**Biomet® Rail System**

**PURPOSE**
The Biomet Rail System consists of a unilateral external fixator rail, modular bone screw clamps, and compression and distraction units. When properly used, the Biomet Rail System 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 Biomet Rail System is a modular unilateral frame consisting of the following components:
1) adult, small, and xs fixator rails (various sizes available to accommodate different length requirements);
2) compression/distraction mechanism;
3) modular fixator components and
4) all associated locking joint bolts and clamp locking screws.

Each fixator uses implantable bone screws. Special wrenches (Fixator T-wrench, Bone Screw T-wrench) are required for proper assembly of the apparatus. The adjustment of the fixator is possible during the course of the treatment.

The fixator is a modular system allowing for individualized frame configuration based upon the specific requirements of the application and indication.

**INDICATIONS**
The Biomet Rail System is a unilateral external fixation device intended for use in the treatment of bone conditions including limb lengthening, corrective osteotomies, arthrodesis, fracture fixation, acute or gradual multiplanar correction, 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 through bone screw holes after device removal.
8. Loosening or breakage of bone screws.
9. Bony damage due to inappropriate screw selection.
11. Equinus deformity.
12. Persistence or recurrence of the initial condition requiring treatment.
13. Reoperation to replace a bone screw or bone screws.
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.

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

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 Biomet Rail System
3. Fracture management and deformity correction procedures should be preoperatively planned to ensure proper bone screw selection.
4. Use extreme care in handling and storage of bone screws. Verify that an adequate supply of bone screws is available at the time of surgery. All bone screws should be inspected 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 considerations.
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. For cases involving distraction osteogenesis, care should be taken to preserve the periosteal sleeve when performing the osteotomy/corticotomy.

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 hygiene is required. A 2% hydrogen peroxide and sterile water solution should be used until wounds are healed. Routine showering should follow with an antibacterial soap. All patients must be instructed on the use and maintenance of their 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 events to the treating physician.
6. Reassess the gap and regenerate bone periodically during healing and make adjustments as necessary.

MATERIALS
The Biomet Rail System is composed of anodized aluminum alloy, titanium, carbon fiber reinforced epoxy, 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 Biomet Rail 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

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

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

**INFORMATION**
For further information, please contact your local Biomet representative or call Customer Service at:

Biomet
100 Interpace Parkway
Parsippany, NJ 07054
(973) 299-9300
(800) 526-2579
[www.biomettrauma.com](http://www.biomettrauma.com)

Or contact your local Biomet Distributor

**NOTE**
US Patent No. 5,941,879 and other patents pending.
Made in the USA

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