Instructions for Use
SPEEDARC™ 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 SPEEDARC™ 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-091210A
SE-111210A
SE-111512A

Basic Structure
- The implants of the SPEEDARC 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 legs to deflect toward each other resulting in compression. In good bone quality, this deflection may not be visible as the legs are constrained by the surrounding tissue.
- DePuy Synthes offers several different types of implants. The implant model number designates its dimensions.

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
SPEEDARC Staple Implants are intended for bone fixation and management of fracture and reconstructive surgery.

Indications for Use
- Fracture and osteotomy fixation and joint arthrodesis of the hand and foot
- Fixation of proximal tibial metaphysis osteotomy
- Fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur and fibula in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and in flat bone such as the pelvis and scapula.

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.

Intended User
This IFU alone does not provide sufficient background for direct use of the Device or System. Instruction by a surgeon experienced in handling these devices is highly recommended.

This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the IFU, the surgical procedures, if applicable, and/or the Synthes "Important Information" brochure as appropriate.
Implantation is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the device is suitable for the pathology/condition indicated and that the operation is carried out properly.

Expected Clinical Benefits
Expected clinical benefits of internal fixation devices such as SPEEDARC 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

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

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
- 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.

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

Magnetic Resonance Environment

MR Compatibility
The SPEEDARC Continuous Compression Implant System has been evaluated for safety and compatibility in the MR environment. The device was tested under non-clinical conditions. Testing has demonstrated the SPEEDARC is MR Conditional. It can be scanned safely under the following conditions:
- Static magnetic field of 1.5-Tesla (1.5T) or 3.0-Tesla (3.0T).
- Spatial gradient field up to:
  - 11,440 G/cm (114.40 T/m) for 1.5T systems
  - 5,720 G/cm (57.20 T/m) for 3.0T systems
- Maximum whole body averaged specific absorption rate (SAR) of:
  - 4.0 W/kg for 15 minutes of scanning at 1.5T
  - 4.0 W/kg for 15 minutes of scanning at 3.0T

1.5T RF heating
- In non-clinical testing with body coil excitation, the implants produced a temperature rise of less than 3.0 °C at a maximum whole body averaged specific absorption rate (SAR) of 4.0 W/kg, as assessed by calorimetry for 15 minutes of scanning in a 1.5T Siemens Espree (MRC30732) MR scanner with SYNGO MR B17 software.

3.0T RF heating
- In non-clinical testing with body coil excitation, the implants produced a temperature rise of less than 3.5 °C at a maximum whole body averaged specific absorption rate (SAR) of 4.0 W/kg, as assessed by calorimetry for 15 minutes of scanning in a 3.0T Siemens Trio (MRC20587) MR scanner with SYNGO MR A30 4VA30A software.
- Caution: The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

Artifact
- The image artifact extends approximately 13 mm from the device, when scanned in nonclinical testing using the sequence: gradient -echo sequencing in a 3.0T Siemens Trio Clinical Scanner (SYNGO MR A30 4VA30A) MR system.

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
1. Create the osteotomy and provisionally fixate with a K-wire as necessary. NOTE: When used for transverse proximal Akin osteotomies, the location of the osteotomy along the metaphyseal flare should be approximately 10 mm from the first metatarsophalangeal joint line.
2. Determine the SPEEDARC Implant size by holding the SPEEDARC Sizing Guide (SG-3) along the metaphyseal flare so that the short prong is near the apex of the flare, the prongs are parallel with and equidistant from the osteotomy, and both prongs are touching bone. Use the corresponding slope on the Sizing Guide to verify that the contour of the implant will match the contour of the bone. NOTE: A standard BME SPEED implant may be the more appropriate choice when flat surfaces are encountered.
3. Open the chosen Implant Kit and its corresponding Drill Kit.
4. While ensuring full reduction, place the Drill Guide across the fusion site so that the elevated prong, marked by an arrow, is placed proximally for proximal Akin osteotomies and distally for distal Akin osteotomies. The elevated prong should be touching bone and aligned parallel to the osteotomy line. It is acceptable that the other prong of the Drill Guide is slightly off the bone. NOTE: The legs of the implant should be at least 4 mm from the osteotomy and, for proximal Akin osteotomies, the proximal leg should not violate the first MTP joint.
5. Drill the first hole into the proximal segment using the drill bit provided in the Drill Kit until a positive stop is felt. Insert a Pull Pin into the first hole. NOTE: The positive stop corresponds to the length of the longer implant leg.
6. While ensuring full reduction, repeat step 5 to create the distal hole. OPTIONAL: Insert another Pull Pin into the second hole. The Drill Guide can be removed leaving the Pull Pins in place to mark the position of the drill holes.
7. Remove the Insertion Tool containing the SPEEDARC implant from the Implant Kit. Remove the Pull Pins from the pre-drilled holes and align the tips of the legs of the SPEEDARC implant parallel with the drill holes. NOTE: The arrow on the Insertion Tool corresponds to the longer leg of the implant. For proximal Akin osteotomies, this arrow should be proximal to the osteotomy.
8. Insert the SPEEDARC 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.
9. Pull the slider button on Inserter upwards to release implant.
10. Align the supplied Tamp with the bridge of the implant and use as needed to completely seat the implant.
11. Repeat steps 1–10 for each additional implant used.
    NOTE: If implants are placed at 90-degrees to each other, stagger them to ensure unobstructed insertion.

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