Dev4
DEVELOPED 4 EXTREMITIES

Eleganz™ Fusion Screw System
Instructions for Use

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

Indications for Use
The Eleganz™ Fusion Screw 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 screws 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 screw insertion with a guide wire or drill.
- Create a countersink in the bone for the head of the screw.
- Insert the bone screw across the fusion 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 bone screw 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.
- Screw insertion into hard bone may result in stresses that fracture the bone. Increase drill size if excessive insertion torque is encountered.

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
Bone screws	Driver handle
K-wires	Driver bits
Drills	Countersinks
Reamers	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™ Fusion Screw 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.

Surgical Technique - Hand

Distal Inter-phalangeal joint (DIP) fusion using a cannulated screw technique:

- Make a transverse incision over the distal interphalangeal (DIP) joint. Remove the cartilage from the middle phalanx condyle and the distal phalanx base using a curette or rongeur.
- Using an antigrade-retrograde technique, advance the provided double-ended 0.8 mm guide wire in an antigrade direction, exiting through the tip of the distal phalanx.
- Reduce the joint and drive the guide wire retrograde to the mid-shaft of the middle phalanx or to the subchondral level of the middle phalanx base for fixation.
- Create small stab incisions on either side of the guide wire using a beaver-style blade. Measure the guide wire length with a depth gauge to determine the required screw length.
- For dense cortical bone, an optional countersink is provided.
- Using the supplied cannulated drill bit, overdrill the guide wire across the DIP joint to the desired depth. Leave the guide wire in place after withdrawing the drill bit.
- Insert the measured cannulated screw over the guide wire and drive the screw head to the desired depth within the distal phalanx.
- Confirm the screw placement using both AP and lateral imaging.
- Remove the guide wire and close the incision.

Surgical Technique - Foot

Proximal Inter-phalangeal (PIP) joint fusion using a cannulated screw technique:

- Estimate the screw length using the K-wire and hemostat technique, positioning them dorsally over the phalangeal bones of the foot. Alternatively, a bone screw can be used in the same manner.
- Make a transverse incision over the proximal interphalangeal (PIP) joint. Remove the cartilage from the proximal phalanx condyle and the middle phalanx base using a curette or rongeur. Alternatively, cup-and-cone reamers are provided for cartilage removal.
- Using an antigrade-retrograde technique, advance the supplied double-ended 0.8 mm guide wire in an antigrade direction, exiting through the tip of the distal phalanx.
- Reduce the joint and drive the guide wire retrograde into the mid-shaft of the proximal phalanx or to the subchondral level of the proximal phalanx base for fixation.
- Make small stab incisions medial and lateral to the guide wire. If screw head positioning is desired within the distal phalanx, use a depth gauge to measure the guide wire length and determine screw selection.
- For dense cortical bone, an optional countersink is supplied.
- Using the supplied cannulated drill bit, overdrill the guide wire across the PIP joint to the desired depth. Leave the guide wire in place after withdrawing the drill bit.
- Insert the measured screw over the guide wire and drive the screw head to the desired depth within the distal or middle phalanx.
- Confirm the screw placement using both AP and lateral imaging.
- Remove the guide wire and close the incision.

Implant Removal

- Expose the head of the bone screw through an incision.
- Using the supplied driver bit, rotate the screw counter-clockwise to remove.
- Kirschner wires may be removed with a pair of pliers.

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Reprocessing Instructions

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, 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 reverse osmosis or deionized 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 reverse osmosis or deionized 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. Thoroughly clean all trays and caddies until they are free from visible soil, using running water and a brush. If visible soil remains, repeat the cleaning procedure.
Disinfection:	Disinfectant solution may be used in accordance with label instructions.
Drying:	Do not exceed 120 °C if thermal drying is used.
Maintenance:	Apply a small quantity of surgical grade lubrication oil 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.
Packaging:	Instruments 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.
Steam Sterilization:	Sterilization Type: Prevacuum • 4 minutes at 132˚ C (270˚ F); 40 minute minimum dry time Do not stack trays during sterilization.

Storage:	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™ Screws, Ti6Al4V per ASTM F136

Eleganz™ K-wires, 316 SS per ASTM F138

MRI Compatibility

The Eleganz™ Fusion Screw 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™ Fusion Screw 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.

Catalog number

Batch code

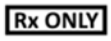
Consult electronic instructions for use at www.dev-4.com


Caution

Non-sterile

Unique device identifier


Manufacturer



Prescription Use Only


Do not use if package is damaged and consult instructions for use


Do not re-use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