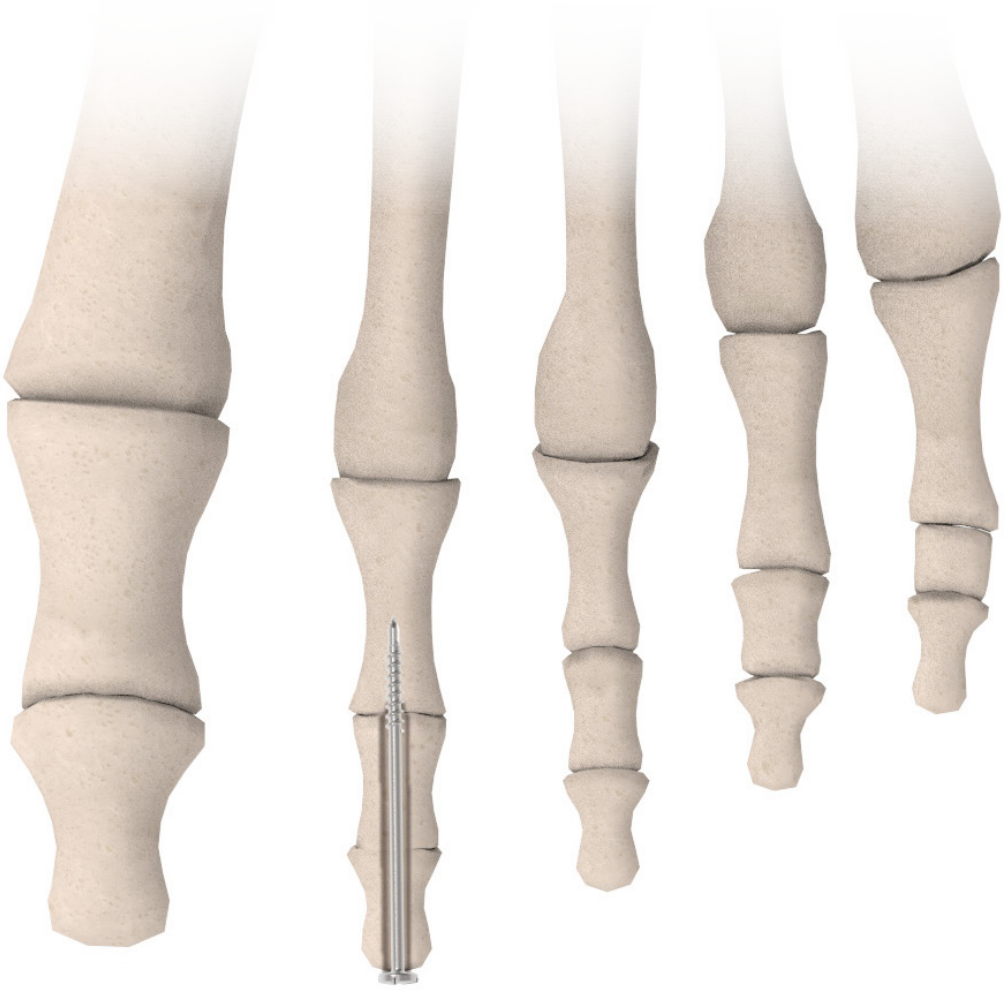
Biologically Oriented Prostheses

BIOPRO

Digital Compression Screw

Surgical Technique



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Indications & Contraindications

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 packaging used for the devices prior to use. Sterilization cannot be assured, and devices should not be used if pouch 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

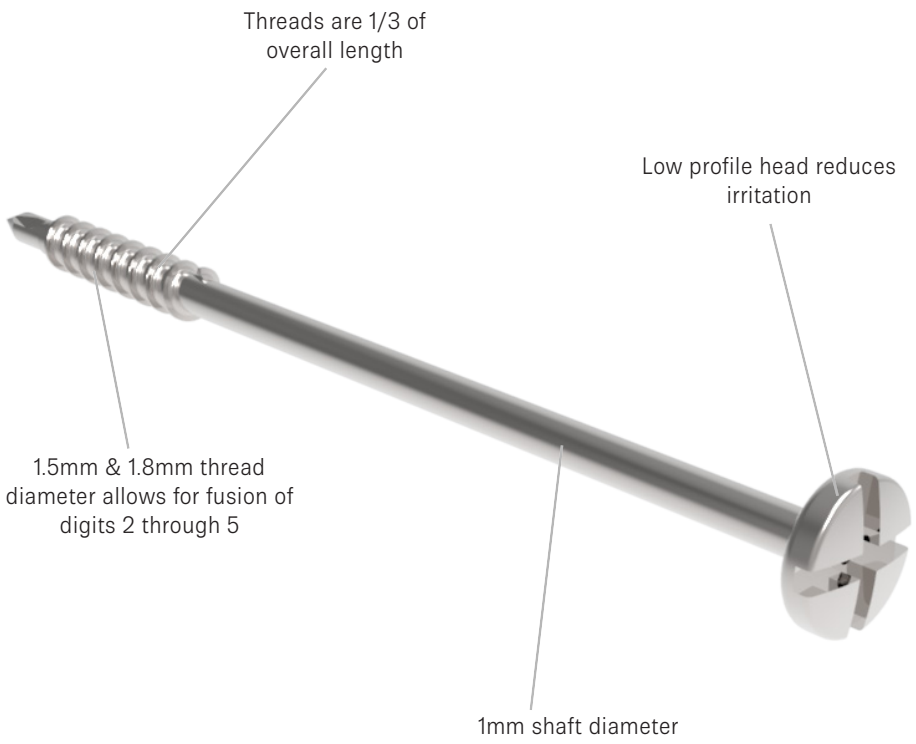
Contact surgeon if a change in performance or pain level is noticed.

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.

Implant Specifications

The Digital Compression Screw (D.C.S.) is a solid, stainless steel screw specifically designed to address digital fusions. The 1.5mm and 1.8mm diameters range from 20mm to 55mm in length, allowing for fusion of the DIPJ, PIPJ, or both. The Digital Compression Screw features a 1mm shaft diameter with either 1.5mm or 1.8mm threads for a lag screw design. Our unique over-drilling technique allows compression and easy removal post fusion.

	Ø1.5mm	Ø1.8mm
Material	Stainless Steel	
Length	20mm to 55mm (5mm increments)	

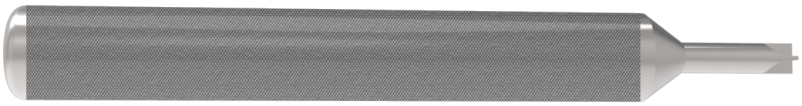


Instrument Specifications

Tracker device
A tracker device is included with every sterile packed screw. The tracker allows for easy introduction of the screw into the drill hole.

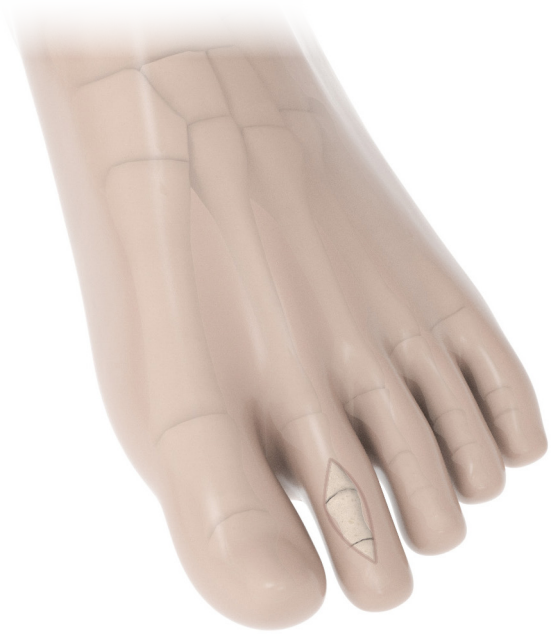
Driver
A reusable driver instrument features etched lines for screw measurement and a detachable screw retainer to secure the screw head onto the driver.

Removal driver
A reusable driver is also provided for removal of the digital compression screw once fusion has been achieved.

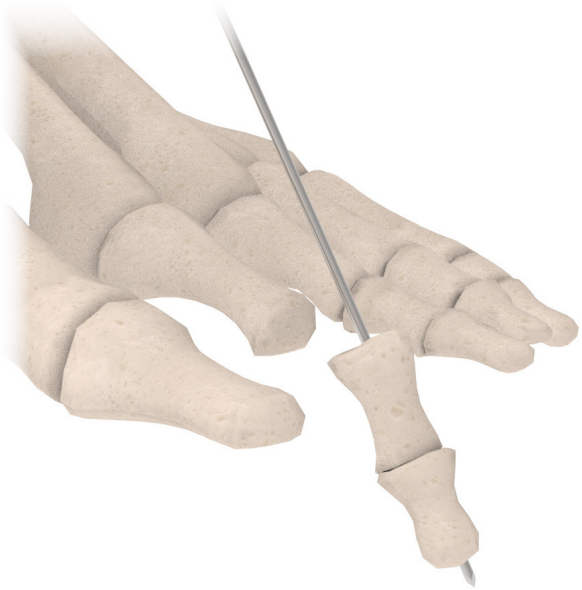


K-wires
BioPro offers .045″ and .062″ K-wires that are to complete the over-drilling technique. K-wires need to be ordered separately.

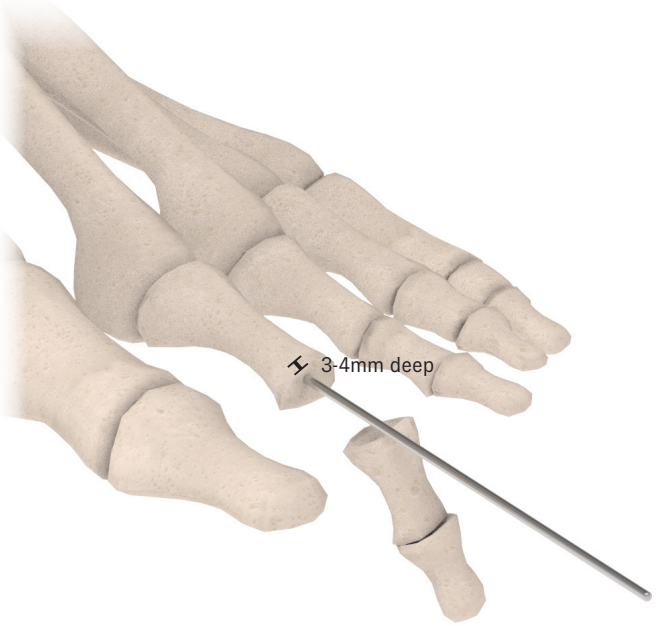
Surgical Technique



Step One:
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 (remove cartilage only and maintain subchondral bone) using either a sagittal or oscillating saw.



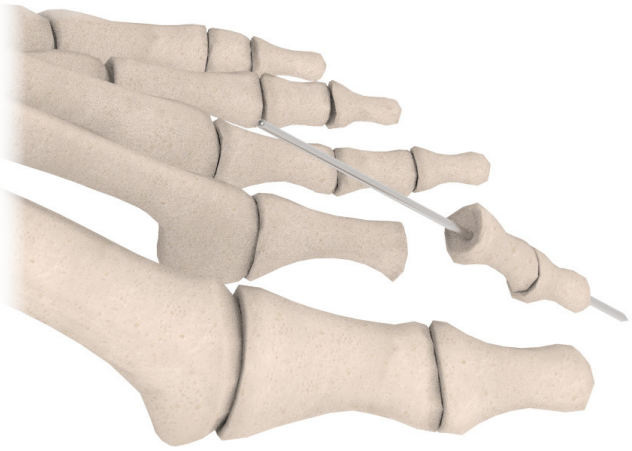
Step Two:
Using an 0.045" K-wire, a hole is drilled through the center of the intermediate phalanx, continuing through the center of the distal phalanx, out through the end of the digit.



Step Three:
Using the same 0.045″ K-wire, a hole is drilled centered in the proximal phalanx approximately 3mm to 4mm in length. This drill hole acts as a guide path for the screw.

Caution

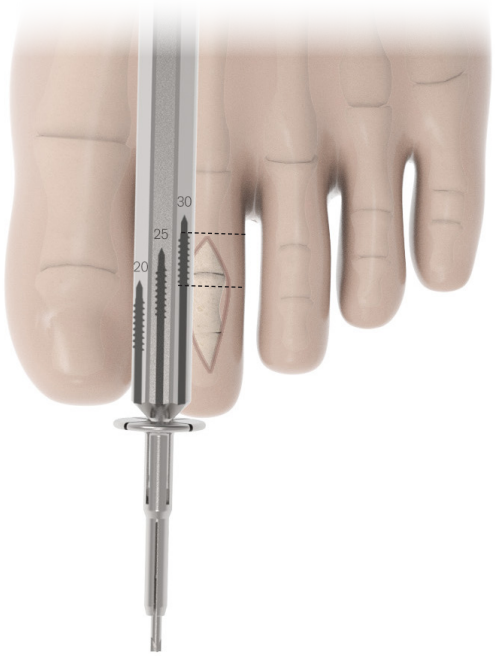
Failure to perform the proper pre-drilling and over-drilling can result in tight screw fit. The additional interference in the cortical bone can cause difficulty in screw insertion, potentially resulting in screw heads breaking off due to the excessive force required or, in malpositioning of the screw.



Step Four:
Using a 0.062″ K-wire, the previous hole is now over drilled with the larger K-wire, through the intermediate and distal phalanx, out through the end of the digit.

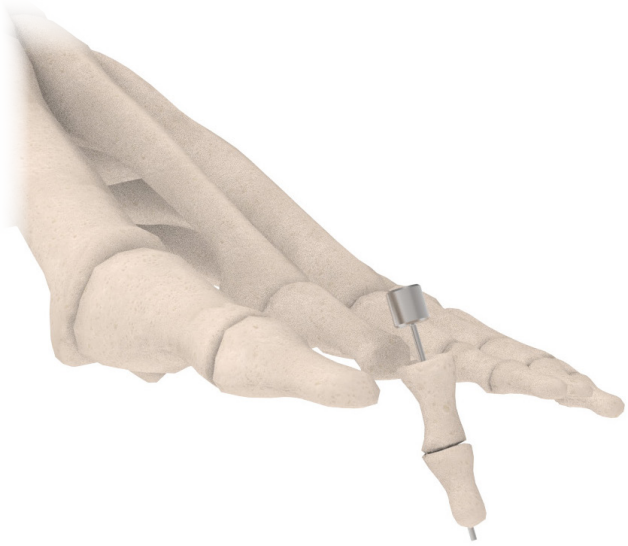
Note
If you choose to step up to the 1.8mm screw during the procedure, the 0.062″ hole must be over-drilled again using a 1.8mm drill bit. This will accommodate the larger outer thread diameter of the 1.8mm screw. (All hospitals should have a 1.8mm drill bit in their screw sets.) A 2.0mm Steinmann pin can also be used.

Step Five:
A small transverse incision (approximately 5mm) 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.

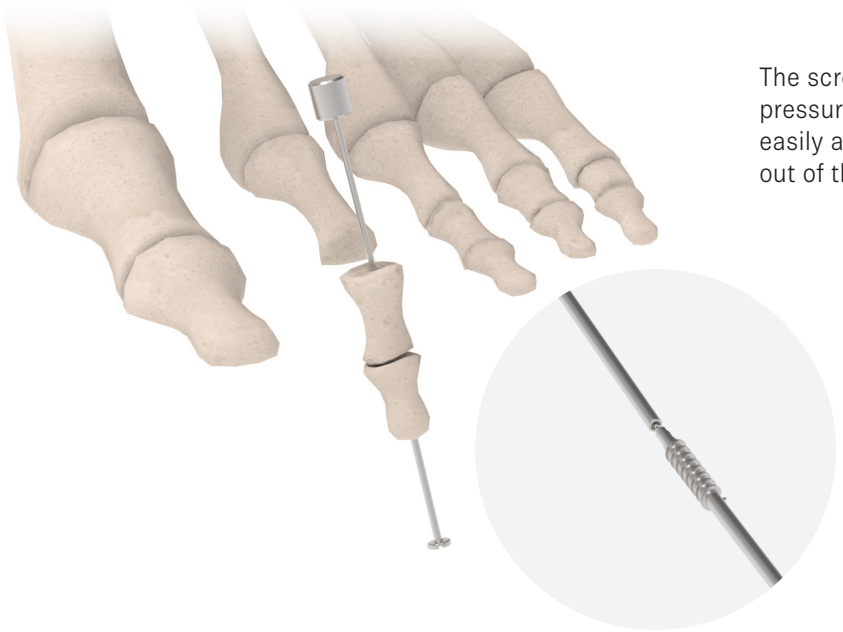


Step Six:
While approximating the proximal and intermediate phalanx in its final position, place the screwdriver on top of the toe, abutting the collar of the retaining clip against the end of the toe, to find the desired screw length. Choosing the correct screw length is very important to obtain optimal thread purchase and tightness.

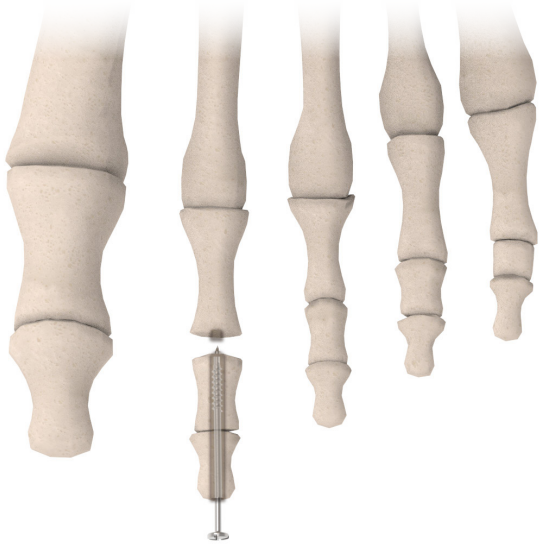
For preferred positioning of threads: measure the screw so the threads are in the joint itself or just past the joint. This allows more threads to grab the subchondral and metaphyseal bone. Since the distal bone has been over-drilled this will still produce the lag effect.



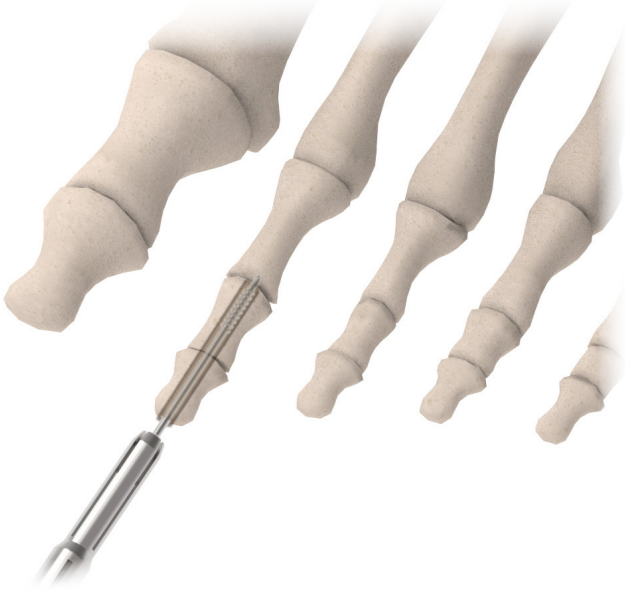
Step Seven:
Once the proper screw length is determined, open the sterile packaged screw and remove the enclosed tracker device. Pass the tracker through the base of the intermediate phalanx out through the end of the toe.



The screw tip is inserted into the tracker and with combined pressure, the tracker allows the screw to find the drill hole easily and as the screw is implanted, the tracker is retrograded out of the surgical site.



Step Eight:
Once the guide extension is visible through the base of the intermediate phalanx the guide extension is inserted into the pilot hole in the center of the proximal phalanx and the screw is tightened..

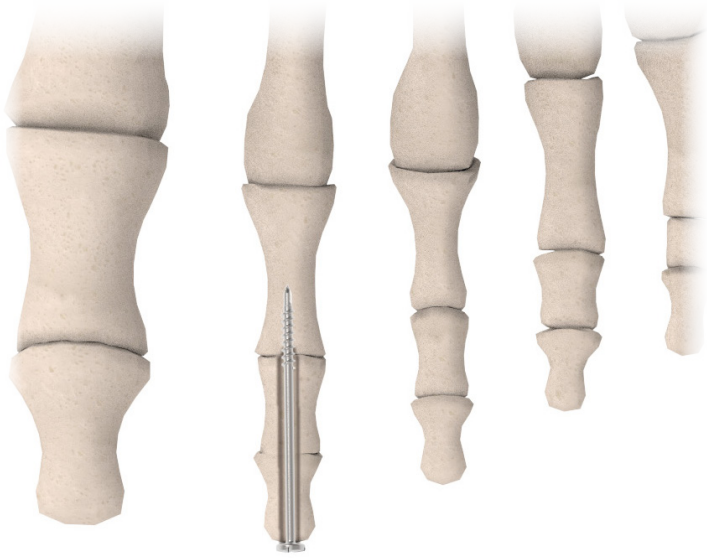


Step Nine:
Using two finger tightening finish inserting the screw until the screw head abuts the end of the distal phalanx and compression of the joint has been achieved.

Note
The screwdriver incorporates a retaining end that will encapsulate the cruciform screw head.

Note
It is always recommended to start with the Ø1.5mm screw. In the event the screw is stripped during implantation, transition to the same length of 1.8mm screw.

Caution
Care should be taken not to over-tighten the screw. Some force may be required for the screw to seat well, however, if excess force is required to tighten the screw, the alignment of the holes or size of the pre-drilling should be evaluated. Over-tightening can result in stripping the screw or screw breakage.



Step Ten:
Close the surgical wounds with suture of choice, including the distal incision.

Note
During the surgical procedure it may be advantageous to use a mini C-Arm to verify screw placement and bone apposition. Postoperative management follows the same procedure as if K-wires were used. This includes several x-rays over the healing phase and the use of an approved surgical shoe during all weight-bearing.

Note (surgical suggestion for Positional Mallet Toe)
If the surgeon is fusing the PIPJ and has an accompanying positional mallet toe deformity, an intra-articular flexor tenotomy can be done prior to all K-wire drilling to align the DIPJ. After the screw is in place the soft tissue will heal in the new position.

Note (suggestion for Structural Mallet Toe without PIPJ Fusion)
Measure the screw length so that the threads are centered in the PIPJ. This will allow excellent purchase and tightness encompassing the subchondral and metaphyseal bone from the proximal and intermediate phalanx. Even though the screw traverses a non-fused joint, this is no different than when a K-Wire is used and passes through the PIPJ. For easier screw positioning and placement for DIPJ fusion, use a 0.045" K-wire to drill the guide hole (through the intermediate phalanx) into the PIPJ.

Postoperative Protocol

Caution

To avoid bending or breaking the screw, the patient must remain in an approved post-operative surgical shoe during all weight bearing until screw removal.

Removal Procedure

The Digital Compression Screw is a non-permanent fixation device which should normally be removed in six to eight weeks. Removal is an easy surgical procedure that may be performed in a hospital, surgery center, or 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 a Betadine paint is applied to the end of the toe.
4. Palpate the screw head to identify the incision location.
5. A small transverse incision is made and soft tissue is dissected free about the screw head and its grooves.
6. Using the BioPro Removal Screwdriver, the screw is retrograded from the site. If the screw just turns, use pick-ups to pry behind the screwhead, causing retrograde pressure and 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.

Implant Ordering

ITEM #	DESCRIPTION	LENGTH
17201	DIGITAL COMPRESSION SCREW 1.5MM	20MM
17202	DIGITAL COMPRESSION SCREW 1.5MM	25MM
17110	DIGITAL COMPRESSION SCREW 1.5MM	30MM
17111	DIGITAL COMPRESSION SCREW 1.5MM	35MM
17112	DIGITAL COMPRESSION SCREW 1.5MM	40MM
17113	DIGITAL COMPRESSION SCREW 1.5MM	45MM
17114	DIGITAL COMPRESSION SCREW 1.5MM	50MM
17115	DIGITAL COMPRESSION SCREW 1.5MM	55MM
17203	DIGITAL COMPRESSION SCREW 1.8MM	20MM
17204	DIGITAL COMPRESSION SCREW 1.8MM	25MM
17116	DIGITAL COMPRESSION SCREW 1.8MM	30MM
17117	DIGITAL COMPRESSION SCREW 1.8MM	35MM
17118	DIGITAL COMPRESSION SCREW 1.8MM	40MM
17119	DIGITAL COMPRESSION SCREW 1.8MM	45MM
17120	DIGITAL COMPRESSION SCREW 1.8MM	50MM
17121	DIGITAL COMPRESSION SCREW 1.8MM	55MM

K-wire & Instrument Ordering

ITEM #	DESCRIPTION
22919	K-WIRE STERILE DOUBLE TROCHAR .035 (1.1MM)
22823	K-WIRE STERILE DOUBLE TROCHAR .045 (1.4MM)
22920	K-WIRE STERILE DOUBLE TROCHAR .062 (1.6MM)
17550	DC SCREW REMOVER
18032	DC SCREW DRIVER

BIOLOGICALLY ORIENTED PROSTHESES

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