Pro-X1™ TROCHANTERIC NAILING SYSTEM

Manufacturer:
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EN	ALL OF THESE INSTRUCTIONS FOR USE MUST BE READ CAREFULLY PRIOR TO CLINCAL USE

Instructions for Use Non-Active Implant

DEVICE DESCRIPTION

The X-BOLT® is a bone fixation device, comprising of an inner drive shaft and an outer sleeve with an expandable section. Rotation of the inner shaft compresses the expandable section at both ends, causing radial expansion of the expandable wings. A set-screw prevents rotation of the X-BOLT® in the nail during this expansion step. Expansion is also reversible, if necessary.
All implants in the Pro-X1™ Trochanteric Nailing System including nails, X-Bolts and screws are made from Grade 23 Titanium Alloy (Ti6Al4V-ELI) in accordance with ASTM and/or ISO standards. The inner drive screw of the X-Bolt is coated with Parylene-C to reduce friction.
For implant sizing and product reference codes please refer to specific surgical technique brochure. The implants and consumables are provided as single sterile packed units. Reusable instruments are provided in a dedicated sterilization tray.

SPECIAL NOTE

Fracture fixation devices are used only as an aid to healing; they are not a substitute for normal intact tissue or bone. The anatomy of human bones presents limitations with respect to the size or thickness of bone screws and thus the strength of implants is limited. With repeated stress in patients with delayed healing or non-union, the appliance may bend, break or pull out of bone. Use only components made from the same material together. Components from different manufacturers should not be mixed. All implantable devices are designed for single use only.
Ensure familiarity with the intended uses, indications / contraindications, compatibility and correct handling of the implant, as covered in the specific operative technique brochure.

INDICATIONS

The Pro-X1™ Trochanteric Nailing System is intended for use in fracture fixation in the femur in adults with osteopenia or osteoporosis and is also indicated for use in:

- Intertrochanteric and subtrochanteric fractures
- Segmental fractures
- Comminuted fractures
- Pathological fractures
- Fractures with bone loss
- Pseudoarthrosis, non-union, mal-union, and delayed union
- Surgically created defects such as osteotomies

CONTRAINDICATIONS

- Physical conditions that would preclude adequate implant support or retard healing such as blood supply impairment, insufficient bone quality or quantity, infection or gross distortion of the femur.
- Conditions which prevent full expansion of the X-BOLT® (osteonecrosis, Paget's disease, osteopetrosis).
- Mental conditions that preclude cooperation with the rehabilitation regimen.
- Use in pediatric patients.
- Known or suspected sensitivity to metal and/or Parylene-C. Although rare, sensitivity reactions and/or allergic reactions to foreign materials may occur. When sensitivity is anticipated, appropriate pre-operative testing should be conducted.
- Re-expansion of the X-BOLT® following reversal of expansion may lead to product failure. Discard X-BOLT® if full expansion has been reversed.
- Connection with other metallic materials of different chemical composition, due to the possibility of electrolytic action and posterior corrosion.
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fracture fixation and/or the device itself.
- Other medical or surgical issues that would preclude the potential benefit of the surgery.

WARNINGS

- These devices are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- All implantable devices are designed for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn may result in deterioration of health or death of patients or users. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection, including but not limited to the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- The correct selection of device components is extremely important. The appropriate type and size should be selected for the patient. Failure to use the correct components or improper positioning, as described in the surgical technique, may result in loosening, bending, cracking, or fracture of the device, bone or both.
- Because of unbalanced muscle forces, extreme loads are placed on implants, substantially reducing the chance of fracture healing with bending or breaking implant components. Additional precautions and internal or external supports should be utilized to enhance the stability of the fracture and to minimize internal stress loading of the implant and broken bone until solid bony union is evident by radiograph. Supplementary procedures such as bone graft or medial displacement osteotomy may also be considered.
- The expandable portion of the X-BOLT® should not engage the fracture line. The X-BOLT® should be long enough to permit telescopic sliding in the event of resorption of the fracture surface.
- Do not expose to heat or extreme cold.

MRI STATUS

The Pro-X1™ Trochanteric Nailing System 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 Pro-X1™ Trochanteric Nailing System 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.

PRECAUTIONS

- Surgeon should make a determination of bone quality based on patient history and fracture pattern to confirm that the bone in the femoral head is osteopenic or osteoporotic.
- If the Bone Crusher is unable to deploy (expand), as confirmed by tactile feedback, the X-BOLT® should not be implanted and an alternative method of fixation should be used.
- Use extreme care in handling and storing implant components. Cutting, bending or scratching the surface of metal components can cause internal stresses which significantly reduce strength and fatigue resistance.
- Continuous screening with an image intensifier (fluoroscopy) during guidewire insertion and whatever cannulated instruments are advanced over a guidewire is recommended to prevent unintended guidewire advancement and penetration into the surrounding areas.
- Intra-operative cleaning of cannulated instruments is recommended to prevent the accumulation of bone debris within the cannulation.
- Postoperative instructions to patients and appropriate nursing care teams are critical. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending or breaking the device. Early weight bearing should only be considered where there are stable fractures with good bone-to-bone contact.
- The surgeon should familiarise themselves with the devices, instruments and surgical technique prior to surgery.

ADVERSE EFFECTS

- Delayed union or non-union of the fracture site.
- Conditions attributable to non-union, osteoporosis, osteomalicia, diabetes, inhibited revascularisation, and poor bone formation can cause loosening, bending, cracking or fracture of implant components.
- Infections, both deep and superficial, may occur.
- Vascular disorders including thrombophlebitis, pulmonary emboli, wound hematomas, and avascular necrosis of the femoral head may result from the surgery and concomitant use of internal fixation devices.
- Leg length discrepancies and subsequent patient limp may occur.
- X-BOLT® cutting through the femoral head (usually associated with osteoporotic bone), penetration of the joint by an X-BOLT® with or without chondrolysis, and failure of an X-BOLT® to slide in the nail, may occur especially with improper X-BOLT® implant assembly and/or surgical technique.
- Penetration of a guide wire/screw into the pelvis may occur.
- Tissue reactions which include macrophage and foreign body reactions adjacent to implants may occur.

REMOVAL AND DISPOSAL OF THE X-BOLT®

Refer to the surgical technique for removal instructions of the X-BOLT® and the hip fracture fixation system. Implants are disposed of as per regional/national guidelines.

STERILIZATION/RESTERILIZATION

All implants are supplied sterile and have been packaged in protective packaging. Do not use if packaging has been damaged as device may not be sterile. All implants have been sterilized using gamma radiation and have been exposed to a minimum of 25 kiloGrays of gamma radiation.

INFORMATION

For further details relating to surgical technique, please refer to the X-BOLT® surgical technique, which can be found at the company's website (www.x-bolt.com). For any further information regarding the X-BOLT® please contact your local X-BOLT® Orthopedics distributor**.**

Explanation of symbols and abbreviations used on product labels:

REF	Catalogue Number
LOT	Batch Code
QTY	Quantity
R_x ONLY	Federal Law in the USA restricts the device to sale by or on the order of a physician
	Do not use if package is damaged
	Keep Dry
	Use by Date
	Date of Manufacture
	Manufacturer
	Consult Instructions for use
STERILE R	Sterilized using Irradiation
	Do Not Re-Use
	Single sterile barrier
Ti ALLOY	Titanium Alloy
MD	Medical Device