RetroFix Screw
Instructions for Use
Non-Sterile
Prescription Use Only
Do Not Reuse

Description and Indications for Use:

The RetroFix screw is a cannulated tapered screw intended to be used as a stand-alone bone screw for internal bone fixation for bone fractures of the ankle.

The screw shaft has a predetermined length with a cannula extending through the length of the shaft. The shaft has a relatively large outside diameter proximal segment, a smaller outside diameter threaded distal segment, and a flared end.

The proximal segment and the distal segment are unitary. The cannula is adapted for use with a surgical k-wire. The screws have cortical threads and come in many different sizes, varying in diameter and lengths. The design allows the surgeon to pick a screw in the operating room based on the size of the patient and exact position of the fracture site. The screws are tapered for better fit and compression of the fracture.

The screws are cannulated to allow the screws to be positioned accurately with the use of a guidewire (k-wire) instruments. The use of the k-wire is temporary and not intended to be implanted.

Our Titanium screws are made of TI-6AL-4V, Passivated and Anodize Color.

Contraindications:

- Patients with a history of allergy to stainless steel, nickel, or titanium
- Pediatric patients with open growth plates (epiphysis)
- Ankle fracture with significant diastasis (to be left to surgeon's judgement)
- Active Infection
- Conditions which tend to retard healing such as blood supply limitations or previous infections
- Insufficient quantity or quality of bone to permit stabilization of the fracture
- Cases with malignant primary or metastatic tumors which preclude adequate bone support or screw fixations
- Foreign-body sensitivity
- Patients who cannot follow post-operative weight-bearing restrictions

Potential Adverse Events:

The following are specific potential adverse effects, which should be understood by the surgeon and explained to the patient. These do not include all potential adverse effects, which can occur with surgery in general, but are important considerations specific to metallic internal stabilization devices. General surgical risks should be explained to the patient prior to surgery:

- Infection or adverse reactions to a foreign body
- Pain, discomfort, or abnormal sensations due to the presence of the implant
- Loosening, bending, cracking, or fracture of the components or loss of fixation of bone attributable to nonunion, osteoporosis, markedly unstable comminuted fractures; loss of anatomic position with nonunion or malunion with rotation or angulation
- Migration of the implant, loosening of the implant
- Delayed correction in alignment
- Decrease in bone density due to stress shielding

Warnings and Precautions:

All devices in this range must be implanted using specific instruments designed for the purpose. In no circumstances should any combination with other devices of a different brand be used. An implant must never be reused. Previous stresses may have created imperfections that can potentially lead to device failure. Protect implants against scratching or nicking. Such stress concentration can lead to failure. Orthopedic instrumentation does not have an indefinite functional life. All re-usable instruments are subjected to repeated stresses related to bone contact, impaction, routine cleaning and sterilization processes. Instruments should be carefully inspected before each use to ensure that they are fully functional. Scratches or dents can result in breakage. Dullness of cutting edges can result in poor functionality. Damaged instruments should be replaced to prevent potential patient injury such as metal fragments into the surgical site. Care should be taken to remove any debris, tissue or bone fragments that may collect on the instrument. Many instruments are intended for use with a specific implant system. It is essential that the surgeon and operating theatre staff are fully conversant with the appropriate surgical technique for the instruments and associated implant, if any.

DO NOT permanently implant K-wires. Use of the K-wires allows you to provisionally secure the screw to the anatomy.

For safe and effective use of this implant system, the surgeon should be familiar with the recommended surgical procedure for this device. In every case, accepted surgical practices should be followed in pre- and post-operative care. 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 bend or cut them.

Single-Use Device:

Products like the RetroFix screws intended for single-use must not be re-used. Contaminated implants must not be reprocessed. Any implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Instruments and Implants Provided Non-Sterile:

The RetroFix screws and accessories are supplied non-sterile must be thoroughly cleaned and steam-sterilized prior to surgical use. Thoroughly clean the sterilization trays, visually inspect, and clean again if needed. Do not stack trays during sterilization.

Cleaning:

Cleaning: Automated

1. Pre-rinse devices under warm, running, potable tap water for two (2) minutes to remove gross debris.

2. Completely submerge the instruments in an ultrasonic cleaning bath filled with enzymatic detergent solution and ultrasonicate for ten (10) minutes.

3. Remove any remaining debris from crevices using a cleaning brush. Pay close attention to threads, crevices, seams, lumens, and any hard-to-reach areas. Actuate any moveable mechanisms, such as hinged joints, box locks, or spring-loaded features to free trapped soil. If the components of the device can be retracted, retract or open the part while cleaning the area. Bend or flex devices with flexible shafts under the cleaning solution while brushing the flexing areas. Clean lumens with a long, narrow, soft-bristled brush.

4. Place the devices in a wire mesh basket and process within a mechanical washer using the following validation parameters:

Treatment	Time (mm:ss)	Temperature	Cleaning Solution
Enzymatic Wash	04:00	60°C	Enzyme Presoak and Cleaner
Wash	02:00	Warm Tap Water	Neutral Detergent
Rinse	02:00	70°C	N/A
Dry	15:00	80°C	N/A

5. Visually inspect the devices. Repeat cleaning if visible soil remains.

It is recommended that devices should be reprocessed as soon as is reasonably practical following use. Any devices with corrosion or discoloration should be disposed of properly.

Sterilization:

The following parameters have been validated to a sterility assurance level (SAL) of $\leq 10^{-6}$:

Method	Steam
Cycle Type	Pre-Vacuum
Temperature	132ºC
Full Cycle Time	4 minutes
Dry Time	30 minutes

Other sterilization methods have not been validated and may damage the product resulting in a device malfunction, injury to the patient, or both. FDA-cleared wraps should be utilized for steam sterilization.

Magnetic Resonance Environment:

The RetroFix Screw has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the RetroFix Screw in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Storage:

Do not store in a damp environment. Keep implants covered until needed. Prior to use, inspect product for signs of damage or contamination. In the operating room and during transport, keep implants separate from contaminated instruments or implants.

Disposal:

Dispose of implants according to facility protocol.

Manufacturer:

Retrofix Screws
1035 Lincolnton Road
Salisbury, NC 28144
1-980-432-8412
Toll free 1-877-226-8147