

Hoffmann® LRF

Bone Transport



Operative technique

Hoffmann LRF

Bone Transport

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This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required. A workshop training is recommended prior to first surgery. All non-sterile devices must be cleaned and sterilized before use. Follow the instructions provided in our reprocessing guide (OT-RG-1). Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly / disassembly instructions. See package insert for a complete list of potential adverse effects, contraindications, warnings and precautions. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient.

Note:
This Operative Guide contains information specific to the Hoffmann LRF System for Bone Transport hardware. For a complete overview of the entire Hoffmann LRF System, it is recommended that the user also references the Hoffmann LRF Circular External Fixation Operative Guide (Content ID: H-ST-1).

Contraindications, Warnings and Precautions

Indications for Use

The Hoffmann LRF System is indicated in pediatric patients and adults for the treatment and fixation of:

- Open and closed fractures
- Post-traumatic joint contracture which has resulted in loss of range of motion
- Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
- Pseudoarthrosis or non-union of long bones
- Limb lengthening by epiphyseal, diaphyseal, or metaphyseal distraction
- Correction of segmental bony or soft tissue defects
- Correction of bony or soft tissue deformity
- Joint arthrodesis
- Management of comminuted intra-articular fractures of the distal radius
- Bone Transport

The Hoffmann LRF System is indicated in adults for:

- Osteotomy
- Revision procedure where other treatments or device have been unsuccessful
- Bone reconstruction procedures
- Fusions and replantations of the foot
- Charcot foot reconstruction
- Lisfranc dislocations

Contraindications

Since external fixation devices are often used in emergency situations to treat patients with acute injuries, there are no absolute contraindications for use. The surgeon's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment for each individual patient. Whenever possible, the device chosen should be of a type indicated for the fracture being treated and / or for the procedure being utilized. Conditions presenting an increased risk of failure include:

- Insufficient quantity or quality of bone which would inhibit appropriate fixation of the device
- Compromised vascularity that would inhibit adequate blood supply to the fracture or operative site
- Previous history of infections
- Any neuromuscular deficit which could interfere with the patient's ability to limit weight bearing
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period
- Malignancy in the fracture area
- Mental, physical or neurological conditions which may impair the patient's ability to cooperate with the post-operative regimen

The following factor is of extreme importance to the eventual success of the procedure:

Patient's activity:

If the patient's activity comprises of significant impact loads (walking, running, lifting or turning) the resulting forces could lead to failure of fixation, the system or both.

The system will not restore function to the level expected with normal healthy bone and the patient should not have unrealistic functional expectations.

Contraindications, Warnings and Precautions

Precautions

Information for patient

Surgeons must instruct the patients to report any unusual changes of the operated site to their physician. Surgeon should immediately evaluate the patient if a change at the fracture site has been detected. The surgeon should evaluate the possibility of subsequent clinical failure, and discuss with the patient the need for reduced activity levels, and / or possible revision surgery in order to aid fracture healing.

The surgeon should discuss all physical and psychological limitations inherent in the use of external fracture fixation appliances with the patient. Particular attention should be given to premature weight bearing, activity levels and the necessity for periodic medical follow-up.

The surgeon must warn patients of surgical risks, and make them aware of possible adverse effects. The patient should be warned that the device cannot and does not replicate a normal healthy bone. The device can break or become damaged as a result of strenuous activity.

Components of the following systems may be used with the Hoffmann LRF System: Monticelli-Spinelli External Fixation System, Apex Pins, Trauma Pelvic Set, Hoffmann II External Fixation System, Hoffmann 3 External Fixation System, Hoffmann II External Fixation System 90° Post, Hoffmann II Miami Post, Hoffmann II Carbon Connecting Rods, Hoffmann II MRI External Fixation System, and Hoffmann II Compact MRI External Fixation System.

Description of Bone Transport Frame:

External circular bone fixation system to provide bone transportation to aid in the correction of massive skeletal defects and severe open fractures or excision of tumors, through distracting until desired correction has taken place. This system is single use.

Description of Bone Lengthening Frame:

External circular bone fixation system to provide fixation of the fracture fragments until bone consolidation occurs and for the correction of deformities. This system is single use.

Warnings

Single use devices cannot be reused, as they are not designed to perform as intended after the first usage. Changes in mechanical, physical or chemical characteristics introduced under conditions of repeated use may compromise the integrity of the design and /or materials leading to diminished safety, performance and /or compliance with relevant specifications. Please refer to the device label to identify single or multiple use and /or re-sterilization release.

The Hoffmann LRF System is MR Unsafe. 

Transport struts are not intended for direct mount to a foot ring.

Safety clips are a single use item. Anytime a safety clip is removed from the strut it should be replaced with a new, unused, safety clip.

Safety clips are required to be used on any bone transport strut that is being placed on a patient.

Bone Transport

Protocol at a Glance

Primary Goals of Bone Transport Surgery

1. Restore osseous integrity (continuity)
2. Maintain mechanical axis
3. Restore length and normal rotation
4. Minimize Infection

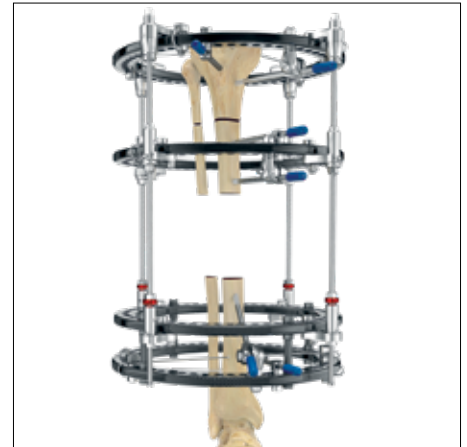
The transport frame is applied to the extremity after limb stabilization and wound debridement has occurred.

The frame is then secured to the extremity through the use of pin and wire fixation. Subsequently, a corticotomy is performed in order to detach a segment from the remaining, healthy bone. This separated piece of bone will become the transport segment. The corticotomy will trigger a reparative process, that combined with bone transport allows for regenerative bone formation through distraction osteogenesis.

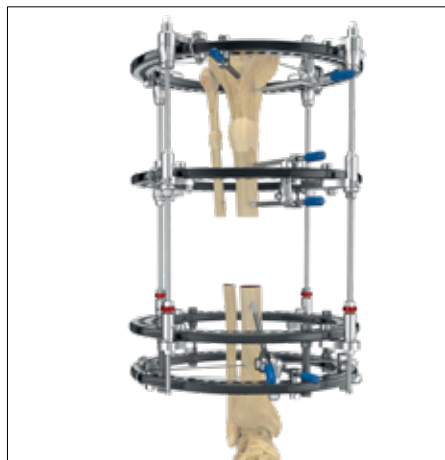
When the gradual distraction of the transport segment commences, the segmental defect can slowly close as new regenerate bone forms and follows the transport segment. "Docking" occurs when the transport segment reaches the distal bone segment. Once in contact, bone union between the transport and distal segment can occur while the new regenerate bone formed during the distraction phase matures and consolidates.



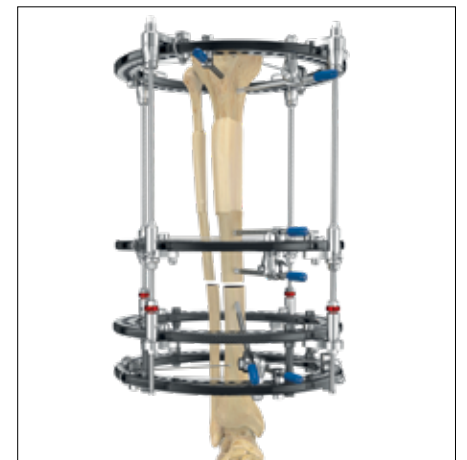
Segmental Defect



Segmental Resection



Bone Transport



Distraction & Regeneration Formation



Bone Docking



Healing

Key Components

Transport Strut Overview

Out of the box configuration

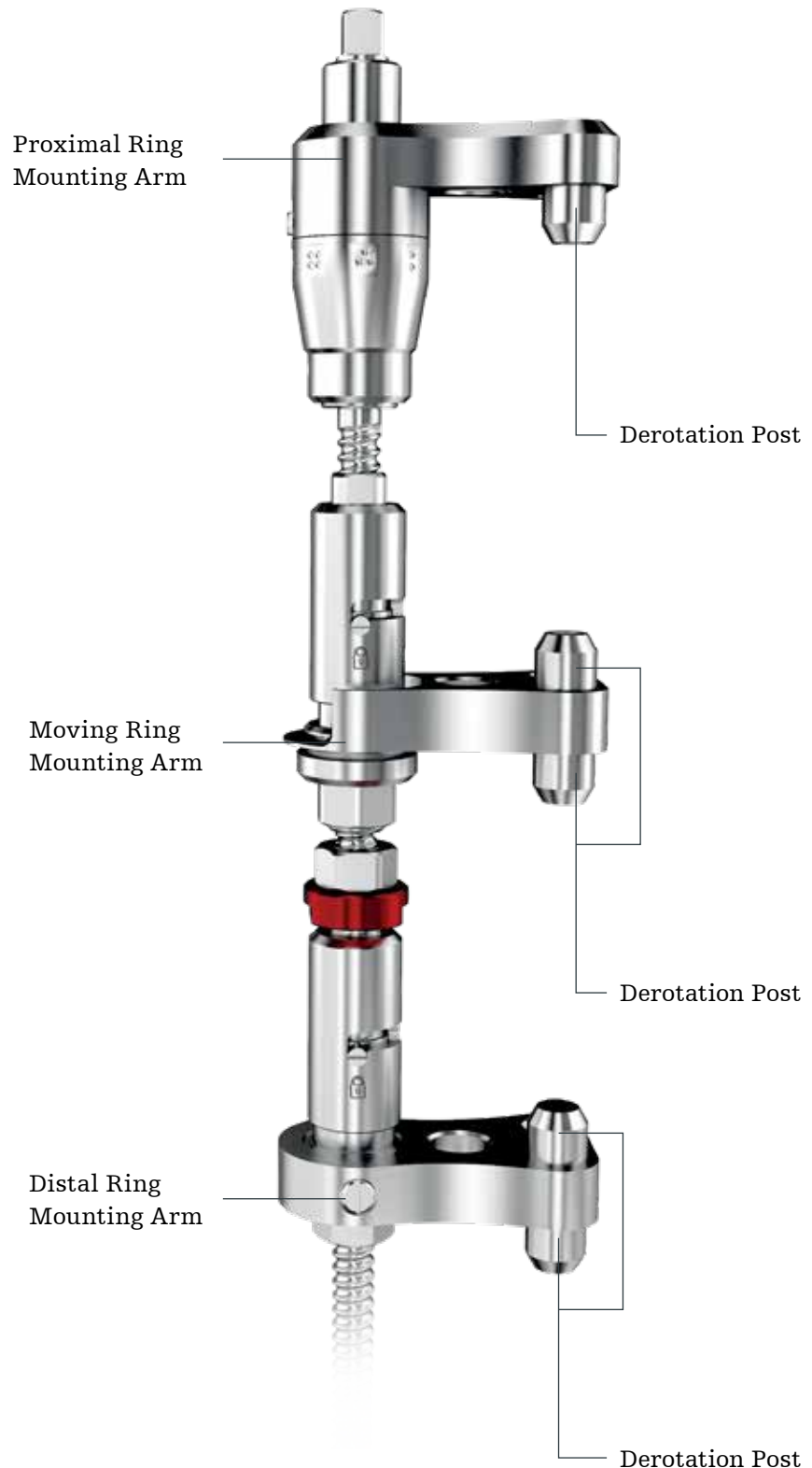
Hoffmann LRF Transport Struts are supplied in the collapsed, locked position. Mounting arms on each strut can be unlocked and repositioned to accommodate proper ring placement within the frame.

Derotation posts on the moving and distal ring mounting arms allow for ring attachment above or below the mounting arm depending upon the anatomy at the affected site.

Transport Struts are designed for bone transport procedures, but can be modified for bone lengthening procedures.

Note:
For ease of assembly and transport, it is recommended to assemble the struts to the rings while still in the collapsed, locked position.

Note:
Transport Struts are single use. Unused struts may be reprocessed, if needed, by following instructions found in the Cleaning and Sterilization guide (OT-RG-1), and the Preparing for Cleaning guide specific to this device (H-CSG-1).



Key Components

Transport Strut Overview

On the Frame Configuration

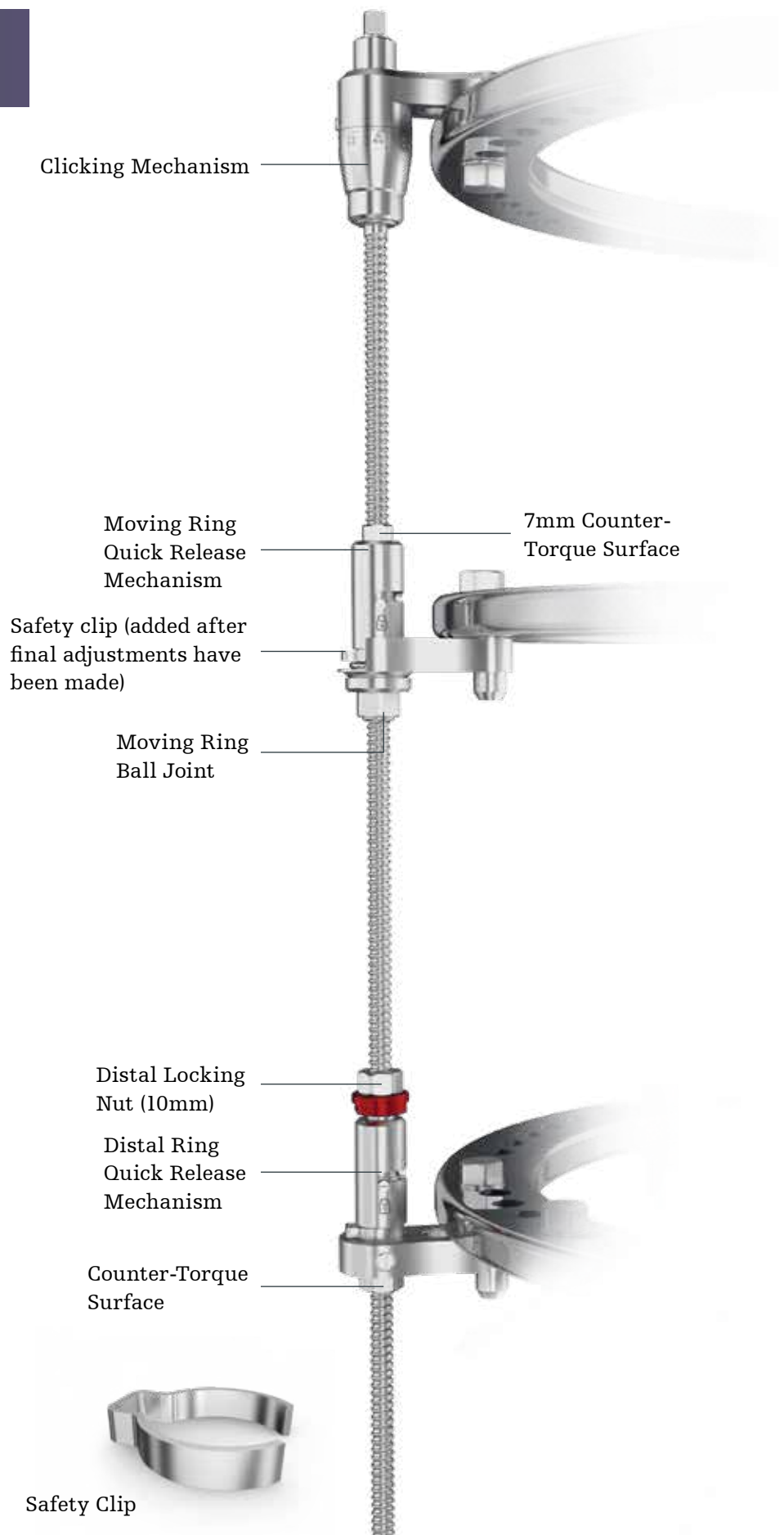
The moving ring is driven by adjustments made to the square driver at the top of the strut. Quick release mechanisms on the moving and distal ring mounting arms allow for rapid adjustment.

Following proper ring placement, the quick release mechanisms are definitively locked in place by attaching a safety clip below the quick release mechanism. Patient should be instructed to periodically check to ensure safety clips are still attached.

Warning:

Safety clips are a single use item. Anytime a safety clip is removed from the strut it should be replaced with a new, unused, safety clip.

Safety clips are required to be used on any bone transport strut that is being placed on a patient.

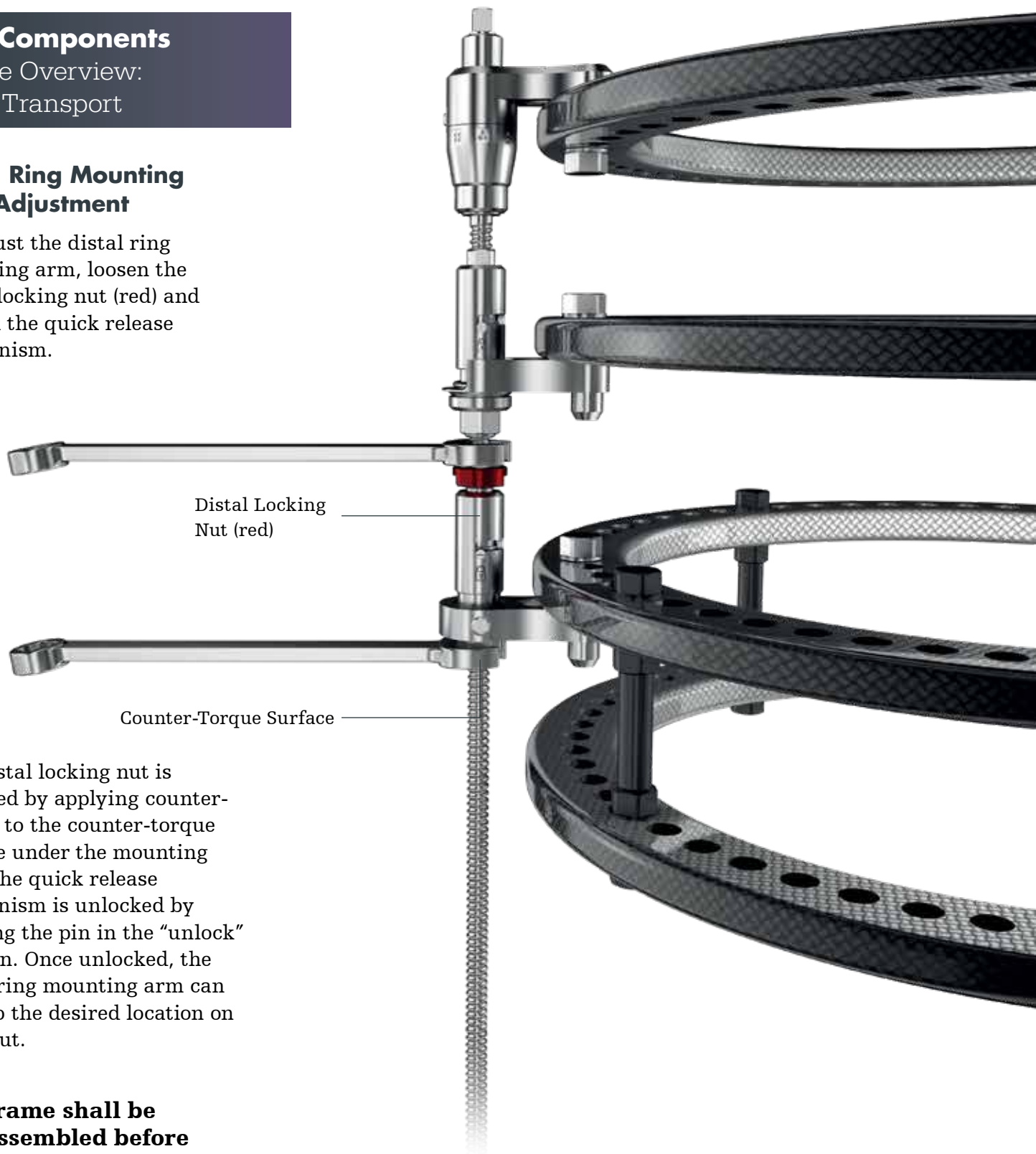


Key Components

Frame Overview:
Bone Transport

Distal Ring Mounting Arm Adjustment

To adjust the distal ring mounting arm, loosen the distal locking nut (red) and unlock the quick release mechanism.



The distal locking nut is loosened by applying counter-torque to the counter-torque surface under the mounting arm. The quick release mechanism is unlocked by aligning the pin in the “unlock” position. Once unlocked, the distal ring mounting arm can slide to the desired location on the strut.

Note:

The frame shall be pre-assembled before surgery with the proximal ring secured in place and the moving and distal rings provisionally locked in place to allow for adjustment during surgery.

Key Components

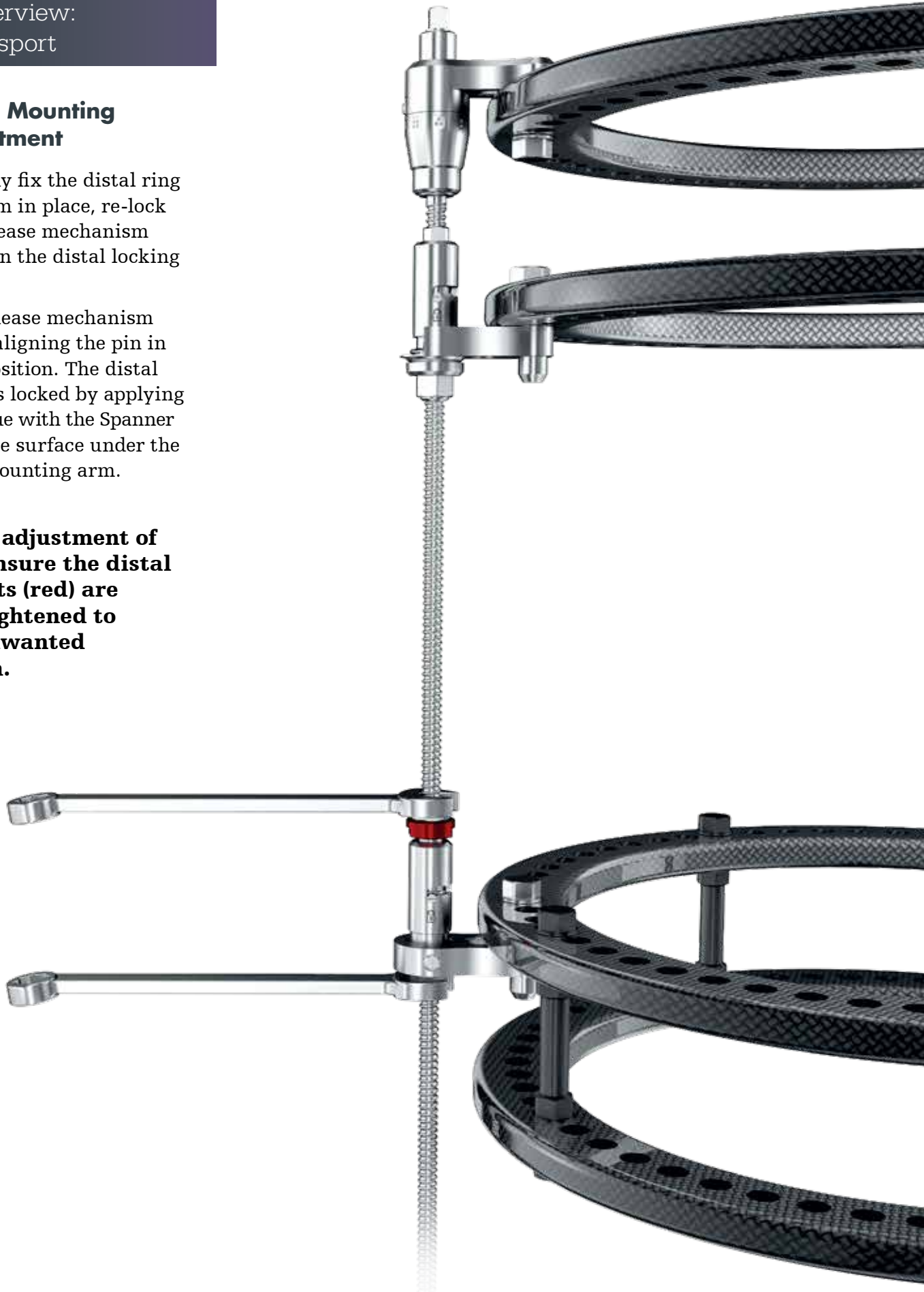
Frame Overview:
Bone Transport

Distal Ring Mounting Arm Adjustment

To definitively fix the distal ring mounting arm in place, re-lock the quick release mechanism and re-tighten the distal locking nut (red).

The quick release mechanism is locked by aligning the pin in the locked position. The distal locking nut is locked by applying counter-torque with the Spanner Wrench to the surface under the distal ring mounting arm.

Warning:
After final adjustment of the ring, ensure the distal locking nuts (red) are securely tightened to prevent unwanted distraction.



Key Components

Frame Overview:
Bone Transport

Moving Ring Mounting Arm Adjustment

To adjust the moving ring mounting arm, unlock the quick release mechanism by aligning the pin in the “unlock” position. Once unlocked, the Moving moving ring mounting arm can slide to the desired location on the strut.

Once proper placement is achieved, re-lock the quick release mechanism by realigning the pin in the locked position.



Key Components

Frame Overview:
Bone Transport

Moving Ring Mounting Arm Adjustment

If necessary, the moving ring ball joint can be unlocked to allow for $\pm 6^\circ$ of multiplanar angulation of the moving ring. The ball joint is unlocked via counter-clockwise revolutions. To unlock the ball joint, use the counter-torque surface (7mm). Once proper placement is achieved, re-tighten the ball joint on the frame.

Caution:

Over-tightening the 7mm counter-torque surface could strip the surface, preventing further unlocking of the ball joint and rapid adjustment of the moving ring. Wrench tightening of the ball joint should only occur when the struts are mounted to rings.

Warning:

Ensure moving ring ball joint nut is securely tightened after proper placement is achieved or after desired angulation is obtained.



Key Components

Frame Overview:
Bone Transport

Ring & Strut Orientation

Transport Struts are connected to rings using Ring Connection Bolts (4933-1-702).



To ensure proper strut spacing and alignment between rings, the suggested strut placement indicators must be utilized.

Note:
Placing struts at the diamond markers (◆) ensures that all four struts are parallel.

The Transport Strut's derotation post should be aligned in the hole denoted by the strut placement indicator.

Note:
For additional confirmation that rings are stacked properly, the labeling on each ring should be facing in the same direction.



Key Components

Frame Overview:
Bone Transport

Ring & Strut Orientation

The struts should be attached to the rings while still in the collapsed position. This will ensure that all struts are parallel along the length of the frame, resulting in ease of movement of the transport ring.

Note:

The maximum dynamic length for the LRF Bone Transport Frame is 375mm (ring-to-ring). The overall frame length can be increased by adding ring level extensions proximally and/or distally.

The minimum distance between the proximal and moving ring is 40mm.

This will allow for 120mm of transport. Transport Struts are offered in one size and are custom cut to length as indicated.



Key Components

Frame Overview:
Bone Transport

Mounting Considerations

When applying the frame, the struts can be oriented in 2 ways: Direct anterior-posterior or with a 45° rotary offset.

Positioning the frame with a strut directly anterior will allow the surgeon to align the frame in the same plane as the bone. This typically requires radiographic visualization. The strut can be visually aligned with the center of both ends of the defect. The struts however may interfere with AP and ML radiographs.

Rotating the frame 45° will position the struts in an orientation that does not obstruct radiographic views. With this approach, however, the user cannot use a strut to assess the frame's alignment and transport trajectory with the bone.



Anterior Alignment



Offset Alignment

Bone Transport Frame Pre-Build Procedure

Ring Spacing: Distal Ring

After frame assembly, rings are spaced to the appropriate locations on the strut as dictated by the anatomy at the affected site.

Step 1

Unlock the distal locking nuts (red) on the four distal mounting arms. Apply a torque wrench to the 10mm counter-torque surface below the mounting arm and loosen the distal locking nut (red) with a second wrench.

Note:

Do not over-loosen the distal locking nut. Loosen just enough to free the mounting arm. Avoid repetitive locking and unlocking of the distal locking nuts.

Step 2

Unlock each of the four quick release mechanisms by aligning the quick release pin in the unlocked position. Once all distal locking nuts and quick release mechanisms are unlocked, the distal ring can be moved freely to the appropriate location.

Step 3

Once proper spacing of the distal ring is achieved, the orientation is definitively locked in place by re-aligning the quick release pin in the locked position and re-locking the distal locking nuts (red).

Note:

If the intended frame height is unknown, the distal locking nut shall remain unlocked, until the frame is adjusted to the proper length on the patient.

Warning:

Failure to lock the distal locking nuts (red) may result in unwanted distraction of the distal ring.



Step 1



Step 2



Step 3

Bone Transport Frame Pre-Build Procedure

Ring Spacing: Distal Ring

Step 4

Once the distal ring is definitively locked into position, excess rod length can be cut off using a rod cutter.

Note:

If patient limb length is unknown at the time of pre-build, this step can happen at the end of the procedure.

Warning:

Special attention should be paid during rod cutting so that debris or small components do not land in the surgical site.

Step 5

Cut threaded rods can be capped with End Caps to cover sharp edges.



Step 4



Step 5

Bone Transport Frame Pre-Build Procedure

Ring Spacing: Distal Ring

Step 6

After positioning the distal ring, the moving ring can be positioned in the proper location for attachment to the planned transport bone segment.

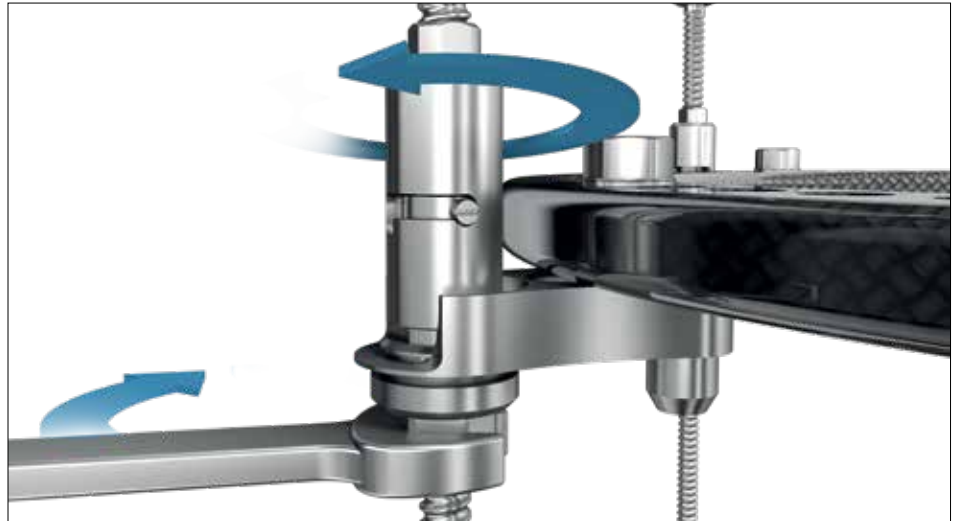
Unlock each of the four quick release mechanisms on the moving ring mounting arms by aligning the quick release locking pin in the unlocked position.

Once unlocked, the moving ring can be grossly adjusted into position.

Step 6b – Optional

If needed, the range of motion permitted by the moving ring mounting arms' ball joints allow the moving ring to be applied in a non-orthogonal fashion.

To unlock the ball joints, use the 10mm end of the spanner wrench to loosen the ball joint release nut. Repeat on all four struts.



Step 6



Step 6b

Bone Transport Frame Pre-Build Procedure

Ring Spacing: Distal Ring Step 7

Once proper positioning of the moving ring is achieved, be sure all four ball joints are completely tightened and quick release mechanisms are in the locked position to prevent unwanted deviation of the moving ring.

Warning:
Moving ring ball joints should only be used to affect initial ring placement. Utilizing the ball joints to acutely reposition the moving fragment prior to docking may disrupt the growth of the regenerate bone.

Final Preparation

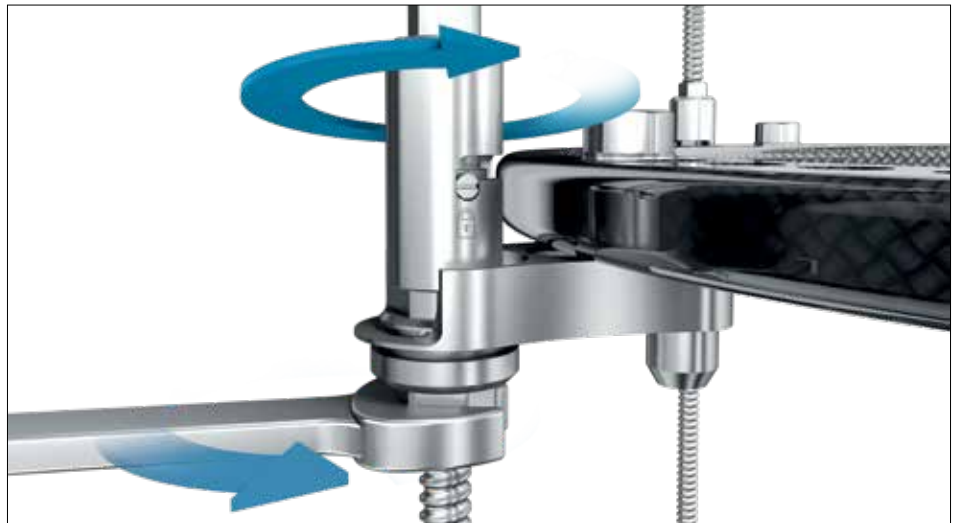
Step 8

Prior to applying the frame, verify the rings are uniformly spaced and parallel with the ruler. It is recommended that the frame span the entire limb. Attaching a second ring level will help accommodate fixation in the distal limb.

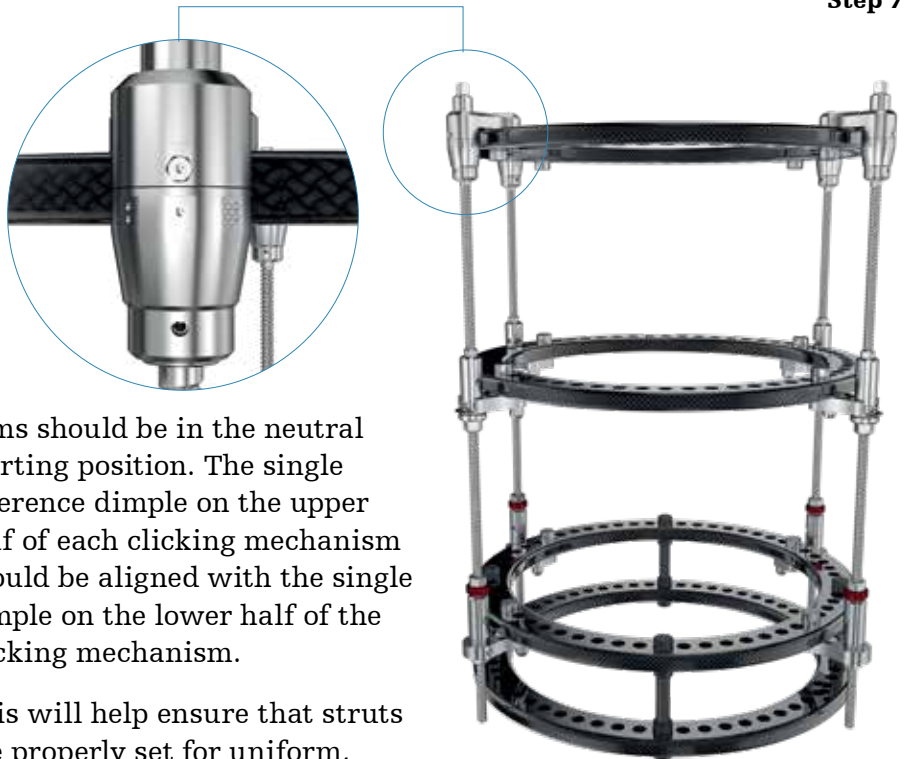
Additionally, this construct approach may provide better rigidity as the transport struts and dynamic portion of the frame can be shorter in length.

Step 9

All four clicking mechanisms on the proximal mounting



Step 7



arms should be in the neutral starting position. The single reference dimple on the upper half of each clicking mechanism should be aligned with the single dimple on the lower half of the clicking mechanism.

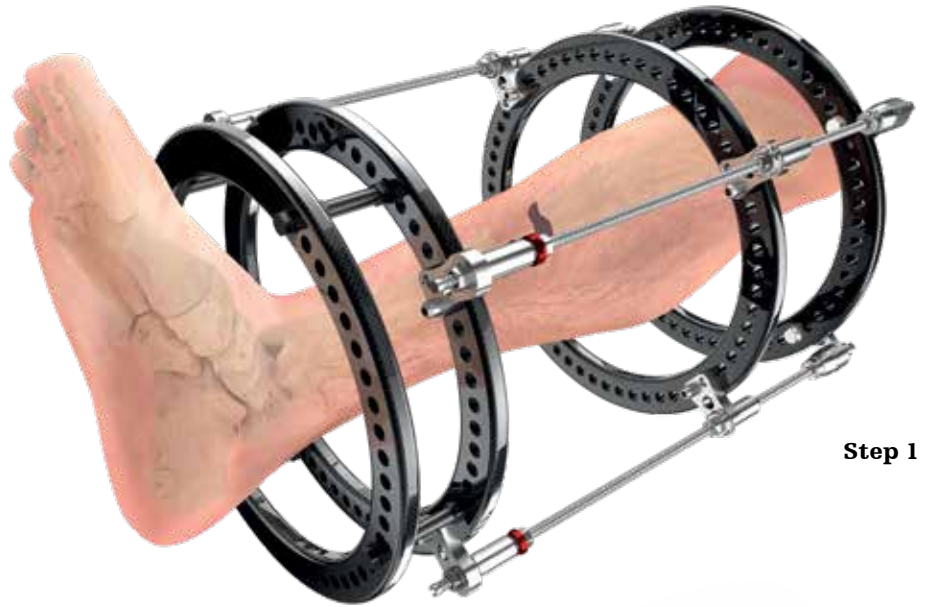
This will help ensure that struts are properly set for uniform, sequential adjustments when the patient begins actuating the frame.

Unlock the quick release on the moving ring mounting arm before setting the clicking mechanism to the neutral starting position to prevent unwanted ring motion.

Operative Guide: Tibial Defect

Step 1

The patient should be in a supine position with flexion in the hip and the knee of approximately 20°. The pre-assembled frame is slid over the affected limb.



Step 1

Step 2

If needed, perform additional adjustments to finalize ring spacing.

Step 3

Ensure all distal locking nuts, ball joint release nuts, and quick release mechanisms are locked and securely tightened.

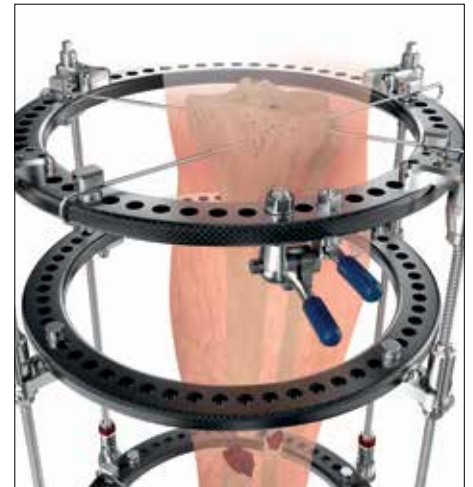
Step 4

At least four points of fixation to the proximal ring are necessary to properly secure the proximal tibia to the frame and to prevent frame shifting when inserting distal ring fixation.

Fixation points may be a combination of wires and/or pins. It is important to note that pin and wire placement will vary by indication and surgeon preference.



Step 3



Step 4

Warning:

In certain incidences, supplemental fixation should be considered (i.e. obese patients or patients that are ambulatory in the early postoperative phase).

Operative Guide: Tibial Defect

Step 5

At least four points of fixation to the distal ring are necessary to properly secure the distal tibia to the frame.

Care must be taken when mounting the distal segment. Using imaging, confirm that the segments are aligned in both the ML and AP views. This will help ensure proper docking as the transport segment moves along the path of travel.

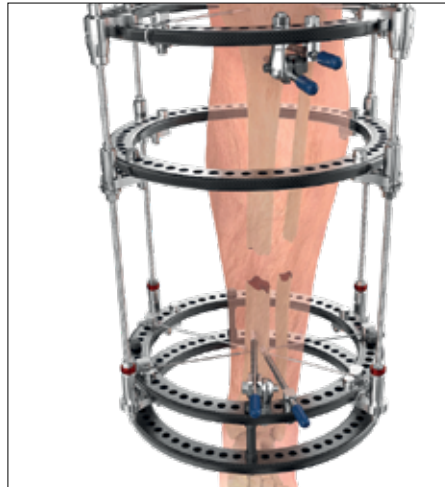
Caution:
Ensure that the distal and proximal bone segments are axially aligned during frame application.

Step 6

The moving ring shall be placed within the distal third of the proximal segment. At least three points of fixation are necessary to properly secure the segment to the frame.

Caution:
Wires should be curled or cut. Cut pins should be capped to prevent skin injury.

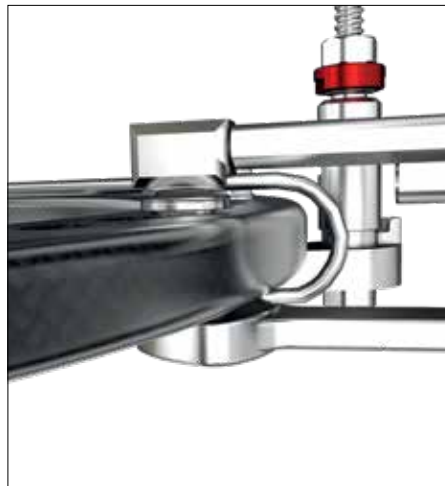
Warning:
All fixation components are to be secured to rings using M8 nuts.



Step 5



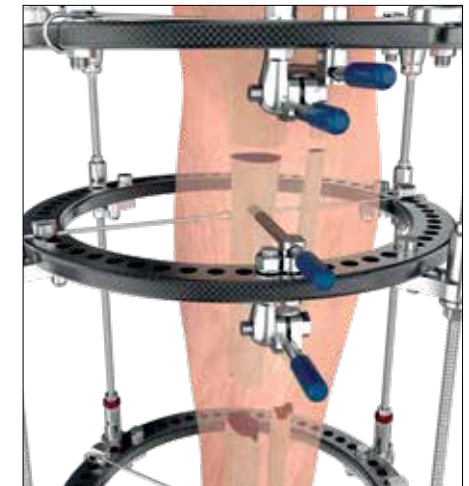
Step 6



Step 7

Step 7

Confirm that all fixation components are securely tightened to the frame. Be sure to use counter-torque.



Step 8

Step 8

A corticotomy is performed to create an intermediate fragment (transport segment) from the remaining, healthy bone. The injury created by the corticotomy will initiate a reparative process in which the regenerate bone will begin to form. Utilize fluoroscopy to ensure that the corticotomy is complete.

Operative Guide: Tibial Defect

Step 9

Perform a final check of all quick release mechanisms and confirm that all are in the locked position. Confirm that all other components are securely tightened.

Make sure that all distal locking nuts (red) are securely tightened before transport is initiated.

Step 10

To prevent inadvertent unlocking, ensure that safety clips have been applied to all struts, directly underneath the quick release mechanisms.

Warning:
Safety clips must be used. Handle with caution so that bending of the safety clips does not occur.

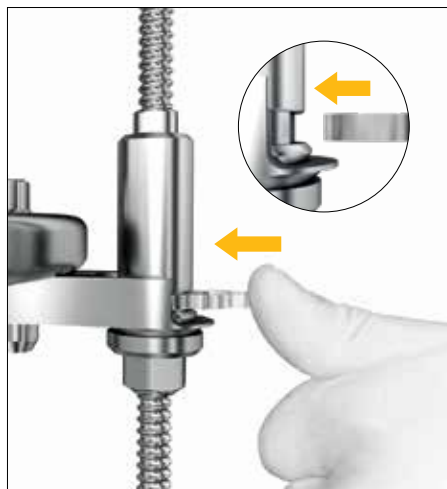
Warning:
Safety clips are a single use item. Anytime a safety clip is removed from the strut it should be replaced with a new, unused, safety clip. See page 22 for removal of safety clip.

Step 11

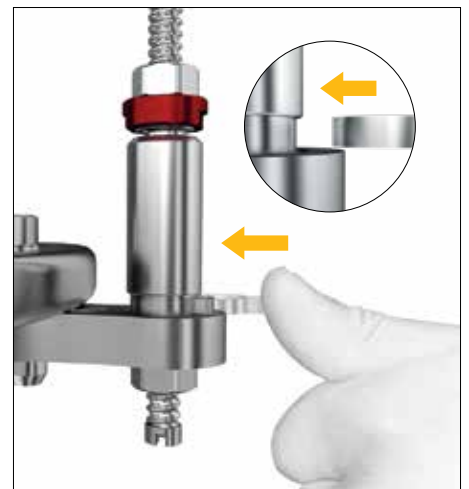
The Lengthening Ruler can be mounted to the frame to monitor the amount of moving ring travel throughout the course of treatment. Using a medium hinge connection bolt and M6 nut, attach a slotted plate to the ring. Using (2) more M6 nuts, attach the lengthening ruler to the slotted plate.



Step 9



Step 10



Step 11

Note:
The lengthening ruler is made from aluminum and should be tightened to the frame using a thumbwheel only. Applying excessive torque while tightening may damage the ruler.

Operative Guide: Removal of Safety clip

Step 1

Removal of the safety clip is done using the pronged end of the telescopic strut wrench.

Step 2

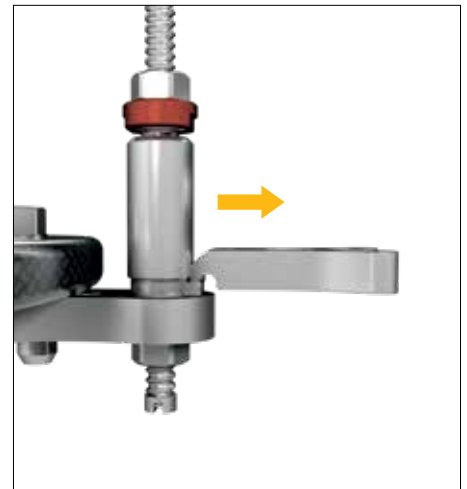
Seat the end of the wrench prongs into the square hook of the safety clip.



Step 3

Use a slow controlled pull to remove the safety clip from the strut.

Warning:
Safety Clips are a single use item. Anytime a safety clip is removed from the strut it should be replaced with a new, unused safety clip.



Warning:
Safety clips must be used. Handle with caution so that bending of the safety clips does not occur.

Step 4

Always replace with a new, unused safety clip back onto the bone transport strut directly below the quick release mechanism.



Operative Guide: Tibial Defect

Post-Transport Lengthening

In certain indications, additional lengthening may be required after transport to fully restore normal limb length. This can be accomplished with a simple modification to the frame. When converting from a bone transport to a bone lengthening frame, attach the moving ring to the distal ring using threaded rods or static struts. This will allow both the moving ring and distal ring to move together in tandem.

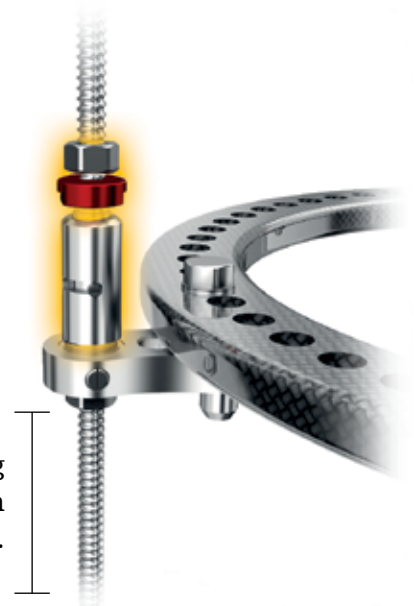
To allow both the moving ring and distal ring as a pair, unlock the distal mounting arms by removing the safety clips and unlocking each quick release.

Note:
Maximum total bone transport and bone lengthening distance should not exceed 120mm.

To ensure that compression is maintained at the docking site, keep all points of fixation in place.

Note:
Prior to lengthening adjustments, verify that there is a sufficient amount of travel (exposed rod) left on the strut to achieve desired length.

Note:
Keep the distal locking nuts and distal quick releases open for the duration of lengthening to allow the moving ring and distal ring to move in tandem.



Ensure desired lengthening distance protrudes through the distal mounting arm.

Distraction & Transport Patient Adjustment

During the distraction phase, the patient can utilize the adjustment driver to actuate the moving segment. The counting wheel on the adjustment driver can be used to keep track of sequential rounds of adjustment.

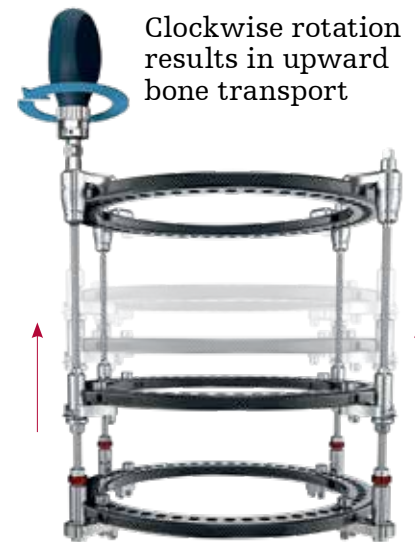
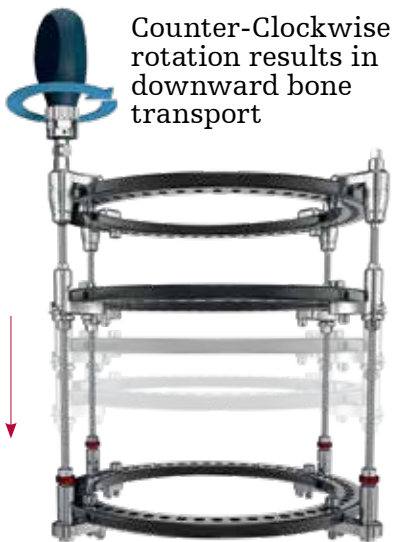
Each "click" of the strut signifies 1 / 4mm of compression or distraction. One complete revolution of the strut (8 clicks) is equal to 2mm of compression /distraction travel.

Caution:

It is recommended that the rate of lengthening not exceed 1mm a day. Faster distraction rates may lead to complications including soft tissue/neurovascular damage and non-union. Slower rates of correction may also lead to complications, such as premature consolidation. Correction rates should be set at the surgeon's discretion.

The patient or caregiver can adjust the frame by engaging the strut's clicking mechanism at the top of the strut. Every quarter millimeter is denoted by a visual, audial, and tactile "click."

To drive the moving ring position from proximal to distal, the patient must administer counter-clockwise adjustments. To drive the moving ring position from distal to proximal, clockwise adjustments must be made.



Caution:

Patients must be careful not to unintentionally rotate the clicking mechanism while seating the adjustment driver.

Note:

The counting wheel on the adjustment driver is intended to help track how many adjustment sessions have taken place throughout the day.

For example - after

making a round of strut adjustments in the morning, the patient can advance the counting wheel on the driver to log their morning adjustment session.

"Clicks" on the adjustment driver are not representative of 1 / 4mm clicks from the strut.

Distraction & Transport

Clicking Mechanism

Dimples located around the strut's clicking mechanism can be used to help track the patient's adjustment progress. Ensure that all four clicking mechanisms start in the neutral position with the single reference marker (proximal) aligned with the single dimple. This will allow patients to perform uniform adjustments.

These dimples will also allow patients to keep a consistent record of their corrections. All four struts should have the same number of dimples matched with the single reference marker. This visual adjustment confirmation may also increase compliance. If one or more struts are inconsistent, the patient and/or caregiver has the ability to compensate with future adjustments.

Note:

All four clicking mechanisms must start in the neutral position with the single reference marker aligned with the single dimple.



Lengthening Frame Considerations

Pre-Build Procedure

The Hoffmann LRF Transport Strut can be modified pre-operatively to perform lengthening procedures.

The struts are capable of up to 120mm of lengthening.

Step 1:

Using a rod cutter, cut and remove the stopper on the threaded end of all four struts.

Caution:

Be careful not to cut struts too short. Pre-operatively plan how long the strut should be and how much length is needed as per the indication. Ensure that each strut has a sufficient amount of rod length left to achieve the desired amount of lengthening.

Warning:

Rod cutting must be performed before the time of surgery to prevent debris or small components landing in the surgical site.

Step 2:

Unlock the distal locking nuts and quick release mechanisms on each of the struts and slide off these unnecessary assemblies.



Step 1



Step 2

Note:

When removing the distal ring mounting arm, ball bearings from the quick release mechanism may become loose and fall out.

Lengthening Frame Considerations

Pre-Build Procedure

Step 3:

Affix a Bone Transport Strut End Cap to each rod.

Note:

Gentle force may be required to seat the end cap on the strut.

Step 4:

Once the distal mounting arms are removed, the moving ring can be unlocked and repositioned to the appropriate distance. The rings should remain parallel.

Step 5

Attach a distal ring to the moving ring using static components. By elongating the frame along the length of the limb, soft tissue stresses will be reduced. Fixation should only be attached to the proximal and most distal ring.

Note:

In pure lengthening cases, the moving ring should act as a “dummy” ring, in that it does not have any fixation on it.

The “dummy” ring is in place to minimize the length of the dynamic portion of the frame (ie. Transport Struts), making it more rigid.



With respect to minimizing soft tissue stress, a longer overall frame and wide spread of the fixation is achieved with the addition of the distal ring level.

Bi-focal Bone Transport Frame Example

The bi-focal frame allows for two moving rings.

Six struts will connect the proximal and distal rings. Three of the struts will connect to one moving ring, and three will connect to the other. Adjacent struts should not be connected to the same moving ring and instead should alternate as shown.

At least four points of fixation are necessary for the proximal and distal rings, and at least three points are necessary for each of the moving rings. Fixation points may be a combination of wires and/or pins. Fixation can be placed in a divergent fashion for increased stability.



Strut - Ring Connectivity



Notes

Notes

Notes

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