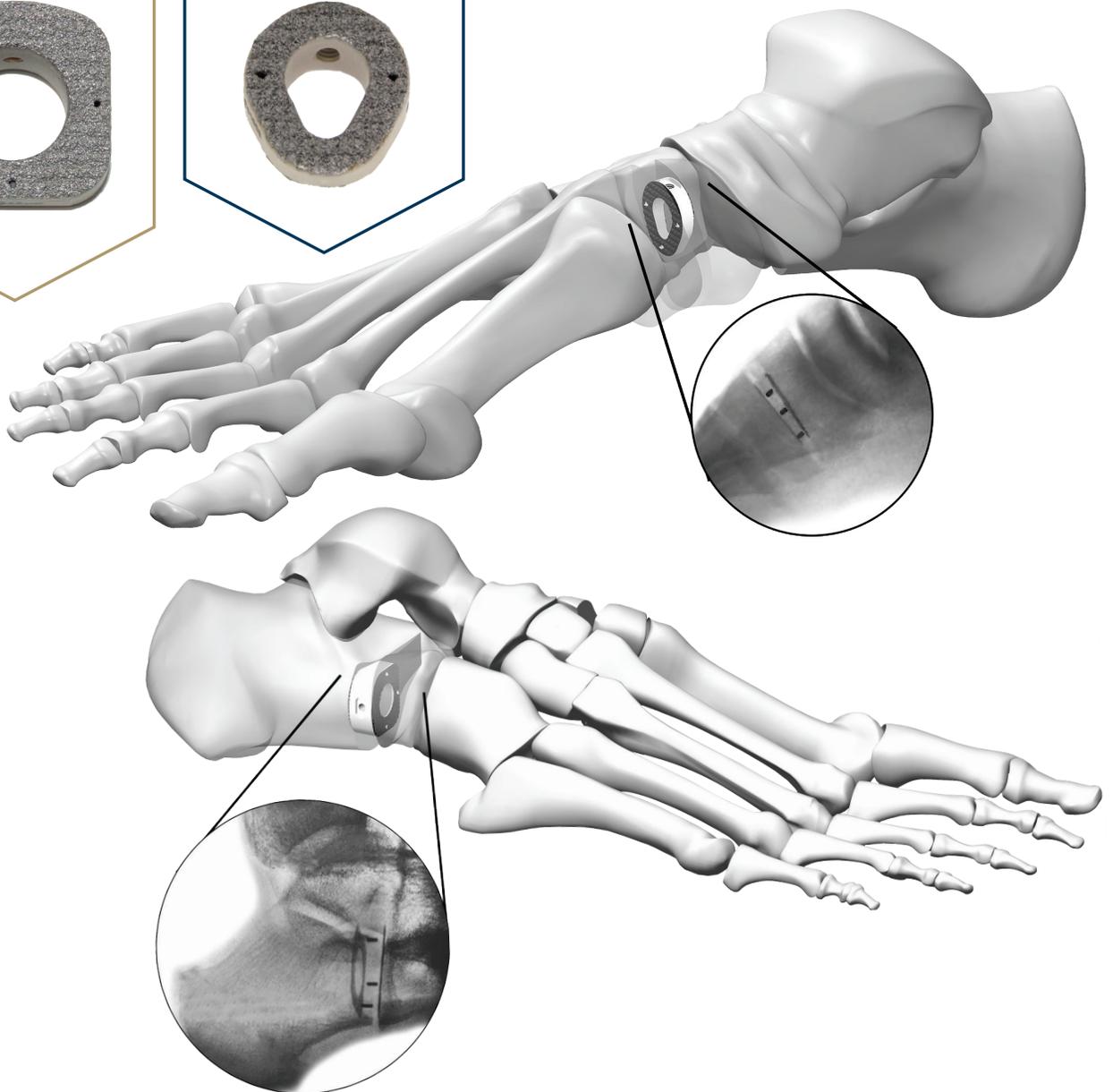


TiPEEK FOOT OSTEOTOMY WEDGE SYSTEM

EVANS PROCEDURE



COTTON PROCEDURE



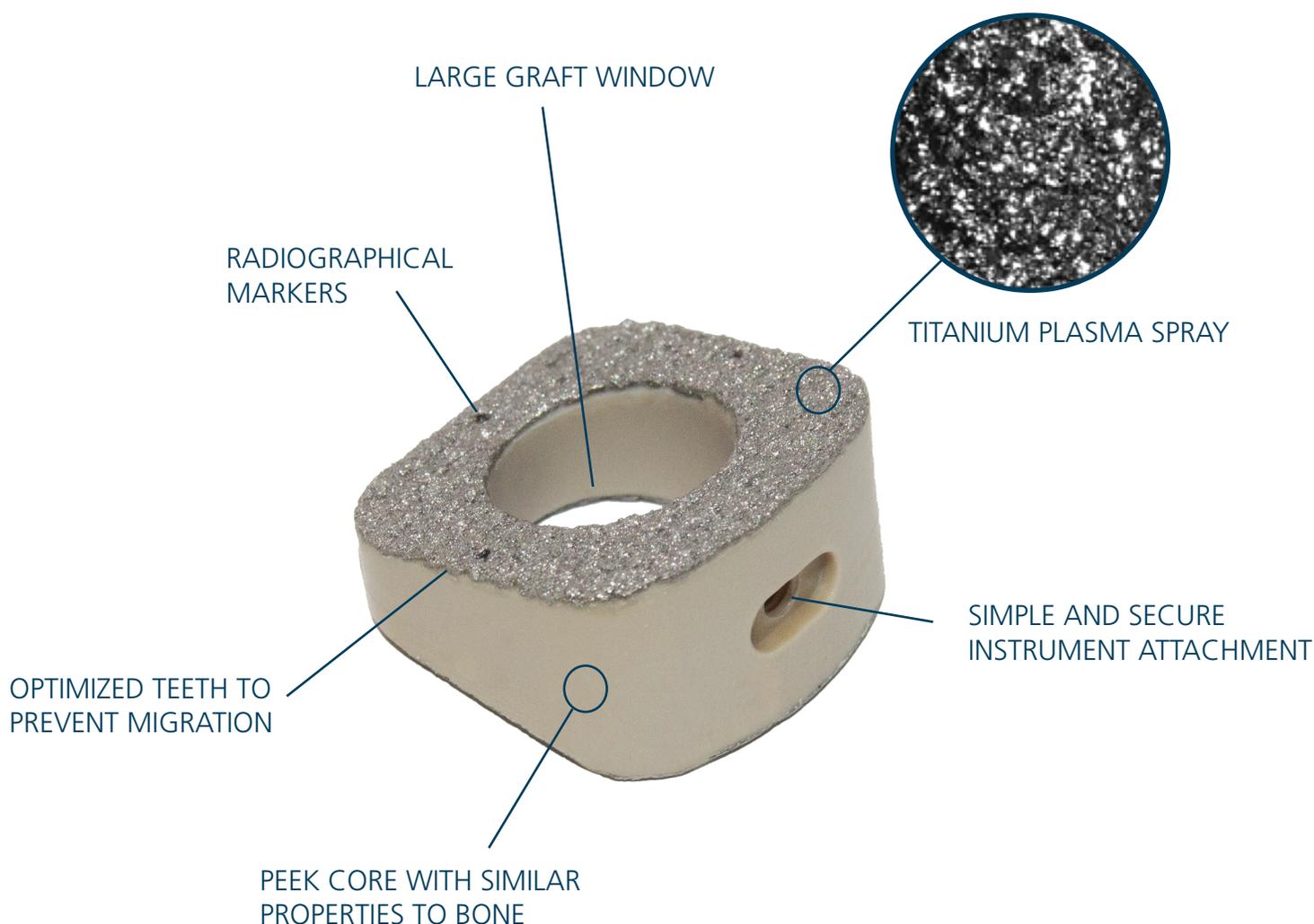
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FEATURES AND BENEFITS

Design Rationale

DePuy Synthes introduces the first and only Titanium plasma sprayed PEEK Cotton and Evans Wedge specifically indicated for fusion. A hybrid design for enhanced visualization, dynamic load sharing capabilities, and rapid osseointegration. The ability to assess fusion status with simple radiographic means as well as clinical issues of delayed union, loss of correction, and device subsidence remain a significant concern for surgeons.¹ The TiPEEK foot wedge implant is an effective alternative to titanium-alloy wedge implants with added radiolucent and biomechanical advantages.



1. Walsh WR; Bertollo N, Christou C. Plasma-sprayed titanium coating to polyetheretherketone improves the bone-implant interface. *The Spine Journal* 2015; 1041-1049

TiPEEK System Indications

The TiPEEK Foot Osteotomy Wedge System is intended to be used for internal bone fixation for bone fractures, fusions, or 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 bone of the foot including osteotomies for Hallux Valgus
- Nonunion of arthrodesis of the Midfoot including Metatarsal/Cuneiform arthrodesis (TMT or Lapidus)

This device is intended for use with ancillary fixation.

The TiPEEK Foot Osteotomy Wedge System is not intended for use in the spine.

CAUTION

Federal Law (USA) restricts this device to sale by or on the order of a physician.

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

WARNING AND POTENTIAL RISKS

The surgeon should be aware of the following:

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. The size and shape of the human foot presents limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
2. The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including from corrosive environments. They should be carefully unpacked and inspected for damage prior to use.
3. All instruments must be cleaned and sterilized prior to surgery.
4. As with all orthopaedic implants, TiPEEK Foot Osteotomy Wedge Implants should never be reused under any circumstances.
5. The TiPEEK Foot Osteotomy Wedge System should never be used with dissimilar materials.
6. Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.
7. Postoperative care is important. The patient should be instructed in the limitations of his/her implant and should be cautioned regarding weight bearing and body stress on the appliance prior to secure bone healing.

PRECAUTIONS

Preoperative:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or pre-dispositions such as those addressed in the Contraindications Section should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. All instruments should be cleaned and sterilized before use.

Intraoperative:

1. Any instruction manuals should be carefully followed.

Postoperative:

1. The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
2. Detailed instructions on the use and limitations of the device should be given to the patient. The risk of bending, loosening, or breakage of an internal fixation device during post-operative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented.
3. To allow maximum chances for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the healing process.
4. If a nonunion develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the foot surgical site be maintained until firm bony union is established and confirmed by radiographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, none of the TiPEEK Foot Osteotomy Wedge System Device components should ever be reused under any circumstances.

STEP 1 - Osteotomy

A skin incision is made and the soft tissues are dissected and retracted providing the desired visualization of the bony anatomy.

Using the oscillating saw create the osteotomy cut. A transverse osteotomy on the dorsal surface of the medial cuneiform aligned toward the deep plantar cortex is shown (Figure 1a) for a Cotton Osteotomy. Anatomical correction is achieved by fully distracting the osteotomy site 4.5-6.5mm.

The Wedge System includes implants for Evans Osteotomies (Figure 1b). An Evans cut would be performed along the calcaneus, beginning 10-15mm proximal to the calcaneal-cuboid joint. Proper distraction of the osteotomy space is 8-12mm.

NOTE

When performing the osteotomy, do not cut completely through the distal cortex.

The Wedge System can be used for other opening wedge indications in the foot.

A provisional K-Wire or pin can be used across the osteotomy site to maintain the opening.

NOTE

The Distractor and the TiPEEK Foot Osteotomy Wedge System Trials should be used to open the osteotomy bone space.

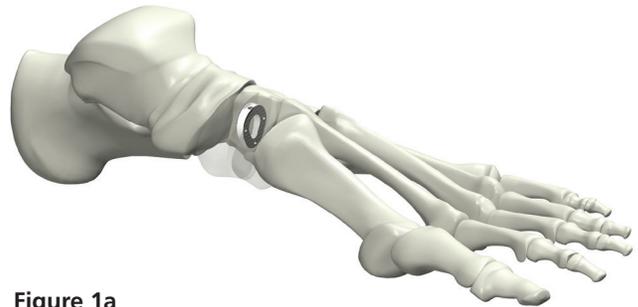


Figure 1a

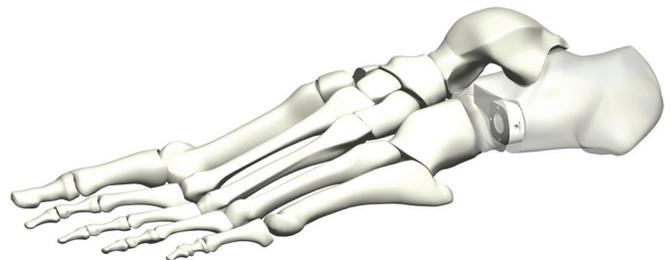


Figure 1b

DETERMINE IMPLANT SIZE

STEP 2 - Trial Implant

Attach the appropriate sized trial to the inserter using two-finger tightness to seat the instruments (Figure 2a). Exchange trials until the correct size is found that fits in the osteotomy space and a height that provides ideal angular bone correction. Make sure the wedge trial sits flush against the bone space to ensure the final placement of the implant is in an optimal position for osseointegration and bone growth (Figure 2b).

Carefully insert the trial into position within the bone space. Confirm positioning with Fluoroscopy (Figure 2c and 2d).

Repeat the trial process until the desired full amount of distraction is achieved within the osteotomy bone space.



Figure 2a

NOTE

Trials are offered in identical heights and increments as the TiPEEK Foot Osteotomy System. The implants should match the trial size.

NOTE

The trials are not for implantation and must be removed before inserting the implant.

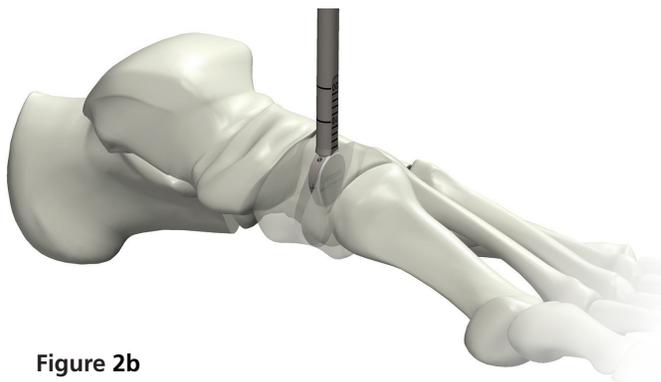


Figure 2b

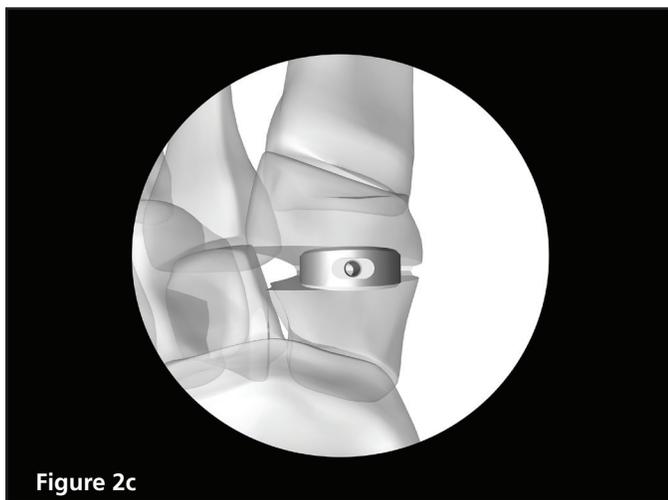


Figure 2c

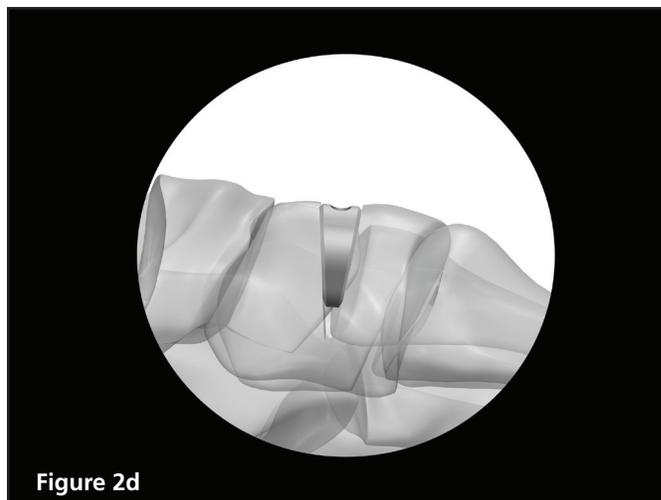


Figure 2d

STEP 3 – Implantation

Attach the appropriate implant size to the inserter, ensuring the inserter is in line with the threaded hole and does not cross thread. Rotate the inserter clockwise until the implant is two-finger tight and seated (Figure 3a).

Fully seat the implant on the inserter tip to ensure the device functions properly and do not over tighten (Figure 3b).



Figure 3a

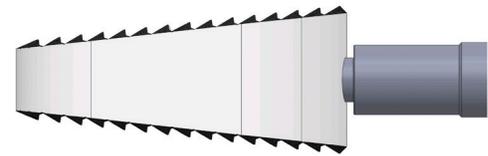
NOTE

The graft window in the implant may be used for the addition of biologic or graft material at the surgeon's discretion. The tamp may be used for graft packing.

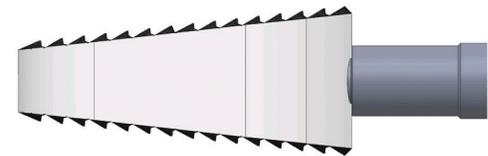
Implant Insertion:

Insert the implant with the straight rod inserter using gentle force to the desired position within the osteotomy space (Figure 3c). Additional distraction should be used to help seat the implant. Disengage the inserter and use the tamp to fine-tune the implant into the final position.

When impacting the implant, care should be taken to ensure that the broad surface of the tamp is fully seated against the implant.



UNSEATED IMPLANT VIEW



SEATED IMPLANT VIEW

Figure 3b

NOTE

Do not use excessive force on straight rod inserter. Use the V-tamp for final positioning and impaction.

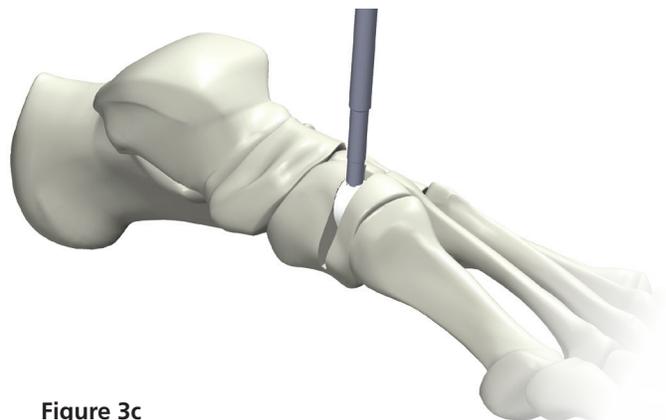


Figure 3c

INSERT WEDGE

STEP 3 (cont'd) – Implantation

Verify final positioning with Fluoroscopy (Figure 3d & 3e). Repeat the position process with the tamp as necessary.

The implants position can be fine-tuned with the tamp. When impacting the implant, care should be taken to ensure that the broad surface of the tamp is fully seated against the implant.

STEP 4 - Supplemental Fixation

Additional fixation can be achieved with a staple, compression screw system 3.0mm in diameter or larger, or with a peanut, t or h plate that is 1.5mm in thickness or greater. Positioning of the plate over the osteotomy site can be seen in Figure 4. Ancillary fixation should be completed so that it does not come in contact with the TiPEEK Foot Osteotomy Wedge Implant. To remove the ancillary screw/plate, use the same system specific instrumentation used to implant the device.

Removal

To remove the implant distract the bone space using the distractor and re-engage the straight rod inserter with the implant. Apply the necessary force to remove the implant from the osteotomy space.

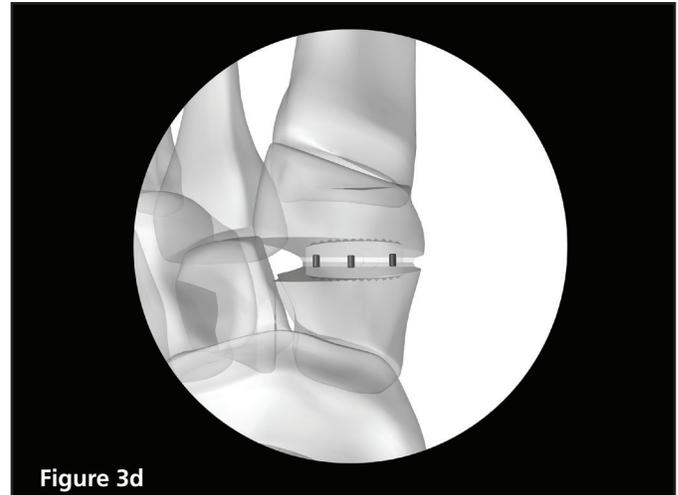


Figure 3d

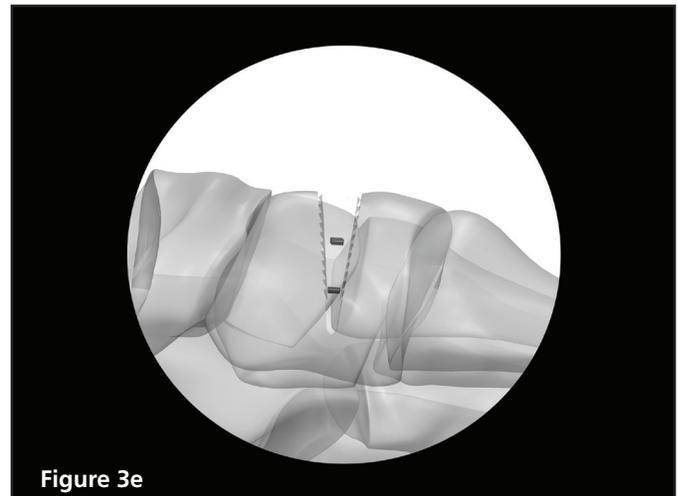


Figure 3e

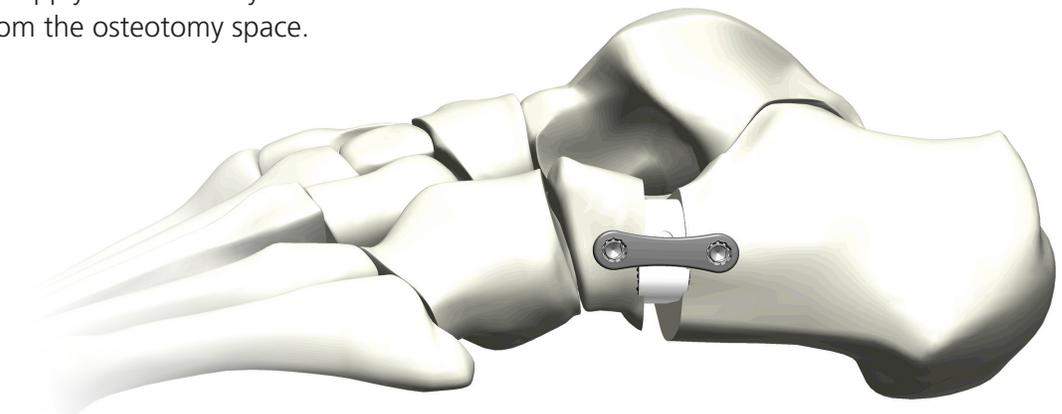


Figure 4

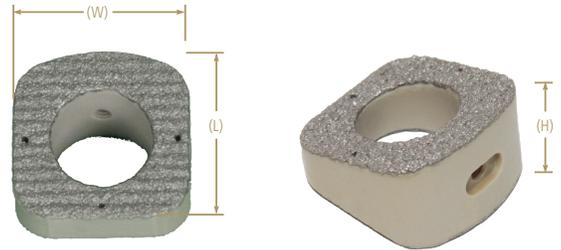
EVANS

HEIGHT**	18 (L) X 18 (W)**	20 (L) X 20 (W)**	22 (L) X 22 (W)**
8	08.844.108S	08.844.208S	08.844.308S
10	08.844.110S	08.844.210S	08.844.310S
12	08.844.112S	08.844.212S	08.844.312S

**SIZES IN MILLIMETERS
ALL TIPEEK IMPLANTS ARE PACKAGED STERILE

Approximate Autograft Volume

HEIGHT	18 X 18	20 X 20	22 X 22
8	0.51 cc	0.74 cc	1.00 cc
10	0.59 cc	0.85 cc	1.15 cc
12	0.67 cc	0.96 cc	1.31 cc



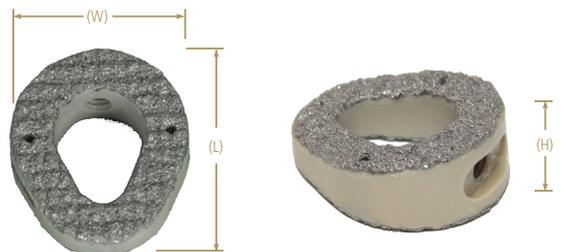
COTTON

HEIGHT**	16 (L) X 14 (W)**	20 (L) X 14 (W)**
4.5	08.844.104S	08.844.204S
5.5	08.844.105S	08.844.205S
6.5	08.844.106S	08.844.206S

**SIZES IN MILLIMETERS
ALL TIPEEK IMPLANTS ARE PACKAGED STERILE

Approximate Autograft Volume

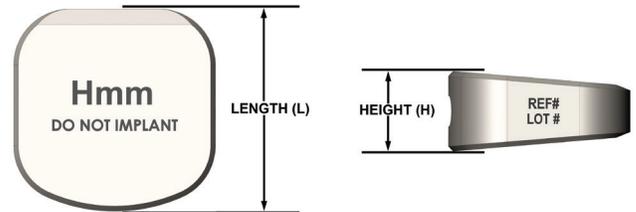
HEIGHT	16 X 14	20 X 14
4.5	0.17 cc	0.25 cc
5.5	0.20 cc	0.27 cc
6.5	0.22 cc	0.31 cc



INSTRUMENTS

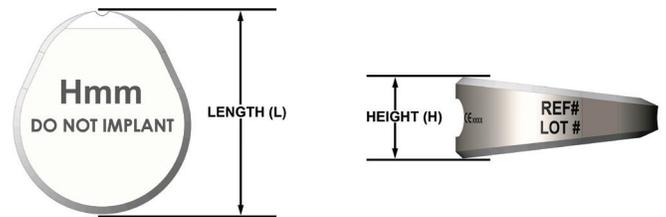
EVANS TRIALS

CODE	DESCRIPTION
03.844.108	Evans 18 x 8mm Trial
03.844.110	Evans 18 x 10mm Trial
03.844.112	Evans 18 x 12mm Trial
03.844.208	Evans 20 x 8mm Trial
03.844.210	Evans 20 x 10mm Trial
03.844.212	Evans 20 x 12mm Trial
03.844.308	Evans 22 x 8mm Trial
03.844.310	Evans 22 x 10mm Trial
03.844.312	Evans 22 x 12mm Trial



COTTON TRIALS

CODE	DESCRIPTION
03.844.104	Cotton 16 x 4.5mm Trial
03.844.105	Cotton 16 x 5.5mm Trial
03.844.106	Cotton 16 x 6.5mm Trial
03.844.204	Cotton 20 x 4.5mm Trial
03.844.205	Cotton 20 x 5.5mm Trial
03.844.206	Cotton 20 x 6.5mm Trial



INSTRUMENTATION

CODE	DESCRIPTION
03.844.150	Straight Rod Inserter 
03.844.151	"V" Tamp 6" 
03.844.152	Hintermann Distractor 
03.844.153	02.4mm Pin (6") 
01.844.100	Wedge Instrument Set
60.844.100	Wedge Instrument Graphic Case

STERILIZATION

The TiPEEK Foot Osteotomy Wedge Implant is provided sterile. All sterile implants will be clearly marked "STERILE". The sterile implant is gamma radiation sterilized. The package should be inspected prior to use to ensure the sterile barrier has not been compromised. Do not re-sterilize. Where specified, do not use the device after expiration date.

The TiPEEK Foot Osteotomy Wedge instrumentation is provided non-sterile and must be cleaned and sterilized prior to use.

Consult the DePuy Synthes Wedge Package Insert for cleaning and sterilization instructions.

Indications for Clinical Use:

TiPEEK System Indications

The TiPEEK Foot Osteotomy Wedge System is intended to be used for internal bone fixation for bone fractures, fusions, or 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 bone of the foot including osteotomies for Hallux Valgus
Nonunion of arthrodesis of the Midfoot including Metatarsal/Cuneiform arthrodesis (TMT or Lapidus)

This device is intended for use with ancillary fixation.

The TiPEEK Foot Osteotomy Wedge System is not intended for use in the spine.

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