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Description	Instruction For Use, Axi+Line, English
Notes	N/A

Revision History

Rev	Effective Date	Summary of Change	DCO#	Author
00	2/23/16	Initial Release	15-076	S. Hartle
01	3/11/16	Added statement if product was re-used.	16-020	S. Hartle
02	8/24/17	Added new Emergo Address	17-082	S. Hartle

Sterile Implants & Instruments

Instructions for Use

Axi+Line™
Proximal Bunion Correction System

Please read this information carefully before using the Axi+Line™ Proximal Bunion Correction System

DESCRIPTION

The Axi+Line™ Proximal Bunion Correction System consists of a sterile multi component bone fixation implant (Proximal Bunion Plate, Locking and Non Locking screws) and a set of accessory instruments designed for preparation of the implant site, and insertion of devices into the bone. The plates and screws are all packaged individually in separate packaging.

SYSTEM COMPONENTS

Axi+Line™ Proximal Bunion Plate: Implantable Ti-6Al-4V ELI
Non Locking Screw: Implantable Ti-6Al-4V ELI
Locking Screw: Implantable Ti-6Al-4V ELI
Instrument Kit: Polycarbonate and surgical grade stainless steel

INDICATIONS FOR USE

The Nextremity Solutions® Axi+Line™ Proximal Bunion Correction System is indicated for fixation of fractures, osteotomies, non-unions and fusions of small bones and small bone segments in the foot and ankle.

CONTRAINDICATIONS

1. Patient conditions including insufficient quantity or quality of bone.
2. Blood supply limitations and previous or active infections that may inhibit healing.
3. Surgical procedures other than for the indications listed.
4. Patients with conditions that limit their ability or willingness to follow postoperative care instructions.
5. The device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature.
6. Foreign-body sensitivity. Where material sensitivity is suspected, appropriate test should be made and sensitivity ruled out prior to implantation.

WARNINGS

This device should only be used by physicians with training in and a thorough understanding of orthopaedic surgery.

1. The Axi+Line™ Proximal Bunion Correction System is for SINGLE USE ONLY. DO NOT RESTERILIZE OR REUSE
2. The Axi+Line™ Proximal Bunion Correction System has not been tested to withstand the forces needed for partial or full weight bearing or excessive activity until healing has occurred. The post-op regimen prescribed by the physician should be strictly followed to avoid stresses applied to the implant. Weight-bearing post operatively should be at the discretion of the surgeon.
3. Do not use if the implants or instruments appear damaged upon inspection.
4. Do not use in conjunction with implants of other metallic alloys.
5. Any decision to remove the device should take into consideration the potential risk to the patient.
6. The Axi+Line™ Proximal Bunion Correction System has not been evaluated for safety and compatibility on the MR environment. The Axi+Line™ Proximal Bunion Correction System has not been tested for heating or migration in the MR environment.
7. The Axi+Line™ Proximal Bunion Correction System must be used only with provided insertion instruments.

CAUTIONS

1. Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. A detailed surgical technique in print and/or electronic formats can be obtained by contacting a Nextremity Solutions® sales representative or found online at www.nextremitysolutions.com/Axiline.
2. Surgical instruments should only be used for their intended purpose.

POTENTIAL ADVERSE EFFECTS

1. Infection, deep and superficial
2. Foreign body reactions
3. Nonunion or delayed union which may lead to breakage of the implant
4. Bending or fracture of implant
5. Loosening or migration of the implant
6. Nerve damage due to surgical trauma
7. Inadequate healing
8. Pain, soft tissue discomfort or abnormal sensation due to the presence of the device

PREPARATION PRIOR TO USE

1. Inspect product for damage. Do not use if the product is damaged.
2. Users of this system are encouraged to contact their Nextremity Solutions® representative if, in their professional judgment, they require a more comprehensive explanation of the surgical technique to be used with this device.
3. Insure that the patient is an appropriate candidate for the intended procedure based on the Indications, Contraindications, Warnings and Precautions listed above.
4. Weight-bearing post operatively should be at the discretion of the surgeon.

DIRECTIONS FOR USE

WARNING: Use only the insertion instruments provided

1. Select left or right Instrument Kit based on operative foot. From preoperative images, select appropriate plate angulation. Prepare site using standard surgical techniques. A typical approach involves an incision just distal to the tarsal metatarsal joint medially to the interphalangeal joint.
2. Place Osteotomy Guide on bone. Align center ridge on Guide with transverse plane of medial aspect of bone. Location should be approximately 1 cm distal of tarsal metatarsal joint.
3. Place a Threaded Wire through proximal wire hole, advancing through two cortices. Maintaining force to hold Guide on bone, place a second Threaded Wire through the distal hole in the Guide. Advance through both cortices. Guide should be held tightly to bone.
4. Place a K-Wire through the three holes, advancing through two cortices. Remove K-Wire. Remove Bushing from Guide using Hex Driver. Remove Guide.
5. Saw through bone along path defined by K-Wire holes.
    a. A secondary plantar cut is optional, depending on bone geometry.
6. Place Plate over Threaded Wires. Place Nuts on each Threaded Wire. Hold Plate to bone as to assist reduction, and advance Nuts in increments using Hex Driver until they are fully seated. Do not over tighten. Reduction should be complete. Verify position of toe is as desired.
7. Secure Plate with Screws. Place Screws in the following order: most proximal, crossing, open distal. Thread Drill Guide into hole using Hex Driver and drill through both cortices. Remove Drill Guide and select appropriate screw size using Depth Gauge. Non-locking Screws are recommended for the first three screws placed for best reduction.
8. Remove Threaded Wires and Nuts. Place the remaining screws using above technique. Locking or Non-Locking screws can be used depending on surgeon preference.

<u>Optional device removal: In the event the device needs to be removed after placement has been completed.</u>

1. Use the driver to carefully remove the screws from the bone.
2. Upon removal of the screws gently remove the Axi+Line™ Proximal Bunion Correction System from the bone with the use of osteotomies.

CAUTION: IF THE DEVICE MUST BE REMOVED, DO NOT REUSE ANY PORTION OF THE DEVICE.

HOW SUPPLIED

The Axi+Line™ Proximal Bunion Correction Plates and Screws are individually sterile packaged. A dedicated Axi+Line™ Instrument Kit is sterile packaged. The components of the Axi+Line™ Proximal Bunion Correction System are for single use only. DO NOT RE-STERILIZE. DO NOT REUSE. If product is re-used it may cause infection and may compromise the mechanical integrity of the product which may lead to failure.

STORAGE AND HANDLING

Store in a cool, dry place and in a manner that protects the integrity of the packaging of all implants and instruments.

PACKAGING AND LABELING

1. Nextremity Solutions® devices should be accepted only if the factory packaging and labeling arrive intact.
2. Contact Customer Service if the package has been opened or altered.

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

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