INTEGRA®

Panta® 2

Arthrodesis Nail System

Instructions for Use

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Arthrodesis Nail System

Instructions for Use

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

Description
The Panta® 2 Arthrodesis Nail System consists of a fusion nail, interlocking screws and an optional end cap. The nails are available in 10, 11, 12 and 13mm diameters and 150, 180, 210 and 240mm lengths. They have holes to accommodate the interlocking screws on either side of the symptomatic joint.

The interlocking screws reduce the likelihood of shortening and rotation at the fusion site. Two types are available: fully threaded screws (23mm - 110mm) and partially threaded (45mm - 110mm) screws.

The end cap is designed to sit flush with the distal end of the nail and can be used to lock the distal calcaneal screw to the nail when the partially threaded screw option is used.

The Panta 2 Arthrodesis Nail System implants (nail, screws and end cap) are made from Titanium alloy (Ti-6Al-4V ELI) according to ASTM F136. These devices do not contain phthalates unless this is indicated on the label.

Magnetic Resonance (MR) Statement
The Panta 2 Arthrodesis Nail System 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 Panta 2 Arthrodesis Nail System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Indications
The Panta 2 Arthrodesis Nail System is intended for use in tibiotalocalcaneal arthrodesis and treatment of trauma to the hindfoot and distal tibia. Indications include:

- Post-traumatic and degenerative arthritis involving both ankle and subtalar joints
- Rheumatoid arthritis
- Revision of failed ankle arthrodesis with subtalar involvement or with insufficient talar body
- Revision of failed total ankle arthroplasty with subtalar intrusion
- Talar deficiency conditions (requiring a tibiocalcaneal arthrodesis)
- Avascular necrosis of the talus
- Neuroarthropathy or neuropathic ankle deformity
- Severe deformity as a result of talipes equinovarus, cerebral vascular accident, paralysis or other neuromuscular disease
- Severe pilon fractures with trauma to the subtalar joint

Contraindications

The implant should not be used in a patient who has currently, or who has a history of:

- Intact asymptomatic subtalar joint
- Active local or systemic infection
- Severe peripheral vascular disease
- Severe longitudinal deformity
- Insufficient quantity or quality of bone to permit stabilization of the arthrodesis
- Obliterated medullary canal or other conditions which tend to retard healing such as blood supply limitations and/or previous infections
- Conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process
- Insufficient plantar pad
- Suspected or documented metal allergy or intolerance

Warnings

Serious post-operative complications may occur from use of the implant in a patient who:

- Lacks good general physical condition
- Has severe osteoporosis
- Demonstrates physiologic or anatomic anomalies
- Has immunological responses, sensitization, or hypersensitivity to foreign materials
- Has systemic or metabolic disorders

These implants are intended as a guide to normal healing and are not intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing. Load bearing or weight bearing in the presence of a delayed union or non-union may eventually contribute to or cause implant breakage due to metal fatigue.

Precautions

Physician must determine if the implant is appropriate for patients who have any of the following conditions:

- Drug and/or alcohol and/or smoke addiction and/or abuse
- Infectious disease
- Malignancy
- Local bone tumors
- Compromised wound healing
- Obesity
- Demonstrated psychological instability, displayed a lack of understanding, inappropriate motivation, or attitude
- Unwillingness to accept the possibility of multiple surgeries for revision or replacement
- Lacks an understanding that a metallic implant is not as strong as normal healthy bone and will bend, loosen, or fracture if excessive demand is placed on it
- Lacks an understanding that their preoperative capacity may not be fully recovered even after successful implantation

Knowledge of surgical techniques, proper reduction, selection and placement of implants, and post-operative patient management are considerations essential to a successful outcome.

Criteria for patient selection are the responsibility of the surgeon. Information contained within this document should be taken into consideration during the selection process. Recognition of the appropriate indications and contraindications and the selection of the proper surgical procedures and techniques determined to be best for the patient are the responsibility of the surgeon. Each surgeon must evaluate the appropriateness of the procedure and instruments used during the procedure based on his or her own training and experience.

The surgeon should discuss with the patient prior to surgery possible risks, precautions, warnings, consequences, complications, and adverse reactions associated with the surgical procedure and implantation of the device.

Each patient must be evaluated by the surgeon to determine the specific risk/benefit relationship in light of the patient's condition and the surgeon's practice, training, experience, and knowledge of the related medical literature.

Adverse Effects

Complications with the use of intramedullary nails have been reported in the medical literature. Any patient undergoing a surgical procedure is subject to intra-operative and post-operative complications.

Each patient's tolerance to surgery, medication, and implantation of a foreign object may be different. Possible risks, adverse reactions, and complications associated with surgery and the use of orthopedic implants should be discussed with and understood by the patient prior to surgery. The implant is made from Titanium alloy; therefore, it is subject to possible reactions and complications, including those listed herein. The patient should not be led to unrealistic expectations as to the performance or results that the surgery and implant can provide. The patient should be informed that the life expectancy of the device is unpredictable once implanted, and that successful results cannot be guaranteed.

IT IS THE RESPONSIBILITY OF THE SURGEON TO PROVIDE THE PATIENT WITH INFORMATION PRIOR TO SURGERY.

The following are the most frequent adverse events after implanting intramedullary nails:

- Loosening, bending, cracking or fracture of the implant components
- Loss of fixation in bone
- Limb shortening or loss of anatomic position with nonunion or malunion with rotation or angulation
- Deep or superficial infection
- Irritation or injury of soft tissues, including impingement syndrome
- Sensitivity or other reaction to the device material
- Tissue reactions which include macrophage and foreign body reactions adjacent to implants
- Pain, discomfort, or abnormal sensations due to presence of the implant
- Hematoma or thrombosis
- Associated stress fractures

Adverse effects may necessitate re-operation, revision or removal surgery and / or amputation of the limb.

Implant removal should be followed by adequate post-operative management to avoid fracture or re-fracture.

Interference risks during medical imaging:

MRI/SCANNER: ask the patient to systematically mention that he/she was implanted with a metallic device.

Packaging - Sterility

The Panta 2 Arthrodesis Nail system consists of sterile and non-sterile implants and instruments. Sterile implants and instruments are sterilized using gamma radiation. Non-sterile implants and instruments are sterilized by following the re-processing instructions as identified below.

Sterile Devices

Check packaging and labeling integrity before use. The sterility is guaranteed as long as the packaging has not been damaged or opened, and is before the expiration date. Re-sterilization of this product is not recommended.

Do not use any device for which the packaging has been damaged or opened outside the operating room. Components within the sterile barriers should be handled under sterile conditions (persons/instruments).

Non-Sterile Devices

For the Panta 2 Arthrodesis Nail System components that are provided non-sterile, they must be cleaned and sterilized prior to use. Do not re-use implants, as they are single use only. Detailed reprocessing instructions are provided in LC-04-0000-0013.

Use of the Products

The surgeon must use the instrumentation recommended in accordance with the surgical technique (LC-04-1010-0006) available from the manufacturer.

The medical device must be used in compliance with the use of the profession and the standard of art.

The correct selection of device components is extremely important. The appropriate type and size should be selected for the patient. Failure to use the largest possible components or improper positioning may result in loosening, bending, cracking or fracture of the device or bone or both. Care must be taken that the correct and appropriate size implant is used in conjunction with the correct instrumentation. Implants manufactured by Integra must not be used

in conjunction with those of any other manufacturer, as component parts may not be compatible. Careful preoperative planning on the basis of radiographic findings should be carried out routinely. Radiographic templates are available for that purpose.

Do not attempt a surgical procedure with faulty, damaged or suspect, or missing instruments or implants. Inspect all components preoperatively to assure utility.

An adequate inventory of sterile implant sizes should be on hand at the time of surgery to ensure the optimum size for the patient.

Alternate fixation methods should be available during the procedure.

Opening of the instruments set must be done according to aseptic condition.

When handling the implants, avoid any contact with other material or tools which may damage the implant surface.

Under no circumstances should the implant be modified.
The multi-component devices should only be used with the appropriate Integra products and should never be used in conjunction with components of any other manufacturers, as these products may not be compatible. Integra accepts no responsibility for such use.

Re-use of the Implants

Orthopedic implants already implanted must never be re-used. Re-use would incur the risk of modifying the properties and performance of the implant and of increasing the likelihood of the complications and/or undesirable effects mentioned earlier arising. The company accepts no responsibility for such re-use.

Information Related to Post-Operative Care

- The patient should be advised that a second more minor procedure for the removal of the implants is usually necessary.
- While the surgeon must make the final decision regarding implant removal, wherever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. In the absence of a bursa or pain, removal of the implant in elderly or debilitated patients is not suggested.
- Post-operative instructions to patients and appropriate nursing care

are critical. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending, or breaking the device. Patients who are obese or non-compliant, as well as patients who could be predisposed to delayed or nonunion must have auxiliary support.
- Even after full healing, the patient should be cautioned that re-fracture is more likely with the implant in place and soon after its removal, rather than later, when the voids in the bone left by implant removal have been filled in completely.
- Patients should be cautioned against unassisted activity that requires walking or lifting.
- Post-operative care and physical therapy should be structured to prevent loading of the operative extremity until stability is evident.
- The patient should be encouraged to report any unusual changes to the operated extremity to his/her surgeon. If evidence suggests loosening of the implant (particular pain and progressive changes in the radiographs) an increased frequency of check-ups is advised and new warning and instructions to the patient may be appropriate regarding further activity restrictions.
- The patient should be encouraged to seek prompt medical attention for any infection that could occur, whether at the operated-member level or elsewhere in the body.

Storage

All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

Product Information Disclosure

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Warning

This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Information

Should any information regarding the products or their uses be required, please contact your sales representative or distributor or directly contact the manufacturer.

The products are manufactured and referenced within the frame of the standards in force. Implantation procedures are described in the surgical technique. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.

Symbols Used on Labeling	
STERILE R	Sterilized using irradiation
LOT	Lot number
REF	Catalog number
	Manufacturer
	Do not use if package is damaged
Cementless	Do not use cement
MATL: Ti6Al4V	Titanium alloy
MATL: SS	Stainless steel
QTY 1	Quantity
	Use-by date (YYYY-MM-DD)
	Consult instructions for use
	Do not re-use
	Date of manufacture (YYYY-MM-DD)
Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Non sterile
	Do not resterilize

For further information or complaints, please contact:

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