

SPEEDSHIFT™ Continuous Compression Implant

Surgical Technique



The AO Principles of Fracture Management

Mission

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

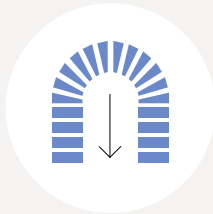
AO Principles^{1,2}

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.

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

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

SPEEDSHIFT™ Continuous Compression Implant

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 securely fix the implant.
- Foreign body sensitivity to metals including nickel. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

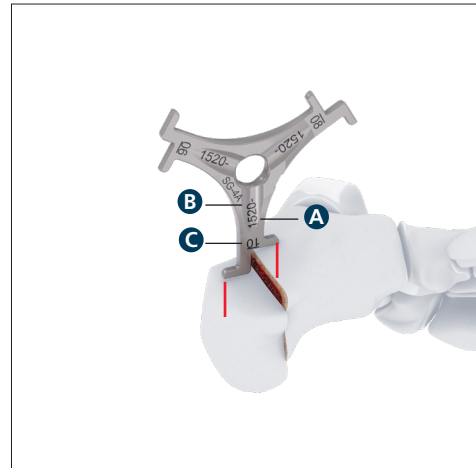
Surgical Technique

1. Determine Implant Size

Create the osteotomy. After obtaining the desired correction, provisionally fixate the osteotomy with a K-wire found in Drill Kit DK-265C. Using the Sizing Guides, determine the width and offset required.

Note: For calcaneal osteotomies, the use of a second Implant should be anticipated and taken into consideration when determining the placement of the first Implant. The Implants should be positioned approximately 1 cm apart.

Note: The Sizing Guides measure both bridge width and offset. This image is measuring a 15 mm bridge **A, 20 mm leg length **B**, and 10 mm offset **C**.**



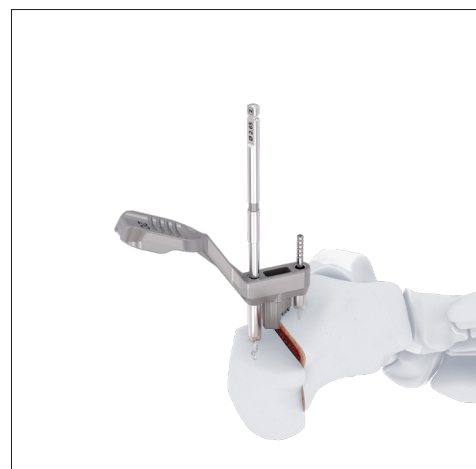
2. Drill

Open the chosen Implant Kit to obtain the Drill Guide. 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.



3. Insert Pull Pins

Insert a Pull Pin into the first hole and, while ensuring full reduction, repeat Step 2 to create the second hole. 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.



4. Select Implant

Remove the Insertion Tool containing the SPEEDSHIFT Implant from the Implant Kit. Remove the Pull Pins from the pre-drilled holes and align the tips of the legs of the Implant parallel with the drill holes.



5. Insert Implant

Insert the SPEEDSHIFT 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.



6. Release Implant

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.



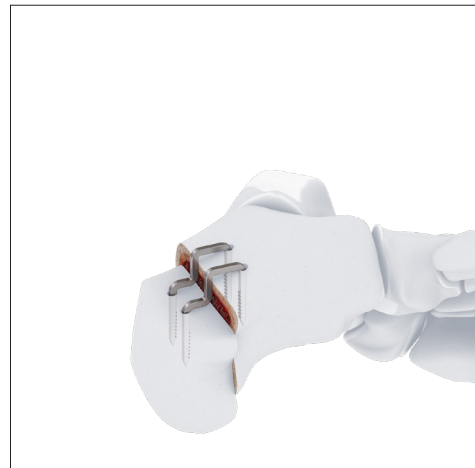
7. Tamp

Align the supplied Tamp with the bridge of the Implant.
Use the Tamp as needed to completely seat the Implant.



8. Repeat for Second Implant

Repeat Steps 1 to 7 for secondary Implant.



Removal

1. Expose the site and the bridge of the Implant.
2. Using forceps, grasp the center of the Implant and remove.

Note: If the Implant is recessed, then use an elevator to lift the Implant bridge and then use forceps to remove the Implant. If solidly connected, straight implants can be removed by cutting the center of the bridge of the Implant and removing the remnants with an elevator.

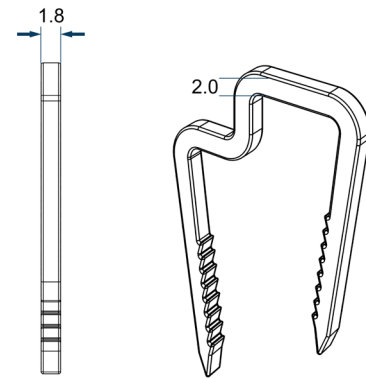
The above steps are an overview of the surgical technique. Complete information regarding indications, contraindications, warnings, care and caution can be found in the Instructions For Use.

Implants and Kits

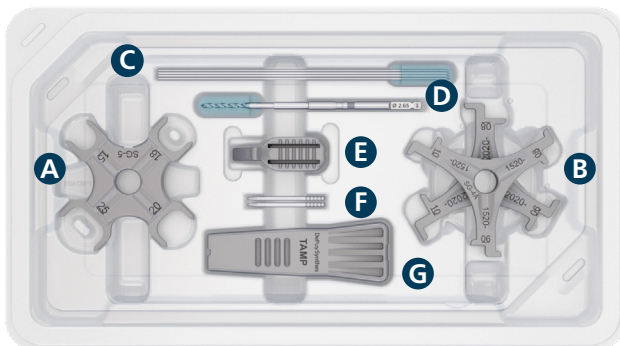
SPEEDSHIFT Continuous Compression Implants

Implant Kit	Bridge*	Legs*	Offset*				
SE-1520-06	15	20	6				
SE-1520-08	15	20	8				
SE-1520-10	15	20	10				
SE-2020-06	20	20	6				
SE-2020-08	20	20	8 </tr <tr> <td>SE-2020-10</td> <td>20</td> <td>20</td> <td>10</td> </tr>	SE-2020-10	20	20	10
SE-2020-10	20	20	10				

*Sizes in millimeters.



DK-265C Drill Kit†



Drill Kit Includes:

- A** SPEEDTITAN® Sizing Guide
- B** SPEEDSHIFT Sizing Guide
- C** 1.37 mm K-wires (4)
- D** 2.65 mm Drill Bit
- E** Drill Guide Handle Adapter
- F** Pull Pins (2)
- G** Tamp

SPEEDSHIFT Implant Kit



Implant Kit Includes:

- A** Drill Guide
- B** Implant pre-loaded on Insertion Tool

†Replacing: DK-265-S, SG-1, OT-1.

Note: DK-265C includes instruments for SPEEDSHIFT and SPEEDTITAN Implant Systems.

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

MRI Safety Information

The SPEEDSHIFT 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.

Manufactured by:



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Not all products are currently available in all markets.
This publication is not intended for distribution in the USA.
All surgical techniques are available as PDF files at
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