FusionFrame™
Ring Lock System

INSTRUCTIONS FOR USE
FUSIONFRAME RING LOCK SYSTEM

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Legal Manufacturer:

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1.1 Description

The FusionFrame Ring Lock System is a circular external fixator that provides a weight bearing scaffold that, in most cases, allows patients to remain mobile throughout the course of treatment. The device is assembled from a selection of discrete components to provide a variety of possible constructs to ensure stability, realignment of bones, application of compressive forces or distraction of bone fragments over a period of time. The FusionFrame consists of externally mounted Rings and ancillary components that are interconnected with Rods. The construct is attached to the bone with a combination of percutaneously applied tensioned Wires. Compression/distraction struts may be attached to the frame to systematically control the gaps between bone fragments and distances between Rings to manage a variety of pathologies. Threaded Rods or struts may be used to reduce and compress fracture zones and lengthen limbs. Rings, rods and other frame elements are available in a range of sizes.

1.2 Indications for use

The FusionFrame Ring Lock System is used to manage a variety of indications and treatments:

- Stabilization of Fractures and Osteotomies.
- Bone deformity correction of lower extremities.
- Arthrodesis of the rear foot, mid foot and ankle joint.
- Limb Lengthening in pediatric patients and adults.

1.3 Contraindications

Surgical procedures other than those listed in the indications section.

Known or suspected allergy to any materials from which the FusionFrame components are made (especially Wires and Pins).

Use of FusionFrame components with components of other origin, not specifically recommended for use with the FusionFrame.

Reconstruction of neck and head, spine or back. Articulation joint: Shoulder, elbow, hip, knee. Presence of active infection.

Any existing or suspected condition that may prevent or inhibit the patient's ability or willingness to follow post-operative protocols during the entire treatment and healing process.

1.4 Components

Full Rings, Half-Rings & 5/8 Rings:

The FusionFrame includes four diameters of Ring sizes: 140, 160, 180, and 205mm. All Rings and Half Rings are 8mm thick. Rings provide the scaffolding and structural support for the overall frame and are the primary platform from which all other components are connected. Two Half Rings, bolted together form a full circular Ring. The size is specified by the inside diameter of the Ring. All FusionFrame Rings are made of aluminum. Prior to application, the surgeon must determine the Ring diameters as a function of patient size and anatomical features. Ring size needs to be

matched to the patient's own measurements and limb dimensions. The inner diameter of the Ring must provide a minimum of 20 - 30mm (or "two finger breadths") of soft tissue clearance along the entire inner circumference of the Ring. Smaller Ring sizes make it more difficult to accurately place Wires and may not allow enough room for possible soft tissue swelling. Larger Rings, without structural augmentation, are more prone to instabilities and possible deformation. Training and experience offer the best guide for proper selection of Ring sizes.

Foot Plates:

The FusionFrame also includes four sizes of Foot Plates: 140, 160, 180, and 205mm; each of which are compatible with their corresponding Ring sizes. Foot Plates are an essential component of the fixator when used for foot and ankle surgery. The Foot Plates are wider than the analogous Full and Half Rings of the same internal diameter. The Foot Plate's outer set of holes are used for interconnecting the footplate with Threaded Rods or struts to the proximal ring levels and must be arranged to coincide with the corresponding holes of the Rings/Half Rings proximal to the Foot Plate. This is necessary to achieve perfect alignment. All unused inner Foot Plate holes and unobstructed outer holes may be used for Wire placement.

Threaded Rods:

The FusionFrame includes 6mm diameter fully threaded stainless-steel Rods with a 1mm thread pitch, in lengths from 60 to 400 mm. In the majority of cases, particularly for Charcot related constructs, the Threaded Rods are adjusted so that all rings are parallel to each other. Moreover, the frame is aligned with the mechanical axis of the limb. For foot and ankle applications, the anterior crest of the tibia is often used as a visual alignment reference.

Oblique Supports:

Oblique Supports may be used to connect a Half Ring mounted across the Foot Plate to the most distal ring on the tibial block, thereby allowing a more symmetrical distribution of loads between the distal tibia and foot. In Charcot frames, Oblique Supports are used to provide additional stability for the forefoot arch which is a Half Ring that is of the same diameter as the Foot Plate and all other Rings in the construct.

Quick Connect struts:

The Quick Connect Struts, available in 3 size ranges 100-115mm, 116-152mm, 150-210mm, provide a systematic means for achieving controlled distraction (or compression) for the purposes of limb lengthening or fracture fixation. The Struts likewise permit gradual and rapid length adjustments and feature universal joints on both ends to perform acute deformity corrections and assist with fracture reductions. A built-in counting knob facilitates the patient's ability to make accurate, 1/4 turns, achieving precisely measured 1/4mm adjustments in the gradual compression or distraction modes.

Threaded Sockets:

The 10mm hexagonal cross section sockets are used as fixed spacers to allow rapid connections between two levels of Rings in a frame construct. They are available in 40 and 60mm lengths. Threaded Sockets are made of Stainless Steel.

Plates:

Plates are used as horizontal spacers, swivels and outriggers to increase the overall adaptability of the FusionFrame™ to address a broader range of patient anatomies and construct possibilities. They are available in two sizes: 20mm (two hole) and 30mm (one hole, one slot). Plates are made of Stainless Steel.

Pin Fixation Cube:

The Half-Pin Fixation Cubes provide a fast means for the fixation of Half-Pins above or below the plane of a given Ring. The trajectories of the pins are constrained to be parallel with the plane of the Ring when placed directly through one of the pin holes of the cube. They are available in 1 – 4 hole/s towers. They are made of Stainless steel.

Pin Fixation Bolt:

Pin fixation bolts are used for the fixation of Half-Pins directly to the surface of a Ring or to one of the holes of a Male or Female Post or one of the smooth (unthreaded) holes of a Pin Fixation Cube. The Half-Pin Fixation Bolts accept all diameters and lengths of Fusion Frame Half-Pins. The oblong bolt head includes 10mm wrench flats.

Universal Hinge:

A Universal Hinge provides an unconstrained cardan joint that may be added to any threaded element, especially threaded rods and struts, to facilitate acute deformity corrections and fracture reductions. They come in one size and are made of Stainless Steel.

90° Hinge:

The 90° Hinges are used to change the plane of the ring by 90° for the purposes of adding a "motor" to a gradual deformity correction construct. 90° Hinges are made of Stainless Steel.

Hexagonal Nuts:

Six-sided Nuts are used for the interconnection and locking of components to ensure stability. Nuts may also be used to make gradual, incremental adjustments to the frame, such as in compression, distraction, limb lengthening, deformity correction or tissue transport.

Counting Nuts:

The four-sided Counting Nuts facilitate controlled compression or distraction and are used to simplify lengthening, shortening, transport and fusion procedures. Each quarter turn of the nut represents 0.25mm of travel along a Threaded Rod and the dot-coded faces enable the patient to keep track of each quarter turn. The Counting Nuts have a 10mm spanner wrench width and are 15mm long.

Bolts:

10mm hexagonal head, 6mm diameter threaded component with 1.0mm pitch. Available in 12, 16 and 20mm lengths.

Universal Wire Fixation Bolts:

Cannulated wire Bolts with a side groove permit the fixation of Wires that are either offset with respect to Ring holes or Wires that are centrally oriented with respect to the Ring holes.

Conical Washer Couple:

The Conical Washer Couples are assemblies consisting of two elements, a "cup" and "saucer," that are packaged together and are used in situations when a non-parallel Ring needs to be mounted to the frame construct. The Conical Washer Couples are used in pairs, one complete assembly is placed on both sides of the ring (situated proximally and distally) for each Threaded Rod in that segment of the construct where non-parallel positioning is required.

Washers:

Used as spacers in combination with Wire Fixation Bolts for securement of Wires that are situated above or below the plane of the Ring. The Slotted Washers may also be used in combination with the 12, 16 and 20mm Bolts in lieu of the Wire Fixation boles to capture offset wires.

Smooth Wires and Wires with Stopper:

The FusionFrame includes both Smooth Wires and Wires with Stoppers (also known as "olive" wires). Both types are available in 1.8mm diameter. Smooth Wires and Wires with Stoppers are 430mm long. The stopper is machined from single bar stock and is not a discrete element that is welded to a smooth wire.

Half pins:

Half-Pins are available in a variety of thread lengths in 5.0 and 6.0mm thread diameters, with a constant, 6mm shaft diameter for all thread sizes. All Fusion Frame Pins feature self-drilling, self-tapping cutting flutes. They are made of implant quality 316L Stainless Steel.

Male and Female Hinges and Posts:

The multi-hole Posts are made of stainless steel and come in either male or female configurations, with 1, 2, 3, or 4 holes. The one-hole Posts are typically referred to as Hinges. One-hole Posts may be used in pairs to form a hinge element for use in gradual deformity correction procedures, or to facilitate reduction. Each of these components features a wrench flat at its base to simplify proper Nut and Bolt tightening.

T-wrench:

The FusionFrame T-Wrench is used for the insertion and removal of Half-Pins and accommodates all sizes of FusionFrame Pins. The Instrument assembly includes a set of adapters for use with power tools.

Wrenches:

Wrenches are used to tighten 10mm conventional Bolts and hexagonal Nuts, as well as grasping the wrench flats on Male and Female Posts. The 10mm span is likewise compatible with Wire Fixation Bolts and Counting Nuts.

Wire Tensioner:

The Wire Tensioner is an indispensable instrument of the FusionFrame. Each tray should contain two Tensioners because some procedures call for simultaneous tensioning on both ends of a wire. In any case, an additional Wire Tensioner should always be available to serve as a backup.

The Tensioner features a ratcheted plier-handle mechanism that delivers one-pump tensioning. The instrument holds onto the head of the Wire Fixation Bolt with its adapter jaws. The jaws allow precise access around all possible frame contours. The user should be aware that the force scale readings may be subject to error. In essence, the reading measures the elongation of an internal spring or the elongation of the Wire. Consequently, the surgeon should use these readings as a relative guide and should not treat them as absolute values

1.5 Material

The Rings, Half-Rings, 5/8 Rings and Foot Plates are made of aluminum and are anodized black with laser markings for proper placement of the components. All Rods, Posts, Nuts, Bolts, Washers, plates, pin fixation bolt, pin fixation cubes, hinges and Wires are made of stainless steel in accordance with ASTM F-138 and ASTM F-899, ASTM B209 and ASTM A564.

1.6 Warnings

A successful result is not achieved in every surgical case. No implant can withstand body loads without supporting bone. In this event, bending, fretting, loosening, disassembly and/or breakage of the device will eventually occur. Reoperation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur. These complications may include but are not limited to:

- Device corrosion with localized tissue reaction and pain.
- Device migration, which may result in injury to soft tissue, visceral organs or joints.
- Loosening or disassembly of implant resulting in additional injury.
- Bending, loosening or breaking of the implant, making removal difficult, impractical or impossible.
- Abnormal sensations, discomfort or pain.
- Increased risk of infection.
- Bone loss due to stress shielding.
- The physical contact of FusionFrame implants with other implants made of a dissimilar metal.
- The FusionFrame is not cleared for Wire attachments or fixation to the pedicular elements of the cervical, thoracic or lumbar spine.
- Patients who smoke or use nicotine based products may experience delayed healing or non-unions, including compromised stability at the Wire interface sites with bone.
- Care should be taken to avoid the growth plates during Wire insertion in skeletally immature patients.

1.7 Precautions

All FusionFrame components and instruments may be required for each surgery. Failure to use dedicated, unique FusionFrame instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require reoperation and removal. Carefully inspect the FusionFrame components prior to use. Instruments or components that are faulty, damaged or suspect should not be used. They should be replaced or sent to GLW for disposition.

Wires are anchored to the frame Rings by means of Wire Fixation Bolts and must be fixed, without bending the Wires (up and down or side to side), exactly where they rest after insertion. Unwarranted Wire bending may result in soft tissue compromise, possible swelling, pain and/or infection.

Do Not Attempt a Surgical Procedure with Faulty, Damaged or Suspect FusionFrame Instruments or Implants. Inspect all components Preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.

1.8 Possible Adverse Effects

Occurrence of any adverse event may require reoperation and removal of the implant. Adverse effects may include but are not limited to:

- Disassembly, fretting, loosening, bending, breakage and/or migration of any component portion.
- Foreign body reaction to the implants.
- Pressure on the skin from component parts where there is inadequate tissue coverage over the implant, causing skin irritation.
- Early or late infection.
- Implants cutting through the bone, especially soft osteoporotic, osteopenic, or cancellous bone.
- Bone forming around the implant, making removal difficult or impossible.
- Non-union or bone fracture.
- Neurovascular compromise including radiculopathy, paralysis, or other serious injuries or disabilities.
- Hemorrhage of blood vessels.
- Cessation of growth of the operated portion of the bone.

2. Application of the FusionFrame Ring Lock System

2.1 Preoperative

This device must be handled and/or implanted by specialized professionals who have studied these instructions and, if applicable, the specific information relating to the device. The device must be used in an operating theatre and in a sterile environment only. The attainment of results in conformity with the potential of the device depends on strict compliance with these instructions and, if applicable, specific information relating to the device.

1. Operating surgeons should have complete understanding of the device and associated techniques. Surgeons are encouraged to obtain instruction from an experienced clinician prior to application.
2. Patient selection should be in accordance with the indications and contraindications for the FusionFrame Ring Lock System.
3. Fracture management, deformity correction and limb lengthening procedures should be preoperatively planned to ensure proper component selection and frame construct.
4. Use extreme care in handling and storage of components. Verify that an adequate supply of components is available at the time of surgery. All components should be inspected and sterilized before application. Damage to the surface of metal components can reduce strength and fatigue resistance. Damaged components should not be used and immediately be replaced.

2.2 Intraoperative

1. Proper Wire placement requires accurate knowledge of cross-sectional anatomy to avoid damage to structures at risk, such as tendons, fascia, muscle tissue, nerves and blood vessels.
2. Correct Wire selections should be made with reference to anatomical and soft tissue envelope size.

3. Wires must always be inserted using proper techniques as described in Section 1.7 above.
4. The mechanical axis of the frame must align with the mechanical axis of the extremity in the A/P and M/L planes.
5. All Wires and other components must be firmly fixed and tightened using proper instrumentation.

2.3 Postoperative

1. Controlled axial motion and weight bearing are advocated when deemed appropriate by the treating surgeon.
2. Wire tension and frame integrity must be monitored regularly.
3. Proper Wire site hygiene is required and all patients must be instructed on the use and maintenance of the fixator.
4. For patients undergoing distraction osteogenesis (limb lengthening), 1mm per day of distraction is recommended. This may be accomplished by 1/4 turns of the compression/distraction mechanisms at six hour intervals. This translates to a "rate and rhythm" of 1/4mm every six hours.
5. Patients should report any adverse or unanticipated effects or reactions to the treating physician.
6. Reassess the gap at the fracture site or osteotomy site periodically during healing and make adjustments as required.

2.4 Application and Training for FusionFrame Ring Lock System

It is the responsibility of the surgeon to be proficient with the procedure before use of these products. Each surgeon must evaluate the appropriateness of the surgical technique used, based on personal medical training and experience.

It is the responsibility of the surgeon to obtain the necessary training prior to application of this system. The surgeon should have specific training, experience, and thorough familiarity with the use of circular external fixation systems. The surgeon must exercise reasonable judgment when deciding which fixator components to use for specific indications.

2.5 Magnetic Resonance (MR) Statement

The MR environment presents risks to patients with metal implants. Review of the available literature documents that metal implants may heat, resulting in tissue damage and may migrate out of position. They may also cause artifacts affecting image quality. Physicians should take these risks into consideration when recommending MR imaging for patients with metal implants.

The FusionFrameTM has not been evaluated for safety and compatibility and also not been tested for heating or migration in the MR Environment. The FusionFrameTM Ring Lock System is MR Unsafe.

2.6 Sterility

All components of the FusionFrame are supplied non-sterile and must undergo an appropriate cleaning process before use (disassembled if necessary) and sterilized using a validated steam sterilization procedure.

3. Cleaning Sterilization, and Inspection

3.1 Description and intended use

The FusionFrame Ring Lock System components and instruments are packaged non-sterile and are manufactured from durable metal and plastic/composite materials.

The instruments are intended to be used in accordance with the Instructions for Use that are associated with this device. All components and instruments are to be cleaned, inspected, and sterilized between uses.

3.2 Inspection before use

Carefully inspect all FusionFrame components and instruments prior to use. Constituent elements that are faulty, damaged or suspect should not be used. They should be replaced or sent to GLW for disposition.

3.3 Preparation / General Guidance for Cleaning

Verify that all components and instruments required for use are available for the case. For manual cleaning, devices should be grouped according to similar metals and materials before subsequent processing to help reduce the chances of galvanic corrosion. Moreover, it is not recommended to use chloride containing cleaning solutions since its use has been linked to corrosion of metallic instruments, particularly stainless steel.

3.4 Manual Cleaning Instructions

The following steps should be completed in sequence. Please note that all instructions provided are as validated by GLW. Depending on the detergent selection, actual processing times and temperature settings may need to be adjusted for optimal processing:

1. Disassemble instruments to their most basic level.
2. Rinse instruments under lukewarm running water to remove all gross soil for one (1) minute. Use a soft bristled brush to aid in the brushing. Agitate the instruments under the running water. Agitation includes actuating all movable parts such as opening and closing hinges and moving the instruments around under the running water. Use a clean soft bristled brush and/or pipe cleaner to brush and aid in the rinse for the exterior and interior of instruments. Use a syringe to flush any lumens one (1) time with 60ml of lukewarm water.
3. Prepare a fresh solution of Enzol® enzymatic detergent with lukewarm tap water using the minimum concentration of 1 oz. per gallon.
4. Allow the immersed devices to soak for a minimum of two (2) minutes.
5. Rinse devices in lukewarm water for a minimum of one and a half (1.5) minutes to remove any detergent residuals. In accordance with Step 2, agitate the instruments under the running water, being sure to actuate all movable parts, and using a soft bristled brush for internal and exterior device surfaces.
6. Prepare an ultrasonic bath using Enzol® enzymatic detergent using the minimum effective concentration of 1 oz. per gallon and lukewarm tap water in a sonicator. Fully immerse the devices in the detergent and sonicate for ten (10) minutes.
7. After sonication, rinse the devices with running deionized water for three (3) minutes. Agitate the instruments under the running water, being sure to actuate all movable parts, and using a clean soft bristled brush for internal and exterior device surfaces and flush all lumens one (1) time with 60 ml of deionized water using a syringe.
8. Dry the devices using a clean lint free cloth and/or filtered compressed air.

3.5 Automated Cleaning Instructions

1. Prepare a solution of Enzol® enzymatic detergent with lukewarm tap water using the minimum concentration of as oz. per gallon.
2. Fully immerse the devices and allow to soak for a minimum of two (2) minutes.
3. Following the soak time, flush any lumens of the device with 60 ml of detergent solution one (1) time using a syringe.
4. Rinse the devices under running deionized water for a minimum of one (1) minute, while agitating the devices. Agitation includes actuating all movable parts, such as opening and closing hinges and moving the devices around under the running water.
5. Use a clean soft bristled brush and/or pipe cleaner to brush and aid in the rinse for the exterior and interior of device components. Use a syringe to flush any lumens one (1) time with 60 ml of lukewarm water.
6. Place the devices into the trays and load the tray set into an automated washer (Steris 444 or equivalent).
7. The washer cycle parameters are as follows:

Phase	Recir-culation Time (Min.)	Water Temperature	Detergent
Pre-wash 1	02:00	Cold Water	N/A
Enzyme Wash	01:00	Hot Water	Enzol® Enzymatic Cleaner 1 oz. per gallon
Wash 1	02:00	60˚C	STERIS Renu-KlenzTM Neutral pH Cleaner ½ oz. per gallon
Rinse 1	10:00	Hot Water	N/A

8. Use the highest available grade of water for the final rinse cycle.
9. After washing, dry the devices using a clean lint free cloth and/or filtered compressed air.

3.7 Inspection after Cleaning

Following cleaning, the instruments must be macroscopically unsoiled and free from any visible dirt or deposits. All movable parts and working tips should be inspected with particular attention.

3.8 Sterilization

The validation protocols were performed in accordance with AAMI ST79:2QQ6 Steam Sterilization and Sterility Assurance in Health Care and AAMI ST77-2006 Containment Devices for Reusable Medical Device Sterilization. All testing was done using the overkill approach with Geobacillus stearothermophilus spores. The results confirmed 10-6 Sterility Assurance Level (SAL) for the sets when using the recommended cycles. In accordance with our validation results, the following cycles are recommended for wrapped goods:

Method	Temp. °C	Exposure time, min.	Drying time, min.
Steam Pre-vacuum	132˚C (270˚F)	4	45

Individuals or hospitals not using the recommended method, temperature, and time are advised to validate any alternative methods or cycles using an approved method or standard.

Wrapping Instructions:

1. Obtain two (2) layers of CSR wrap.
2. Place two (2) towels on the wrap adjacent to one another with a 3-inch overlap. Then place the construct, on its side perpendicular to the junction, on the towels.
3. Tuck the towels inward.
4. Place a third towel over the top of the construct.
5. Wrap the Construct within the two (2) layers of CSR wrap using the simultaneous double-wrapping envelope fold per AAMI ST79 and secure with SPS medical steam sterilization tape.

Symbols used on labeling:

Symbol	Definition
	Catalog number.
	Batch number.
	Manufacturer.
	Consult Instructions for use.
	Do not re-use.
	For prescription use only
	Non-Sterile