Instructions For Use

Ortho Solutions COGNiTiON™ Staple System

US

These instructions are to be utilised for the **COGNiTiON™ Staple System** manufactured by Ortho Solutions UK Ltd West Station Business Park, Spital Road, Maldon, CM9 6FF, United Kingdom, Phone: +44(0)1621 843599 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 00148_23 COGNiTiON Staple System Surgical Technique.

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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 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

Ortho Solutions UK Ltd (OS) COGNiTiON™ Staple System consists of superelastic orthopedic staples available in a range of sizes and shapes for bony fixation in the hand and foot. The COGNiTiON™ implants are manufactured from Nitinol material (ASTM F2063) and are provided sterile. COGNiTiON™ accessory instruments are provided non-sterile.

2. PRODUCT MATERIAL

CoGNiTiON staples are made of Nitinol (ASTM F2063), an alloy of nickel and titanium. All accessory instruments in direct contact with the patient, such as drill bits and pins, are made of stainless steel (ASTM F899, ASTM F138/ISO 5832-1).

3. INDICATIONS FOR USE

The Ortho Solutions COGNiTiON™ Staple System is indicated for hand and foot bone fragments, osteotomy, fixation and joint arthrodesis. The COGNiTiON™ Staple System is not intended for spinal use.

4. CONTRAINDICATIONS

- Active or latent infection
- Sepsis
- Osteoporosis
- Insufficient bone quantity and / or quality
- Sensitivity to the implant material
- Any condition not described in the indications

5. WARNINGS & PRECAUTIONS

"Warning: This device contains nitinol, an alloy of nickel and titanium. Persons with allergic reactions to these metals may suffer an allergic reaction to this implant. Prior to implantation, patients should be counselled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these materials."

- Do not use if current date exceeds label expiry
- Implants must not be re-used or re-sterilized
- 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
- Bending or fracture due to applied excessive stresses and load bearing
- Failure to follow postoperative care instructions
- Electrolytic action and corrosion due to implanting with other metallic devices of different chemical composition
- If an unexplained change in the device performance is noticed, contact the manufacturer or its authorized clinical support specialist
- Do not use other manufacturers instruments or implants in conjunction with the COGNiTiON™ implants

6. MRI SAFETY INFORMATION

The COGNiTiON™ Staple 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 of the COGNiTiON™ Staple System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

7. 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

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, such as use with non-compatible instruments/devices, or incorrect patient information and consequent incorrect patient behavior.

8. 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

9. 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/

10. STERILIZATION

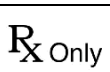
Ortho Solutions reusable instrument(s) are supplied non-sterile unless it is clearly and explicitly labelled as sterile. Non-sterile devices must be sterilized prior to use. All non-sterile reusable instruments must First be cleaned using established methods before sterilization and introduction into 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:

Cycle Type	EXPOSURE TIME	DRYING TIME
Prevacuum Air Removal	4 minutes 132ºC (270ºF)	≥20 minutes

11. 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	Application
	Use By	Sterile
	Do not use if package is damaged	Sterile
	Do not reuse	Sterile
	Do not resterilize	Sterile
	Sterilized 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 surgical technique or IFU	Sterile and non-sterile
	Medical Device	Sterile and non-sterile
	Manufacturer	Sterile and non-sterile
	Federal law (USA) restricts this device to sale by or on the order of a physician	Sterile and non-sterile

12. 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.

13. COMPLAINTS/FEEDBACK

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:	**U.S. Contact (Authorized Representative/Importer):**
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