CHS™ Compression Hip Screw System

ATTENTION OPERATING SURGEON

DESCRIPTION
The CHS (Compression Hip Screw System) is a fracture fixation appliance to be used in treatment of fractures to the proximal femur. The components for the CHS (Compression Hip Screw System) include plate lag screw with compression screw.

MATERIALS
316 LVM Stainless Steel

INDICATIONS
The CHS (Compression Hip Screw System) may be used primarily for fixation of bone fractures. Specific indications include open reduction and internal fixation of a wide variety of fractures of the proximal femur: Intracapsular fractures, Intertrochanteric fractures and Subtrochanteric fractures.

Patient selection factors to be considered include:
1. need for alignment, stabilization and reduction 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 limitation 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 bone 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 in the medical and surgical aspects of the implant, as well as the mechanical and metallurgical aspects of the implant.

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. Implating 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. 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.

6. 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 versus benefits when deciding whether to remove the implant. Adequate postoperative management to avoid refracture should follow implant removal.

**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 that 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 presence of the device.
8. Nerve damage due to surgical or preexisting trauma.
11. Inadequate healing.

**STERILITY**

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 nonsterile even though the recommended guideline is followed.

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

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