Instructions for Use
SPEEDTRIAD™ Continuous Compression Implant System

This instruction for use is not intended for distribution in the USA.

Not all products are currently available in all markets.

Manuals are subject to change;
the most current version of each manual is always available online.
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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

The SPEEDTRIAD™ Continuous Compression Implant System gives the surgeon a means of bone fixation and helps in the management of fracture and reconstructive surgery.

Devices in scope:
SE-181508TRC
SE-201508TRC

Basic Structure
- The implants of the SPEEDTRIAD Continuous Compression Implant System are made of biocompatible Nitinol and are designed to exhibit superelastic properties at room temperature. Each implant is constrained in an open shape during storage and insertion. Once inserted, release from the constraining device causes the implant's single leg to pull towards the other set of legs resulting in compression. In good bone quality, deflection may not be visible as the single leg is constrained by the surrounding tissue.
- DePuy Synthes offers several different types of implants. The implant model number designates its dimensions. EXAMPLE: SE-181508TRC has a 18 mm bridge length, 15 mm legs, 8 mm bridge width, and 3 legs centered symmetrically.

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Material
Nitinol

Intended Use
The SPEEDTRIAD is a nitinol implant which is intended for use in extremity bone fracture fixation, osteotomy fixation and joint arthrodesis.

Indications
The SPEEDTRIAD Continuous Compression Implant System is indicated for fracture and osteotomy fixation and joint arthrodesis of the hand and foot.

Contraindications
- Comminuted bone surface that would militate against staple placement.
- Pathologic conditions of bone such as osteopenia that would impair the ability to securely fix the implant.
- Foreign body sensitivity to metals including nickel. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

Expected Clinical Benefits
Expected clinical benefits of internal fixation devices such as SPEEDTRIAD Continuous Compression Implant System when used according to instructions for use and recommended technique are,
- Stabilize bone segment and facilitate healing
- Restore anatomical relationship and function

Magnetic Resonance Environment

MRI Safety Information
Non-clinical testing demonstrated that the SPEEDTRIAD Implant is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:
- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000 Gauss/cm (extrapolated) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode of operation for the MR system
- Under the scan conditions defined, the SPEEDTRIAD Implant is expected to produce a maximum temperature rise of 1.9 °C after 15 minutes of continuous scanning (i.e., per pulse sequence).

Artifact Information
- In non-clinical testing, the image artifact caused by the SPEEDTRIAD Implant extends approximately 10 mm from this device when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:
Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, malunion, non-union, bone damage and damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck's disease, allergy/hypersensitivity reactions, and side effects associated with implant failure and hardware prominence.

Sterile Device

STERILE R Sterilized using irradiation

Do not resterilize

Single-Use Device

Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or clinical reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.
Furthermore, re-use or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Warnings and Precautions

Warnings
- The implants cannot be expected to replace normal healthy bone or withstand the stress placed upon the device by full or partial weight bearing or load bearing in the presence of nonunion, delayed union or incomplete healing. Therefore, it is important that immobilization of the treatment site using routine methods (casting, splints, etc.) be maintained until bone healing has occurred (4–6 weeks).
- Reduction of the site should be achieved and maintained prior to implanting the device. The compressive force of the staple closing should not be relied upon to achieve closure or reduction of a fracture line.
- Any additional processing or reprocessing of the implant may affect the shape memory properties of the nitinol, changing or otherwise reducing the effectiveness of the implant.
- Reprocessing of any instrument may affect its compatibility with other instruments and the usability of the reprocessed instrument.
- If sterilization is compromised prior to insertion, a different sterile implant or associated instrument(s) will need to be used. Product cannot be re-sterilized due to the heat lability of the polycarbonate materials.
- Prior to use, check the product expiration date and verify the packaging integrity. Product with damaged packaging should be discarded and must not be used, as sterility cannot be assured.
- Once the implant has been deployed from the Insertion Tool, it should be discarded and must not be used or reloaded on to the Insertion Tool. A different implant kit must be used.

Combination of Medical Devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Implant Removal
1. Expose the site and the bridge of the implant.
2. Using forceps grasp the center of the implant and remove. If the implant is recessed, then use an elevator to lift the implant bridge and then use forceps to remove the implant. If the implant is solidly connected, cut the bridge with wire cutters and twist and remove each implant leg.

Disposal
Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol.

Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

Special Operating Instructions
Instructions (Medial Placement – Chevron Osteotomy):
1. Expose the distal first metatarsal head and perform a medial exostectomy. Perform the osteotomy with the angle of the osteotomy according to surgeon preference and shift the metatarsal head laterally until the desired correction is achieved. Hold the osteotomy reduction with a temporary K-wire found in the Drill Kit DK-200C and remove the proximal medial overhanging bone to create a flat surface for the implant. NOTE: The K-wire needs to be inserted in such a way so that it does not interfere with the fixation.
2. Determine the correct implant size by using the SPEEDTRIAD Sizing Guides. The single leg of the implant will be placed proximally and the dual legs distally. If desired, use a sterile marker through the holes of the Sizing Guide to mark the positions of the drill holes. NOTE: The implant is available with centralized legs.
3. Open the chosen Implant Kit and obtain the Drill Guide.
4. While ensuring that the bone segments are in full contact, place the Drill Guide across the osteotomy site. The implant should be positioned such that the apex of the osteotomy lies between the two distal legs. NOTE: The orientation of the guide should prevent inadvertent perforation of the metatarsal head into the joint when making the drill holes. The axis of the Drill Guide must be perpendicular to the osteotomy and the metatarsal head. All three prongs of the Drill Guide should be in contact with bone at all times while drilling.
5. Drill the first hole on the distal side using the Drill Bit provided in the Drill Kit until the positive stop is reached.
6. Insert a Pull Pin into the first distal hole and drill the second distal hole.
7. Insert a Pull Pin into the second distal hole, and while ensuring that the bone segments are in full contact, drill the proximal hole. The Drill Guide can be removed leaving the Pull Pins in place to mark the position of the drill holes.
8. Remove the Insertion Tool containing the SPEEDTRIAD implant from the implant kit. Remove the Pull Pins from the pre-drilled holes and align the tips of the legs of the SPEEDTRIAD implant parallel with the drill holes.
9. Insert the SPEEDTRIAD implant as far as possible into the pre-drilled holes. NOTE: To ensure proper implant placement, fluoroscopy may be used prior to releasing the implant.
10. Pull and hold the slider button away from the implant to release the implant from the Insertion Tool. Ensure that the prongs of the Insertion Tool have disengaged completely from the implant prior to removing the Insertion Tool. This should prevent accidental lifting of the implant around the surgical site.
11. Align the supplied Tamp with the bridge of the implant, and while stabilizing the metatarsal head, use the Tamp as needed to completely seat the implant. Remove the proximal medial overhanging bone, remove the provisional K-wire and close using established technique.

Instructions (Dorsal Placement – Chevron Osteotomy):
1. Expose the distal first metatarsal head and perform a medial exostectomy. Perform the osteotomy with the angle of the osteotomy according to surgeon preference and shift the metatarsal head laterally until the desired correction is achieved. Hold the osteotomy reduction with a temporary K-wire found in the Drill Kit DK-200C. NOTE: The K-wire needs to be inserted in such a way so that it does not interfere with the fixation. In addition, shaving a small amount of dorsal bone off the metatarsal head may be necessary to properly seat the implant.
2. Determine the correct implant size by using the SPEEDTRIAD Sizing Guides. The single leg of the implant will be placed proximally and the dual legs distally. If desired, use a sterile marker through the holes of the Sizing Guide to mark the positions of the drill holes. NOTE: The implant is available with centralized legs.
3. Open the chosen Implant Kit and obtain the Drill Guide.
4. While ensuring that the bone segments are in full contact, place the Drill Guide across the fusion site. The SPEEDTRIAD Implant should be placed such that the distal legs do not make contact with the apex of the osteotomy. All three prongs of the Drill Guide should be in contact with bone at all times while drilling.
5. Drill the first hole on the distal side using the Drill Bit provided in the Drill Kit until the positive stop is reached.
6. Insert a Pull Pin into the first distal hole and drill the second distal hole.
7. Insert a Pull Pin into the second distal hole, and while ensuring that the bone segments are in full contact, drill the proximal hole. The Drill Guide can be removed leaving the Pull Pins in place to mark the position of the drill holes.
8. Remove the Insertion Tool containing the SPEEDTRIAD implant from the implant kit. Remove the Pull Pins from the pre-drilled holes and align the tips of the legs of the SPEEDTRIAD implant parallel with the drill holes.
9. Insert the SPEEDTRIAD implant as far as possible into the pre-drilled holes. NOTE: To ensure proper implant placement, fluoroscopy may be used prior to releasing the implant.
10. Pull and hold the slider button away from the implant to release the implant from the Insertion Tool. Ensure that the prongs of the Insertion Tool have disengaged completely from the implant prior to removing the Insertion Tool. This should prevent accidental lifting of the implant around the surgical site.
11. Align the supplied Tamp with the bridge of the implant, and while stabilizing the metatarsal head, use the Tamp as needed to completely seat the implant. Remove the proximal medial overhanging bone, remove the provisional K-wire and close using established technique.

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