FLOW-NAIL™ WITH LAGLOCK™

Trochanteric Nail

Instructions for Use

DESCRIPTION

The Flow-FX Flow-Nail is designed as a trochanteric nail system for fixation of stable and unstable proximal fractures of the femur and is composed of an intramedullary nail, sliding, fenestrated lag screw, anti-rotation screw, cortical screws and accompanying instruments. The Laglock™ system includes the modified lag screw and Flow-Nail™ designed to use as a static construct limiting movement at the fracture site when needed.

The Flow-Nail can also be used for the delivery of bone void fillers.

INDICATIONS

The Flow-Nail is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric, intertrochanteric, and high subtrochanteric fractures and combinations of these fractures. The Flow-Nail can also be used to deliver injectable bone void fillers to a surgical site.

MATERIALS

The Flow-Nail implant components are made of titanium alloy (Ti-6Al-4V) conforming to ASTM F136.

CONTRAINDICATIONS

- Insufficient quantity or quality of bone, conditions that retard healing (not including pathological fractures) and conditions causing poor blood supply or obliteration of the medullary canal or femoral neck and head.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Material sensitivity documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

WARNINGS

- For professional use only.
- Do not use this system without fully reading the instructions for use.
- The surgeon should be familiar with the general principles and technique of intramedullary nails to treat stable and unstable proximal fractures of the femur including pertrochanteric, intertrochanteric, and high subtrochanteric fractures and combinations of these fractures and the Flow-Nail System.
- The surgeon should be familiar with the general principles and technique of delivering bone void filler using the Flow-Nail System.
- Surgeons should follow the surgical technique.
- Selection of the correct Nail and Lag Screw length is very important. Determination of the alignment of the femoral neck and head should be performed using fluoroscopy and/or designated gauges.
- Use of contrast media in patients with a known contraindication to contrast.
- If delivery of a bone void filler is required in an area adjacent to a joint, injection of 4cc of radiopaque contrast through the side port cannula is recommended to confirm the integrity of the articular surface. If the articular surface is not intact, delivery of bone void filler in that area is not recommended.
- Patients should be cautioned against significant load bearing prior to good callus formation. Patients who are either noncompliant or predisposed to delayed union or non-union, must have auxiliary support.
- Periodic x-rays are recommended for at least six months to detect any changes in position, nonunion, loosening, bending or cracking of components.

- Patients should be cautioned that even after complete healing there is a higher risk for re-fractures while the Nail is in position.
- Postoperative care and physical therapy should be structured to prevent excessive loading of the operated extremity.
- All implants and all instruments are provided non-sterile. All non-sterile implants and instruments must be sterilized prior to surgery in accordance with the Sterilization Section.
- Screws and hardware from other device manufacturers should not be combined with the Flow-Nail System.
- Flow-Nail implants should only be used for delivery of bone void fillers that have been validated for use with the device.

PRECAUTIONS / INSPECTION

- The Flow-Nail implants, the Trocar-Tipped Guide-wire, and the Side Port Cannula for the application of bone void filler are one-time use. The Side Port Cannula and Trocar-Tipped guide-wire will be disposed of in accordance with local requirements. The implants are intended to remain in the patient.
- The Flow-Nail Instrument set, with exception of the Side Port Cannula and Trocar-Tipped Guide-Wire, is intended to be reusable and will be cleaned and sterilized in accordance with the Sterilization Section.
- The Side Port Cannula should be examined for structural integrity before use.
- Proper handling and storage of the system components is mandatory. Damage or alterations may produce stresses and cause defects, which could become the focal point for failure.
- All implants and instruments must be inspected prior to use for any damage. Do not use if damage exceeds normal standards for implants and instruments.

MRI SAFETY INFORMATION

The Flow-FX Flow-Nail 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 the Flow-FX Flow-Nail in the MR environment is unknown. Performing an MR exam on a person who has this medical device may results in injury or device malfunction.

ADVERSE EFFECTS

The adverse events include but are not limited to:

- Implants may migrate, cause pain or stress shield bone even after a fracture has healed.
- Pain, discomfort, nerve or soft tissue damage etc.
- Metal sensitivity or allergies.
- Trauma.
- A pulmonary embolism may result from using this hardware with an injectable bone void filler.

STERILITY

Implants

The Flow-FX implants are provided non-sterile.

Instruments

The Flow-FX instruments are provided non-sterile.

Scope

These cleaning instructions apply to the reusable manual orthopedic surgical instruments used to prepare the bone and implant the Flow-Nail Trochanteric Nail implant set.

The Side Port Cannula and the Trocar-Tipped Guide-Wires are single use instruments and should be discarded after each use.

WARNINGS AND LIMITATIONS

Automated cleaning may not be effective. A thorough, manual cleaning process is recommended.

Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used. Enzymatic and cleaning agents with neutral pH are recommended.

Repeated processing, according to these instructions, has minimal effect on Flow-Nail reusable manual instruments. End of life is normally determined

by wear and damage due to use.

INSTRUCTIONS AT POINT OF USE

Separate any nested instruments and disassemble any instruments that can be disassembled without using tools. Please refer to the surgical tray graphics for the expected state of disassembly.

In addition, the BVF Gauge (101-71) shall be separated into two parts for cleaning and reassembled for sterilization. The separation is accomplished by completing the following procedure.

1. Extend the collar until the set screw is adjacent the 90 notch position.
2. Rotate the collar further clockwise (to the left when viewed from the notch position) until the set screw engages the collar release slot and is unable to rotate further.
3. Slide the collar out of the device.
4. Re-assembly is accomplished by reversing the removal process.

Remove excess body fluids and tissue with a disposable, non-shedding wipe and cover with a damp cloth or submerge in a basin of sterile water. Body fluids and tissue should not be allowed to dry on instruments prior to cleaning.

CONTAINMENT / TRANSPORTATION

Universal precautions for handling contaminated/ bio-hazardous materials should be observed.

Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.

MANUAL CLEANING PROCEDURE

1. Prepare neutral pH enzyme and cleaning agents at the use-dilution and temperature recommended by the manufacturer.
2. Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes. Use a soft-bristled brush to gently clean the device (paying close attention to all threads, crevices and other hard-to-clean areas) until all visible soil has been removed. Any instruments with lumens or cannulas should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush). The enzyme solution should be changed when it becomes grossly contaminated.
3. Remove the device from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.
4. Prepare the neutral pH cleaning (detergent) solution and place in a sonication unit.
5. Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 45-50 kHz.
6. Rinse instrument in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream.
7. Repeat steps 5 and 6 with freshly prepared cleaning solution until the instruments are thoroughly clean.
8. Dry instrument with a clean, disposable, absorbent, non-shedding wipe.

AUTOMATED CLEANING PROCEDURE

Automated washer/disinfector systems are not recommended as the sole cleaning method for complex surgical instruments. These instruments should be cleaned following the manual cleaning procedure above. An automated system may be used as a follow-up method but is not required.

Automated washer/disinfector systems are recommended for cleaning the Flow-Nail implants. For effective automated cleaning of the implant tray, remove the tray cover, remove the removable tray and place it in a covered wire basket and expose the bottom layer of the tray.

DISINFECTION

Disinfection is only acceptable as an adjunct to full sterilization for reusable surgical instruments. See sterilization section below.

INSPECTION / FUNCTION TESTING

1. Carefully inspect each instrument to ensure that there is no visible contamination and that all visible blood and soil has been removed. If visible contamination is evident, repeat the Manual Cleaning Procedure above.
2. Visually inspect for damage and/or wear, corrosion, pitting, discoloration or separation of parts. If there is any evidence of damage, do not use the instrument.
3. Check the action of moving parts (such as hinges and box-locks) to ensure smooth operation throughout the intended range of motion.
4. Check instruments with long slender features (particularly rotating instruments) for distortion.
5. When instruments form part of a larger assembly, check that the devices assemble readily with mating components.

INSPECTION / FUNCTION TESTING FAILURE

If an instrument fails inspection or a functional test due to improper cleaning, repeat the cleaning procedure. If the instrument continues to fail after repeated cleanings, discard the instrument.

If an instrument fails inspection or a functional test due to wear or damage, discard the instrument.

MAINTENANCE

Lubricate hinges, threads and other moving parts with a commercial water-based surgical grade instrument lubricant (such as instrument milk) to reduce friction and wear.

PACKAGING

1. Individually – a standard polyethylene/Tyvek (or equivalent) sterilization pouch of the appropriate size may be used for single instruments. Ensure that the pack is large enough to contain the instrument without stressing the seals or tearing the packaging.
2. In Sets – sets of instruments may be loaded into dedicated instrument trays or general purpose sterilization trays for sterilization. If applicable, use standard medical grade steam sterilization wrap following the AAMI wrap method (ANSI/AAMI ST79-2010).

STERILIZATION

The following steam sterilization method should be performed:

PROCEDURE	FRACTIONATED VACUUM PROCEDURE
Exposure Time	4 minutes
Temperature	132°C
Drying Time (Implant Tray)	30 minutes
Drying Time (Instrument Tray)	45 minutes

STORAGE

1. Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature and humidity extremes.
2. Sterile instrument packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.

STORAGE INSTRUCTIONS

Implants should be stored at room temperature.

CAUTION

Federal law restricts this device to sale by or on order of a physician.

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