Bone Fixation System

Instructions for Use

DYNACLIP®

BONE FIXATION SYSTEM

Instructions for Use

1. DEVICE DESCRIPTION

The MedShape 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 are sterile packed and are single-use only. 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. STERILITY

The DynaClip implants and instruments are provided pre-sterilized in single-use kits. 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.

10. 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 acitvities.

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

11. 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).

12. 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.

Operation

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 Universal Drill Guide to the repair site. Insert appropriate drill bit into the Universal 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.

13. 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 MedShape sales representative or MedShape Customer Service for a replacement.

14. STORAGE

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

15. WARRANTY INFORMATION

Limited Liability:

Each DynaClip Bone Fixation System is guaranteed for materials, function, and workmanship for a single patient use.
MedShape 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 MedShape or a MedShape 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 MEDSHAPE'S PART.

Return Conditions:

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

16. 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.

MedShape, Inc.

Catalog Number.

Lot Number.

Quantity.

Expiration Date.

Do Not Reuse.

Manufacturer.

Do Not Use If Package Is Damaged.

Sterilized Using Gamma Irradiation.

MR Unsafe.

Rx Only

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

MedShape, Inc.
1575 Northside Drive, NW, Suite 440
Atlanta, Georgia 30318 USA
T: 877-343-7016
T: +1-404-249-9155
F: 877-343-7017
www.medshape.com

Pat.:http://www.medshape.com/patents.html
MK-10156 Rev. 01 Issued 3/2020