OrthoSolutions Group
Advancing Foot & Ankle Care

System 26
Foot & Ankle Screws

Instructions For Use

Ortho Solutions System26™ Screw System

Sterile and Non-Sterile Implants and Instruments

GB and EU

These instructions are to be utilised for the **System26™** manufactured by Ortho Solutions UK Ltd West Station Business Park, Spital Road, Maldon, CM9 6FF, United Kingdom, Phone: +44(0)1621 843599, Fax: +44(0)1621 858953, www.orthosol.com. All instructions provided in this document must be followed. Refer to the Surgical Technique (Ref: OS TD 00192_19 System26™ Design Rationale and Surgical Technique) available at https://www.orthosol.com/surgical-techniques/ for complete instructions for clinical use:

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This document is subject to continuous revision. Please verify that the current printed version is identical to the one at **www.orthosol.com**.

Users may request a paper copy of this, or a translation into any required EU language, at no additional cost by contacting Ortho Solutions using the details provided in the "Complaints/ Vigilance/ Feedback and Contact" section below.

EC REP

Authorised representative in EU.
Advena Ltd
Tower Business Centre,
2nd Flr., Tower Street,
Swatar, BKR 4013 Malta.

1. DEVICE DESCRIPTION

The Ortho Solutions System26 sterile implants are comprised of non-cannulated / cannulated bone screws and washers manufactured from Titanium Alloy (to ISO 5832-3/ASTM F136) and bone staples manufactured from Stainless Steel (ISO 5832-1/ASTM F138) for implantation within the human body. The instrumentation is made from medical grade raw materials including stainless steel, titanium and silicone. The System26 implants are threaded screws offered in a 'headed', 'headless' and 'Twist Off' design. The screws are available in a range of diameter sizes between 2mm and 8mm, (each identified with a Type III colour anodising) with lengths between 10mm and 120mm. The reusable instrumentation is provided non-sterile in dedicated instrumentation trays. Implants and consumables are provided sterile by gamma irradiation certified to a 5-year shelf life. The System26 instrument(s) include guide wires and size specific guides, drill bits and size specific guides, depth gauges, countersinks, screwdriver shafts, ratcheting screwdriver handles and bone clamps. These instrument(s) are used to ensure correct positioning and placement of the implants. All K-Wires, drills, countersinks and easy outs within System26 Instrument sets are intended for single use only.

2. INDICATIONS FOR USE

System26 is intended for implantation within the human body for fixation and stabilisation of small and large bone fractures to facilitate healing.
The implants are all single use and is indicated for aligned bone fracture repair and arthrodesis, osteotomy, joint fusion, and bone fragment fixation.

3. CONTRAINDICATIONS

Use of the Ortho Solutions System26 is contraindicated in cases of:

- Active or latent infection
- Suspected sepsis
- Osteoporosis and/ or insufficient bone quality
- Sensitivity to the implant material
- Infection (local or systemic)
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- All concomitant pathologies that could affect the function of the implant
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment

4. ADVERSE EFFECTS

In all surgical procedures, the potential for complications and adverse reactions exist. The risks and complications with these implants include:

- 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
- Electrolytic action and corrosion due to implanting with other metallic devices of different chemical composition

Inform Ortho Solutions immediately if any complications occur which are associated with the implants or surgical instruments used. If premature failure of the implant occurs in which the design, surface quality or mechanical integrity is suspected, please return (in a cleaned, disinfected and sterile condition) the suspected device to Ortho Solutions. Ortho Solutions cannot be held responsible for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behaviour.

5. WARNINGS & PRECAUTIONS

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Implants must not be re-used or re-sterilised.
- 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.
- Do not use if current date exceeds label expiry.
- Despite correct selection, placement, and use, certain events may still occur, including device breakage under extreme mechanical loads, loosening due to patient non-compliance with post-operative care, or allergic reaction to materials in sensitive individuals. Users should communicate these risks to patients as part of the informed consent process.

6. MR SAFETY INFORMATION

System26 has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artefact in the MR environment. The safety in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

1. REPROCESSING INSTRUCTIONS

Ortho Solutions reusable instruments are supplied non-sterile unless clearly and explicitly labelled as sterile. Non-sterile reusable devices must be cleaned and inspected prior to sterilisation and introduction into a sterile surgical field. Devices should be disassembled where applicable prior to cleaning.

For guidance on each step refer to:

- **Cleaning parameters and reprocessing procedure:** OS TD 00019_18 Cleaning and Sterilisation Instructions.
- **Disassembly instructions (where applicable):** OS TD 00081_25 Non-Sterile Device Disassembly Instructions.
- **Device inspection and end-of-life criteria:** OS TD 00334_25 Non-Sterile Device Lifetime Manual.

These documents are available at: www.orthosol.com/eifu/

7. STERILISATION INSTRUCTIONS

All non-sterile reusable devices may be sterilised in an autoclave. Autoclaves must comply with EN 285 and EN 13060 standards for validation, servicing, and maintenance, which are the responsibility of the hospital.

GB: Sterilisation of the instruments in the instrumentation case/trays using 'moist heat sterilisation' as recommended by UK HTM 01-01 is validated to a SAL of 10-6. Both sterilisation and dry time testing is validated according to ISO 17664 and 17665-1 using the half-cycle method. The recommended steam sterilisation parameters for non-sterile instrumentation according to UK HTM 01-01 are as follows:

Cycle Type	Exposure Time	Cycle Temp.	Drying Time
Prevacuum Air Removal	3 minutes	134 - 137°C / 273 - 279°F	≥ 20 minutes

8. USE ORTHO SOLUTIONS INSTRUMENTS ONLY

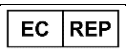
The use of surgical instruments other than those supplied by Ortho Solutions may cause damage to the implants, handing issues, or other complications. Only use Ortho Solutions instruments for implantation of the System26 implants to avoid compatibility issues.

9. STORAGE AND HANDLING

Store the device in a clean, dry environment, away from direct sunlight and sources of heat or moisture. Do not use if packaging is damaged or if the use-by date for sterile device has expired. Maintain packaging integrity to ensure sterility until point of use.

10. SYMBOL GLOSSARY

The Unique Device Identifier (UDI) for this product is affixed on the product packaging. The Basic UDI-DI is registered in the EUDAMED/UK MHRA database as applicable. **Basic UDI-DI**: 50556629077K

Symbol	Title of Symbol	Application
	Use By	Sterile
	Do not use if package is damaged	Sterile
	Do not reuse	Sterile
	Do not re-sterilise	Sterile
	Sterilised using irradiation	Sterile
	Non-Sterile	Non-sterile
	Batch Number	Sterile and non-sterile
	Catalogue Number	Sterile and non-sterile
	Consult instructions for use	Sterile and non-sterile
	Caution – surgeon must be fully trained in the surgical technique or IFU.	Sterile and non-sterile
	Medical Device	Sterile and non-sterile
	Manufacturer	Sterile and non-sterile
	Authorised representative	Sterile and non-sterile
	Applied per part number as appears on the device packaging, or the device.	Sterile and non-sterile
	Applied per part number as appears on the device packaging, or the device.	Non-sterile & Non-measuring
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11. COMPLAINTS/VIGILANCE/FEEDBACK AND CONTACT

This device is subject to vigilance and post-market surveillance requirements under EU MDR 2017/745 and UK MDR 2002 (as amended). Users and healthcare professionals are encouraged to report to Ortho Solutions any malfunction, deterioration in performance or characteristics, inadequacy or inaccuracy in the information supplied with the device or any other event that might pose a serious risk to public health or could lead to or has led to a serious incident, in accordance with Article 87 of the EU MDR and Regulation 44ZC of the UK MDR.

For complaints originating in the EU, users should notify also Ortho Solutions' EU Authorised Representative: Advena Ltd., Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013, Malta. Additionally, incidents can also be reported to the relevant Competent Authority in the EU Member State or to MHRA (UK), as applicable.

To report a complaint, adverse incident, or any suspected nonconformity of the device, please contact Ortho Solutions Regulatory Affairs department without undue delay and no later than 2 days at regulatory@orthosol.com or at the addresses provided below.

For general product feedback, please use our feedback portal at https://orthosol.com/customer-feedback/ or email sales@orthosol.com.

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