INSTRUCTIONS FOR USE

CrossTIE™ Intraosseous Fixation System

MANUFACTURER

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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 CrossTie™ Intraosseous Fixation System gives the surgeon a means for fixation of fractures, fusions and osteotomies of the toes in the management of hammertoe, claw toe, mallet toe and other interdigital fusions. The CrossTie™ Intraosseous Fixation System includes implants and the related instrumentation needed for implantation. The implants are made of biocompatible, implant grade PEEK and the instruments are made from surgical grade metals. The implant is made from one-piece construction and available in various sizes for optimal fit in the bone. The implant also features a hole in the distal end of the implant to be used at the surgeon's discretion to facilitate joint reduction. Each implant is designed to be used with a reamer that is also provided. The amount of purchase or fixation in the bone will depend on the spatial orientation of the bones, bone quality, surgical technique, etc. Implant components are provided sterile and are intended for single use only.

Instrument System

Instruments used with the CrossTie™ Intraosseous Fixation System include the following: Reamer and Driver. Instrument components are provided sterile packaged. Instruments and reamers may be provided sterile for single use or non-sterile.

INDICATIONS

The CrossTie™ Intraosseous Fixation System is indicated to aid in the fixation of fractures, fusions, and osteotomies of the toes, such as hammertoe, claw toe, mallet toe and inter-digital fusions

Contraindications

The CrossTie™ Intraosseous Fixation System is contraindicated for use in patients with the following conditions:

- Active or suspected infection
- Irreparable tendon system
- Possibility for conservative treatment
- Patients with high levels of activity
- Comminuted bone surface that would prevent proper implant placement.
- Pathological bone conditions that would prevent secure implant fixation
- Physiological or psychological conditions that limit the patient's ability and/or willingness to follow instructions during the healing process.
- Inadequate skin, bone, or neurovascular status
- Skeletally immature patients with open epiphyses

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

WARNINGS

- Surgeon familiarity with the device, instrumentation, and surgical technique prior to surgery is crucial to proper device installation. Improper insertion technique, coupled with excessive force, can potentially lead to breakage of the implant. Refer to CrossTie Surgical Technique for proprer insertion method.
- 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.
- Any additional processing or reprocessing of the implant may affect the material properties, potentially reducing the effectiveness of the implant.
- Drill bits and reamers are designed for use specifically with the supplied implants. Re-use or reprocessing may affect the compatibility with other instruments and usability of the instruments.
- If it is suspected that sterilization is compromised prior to implantation, another sterile implant should be used. Product should not be re-sterilized.
- The CrossTie™ Intraosseous Fixation System has not been evaluated for safety and compatibility in the MR environment. The CrossTie™ Instraosseous Implant has not been tested for heating or migration in the MR environment.

Dispose of used device in accordance with healthcare facility policy and local regulations.

COMPLICATIONS

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 anticipated adverse device effects are the same as those anticipated devices and surgical techniques associated with the currently available intraosseous, hammertoe, mallet toe, and claw toe fixation procedures.

Adverse Events

The following list includes potential complications typically associated with these types of devices. The following adverse effects should be understood by the surgeon and patient prior to surgery. The occurrence of such events may necessitate removal of the implant. In rare instances arthrodesis of the involved joint or amputation of the limb may be required;

- Prolonged healing
- Pain
- Damage to blood vessels or hematoma
- Failure or breakage of the implant or part of the implant as a result of trauma, strenuous activity, improper alignment, incomplete implant seating, duration of service, loss of fixation, non-union, or excessive weight
- Damage to nerves and vessels
- Infection, painful, swollen or inflamed implant site
- Loosening, dislocation or migration of the implant requiring revision surgery
- Edema
- Delayed union or malunion

- Allergic reaction(s) to implant material(s)
- Muscle tendon impalement and excessive operative bleeding
- Nonunion pseudoarthrosis development and persistence and failure of the bone regenerating satisfactorily
- Loss of bone mass
- Venous thrombosis, pulmonary embolism, cardiovascular problems
- Inability to compress the bone surface due to poorly fixated implant

Adverse Events related to CrossTie™ Intraosseous Fixation System
No additional risks are associated with CrossTie™ Intraosseous Fixation System.

HOW SUPPLIED, CLEANING AND STERILIZATION
Implants
The implants are provided sterile to the end user

Implant packaging and implants should be inspected to ensure there is no damage. If the implants' packaging or implants' integrity has been compromised, contact the manufacturer for further instructions.

Implants are for single use only.

Instrument System
Instruments are provided sterile to the end user. Instruments and reamers may be provided sterile or non-sterile. Instrument packaging and instruments should be inspected to ensure there is no damage. If the instruments' packaging or instruments' integrity has been compromised, contact the manufacturer for further instructions.

CARE AND CAUTION
- Instruments for the CrossTIE™ Instraosseous Fixation system are provided sterile and are for single use only.
- Instruments and reamers may be provided sterile for single use only or non-sterile.
- The mechanical characteristics and performance of the sterile implants and instruments may be altered if re-sterilized. Since this could potentially adversely affect device integrity and performance, CrossRoads Extremity Systems, LLC warns against resterilization of its single use implants and instruments.
- Inspect the sterile packaging used for the implants and instruments prior to use. If the packaging and/or seal is damaged, sterilization may be compromised and the implant and/or instrument should not be used.
- CrossTie™ implants and instruments may be stored at room temperature.

Instruments and reamers may be provided non-sterile to the end user and must be cleaned and sterilized before each use in accordance with the instructions below.

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 5 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 one minute; use a syringe to repeatedly flush any very narrow lumens.
6. **Bathe** in a detergent solution prepared per manufacturer directions for 5 minutes.
7. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe.
8. **Rinse** thoroughly /flush with deionized / reverse osmosis (RO/DI) water.
9. **Sonicate** for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions.
10. Rinse thoroughly /flush with RO/DI water.
11. **Dry** with a clean, soft, absorbent, disposable cloth.
12. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary reclean until it is visibly clean.

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.

The minimum recommended steam sterilization conditions for **non-sterile implants and reusable instruments** are as follows:

FOR PREVACUUM STEAM STERILIZATION ONLY:
1. Double wrap the assembled tray in a FDA cleared wrap or FDA cleared sterilization container.

2. Autoclave according to the following parameters:
Steam Sterilization – PREVACUUM

Cycle Type	Parameter	Minimum Set Point
Prevacuum 270 ˚F (132 ˚C)	Exposure Temperature	270˚F (132˚C)
	Exposure Time	4 minutes
	Dry Time	20-30 minutes

Steam Sterilization – GRAVITY DISPLACEMENT

Cycle Type	Parameter	Minimum Set Point
Gravity Displacement 270 ˚F (132 ˚C)	Exposure Temperature	270˚F (132˚C)
	Exposure Time	15 minutes
	Dry Time	15 -30 minutes

3. 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 ANSI/AAMI ST79:2010 guidelines 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.

OTHER SUPPLIES AND EQUIPMENT NEEDED
- Standard OR equipment used in patient preparation and surgical exposure.
- Power drill with pin driver attachment .

IMPLANT MATERIALS
The CrossTie™ Intraosseous Implants are manufactured from implantable grade PEEK (Polyetheretherketone), ASTM F2026.

SYMBOLS

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

	Caution consult accompanying documents
	Catalogue number
	Consult instructions for use
	Contents of package
	Do not reuse
	Lot number
	Manufacturer
	Sterilized using irradiation
	Prescription only - device restricted to use by or on the order of a physician
	Use By: YYYY-MM (YYYY is year; MM is month)

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