The purpose of the Zimmer® Trabecular Metal™ Ankle Interpositional Spacer is to fill bone voids that may be present in the talus and tibia while fusing the ankle joint. These bone voids often occur when a Total Ankle Prosthesis is being revised to an ankle fusion. This spacer device is intended to be an adjunct to a fusion device.

The Zimmer Trabecular Metal Ankle Interpositional Spacer is available in 3 base sizes (S, M, L) with four heights (25, 30, 35, and 40mm). The base sizes were optimized by analyzing human ankles from a wide range of both genders and ethnicities. The base sizes are targeted to a talus that is cut 10mm from its most proximal point.

The purpose of the Ankle Fusion Spacer is to maintain the height of the ankle joint when a primary ankle fusion procedure is performed. Joint height is typically lost when the proximal talus and distal tibia are resected to clear the diseased area of the joint and create flat surfaces for a fusion. This spacer device is intended to be an adjunct to a fusion device.

The Ankle Fusion Spacer is available in 3 base sizes (S, M, L) with a height of 7.5mm.

Both implant designs feature a 14mm hole through the center of the device which can accommodate an ankle fusion device. Additionally, the implants have been designed so that ancillary fixation can be used with the devices if necessary.

**Note:** These products are contraindicated for use with Stainless Steel Fusion or Ancillary Fixation Devices. Care should be taken to avoid contact with ancillary devices. Nails larger than 10mm in diameter should not be used.

These systems feature a common resection guide to assist in making accurate cuts for both the height and the width of the implant.
Positioning the Ankle Alignment Guide

Start by making an anterior incision to expose the ankle joint. Clean out any loose debris and take steps to ensure that the exposure allows good visualization into the joint where the proximal talus and distal tibia are easily seen.

Technique Tip: The incision should be centered over the anterior ankle joint, in the interval between the anterior tibial tendon and the extensor hallucis. The recommended exposure is just lateral to the tibialis anterior tendon so its sheath is not disturbed and it is retracted medially with the retinaculum.

Achieving accurate placement of the alignment and cutting guides are crucial steps to ensure that resections will be made that align with the IM canal of the tibia. When this alignment is properly achieved, it allows the Trabecular Metal spacer device and the ankle fusion device to properly align so that they can be used together.

Assemble the ankle resection and alignment guide construct by choosing either a Short or Long Extension Rod based on the anatomy of the patient and insert it into the Proximal Tibial Anchor. (Figure 1) Attach the Ankle Resection Frame to the Extension Rod by sliding the A/P rod of the frame through the appropriate Ankle Extension Rod. (Figure 2) At this point, a proper size Ankle Resection Guide should be attached to the Ankle Resection Frame. This is done by aligning the Ankle Resection Guide on the anterior side of the Ankle Resection Frame and aligning the screw holes. The screws attach to the frame using the 3.5mm Female Hex Driver. (Figure 3)
When the three described instruments have been assembled, start by aligning the proximal aspect of the Proximal Tibial Anchor with the tibial tubercle. When the proper axis position on the tubercle has been located, insert a 125mm Threaded Fixation Pin through the Proximal Tibial Anchor into the tibial tubercle at that point. (Figure 4)

**Note:** *This pin should be inserted percutaneously into the tibial tubercle.*

Ensure that the slope of the Ankle Alignment Guide Assembly can be positioned parallel to the long axis of the tibia by loosening the knob at the proximal end of the Proximal Tibial Anchor and re-tightening when the proper slope has been achieved. (Figure 5)

The Ankle Alignment Guide Assembly axis can be adjusted medially or laterally from this point as well as proximally or distally to properly align the shaft to the tibia and account for any deformities that may be present. (Figure 6) The Ankle Alignment Guide Assembly position relative to the pin can then be secured by tightening the knob adjacent to the pin location and the knob on the anterior aspect of the Proximal Tibial Anchor.
Positioning the Cutting Guide

Near the base of the Ankle Resection Frame is a scribe line that should be positioned up to a 5mm talus resection from its most proximal aspect if using the Ankle Fusion Spacer or a 10mm talus resection if using the Ankle Interpositional Spacer. Telescope the alignment assembly in order to achieve this position.

When this position has been achieved, lock the Ankle Alignment Guide Assembly length in place by tightening the knobs on the distal aspect of both the Proximal Tibial Anchor and the Extension Rod. (Figure 7)

The Ankle Resection Guide should be positioned close to the bone for saw blade stability. This can be achieved by sliding the Ankle Resection Frame more posteriorly along the Anterior/Posterior rod. This position can be locked into place by tightening the knob adjacent to this assembly.

Note: Ensure that the foot sits at a 90 degree angle to the tibia before pinning the construct in place.

With the Ankle Alignment Guide Assembly positioned both parallel to the long axis of the tibia and aligned for the appropriate talus resection, use 80mm Threaded Fixation Pins to lock the Ankle Alignment Guide Assembly into place.

The Ankle Alignment Guide Assembly is properly positioned when the long axis of the guide matches the slope of the tibia and the Ankle Resection Guide is pinned in place where the tibia and talus are aligned at neutral from a varus/valgus standpoint.
Start by placing two pins through the proximal portion of the Ankle Resection Frame and into the tibia. (Figure 8) Follow this by placing two pins through the distal portion of the Ankle Resection Frame and into the talus. (Figure 9) There is an additional pin hole at the distal end of the Extension Rod that can be utilized for additional stability.

**Note:** Depending on the size of the incision, some pins may need to be inserted percutaneously.

Position the appropriate size (S, M, L) Ankle Resection Guide attached to the Ankle Resection Frame by loosening the screws with the 3.5mm Female Hex Driver. (Figure 10) To properly position the Ankle Resection Guide, identify the distal aspect of the cutting guide and align it on the talus by sliding the Ankle Resection Guide proximally or distally relative to the Ankle Resection Frame into a position where the talus cut should be made. The distal aspect of the Ankle Resection Guide is the guide for the talus cut.

**Note:** It is recommended that the talus should be cut up to 5mm when using the Ankle Fusion Spacer and up to 10mm when using the Ankle Interpositional Spacer.
When the desired resection level has been determined, lock the Ankle Resection Guide into place on the Ankle Resection Frame by using the 3.5mm Female Hex Driver to tighten the hex screws on each side of the Resection Guide.

**Note:** It is recommended that an x-ray be taken to confirm that the cutting guide has been properly positioned before making any cuts. *(Figure 11)*

### Bone Preparation

With the cutting guide locked into place, cut the talus with a 0.039” reciprocating or oscillating saw using the distal surface of the Ankle Resection Guide. *(Figure 12)*

**Note:** This cut is not captured; it is the distal surface of the Ankle Resection Guide.

After the talus cut has been made, inspect the surface of the talus to ensure that a clean cut has been made and a good cortical rim exists which can support the implant. If necessary, the Ankle Resection Guide can be repositioned to make a more distal cut by loosening the screws with the 3.5mm Female Hex Driver and translating the Ankle Resection Guide distally, then re-locking the hex screws.
With the cutting guide still locked in place, determine the necessary height of the tibial cut. For the Ankle Fusion Spacer, this will be the 7.5mm slot. (Figure 13)

When preparing for the Ankle Interpositional Spacer a 25, 30, 35, or 40mm height device can be selected. The appropriate height can be determined by placing a saw blade through the respective slots to define where the tibial bone begins. (Figure 14)

**Technique Tip:** Use a reciprocating saw to cut the tibia through the most distal slot on the tibial bone where a flat surface can be achieved to support the implant.

Cut the side walls with a reciprocating saw through the slots up to the point of the tibial resection. (Figure 15)

**Technique Tip:** Be sure to avoid over-resecting the bone proximally.

**Note:** Bone may not be present on the lateral side.

When the cuts are complete, remove the Ankle Resection Guide from the Ankle Resection Frame to examine the distal tibia cut to ensure that a clean surface exists to support the implant. Record the height of cut chosen for the final implant selection.
Assess Component Fit

**Note:** *It is recommended that this assessment takes place with the Alignment Guide Construct pinned in place with the Ankle Resection Guide removed.*

In order to assess fit, select the chosen size provisional component. Use the Ankle Distractor to hold open the prepared site. With the bones distracted, use the Inserter/Extractor to securely grasp the selected provisional from the anterior side and insert it into the space. *(Figure 16)*

Release the provisional from the Inserter/Extractor and position the appropriate Tamp on the anterior surface of the provisional. Using a mallet, tap the Tamp on the Provisional until it is seated in its desired location. Release the Ankle Distractor and assess final fit and soft tissue stability.

To remove the provisional, grasp the provisional with the Inserter/Extractor.

Consider up-sizing to a larger size if better cortical support on the talus can be achieved without the device overhanging the bone. Be sure to re-cut the side walls when up-sizing to a larger size. This is achieved by attaching the new desired size Ankle Resection Guide to the Ankle Frame and using the side slots to re-cut the tibia to the height of the larger component.

After completing a final assessment of the Provisional component placement, remove the Provisional and inspect the cuts. Clean up any corners with a rasp or a saw where an intersecting cut may have created a stress riser.
Remove the Ankle Alignment Guide Assembly from the bones and pull any remaining pins. Be sure to loosen the screw that captures the 125mm threaded pin from the tibial tubercle first.

To disassemble the Ankle Alignment Guide Assembly, remove the Ankle Resection Guide and Ankle Resection Frame from the Ankle Alignment Guide Assembly by loosening the screw adjacent to the A/P rod. To disassemble the Ankle Resection Frame and the Ankle Resection Guide, use the 3.5mm Female Hex Driver to loosen the two screws and pull the two components apart.

Loosen the screws on the distal ends of both the Proximal Tibial Anchor and the Extension Rod to pull the components apart.

**Note:** The screws on the guide instruments are captured and should not be removed.

### Component Implantation

Use the Ankle Distractor to open up the joint. Grasp the appropriate size Trabecular Metal Implant from the anterior side with the Inserter/Extractor. Insert the chosen Trabecular Metal Implant into the bone void until resistance is met before releasing the component from the Inserter/Extractor. *(Figure 17)*

Position the appropriate Tamp on the anterior center of the component and tap the implant into its final position using a mallet. When the final position has been achieved, release the Ankle Distractor and ensure good bony contact with both the proximal talus and the distal tibia. *(Figure 18)*
When the implant is in its proper position, it should have good cortical support on the talus with no overhang. Note that the M/L tapered end of the implant should be on the posterior side of the talus.

Bone graft or other materials may be used to shield exposed Trabecular Metal Material from soft tissue if necessary.

**Note:** Do not stack one Trabecular Metal device on top of another.

**Note:** Avoid excess pre-compression of the ankle fusion device.

**Subsequent Implant Removal**

Should Implant removal become necessary, the fusion device and ancillary fixation should be removed first. The Trabecular Metal Implant can be removed by using a saw to cut the bone just proximal to the tibial interface and just distal to the talus interface. The implant can then be removed with the Inserter/Extractor. If necessary, the Ankle Distractor can also be used to create space between the bones when extracting the implant.
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