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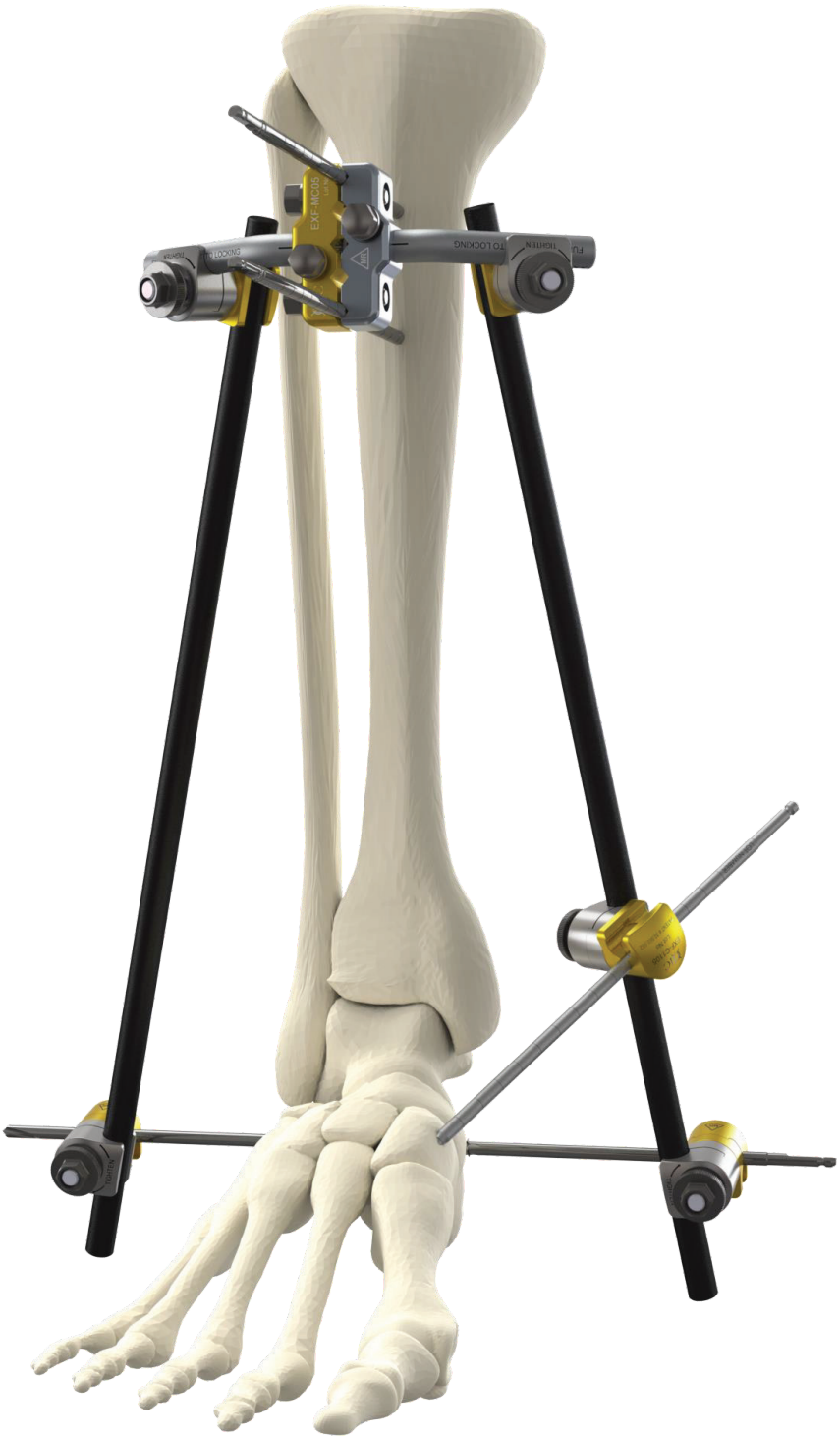

OIC External Fixation System
Surgical Technique Guide

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Table of Contents

The technique description herein is made available to the healthcare professional to illustrate the author's suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the specific needs of the patient.

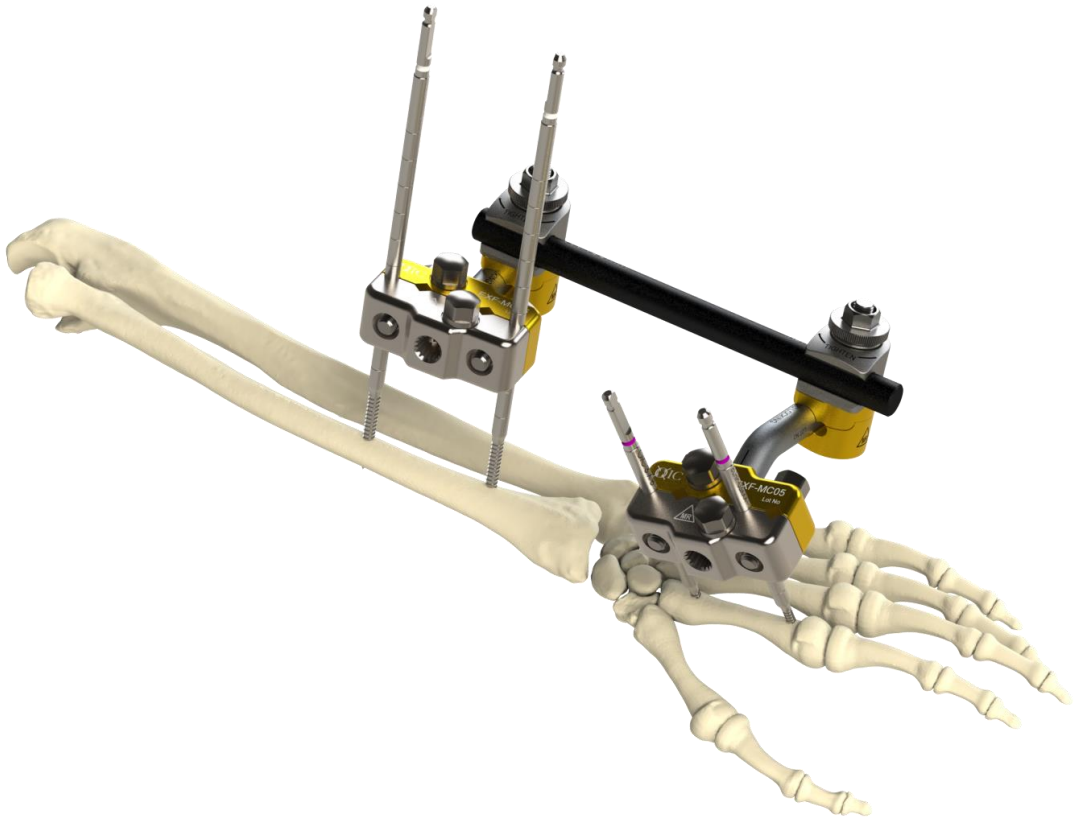
System Features

INTRODUCTION

The OIC External Fixation System is a cost-effective product that incorporates design features of modern external fixation systems that obtain optimal clinical results with minimal surgical time. Instrumentation is elegantly simple and tray layouts are thoughtfully designed to promote operational efficiencies from the back table.

DESIGN FEATURES

- *Pins*: Self drilling/self-tapping, or blunt tipped 3mm, 4mm, and 5mm stainless steel pins produced in a variety of thread and pin lengths. Both partially threaded half pins, and a centrally threaded full pin are available.
- *Clamps*: Patented combination clamp system that allows for bar-to-bar or pin-to-bar fixation with 360° of freedom.
- *Multiple Pin Clamps*: 5 hole or 7 hole to optimize construct creation and stability
- *Posts*: 0° and 30° posts for multiple pin clamps to provide construct versatility
- *Bars*: Carbon fiber 11mm bars



Indications and Warnings

INDICATIONS FOR USE

The OIC External Fixation system is intended to be used in adult and pediatric patients for provisional fixation of open and/or unstable fractures in the lower and upper extremities and pelvis. It may also be used for temporary fixation of peri-articular or intra-articular fractures. Additionally, the device can be used on fractures where soft tissue injury or an infected fracture site may preclude the use of other fracture fixation treatments.

CONTRAINDICATIONS

- Mental conditions that preclude cooperation with the rehabilitation regimen
- Patients with bone conditions or fracture patterns that prevent secure implantation of multiple pins in the coronal plane
- Patients with metal allergy that precludes use of stainless steel pins or instruments

WARNINGS

- The bone should be drilled slowly so that heat buildup does not cause tissue or bone necrosis.
- Pin placement should avoid locations that will lead to damage to muscles, tendons, vessels, or nerves.
- Use care when handling sharp pin, trocar, and drill tips.

Indications and Warnings

PREOPERATIVE PLANNING

Surgical Technique – Correct surgical technique is essential to a successful outcome. Proper reduction of fractures and proper placement of implants are necessary to effectively treat patients using metallic surgical implants. Please review the surgical technique for effective surgical procedures.

Implant and External Component Selection – Proper type and size of implants and components must be selected to insure effective treatment of patients. The following factors should be considered:

- A patient's size, strength, skeletal characteristics, skeletal health, and general health – Overweight or musculoskeletally deficient or unhealthy patients may create greater loads on implants that may lead to breakage or other failure of the device.
- A patient's activity level during the time the implant is in the patient's body, including such factors as whether the patient's occupation or typical activities include running, heavy lifting, impact loading, or the like.
- Whether a patient has a degenerative or progressive disease that delays or prevents healing and leads to exceeding the effective life of the device.
- If a patient is suspected of having material or foreign body sensitivities, appropriate testing should be accomplished prior to implantation.
- Mental conditions or substance abuse problems that may prevent a patient from understanding or following directions or observing precautions.

Device Alterations – The ends of the pins protruding beyond the clamps after the system is assembled may be cut to reduce excess length. Hold the end of the pin when cutting. Cover the protruding ends of the pins with pin caps. Other than cutting the ends of the pins, the components are not designed to be physically altered, bent, notched, gouged, reamed, scratched or cut.

Component Compatibility – Components such as clamps, rods, pins and posts are available in many styles and sizes and are manufactured from various types of metals. The component material is provided on the outside carton label. Do not mix components from different manufacturers.

Implant Removal – The patient should be advised that a second procedure for the removal of implants will be necessary.

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that the External Fixation System is MR Conditional for use external to the scanner bore. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T)
- Maximum spatial field gradient of 1,180 G/cm (11.8 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4.0 W/kg
- Implant should be located outside the scanner bore

RF Heating – Under the scan conditions defined above, the External Fixation System is expected to produce a maximum temperature rise of less than 1 ºC after 15 minutes of continuous scanning.

MR Artifact – In non-clinical testing, the image artifact caused by the device is not detectable when the External Fixation System is located outside the scanner bore.

NO REUSE

Surgical implants and components are NEVER TO BE REUSED. Stresses and fractures, even though not noticeable by visual inspection, may have been created during implantation or use. Single use devices should not be reused due to risks of breakage, failure or patient infection.

POSSIBLE ADVERSE EFFECTS

- Loosening, bending, cracking or fracture of the implant or components
- Limb shortening or loss of anatomic position with nonunion or malunion with rotation or angulation
- Infections, both deep and superficial
- Irritational injury of soft tissues, including impingement syndrome
- Tissue reactions which include macrophage and foreign body reactions adjacent to implants
- Metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients

PATIENT POSITIONING

Patient is placed on a radiolucent table to allow for appropriate imaging. Care is taken to pad all bony prominences. A triangle or positioning foam can be utilized for positioning as needed. The image intensifier should be positioned so that AP and lateral views of the operative extremity can be easily obtained.

CONSTRUCT FORMATION AND PIN PLACEMENT

The OIC external fixation system allows for a wide variety of constructs. Pin placement and construct type depends on the injury or condition being addressed. Half or full pin use, single clamp or multipin clamp use and number of bars is all left to individual surgeon discretion.

Although many construct types can be created, basic principles of external fixation should be followed. Avoid placing pins in zone of injury. Place all clamps and bars at least two centimeters above soft tissue to allow for swelling and dressing placement. Construct stability increases with pin spread, increases with the number of pins, decreased bone to bar distance, in line bar stacking, utilization of multiple pin clamps and 90 degree sidebar utilization.

Choose appropriate pin insertion site as indicated by the fracture pattern or condition being addressed. Make a stab incision and dissect down to bone to limit risk of soft tissue injury. Pin core diameter should be less than 1/3 of bone diameter. Predrilling for pin insertion is optional for 3mm, 4mm, and 5mm self-drilling and self-tapping pins. If predrilling is desired, insert tissue protector drill sleeve through the incision and centralize on bone. For 5mm pins, use the Ø4.2mm drill to predrill bone through sleeve under fluoroscopic guidance to ensure safety. For 4mm pins, use the Ø3.2mm drill; and for 3mm pins use the Ø2.4mm drill. Remove drill sleeve and insert pin in a bicortical fashion. Take care not to insert pin too far so as not to injure structures on far side of bone.

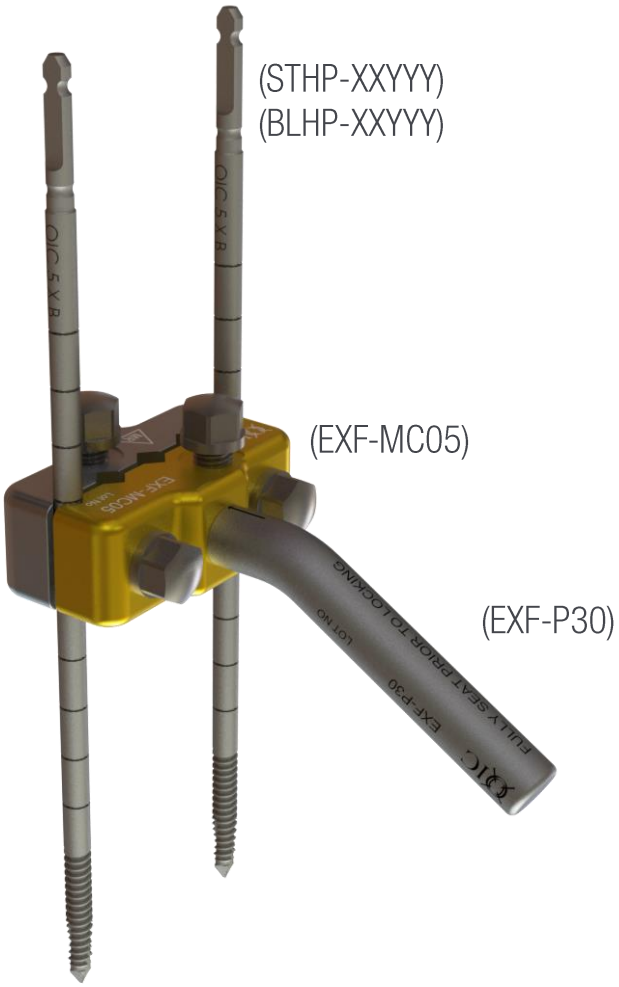


FIG 1: 5 Hole pin clamp with 5mm self-tapping pins and 30° post

MULTIPLE PIN CLAMP USE

If a multiple pin clamp is utilized, tissue protector sleeve (01-EXF01; 01-EXF02) can be used through desired hole in clamp to optimize pin placement and ensure proper spacing. Once pins have been placed and clamp in desired position clamp can be tightened onto pins with 10mm wrench (01-EXF05). Posts can then be attached to clamp and tightened with 10mm wrench (FIG 1). Care should be taken to ensure posts are fully seated prior to tightening.

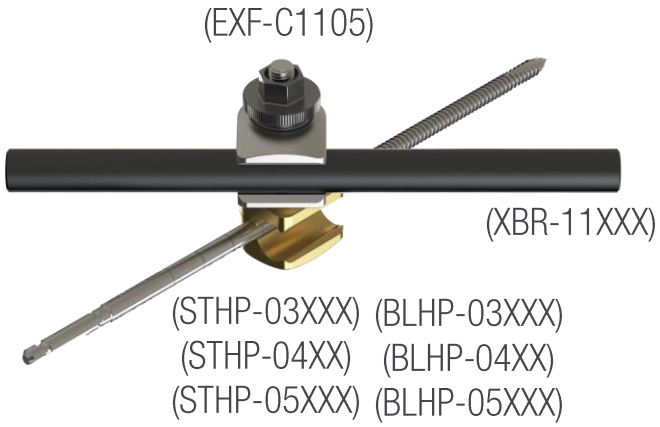


FIG 2: Bar to pin

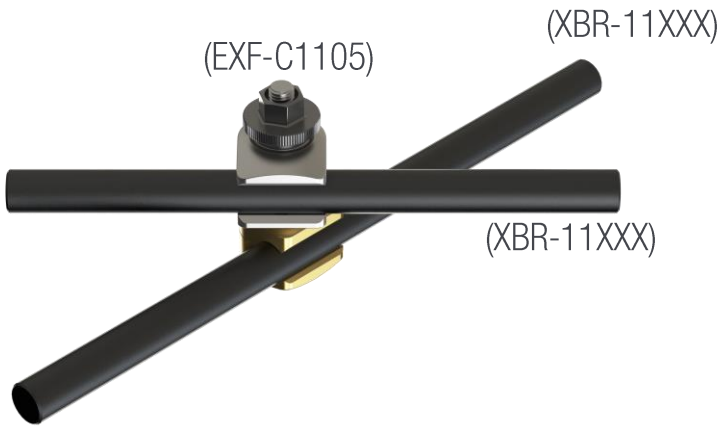


FIG 3: Bar to bar

COMBINATION CLAMP

OIC combination clamps (EXF-C1105) can be used for bar (XBR-11XXX) to pin (STHP-03XXX; STHP-04XX; STHP-05XXX; BLHP-03XXX; BLHP-04XX; BLHP-05XXX) (FIG 2) and bar to bar (FIG 3) constructs. Snap pins or bars into clamp in the standard fashion, achieve reduction and tighten all clamps with 10mm wrench (01-EXF05).

SAMPLE CONSTRUCTS – PELVIC CONSTRUCT

NOTE: Sample constructs shown are examples. Other constructs not shown in the surgical technique can be used.

PELVIC CONSTRUCT		
PART #	DESCRIPTION	QTY
STHP-0565L	Self Tapping Pins 4mm x 65mm	2
XBR-11200	Carbon Fiber Bar 11mm x 200mm	2
EXF-C1105	Bar to Pin Clamp	3

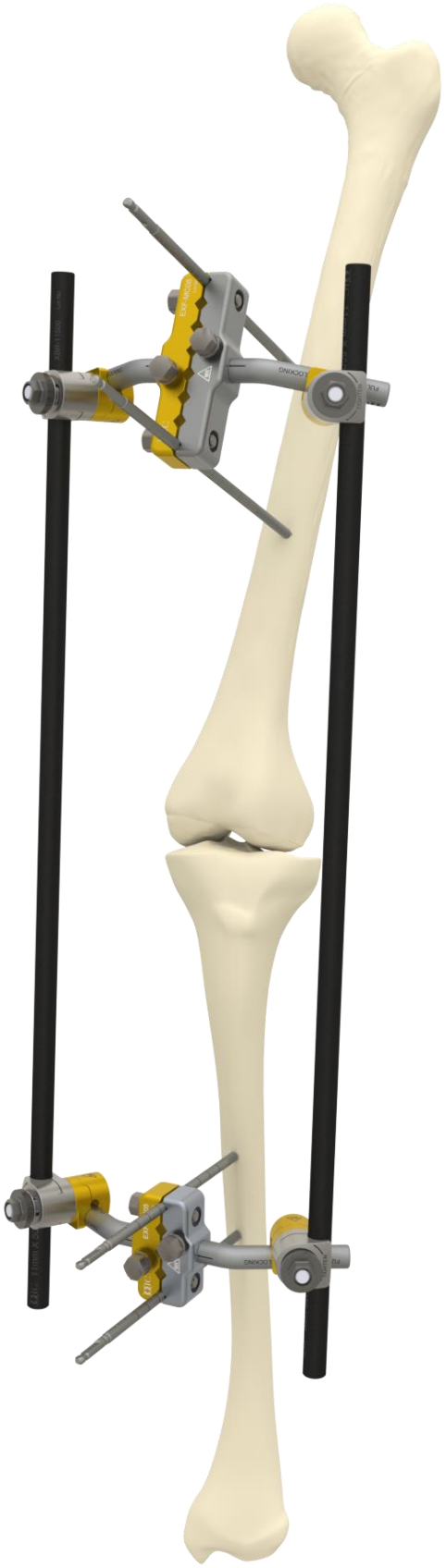
SAMPLE CONSTRUCTS – TIBIA BOX CONSTRUCT

NOTE: Sample constructs shown are examples. Other constructs not shown in the surgical technique can be used.

TIBIA BOX CONSTRUCT		
PART #	DESCRIPTION	QTY
STHP-0535M	Self Tapping Pins 5mm x 35mm	4
XBR-11300	Carbon Fiber Bar 11mm x 300mm	2
EXF-P30	30 Degree Post	4
EXF-MC05	Multi Hole Clamp – 5 hole	1
EXF-MC08	Multi Hole Clamp – 8 hole	1
EXF-C1105	Bar to Pin Clamp	4

SAMPLE CONSTRUCTS – KNEE SPANNING CONSTRUCT

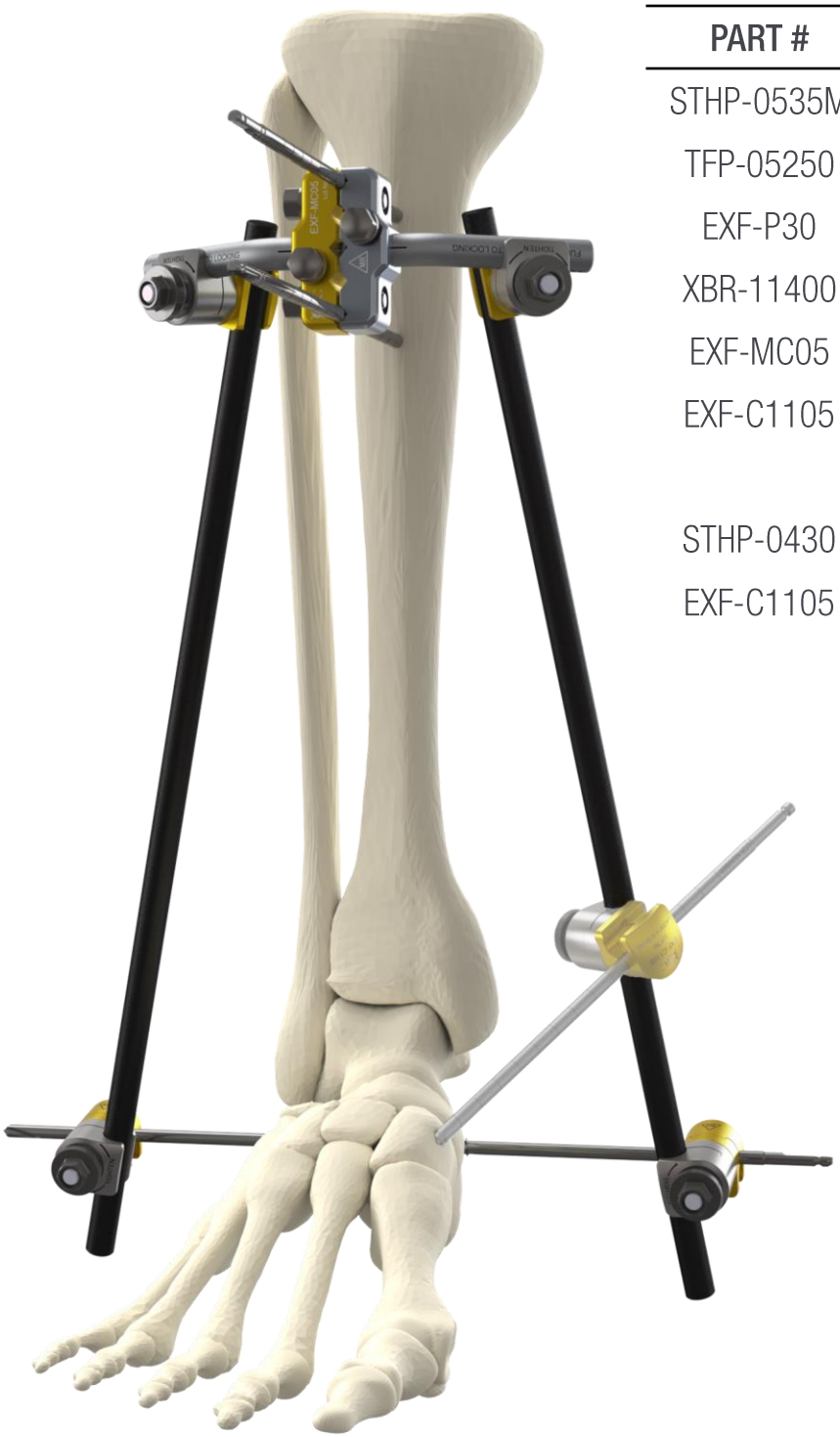
NOTE: Sample constructs shown are examples. Other constructs not shown in the surgical technique can be used.



KNEE SPANNING CONSTRUCT		
PART #	DESCRIPTION	QTY
STHP-0565L	Self Tapping Pins 5mm x 65mm	2
STHP-0535M	Self Tapping Pins 5mm x 35mm	2
XBR-11500	Carbon Fiber Bar 11mm x 500mm	2
EXF-P30	30 Degree Post	4
EXF-MC05	Multi Hole clamp – 5 hole	1
EXF-MC08	Multi Hole clamp – 8 hole	1
EXF-C1105	Bar to Pin Clamp	4

SAMPLE CONSTRUCTS – TIBIA DELTA FRAME WITH OR WITHOUT FOOT PIN CONSTRUCT

NOTE: Sample constructs shown are examples. Other constructs not shown in the surgical technique can be used.

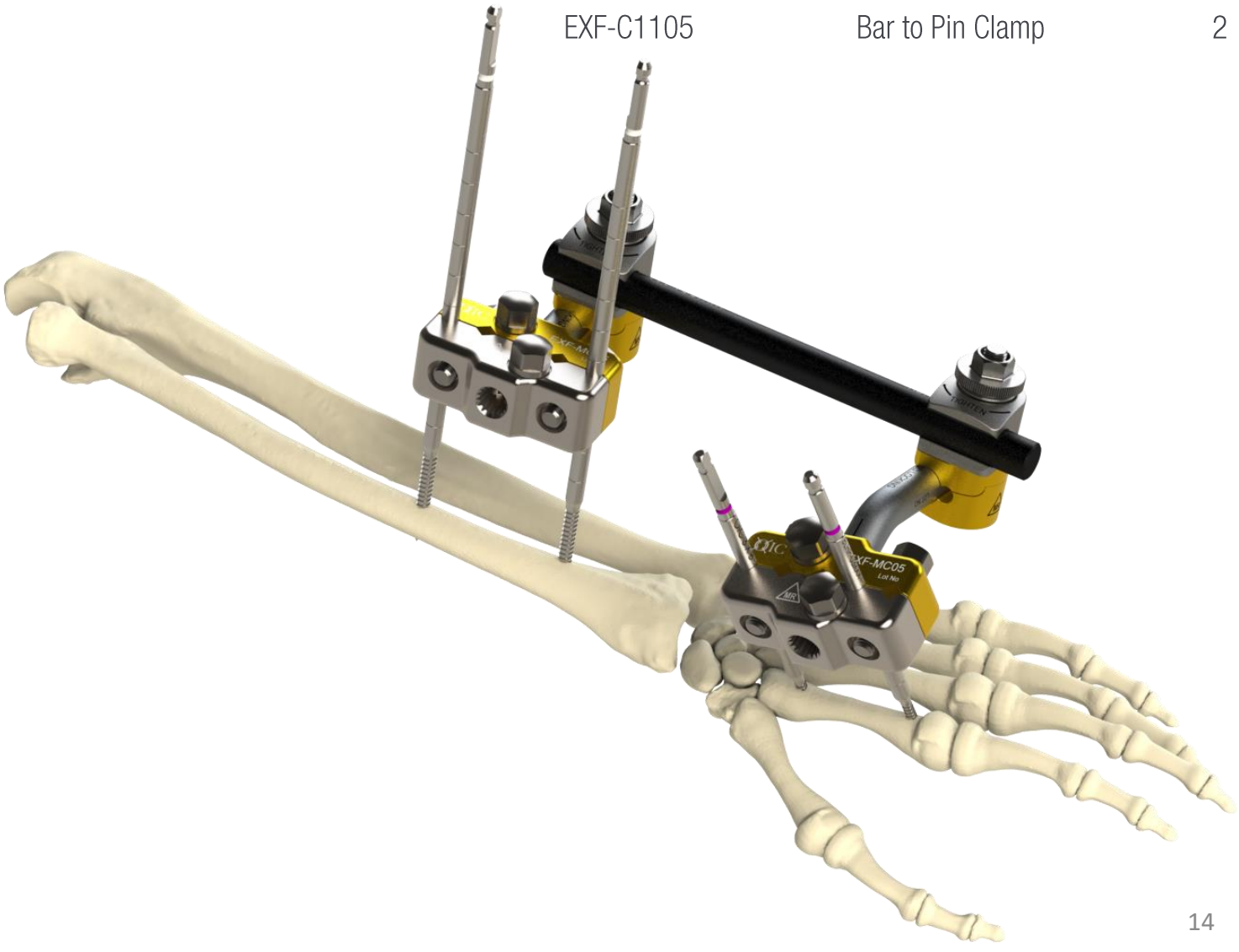


TIBIA DELTA FRAME WITH OR WITHOUT FOOT PIN CONSTRUCT		
PART #	DESCRIPTION	QTY
STHP-0535M	Self Tapping Pins 5 mm x 35mm	2
TFP-05250	Trans-fixation Pin 5mm x 250mm	1
EXF-P30	30 Degree Post	2
XBR-11400	Carbon Fiber Bar 11m x 400mm	2
EXF-MC05	Multi Hole Clamp – 5 hole	1
EXF-C1105	Bar to Pin Clamp	4
	OPTIONAL FOOT PIN	
STHP-0430	Self Tapping Pin 4mm x 30mm	1
EXF-C1105	Bar to Pin Clamp	1

SAMPLE CONSTRUCTS – WRIST SPANNING CONSTRUCT

NOTE: Sample constructs shown are examples. Other constructs not shown in the surgical technique can be used.

WRIST SPANNING CONSTRUCT		
PART #	DESCRIPTION	QTY
STHP-0320S	Self Tapping Pin 3mm x 20mm	2
STHP-0435M	Self Tapping Pin 4mm x 35mm	2
EXF-P30	30 Degree Post	1
EXF-11200	Carbon Fiber Bar 11mm x 200mm	1
EXF-MC05	Multi Hole Clamp – 5 hole	2
EXF-C1105	Bar to Pin Clamp	2



POSTOPERATIVE CARE

After completion of procedure all pin sites should be inspected to ensure there is no skin tenting or soft tissue impingement. Sterile dressings can be placed around pins to prevent bleeding or hematoma formation. We recommend daily cleaning with soap and water, chlorhexidine or alcohol.

Care Prior to Bony Union – Postoperative follow-ups and radiographs are recommended. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending or breaking the device. Early weight bearing should only be considered where there are stable fractures with good bone-to-bone contact and should not be considered for patients who are obese and/or noncompliant, as well as patients who could be pre-disposed to delayed or non-union. Patients and nursing care providers should be advised of these risks.

Care Subsequent to Bony Union – Even after bony union, the patient should be cautioned that a fracture is more likely with the device in place and soon after its removal, rather than later, when voids in the bone left by implant removal have been filled in completely. Patients should be cautioned against unassisted activity that requires walking or lifting. Postoperative care and physical therapy should be structured to prevent loading of the operative extremity until stability is evident. Additional postoperative precautions should be taken when the fracture line occurs within 5 cm of the voids left after removal of the pins.

IMPLANT REMOVAL

The operating surgeon will make final recommendations regarding removal of implants, considering all facts and circumstances. After bone healing is observed, the device serves no purpose and must be removed.
Patients should be directed to seek medical opinion before entering potentially adverse environments that could affect the performance of the implant, such as electromagnetic or magnetic fields, including a magnetic resonance environment.

Catalog Information

Instrument

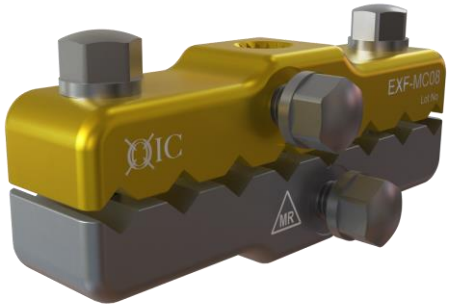
DR40-200C	4.0 mm Drill for 5.0mm Pin	
DR32-165C	3.2mm Drill for 4.0mm Pin	
DR24-140C	2.4mm Drill for 3.0mm Pin	
01-EXF01	Tissue Protector	
01-EXF02	Tissue Protector	
01-EXF03	Trocar	
01-EXF04	10mm Hex and Pin Driver	
01-EXF05	10mm Wrench	

Catalog Information

Clamps

EXF-MC05	5 Hole Pin Clamp

EXF-MC08	8 Hole Pin Clamp

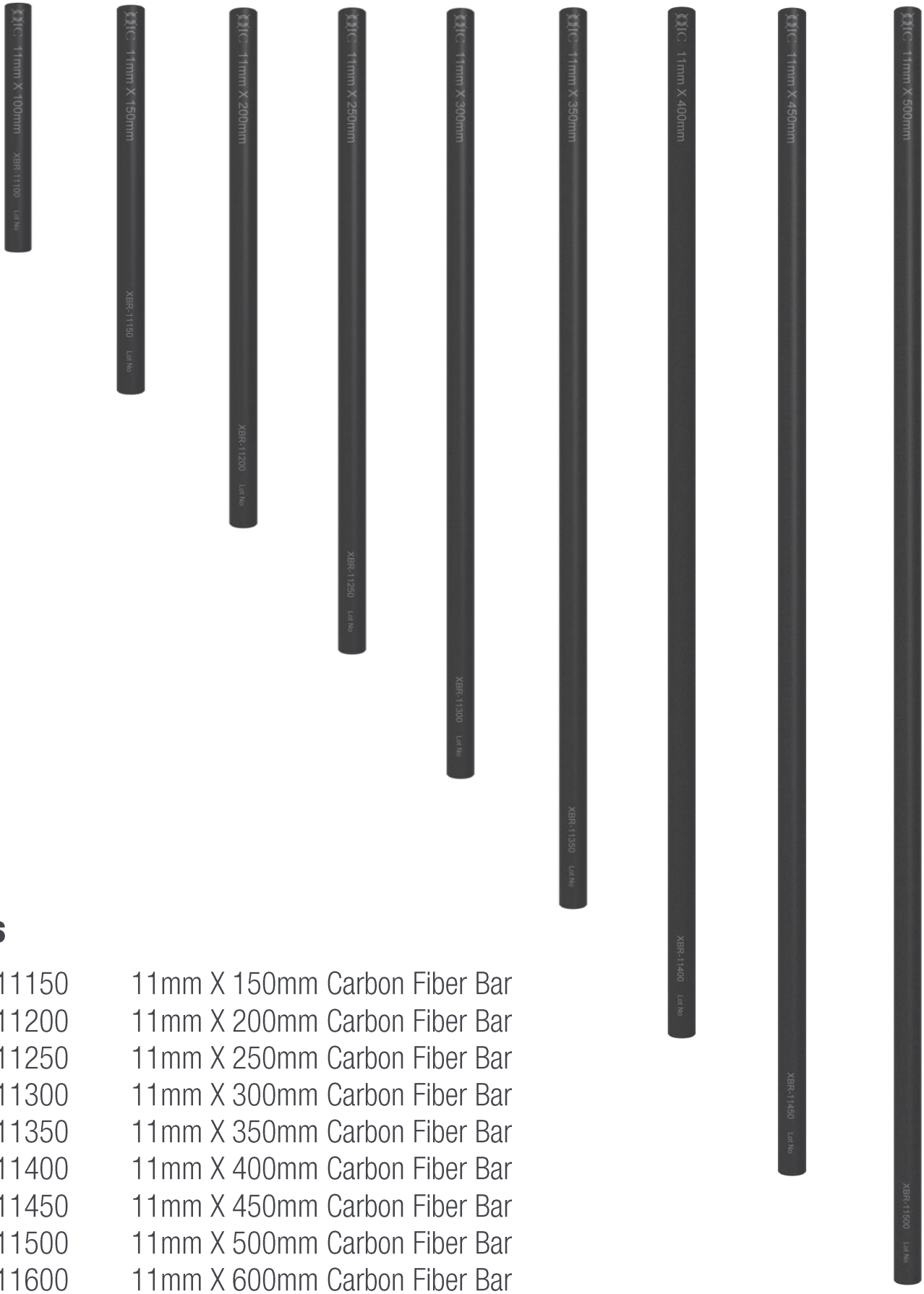


EXF-C1105	Combination Clamp

Posts

EXF-P00	Straight Post

EXF-P30	30° Bent Post



Bars

XBR-11150	11mm X 150mm Carbon Fiber Bar
XBR-11200	11mm X 200mm Carbon Fiber Bar
XBR-11250	11mm X 250mm Carbon Fiber Bar
XBR-11300	11mm X 300mm Carbon Fiber Bar
XBR-11350	11mm X 350mm Carbon Fiber Bar
XBR-11400	11mm X 400mm Carbon Fiber Bar
XBR-11450	11mm X 450mm Carbon Fiber Bar
XBR-11500	11mm X 500mm Carbon Fiber Bar
XBR-11600	11mm X 600mm Carbon Fiber Bar

Pins

Catalog Information

SIZES OFFERED FOR BLHP AND STHP			
	SHAFT DIAMETER	THREAD LENGTH (5MM INCREMENTS)	OVERALL LENGTH
STHP	3.0mm	10-25mm	S – 95mm M – 110mm
BLHP AND STHP	4.0mm	15-70mm	150mm
	5.0mm	30-70mm	M – 150mm L – 200mm

BLHP-04XX Blunt Pins 4mm

BLHP-05XXX Blunt Pins 5mm

STHP-03XXX Self-Tapping Pins 3mm

STHP-04XX Self-Tapping Pins 4mm

STHP-05XXX Self-Tapping Pins 5mm

TFP-05250 Trans-fixation Pin 5mm x 250mm

CAP-0525 Pin Cap

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