OrthoSolutions Group

VOLITION™ PLATING SYSTEM

Ankle Fracture Plates

Instructions For Use for Ortho Solutions Volition™ Plating System

Implants and Instruments

These instructions are to be utilised for the **Volition™ Plating System** 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.

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EC REP

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1. DEVICE DESCRIPTION

The Volition™ Plating System consists of implant plates for extremity fracture fixation. The plates feature polyaxial locking screw holes compatible with the system's 2.7 mm, 3.5 mm, and 4.0 mm bone screws, available in locking & non-locking versions. Washers are available for use with the system's non-locking screws when the screws are used for fixation without the plates.

2. PRODUCT MATERIAL

Volition™ Implants, plates and screws are made of titanium alloy (ASTM F136, ISO 5832-3). K-Wires, Drills and Countersinks are made of stainless steel (ASTM F899, F138, F139). Other instruments in direct contact with the patient are made of stainless steel or titanium.

3. COLOUR CODING

Volition™ implants are colour coded to facilitate ease of use in surgery as below.

Device Description	Colour Code
2.7mm Locking and Non-Locking Screws (and Associated Components)	Light Blue
3.5mm Locking and Non-Locking Screws (and Associated Components)	Magenta
4.0mm Locking and Non-Locking Screws (and Associated Components)	Gold

4. INTENDED PURPOSE

The Volition™ Plating System is intended to be used for the fixation of bones to facilitate healing.

5. INDICATIONS FOR USE

The Volition™ Plating System is indicated for use in stabilization and fixation of fractures and reconstruction of small bones in the foot and ankle.

6. CONTRAINDICATIONS

- Active or latent infection.
- Suspected sepsis.
- Osteoporosis or insufficient bone quality to provide adequate support / fixation of the device.
- Sensitivity to the implant material.
- 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.

7. 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 are for single use only.
- Single use devices must not be re-used. Devices labelled as single use may not perform as intended if reused. Use of these devices causes irreversible changes to the micro and macro structure of the material; consequently, performance characteristics of the device will be suboptimal 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, or endotoxinic reactions.
- Discard any damaged components.
- Only sterile devices should be placed in the operative field.
- Improper insertion of the device during implantation may result in implant loosening or migration.
- Ensure that the screwdriver/screw head connection is precisely aligned in an axial direction to reduce the likelihood of damage to the driver tip and implant.
- Contouring or bending implants should be avoided, where possible, because it may reduce the device's fatigue strength and cause failure under load. If contouring is necessary, avoid sharp bends, reverse bends, or bending the device at a screw hole. When contouring implants, only Ortho Solutions instruments must be used in accordance with the specified procedures (see surgical technique).
- Loosening or migration and loss of fixation due to incorrect implantation, delayed union, non-union and incomplete healing.
- The use of surgical instruments or implants other than those supplied by Ortho Solutions may cause damage to the implants or other complications. Do not use this device in conjunction with components from any other manufacturer's system unless otherwise specified (see surgical technique).
- When removing olive wires or k-wires with threaded tips, the drill/wire-driver must be operated in the reverse direction to avoid potentially fracturing the devices.

8. ADVERSE EFFECTS

In all surgical procedures, the potential for complications and adverse reactions exists. 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 implantation 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.

9. MRI SAFETY INFORMATION

This Volition™ Plating System 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.

10. CLEANING INSTRUCTIONS

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.

10.1. PREPARATION

Processing begins at the point of use and prompts 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 dependent on cannulation sizes.
- Brushes – soft, firm, bottle.
- Appropriate Personal Protective Equipment (PPE).
- Lint free cloth.

10.2. 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.

10.3. 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.

10.4. 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	Min. Duration	Temperature
Pre-Cleaning	Running	4 minutes	20°C (68°F)
Cleaning	Running	5 minutes	Per detergent manufacturer instructions, typically 55°C (131°F)
Neutralization	Running	2 minutes	20°C (68°F)
Intermediate Rinse	Deionized	2 minutes	20°C (68°F)
Thermal Disinfection (A0 ≥ 3,000)	Deionized	5 minutes	≥ 90°C (≥ 194°F)
Drying	-	19 minutes	90°C (194°F)

10.5. 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. Inspection should verify:

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

11. STERILISATION INSTRUCTIONS

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.

USA: Sterilization of the devices in the sterilization case/trays, double-wrapped per ANSI/AAMI ST79 using FDA-cleared sterilization wraps and autoclave indicator tape, using the recommended parameters is validated to a sterility assurance level (SAL) of 10^{-6}. The following sterilization cycle is recommended:

Cycle Type	Exposure Time	Cycle Temp.	Drying Time
Dynamic air removal (prevacuum) steam	4 minutes	132˚C (270˚F)	≥ 20 minutes

UK/Global: In addition to the above parameters, 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 sterilization parameters for non-sterile instrumentation according to UK HTM 01-01 are as follows:

Cycle Type	Exposure Time	Cycle Temp.	Drying Time
Dynamic air removal (prevacuum) steam	3 minutes	134 - 137°C / 273 - 279°F	≥ 20 minutes

12. 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
	Medical Device	Sterile and non-sterile
	Manufacturer	Sterile and non-sterile
	Authorised representative	Sterile
CE 2797	Applied per part number as appears on the device packaging, or the device.	Sterile and non-sterile
CE	Applied per part number as appears on the device packaging, or the device.	Non-sterile & Non-measuring

13. COMPLAINTS/FEEDBACK

Any adverse event or incident arising from the use of Ortho Solutions devices in any country must be reported to regulatory@orthosol.com upon discovery or awareness of event without undue delay. Any feedback related to the use of Ortho Solutions devices must be reported via https://orthosol.com/customer-feedback/ or sales@orthosol.com.

CE 2797

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