

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.

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.

7. CLEANING AND STERILISATION OF REUSABLE INSTRUMENTS

Ortho Solutions reusable instruments are supplied non-sterile unless clearly and explicitly labelled as sterile. Non-sterile devices must be sterilised prior to use. All non-sterile reusable instruments must first be cleaned using established hospital methods before sterilisation and introduction into a sterile surgical field. Refer to *OS TD 00019_18 Cleaning and Sterilisation Instructions* (available at <https://www.orthosol.com/eifu/>) for recommended cleaning and sterilisation parameters.












8. REPROCESSING OF SINGLE USE DEVICES

Devices labelled as single use may not perform as intended if reused. Use of these devices cause irreversible changes to the micro and macro structure of the material; consequently, performance characteristics of the device will be sub-optimal if re-used. Reuse of a single use device may lead to an increased risk of infection, failure of the device to perform as intended, material degradation, and endotoxin reactions.

9. USE ORTHO SOLUTIONS INSTRUMENTS ONLY

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

10. SYMBOL GLOSSARY

Symbol	Title of Symbol	Application
	Use By	Sterile
	Do not use if package is damaged	Sterile
	Do not reuse	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
	Manufacturer	Sterile and non-sterile
	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician	Sterile and non-sterile



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¹ CE marking and the notified body number is applied per part number and appears on the device packaging, or the device if applicable.