Dev4
DEVELOPED 4 EXTREMITIES

Eleganz™ Intramedullary Threaded Nail System
Instructions for Use

Description
The Eleganz™ Intramedullary Threaded Nail System is designed to provide fixation of small bone arthrodeses, fractures, and osteotomies during the bone healing process. The Eleganz™ Intramedullary Threaded Nail System also includes instruments for bone preparation and implant placement.

Indications for Use
The Eleganz™ Intramedullary Threaded Nail System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Examples include scaphoid and other carpal fractures, metacarpal and phalangeal fusions, and bunionectomies.

The nails are not intended for interference or soft tissue fixation.

Contraindications
- Active or latent infection
- Osteoporotic bone that is susceptible to fracture.
- Conditions that limit the patient's ability or willingness to follow postoperative instructions with the healing regimen.
- Foreign body sensitivity or hyper-reactivity.
- Physical conditions that retard the healing process.

Instructions for Use
- Expose the joint surfaces.
- Remove cartilage and subchondral bone as necessary with a rongeur or reamer.
- Position the bones as desired for fixation.
- Prepare the bone for nail insertion with a guide wire or drill.
- Create a countersink in the bone for the head of the nail.
- Insert the nail across the fracture site.

Warnings
- For safe and effective use of this system, the surgeon should be familiar with the recommended surgical procedure for these devices. Improper selection, placement, positioning, or fixation of the implant may result in unusual loading conditions which could affect the long- term service life of the implant.

- In every case, accepted surgical practices should be followed in post-operative care. The patient should be made aware of the limitations of the nail and that physical activity and full weight bearing have been implicated in premature failure of similar devices.
- Patient sensitivity to implant materials should be considered and assessed prior to surgery.
- Nail insertion into hard bone may result in stresses that fracture the bone. Increase drill size if excessive insertion torque is encountered.
- For non-skeletally mature patients, the growth plates must not be crossed by implants.

Sterility

Implants and instruments are provided non-sterile and must be steam sterilized by the user according to these instructions for use.

Lifetime

Some devices in this system are single use only and shall be discarded after removal from the instrumentation tray.

Single use devices	Multiple use devices
Nails	Driver handle
Kirschner wires	Driver bits
Reamers	Countersinks
	Depth gauges

Multiple use instruments have a lifetime that is affected by usage, handling, and processing. Assess multiple use instruments for acceptability prior to re-use.

Adverse Effects

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

- Infection
- Pain, discomfort, or abnormal sensations due to presence of the implant

- Metal sensitivity/allergic reaction to a foreign body
- Migration of the implant, loosening of the implant
- Delayed correction in alignment
- Decrease in bone density due to stress shielding
- Bursitis

Target Population

The Eleganz™ Intramedullary Threaded Nail System may be used in adult patient populations only.

Surgical Technique

Detailed surgical techniques to promote safe and effective use of the device are available through Dev4. The techniques describe device insertion and removal.

Product Handling

Store implants unopened in their respective protective packaging until use. When removing the implant from its packaging, observe all relevant aseptic instructions. Protect the prosthesis from contact with objects which may damage the surface finish. Inspect each implant prior to use and dispose of implants that exhibit damage. Contouring or clamping of implants should be avoided if possible. It is recommended that the implants should not be cut, sharply bent or re-bent, notched or scratched. These alterations can produce defects or stresses which may lead to failure of the implant.

Inspect the product for damage or contamination prior to use.

Reprocessing Instructions

Instruments that have been used should undergo the reprocessing steps below, followed by sterilization.

Caution	Long, narrow cannulations and blind holes require particular attention during cleaning.
Limitations on Processing	Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.

Point of use:	Remove excess soil with disposable cloth/paper wipe. Prevent blood and body fluids from drying on the devices by soaking or rinsing in water immediately after use.
Containment and transportation:	No particular requirements. It is recommended that instruments are reprocessed as soon as is reasonably practical following use.
Preparation for cleaning:	No particular requirements. Disassembly not required.

Cleaning — Manual:	Equipment: Enzymatic and neutral detergents, cleaning stylet, cleaning brush, basin, critical water, running water. Method for Cleaning Devices: 1. Rinse visual soil from devices under warm running tap water. 2. Prepare enzymatic detergent solution according to manufacturer's instructions, using room temperature tap water. 3. Completely immerse devices in the enzymatic detergent solution for 1 minute. 4. Thoroughly brush all surfaces with a soft brush for at least 30 seconds or until all visible soil is removed. Run cleaning stylet and cleaning brush through all lumens at least 3 times. Using a syringe, aggressively flush internal features with the detergent solution. Ensure that configurable instruments are cleaned in both open and closed positions. 5. Remove the devices from the detergent solution and rinse under cool running tap water. Using a syringe, aggressively flush internal features with water. 6. Prepare neutral detergent solution according to manufacturer's instructions, using warm tap water. 7. Completely immerse devices in the neutral detergent solution for 3 minutes. 8. Thoroughly brush all surfaces with a soft brush for at least 30 seconds or until all visible soil is removed. Run cleaning stylet and cleaning brush through all lumens at least 3 times. Using a syringe, aggressively flush internal features with the detergent solution. Ensure that configurable instruments are cleaned in both open and closed positions. 9. Remove the devices from the detergent solution and rinse under critical water. Using a syringe, aggressively flush internal features with water. 10. Prepare enzymatic detergent solution for ultrasonic cleaning machine according to manufacturer's instructions. 11. Treat the devices in ultrasonic cleaning machine for 10 minutes. 12. Remove the devices from the ultrasonic cleaning machine and thoroughly rinse under critical water. Using a syringe, aggressively flush internal features with water. 13. Fully dry the device. 14. Visibly examine the device for cleanliness. If visible soil remains, repeat the cleaning procedure. If visible soil remains, repeat the cleaning procedure.
Drying:	Do not exceed 120 °C if thermal drying is used.

Maintenance:	Apply a small quantity of water-based surgical grade lubricant to moving parts. Discard blunt or damaged instruments.
Inspection and functional testing:	All components, trays, and caddies should be inspected to confirm that they are visually clean. Repeat the cleaning procedure as needed. Hinged instruments: Check for smooth movement of hinge without excessive laxity. Ratchet mechanisms should be checked for action. All instruments: Visually inspect for damage and wear. Cutting edges should be free of nicks and present a continuous edge. Check instruments with long, slender features (particularly rotating instruments) for distortion. Where instruments form part of a larger assembly, check assembly with mating components.

Sterilization Instructions

Instruments and implants should be loaded into the system instrument trays and wrapped prior to steam sterilization. Wrap the trays using an FDA-cleared sterilization wrap such as Kimguard KC600.

The trays should be steam sterilized according to the following parameters:

- Pre-vacuum; 4 minutes at 132˚ C (270˚ F); 40 minute minimum dry time

Do not stack trays during sterilization.

Storage Instructions

Items should be stored under controlled conditions in a manner that minimizes the potential for contamination per ANSI/AAMI ST79. Refer to sterilization wrap or rigid container manufacturer's IFU for limits on sterile product storage time and storage requirements for temperature and humidity.

The parameters above were validated by Dev4 under laboratory conditions, however these parameters and other sterility methods must be re-validated by the end users to ensure that sterility can be achieved on site. Users should validate this process in their local environment to appropriate standards and guidelines such as ANSI/AAMI ST79.

Material Specifications

Eleganz™ Nails, 316 SS per ASTM F138

MRI Compatibility

The Eleganz™ Intramedullary Threaded Nail 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 the Eleganz™ Intramedullary Threaded Nail 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.

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

Symbol	Meaning	Standard	Reference
	Catalog Number	ISO 15223-1	5.1.6
	Batch Code	ISO 15223-1	5.1.5
	Consult electronic instructions for use at www.dev-4.com	ISO 15223-1	5.4.3
	Caution	ISO 15223-1	5.4.4
	Non-Sterile	ISO 15223-1	5.2.7
	Unique Device Identifier	ISO 15223-1	5.7.10
	Manufacturer	ISO 15223-1	5.1.1
	Prescription Use Only	21 CFR 801.15 21 CFR 01.109	(c)(1)(i)(F) (b)(1)
	Do not use if package is damaged and consult instructions for use	ISO 15223-1	5.2.8
	Do not re-use	ISO 15223-1	5.4.2

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