Instructions For Use: Non-Sterile / Single Use
Fuse ULTRA Foot Plating System

Device Description

The Fuse ULTRA Foot Plating System is available in a range of plate types, shapes and sizes, for implantation in the human body. The implant devices are manufactured from titanium alloy (to ISO 5832-3/ASTM F-136). Plate and screw components are provided *non-sterile* using *moist heat sterilization* according to AAMI guidelines. The Fuse ULTRA Foot Plating System has not been evaluated nor tested for safety, compatibility, heating or migration in the MR environment.

Indications For Use

The intended use of the Fuse ULTRA Foot Plating System fixation device(s) is to draw two or more aligned small bone fragments together to facilitate healing. The Fuse ULTRA Foot Plating System is indicated for use in stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones in the feet, ankles, and toe skeleton. This implant should only be used with the Fuse ULTRA Foot Plating System. Combination with other implants or instrumentation is not permissible. The Fuse ULTRA Foot Plating System is not intended for spinal use.

Adverse Effects

- Fracture of the implant due to excessive loading
- Incomplete or inadequate healing
- Implant migration and/or loosening
- Pain, discomfort or abnormal sensations due to the presence of an implant
- Nerve damage resulting from surgical trauma
- Bone necrosis or bone resorption
- Delayed or non-union of bone fragments
- Allergic reaction to the implant materials

Contraindications

- Active or latent infection
- Sepsis
- Osteoporosis
- Insufficient bone quality and/or quantity
- Sensitivity to the implant material
- Any condition not described in the indications

Warnings & Precautions

- Implants must not be re-used
- Improper insertion of the device during implantation may result in implant loosening or migration
- Loosening or migration and loss of fixation due to incorrect implantation, delayed union, non-union and incomplete healing
- Bending or fracture due to applied excessive stresses and load bearing
- Failure to follow postoperative care instructions
- Electrolytic action and corrosion due to implanting with other metallic devices of different chemical composition

Sterilization of Implants & Instrumentation

Sterilization of the implants and instruments in the sterilization case/trays using *moist heat sterilization* as recommended by the AAMI guidelines are validated to an SAL of 10-6. Both sterilization and dry time testing are validated according to ISO 17664 & 17665-1 using the half-cycle method. The recommended steam sterilization parameters for *non-sterile* implants and instrumentation according to ANSI/AAMI ST79:2006 standard are as follows:

Item	Exposure Time	Drying Time
Wrapped Instruments – Case/Tray	4 minutes 132°C (270°F)	20 to 30 minutes

Reprocessing of Single Use Devices

Devices labelled as *single use* may not perform as intended if reused. Use of these devices can cause irreversible changes to the micro and macro structure of the material; consequently, performance characteristics of the device will be sub-optimal if re-used. Implant plates where 'in-surgery' bending of a plate using bending pliers must NOT BE RETURNED to case set and must be discarded. Reuse of a *single use* implant device may lead to:

•An increased risk of infection •Material degradation •Endotoxic reactions

⚠ Surgeons must be fully trained in the surgical technique

Single Use Only

Rx Only Caution: Federal law (USA) restricts this device to sale by or on the order of a physician

Resignation of Guarantee

CPM Medical Consultants, LLC accepts no responsibility for claims deriving from the misuse of the product of non-compatible instruments & devices.

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