



The Gold Standard Changed IN THE 1970s!

In the 1970s, intramedullary nails supplanted surgical plates as the gold standard for treating femoral and tibial fractures.

- Nails are now generally accepted as advantageous over plates because nails:
- Reduce skin and soft-tissue trauma
 - Decrease infection rates
 - Are load sharing instead of load bearing to expedite patient rehabilitation
 - Cause less patient pain with fewer requests for implant removal

Despite these advantages, fibula fractures are still predominantly repaired with surgical plates. Plates generally deliver an anatomic reduction, but require a substantial incision and frequently cause patient discomfort with subsequent removal. Peer-reviewed literature demonstrates incision-site infections and healing are significant issues which surgeons take multiple precautions to avoid.

FibuLock™ Holds Your Reduction

In most cases, the fibula can be reduced percutaneously with slight traction and the application of forceps. However, surgeons can use the same reduction methods they would use for a plate through a much smaller incision.



Forceps hold reduction



Fibular reaming



FibuLock™ nail implantation

It's Now Time for FIBULA NAILING

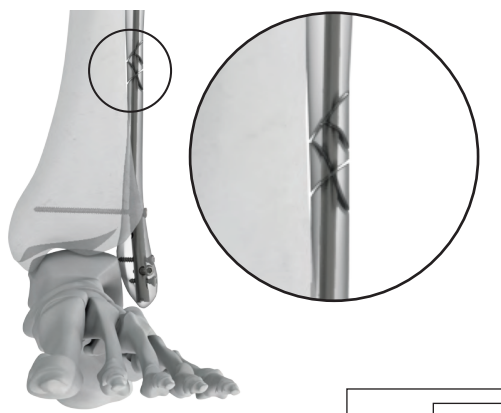
The Sonoma FibuLock™ nail is the first intramedullary device that has the **same indications as plates** and delivers anatomic reductions with all of the other advantages of intramedullary nailing.



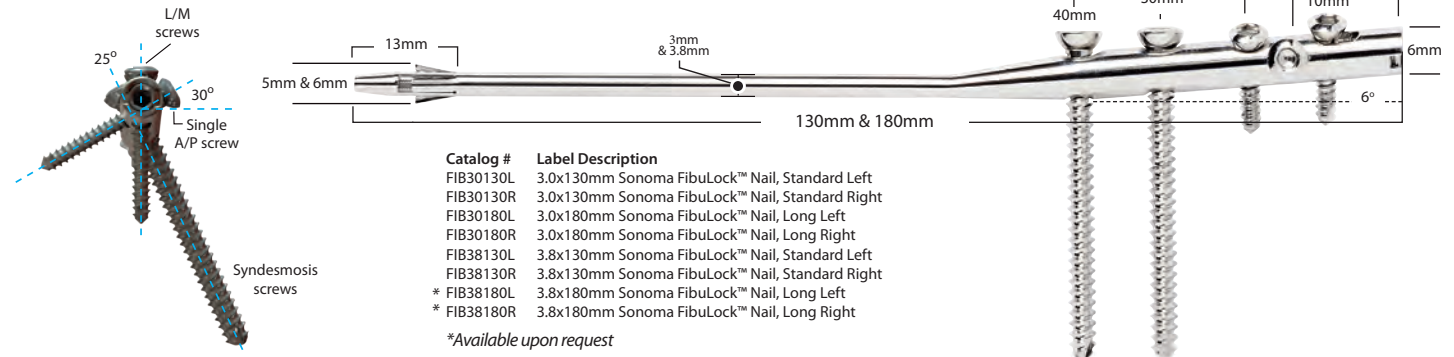
Spanning **COMMINUTION**

Like femoral and tibial nails, the FibuLock™ nail is an excellent solution for comminuted fractures.

The FibuLock™ nail can be used to span a highly comminuted portion of the fibula to avoid making an incision over the fragmented bone. The nail then holds the fibula to length and rotation while the soft-tissue envelope maintains the bone fragments in proximity for healing.

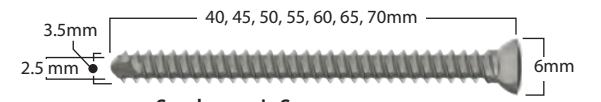


SPECIFICATIONS



Catalog #	Label Description
FIB30130L	3.0x130mm Sonoma FibuLock™ Nail, Standard Left
FIB30130R	3.0x130mm Sonoma FibuLock™ Nail, Standard Right
FIB30180L	3.0x180mm Sonoma FibuLock™ Nail, Long Left
FIB30180R	3.0x180mm Sonoma FibuLock™ Nail, Long Right
FIB38130L	3.8x130mm Sonoma FibuLock™ Nail, Standard Left
FIB38130R	3.8x130mm Sonoma FibuLock™ Nail, Standard Right
* FIB38180L	3.8x180mm Sonoma FibuLock™ Nail, Long Left
* FIB38180R	3.8x180mm Sonoma FibuLock™ Nail, Long Right

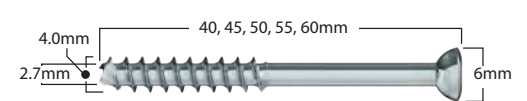
*Available upon request



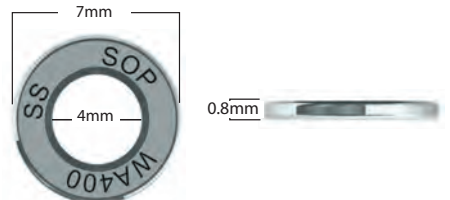
Catalog #	Label Description
CO3540-D	3.5mm x 40mm Quick Thread Cortical Screw
CO3545-D	3.5mm x 45mm Quick Thread Cortical Screw
CO3550-D	3.5mm x 50mm Quick Thread Cortical Screw
CO3555-D	3.5mm x 55mm Quick Thread Cortical Screw
CO3560-D	3.5mm x 60mm Quick Thread Cortical Screw
CO3565-D	3.5mm x 65mm Quick Thread Cortical Screw
CO3570-D	3.5mm x 70mm Quick Thread Cortical Screw



Catalog #	Label Description
SC2712	2.7mm x 12mm Self Tapping Cortical Screw
SC2714	2.7mm x 14mm Self Tapping Cortical Screw
SC2716	2.7mm x 16mm Self Tapping Cortical Screw
SC2718	2.7mm x 18mm Self Tapping Cortical Screw
SC2720	2.7mm x 20mm Self Tapping Cortical Screw



Catalog #	Label Description
CA4040-C	4.0mm x 40mm Cancellous Screw, Cannulated
CA4045-C	4.0mm x 45mm Cancellous Screw, Cannulated
CA4050-C	4.0mm x 50mm Cancellous Screw, Cannulated
CA4055-C	4.0mm x 55mm Cancellous Screw, Cannulated
CA4060-C	4.0mm x 60mm Cancellous Screw, Cannulated



Catalog #	Label Description
WA4000	4.0mm Medial Malleolus Bone Screw Washer



Catalog #	Label Description
FIB6000	Sonoma FibuLock™ Nail End Cap

References

1. K.E. Bugler, T.O. White, P.T. Appleton, M.M. McQueen and C.M. Court-Brown. A Prospective, Randomised Controlled Trial Of A Fibular Nail Versus Standard Open Reduction And Internal Fixation For Fixation Of Ankle Fractures In Elderly Patients. Bone Joint J 2013 vol. 95-B no. SUPP 25 8
2. Avilucea F, et al. The Costs of Operative Complications for Ankle Fractures: A Case Control Study. Advances in Orthopedics. 2014

Prior to the use of the Sonoma Orthopedic Products FibuLock™ nail system, the surgeon should refer to the product instruction for use (IFU) for complete indications, warnings, precautions and contra indications. Package inserts are also available by contacting Sonoma Orthopedic Products, Inc.



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LB-1343 Rev B



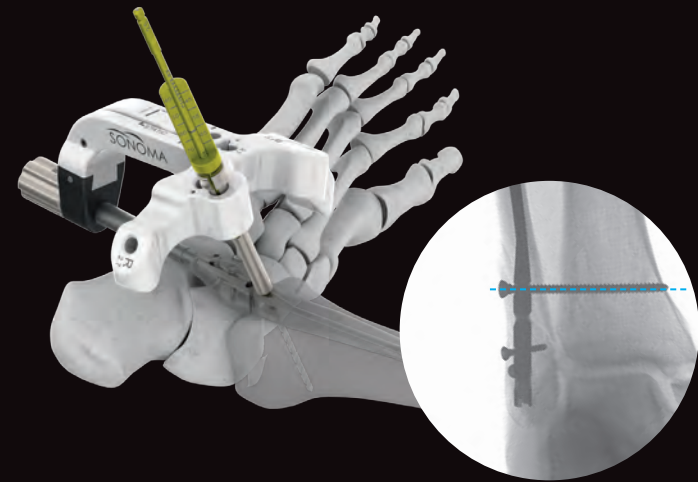
FibuLock™ Nail Ankle Fracture System

Locks Anatomic Reductions for Weber A, B and C Fractures



Plate Features In A Nail...

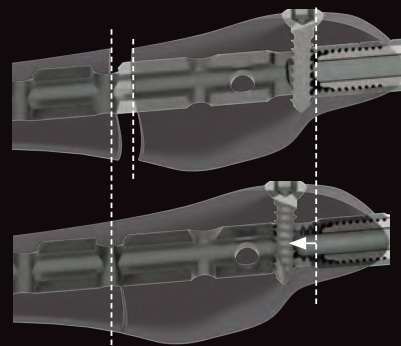
SYNDESMOSIS FIXATION, COMPRESSION and REMOVAL



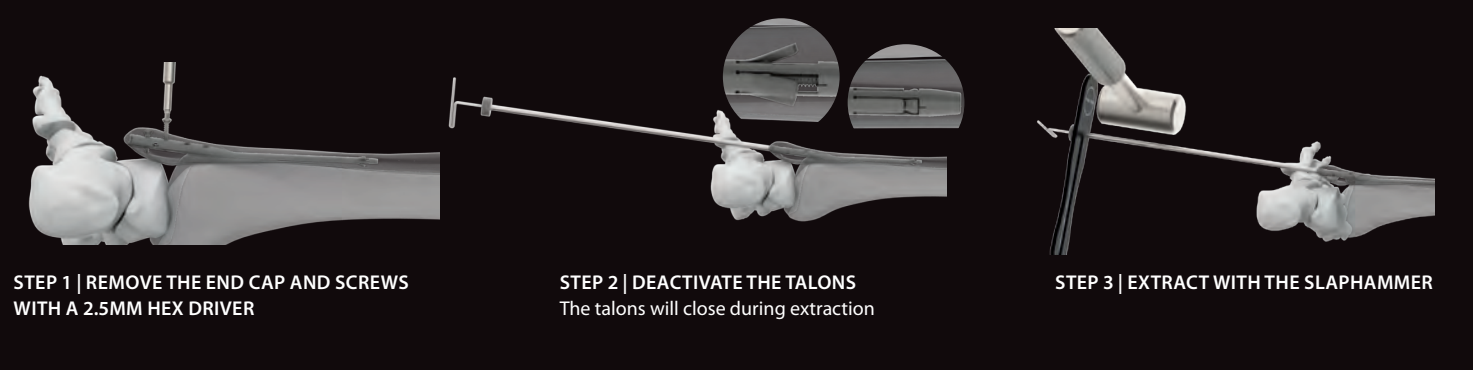
Patented COMPRESSION
The FibuLock™ nail features a patent-pending mechanism that provides 2.5mm of compression.

Simple SYNDESMOSIS

The anatomic angulation of the FibuLock™ nail combined with the screw targeting outrigger ensures the syndesmosis screw will be parallel to the plafond. "Quick Thread" screws bore into bone twice as fast as traditional screws to expedite the procedure.



Removal TECHNIQUE

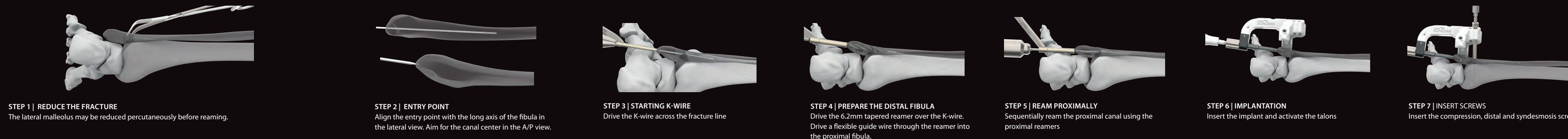


STEP 1 | REMOVE THE END CAP AND SCREWS WITH A 2.5MM HEX DRIVER

STEP 2 | DEACTIVATE THE TALONS
The talons will close during extraction

STEP 3 | EXTRACT WITH THE SLAPHAMMER

Surgical TECHNIQUE



STEP 1 | REDUCE THE FRACTURE
The lateral malleolus may be reduced percutaneously before reaming.

STEP 2 | ENTRY POINT
Align the entry point with the long axis of the fibula in the lateral view. Aim for the canal center in the A/P view.

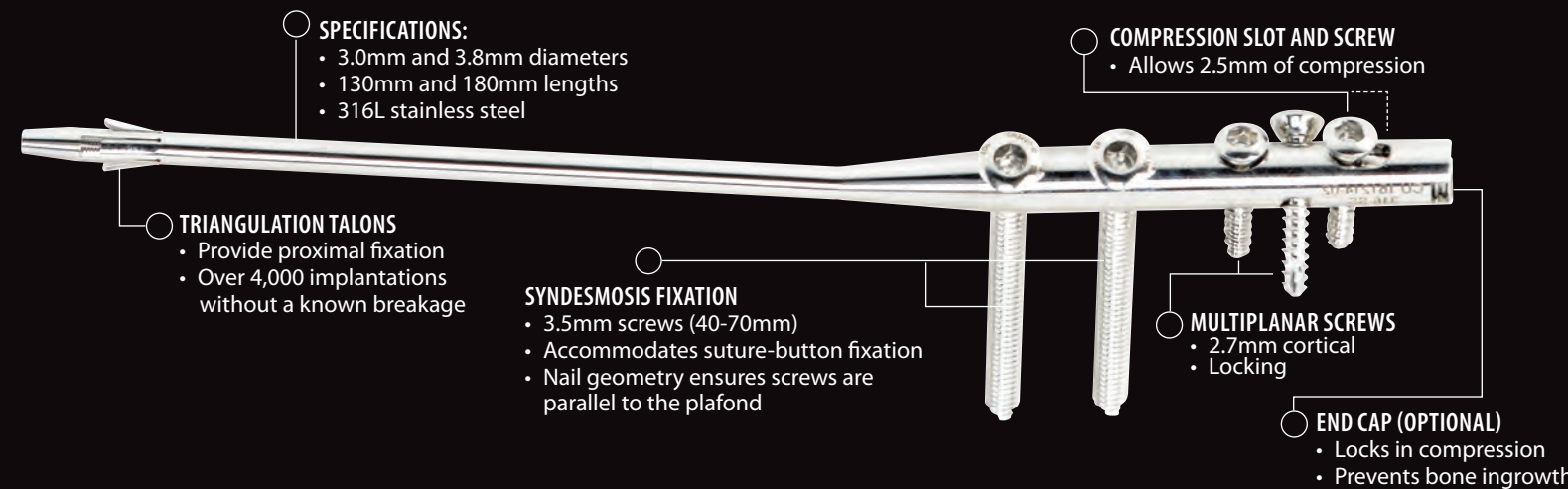
STEP 3 | STARTING K-WIRE
Drive the K-wire across the fracture line

STEP 4 | PREPARE THE DISTAL FIBULA
Drive the 6.2mm tapered reamer over the K-wire. Drive a flexible guide wire through the reamer into the proximal fibula.

STEP 5 | REAM PROXIMALLY
Sequentially ream the proximal canal using the proximal reamers

STEP 6 | IMPLANTATION
Insert the implant and activate the talons

STEP 7 | INSERT SCREWS
Insert the compression, distal and syndesmosis screws



SPECIFICATIONS:

- 3.0mm and 3.8mm diameters
- 130mm and 180mm lengths
- 316L stainless steel

TRIANGULATION TALONS

- Provide proximal fixation
- Over 4,000 implantations without a known breakage

SYNDESMOSIS FIXATION

- 3.5mm screws (40-70mm)
- Accommodates suture-button fixation
- Nail geometry ensures screws are parallel to the plafond

COMPRESSION SLOT AND SCREW

- Allows 2.5mm of compression

MULTIPLANAR SCREWS

- 2.7mm cortical
- Locking

END CAP (OPTIONAL)

- Locks in compression
- Prevents bone ingrowth

Reduced COST AND COMPLICATIONS

A recent study investigated whether intramedullary nailing of fibula fractures would reduce the incidence of wound and implant issues while delivering the same union and reduction rates as surgical plates. The study compared 50 plate and 50 intramedullary nail patients. The average patient age was 74-years-old and 75% were women. Functional results were slightly better for the intramedullary nail group, and the following table lists the complication results at 12-months.¹

COMPLICATION	PLATES		NAILS		P VALUE
	NUMBER OF PATIENTS	PERCENTAGE OF TOTAL	NUMBER OF PATIENTS	PERCENTAGE OF TOTAL	
Wound Infections	8	16%	0	0	0.002

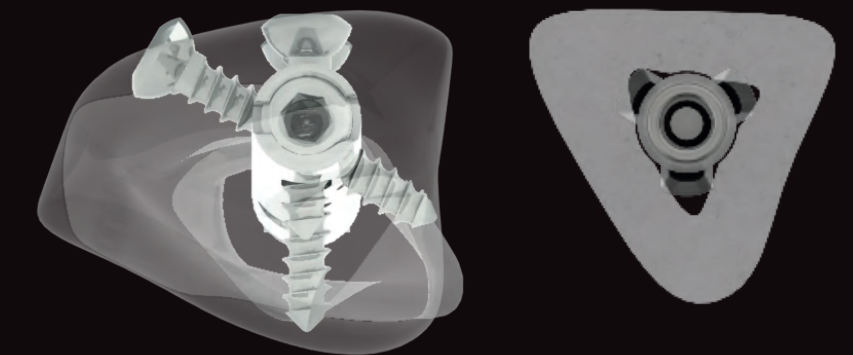
In addition, the costs of treating intramedullary patients were lower. This finding is supported by a 2014 study by The Vanderbilt Orthopaedic Institute Center for Health Policy which examined the hospital economic impact of plate repair complications in patients with isolated ankle fractures without associated injuries.² Infections (1.8%) and hardware-related pain (2.3%) added \$78,000 and \$39,000 respectively to the cost of treating each patient. **If the increased expense for this small subset of patients was distributed across all 439 patients within the study, it would add \$2,300 to the cost of each patient's care.**

Mechanisms to MAINTAIN STABILITY

Most biomechanical research indicates the fibula sees 4% to 15% of body weight through mild compressive, bending and rotational loads. The FibuLock™ nail stabilizes the fractured canal against these forces with four mechanisms:

1. **Proximal triangulation talons** – Unlike other long bones, the fibula has a triangular cross section. The talons of the FibuLock™ nail are designed to engage the apexes of the triangular canal geometry to resist compression and rotation.
2. **Shaft interference fit** – The shaft locks into the canal as it is forced to flex in response to the slight curvature of the bone
3. **Multiplanar locking screws** – Provide distal fixation
4. **Compression mechanism** – Increases proximity of bone fragments if necessary

Due to these stability and alignment mechanisms, the FibuLock™ nail is indicated for Weber A (high), B and C ankle fractures.



Fibula cross section with FibuLock™ multiplanar screws (distal view)

Fibula cross section with FibuLock™ talons deployed (proximal view)