Instructions For Use

Ortho Solutions Volition™ Plating System

Non Sterile Implants and Instruments

US

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.

Ortho Solutions UK Limited West Station Business Park, Spital Road
Maldon, Essex, UK CM9 6FF

Tel: +44(0)1621 843 599
Fax: +44(0)1621 858 953
Email: sales@orthosol.com
Website: www.orthosol.com

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 IFU at no additional cost by contacting Ortho Solutions using the details provided in the "Complaints / Medical Device Reporting / Feedback and Contact" section below.

℞ Only

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

This device has been reviewed and cleared for sale in United States by the U.S. Food and Drug Administration.

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.

These devices are supplied non-sterile and, although bacterial endotoxin testing is performed during the validated final cleaning process, no claim of non-pyrogenicity is made for the finished, non-sterile device. Prior to clinical use, the device must be cleaned and sterilized by the user in accordance with Ortho Solutions' validated reprocessing instructions (OS TD 00019_18) to ensure sterility and minimize the risk of pyrogenic contamination.

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 for repair of fractures and fusions of the foot & ankle, and other small bones.

5. INDICATIONS FOR USE

The Volition™ Plating System is indicated for use in stabilization and fixation of fractures or osteotomies, revision procedures, joint fusion, and reconstruction of small bones of the toes, feet and ankles including the distal fibula and tibia, talus, and calcaneus, as well as the fingers, hands, and wrists.

In addition, the non-locking screws and washers are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

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

- Discard any corroded, worn, or damaged components. Do not return these components to the sterilization case.
- 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.
- Refer to the device label to identify the device as single-use or reusable.
- 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.
- Only sterile devices should be placed in the operative field.
- Improper insertion of the device during implantation may result in implant loosening or migration.
- 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).
- The implants are intended to temporarily stabilize bones. Abnormal or excessive loading prior to bony union may lead to complications such as implant fracture or loosening and subsequent loss of bone fixation. Adequate post-operative management is advisable until bone healing has completed.
- 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).
- Implants should be examined for damage prior to use.
- Instruments should be examined for corrosion, wear, or damage prior to use.
- Ortho Solutions does not recommend specific cleaning and/or disinfection agents. Manual cleaning has been validated in accordance with AAMI TIR30. Facilities choosing alternative cleaning agents must ensure these are equivalent and validated for effectiveness.
- 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 behavior.

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 sterilization 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 may be found at www.orthosol.com/eifu/

11. STERILIZATION

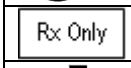
Devices are supplied non-sterile unless they are clearly and explicitly labeled as sterile. Non-sterile devices must be sterilized prior to use as follows. All non-sterile reusable instruments must first be cleaned using established hospital methods before sterilisation and introduction into a sterile surgical field.

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:

Tray Type	Cycle Type	Exposure Time	Cycle Temp.	Drying Time
Volition MTPJ / Utility (VOL-T)	Prevacuum Air Removal	4 minutes	132°C (270°F)	≥30 minutes
Volition Ankle Fracture (VAF-T)	Prevacuum Air Removal	4 minutes	132°C (270°F)	≥20 minutes

12. SYMBOL GLOSSARY

This device is labeled with a Unique Device Identifier (UDI) in accordance with applicable U.S. FDA requirements and 21 CFR Part 830. Refer to the product packaging for UDI information. Before use, verify that the product labeling matches the intended procedure and patient.

Symbol	Title of Symbol
	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
	Medical Device
	Non-Sterile
	Consult IFU

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 / MEDICAL DEVICE REPORTING / FEEDBACK AND CONTACT

This device is subject to complaint handling and Medical Device Reporting requirements under 21 CFR Part 803 and 21 CFR Part 820. Users and healthcare professionals are encouraged to report to Ortho Solutions any malfunction, that has caused or contributed to a death or serious injury, or that would be likely to cause or contribute to a death or serious injury if it were to recur, as well as any failure, improper performance, or labeling/IFU inaccuracies that could impact patient safety. Any event meeting the criteria for mandatory reporting under 21 CFR 803 should also be reported to the U.S. Food and Drug Administration (FDA) through the MedWatch program:

- Online: https://www.accessdata.fda.gov/scripts/medwatch/
- By phone: 1-800-FDA-1088

To report a complaint, adverse event, or any suspected nonconformity of the device, please contact Ortho Solutions without undue delay at regulatory@orthosol.com or at the addresses provided below. Reports should be submitted as soon as possible, and no later than 10 working days from the date of awareness.

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

Manufacturer:
Ortho Solutions UK Ltd
West Station Business Park, Spital Road
Maldon, Essex CM9 6FF, United Kingdom
Phone: +44(0)1621 843 599
Email: regulatory@orthosol.com
Website: www.orthosol.com

U.S. Contact (Authorized Representative/Importer):
Ortho Solutions Inc
209 10th Avenue S Ste. 416
Nashville, TN 37203
USA

E. USteam@orthosol.com / US.Sales@orthosol.com
T. +1 978-416-0301 / +1 (615) 899-3668
F. +1 978.416.4106