INSTRUCTIONS FOR USE, USA

CURVAFIX® IM SYSTEM

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

The CurvaFix® IM Implant is intended for the fixation of fractures of the pelvis.

DESCRIPTION

The CurvaFix IM System includes the 9.5mm CurvaFix IM Implant, the 7.5mm CurvaFix IM Implant, disposable CurvaFix accessories, and reusable CurvaFix instruments. The CurvaFix IM Implant is an implantable intramedullary device for fixation of pelvic fractures. It has a threaded, self-tapping distal end, a proximal end feature for driving torque, and a lock feature that changes the IM implant from a flexible to rigid state after implantation. If explantation is required, the IM implant can be unlocked into a flexible state before removal. The patient contacting device materials of the CurvaFix IM system include stainless steel and polyamide (exchange tube).

CONTRAINDICATIONS

Active Infection; Conditions which tend to retard healing such as blood supply limitations; previous infections; Insufficient quantity or quality of bone to permit stabilization of the pelvic ring fracture; Lack of musculocutaneous cover; Muscular deficit, neurological deficiency or behavioral disorders which could submit the osteosynthesis to abnormal mechanical strains; Cases with malignant primary or metastatic tumors which preclude adequate bone support for screw fixations; Conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process; Foreign body sensitivity; Pelvis intracortical space not large enough to accept a device; Any condition not described in the Indications for Use.

WARNINGS

For safe and effective use of this implant system, the surgeon should be trained on the recommended surgical procedure for this device. In every case, accepted surgical practices should be followed in postoperative care. The CurvaFix IM System Surgical Technique Guide can be obtained at no charge by contacting Customer Service by phone at +1 (425) 276-8800 or by email at support@curvafix.com.

Accurate implant position is critical to the outcome of the procedure and particular attention should be paid to this. The patient should be made aware of the limitations of the implant and that physical activity has been implicated in premature failure of similar devices. Patient sensitivity to implant materials should be considered and assessed prior to surgery. Do not modify implants. Do not use the CurvaFix IM System with components from other systems.

MRI SAFETY INFORMATION

The CurvaFix IM Implant has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of CurvaFix IM Implant in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

PACKAGING AND STERILITY

The CurvaFix IM Implant and CurvaFix accessories are provided sterile and are intended for single use only. Do not use a CurvaFix IM Implant or accessory if the package is opened or damaged or if the expiration date has passed. Once used or attempted in use, the CurvaFix IM Implant and CurvaFix Accessories must be discarded. Do not attempt to reprocess or resterilize a CurvaFix IM Implant or accessory.

The CurvaFix Instruments are provided non-sterile. CurvaFix Instruments must be thoroughly cleaned and sterilized prior to use.

CARE AT THE POINT OF USE

Remove excess soil with disposable, non-shedding wipes.

INSTRUMENT CLEANING & STERILIZATION

The CurvaFix instruments must be cleaned after first use and prior to sterilization. All reusable instruments must be disassembled (if applicable) prior to cleaning and sterilization. It is recommended that instruments be cleaned as soon as reasonably practical after use to keep soil from drying.

Manually clean each instrument using the following steps.

1. Rinse under room temperature potable water. Use an instrument brush to mechanically clean instrument until visible soil has been removed. Do not use metal or wire wool brushes.

2. Rinse under warm (85-104°F) running potable water for one minute.

3. Fully immerse the instruments in a neutral pH (7.0) enzymatic cleaner made per manufacturer's recommendations using lukewarm (68-104°F) tap water. Ensure the entire instrument is submerged and soak for 5 minutes.

4. Manually clean (scrub) the instruments using a soft-bristle brush removing all remaining visible soil and debris. Ensure that any hinges or joints, lumens, rough surfaces, blind holes are free of soil. Pay particular attention to any threads, pivots, cannula, recesses, blind holes or difficult to reach areas. Be sure to thoroughly clean cannulated products using an appropriate size brush. The brush should be repeatedly run through the entire length of the cannula using a twisting motion. Do not use metal or wire wool brushes. Flush the cannula with water until the rinse stream is clear.

5. Rinse the instruments thoroughly for 1 minute with room temperature water. Water must be purified (deionized (DI), distilled, etc.). Use a syringe, water jet, or pipette to flush cannula, blind holes, and channels.

6. If soil or debris are still visible repeat steps 1-4 until all visible soil or debris have been removed from the device.

7. Dry the device thoroughly using a clean, soft, lint-free cloth or compressed air (30-40psi).

Carefully inspect all instruments within the system to ensure they are suitable for use and have not been damaged (i.e. cracks, bends, twisting, dull cutting surfaces, etc.). Do not use damaged or defective instruments.
Steam Sterilize the instruments using the following validated process parameters. The instrument case should be double wrapped with an FDA cleared wrap.
Cycle - Prevacuum
Temp - 132°C
Exposure time – 4 minutes
Dry Time – 30 minutes

MANUFACTURED BY:
CurvaFix, Inc.
1406 140th Place NE, Suite 107
Bellevue WA 98007
CurvaFix.com

SYMBOL DESCRIPTIONS:

REF	Model Number	ISO 15223-1, 5.1.6 ISO 7000 - 2493
LOT	Lot Number	ISO 15223-1, 5.1.5 ISO 7000 - 2492
STERILE R	Sterilized using irradiation	ISO 15223-1, 5.2.4 ISO 7000 - 2502
	Use By Date	ISO 15223-1, 5.1.4 ISO 7000 - 2607
Rx Only	Prescription Only	21 CFR 801.15(c)(1)(i)F 21 CRF 801.109
	Caution, consult accompanying documents	ISO 15223-1, 5.4.4 ISO 7000 - 0434
	Consult Instructions For Use	ISO 15223-1, 5.4.3 ISO 7000 - 1641
	Do Not Reuse	ISO 15223-1, 5.4.2 ISO 7000 - 1051
	Do Not Use if Package is Damaged	ISO 15223-1, 5.2.8 ISO 7000 - 2606
	Manufacturer	ISO 15223-1, 5.1.1 ISO 7000 - 3082