



Zimmer®
XtraFix®
External Fixation
System
Large and Small

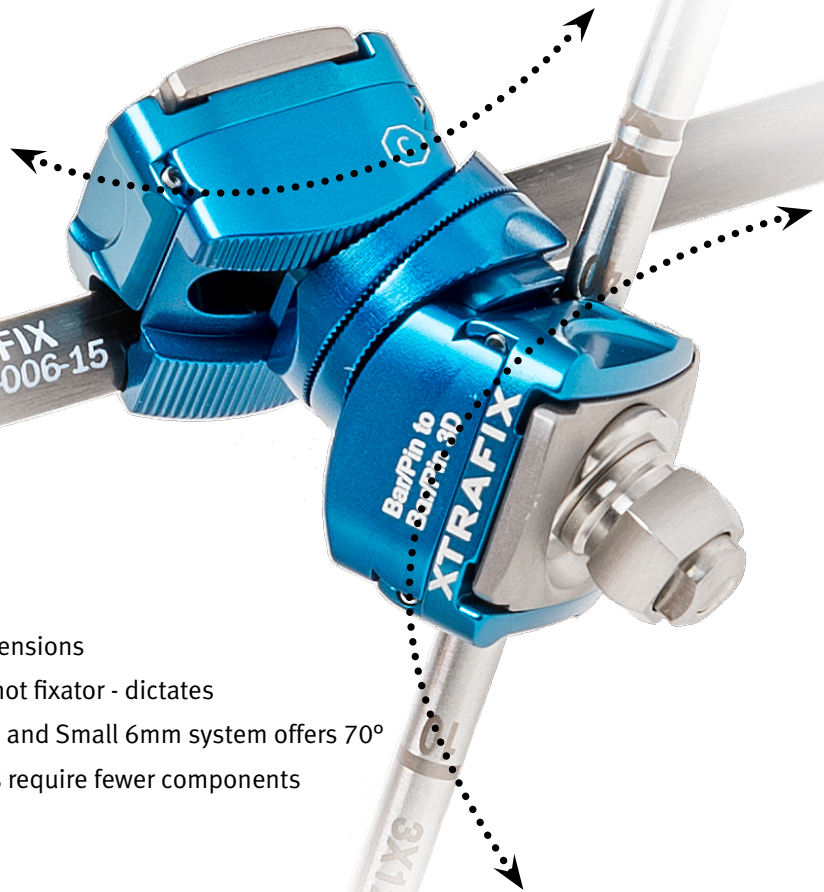


Build Rigid Constructs Faster



Maximum efficiency is the design philosophy.

The *XtraFix*® External Fixation System allows surgeons to build rigid constructs, using fewer components, in less time.



3-D Bar/Bar and Bar/Pin Clamps

- Independent pin placement in three dimensions
- Pins can be placed where the fracture - not fixator - dictates
- Large 11mm system offers 80° of motion and Small 6mm system offers 70°
- Flexible configurations means constructs require fewer components

SwivLoc Technology

- Facilitates provisional fracture reduction by allowing Bars to snap into Clamps
- Bars will not pop-off clamps during assembly



XtraFix Large 11 mm Multi-Pin Efficiency Clamps

45mm and 75mm Multi-Pin Efficiency Clamps replace five traditional components with one, eliminating the need for connecting posts and additional clamps.



45mm Pin Clamp, 2-Bar

- Five parts in one: replaces 1 x 45mm Multi-Pin Clamp, 2 x Bar-to-Bar Clamps, and 2 x Posts
- Requires tightening of one nut versus six nuts with the traditional five components

75mm Pin Clamp, 2-Bar

- The 75mm, 2-Bar Clamp allows the Pins to be locked independently from the Bars
- The nuts above each jaw also independently lock each Bar Clamp, one at a time



XtraFix Small 6mm Multi-Pin Efficiency Clamps

- The 2-Bar 33mm Pin Clamp does not need to be tightened to Pins, as one nut tightens the Clamp to Bars and Pins
- The 1-Bar 33mm Pin Clamp attaches to two Pins and has a pivoting, swivel Bar attachment that allows for easy connection to a single Bar

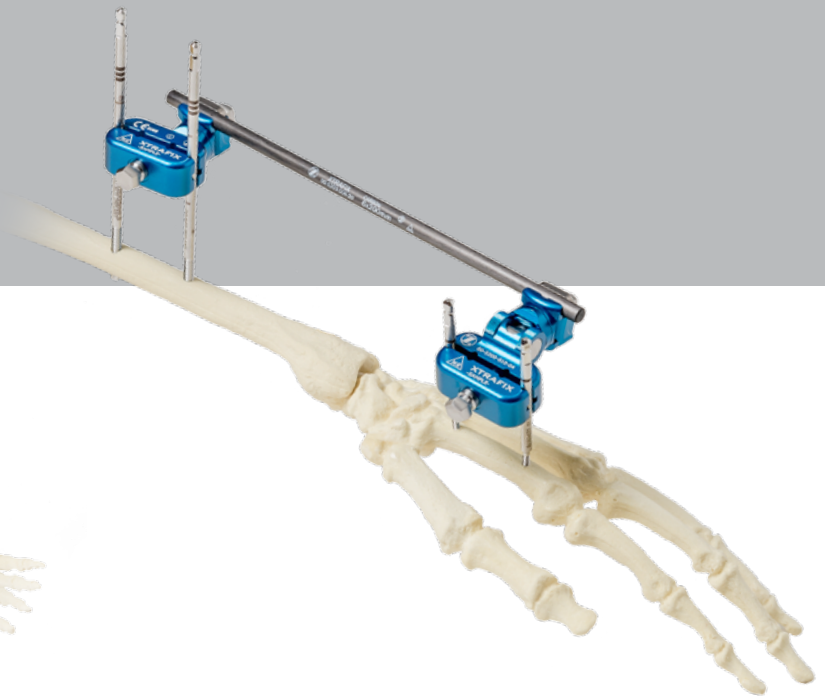
Efficiency Constructs



Ankle-Spanning Construct (dropfoot)

Large Set

- Single Transfixing Pin, Metatarsal Pin(s), 1 Multi-Pin Efficiency Clamp, 3 Bars and 4 Pin-to-Bar Clamps
- The Metatarsal Pins can be connected with either an 11mm or 6mm Bar depending on surgeon preference.



Wrist Construct (1-Bar)

Small Set

- Two 1-Bar Multi-Pin Efficiency Clamps, 4 Pins and Bar

A pivoting, swivel bar attachment allows for an easy connection to a single bar and also provides flexible pin placement.



Knee-Spanning Construct

Large Set

- 2 Multi-Pin Efficiency Clamps, 2 Bars and 4 Pins

Fewer parts are required to span a knee when utilizing the 75mm or 45mm Multi-Pin Efficiency Clamps.



Pelvic Construct (Ischium Spine)

Large Set

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

Blunt or Self-Drilling/Self-Tapping Pins aid in precise hip fixation.

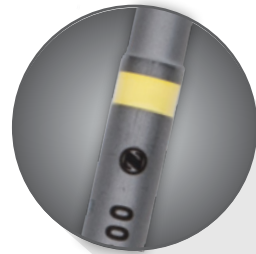


Universal Compatibility

The *XtraFix* Large 11mm and Small 6mm Systems can easily be connected to one another via a single Clamp. The Large 11mm Pin/Bar Clamp is the transitional component that allows surgeons to accommodate small extremity fractures in large constructs.

Pins and Drills

- All *XtraFix* Pins, Drills, Trocars and Tissue Protectors are color coded for easy identification
- Step up feature allows Pins in each system to be used with all the Clamps in their respective systems



Step up feature

All *XtraFix* Pins and Instruments are color coded for easy identification. Pins are made of high strength stainless steel.



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.

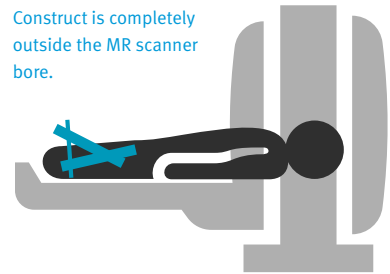
The largest image artifact extends approximately 63mm from the device when scanned in nonclinical testing using the Gradient Echo (GE) sequence in a 3T Siemens Medical Systems Tim Trio (running Syngo MR V17 software) using the Body RF Coil.

Position of XtraFix Small 6mm System in the MR Environment

The entire construct should be visible outside the MR scanner bore.

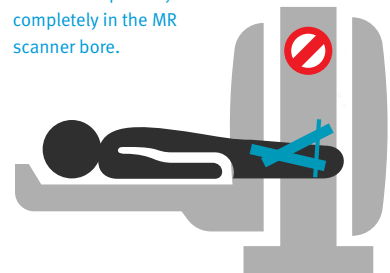
Correct Placement

Construct is completely outside the MR scanner bore.



Incorrect Placement

Construct is partially or completely in the MR scanner bore.



Contact your Zimmer representative or visit us at www.zimmer.com

