographic visualization and surgical access

Multiple Screw Clamp

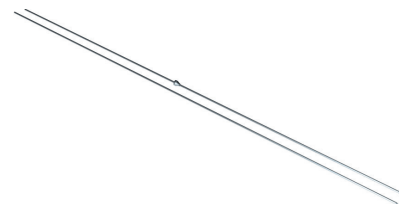


- Patented easy and fast multi-screw fixation
- Requires 5mm Allen Wrench or 10mm hex wrench for clamp locking.

Wires and Bone Screws

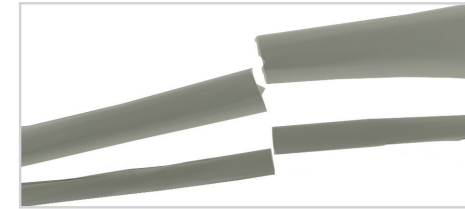


- Both straight and olive stainless steel wires in a variety of diameters (1.6, 1.8 & 2mm)
- Available in Ti & SS, and Trocar and Bayonet tips.
- Two sizes: 4.5mm and 6mm diameter tapered screws with 6mm universal shank
- Trocar for fast easy fixation, or blunt point screws requiring pre-drilling for less tissue disturbance
- Available either uncoated or with Hydroxi-Apatite



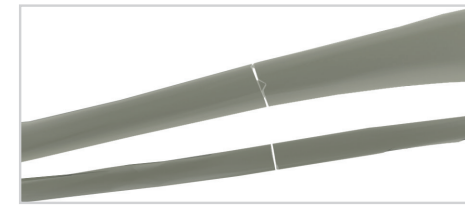
Bone Screw Insertion

1



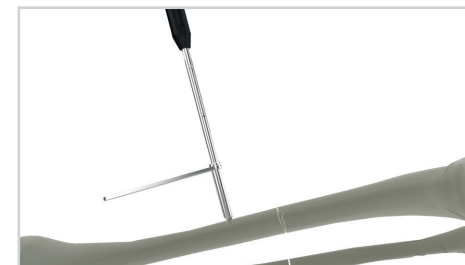
Pre-operative planning is recommended prior to the application. Assess potential screw site locations based on available bone stock and soft tissue considerations. Additional modules may be utilized for horizontal screw placement or fracture specific applications. Prep and drape in routine way.

2



Obtaining a preliminary reduction is recommended. A 1 cm incision is made and blunt dissection continued to the 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



When using Blunt Tip Screws: 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



Using the non-dominant hand, once the screw site has been 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 the drill bit into the drill guide and drill both near and far cortices. Be sure the 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.

Pelvic Fractures Fixation



Insert two 6mm bone screws into each iliac crests and connect them with an anterior frame.

Identify the ASIS and the insertion points are 2cm posterior for the first bone screw. Insert the second bone screw approximately 2-3cm posterior to the first along the crest. A small incision is centered over the iliac crest/tubercle. Dissect sharply down to bone. Identify the medial and lateral borders of the crest. Use the 4.8mm drill and drill guide to drill the cortex in the middle to a depth of approximately 1cm. Insert a 6mm bone screw through the soft tissue sleeve. Care must be taken to ensure that the bone screw does not penetrate the inner or outer table of the crest.

Insert the second bone screw in similar way. Connect two bone screws with clamps on both the left and right side. The trapezoidal shaped frame allows the patient to sit up in bed.

Knee Spanning



Insert the first tibial bone screw distal to the injured zone and distal to the planned fixation. Locate the bone screw AP Plane, along the center of the anterior tibial crest.

Insert the second bone screw distally in the area of the diaphyseal-metaphyseal junction. Two bone screws are inserted straight into the anterior surface of the femoral diaphysis. For stability of the frame, the distance between the screws should be maximized.

Connect all the bone screws to each other with bars (50-3023-XX) and clamps (50-3011-10) anterior to the knee joint. Using traction and manipulation, the fracture is reduced and the clamps tightened definitively taking care to keep the knee flexed approximately 15° to relax the posterior neurovascular structures.

Additional clamps and bars can be attached to the frame to increase the stability of the frame.

Long Bone Fixation



Insert four bone screws with maximum distance along the diaphyseal axis of the bone.

Insert one screw on both side of the fractures as far from the fracture line as can be achieved for correct screw placement.

Insert two additional bone screws as close as possible on both sides of the fracture.

Attach the clamps onto the bone screws. Connect the appropriate length bar(s) into the clamps. Maintain the fracture reduction until all the clamps are fully tightened.

If maintaining fracture reduction is difficult, the proximal and distal bone screws can be connected with separate short bars. Connect the clamps to each short bar and a long bar in order to stabilize the proximal and distal fractures.

After the reduction and alignment of the frame, clamps should be tightened using the wrench, ensuring all nuts are tightened starting from one end of the frame proceeding to the other end.

Metaphyseal Hybrid Fixation

External fixation can be used in the provisional or definitive treatment of tibial fractures. It is a useful tool for patients who cannot physiologically tolerate internal fixation, have a vascular injury with prolonged ischemia time, or have a severe soft tissue injury. In addition highly comminuted proximal or distal third fracture patterns may interfere with internal fixation techniques, necessitating an alternative operative modality. Intra and peri-articular fractures where the fracture pattern and available bone stock preclude the introduction of larger diameter bone screws.

Obtaining an anatomic reduction of the joint surface is the first step in placing a hybrid external fixator in the periarticular area. This can be accomplished percutaneously if the joint surface is non-displaced the external fixator can be placed immediately. If an open reduction is required, trans-articular fixation should be performed first, with definitive reconstruction delayed until the soft tissue envelope has a chance to heal, typically after 7 to 14 days.

Proximal Tibia Fractures



Use tensioned olive wires to fix in the peri-articular segment. Use bone screw in far segment

to the fracture site. Followed by connect the frame and reduce the fracture. Add supporting bars to prevent collapse and loss of reduction. Final placement of a third fixation point in the metaphysis may be required.

Introductions for Safe wire placement

Insert the first wire posterolaterally, just in front of the fibula exiting anteromedially. As opposed to the ankle the fibular head should not be included in the fixation.

Insert the second wire from posteromedially, anterior to the medial head of the gastrocnemius, exiting anterolaterally. To increase the strength of the construct, wire divergence should be maximized. The third wire should be inserted anterior to the point of intersection of the first two wires, thereby also increasing the strength of the construct. Whenever possible, wires should be kept to a minimum of 15mm from the joint surface to avoid penetrating the knee joint capsule. This will decrease the associated risk of septic arthritis.

Distal Tibia (Pilon) Fractures



First choose an adequate size ring to allow 2 finger breadths distance around the ankle. Elevate the ankle on 4-5 cloth towels to allow clearance for placement of the tensioned wires.

The first tensioned olive wire is placed from the posterolateral aspect of the fibula exiting anteromedially. The wire should exit medial to the tendon of tibialis anterior to avoid neurovascular injury. The second wire is then placed from posteromedial to anterolateral. Posteromedial placement should be just anterior to the posterior medial edge of the tibia and the exit should be between the peroneal tendons and toe extensors. This wire placement will allow for maximum spread utilizing the "safe zones" as described by Behrens and Searls to avoid neurovascular damage.

Connecting the Ring

Use the appropriate diameter ring. Keep in mind that if hybrid fixation is done acutely the proximal/distal soft tissue envelope may significantly swell, thereby making the 2/3 ring chosen too small.

Connect the wires to the ring by use of the Advanced or Standard Wire Clamps and tension to the appropriate level.

Insert two 6mm screws in the distal diaphysis. Use a 5-Hole Clamp or two independent pin clamps. Once the half pins are inserted the distal and proximal segments are attached using appropriate bars. Use the hybrid ring connector or proximal shaft of one or two screws to connect the ring.

Make a triangular type configuration. Once all connections have been established the fracture is reduced and aligned by the use of ligamentotaxis. The frame is tightened and fluoroscopy imaging is done to confirm length, alignment and rotation. Additional bars can be added to increase frame stiffness and rigidity.

The final step involves placement of a point of fixation in the peri-articular segment. This can be achieved with either a bone screw or tensioned wire.

Ankle Spanning



Insert the bone screws on the anteromedial surface of the tibia. Use a 5-Hole clamp to insert two screws through the 1st & 5th holes. Utilizing a small skin incision dissect down to bone using blunt dissection. In order to maintain a parallel relationship to the first bone screw insert the second screw using the 5-Hole clamp as a guide. Insert a 6mm calcaneal bone screw from medial to lateral. Make a small incision posterior and distal to the neurovascular bundle, followed by blunt dissection down to the bone. Insert the calcaneal screw into the bone parallel to the ankle joint. Insert a 4.5mm bone screw from the medial side into the medial and middle cuneiform. Make a small incision over the midpoint of the medial cuneiform followed by blunt dissection down to the bone. Connect the bone screws in a triangular formation using the clamps and bars. Apply traction to the leg along its long axis, using the calcaneal screw. Once adequate reduction is achieved, tighten the clamps over the tibia and calcaneus. The foot is then dorsiflexed to the neutral position and clamps connecting the cuneiform bone screws are tightened. All clamps should be checked for definitive locking.

Humeral and Elbow Bridging Humeral Shaft Frame Construction



Insert the proximal bone screws from lateral to medial, followed by insertion of the distal screws lateral to medial or posterior to anterior. All bone screws must be inserted using open incisions, with the bone visualized, and using soft tissue guides to protect the neurovascular structures. A simple single stacked frame is usually sufficient for the humerus. If needed, the frame can be double stacked. Perform the reduction using manual traction and tighten all clamps definitively.

Elbow Bridging Frame Construction



Insert two distal humeral bone screws posteriorly from a dorsal direction. Insert two 4.5mm ulnar bone screws into the forearm from a dorsal direction. Connect clamps to each screw and attach to bars in the ulnar and humeral fragments. These two fragments are connected with one bar and two clamps. An additional bone screw can be used to increase the stabilization of the radio-ulnar joint.

Wrist Fractures Fixation



Insert two 3.3mm screws each into the second metacarpal and the radius.

Connect 6mm clamps to each screw and attach to 6mm bars in the metacarpal and radius fragments separately. Reduce the fracture by using the partial frames as handles.

Connect the metacarpal and radial fragments with a 6mm bar and two clamps.

NOTE: Implant the bone screws into the second metacarpal with an angle of 40° to 60° between the proximal and distal bone screw.

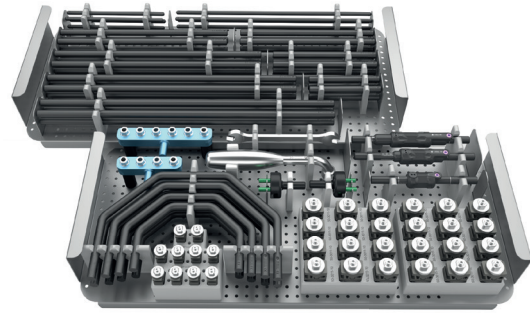
Suggested Screw Site Care

Wrap dry sterile gauze around the shanks of the bone screws to prevent pistoning of the soft tissues on the bone screws. Use a solution of 2% hydrogen peroxide and sterile water on the pin sites until the wounds have healed and sutures are removed.

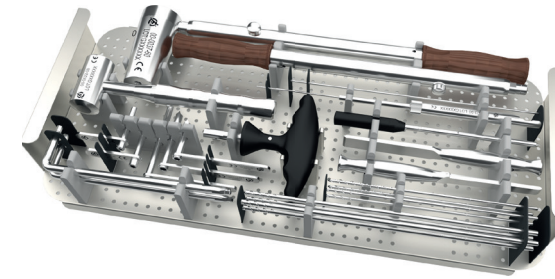
The patient should be instructed to shower on a daily basis using soap and water and reapply gauze dressings as a means for routine bone screw hygiene. Screw sites should be monitored during subsequent clinical visits. All fixator locking components should be evaluated for tightness during subsequent clinical visits.

Fixator Removal

The fixator can be removed as a simple outpatient procedure. Before the frame removal, an appropriate dose of paracetamol is given to the patient. The clamps are loosened and the fixator clamps and carbon bars are disassembled from the bone screws. Turn the bone screws counterclockwise provides to loosen them. Discard the bone screws after removal.



00-9069-04	UniX Bar Fixator Set	
00-8109-04	UniX Bar Fixator Case	1
00-2050-08	8/10mm Hex Bolt Wrench	1
00-2053-00	Large Bar Clamp Wrench	1
50-3011-06	Multiaxial Small Bar Clamp, 6/6/4	10
50-3011-10	Multiaxial Large Bar Clamp, 6/10/10	24
50-3015-04	3/4 Hole Screw Clamp	1
50-3015-06	5/6 Hole Screw Clamp	1
50-3016-00	Large Bar Fixator Ring Adapter	2
50-3023-10	100mm Carbon Fiber Rod w/marker	4
50-3023-15	150mm Carbon Fiber Rod w/marker	4
50-3023-20	200mm Carbon Fiber Rod w/marker	4
50-3023-25	250mm Carbon Fiber Rod w/marker	4
50-3023-30	300mm Carbon Fiber Rod w/marker	4
50-3023-35	350mm Carbon Fiber Rod w/marker	4
50-3023-40	400mm Carbon Fiber Rod w/marker	4
50-5028-15	Unix Supplemental Rod, Short	4
50-5028-30	Unix Supplemental Rod, Long	4
50-3031-12	Metaphyseal Bar, 120mm ID, Small	2
50-3031-15	Metaphyseal Bar, 150mm ID, Medium	2
50-3031-18	Metaphyseal Bar, 180mm ID, Large	2
50-3031-21	Metaphyseal Bar, 210mm ID, X-Large	2
50-3041-01	Distraction Unit, Short	1
50-3041-02	Distraction Unit, Medium	1
50-3041-03	Distraction Unit, Long	1



00-9069-00	External Fixator General Instrument Set	
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

Bone Screws

Diameter	Shaft Length	Thread Length	Blunt Tip	Trocar Tip
3.0mm	90mm	30mm		50-1073-93 (SS)
		30mm		50-1083-93 (Ti)
4.5mm	100mm	20mm	50-1084-102B	50-1084-102
		40mm	50-1084-104B	50-1084-104
	120mm	20mm	50-1084-122B	50-1084-122
		30mm	50-1084-123B	50-1084-123
		40mm	50-1084-124B	50-1084-124
		50mm	50-1084-125B	50-1084-125
	150mm	30mm	50-1084-153B	50-1084-153
		40mm	50-1084-154B	50-1084-154
		50mm	50-1084-155B	50-1084-155
6.0mm	100mm	30mm	50-1086-103B	50-1086-103
	110mm	30mm	50-1086-113B	50-1086-113
		40mm	50-1086-114B	50-1086-114
	120mm	20mm	50-1086-122B	50-1086-122
		30mm	50-1086-123B	50-1086-123
		40mm	50-1086-124B	50-1086-124
		50mm	50-1086-125B	50-1086-125
	130mm	30mm	50-1086-133B	50-1086-133
	140mm	40mm	50-1086-134B	50-1086-134
	150mm	30mm	50-1086-153B	50-1086-153
		40mm	50-1086-154B	50-1086-154
		50mm	50-1086-155B	50-1086-155
		60mm	50-1086-156B	50-1086-156
	160mm	30mm	50-1086-163B	50-1086-163
		40mm	50-1086-164B	50-1086-164
	180mm	20mm	50-1086-182B	50-1086-182
		30mm	50-1086-183B	50-1086-183
		40mm	50-1086-184B	50-1086-184
		50mm	50-1086-185B	50-1086-185
		60mm	50-1086-186B	50-1086-186
	200mm	30mm	50-1086-203B	50-1086-203
		40mm	50-1086-204B	50-1086-204
		50mm	50-1086-205B	50-1086-205
		60mm	50-1086-206B	50-1086-206
	220mm	30mm	50-1086-223B	50-1086-223
		40mm	50-1086-224B	50-1086-224
		50mm	50-1086-225B	50-1086-225
		60mm	50-1086-226B	50-1086-226
	250mm	30mm	50-1086-253B	50-1086-253
40mm		50-1086-254B	50-1086-254	
50mm		50-1086-255B	50-1086-255	
300mm	60mm	50-1086-306B	50-1086-306	

HA coating is available for all the screw types with an "H" added the end of the part number eg 50-108X-XXXHB or 50-108X-XXXH.

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Bar Fixator



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