MBD Plating System

FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON

DESCRIPTION

The Plating System consists of plates and screws manufactured from commercially pure titanium and titanium alloy. The plates are available in a variety of lengths and attach to the bone with 4.0mm bone screws. The system also contains 2.5mm fragment screws.

MATERIALS

Unalloyed Grade 4 Titanium	ASTM F67
Titanium Alloy (Ti-6Al-4V)	ASTM F-136

INDICATIONS

The MBD Plating System is designed for the fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia and fibula.

STERILIZATION

The MBD Plating System is provided in a NONSTERILE condition.

1. The non-sterile system must be sterilized prior to use. All packaging materials must be removed prior to sterilization.
2. Re-sterilization of sterile products which have been opened is permissible as long as the components have not been previously implanted, not been exposed to biological contamination, nor appear to have compromised mechanical integrity.

The following steam sterilization parameters referenced in ANSI/AAMI ST79:2010 are recommended:

Method	Cycle	Temperature	Exposure Time	Drying Times
Steam	Pre-vacuum (Wrapped)*	132°-135°C (270°-275° F)	4 Minutes	30 Minutes

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. *FDA cleared wrap.

CONTRAINDICATIONS

1. Skeletal immaturity.
2. Active infection.
3. Patient conditions including blood supply limitations, and insufficient quantity or quality of bone.
4. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions or materials.
5. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

WARNINGS

Internal fixation devices aid the surgeon in the alignment and stabilization of skeletal fractures and provide a means of fracture management in reconstructive surgical applications. While these devices are generally successful in attaining these goals, they cannot be expected to replace normal healthy bone or withstand the stress placed upon the device by full or partial weight bearing or load bearing, particularly in the presence of nonunion, delayed union, or incomplete healing. Metallic bone fixation devices are internal splints that align the fracture until normal healing occurs. The size and shape of bones and soft tissue place limitations on the size and strength of implants. If there is delayed union or nonunion of bone in the presence of weight bearing, or load bearing, the implant could eventually break. Therefore, it is important that immobilization (use of external support, walking aids, braces, etc.) of the fracture site be maintained until firm bony union (confirmed by clinical and radiographic examination) is established. Surgical implants are subject to repeated stresses in use, which can result in fatigue fracture. Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the service life of the implant. It is important to recognize that these implants may break at any time if they are subjected to sufficient stresses. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but also must be aware of the mechanical and metallurgical aspects of the surgical implants.

The following are specific warnings, precautions and adverse effects which must be understood by the surgeon and explained to the patient.

1. **Correct selection of the implant is extremely important.** The potential for success in fracture fixation is increased by the selection of the proper type of implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal healthy bone. These devices are **not** designed to withstand the unsupported stress of full weight bearing, or load bearing.
2. **The devices can break when subjected to increased loading associated with nonunion or delayed union.** Internal fixation devices are load-sharing devices that hold a fracture in alignment until healing occurs. If healing is delayed, or does not occur, the implant can be expected to break, bend or fail. Loads produced by weight bearing, and activity levels may dictate the longevity of the implant. Stresses on an implant can include weight of the limb alone, muscular forces or repeated force of relatively small magnitude, any of which can result in failure of the implant.
3. **Implant materials are subject to corrosion.** Implanting metals and alloys subjects them to constantly changing environments of salts, acids, and alkalis that can cause corrosion. Putting dissimilar metals and alloys in contact with each other can accelerate the corrosion process that may enhance fracture of implants. Every effort should be made to use compatible metals and alloys when marrying them to a common goal, i.e., screws and plates. Implant components from different manufacturers

should not be mixed for metallurgical, mechanical and functional reasons.

4. **Correct handling of implants is extremely important.** Contouring of metallic implants should be avoided where possible. If contouring is necessary, the surgeon should avoid sharp bends, reverse bends or bends through the screw hole of a plate. Notches or scratches put in the implant during the course of surgery may contribute to breakage. Intraoperative fracture of screws can occur if excessive force (torque) is applied while seating bone screws.
5. **Remove after fracture has healed.** Implants can loosen, fracture, corrode, migrate, or cause pain. If an implant remains implanted after complete healing, the implant may cause stress shielding, which may increase the risk of refracture in an active patient. The surgeon should weigh the risks verses benefits when deciding whether to remove the implant. Adequate postoperative management to avoid refracture should follow implant removal.
6. **Adequately instruct the patient.** Postoperative care is very important. The patient's ability and willingness to follow instruction is one of the most important aspects of successful fracture management. Patients with senility, mental illness, alcoholism, and drug abuse may be at higher risk. These patients may ignore instructions and activity restrictions. The patient is to be instructed in the use of external supports, walking aids, and braces that are intended to immobilize the fracture site and limit weight bearing or load bearing. The patient is to be made fully aware and warned that the device does not replace normal healthy bone, and that the device can break, bend or be damaged as a result of stress, activity, load bearing, or weight bearing. The patient is to be made aware and warned of general surgical risks, possible adverse effects, and to follow the instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examination as long as the device remains implanted.
7. **Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.**
8. **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.

POSSIBLE ADVERSE EFFECTS

1. Bending or fracture of the implant.
2. Loosening or migration of the implant.
3. Metal sensitivity, or reaction to a foreign body.
4. Decrease in bone density due to stress shielding.
5. Pain, discomfort, or abnormal sensation due to the presence of the device.
6. Nerve damage due to surgical trauma.
7. Necrosis of bone.
8. Postoperative bone fracture and pain.
9. Inadequate healing.
10. Early or late postoperative infection and/or allergic reaction.

INSTRUMENTS

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. It is recommended that all instruments be regularly inspected for wear and disfigurement.

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

CLEANING INSTRUCTIONS

All instruments must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into the sterile surgical field. Pay special attention to flush and clean all lumens prior to sterilization.

Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; therefore, these solutions are not recommended.

MAGNETIC RESONANCE (MR) STATEMENT

The MBD Plating System has not been evaluated for safety and compatibility in the MR environment. MBD Plating System has not been tested for heating or migration in the MR environment.

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

Comments or requests for additional information should be directed to:
MBD Medical, LLC
52 Highland Avenue, Suite B
Bethlehem, PA 18017
Tel: 610-954-7901

MBD™ Medical, LLC