



EMERGE CANNULATED SCREW FIXATION SYSTEM

INDICATIONS FOR USE

FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON

DESCRIPTION: The Emerge Cannulated Screw Fixation System is designed to provide fixation of various fractures and osteotomies while they heal. The device consists of stainless steel or titanium screws available in a variety of sizes ranging in diameter from 2.4mm up to 7.3mm and overall lengths from 17mm up to 150mm.

INFORMATION FOR USE: The surgeon must select the type and size implant that best meets the patient's surgical needs.

INDICATIONS: The Emerge Cannulated Screw Fixation System is intended to provide bone fixation in the management of fractures of both small and large bones and bones fragments, including those in the foot, patella, ankle, wrist and elbow and arthrodesis of the foot, wrist, elbow and small and long bone osteotomies.

CONTRAINDICATIONS: Active or latent infection. Osteoporosis, insufficient quantity or quality of bone/soft tissue. Material sensitivity. If suspected, tests are performed prior to implantation. Sepsis. Patients who are unwilling or incapable of following postoperative care instructions. This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

WARNINGS: For safe effective use of this implant, the surgeon must be thoroughly familiar with this type of implant, the methods of application, instruments, and the recommended surgical technique for this type of device.

The device is not designed to withstand the stress of weight bearing, load bearing, or excessive activity. Device breakage or damage can occur when the implant is subjected to increased loading associated with delayed union, nonunion, or incomplete healing.

Improper insertion of the device during implantation can increase the possibility of loosening or migration. The patient must be cautioned, preferably in writing, about the use, limitations, and possible adverse effects of this implant.

The Emerge Cannulated Screw Fixation System has not been evaluated for safety and compatibility in the MR environment. Additionally, the device has not been tested for heating or migration in the MR environment.

There exists the possibility of the device failing as a result of loose fixation and/or loosening, stress, excessive activity, or weight bearing or load bearing, particularly if the implant experiences increased loads due to delayed union, nonunion, or incomplete healing. The patient must be warned that failure to follow postoperative care instructions can cause the implant and/or treatment to fail.

PRECAUTIONS: An implant shall never be reused. Previous stresses may have created imperfections, which can lead to a device failure. Instruments, particularly drills and hex drivers, shall be inspected for wear or damage prior to usage. Protect implants against scratching and nicking. Such stress concentrations can lead to failure.

ADVERSE EFFECTS: Fracture of the implant due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion. Implant migration and/or loosening. Metal sensitivity or histological or allergic reaction resulting from implantation of a foreign material. Pain, discomfort, or abnormal sensations due to the presence of an implant. Nerve damage resulting from the surgical trauma. Necrosis of bone or bone resorption. Necrosis of the tissue or inadequate healing.

STERILITY: The product is provided both sterile and non-sterile. Sterile devices were exposed to a minimum dose of 25.0-kGy gamma irradiation. Resterilization of a sterile device may only be performed if the original sterile package has been opened in error but the contents not handled. Sterilization should be performed using the following method:

STERILIZATION METHODS

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| Pre-vacuum autoclave | |
| Minimum Temperature: | 270° F (132° C) for 8 minutes |
| Minimum Dry Time: | 20 minutes |

- Please consider your sterilization equipment manufacturer's written instructions for the specific sterilizer and load configuration used.
- Follow current AORN "Recommended Practices for Sterilization in Perioperative Practice Settings" and ANSI/AAMI ST79: 2006 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Flash sterilization is not recommended, but if used, should only be performed according to requirements of ANSI/AAMI ST79: 2006 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

STORAGE INSTRUCTIONS: Store in a cool dry place and keep away from direct sunlight. Prior to use, inspect product package for signs of tampering, or water contamination. Use oldest lots first.

CAUTION: Federal Law (USA) restricts the product sale by or on the order of a physician or hospital.

For more information about products, please visit www.emergemedical.com or contact Customer Service at (866) 553-0376

Manufactured and distributed by:



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