



**Zimmer®
XtraFix® External
Fixation
System**

Large & Small

Surgical Technique



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XtraFix External Fixation System

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Introduction

In 1897, Dr. Clayton Parkhill of Denver, Colorado, reported on the first successful use of an external fixation device in fracture treatment. Five years later, Dr. Albin Lambotte of Belgium developed a unilateral fixator that allowed active motion without splinting. Lambotte's more rigid device was made of better materials and used more Pins in combination with steel Bars.

In the 1930s, Dr. Roger Anderson developed the concept of independent Pin placement with individual pin-to-bar clamps. At about the same time, Dr. Raoul Hoffmann developed the Multi-Pin Clamp technique. Over the next 60 years, external fixators continued to become more rigid. In most cases, they were used as a primary means of fracture management.

Since the 1980s, however, the use of external fixation has evolved to become a temporary way to support soft tissues and maintain fracture alignment until a more definitive internal fixation procedure such as periarticular plating or IM nailing can be performed.

The flexibility of more contemporary devices gives the surgeon the ability to progressively increase the frame rigidity while allowing physical therapy or weight bearing. These same devices allow surgeons to decrease frame rigidity to promote secondary bone healing prior to complete removal of the frame.

The *XtraFix* External Fixation System is a modular system that offers surgeons advances in design technology and materials. The system design philosophy is based on increasing efficiency. Each component incorporates the most useful features from the many different systems currently on the market, and combines them into one time-saving device. *XtraFix* allows surgeons to build rigid constructs, using fewer components, in less time.

Design Goals

The most important functional design goal of an external fixation system is to provide fracture stability.

Efficiency

All clamps have a SnapLoc latch that actively prevents bars and pins from popping out. Clamps also feature one-nut tightening. This reduces the total number of nuts required to tighten a frame, and saves intra-operative time.

Independent Locking Clamps within the system have two nuts which allow surgeons to tighten the Pin or Bar sides of the Clamp individually.

Efficiency Multi-Pin Clamps have 2-Bar and 1-Bar jaw attachments built-in to the clamp with the goal of reducing the number of components required to construct a frame. Quick-connect ends are designed into pins and drills to save time during implantation.

All pins and instruments are color coded to simplify steps for the surgical team. Each pin, whether it is a 5mm/6mm diameter shank (*XtraFix* Large 11mm System) or a 4mm diameter shank (*XtraFix* Small 6mm System), is also sized to reduce overall clamp inventory.

Pin Placement

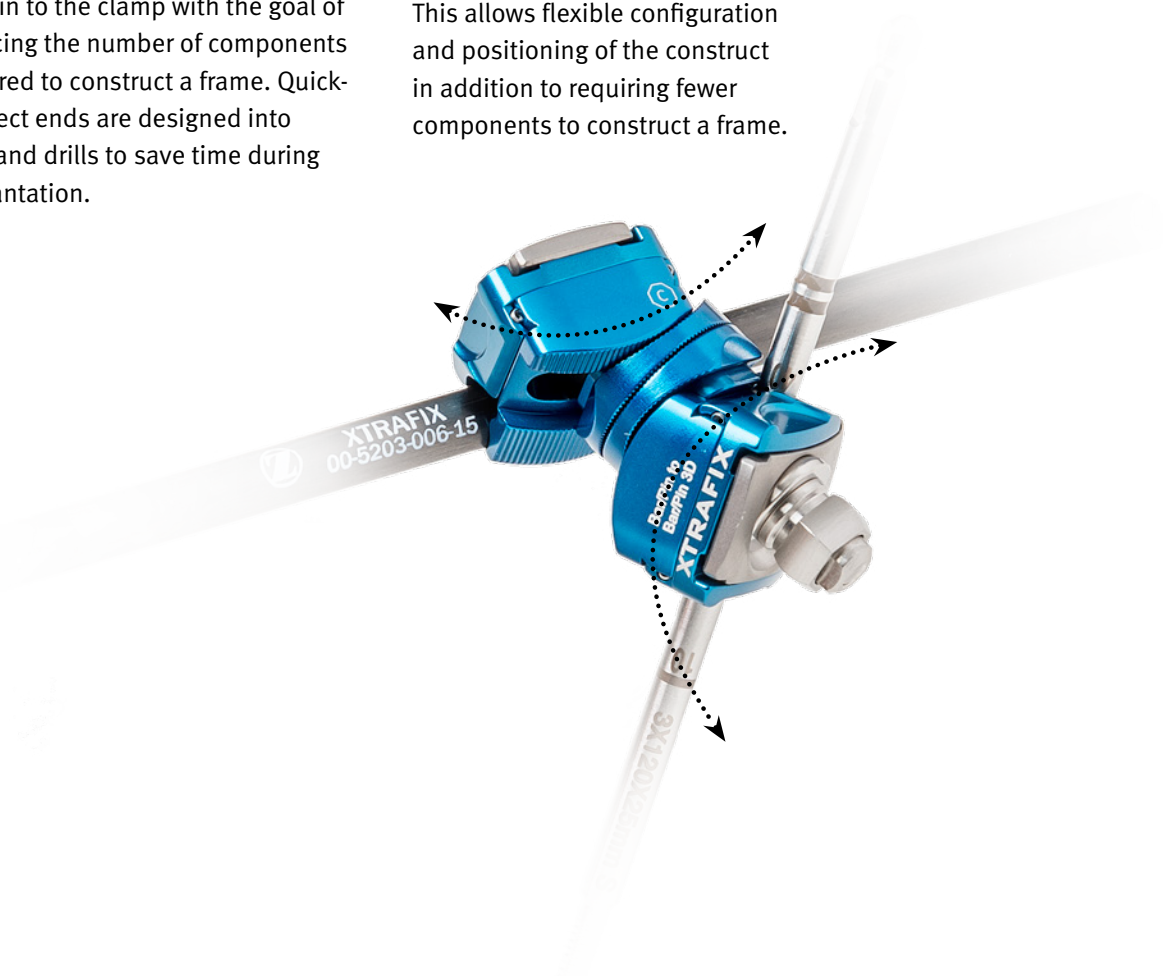
Pin orientation should be dictated by patient anatomy and the characteristics of fracture fragments. Clamps in the *XtraFix* Large 11mm and Small 6mm systems possess 80 degrees and 70 degrees of motion, respectively, to allow independent pin placement in three dimensions. This allows flexible configuration and positioning of the construct in addition to requiring fewer components to construct a frame.

Options

Components are available in a wide selection of pin and bar diameters and lengths. For example, the *XtraFix* Large 11mm set carries the smallest diameter pin (3mm) available on the market for that size set. Transitioning from *XtraFix* Large 11mm to Small 6mm components on the same frame is facilitated by *XtraFix* Large 11mm Pin-to-Bar Clamps.

Construct Materials

XtraFix clamps are made primarily of aluminum, and pins are made from high strength stainless steel. Bars come in glass fiber and carbon fiber.



MRI Information

XtraFix Large 11mm System

Non-clinical testing has demonstrated the *XtraFix* Large 11mm System with glass fiber bars only is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 or 3 Tesla,
- Spatial gradient field of 1500 Gauss/cm or less,
- Maximum whole body averaged specific absorption rate (WB SAR) of 2.0 W/kg for 15 minutes of scanning in a 1.5 or 3 Tesla scanner,
- Normal operating mode only,
- All bars in the external fixation construct should be glass-fiber/epoxy bars.

Testing of the *XtraFix* Large 11mm System with bars other than those made of glass fiber has not been performed. Scans should only be done with glass fiber bars. All other bar materials, in particular carbon fiber bars, can lead to substantial heating of the devices and scans should not be performed. The following data on heating is based on testing done with glass fiber bars:

In non-clinical testing in a 1.5T or 3T MR scanner the *XtraFix* Large 11mm System produced a temperature rise of less than 8°C at a maximum whole-body averaged specific absorption rate (WB-SAR) of 2 W/kg for 15 minutes of MR scanning.

The largest image artifact extends approximately 60mm from the device when scanned in nonclinical testing using the Spin Echo (SE) sequence in a 3T Siemens Medical Systems Tim Trio (running Syngo MR V17 software) using the Body RF Coil.

XtraFix Small 6mm System

Non-clinical testing has demonstrated the *XtraFix* Small 6mm System is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 or 3 Tesla,
- Spatial gradient field of 1250 Gauss/cm or less,
- Maximum whole body averaged specific absorption rate (WB SAR) of 2.0 W/kg for 15 minutes of scanning in a 1.5 or 3 Tesla scanner,
- Normal operating mode only,
- Any *XtraFix* Small 6mm System frame must be entirely outside the MR scanner bore as otherwise it can lead to substantial heating of devices. Therefore, MRI scanning of body parts where the *XtraFix* Small 6mm System frame is located should not be done.

In non-clinical testing in a 1.5T or 3T MR scanner the *XtraFix* Small 6mm System produced a temperature rise of less than 3.1°C at a maximum whole-body averaged specific absorption rate (WB-SAR) of 2 W/kg for 15 minutes of MR scanning with the construct not closer than 50 cm from the center of the magnet of the MR scanner.

The largest image artifact extends approximately 63mm from the device when scanned in nonclinical testing using the Spin Echo (SE) sequence in a 3T Siemens Medical Systems Tim Trio (running Syngo MR V17 software) using the Body RF Coil.

XtraFix Large 11mm System Efficiency Multi-Pin Clamps

45mm, 2-Bar Efficiency Multi-Pin Clamp

- One Efficiency Multi-Pin Clamp instead of five outrigger components.
- Five parts in one: replaces 1 x 45mm Multi-Pin Clamp, 2 x Bar-to-Bar Clamps, and 2 x Posts
- Requires tightening of 1 nut versus 6 with the five individual components (Fig. A).
- The 45mm, 2-Bar Clamp is locked on the Pins and both Bars by tightening only one nut. Use the wrench of choice to tighten the nut (Fig. B).



75mm, 2-Bar Efficiency Multi-Pin Clamp

- The 75mm, 2-Bar Clamp can be used when more distance is desired between both the bars and pins.
- Lock pins and bars independently: the 75mm, 2-Bar Clamp allows the Pins to be locked independently from the Bars (Fig. C).
- The nuts above each bar jaw also independently lock each bar clamp, one at a time (Fig. D).



45mm, 1-Bar Efficiency Multi-Pin Clamp

- When two transfixing pins are preferred (e.g. through the calcaneus in an ankle delta frame), the XtraFix Large 11mm System offers surgeons a choice in efficiency clamps.
- The 45mm, 1-Bar Clamp attaches to two pins and has a pivoting, swivel bar attachment that allows for easy connection to a single bar (Fig. E).

NOTE: This clamp could also be used in other situations: a pelvic Multi-Pin Clamp, a 1-Bar Clamp with a post, a Bar-to-Bar Clamp attached on one side, etc.



XtraFix Large 11mm System Surgical Technique

Choose Pin Size

XtraFix Large 11mm stainless steel half pins are self-tapping and self-drilling and can be used with or without pre-drilling. The aggressive flute design helps to cut effectively and quickly (Fig. 1).

Pins are available in short and long threads to accommodate different bone sizes and to minimize thread exposure above soft tissue (Fig. 2).

Large 11mm System Pins also have quick connect ends that attach directly to most power equipment. This saves time compared to manually attaching pins to a tri-shank Jacobs Chuck (Fig. 3).

Stainless steel blunt tip half pins are also available in the Large 11mm if surgeons desire more feel during insertion after pre-drilling (Fig. 4).



Fig. 1



Fig. 2



Fig. 3

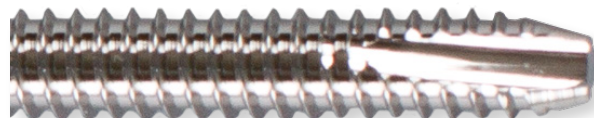


Fig. 4

Select Tissue Protector and Trocar

Once the diameter and length of the pin is chosen, select the corresponding size of trocar & tissue protector. The system is color-coded and sized Short (S), Medium (M), Long (L), 6mm (6), and Transfixing (T) to make matching instruments to pins easy (see Fig. 5 and the chart below). It is important to select the correct tissue protector if the user wants to later utilize depth marks on the drills and pins.



Fig. 5

Pin Type	Trocar and Tissue Protector Size	Pin Color	Corresponding Pin Sizes
Self Drilling/ Self-Tapping Pins	Short (S)	Blue	3mm x 100mm x 15mm 3mm x 100mm x 25mm 4mm x 100mm x 20mm 4mm x 100mm x 35mm
	Medium (M)	Yellow	5mm x 160mm x 35mm 5mm x 160mm x 55mm
	Long (L)	Orange	5mm x 200mm x 45mm 5mm x 200mm x 65mm 5mm x 250mm x 85mm
	6mm (6)	Green	6mm x 200mm x 55mm 6mm x 250mm x 85mm
	Transfixing (T)	Black	5mm x 275mm, 6mm Thread Transfixing Pin
Blunt Tip Pins	Short (S)	Blue	3mm x 100mm x 15mm blunt tip 4mm x 100mm x 20mm blunt tip
	Medium (M)	Yellow	5mm x 160mm x 35mm blunt tip 5mm x 160mm x 55mm blunt tip
	Long (L)	Orange	5mm x 200mm x 45mm blunt tip 5mm x 200mm x 65mm blunt tip

Securing Tissue Protectors

Tissue protectors lock directly into Multi-Pin Clamps or into the Tissue Protector Handle (for simple pin-to-bar constructs). These two options allow surgeons to quickly and easily anchor tissue protectors against the bone.

Lock a Tissue Protector into the Handle by pressing down and turning 90°.

Drill Guide

To create a drill guide, lock 2 x Tissue Protectors between the pin holes of Efficiency Multi-Pin Clamps. Slide Tissue Protectors between the pin holes of an Efficiency Multi-Pin Clamp and lock each by turning 90 degrees. It helps to hand-tighten the nut near each Tissue Protector to secure them within the clamp during pin placement.

Insert the corresponding Trocar through the Tissue Protector, and then insert the assembly through the soft tissues until reaching cortical bone (Fig. 6).

The distal end of each Tissue Protector has an edge with teeth to help stabilize the assembly on the bone (Fig. 6).

Note: Tissue Protectors may also be left in the unlocked position if the height needs to vary between the first and second Tissue Protector (Fig. 7).

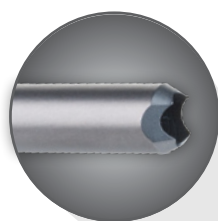
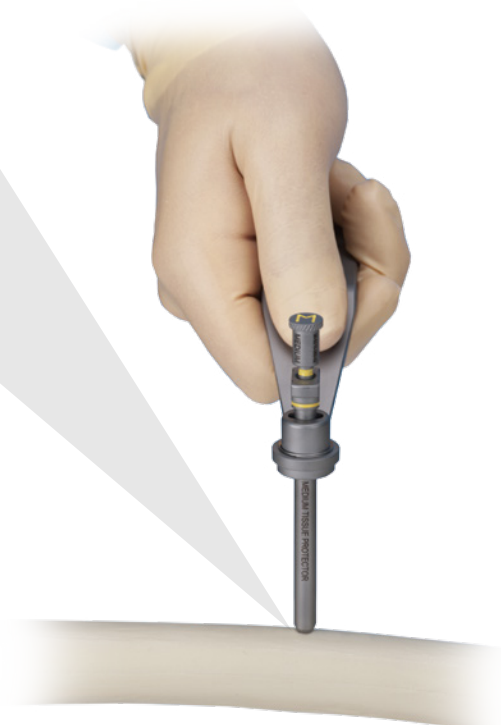
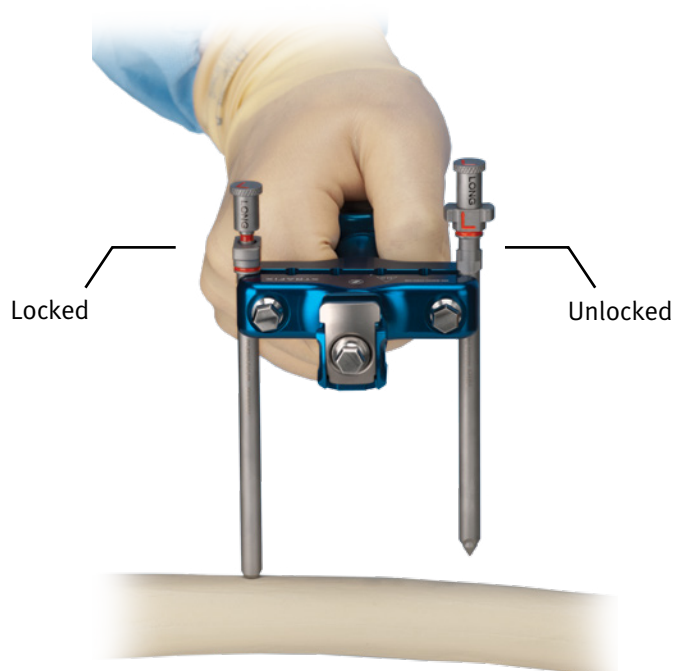


Fig. 6



Tissue Protector in Tissue Protector Handle



Tissue Protectors in Multi-Pin Clamp

Fig. 7

Remove Trocar and Insert Drill (Optional)

Pre-drilling is not required with self-drilling and self-tapping pins.* However, if desired, pre-drilling is very simple and takes only one step. *XtraFix* drills are “stepped up” in diameter from the drill flute to drill shaft so they fill the inner chamber of the tissue protector. This provides accurate drilling and eliminates the need for a drill sleeve.

The drill bit diameter is undersized appropriately compared to the corresponding pin diameter to insure the pins fit snugly into the drilled bone. For example, the drill bit diameter for a 5mm pin is 4.0mm.

In addition, drills are also color-coded to ensure proper depth calibration (Fig. 8).

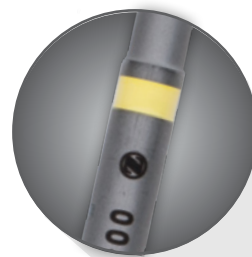


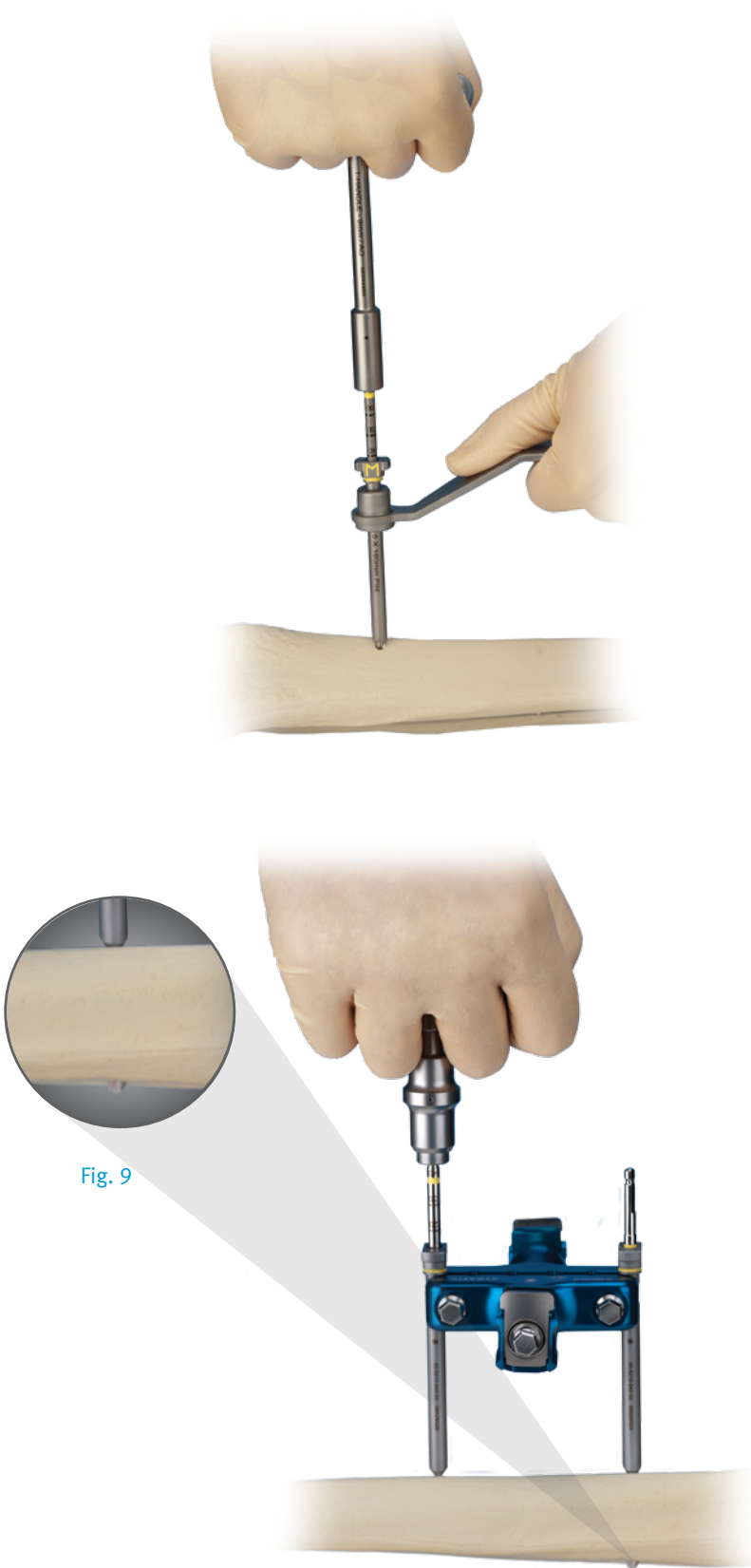
Fig. 8

TISSUE PROTECTOR SIZE	CORRESPONDING DRILL BIT SIZES
	11mm Large
Short (S)	2.4mm Blue Short Stepped Drill (3mm Pins) 3.2mm Blue Short Stepped Drill (4mm Pins)
Medium (M)	4.0mm Yellow Medium Stepped Drill (5x160mm Pins)
Long (L)	4.0mm Orange Long Stepped Drill (5x200mm & 250mm Pins)
6mm (6)	4.5mm Green 6mm Stepped Drill (6x200mm & 250mm Pins)
Transfixing (T)	No Drill Required; Black Transfixing Pin is its own drill through the calcaneus

* Blunt tip self-tapping Pins are not self-drilling. They are optional items that require the use of drills and are available upon request.



When drilling, note the calibrated depth marks on the drill bit once the second cortex of the bone has been penetrated (Fig. 9). The number visible on the bit just above the tissue protector indicates hole depth. This aids in determining the pin thread length.



Remove Trocar (or Drill) and Insert Pin

Once drilling is complete, dispose of the used drill bit and select the appropriate pin.

As mentioned earlier, the *XtraFix* pins attach directly to most power equipment. However, if a surgeon wishes to insert the pin without a power drill, they can utilize the T-Handle 9mm/AO Wrench. It is a combination tool for placing pins as well as tightening clamp nuts.

Slide the quick-connect end of the pin into the base of the T-Handle and rotate both the handle and pin in either direction until the pin locks in place. The pin will give tactile and audible feedback that it fit into the AO channel of the wrench. If using the shorter “locking” T-Handle, pull up on the base of the shaft, and rotate the wrench until the pin locks in place. Release the base to lock the pin into the wrench. This allows for additional manual manipulation and joystick-like movements.

Pin Depth Marks

Once the pin is secure, proceed by inserting the pin into the tissue protector.

The pin has the same depth marks as its corresponding drill (Fig. 10). The number visible on the pin at the top of the tissue protector is the number of millimeters the pin is protruding from the bottom of the tissue protector and into the bone.

If a pilot hole has been pre-drilled, simply insert the pin to the same depth mark as was measured with the drill bit. This saves time and may reduce fluoro exposure.

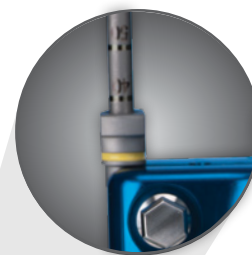
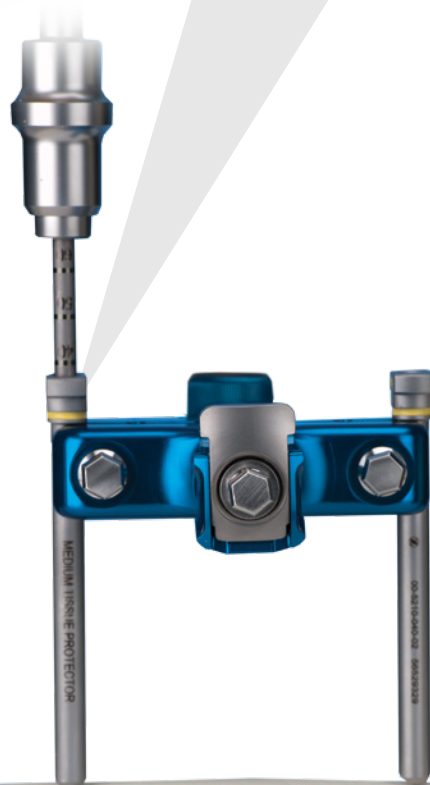


Fig. 10



Attaching Clamps to Pins

For Pin-to-Bar Clamps

The Pin-to-Bar Clamp (and all Bar connectors in the Large 11mm System) has a SnapLoc latch that encircles the bar/pin and actively captures them throughout the procedure. This eliminates troublesome “pop-offs” that can waste precious time and effort while achieving proper reduction.

Clamps should already be in the “open” position when sitting in the set.

To open the latch on a clamp:

- Grasp the waist of the clamp (mid-section between the bar jaws) using one hand
- Use the other hand to grasp the clamp latch between the index finger and thumb
- Pull back on the latch until hearing a “click”

Use this same process to remove a locked clamp from a pin or bar.

Attach the Pin-to-Bar Clamp onto the pin. The locking latch will give tactile and audible feedback that it has locked the clamp to the pin (Fig. 11).

The *XtraFix* Large Pin-to-Bar Clamps accept both 5mm and 6mm diameters.

Note: All *XtraFix* Large Pin-to-Bar Clamps are compatible with every size pin in the large set. See pages 6 and 7 for more information.



Fig. 11

Independent Locking (Single Adjustable) Clamp

An Independent Locking (Single Adjustable) Clamp is an optional item in the *XtraFix* Large 11mm set. This particular clamp allows a surgeon to independently tighten one jaw over a pin while leaving the bar jaw of the clamp loose in order to slide along a bar. When tightening the pin side nut, the clamp both tightens over the pin and locks the pin side orientation in relation to the bar side of the clamp. This clamp is particularly useful when using a compression/distraction device.

Compression/Distraction Device

The compression/distraction device is used in conjunction with Independent Locking clamps. To use it with a Large construct, ensure the fork side marked “11mm” is facing the Large clamp (Fig. 12).

Important: The Compression/Distraction device should only be used with Independent Locking (Single Adjustable) clamps.



Fig. 12

Attaching Clamps to Pins

For Multi-Pin Clamps

After inserting the pins through multi-pin clamps, turn the tissue protectors 90 degrees to unlock. Loosen any tightened pin clamp nuts and remove the tissue protectors by pulling straight up and sliding out of the clamp pin hole, leaving the multi-pin clamp to grab onto the pin (Fig. 13).

Secure the multi-pin clamp to the pins by tightening the two nuts on the outside of the clamp (Fig. 14).

Note: The 2-Bar 75mm Pin Clamp can be tightened to the pins and bars independently. The 2-Bar 75mm Multi-Pin Clamp is larger and has more nuts to tighten compared to the 2-Bar 45mm Multi-Pin Clamp.



Note: The 2-Bar 45mm Pin Clamp does not need to be tightened to the pins in a separate step since one nut tightens the clamp to both the bars and pins simultaneously.

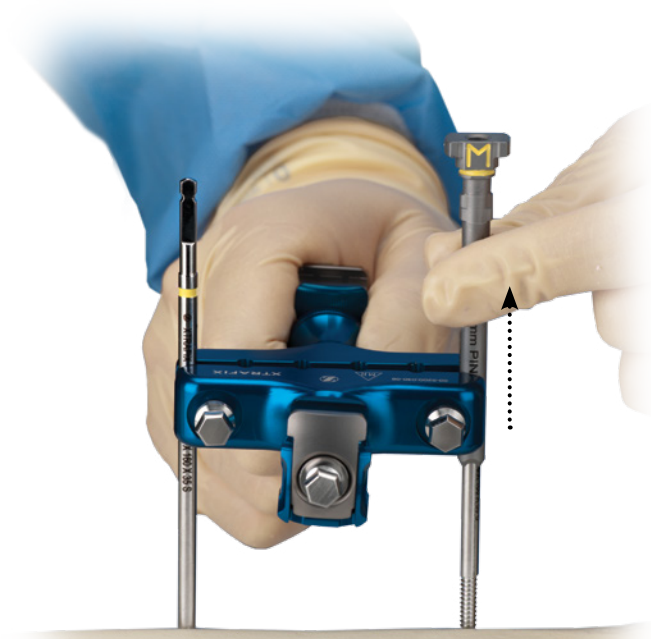


Fig. 13

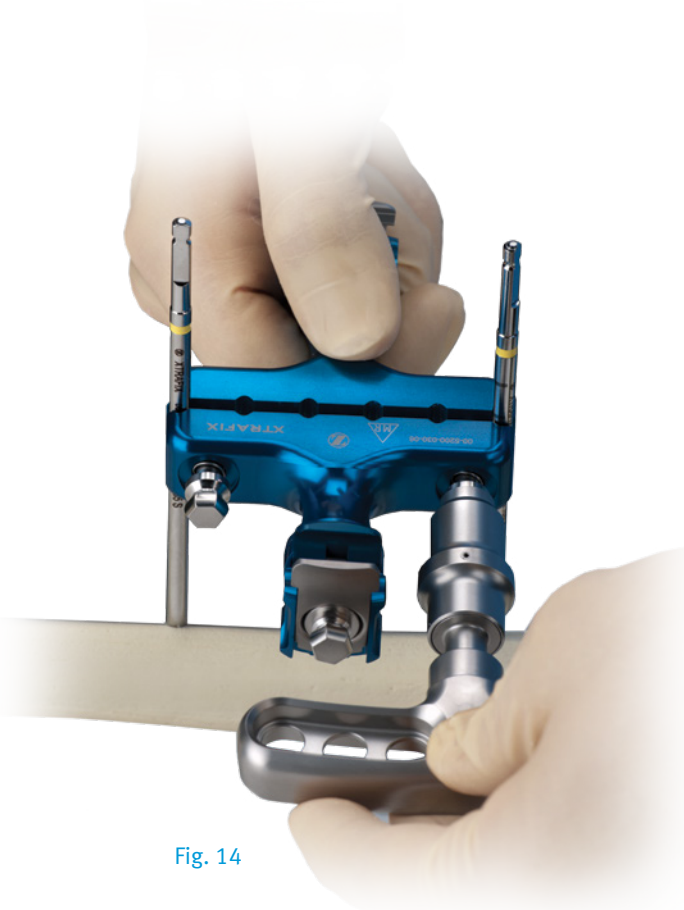


Fig. 14

Attaching Bars

The technique for attaching bars to clamps is identical to the process for attaching pins. It is also the process for attaching clamps to posts. Simply insert the bar and pinch the bar and the back side of the SnapLoc latch together to lock the jaws (Fig. 15).

The latch provides tactile and audible feedback when a bar is secured within the clamp. Listen for a “click” when inserting a bar into the clamp.

Attaching a clamp to a pin:

- Push the clamp onto a pin with sufficient force until hearing a “click” (Fig. 15).
- Grasp the clamp and bar between the index finger and thumb, and squeeze together firmly. This technique aids positive attachment (Fig. 16).

Key Reduction Feature: With the bar and pin(s) now secured to a clamp, the clamp still has 80 degrees of motion. At this point, all components of the frame are constructed prior to final tightening. The motion feature in each clamp allows bars and pins to move in three dimensions. This provides valuable benefit to the surgeon in achieving proper reduction.

Once the bar is in its final desired position, the clamp can be secured by tightening the nut with one of the supplied wrenches. Clamp nuts should be positioned in a convenient and/or accessible manner.

Note: When removing or loosening the clamps, always loosen the nut fully. Otherwise, the clamp may not unlock fully (Fig. 16).

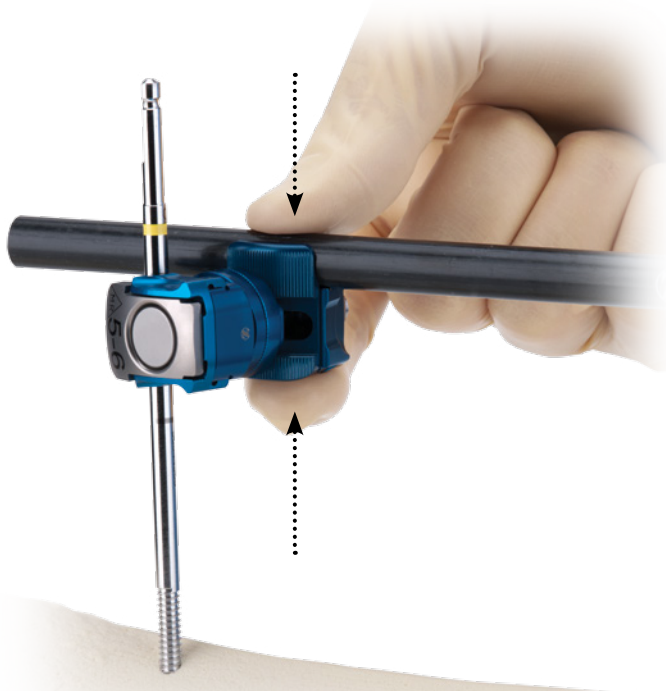


Fig. 15

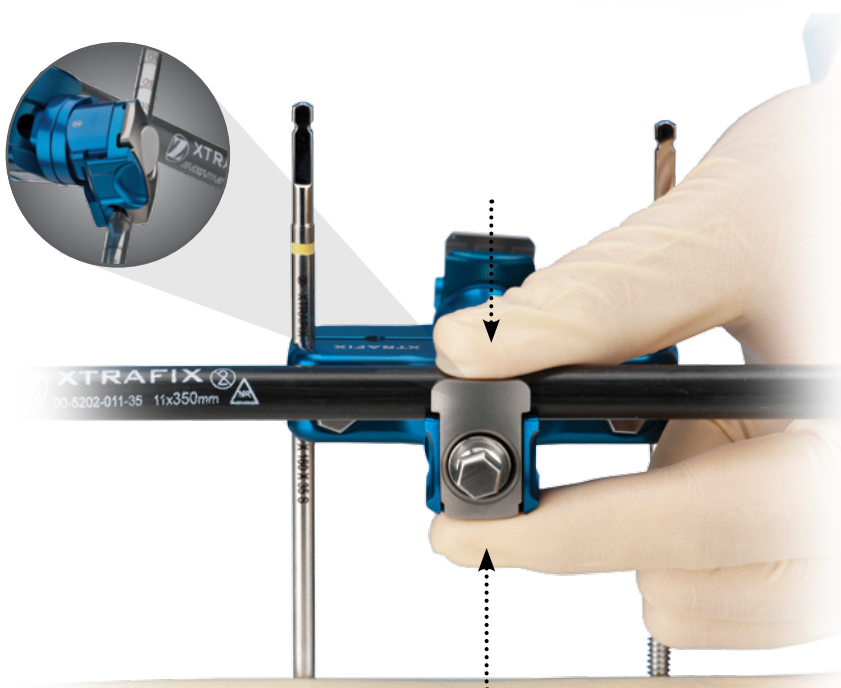


Fig. 16

Attaching End Caps (Optional)

Flexible end caps are available for fitting over the ends of pins and bars. The purpose of these end caps is to protect the patient from any sharp edges of the external fixator frame.

Transitioning from Large 11mm to Small 6mm System

The transition clamp for both sets is the *XtraFix* Large 11mm Pin-to-Bar Clamp.

If a surgeon desires to transition from a Large 11mm Bar/Clamp construct down to a Small 6mm Bar/Clamp construct, it can be achieved using a Large 11mm Pin-to-Bar Clamp.

Place an 11mm Bar in the large jaw of the clamp and a 6mm Bar in the small jaw of the clamp labeled “5 – 6.” Once a 6mm Bar is connected to the frame via the Large 11mm Pin-to-Bar Clamp, any other Small 6mm set clamps/bars/pins can be connected to the frame.

Attaching Posts to Multi-Pin Clamps (Optional)

The *XtraFix* Large 11mm System also offers Multi-Pin Clamps with post holes that allow for a more traditional construct: a 45mm 4-Pin Clamp and 105mm 8-Pin Clamp. Attach the desired post (Straight, 30°, or 90°) and tighten the post bolt (Fig. 17).

Note: When using the 105mm Pin Clamp with two posts on a single side, make sure both posts are in place before tightening the corresponding top bolt. Otherwise the second post may not fit into the post opening (Fig. 18).



Fig. 17



Fig.18

Removing Bars

To remove bars or pins from a clamp: (Fig. 19).

- Grasp the mid-section of the clamp with one hand
- Grasp the clamp latch using the index finger and thumb from the other hand
- Pull back on the latch until the clamp detaches from the bar or pin

Be sure not to pull the bar/pin simultaneously out of the clamp while trying to unlock the latch. The clamp will not open easily with outward pressure on a bar/pin (Fig. 20).

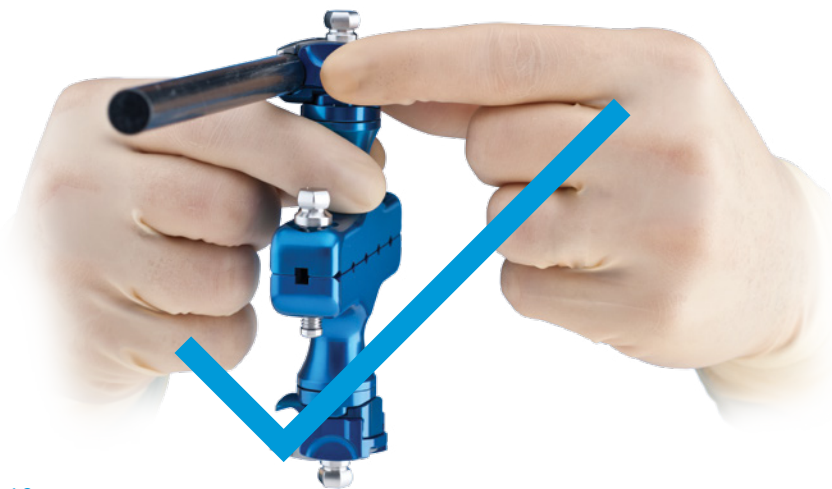


Fig. 19



Fig. 20

XtraFix Small 6mm Efficiency Multi-Pin Clamps

33mm, 2-Bar Efficiency Multi-Pin Clamp

- The 33mm, 2-Bar Clamp is locked on the pins and both bars by tightening only one nut (Fig. A).

33mm, 1-Bar Efficiency Multi-Pin Clamp

- When one bar is preferred for a Distal Radius frame, use the 33mm 1-Bar Clamp (Fig. B).
- The 33mm, 1-Bar Clamp attaches to two pins and has a pivoting, swivel bar attachment that allows for easy connection to a single bar.



Fig. A



Fig. B

XtraFix Small 6mm System Surgical Technique

Choose Pin Size

XtraFix Small 6mm System stainless steel half pins are self-tapping and self-drilling and can be used with or without pre-drilling. The aggressive flute design helps to cut effectively and quickly (Fig. 1).

Pins are available in short and long threads to accommodate different bone sizes and to minimize thread exposure above soft tissue (Fig. 2).

The *XtraFix* Small 6mm pins have a quick connect feature that fits with the Quick Connect to Small AO Adapter provided in the set. This allows the surgeon to attach the pins to power and saves time compared to manually attaching pins to a tri-shank Jacobs chuck (Fig. 3).

Stainless steel Blunt Tip half pins are also available with if surgeons desire more feel during insertion after pre-drilling (Fig. 4).



Fig. 1



Fig. 2



Fig. 3



Fig. 4

Select Tissue Protector and Trocar

Once the diameter and length of the pin is chosen, determine whether to use Modular Tissue Protectors with a Multi-pin Clamp, or the Tissue Protector-with-Handle to construct a modular frame. The system is sized Small (Sm) and color-coded Brown with 1, 2, or 3 rings to make matching instruments to pins easy (Fig. 5). See chart below.



Fig. 5

Set Size	Trocar and Tissue Protector Size	Pin Color	Corresponding Pin Sizes
Small 6mm	Small (Sm) Brown	1 Brown Ring	2.5mm x 20mm x 80mm 2.5mm x 25mm x 120mm
		2 Brown Ring	3.0mm x 20mm x 80mm 3.0mm x 25mm x 120mm
		3 Brown Ring	4.0mm x 20mm x 80mm 4.0mm x 25mm x 120mm

Securing Tissue Protectors

The *XtraFix* Small 6mm System set has a single tissue protector size that comes in two options.

A one-piece Tissue Protector with Handle is provided in the set for drilling pins freehand for modular pin- to-bar constructs.

Drill Guide

To create a drill guide, lock 2 x Tissue Protectors between the pin holes of Efficiency Multi-Pin Clamps (Fig. 7). Slide Tissue Protectors between the pin holes of an Efficiency Multi-Pin Clamp and lock each by turning 90 degrees.

Note: Both Modular Tissue Protectors must be inserted into the Multi-Pin Clamp before twisting/locking them into place.

Note: The “wing” features on the outside of the Tissue Protector assist with locking it into the Multi-Pin Clamp.

Insert the corresponding trocar through each tissue protector, and insert the assembly through the soft tissues until the distal tip touches bone (Fig. 6). The trocar may be removed after navigating tissue protectors through the soft tissues.

The distal end of each tissue protector has an edge with teeth to help stabilize the assembly onto bone (Fig. 6).

Note: Tissue protectors may also be left in the unlocked position if the height needs to vary between the first and second tissue protector (Fig. 7).

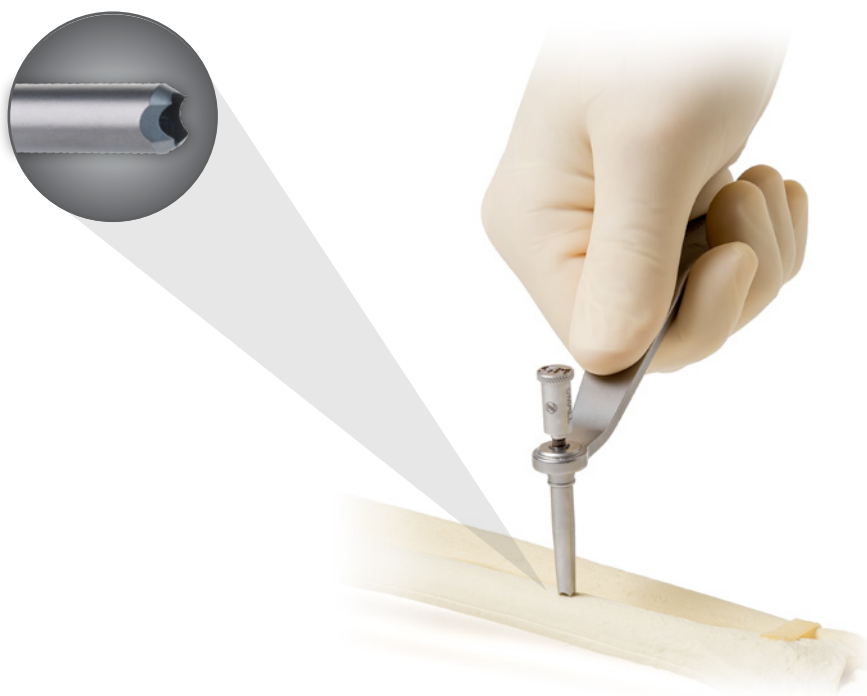


Fig. 6 Small Tissue Protector with Handle

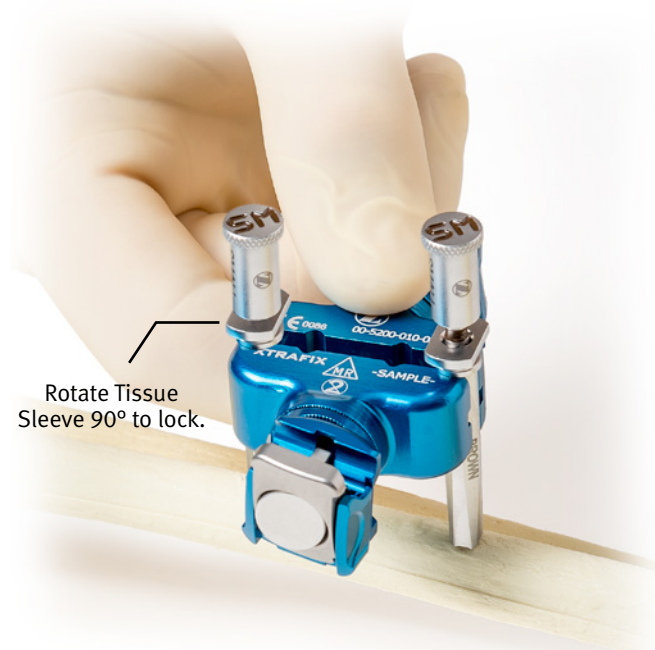


Fig. 7 Small Tissue Protectors in unlocked position in Multi-Pin Clamp

Remove Trocar and Insert Drill
(Optional)

Pre-drilling is not required with self-drilling/self-tapping pins.* However, if pre-drilling is desired, it is very simple and takes only one step.

XtraFix drills are “stepped up” in diameter from the drill flute to drill shaft so they fill the inner chamber of the tissue protector. This provides accurate drilling and eliminates the need for a drill sleeve.

The drill bit diameter is undersized appropriately to the corresponding pin core diameter to ensure the pins fit snugly into the drilled bone. For example, the drill bit diameter for a 4mm pin is 3.2mm.

In addition, drills are also color-coded Brown with 1, 2, or 3 rings to aid with drill size identification.

When drilling, note the calibrated depth marks on the drill bit. Once the second cortex of the bone has been penetrated, the number visible on the drill just above the Tissue Protector indicates hole depth. This aids in determining the pin thread length. (Fig. 8)

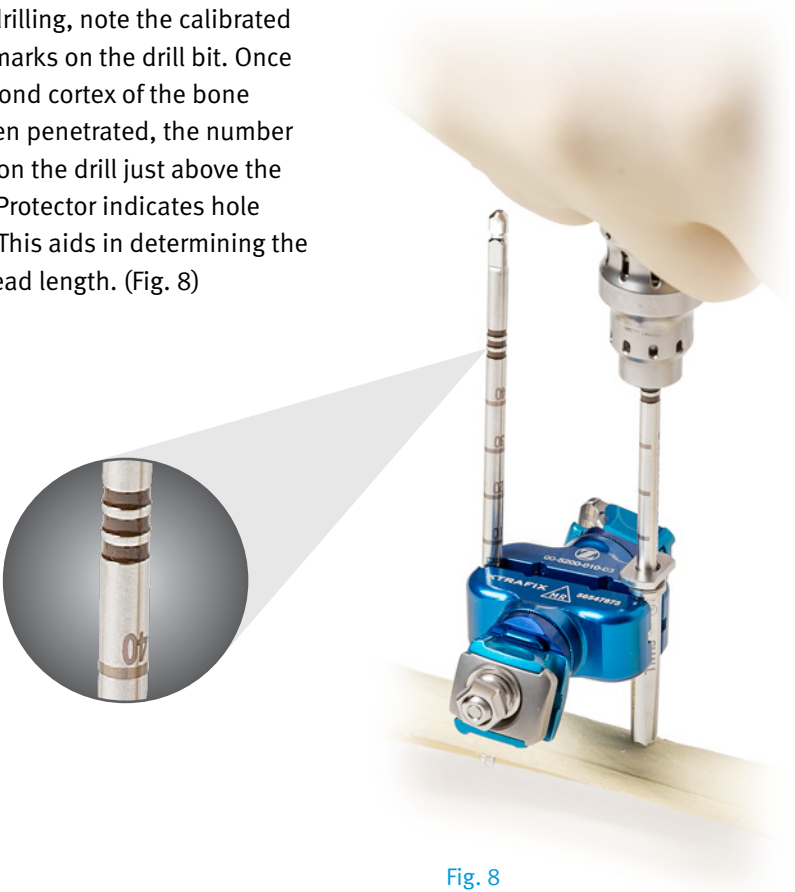


Fig. 8

Set Size	Tissue Protector Size	Color	Corresponding Drill Bit Sizes	Pin Size
Small 6mm	Small (Sm)	1 Brown Ring	2.0mm Small Stepped Drill (2.5mm Pins)	2.5 x 80 x 20mm 2.5 x 120 x 25mm
		2 Brown Rings	2.5mm Small Stepped Drill (3mm Pins)	3.0 x 80 x 20mm 3.0 x 120 x 25mm
		3 Brown Rings	3.2mm Small Stepped Drill (4mm Pins)	4.0 x 80 x 20mm 4.0 x 120 x 25mm

* Blunt tip pins are not self-drilling. They are optional items that require the use of drills and are available upon request.

Remove Trocar (or Drill) and Insert Pin

Once drilling is complete, dispose of the used drill bit and select the appropriate pin. As mentioned earlier, *XtraFix* Small 6mm pins have a quick connect feature that fits with the Quick Connect-to-Small AO Adapter allowing the surgeon to attach pins to power.

If a surgeon wishes to insert the pin without a power drill, use the T-Handle 9mm/Quick Connect Wrench. It is a combination tool used to tighten or loosen pins and clamp nuts.

Slide the top of the pin into the base of the T-Handle, pull back the latch on the handle, and rotate the pin until it locks in place. The pin will give tactile and audible feedback that it has fit into the quick connect channel of the wrench. This allows for additional manual manipulation and joystick-like movements.

Once the pin is securely attached, proceed by inserting it through the Tissue Protector. Note the pin has the same depth marks as its corresponding drill (Fig. 9). The number visible on the pin at the top of the Tissue Protector is the depth the pin is protruding from the bottom of the tissue protector into bone.

If a pilot hole was prepared, simply insert the pin to the same depth mark as was used with the drill bit. This saves time and may reduce fluoro exposure.

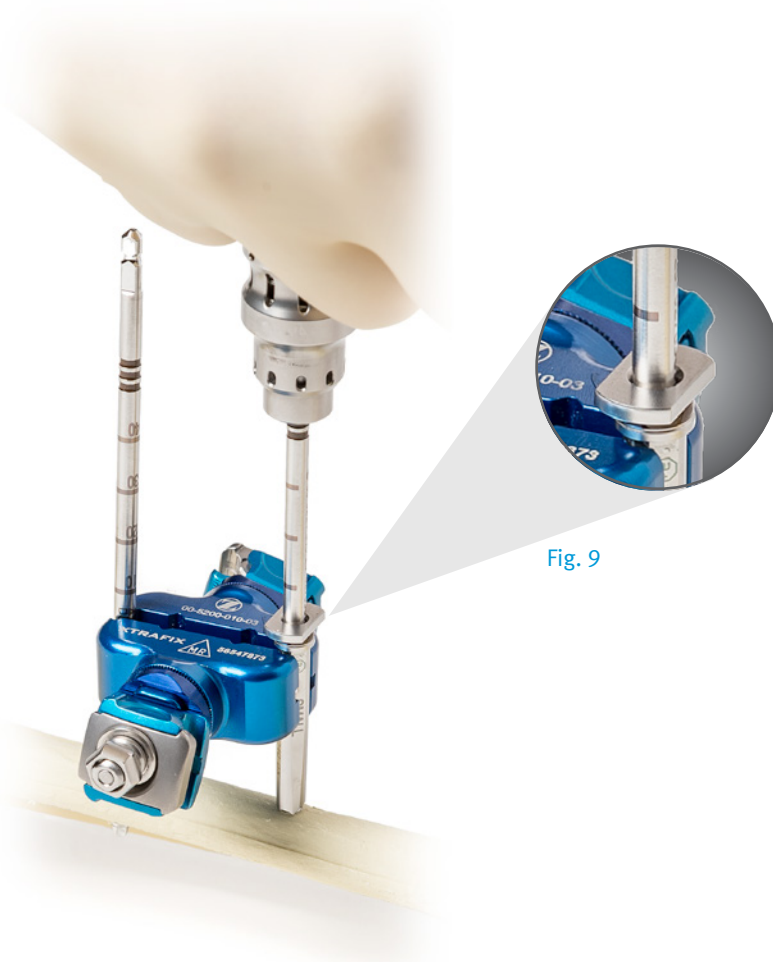


Fig. 9

Attaching Clamps to Pins

For Pin-to-Bar Clamps

The main clamp in the Small 6mm set is a universal (or combination) Bar/Pin-to-Bar/Pin Clamp (Fig. 10). This means that both clamp jaws can accept either a bar or a pin. The Bar/Pin-to-Bar/Pin Clamp accepts 4mm pin shaft diameters and 6mm bar diameters.



Fig. 10

Bar/Pin-to-Bar/Pin Clamps have a SnapLoc latch that locks over bars or pins and stays securely attached throughout the procedure. This eliminates troublesome “pop-offs” that can waste precious time and effort while achieving proper reduction.

Attaching a Clamp to a Pin:

- Push the clamp onto a pin with sufficient force until hearing a “click” (Figs 11a and 11b).
- Grasp the clamp and bar between the index finger and thumb, and squeeze together firmly. This technique aids positive attachment (Fig. 11c).

The SnapLoc latch should already be in the “open” position when sitting in the set. To open the latch on a clamp:

- Grasp the waist of the clamp (mid-section between the bar jaws) using one hand
- Use the other hand to grasp the SnapLoc latch between the index finger and thumb
- Pull back on the latch until hearing a “click”

Use this same process to remove a locked clamp from a pin or bar.

Note: *XtraFix Small* includes 2.5, 3.0, and 4.0mm diameter pins. 2.5mm and 3.0mm pins have stepped-up shaft diameters.

Note: All *XtraFix Small* 6mm Bar/Pin-to-Bar/Pin Clamps are compatible with 2.5, 3.0, and 4.0mm pins as well as 6mm bars.

Independent Locking (Single Adjustable) Clamp

An Independent Locking (Single Adjustable) clamp is a different style clamp included in the *XtraFix Small* 6mm set. This clamp allows a surgeon to independently tighten one jaw over a pin while leaving the bar jaw of the clamp loose in order to slide along a bar. This clamp is particularly useful when using a compression/distraction device.

Note: When using the Small Independent Locking Clamp, first place the pin in the jaw marked “PIN” on the top side of the clamp jaw. This will ensure that the clamp both tightens over the pin and locks the pin side’s orientation relative to the bar side of the clamp.

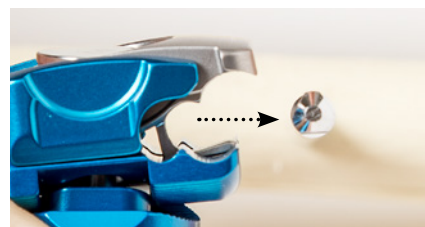


Fig. 11a



Fig. 11b



Fig. 11c

Compression/Distraction Device

The compression/distraction device is used in conjunction with Independent Locking Clamps. To use it with a small construct, ensure the fork side marked “6mm” is facing the small clamp. (Fig. 12)

Important: The Compression/Distraction device should only be used with Independent Locking (Single Adjustable) Clamps.

Attaching Clamps to Pins

For Multi-Pin Clamps

After pins are inserted through the Multi-Pin Clamps, twist both Tissue Protectors 90 degrees before sliding them out of the clamps. Remove the Tissue Protectors by pulling straight up and sliding off each pin, leaving the multi-pin clamp to grab onto the pin (Fig. 13).

Leave the clamp fixed to the pin until attaching a bar.



Note: The 33mm 2-Bar Efficiency Multi-Pin Clamp (on left) does not need to be tightened to the pins, as one nut tightens the clamp to bars and pins.

Note: The 33mm 1-Bar Efficiency Multi-Pin Clamp (on right) needs to be tightened to the pins and bars independently since it is not a one-nut tightening clamp.

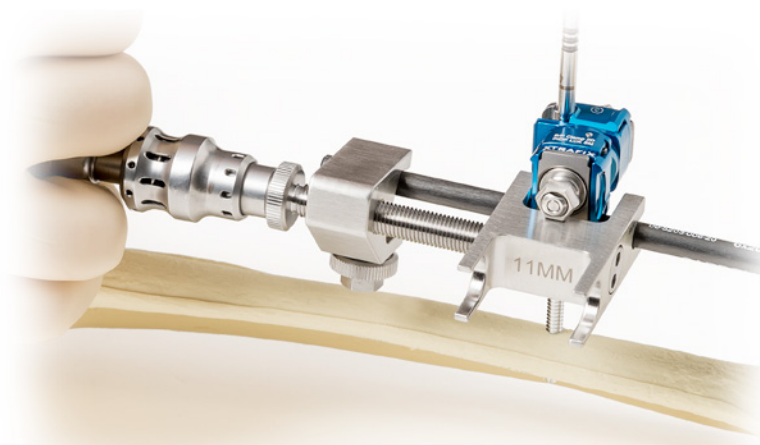


Fig. 12

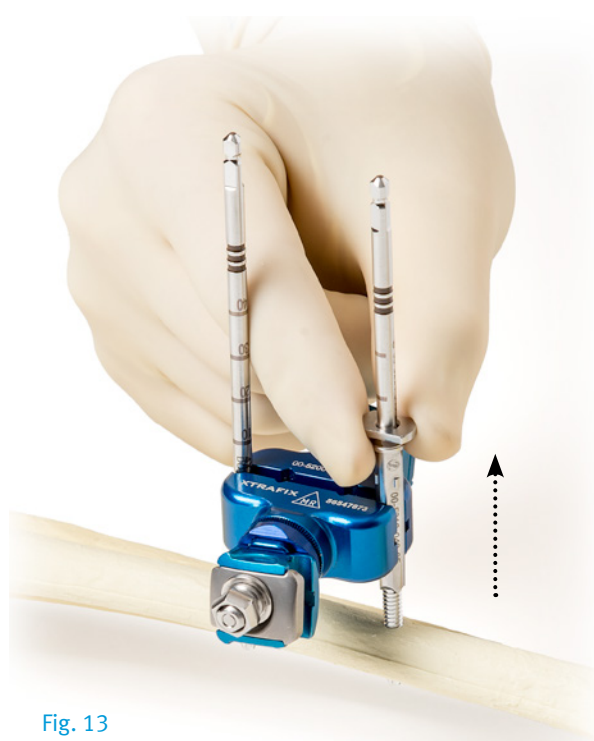


Fig. 13

Attaching Bars

The technique for attaching bars to clamps is identical to the process for attaching pins. Simply push the bar hard into the clamp jaw until hearing an audible “click.” An alternate method of locking the clamp over the bar is pinching the bar and back side of the latch together between two fingers (Fig. 14).

Use the same technique for attaching bars to Efficiency Multi-Pin Clamps. Push the bar hard into the clamp jaw until hearing an audible “click” (Fig. 15).

Key Reduction Feature: With the bar and pin(s) now secured to a clamp, the clamp still has 70 degrees of motion. At this point, all components of the frame are constructed prior to final tightening. The motion feature in each clamp allows bars and pins to move in three dimensions. This provides valuable benefit to the surgeon in achieving proper reduction and alignment.

Once the bar is in its final desired position, the clamp can be secured by tightening the nut with one of the wrenches in the set. While constructing the frame ensure clamp nuts are positioned in a convenient and/or accessible manner (Fig. 15).

Note: When removing the clamps, always loosen the nut fully. Otherwise, the clamp may not unlock properly.

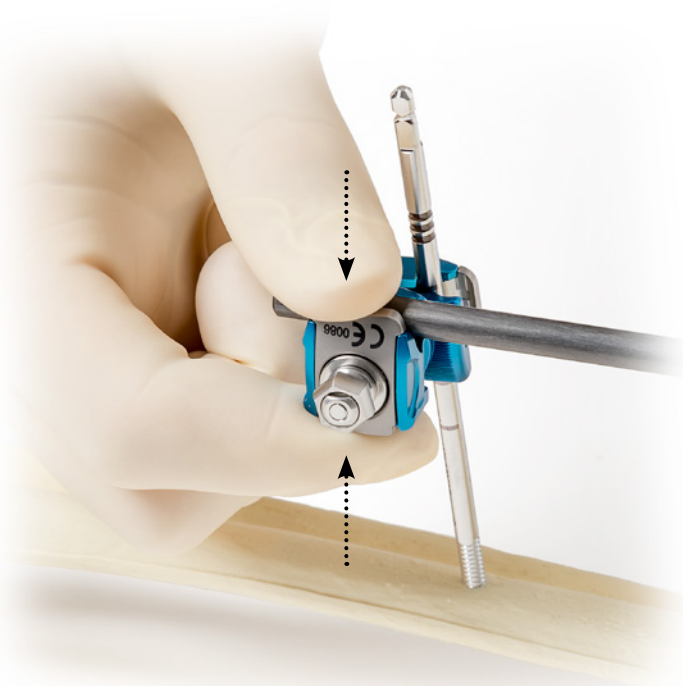


Fig. 14

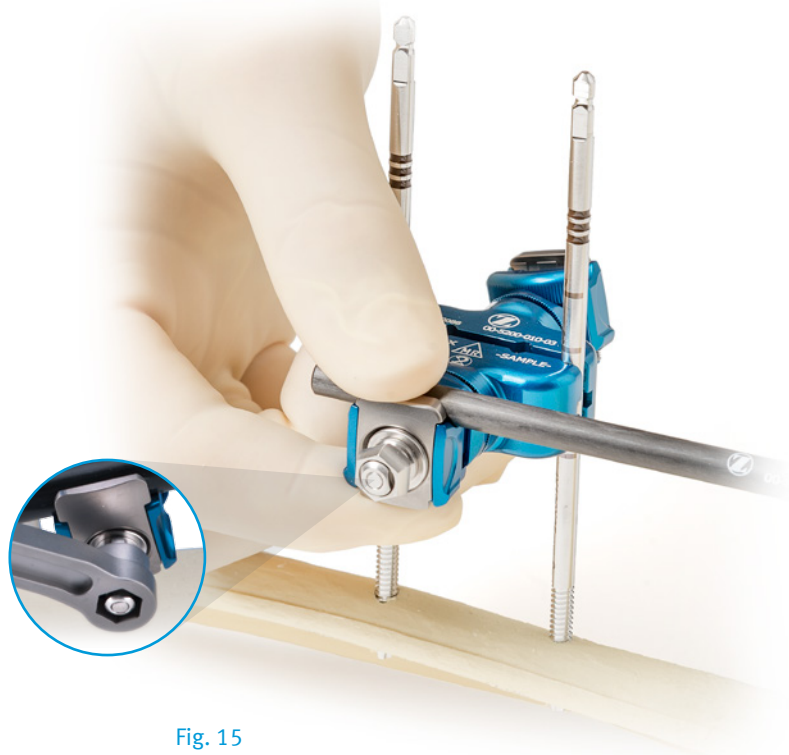


Fig. 15

Attaching End Caps (Optional)

Flexible end caps are available for fitting over the ends of pins and bars. The purpose of these end caps is to protect the patient from any sharp edges of the external fixator frame.

Removing Bars

To remove bars or pins from a clamp:

- Grasp the mid-section of the clamp with one hand
- Grasp the clamp latch using the index finger and thumb from the other hand
- Pull back on the latch until the clamp detaches from the bar or pin (Fig. 16a and 16b)

Be sure not to pull on the bar or pin while trying to unlock the latch. It is difficult to open the clamp latch with outward pressure on a bar/pin (Fig. 17).



Fig.17 Do not pull up on bars/pin



Fig. 16a

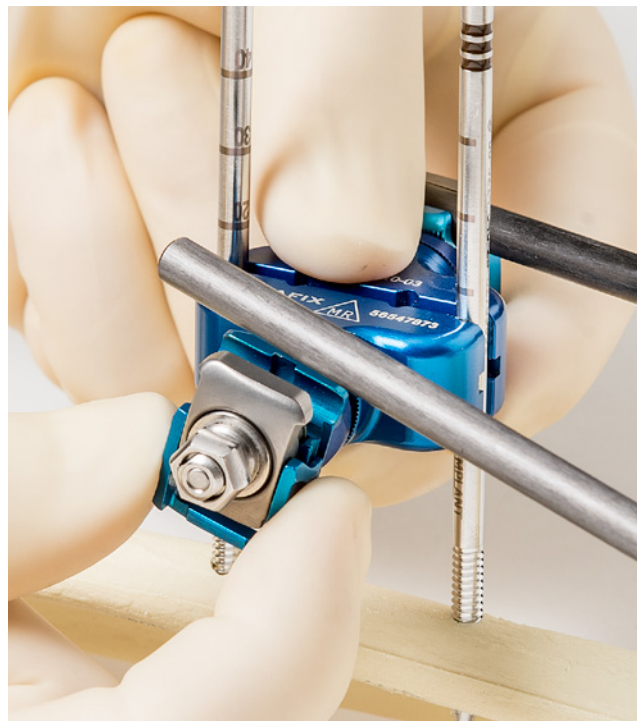


Fig.16b

Sample Constructs

Pin-to-Bar Construct

The unmatched 70 degrees of motion in the *XtraFix* Small Clamp and 80 degrees in the Large System Clamp allow pins to be placed where the fracture - not the fixator - dictates.



Knee-Spanning Construct

Fewer parts are required to span a knee when utilizing 75mm 2-Bar Efficiency Multi-Pin Clamps. This construct saves time and cost.



Ankle-Spanning Construct (basic)

Large Set

Single Transfixing Pin, Bar-to-Pin
Clamps

This construct is the most common ankle delta frame. The Efficiency Multi-Pin Clamp saves time and cost when placing tibial pins.



Ankle-Spanning Construct (dropfoot)

Large Set

Single Transfixing Pin, Metatarsal
Pin(s), Pin-to-Bar Clamps

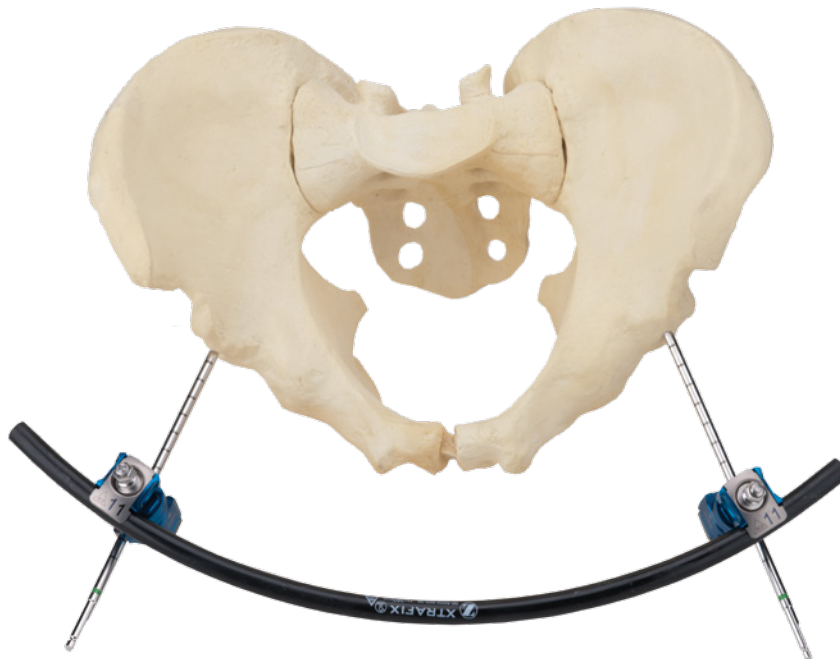
The metatarsal pins can be connected with either an 11mm or 6mm bar depending on surgeon preference.



Pelvic Construct (Ischium Spine)

Large Set

Two 6mm (green) Pins, Pin-to-Bar
Clamps, Curved Bar



Pelvic Construct (Iliac Crest)

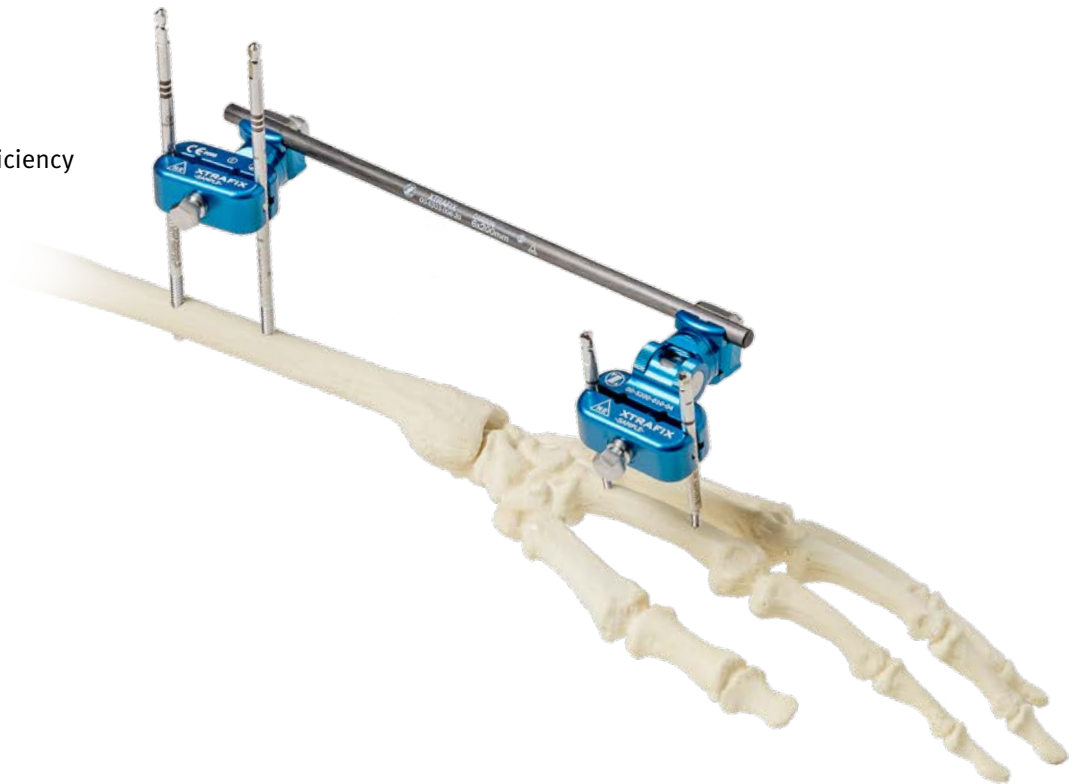
Large Set

Four 6mm (green) Pins, 1-Bar Pin
Clamps, Curved Bar



Wrist Construct (1-Bar)**Small Set**

Four Pins, Two 33mm 1-Bar Efficiency Multi-Pin Clamps, and 1 Bar

**Wrist Construct (2-Bar)****Small Set**

Four Pins, Two 33mm 2-Bar Efficiency Multi-Pin Clamps, and 2 Bars



References

¹Design encircles the bar/pin to provide a positive and secure connection

Disclaimer

This documentation is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.

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