

# EXTREMITY IMPLANT SET

## STANLEY WRIST FUSION PIN

### Instructions for Use

Manufactured by:



#### Osteotec Limited

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#### DESCRIPTION

The OsteoTec product range of Extremity Implants specifically the Stanley Wrist Fusion Pins comprises of a Steinmann pin with a recessed end to aid impaction and a dedicated "arrow head" point for implantation into the human body to fuse the wrist. Manufactured from certified stainless steel, the pins can be used individually or in pairs. 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. Micro motion should also be avoided wherever possible.

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 entirely the 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 in the vicinity of pin entry points.

#### INDICATIONS

The implants for the range of Extremity Implant specifically the Stanley Wrist Fusion Pins are designed to fuse the wrist in order to abolish the pain of rheumatoid arthritis and/or to correct either instability or deformity of the joint. They are indicated for:

- Deformity due to radial tilt of wrist.
- Instability of the wrist due to ligament pathology.
- Almost fused but painful Rheumatoid joints.
- Rheumatic soft bone which does not provide adequate grip for screws.

#### ADVERSE EFFECTS

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

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

#### WARNINGS AND PRECAUTIONS

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

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 manufacturers 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 any 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
- Endotoxin reactions