

RIPTIDE™ Cotton

Reconstructive Interpositional PEEK Titanium Wedge System

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Reconstructive Interpositional PEEK Titanium Wedge System Cotton 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

Cotton Technique

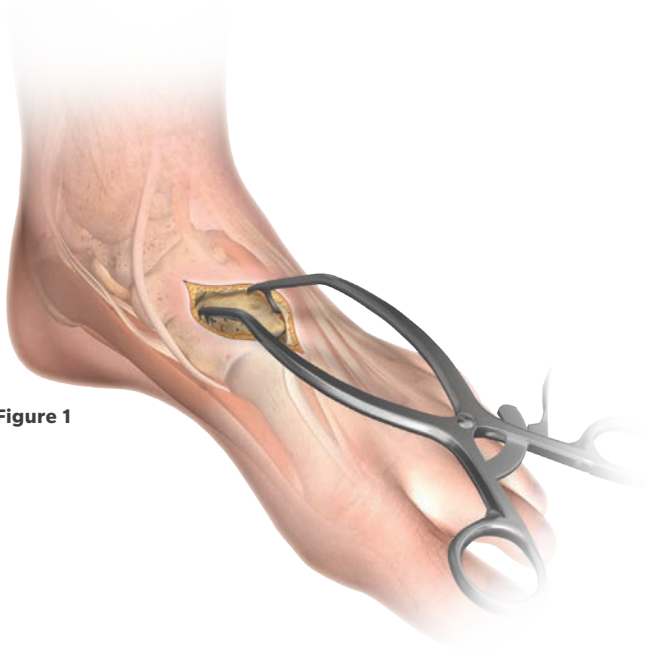


Figure 1

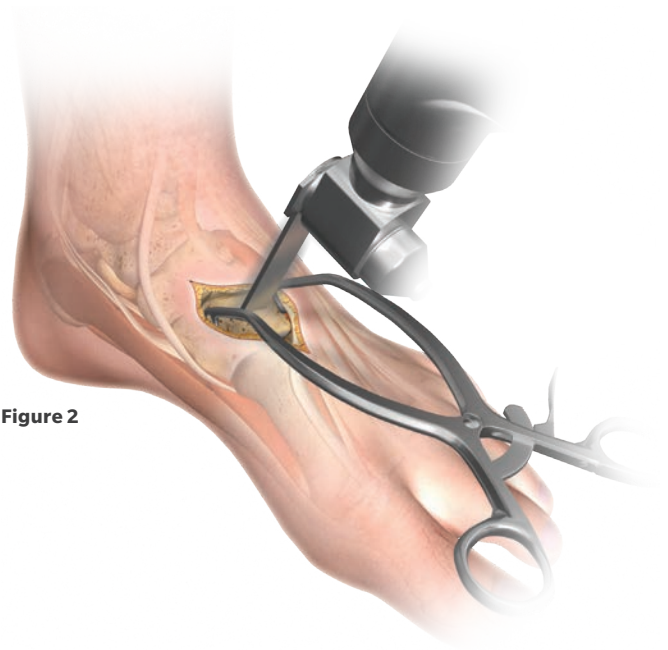


Figure 2

Incision

Make a dorsal incision over the medial cuneiform. Retract the extensor hallucis longus, and anterior tibial tendons; dissect soft tissues on the medial cuneiform (Figure 1). The medial and lateral cortices should be visualized to ensure a complete transverse cut across the entire medial cuneiform.

Osteomy Cut

Make a transverse osteotomy on the dorsal surface of the medial cuneiform close to center of bone toward the deep plantar cortex (Figure 2). Do not transect the plantar cortex instead allowing the bone to create a stable hinge plantarly. Be careful not to extend the saw cut to the plantar cortex; too shallow a cut may result in fracture of the bottom $\frac{1}{4}$ of the cuneiform. An osteotome provides a good tool to “crack” open the osteotomy.

Reconstructive Interpositional PEEK Titanium Wedge System

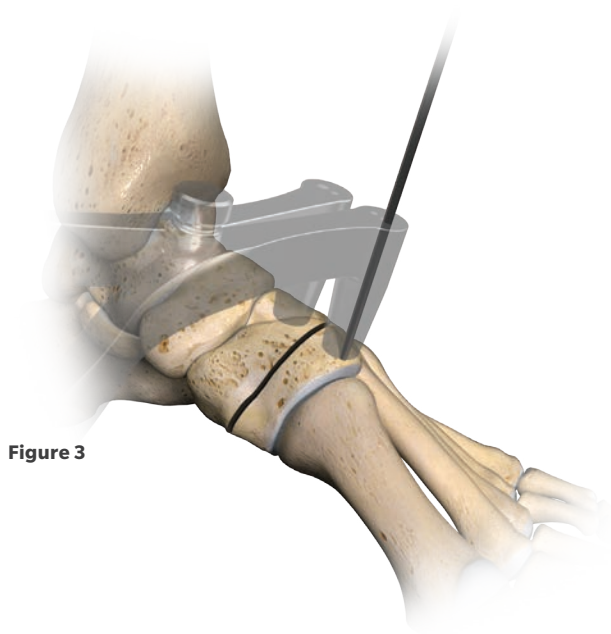


Figure 3

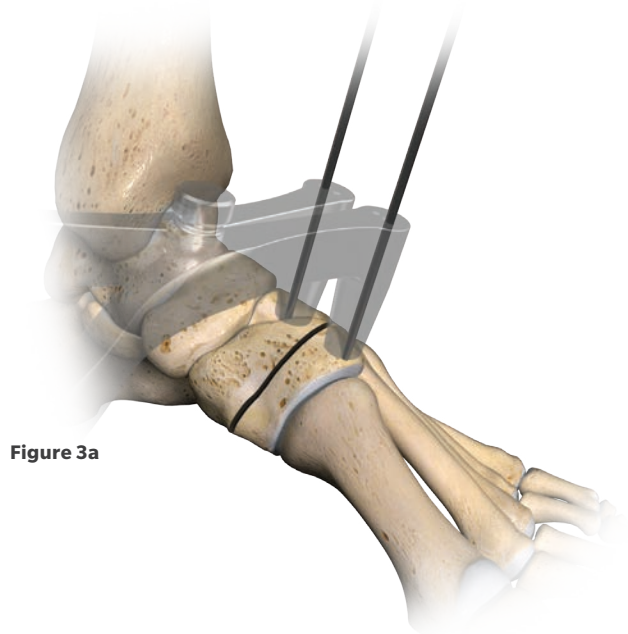


Figure 3a

Distraction

Create distraction at osteotomy site by wedging the bone apart or using a distractor. Utilize a Hintermann distractor to aid in more controllable distraction and access to the osteotomy site (Figure 3, 3a). When using the Hintermann, keep instrument as close to bone as possible so it does not slide up on the wires and bend the wires. 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 4). Assess whether appropriate correction occurs with wedge via fluoroscopically (shape and size). Once appropriate correction is verified, ensure wedge trial is in close contact with the osteotomy interface so that the implant wedge can be placed in an optimal environment for biological fixation.

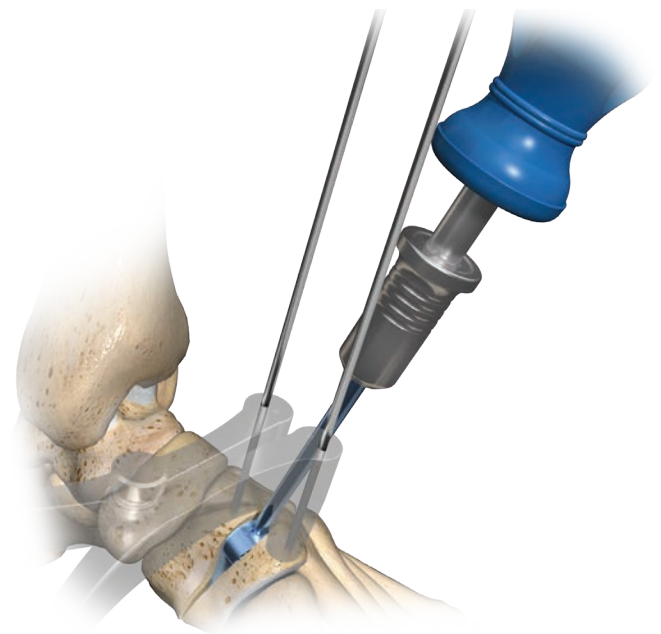


Figure 4

Reconstructive Interpositional PEEK Titanium Wedge System

Cotton Technique



Figure 5

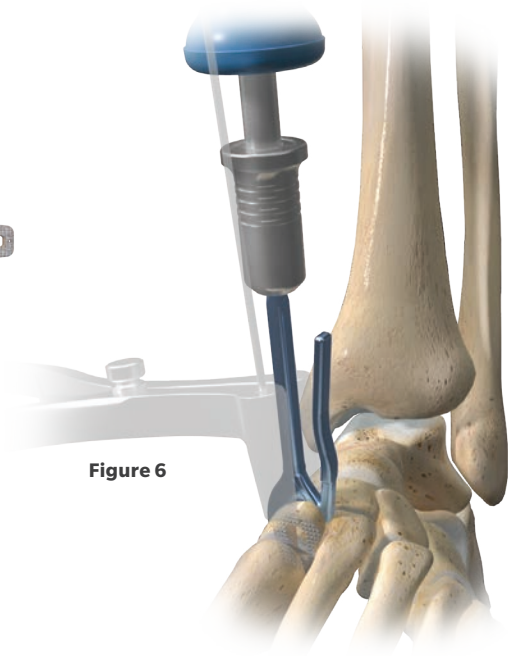


Figure 6

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 Cotton Reconstructive Wedge as determined by trial implant (Figure 5). Engagement lever facilitates attachment/detachment of wedge on inserter. Most surgeons are satisfied with the correction made with a 4 or 6 mm implant width.

Note: Inserter may be used without driver for difficult to reach locations. Use with handle is optional, but provides more stability while inserting. Place construct into osteotomy cut. Seat implant so that is slightly recessed, resting within the walls of the surrounding medial cuneiform (Figure 6).

Note: A dorsal implant prominence may cause tendon irritation. Too lateral an implant placement may rub on the middle cuneiform.

Reconstructive Interpositional PEEK Titanium Wedge System

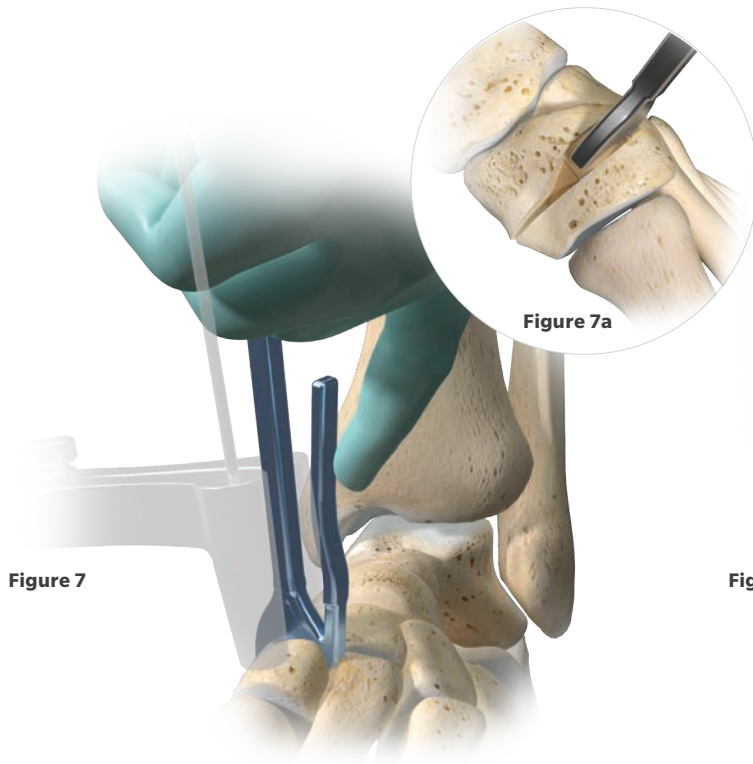


Figure 7

Check final position fluoroscopically: 1) ensure far cortex is not compromised and 2) 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 squeezing the engagement lever against the holder (Figure 7).

Note: If additional fine tuning of implant positioning is needed, utilize tamp (Figure 7a).

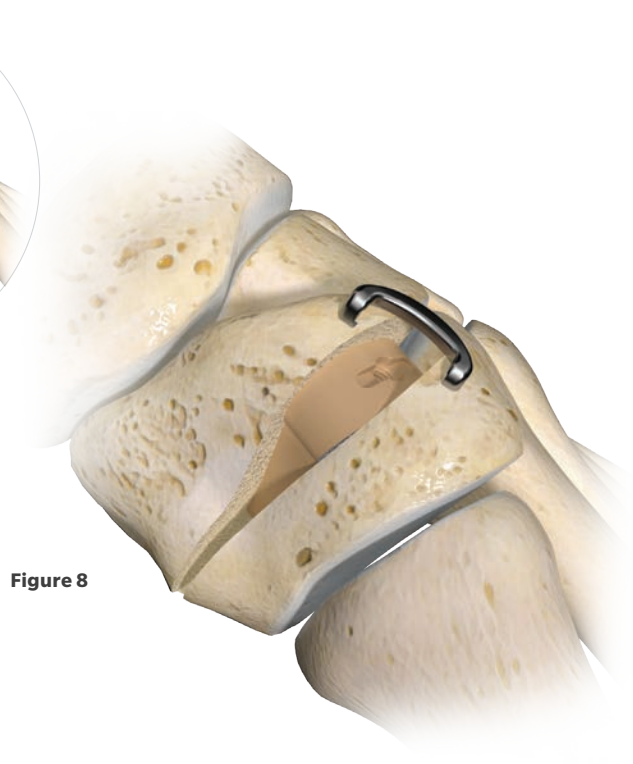


Figure 8

Ancillary Fixation with Staple

Ancillary fixation is required when using the RIPTIDE Wedge System (Figure 8). Refer to the Zimmer Biomet Arcus® Staple System Surgical Technique (LIT-1526 Rev. 05) for a detailed protocol.

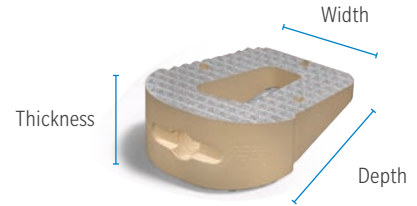
Wound Closure and Post Operative Care







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

Reconstructive Interpositional PEEK Titanium Wedge System

Implants

RIPTIDE Wedge System implant sizing
Cotton Wedges



Footprint Image	Part Number	Width (mm)	Depth (mm)	Thickness (mm)	Thickness Image
 *	6ZBZC1504 6ZBZC1506 6ZBZC1508	15	15	4 6 8	 ** 4mm
 *	6ZBZC2004 6ZBZC2006 6ZBZC2008	15	20	4 6 8	 ** 6mm
 *	6ZBZC2506 6ZBZC2508	15	25	6 8	 ** 8mm

* Images shown at actual size

** Image shown at actual sizes for part numbers 6ZBZC2004, 6ZBZC2006, 6ZBZC2008

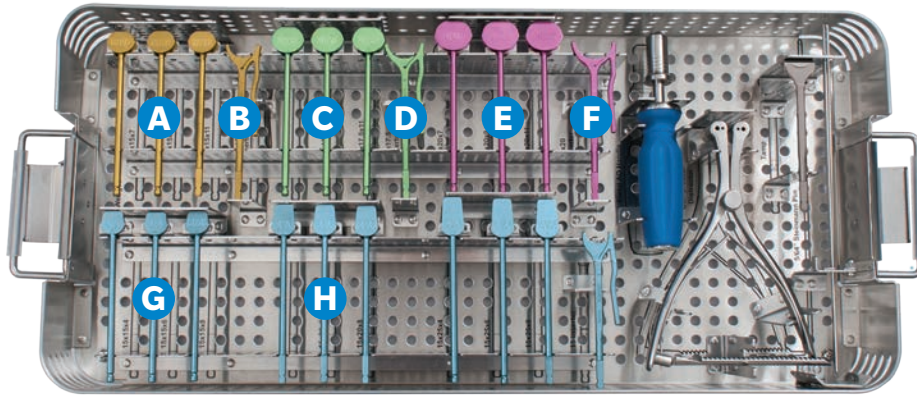
Tyber Medical is the legal manufacturer for the RIPTIDE Cotton Wedges.








Explant Information

Remove the ancillary fixation using the appropriate instrumentation for the fixation device. Use forceps, or other desired general instruments to pull the wedge out. If necessary use a saw and a small blade to cut along the surface of the wedgebone interface to free the wedge from the bone.

Reconstructive Interpositional PEEK Titanium Wedge System

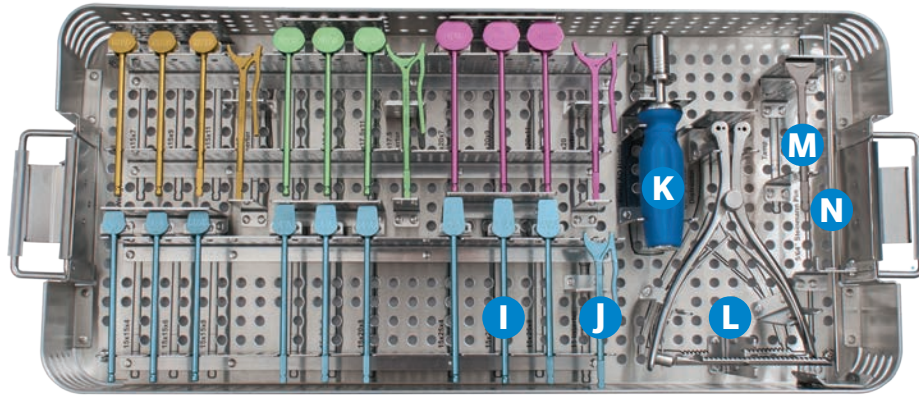
Instruments









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

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.

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