OrthoSolutions Group

Advancing Foot & Ankle Care

System 26

Foot & Ankle Screws

## Instructions For Use

# Ortho Solutions System26™ Screw System

## Non Sterile Implants and Instruments

## US

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) 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 IFU at no additional cost by contacting Ortho Solutions using the details provided in the "Complaints / Medical Device Reporting / Feedback and Contact" section below.

℞ Only

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

This device has been reviewed and cleared for sale in United States by the U.S. Food and Drug Administration.

## 1. DEVICE DESCRIPTION

The Ortho Solutions System26 bone screws are comprised of non-cannulated / cannulated bone screws and washers manufactured from Titanium Alloy (to ISO 5832-3/ASTM F136) for implantation within the human body. The instrumentation is made from medical grades of stainless steel and silicone. The System26 implants are threaded screws offered in both a 'headed' and 'headless compression' design. The implant screws are available in a range of diameter sizes between 2mm and 8mm, (each identified with a Type III color anodising) with lengths between 10mm (smallest length) and 120mm (largest length). The implant screw devices and associated instrumentation are available in specifically designed, modular trays and are provided non-sterile to the end user for single use. Do not use instruments for anything other than the intended purpose. The System26 instrument(s) include guide wires and size specific guides, drill bits and size specific guides, tissue protectors, depth gauges, countersinks, screw driver shafts, ratcheting screw driver handles and bone distractors. These instrument(s) are used to ensure correct positioning and placement of the screws. All K-Wires, drills and countersinks within System26 Instrument sets are intended for single use only. K-wires are manufactured from implant grade cobalt chrome and stainless steel (ISO 5832). Drills and countersinks are manufactured from instrument grade stainless steels (ASTM F899).

These devices are supplied non-sterile and, although bacterial endotoxin testing is performed during the validated final cleaning process, no claim of non-pyrogenicity is made for the finished, non-sterile device. Prior to clinical use, the device must be cleaned and sterilised by the user in accordance with Ortho Solutions' validated reprocessing instructions (OS TD 00019_18) to ensure sterility and minimise the risk of pyrogenic contamination.

## 2. MR SAFETY INFORMATION

The Ortho Solutions System26 bone screws and washers have not been evaluated for safety or compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Ortho Solutions System26 Bone Screws and Washers in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

## 3. 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.

## 4. CONTRAINDICATIONS

Use of the Ortho Solutions System26 Cannulated Screw System is contraindicated in cases of active or latent infection, suspected sepsis, osteoporosis, insufficient bone quality and sensitivity to the implant material. Additionally, all applications that are not defined by the indications are contraindicated.
Surgical success can also be adversely affected by infection (both local or systemic), vascular, muscular or neurological pathologies that compromise the concerned extremity, all concomitant pathologies that could affect the function of the implant and 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.

## 5. 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

The possible complications listed are not typical of Ortho Solutions System26 Cannulated Screw System or other product ranges but rather in principle complications with any implant. 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 a causal relationship with its 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.

## 6. 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-sterilized.
- 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.
- Failure to follow postoperative care instructions.
- Never use metal brushes or steel wool for cleaning, only use soft brushes or wires to prevent mechanical abrasion on the surface of the device.
- Ortho Solutions does not recommend specific cleaning and/or disinfection agents. Manual cleaning has been validated in accordance with AAMI TIR30. Facilities choosing alternative cleaning agents must ensure these are equivalent and validated for effectiveness.
- Always follow the manufacturer's instructions for cleaning agents and equipment.
- 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.

## 7. REPROCESSING INSTRUCTIONS

Ortho Solutions devices are supplied non-sterile unless clearly and explicitly labelled as sterile. Non-sterile devices must be cleaned and inspected prior to sterilization 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 Non-Sterile Device Reprocessing 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 may be found at* www.orthosol.com/eifu/

## 8. STERILISATION OF INSTRUMENTATION

Ortho Solutions instrument(s) and single use devices are supplied non-sterile unless clearly and explicitly labelled as sterile. Non-sterile devices must be sterilised prior to use. All implants and instruments must first be cleaned using established hospital methods before sterilisation and introduction into a sterile surgical field. Sterilisation of the instruments in the instrumentation case/trays using 'moist heat sterilisation' as recommended by the AAMI guidelines is validated to a SAL of $10^{-6}$. An FDA cleared wrap shall be used for the sterilisation. The recommended steam sterilisation parameters for non-sterile instrumentation according to ANSI/AAMI ST79 are as follows:

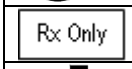
| CYCLE TYPE | EXPOSURE TIME | EXPOSURE TEMPERATURE | RECOMMENDED DRYING TIME |
|---|---|---|---|
| Prevacuum Air Removal | 4 minutes | 132°C (270°F) | ≥ 20 minutes |

## 9. 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 difficulties, e.g. causing delay or failures in the surgical procedure. Only use Ortho Solutions instruments for implantation of the System26 screws to avoid compatibility issues.

## 10. SYMBOL EXPLANATIONS

This device is labeled with a Unique Device Identifier (UDI) in accordance with applicable U.S. FDA requirements and 21 CFR Part 830. Refer to the product packaging for UDI information. Before use, verify that the product labeling matches the intended procedure and patient.

| Symbol | Title of Symbol |
|---|---|
|  | Indicates the need for the user to consult the instructions for use - Surgeon must be fully trained in the surgical technique |
|  | Do not reuse |
|   | Caution: Federal law (USA) restricts this device to sale by or on the order of a physician |
|  | Manufacturer |
|   | Batch Number |
|   | Catalogue Number |
|   | Medical Device |
|   | Non-Sterile |
|  | Consult IFU |

## 11. 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.

## 12. COMPLAINTS / MEDICAL DEVICE REPORTING / FEEDBACK AND CONTACT

This device is subject to complaint handling and Medical Device Reporting requirements under 21 CFR Part 803 and 21 CFR Part 820. Users and healthcare professionals are encouraged to report to Ortho Solutions any malfunction, that has caused or contributed to a death or serious injury, or that would be likely to cause or contribute to a death or serious injury if it were to recur, as well as any failure, improper performance, or labeling/IFU inaccuracies that could impact patient safety. Any event meeting the criteria for mandatory reporting under 21 CFR 803 should also be reported to the U.S. Food and Drug Administration (FDA) through the MedWatch program:

- Online: https://www.accessdata.fda.gov/scripts/medwatch/
- By phone: 1-800-FDA-1088

To report a complaint, adverse event, or any suspected nonconformity of the device, please contact Ortho Solutions without undue delay at regulatory@orthosol.com or at the addresses provided below. Reports should be submitted as soon as possible, and no later than 10 working days from the date of awareness.

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

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