

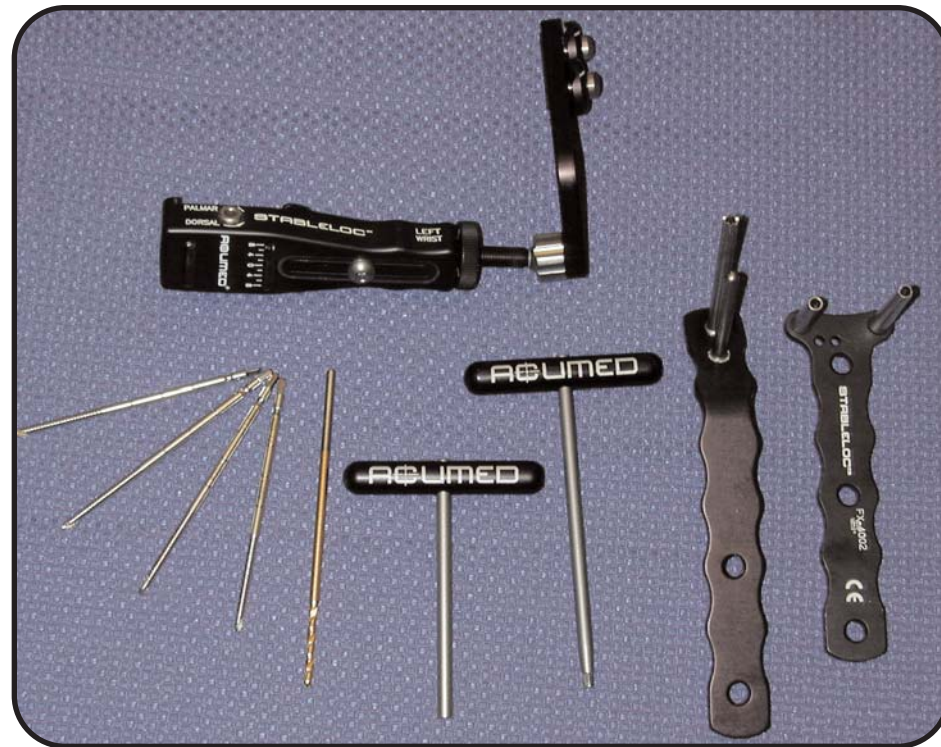
STABLELOC EX

Stableloc EX Kit

Left Fixator FX-301L
Right Fixator FX-301R

Stableloc EX Kit includes either Left or Right Fixator and the following items:

Standard Drill Guide	FX-4002
EX Drill Guide	FX-1002
HEx Driver	FX-4003
Pin Driver	FX-4008
2.5mm Drill	FX-4006
3.2mm Steriles Pins	FX-4004
	(2 pkg x 2)



DESCRIPTION: External fixator pins are designed to be used in conjunction with the Acumed External Fixators for fractures.

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 all Acumed External Fixator to address fracture reduction and alignments. Stableloc External Fixator Pins are 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.

WARNINGS: 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 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 nonsterile. Sterilization may be performed using one of the following methods. For a gravity displacement autoclave, set at 250° F (121°C) for 30 min. For a prevacuum autoclave, set at 270° F (132°C) for 4 min., or at 273°F-279°F (134°C to 137°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.

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

ACUMED®



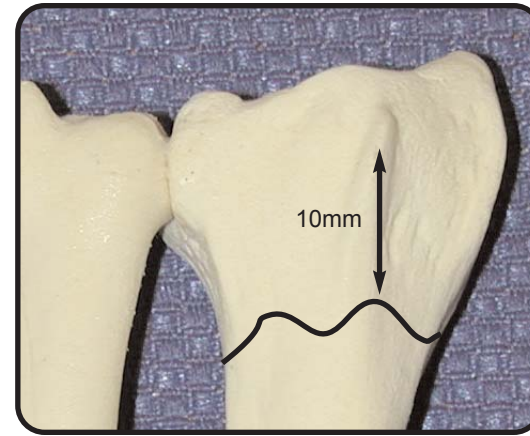
STABLELOC EX SURGICAL TECHNIQUE

STABLELOC EX

Surgical Technique



1) Separate drill guides are used for the proximal pins and the distal pins. (The proximal pins use the standard drill guide while the distal pins use the custom EX drill guide)



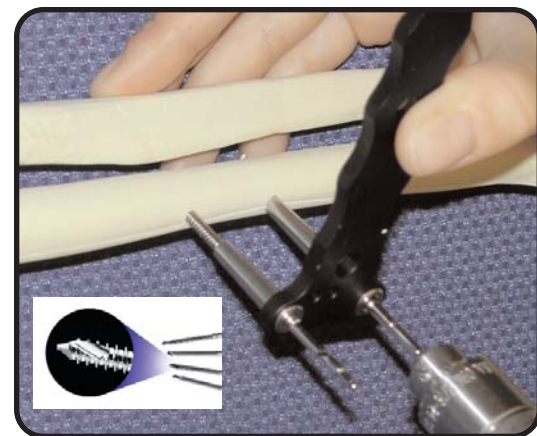
2) To use the Stableloc EX External Fixator there needs to be at least 10mm of intact distal radius to secure the distal pins.



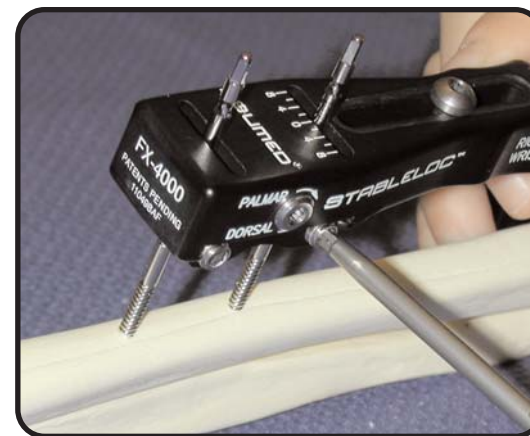
3) Proximal and distal pin positions are determined and marked on the skin. The distraction mechanism should be neither fully extended or compressed when locating pin sites.



4) The proximal pins are placed first using the standard drill guide. The 2.5mm drill is inserted through the longer of the two barrels on the drill. (The pins may be used as self-drilling)



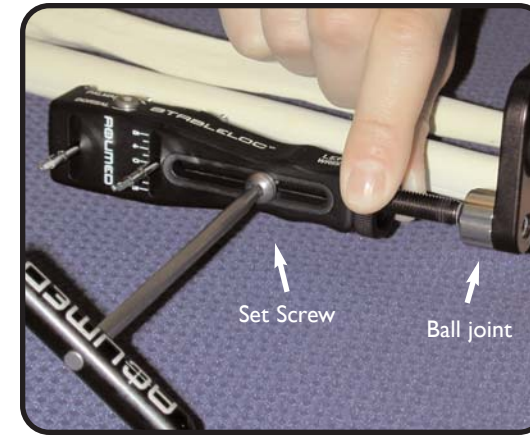
5) After the first pin is inserted, the shorter barrel is placed over the pin which ensures proper space between the pins (25mm). The second pin is then drilled and inserted. (Self-drilling pin shown)



6) The Stableloc EX can now be placed on the radius. The set screws are provisionally tightened.

STABLELOC EX

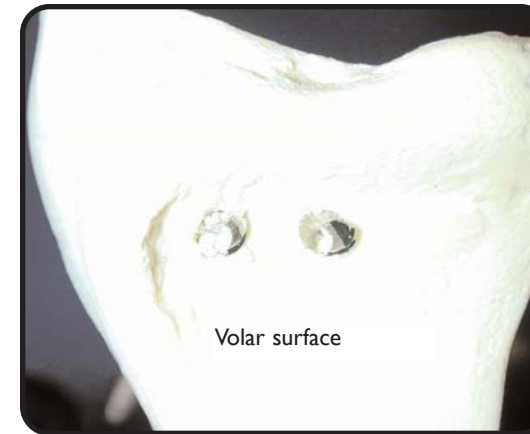
Surgical Technique



7) The distal ball joint may be adjusted, if needed, to allow for proper placement of the distal pins. The length of the fixator may be adjusted by loosening the set screw in the distraction window.



8) The first distal pin may be inserted using the dedicated EX drill guide placed over the outrigger. The pins may be angled to achieve a converging pin pattern.



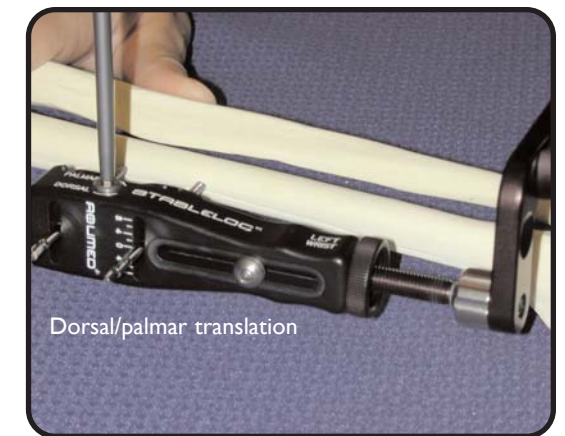
9) Care must be observed so the converging pins exit the intact volar aspect of the radius and do not come in contact with each other. The pins may be used as joysticks reducing the fracture.



10) The distal pins are then secured to the distal pin clamps by aligning the pins with the white lines on the clamps. (One clamp may need to be loosened and temporarily moved.)



11) After all pins are secured the ball joint may be loosened to make adjustments. If length is needed at this time, the set screw in the distraction window is loosened and the distraction wheel is rotated.



12) If a distal fragment needs to be translated in either a palmar or dorsal direction, the adjustment at the proximal end of the fixator can be used. Tighten all set screws prior to closure.