Smith-Nephew

ALLOGRAFT WEDGE System

Surgical Technique



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Description

The Smith+Nephew ALLOGRAFT WEDGE is a preshaped wedge derived from human allograft. The implant is designed to incorporate autogenous and allogenic properties for flatfoot deformity corrections.

Uses

The implant is restricted to homologous use for the repair, replacement or reconstruction of bony defects by a qualified healthcare professional (e.g., physician or podiatrist). This includes filling bone voids or gaps of the skeletal system (e.g., extremities, spine, ilium and/or pelvis) that are not intrinsic to the stability of the bony structure.

Warnings

- Do not resterilize.
- Do not use if the product package is damaged or opened.
- The same potential medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. As with any human tissue implant, the potential for transmission of infectious agents may exist. A small number of patients may experience localized immunological reactions to the implant.
- The surgeon is responsible for informing the patient of the risks associated with their treatment and the possibility of complications or adverse reactions.

Precautions

- Prior to use, the surgeon must become familiar with the implant and the surgical procedure.
- The implant should not be used where defect stabilization is not possible or where an active infection is present at the surgical site. Supplemental fixation is required for use in osseous defects that are intrinsic to the stability of the bony structure.

Caution: Federal law restricts this device to sale by or on the order of a physician or practitioner.

See package insert for full prescribing information.

Nota Bene

The following technique is for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of treating physicians to determine and utilize the appropriate products and techniques according to their own clinical judgment for each of their patients. For more information on the product, including its indications for use, contraindications, and product safety information, please refer to the product's label and the Instructions for Use packaged with the product.

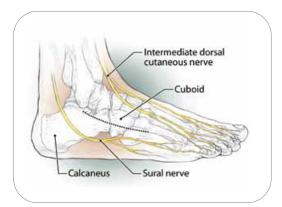


Figure 1-1

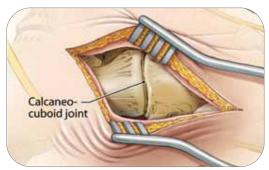


Figure 1-2

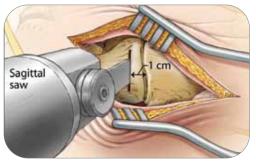


Figure 1-3

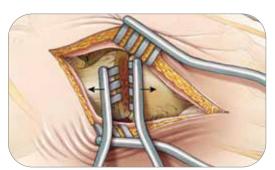


Figure 1-4

Evans Osteotomy Surgical Technique

Application

Pre-operative considerations

The surgical approach for each patient should be individualized. A pre-operative discussion focusing on the patient goals and expectations should be carried out and the alternative treatment options reviewed. The optimal surgical approach and implant can then be determined based on the individual case.

Step 1 - Surgical approach

- **1-1** Make an oblique incision over the distal lateral calcaneus. Take care to avoid intermediate dorsal cutaneous nerve superiorly and the sural nerve inferiorly. Expose the lateral surface of the calcaneus by deepening the incision through the superficial facia.
- 1-2 Locate the calcaneocuboid joint.
- **1-3** Make a cut completely through the calcaneus, one centimeter proximal to the calcaneocuboid joint, using a sagittal saw.
- **1-4** Open the osteotomy with a spreader, lengthening the lateral column. Avoid opening the calcaneocuboid joint to prevent instability.

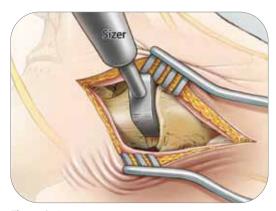


Figure 2-1

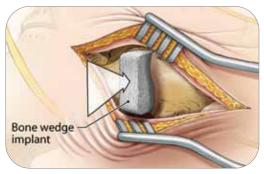


Figure 4-1

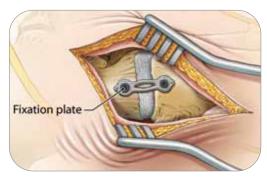


Figure 5-1

Step 2 • Implant selection

2-1 Determine the size of the implant using the Smith+Nephew ALLOGRAFT WEDGE Instrument Set or other suitable measuring instrument.

Select an ALLOGRAFT WEDGE implant. Using aseptic technique, remove the ALLOGRAFT WEDGE inner package from its outer package and place the package in the sterile field. Aseptically remove the ALLOGRAFT WEDGE from the inner package.

Step 3 - Implant hydration

3-1 Cover the implant with a room temperature solution of sterile United States Pharmacopeia water, or physiological saline. Submerge the implant completely to ensure adequate hydration. The implant must remain in sterile solution for a minimum of 30 seconds, and until implantation.

Step 4 • implantation

4-1 Insert ALLOGRAFT WEDGE into osteotomy. Impact with tamp until the implant is flush with host bone. Make adjustments to ALLOGRAFT WEDGE with bone rongeur or sagittal saw if necessary.

Step 5 • Implant fixation

5-1 Installation of a fixation plate is recommended when using ALLOGRAFT WEDGE. The Smith+Nephew UNI-CP° Compression Plate may be used to secure the ALLOGRAFT WEDGE.

Cotton Osteotomy Surgical Technique

Application

Pre-operative considerations

The surgical approach for each patient should be individualized. A pre-operative discussion focusing on the patient goals and expectations should be carried out and the alternative treatment options reviewed. The optimal surgical approach and implant can then be determined based on the individual case.

Step 1 - Surgical approach

- 1-1 Make a linear incision exposing the medial cuneiform. Take care to avoid disrupting the hallucis longus tendon.
- 1-2 Perform the cotton osteotomy in a dorsal to plantar direction across the medial cuneiform, and open using a osteotome.

Step 2 • Implant selection

2-1 Determine the size of the implant using the ALLOGRAFT WEDGE Instrument Set or other suitable measuring instrument. Select an ALLOGRAFT WEDGE implant. Using aseptic technique, remove the ALLOGRAFT WEDGE inner package from its outer package and place the package in the sterile field. Aseptically remove the ALLOGRAFT WEDGE from the inner package.

Step 3 • Implant hydration

3-1 Cover the implant with a room temperature solution of sterile United States Pharmacopeia water, or physiological saline. The implant must remain in sterile solution for a minimum of 30 seconds, and until implantation.

Step 4 • Implantation

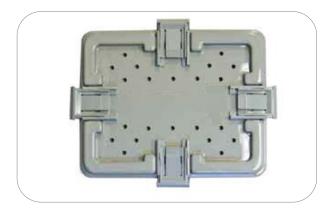
4-1 Insert ALLOGRAFT WEDGE into osteotomy. Impact with tamp until the implant is flush with host bone. Make adjustments to ALLOGRAFT WEDGE with bone rongeur or sagittal saw if necessary.

Step 5 • Implant fixation

5-1 Installation of a fixation plate is recommended when using ALLOGRAFT WEDGE. The UNI-CP^{\(\delta\)} Compression Plate may be used to secure the ALLOGRAFT WEDGE.

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Product information





Implants-Wedges

Reference	Description
WEDGE06	ALLOGRAFT WEDGE (6mm)
WEDGE08	ALLOGRAFT WEDGE (8mm)
WEDGE10	ALLOGRAFT WEDGE (10mm)
WEDGE12	ALLOGRAFT WEDGE (12mm)

Instruments (non-sterile)

Reference	Description
39-0006	6mm Trial
39-0008	8mm Trial
39-0010	10mm Trial
39-0012	12mm Trial
39-0000	ALLOGRAFT WEDGE Impactor

Tray

Reference	Description
39-5000	Instrument Case Assembly
39-5001	Instrument Case Lid
39-5002	Instrument Case Base

