

FRS[®]
FRS[®] Screw

**Basic Product and Instrument
Utilization technique**

FRS® Screw

Features and Benefits:

- Screw designed specifically for digital shaft osteotomies
- Titanium alloy — For implant strength and biocompatibility
- Cannulated — Allows for accurate screw-length measurement and the ease of guided insertion
- Headless — Inserted below the bone surface to minimize soft tissue irritation
- Self-tapping to ease insertion procedure
- Dual thread design — Cortical (proximal portion) and cancellous (distal portion) utilized to create compression across osteotomy site as the screw is inserted
- Dedicated instrumentation accommodates varied surgical techniques
 - Osteotomy guide for precise bone cuts in certain osteotomy procedures
 - Modular tray accommodates instrument and implant customization, and includes a screw-length gauge
 - Instrumentation has dual (depth gauge and reverse ruler) screw-length measurement options
 - Offset osteotomy clamp aids and stabilizes osteotomy fragments
- Screw design permits downsizing without compromising bone compression
- Multiple screw lengths, 10-34 mm, meet the needs of multiple anatomical applications
- Screw diameters:
 - 10-22 mm long 2.5 mm distal/3.3 mm proximal
 - 24-34 mm long 3.0 mm distal/3.9 mm proximal
- Intended Use: Fixation of fracture or osteotomies of the foot such as:
 - Hallux valgus correction
 - Akin Osteotomies
 - MTP arthrodesis
 - Interphalangeal arthrodesis

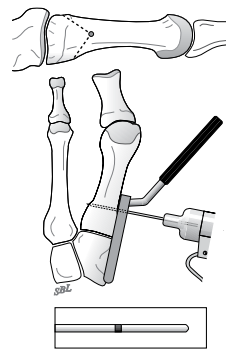


Figure 1

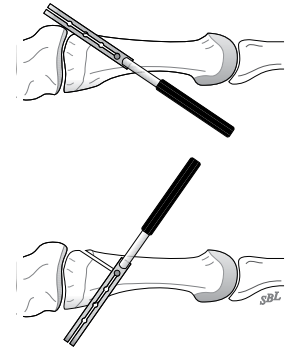


Figure 2

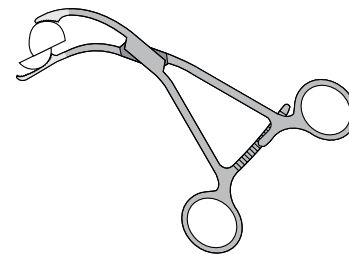


Figure 3

Surgical Technique

Bone Resection

In certain procedures, perform bone cuts using an osteotomy guide (Cat. No. A5734). Insert the 1.0 mm x 70 mm smooth guide pin (Cat. No. PA010) at the apex of the osteotomy (Figure 1).

Note: The 1.0 mm diameter pin is marked with a black band around the circumference of the rounded proximal end.

Pivot the osteotomy guide on the guide pin. Insert a micro-sagittal saw within the guide's track to perform the bone cuts (Figure 2). Utilize the osteotomy clamp (Cat. No. PA720) to hold and/or compress the bone cuts during screw insertion. It is especially helpful when working with offset bone fragments (Figure 3).

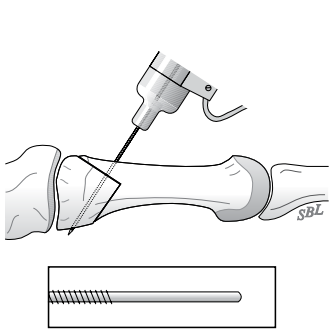


Figure 4

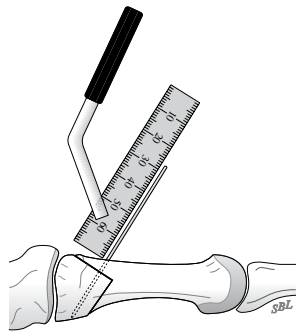


Figure 5

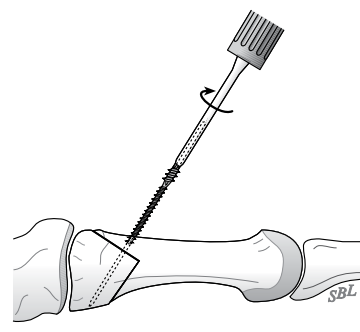


Figure 7

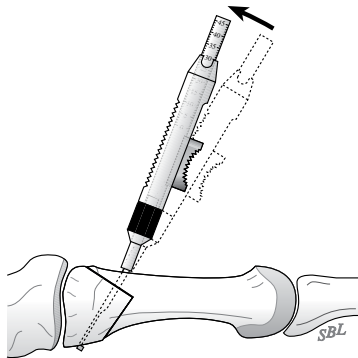


Figure 6

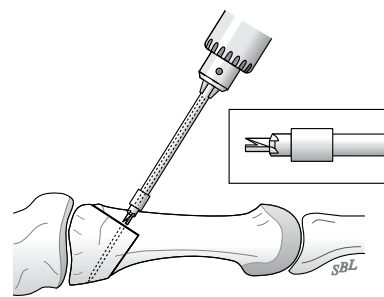


Figure 8

Screw Insertion Method

Pre-drill the screw hole with the 2.0 mm diameter x 70 mm long threaded pin (Cat. No. PA016). Depending on the selected technique, confirm that the hole extends to the distal bone cortex (Figure 4).

Note: The 2.0 mm diameter threaded pin is smooth at its proximal end.

Utilize the reverse ruler (Cat. No. A5736) to determine the proper screw length by positioning it against the proximal cortex and reading the corresponding length (Figure 5).

Alternatively, if a precise cortex-to-cortex measurement is desired, retrieve the threaded pin and insert the depth gauge (Cat. No. A5733) to measure the proper screw length. The gauge's stylus should catch the outside rim of the distal cortex hole. Slightly leverage the depth gauge, as shown, to ease catching the distal cortex (Figure 6).

Note: Depending on bone quality, the FRS Screw applies approximately 1 mm – 2 mm of compression across the osteotomy site. This amount should be

considered when selecting the appropriate screw length for cortex-to-cortex applications.

Remove the 2.0 mm diameter threaded pin. Use the cannulated modified relief drill bit (Cat. No. PA019) to enlarge the proximal cortex hole before inserting the screw over the smooth 0.8 mm diameter x 70 mm guide pin (Cat. No. PA009) (Figures 7 and 8).

Note: Hold the bone segments together, preferably with a bone clamp, and insert the screw slowly, especially when inserting the proximal end of the screw.

Use the cannulated relief drill bit to enlarge the proximal cortex hole before inserting the screw over the guide pin (Figure 7 and 8).

Note: Hold the bone segments together, preferably with a bone clamp, and insert the screw slowly, especially when inserting the proximal end of the screw. With extremely hard bone, employ the screw insertion method, and utilize the relief drill bit to expand the proximal cortex before screw insertion.

Essential Product Information

Important

This Essential Product Information does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

Indications

Orthopaedic screws and pins are intended to provide the orthopaedic surgeon a means of bone fixation and help in the general management of fractures and reconstructive surgeries. 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.

Contraindications

The FRS Screw is contraindicated: in the presence of active infection; in cases with malignant primary or metastatic tumors which preclude adequate bone support or fixation unless supplemental means of fixation are used; in conditions that tend to retard healing such as blood supply limitations, previous infections, etc.; if insufficient quantity or quality of bone does not permit stabilization of the fracture complex; in conditions that restrict the patient's ability or willingness to follow postoperative instructions; and in cases where material sensitivity is suspected.

Warnings and Precautions

This device is intended for partial weight-bearing or nonweight-bearing applications and cannot be expected to withstand the unsupported stresses of full weight bearing. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Adverse Events The following are the most frequent adverse events after fixation with orthopaedic screws and pins: loosening, bending, cracking or fracture of the components or loss of fixation in bone attributable to nonunion, osteoporosis, markedly unstable comminuted fractures; loss of anatomic position with nonunion or malunion with rotation or angulation; infection and adverse reactions to the device material.

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For product information, including indications, contraindications, warnings, precautions and potential adverse effects, see the package insert.

Implants

Cat. No.	Description
P2010	FRS Screw 10 mm L x 2.5 mm Diameter
P2012	FRS Screw 12 mm L x 2.5 mm Diameter
P3014	FRS Screw 14 mm L x 3.0 mm Diameter
P3016	FRS Screw 16 mm L x 3.0 mm Diameter
P3018	FRS Screw 18 mm L x 3.0 mm Diameter
P3020	FRS Screw 20 mm L x 3.0 mm Diameter
P3022	FRS Screw 22 mm L x 3.0 mm Diameter
P1024	FRS Screw 24 mm L x 3.0 mm Diameter
P1026	FRS Screw 26 mm L x 3.0 mm Diameter
P1028	FRS Screw 28 mm L x 3.0 mm Diameter
P1030	FRS Screw 30 mm L x 3.0 mm Diameter
P1032	FRS Screw 32 mm L x 3.0 mm Diameter
P1034	FRS Screw 34 mm L x 3.0 mm Diameter

Instruments

Cat. No.	Description
A5733	Depth Gauge
A5734	Osteotomy Guide
A5736	Reverse Ruler
A5737	Cannulated Screwdriver
P1000	Instrument/Implant Tray
P1001	FRS/SOC® Pin Insert Tray
P1003	Tray Base
P1004	Tray Lid
P1005	Instrument Insert
PA009	Guide Pin, 0.8 mm x 70 mm 6/Pk
PA010	Guide Pin, 1.0 mm x 70 mm 6/Pk
PA016	Threaded Pin, 2.0 mm x 70 mm
PA017	FRS Screw Forceps
PA019	FRS Modified Relief Drill
PA720	Osteotomy Clamp



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