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ENGLISH

Instruction leaflet - Please read prior to use

ORTHOFIX®
ANKLE COMPRESSION NAILING SYSTEM

RX ONLY

⚠ Attention, see instructions for use PQ ACN, PQ IOP.

Limitations and restrictions on reprocessing
PRODUCTS LABELED FOR SINGLE-USE MUST NOT BE REUSED. Repeated reprocessing has minimal effect on reusable instruments. End of life is normally determined by wear and damage due to use.

INDICATIONS
The Orthofix Ankle Compression Nailing System is intended to facilitate tibiotalocalcaneal arthrodesis (fusion). Specific indications include:
1. Avascular necrosis of the talus
2. Failed total ankle arthroplasty
3. Trauma (malunited tibial pilon fracture)
4. Severe deformity or instability as a result of talipes equinovarus, cerebral vascular accident, paralysis or other neuromuscular disease
5. Revision ankle arthrodesis
6. Neuroarthropathy
7. Rheumatoid arthritis
8. Osteoarthritis
9. Pseudarthrosis
10. Post-traumatic arthrosis
11. Previously infected arthrosis
12. Charcot foot
13. Severe end-stage degenerative arthritis
14. Severe defects after tumor resection
15. Pantalar arthrodesis

DESCRIPTION
The Orthofix Ankle Compression Nailing System consists of Intramedullary Nailing Implants with respective end-caps, locking screws. These implants are not intended to replace normal healthy bone. Loads produced by weight bearing and activity levels will dictate the longevity of the implant. The patient should understand that stress on an implant can be produced without actual weight bearing. In the absence of solid bony union, the weight of the limb alone, muscular forces associated with moving a limb, or repeated stresses of apparent relatively small magnitude, can result in failure of the implant. Therefore, the patient should follow the postoperative instructions given by the surgeon.
The product is intended for professional use only. Surgeons who supervise the use of the product must have full awareness of orthopedic fixation procedures and should have received adequate training in the use of the product. Prior to surgery, surgeons should be familiar with the devices, instruments and surgical procedure, including the application and removal. Detailed operative technique guidance is available on request; please contact Orthofix or your local distributor.

CONTRAINDICATIONS
The Orthofix Ankle Compression Nailing System is not designed or sold for any use except as indicated. Use of the Intramedullary Nailing Implants is contraindicated in the following situations:
1. Active or latent infection in the affected area.
2. General medical conditions including: impaired blood supply, pulmonary insufficiency (i.e. ARDS, fat embolism)- and insufficient quantity or quality of bone.
3. Patients who are unwilling or incapable of following post-operative care instructions.
4. Suspected or documented metal allergy or intolerance.
5. Severe longitudinal deformity
6. Insufficient plantar heel pad
7. Situations where an isolated ankle or subtalar fusion can be performed
8. Dysvascular limb

GENERAL WARNINGS
1. Processing and re-processing of instrumentation should be performed according to the dedicated leaflet PQ IOP.
2. Ensure that all components needed for the operation are available and fully functional in the operating theatre before surgery. Perform targeting and functional control before the insertion of the nail as well to avoid nail damage during drilling operation.
3. Implants, nail end caps, locking screws as well as certain parts of the instrumentation (where indicated on the label), are for single use only and must never be reused. If any implant has come into contact with any body fluid it should be considered to have been used.
4. Smoking, chronic steroid use and the use of other anti-inflammatory drugs have been shown to affect bone healing and could potentially have an adverse effect on bone repair during fracture healing.
5. Components of this device are not approved for screw attachment to the posterior elements of the cervical, thoracic, or lumbar spine.
6. Implants can loosen, fracture, corrode, migrate, or cause pain. If an implant remains implanted after complete healing, the implant may cause stress shielding, which may increase the risk of refracture in an active patient. The surgeon should weigh the risks verses benefits when deciding whether to remove the implant. Adequate postoperative management to avoid refracture should follow implant removal.
7. MRI safety not tested.

GENERAL PRECAUTIONS
1. Implants are made of titanium alloy. Do not use with implants of dissimilar metals, since this may cause an electrolytic reaction.
2. Do not use components of the Orthofix nailing system in conjunction with products of other manufacturers, unless otherwise specified.
3. Care should be used in the handling and storage of the components. The implants should not be scratched, notched or otherwise damaged as these may reduce the functional strength of the component. Contours or bending of an implant should be avoided.
4. All components should be carefully examined prior to use. Product integrity, sterility (in the case of sterile products) and performance are assured only if the packaging is undamaged. DO NOT USE if packaging is compromised or if a component is believed to be faulty, damaged or suspect.
5. It is suggested to verify all the system assembly prior to the implantation.
6. Correct selection of the implant size is extremely important. The appropriate size should be selected for the patient. Failure to use the correct components or their improper positioning may result in loosening, bending, cracking, or fracture of the device or bone or both. The X-Ray Ruler should be used to determine the appropriate nail diameter and length in order to ensure the nail does not protrude from the base of the calcaneus and cause pain.
7. Care should be taken to attach all components correctly, ensuring that any location marks correspond, and locking them securely. It is important to check that the required joint between instrument remain firmly fixed during the procedure.
8. Protect the plantar neurovascular structures, both in the dissection and during the procedure, as these structures are at risk. Joint exposure and preparation is required.
9. Targeting devices: Alignment of the Talar Screw should be checked to confirm the position of the internal mechanism. For alignment check ensure that all holes in the nail are properly targeted by the appropriate Targeting Assembly. If both PA and LM screws will be used in calcaneus or talus, swing the Distal Targeting Assembly to both PA and LM positions and ensure proper targeting. Ensure all holes are targeted properly before drilling the hole. As with any targeting device, success depends on many factors and cannot be guaranteed in all cases. A free hand technique can be used alternatively. Use fluoroscopy to ensure that drill has properly targeted the nail.
10. The length of locking screws should be determined by using the Drill Guide pressed firmly against the cortex and reading the appropriate screw length directly from the calibrations on the 4.3mm Calibrated Drill, or by using the Long Depth Gauge through the Screw Guide.
11. At least one locking screw should be inserted in each bone segment (tibia, talus, calcaneus). Provide adequate countersink for threaded head screws and low profile screws if inserted in the calcaneus to avoid soft tissue damage.
12. When locking screws are inserted, care should be taken not to penetrate the articular surface.
13. Surgeon must use care during oblique screw placement as the oblique mechanism allows up to 10 degrees of angulation. Surgeon must be careful to not hit other calcaneal or talar screws when using this oblique screw.
14. It is important that the locking screws are not inserted close to the fracture line, as effective screw fixation may be compromised, causing implant or fixation failure. In very distal fractures, it is important to ensure that the more proximal of the distal locking screws is at least 1 cm distal to the fracture line.
15. There should never be an empty locking hole between locking screws and the fracture, nor at the fracture site. Care should be taken to use locking screws of correct diameter, length and type.
16. Threaded head screws are intended to be used in the calcaneus.
17. Nails are inserted with or without reaming, depending on nail diameter (1-1,5 mm more than nail diameter), patient, fracture type and bone diameter and quality. This decision is up to the operating surgeon.
18. Countersink the nail 5.0mm-10mm to allow for desired compression. This also prevents painful prominence in plantar soft tissue. NOTE: To avoid excessive penetration of the drill bit and subsequent loss of "working" threads, check that the colored mark on the drill bit 6.1 is not hidden by the soft tissue sleeve while countersinking for screw head. Use fluoroscopy to ensure that drill does not hit the ML screws already inserted into the nail.
19. Use of end cap is mandatory to avoid bone ingrowth and to lock calcaneal screws. The length of the end caps should be chosen carefully, in order to avoid protrusion from the calcaneus.
20. Hammering of the nails may only be performed through the locking rods or with specifically designed insertion tools. Hammering should always be gentle; vigorous hammering should never be necessary. The surgeon should never persist with hammering if the implant is not advancing, but should review the situation, and consider further reaming or, if this is not possible, a smaller implant.
21. Cannulated instruments should be inspected prior to use to confirm that the lumen is free from obstruction. The correctly sized K-wire should be passed through it, to check that it slides easily, before and after each use.
22. It is recommended that all wires that are used to guide cannulated instruments or implants should be single patient use only. Prior to any use, they should be checked and should be discarded if found to be scratched or bent.
23. During the introduction of any instrument or implant over a wire, the wire tip should be screened, using fluoroscopy, as continuously as possible to exclude inadvertently driving the wire further than intended. This is particularly important when the wires are pointing towards potentially dangerous locations. The surgeon should check that there is no bony or other debris built up on the wire or inside the instrument or implant which might cause it to bind on the wire and push it forward.
24. After the procedure, check that fracture reduction and the position of all implants are correct using the image intensifier.
25. Tibiotalar compression, up to 7mm, may be achieved with the internal compression mechanism and should be monitored with fluoroscopy. When necessary, external compression can be applied. Once the Heel Cup is in contact with soft tissue, care should be taken to monitor (using fluoroscopy) the amount of compression applied to avoid collapse of the joint and avoid soft tissue impingement.
26. General advice on weightbearing (unless otherwise specified): full weightbearing can be commenced when there is radiological evidence of bridging callus. Where there is good contact between the two intact segments of bone, so that load sharing can be anticipated, early weightbearing as tolerated should be encouraged. When the bone is comminuted or there is bone loss, so that load sharing will not be possible until callus is formed, weightbearing should be partial only initially. The exact amount of load to be carried depends on the size of implant inserted and the stature of the patient. Hip and knee mobility should always be encouraged within the pain limits. However, the best clinical results are obtained by encouraging early

mobility and full weightbearing as tolerated as early as possible and according to the patient's condition.

27. Careful monitoring of the progress of healing must be undertaken in all patients. If callus is slow to develop, other measures may be required to promote its formation, such as dynamisation of the implant, a bone graft, or replacing the implant.
28. Additional equipment may be required for fixation application and removal such as soft tissue retractors, flexible reaming set, cannulated drills, etc.
29. Patients should be instructed to report any adverse or unanticipated effects to the treating surgeon.

30. Before inserting the Slotted Hammer Adaptor, for proper nail removal unlock the talar screw by inserting and turning the Locking Driver (177301) counterclockwise and, if necessary, release the internal compression mechanism by inserting and turning the Compression Driver (177305) counterclockwise. To remove the nail, insert the Adaptor before removing all the screws. If broken screws are needed to be removed, use the vise grips.
31. It is essential that the proper Operative Technique be followed for Orthofix Ankle Hindfoot Nailing (AHN) System implantation. Refer to the Orthofix Ankle Hindfoot Nailing (AHN) System Operative Technique.

POSSIBLE ADVERSE EFFECTS

1. Loosening, bending or breakage of implanted components.
2. Loss of anatomic positioning with malunion.
3. Scar formation possibly causing pain and/or neurological compromises around nerves.
4. Intrinsic risks associated with anesthesia and surgery. Hemorrhage, hematoma, seroma, embolism, edema, stroke excessive bleeding, phlebitis, wound or bone necrosis, wound infection or damage to blood vessels or nerves.
5. Non-union or delayed union, which may lead to implant breakage.
6. Metal sensitivity, or allergic reaction to a foreign body.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.

IMPORTANT

A successful result is not achieved in every surgical case.
Additional complications may develop at any time due to improper use, medical reasons or device failure that require surgical re-intervention to remove or replace the internal fixation device.
Preoperative and operative procedures including knowledge of surgical techniques and proper selection and placement of the device are important considerations in the successful utilization of the devices by the surgeon.
Proper patient selection and the patient's ability to comply with physician instructions and follow the prescribed treatment regimen will greatly affect the results. It is important to screen patients and select optimal therapy given physical and/or mental activity requirements and/or limitations. If a surgical candidate exhibits any contraindication or is predisposed to any contraindication, DO NOT USE the Orthofix Ankle Compression Nailing System.

MATERIALS

The Orthofix Ankle Compression Nailing System is comprised of implantable titanium parts while the instrumentation is made of stainless steel or aluminum alloy and plastic. Those components of the instrumentation that come into contact with patients are made of surgical grade stainless steel or plastic.

STERILITY

All implantable components of the Orthofix Ankle Compression Nailing System are supplied STERILE. The instrumentation is supplied NON-STERILE (except two guide wires which are gamma sterilized and provided in sterile packaging) and requires cleaning and sterilization prior to use, following the respective recommended procedures. Please review the product label to determine the sterility of each device.

INSTRUCTIONS FOR PROCESSING NEW DEVICES SUPPLIED "NON-STERILE" PRIOR TO THEIR FIRST USE

A new product means any device taken out of its original Orthofix packaging. These products must be removed from their original packaging, cleaned and sterilized according to the Instructions for the safe processing of the Orthofix Ankle Compression Nailing System PQ IOP.

Information on cleaning and sterilization of reusableinstrumentation can be found in the Orthofix PQ IOP,supplied with the instrumentation.

RISKS DUE TO THE RE-USE OF "SINGLE USE" DEVICE

IMPLANTABLE DEVICE*

The "SINGLE USE" implantable device* of Orthofix is identified through symbol ⊗ reported on the product label. After the removal from the patient, the implantable device* has to be dismantled.
The re-use of implantable device* introduces contamination risks for users and patients.
The re-use of implantable device* can not guarantee the original mechanical and functional performances, compromising the effectiveness of the products and introducing health risks for the patients.

(*): Implantable device
Any device which is intended:
Any device intended to be totally / partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also
considered an implantable device.

NON IMPLANTABLE DEVICE

The "SINGLE USE" non implantable device of Orthofix is identified through symbol ⊗ reported on the label or are indicated in the "Istructions For Use" supplied with the products.
The re-use of "SINGLE USE" non implantable device can not guarantee the original mechanical and functional performances, compromising the effectiveness of the products and introducing health risks for the patients.

INFORMATION

For further information please contact your local representative or call 800.266.3349 (within US) or +39 0456719000 (Customer Service International, outside US).

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

SYMBOL

	See instructions for use PQ ACN - PQ IOP
⊗	Single use. Do not reuse
STERILE EO	STERILE. Sterilised with ethylene oxide
STERILE R	STERILE. Sterilised by irradiaton
NON STERILE	NON STERILE
REF	Catalogue number
LOT	Lot number
	Expiry date (year-month)
CE 0123	Ce marking in conformity to MDD 93/42/ECC as amended by 2007/47/EC
	Date of manufacture/Manufacturer
	Do not use if package is opened or damaged