Instructions for Use
BME SPEED™ 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.

EC REP

Authorised Representative

DePuy Ireland UC
Loughbeg
Ringaskiddy
Co. Cork Ireland

Manuals are subject to change;
the most current version of each
manual is always available online.
Printed on: Aug 13, 2020

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

CE
0123

SE_801369 AA 03/2020

Instructions for Use

The BME SPEED™ 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-0907
SE-0910
SE-1108
SE-1110
SE-111513
SE-1308
SE-1310
SE-1312
SE-131513
SE-1510
SE-1512

Basic Structure
- The implants of the BME SPEED 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
BME SPEED Staple Implants are intended for bone fixation and management of fracture and reconstructive surgery.

Indication for Use
- Fracture and osteotomy fixation and joint arthrodesis of the hand and foot.
- Fixation of proximal tibial metaphysis osteotomy.
- Fixation of small fragments of bone (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, fibula and tibia 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 BME SPEED 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

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.

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 BME SPEED 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 implant 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 13mm 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
– Expose the site and the bridge of the implant.
– 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 staple 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 for BME SPEED Implants When Using DK-200C or DK-265C Drill Kits:
1. Determine the correct Implant size by using the BME SPEED Sizing Guide (SG-1) to measure the fusion site.
2. Open the chosen Implant Kit and its corresponding Drill Kit.
3. While ensuring full reduction, place the Drill Guide across the fusion site with both prongs touching bone. Drill the first hole using the Drill Bit provided in the Drill Kit until the positive stop is reached.
4. Insert a Pull Pin into the first hole and, while ensuring full reduction, repeat step 3 to create the second 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. If desired, create a 1.0–1.5 mm trough in line with the two drill holes so that the implant can be recessed.
5. Remove the Insertion Tool containing the BME SPEED Implant from the Implant Kit. Remove the Pull Pins from the pre-drilled holes and align the tips of the legs of the BME SPEED Implant parallel with the drill holes.
6. Insert the BME SPEED Implant as far as possible into the predrilled holes. Note: To ensure proper implant placement, fluoroscopy may be used prior to releasing the implant.
7. Press the distal third of the central button with thumb while simultaneously twisting the insertion tool until disengagement has been verified. Additional implant disengagement options:
  – Press button with thumb to release.
  – Twist insertion tool in either direction to release
8. Align the supplied Tamp with the bridge of the implant and use as needed to completely seat the implant.
9. Repeat steps 1–8 for each additional implant used. Tip: If implants are placed at 90-degrees to each other, stagger them to ensure unobstructed insertion. If a second implant is placed with the bridge in close proximity to another, insert the implant with the open side facing the first Implant. This allows unobstructed release of the Implant from the Insertion Tool.

Instructions for BME SPEED Implants When Using the DK-200HW Hand & Wrist Drill Kits:
1. Expose, prepare and reduce the fusion site. If necessary, use a K-wire located in the DK-200HW Drill Kit for temporary fixation.
2. Determine the correct implant bridge size using the Sizing Guide or the Drill Guide located in the DK-200HW Drill Kit. NOTE: Leg length will be selected in Step 7 using the Depth Gauge or by reading the calibrated depth lines on the Drill Bit (see Step 4).
3. While ensuring that both bones are in full contact, place the chosen Drill Guides across the fusion site. All prongs of the Drill Guide should be in contact with bone, which may require contouring of the bone surface to properly seat the Drill Guide. NOTE: Accurate positioning of the Drill Guide can be accomplished by driving K-wires into the drill tubes and verifying placement with fluoroscopy.
4. Using the 2.0 mm Drill Bit located in the DK-200HW Drill Kit, create the first hole by drilling through the far cortex or until the far cortex is felt. NOTE: The three laser marks on the Drill Bit correspond to 10, 15, and 20 mm when they reach the top of the drill tube.
5. Insert a Pull Pin into the first hole and repeat step 4 to create the second drill hole. NOTE: The Drill Guide can be removed leaving the Pull Pins in place to mark the position of the drill holes.
6. Remove the Drill Guide and Pull Pins and, if desired, create a 1.0–1.5 mm trough in line with the two drill holes so that the implant can be recessed.
7. Use the Depth Gauge to determine the depth of the drill holes and to select the appropriate implant leg length. For bicortical drilling, use the hook on the pin of the Depth Gauge to engage the opposite face of the bones and determine the depth. For monocortical drilling, insert the pin as far into the hole as possible and add 1 mm to the depth reading obtained. NOTE: The Depth Gauge is accurate to within +/- 1 mm.
8. Remove the Insertion Tool containing the selected BME SPEED implant from the implant kit and align the tips of the legs of the implant parallel with the drill holes. NOTE: The Drill Guide Tip located in the implant kit may be discarded.
9. Insert the implant as far as possible into the predrilled holes. NOTE: To ensure proper implant placement, fluoroscopy may be used prior to releasing the implant.
10. Press the distal third of the central button with thumb while simultaneously twisting the insertion tool until disengagement has been verified.
11. Align the Tamp with the bridge of the implant and use as needed to completely seat the implant. NOTE: Turning the Tamp 45-degrees will allow the implant to be recessed if a trough was created in Step 6.
12. Repeat steps 2–11 for each additional implant used. NOTE: If implants are placed at 90-degrees to each other, stagger them to ensure unobstructed insertion.

CE
0123

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
www.jnjmedicaldevices.com