The Pinit Plate® Small Bone Fusion System is a super low profile, modular bone plate and screw system designed to stabilize a bunionectomy with a medial to lateral approach. The system is available in multiple size options for fracture fixation, osteotomies, reconstruction or arthrodesis of small bones and joints in the upper and lower extremities.

- 2-Point Bicortical Screw Fixation
- Avoids Contact with Sesamoids
- No Splitting/Fracture of Dorsal Cortex
- No Measuring Through Osteotomy Site
- Complete sterile and disposable off-the-shelf kit
**Description**

The Pinit Plate® Small Bone Fusion System consists of 2-hole bone plates made available in three length options (8 mm, 12 mm, 14 mm hole-to-hole), two thickness options (0.8 mm and 1.6 mm) and 2.0 mm diameter bone screws having lengths varying from 8 mm to 24 mm (in 2 mm increments). The bone plate is pre-assembled with a suture loop intended to provide traction force required to achieve compression between bone segments. The bone screws have a snap-off feature designed to work with the plate and/or as a stand alone fixation fastener. 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.
Surgical Technique

These illustrations demonstrate the use of the Pinit® Plate system for the case of a chevron bunionectomy. The steps will remain the same for other osteotomies, arthrodesis or fracture fixation cases.

1. Use the **Measuring Guide** over the implant site to determine appropriate **Bone Plate** length and **Bone Screw** length.

   *Note: It may be necessary to determine the **Screw** length on either side of the fracture or osteotomy.*

![Bone Plate Measurement](image1)

![Bone Screw Length Measurement](image2)

2. Insert the **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 the **Screw** inside the **Plate** hole not containing the suture (distal hole). Power drive the **Screw** into distal bone segment while keeping the suture in tension proximally.

*Note: Apply tension as necessary to avoid spinning of the **Plate** while driving the **Screw** into bone.*

4. Bend or tilt the pin/wire driver away from the centre axis to snap-off the shaft from the **Screw** head once the **Plate** is in contact with bone, and the **Screw** head is seated flush with the **Plate**.

*Note: Over driving or excessive spinning of the **Screw** within the bone will lead to stripping of threads and poor fixation. The hand held **Screw Driver** may be used to adjust final placement of the **Screw**.*
5. Apply traction or compression force proximally with help of suture to close gap between the two bone segments across the osteotomy site. Drive the second appropriate length Snap-Off Screw using a pin/wire driver into proximal Plate hole while maintaining tension on the suture until the Screw head is seated flush with Plate.

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

Note: Additional stability can be acheived if desired by inserting a Snap-Off Screw across the osteotomy site.
**Warnings & 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

- 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.

Instrumentation

Gauge Kit

Screw Driver
### Catalog Numbers

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<tr>
<th>Plates</th>
<th>Screws</th>
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<tr>
<td>9A0P-1A08 0.8mm thick, Plate, 8mm length</td>
<td>9A2A-B008 Screw, Snap-off, 8mm</td>
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<td>9A0P-1A12 0.8mm thick, Plate, 12mm length</td>
<td>9A2A-B010 Screw, Snap-off, 10mm</td>
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<td>9A0P-1A14 0.8mm thick, Plate, 14mm length</td>
<td>9A2A-B012 Screw, Snap-off, 12mm</td>
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<td>9A0P-2A08 1.6mm thick, Plate, 8mm length</td>
<td>9A2A-B014 Screw, Snap-off, 14mm</td>
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<td>9A0P-2A12 1.6mm thick, Plate, 12mm length</td>
<td>9A2A-B016 Screw, Snap-off, 16mm</td>
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<td>9A0P-2A14 1.6mm thick, Plate, 14mm length</td>
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<tr>
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<td>9A09-4000 Screw Driver</td>
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<td>9A2A-B024 Screw, Snap-off, 24mm</td>
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For more information, visit our website:  
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This pamphlet and information is intended for markets where regulatory approval has been granted.