



## BioPro Digital Compression Screw

**Indications**

- Digital fusion for the correction of hammertoe deformities in the foot and osteoarthritis, degenerative arthritis and post traumatic arthritis
- Digital fusion in the hand for osteoarthritis, rheumatoid arthritis, degenerative arthritis, post traumatic arthritis and chronic mallet finger

**Contra-indications**

- A general health problem that might pose a significant threat to the life of the patient if subjected to a major surgical procedure
- An active infection or a previous infection that has not been quiescent for at least six months
- A local or systemic infection
- Significant deficiency in the vascular supply to the extremity
- It is not intended for use in the spine.

**Warning:** The Digital Compression Screw has not been evaluated for safety and compatibility in the MR environment and has not been tested for heating or migration in the MR environment. The safety of the device in the MR environment is unknown. Scanning patients who have these devices may result in patient injury. Contact surgeon if a change in performance or pain level is noticed.

Sterile:

**Sterilized with ethylene oxide gas. Caution: For one procedure only. Do not re-sterilize. Do not use if package is open or damaged.** This is a single use device. Re-use of this device can result in the transfer of materials not limited to bone, tissue, blood, or infectious disease. The device is provided sterile and re-sterilization of the device has not been validated.

**Instructions for use:**

1. A skin incision of choice is made over the proximal interphalangeal joint and all soft tissue dissection is performed to expose the articular surface of the head of the proximal phalanx and base of the intermediate phalanx. The cartilaginous surfaces are removed using either a sagittal or oscillating saw.
2. Using a 0.045 in. K-wire, a hole is drilled through the center of the intermediate phalanx continuing through the center of the distal phalanx out through the toe.
3. Using a 0.062 in. K-wire, the previous hole is now over drilled with the larger K-wire through the intermediate and distal phalanx out through the toe. *Note: Using the 1.8mm Screw - If you choose to step up to the 1.8mm screw during the procedure, the 0.062 in. hole must be overdrilled again using a 1.8mm drill bit. This will accommodate the larger outer thread diameter of the 1.8mm screw. (All hospitals should have a 1.8mm drill bit in their screw sets.)*
4. Using a 0.035 in. K-wire, a hole is drilled centered in the proximal phalanx approximately 3mm to 4mm in length. This drill hole acts as a glide path for the Digital Compression Screw.
5. A small transverse incision (approximately 5 mm) is made at the end of the toe using the identifiable K-wire hole as the center of the incision. The soft tissue is dissected about the distal tuft.
6. While approximating the proximal and intermediate phalanx in its final position, place the top of the screwdriver on top of the toe, abutting the inside of the handle against the end of the toe, to find the desired screw length. Choosing the correct screw length is very important to obtain optimal thread purchase and tightness.

**IMPORTANT NOTES:** To avoid bending or breaking the screw, patient must remain in an approved post-operative surgical shoe during all weight bearing until screw removal. Indicated for 2nd, 3rd and 4th digits only.

**REMOVAL PROCEDURE:** The Digital Compression Screw is a non-permanent fixative device which normally should be removed in six to eight weeks. Removal is an easy surgical procedure that may be performed in a hospital, surgery center, or an in-office setting. The following is an example of an in-office procedure:

1. A digital block is performed with anesthetic of choice.
2. A penrose drain may be used for hemostasis.
3. A prep is performed or Betadine paint at the end of the toe.
4. To identify the incision location, often times the screw head can be palpated, or identify the previous incision line.
5. A small transverse incision is made and soft tissue is dissected free about the screwhead and its grooves.
6. Using the BioProScrewdriver, the screw is retrograded from the site. If the screw just turns, use pick-ups to pry behind the screwhead, causing retrograde pressure assisting the screwdriver.
7. One nylon suture may be used, followed by a sterile dressing.
8. Suture may be removed at the first week post-op.



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8. Suture may be removed at the first week post-op.



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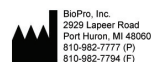
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