ACUMED

STABLELOC

Surgical Technique

10950 S.W. 5th Street, Suite 170
Beaverton, OR 97005
U.S.A.
(888)627-9957
(503)627-9957
Printed in U.S.A.

TABLE OF CONTENTS

View of Definitive Stableloc..... pg 3

Instrumentation..... pg 3

Pre-Surgical Planning..... pg 4

Insertion of Distal Pins..... pg 4

Insertion of Proximal Pins..... pg 5

Application of Stableloc Fixator..... pg 5

Distraction Adjustment..... pg 6

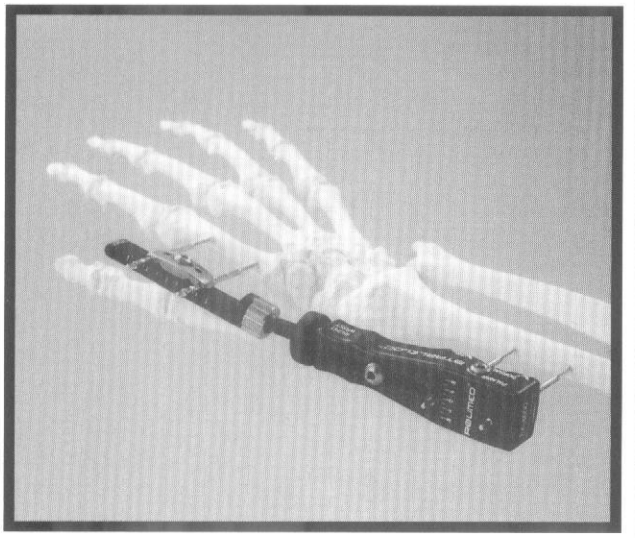
Dorsal/Palmar Translation..... pg 6

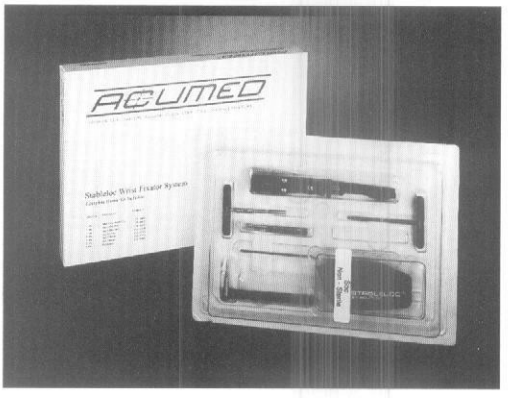
Radial/Ulnar Deviation..... pg 7

Flexion/Extension..... pg 7

Final Adjustments..... pg 8

Stableloc Soc..... pg 8





Stableloc External Wrist Fixator

Designed for the treatment of distal radius fractures where ligamentotaxis and independent adjustments are desired.

Once the fixator is applied, several key independent adjustments can be made without significantly compromising reduction.

The Radiolucent body aids in the visualization of the fracture and the joint space.

The Stableloc Soc (cover) is placed over the fixator upon completion of case for increased patient acceptance of device.

Acumed provides a REFURBISH PROGRAM for hospitals which choose to re-use the Stableloc.

The surgeon will want to keep the hex driver for in-office adjustments, and the pin driver for pin removal at the appropriate time.

Instrumentation

Items Included in a Sterile Stableloc Kit:

1- Stableloc Fixator: Item# FX-4000

1- Drill Guide: Item# FX-4002

1- Hex Driver: Item# FX-4003

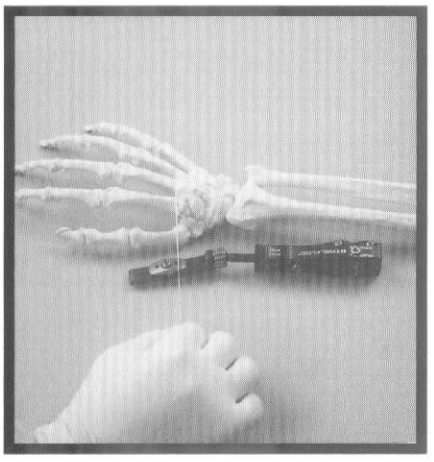
1- Pin Driver: Item# FX-4008

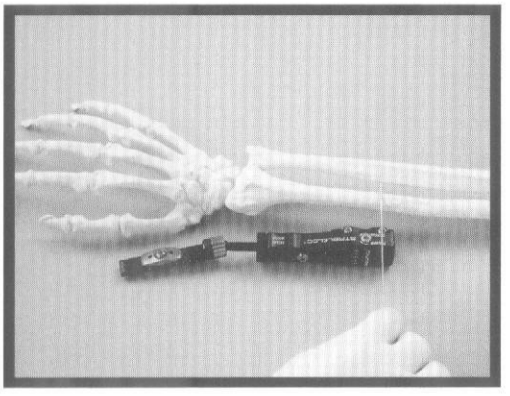
1- Drill: Item# FX-4006

1- Stableloc Soc (cover): Item# FX-4005

4- 3.2mm Self Drilling Pins: Item# FX-4004

TIP VIEW





Pre-Surgical Planning

Goal: Determine the proper position of the fixator in relation to the radius, the 2nd metacarpal and the center of wrist rotation.

Procedure:

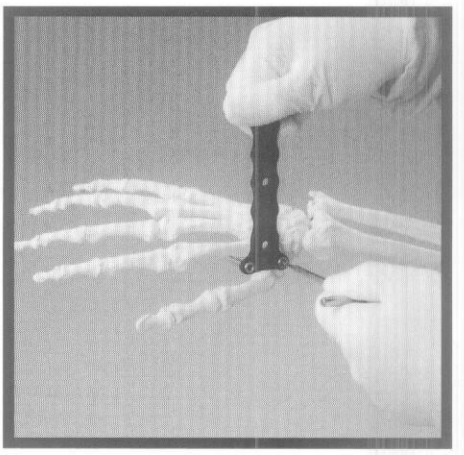
Align the fixator with the extended extremity, lining up the approximate center of wrist rotation with the ball joint. Locate and mark the position of the proximal and distal pins.

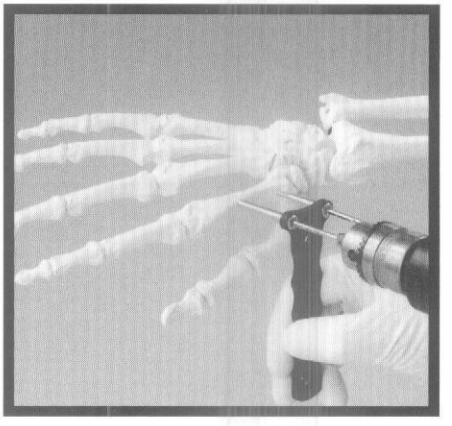
The fixator should be neither fully distracted nor fully compressed when determining pin positions.

Placing the fixator in the transverse plane or rotated dorsally up to 20 degrees will increase the accuracy of subsequent adjustments.

Important point !

- ***This step insures that the fixator pins are placed within the working range of the fixator.***





Insert Distal Pins

Goal: To insert both of the distal pins into the second metacarpal.

Procedure:

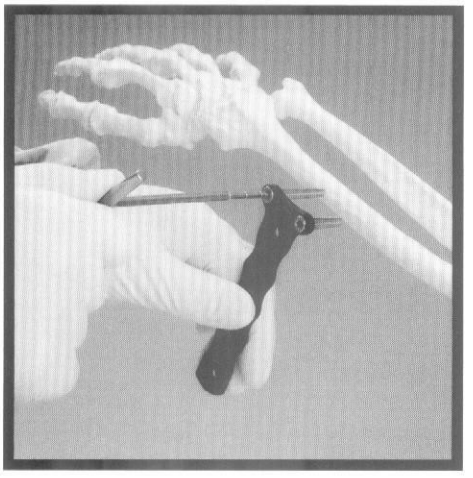
The appropriate incision(s) and dissection steps are carried out.

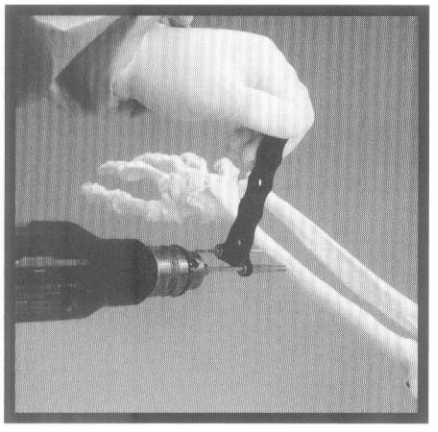
Using either a freehand technique or centering the longer cannula of the drill guide on the bone, the first pin is pre-drilled and inserted with the pin driver through the base of the second metacarpal and extending into the first cortex of the third metacarpal, if desired. Due to the unique pin design, they may be used as self-drilling, so the pre-drilling step may be omitted.

Rotate the drill guide 180 degrees so the short cannula is placed over the previously inserted pin. Making sure the longer cannula is centered on the bone, pre-drill and insert the second pin. Advance the pins until two to three threads have extended through the far cortex.

Important point !

- ***The drill guide assures the pins are placed parallel.***





Insert Proximal Pins

Goal: Insertion of the proximal pins into the radius.

Procedure:

After an incision and careful dissection to the radius has been completed, the center of the radius is identified.

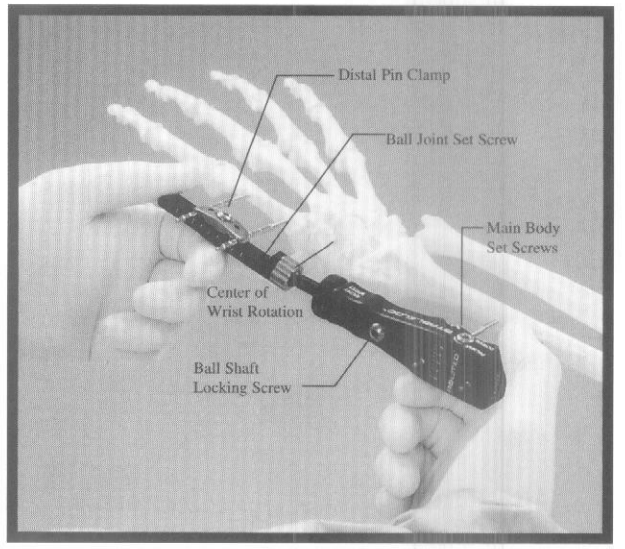
Using the long cannula on the drill guide, drill through the radius and insert pin. The pins may also be used as self-drilling as described earlier.

Remove drill guide and rotate 180 degrees placing the shorter cannula over the previously inserted pin.

Pre-drill and place second pin in same manner as the first radius pin.

Important point !

- ***Use care when drilling through the radius to avoid over drilling.***



Apply Stableloc Fixator

Goal: Apply fixator to the distal and proximal pins.

Procedure:

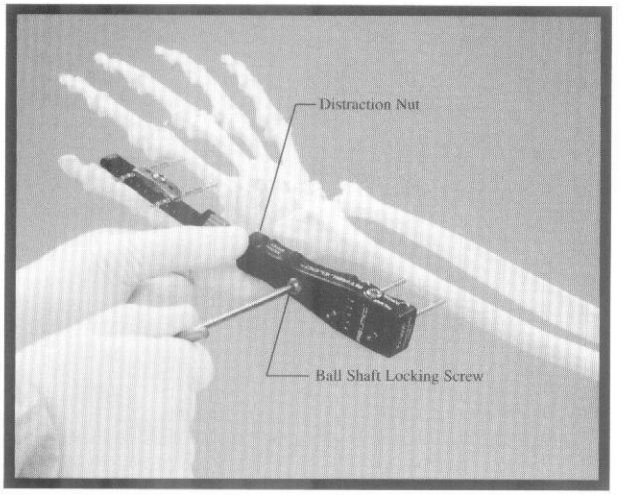
Making sure the distal clamp is loose and the main body set screws are loose, slide the fixator onto the pins.

Align the Stableloc on the wrist so the ball joint is centered over the "center of wrist rotation".

Lightly tighten the distal pin clamp, the ball shaft locking screw, the ball joint set screw and the main body set screws provisionally locking the fixator into position.

Important point !

- ***Placing the ball joint over the "center of wrist rotation" will aid in the accuracy of subsequent adjustments.***



Distraction/Ligamentotaxis

Goal: To apply distraction to aid fracture reduction.

Procedure:

Make sure the distraction nut has advanced down the threaded ball shaft and is adjacent to the main body of the fixator.

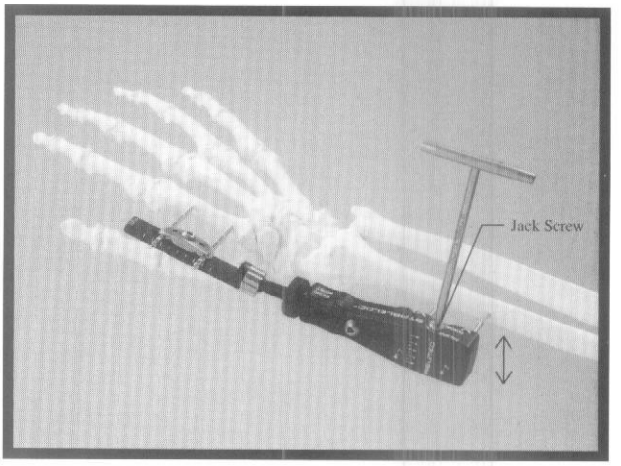
Loosen the ball shaft locking screw.

Turn the distraction nut towards the housing to apply the required amount of distraction. One complete revolution of the nut equals 1mm of distraction.

Lock the ball shaft locking screw.

Important point !

- ***The distraction nut is marked with "A,B,C,D" as a reference to indicate where distraction began.***



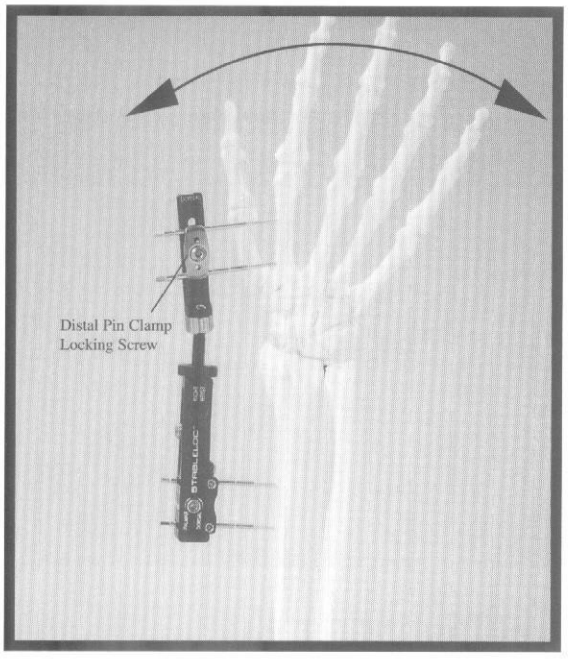
Dorsal/Palmar Translation

Goal: Correction of Palmar Tilt.

Procedure:

Place the hex wrench into the jack screw on the dorsal side of the main body of the fixator. Turn the wrench *clockwise for palmar* translation and *counterclockwise for dorsal* translation.

You are able to determine the amount of translation by the scale on the side of the Stableloc. There is 8mm of translation available in either direction.



Radial/Ulnar Deviation

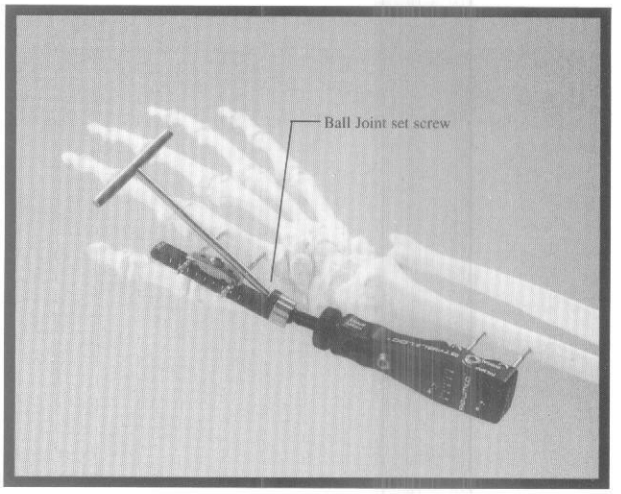
Goal: To gain proper anatomic alignment of the fracture in the radial/ulnar plane.

Procedure:

Loosening the distal pin clamp allows free movement in both the M/L and radial/ulnar direction.

Important point !

- ***Traction can be lost when the the distal pin clamp locking screw is loosened.***



Flexion/Extension

Goal: To achieve the desired angle of wrist flexion.

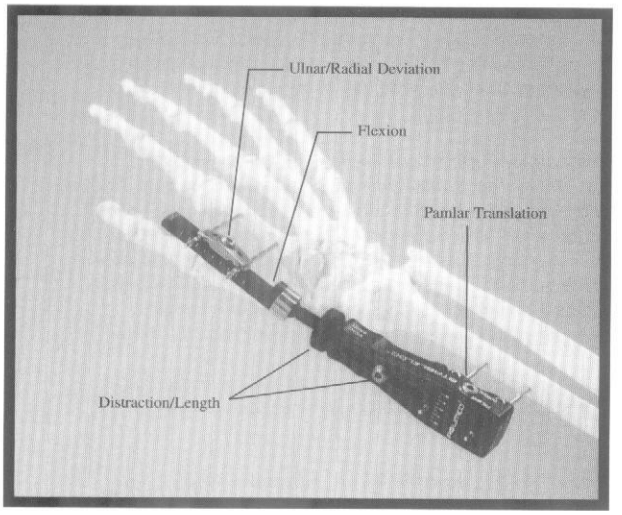
Procedure:

With the ball joint located at the center of wrist rotation:

Loosen the ball joint set screw.

Adjust the angle of flexion desired.

Lock the ball joint set screw.



Final Adjustments of Fixator

Goal: To insure that the fracture is in proper anatomic alignment by utilizing independent adjustments.

Procedure:

Radial/Ulnar Deviation:

With the distal pin clamp loose, you are free to radial or ulnar deviate the wrist. Tighten pin clamp.

Flexion/Extension:

The ball joint set screw is loosened to allow for the desired amount of flexion/extension. Tighten ball joint set screw.

Distraction/Length:

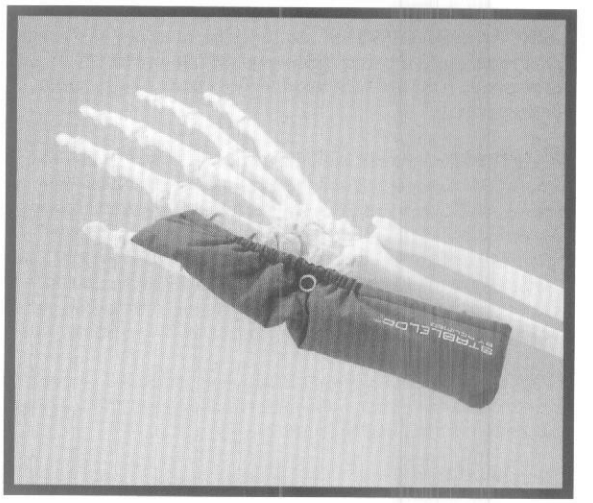
Rotate the distraction nut towards the main body of fixator. Loosen the ball shaft locking screw and rotate nut until distraction is complete. Tighten the locking screw.

Dorsal/Palmar Translation:

The hex wrench is placed in the jack screw and rotated until the desired amount of translation is achieved.

Important point !

- ***There is no need to tighten jack screw controlling dorsal/palmar translation. This is self-locking.***



Stableloc Fixator with Soc/Cover

After completion of all adjustments, the fixator is locked into final position. Wounds are dressed in routine sterile fashion and dry sterile gauze is wrapped around the pins to prevent pistoning of the pins and soft tissue.

The Stableloc Soc can then be applied to facilitate patient acceptance of the device.

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 Fixators 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 presterile. Sterilization may be performed 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 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.

DESCRIPTION: Acumed Disposable, Single Use Surgical Instruments are available for a wide variety of surgical techniques and implant systems. These instruments should be discarded after each use.

WARNINGS: 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.

PRECAUTIONS: A Single Use Instrument shall never be reused. Previous stresses may have created imperfections which can lead to failure. Protect instrument appliances against scratching and nicking. Such stress concentrations can lead to failure.

STERILITY: With the exception of the Stableloc Soc which is provided nonsterile, all other parts are presterile and were exposed to a minimum dose of 25.0 k Gy gamma radiation. Resterilization may 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 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.

ACUMED®

♦ Acumed, Inc ♦ 10950 SW 5th, Suite 170 ♦ Beaverton, OR 97005 U.S.A. ♦
♦ (888) 627-9957 ♦ Fax: (503) 520-9618 ♦