BMP™ Cable Implants for Internal Fixation

ATTENTION OPERATING SURGEON

DESCRIPTION
BMP Cable Implants are fixation devices intended for circumferential banding of the bone. BMP cerclage cables, crimps, plates and trochanter grips are intended to stabilize fractures of the skeletal system. Components are available in a variety of sizes.

MATERIALS
316 LVM Stainless Steel
CoCrMo Alloy

INDICATIONS
There are several items that make up this system. They will be listed separately with their intended use:

Cable Implants Indications:
1. Femur and Tibial Fractures
2. Prophylactic banding
3. Trochanteric reattachment
4. Olecranon fractures
5. Patella fractures
6. Ankle fractures
7. Fixation of spiral fractures in conjunction with I/M nailing and screwing techniques
8. Sternum fixation after open chest surgery
9. Stabilization of cortical only strut graft

Trochanteric Grip Indication:
1. Reattachment of greater trochanter following osteotomy for total hip or total hip procedures or trochanteric advancement

Cable Plate Indications:
1. Fixation of femoral, tibial or humeral fractures near the site of an intramedullary implant
2. Fixation of fractures where a combination of screws and cerclage cables would improve stabilization

Supracondylar Cable Plate Indications:
1. Distal femoral fractures
2. Subtrochanteric fractures

Lateral Trochanteric Plate Indications:
1. Extended trochanteric osteotomies
2. Trochanteric fractures

Patient selection factors to be considered include:
1. need for alignment and stabilization of bone fractures,
2. ability and willingness of the patient to follow postoperative care instructions until healing is complete, and
3. a good nutritional state of the patient.

CONTRAINDICATIONS
1. Infection
2. Patient conditions including blood supply limitations, obesity and insufficient quantity or quality of bone.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. 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. Internal 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. The surgeon must be thoroughly knowledgeable, not only in the medical and surgical aspects of the implant, but also with regard to the mechanical and metallurgical aspects of the surgical implants.

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.

3. Implant materials are subject to corrosion. Implanting metals and alloys subjects them to constant 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.

4. Correct handling of implants is extremely important. Intraoperative fracture of screws can occur if excessive force (torque) is applied while seating bone screws. Notches or scratches put in the implant during the course of surgery may contribute to breakage.

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 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, or drug abuse may be at higher risk of device failure. 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. Do not attempt screw fixation within a fracture line. Adequate fixation will be compromised if screws are placed within the fracture line.
8. Improper bending of the BMP Cable Plate can cause damage to the crimp sleeves while not allowing passage of cables. This can lead to implant failure and surgical procedure failure.

9. The Biomet ratchet style BMP Crimer is designed to crimp the cerclage cable sleeve using one compression. Additional crimping can be expected to cause the sleeve to fracture, possibly leading to failure of the implant and surgical procedure.

10. Properly locate the BMP Crimer against the crimp sleeve. Improper seating of the crimper can cause the instrument to scythe across the top of the sleeve damaging the crimp sleeve and/or the cable.

11. When using crimp sleeves not attached to a plate, place the crimp with the narrow side down and the wide side up to properly receive the jaws of the BMP Crimer.

12. Center the BMP Crimer on the crimp sleeve. Failure to center BMP Crimer jaws on the crimp sleeve can cause damage to the sleeve and the corresponding section of the cable. This can lead to implant failure and surgical procedure failure.

PRECAUTIONS
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.

POSSIBLE ADVERSE EFFECTS
1. Nonunion or delayed union, which may lead to breakage of the implant
2. Bending or fracture of the implant
3. Loosening or migration of the implant
4. Metal sensitivity, or allergic reaction to a foreign body
5. Limb shortening due to compression of the fracture or bone resorption
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensation due to the presence of the device
8. Nerve damage due to surgical or preexisting trauma
9. Necrosis of bone
10. Intraoperative or postoperative bone fracture and/or postoperative pain
11. Inadequate healing
12. Infection

STERILIZATION
Unless supplied sterile, metallic internal fixation devices must be sterilized prior to surgical use. Product provided sterile is sterilized by exposure to a minimum dose of 2.5 Megarads (25kGy) gamma radiation. Where specified, do not use implants after expiration date. These guidelines also apply to devices provided sterile where the integrity of the packaging has been compromised and re-sterilization is required prior to initial use.

Pre-Vacuum Steam Sterilization:
Temperature: 270° – 275°F (133° – 135°C)
Time: Fifteen (15) Minutes
Note: Allow for cooling

Since Biomet is not familiar with individual hospital handling methods, cleaning methods and bioburden, Biomet cannot assume responsibility for sterility of products provided as non-sterile even though the recommended guideline is followed.
CAUTION
Federal law (USA) restricts this device to sale by or on the order of a physician.

INFORMATION
For further information, please contact the Customer Service Department at:
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