CrossRoads Extremity Systems
6423 Shelby View Drive, Suite 101
Memphis, TN 38134
+1 901-221-8406

CAUTION: Federal Law (U.S.) restricts this device to the sale, distribution, and use by or on the order of a physician.

DEVICE DESCRIPTION

Implants:
The TRILEAP™ Plating System is intended for reduction, temporary fixation, fusion and stabilization of bones. The system consists of a family of implantable devices consisting of 2.0mm, 2.5mm, 3.0mm, 3.5mm and 4.0mm non-contoured and anatomic procedure specific plates, cortical screws, variable angle locking screws, and Jones screws available in various sizes. System implants are manufactured from titanium alloy and intended for single use only.

Instruments & Trays:
Instruments that may be used with the TRILEAP™ Plating System include Drill Guides, Drill Bits, Cannulated Reamers, Depth Gauges, Bending Pins, Screwdrivers and other instrumentation for general surgery. General instruments are manufactured from stainless steel, aluminum, silicone and plastic. Dedicated system organizational trays are for use in health care facilities for the purpose of containing and protecting medical devices during transportation and storage.

MRI SAFETY INFORMATION

MRI Safety has been evaluated for the TRILEAP™ Plating System implants and has been determined to be MR Conditional. If information about a specific parameter is not included, there are no conditions associated with that parameter.

A person with the TRILEAP™ Plating System implants may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	TRILEAP™ Plating System
Static Magnetic Field Strength (B_0)	1.5 Tesla or 3.0 Tesla
Maximum Spatial Field Gradient	20 T/m (2,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Volume RF Body Coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	1 W/kg
Scan Duration	Under the scan conditions defined, a patient can be scanned continuously for 60 minutes.
MR Image Artifact	The presence of this implant may produce an image artifact.

The surgeon is responsible for printing and providing the Patient Implant Card to the patient.

INDICATIONS

The TRILEAP™ Plating System is indicated for fixation of bones and bone fragments of the foot and ankle in adults and adolescents (aged 12 -21 years) where the growth plates have fused.

PRECAUTIONS

Following the instructions for use provided in product literature may minimize the potential for complications or adverse reactions with any implant. It is the responsibility of each surgeon using implants to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedure and the potential complications that may occur. The benefits derived from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are common. The patient's mental status must also be considered. Willingness and/or ability to follow post-operative instructions may also impact the surgical outcome. Surgeons must balance many considerations to achieve the best result in individual patients.

WARNING

- Surgeon familiarity with the device, instrumentation, and surgical technique prior to surgery is crucial to proper device installation. Refer to the surgical technique guide available at www.jnjmedtech.com/
- As with any implant system, the implants cannot be expected to replace normal healthy bone or withstand the stress placed upon the device by full or partial weight-bearing or load bearing in the presence of nonunion, delayed union or incomplete healing. Therefore, it is important that immobilization of the treatment site using routine methods be maintained until bone healing has occurred.
- Reduction of the site should be achieved and maintained prior to implanting the device. The compressive force of the implant should not be relied upon to achieve closure or reduction of a fracture line.
- Dispose of used device in accordance with healthcare facility policy and local regulations.
- Instruments may have sharp edges or moving joints that may pinch or tear user's glove or skin.
- Handle devices with care and dispose of worn bone cutting instruments in an approved sharps container.
- Do not strike the back of the Periosteal Elevator.
- Use of incorrect instrumentation for bending may weaken the plate and lead to premature plate failure (e.g., breakage).
- Do not bend the plate using the threaded drill guide. Damage may occur to the plate hole threads.
- Do not measure with the calibration on drill bits when using lag screw technique.
- Avoid applying excessive force on drill guides. Avoid over torquing when threading the drill guide into variable angle locking screw holes.
- Over torquing can give a false impression of guide seating.
- Over torquing and cross threading may cause screw hole damage.
- Improper placement of threaded drill guide can lead to locking screws not locking into the locking plate hole.
- Use care in carefully pushing in depth gauge measuring insert hook tip. Hook tip may be sharp and may pinch or tear user's glove or skin.
- Speed of drilling and speed of screw insertion directly correlate to temperature at the bone interface. High temperatures could impact screw to bone interface and may impact clinical outcome.
- A single use device (SUD) that comes into contact with human blood or tissue should not be re-used and should be returned to the manufacturer or properly disposed.

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications exists. Surgical procedures involving these devices should not be attempted by physicians unfamiliar with possible adverse clinical events which may occur during or after the procedure and could require additional surgery for implant revision. The risks and complications with this system include:

- Infection or painful, swollen, or inflamed implant site
- Failure or breakage of the implant or part of the implant
- Loosening or dislocation of the implant requiring revision surgery
- Bone resorption or over-production
- Allergic reaction(s) to implant material(s)
- Untoward histological responses possibly involving macrophages and/or fibroblasts
- Migration of particle wear debris possibly resulting in a bodily response
- Edema
- Muscle tendon impalement and excessive operative bleeding

The anticipated adverse device effects are the same as those associated with the currently available fixation procedures.

CARE AND CAUTION

Implants

- Implants are provided non-sterile to the end user and must be cleaned and sterilized before each use in accordance with the validated instructions below consistent with ANSI AAMI ST98.
- Implant packaging and implants should be inspected to ensure there is no damage. If the implants' packaging or implants' integrity has been compromised use an alternate item and contact the manufacturer for further instructions.
- Implants are for single use only. A single use device (SUD) that comes into contact with human blood or tissue should not be re-

used and should be returned to the manufacturer or properly disposed.

Cleaning

1. **Rinse** with cold tap water to remove gross contamination.
2. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 10 minutes.
3. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.
4. **Rinse** with cold tap water for a minimum of two minute; use a syringe to repeatedly flush any very narrow lumens.
5. **Rinse** thoroughly /flush with deionized / reverse osmosis (RO/DI) water.
6. **Sonicate** for a minimum of 15 minutes in an enzymatic detergent solution prepared per manufacturer directions.
7. Rinse thoroughly/flush with RO/DI water for a minimum of two minutes.
8. **Dry** with a clean, soft, absorbent, disposable cloth.
9. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary reclean until it is visibly clean. Visually inspect each implant; ensure that the laser markings are legible. If an implant is not acceptable for use, return to the manufacturer.

The minimum recommended steam sterilization conditions for non-sterile implants are as follows:

FOR PREVACUUM STEAM STERILIZATION ONLY:

1. Double wrap the assembled tray with lid in an FDA cleared wrap or FDA cleared sterilization container.
2. Trays may be stacked internally up to three (3) high. Do not stack wrapped trays during sterilization.
3. Autoclave according to the following parameters:

Cycle Type	Parameter	Minimum Set Point
Prevacuum	Exposure Temperature	270˚F (132˚C)
	Exposure Time	4 minutes
	Dry Time	30 minutes*

*CrossRoads Extremity Systems recommends a minimum dry time of 30 minutes for this device when sterilized using the parameters recommended above. However, because dry time can be influenced by various factors such as autoclave performance, sterilization load, sterilization wrap/package materials, steam quality, varying cool-down time, and environmental conditions, adequate drying of this device should be verified by visual inspection.

4. After sterilization, remove the component from its wrapping or container using accepted sterile technique with powder-free gloves.

Ensure that the component is at room temperature prior to use. Avoid contact with hard objects that may cause damage.

These recommendations are consistent with AAMI TIR 12, ANSI/AAMI/ISO 17665-1 and ANSI/AAMI ST79 and have been developed and tested using specific equipment.

Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

Instruments & Trays

- Instruments & trays are provided non-sterile to the end user.
- Packaging and devices should be inspected to ensure there is no damage. If the packaging or integrity has been compromised, contact the manufacturer for further instructions.
- All devices must be thoroughly cleaned per the following validated instructions below consistent with ANSI AAMI ST98.
- Do not stack trays in a mechanical washer.
- CrossRoads Extremity Systems devices must be cleaned separately from CrossRoads Extremity Systems instrument trays. Lids should be removed from trays for the cleaning process, if applicable.
- Organizational trays are not intended to maintain sterility.
- Long, narrow cannulations, blind holes and intricate parts require particular attention during cleaning.
- Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on CrossRoads Extremity Systems instrumentation.

Cleaning

1. **Disassemble** all components as per manufacturer instructions (if appropriate). **Open** all hinged instruments.
2. **Rinse** with cold tap water to remove gross contamination.
3. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 10 minutes.
4. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.
5. **Rinse** with cold tap water for a minimum of two minute; use a syringe to repeatedly flush any very narrow lumens.
6. **Rinse** thoroughly /flush with deionized / reverse osmosis (RO/DI) water.
7. **Sonicate** for a minimum of 15 minutes in an enzymatic detergent solution prepared per manufacturer directions.
8. Rinse thoroughly /flush with RO/DI water for a minimum of two minutes.
9. **Dry** with a clean, soft, absorbent, disposable cloth.
10. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary reclean until it is visibly clean. Visually inspect each instrument for deterioration such as corrosion and worn components; ensure that the laser markings are legible. Visual inspection must be performed at each cleaning to determine if an instrument is acceptable for use. If an instrument is not acceptable for use, return to the manufacturer.

Note: Brushes (i.e. pipe cleaners) could be used for cleaning most lumens; however, the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches is recommended. Clean trays only with neutral pH detergents approved for use with anodized aluminum.

The minimum recommended steam sterilization conditions for reusable instruments are as follows:

FOR PREVACUUM STEAM STERILIZATION ONLY:

1. Double wrap the assembled tray with lid in an FDA cleared wrap or FDA cleared sterilization container.
2. Trays may be stacked internally up to three (3) high. Do not stack wrapped trays during sterilization.
3. Autoclave according to the following parameters:

Cycle Type	Parameter	Minimum Set Point
Prevacuum	Exposure Temperature	270˚F (132˚C)
	Exposure Time	4 minutes
	Dry Time	30 minutes*

*CrossRoads Extremity Systems recommends a minimum dry time of 30 minutes for this device when sterilized using the parameters recommended above. However, because dry time can be influenced by various factors such as autoclave performance, sterilization load, sterilization wrap/package materials, steam quality, varying cool-down time, and environmental conditions, adequate drying of this device should be verified by visual inspection.

4. After sterilization, remove the component from its wrapping or container using accepted sterile technique with powder-free gloves.

Ensure that the component is at room temperature prior to use. Avoid contact with hard objects that may cause damage. Any instruments which are disassembled for cleaning and sterilization must be reassembled prior to use.

These recommendations are consistent with AAMI TIR 12, ANSI/AAMI/ISO 17665-1 and ANSI/AAMI ST79 and have been developed and tested using specific equipment on the system devices.

Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

The recommendations provided above have been validated by the medical device manufacturer as being capable of preparing a non-sterile CrossRoads Extremity systems medical device. It remains the responsibility of the processor to ensure that the processing is actually performed, using equipment, materials and personnel in the reprocessing facility, and achieves the desired result. This requires verification and routine monitoring of the process. Likewise, any deviation by the processor from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences.

All users should be qualified personnel with documented expertise, competency and training. Users should be trained on hospital policies and procedures along with current applicable guidelines and standards.

Users should don appropriate personal protective equipment (PPE) when processing devices in accordance with the Department of Environmental and Occupational Health and Safety's (OSHA) bloodborne pathogen guidelines.

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

THERE IS NO EXPRESS OR IMPLIED WARRANTY, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ON CROSSROADS EXTREMITY SYSTEMS, LLC PRODUCT(S) DESCRIBED IN THIS PUBLICATION. UNDER NO CIRCUMSTANCES SHALL CROSSROADS EXTREMITY SYSTEMS, LLC BE LIABLE FOR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OTHER THAN AS EXPRESSLY PROVIDED BY SPECIFIC LAW. NO PERSON HAS THE AUTHORITY TO BIND CROSSROADS EXTREMITY SYSTEMS, LLC TO ANY REPRESENTATION OR WARRANTY EXCEPT AS SPECIFICALLY SET FORTH HEREIN.

Descriptions or specifications in CrossRoads Extremity Systems, LLC printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties.

CrossRoads Extremity Systems, LLC will not be responsible for any direct, incidental, or consequential damages resulting from reuse of the product.

TRILEAP™ is a trademark of CrossRoads Extremity Systems, LLC
Product and/or its use are covered by patents pending.

RECOMMENDED PROCEDURE

- Expose the fracture or fusion site and resect cartilage if needed according to surgeon preference, location, and fixation goal.
- Reduce fracture or fusion site.
- Select a proper implant (non-contoured plate, anatomic procedure specific plate, or screws).
- If needed, use bending pliers or bending irons to bend the plate.
- Use K-wire and/or wire tacks for temporary fixation of the plate on the bone.
- Use the proper drill bit and drill sleeve to drill screw holes per the below table according to screw size (2.0mm, 2.5mm, 3.0mm mini head, 3.0mm small head, 3.5mm, 4.0mm, etc.), type (cortex, variable angle locking, or Jones) or drilling preference (free hand or guided drilling).
- Use the proper depth gauge to measure the screw length.
- Insert screw using the corresponding screwdriver.
- Repeat for other applicable holes.
- Remove K-wires.

STANDARD IMPLANT REMOVAL

- Create an incision and access the implant.
- Free the screw recess from bone tissue to ensure that the screwdriver can be fully inserted.
- Check the condition and the geometry of the recess of the exposed screw head.
- Connect the screwdriver shaft to the quick coupling handle.
- Insert the screwdriver fully into the screw recess and remove.
- To remove locking screws, first unlock all screws from the plate; then remove the screws completely from the bone.
- For plating constructs, the last screw removed should be a non-locking screw on the shaft. This prevents the plate from spinning when locking screws are removed.
- For plating constructs, when all the screws have been removed, the plate can be removed.
- Close the incision.

Instrument	**2.0mm** Blue	**2.5mm** Magenta	**3.0mm** Gold	**3.0mm** Rose Red	**3.5mm** Purple	**4.0mm** Green
Drill bit	1.6mm	2.0mm			2.7mm	
Drill guide-Cone	1.6mm	2.0mm			2.7mm	
Drill guide-Coaxial	1.6mm	2.0mm			2.7mm	
Drill guide-Free hand	1.6mm	2.0mm			2.7mm	
Screwdriver	T6	T8		T15		
Drill guide for lag technique	1.6/2.0	2.0/2.5	N/A	N/A	2.7/3.5	N/A

Instrument	**4.5mm** Gold	**5.5mm** Blue	**6.5mm** Magenta
Drill bit	3.0mm	4.0mm	5.0mm
Drill guide-Free hand	3.0mm	4.0mm	5.0mm
Tap	4.5mm	5.5mm	6.5mm
Screwdriver	T15	T25	T25

	Caution consult accompanying documents
	Catalogue number
	Consult instructions for use
	Contents of package
	Do not reuse
	Lot number
	Manufacturer
	Prescription only - device restricted to use by or on the order of a physician
	MR Conditional

SYMBOLS

Refer to package labels to determine which symbols are relevant to the device in the package

Note: For recognized manufacturer, refer to the product label.