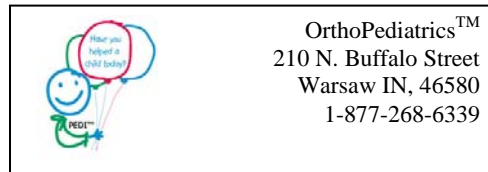




Scwire 2.5 – Instructions for Use



The complete set of directions for use for the Scwire v.2.5 consists of the following P/Ns:

- P/N 01-1070-500 - Surgical Technique Scwire v.2.5
- IFU-99-1070-001- Instructions for Use Scwire v.2.5 (this document)
- CI-0001 - Instrument Care Cleaning and Sterilization Instructions

1. Description

The Scwire v.2.5 is an orthopedic fracture fixation system including single-use implants, and manual reusable orthopedic surgical instruments. The devices are supplied non-sterile, and are to be cleaned and sterilized prior to use, see CI-0001 Instrument Care, Cleaning and Sterilization Instructions.

The Scwire device is a threaded stainless steel implant that provides the orthopedic surgeon a means of bone fixation and helps generally in the management of fractures and reconstructive surgeries. The percutaneous design is self-tapping and self-drilling, achieved by the trocar cutting point and threaded end. There are three styles of Scwire devices, a standard compression pin (new P/N 00-1070-001,002, old P/N 10000-10 and -20), a shorter anchor thread pin called the “mini” (New P/N 00-1070-004, old P/N 10000-03), and a pin used primarily for hammer-toe, called the “FD” (new P/N 00-1070-003, old P/N 10002-20) which has an additional feature, a “retrograde insertion tip”. The variable dimensions for the screws that affect the use for different applications include:

- The “fragment length” or the distance from the distal cancellous thread to the proximal compression thread;
- The “anchor length” or the length of the distal cancellous thread;
- The “compression thread” length or the proximal thread section length, and;
- The total length

The Scwire device provides for a fixed level of compression to be exerted on fracture or osteotomy fragments as needed by use of the provided compression nuts. The Scwire device has a customizable length, and can be cut with supplied or a standard pin cutter. Washers are provided for use as needed in instances where bone mass is insufficient for support in fixation.



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The standard contents of the Scwire Kit (P/N 01-1070-020) include:

Component:	Part Number:	Qty/Kit
v2.5-10 screw	00-1070-001	3
v2.5-20 screw	00-1070-002	3
v2.5-Mini screw	00-1070-004	4
v2.5-FD screw	00-1070-003	10
Compression nut	00-1070-005	1 (3 pack)
Sterilization tray	01-1070-002	1
Washer	00-1070-006	1 (6 pack)
Socket wrench	01-1070-003	2
Soft tissue protector	01-1070-004	1
Extraction tool	01-1070-005	1
Cannulated cutter	01-1070-006	1
Counter sink	01-1070-007	1

Replacement components may be ordered by contacting Customer Service.

2. Intended Use / Intended Purpose / Indications for use

The Scwire system is intended for orthopedic fracture fixation of osseous fragments of small bones (fractures and osteotomies) including distal fragments of long bones. The principal areas of use are the upper and lower extremities and the hands and feet. The device may be used for selected fractures elsewhere in the body so long as medically indicated and bone mass compatible. The device is not intended for spinal applications. The device is may be inserted percutaneously. The device is to be implanted by a physician in a clinical setting (hospital or surgery center) but may be removed as needed in a physician's office under local anesthetics and sterile conditions.

Specific indications and anatomical sites include:

- Scaphoid fractures
- Lunate fractures
- Capitate
- Carpal fractures & non-unions
- Capitellum fractures
- Humeral head fractures
- Trapezial fractures
- Metacarpal and metatarsal fractures
- Phalangeal fractures
- Distal radial fractures
- Ulnar sytloid fractures
- Osteo-chrondal fractures
- Small joint fusions
- Glenoid fractures



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- Intercarpal fractures
- Inerphalangeal fractures
- Metatarsal osteotomies
- Tarsal fusions
- Malleolar fractures
- Hammer toe fixation

3. Contraindications

Open epiphysis.

4. Precautions

See Surgical Technique P/N 01-1070-500, and Care Cleaning and Sterilization Instructions CI-0001.

5. Information to Avoid Risks for Partial Weight Bearing and Non-weight Bearing Orthopedic Appliances

These implants are intended as a guide to normal healing, and are NOT intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing. Delayed unions or non-unions in the presence of load bearing or weight bearing might eventually cause the implant to break due to metal fatigue. All metal surgical implants are subject to repeated stresses in use, which can result in metal fatigue.

In using partial weight bearing or non-weight bearing appliances (orthopedic devices other than prosthesis) a surgeon should be aware of the following:

- A. No partial weight bearing or non-weight bearing device can be expected to withstand the unsupported stresses of full weight bearing. Until firm bone union is achieved, the patient should employ adequate external support and restrict physical activities that would place stress upon the implant or allow movement at the fracture site and delay healing.
- B. Failure to immobilize a delayed union or nonunion of bone will result in excessive and repeated stresses which are transmitted by the body to any temporary internal fixation device prior to the healing of the fracture. Due to normal metal fatigue, these stresses can cause eventual bending or breakage of the device. Therefore, it is important that immobilization of the fracture site is maintained until firm bony union (confirmed by clinical and roentgenographic examination) is established.

Special precautions are necessary if temporary internal fixation device is used to treat an unstable intertrochanteric fracture or a subtrochanteric fracture. These fractures are more difficult to reduce and result in unusually strong unbalanced muscle forces, which cause



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greater stress to be transmitted to the temporary internal fixation device than other types of femoral fractures.

- C. Correct selections of the implants are extremely important. The patient must be warned that noncompliance with postoperative instruction could lead to breakage of the implant requiring revision surgery to remove the device.
- D. Preoperative and operative procedures, including knowledge of surgical techniques, good reduction, proper selection and placement of the implants are important considerations in the successful utilization of temporary internal fixation devices. See the surgical techniques P/N 01-1070-500 for specific surgical procedures.
- E. In evaluating patients for orthopedic appliance application, the patient's weight, occupation, activity level, mental condition, foreign body sensitivity and any degenerative diseases are of extreme importance to the eventual success of the procedure. These conditions must be evaluated as part of the preoperative planning.
- F. Correct handling of the implants is extremely important. The device should not be bent sharply, reverse bent, notched or scratched. All of these operations can produce effects in the surface finish and internal stress concentrations, which may become the focal point for eventual failure of the appliance.
- G. No metallic surgical implants should be reused. Any metal implant, once used, should be discarded. Even though it appears undamaged, it may already have small defects and internal stress patterns, which may lead to fatigue failure.
- H. Detailed written instructions on the use and limitation of the device should be given to the patient. See section 11 below. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending or breakage of the device are complications which may occur as a result of weight bearing or muscle activity. An active patient, debilitated or demented patient who cannot properly utilize weight support devices may be particularly at risk during postoperative rehabilitation.
- I. Removal of the device. While the surgeon must make the final decision on the implant removal it is the position of the Orthopedic Surgical Manufacturers Association that, whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger and more active patients.
- J. 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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6. Materials:

- A. Implants: Stainless Steel per 316 LVM, ASTM F 139, Gr. 2, ISO 5832-1
- B. Reusable Instruments: Stainless Steel per ASTM F899-07
- C. Instrument Tray: Radel R-5000, Polyphenylsulfone

7. Risks posed by the presence of the device during MRI

MR safe (according to definition in ASTM F 2052-02) —the implants are bone screws made of Stainless Steel, compliant with ASTM F 138-03, and provide a completely nonmagnetic microstructure which will not cause torque, displacement or heating in a Magnetic Resonance Imaging (MRI) environment. However, the device will cause an imaging artifact which would obscure the target imaging area if the device is implanted in the area targeted.

8. Other Information

The surgical techniques for the Scwire system are covered in P/N 01-1070-500.

Implants are single-use, supplied non-sterile. Instruments are reusable, supplied non-sterile. All products must be cleaned and sterilized in accordance with AAMI ST79-2006 or similar method before each use. See CI-0001- Instrument Care, Cleaning and Sterilization Instructions.

Quantities of screws used for the fixation is dependent on the specific indications, anatomical sites and the discretion of the orthopedic surgeon.

Duration of implantation depends on the treatment for the particular indication. Three durations of use may be employed: temporary – provisional use of screw during surgery, interim – 30 days or longer during the healing process, and permanent – used for fixation during healing but left in place if there is no medical reason to remove (see 5 I).

The Scwire screws may be used with standard orthopedic power drivers as indicated in the surgical technique. Set the driver on low speed during use. See Surgical Technique, P/N 01-1070-500 for more specific instructions on use of the driver with the devices in specific applications.

Storage and handling of the Scwire system including accessory instruments should be handled according to ASTM F 565 Standard Practice for Care and Handling of Orthopedic Implants and Instruments and ASTM F 1744 Standard Guide for Care and Handling of Stainless Steel Surgical Instruments. Maintenance and calibration are not required, the instruments are to be replaced if worn or damaged in a way that compromises safety or their



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intended function. For specific instructions on the Scwire System see CI-0001 Instrument Care, Cleaning and Sterilization Instructions.

9. Customer Service

Replacement components may be ordered by contacting Customer Service at:
OrthoPediatrics, Corp., 210 N. Buffalo Street, Warsaw, IN 46580
Phone: 877-268-6339
Fax: (574) 268-6302
Email: jminaudo@orthopediatrics.com