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 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 proper 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™ Intraosseous Implant has not been tested for healing or migration in the MR environment.

DISPOSAL

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
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- 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.

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™ Intraosseous Fixation system are provided sterile and are for single use only.
- 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.
- 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 re-sterilization 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.

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 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 with deionized / reverse osmosis (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 re-clean 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:

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Parameter</th>
<th>Minimum Set Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevacuum</td>
<td>Exposure Time</td>
<td>270°F (132°C)</td>
</tr>
<tr>
<td>270°F (132°C)</td>
<td>Exposure Temperature</td>
<td>4 minutes</td>
</tr>
<tr>
<td>270°F (132°C)</td>
<td>Dry Time</td>
<td>20-30 minutes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Parameter</th>
<th>Minimum Set Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gravity Displacement</td>
<td>Exposure Time</td>
<td>270°F (132°C)</td>
</tr>
<tr>
<td>270°F (132°C)</td>
<td>Exposure Temperature</td>
<td>15 minutes</td>
</tr>
<tr>
<td>270°F (132°C)</td>
<td>Dry Time</td>
<td>15-30 minutes</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>!</td>
<td>Caution consult accompanying documents</td>
</tr>
<tr>
<td>REF</td>
<td>Catalogue number</td>
</tr>
<tr>
<td>i</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>CONT</td>
<td>Contents of package</td>
</tr>
<tr>
<td>☢</td>
<td>Do not reuse</td>
</tr>
<tr>
<td>LOT</td>
<td>Lot number</td>
</tr>
<tr>
<td>Sterile</td>
<td>R</td>
</tr>
<tr>
<td>Sterile</td>
<td>Sterilized using irradiation</td>
</tr>
<tr>
<td>RX</td>
<td>Prescription only - device restricted to use by or on the order of a physician</td>
</tr>
<tr>
<td>Use By:</td>
<td>YYYY-MM (YYYY is year; MM is month)</td>
</tr>
</tbody>
</table>

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