INSTRUCTIONS FOR USE: SYSTEM26 CANNULATED SCREW SYSTEM

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 silicon. 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). No pyrogenic testing was performed on the System26 bone screw system. System26 in non-pyrogenic.

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

The Ortho Solutions System26 cannulated screws (headed and headless compression) and washers are indicated for use over a guide pin or wire for aligned bone fracture repair and arthrodesis, osteotomy, joint fusion and bone fragment fixation appropriate with the size of the screw. Washers of matching size to the headed cannulated bone screw may be used in certain applications for deficient osteopenic bone. The non-cannulated 2.0mm (headed, headless compression and Twist-Off) bone screws are applicable, as well, for bone fracture repair and arthrodesis, osteotomy, joint fusion and bone fragment fixation appropriate with the size of the screw.
System26 non-cannulated 2.0mm (headed, headless compression and Twist-Off) bone screws and cannulated (headed and headless compression) bone screw sizes of 2.0mm, 2.5mm 3.0mm are indicated for treating small bone fractures as well as performing osteotomies, arthrodesis and joining cancellous bone fragments in the upper and lower limb and extremities.
System26 cannulated bone screw sizes (headless compression and headed with optional washer) of 4.0mm, 5.0mm, 6.5mm, and 8.0mm are indicated to be used with large and long bones. 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; femoral neck and femoral head fractures; femoral supracondylar fractures; tibial plateau fractures; fractures of the head of the humerus; fractures of the tibia; cooper fractures of the tibia; bone fractures of the radius, wrist, ankle, elbow, and shoulder; ligament fixation of the proximal humerus; bone fractures of the acetabulum and dorsal pelvic ring; condylar fractures; ligament avulsion injuries; malleolar and navicular fractures; bone fractures of the calcaneus and talus; arthrodesis of the ankle joint; arthrodesis of foot joints and; avulsion fractures.

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 / or 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.
- 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. Enzol (Johnson and Johnson) was used for validation of manual cleaning.
- Always follow the manufacturer's instructions for cleaning agents and equipment.

7. CLEANING OF INSTRUMENT(S) (INSTRUCTIONS NOT INTENDED FOR IMPLANTS AND SINGLE USE ITEMS)

Thorough cleaning and disinfection are vital to reprocessing re-useable medical devices and adequate sterilisation depends on the thoroughness of cleaning.

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, microorganisms, and pyrogens. Furthermore, thorough rinsing is necessary to remove any residual cleaning agents from the medical device which could reduce the effectiveness of the sterilisation process. 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. 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.

Disassemble devices where required (contact Ortho Solutions if unsure). Pre-soak instrument(s) with an enzymatic solution for between 1 to 10 mins until all soil on the instrument(s) (that may have dried on the instrument(s) between the time of use and the time cleaning is begun) is softened. Thorough rinsing facilitates the removal of any residue from the soaking process (Personnel should refer to the manufacturers written instructions for the correct dilution, temperature, and soak time). Avoid using excessive force when handling/cleaning surgical instrument(s).

7.2. PRE-CLEANING INSTRUCTIONS FOR SPECIFIC DEVICES

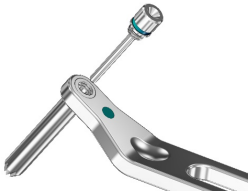
The following instructions should be followed prior to the manual or automated cleaning methods for all ratchet handle devices.

Figure 1 OS900020-NS - Axial Handle Ratcheting Cannulated AO QC

1. DO NOT DISSASEMBLE
2. Where possible retract collars to gain access to otherwise hidden / concealed areas of the device.
3. The cannulation (if present) should be thoroughly cleaned with the appropriate sized soft bristle lumen brushes and/or syringe.
4. Continue with subsequent cleaning via available method (manual or automated). Following cleaning. Check the actuation of the moving parts to ensure smooth operation.
5. **Do not reuse any damaged or defective instrument(s).**

7.3. ASSEMBLY DEVICES

Devices assembled for the procedure or devices that are assemblies of more than one component should be disassembled prior to cleaning and disinfection. Parts that need to be reassembled after cleaning and denomination and that are non-interchangeable should be kept together during processing to ensure correct reassembly.



All drill guides (and soft tissue protector) and mating k-wire guides must be completely disassembled for cleaning and disinfection. Cannulations should be cleaned with the appropriate sized soft bristle lumen brushes.

Figure 2 Drill guide with k-wire guide insert.

Depth gauge probes should be disassembled for cleaning and decontamination. Method: Remove the inner sliding probe from the outer body by withdrawing it from the back of the outer body. Reassemble by reinserting the inner probe after cleaning and decontamination.

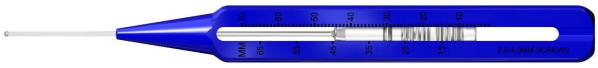


Figure 3 OS900071-NS - Depth Gauge Probe For 2.0-4.0mm Screws

7.4. MANUAL CLEANING

1. Submerge instrument(s) in an enzymatic detergent safe for use with medical devices. (Detergents should only be used per manufacturer's instructions).
2. Soak the instrument(s) for between five (5) and ten (10) minutes in the protein solubilizing detergent.
3. 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.
4. Rinse instrument(s) with warm (38 - 49°C or 100 - 120°F) water.
5. 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.
6. 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.
7. Rinse the instrument(s) with deionized water for a minimum of one (1) minute.
8. Dry the exterior of instrument(s) with a clean lint-free cloth.
9. Visually inspect the instrument(s) for any remaining soil and repeat the above steps if necessary.

7.5. AUTOMATED CLEANING

1. Run the automatic wash cycle as per the manufacturers validated parameters.
2. Following cleaning, thoroughly rinse the devices with warm (38-49˚ C (100-120˚F)) demineralized water for at least one (1) minute.
3. Visually inspect the instrument(s) for any remaining soil and repeat the above steps if necessary.
4. Dry the exterior of instrument(s) with a clean lint free cloth.

7.6. INSPECTION

Prior to sterilisation all instrument(s) should be inspected for damage / wear. Generally visual inspection under the naked eye with 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. If corrosion is identified, do not use the device, and contact customer services or your sales representative for a replacement.
2. Inspect instrument(s) and instrument cases for damage.
3. Check action of moving parts to verify correct device function.
4. Visual inspection of devices such as easy outs is important in identifying damage/wear that may affect proper function. If damage/wear is suspected do not use the device and contact customer services or your sales representative for a replacement.

8. STERILISATION OF INSTRUMENTATION

Ortho Solutions instrument(s) and single use devices are supplied non-sterile unless it is 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:

ITEM	EXPOSURE TIME	EXPOSURE TEMPERATURE	RECOMMENDED DRYING TIME
Wrapped Instrument(s)	4 minutes	132^{0}C (270^{0}F)	20 to 30 minutes

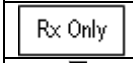
9. REPROCESSING OF SINGLE USE DEVICES

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

11. SYMBOL EXPLANATIONS

	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
	Non-Sterile
	Consult IFU

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