Instructions For Use

Ortho Solutions Succession® TTC Nail System

Implants and Instruments

These instructions are to be utilized for the **Succession**® **TTC Nail 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.ortho- sol.com. All instructions provided in this document must be followed. Refer to the Surgical Technique (Ref: OS TD 00245_24) for complete instructions for clinical use.

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

1. DEVICE DESCRIPTION

The Succession® TTC Nail System consists of a range of implant intramedullary nails, cortical screws and end caps that are intended to provide bone fixation through normal healing and to provide management of reconstructive surgeries. The primary objective of the Succession® TTC Nail System is for pain relief, deformity correction and effective bone fusion. The Succession® TTC Nail system offers intramedullary nail lengths ranging from 190mm to 250mm in a variety of diameters (Ø10mm, Ø11mm, Ø12mm). Each nail contains StageLock™ compression features that allow for independent compression across the tibiotalar and subtalar joints. The Succession® TTC Nail surgical approach for insertion can be through a standard lateral or medial approach to the ankle and subtalar joint, separate anterior ankle and mini-subtalar incision or arthroscopic tibiotalocalcaneal (TTC) fusion. Arthroscopic burr preparation can be used by those familiar with the technique, allowing percutaneous nail insertion. The Succession® cortical screws are intended to be used with the Succession® TTC Nail system and permit medial-lateral fixation in the tibia (M/L screws, diameter Ø5mm), along with posterior-anterior fixation across the subtalar joint (P/A screws, diameter Ø6mm). The Succession® End Cap is intended to be threaded into the end of the Succession® TTC nail at the end of the surgical procedure to prevent fibrous in-growth. This also permits lengthening of the distal end of the nail after screw implantation to enable anchorage in the harder cortical bone of the calcaneal tuberosity.

Ortho Solutions Succession® TTC Nail system implants will be provided sterile by gamma radiation certified to a 5-year shelf life.

2. PRODUCT MATERIAL

The Succession® TTC Nail System intramedullary nails, cortical screws and end caps are made of type II anodized titanium alloy (Ti6Al4V ELI) to ASTM F136. The K-wires, drills, and reaming rods are made of stainless steel (ASTM F899, ASTM F138, ISO 5832-1). The exchange tube is made from fluorinated ethylene propylene NP-120. Other instruments in direct con- tact with the patient are composed of stainless steel or nickel-titanium alloy.

3. INTENDED PURPOSE

The Succession® TTC Nail System is intended to be used for bone fixation to facilitate tibiotalocalcaneal arthrodesis.

4. INDICATIONS FOR USE

The Succession® TTC Nail System is a tibiotalocalcaneal (TTC) solid fusion system that has been developed for the following indications:

- Failed ankle replacement
- Arthritis of the ankle and subtalar joint
- Correcting neuromuscular imbalance of hindfoot, where bone fusion is required
- Revision of failed ankle and/or subtalar fusion
- Revision of failed tibiotalocalcaneal (TTC) fusion
- Talar Avascular Necrosis (AVN)
- Charcot
- Trauma
- Neuroarthropathy
- Pseudoarthrosis
- Rheumatoid arthritis

5. CONTRAINDICATIONS

- Pre-existing deep active infection.
- Soft tissue defects, unless concomitant procedures planned.
- Patients with psychiatric or neurological conditions who are unwilling, or incapable of adhering to post-operative care instructions.
- Foreign body sensitivity to implant material.
- Any condition not described in the indications.

6. WARNINGS & PRECAUTIONS AND LIMITATIONS

The following warnings, precautions, and limitations must be reviewed and understood prior to using the Succession® TTC Nail System. Failure to follow these instructions may result in patient injury, device failure, or suboptimal clinical outcomes.

- For use with skeletally mature patients.
- Appropriate patient selection and compliance will increase the likelihood of a satisfactory outcome.
- Correct selection of size is important and increases the likelihood of a satisfactory outcome.
- 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.
- Refer to the device label to identify the device as single-use or reusable.
- Only sterile devices should be placed in the operating field.
- Improper insertion of the device during implantation may result in implant loosening or migration.
- 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 and their packaging should be examined for damage prior to use.
- Instruments should be examined for corrosion, wear, or damage prior to use.
- Instrumentation provided with the implants must be used in accordance with the approved surgical technique.
- Internal stresses from a previous use may cause early failure.
- The implantation of the Succession® TTC System should be performed only by qualified orthopedic surgeons who have received specific training in the use of this device. For detailed surgical guidance, procedural steps, and any applicable surgery specific precautions, refer to the Succession® TTC NAIL System Surgical Technique Guide (Ref: OS TD 00245_24).
- Do not use if current date exceeds label expiry date.
- If an unexplained change in the device performance is noticed, contact the manufacturer or its authorized clinical support specialist.

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, loss of anatomic position.
- 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.

8. MRI SAFETY INFORMATION

The Succession® TTC Nail System has not been evaluated for safety and compatibility in magnetic resonance (MR) environment. It has not been tested for heating, migration, or image artefacts in the MR environment. The safety of the Succession® TTC Nail System in the MR environment is unknown. Scanning a patient who has this device may result in serious patient injury.

9. CLEANING INSTRUCTIONS

Thorough cleaning and disinfection are vital to reprocessing re-useable medical devices and ensuring effective sterilization. Cleaning should be performed in a manner designed to minimize 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. Deionized water is recommended and helps prevent discoloration 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 Type	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.

9.1. PREPARATION

Processing begins at the point of use and prompt 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 minimize or eliminate delays between steps. Delays may create conditions favorable to microbial growth, which may increase the challenge to subsequent steps such as cleaning and disinfection / sterilization.

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).

9.2. PRE-CLEANING

The following pre-cleaning procedure must be followed prior to either manual or automated cleaning.

1. Disassemble devices as much as possible and open any articulated devices as much as possible.
2. Submerge devices 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.
   Ultrasonically clean the devices 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.
3. Clean the devices using soft brushes where possible. Firm bristle brushes may be required on heavily soiled devices. Use bottle brushes (e.g. Antimicrobial bottle brushes – Key Surgical) of appropriate diameter for cannulations, and pass the brush down the entire length of cannulation at least three times. Never use metallic brushes or steel wool.
4. Operate moving parts, ensuring concealed areas are also cleaned.
5. Rinse in running water for a minimum of one (1) minute, paying attention to cannulations. Rinse at least three (3) times.
6. Inspect devices and repeat above steps if necessary.
7. Allow devices to drain on an absorbent, lint-free cloth or place immediately into wire baskets for automated washing where possible.

9.3. MANUAL CLEANING

1. Disassemble devices as much as possible and open any articulated devices as much as possible.
2. Submerge devices in an enzymatic detergent safe for use with medical devices.
3. Soak the devices for between five (5) and ten (10) minutes in the detergent.
4. Scrub the devices with the appropriate brush, cloth, or sponge and agitate the devices in the solution while 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 devices with warm (38-49°C | 100-120°F) water.
6. Place devices in a bath containing warm (38-49°C | 100-120°F) water and agitate by hand for a minimum of three (3) minutes.
7. Ultrasonically clean the devices 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 devices with deionized water for a minimum of one (1) minute.
9. Dry the exterior of devices with a clean lint-free cloth.
10. Visually inspect the devices for any remaining soil and repeat the above steps if necessary.

9.4. AUTOMATED CLEANING

1. Disassemble devices as much as possible and open any articulated devices as much as possible.
2. Place disassembled devices directly on the washer trays, connecting cannulations to rinsing ports where possible and ensuring that de- vices are positioned in a way to prevent the retention of water residue.
3. Run the automated washer per the following parameters:

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)

4. Visually inspect the devices for any remaining soil and

repeat the above steps if necessary.

9.5. INSPECTION

Prior to sterilization, all devices should be inspected for soil, damage/wear, and corrosion. Generally, visual inspection with the naked eye under good lighting conditions will suffice.

1. Inspect all devices to ensure all soil / visible blood has been completely removed.
2. Inspect devices (including sterilization cases, trays, and caddies) for damage or corrosion.
3. Check action of moving parts to verify correct device function.
4. If damage/wear or corrosion is suspected, do not use the device. Contact Ortho Solutions Customer Services or your Sales Representative for a replacement.

10. 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.

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 sterilization and introduction into a sterile surgical field.

Sterilization of the devices in the sterilization case/trays, double-wrapped using FDA-cleared sterilization wraps and autoclave indicator tape, using the recommended parameters has been validated in accordance with ANSI/AAMI ST79 and AAMI TIR12:2020 to a sterility assurance level (SAL) of 10^{-6}. These standards support safe and effective reprocessing of reusable surgical instruments in health care settings. 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)	≥ 30 minutes

12. 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.

Caution: Surgeon must be fully trained in the surgical technique

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

13. 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 date	Sterile
	Do not use if package is damaged and consult instructions for use	Sterile
	Do not re-use	Sterile and non-sterile single use
	Do not re-sterilize	Sterile
	Sterilized using irradiation	Sterile
	Non-sterile	Non-sterile
	Batch code	Sterile and non-sterile
	Catalogue number	Sterile and non-sterile
	Consult instructions for use	Sterile and non-sterile
	Caution	Sterile and non-sterile
	Medical device	Sterile and non-sterile
	Manufacturer	Sterile and non-sterile

Symbols used in this Instructions for Use comply with ISO 15223-1 and/or ISO 7000, as applicable

14. COMPLAINTS/FEEDBACK AND CONTACT

This device is subject to the Medical Device Reporting (MDR) requirements under 21 CFR Part 803. Users are encouraged to report any unexpected performance, malfunction, or failure that could result in serious injury or death. To report complaints, adverse events, or potential device issues, contact Ortho Solutions or its authorized U.S. agent without undue delay 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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