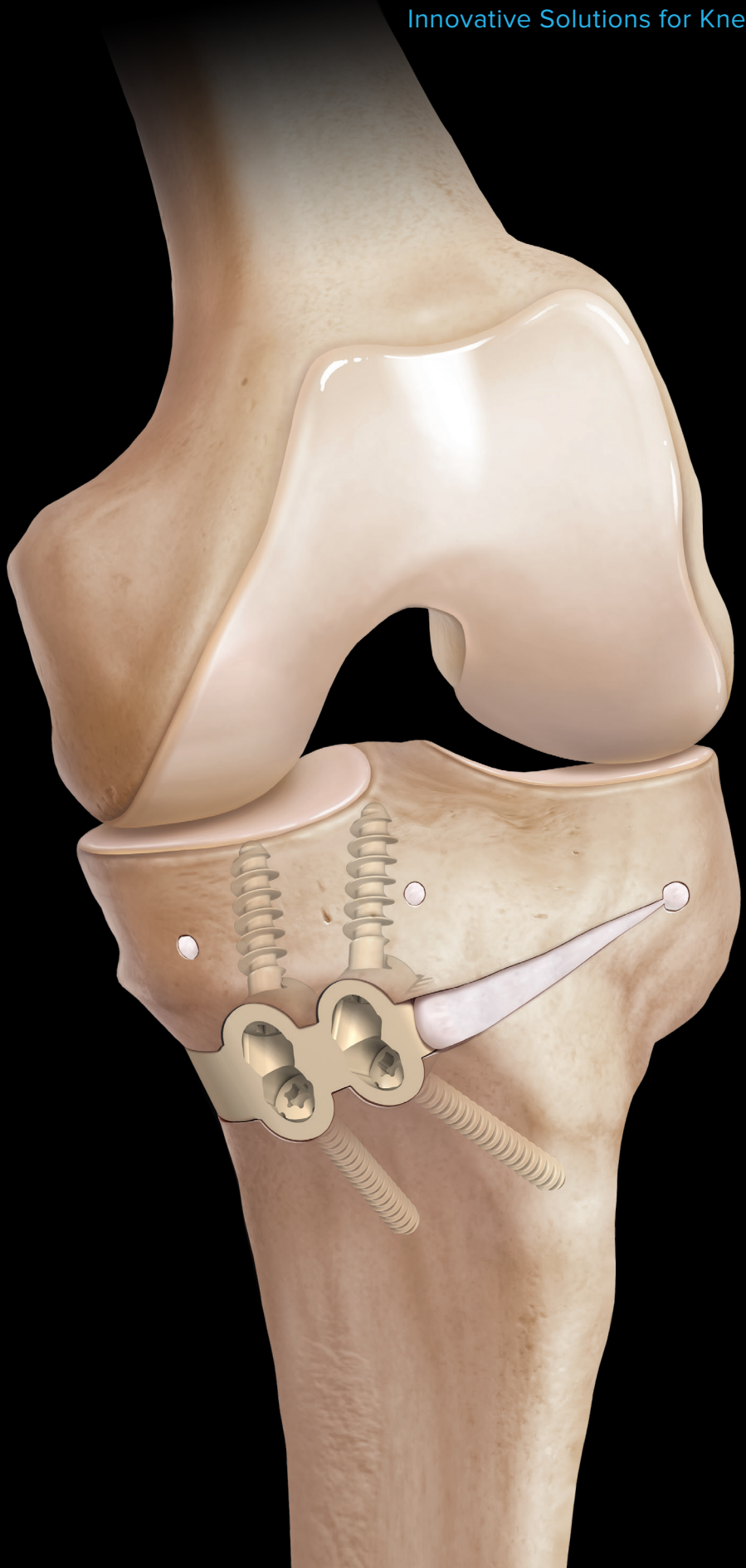
iBalance® High Tibial Osteotomy (HTO) System

Innovative Solutions for Knee Realignment

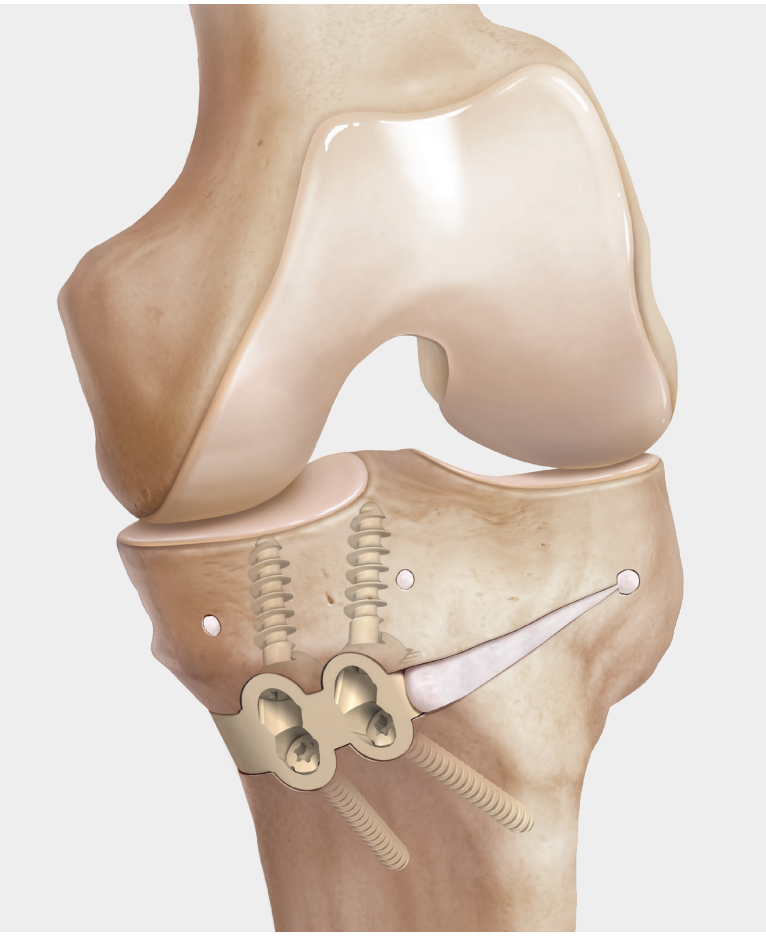


HTO Medial Peek Implant

A Proven, Leading-Edge Solution for High Tibial Osteotomies

The iBalance® HTO medial PEEK implant creates a stable construct by supporting the osteotomy opening along the posterior/medial and anterior/medial cortices of the tibia. The implant's construct, coupled with a very substantial lateral bone bridge provided by the hinge pin, promotes postoperative stability. Therefore, during load bearing, the tibial plateau is not allowed to rotate posteriorly (ie, decrease A/P slope) or anteriorly (ie, increase A/P slope).

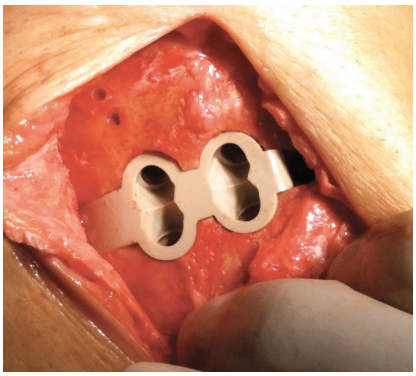
The iBalance HTO implant and anchors are intended for permanent implantation and negate the need for a second surgical procedure to remove hardware due to overlying soft-tissue irritation.



Superior Match to Cortical Bone[1]

- Implant shape distributes loading along the posterior/medial and anterior/medial cortices of the proximal tibia
  - Supporting in excess of 18 kN (+4000 lbf) in compression[2]
- Keyholes: figure-8 design

Anatomically Sized for the Patient



- Implant profile flush with bone potentially providing minimal soft-tissue irritation
- Built-in slope preserving angles
- Provides an angular solution for angular correction
- **Small** = 6˚ to 15˚
- **Medium** = 5˚ to 15˚
- **Large** = 5˚ to 15˚
- **Extra Large** = 5˚ to 14˚

Bone Growth

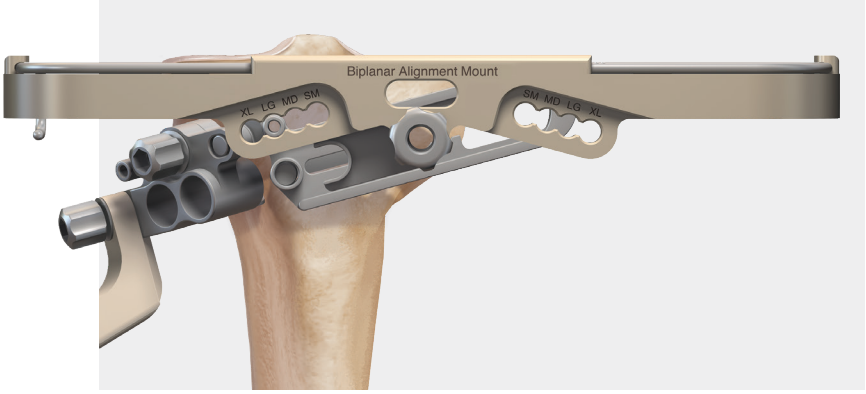
Patient: 3-years, 6-months post-op.
Konrad Slynarski, MD, PhD, CMS Clinic

- PEEK material more closely matches modulus of bone compared to metal implants[1]
- Allows microstrain transfer to stimulate new bone growth[3]
- Intended for permanent implantation and facilitates revision to TKA
- OSferion β-TCP wedges, AlloSync™ putty, and AlloSync Pure and BoneSync™ cement can be hydrated with a biologic fluid prior to implantation. Quickset™* cement is another option that can be used to fill any remaining voids around the iBalance HTO implant.

*Quickset is a trademark of Graftys, S.A.

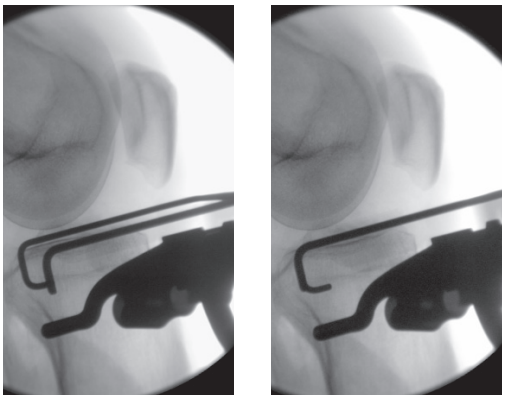
HTO Instrumentation Making a Historically Artistic Technique Guided and Reproducible

Reproducibility Through the Precision of Fluoroscopy



In conjunction with fluoroscopy, the biplanar alignment guide aligns the iBalance® HTO instrumentation to the A/P slope plane and sagittal plane of the tibia.

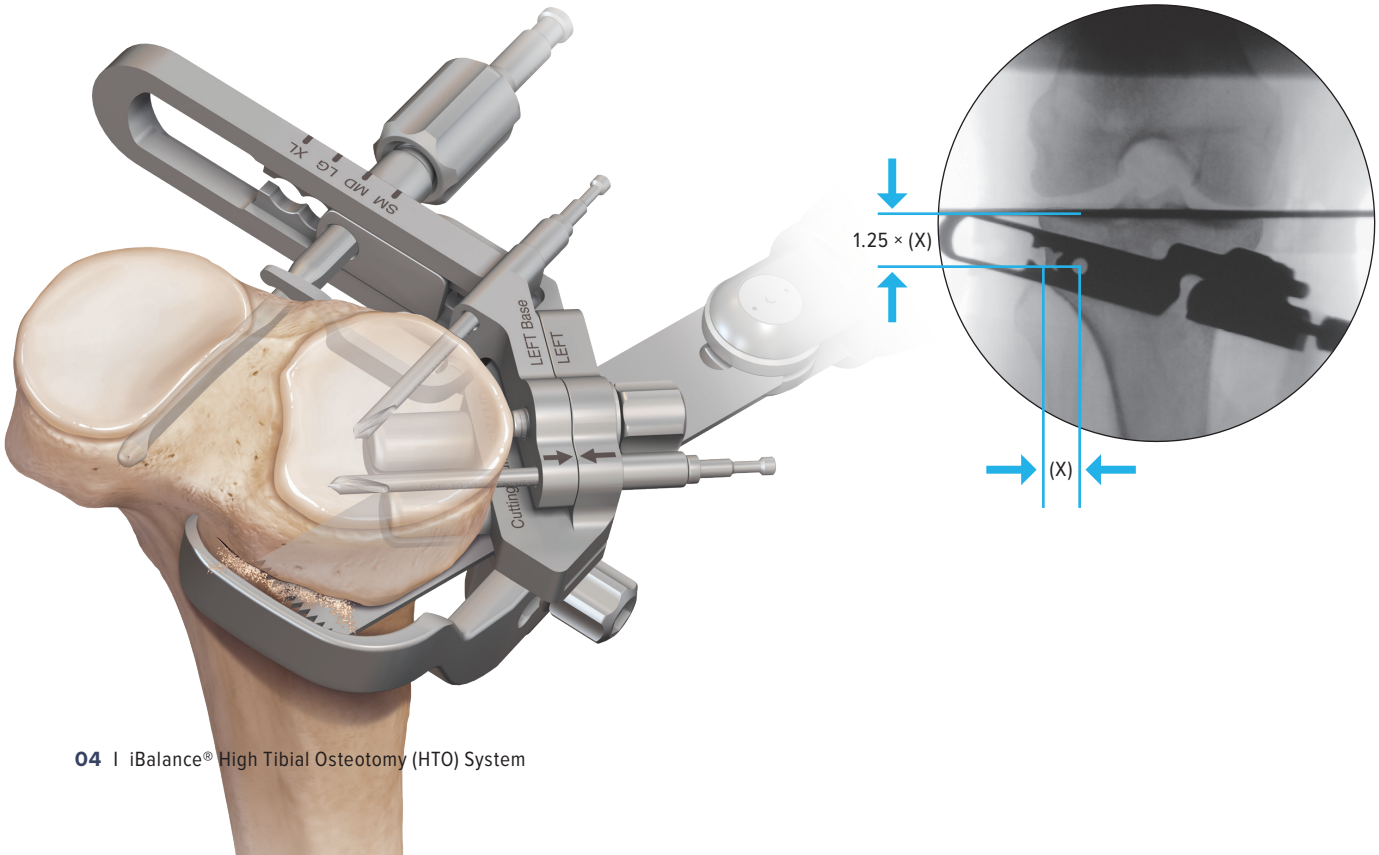
Innovative Hinge Pin



The 4.5 mm bicortical hole defines the lateral end of the osteotomy cut, acting as a stress reliever, and dramatically reduces lateral cortex fracture. The hinge pin creates lateral border of the “protective envelope” during cutting.

Minimize Risk

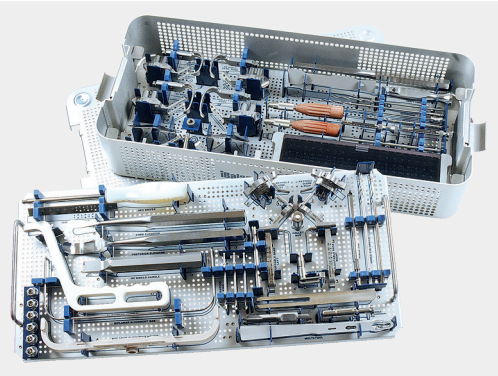
An innovative “protective envelope” (the protective bundle that protects soft-tissue structures, created by the hinge pin, the patellar tendon protector, and the NV shield) insures confident cuts with a sagittal saw. It protects/isolates all soft tissues so patellar tendon and neurovascular structures are protected.[4]



Step-by-Step Technique

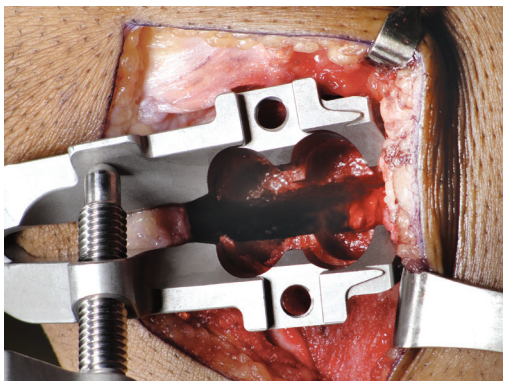
The step-by-step guided technique of the iBalance® HTO system builds surgeon confidence through reproducibility. The iBalance HTO system is ideal for any surgeon who wants to master high tibial osteotomies. Reference the surgical technique guide (**LT1-00077-EN**) for step-by-step surgical instructions.

Precision and Accuracy Yeild Predictability



- Instrumented, guided-system approach with precise cuts using a sagittal saw compared to osteotome
- Step-by-step surgical technique (**LT1-0122-EN**) references the patient's anatomy
- Guided instrumentation allows the same cut every time, making HTO reproducibility a reality

Opening Jack

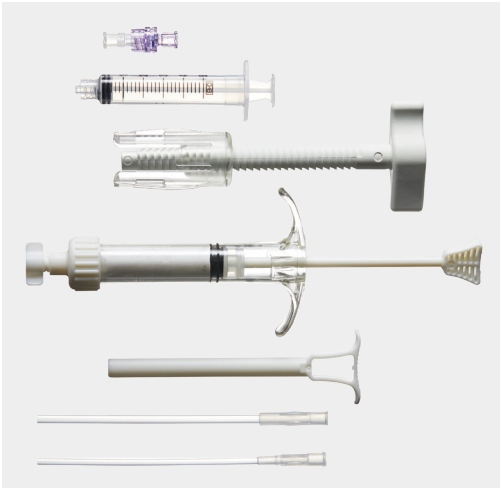


- Opens the osteotomy in a controlled manner, enabling the cortical and cancellous trabecular microstructures to relieve stress and aid in the prevention of lateral cortex macrofractures[5]
- Allows the implant to be easily seated into the osteotomy

AlloSync™ Pure Demineralized Bone Matrix

- AlloSync Pure demineralized bone matrix is derived from 100% demineralized bone with no extrinsic carriers.
- The proprietary rice-shape fiber technology used to process AlloSync Pure demineralized bone matrix increases the osteoinduction and osteoconductive surface area to accelerate cellular ingrowth.[6]
- AlloSync Pure demineralized bone matrix may be hydrated with bone marrow concentrate (BMC), platelet-rich (PRP), blood, saline, or other cellular components.

BoneSync™ Cement



- BoneSync cement is a fast-setting calcium phosphate cement that can be mixed with saline, blood, or bone marrow aspirate (BMA).
- After setting, BoneSync cement is drillable to allow additional screw placement.

Quickset™ Calcium Phosphate Cement

- The mixing system is a dual-chambered syringe containing a powder and mixing liquid.
- The powder chamber contains a mixture of calcium phosphates and an organic polysaccharide polymer; the polysaccharide is a highly biocompatible polymer that optimizes viscosity, cohesiveness, and macroporosity.
- The mixing liquid consists of a sodium phosphate solution, which facilitates the setting time (crystallization) of the Quickset cement
- The end product is a calcium-deficient apatite very similar to the mineral phase of bone.

OSferion

- OSferion is an osteoconductive bone graft substitute and bone void filler consisting of 100% beta-tricalcium phosphate (β-TCP).
- OSferion wedges are intended to be used in conjunction with the distal femoral and high tibial opening wedge osteotomy plates and screws to promote healing and provide added rigidity to the repair.
- OSferion can be easily trimmed to size using a rongeur.

AlloSync™ Putty

- AlloSync putty provides an off-the-shelf, ready-to-use bone graft that has both osteoinductive and osteoconductive properties.
- Reverse phase medium (RPM) carrier provides superior handling, allowing the graft to resist irrigation and be used in a fluid environment.
- AlloSync putty is moldable and can be packed into any defect size or shape.

Ordering Information

iBalance® HTO Instrument Set (AR-**13400S**)

Product Description	Item Number
Steel Rule, 120 mm	AR-**13410**
Cobb Elevator	AR-**13411-01**
Posterior Elevator	AR-**13411-02**
NV Shield, left, SM/MD	AR-**13412-01**
NV Shield, right, SM/MD	AR-**13412-02**
NV Shield, left, LG/XL	AR-**13412-03**
NV Shield, right, LG/XL	AR-**13412-04**
Fastener and Lock Washer	AR-**13413**
NV Shield Handle	AR-**13414**
Hex Driver	AR-**13415**
Adjustable Base, left	AR-**13416-01**
Adjustable Base, right	AR-**13416-02**
Keyhole Guide, left	AR-**13417-01**
Keyhole Guide, right	AR-**13417-02**
Alignment Handle	AR-**13418**
Hinge Pin Aimer	AR-**13419-01**
Hinge Pin Aimer, collet nut	AR-**13419-02**
Biplanar Alignment Mount	AR-**13420-01**
Biplanar Alignment Bar	AR-**13420-02**
Multitool	AR-**13421**
Fixation Pin	AR-**13422**
Tissue Protector	AR-**13423**
Hinge Pin Drill, AO connection	AR-**13424-01**
Hinge Pin Drill, chuck connection	AR-**13424-02**
Hinge Pin	AR-**13424-03**
Hinge Pin Drill Stop	AR-**13424-04**
Keyhole Reamer	AR-**13425**
Keyhole Provisional Pin	AR-**13426**
Cutting Guide, left, SM/MD	AR-**13427-01**
Cutting Guide, right, SM/MD	AR-**13427-02**
Cutting Guide, left, LG/XL	AR-**13428-01**
Cutting Guide, right, LG/XL	AR-**13428-02**
Medial Osteotome, beveled	AR-**13429-01**
Osteotome Handle	AR-**13429-02**
Opening Jack, back arm	AR-**13430-01**
Opening Jack, front arm	AR-**13430-02**
Opening Jack Fastener	AR-**13430-03**
Opening Jack Turn Key	AR-**13430-04**
Correction Guide, SM/MD	AR-**13431-01**
Correction Guide, LG/XL	AR-**13431-02**
Graft Tamp	AR-**13432**
Anchor Drill Guide	AR-**13433**
Anchor Drill, chuck connection	AR-**13434-01**
Anchor Drill, AO connection	AR-**13434-02**
Anchor Depth Gauge	AR-**13435**
Anchor Tap Guide	AR-**13436**
Cortical Bone Tap, 4.5 mm	AR-**13437**
Driver Handle	AR-**13438**
Anchor Driver	AR-**13439**
HTO Hinge Pin EM Guide	AR-**13440-01**
HTO Hinge Pin EM Guide, large	AR-**13440-02**
iBalance Instrument Case	AR-**13400C**

iBalance Implants

Product Description	Item Number
iBalance HTO Implant, SM 12˚	AR-**13400S-12**
iBalance HTO Implants, SM 6˚/MD 5˚ – SM 15˚/MD 13˚	AR-**13400M-05** – **13**
iBalance HTO Implant, MD 14˚ and 15˚	AR-**13400L-14** and **15**
iBalance HTO Implant, LG 5˚	AR-**13400L-05**
iBalance HTO Implants, LG 6˚/XL 5˚ – LG 15˚/XL 14˚	AR-**13400L-06** – **15**

iBalance Anchors

Product Description	Item Number
iBalance HTO Anchors, cancellous, 20 mm-32 mm	AR-**13401-20** – **32**
iBalance HTO Anchors, cortical, 24 mm-52 mm	AR-**13402-24** – **52**

Ordering Information (Cont)

OSferion

Product Description	Item Number
OSferion Osteotomy Wedge, 7 mm × 30 mm	AR-**13370-1**
OSferion Osteotomy Wedge, 10 mm × 30 mm	AR-**13370-2**
OSferion Osteotomy Wedge, 12 mm × 35 mm	AR-**13370-3**
OSferion Osteotomy Wedge, 15 mm × 35 mm	AR-**13370-4**
OSferion Trapezoid, 8 mm × 25 mm × 7 mm, 75˚	AR-**13372-1**
OSferion Trapezoid, 9 mm × 25 mm × 7 mm, 75˚	AR-**13372-2**
OSferion Trapezoid, 10 mm × 25 mm × 7 mm, 75˚	AR-**13372-3**

AlloSync™ Products

Product Description	Item Number
AlloSync Pure Demineralized Bone Matrix	
AlloSync Pure Demineralized Bone Matrix, 1.0 cc	ABS-**2010-01**
AlloSync Pure Demineralized Bone Matrix, 2.5cc	ABS-**2010-02**
AlloSync Pure Demineralized Bone Matrix, 5.0 cc	ABS-**2010-05**
AlloSync Pure Demineralized Bone Matrix, 10.0 cc	ABS-**2010-10**
AlloSync Putty	
CB DBM Putty, 5 cc	ABS-**2014-05**
CB DBM Putty, 10 cc	ABS-**2014-10**

BoneSync™ Cement

Product Description	Item Number
Fast-Setting Drillable Calcium Phosphate Cement, 3 cc	ABS-**3103**
Fast-Setting Drillable Calcium Phosphate Cement, 5 cc	ABS-**3105**
Fast-Setting Drillable Calcium Phosphate Cement, 10 cc	ABS-**3105-2**

Quickset™ Cement

Product Description	Item Number
Quickset Cement, 5 cc	ABS-**3005**
Quickset Cement, 8 cc	ABS-**3008**
Quickset Cement, 16 cc	ABS-**3016**

Products may not be available in all markets because product availability is subject to the regulatory approvals and medical practices in individual markets. Please contact your Arthrex representative if you have questions about the availability of products in your area.

References

1. Arthrex, Inc. LA1-00056-EN. Naples, FL; 2018.
2. Arthrex, Inc. Data on file (APT 1921). Naples, FL; 2011.
3. Carpenter RD, Klosterhoff BS, Torstrick FB, et al. Effect of porous orthopaedic implant material and structure on load sharing with simulated bone ingrowth: a finite element analysis comparing titanium and PEEK. *J Mech Behav Biomed Mater.* 2018;80:68-76. doi:10.1016/j.jmbbm.2018.01.017
4. Kim J, Allaire R, Harner CD. Vascular safety during high tibial osteotomy: a cadaveric angiographic study. *Am J Sports Med.* 2010;38(4):810-815. doi:10.1177/0363546510363664
5. Arthrex, Inc. LA0126A. Naples, FL; 2010.
6. Arthrex, Inc. LA1-000006-en-US. Naples, FL; 2019.

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