DynaNail Helix™
Fixation System

Instructions for Use

enovis™

1. DEVICE DESCRIPTION
The DynaNail Helix™ Fixation System consists of the following components:
- DynaNail Helix Threaded Bone Fastener
- DynaNail Helix Washer

The DynaNail Helix Fixation System is implanted using the Ancillary Surgical Instruments.

The DynaNail Helix Threaded Bone Fastener is manufactured from nickel titanium alloy and titanium alloy (Ti6Al-4V ELI) and is available in multiple lengths. The DynaNail Helix Washer is manufactured from titanium alloy (Ti6Al-4V ELI).

The Ancillary Surgical Instruments are specifically designed for use with the DynaNail Helix Fixation System. These specialized instruments are required to correctly perform the DynaNail Helix implantation procedure and to remove the DynaNail Helix Threaded Bone Fastener and DynaNail Helix Washer if required, following implantation.

2. INDICATIONS FOR USE
The DynaNail Helix Fixation 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.

3. CONTRAINDICATIONS
- Patients with an active local or systemic infection.
- Patients with an active soft tissue infection or osteomyelitis of foot and ankle.
- Patients with severe peripheral vascular disease.
- Patients with an obliterated medullary canal or other conditions that tend to retard healing such as blood supply limitations or previous infections.
- Patients with a dysvascular limb.
- Patients with an insufficient quantity or quality of bone to permit fusion of the joints or stabilization of the arthrodesis.
- Patients with conditions that restrict his or her ability or willingness to follow postoperative instructions during the healing process.
- Patients with foreign body sensitivity is suspected, or documented metal allergy or intolerance. Where material sensitivity is suspected, appropriate tests should be conducted, and sensitivity ruled out prior to implantation.

4. WARNINGS
The DynaNail Helix Threaded Bone Fastener and DynaNail Helix Washer are supplied sterile for single use only.

DO NOT ATTEMPT TO RESTERILIZE. Resterilization may result in loss of proper mechanical function of the device and could result in patient injury.

Carefully inspect product packaging and all device components for damage or defects prior to use. Do not use device if it appears defective, damaged or otherwise compromised.

The DynaNail Helix™ Fixation System is intended to facilitate healing but is not designed to support the patient's body weight in the presence of a delayed union or nonunion of bone. Until firm bony union is achieved, the patient should employ adequate external support and restrict physical activities that would place stress upon the implant or allow movement at the site and delay healing. Therefore, it is important that immobilization of the site is maintained until firm bony union (confirmed by clinical and radiological examination) is established. Failure to immobilize the site during healing may result in bending and/or breakage of the device and/or failed fusion.

Do not modify the implant. Modified devices may not perform as intended and could result in patient injury.

The DynaNail Helix Threaded Bone Fastener is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine. Use of the implant or system components for these purposes may result in patient injury.

Serious postoperative 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.

This device contains NiTiNOL, an alloy of nickel and titanium. Persons with allergic reactions to these metals may suffer an allergic reaction to this implant. Prior to implantation, patients should be counseled on the materials contained in the device, as well as the potential for allergy/hypersensitivity to the materials.

5. PRECAUTIONS

The DynaNail Helix Fixation System should only be used by those physicians who have been trained in the appropriate, specialized procedures. Knowledge of appropriate surgical techniques, instrumentation, proper selection and placement of implants and postoperative patient care and management are essential to a successful outcome.

Correct selection of the DynaNail Helix Threaded Bone Fastener and DynaNail Helix Washer is extremely important. Carefully select the

appropriate DynaNail Helix™ Threaded Bone Fastener and DynaNail Helix Washer based on the needs of each individual patient. For best results, ensure that the device is properly positioned. Failure to do so may result in loosening, bending, cracking or fracture of the device or injury to the patient's bone or both.

Always handle the DynaNail Helix Threaded Bone Fastener and DynaNail Helix Washer carefully. The surfaces of the implants must always be protected from damage during handling. Avoid contacting the implants with other tools or materials that could notch, scratch or otherwise damage the implant surfaces. Damage to the implant's surface finish may result in loss of proper mechanical function of the device.

Never attempt to reuse. Once the DynaNail Helix Threaded Bone Fastener and DynaNail Helix Washer have been removed from the packaging, the devices should be either used or discarded. Never attempt to reuse the devices, even though they may appear undamaged.

The surgeon must make the final decision regarding implant removal. In the absence of a bursa or pain, removal of the implant in elderly or debilitated patients is not recommended. Extreme care must be taken when following the technique for removal of the device.

Use only DynaNail Helix Fixation System components. The DynaNail Helix Fixation System components manufactured by Enovis must not be used in conjunction with screws, wire bands, or other metallic devices manufactured by any other manufacturer, as component parts may not be compatible.

6. POTENTIAL ADVERSE EFFECTS

Potential adverse effects resulting from the use of the DynaNail Helix Fixation System include, but are not limited to, the following:

- Loosening, bending, cracking or fracture of the implant components.
- Loss of fixation in bone attribute to nonunion, osteoporosis and/or markedly unstable comminuted fractures.
- Loss of anatomic positioning with nonunion or malunion with rotation or angulation.
- Bone resorption or over-production.
- Deep or superficial infection.
- Irritational injury of soft tissues, including impingement syndrome.
- Sensitivity, allergies, or other reaction to the device material. The DynaNail Helix Fixation System implants includes nickel and titanium materials. If sensitivity to nickel or titanium is suspected, appropriate testing should be conducted prior to use.
- Tissue reactions including macrophage and foreign body reactions adjacent to implants.
- Pain, discomfort, or abnormal sensations due to presence of the implant.

- Hematoma or thrombosis.

Adverse effects may necessitate reoperation, revision, or removal surgery and/or amputation of the limb. Implant removal should be followed by adequate postoperative management to avoid fracture or refracture.
To minimize possible interference risks during medical imaging such as magnetic resonance imaging (MRI), advise the patient to mention that he/she was implanted with a metallic device.

7. MRI SAFETY INFORMATION
The DynaNail Helix™ Fixation 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 DynaNail Helix Fixation System in the MR environment is unknown. Scanning a patient who has this medical device may result in patient injury.

8. PATIENT SELECTION INFORMATION
The surgeon is responsible for patient selection. When evaluating patients for implantation using the DynaNail Helix Threaded Bone Fastener and DynaNail Helix Washer, always consider the patient's weight, occupation, activity level and the presence of any degenerative disease.

The surgeon is responsible for understanding the appropriate indications and contraindications associated with the device and selecting the surgical procedures and techniques determined to be best for each individual patient. Each surgeon must evaluate the appropriateness of the device and the procedure used to implant the device based on his/her own training and experience.

The physician must determine if the device is appropriate for patients having any of the following physical or emotional conditions:
- Drug and/or alcohol and/or smoke addiction and/or abuse.
- Infectious disease.
- Malignancy.
- Local bone tumors.
- Systemic or metabolic disorders or replacement.
- Compromised wound healing.
- Obesity.
- Demonstrated psychological instability, 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.

9. PATIENT COUNSELING INFORMATION

It is the responsibility of the surgeon to provide the patient with appropriate information prior to surgery. Prior to surgery, the surgeon should discuss with the patient all possible risks versus potential benefits of treatment considering the patient's preoperative condition and expectations for improvement in his/her condition postoperatively. The patient should not have unrealistic expectations regarding the results that the surgery and implant may provide. In order to make an informed decision, the patient should clearly understand all applicable warnings, precautions, possible intraoperative and postoperative complications and possible adverse effects associated with the surgical procedure and implantation of the device. Each patient should understand that the implant is manufactured from titanium alloys which may cause possible reactions and complications, including those listed herein. The patient should be informed that the life expectancy of the device is unpredictable once implanted and that successful results cannot be guaranteed.

The patient should be provided with detailed written instructions regarding postoperative care, and the use and limitations of the device. Postoperative care and physical therapy should be structured to prevent loading of the operative extremity until stability is evident. Patients who are obese or noncompliant, as well as patients who could be predisposed to delayed union or nonunion must have auxiliary support. Patients should be cautioned against unassisted activity that requires walking or lifting.

Any patient who cannot properly utilize weight support devices may be particularly at risk during postoperative rehabilitation. The patient should be advised that noncompliance with postoperative instructions could lead to loosening, bending or breakage of the implant, requiring revision surgery to remove the device. The patient should be encouraged to report to his/her surgeon any unusual changes to the operated extremity. If evidence suggests loosening of the implant (particularly pain and/or progressive changes in the radiographs), an intensified schedule of check-ups is advised and new warnings and instructions to the patient may be necessary to further restrict activities.

The patient should be encouraged to receive prompt medical attention for any infection that may occur, either at the surgery site or elsewhere in the body.

10. PREOPERATIVE PLANNING INFORMATION

Careful preoperative planning must be conducted based on radiographic findings.

Never attempt a surgical procedure with defective, damaged or otherwise compromised instruments or implants. Inspect all components preoperatively to ensure that the device components and instruments are appropriate for use.

It is the physician's responsibility to determine the correct size of the DynaNail Helix™ Threaded Bone Fastener and DynaNail Helix Washer to be implanted. The physician should always have a full inventory of sterile DynaNail Helix Threaded Bone Fasteners and DynaNail Helix Washers on hand at the time of surgery to ensure availability of the optimum size for the patient.

If any of the components are damaged during attempted placement, additional sterile components of the same size should be available.
Alternate fixation methods should also be available for use if the DynaNail Helix Threaded Bone Fastener and DynaNail Helix Washer cannot be successfully implanted.

Handling of the Ancillary Surgical Instruments must be performed in accordance with aseptic handling practices to maintain sterility following sterilization by the healthcare facility.

11. REQUIRED ITEMS
Ancillary Surgical Instruments are required to complete the implant procedure and to remove the DynaNail Helix Threaded Bone Fasteners and DynaNail Helix Washers following implantation, if required.

Intraoperative fluoroscopy (C-Arm) should be available and utilized as required to confirm correct positioning of the DynaNail Helix Fixation System implants.

12. DIRECTIONS FOR USE
General Technique:
1. Insert the DynaNail Helix Threaded Bone Fastener into the pre-drilled hole, with or without a DynaNail Helix Washer, and advance the device fully.
2. Release the DynaNail Helix Threaded Bone Fastener from the Inserter Body Assembly by unscrewing the Connection Bolt.
3. Check final position of DynaNail Helix Fixation System implant(s) using fluoroscopy, close wounds, and end procedure.

13. HOW SUPPLIED
The DynaNail Helix Threaded Bone Fastener and DynaNail Helix Washer are provided sterile for single use only. Carefully inspect sterile packaging for damage prior to use. If the sterile packaging is found to be damaged or open, do not use the device or attempt to re-sterilize. Call your Enovis sales representative for a replacement.

The DynaNail Helix Ancillary Surgical Instruments are provided NON-STERILE. Each Ancillary Surgical Instrument must be properly cleaned and

sterilized prior to first use and before each subsequent use in accordance with the guidelines provided herein.

14. CLEANING AND STERILIZATION PROCEDURES (DEPLOYMENT FRAME AND ANCILLARY SURGICAL INSTRUMENTATION ONLY)

CLEANING
Each Ancillary Surgical Instrument must be cleaned in accordance with appropriate healthcare facility procedures prior to sterilization.

Instruments should be cleaned as soon as reasonably practical after use, according to the health care facility's infection control and hazardous waste management procedures. Ideally, all components should be cleaned within 30 minutes and after no more than 4 hours of use to minimize the potential for saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on the instrument prior to cleaning. Keep instruments moist after use to prevent soil from drying on them.

The Ancillary Surgical Instruments should be fully disassembled into component parts prior to cleaning. Refer to the Instrument Tray and/or illustration in Enovis' Surgical Technique Guide for the completely disassembled components. No reassembly is necessary as the instruments remain in their fully disassembled form during cleaning and sterilization. Note: If you have questions concerning the disassembly of the instruments, contact the Enovis™ Customer Service or your local Enovis sales representative.

Do not rely upon automated cleaning using a washer/disinfector alone as this may not be effective for devices and instruments with cannulations, blind holes, mated surfaces and other complex features. A thorough manual or combination manual/automated cleaning process is required.

For manual washing, Enovis recommends using cold demineralized or distilled water along with a neutral pH (7-8.5) enzymatic detergent. Follow the manufacturer's instructions for mixing, preparing, and using such detergents. Manual cleaning should be done while the instrument is immersed. All instruments should be thoroughly cleaned. Refer to Table A for manual cleaning steps.

Cannulated portions should be cleaned with a soft-bristled nylon brush, pipe cleaner, or appropriately sized guidewire. In the case of very small dimension cannulations, a wire can be used to ensure that foreign material has been removed from the cannulation. Visually inspect all instruments to ensure that all blood, saline, and traces of tissue are removed, and instruments are "visibly clean."

Refer to Table A for further cleaning instructions.

TABLE A. Additional Enovis Cleaning Instructions

Warnings	These guidelines are not intended for Enovis™ implants or single-use disposable instruments - only for reusable instruments that are supplied non-sterile but are intended to be used in a sterile state.
	Use care in handling and storage of the instruments. Prior to surgery, instruments should be fully inspected for any evidence of damage or corrosion.
	Prolonged exposure to saline may result in corrosion of stainless steel instruments.
	The quality of water should be carefully considered for use in cleaning reusable devices. Water hardness is a concern because deposits left on medical devices may result in ineffective cleaning and sterilization. The health care facility is responsible for maintaining water quality that is compliant with AAMI TIR34.
	All cleaning should be performed in a manner designed to minimize exposure to bloodborne pathogens.

Manual Cleaning	Follow Universal Precautions for handling and transporting contaminated instruments to the designated cleaning area. Contaminated instruments should be transported to the area for cleaning in a way that avoids contamination of personnel and hospital. 1. Use flowing water and disposable wipes to remove excess soil. 2. Presoak the instruments with an enzymatic solution for a minimum of five (5) minutes. 3. Following the presoak the instruments should be wiped or scrubbed using a brush, cloth or sponge that does not mar the surface of the instrument. 4. Rinse parts under cold (<45°C) potable water for a minimum of one (1) minute. 5. Repeat the process until no visible debris remains. 6. Soak the instruments in Ultra Clean System Low Foam Detergent (pH neutral) for a minimum of one (1) minute. Remove soil from surfaces with a soft-bristled nylon brush and from cannulated parts with a soft-bristled nylon brush, pipe cleaner, or appropriately sized guidewire. Ensure that all blood, saline, and traces of tissue are removed. The use of abrasive compounds or excessively acidic or alkaline solutions may cause damage to the instruments and should be avoided. 7. Rinse parts under warm or hot flowing, potable water for a minimum of one (1) minute including direct contact with all surfaces for at least ten (10) seconds. 8. Repeat rinsing step using distilled, reverse osmosis or deionized water.
Automated Cleaning/Disinfection	Washer-decontaminators may also be used in addition to manual cleaning. When utilizing an automated cleaner, follow equipment manufacturers' instructions for use, incorporating a low foaming, pH neutral detergent. Take care to place difficult-to-clean parts near the center of the rack, open-side down, minimizing touching between parts. Place small parts in baskets to prevent dislodging.

Cleaning Verification	Visually inspect all instruments for any remaining debris prior to sterilization. According to ANSI/AAMI standards ST79:2017, the accepted standard for the degree of cleanliness is visibly clean. To deduct any residual blood or protein particulates that may be trapped in visually obstructed areas, the instrument may be submerged in a 2% hydrogen peroxide solution. The appearance of bubbles confirms the presence of protein and the instrument should be re-cleaned. Rinse instruments following exposure to hydrogen peroxide. If bubbles were present or instruments were not deemed visibly clean, steps 1-8 of the manual cleaning process should be repeated.
Inspection and Functional Testing	Repeated reprocessing has minimal effect on the devices. Visually inspect all instruments for damage and wear. Cutting edges should be free of nicks and present a continuous edge. Discard blunt or damaged instruments. Confirm that any moving parts function properly. End of life is normally determined by wear and damage due to use. Contact Enovis™ customer service for replacements.
Packaging	Single: A standard packaging material may be used. Ensure that the pack is large enough to contain the instrument without stressing the seals. In Sets: Load Enovis Surgical Instruments into the appropriate instrument trays. Ensure that cutting / sharp edges are protected.
Storage	Packaged and sterilized instruments should be stored in an area that provides protection from dust, moisture, insects, vermin, and extremes of temperature and humidity. Containment devices can be stacked for storage.

STERILIZATION

Recommended sterilization methods have been validated to sterility assurance levels (SAL) in compliance with federal and international standards. It is the responsibility of the user to ensure that the sterilization process is actually performed using qualified equipment, materials, and personnel such that the recommended parameters are achieved. The adequacy of any healthcare

facility sterilization procedure must be suitably tested. It is critical that the appropriate process parameters be validated for each healthcare facility's sterilization equipment and product/load configuration by persons who have training and expertise in sterilization processes to substantiate the process and its reliability and reproducibility.

Any recommendations provided herein are provided as general guidelines only. It is important that adequate cleaning be carried out prior to sterilization. The healthcare facility is responsible for in-house procedures for the reassembly, inspection and packaging of the instruments after they are thoroughly cleaned in a manner that will ensure steam sterilant penetration and adequate drying. Reusable instruments should be placed in suitable packaging for the sterilization process (i.e. central supply room wrap (CSR), paper/plastic pouches, rigid containers, etc.) and sterilized prior to surgical use.

Always follow the sterilizer manufacturer recommendations. When sterilizing multiple sets, ensure that the manufacturer's maximum load is not exceeded.

The DynaNail Helix™ Instrument Tray is designed to hold all the Ancillary Surgical Instruments during sterilization. The Ancillary Surgical Instruments must be placed in the designated location within the DynaNail Helix Instrument Tray. Do not add other instruments to the DynaNail Helix Instrument Tray that are not part of the standard configuration supplied by Enovis™. Do not stack the DynaNail Helix Instrument Trays during sterilization.

Moist heat/steam is the only method that has been validated for reprocessing by Enovis. Sterrad or hydrogen peroxide based gas systems have not been validated. Gravity displacement sterilization is **not recommended** due to extended cycle times.

Recommended Steam Sterilization Parameters
Time and temperature parameters required for sterilization vary according to type of sterilizer and cycle design. Please review the instructions of the sterilizer, manufacturer, or healthcare facility procedures prior to sterilization.

Cycle Type	Minimum Temperature	Minimum Exposure Time Wrapped	Minimum Drying Time
Prevaccuum/Pulsating Vacuum/Flash Autoclave	132° C (270° F)	4 minutes	30 minutes

1. AAMI/AORN steam sterilization cycles with cycle times longer than those listed are also acceptable. In the US, users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (132°C, 4 minutes).
2. FDA-cleared medical grade steam sterilization compatible wrap that has been validated to allow sterilant penetration and to subsequently maintain sterility.
3. Rigid sterilization container that complies with ANSI/AAMI ST46.
4. Drying times vary according to load size and should be increased for larger loads.

Packaged and sterilized instruments should be stored in an area that provides protection from dust, moisture, insects, vermin, and extremes of temperature and humidity. Containment devices can be stacked for storage.

15. REUSE LIFE
The Ancillary Surgical Instruments should not be reused if visible deterioration such as corrosion or damage resulting from use or handling is evident. Please remove any damaged device or instrument from use and call your Enovis™ sales representative for a replacement.

16. STORAGE
Store the DynaNail Helix™ Threaded Bone Fastener and DynaNail Helix Washer in a dry place at room temperature (20°C to 25°C). Store the Ancillary Surgical Instruments in the DynaNail Helix Instrument Tray.

17. WARRANTY INFORMATION

Limited Liability
The DynaNail Helix Threaded Bone Fastener and DynaNail Helix Washer are guaranteed for materials, function, and workmanship for a single patient use.

The Ancillary Surgical Instruments are guaranteed to be free from defects due to materials or workmanship and have a one (1) year limited warranty.

Enovis shall not be liable, expressly or implied for any damage which might arise or be caused, whether by the customer or by any of the users of the product, as a result of:
- Misuse, mishandling and/or improper operation.
- Repairs or modifications performed other than by Enovis or an Enovis authorized repair facility.
- Use in any manner or medical procedure other than those for which it is designed; and any special, indirect and/or consequential damages of any kind and however caused arising from the sale or use of the product.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS, IMPLIED, AND/OR STATUTORY, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS, AND/OR SUITABILITY FOR A PARTICULAR PURPOSE, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON ENOVIS' PART.

Return Conditions

In the event the device must be returned for any reason, return the product in the original packaging. Contact Customer Service or an authorized Enovis™ representative to receive a return authorization number prior to return shipment.

17. SYMBOLS GLOSSARY

Symbol	Standard	Ref #	Title	Definition
	ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information To Be Supplied	5.4.3	Manufacturer	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information To Be Supplied	5.4.4	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information To Be Supplied	5.1.6	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified. NOTE: Synonyms for "catalog number" are "reference number" and "reorder number".
	ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information To Be Supplied	5.1.5	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified. NOTE: Synonyms for "batch code" are "lot number" and "batch number."
			Quantity	Indicates the quantity

	ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information To Be Supplied	5.1.4	Use-by Date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information To Be Supplied	5.4.2	Do Not Reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information To Be Supplied	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information To Be Supplied	5.2.8	Do Not Use if Package Is Damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information To Be Supplied	5.2.4	Sterilized Using Irradiation	Indicates a medical device that has been sterilized using irradiation.
	ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information To Be Supplied	N/A	MR Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.
R_X Only			Prescription Only	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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