

RIPTIDE™ Evans

Reconstructive Interpositional PEEK Titanium Wedge System

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Reconstructive Interpositional PEEK Titanium Wedge System Evans Osteotomy Procedure

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Reconstructive Interpositional PEEK Titanium Wedge System

INDICATIONS FOR USE

Reconstructive Interpositional PEEK Titanium Wedge System Indications

The Zimmer Biomet Reconstructive Interpositional PEEK Titanium Wedge System is intended to be used for internal bone fixation for bone fractures, fusions, and osteotomies in the ankle and foot such as:

- Cotton and Evans Wedges
 - » Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
 - » Opening wedge of Medial Cuneiform of Cotton osteotomies
 - » Lateral Column Lengthening (Evans Lengthening Osteotomy or Calcaneal Z Osteotomy)
- Midfoot Wedges
 - » Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
 - » Nonunion of arthrodesis of the Midfoot including Metatarsal/Cuneiform arthrodesis (TMT or Lapidus)

The device is intended for use with ancillary fixation.

The Zimmer Biomet RIPTIDE is not intended for use in the spine.

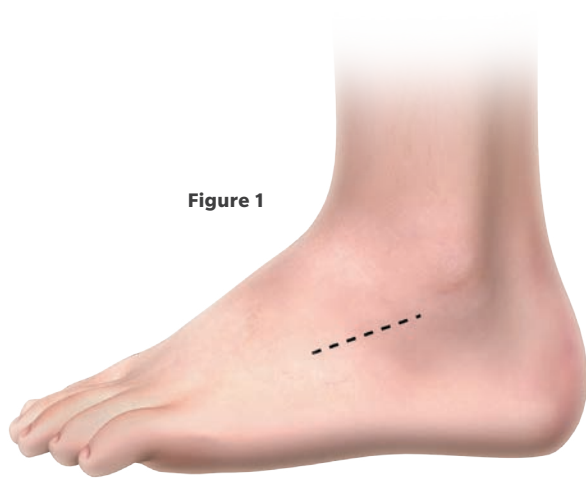
CONTRAINDICATIONS

The operation should not be carried out against the following contraindications:

- Bone tumors in the region of the implant anchoring
- Unwillingness or inability of the patient to follow the instructions for postoperative treatment
- Any medical or surgical condition that could preclude the potential success of the implantation
- Pregnancy
- Osteoporosis or similar bone density loss
- Systemic or metabolic illnesses
- Drug abuse or alcoholism
- Generally poor condition of the patient
- Adiposity
- Psychosocial issues; lack of co-operation by the patient
- All cases that are not listed under indications

Reconstructive Interpositional PEEK Titanium Wedge System

Evans Technique



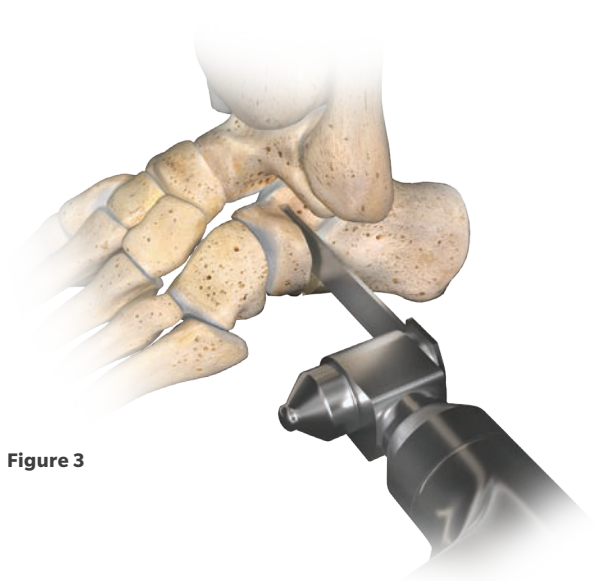
Incision

Make an incision just below the sinus tarsi, extending laterally approximately 3 cm proximal to the calcanealcuboid joint (Figure 1).

Osteomy Cut

Carefully reflect extensor digitorum muscle belly superiorly and retract the peroneal tendons along with the sural nerves inferiorly to expose the lateral calcaneal and calcaneocuboid joint (Figure 2).

10-12 mm proximal to the calcaneocuboid make an osteotomy parallel to calcaneocuboid joint leaving the medial cortex intact (Figure 3).



Reconstructive Interpositional PEEK Titanium Wedge System

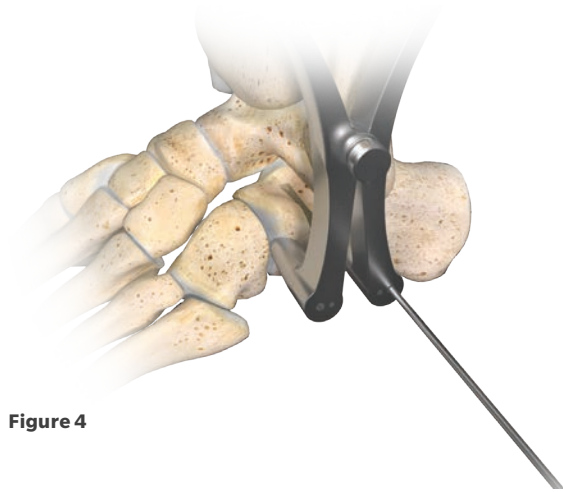


Figure 4

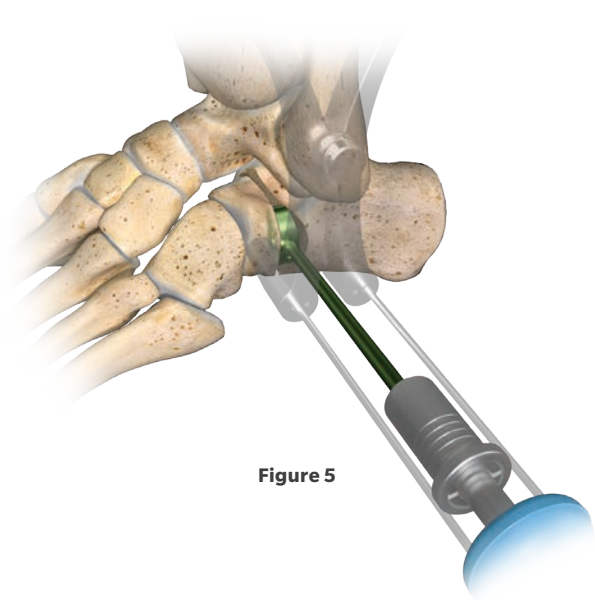


Figure 5

Distraction

Place a 2.0 mm (or 1.6 mm) Steinmann pin on each side of the osteotomy and utilize a distractor to aid in distraction and access to the osteotomy site (Figure 4).

Exchange colored trial inserters (start with smaller trials first then proceed with thicker/larger trials) into the distracted osteotomy site until the footprint matches the size of the osteotomy site (Figure 5). Assess whether appropriate correction occurs with wedge both clinically and fluoroscopically (shape and size).*

Reconstructive Interpositional PEEK Titanium Wedge System

Evans Technique



Figure 6

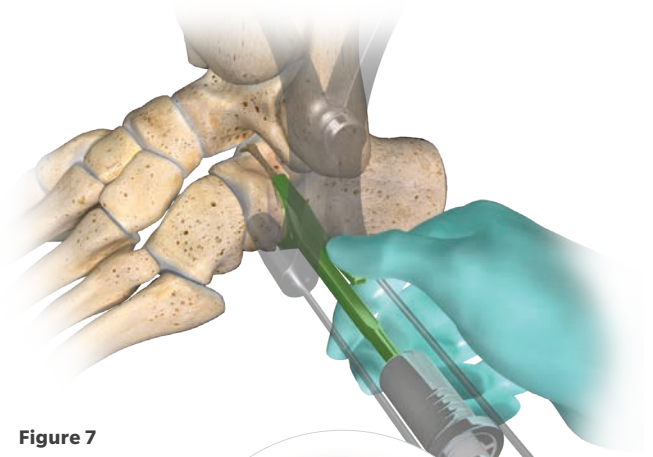


Figure 7

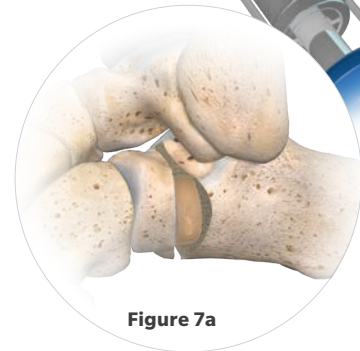


Figure 7a

Implant Insertion

Connect the driver handle to inserter that corresponds to the footprint of wedge determined during trial. Inserter will be same color as trial color. Attach the RIPTIDE Evans Wedge as determined by trial implant (Figure 6).

Note: Wedges may be used with allograft such as Bonus® Triad Allograft packed in the graft window of the wedges. Use with handle is optional; however, coupling with the handle provides more stability while inserting.

Seat the implant into the osteotomy site slightly recessed resting within the walls of the calcaneus (Figure 7, 7a). Check final position fluoroscopically: 1) ensure the far cortex is not compromised and 2) ensure adequate correction of deformity has occurred. If distractor is still in place, loosen and remove it. Ensure the wedge maintains good bone contact with each side of the osteotomy site. Release implant from inserter by holding down on engagement lever.

Reconstructive Interpositional PEEK Titanium Wedge System



Figure 8a

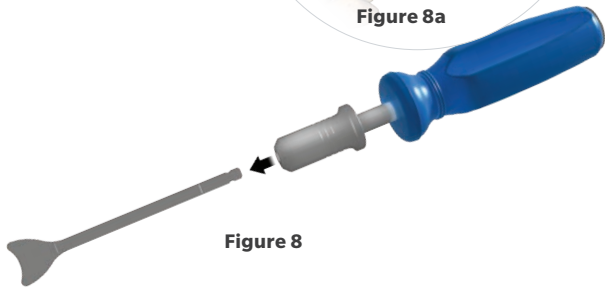


Figure 8

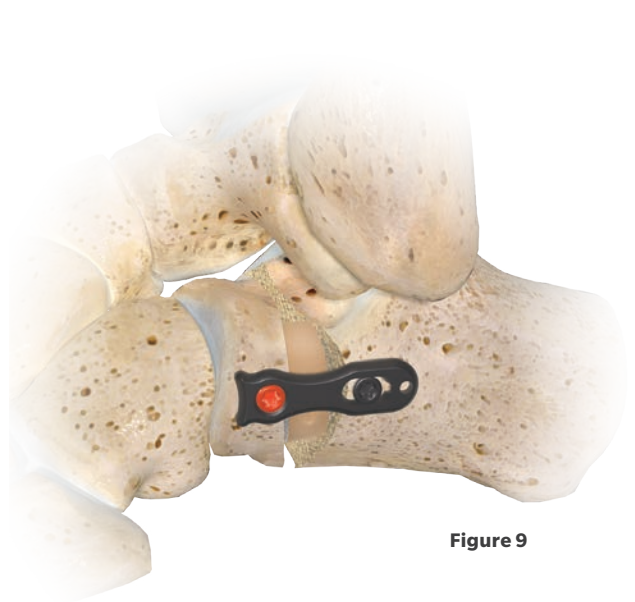


Figure 9

Note: If additional fine tuning of implant positioning is needed, utilize tamp. Connect proximal end of tamp to AO handle (Figure 8). Place tamp curve on outer skin of implant. Use hammer on distal end of handle to fine tune implant position (Figure 8a).

Ancillary Fixation with Plate

Ancillary fixation is required when using RIPTIDE Evans Wedges (Figure 9). Refer to the Zimmer Biomet Stratum™ Foot Plating System surgical technique (2698.1 Us-en Rev0179) for a detailed protocol.

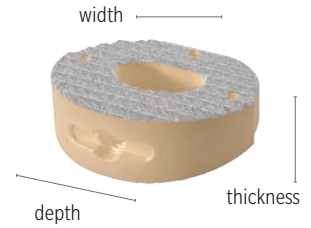
Wound Closure and Post Operative Care







After confirmatory AP and lateral X-rays, suture individual layers of soft tissue. Follow appropriate post operative protocol based on surgeon preference.

Reconstructive Interpositional PEEK Titanium Wedge System

Implants

RIPTIDE Wedge System implant sizing
Evans Wedges



Footprint Image	Part Number	Width (mm)	Depth (mm)	Thickness (mm)	Thickness Image
 *	6ZBZE1807 6ZBZE1809 6ZBZE1811	18	15	7 9 11	 ** 7mm
 *	6ZBZE2107 6ZBZE2109 6ZBZE2111 6ZBZE2112	21	17.5	7 9 11 12	 ** 9mm
 *	6ZBZE2407 6ZBZE2409 6ZBZE2411	24	20	7 9 11	 ** 11mm

* Images shown at actual size

** Image shown at actual sizes for part numbers 6ZBZE2107, 6ZBZE2109, 6ZBZE2111
Tyber Medical is the legal manufacturer for the RIPTIDE Evans Wedges.

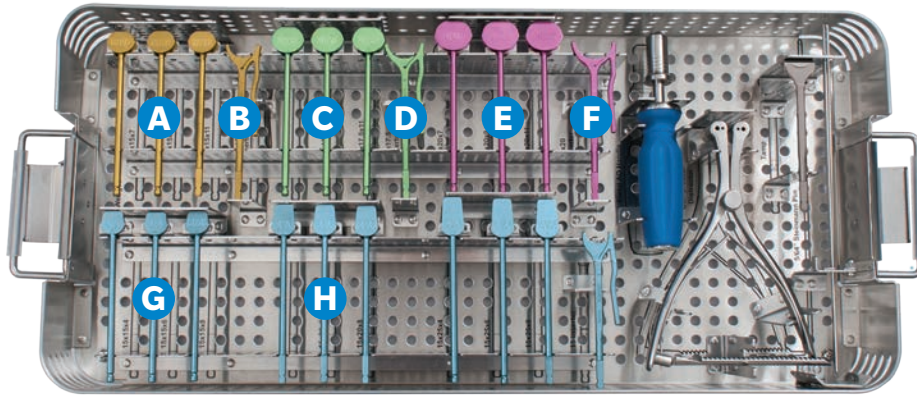
12mm not shown









Explant Information

Remove the ancillary fixation device using the same device-specific instrumentation used to implant the device. Use forceps, or other desired general instruments to pull the wedge out. If necessary use an osteotome along the surface of the wedge-bone interface to free the wedge from the bone.

Reconstructive Interpositional PEEK Titanium Wedge System

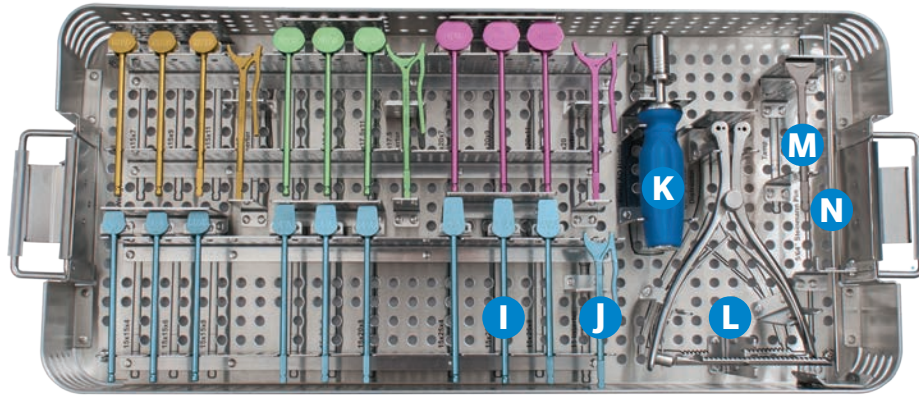
Instruments









Product	Label	Part Number	Size	Description
	A	110003909 110003905 110003901	18 x 15 x 7 18 x 15 x 9 18 x 15 x 11	Wedge Trial P1 18x15
	B	110004029	18 x 15	Wedge Inserter P1 18x15
	C	110003891 110003887 110003883	21 x 17.5 x 7 21 x 17.5 x 9 21 x 17.5 x 11	Wedge Trial P1 21x17.5
	D	110004025	21 x 17.5	Wedge Inserter P1 21x17.5
	E	110003873 110003869 110003865	24 x 20 x 7 24 x 20 x 9 24 x 20 x 11	Wedge Trial P1 24x20
	F	110004021	24 x 20	Wedge Inserter P1 24x20
	G	110003964 110003960 110003954	15 x 15 x 4 15 x 15 x 6 15 x 15 x 8	Wedge Trial P2 15x15
	H	110003946 110003942 110003936	15 x 20 x 4 15 x 20 x 6 15 x 20 x 8	Wedge Trial P2 15x20

Reconstructive Interpositional PEEK Titanium Wedge System

Instruments



Product	Label	Part Number	Size	Description
	I	110003928 110003924 110003918	18 x 15 x 7 18 x 15 x 9 18 x 15 x 11	Wedge Trial P2 15x25
	J	110004033	15	Wedge Inserter P2
	K	110005225	—	AO Connect Handle
	L	010001467	—	Closed Comp/Dist Instrument
	M	110004037	—	Wedge Tamp
	N	27-361008	2mm	Steinmann Pin "Non-Sterile" (6/pk)
		6ZB000011*	—	RIPTIDE Cotton Porous Metal Foot & Ankle Reconstruction Wedge Instrument Case Only
		6ZB000010*	—	RIPTIDE Cotton Porous Metal Foot & Ankle Reconstruction Wedge Instrument Case Kitted

*Tyber Medical is the legal manufacturer for the RIPTIDE case and tray.

This material is intended for health care professionals. For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert or contact your local representative; visit www.zimmerbiomet.com for additional product information.

Zimmer Biomet does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure. Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

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