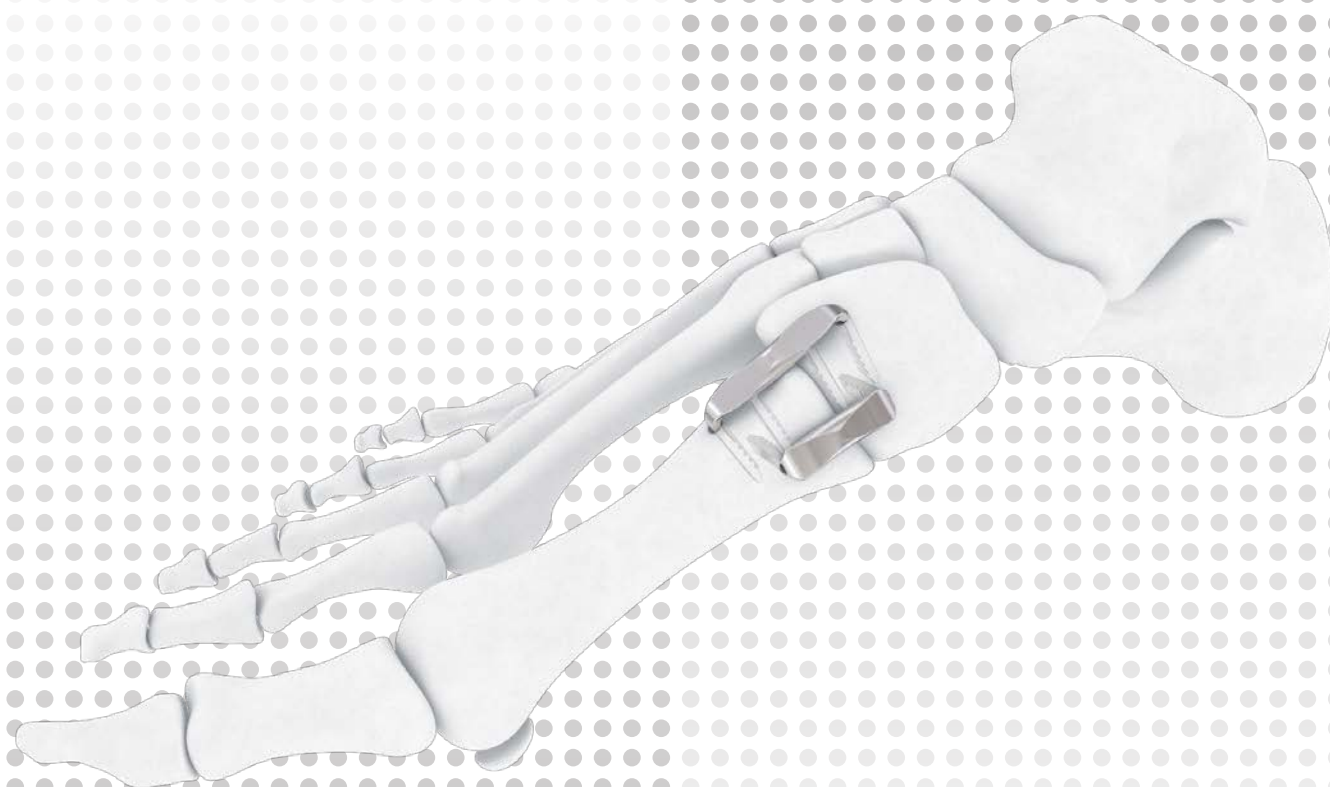


# BME ELITE™ Continuous Compression Implant

## Surgical Technique



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 Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

**Processing, Reprocessing, Care and Maintenance**

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

<http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance>

For general information about reprocessing, care and maintenance of DePuy Synthes reusable devices, instrument trays and cases, as well as processing of DePuy Synthes non-sterile implants, please consult the Important Information leaflet (SE\_023827) or refer to:

<http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance>

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# The AO Principles of Fracture Management

## Mission

The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

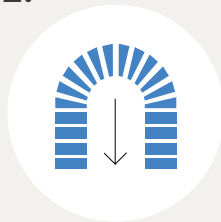
### AO Principles<sup>1,2</sup>

1.



Fracture reduction and fixation to restore anatomical relationships.

2.



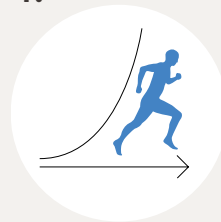
Fracture fixation providing absolute or relative stability, as required by the “personality” of the fracture, the patient, and the injury.

3.



Preservation of the blood supply to soft-tissues and bone by gentle reduction techniques and careful handling.

4.



Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

<sup>1</sup> Müller ME, Allgöwer M, Schneider R, Willenegger H. Manual of Internal Fixation. 3<sup>rd</sup> ed. Berlin, Heidelberg New York: Springer 1991.

<sup>2</sup> Buckley RE, Moran CG, Apivatthakakul T. AO Principles of Fracture Management: 3<sup>rd</sup> ed. Vol. 1: Principles, Vol. 2: Specific fractures. Thieme; 2017.

# BME ELITE™ Continuous Compression Implant

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Intended Use, Indications, Contraindications and Warnings can be found in the corresponding system Instructions for Use.

# Surgical Technique

## Preparation

Expose, prepare, and reduce the fusion site. If necessary, use a K-wire for temporary fixation.

### 1. Determine Implant Size

Determine the correct Implant bridge size and configuration using the BME ELITE™ Drill Guide Kit. Leg lengths will be selected in Step 5 using the Depth Gauge.

### 2. Determine Implant Placement

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 can be accomplished by driving K-wires into the drill tubes and verifying placement with fluoroscopy.

#### ■ Note:

Level fusion site to ensure Drill Guide sits flush to prevent Drill Guide rocking.

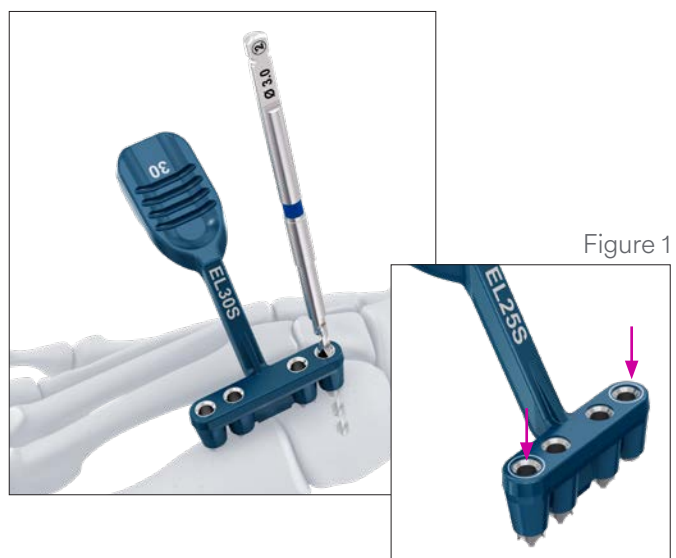


### 3. Drill

Drill the first hole through the far cortex or until the positive stop, which corresponds to 27 mm, is reached.

#### ■ Note:

The EL-25S Drill guide is used for both the EL-2520S2 (2-leg) and EL-2520S4 (4-leg) implants. The white circles on the outer-most holes of the drill guide denote the drill holes to be used when using the drill guide for the EL-2520S2 (2-leg) implant. See Figure 1.



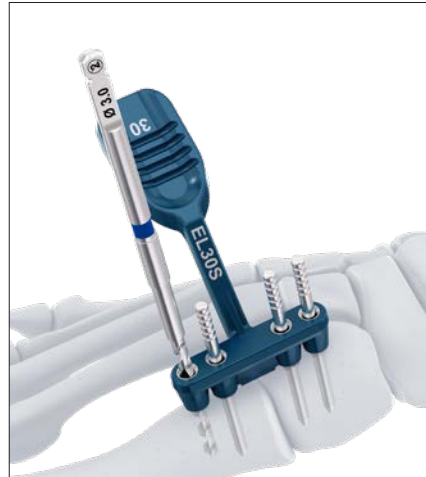
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## 4. Insert Pull Pins

Insert a Pull Pin into the first hole and repeat Step 3 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. To ensure proper placement, fluoroscopy may be used prior to removing Pull Pins.

### ■ Note:

When using BME ELITE™ Y Implant, drill the first hole nearest the Drill Guide handle to aid with Implant placement.



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## 5. Measure Depth

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.



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## 6. Select Implant

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.



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## 7. Insert Implant

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.



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## 8. Release Implant

Pull and hold the slider button away from the Implant to release the Implant from the Insertion Tool.

■ **Note:**

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.



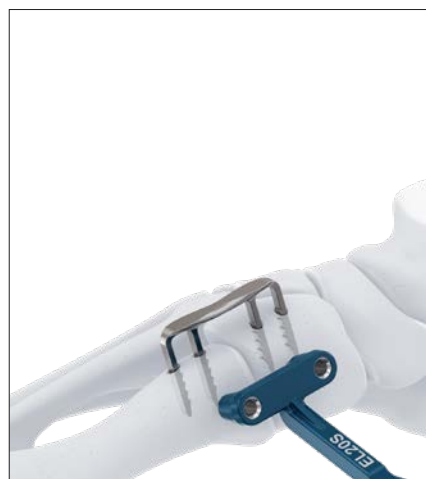
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## Option: Second Orthogonal Implant

If Implants are to be placed 90° to each other, do not tamp down the first Implant and repeat steps 1 to 8 with the second Implant. Use the first Implant's raised bridge to align the Drill Guide for the second Implant. A K-wire can be placed through the Drill Guide and the placement checked under fluoroscopy to confirm that the legs of the second Implant will not interfere with the original Implant.

■ **Note:**

Aim the medial implant placement plantarly away from the intercuneiform joint as needed.





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## 9. Tamp

Align the Tamp with the bridge of the Implant and use as needed to completely seat the Implant.



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## 10. Repeat as Necessary

Repeat Steps 1 to 9 for each additional Implant used.



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## Removal

1. Expose the site and the bridge of the Implant.
2. Use the forceps or the needle driver to grasp the Implant and remove.

### ■ Note:

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 either cutting the bridge of the implant or cutting the leg of the implant near the bridge and removing the remnants with an elevator.

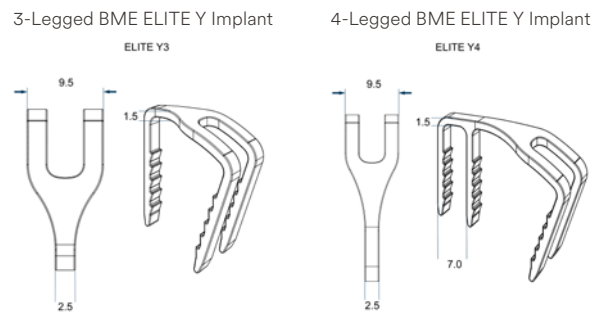
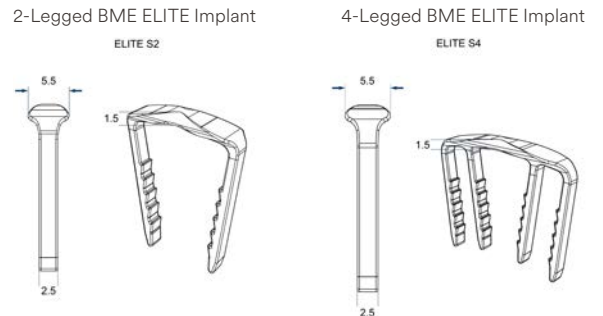
# Implants and Kits

## BME ELITE Continuous Compression Implants

BME ELITE Continuous Compression Implants			
Implant Kit	Bridge*	Legs*	No. of Legs
EL-1515S2	15	15	2
EL-1815S2	18	15	2
EL-1818S2	18	18	2
EL-2015S2	20	15	2
EL-2020S2	20	20	2
EL-2520S2	25	20	2
EL-2520S4	25	20	4
EL-3020S4	30	20	4

BME ELITE Y Continuous Compression Implants			
Implant Kit	Bridge*	Legs*	No. of Legs
EL-201507Y3	20	15	3
EL-202007Y3	20	20	3
EL-251507Y4	25	15	4
EL-252007Y4	25	20	4
EL-301507Y4	30	15	4
EL-302007Y4	30	20	4

\*Sizes in millimeters.  
Leg configuration for 3 and 4 leg Implants are the same.



Degree of curvature of BME ELITE Y Implants in the closed position is 20°

ALL SIZES IN MILLIMETERS

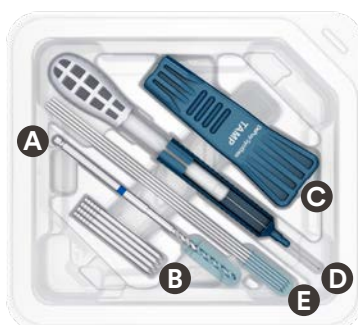
## Corresponding Drill/Drill Guide Kit

Part Number	Drill Bit Size	Drill Guides	Pull Pins	Tamp	K-wires	Depth Gauge
DK-300	<b>A</b> 3.0 mm	–	<b>B</b> Included (4)	<b>C</b> Included	<b>D</b> 4×1.6 mm	<b>E</b> Included
EL-DTS	–	<b>F</b> 15, 18, 20, 25, 30	–	–	–	–
EL-DTY	–	<b>G</b> 20, 25, 30	–	–	–	–

### DK-300 Drill Kit

### EL-DTS Drill Guide Kit

### EL-DTY Drill Guide Kit



#### Note:

All implants and instruments of the BME ELITE product line are single use. Do not resterilize. Dispose of all unused items after surgery.

# MRI Safety Information

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**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 less than 3°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

## **Artifact**

- 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.

Not all products are currently available in all markets.  
This publication is not intended for distribution in the USA.  
Intended use, Indications and Contraindications can be found in the corresponding system Instructions for Use.  
All Surgical Techniques are available as PDF files at [www.depuysynthes.com/ifu](http://www.depuysynthes.com/ifu)



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