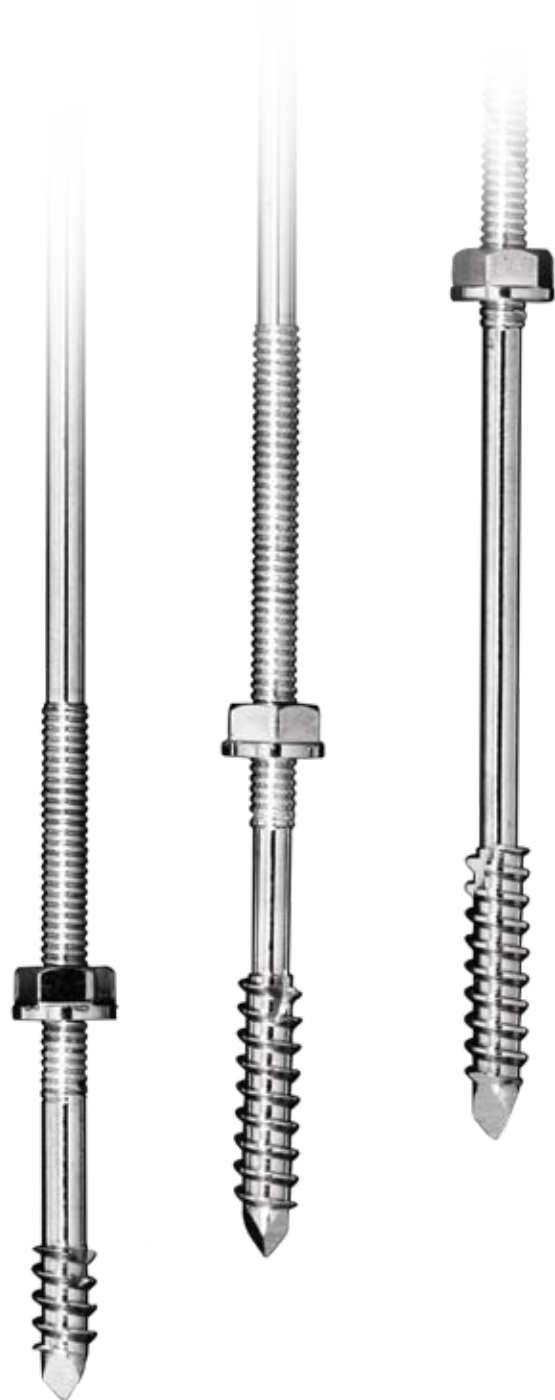
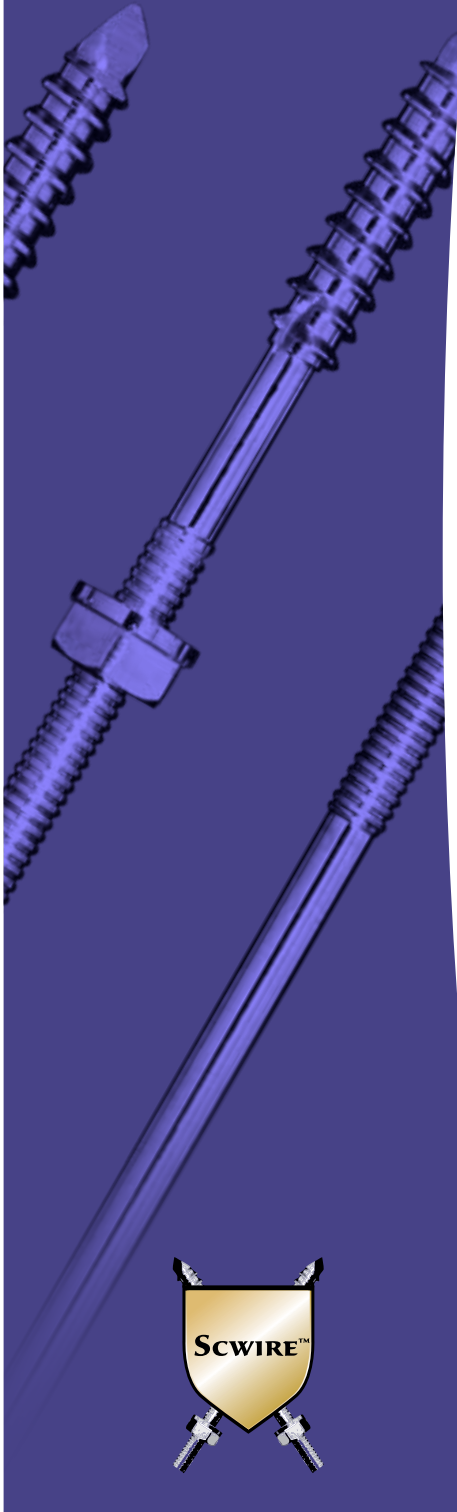


**Scwire –  
Antegrade Insertion  
Surgical Technique**



# Surgical Technique – Antegrade Insertion

## 1 Preparation

Prepare patient for surgery following accepted procedures. The skin incision is the surgeon's choice and will be dictated by the type of procedure being performed. Preparation of the bones for fixation is performed per the surgical protocol dictated by the surgeon performing the surgery.

## 2 Device Selection

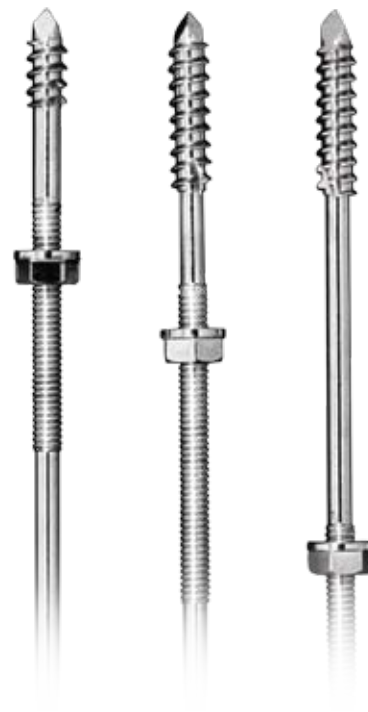
Following sterilization of the kit according to instructions and following the surgeon directed surgical protocol, remove the appropriate length Scwire device from the surgical tray. Load the Scwire device's smooth, proximal end in the chuck of a standard power driver (Fig. 1). A standard cannulated power drill or wire driver of appropriate size may be used.

**NOTE:** Do not tighten the chuck on the anchor threads or the compression threads.

**NOTE:** The Scwire device is a self-tapping, self-drilling device. Pre-drilling/tapping is not required.



Figure 1



### 3 Device Insertion

Make a small “stab” incision down to the bone and retract and/or remove any soft tissue overlying the bone so as to enable the Soft Tissue Protector to be positioned directly on the bone.

**NOTE:** There are two different length guide tubes on the Soft Tissue Protector. Therefore, when implanting the Scwire, take care to insert the Scwire device through the longer of the guide tubes. Conversely, when using the Scwire – 10 or the Scwire Mini, take care to insert the Scwire device through the shorter of the guide tubes.

Advance the Scwire device through the Soft Tissue Protector and position the trochar tip of the anchor threads at the insertion site. Position the driver on low speed and slowly advance the Scwire device into the bone through the Soft Tissue Protector until the distal anchoring threads are buried into the bone (Fig. 2A).

**CAUTION:** Percutaneous placement of a threaded device near neurovascular structures requires in-depth knowledge of the anatomy and may require the use of the Soft Tissue Protector.

**CAUTION:** Do not accidentally drive the Soft Tissue Protector into the bone. If the Scwire device is advanced to the point that the Compression Nut comes into contact with the Soft Tissue Protector, there is a risk that the Soft Tissue Protector may be driven into bone. Rotate the Compression Nut back or remove the Soft Tissue Protector to avoid this situation.

Once the anchor threads are buried into the bone, the Soft Tissue Protector is no longer needed and may be disengaged by sliding the Scwire device through the slot on the side of the Instrument (Fig. 2B).

Once the Soft Tissue Protector is removed, slowly advance the Scwire device across the fracture site with imaging guidance. The anchor threads of Scwire device should be advanced to the point where the trochar tip of the anchor threads engages the opposite cortex of the distal bone fragment (Fig. 2C). The anchor threads should not protrude the opposite cortex.

**NOTE:** Advance the Scwire device such that compression thread section is optimally positioned for the Compression Nut to compress the fragments. Ensure sufficient compression thread is within the proximal fragment, but is also exposed sufficiently to engage the Compression Nut. See Figure 2C.



Figure 2A



Figure 2B



Figure 2C

## 4

# Fracture Site Compression



Figure 3A



Figure 3B

Upon attaining optimum positioning of the anchor threads, the Scwire device is disengaged from the power driver. The Socket Wrench is passed over the proximal end of the Scwire device and the Compression Nut engaged, see Figure 3A.

**NOTE:** Ensure that no soft tissue is left between the bone and the Compression Nut. Soft tissue left between the bone and Compression Nut may interfere with compression and/or advancement of the Compression Nut.

**CAUTION:** Ensure that nut is seated against the bone with no tissue between the nut and bone to ensure stable fixation and to prevent tissue necrosis.

**CAUTION:** Monitor compression using imaging. Care must be taken not to over compress.

The Socket Wrench is then rotated in a clockwise manner until it tightens the Compression Nut against the near cortex (Fig. 3B). Optimum compression at the fracture site is achieved by further tightening the Compression Nut. It is recommended that compression at the fracture site be confirmed via imaging.

## 5 Optional Washer

### Flat Washers – Optional

In certain instances the condition of the bone stock may require the addition of a washer to increase the surface area of the Compression Nut.

**USE OF FLAT WASHER:** The Flat Washer may be used to increase the effective surface area of the Compression Nut when fixing fractures in osteoporotic bone and other appropriate situations. When using the Flat Washer, the surgeon must:

- a. *Optimally position the anchor threads according to steps 1-3.*
- b. *Remove the Compression Nut. When removing the Compression Nut it is recommended that the nut be retained in a forceps to prevent it from being dropped or misplaced.*
- c. *Pass the Flat Washer over the exposed end of the Scwire device.*
- d. *Place the Compression Nut onto the Scwire device, disengage the forceps, thread the Compression Nut onto the compression threads, and compress as necessary.*

## 6 Optional Counter Sink

### Counter Sink Tool – Optional

In instances where the prominence of the Compression Nut may cause post-operative tissue irritation, the Counter Sink Tool can be used to countersink the Compression Nut. For that purpose a Counter Sink tool has been included in the instrumentation.

**USE OF CANNULATED COUNTER SINK:** The Cannulated Counter Sink may be used to reduce the prominence of the Compression Nut. When using the Cannulated Counter Sink, the surgeon must:

- a. *Optimally position the anchor threads according to steps 1-3.*
- b. *Remove the Compression Nut. When removing the Compression Nut it is recommended that the nut be retained in a forceps to prevent it from being dropped or misplaced.*
- c. *Pass the Cannulated Counter Sink over the proximal end of the Scwire device until it contacts the near cortex of the distal tip.*
- d. *Employing a clockwise rotating motion with the counter sink, create the desired depression in the cortex.*
- e. *Place the Compression Nut onto the Scwire device, disengage the forceps, thread the Compression Nut onto the compression threads, and compress as necessary.*

**CAUTION:** *Ensure that the Counter Sink does not penetrate the cortex of the bone and that a ledge of cortical bone remains to support the Compression Nut.*

## 7

## Cut to Length



Figure 4

Following reduction and compression of the fracture, the proximal end of the Scwire device may be cut using the Cannulated Cutters. The Scwire device may be cut percutaneous or cut flush with the Compression Nut, creating a subcutaneous sized device (Fig. 4).

**FOR PERCUTANEOUS USE:** Pass the Cannulated Cutters over the exposed proximal end of the device. Cut the exposed proximal shaft of the device to the desired length. The exposed end may be left prominent and managed accordingly.

**CREATING A SUBCUTANEOUS DEVICE:** Pass the Cannulated Cutters over the exposed proximal shaft on the device. Position the Cannulated Cutter to cut the proximal shaft of the device flush with the Compression Nut and cut the shaft.

**NOTE:** *It may be necessary to retract the incision to allow the Cannulated Cutter to advance flush to the Cannulated Cutter to advance flush to the Compression Nut.*

The fixation is now complete and the surgical site should be managed in the manner appropriate for the surgery.

**CAUTION:** *Do not mix dissimilar metal implants. The Scwire implants are stainless steel. Mixing of dissimilar metals can accelerate the corrosion process.*

# Removal

The Scwire device may be removed by either gripping the exposed distal end of the Scwire device or engaging the Compression Nut and rotating the device in a counter-clockwise manner, the method of removal being dictated by the type of implantation.

**REMOVAL FOR PERCUTANEOUS IMPLANTATION:** If the device has been left percutaneous, one should grip the exposed end of the Scwire device for removal. When removing a percutaneous Scwire device, a forceps or the Scwire Extraction Tool may be employed to grip the distal end. To ensure the comfort of the patient, it is recommended that the extraction site be treated with a local anesthetic. A small “stab” incision may be required to facilitate the removal of the compression nut. Appropriate sterile procedures must be followed.

**REMOVAL FOR SUBCUTANEOUS DEVICE:** If the Scwire device was implanted as a subcutaneous device, the Compression Nut should be engaged for removal. When removing a Scwire “Subcutaneous Device,” the Socket Wrench or Scwire Extraction Tool should be used to engage the Compression Nut. A small incision will be required to locate the Compression Nut for removal. Appropriate sterile procedures must be followed.

**CAUTION:** *The Scwire device is a threaded, anchoring device. To remove the device it should be rotated counter clockwise. The device cannot be removed by pulling.*



PROD #	PRODUCT
00-1070-004	2.5mm Mini
00-1070-001	2.5mm – 10mm
00-1070-002	2.5mm – 20mm
00-1070-005	2.5mm Compression Nut (3)
00-1070-006	2.5mm Flat Washer (6)
01-1070-003	Socket Wrench
01-1070-004	Soft Tissue Protector
01-1070-005	Removal Tool
01-1070-006	Cannulated Cutter
01-1070-007	Counter Sink
01-1070-002	Case/Tray

**CAUTION:** Federal law restricts this device to sale by or on the order of a Physician.

**CAUTION:** Devices are supplied Non-Sterile, clean and sterilize before use according to instructions.

**CAUTION:** Implant components are single-use. Do not reuse.

**CAUTION:** This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

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