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Extremity Implant Set

INSTRUCTIONS FOR USE

DESCRIPTION

The OsteoTec product range of Extremity Implants comprises of Kirschner wires, bone screws and plates and other different elements for implantation into the human body to treat a wide range of unstable fractures and/or osteotomies in small bones. Manufactured from certified stainless steel, the items can be used individually or in combination with each other. It is important that the instruments used are those specifically designed for the implant to ensure accurate installation.

MIXING AND MATCHING

The product should not be implanted into the human body in contact with implants of dissimilar materials, as this mixing may give rise to galvanic corrosion. Also crevices and micro motion should be avoided wherever possible. The extremity implant range is manufactured to recognised international standards.

Intercompany product mixing may sometimes be undertaken but the surgeon should satisfy him/herself that the product tolerances and materials are compatible. Technical specifications for Osteotec's products are normally available on request.

CONDITIONS OF USE

Full understanding of the implant and its surgical technique is the full responsibility of the surgeon, as is advising the patient against premature weight bearing, activity levels and periodic medical follow up and cleaning of the wound, especially around any wires.

INDICATIONS

The implants for the Extremity Implant range are designed to treat a wide range of unstable fractures and/or osteotomies in small bones. They are indicated for:

- Small hand and wrist bone fractures
- Forefoot and midfoot interfragmentary fractures
- Osteotomy procedures
- Other medical conditions outside the scope of these indications.

ADVERSE EFFECTS

In any surgical procedure the potential for adverse effects exists. Such adverse effects are:

- Abnormal sensation and/or pain due to the implant
- Metal sensitivity
- Infection
- Loosening of the wires or screws
- Other conditions that may place the patient at risk.

WARNINGS AND PRECAUTIONS

Contouring of the implants is to be avoided where possible. If contouring is necessary, the device should not be bent sharply, reverse bent, notched or scratched.

The surgeon should discuss all physical and psychological limitations inherent with the use of these implants with the patient.

The patient should be instructed to report any unusual changes around the operated site to the physician – for example, signs of infection.

Successful application could be assessed both visually and by using an image intensifier.

CONTRAINDICATIONS

- Active local infection
- Physiologically or psychologically inadequate patient
- Failure to obtain the patient's consent
- Poor or insufficient bone stock

The judgement of whether an implant is suitable for a particular patient is at the surgeon's discretion.

PACKAGING

Devices labelled sterile should only be assumed thus, so long as the manufacturer's original packaging is intact. All extremity implant products should be received in an intact package. Damaged packages or products should not be used and should be discarded.

STERILITY

The condition of the device is denoted by the symbol "STERILE R" or "NON STERILE" as appropriate. Devices labelled sterile should only be assumed thus, so long as the manufacturer's original packaging is intact with due regard to the expiry date shown on the product labelling.

STERILE PRESENTATION: Products bearing a "STERILE R" symbol have been pre-sterilised by gamma irradiation and benefit from two sterile barrier packages closest to the product. All other packaging should be regarded as for transit and storage purposes only and NOT to represent a sterile barrier.

STERILISATION OF IMPLANTS SUPPLIED IN NON STERILE CONDITION: Where a product is marked as "NON STERILE" it should be cleaned to remove the residual chemical and biological contamination, before sterilisation as specified under the heading "Re-sterilisation". Products supplied by Osteotec have been prepared for autoclave sterilisation.

RE-STERILISATION

Sterilisers vary in design and performance characteristics, so cycle parameters should always be verified against the steriliser manufacturer's instructions for the specified steriliser and load configuration being used. The implants prior to sterilisation should be packaged appropriately for the sterilisation technique used.

The most common temperature and time parameters for wrapped or containerized devices are for: Pre-vacuum cycles, minimum 4 minutes at 133°C to 137°C and for: Gravity-displacement cycles, a 10 - 15 minute exposure time at 133°C to 135°C or a 15 - 30 minute exposure time at 121°C to 123°C. Drying - for 20 to 50 minutes, factors affecting drying times include contents of the steriliser, steam quality and equipment maintenance. Cooling – all devices removed from the steriliser after sterilisation processing must be allowed to cool thoroughly. They should not be touched during the cooling process. Re-sterilised product must be properly labelled and marked with an expiry date mandated by hospital policy. Sterilization can also be carried out in accordance with HTM 2010 (Sterilization).

MATERIALS

All extremity implant products are manufactured to appropriate standards from certified stainless steel to ISO5832/BS7252 Part 1.

ENVIRONMENTAL STORAGE/CONDITIONS

The Extremity Implants are intended to be used and stored under normal operating environmental conditions.

SINGLE USE

Osteotec's Extremity Implants are intended for SINGLE USE ONLY and should under no circumstances be re-used or re-sterilised if they become contaminated.

REPROCESSING OF SINGLE USE DEVICES

Devices labelled as single use only may not perform as intended by the manufacturer if re-used. Use of these devices cause irreversible changes to the micro and macro structure; consequently performance characteristics of the device will be sub-optimal if re-used. Re-use of a single use device may lead to:

- An increased risk of infection
- Material degradation
- Failure of the device to perform as intended
- Endotoxic reactions