

Biomet Trauma
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Revision A
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Biomet® VS Osteotomy System

ATTENTION OPERATING SURGEON

PURPOSE

The Biomet VS Osteotomy System includes a titanium osteotomy plate titanium bone screws, and instruments. When properly used, the Biomet VS Osteotomy System will provide stable fixation for patients undergoing corrective osteotomies.

DESCRIPTION

The Biomet VS Osteotomy System consists of a specialized plate design that will facilitate mechanical axis realignment in patients with uneven load distribution in the joint. The system consists of the following components:

1. titanium plates
2. titanium bone screws
3. special instruments used in plate and screw implantation.

Special screwdrivers are required for proper insertion of the system.

MATERIALS

The Biomet VS Osteotomy plates and bone screws are manufactured from medical grade titanium. Specifically, the plates are made from titanium alloy (Ti-6Al-4V ELI).

INDICATIONS

The Biomet VS Osteotomy System is intended for fixation following acute corrective opening wedge osteotomies in long bone.

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.

PRECAUTIONS

Device is single use only.

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.

Instruments are available to aid in the accurate implantation of internal fixation devices. Intraoperative fracture or breaking of instruments has been reported.

Surgical instruments are subject to wear with normal usage. Instruments, which 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

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. Failure of bone to regenerate satisfactorily, development of nonunion or pseudarthrosis.
6. Fracture through bone screw holes after device removal.
7. Loosening or breakage of the plate and bone screws.
8. Bony damage due to inappropriate bone screw selection.
9. Bone deformity.
10. Persistence or recurrence of the initial condition requiring treatment.
11. Reoperation to replace a component.
12. Foreign body reaction to bone screws or plate.
13. Tissue necrosis secondary to insertion of implants.
14. Chronic drainage of incision and or osteomyelitis.
15. Limb length discrepancy.
16. Excessive operative bleeding.
17. Intrinsic risks associated with anesthesia.
18. Intractable pain.
19. Bone sequestration secondary to rapid drilling of bony cortex with heat build-up and bone necrosis.
20. Vascular disorders including thrombophlebitis, pulmonary embolus, wound hematomas, avascular necrosis.
21. Early or late postoperative infection and allergic reaction.

APPLICATION OF THE BIOMET VS OSTEOTOMY 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 Biomet VS Osteotomy System.
3. Deformity correction procedures should be preoperatively planned to ensure proper 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.
5. Correct plate and bone screw selection should be made during preoperative planning.

INTRAOPERATIVE

1. Proper bone screw placement requires anatomical consideration to avoid nerve and vessel damage.
2. Predrilling for bone screw placement utilizing the proper drill bit is imperative.
3. All screws and miscellaneous parts must be tightened with the proper instrumentation.

POSTOPERATIVE

1. Weight bearing is advocated when deemed appropriate by the treating surgeon.
2. Patients should report any adverse or unanticipated effects to the treating physician.
3. Patients should be instructed to complete postoperative therapy and exercise as ordered by the treating physician.

MAGNETIC RESONANCE (MR) STATEMENT

The effects of the MR environment have not been determined for this device. This device has not been tested for heating or migration in the MR environment.

STERILITY

The Biomet VS Osteotomy System is provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. The following steam sterilization parameters are recommended.

Cycle:	Vacuum Steam
Temperature:	270°F (132°C)
Time:	8 minutes
Note:	Allow for cooling

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.

All trademarks herein are the property of Biomet, Inc. or its subsidiaries unless otherwise indicated.

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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CE 0086

Symbol Legend	
	Manufacturer
	Date of manufacture
	Do not reuse
	Caution, see instructions for use
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Sterile
	Sterilized using aseptic processing techniques
	Sterilized using steam or dry heat
	Use by date
	WEEE device
	Catalogue number
	Batch code
	Flammable
	Authorized representative in the European Community