Instructions For Use for Ortho Solutions COGNiTiON™ Staple System Implants and Instruments

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, Fax: +44(0)1621 858953, www.orthosol.com. All instructions provided in this document must be followed. Refer to the Surgical Technique (Ref: OS TD 00148_23) for complete instructions for clinical use.

Ortho Solutions UK Limited **Unit 5, West Station Business Park,** **Spital Road, Maldon, Essex, CM9 6FF, UK** **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.**	℞ Only **Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.**

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. 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.

3. ADVERSE EFFECTS

- 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

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. 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

Do not use if the package is damaged or opened. Contents may not be sterile and may cause infection in the patient.

Single use only.

Do not resterilise.

Sterilized using irradiation.

8. REPROCESSING OF REUSABLE INSTRUMENTATION

8.1. 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.

8.2. 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

8.3. MANUAL CLEANING OF REUSABLE INSTRUMENTS

Disassemble devices as much as possible and open any articulated or hinged devices as much as possible.

Pre-soak devices for at least one (1) minute in a mild pH enzymatic solution, such as Enzol® by Advanced Sterilization Products® or similar. Refer to manufacturer's instructions for proper dilution, temperature, and soak time. Completely submerging will moisten and loosen blood and debris, thereby making the cleaning of devices more efficient. Rinse the devices with deionized water for a minimum of one (1) minute.

Clean instruments and devices in water and detergent solutions less than 60°C (140°F). Rehydration of blood and other debris can be achieved via submerging the devices in low foaming, pH neutral enzymatic detergent, such as Renu-Klenz® by Steris Corporation®, or similar detergents that are safe for use with medical devices, for a minimum of five (5) minutes. Scrub the devices using soft brushes where possible, while firm bristle brushes may be required on heavily soiled devices. Never use metallic brushes or steel wool as these will cause damage and lead to corrosion. Ensure extra attention to hinges, joints and textured areas. If the instrument articulates, repeatedly open and retract the device while scrubbing in submersed bath. Cannulated instruments are to be cleaned using nylon brushes and syringes. Using a fresh detergent bath, ultrasonically clean instruments for a minimum of ten (10) minutes at 40 kHz frequency in a neutral pH solution.

Rinse under warm (38-49°C | 100-120°F) flowing water for a minimum of one (1) minute, paying attention to cannulations and ensuring every surface direct contact for at least ten (10) seconds. Repeat this process using deionized water. Final rinsing of instruments is achieved in bath of warm water (38-49°C | 100-120°F) agitating by hand for at least three (3) minutes.

Verify devices by visually inspecting all surfaces and repeat above steps if necessary. Ensuring concealed areas are also cleaned by flushing the instrument in a
3% hydrogen peroxide solution. Indication of blood remaining in hidden surface can be identified if bubbling is present and thus cleaning cycle needs to be repeated. Thoroughly rinse the devices with deionized water for a minimum of one (1) minute after subjecting to hydrogen peroxide. Repeat the above steps if verification fails.

Inspect & Functional Test all instruments by operating all moving parts to ensure function. Visually inspect each device for undue damage or wear. Ensure all assemblies are able to easily engage and no nicks, cuts or dings are present.

Dry devices by allowing to drain in a basket or on an absorbent, lint free cloth ensuring that concave surfaces are face down. Hidden or internal spaces within the devices can be dried using compressed air.

8.4. AUTOMATED CLEANING

Disassemble instrument(s) as much as possible and open any articulated instrument(s) as much as possible.
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)

8.5. 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:

- All soil / visible blood has been completely removed from all surfaces, slots, cannulations, holes and moving parts.
- Instrument(s) and instrument cases for damage.
- Action of moving parts to ensure correct device function.
- 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.

8.6. 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 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:

ITEM	EXPOSURE TIME	DRYING TIME
Wrapped Instruments – Case/Tray	4 minutes 132ºC (270ºF)	20 to 30 minutes
	3 minutes 134 - 137ºC (273 - 279ºF)	40 mBar for 5-10 minutes

9. RESIGNATION OF GUARANTEE

Ortho Solutions UK Ltd accepts no responsibility for claims deriving from the misuse of the product or from the use of non-compatible instruments/ devices.

Surgeon must be fully trained in the surgical technique

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10. SYMBOL GLOSSARY

Symbol	Title of Symbol	Application
	Use By	Sterile
	Do not use if package is damaged	Sterile
	Do not reuse	Sterile
	Do not resterilise	Sterile
STERILE R	Sterilized 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

11. 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.