enovis™

DynaClip®

Bone Fixation System

Instructions for Use

1. DEVICE DESCRIPTION
The Enovis DynaClip® Bone Fixation System is intended for internal fixation of small bones. The DynaClip Implant and Inserter comprise the DynaClip Device System. The DynaClip Implant is available in several different size and leg configurations.

2. MATERIAL
Nickel-Titanium Alloy (NiTiNOL)

3. INDICATIONS FOR USE
- Fracture, osteotomy fixation and joint arthrodesis of the hand and foot.
- Fixation of proximal tibial metaphysis osteotomy.
- Fixation of small fragments of bone (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula, and tibia in the lower extremities; the humerus, ulna, or radius in the upper extremities; the clavicle and ribs; and in flat bones such as the pelvis, scapula, and sternum.

4. PATIENT SELECTION
Patient selection factors to be considered include: 1) need for alignment and stabilization of bone fractures, 2) ability and willingness of the patient to follow postoperative care instructions until healing is complete, and 3) a good nutritional state of the patient.

5. CONTRAINDICATIONS
1. Infection.
2. Patient conditions including blood supply limitations, obesity, and insufficient quantity or quality of bone.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of device.

6. WARNINGS
Internal fixation devices aid the surgeon in the alignment and stabilization of skeletal fractures and arthrodesis. While these devices are generally successful in attaining these goals, they cannot be expected to replace normal healthy bone or withstand the stress placed upon the device by full or partial weight bearing or load bearing, particularly in the presence of nonunion, delayed union, or incomplete healing. Internal fixation devices are internal splints that aid in alignment of the fracture until normal healing occurs. The size and shape of bones place limitation on the size and strength of implants. If there is delayed union or nonunion of bone in presence of weight bearing, or loading, the implant could eventually fail. Therefore, it is important that protective measures including reduction in activity and weight bearing and

possible use of immobilization (use of external support, walking aids, braces, etc.) of the fracture site be maintained until firm bony union (confirmed by clinical and radiographic examination) is established. Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the life of the implant. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant but also aware of the mechanical and metallurgical aspects of the surgical implants.

1. **Correct selection of the implant is extremely important.** The potential for success in fracture fixation and arthrodesis is increased by the selection of the proper type of implant. While proper selection can minimize risks, the size and shape of human bones present limitations on the size and strenght of implants. Internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal healthy bone. These devices are not designed to withstand the unsupported stress of full weight bearing, or load bearing.
2. **The devices can break when subjected to increased loading associated with nonunion or delayed union.** Internal fixation devices are load sharing devices that hold a fracture in alignment until healing occurs. If healing is delayed, or does not occur, the implant can be expected to break, deform or fail. Loads produced by weight bearing, and activity levels may dictate the longevity of the implant.
3. **Implant materials are subjected to corrosion.** Implanting metals and alloys subjects them to constant changing environments of salts,acids, and alkalis that can cause corrosion. Putting dissimilar metals and alloys in contact with each other can accelerate the corrosion process that may enhance failure of implants. Every effort should be made to use compatible metals and alloys when marrying them to common goal, i.e. screws and plates.
4. **The DynaClip Bone Fixation System implants contain Nickel.** Literature supports that a small percentage of the patient population may have a biological sensitivity to Nickel. Nickel sensitization test is recommended for all patients before using nickel containing implants.
5. **These implants may be surgically removed after healing.** 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 re-fracture with an active patient. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Adequate postoperative management to avoid re-fracture should follow implant removal.
6. **Adequately instruct the patient.** Postoperative care is important. The patient's ability and willingness to follow instructions is one of the most important aspects of successful fracture repair and arthrodesis. Patients with senility, mental illness, alcoholism, or drug abuse may be at a higher risk of device failure. These patients may ignore instructions and

activity restrictions. The patient is to be instructed in the use of external supports, walking aids, and braces that are intended to immobilize the fracture site and limit weight bearing, or load bearing. The patient is to be fully aware and warned that the device does not replace normal healthy bone, and that the device can break, bend or be damaged as a result of stress, activity, load bearing, or weight bearing. The patient should be made aware of general surgical risks, possible adverse activity, and to follow instructions of the treating physician. The patient should be advised of the need for regular postoperative examinations as long as the device remains implanted.

7. **Do not attempt fixation within a fracture line.** Adequate fixation and healing will be compromised if placed within fracture line.
8. Remove items from the sterile package using aseptic technique.
9. Always use a drill guide when drilling bone for placement of the DynaClip Bone Fixation System implant.
10. Use of the DynaClip Bone Fixation System on poor quality bone may lead to fixation failure or migration of the implants.
11. When using the DynaClip Bone Fixation System, care must be taken in ensuring that critical structures such as blood vessels and nerves do not abut against the edges of the implant.

7. PRECAUTIONS

Do not reuse implants. While an implant may appear undamaged, previous stress and handling may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been even momentarily in a different patient.

The DynaClip instrumentation is available to aid in the accurate implantation of the DynaClip Bone Fixation System implant. These instruments should only be used for their intended purpose.

8. POSSIBLE ADVERSE EFFECTS

1. Nonunion or delayed union which may lead to breakage of the implant.
2. Bending or fracture of the implant.
3. Loosening or migration of the implant.
4. Metal sensitivity or allergic reaction to a foreign body.
5. Limb shortening due to compression of the fracture or bone resorption.
6. Pain, discomfort, or abnormal sensation due to presence of the device.
7. Nerve damage due to surgical trauma.
8. Necrosis of bone.
9. Intraoperative or postoperative bone fracture and/or postoperative pain.
10. Inadequate healing.

9. MRI Safety Information

The DynaClip Bone Fixation 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 DynaClip Bone Fixation 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.

10. STERILITY

The DynaClip implants are provided pre-sterilized. The DynaClip instruments are provided in both sterile packed (single-use Procedure Pack) and non-sterile (reusable) offerings. Pre-sterilized implants and instrument kits should be inspected prior to use. Implants and instruments should not be used if package or seal is damaged.

The DynaClip Implant Kit is sterilized by exposure to gamma irradiation. Do not re-sterilize. Do not use Implant Kits after expiration date.
The DynaClip Procedure Pack is sterilized by exposure to gamma irradiation. Do not re-sterilize. Do not use after expiration date.

The DynaClip non-sterile instruments must be properly cleaned and sterilized prior to first use and before each subsequent use in accordance with the guidelines provided herein.

11. PATIENT COUNSELING INFORMATION

It is the responsibility of the surgeon to provide the patient with appropriate information 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.

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 excessive loading of the operative extremity until sufficient healing has occurred. The patient should be advised that noncompliance with postoperative instructions could lead to loss of fixation or device failure requiring revision surgery to remove the device. The patient should be encouraged to report to his/her surgeon regarding any unusual changes to the operated extremity. If evidence suggests fixation failure, breakage, or migration of the implant, 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 infection that may occur at surgery site or elsewhere in the body.

12. PREOPERATIVE PLANNING INFORMATION
Careful preoperative planning must be conducted.

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.

Handling of the DynaClip Bone Fixation System must be performed in accordance with aseptic handling practices to maintain sterility following sterilization by the manufacturer (Device).

13. GENERAL DIRECTIONS FOR USE
In a typical application, the surgical exposure for insertion of a staple is similar to the insertion of bone screws or a screw and plate system. The staple is generally located to span a fracture or osteotomy. The arms of the staple, in its final state, are biased inwards providing compression across the fracture, osteotomy or arthrodesis site. The site is reduced, and holes (one for each leg of the staple) are drilled through the near cortex and no further than beyond the opposite cortex using the guide and drill bit matched to the cross section of the staple legs. The staple is inserted into the resulting holes.

<u>Operation</u>
The implantation technique outlined below is intended to illustrate an example procedure using the DynaClip Bone Fixation System. Depending on the surgical anatomy, the fracture or osteotomy to be treated and the surgeon, the procedure may include additional or fewer steps. Proper selection of DynaClip implants is dependent upon the surgical anatomy, the fracture or osteotomy to be treated and the surgeon.

1. Reduce or re-approximate fracture, osteotomy, or joint. Apply temporary reduction and fixation.
2. Apply the appropriate Drill Guide to the repair site. Insert appropriate drill bit into the Drill Guide. Drill first hole to the depth of the appropriate leg length of the implant. Calibration depth marks on the drill bit can be used as an approximate measure of drill penetration to match the length of the implant legs. Place appropriate Locator Pin in the first drill hole.
3. Repeat Step 2 to create each additional hole. Additional Locator Pins may be used for confirmation of depth and/or to maintain position prior to implanting the device.
4. Remove the Universal Drill Guide and Locator Pins.
5. When ready to introduce the implant to the prepared surgical site, remove the Inserter loaded with the DynaClip Implant from the sterile package.
6. Insert the DynaClip Implant into the drilled holes.
7. Pull up on the sleeve of the Inserter and slide the Inserter in the direction indicated by the arrow to disconnect the DynaClip Implant.

8. Seat the DynaClip Implant by using either manual pressure or the bottom metal tip of the Inserter to tamp the proximal end of the DynaClip Implant.
9. Radiographically, verify that arms have compressed or converged.

14. HOW SUPPLIED

The DynaClip Bone Fixation System is 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 resterilize. Call your Enovis sales representative or Enovis Customer Service for a replacement.

The DynaClip instruments are provided in both sterile packed (single use Procedure Pack) and non-sterile (reusable) offerings. Carefully inspect sterile packaging for damage prior to use. If the sterile packaging is found to be damaged or open, do not use the instruments or attempt to resterilize. Call your Enovis sales representative or Enovis Customer Service for a replacement.

15. CLEANING AND STERILIZATION PROCEDURES (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 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 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 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 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 DynaClip Instrument Case is designed to hold all the Ancillary Surgical Instruments during sterilization. The Ancillary Surgical Instruments must be placed in the designated location within the DynaClip Instrument Case. Do not add other instruments to the DynaClip Instrument Case that are not part of the standard configuration supplied by Enovis. Do not stack the DynaClip Instrument Cases 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.

16. 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.

17. STORAGE
Store the DynaClip Bone Fixation System in a dry place at room temperature (20°C to 25°C).

18. WARRANTY INFORMATION
Limited Liability:
Each DynaClip Bone Fixation System is guaranteed for materials, function, and workmanship for a single patient use.

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 LIABLITIES ON ENOVIS' PART.

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

19. SYMBOLS

Consult Instructions for Use. Read all package insert warnings, precautions, and instructions. Failure to do so may result in severe patient injury.

The use of this product is intended to be limited to persons trained in the procedure and knowledgeable of the inherent risks. The patient should be fully informed about the need to limit activity during healing.

Catalog Number

Lot Number

Quantity

Expiration Date

Do Not Reuse.

Do Not Use If Package Is Damaged.

Sterilized Using Gamma Irradiation

R_x Only

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

enovis™

MedShape, Inc.
1575 Northside Drive, NW
Suite 440
Atlanta, GA 30318
USA
T: 877-343-7016
F: 877-343-7017
www.djoglobal.com

Printed in USA.
MK-10156 Rev 04 CRO-2023-0046