Fusion ORTHOPEDICS

IFU

DynaBridge

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

DESCRIPTION OF THE MEDICAL DEVICE
The DynaBridge Superelastic implant is a Nitinol (Nickel-Titanium Alloy) bone implant intended primarily for fixation of fractures, osteotomy, and arthrodesis of the hand, foot, and bones appropriate for the size of the device. The Implant is offered in a range of sizes to address a variety of indications and patient anatomy with bridge sizes from 9mm to 25mm. The system is offered sterile and non-sterile.

INDICATIONS FOR USE
DynaBridge is indicated for:
- Fracture and osteotomy fixation and joint arthrodesis of the hand and foot.
- Fixation of proximal tibial metaphysis osteotomy.
- Hand and foot bone fragment and osteotomy fixation and joint arthrodesis.
- Fixation of small bone fragments (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 bone such as the pelvis, scapula and sternum.

CONTRAINDICATIONS
- Comminuted bone surface that would militate against staple placement.
- Pathologic conditions of bone such as osteopenia that would impair the ability to securely fix the implant.
- Foreign body sensitivity to metals including nickel. Where material sensitivity is suspected, appropriate testss should be made prior to implantation.
- Local or systemic, acute or chronic inflammation or infection.
- Growing patients with open Ephesus.

PRECAUTIONS
Only experienced surgeons should perform in the implementation of the DynaBridge Implant with specific training in treating its associated indications. Because of the technically demanding nature of the procedure, surgeons should preoperatively plan to ensure that the risks presented to the patient are minimized.

Under no circumstances should damaged components or surgically excised components be used. Implants that have already been in contact with body fluids or body tissues must not be resterilized and are for single use only.

Processing or reprocessing of the implant may affect the shape memory properties of the nitinol, changing or otherwise reducing the effectiveness of the implant.

Correct selection of the Implant is extremely important. The morbidity as well as patient weight, height, occupation and/or degree of physical activity should be considered. Only patients that meet the criteria described in the Indications for Use section should be selected. Pre-operative assessment of the suitability of the patients' anatomy for accepting implants is made on the basis of X-Rays, CT scans and other radiological studies.

Adequately instruct the patient. The physician should inform the patient about orthopedic implant advantages and disadvantages, post-operative limitations, weight/load bearing stresses which could affect bone healing, implant limitations, and the fact that premature physical activity and full weight/load bearing stresses have been implicated in premature loosening, damage and/or fracture of orthopedic prostheses.

ADVERSE EFFECTS
• Infection • Hematoma • Allergy • Thrombosis • Misalignment of anatomical structures • Bone non-union or delayed union • Tissue damage resulting from improper placement of implants or instruments • Pain, discomfort or wound healing complications at the surgical site • Dislocation, migration and/or subluxation of the Implant from improper positioning, trauma, loss of fixation and/or muscle and fibrous tissue laxity. Adverse effects may necessitate re-operation, revision or removal surgery, and arthrodesis of the involved joint.

DIRECTIONS FOR USE
The implants cannot be expected to replace normal healthy bone or withstand the stresses placed upon the device by full or partial weight bearing or load bearing in the presence of nonunion, delayed union or incomplete healing. Therefore, it is important that the immobilization of the treatment site using routine methods (casting, splints, etc.) be maintained until bone healing has occurred (4-6 weeks).

Before using the DynaBridge System, the surgeon should be thoroughly familiar with the DynaBridge Surgical Technique Manual. Pre-Operative planning by the surgeon should determine the size of implant required and an adequate supply of the implant sizes should be available prior to surgery, including larger and smaller sizes than those expected to be used.

Reduction of the site should be achieved and maintained prior to implanting the device. The compressive force of the implant closing should not be relied upon to achieve closure or reduction of a fracture line.

Do not use implants or instruments from any other system or manufacturer. For complete instructions regarding the proper use and application of DynaBridge Implants and Instruments, please refer to the DynaBridge Surgical Technique Manual. A comprehensive manual can be found at www.fusionorthopedics.com/surgicaltechnique

CARE AND HANDLING
The DynaBridge Implants and Instruments described in this package insert are either provided sterile or non-sterile as indicated on the individual product's label. Implants and instruments that are presented in instrument trays are provided non-sterile.

Implants provided sterile are sterilized using gamma radiation. Implants in sterile packaging should be inspected to ensure that the packaging has not been damaged or previously opened. Sterile implants and instruments should not be used after the expiration date. If the outer package, seal, or inner package integrity has been compromised, sterilization cannot be assured and the device should not be used. Contact the manufacturer for further instructions. The implants should be opened using aseptic OR technique; they should only be opened after the correct size has been determined.

An implant should never be re-sterilized after contact with body tissues or fluids.

Devices labeled for single-use only should never be reused.

The mechanical characteristics of sterile instruments and implants may be altered if they are re-used as this would compromise device integrity, performance, and standards conformance. Examples of hazards related to the reuse of these devices include, but are not limited to: significant performance degradation, cross-infection, and contamination.

All implants are intended for single use only. Instruments for single use only are as indicated on the individual product's label. Implants and instruments may be provided either sterile or non-sterile.

All DynaBridge components should be carefully inspected to ensure proper working condition. Damaged or broken DynaBridge System devices must not be used and should be returned to Fusion Orthopedics for evaluation.

Implants provided non-sterile should be processed according to the recommended parameters for instruments as outlined (below) in the instructions for use and according to standard hospital procedure. DynaBridge System Implants and Instruments provided non-sterile should be stored in the original packaging until cleaned and sterilized. Implants and instruments should be stored at room temperature.

STERILIZATION, CLEANING AND DISINFECTION
PREPARATION FOR CLEANING
Clean the device until there is no visual contamination of the instruments directly after application (within a maximum of 2 h).

For this, use only running water or a disinfectant solution; the disinfectant should be aldehyde-free (otherwise fixation of blood impurities), possess a fundamentally approved efficiency, be suitable for the disinfection of instruments and be compatible with the instruments. For manual removal of impurities only a soft brush or a clean soft tissue is to be used, in no case metal brushes or steel wool.
Rinse all lumens five (5) times by application of a single-use syringe (minimum volume 10ml).

MANUAL CLEANING
1. Soak instruments for a minimum of five (5) minutes in enzymatic detergent made with potable water.
2. Deliberately brush and pay considerable attention to areas of high exposure, accumulation, or retention of soil.
3. Rinse thoroughly with warm water. Final rinses conducted with warm (30º C to 40º C) purified water (reverse osmosis processed, or better), with a minimum rinse time of 30 seconds.
4. Check the instruments for visible soil (see "Verifying Cleaning"). Repeat cleaning if soil is visible.

For Devices with challenging design features (cannulations, annodized color bands, handle interfaces, hinged instruments, instruments with crevices):

1. Immerse instrument and soak for a minimum of five (5) minutes in enzymatic detergent.
2. Use cleaning brushes/pipe cleaners to remove additional soil from challenging design features and areas of high exposure, accumulation, or retention of soil such as: cannulations, annodized color bands, handle/ chuck interfaces, hinged instruments, or instruments with crevices.
   a. Scrub interfaces several times using a twisting action if possible. If components of the instrument can be retracted or moved, it is necessary to retract or open the part in order to access and clean these areas.
   b. Scrub inside cannulas/holes with a tight-fitting brush or pipe cleaner using a twisting action. The brush or pipe cleaner should be of an appropriate size to ensure that full depth of the feature is reached.
   c. Scrub around hinged/mated surface areas with a brush or pipe cleaner.
   d. Scrub all crevices, such as those found around color bands, using a cleaning brush or pipe cleaner.
3. Sonicate instrument in its fully opened position for a minimum of 15 minutes in an ultrasonic cleaner containing warm enzymatic detergent.
4. Rinse thoroughly with warm water, making sure to irrigate the challenging design features. If the components of the instrument are moveable or can be retracted, it is necessary to retract or open the part for thorough rinsing at these locations. Blind holes should be repeatedly filled and emptied.
5. Check instruments for visible soil (see "Verifying Cleaning"). Repeat cleaning if soil is visible.

VERIFYING CLEANING
1. After thoroughly cleaning, visually inspect devices under normal lighting for the removal of visible soil.
2. **Optional:** For difficult to view design features, such as cannulation, apply 3% hydrogen peroxide. Bubbling is indicative of the presence of blood.

Note: Rinse the instruments thoroughly with warm water following hydrogen peroxide testing. Repeat cleaning if not visibly clean and re-inspect.

INSPECTION AND FUNCTION TESTING

Device/Feature	Flaw
All reusable devices	Visually inspect for damage or wear.
Hinged instruments	Check for smooth movement of hinge without excessive "play."
Locking mechanisms	Check for action.
Cutting features	Check edges for distortion/large nicks. Edges should be continuous.
Trials	Articular surfaces should be smooth and free of cracks and deep nicks.
Mating parts	Check to make sure that mating parts fit together without complications.
Reamer/drill bits	Inspect "chuck" end for burrs and distortion that might hinder insertion into a drill.
Hammering surfaces	Inspect for burrs and large nicks.
Driving instruments	Inspect plastic ends for cracks and large nicks.
Metal surfaces	Inspect for corrosion and major deformation.

STERILIZATION
Sterilize devices inside their respective trays according to the parameters indicated below:

Sterilization Method	Gravity Steam	Pre-Vacuum Steam
Wrapping	Single	Single
Exposure Temperature	132°C (270°F)	132°C (270°F)
Minimum Cycle Time	15 minutes	4 minutes
Minimum Dry Time	30 minutes	30 minutes

The wrap should be FDA cleared for the proposed cycle specifications.

WARNING: Total drying time depends on several factors. These include, but are not limited to: altitude, humidity, type of wrap, preconditioning, size of chamber, mass of load, material of load, and placement in chamber. Verify that drying time set in each autoclave yields dry surgical equipment.
These instructions were developed using guidance from ISO 17665, AAMI TIR 12, and AAMI ST79. Fusion Orthopedics recommends that all users observe these standards.

MATERIALS
Nitinol per ASTM F2063. The specialized instruments are made primarily of surgical grade stainless steel, aluminum, and titanium alloy.

MAINTENANCE
If any of the instrument(s) exhibit any of the flaws listed above, adequately dispose of the device(s).
For more information regarding cleaning and sterilization of the DynaBridge Implants or Instruments, please visit www.fusionorthopedics.com/cleaning

MAGNETIC RESONANCE (MRI) COMPATIBILITY
The DynaBridge Implant 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 DynaBridge Implant in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CUSTOMER SERVICE
For further information regarding the DynaBridge, a copy of the DynaBridge Surgical Technique Manual, or the Cleaning And Sterilization Protocol Manual, please contact Fusion Orthopedics, LLC, your local Fusion Orthopedics Distributor, or visit FusionOrthopedics.com

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