

I. General

The Super Scaffold™ (Intramedullary Fixation Scaffold System) is a hollow fenestrated cylinder implant fabricated from nitinol alloy with a section that increases its diameter while shortening its length. Features on the cylinder's surface lock in to bone. The Super Scaffold™ implant has distal and proximal segments which vary in length and extent of contraction. The Super Scaffold™ gives the surgeon a means of end-to-end bone fixation for the long bones of the foot and hand (inter-phalangeal or phalangeal-metatarsal/metacarpal).

II. Basic Structure

The Super Scaffold™ is retained in an instrument, advanced into bone and released so that the elastic properties of nitinol will cause the Super Scaffold™ to expand its diameter and shorten its length. The Super Scaffold™ is designed to expand and lock into the intramedullary space and pull together and compress bone as the Super Scaffold™ shortens. This shape change may not occur when the Super Scaffold™ is constrained by bone. In this condition the implant applies the maximum fixation force and has the greatest potential shape change. This potential shape change may pull the bone segments together if bone interfacial resorption occurs.

III. Indications for Use

1. The Super Scaffold™ is indicated for small bone fixation, reconstruction and fusion such as inter-digital fusion of the fingers and toes.

IV. Contraindications

1. Comminuted bone surface, which would militate against Super Scaffold™ placement.
2. Pathologic conditions of bone such as osteopenia, which would impair the ability to securely fix the Super Scaffold™.
3. Foreign body sensitivity to metals including nickel. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

V. Warnings

1. Immobilization, in addition to this internal fixation, until bone healing (4-6 weeks) should be achieved by routine methods (casting, splints, etc.).
2. Reduction of the site should be achieved and maintained prior to removal of the Lock Plate. The compressive force of the Super Scaffold™ should not be relied upon to achieve closure of reduction of bone.
3. Implant removal is recommended to avoid implant breakage in the event of a malunion or nonunion of the fusion site.
4. The Super Scaffold™ has not been evaluated for safety, compatibility, heating or migration in the Magnetic Resonance environment.

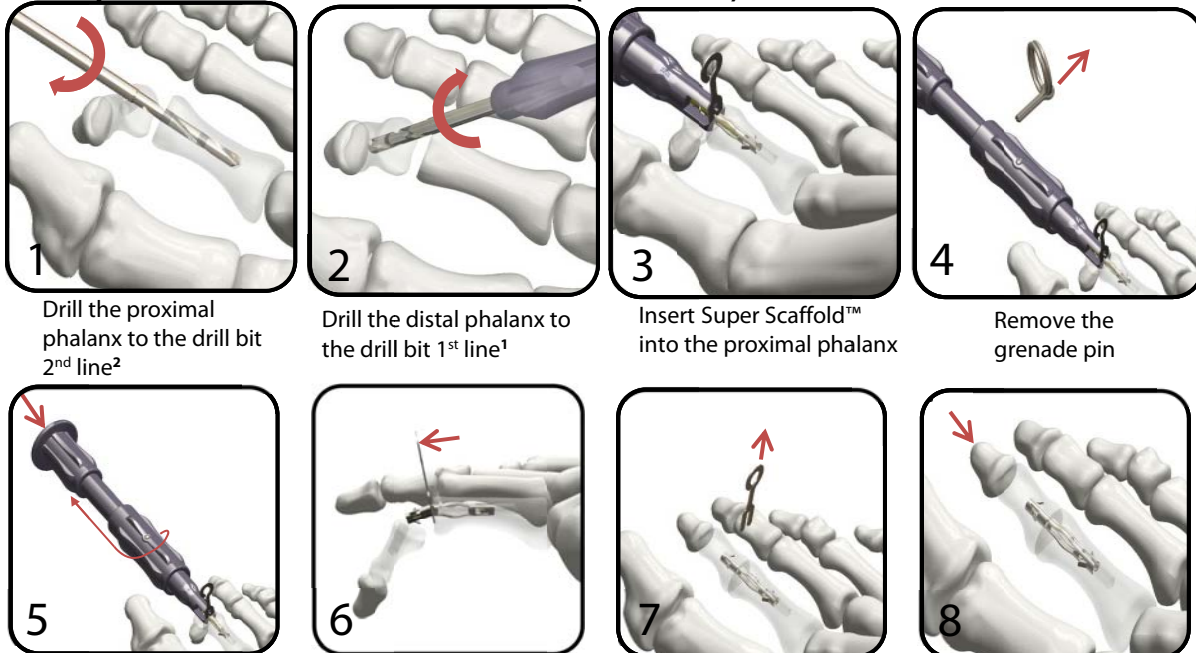
VI. Use and Storage Considerations

Super Scaffold™ and instruments should not be subjected to storage or shipping temperatures in excess of 76.7°C (170°F).

VII. Clinical Use Examples

1. Foot Surgery: metatarsal to phalangeal and interphalangeal arthrodesis.
2. Hand Surgery: metacarpal to phalangeal and interphalangeal arthrodesis.

VIII. Implant Placement Instructions for Use (foot shown)



1 Drill the proximal phalanx to the drill bit 2nd line²

2 Drill the distal phalanx to the drill bit 1st line¹

3 Insert Super Scaffold™ into the proximal phalanx

4 Remove the grenade pin

5 Turn knob clockwise and slide knob back **If resistance is encountered during retraction, rotate Lock Plate back and forth around implant while continuing to pull back on the knob*

6 Reduce distal phalanx while applying gentle forward pressure to Lock Plate

7 Remove the Lock Plate by pulling it from the Super Scaffold™

8 Push bones together

IX. Implant Removal Instructions

1. Prior to Super Scaffold™ release from the instrument in the proximal bone:
 - a. During implantation removal of the Super Scaffold™ from the proximal bone prior to release of the implant from the Super Scaffold™ instrument (Step 5) can be achieved by counter clockwise rotation of the implant and instrument while pulling the instrument and Super Scaffold™ from bone. The bone anchors on the Super Scaffold™ are angled so they deflect inwards when the Super Scaffold™ is turned counter clockwise.
2. If Super Scaffold™ loosening occurs:
 - a. Stabilization of a loose implant until fusion occurs can be accomplished by placement of a K-wire through the fixated bones and lumen of the Super Scaffold™.
 - b. Distract the phalanx to open the joint and expose the implant. Clear tissue from the lumen of the implant with a pick, drill or burr. Turn the protruding portion of the Super Scaffold™ counter clockwise 1 turn while pulling gently to collapse the fixation features, then turn while pulling to remove the implant from bone.
3. If Super Scaffold™ breakage occurs:
 - a. Open the joint. Hold the visible ends of the implant with a needle driver and twist counter clockwise 1 turn, then pull gently while turning counter clock-wise to remove each the distal and proximal portions of the implant.
4. If removal is required and the joint is fused or tissue cannot be fully removed from the Super Scaffold™ lumen, removal of the implant may require soft tissue and bone dissection to fully expose the implant to allow its removal through a slot in the bone.

CAUTION: Removal of the Super Scaffold™ from osteopenic bone may result in bone damage or fracture.

Note¹: Drill to 1st edge of 1st line for Super Scaffold™ with 6.5mm distal length; drill to 2nd edge of 1st line for 8.5mm distal length.

Note²: Drill to 1st edge of 2nd line for Super Scaffold™ with short proximal length; drill to 2nd edge of 2nd line for long proximal length.