ATTENTION OPERATING SURGEON

PURPOSE
The DynaFix Vision Unilateral System is a single use, external fixation device consisting of a unilateral external fixator. When properly used, the Biomet DynaFix Fixators 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.

The DynaFix Vision External Fixation System is a modular external fixator consisting of the following components: rods; bone screws; clamps; rod to rod clamps wire clamps; pins; compression/distraction mechanism; modular fixator components. When properly used, the DynaFix Vision Fixators may preserve limb function by minimizing operative trauma to anatomical structures, and preserving blood supply.

DESCRIPTION
The DynaFix Vision Unilateral System is a modular unilateral frame consisting of the following components: fixator arms (comprised of male and female components; compression distraction mechanism; central body component; and 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 DynaFix Vision External Fixation System is a modular external fixator consisting of the following components: rods; bone screws; clamps; rod to rod clamps; wire clamps; pins; compression/distraction mechanism; modular fixator components. 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. When appropriate longer rod lengths should be double stacked to increase stiffness frame stiffness.

MATERIALS
The DynaFix Vision Unilateral System and the DynaFix Vision External Fixation System are composed of anodized aluminum alloy, titanium, carbon fiber reinforced epoxy, Pyromet® 718/cobalt chrome and stainless steel. All bone screws are made of 316L stainless steel.

INDICATIONS
The DynaFix Vision Unilateral System and the DynaFix Vision External Fixation System are external fixation devices intended for use in children and adults 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.

The Biomet® Vision FootRing System, a subsystem of the DynaFix Vision External Fixation System, is 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. Additional indications for the Vision FootRing System include:

- Correction of deformity
- Revision procedures where other treatments or devices have been unsuccessful
- Bone reconstruction procedures
- Fusions and replantations of the foot
- Charcot reconstruction and Lisfranc dislocations
- Ankle distraction (arthrodiastasis)

CONTRAINdications
Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.

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

Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

In pediatric patients, care should be taken to avoid the growth plate during screw insertion.

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

Device is single use only. After use, the device may be a potential biohazard. Reuse of devices labeled for single-use may result in product contamination, patient infection and/or failure of the device to perform as intended.

PRECAUTIONS
Specialized instruments are designed to aid in the accurate implantation of the internal fixation devices. The use of instruments or implant components from other systems can result in inaccurate fit, incorrect sizing, excessive wear and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments that have experienced extensive use or excessive force are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement, prior to surgery.

All trial, packaging, and instrument components must be removed prior to closing the surgical site. Do not implant.

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.
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 length 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, wound hematomas, avascular necrosis.
25. Early or late postoperative infection and allergic reaction.

APPLICATION OF THE DYNAFIX VISION UNILATERAL SYSTEM AND THE DYNAFIX VISION EXTERNAL FIXATION 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 DynaFix Vision Unilateral System and the DynaFix Vision External Fixation 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.

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.

MRI INFORMATION
The DynaFix Vision External Fixation and Unilateral Systems have not been evaluated for safety and compatibility in the MR environment. The devices have not been tested for heating or migration in the MR environment. The risks associated with a passive implant in an MR environment have been evaluated and are known to include heating, migration, and image artifacts at or near the implant site.

STERILITY
The DynaFix Vision Unilateral System and the DynaFix Vision External Fixation System are provided non-sterile 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.

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Repeated sterilization of carbon fiber reinforced epoxy is not recommended.

Individuals or hospitals not using the recommended method, temperature, and time are advised to validate any alternative methods or cycles using an approved method or standard.

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

Comments regarding this device can be directed to Attn: Regulatory dept., Biomet Inc., P.O. Box 587, Warsaw, IN 46581 USA, FAX: 574-372-3968.

Pyromet® is a registered trademark of CRS Holdings, Inc.

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CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product (description) label.

Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estate
Bridgend, South Wales
CF31 3XA UK
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