COVISION
ORTHOPAEDICS

IMPORTANT MEDICAL INFORMATION
COVISION FRACTURE FIXATION DEVICES

Description:

Fracture fixation devices are used only as an aid to healing; they are not a substitute for normal intact tissue or bone. The anatomy of human bones presents limitations with respect to the size or thickness of bone screws or plates and thus the strength of implants is limited. Fracture fixation devices are available in many styles and sizes and are made from various types of metal used in surgical implants. The component material is provided on the implants and labels. Use only components made from the same material together. Do not mix dissimilar metals or components from different manufacturers. *All implantable devices are designed for single use only.* These fracture fixation devices are not approved for fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Through the advancement of surgical implants, the surgeon has been provided a means of correcting deformity, stabilising and reducing pain for many patients. While the implants used are largely successful in attaining these goals, it must be recognized that they are manufactured from metal and that no implant can be expected to withstand the activity levels and loads as would normal, healthy bone. The surgeon must evaluate each situation individually based on the patient's clinical presentation in making any decisions regarding implant selection.

Surgical Technique:

A general surgical technique is applied. Firstly the bone fracture is reduced and then a plate is screwed to the bone for fixation, Surgeons must be familiar with the applicable operative technique and instructions for use for each type of product. This IFU and the package label contain essential warnings and precautions for each surgery. Additionally, the surgical technique should be referenced for detailed information about implant selection, relevant product details, proposed surgical instructions, and/or assembly use. The surgeon should contact Covision for the proposed product specific surgical technique.

In using fixation implants, the surgeon should be aware of the following:

• **The correct selection and sizing of the implant is extremely important.** Selection of the proper size, shape, and design of the implant increases the potential for success. The implants require careful seating and adequate bone support.

• In selecting patients for surgery, the following factors can be critical to the eventual success of the procedure:

1. **Patient's occupation or activity.** If the patient is involved in an occupation or activity which includes substantial lifting or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The implant will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
2. **Condition of senility, mental illness, or alcoholism.** These conditions, among others, may cause reduced compliance of the patient which can lead to ignoring certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
3. **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

Indications:

Fracture fixation devices are intended for use in stabilization of fresh bone fractures, revision procedures, joint fusion and reconstruction of bones in paediatric and adult patients. This device is not approved for fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Contraindications:

The physician's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

• Any active or suspected latent infection or marked local inflammation in or about the affected area.
• Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site
• Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation of the devices
• Material sensitivity, documented or suspected.
• Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure the device itself.
•Patients having inadequate tissue coverage over the operative site.
• Implant utilization that would interfere with anatomical structures or physiological performance.
•Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
•Other medical or surgical conditions which would preclude the potential benefits of surgery.

Patient Selectipn:

Use of surgical fixation hardware requires consideration of the following general indications:

• Good condition of the patient
• Good neurovascular status
• Adequate skin coverage
• Possibility of a functional musculotendinous system
• Adequate bone stock to receive implant
• Availability of post-operative therapy

• Cooperative patient

Potential Complications And Adverse Reactions:

In any surgical procedure, the potential for complications exists. The risks and complications with these implants include:
• Infection or painful, swollen or inflamed implant site
• Fracture of the implant
• Loosening or dislocation of the implant requiring revision surgery
• Bone resorption or over-production
• Allergic reaction(s) to implant material(s)
• Untoward histological responses possibly involving macrophages and/or fibroblasts
• Migration of particle wear debris possibly resulting in a bodily response
• Embolisms

Precautions:

Following the instructions for use provided in product literature can minimize the potential for complications or adverse reactions with any implant.
It is the responsibility of each surgeon using implants to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedure and the potential complications that may occur. The benefits derived from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are common. The patient's mental status must also be considered. Willingness and/or ability to follow post-operative instructions may also impact the surgical outcome. Surgeons must balance many considerations to achieve the best result in individual patients.
If excessive loading cannot be prevented, an implant should not be used.
The main goal of surgery with this implant is to establish bony fusion. Abnormal or excessive forces could lead to delayed union, non-union, or failure of the implant. Abnormal loading and subsequent wear may be caused by:
• Uncorrected instability
• Improperly sized implant
• Inadequate soft tissue support
• Implant malposition
• Excessive motion
• Uncorrected or recurrent deformity
• Patient misuse or overactivity
Proper fixation at the time of surgery is critical to the success of the procedure. Bone stock must be adequate to support the device.

Some preventative measures to consider minimizing the potential risk for complications:
• Follow guidelines for the indications and contraindications provided above
• Identify prior pathologies
• Stabilize collapsed deformities
• Bone graft pre-existing cysts
• Use a properly sized implant
Avoid damaging/scratching the implant surfaces or excessive bending to minimize the potential for early fatigue failure.
If complications develop, possible corrective procedures include:
• Reduced weightbearing
• Medication
• Implant removal

Replacement of the implant:

Over time, metallic implants may loosen, fracture, or cause pain after bone fracture or osteotomy is healed. Removal of metallic implants is at the surgeon's discretion, and the appropriateness of the selected procedure will be based on the surgeon's personal medical training and experience. It is imperative that adequate post-operative care and protection be provided by the surgeon.

Recommendations Regarding Device Fragments:

1. Use medical devices in accordance with their labelled indications and the manufacturer's instructions for use, especially during insertion and removal.
2. Inspect devices **prior to use** for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fracture during a procedure.
3. Inspect devices **immediately upon removal from the patient** for any signs of breakage or damage.
4. If the device is damaged, retain it to assist with the manufacturer's analysis of the event.
5. Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
6. Advise the patient of the nature and safety of unretrieved device fragments including the following information:
a. The material composition of the fragment (s) (if known);
b. The size of the fragment (s) (if known);
c. The location of the fragment (s)
d. The potential mechanisms for injury, e.g., migration, infection;
e. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment (s).
Clinical results depend on surgeon and technique, pre-operative and post-operative care, the implant, patient pathology and daily activity. It is important that surgeons obtain appropriate informed consent and discuss the potential for complications with each patient prior to surgery. This may include a review of alternative, non-implant procedures such as soft tissue reconstruction or arthrodesis.

Concerning Magnetic Resonance Environments:

The devices described in this package insert have not been evaluated for safety in the MR environment. The devices described in this package insert have not been tested for heating or migration in the MR environment.

Handling And Sterilization:

This product is for single use only. An implant should never be re-sterilized after contact with body tissues or fluids. Devices labelled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

Implants provided non-sterile must be sterilized by a hospital validated steam autoclaving process in appropriate protective wrapping when necessary. If necessary components must be cleaned prior to sterilization in compliance with hospital validated cleaning processes or cleaning equipment manufacturers' user instructions and recommendations for chemical detergent is required. All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.
The following process parameters are validated by Covision and recommended for sterilization.

Steam Sterilization		
Cycle Type	Parameter	Minimum Set Point
Prevacuum 273°F (134°C)	Exposure Temperature	273°F (134°C)
	Exposure Time	4 minutes
	Dry Time	20 minutes

These recommendations have been developed and validated using specific equipment. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment.

Definitions:

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

LOT	Batch code		Date of manufacture		Consult Instruction For Use		Manufacturer
REF	Catalogue number	NON STERILE	contents packed without sterilization		Do not re-use	STERILIZE	Do not Resterilize
EC REP	Authorized representative in the European Community						

Information

Should any incident occur with implantable device, call the phone number given below.
For further information, please contact Customer Service Tel: +44 (0) 1909 733 737

CE 2195

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