

The image shows two views of the FastFrame Ankle Spanning Surgical Technique. The main view is a side profile of the device, which consists of a long, teal-colored shaft with black end caps and red locking levers. The shaft is labeled with 'FastFrame ANKLE SPANNING' and '47-5300-070-00'. A smaller view at the top shows the device from a different angle, highlighting the joint mechanism. The background is white with a blue diagonal band.

FastFrame™ External Fixation System

Ankle Spanning Surgical Technique



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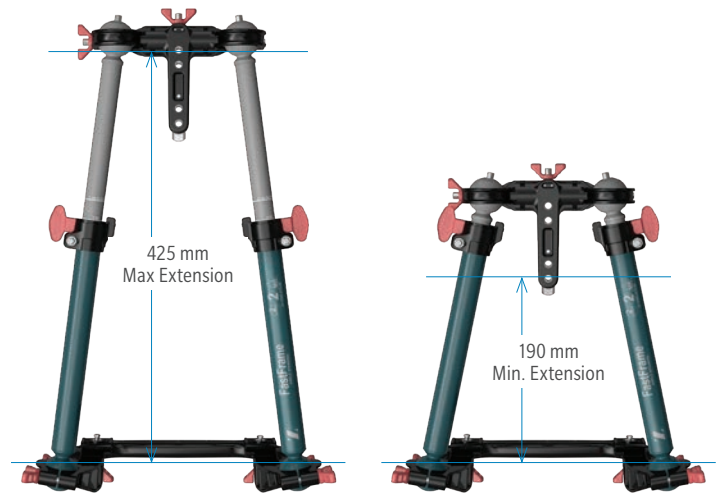
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Introduction

The FastFrame External Fixation System – Ankle Spanning is a single-use external fixator consisting of the following components that are manipulated by the end user: clamps, telescoping rods, a built in ankle bridge, and half-pin bone screws. This system will be sterile packed in its fully assembled state and will not require any intraoperative assembly by the clinicians.

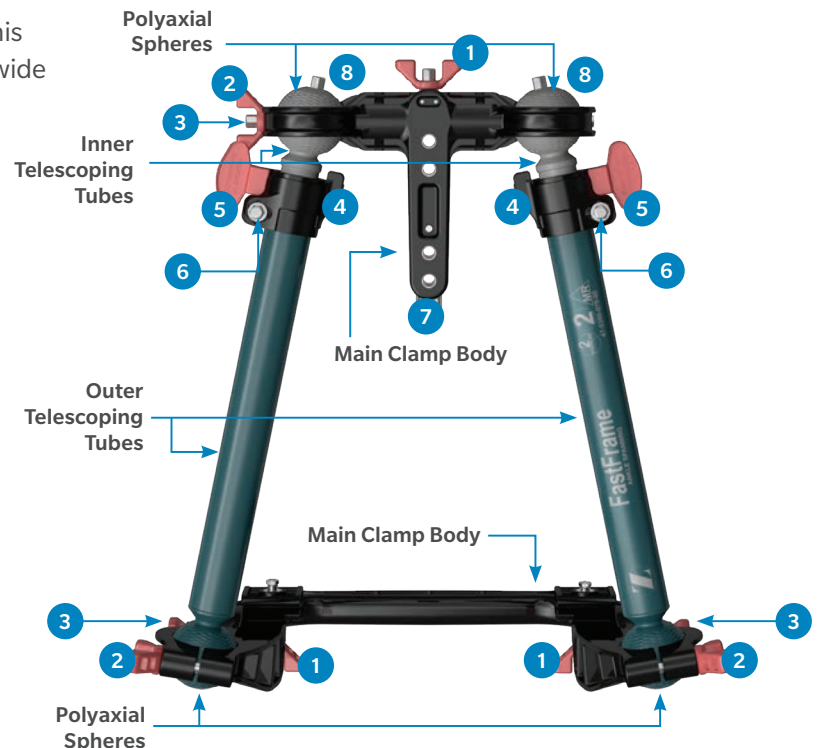
The main clamp bodies will be interconnected to each other with adjustable (telescoping) tubes that allow the clamps to rotate, pivot, and translate with respect to the long axis of the bone. This will allow the clamps to properly reduce the fracture and subsequently rigidly fix the bones in place.

The telescoping tubes result in a total range of accommodated pin placement of 235mm. The fully collapsed frame is 190mm long (from the innermost pin location of the tibial clamp to the center of the transfixing pin) while the fully extended frame is 425mm long from outermost pin location of the tibial clamp to the center of the transfixing pin. This length adjustment allows for proper fitment on a wide variety of patient sizes.



Available Pin Placement Range of the Frame

- 1 Clamp to Pin Lockout Wing Nut
- 2 Polyaxial Lockout Wing Nut
- 3 Polyaxial Lockout Bolt
- 4 Telescoping Lockout Clamp
- 5 Lockout Tab
- 6 Telescoping Lockout Bolt
- 7 Clamp Slider
- 8 Backup Telescoping Lockout Bolt





Ankle Spanning Frame



Ankle Spanning Frame with Optional Clamp

INDICATIONS

The FastFrame External Fixation System - Ankle Spanning is indicated for use in treatment of distal tibia and foot fractures. Specifically, the system is intended for:

- Stabilization of open or closed fractures about the ankle, typically in the context of polytrauma or where open or alternative closed treatment is undesirable or otherwise contraindicated;
- Arthrodesis and osteotomies with associated soft tissue problems about the ankle;
- Stabilization of limbs after removal of total ankle arthroplasty for infection or other failure;
- Stabilization of non-unions about the ankle; and
- Intraoperative temporary stabilization to assist with indirect reduction.

*In the European Union (EU)/ European Economic Area (EEA), the FastFrame External Fixation System –Ankle Spanning is indicated for use in treatment of ankle fractures. Specifically, the system is intended for temporary stabilization of open or closed fractures, typically in the context of polytrauma or where open or alternative closed treatment is undesirable or otherwise contraindicated.

The FastFrame External Fixation System – Ankle Spanning Optional Clamp Assembly is intended to support the foot during the use of FastFrame External Fixation System – Ankle Spanning system.

CONTRAINDICATIONS

- Active or suspected infection
- Conditions that limit the patient’s ability and/ or willingness to follow instructions during the healing process.
- Inadequate skin, bone, or neurovascular status

Contraindications may be relative or absolute and are left to the discretion of the surgeon.

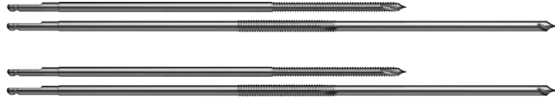


Figure 1

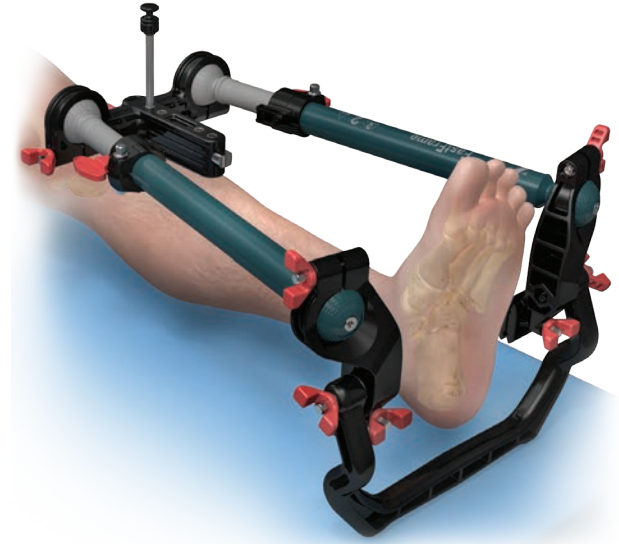


Figure 2

Tibia & Transfixing Pin Placement

The FastFrame™ External Fixation System – Ankle Spanning kit comes equipped with two self drilling, self tapping 5 mm X 200 mm X 65 mm thread pins, and two 5 mm X 275 mm transfixing pins. Each pin has an AO quick connect feature for easy connect to most power equipment (Figure 1).

It is recommended to place the first pin in the tibia. If desired, both tibia pins can be placed prior to placing transfixing pins. To place the tibia pin(s), insert the tissue sleeve and trocar through the desired pin hole on the proximal clamp.

ⓘ **Note:** It is important to gauge the distance between the fracture site and your pin placements to optimize frame expansion and minimize risk of infection.

Using the trocar, make a mark on the skin for the incision. After the mark has been made, make the incision, and gain access to the bone using the tissue sleeve and trocar to transect the soft tissues (Figure 2).

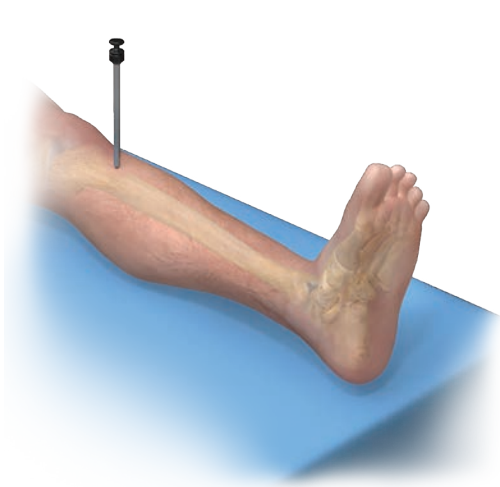


Figure 3

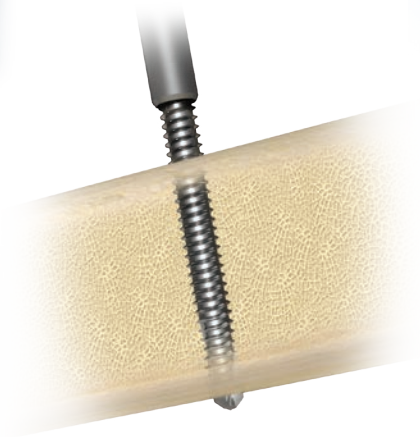


Figure 4



Figure 5

Tibia & Transfixing Pin Placement (cont.)

When placing the first tibia pin, the trocar and tissue sleeve can be used through the frame or independently, if desired. If the first tibia pin is placed independently, it is recommended to place the frame over this pin to use as a guide for placement of the additional tibia pin. (Figure 3 & 5).

Remove the trocar from the tissue sleeve and insert the first pin through the tissue sleeve on the tibia. Drill the pin into the tibia deep enough to provide bi-cortical fixation. Excessive drilling beyond the far cortex is not recommended, as this will place soft tissues at risk (Figure 4).

⚠ **Warning:** Unicortical fixation does not provide adequate fixation

The FastFrame External Fixation System – Ankle Spanning Frame accommodates pin placements from 190mm to 425mm. Ensure that your first pin allows for subsequent frame expansion and reduction (Figure 5).

⚠ **Note:** Do not fully tighten proximal clamp slider bolt until both proximal pins have been drilled and frame has been applied. If desired, provisional tightening by hand can be done to adjust frame height. However, when drilling or placing pins, clamp slider must be fully loosened.



Figure 6

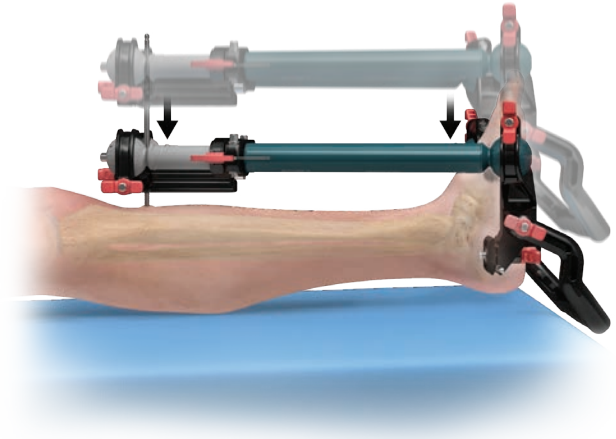


Figure 7

Tibia & Transfixing Pin Placement (cont.)

Placing the transfixing pin prior or after the tibial pins is at the surgeon's discretion. The transfixing pin is drilled medial to lateral through the calcaneus until the pin threads are centered on the calcaneus and adequate purchase is made (Figure 6).

- ⓘ Note: Place the first transfixing pin more posteriorly in the calcaneus to allow for the second transfixing pin to be placed anteriorly.

Frame Placement

When placing the frame over the first tibial pin, choose a pin hole on the tibial clamp such that there is adequate bone (either proximal or distal to the first pin) for placement of the subsequent tibial pin. While placing the frame over the first transfixing pin, position it on the posterior transfixing pin clamp such that there is adequate bone on the anterior for placement of the second transfixing pin.

The first tibial pin can be placed through any of the 4 clamp holes of the tibial clamp, but the first transfixing pin is recommended to be placed in the posterior ankle clamp position to facilitate proper alignment of the frame through rest of the process. This versatility in frame placement allows for flexibility in determining the remaining pin placements with respect to the patient anatomy, fracture location, and also with respect to minimum and maximum frame expansion lengths (Figure 7).

- ⓘ **Note:** Do not fully tighten frame onto pins until both tibial pins, and both transfixing pins have been placed, and frame is in final position. Remove tissue sleeves prior to locking clamps.

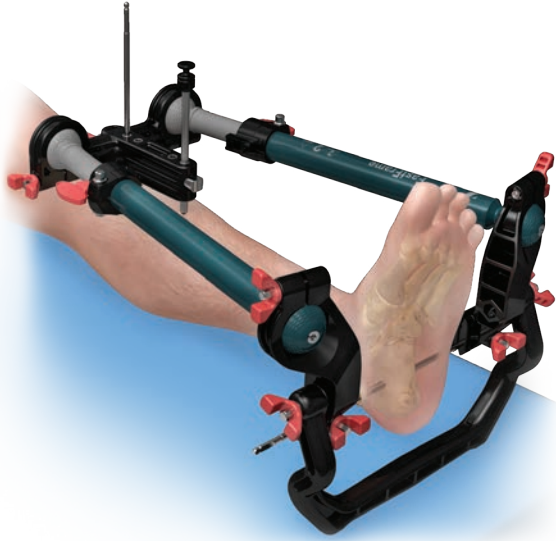


Figure 8

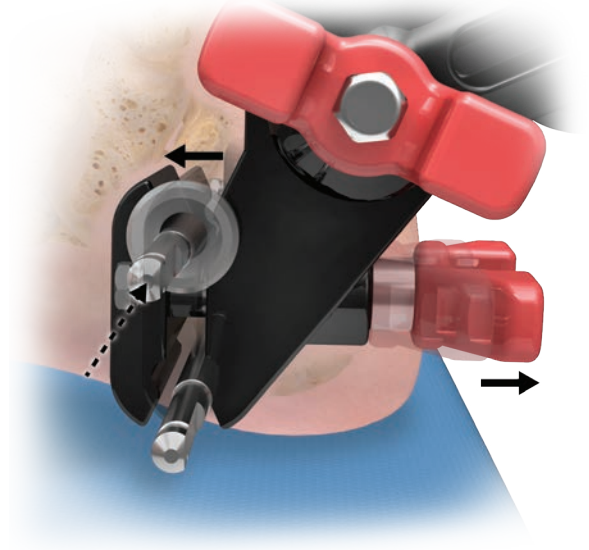


Figure 9

Drill Remaining Pins Through Frame

If both tibia pins were not placed previously, place the tissue sleeve and trocar for the remaining tibial pin (Figure 8). Using the trocar, make a mark on the skin for the incision of the second tibial pin. After the mark has been made, make the incision, and gain access to the bone using the tissue sleeve and trocar to transect the soft tissues.

Remove the trocar from the tissue sleeve and insert the final tibial pin through the tissue sleeve. Drill the pin into the bone deep enough to provide bi-cortical fixation. Excessive drilling beyond the far cortex is not recommended, as this will place soft tissues at risk.

- ⓘ **Warning:** Unicortical fixation does not provide adequate fixation.
- ⓘ **Caution:** Be aware of pin spacing and location, being sure to avoid surrounding critical nerve and soft tissue landmarks.

For placement of the final transfixing pin, insert a transfixing pin tissue sleeve into both medial and lateral transfixing pin clamps in the anterior pin position (Figure 9). Press on the wing nuts on the transfixing pin clamps to allow for clearance of the transfixing pin tissue sleeves through the clamps. When placing the final transfixing pin, be sure to align the pin through the tissue sleeves and clamps, such that the pin is parallel to the first transfixing pin by drilling medial to lateral through the calcaneus.

Once the threaded portion of the pin has cleared the medial tissue sleeve, pay close attention to the trajectory of the pin to ensure it passes through the lateral tissue sleeve situated in the lateral transfixing pin clamp. Continue to drill medial to lateral until the pin threads are centered in the calcaneus and adequate purchase is made. Remove both transfixing pin tissue sleeves to allow transfixing pin clamps to collapse onto both transfixing pins.



Figure 10a

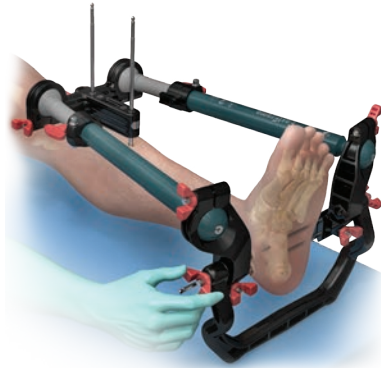


Figure 10b

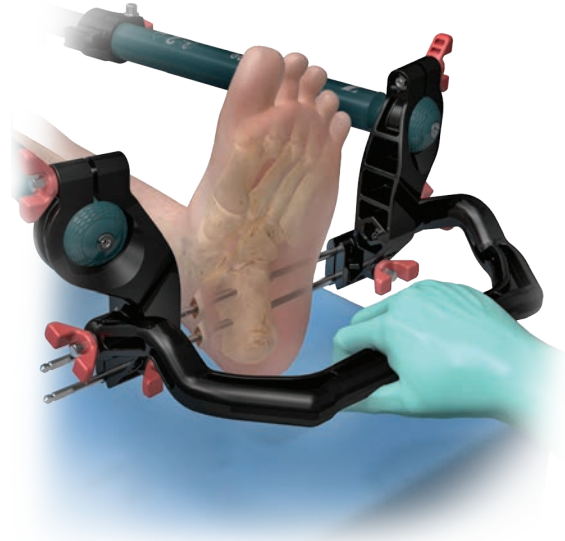


Figure 11

Lock Clamps Over Pins

When both tibial pins are in place, provisionally tighten the clamp over pins by hand using the wing nut on the clamp slider bolt (Figure 10a).

Ensure both transfixing pins are in the appropriate clamp grooves, and tighten the medial and lateral clamps with the wing nuts to create a provisional grip on the transfixing pins (Figure 10b).

Note: Remove tissue sleeves prior to locking the clamps, if not done already.

Ankle Fracture Reduction

In its current state, the frame can freely expand and contract. Achieve the initial stabilization by holding the frame around the clamps and pulling/rotating until desired reduction and alignment is achieved. The clamps can be used for grip while extending the frame to achieve the intended reduction and alignment. To aid in reduction, use the FastFrame Ankle Bridge as a handle to help expand the frame (Figure 11). Once the initial reduction and alignment of the fracture is satisfactory, provisionally lock the two distal ankle spheres using the wing nuts to maintain orientation of the foot.

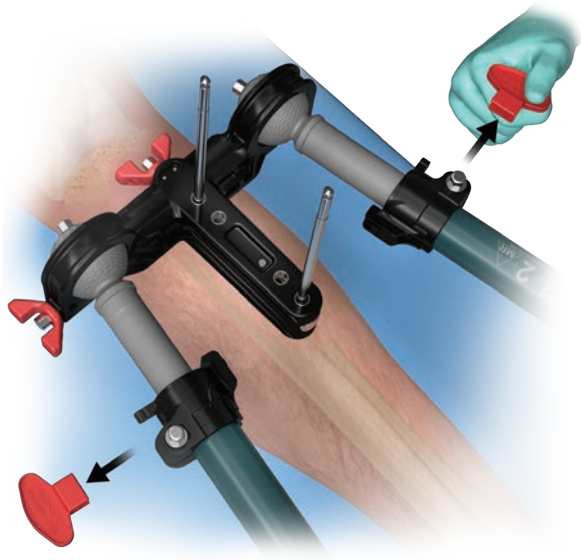


Figure 12



Figure 13

Ankle Fracture Reduction (cont.)

Then pull the red tabs to enable the traction retention capability (Figure 12). The frame will then become uni-directional and hold traction of bone segments so length is automatically maintained. The frame will not contract in size once the red lockout tabs are removed. However the frame still has the capability to expand as necessary.

ⓘ **Note:** Polyaxial spheres can be easily locked and unlocked to achieve hands-off fluoroscopy and to fine tune fracture reduction. Removing the red lock out tabs will lower the silver levers beneath limiting the frame contraction. The tabs can also be reinstalled, by slightly lifting the silver levers, to allow the shortening of the frame in case of over expansion.

Final Frame Locking

Utilize the T-Handle driver to conduct final frame locking (Figure 13). Note the 1 – 5 number sequence on each nut and tighten the nuts in that order (Figure 14, Refer to the next page).

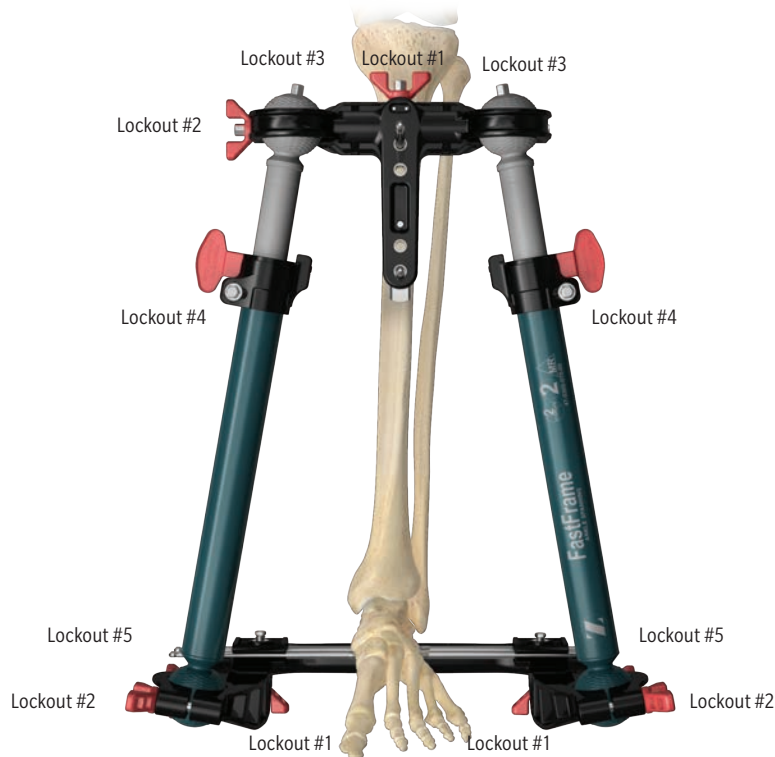


Figure 14



Figure 15

Final Frame Locking (cont.)

The first bolts to tighten are the clamp slider bolts on each clamp, which are indicated with the number **1**. This fixes the clamps to the pins. Second, tighten the polyaxial lockout bolts on each clamp, which are indicated with the number **2**. This fixes the clamps to the bars. Third, lock the two backup telescoping lockout bolts indicated with the number **3**. This provides initial fastening of the telescoping bars. Finally, lock the two telescoping lockout bolts along the tube/bars near the red tabs, which are indicated with the number **4**. This provides complete fixation of the telescoping bars.

The final lockout bolts will be the FastFrame Ankle Bridge, which are indicated with the number **5**. This bridge is designed to aid in reduction, as well as provide a kickstand functionality to the frame. The FastFrame Ankle Bridge will keep the frame elevated post operatively (Figure 15).

- ⊖ **Note:** Ensure telescoping lockout clamp bolts are rotated to face outward for ease of tightening.
- ⊖ **Note:** Relaxing pin site tension may be beneficial if there is a high degree of stress or pressure around pin sites.



Figure 16



Figure 17

Fastframe External Fixation System – Ankle Spanning Optional Clamp Assembly

At the surgeon's discretion, the Optional Clamp Assembly may be added to the medial or lateral lower leg of the fully locked out ankle frame in order to hold the foot in a fixed position relative to the tibia. The Optional Clamp Assembly may be used with either 1 or 2 optional pins inserted into the desired metatarsal location.

Snap the tube clamp around the desired leg of the ankle frame assembly. Engage the tube clamp bolt into the nut on the far side of the clamp, but do not fully tighten. The tube clamp should be free to slide up and down the leg of the frame. Slide the tube clamp into a position such that the spherical pin clamps can be positioned appropriately for the desired pin location(s) in the metatarsal (Figure 16).

To place the first optional pin, insert the desired number of pins (1 or 2) through the pin sphere clamps of the Optional Clamp Assembly (Figure 17). Use the pin tip(s) to make a mark(s) on the skin for the incision. After the mark(s) has been made, remove the pins from the spherical clamps and pivot the Optional Clamp Assembly away from the metatarsal to give access for pin insertion. Make the incision(s) and gain access to the bone using the optional kit tissue sleeve to transect the soft tissues.

ⓘ **Note:** The tissue sleeve cannot be used through the Optional Clamp Spheres.

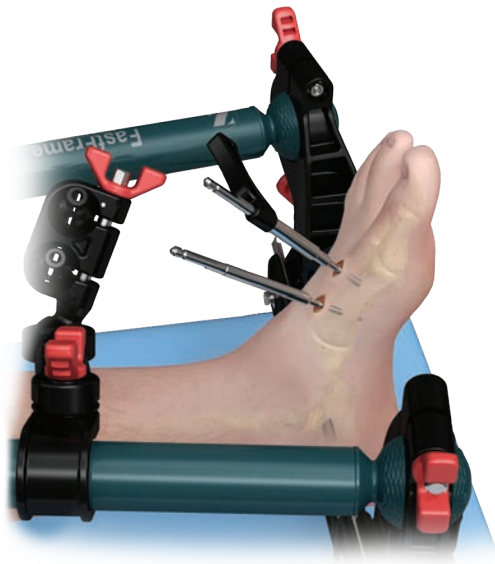


Figure 18

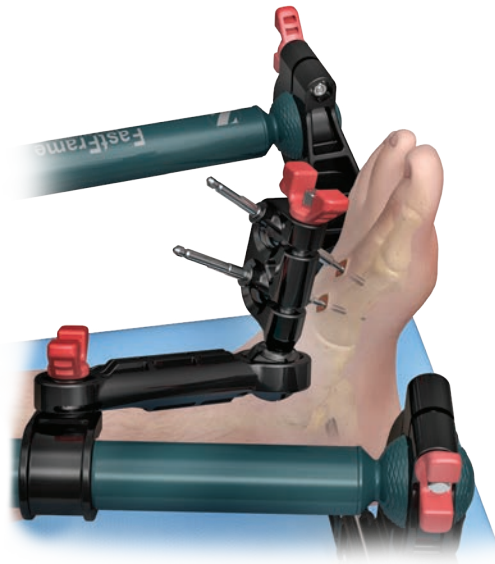


Figure 19

Fastframe External Fixation System – Ankle Spanning Optional Clamp Assembly (cont.)

Insert the first pin through the tissue sleeve on the metatarsal. Drill the pin into the bone deep enough to provide bi-cortical fixation (Figure 18). Drilling beyond the far cortex is not recommended, as this will place soft tissues at risk.

ⓘ **Warning:** Unicortical fixation does not provide adequate fixation. If a second optional pin is desired, repeat the above steps for insertion.

Once the desired number of pins have been inserted, place the spherical pin clamps over the pins and adjust the position of the foot to obtain desired alignment (Figure 19). The wingnuts can then be used to provisionally lockout the Optional Clamp Assembly (Figure 20, refer to the next page). Adjustments may be made by loosening one or both lockouts.

Utilize the T-Handle driver to conduct final locking of the Optional Clamp Assembly. Order of the lockouts for this device is not critical.

ⓘ **Note:** The tube clamp can be placed onto the medial or lateral leg of the ankle frame in 2 different orientations. If desired fit on the patient cannot be achieved, the Optional Clamp Assembly should be removed from the Ankle frame. The tube clamp can then be rotated 180° and placed back on the frame. Follow the same order above to then place the clamp body over the optional pins, adjust alignment, and lockout.

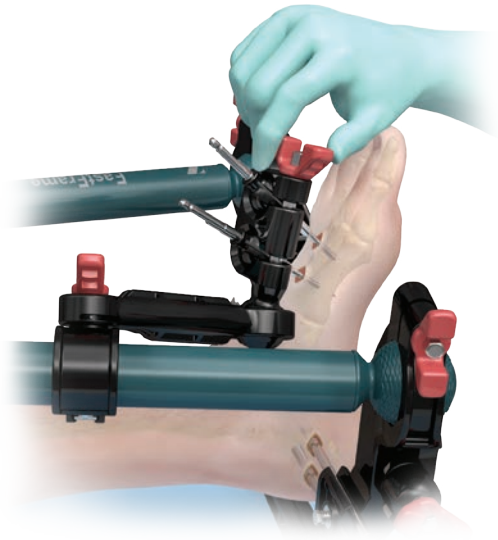


Figure 20

Fastframe External Fixation System – Ankle Spanning Optional Clamp Assembly (cont.)

Pin Care

Using dry gauze dressings, wrap each pin site to ensure blood is absorbed and swelling is reduced. Once the site is dry, it is best left open. Pin tract care varies per doctor or nurse. It is important to keep the site clean through washings and respective maintenance. Pin tract infections are noticeable through pain, discharge of pus, or swelling. Please address immediately if these signs are noticeable.

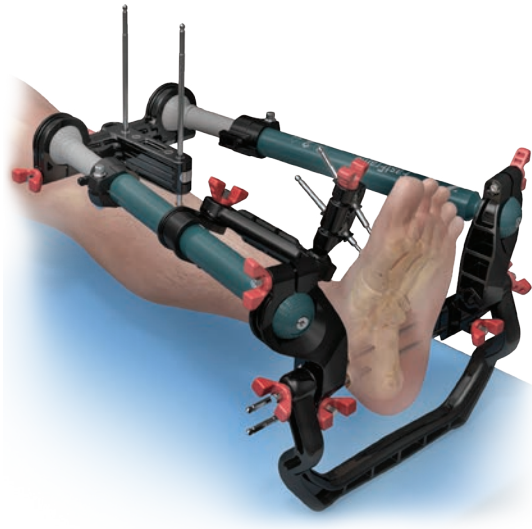


Figure 21a

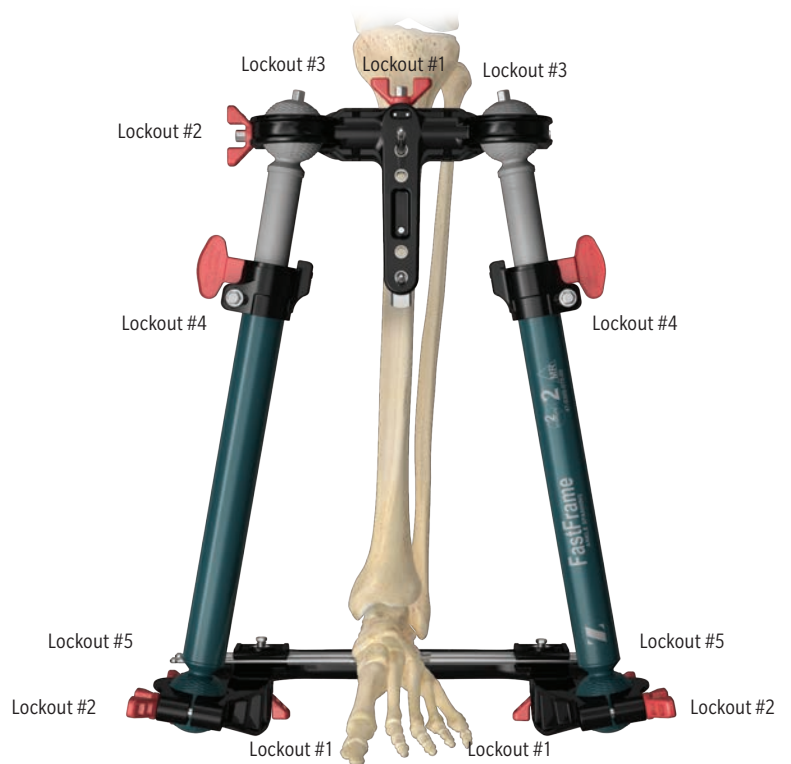


Figure 21b

Implant Removal

For the removal of the FastFrame External Fixation System – Ankle Spanning loosen all bolts identified by numbers 1-5 manually, or by using the driver (Figure 21a & 21b).

By untightening all of the bolts, the frame becomes dislodged from its final construct state. Its important to note that you should loosen the 2 clamp slider bolt last. This prevents the frame from sliding down towards the patient and allows for an easier removal of the system.

ⓘ **Note:** When loosening the number 3 bolt, ensure to loosen it fully as this unlocks the internal mechanism. The bolt may feel loose, prior to achieving release of the internal mechanism. Continue to turn until the internal mechanism is fully reversed. (Minimum 3 full rotations)

Pin removal depends on a case by case basis and will be left at the surgeon's discretion.

MRI Safety Information - MR Conditional

MR Conditional

Non-clinical testing has demonstrated that both the FastFrame External Fixation System – Ankle Spanning and FastFrame External Fixation System – Ankle Spanning when used with the FastFrame External Fixation System – Ankle Spanning Optional Clamp Assembly are MR Conditional. A patient with this device can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5 or 3-Tesla
- Spatial gradient magnetic field of 2,000-gauss/cm (2.0-T/m) or less
- Maximum whole body averaged specific absorption rate (WB SAR) of 2.0-W/kg
- Normal Operating Mode of operation for the MR system
- Under the scan conditions defined above, the FastFrame External Fixation System – Ankle Spanning is expected to produce a maximum temperature rise of less than 2°C after 15-minutes of continuous scanning with this device positioned completely outside of the scanner bore to ensure patient safety.
- Under the scan conditions defined above, the FastFrame External Fixation System – Ankle Spanning when used with the FastFrame External Fixation System – Optional Clamp Assembly is expected to produce a maximum temperature rise of less than 2°C after 15-minutes of continuous scanning with this device positioned completely outside of the scanner bore to ensure patient safety.

ⓘ Important: The FastFrame External Fixation System – Ankle Spanning and the FastFrame External Fixation System – Ankle Spanning when used with the FastFrame External Fixation System – Optional Clamp Assembly must be entirely outside of the bore of the MR system. (Refer to the figure below)

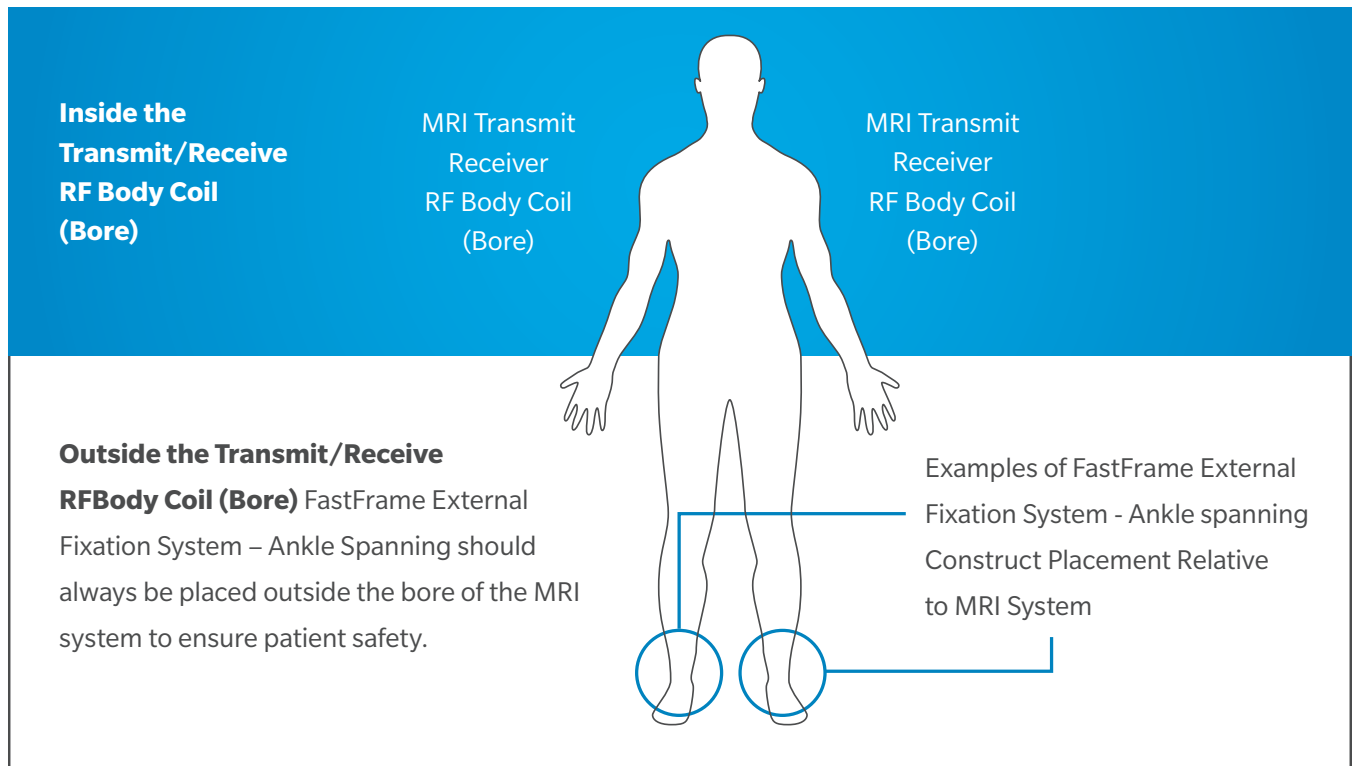
Warnings

- Using MRI in patients with the FastFrame External Fixation System – Ankle Spanning components and the FastFrame External Fixation System – Ankle Spanning Optional Clamp Assembly components can only be performed under these specific conditions. Importantly, it is not allowed to scan a patient with the FastFrame External Fixation System – Ankle Spanning components directly inside the Transmit/Receive RF Coil (Bore). Using other parameters may result in severe implant heating, and MRI could result in serious injury to the patient.
- Close patient monitoring and communication with the patient during the MRI examination is required. Immediately stop the MRI examination if the patient reports heating, pain, or any unusual sensation.
- Ensure that the patient's arms and legs do not touch each other or the scanner during the scan sequence.
- Ensure that the fixator frame (aside from the pins) does not touch the patient's body during scan sequence.
- Ensure that if a patient has a fixator on each leg that the two fixators do not touch each other and are separated by a non-conductive pas during the scan sequence.








Artifact Information

The largest image artifact extends approximately 35-mm from the device when scanned using a gradient echo (GRE) pulse sequence in a 3-Tesla MR system.

IMPORTANT: The FastFrame External Fixation System – Ankle Spanning and the FastFrame External Fixation System – Ankle Spanning when used with the FastFrame External Fixation System – Optional Clamp Assembly must be entirely outside of the bore of the MR system. (Refer to the figure below)






FastFrame External Fixation System - Ankle Spanning

Product	Description	Quantity per kit	Part Number
	FastFrame Ankle Frame	1	47-5300-070-00
	Fixation Half-pin	2	
	Transfixing Pin	2	
	T-Handle Driver	1	00-5300-050-01*
	Tissue Sleeve Assembly	2	
	Transfixing Pin Tissue Sleeve	2	
	Lockout Tab	2	

The Pins, Driver, Tissue Sleeve and Lockout Tab are included in the Ankle Spanning Kit, 47-5300-070-00

*A sterile version of the T-Handle driver is included in the Fast Frame Ankle Frame kit 47-5300-070-00, additionally a non-sterile version (00-5300-050-01) is available separately.

Optional Clamp Assembly available as a separate kit

	FastFrame Clamp Assembly	1	47-5300-070-01
	Tissue Sleeve	1	
	Pin	2	

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Check for country product clearances and reference product specific instructions for use.

Zimmer Biomet does not practice medicine. This technique was developed in conjunction with healthcare professionals. This document is intended for surgeons and is not intended for laypersons.

Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

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