THE XCALIBER META-DIAPHYSSEAL FIXATOR
GENERAL POINTS

The XCaliber Fixator is made of radiolucent material for unobstructed X-ray visualization. The metallic bolts and the cam and bush of each ball-joint, are the only radio-opaque components. Because it is radiolucent and made of a composite material, the ball-joint deforms after repeated tightening. It can be adjusted on the patient if repositioning of the fracture is required, but will not be strong enough for use on a second patient. In addition the joint is sealed and cannot be dismantled for cleaning.

The XCaliber Fixator is strictly single patient use.

EQUIPMENT REQUIRED

| 99-91215 | XCaliber Meta-Diaphyseal Kit with Dynamic Compression/Distraction Unit, sterile |
| 19200    | XCaliber Manipulation Forceps |
| 99-91038 | Supplementary Screw Holder (Bar and Clamps), sterile |
| 90037    | Supplementary Screw Holder |

Standard instrumentation for screw insertion

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CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. Contents sterile unless package opened or damaged; Do not use if package is opened or damaged.
DIAPHYSEAL FRACTURES

TIBIA

Reduce the fracture as anatomically as possible, emphasizing rotational correction. A stable, good reduction on a fracture table with skeletal traction is recommended.

Screw Insertion

Insert screws into the shortest or most difficult segment first, from the anterior or antero-medial aspect of the tibia. Make a 15-20mm incision so that the skin around each screw is not too tight. The underlying tissues also require broad dissection down to the bone.

Insert a screw guide perpendicular to the longitudinal axis of the bone. Use a trocar to locate the midline by palpation. Keep the screw guide in contact with the cortex by gentle pressure, withdraw the trocar, and tap the screw guide lightly to anchor its distal end.

Note: If the placement of this screw is critical because it is close to a joint, the position can first be checked by inserting a 2mm Kirschner wire. A screw guide and drill guide can be centred over the wire and the bone drilled with the 3.2mm cannulated drill bit.

Insert the correct drill guide into the screw guide. Use screw guides for every screw insertion to minimize soft tissue trauma. When using the standard 5-6mm bone screws, we recommend a 3.2mm drill bit for cancellous bone, and a 4.8mm drill bit for cortical bone.

If self-drilling XCaliber bone screws are being used, we recommend that they are used self-drilling in cancellous bone. However, in diaphyseal bone, pre-drilling is recommended; use a 4.8mm drill bit through a drill guide when the bone is hard; when the bone quality is poor, or in the metaphyseal region where the cortex is thin, a 3.2mm drill bit should be used.
Fixator Application

If desired, the T-clamp may be removed for this application. Leave the screw guide in position and apply the XCaliber Fixator with the central body locking nut and cams loosened. Before screw insertion into the second bone fragment, adjust the fixator body to the correct length, making sure that it is neither completely closed nor fully open. This will allow for final reduction. Check that the central body locking nut faces away from the bone so that it can be tightened, and that it does not obstruct views of the fracture site. The fixator body should be parallel to the bone axis. Insert a screw guide into the second clamp, as far as possible from the first for maximal stability; make the incision, and insert it down to the bone as before. Tighten the clamp locking screws with the Allen wrench to ensure that the clamps grip the screw guides. Repeat the screw insertion procedure as before.

Drill at 500-600 rpm through the first cortex with the correct drill bit and drill stop, checking that the drill bit is at right angles to the bone. The force applied to the drill should be firm and the drilling time as short as possible to avoid thermal damage. Stop at the second cortex, offset the stop collar by 5mm, and continue through the bone. Ensure that the drill bit completely penetrates the second cortex. If a preliminary K-wire has been used, a cannulated drill bit can be used over the wire.

Note: Kirschner wires which are used for this purpose and cannulated drill bits should NEVER be reused.

Remove the drill bit and drill guide, keeping pressure on the handle of the screw guide. Insert the selected screw and turn it with the T-wrench until it reaches the second cortex. A further 5 or 6 half turns are then normally required to ensure that about 2mm of the screw protrudes beyond the second cortex.

Diaphyseal bone screws should always be inserted in the centre of the bone axis, to avoid weakening it. In all cases the surgeon should be mindful of the amount of torque required to insert the screw. If it seems tighter than usual, it is safer to remove the screw and clean it, and drill the hole again with a 4.8mm drill bit, even if it has already been used.

Warning! As the thread is tapered, repositioning the screw by turning counterclockwise will loosen the bone-screw interface. If the self-drilling XCaliber Bone Screws are being used, please refer to the Insertion Technique PG 20.
Partially loosen the clamp locking screws and remove the screw guides. Position the XCaliber fixator at least 2cm from the skin to allow for post-operative swelling and cleaning. Align the body parallel to the major axis of the segment being treated.

Fully tighten the clamp locking screws.

Place the remaining screw guides in the inner screw seats of the clamps down to the bone; tighten the clamp locking screws to ensure that the screw guides are parallel, and insert the bone screws as before. The number of screws in each clamp is determined by the stability of the fracture, the weight of the patient, the bone-fixator distance and the quality of the bone. In adults we generally recommend that three screws are used each side of the fracture. In this case, a third central screw is inserted after the two outer screws.

Obtain final reduction with manipulation forceps. Place hooks of forceps over bone screws. Tighten the nut to lock the forceps in place. Insert Allen wrench through hole in handle if greater torque is required.

Accurate reduction is aided by the fact that the fixator is radiolucent, allowing unobstructed views on image intensification. Hold the reduction in a good position, while an assistant PARTIALLY tightens the cams with the Allen wrench. Tighten the central body locking nut.

Check reduction and lock the cams definitively.

Note: Final locking of the ball-joints is achieved with the Allen wrench; a torque wrench is not required. The cams can be locked from either side of the clamp. They should be turned towards the thicker section of the coloured insert until tightly closed, and the cam is at least 50% of the way across the recess.
The dynamic C-D unit is designed to allow early dynamization of the fracture, by cyclic micromovement on weightbearing, up to 2mm at the fracture site. Attach the unit to the fixator pins and lock it firmly in position. Loosen the body locking nut.

Note: For full dynamization, remove the C-D unit and leave the body locking nut undone. This is normally recommended at 4 weeks, but should be delayed in cases of bone deficit or unstable fractures. Healing time is shortened and non-union rate decreased if full dynamization is carried out at the correct time.

SUPPLEMENTARY SCREWS

A fracture will be held in a more stable position if the nearest bone screws are applied fairly close to the fracture margin, and if these distances are equal on both sides of the fracture. A minimum of 2cm is recommended between the fracture and the nearest screw. A supplementary screw holder is supplied to achieve this. A screw should be inserted into the longer bone segment at an equal distance from the fracture as the nearest screw in the short segment, using a screw guide. This screw is attached to the fixator either with a clamp over the fixator body, or over the nearest convenient bone screw. A 6mm Allen wrench should be used to tighten the supplementary screw holder clamps. A supplementary screw can also be used to stabilize a third fragment. This screw should be removed before the fixator is dynamized. When a supplementary screw is used, it is normally sufficient to use 2 screws in the clamp in positions 1 and 3.

COMPRESSION-DISTRACTION UNIT

To achieve compression or distraction, remove the plastic covers from the pins on the fixator body, attach the compression-distraction (C-D) unit and lock it in position with the Allen wrench. With the central body locking nut loosened, use the Allen wrench to turn the central element of the compression-distraction unit either clockwise or counterclockwise, (one full turn clockwise = 1mm compression; one full turn counterclockwise = 1mm distraction). Compression is never recommended in a fresh fracture. Release any skin tension around the screws by extending the skin incision.
HUMERUS

Reduce the fracture, with particular attention to correction of rotational displacement. Apply the fixator to the lateral aspect of the bone. Insert 4 screws, 2 in each clamp, beginning with the shortest segment. Position the second group of screws so that the body of the fixator is open at least 1cm. Screws should never be less than 2cm from the fracture line. Use a supplementary screw if indicated as for the tibia. Obtain final reduction and lock the fixator as above.

Note: When unusually high loading conditions are likely, such as weightbearing with a femoral application or when the patient is very heavy, before the ball-joints are locked the fixator body should be aligned so that the body locking nut is at 90 degrees to the plane of the bone screws. In addition for increased stability the compression-distraction unit may be applied to the fixator body and locked into place.

FEMUR

Reduce the fracture, with particular attention to correction of rotational displacement. Apply the fixator to the lateral aspect of the femur. Insert 6 screws, 3 in each clamp, beginning with the shortest segment. Position the second group of screws so that the body of the fixator is open at least 1cm. Screws should never be less than 2cm from the fracture line. Use a supplementary screw if indicated as for the tibia. Obtain final reduction and lock the fixator as above.

Note: When unusually high loading conditions are likely, such as weightbearing with a femoral application or when the patient is very heavy, before the ball-joints are locked the fixator body should be aligned so that the body locking nut is at 90 degrees to the plane of the bone screws. In addition for increased stability the compression-distraction unit may be applied to the fixator body and locked into place.

METAPHYSEAL FRACTURES

TIBIA: PROXIMAL METAPHYSEAL FRACTURES

Antero-Medial Application

Insert the most anterior proximal screw first freehand, 2cm distal to the knee joint. OsteoTite (HA-Coated) bone screws may be useful in this application. Position the screw within its screw guide in the proximal seat of the straight clamp. When using the T-clamp, the first screw should always be inserted in this screw seat.
Anterior Application

Insert the first screw in the proximal seat of the straight clamp and the second screw so that it converges slightly with the first, in the screw seat at the other end of the clamp.

Note: OsteoTite (HA-Coated) bone screws may be useful in this application.
TIBIA: DISTAL METAPHYSICAL FRACTURES

Insert the most posterior distal screw first, freehand, immediately anterior to the posterior border of the medial malleolus. Insert it with a screw guide into the most distal seat of the straight clamp. Insert the second distal screw in one of the seats of the T-clamp. A triangular screw configuration will be the most stable if there is room for the screws.

Note: OsteoTite (HA-Coated) bone screws may be useful in this application.

If the placement of this screw is critical because it is close to a joint, the position can first be checked by inserting a 2mm Kirschner wire. A screw guide and drill guide can be centred over the wire and the bone drilled with the 3.2mm cannulated drill bit.

Insert the diaphyseal screws, ensuring that the fixator body is not completely closed. Lock the fixator as above.

Insert the diaphyseal screws, checking that the fixator body is not fully closed. Lock the fixator as above.
FEMUR: DISTAL METAPHYSEAL FRACTURES

Apply the XCaliber Fixator laterally, inserting the most anterior distal screw first, about 1cm behind the anterior edge of the lateral condyle. With this screw and its screw guide in the most distal seat of the straight clamp, insert the second distal screw in one of the seats of the T-clamp. Three screws should be used distally, in a triangular configuration if possible.

Note: OsteoTite (HA-Coated) bone screws may be useful in this application.

If the placement of this screw is critical because it is close to a joint, the position can first be checked by inserting a 2mm Kirschner wire. A screw guide and drill guide can be centred over the wire and the bone drilled with the 3.2mm cannulated drill bit.

Insert the diaphyseal screws, checking that the fixator body is open at least 1cm. Lock the fixator as above.
Operative Technique Contributing Surgeon:
S. Berki, MD
V. Caiaffa, MD
F. Lavini, MD
M. Manca, MD
Instructions for Use: See actual package insert for Instructions for Use.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience. Please refer to the “Instructions for Use” supplied with the product for specific information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.