BIOLOGICALLY ORIENTED PROSTHESES
BIOPRO

BioPro Digital Compression Screw (DCS) Instructions for Use

For the most current instructions for use and symbol glossary visit www.bioproimplants.com/ifu. Instructions for Use should always be reviewed before using or implanting a device. To receive a printed IFU within 5 business days, please contact orders@bioproimplants.com

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

Description
The Digital Compression Screw (D.C.S.) is a solid, stainless-steel screw specifically designed to address digital fusions and is available in two diameters and multiple lengths.

Material
Stainless Steel (ASTM F138)

Indications for use:
1. Digital fusion for the correction of hammertoe deformities in the foot and osteoarthritis, degenerative arthritis, and post traumatic arthritis
2. Digital fusion in the hand for osteoarthritis, rheumatoid arthritis, degenerative arthritis, post traumatic arthritis and chronic mallet finger

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

Precautions and Handling
- Inspect the sterile blisters used for the devices prior to use. Sterilization cannot be assured, and devices should not be used if blister or seal is damaged.
- Screws are a single use device
- Do not autoclave screws

Potential Complications and Adverse Effects
- Allergic reactions to stainless steel
- Delayed or Non-union of bone
- Delayed Healing
- Screw may bend or break
- Screw may extrude or back out of the surgical site

Contact surgeon if a change in performance or pain level is noticed.

MR Safety Information
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.

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: If you choose to step up to the 1.8mm screw during the procedure, the 0.062 in. hole must be over drilled again using a 1.8mm drill bit. This will accommodate the larger outer thread diameter of the 1.8mm screw.
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. Contact surgeon if a change in performance or pain level is noticed.

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 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 BioPro Screwdriver, 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.

Cleaning and Sterilization Introduction

These guidelines are intended to provide a better understanding of the care and handling of BioPro digital compression screwdriver. These guidelines are not intended for use with electrical, pneumatic or other powered surgical instruments. Screwdrivers are shipped in a NON-STERILE condition and must be cleaned and sterilized prior to use.

General Care and Handling

Avoid undue stress or strain when handling or cleaning. Tap water can contain many minerals that may discolor and stain the driver; therefore, it is recommended that deionized water be used for the final rinsing to prevent spotting.

Note: The collet should be dissembled from the driver prior to cleaning.

Cleaning: Follow these steps to thoroughly clean all k-wires

1. Submerge the driver in an enzymatic detergent. Prepare detergent according to the manufacturer's recommendations. Soak the driver for twenty (20) minutes in the protein solubilizing detergent.
2. Scrub the submerged driver with a soft sponge and agitate.
3. Rinse in warm (38-49 degree C) tap water for one (1) minute.
4. Ultrasonically clean the driver for ten (10) minutes in a neutral pH detergent (Neutrad or acceptable alternative). Prepare the detergent according to the manufacturer's recommendations.
5. Rinse the driver with deionized water for at least three (3) minutes.
6. Dry the driver thoroughly with a clean, lint free cloth.
7. Visually inspect driver for any damage or remaining contaminates. The driver should be visually clean.
8. Repeat cleaning procedure if necessary if contamination remains.
9. Reassemble the driver.

Sterilization

Following the cleaning process, place a sterilization indicator with the k-wires. The k-wires are to be wrapped in a double layer of CSR wrap. Steam sterilization is required with the following parameters:

For pre-vacuum cycle:

Wrapped items: 4 minutes exposure at a minimum temperature of 132° C (270° F), maximum temperature of 143° C (290°F), 4 pulses, 30 minutes dry time.

Unique Device Identification (UDI)

All BioPro components can be identified by M209XXXXX, where "XXXXX= Item #". For a complete listing of BioPro item numbers visit www.bioproimplants.com/udi

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