Instructions For Use

Ortho Solutions Volition™ Plating System

Sterile and Non-Sterile Implants and Instruments

GB and EU

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. Refer to the applicable Surgical Technique available at www.orthosol.com/surgical-techniques/ for complete instructions for clinical use: OS TD 00089_21 Volition Ankle Fracture Surgical Technique, OS TD 00134_21 Volition MTPJ & Utility Plates Surgical Technique, and OS TD 00094_23 Volition Plate Guide Instructions for MTPJ In-Line, Standard and Revision Plates.

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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, or a translation into any required EU language, at no additional cost by contacting Ortho Solutions using the details provided in the "Complaints/ Vigilance/ Feedback and Contact" section below.

EC REP

Authorised representative in EU.
Advena Ltd
Tower Business Centre,
2nd Flr., Tower Street,
Swatar, BKR 4013 Malta.

1. DEVICE DESCRIPTION

The Volition™ Plating System consists of plates, screws, and washers for foot and ankle bone 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. Additionally, 4.0 mm and 3.5 mm cannulated compression screws are supplied with ankle fracture and MTP / utility plates respectively for optional supplementary fixation. Washers are also available for use with the headed cannulated compression screws.

2. PRODUCT MATERIAL

Volition™ implants 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 bone fixation to facilitate healing.

5. INDICATIONS FOR USE

Volition™ Ankle Fracture is indicated for fracture fixation and bone reconstruction in the foot and ankle.

Volition™ Utility is indicated for fracture fixation, joint arthrodesis, and bone reconstruction in the foot and ankle. The MTP plates are indicated for arthrodesis of the metatarsophalangeal joint.

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.
- 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.

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. 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 sterilisation 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 are available at: www.orthosol.com/eifu/

11. STERILISATION INSTRUCTIONS

All non-sterile devices may be sterilised in an autoclave. Autoclaves must comply with EN 285 and EN 13060 standards for validation, servicing, and maintenance, which are the responsibility of the hospital.

GB: 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:

Tray Type	Cycle Type	Exposure Time	Cycle Temp.	Drying Time
Volition MTPJ / Utility (VOL-T)	Prevacuum Air Removal	3 minutes	134 - 137°C / 273 - 279°F	⩾30 minutes
Volition Ankle Fracture (VAF-T)	Prevacuum Air Removal	3 minutes	134 - 137°C / 273 - 279°F	⩾20 minutes

12. SYMBOL GLOSSARY

The Unique Device Identifier (UDI) for this product is affixed on the product packaging. The Basic UDI-DI is registered in the EUDAMED/UK MHRA database as applicable. **Device Basic UDI-DI:** 505566290279

Symbol	Title of Symbol	Application
	Use By	Sterile
	Do not use if package is damaged	Sterile
	Do not reuse	Sterile
	Do not re-sterilise	Sterile
STERILE R	Sterilised using irradiation	Sterile
NON STERILE	Non-Sterile	Non-sterile
LOT	Batch Number	Sterile and non-sterile
REF	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
MD	Medical Device	Sterile and non-sterile
	Manufacturer	Sterile and non-sterile
EC REP	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
UK CA 0086	Applied per part number as appears on the device packaging, or the device.	Sterile and non-sterile
UK CA	Applied per part number as appears on the device packaging, or the device.	Non-sterile & Non-measuring

13. 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.

14. COMPLAINTS/VIGILANCE/FEEDBACK AND CONTACT

This device is subject to vigilance and post-market surveillance requirements under EU MDR 2017/745 and UK MDR 2002 (as amended). Users and healthcare professionals are encouraged to report to Ortho Solutions any malfunction, deterioration in performance or characteristics, inadequacy or inaccuracy in the information supplied with the device or any other event that might pose a serious risk to public health or could lead to or has led to a serious incident, in accordance with Article 87 of the EU MDR and Regulation 44ZC of the UK MDR.

For complaints originating in the EU, users should notify also Ortho Solutions' EU Authorised Representative: Advena Ltd., Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013, Malta. Additionally, incidents can also be reported to the relevant Competent Authority in the EU Member State or to MHRA (UK), as applicable.

To report a complaint, adverse incident, or any suspected nonconformity of the device, please contact Ortho Solutions Regulatory Affairs department without undue delay and no later than 2 days at regulatory@orthosol.com or at the addresses provided below.

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

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