Pinit™ Plate Small Bone Fusion System
Bone Plate & Screw System

Description

The Pinit™ Plate Small Bone Fusion System consists of 2-hole bone plates made available in three length options and two thickness options, and 2.0 mm diameter bone screws having lengths varying from 8 mm to 24 mm. The bone plate is pre-assembled with a suture loop intended to provide a traction force required to achieve compression between bone segments. The bone screws have a snap-off feature designed to work with the plates and/or as standalone bone fixation fasteners. All implant components are manufactured from implant grade stainless steel.

Materials

Bone Plates:	316L Stainless Steel
Bone Screws:	316L Stainless Steel
Suture:	Ultra High Molecular Weight Polyethylene
Surgical Instruments:	Medical Grade Stainless Steel and High Temperature Plastics

Indications for Use

Intended for the treatment of fracture fixation, osteotomies (ex. Akin, Chevron, Scarf, Weil), reconstruction, revision surgery and arthrodesis of small bones in the upper and lower extremities.

Patient Population

Patient Selection Factors to be Considered Include:

- Failure of previous conservative treatment options in correcting deformity and achieving pain relief.
- Adequacy of bone stock to support implant components.
- Patient's age indicative of skeletal maturity.
- Functionality and/or stability of patient's musculotendinous system.

- Patient's overall well-being, including the ability and willingness to follow pre and post-operative treatment regimen.

Contraindications

Absolute Contraindications with the use of Pinit™ Plate Small Bone Fusion System Include:

- Previous or current infection at or near the implantation site.
- Pre-existing conditions such as limited blood supply that may significantly affect the healing response.
- Patients having malignant primary or metastatic tumors that may preclude adequate bone support or screw fixation.
- Patients with known allergies or hypersensitivity to implant grade stainless steel and/or surgical suture typically used in prosthetic devices.

Relative Contraindications with the use of Pinit™ Plate Small Bone Fusion System Include:

- Poor bone quality or quantity that may lead to inadequate stabilization/fusion of the joint complex.
- Metabolic disorders that may impair the formation or healing of bone.
- Infections at remote sites which may spread to the implant site.
- Rapid joint destruction or bone resorption visible on roentgenogram.

Warnings and Precautions

- Pre-operative and operative procedures, including knowledge of surgical technique, proper selection and placement of implant components are important considerations in the successful utilization of the Pinit™ Plate Small Bone Fusion System.
- The potential for success in joint fusion and/or fracture fixation is increased by proper implant selection. The patient's anatomy and indication will determine the size of the bone plate and screws to be used. The size and shape of human bones presents limitations on the size and strength of the implant components.
- To achieve desired outcomes with the Pinit™ Plate Small Bone Fusion System, pre-operative patient evaluation is extremely important. Patient's weight, occupation, activity level, mental condition, foreign body sensitivity and any degenerative diseases are important factors to consider. These conditions must be evaluated as a part of the pre-operative planning.

- The Pinit™ Plate Small Bone Fusion System implant components are manufactured from metal, and CANNOT be expected to withstand the range of motion, activity level and loads experienced by normal, healthy bone. These implants are intended to be used as a guide to normal healing, and not to replace normal body structure.
- It is very important to maintain the implant site in an immobilized state until bony union is confirmed via clinical or radiographic examination. Failure to do so will result in excessive and repeated stresses being placed on implant components, which can lead to bending or breaking of the implants due to normal metal fatigue.
- The presence of motion or forces across the fusion site in cases of delayed union or nonunion may lead to implant bending or breakage due to metal fatigue.
- All surgical implants are subjected to repeated stresses that can result in failure. The use of an implant should be avoided if excessive loading cannot be prevented at or near the implant site.
- Post-operative care is extremely important. The surgeon must warn the patient against noncompliance with post-operative instructions, which could lead to implant bending or breakage requiring a revision surgery and/or implant removal.
- Unless otherwise noted, the patient should employ adequate external support and restrict physical activities that may lead to stresses being placed on the implant components or allow motion at the fusion site and thus lead to delayed healing. An active, debilitated or demented patient who cannot properly utilize weight support devices may be at higher risk during post-operative rehabilitation.
- Accepted practices in post-operative care should be used. The patient is to be instructed and monitored to ensure a reasonable degree of compliance to post-operative instructions and activity restrictions. Excessive activity, impact, and weight gain have been implicated in the reduction of the benefit and service life of prosthetic devices.
- Correct implant handling is extremely important for successful outcomes. Implant components should not be bent, reverse bent, notched or scratched. All of these operations can produce defects in the surface finish and cause internal stress concentrations, which may become the focal point for eventual failure of the implant system.
- No other metallic or non metallic implantable devices are to be used in conjunction with the Pinit™ Plate Small Bone

Fusion System at the implant site. Doing so may compromise implant performance and patient safety.

- No implant component must be reused. The Pinit™ Plate Small Bone Fusion System implant components are Single Use devices that have not been designed to undergo or withstand any form of alterations, such as disassembly, cleaning or re-sterilization, after single patient use. Reuse can eventually compromise implant performance and patient safety.
- Implant removal is at the sole discretion of the surgeon. Whenever possible and practical for the individual patient, the Pinit™ Plate Small Bone Fusion System implant components should be removed once their service as an aid to the healing process is accomplished, particularly in younger and more active patients. Great care must be taken while removing the implant components.
- The Pinit™ Plate Small Bone Fusion System should be inspected by surgeon or surgical staff prior to use for any signs of wear or damage. Any discrepancies, damages or other issues with the packaging, labeling or implant components should be reported and brought to the notice of the manufacturer.
- The Pinit™ Plate Small Bone Fusion System (bone plates and bone screws) has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating or migration in the MR environment.

Possible Adverse Effects and Complications

- Loosening, bending, cracking or fracture of the bone plate and bone screws attributable to malunion, nonunion or osteoporosis.
- Loss of anatomic position with malunion or nonunion with rotation or angulation.
- Infection, both deep or superficial, or allergic reaction.
- Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions. Particulate wear debris and mild tissue discoloration from metallic components have been noted in other prosthetic devices constructed from similar materials. Some types of wear debris have been associated with osteolysis and implant loosening.
- Embolism
- Tissue reactions such as macrophage and foreign body reaction at or near implant site.

- Fretting or crevice corrosion can occur at the interface of bone plate and bone screws.
- Fatigue fracture of the implants as a result of bone resorption around the implant components.
- Intraoperative or postoperative bone fracture.
- Post-operative pain or incomplete resolution of pre-operative symptoms.

Sterility

The Pinit™ Plate Small Bone Fusion System components i.e. bone plates, bone screws and instruments are individually packaged and provided STERILE. All components are sterilized by exposure to gamma irradiation. Do not resterilize any components. Do not use if packaging is opened or damaged. Do not use if beyond expiration date.
For Single Use Only.

Caution

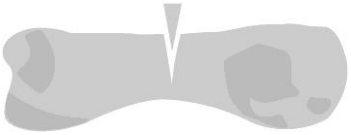
Federal Law (USA) restricts this device to sale by or on the order of a physician.

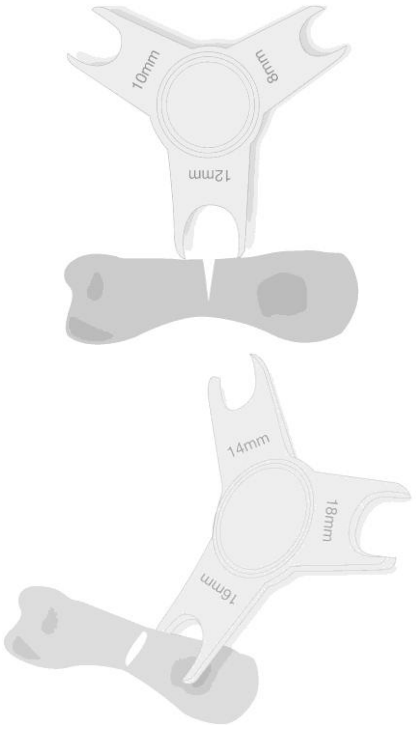
Surgical Procedure

A Surgical Technique Guide that outlines the procedure with the use of the **Pinit™ Plate Small Bone Fusion System** is available. It is the surgeon's responsibility to become familiar with the procedure and obtain necessary training prior to performing implantation using this system. All surgeons are required to evaluate the appropriateness of the described surgical technique based on personal experience and medical training.

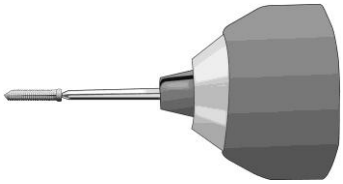
A basic outline of the procedure is provided herein, and is as follows:

1. Use **Measuring Guide** over implant site to determine appropriate plate size and screw length required. Note: It may be necessary to determine screw length required on either side of the fracture or osteotomy.

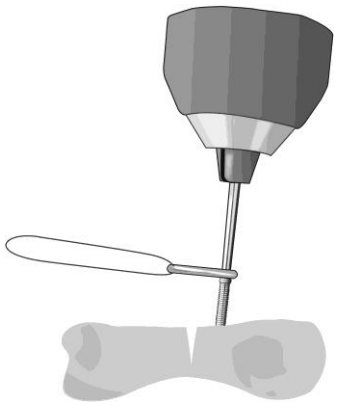




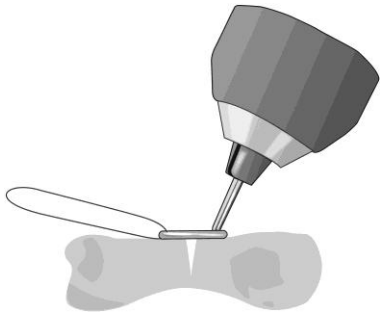
2. Insert **Snap-Off Screw** into a self-retaining pin/wire driver to engage it at the shaft. Note: Improper handling or engaging the driver chuck in close proximity to the screw may cause damage and render it unusable.



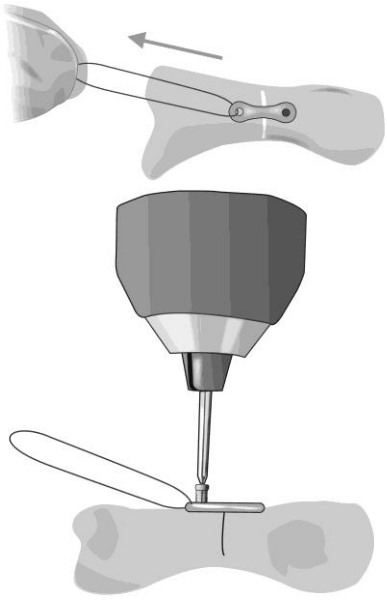
3. Place screw inside **Bone Plate** hole not containing suture (distal hole). Power drive screw into distal bone segment while keeping suture in tension proximally. Note: Apply tension as necessary to avoid spinning of plate while driving screw into bone.



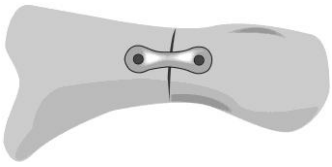
4. Bend or tilt pin/wire driver away from centre axis to snap-off shaft from screw once bone plate is in contact with bone, and bone screw head is seated flush with bone plate. Note: Over driving or excessive spinning of screw within bone will lead to stripping of threads and poor fixation. The hand held screw driver may be used to adjust final placement of screw.



5. Apply traction or compression force proximally with help of suture to close gap between two bone segments across fracture/osteotomy site. Drive second appropriate length snap-off screw using pin/wire driver into proximal bone plate hole while maintaining tension on suture until screw head is seated flush with bone plate.



6. Snap-off shaft from screw and use hand held screw driver to adjust screw position if necessary. Remove suture from final construct and discard. Intra-operative fluoroscopy is recommended to confirm final device placement.



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