# INSTRUCTIONS FOR USE: System26 (Sterile)

## 1. DEVICE DESCRIPTION

The Ortho Solutions System26 is 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 silicon. 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

The Ortho Solutions System26 cannulated screws (headed and headless) are indicated for use over a guide pin or wire for aligned bone fracture repair and arthrodesis, osteotomy, joint fusion and bone fragment fixation. The staples are indicated for fixation of bone fractures, bone reconstruction and fixation of soft tissue to bone. System26 Twist Off screws and cannulated headless screw sizes of 2.0mm, 2.5mm 3.0mm are indicated for treating small bone fractures as well as performing osteotomies, arthrodesis, joint fusion and bone fragment fixation in the lower limb and extremities. System26 headless and headed cannulated screw sizes of 4.0mm, 5.0mm, 6.5mm, and 8.0mm are indicated to be used in large bone fractures, as well as performing osteotomies, arthrodesis of the ankle joint and other bone fragment fixation in the lower limb and extremities. Washers may be used in conjunction with headed screws (4.0mm and above only) in certain applications for deficient osteopenic bone. Specific indications, which are dependent in part on the diameter of the screw include: minimally invasive bone fracture/joint reconstructions, additive osteosynthesis for complex joint fractures, multiple-fragment joint fractures, bone fractures of the foot and ankle; ligament avulsion injuries, malleolar and navicular fractures, bone fractures of the calcaneus and talus, arthrodesis of foot joints and avulsion fractures.

## 3. CONTRAINDICATIONS

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

- Active or latent infection
- Suspected sepsis
- Osteoporosis or insufficient bone quality and / or 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.
- 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.

## 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

Thorough cleaning and disinfection are vital to reprocessing re-useable medical devices and ensuring effective sterilisation. Cleaning should be performed in a manner designed to minimise exposure to blood borne pathogens. Reusable medical devices should be kept moist immediately after use until cleaning. Thorough cleaning and rinsing should be carried out as soon as possible.

The purpose of cleaning and rinsing is to remove all adherent visible soil and to reduce the number of particulates and microorganisms. Furthermore, thorough rinsing is necessary to remove any residual cleaning agents from the medical device. Cleaning primarily removes rather than kills microorganisms.

Water quality should be carefully considered for use in preparing enzymatic detergents and for rinsing in the cleaning procedure. Water hardness is a concern because deposits left on the device may result in ineffective cleaning and decontamination. Deionised water is recommended and helps prevent discolouration and staining associated with mineral residues found in tap water.

The detergents listed below were used for cleaning validations. Ortho Solutions does not recommend specific cleaning and/or disinfection agents, others may be equivalent in performance. Always follow the manufacturer's instructions for cleaning agents and equipment.

| Cleaning | Manufacturer | Product |
|---|---|---|
| Manual | Johnson and Johnson | Enzol |
| Automated | Dr. Weigert | neodisher MediZym |

When conducting automated cleaning, pre-cleaning with an ultrasonic bath is highly recommended. When manual cleaning is conducted immediately after the procedure, the pre-cleaning step may be omitted. Automated cleaning methods are preferred over manual cleaning when available.

### 7.1. PREPARATION

Processing begins at the point of use and prompt initial cleaning steps and/or measures to prevent the drying of soil on the device surface prior to cleaning should be taken to facilitate subsequent cleaning steps. **Reprocessing procedures should minimise or eliminate delays between steps.** Delays may create conditions favourable to microbial growth, which may increase the challenge to subsequent steps such as cleaning and disinfection / sterilisation.

Recommended equipment:

- Ultrasonic cleaning bath
- Freshly prepared enzymatic cleaning detergent
- Syringes – various sizes dependant on cannulation sizes
- Brushes – soft, firm, bottle
- Appropriate Personal Protective Equipment (PPE)
- Lint free cloth

### 7.2. PRE-CLEANING

1. Disassemble instrument(s) as much as possible and open any articulated instrument(s) as much as possible.
2. Submerge instrument(s) in an enzymatic cleaning detergent. Ensuring that all surfaces are thoroughly wetted, remove gross soil, using syringes to clean difficult to wet areas such as cannulations and crevices. **Ensure air is not trapped**.
3. Ultrasonically clean the instrument(s) in the detergent for a minimum of ten (10) minutes. The enzymatic detergent should be changed before it becomes heavily soiled so that effective ultrasonic cleaning is not inhibited.
4. Clean the devices using soft brushes where possible. Firm bristle brushes may be required on heavily soiled instrument(s). Use bottle brushes (e.g. Antimicrobial bottle brushes – Key Surgical) of appropriate diameter for cannulations, pass the brush / down the whole length of cannulation at least three times. **Never use metallic brushes or steel wool**.
5. Operate moving parts, ensuring concealed areas are also cleaned.

6. Rinse in running water for a minimum of one (1) minute, paying attention to cannulations. Rinse at least three (3) times.
7. Inspect devices and repeat above steps if necessary.
8. Allow devices to drain on an absorbent, lint free cloth or place immediately into wire baskets for automated washing where possible.

### 7.3. MANUAL CLEANING

1. Disassemble instrument(s) as much as possible and open any articulated instrument(s) as much as possible.
2. Submerge instrument(s) in an enzymatic detergent safe for use with medical devices.
3. Soak the instrument(s) for between five (5) and ten (10) minutes in the detergent.
4. Scrub the instrument(s) with the appropriate brush, cloth, or sponge and agitate the instrument(s) in the solution whilst scrubbing and paying close attention to textured areas, crevices, blind holes, hinges, joints, and cannulations. Actuate any moving parts to loosen any trapped soil.
5. Rinse instrument(s) with warm (38 - 49°C or 100 - 120°F) water.
6. Place instrument(s) in a bath containing warm (38 - 49°C or 100 - 120°F) water and agitate by hand for a minimum of three (3) minutes.
7. Ultrasonically clean the instrument(s) for ten (10) minutes in a neutral pH detergent. Prepare the detergent according to the manufacturer's recommendation. The enzymatic detergent solution should be changed before it becomes heavily soiled so that effective ultrasonic cleaning is not inhibited.
8. Rinse the instrument(s) with deionised water for a minimum of one (1) minute.
9. Dry the exterior of instrument(s) with a clean lint-free cloth.
10. Visually inspect the instrument(s) for any remaining soil and repeat the above steps if necessary.

### 7.4. AUTOMATED CLEANING

1. Disassemble instrument(s) as much as possible and open any articulated instrument(s) as much as possible.
2. Place disassembled instrument(s) directly on to the washer trays, connecting cannulations to rinsing ports where possible and ensuring that instrument(s) are positioned in a way to prevent the retention of water residue.

| Step | Water | Minimum Time (mins) | Temperature |
|---|---|---|---|
| Pre-cleaning | Running | 4 | 20°C / 68°F |
| Cleaning | Running | 5 | 40°C / 131°F[1] |
| Neutralisation | Running | 2 | 20°C / 68°F |
| Intermediate Rinse | Deionised | 2 | 20°C / 68°F |
| Disinfection (Ao value > 3,000) | Deionised | 5 | ≥90°C / 194°F |
| Drying | - | 19 | 90°C / 194°F |

### 7.5. INSPECTION

Prior to sterilisation all instrument(s) should be inspected for damage / wear. Generally visual inspection with the naked eye under good lighting conditions will suffice. As well as damage and wear all instrument(s) should be:

1. Inspected to ensure all soil / visible blood has been completely removed from all surfaces, slots, cannulations, holes and moving parts.
2. Inspect instrument(s) and instrument cases for damage.
3. Check action of moving parts to verify correct device function.
4. If damage/wear or corrosion is suspected do not use the device and contact Ortho Solutions Customer Services or your Sales Representative for a replacement.

## 8. STERILISATION

Ortho Solutions reusable instrument(s) are supplied non-sterile unless it is 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. 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:

| Item | Exposure Time | Exposure Temperature | Recommended Drying Time |
|---|---|---|---|
| Wrapped Instrument(s) | 3 minutes | 134 - 137$^0$C / 273 - 279$^0$F | 20 to 30 minutes |

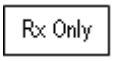
## 9. REPROCESSING OF SINGLE USE DEVICES

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, endotoxinic reactions.

## 10. 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 avoiding compatibility issues.

## 11. 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] According to detergent manufacturer instructions. Typically, 55°C / 131°F

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