At Biomet, engineering excellence is our heritage and our passion. For over 25 years, through various divisions worldwide, we have applied the most advanced engineering and manufacturing technology to the development of highly durable systems for a wide variety of surgical applications.

**Anterior Angular Hinge Fixator**

To learn more about this product, contact your local Biomet Sales Representative today.
DFS® Anterior Angular Hinge Fixator

- Correction of frontal plane, varus and valgus, metaphyseal deformities of the proximal tibia
- Ability to adjust up to 60° of angular correction
- Capability of providing up to 5cm of lengthening
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Introduction

The DFS® Anterior Angular Hinge Fixator was designed for the correction of frontal plane, varus and valgus, metaphyseal deformities of the proximal tibia. Correction can be made acutely or gradually. The unique design of the fixator hinge allows for up to 60° of angular correction with the ability to adjust the level of the hinge to the center of the deformity. The fixator also possesses the capability of providing up to five centimeters of compression/distraction.
Equipment Required

Fixator
DFS® Anterior Angular Hinge Fixator (P/N) 06150

Spacers and Templates
- 9mm Bone Screw Spacer - P/N 06175
- 9mm Spacer Template - P/N 06177
- 12 mm Bone Screw Spacer - P/N 06180
- 12 mm Spacer Template - P/N 06182
- 15 mm Bone Screw Spacer - P/N 06185
- 15 mm Spacer Template - P/N 06187

Instrumentation
- 3.2mm Drill Bit - P/N 03030
- 3.2mm Drill Guide - P/N 03065
- 4.8mm Drill Bit - P/N 03010
- 4.8mm Drill Guide - P/N 03060
- Trocar - P/N 03075
- Soft Tissue Sleeves - P/N 03090
- DFS® T-Wrench For Bone Screws - P/N 03125
- DFS® 5mm Allen wrench - P/N 03110

Ancillary Equipment
- Enhanced Access CD Mechanism 0-5cm - P/N 01430
- Enhanced Access CD Wrench - P/N 03140
- Modular CD Mechanism - P/N 01180
- Dynamization Component 0-5cm - P/N 01160
- Bone Screw Covers - P/N 03320
- End Cap - P/N 01175
- Angulating Screw Clamps - P/N 06240

The following are suggested screw sizes; however, each patient should be evaluated pre-operatively and bone screws should be chosen based on individual patient needs. Bone screw diameter should never exceed one-third the diameter of the bone. Bone screws are available in stainless steel.

Cancellous, 6.0/5.0 Taper
- 120mm Long/60mm Thread P/N B60-12060
- 140mm Long/50mm Thread P/N B60-14050
- 150mm Long/60mm Thread P/N B60-15060

Cortical, 6.0/5.0 Taper
- 110mm Long/40mm Thread P/N A60-11040
- 120mm Long/40mm Thread P/N A60-12040
- 130mm Long/40mm Thread P/N A60-13040
Anterior Angular Hinge Positioning

Multiplanar Fixation with bone screw placement superior and inferior to T-clamp.

Bone screw spacers and templates.

9mm Bone Screw Spacer (P/N 06175)
12mm Bone Screw Spacer (P/N 06180)
15mm Bone Screw Spacer (P/N 06185)

9mm Spacer Template (P/N 06177)
12mm Spacer Template (P/N 06182)
15mm Spacer Template (P/N 06187)
Anterior Angular Hinge Positioning (cont’d)

Raising The Level Of The Hinge
Using Bone Screw Spacers to adjust the level and placement of the fixator hinge. Line represents the level of the hinge.

Position of hinge with standard 6mm bone screw spacers and bone screw placement on the inferior side of T-Clamp.

Position of hinge with 9mm bone screw spacers and bone screw placement on the inferior side of T-Clamp.

Position of hinge with 12mm bone screw spacers and bone screw placement on the inferior side of T-Clamp.

Position of hinge with 15mm bone screw spacers and bone screw placement on the inferior side of T-Clamp.

Lowering The Level Of The Hinge
Using Bone Screw Spacers to adjust the level and placement of the fixator hinge. Line represents the level of the hinge.

Position of hinge with standard 6mm bone screw spacers and bone screw placement on the superior side of T-Clamp.

Position of hinge with 9mm bone screw spacers and bone screw placement on the superior side of T-Clamp.

Position of hinge with 12mm bone screw spacers and bone screw placement on the superior side of T-Clamp.

Position of hinge with 15mm bone screw spacers and bone screw placement on the superior side of T-Clamp.
Surgical Technique

Fixator Preparation

The Anterior Angular Hinge Fixator (P/N 06150) is shipped with four standard bone screw clamps and two silver template clamps. The template clamps are positioned on the superior aspect of the T portion of the clamp, whereas the bone screw clamps are positioned on the inferior side. Additional bone screw and template clamps can be ordered separately and are available in 9, 12 and 15mm offsets to allow for variable positioning of the hinge. These clamps should be used to position the level of the hinge to the corresponding level of the tibial deformity and location of planned corticotomy. In the child, pin placement should be planned to avoid injury to the physis. This should be done prior to insertion of the bone screws to determine what bone screw and template clamps should be used.

Once the appropriate bone screw and template clamps have been chosen, the standard clamps should be removed from the device and the appropriate template clamps should be attached to the T portion of the clamp. It is important to note that the fixator will accommodate bone screws on either side of the T. Placement of the bone screws in relation to the T portion of the fixator will be dictated by the point of the deformity, the location of the corticotomy and in children, the level of the physis.

A more rigid construct may be obtained by having two planes of fixation on the T portion of the clamp. This can be achieved by having screws above and below the clamp or by using bone screw spacers of different sizes. In utilizing the above option, one can obtain more bone to screw interface by criss-crossing the bone screws.

Acute correction of rotation can be obtained by inserting the tibial shaft pins the desired number of degrees off the axis. Once the osteotomy is complete, the pins in the distal clamp are rotated to the Anterior Angular Hinge. Similarly, acute flexion or extension can be obtained by inverting the tibial diaphyseal pins at an angle to the proximal pins. Once the osteotomy is complete the distal pins are brought into a parallel position to the proximal pins and attached to the fixator.
Surgical Technique (cont’d)

Bone Screw Insertion and Fixator Templating

Patients should be placed in the supine position and prepped and draped in routine sterile fashion with the operating table set 10-20 degrees in the Trendelenberg position to level the tibia. Alternatively, placing a bump under the heel will make the tibia horizontal and therefore perpendicular to the image beam. Once the leg is rotated so that the patella is forward, utilize fluoroscopy and a marking pen to draw a line parallel with the tibial plateau to identify the level of the joint. Bone screw positioning should take into consideration the posterior slope of the tibial plateau. For pediatric applications, care should be taken to avoid the proximal tibial physis.

All bone screw clamps should be removed from the T portion of the Anterior Angular Hinge Clamp. The template clamps should be applied to the device. A sterile two finger breadth bump should be placed underneath the proximal portion of the fixator to allow for adequate height between the fixator and the soft tissue. Using the clamp and templates at this position will insure that the bone screw convergence will not exceed the limitation of the T portion of the device.

The fixator is now dialed out to match the amount of angulation on the proximal tibial metaphysis. This will facilitate distal bone screw targeting. It is important to note that once the T-portion of the device is in a fixed position that the distal portion of the device is aligned parallel to the shaft of the tibia. This applies for all frontal plane corrections, both varus and valgus in nature. Using the fixator as a template, the first bone screw is inserted. The bone screw should be inserted anterior to posterior allowing for convergence across the medial condyle of the tibial plateau. The first bone screw must not violate the level of the joint space and in children, must avoid penetration of the physis. This bone screw must also be far enough away from the planned osteotomy site to allow for placement of the second bone screw. AP and lateral imaging on the operating table are necessary to accommodate the normal 9° of posterior sloping of the proximal tibia.

Application of 6mm spacer template to the inferior aspect of the T-clamp

The fixator is now dialed out to match the amount of angulation on the proximal tibial deformity.
A 1cm incision is made and blunt dissection is carried down to the bone. The trocar and soft tissue guide are inserted into the template clamp of the fixator. Once the soft tissue guide has engaged bone, the trocar is removed and gentle pressure is maintained on the soft tissue guide. A mallet is then used to tap the soft tissue guide to seat it into the bone. A 3.2mm drill guide is then inserted into the soft tissue guide. A corresponding 3.2mm drill bit is loaded into the drill and inserted into the drill guide. The first bone screw should take into consideration the posterior slope of the tibial plateau so as not to violate the posterior aspect of the joint capsule. This will insure that the fixator will rest in a position that is parallel to the shaft of the tibia. The bone is then drilled until the bit reaches the far cortex.

_Caution:_ Unlike cortical bone, the tactile sensation of drilling in cancellous bone is much softer. Image intensification is recommended to confirm the position of the drill bit.

Rotating the leg and image intensification beam to visualize the posterior cortex is helpful in determining drill bit positioning. Upon reaching the far cortex, the drill stop on the drill is positioned 5mm proximal to the soft tissue guide and locked into position with a 3mm allen wrench. This is done to prevent over penetration of the drill bit. Drilling of the far cortex is then completed under image intensification making sure that bi-cortical penetration has been achieved.

The drill bit is then removed and gentle pressure is maintained on the soft tissue guide to prevent losing the pre-drilled hole. The appropriate length cancellous screw is then inserted into the soft tissue guide using the T-wrench for bone screws. It is important to utilize image intensification during the insertion of the bone screws. Bi-cortical penetration of the bone screws is recommended with no less than 2 threads beyond the far cortex. Again, rotating the leg and image intensification beam is helpful in determining screw positioning.

Care should be taken to avoid over convergence and exiting of the bone screw into the popliteal fossa.
Surgical Technique (cont’d)

Care should be taken to avoid over penetration as the bone screws are tapered and will lose purchase if they are backed out.

The second screw is now prepared for insertion, following the same insertion technique as previously described, but utilizing the remaining template clamp. The pre-drilled tract should be targeted to converge across the lateral condyle. Care should be taken to avoid overpenetration into the popliteal fossa. It is important to utilize the drill stop and image intensification to prevent over drilling.

Care should be taken to avoid over penetration as the bone screws are tapered and will lose purchase if they are backed out.

After the proximal bone screws have been inserted, the soft tissue guides and silver template clamps should be taken off the device and replaced with the definitive bone screw clamps. It may be helpful to remove the silver template clamps one at a time to make sure that the replacement bone screw clamps are in exactly the same position as the template clamps. The definitive bone screw clamps should be locked leaving adequate distance (3-5 cm) between the soft tissue and the fixator to allow for swelling and subsequent bone screw hygiene. Check to be sure that the hinge is directly over the deformity and in the plane of the deformity. Rotation of the device with respect to the tibia can result in an incompletely or over corrected deformity or undesirable flexion or extension of the tibia through the osteotomy.

The appropriate length cancellous screw is then inserted into the soft tissue guide using the T-wrench for bone screws.

Insertion of the trocar for distal bone screw application.
Insertion Of Distal Bone Screws

A 4.8mm drill bit is now used for insertion of the distal bone screws. The fixator will serve as its own template for the distal cluster of fixation screws. Using the 5mm allen wrench, the locking set screw on the central portion of the fixator can be loosened to rotate the distal bone screw clamp. This may facilitate accurate placement of the screws in the diaphysis. Bone screws should be placed medial to the tibial crest on the subcutaneous border. It is recommended that the distal bone screw clamp be placed parallel to the shaft of the tibia.

Using the 5mm allen wrench, the clamp cover screws are loosened to allow for the introduction of the soft tissue guides. For optimal stabilization, the bone screws should be placed in holes one, three and five of the bone screw clamp. To allow for subsequent compression of the corticotomy, the male telescoping arm of the fixator is opened 1cm. This is achieved by loosening the locking set screw on the inferior side of the bone screw clamp closest to the central portion of the fixator.

Similar to the proximal bone screws, a 1cm incision is made and blunt dissection is carried down to the bone. The trocar and soft tissue guide are inserted into the bone screw clamp and provisionally locked in place. The trocar is removed and the 4.8mm drill guide is inserted into the soft tissue guide.
Surgical Technique (cont’d)

The corresponding 4.8mm drill bit is then inserted into the drill and then into the drill guide. Drilling is commenced utilizing fluoroscopy to prevent over drilling. Upon reaching the far cortex, the drill stop on the drill is positioned 5mm proximal to the soft tissue guide and locked into position with a 3mm allen wrench. This is done to prevent over penetration of the drill bit. Drilling of the far cortex is then completed making sure that bi-cortical penetration has been achieved.

The drill bit is then removed and gentle pressure is maintained on the soft tissue guide to prevent losing the pre-drilled hole. The appropriate length cortical screw is then inserted into the soft tissue guide using the T-wrench for bone screws. Bi-cortical penetration of the bone screws is recommended with no less than 2 threads beyond the far cortex. The most distal bone screw is then inserted repeating the above referenced steps.

*Care should be taken to avoid over penetration as the bone screws are tapered and will lose purchase if they are backed out.*

The fixator is then removed from the bone screws and the corticotomy can now be performed. Marking the position of the bone screw clamps on the arc will facilitate reapplication of the device once the corticotomy has been performed. This will prevent the loss of original position of the clamp over the point of deformity.
Corticotomy

A 2cm anterior midline incision is made longitudinally and the patellar tendon is retracted and blunt dissection is continued to the level of the periosteum. The periosteum is incised longitudinally and subsequent sub-periosteal dissection with a small periosteal elevator.

Using a 3.2mm or smaller drill bit and the corresponding soft tissue and drill guide, multiple bicortical drill holes are made transversely, parallel to the joint space at the desired level of bone separation. A small chisel or osteotome and mallet are used to connect the pre-drilled holes and complete the corticotomy. The periosteum and incision are then closed and the fixator is then reapplied to the bone screws. In cases of genu varum, a 1cm, midshaft fibulectomy should be performed if the desired amount of correction exceeds 15°. The fibular osteotomy may be useful to achieve correction and prevent any inadvertent damage to the peroneal nerve and muscle compartments.

In cases of genu valgum, a 1cm or more midshaft fibulectomy is recommended to prevent the fibula from obstructing the desired amount of correction. Both proximal and distal ends of the fibular osteotomy should be cut obliquely to allow sliding during correction and avoiding damage to the peroneal nerve by pushing the proximal fibula proximally.

Using the incremental distraction feature of the device, the completeness of the corticotomy is verified under image intensification. Once completeness has been confirmed, the fixator and corticotomy are then compressed for a latency period 7-10 days. For acute corrections, the fixator can be dialed out intra-operatively to accommodate the desired amount of correction. Prophylactic subcutaneous Anterolateral compartment fasciotomy may be desirable to reduce incidence of compartment syndrome. Acute corrections in the adult population may benefit from the use of supplemental bone grafting and subsequent compression. Once the completeness of the corticomy has been checked and the incisions have been closed, final fixator positioning and tightening should be performed using the 5mm allen wrench.

For gradual corrections, once the fixator has been tightened, and the completeness of the corticotomy has been confirmed, the fixator should be compressed to its original position for 7-10 days.

Insertion of the enhanced access c/d mechanism
For gradual corrections, the fixator and coricotomy should be compressed for a latency period of 7-10 days. Once the inflammatory process of bone healing has subsided, the angular correction can be addressed on a daily basis. In order to employ the gradual lengthening feature of the device, a compression distraction unit is inserted into the telescoping arm of the fixator and locked in place. In order to open up the corticotomy site and to provide for unobstructed angulation, the frame should be distracted at a rate of four 1/4 turns per day for five days. After the corticotomy has been distracted, the patient is instructed to lock the position of the distal bone screw clamp. This is achieved by tightening the locking set screw closest to the central portion of the fixator.

The patient is then instructed to use the 5mm allen wrench in the medial side of the hinge portion of the fixator to start the angular correction.

Using the 5mm allen wrench to lock in the c/d mechanism with a set screw.

Loosening the proximal set screw to allow for compression or distraction.

Using the enhanced access c/d to distract at a rate of four 1/4 turns per day.
Patients with a varus deformity should be instructed to insert the wrench into the medial aspect of the hinge and turn it clockwise to produce a valgus correction. Angulation can proceed at a rate of 1/4 turn per day until the desired degree of correction has been met.

If length needs to be addressed, it should be accomplished after angulation has been corrected. Scanograms may be helpful in the preoperative determination of any limb length discrepancy. The distal fixator arm will distract a total of 5cm. On a daily basis, the patient is instructed to loosen the locking set screw on the telescoping clamp. Using the 5mm allen wrench, the distraction unit can be turned in a clockwise manner at a rate of four 1/4 turns until the desired amount of length has been achieved.
Package Insert

**Purpose**
The EBI X FIX® System includes or consists of a unilateral external fixator. When properly used, the EBI X FIX® Fixator may preserve limb function by minimizing operative trauma to anatomical structures, preserving blood supply and providing for controlled axial motion capabilities to enhance a biological stimulus to fracture healing.

**Description**
The EBI X FIX® Fixator is a modular unilateral frame consisting of the following components:

1) fixator arms (comprised of male and female components);
2) compression/distraction mechanism;
3) central body component;
4) modular fixator components and
5) all associated locking joint bolts and clamp locking screws.

Each fixator frame utilizes implantable bone screws. Special wrenches (bone screw wrench, fixator wrench) are required for proper assembly of the apparatus. Adjustment of the fixator is possible during the course of treatment. The fixator is a modular system allowing for individualized frame configuration based upon the specific requirements of the application and indication.

**Indications**
The EBI X FIX® System is a unilateral external fixation device intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality.

**Contraindications**
Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions. Patients with a known allergy to silver should not use the silver coated bone screws.

**Possible Adverse Effects**
1. Nerve or vessel damage.
2. Superficial or deep bone screw tract infection, osteomyelitis and septic arthritis.
3. Edema or swelling; possible compartment syndrome.
4. Joint contracture, subluxation, dislocation or loss of range of motion.
5. Premature bone consolidation during distraction osteogenesis.
6. Failure of bone to regenerate satisfactorily, development of nonunion or pseudarthrosis.
7. Fracture of regenerate bone or through bone screw holes after device removal.
8. Loosening or breakage of the bone screws.
9. Bony damage due to inappropriate bone screw selection.
10. Bone deformity. Pressure on the skin caused by external components when clearance is inadequate.
11. Equinus deformity.
12. Persistence or reoccurrence of the initial condition requiring treatment.
13. Reoperation to replace a component or entire frame configuration.
14. Abnormal growth plate development in patients who are skeletally immature.
15. Foreign body reaction to bone screws or frame components.
16. Tissue necrosis secondary to bone screw insertion.
17. Pressure on the skin caused by external components when clearance is inadequate.
18. Chronic drainage of bone screw sites after device removal; bone screw site osteomyelitis.
19. Limb lengthening discrepancy.
20. Excessive operative bleeding.
22. Intractable pain.
23. Bone sequestration secondary to rapid drilling of bony cortex with heat build-up and bone necrosis.
24. Vascular disorders including thrombophlebitis, pulmonary embolus, would hematoma, avascular necrosis.

**WARNING:** This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

**Precautions**
Do not reuse implants/devices. While an implant/device may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant/device. Do not treat patients with implants/devices that have been even momentarily placed in or used on a different patient.

**Application of The EBI X FIX® System**

**Preoperative**
1. Operating surgeons should have complete understanding of the device and associated techniques. Surgeons are encouraged to obtain instruction from an experienced clinician prior to application.
2. Patient selection should be in accordance with the indications and contraindications for the EBI X FIX® System.
3. Fracture management, deformity correction and limb lengthening procedures should be preoperatively planned to ensure proper frame and component selection.
4. Use extreme care in handling and storage of components. Verify that an adequate supply of components is available at the time of surgery. All components should be inspected and sterilized before application. Damage to the surface of metal components can reduce strength and fatigue resistance.

**Intraoperative**
1. Proper bone screw placement requires anatomical consideration to avoid nerve and vessel damage.
2. Correct bone screw selection should be made with reference to anatomical and soft tissue size.
3. Predrilling for bone screw placement utilizing the proper drill bit is imperative.
4. Due to the tapered design, bone screws may not be backed out after insertion or they will lose purchase.
5. All screws and miscellaneous parts must be tightened with the proper instrumentation.
6. Use of the Biomet DYNAFIX Standard Fixator in HTO procedures utilizing a hemicorticotomy technique may cause the device to bind. Biomet recommends that surgeons utilizing this technique use our kit, part numbers 90110 or 90115. A loaner bank (PN 08100) is also available.

Postoperative
1. Controlled axial motion and weight bearing are advocated when deemed appropriate by the treating surgeon.
2. Screw and frame integrity must be monitored regularly.
3. Bone screw site hygiene is required and all patients must be instructed on the use and maintenance of the fixator and bone screws.
4. For patients undergoing distraction osteogenesis, 1mm per day distraction is recommended. This may be accomplished by 1/4mm turns of the compression/distraction mechanism at six hour intervals.
5. Patients should report any adverse or unanticipated effects to the treating physician.
6. Reassess the gap at the fracture site periodically during healing and make adjustments as necessary.

Materials
The EBI X FIX® System is composed of anodized aluminum alloy and stainless steel. All bone screws are made of 316L stainless steel; select sizes are available with silver coating.

Packaging
Factory labeling should be intact upon receipt of the equipment.

Sterilization
The EBI X FIX® System is provided nonsterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. All fixator components should be sterilized in a loosened state such that components may move freely. The following steam sterilization parameters are recommended.
Cycle: Vacuum Steam
Temperature: 270°F/132°C
Time: 8 minutes
Note: Allow for cooling

Caution
Federal law (USA) restricts this device to sale by or on the order of a physician.

Further Information
This brochure describes a surgical technique used by Richard Davidson, M.D. The surgeon who performs any implant procedure is responsible for determining the appropriate products(s) and utilizing technique(s) for in each individual patient. The contents of this manual are intended to be only a guide and are not intended to set a standard of care.
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