

# ACUMED



# ΑΦΙΜΕΔ



*External  
Fixation Systems*

# STABLELOC

# STABLELOC

## Indication: Distal Radius Fractures

The **Stableloc External Fixator** is a lightweight, radiolucent device for the repair of unstable distal radius fractures. Designed to incorporate the best features of the most popular wrist fixators on the market today, the **Stableloc** allows the surgeon to gain the initial reduction with the fixator in place, and then independently adjust only those planes needing correction. For convenience, the device is packed sterile with everything needed to complete a case, including instrumentation and pins.

**Radial/Ulnar Deviation** is achieved with the distal pin clamp. Grooved slots in the pin clamp allow the pins to be spaced 15mm, 20 mm or 25mm apart depending on the patient. Note: the 25mm drill guide comes standard with the sterile kit. The 15mm and 20mm guides may be ordered separately.

**Flexion** adjustment is controlled with a single ball joint placed at the center of wrist rotation. The ball joint may also aid in the initial reduction by providing the surgeon the tactile sensation of feeling the fracture re-aligning.

**Incremental Length** adjustment facilitates the principal of ligamentotaxis by applying controlled traction across the wrist joint to aid fracture reduction.

**Dorsal/Palmar Translation** applies controlled incremental force through the metacarpals to re-establish the natural palmar tilt of the distal radius. The fixator allows up to 16mm of palmar or dorsal travel.

**Secure Fixation** is maintained with four unique 3.2mm pins that may be used as either self-drilling or pre-drilled with the 2.5mm drill provided in every sterile kit. A unique thread geometry facilitates insertion and maximizes bone purchase but will not loosen if the pin needs to be backed out slightly. Optional 2.7mm pins are available on request.





## Sterile Pack

*Sterile Stableloc System* is a complete and cost effective solution with simple instrumentation,

## Radiolucent



*Radiolucent housing* to aid in fracture visualization for accurate fracture reduction.

## Unique Pin Design



## Cover

*The Stableloc Cover* facilitates patient acceptance.



For many years, external fixation has been a well accepted technique to stabilize a variety of fractures. Acumed is committed to providing unique and innovative fracture management solutions for the upper and lower extremities and has developed a dedicated line of external fixators suited especially for these areas. From our unique Colles management systems to our innovative small bone fixation and distraction units, we designed each system to provide ease of application, stability, and precise fracture reduction.

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# STABLELOC EX

## Indications: Distal Radius Fractures and Osteotomies

The **Stableloc EX** is a user friendly, lightweight non-bridging fixator which will allow for early range of motion. The device permits joy stick manipulation of the distal fragment to allow anatomic correction of palmar tilt and radial angulation. For osteotomy procedures, an independent length adjustment allows for precise and accurate distraction. The **Stableloc EX** utilizes the same minimal instrumentation as the standard **Stableloc** to facilitate ease of application.

**Minimum intact distal fragment required for pin fixation.**



**Versatile Pin Placement Options** allow the surgeon to adjust the pin angle to assure secure fixation in the distal fragment.

**Left & Right Fixators Available.**

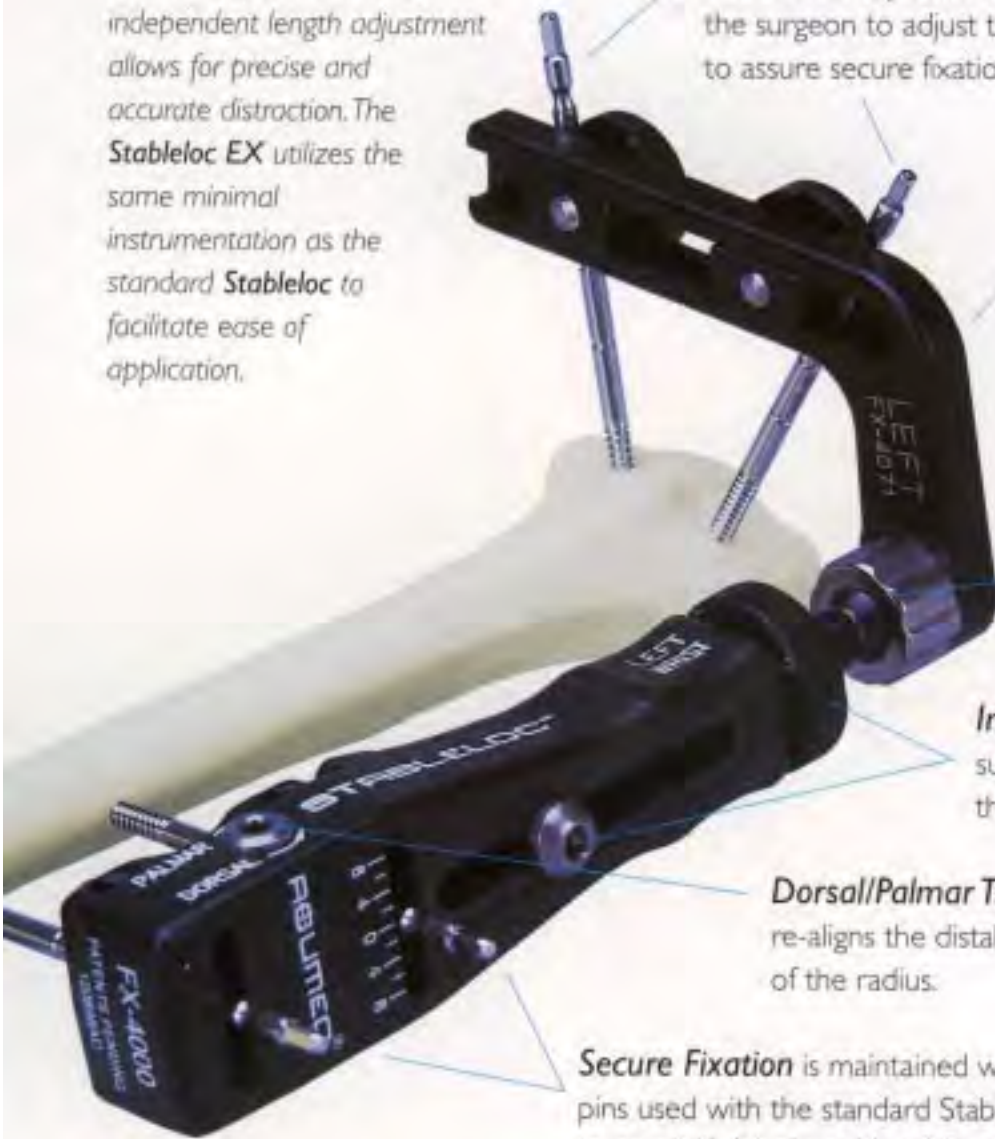
**Radiolucent Housing** aids in fracture visualization. See X-Ray on previous page.

**Ball Joint** allows joy stick manipulation to gain anatomic reduction.

**Incremental Length** adjustment allows the surgeon to independently distract across the fracture/osteotomy site.

**Dorsal/Palmar Translation** anatomically re-aligns the distal fragment with the shaft of the radius.

**Secure Fixation** is maintained with the same unique self-drilling pins used with the standard **Stableloc**. The surgeon may choose to pre-drill the pins with a 2.5mm drill. Optional 2.7mm pins are available upon request.



# SMALL BONE FIXATOR

**Indications:** Stabilization of open fractures, periarticular fractures, corrective osteotomies, joint arthrodeses, articular fractures, diaphyseal fractures, infected fractures and non-unions of the metacarpals and phalanges.

	Acumed	EBI	Howmedica
Lateral Bending (N/cm)	434.4	461.9	75.9
Compression (N/cm)	500.4	1029.7	219.9
Torsion (N/cm)	5.06	4.8	3.98

All stiffness measurements are from a poster presented by Tun, Jebson, Goldstein and Kekiya at the AAHS Annual Meeting, Jan.7-10, 1998.

Acumed offers the **Small Bone Fixator** as a simple to use, cost effective, versatile and stable solution for external fixation. The benefits of the use of external fixation for hand injuries include the following: minimal exposure of the fracture site, no second procedure necessary to remove hardware and adequate stabilization when internal fixation may not be possible due to poor hardware to bone contact.

**Simple Instrumentation** includes a wire guide assuring parallel placement of the K-wires and a hex key for securing the clamps.

**Standard Size K-wire** from .035" to .062" eliminates the need for pre-drilling to install expensive custom pins.

**Rigid Fixation.** This device compares favorably to the leading small external fixators on the market. See comparison above.

**Versatile Pin Placement** allows the surgeon to determine the pin placement based on the fracture, not the fixator. The clamps swivel and rotate to connect the clamps with the connecting bar(s) to build a frame around the fracture.



# INEMA ΣΟΦΟΥΛΗ 83 ΡΟΔΟΣ τηλ : 2241032238

## SMALL BONE DISTRACTOR

**Indications:** Open or closed fractures, aseptic and infected non-unions, corrective osteotomies, length maintenance due to segmental bone loss, and distraction lengthening of the metacarpals, metatarsals, and phalanges.

The **Acumed Small Bone Distractor** is a lightweight, low profile fixator. In addition to its listed indications above, the device can also provide compressive forces to secure a fracture or osteotomy in conjunction with a bone graft. Soft tissue dissection or disturbance of the bone biology is not needed, as the device acts as its own template and utilizes minimally invasive 1.1mm (.045") to 1.5mm (.062") threaded K-Wires which can be introduced percutaneously to secure and stabilize the corrective procedure.



**Multiple Distractors** may be linked via a wire clamp on the end of device.



### **K-Wire Insertion Holes.**

Terminally threaded 1.5mm (.062") K-Wires are provided with the kit. Threaded or smooth K-Wires ranging from 1.1mm (.045") to 1.5mm (.062") can also be used.

### **Removable Handle**

allows the surgeon to easily manipulate the device to facilitate fracture/osteotomy alignment and minimize X-ray exposure.

### **Distraction/Compression Adjustment Knob.**

Easy to read markings provides adjustment as needed to achieve appropriate distraction/compression.

### **Distraction/Compression Scale**

permits approximately 20mm of travel for precise adjustment.

# ORDER INFO / WARNINGS

## STABLELOC

### FX-4001 Complete Stableloc System

FX-4000 Stableloc Assembly

FX-4005 Stableloc Soc

FX-4004 Sterile Pins

FX-4006 Drill

FX-4003 Hex Driver

FX-4002 Drill Guide

FX-4008 Pin Driver

## STABLELOC EX

### FX-301L Complete Stableloc EX System Left

### FX-301R Complete Stableloc EX System Right

FX-300L Stableloc-EX Assembly (Left)

FX-300R Stableloc-EX Assembly (Right)

FX-4004 Sterile Pins

HK-0032 Hex Key

FX-4006 Drill

FX-4003 Hex Driver

FX-4008 Pin Driver

FX-1002 EX Drill Guide

FX-4002 25mm Drill Guide

## SMALL BONE FIXATOR SET

SM-5100 Housing Assembly

SM-5200 Outrigger Assembly

SM-5063 63mm Shaft

SM-5089 89mm Shaft

SM-5080 Pin Guide

HK-0024 Hex Key

SM-5060 Tray

## SMALL BONE DISTRACTOR

BDI-400 Small Bone Distractor

AT-7004 Hex Key

WS-1504STT K-wire

**Description:** Stableloc fixator pins are designed to be used in conjunction with the Stableloc External Fixator for fractures of the distal radius. **Information for Use:** Physiological dimensions limit the sizes of implant appliances. The surgeon must select the type and size that best meets the patient's requirements for close adaptation and firm seating with adequate support. **Indications:** Used in conjunction with the Stableloc External Fixator to address fracture reduction and alignment in the distal radius. **Contraindications:** Active or latent infection, Osteoporosis, insufficient quantity or quality of bone/soft tissue. Material sensitivity. If suspected, tests are to be performed prior to implantation. Sepsis. Patients who are unwilling or incapable of following post-operative care instructions. This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

**Warning:** For safe and effective use of this implant, the surgeon must be thoroughly familiar with the implant, the method of application, instruments, and the recommended surgical technique for this device.

The device is not designed to withstand the stress of weight bearing, load bearing, or excessive activity. Device breakage or damage can occur when the implant is subjected to increased loading associated with the delayed union, nonunion, or incomplete healing.

Improper insertion of the device during implantation can increase the possibility of loosening and migration.

The patient must be cautioned, preferably in writing, about the use, limitations, and possible adverse effects of this implant including the possibility of the device falling as a result of loose fixation and/or loosening stress, excessive activity, or weight bearing or load bearing, particularly if the implant experiences increased loads due to delayed union, nonunion, or incomplete healing. The patient must be warned that failure to follow postoperative care instructions can cause the implant and/or treatment to fail.

**Precautions:** An implant shall never be reused. Previous stresses may have created imperfections which can lead to device failure. Instruments shall be inspected for wear

or damage prior to usage. Protect implant appliances against scratching and nicking. Such stress concentrations can lead to failure. **Adverse Effects:** Fracture of the implant due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion. Implant migration and/or loosening. Metal sensitivity or histological or allergic reaction resulting from implantation of a foreign material. Pain, discomfort, or abnormal sensations due to the presence of an implant. Nerve damage resulting from surgical trauma. Necrosis of bone or bone resorption. Necrosis of tissue or inadequate healing. **Sterility:** This product is provided presterile and nonsterile. The presterile was exposed to a minimum dose of 25.0 kGy gamma irradiation. Reesterilization may only be performed if the original sterile package has been opened in error using one of the following methods. For a gravity displacement autoclave, set at 250° F (121° C) for 30 minutes. For a prevacuum autoclave, set at 270° F (132° C) for 4 minutes, or at 275° F (134° C) for 3 minutes. The non-sterile may be sterilized according to any of the methods stated above. Please consider your equipment manufacturer's written instructions for the specific sterilizer and load configuration being used and current AORN standards and recommended practices.

**Storage Instructions:** Store in a cool dry place, and keep away from direct sunlight. Prior to use, inspect product package for signs of tampering, damage, or water contamination. Use oldest lots first.

**Warning:** For safe and effective use of any Acumed instrument, the surgeon must be thoroughly familiar with the instrument, the method of application, and the recommended surgical technique.

Instrument breakage or damage can occur when an instrument is subjected to excessive loads, speeds, or dense bone. The patient must be cautioned, preferably in writing as to the risks associated with these types of instruments.

**Caution: Federal Law (USA) restricts this product to sale by or on the order of a physician or hospital.**





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The devices shown are  
covered by one or more of  
the following patents or  
patents pending: Patent  
5,545,162; Patent  
5,662,649; and Patent  
5,624,440.