Instructions for Use
BME ELITE™ 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 BME ELITE™ 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:
EL-1515S2
EL-1818S2
EL-2020S2
EL-2520S4
EL-3020S4
EL-201507Y3
EL-202007Y3
EL-251507Y4
EL-252007Y4
EL-301507Y4
EL-302007Y4

Basic Structure
- The implants of the BME ELITE 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 allows 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 configurations of BME ELITE Implants. The implant model number designates its shape and dimensions. Example: EL-3020S4 has a 30 mm bridge length and 20 mm leg length in a straight configuration with 4 legs.

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 ELITE 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 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 ELITE 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

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

MRI Safety Information
Non-clinical testing demonstrated that the BME ELITE 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 BME ELITE Implant is expected to produce a maximum temperature rise of <3 °C after 15 minutes of continuous scanning (i.e., per pulse sequence).

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

Implant Removal
1. Expose the site and the bridge of the implant.
2. Using forceps grasp the implant and remove. If the implant is recessed, use an elevator to lift the implant bridge and then use forceps to remove the implant. If solidly connected, implants can be removed by cutting the bridge of the implant and removing the remnants with an elevator.

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. Expose, prepare and reduce the fusion site. If necessary, use a K-wire for temporary fixation.
2. Determine the correct implant bridge size and configuration using the BME ELITE Drill Guide Kits. Leg length will be selected in Step 6 using the BME ELITE Depth Gauge.
3. While ensuring that both bones are in full contact, place the chosen Drill Guide 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. Accurate positioning of the Drill Guide can be accomplished by driving K-wires into the drill tubes and verifying placement with fluoroscopy.
4. Drill the first hole through the far cortex or until the positive stop, which corresponds to 27 mm, is reached.
5. Insert a Pull Pin into the first hole and repeat Step 4 to create each additional hole. 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 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. The Depth Gauge is accurate to within +/– 1 mm.
7. Remove the Insertion Tool containing the selected BME ELITE Implant from the implant kit and align the tips of the legs of the implant parallel with the drill holes.
8. Insert the BME ELITE Implant as far as possible into the predrilled holes. To ensure proper implant placement, fluoroscopy may be used prior to releasing the implant.
9. 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 from the surgical site.
10. Align the Tamp with the bridge of the implant and use as needed to completely seat the implant.
11. Repeat steps 2–10 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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