



ONX Large External Fixation System

SURGICAL TECHNIQUE



System Description

The ONX Large External Fixation System includes a variety of components including clamps, 11mm rods, posts and half pins. This provides surgeons a broad range of frame construct options that can be used to stabilize/immobilize fractures or surgically created instability of the femur, tibia, knee joint, ankle and pelvis.

GENERAL CONDITIONS OF USE:

The safe implantation of external fixation systems requires an in-depth knowledge of human anatomy as well as common anatomical variations along with a thorough understanding of the specific clinical circumstances. The use of the ONX Large External Fixation System should be performed only by experienced surgeons with specific training in the use of external fixation. In addition, the surgeon must be knowledgeable of the mechanical and metallurgical limitations of this system. The ONX Large External Fixation System should not be used in conjunction with components from a different source, a different manufacturer, or made of a different material. After bone healing occurs, these devices serve no functional purpose and should be removed. The decision regarding when to remove the external fixation device is made between the surgeon and the patient with due regard to treatment options.

See IFU for a more detailed description



Indications and Contraindications

INDICATIONS FOR USE OF ONX LARGE EXTERNAL FIXATION SYSTEM

- Stabilization/fixation of:
 - Long bone fractures in tibia and femur
 - Fractures of pelvis and ankle
 - Peri-articular and intra-articular fractures of knee and ankle
- Joint Arthrodesis
- Non-unions and mal-unions
- Osteotomies

CONTRAINDICATIONS FOR USE OF ONX LARGE EXTERNAL FIXATION SYSTEM

- Insufficient quantity or quality of bone which would inhibit appropriate fixation of the fixation system.
- Patients with a suspected or documented metal allergy or intolerance.
- Compromised vascularity that would inhibit the blood supply to the operative site.
- Recent or active infection.



Warnings & Precautions

Please locate Instructions for Use (IFU at www.orthonovis.com/ifu for a complete list of Warnings, Precautions, Potential Risks and Potential Adverse Effects.

All non-sterile devices must be cleaned and sterilized before use. Please follow the instructions provided within the Instructions for Use (IFU at www.orthonovis.com/ifu)

These warnings do not include all possible adverse surgical effects, but are particular to metallic fixation devices. Explain general surgical risks to the patient before surgery.

WARNINGS

1. Bone pin placement requires accurate anatomic alignment to avoid damage to nerves, blood vessels and tendons.
2. The patient should be advised that the device cannot and does not replicate a normal healthy bone. The device can break or become damaged as a result of trauma or strenuous activity. The ONX Large External Fixation System has a finite expected service of life.
3. The surgeon must discuss all relevant risks, including the finite lifetime of the device with the patient, when necessary.
4. All non-sterile devices must be cleaned and sterilized before use.
5. All ONX Large External Fixation components are intended for single use only.
6. The compatibility of different product systems has not been tested and is considered “off-label” for use.
7. Pre-drilling should be done using a low drill speed to minimize heat that can injure bone and soft tissue.
8. Use caution when handling the sharp tip of the Bone Pin. If the Bone Pins are to be cut, the pin ends should be held by the surgeon or an assistant during this process. Eye protection is recommended for all operating room personnel.
9. As with all percutaneous skeletal fixations, pin track care is important in reducing the incidence of infection.

PRECAUTIONS

1. Surgeon familiarity with the device, instrumentation, and surgical technique prior to surgery is crucial to proper device installation.
2. Patient cooperation and participation are important to effective use of the ONX Large External Fixation System. Advise your patient to report adverse or unanticipated effects as soon as possible.
3. Skeletal pin security in bone and device integrity should be routinely checked by the surgeon. Pin track infections need prompt recognition and treatment and may require early device removal.
4. Adequately instruct the patient. Postoperative care and the patient’s ability and willingness to follow instructions are among the most important aspects of successful bone healing. Inform the patient about the system limitations, and to limit physical activities.



Technical Details

MRI SAFETY

The ONX Large External Fixation System has not been evaluated for safety and compatibility in the MR environment. The ONX Large External Fixation System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the ONX Large External Fixation System implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

SURGICAL TECHNIQUE

PATIENT POSITIONING:

Positioning of the patient shall be determined by the operating surgeon.

TECHNIQUE:

Basic principles of technique apply to all large external fixator frames. The exact frame construct chosen should be dictated by the soft tissue injury and fracture pattern. Major technique principles include Pin Insertion and Frame Completion.

PIN INSERTION:

Insert Drill Sleeve Assembly: Make a stab incision. Pass the trocar assembly through the soft tissue until the trocar contacts the desired pin placement site on the bone.

Drill Both Cortices: Remove the trocar and drill both cortices using drill bit to create pilot hole

Insert the Threaded Pin: Insert the desired pins into the bone, through the pin guide handle or pin cannula.

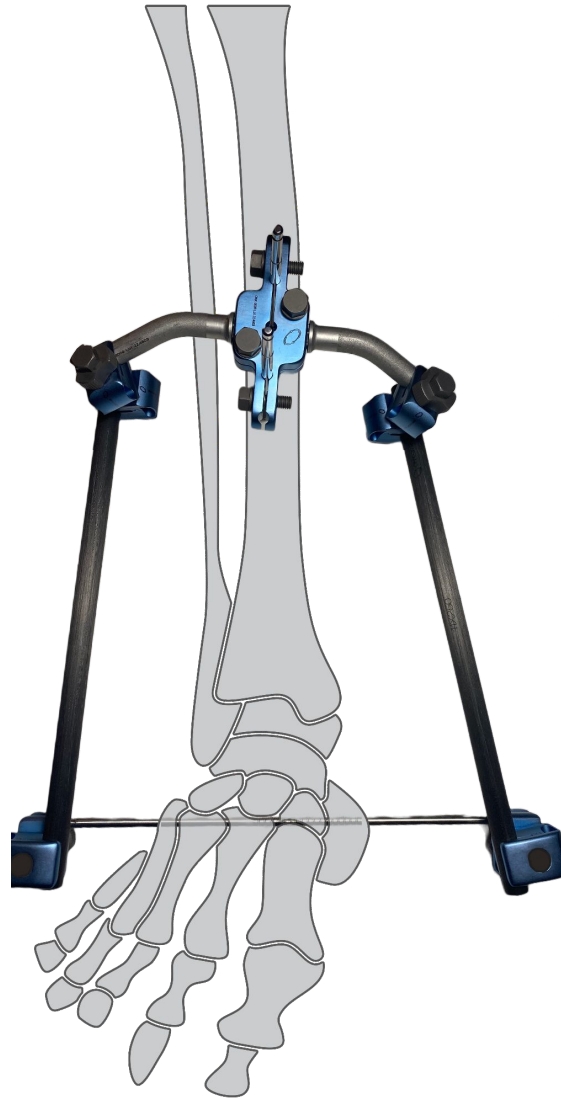
Note: If the Multiple Pin Clamp will be used in the final construct it must be used in the pin placement procedure. Use the pin cannula within the Multiple Pin Clamp to guide the direction of all the pins.

FRAME COMPLETION:

Frame constructs are completed by the addition of various rods and clamps. The exact construct is determined by the soft tissue injury.

Once the pins are in the desired position the construct can be built using the 11mm diameter rods and clamps. The clamps can be tightened by hand until the final positioning of the clamp is complete. The T-Handle Wrench can be used to final tighten all bolts.

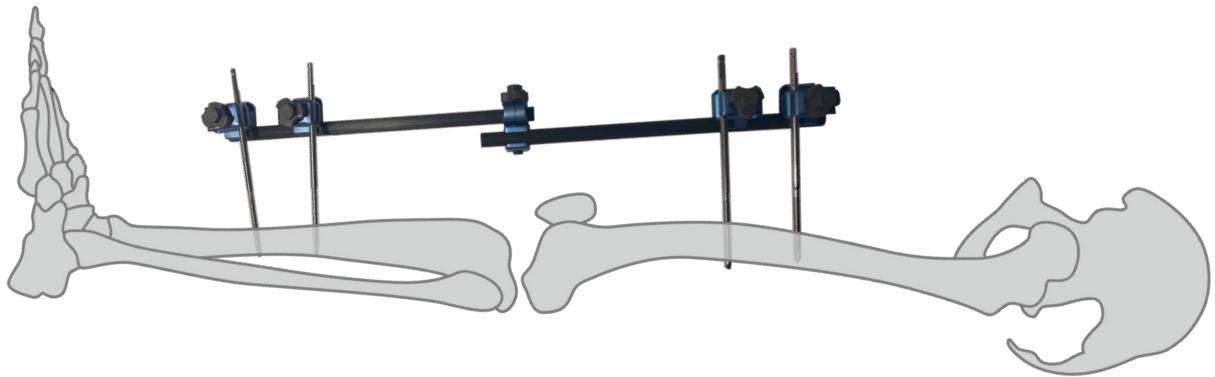
Ankle Frame



Ref #	Description	QTY
ONX-3002	5.0mm x 150mm Self Drill SS Pin	2
ONX-3005	7.0mm x 245mm Trocar SS TransFix Pin	1
ONX-3006	Multiple Pin Clamp	1
ONX-3009	30° Clamp Post	2
ONX-3007	Large Clamp, Bar to Bar	2
ONX-3008	Large Clamp, Bar to Pin	2
ONX-3014	11mm x 350mm Carbon Fiber Rod	2

→ PRODUCT CONFIGURATION IS CONTINGENT UPON SURGEON CLINICAL PREFERENCE.

Knee Frame

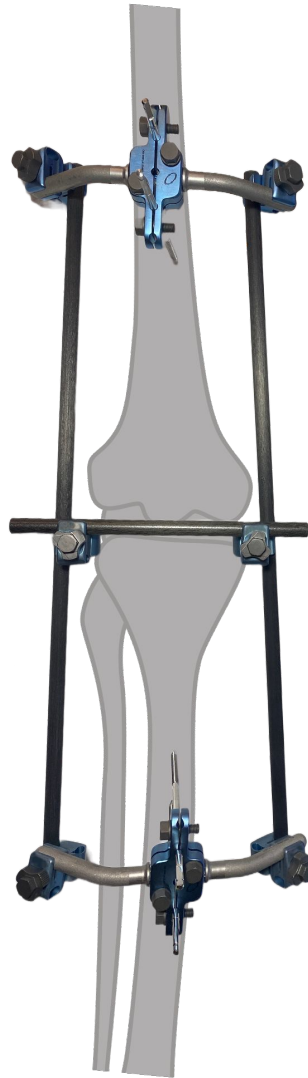


Ref #	Description	QTY
ONX-3002	5.0mm x 150mm Self Drill SS Pin	2
ONX-3003	5.0mm x 200mm Self Drill SS Pin	2
ONX-3007	Large Clamp, Bar to Bar	1
ONX-3008	Large Clamp, Bar to Pin	4
ONX-3015	11mm x 400mm Carbon Fiber Rod	2

→ PRODUCT CONFIGURATION IS CONTINGENT UPON SURGEON CLINICAL PREFERENCE.



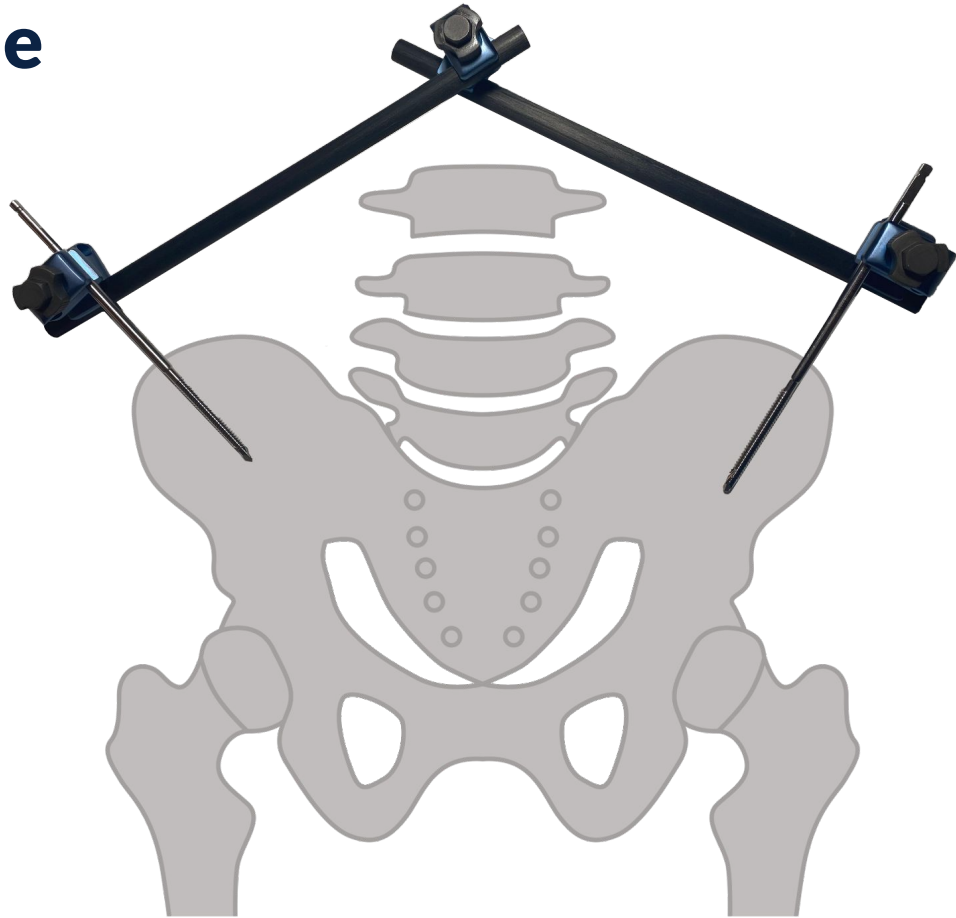
Knee Frame



Ref #	Description	QTY
ONX-3002	5.0mm x 150mm Self Drill SS Pin	2
ONX-3003	5.0mm x 200mm Self Drill SS Pin	2
ONX-3006	Multiple Pin Clamp	2
ONX-3007	Large Clamp, Bar to Bar	6
ONX-3009	30° Clamp Post	4
ONX-3011	11mm x 200mm Carbon Fiber Rod	1
ONX-3016	11mm x 450mm Carbon Fiber Rod	2

→ PRODUCT CONFIGURATION IS CONTINGENT UPON SURGEON CLINICAL PREFERENCE.

Pelvis Frame



Ref #	Description	QTY
ONX-3003	5.0mm x 200mm Self Drill SS Pin	2
ONX-3007	Large Clamp, Bar to Bar	1
ONX-3008	Large Clamp, Bar to Pin	2
ONX-3013	11mm x 300mm Carbon Fiber Rod	2

→ PRODUCT CONFIGURATION IS CONTINGENT UPON SURGEON CLINICAL PREFERENCE.

Components

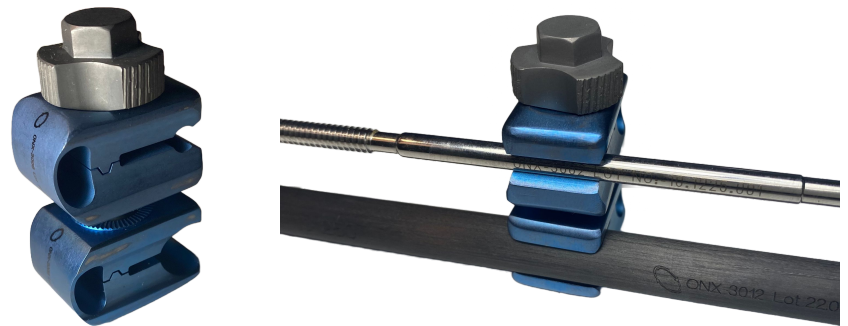
ROD-TO-ROD CLAMPS

The rod-to-rod clamps is designed to snap onto 11mm rods



ROD-TO-PIN CLAMPS

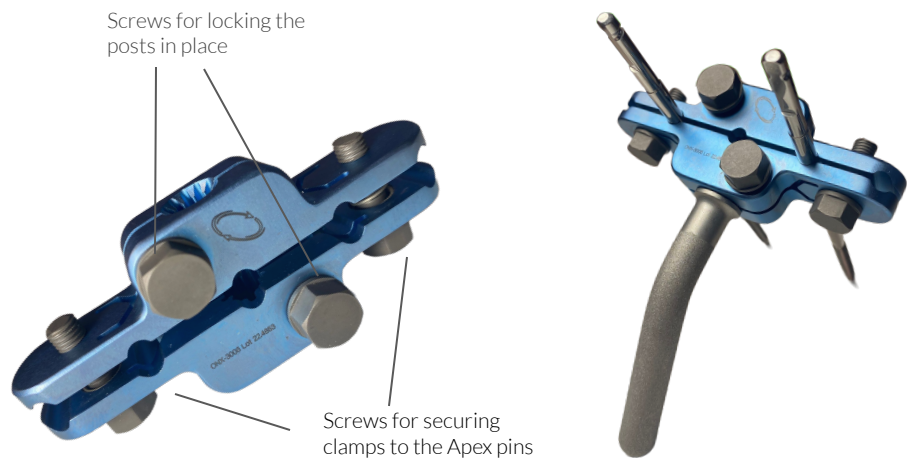
The rod-to-pin clamp is designed to snap on 11mm rods along with 4mm / 5mm / 6mm pins



MULTIPLE PIN CLAMPS

The multiple pin clamp (5 holes) can be used if parallel pin placement is desired.

The multiple pin clamp can also accept the 30-degree posts when this is requested by surgeon

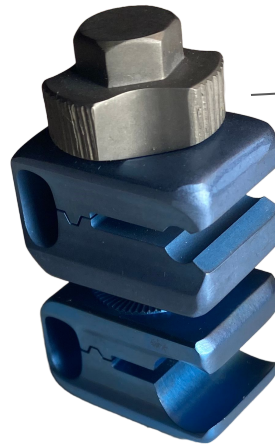


Components (cont.)

TIGHTENING OF CLAMPS

Provisional tightening of a clamp can be accomplished with either the T-Handle (ONX-3019) or Wrench (ONX-3018)

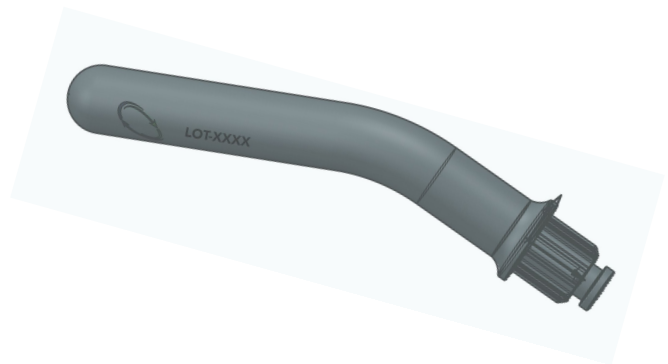
Final tightening of a clamp can be accomplished with either the T-Handle (ONX-3019) or Wrench (ONX-3018)



Screws to secure clamps to the pins and/or rods

POSTS

30 degree angled 11mm posts available to be used in conjunction with the multiple pin clamp. Once inserted into the clamp completely, the posts will become locked once the bolts located on the top of the clamp are tightened completely



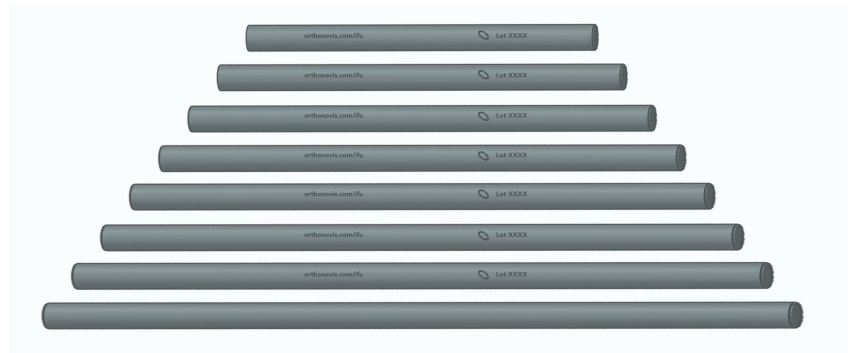


Components (cont.)

RODS

The 11mm reinforced carbon fiber rods are available in lengths of 150mm to 500mm.

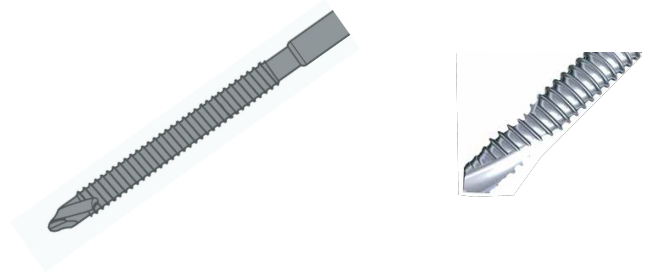
The carbon fiber rods are designated as single patient use only. Once used on a patient they have to be disposed of.



PINS

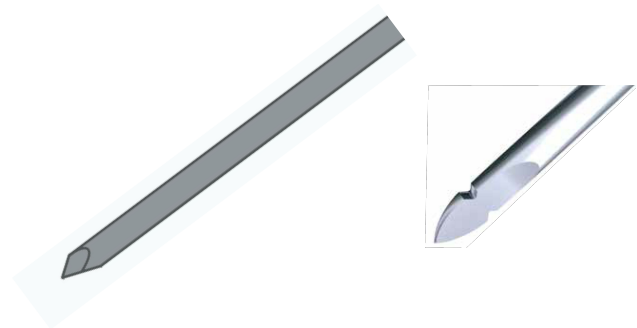
Half Pins

Half pins are offered as self drilling pins. Pre-drilling is always optional and at the surgeons discretion.



Transfix Pins




Transfix pins require pre drilling prior to placement using the 3.75mm Drill (ONX-3023).





Components (cont.)






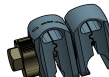






GENERAL GUIDELINES FOR PRE-DRILLING

-  Always pre-drill with a new, sharp drill
-  Drill slowly to help prevent thermal injury
-  When placed through an exposed bone surface, irrigating the interface can reduce heating

Pin Diameter	Pin Length	Thread Length	Drill Bit
4mm	150mm	35mm	3.75mm
5mm	150mm	40mm	3.75mm
5mm	200mm	40mm	3.75mm
6mm	245mm	50mm	3.75mm












Fixation Components for the ONX Large External Fixation System

ONX-3001	4mm x 150mm Self Drill, Stainless Steel, Half Pin	
ONX-3002	5mm x 150mm Self Drill, Stainless Steel, Half Pin	
ONX-3003	5mm x 200mm Self Drill, Stainless Steel, Half Pin	
ONX-3005	7mm x 245mm Stainless Steel, Transfix Pin	
ONX-3006	Multiple Pin Clamp, Large, Clip-On, 5 Hole	
ONX-3007	Clamp, Rod-to-Rod, Large, Clip-On	
ONX-3008	Clamp, Rod-to-Pin, Large, Clip-On	
ONX-3009	Post, 30 Degree, 11mm Diameter	
ONX-3010	11mm x 150mm Carbon Fiber Rod	
ONX-3011	11mm x 200mm Carbon Fiber Rod	
ONX-3012	11mm x 250mm Carbon Fiber Rod	
ONX-3013	11mm x 300mm Carbon Fiber Rod	
ONX-3014	11mm x 350mm Carbon Fiber Rod	



Fixation Instruments for the ONX Large External Fixation System (cont.)

ONX-3015	11mm x 400mm Carbon Fiber Rod	
ONX-3016	11mm x 450mm Carbon Fiber Rod	
ONX-3017	11mm x 500mm Carbon Fiber Rod	
ONX-3018	Combination Wrench	
ONX-3019	T-Handle w/ AO Female Connector	
ONX-3020	Single Pin Guide Handle	
ONX-3021	Trocar Punch	
ONX-3022	Pin Cannula	
ONX-3023	3.75mm Drill	



PLEASE SEE COMPLETE IFU AT WWW.ORTHONOVIS.COM/IFU

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