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Description
The Integra™ 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.
Evans Osteotomy Surgical Technique

As the distributor of this implant, Integra does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.

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 fascia.

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.
Step 2 • Implant Selection

2-1 Determine the size of the implant using the Integra™ Allograft Wedge Instrument Set or other suitable measuring instrument.

Select an Integra™ Allograft Wedge implant. Using aseptic technique, remove the Integra™ Allograft Wedge inner package from its outer package and place the package in the sterile field. Aseptically remove the Integra™ Allograft Wedge from the inner package.

Step 3 • Implant Hydration

3-1 Cover the implant with a room temperature solution of either sterile or USP 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 Integra™ Allograft Wedge into osteotomy. Impact with tamp until the implant is flush with host bone. Make adjustments to Integra™ 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 Integra™ Allograft Wedge. The Integra™ Uni-CP™ Compression Plate may be used to secure the Integra™ Allograft Wedge.
Cotton Osteotomy Surgical Technique

As the distributor of this implant, Integra does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.

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 Integra™ Allograft Wedge Instrument Set or other suitable measuring instrument.

Select an Integra™ Allograft Wedge implant. Using aseptic technique, remove the Integra™ Allograft Wedge inner package from its outer package and place the package in the sterile field. Aseptically remove the Integra™ Allograft Wedge from the inner package.

Step 3 • Implant Hydration

3-1 Cover the implant with a room temperature solution of either sterile or USP 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 Integra™ Allograft Wedge into osteotomy. Impact with tamp until the implant is flush with host bone. Make adjustments to Integra™ 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 Integra™ Allograft Wedge. The Uni-CP™ Compression Plate may be used to secure the Integra™ Allograft Wedge.
### Implants - Wedges

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<tbody>
<tr>
<td>WEDGE06</td>
<td>Integra Allograft Wedge (6mm)</td>
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<td>WEDGE08</td>
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<td>WEDGE10</td>
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<td>WEDGE12</td>
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### Instruments (Non-Sterile)

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<tbody>
<tr>
<td>39-0006</td>
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<td>Allograft Wedge Impactor</td>
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### Tray

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<tr>
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<tbody>
<tr>
<td>39-5000</td>
<td>Allograft Wedge Instrument Case Assembly</td>
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<td>39-5001</td>
<td>Allograft Wedge Instrument Case Lid</td>
</tr>
<tr>
<td>39-5002</td>
<td>Allograft Wedge Instrument Case Base</td>
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