# Flex-Thread™ Distal Fibula Intramedullary Nail System

## Non-Sterile Procedure Instrument Tray

**Rx Only**

**Reprocessing Instructions**

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## 1. DESCRIPTION

The Flex-Thread™ Distal Fibula Intramedullary Nail System is comprised of an intramedullary fixation device with a flexible threaded tip to engage the proximal portion of a fibula and cortical screws to further enhance stability and fixation of the fibula. The system is comprised of sterile implants and instruments for single use only. Other instruments are provided non-sterile and may be reprocessed in accordance with this document.

## 2. INDICATIONS FOR USE

The Flex-Thread™ Distal Fibula Intramedullary Nail System is intended for use in the fixation of fibula fractures and osteotomies.

## 3. HOW SUPPLIED

All implants of the Flex-Thread™ Distal Fibula Intramedullary Nail System (Flex-Thread™ Fibula System) are provided individually sterile packaged and for single use only. Certain instruments are also individually sterile packaged and for single use only. Sterile components are provided in a convenient FlowerCube™.

The instruments listed in the table below are provided non-sterile in a tray which must be sterilized prior to use and reprocessed in accordance with this document.

| | |
|---|---|
| Wires and Stabilization Sleeves | |
| 8531-1 | K-Wire, 1.6mm x 12", Trocar/Spade Tip, Flex-Thread™ |
| 8117-1 | K-Wire, 1.6mm x 8” long, Trocar Tip |
| 8804-1 | 1.6mm K-Wire Stabilization Sleeve |
| 8808-1 | 1.1mm x 22” Fracture Finger Guide Wire |
| Drivers | |
| 8555-1 | Screwdriver Shaft, T25, AO Quick Connect, Flex-Thread™ |
| Reamers and Reamer Sleeves | |
| 8527-1 | Cannulated Reamer, 6.3mm, AO Quick Connect, Flex-Thread™ |
| 8789-1 | Cannulated Reamer, 4.2mm, AO Quick Connect, Flex-Thread™ |
| 8802-1 | 3.2mm Reamer Sleeve, Tissue Protector |
| Tissue Protectors | |
| 8532-1 | Soft Tissue Protector Assembly, 1.6mm/6.3mm, Flex-Thread™ |
| 8544-1 | K-Wire Offset Sleeve, 1.6mm, Flex-Thread™ |
| Aiming Arm Assembly | |
| 8433-1 | Aiming Arm Assembly, Flex-Thread™ |
| Reduction Device Assembly | |
| 8533-1 | Reduction Device Assembly, Flex-Thread™ |
| Inserter | |
| 8435-1 | Inserter Shaft, Flex-Thread™ |
| 8439-1 | Inserter Draw Rod, Flex-Thread™ |
| 8437-1 | Inserter Handle, Ratchet, Flex-Thread™ (Blue) |
| Screw and Drill Sleeves | |
| 8534-1 | Screw Sleeve, 6.3mm, Primary, Flex-Thread™ |
| 8535-1 | Locking Wire Sleeve Assembly, 1.6/6.3, Flex-Thread™ |
| 8536-1 | Locking Drill Sleeve Assembly, 2.0/6.3, Flex-Thread™ |
| 8537-1 | Locking Drill Sleeve Assembly, 2.5/6.3, Flex-Thread™ |

| | |
|---|---|
| 8800-1 | Locking Drill Sleeve Assembly, 3.7/6.3, Flex-Thread™ |
| 8538-1 | K-Wire Offset Sleeve, Standalone, 1.6mm, Flex-Thread™ |
| Miscellaneous | |
| 8542-1 | Instrument Sterilization Tray, Flex-Thread™ |
| 8553-1 | Bone Reduction Forceps 5" curved 10mm serrated with pointed tips |
| 8548-1 | Handle, Small AO Adapter |
| 8806-1 | Fracture Finger |

## 4. MATERIAL

The non-sterile, reusable instruments are made of medical grade stainless steel and aluminum.

## 5. WARNINGS AND PRECAUTIONS

5.1. Caution should be exercised when handling instruments with sharp points or cutting/drilling edges. Anytime instruments are to be cleaned (either contaminated or potentially contaminated), personal protective equipment should be used.

5.2. Instruments should remain moistened prior to cleaning, do not allow instruments to dry.

5.3. Do not use metal brushes or scouring pads during the manual cleaning process.

5.4. Use cleaning agents with low foaming surfactants for manual cleaning to enable visualization of the instruments in the cleaning solution. The cleaning agents selected must be easily rinsed from the instrument.

5.5. Enzymatic-neutral pH cleaning solutions are recommended for cleaning reusable instruments.

5.6. Some instruments are aluminum with an anodized surface. These instruments must not come into contact with strong acidic or alkaline cleaners and disinfectants, or solutions that contain iodine or chlorine.

5.7. For exposed features (e.g., cavity preparation tool blades), saturate the crevices with copious amounts of cleaning solution to flush out any soil. Scrub the surface with a soft bristled brush to remove all visible soil from the surface and crevices. Rotate the instruments while scrubbing to ensure all surfaces and crevices are clean.

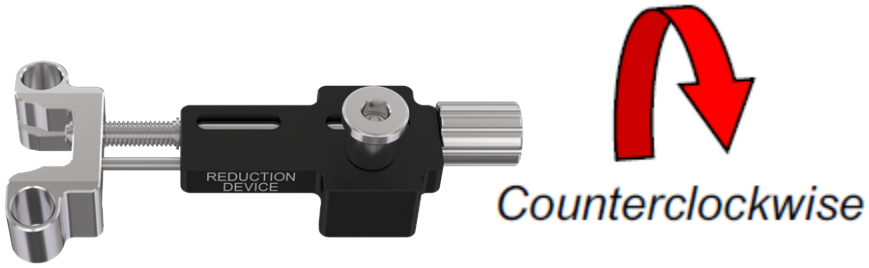
5.8. Do not use any lubricants on the instruments.

## 6. INSTRUMENT PREPARATION

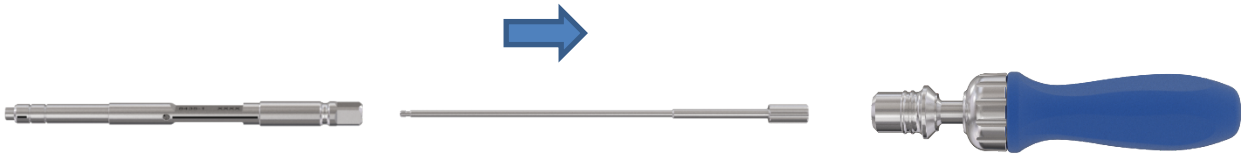
Instrument trays, cases, and lids must be cleaned separately from instruments.

Remove major contaminants in the operating room before returning the instruments to the tray. It is preferable to remove contaminants using a dry method. If contaminants are removed using a wet method, place the instruments in a prepared solution directly after they are used. The instruments must be disassembled and open as much as possible. The entire product (including grooves, holes, lumens, etc.) must be sufficiently flushed and covered with solution.


Remove and drill sleeves, drill guides, distraction device, K-wires, etc. from the aiming arm prior to cleaning and sterilization.




Remove any drill guides and K-wires used with the distraction device and put the carriage midway through travel by turning the thumb screw in the appropriate direction prior to cleaning and sterilization.



Remove the handle from draw rod/inserter shaft. Remove draw rod from inserter shaft prior to cleaning and sterilization.

## 7. INSTRUMENT CLEANING

Remove all devices from the Instrument Set. Ensure any moving parts are in the middle of their travel and NOT fully tightened. Remove any pins or wires that may be inside the cannulated instruments. Disassemble instruments as described in Section 6 above prior to cleaning. Clean the instruments after each use according to the following instructions:

1. Rinse the device under running utility water for two (2) minutes to remove visible soil. Actuate all fixture knobs and scrub with a soft-bristled brush while rinsing.
2. For cannulated instruments, flush the cannula with utility water for two (2) minutes.
3. Prepare a fresh enzymatic-neutral pH detergent (such as Enzol® Enzymatic Detergent) solution per the detergent manufacturer's recommendations and place the solution in an ultrasonic cleaner.
4. Immerse the device in the detergent solution and sonicate for twenty (20) minutes. Moving parts should NOT be completely tightened while sonicating.
5. Scrub device, including any cannulations, with a soft-bristled brush to remove any remaining debris if necessary.
6. Rinse the device with critical water for two (2) minutes. Actuate moving parts and flush all surfaces during this final rinse.
7. Dry the device with a clean, soft, lint-free cloth.
8. Automated washing may be used after manual washing is complete.
9. Examine the device under normal lighting for visible soil. If present, repeat cleaning.
10. Visually inspect under normal lighting for wear and function.
    a. Do not use an instrument if any visible wear, damage, or corrosion is identified. Contact a company representative for replacement.
    b. Do not use an instrument if it does not function as intended. Contact a company representative for replacement.
    c. The useful life of the instruments is depended upon compliance with these instructions for use.
11. Leave moving parts in the middle of their travel for sterilization.

## 8. AUTOMATED CLEANING/DISINFECTION INSTRUCTIONS

8.1. Automated washing systems are not recommended as the only cleaning method for these surgical instruments.

8.2. As previously described, an automated cleaning system may be used after manual cleaning is complete.

8.3. All surgical instruments and trays should be thoroughly inspected prior to sterilization to ensure the cleaning was effective.

## 9. STERILIZATION INSTRUCTIONS

The tray and instruments should be inspected to ensure they were thoroughly cleaned prior to sterilization. If any soil is present, they should be re-cleaned.

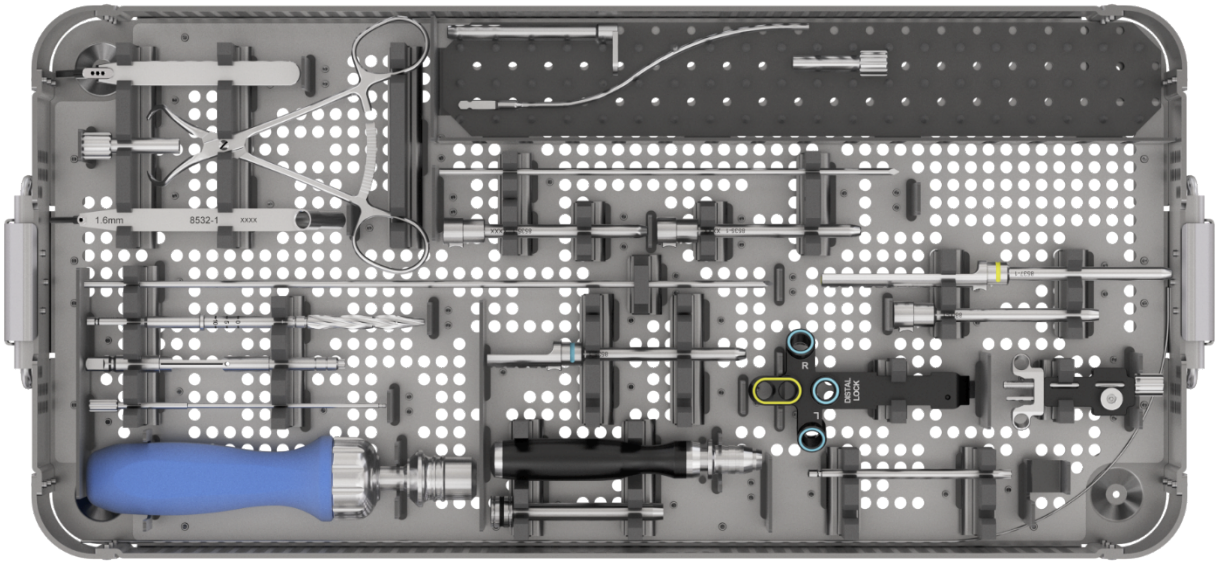
Use the provided instrument tray wrapped in FDA-cleared steam sterilization wrap. Do not stack trays during sterilization. The following sterilization parameters have been validated in FDA-cleared sterilizers and with FDA-cleared sterilization accessories.

| Cycle | Minimum Exposure Time | Minimum Temperature | Minimum Drying Time |
|---|---|---|---|
| Pre-vacuum Autoclave | 4 Minutes | 132°C | 20 Minutes |
| Pre-vacuum Autoclave | 3 Minutes | 135°C | 16 Minutes |

Other configurations and sterilization parameters may also be suitable, but the user must validate any deviation from these instructions.

## 10. INSTRUMENT SET LAYOUT

Each bracket is designed to hold a specific instrument denoted by the item's name and model number. For items that do not have a dedicated bracket, place on the pin mat in the bottom tray.



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