InstaFix™
Shape Memory Fixation System

ATTENTION OPERATING SURGEON AND STAFF

DESCRIPTION
InstaFix™ Shape Memory Fixation implants are intended for internal fixation of small bones.

MATERIAL
Nickel-Titanium Alloy (NiTi

INDICATIONS FOR USE
InstaFix™ Shape Memory Fixation implants are intended for use in:

- Fixation of Osteotomies of the Hand, Foot and Tibia
- Arthrodesis of the Joints of the Hand and Foot
- Fixation of Soft Tissue to Bone, as in the case of the Anterior Cruciate Ligament

InstaFix™ Shape Memory Fixation implants are also indicated for adjunctive fixation of Small Bone Fragments of:

- The Upper Extremity, such as the Radius, Ulna, Humerus, Clavicle and Scapula
- The Lower Extremity, such as the Tibia, Fibula and the Femur
- The Upper Torso, such as the Sternum and the Ribs

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.

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.

WARNINGS
Internal fixation devices aid the surgeon in the alignment and stabilization of skeletal fractures, arthrodesis and attachment of soft tissue to bone. 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 and soft tissue place limitation on the size and strength of implants. If there is delayed union or nonunion of bone in the presence of weight bearing, or load bearing, 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 must be 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, arthrodesis and soft tissue attachment 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 strength 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 subject 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 InstaFix™ Shape Memory Fixation 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 instruction is one of the most important aspects of successful fracture, arthrodesis and soft tissue repair management. Patients with senility, mental illness, alcoholism, or drug abuse may be at 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 made 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 effects, and to follow instructions of the treating physician. The patient should be advised of the need for regular postoperative follow-up 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 implants are placed within the fracture line.

8. Remove Items from the sterile package using aseptic technique.

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9. Always use a drill guide when drilling bone for placement of the InstaFix™ Shape Memory implant.
10. Use of the InstaFix™ Shape Memory Fixation System on poor quality bone may lead to fixation failure or migration of the implants.
11. When the InstaFix™ Shape Memory Fixation System is used, soft tissue is closed over the device. As with all implants, care must be taken in ensuring that critical structures such as blood vessels and nerves do not abut against edges of the implant.

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 placed in a different patient.

The InstaFix™ instrumentation is available to aid in the accurate implantation of the InstaFix™ Shape Memory Fixation implant. These instruments are sterile packed and are single-use only. These instruments should only be used for their intended purpose.

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 the 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.

STERILITY
The InstaFix™ 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 InstaFix™ Implant Kit is sterilized by exposure to gamma radiation. Do not re-sterilize. Do not use Implant Kits after expiration date.

The InstaFix™ Accessory Kit is sterilized by exposure to gamma radiation. Do not re-sterilize. Do not use Accessory Kits after expiration date.

The InstaFix™ Sizer Kit is sterilized by exposure to gamma radiation. Do not re-sterilize. Do not use Sizer Kits after expiration date.

General Application of InstaFix™ Shape Memory Fixation System
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 arm 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 arm. The staple is inserted into the resulting holes.

Operation
This brief procedure is intended to illustrate an example of InstaFix™ Shape Memory 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 InstaFix™ implants are dependent upon the surgical anatomy, the fracture or osteotomy to be treated and the surgeon. The implantation technique outlined below describes the implantation of an InstaFix™ Shape Memory Fixation implant.

InstaFix™ Shape Memory Fixation System
Step 1: Reduce or re-approximate fracture, osteotomy, joint, or soft tissue attachment site. Apply temporary reduction and fixation.
Step 2: Use the InstaFix™ sizers to identify an appropriate size of implant to be used as indicated.
Step 3: Apply the drill guide to the site of repair. Insert appropriate drill bit into drill guide. Drill first hole to the depth of the appropriate arm length of the implant. Calibration depth marks on the drill bit provide an approximate measure of drill penetration to match length of the implants arms. Place appropriate locating pin in the first drill hole.
Step 4: Drill the second hole as described above. A second locating pin may be used for confirmation of depth and/or to maintain position prior to implanting the device.
Step 5: Remove the drill guide and pins.
Step 6: When ready to introduce the implant to the prepared surgical site, remove delivery device containing the implant from the sterile package.
Step 7: Introduce the InstaFix™ implant into drilled holes.
Step 8: Slide the window proximally on the delivery device and pivot forward to disconnect the implant.
Step 9: Seat the implant, using either manual pressure or aligning the delivery device over the implant and tapping the proximal end.
Step 10: If a patient's body temperature is below normal, warm saline should be applied to expedite implant activation.
Step 11: Radiographically, verify that arms have compressed or converged.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Authorized Representative: OsteoMed 3885 Arapaho Road Addison, TX 75001 Customer Service: 800.456.7779 | Fax: 800.390.2620 | customer.service@osteomed.com