

## LAVENDER MEDICAL LIMITED METALLIC INTERNAL FIXATION DEVICES ATTENTION OPERATING SURGEON

### DESCRIPTION

Lavender Medical distributes a variety of internal fixation devices intended to aid in the alignment and stabilisation of fractures to the skeletal system. While these devices are generally successful in attaining these goals, they cannot be expected to replace normal, healthy bone or to withstand stress placed upon the device by full or partial weight bearing, particularly in the presence of non-union, delayed union or incomplete healing. The use of external support (e.g., walking aids, braces) is recommended as a part of the treatment. The surgeon is to be thoroughly familiar with the implant, the method of application, instruments and the surgical procedure. In all cases sound orthopaedic practice is to be followed and the surgeon must select a type of internal fixation device appropriate for the treatment. The patient is to be warned of the risks involved in the use of the device as listed, including the possible adverse effects.

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 as a result of stress, activity or weight bearing. The patient is to be warned that failure to follow post-operative care instructions can cause failure of the device or the treatment. Senility, mental illness, alcoholism and other conditions may cause the patient to ignore certain necessary limitations and precautions in the use of the internal fixation device, leading to failure or other complications.

### INDICATIONS

1. Fresh fractures.
2. Osteotomy.
3. Revision procedures where other treatments or devices have failed.
4. Arthrodesis.

### CONTRAINDICATIONS

1. Active infection.
2. Patient conditions including: blood supply limitations, insufficient quantity or quality of bone or latent infections.
3. Patients with mental or neurological conditions who are unwilling or incapable of following post-operative care instructions.
4. Foreign body sensitivity. Where material sensitivity is suspected, tests are to be made prior to implantation.

### SUGGESTIONS CONCERNING PARTIAL WEIGHT BEARING AND NON-WEIGHT BEARING ORTHOPAEDIC APPLIANCES AND RECONSTRUCTIVE IMPLANTS (Prepared by the Orthopaedic Surgical Manufacturers Association - USA)

The use of metallic surgical implants has given the surgeon a means of bone fixation and helps generally in the management of fracture and reconstructive surgery. However, these implants are intended only to assist healing and are not intended to replace normal body structures. Metallic bone fixation devices are internal splints which align the fracture while normal healing occurs. The size and shape of bones and soft tissue places limitations on the size and strength of implants. If there is delayed union or non-union of bone in the presence of weight bearing or load bearing, the implant could eventually break due to metal fatigue. Therefore it is important that immobilisation of the fracture site be maintained until firm bony union (confirmed by clinical and radiographic examination) is established. All metallic surgical implants are subject to repeated stresses in use which can result in metal fatigue. Factors such as the patients weight, activity level and adherence to weight bearing, or load bearing instructions have an effect on the load and number of cycles to which the implant is subjected.

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 surgical implants. Post-operative care is extremely important. The patient should be warned that non-compliance with post-operative instructions could lead to breakage of the implant and/or possible migration requiring revision surgery to remove the device.

The following are specific warnings, precautions and adverse effects which should be understood by the surgeon and explained to the patient. Warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

### WARNINGS

1. Correct selection of the implant is extremely important. The potential for success of fracture fixation is increased by the selection of the proper size, shape and design of the implant. While proper selection can help minimise risks, the size and shape of human bones present limitations on the size and strength of implants. Metallic internal fixation devices cannot withstand 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. These devices can break when subjected to the increased loading associated with delayed union or non-union. Internal fixation devices are load sharing devices which hold a fracture in alignment until healing occurs. If healing is delayed or does not occur, the implant could eventually break due to metal fatigue. Loads produced by weight bearing and activity levels will dictate the longevity of the implant. Notches or scratches put in the implant during the course of surgery may also contribute to early breakage.
3. CORROSION. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids and alkalis which can cause corrosion. Putting dissimilar metals in contact with each other can accelerate the corrosion process which in turn may enhance fatigue fracture of implants. Thus, every effort should be made to use compatible metals and alloys when marrying them to a common goal, i.e., screws in a bone plate.

### PRECAUTIONS

1. SURGICAL IMPLANTS MUST NEVER BE RE-USED. An explanted metal implant should never be re-implanted, even though the device may appear undamaged it may have small defects and internal stress patterns which may lead to early breakage.
2. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. Contouring of metallic implants should be avoided where possible. If contouring is necessary, or allowed by design, the surgeon should avoid sharp bends, reverse bends or bending the device at a screw hole. The operating surgeon should avoid any notching or scratching of the device when contouring it. These factors may produce internal stresses which may become the focal point for eventual breakage of the implant. Intraoperative fracture of the screws can occur if excessive force (torque) is applied while seating bone screws into position.
3. REMOVAL AFTER FRACTURE HEALING. Metallic implants can loosen, fracture, corrode, migrate, cause pain or stress shield bone even after a fracture has healed, particularly in young, active patients. If an implant remains implanted after complete healing it can actually increase the risk of re-fracture in an active individual. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate post-operative management to avoid re-fracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.
4. ADEQUATELY INSTRUCT THE PATIENT. Post-operative care and the patients ability and willingness to follow instructions are one of the most important aspects of successful fracture healing. This is particularly important should the device be used to treat an unstable fracture, such as intertrochanteric or subtrochanteric. The patient must be made aware of the limitations of the implant and that physical activity and full weight bearing, or load bearing, have been implicated in premature loosening, migration, bending or fracture of internal fixation devices. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will fracture under normal weight bearing, or load bearing, in the absence of complete bone healing. An active, debilitated or demented patient who cannot properly use

weight supporting devices may be particularly at risk during post-operative rehabilitation. The patient must be warned to inform any other medical practitioner who may treat him in the future of the presence of the implant.

#### POSSIBLE ADVERSE EFFECTS

1. Non-union or delayed union which may lead to breakage of the implant.
2. Bending or fracture of the implant. Loosening and/or migration of the implant.
3. Metal sensitivity or allergic reaction to a foreign body.
4. Limb shortening due to compression of the fracture or bone resorption.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort or abnormal sensations due to the presence of the device.
7. Nerve damage due to surgical trauma.
8. Necrosis of bone.

#### STERILITY

1. Metallic internal fixation devices which are supplied in the sterile condition are clearly marked "STERILE" on the packaging.
2. Metallic internal fixation devices which are supplied in the non-sterile condition must be sterilized prior to surgical use. These devices may be sterilized by using high temperature steam (autoclaving). The sterilization process must be properly validated and routinely controlled. The sterility of devices sterilized by this method is the responsibility of the user.
3. Metallic internal fixation devices which were originally supplied in the sterile condition, but whose sterility has been compromised due to the packaging having been inadvertently damaged or opened may be re-sterilized using the method described in (2) above.