

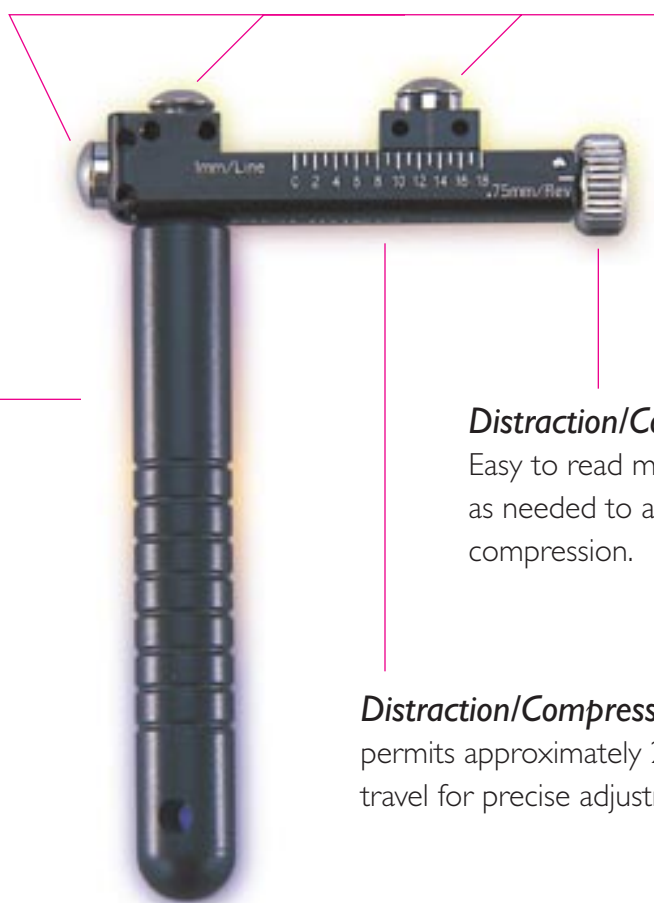
SMALL BONE DISTRACTOR

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.



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

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.

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 (4pk)
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 (4pk)
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 postoperative care instructions. This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

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 failing 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 was exposed to a minimum dose of 25.0 kGy gamma irradiation. Resterilization 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. 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.

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.