Fusion ORTHOPEDICS

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FuzeFix™ Max FT System

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

DESCRIPTION OF THE MEDICAL DEVICE
The FuzeFix Max FT System consists of cannulated, fully threaded headless bone screws are offered in 2.5mm to 4.5mm diameters with lengths ranging from 8mm to 60mm. System instrumentation includes drill bits, proximal reamers, K-wires, guides, depth gauges, screw removal tools, driver shafts, and handles to facilitate the placement of the screws. The implants are intended for single use only. Instruments designed for bone removal are intended for single use only, such as: drill bits, countersinks, reamers, and K-wires.

INDICATIONS FOR USE
The FuzeFix Max FT System is intended for use in the stabilization and fixation of bone fractures, osteotomies, non-unions, and reconstruction, tendon reattachment, and arthrodesis of the hand, foot, wrist, and ankle. The FuzeFix Max FT System is indicated for: Osteochondral fragments (talar vault, femoral condyle), apical fragments (radial head, patellar rim, navicular, metacarpal/metatarsal), cancellous fragments (talus), Carpal, metacarpal, and small hand bone, tarsal and metatarsals, phalanges, Intra-articular fractures, ankle, proximal and distal humerus, proximal and distal radius, proximal and distal ulna, osteochondral fixation and fractures, Osteochondritis Dissecans, Fixation of fractures and osteotomies about the knee, Oblique fractures of the fibula, Reconstructive surgeries of the foot, and malleolar fixation. Not intended for use in the spine.

CONTRAINDICATIONS
- Local or systemic, acute or chronic inflammation;
- Active infection or inflammation;
- Growing patients with open epiphyses;
- Poor or insufficient bone stock;
- Metal sensitivity or allergic reaction to foreign bodies;
- Material conditions that preclude cooperation with the rehabilitation regimen.

PRECAUTIONS
- Only experienced surgeons should perform the implantation of the FuzeFix Max FT System device with specific training in treating its associated indications. Because of the technically demanding nature of procedure, surgeons should preoperatively plan to ensure that the risks presented to the patient are minimized. Pre-operative assessment of the suitability of the patients' anatomy for accepting implants is made on the basis of X-Rays, CT scans and other radiological studies.
- Only patients that meet the criteria described in the Indications for Use section should be selected.
- Under no circumstances should damaged components or surgically excised components be used. Implants that have already been in contact with body fluids or body tissues must not be resterilized and are for single use only.
- Correct selection of the implant is extremely important. When selecting implants, the morbidity as well as patient weight, height, occupation and/or degree of physical activity should be considered.
- Proper Implant handling before and during the operation is crucial. Handle the implant components properly. If applicable, ensure packaging integrity. Do not allow the implant surfaces to be damaged.
- All implants and instruments are intended for single use only. Single use devices should not be re-used. Possible risks associated with re-use of single use devices include: Mechanical malfunction and transmission of infectious agents.

Adequately instruct the patient. The physician should inform the patient about orthopedic implant advantages and disadvantages, post-operative limitations, weight/load bearing stresses which could affect bone healing, implant limitations, and the fact that premature physical activity and full weight/load bearing stresses have been implicated in premature loosening, damage and/or fracture of orthopedic prostheses.

ADVERSE EFFECTS
- Tissue damage resulting from improper placement of implants or instruments;
- Infection;
- Hematoma;
- Allergy;
- Thrombosis;
- Pain, discomfort or wound healing complications at the surgical site;
- Misalignment of anatomical structures;
- Bone non-union or delayed union;
- Dislocation, migration and/or subluxation of implant from improper positioning, trauma, loss of fixation and/or muscle and fibrous tissue laxity;
- Implant fracture.

Adverse effects may necessitate re-operation, revision or removal surgery, arthrodesis of the involved joint, and/or amputation of the limb.

DIRECTIONS FOR USE
To implant the FuzeFix Headless FT System device, use only the specialized FuzeFix Headless FT System instrumentation. Do not use implants or instruments from any other system or manufacturer. All FuzeFix Headless FT System components should be carefully inspected to ensure proper working condition. Critical areas, including joint surfaces, should be checked for wear, damage or irregularities. Damaged or broken FuzeFix Headless FT System devices must not be used and should be returned to Fusion Orthopedics for evaluation.

Before using the FuzeFix Headless FT System, the surgeon should be thoroughly familiar with the FuzeFix Headless FT System Surgical Technique Manual. Pre-operative planning by the surgeon should determine the size of implant required and an adequate supply of the implant sizes should be available prior to surgery, including larger and smaller sizes than those expected to be used.

For complete instructions regarding the proper use and application of FuzeFix Headless FT System implants and instruments, please refer to the appropriate FuzeFix Headless FT Compression System Surgical Technique Manual. A comprehensive manual can be found at www.fusionorthopedics.com/surgicaltechnique

CARE AND HANDLING
FuzeFix Headless FT System implants described in this package insert are either provided sterile or non-sterile as indicated on the individual product's label. Implants and instruments that are presented in instrument trays are provided non-sterile.

Implants in sterile packaging should be inspected to ensure that the packaging has not been damaged or previously opened. Sterile implants and instruments should not be used after the expiration date. If the outer package, seal, or inner package integrity has been compromised, sterilization cannot be assured and the device should not be used. Contact the manufacturer for further instructions. The implants should be opened using aseptic OR technique; they should only be re-opened after the correct size has been determined.

An implant should never be re-sterilized after contact with body tissues or fluids. Devices labeled for single-use only should never be reused. The mechanical characteristics of sterile instruments and implants may be altered if they are re-used as this would compromise device intergrity, performance, and standards conformance. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant performance degradation, cross-infection, and contamination.

Implants provided non-sterile should be processed according to the recommended parameters for instruments as outlined (below) in the instructions for use and according to standard hospital procedure. FuzeFix Headless FT System implants and instruments provided non-sterile and should be stored in the original packaging until cleaned and sterilized. Implants and instruments should be stored at room temperature.

PREPARATION FOR CLEANING, CLEANING, AND STERILIZATION

PREPARATION FOR CLEANING:
Clean the device until there is no visual contamination of the instruments. It is reccomended that devices be treated promtly after application and while still moist (within a maximum of 2 hours). The quality of water used for diluting cleaning agents and for rinsing should be carefully considered. Application of purified (reverse osmosis processed, or better) water or sterile water for rinsing purposes with less than 10 cfu/ml and 0.25 EU/ml is higly reccommended. For manual removal of impurities only a soft brush or a clean soft tissue is to be used, in no case metal brushes or steel wool. Rinse all lumens/cannulations five (5) times by application of a single-use syringe (minimum volume 10ml).

MANUAL CLEANING:
1. Soak instruments for a minimum of five (5) minutes in enzymatic detergent made with potable water.
2. Deliberately brush and pay considerable attention to areas of a high exposure, accumulation, or retention of soil.
3. Rinse thoroughly with warm (30º C. to 40º C.) purified water (reverse osmosis processed, or better), with a minimum rinse time of 30 seconds.
4. Check the instruments for visible soil (see "Verifying Cleaning"). Repeat cleaning if soil is visible.

For Devices with challenging design features (cannulations, annodized color bands, handle interfaces, hinged instruments, instruments with crevices):

1. Immerse instrument and soak for a minimum of five (5) minutes in enzymatic detergent.
2. Use cleaning brushes/pipe cleaners to remove additional soil from challenging design features and areas of high exposure, accumulation, or retention of soil such as: cannulations, annodized color bands, handle/ chuck interfaces, hinged instruments, or instruments with crevices.
   a. Scrub interfaces several times using a twisting action if possible. If components of the instrument can be retracted or moved, it is necessary to retract or open the part in order to access and clean these areas.
   b. Scrub inside cannulas/holes with a tight-fitting brush or pipe cleaner using a twisting action. The brush or pipe cleaner should be of an appropriate size to ensure that full depth of the feature is reached.
   c. Scrub around hinged/mating surface areas with a brush or pipe cleaner.
   d. Scrub all crevices, such as those found around color bands, using a cleaning brush or pipe cleaner.
3. Sonicate instrument in its fully opened position for a minimum of 15 minutes in an ultrasonic cleaner containing warm enzymatic detergent.
4. Rinse thoroughly with warm (30º C. to 40º C.) purified water (reverse osmosis processed, or better), with a minimum rinse time of 30 seconds, making sure to irrigate the challenging design features. If the components of the instrument are moveable or can be retracted, it is necessary to retract or open the part for thorough rinsing at these locations. Blind holes should be repeatedly filled and emptied.
5. Check instruments for visible soil (see "Verifying Cleaning"). Repeat cleaning if soil is visible.

VERIFYING CLEANING
1. After thoroughly cleaning, visually inspect devices under normal lighting for the removal of visible soil.
2. **Optional:** For difficult to view design features, such as cannulation, apply 3% hydrogen peroxide. Bubbling is indicative of the presence of blood.

Note: Rinse the instruments thoroughly with warm (30º C. to 40º C.) purified water (reverse osmosis processed, or better), with a minimum rinse time of 30 seconds following hydrogen peroxide testing. Repeat cleaning if not visibly clean and re-inspect.

INSPECTION AND FUNCTION TESTING

Device/Feature	Flaw
All reusable devices	Visually inspect for damage or wear.
Hinged instruments	Check for smooth movement of hinge without excessive "play."
Locking mechanisms	Check for action.
Cutting features	Check edges for distortion/large nicks. Edges should be continuous.
Trials	Articular surfaces should be smooth and free of cracks and deep nicks.
Mating parts	Check to make sure that mating parts fit together without complications.
Reamer/drill bits	Inspect "chuck" end for burrs and distortion that might hinder insertion into a drill.
Hammering surfaces	Inspect for burrs and large nicks.
Driving instruments	Inspect plastic ends for cracks and large nicks.
Metal surfaces	Inspect for corrosion and major deformation.

STERILIZATION
Sterilize devices inside their respective trays according to the parameters indicated below:

Sterilization Method	Gravity Steam	Pre-Vacuum Steam
Wrapping	Single	Single
Exposure Temperature	132°C (270°F)	132°C (270°F)
Minimum Cycle Time	15 minutes	4 minutes
Minimum Dry Time	30 minutes	30 minutes

The wrap should be FDA cleared for the proposed cycle specifications.

WARNING: Total drying time depends on several factors. These include but are not limited to: altitude, humidity, type of wrap, preconditioning, size of chamber, mass of load, material of load, and placement in chamber. Verify that drying time set in each autoclave yields dry surgical equipment.

These instructions were developed using guidance from ISO 17665, AAMI TIR 12, and AAMI ST79. Fusion Orthopedics recommends that all users observe these standards.

MAINTENANCE:
If the any of instruments exhibit any of the flaws listed above adequately dispose of the devices.

For more information regarding cleaning and sterilization of the FuzeFix Headless FT System implants or Instruments, please visit www.fusionorthopedics.com/cleaning

MAGNETIC RESONANCE (MRI) COMPATIBILITY
The FuzeFix Headless FT System implant has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in MR environment. The safety of the FuzeFix Headless FT System implant in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

MATERIAL SPECIFICATIONS
The FuzeFix Implants are manufactured of Titanium Alloy (Ti6Al4V) per ASTM F136. All associated instruments are made of Surgical Grade Stainless Steel.

CUSTOMER SERVICE
For further information regarding the FuzeFix Headless FT System, a copy of the FuzeFix Headless FT System Surgical Technique Manual, or the Cleaning and Sterilization Protocol Manual, please contact Fusion Orthopedics, LLC, your local Fusion Orthopedics Distributor, or visit FusionOrthopedics.com

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