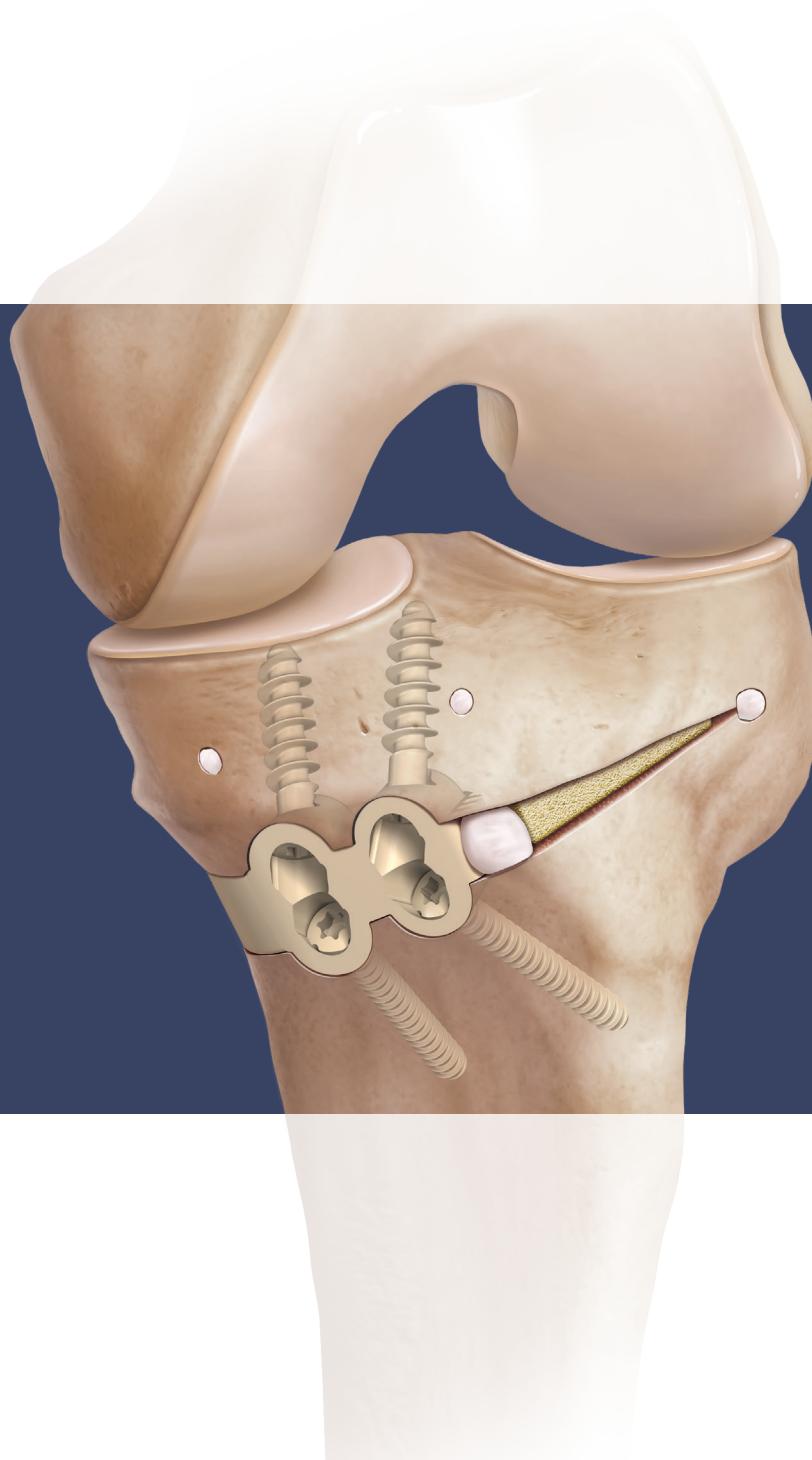


iBalance[®] HTO System

for Medial High Tibial Opening Wedge Osteotomy



Arthrex[®]

iBalance®

Implant Design Rationale

The iBalance HTO system consists of a nonabsorbable polyetheretherketone (PEEK) implant and anchors that are inserted into the proximal tibial opening wedge osteotomy site during HTO procedures to maintain and fixate the osteotomy. This is an alternative option to traditional metal plates and screws. The iBalance HTO implants and anchors are intended for permanent implantation and, in some cases, negate the need for a second surgical procedure to remove hardware

due to overlying soft-tissue irritation. The system also includes an instrument set highly specific to the implants that create a safety “envelope” with unique retractors, allowing the surgeon to create all cuts safely and reproducibly while significantly reducing chances of neurovascular injury and lateral hinge fractures. The instruments also allow for alignment of the osteotomy to the sagittal and coronal planes to preserve tibial slope.

Surgical Site Requirements

The surgical center is responsible for providing the following instruments and equipment for a successful procedure:

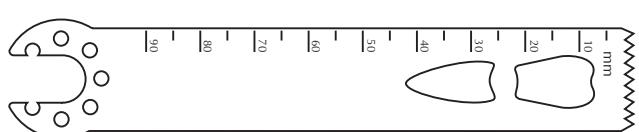
- Standard open knee surgical instrument set
- Large bone oscillating saw
- Pin driver
- Chuck drill
- Standard C-arm fluoroscope
- Oscillating saw blade

IMPORTANT: The saw blade must meet the following dimensional requirements to be used with the iBalance HTO system:

- Width: 19 mm to 20 mm
- Thickness: 1.19 mm to 1.27 mm
- Length: 85 mm (minimum)



Large Bone Drill V-600



Oscillating Saw Blade, 90 mm x 19 mm AR-600-102S

Preoperative Planning for Correction Angle and Implant Size

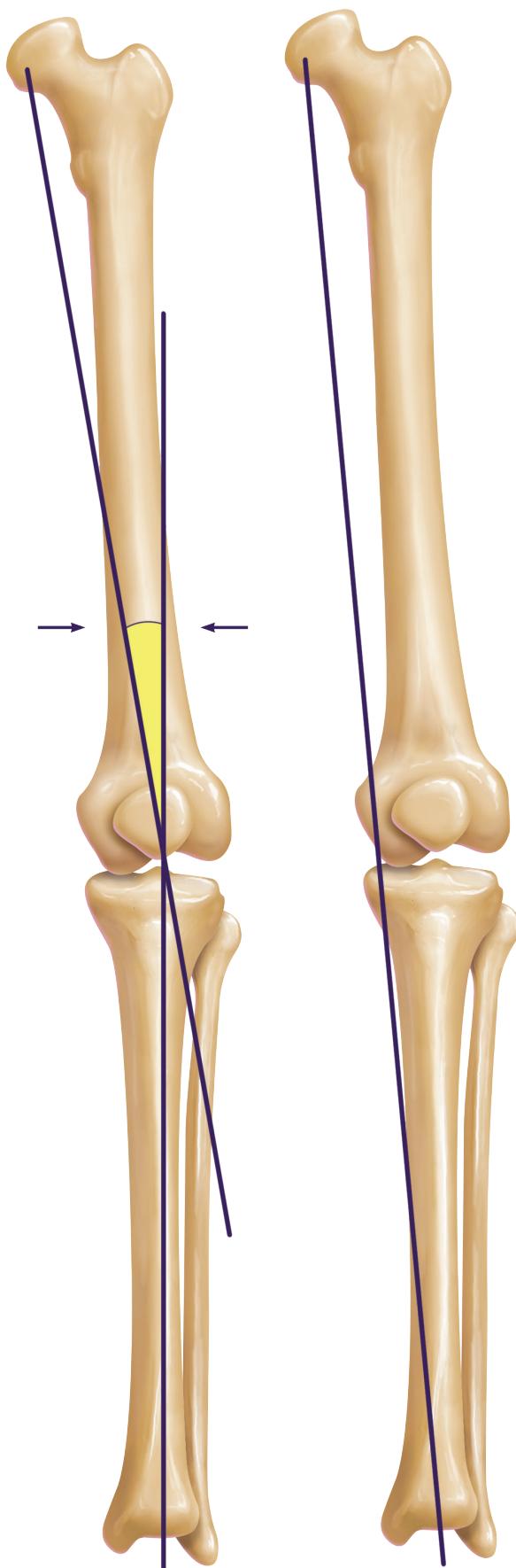
Using the full-length, standing A/P radiograph, draw a line from the center of the femoral head to the center of the tibiotar joint. This demonstrates the patient's mechanical axis. Draw another line from the center of the femoral head to a point midway in the lateral knee or a point located at the 62.5% of the width of the proximal tibia, depending on the amount of correction the surgeon is planning (ie, 80 mm [width of proximal tibia] × 0.625 = 50 mm).

Using the digital radiograph tools, the tibial width can be measured.

Estimate the iBalance® HTO system instrument size using this table:

| Small | Medium | Large | Extra Large |
|---------------|---------------|---------------|---------------|
| 64 mm - 70 mm | 70 mm - 78 mm | 78 mm - 88 mm | 88 mm - 96 mm |

| Corresponding Medial Opening | | | | |
|------------------------------|----------|----------|----------|-------------|
| Correction | Small | Medium | Large | Extra Large |
| 5° | | 6.26 mm | 6.62 mm | 7.69 mm |
| 6° | 6.26 mm | 7.25 mm | 7.69 mm | 8.76 mm |
| 7° | 7.25 mm | 8.25 mm | 8.76 mm | 9.83 mm |
| 8° | 8.25 mm | 9.25 mm | 9.83 mm | 10.90 mm |
| 9° | 9.25 mm | 10.25 mm | 10.90 mm | 11.98 mm |
| 10° | 10.25 mm | 11.25 mm | 11.98 mm | 13.05 mm |
| 11° | 11.25 mm | 12.26 mm | 13.05 mm | 14.13 mm |
| 12° | 11.25 mm | 13.26 mm | 14.13 mm | 15.21 mm |
| 13° | 12.26 mm | 14.27 mm | 15.21 mm | 16.29 mm |
| 14° | 13.26 mm | 15.28 mm | 16.29 mm | 17.37 mm |
| 15° | 14.27 mm | 16.29 mm | 17.38 mm | |



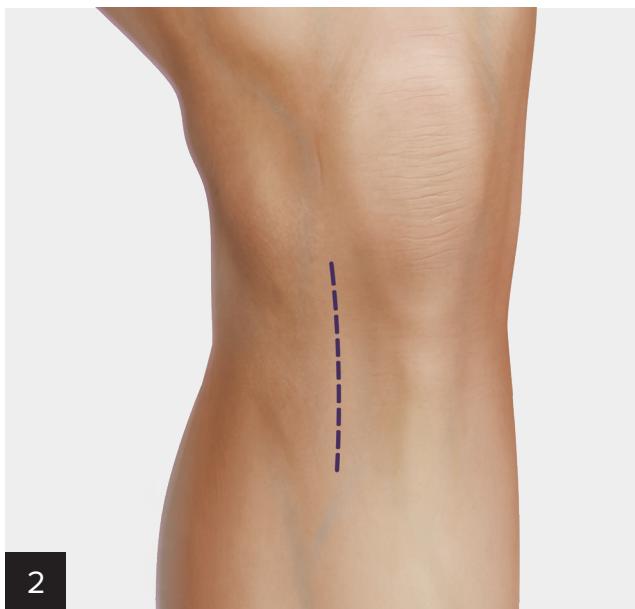
Surgical Technique



Confirm the tibial width measurement intraoperatively using AP fluoroscope imaging and the iBalance® steel rule. Obtain measurements both anterior and posterior to the proximal tibia and average the two readings for the tibial plateau width. This method provides compensation for parallax and magnification of the fluoroscope image and confirms the preoperative planning.

$$\text{Tibial width} = (\text{width anterior} + \text{width posterior}) \div 2$$

The intraoperative measurement is then used to confirm the iBalance HTO instrument and implant size: SM (small), MD (medium), LG (large), or XL (extra large) according to the table on the previous page.

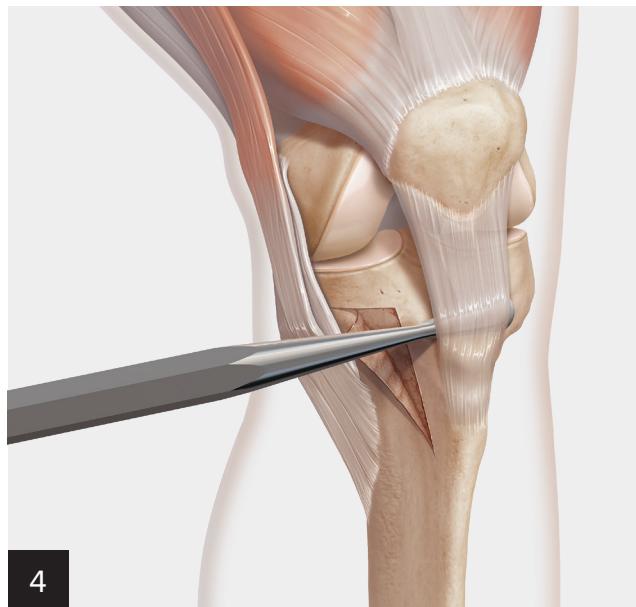


Surgical Approach: Plan a longitudinal incision midway between the tibial tubercle and the posterior border of the tibia. Start the incision just distal to the joint line and extend distally 7 cm to 9 cm.



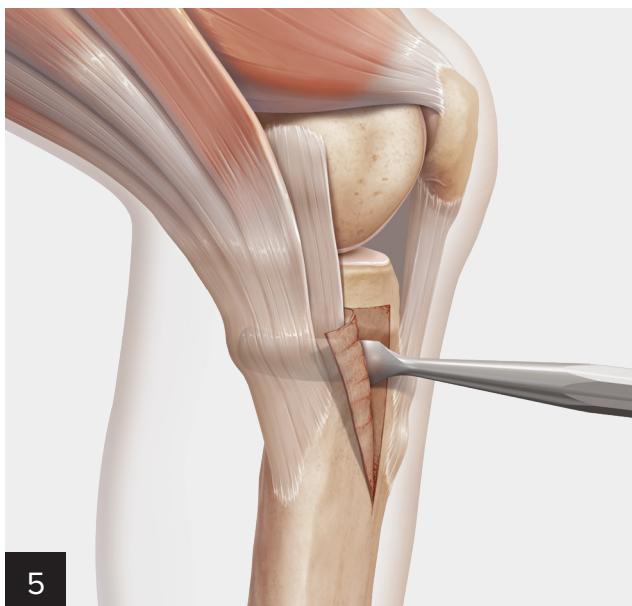
3

Clear/dissect tissue to the level of the pes/sartorius fascia. Plan an inverted L-shaped incision through the periosteum and upper aspect of the sartorius attachment on the pes anserine bursa. The inverted portion of the L-shaped incision should be at least 1 cm distal to the joint line and parallel to the tibial slope to ensure avoidance of the joint space.



4

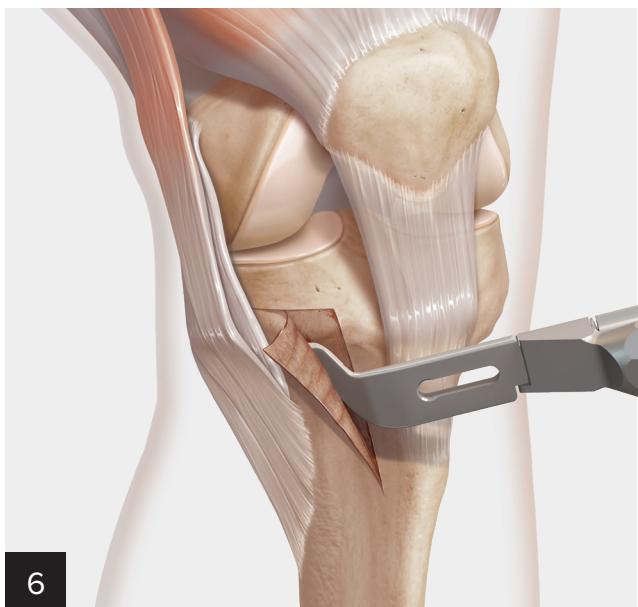
Identify the retropatellar tendon space and expose with the Cobb elevator. Partially elevate the proximal aspect of the pes anserine tendons from their distal insertion through the inverted L-shaped incision. Sharply dissect deeply to the proximal and anterior fibers of the superficial MCL. The Cobb elevator may be used to complete the dissection.



5

Advance the posterior elevator along the medial aspect of the tibia to the posterior border. Slide the tip of the elevator deep to the popliteus musculature, fascia tissue, and periosteum. From the posterior border, continue to advance the elevator deep to the popliteus musculature and toward the fibular head. When fully inserted, the elevator tip should rest under the popliteus muscle.

Remove the elevator and palpate along the posterior margin of the tibia to ensure adequate elevation of the popliteus musculature, fascia, and periosteum.



6

Assemble the NV shield and handle. Insert the NV shield through the elevated sleeve. Ensure that the tip of the NV shield remains in contact with the bone surface during the entire insertion in the same manner as used with the posterior elevator.



7

Posteriorly, direct the tip of the NV shield deep to the medial edge of the popliteus musculature and toward the fibular head. When fully inserted, the NV shield tip should rest deep to the popliteus muscle. Confirm the NV shield position is oriented approximately 15° from the tibial plateau with a radiographic image. Remove the NV shield.

Set Up the Fluoroscope as Follows

- The C-arm must approach the patient from the lateral side of the operative knee for optimal maneuverability and viewing. Support the knee in a fixed position of extension.
- Position the fluoroscope monitor such that it can be easily viewed from the operative field.
- Adjust the rotation and alignment of the image on the fluoroscope monitor such that the image corresponds to the actual positions of the femur, tibia, and anterior and posterior knee.
- Establish the lateral view by aligning the medial and lateral plateaus.
- Establish tibial rotation by aligning the posterior aspects of the medial and lateral tibial plateaus.



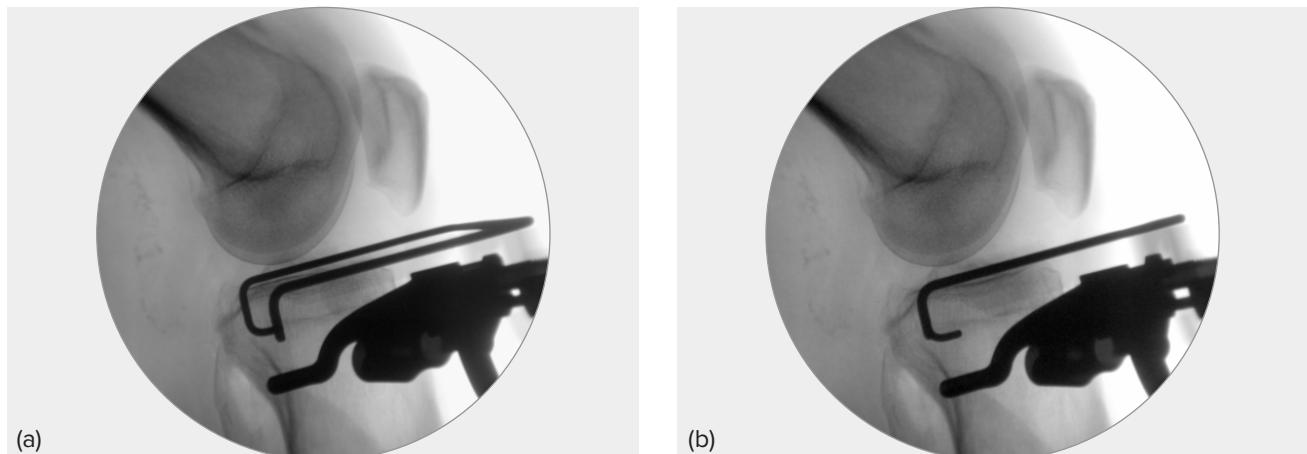
8

Assemble the adjustable base, keyhole guide, and alignment handle. Grasp the alignment handle and insert the base and keyhole guide through the incision onto the proximal tibia. Slide the patellar tendon protector (**c**) into the exposed deep infrapatellar bursa, deep to the patellar tendon, and proximal to the tibial tubercle.

Position the medial aspect locator (**a**) on the medial aspect of the tibia. Position the AM tab (**b**) onto the anteromedial surface of the tibia.

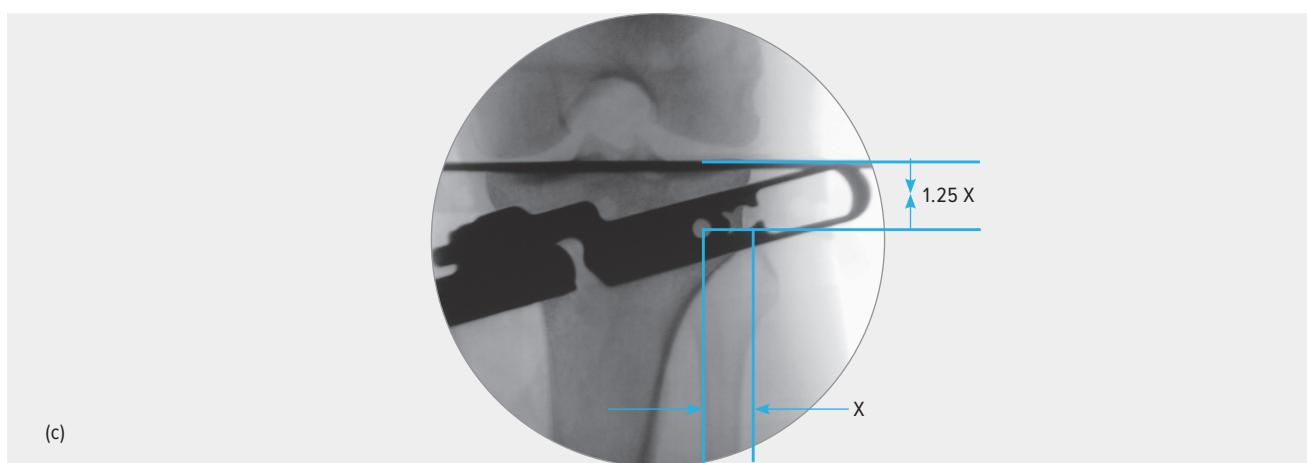
Biplanar Alignment

With fluoroscopic imaging in the lateral view, begin to adjust the alignment handle to align the biplanar alignment bar **(a)**. Align the medial and lateral arms of the alignment bar until they appear as a single bar **(b)**. Rest the “single bar” along the AP slope of the tibial plateau so it is coincident with it. Insert a fixation pin through the anterior hole in the adjustable base until the flange on the fixation pin seats against the base.



Reposition the fluoroscope to the AP view **(c)**. Check to ensure the following conditions are met:

- The medial aspect locator is directly against the medial aspect of the tibia.
- The AM tab is against the anteromedial surface of the tibia.
- The fluoroscope is aligned with the hinge pin hole (AP view) until the hole appears as a complete circle **(c)**. Confirm that the distance from the hinge pin to the lateral plateau is at least 1.25 times greater than the distance from the hinge pin to the nearest lateral cortex.



If the hinge pin hole is too close to the lateral plateau, adjust the position by rotating it around the frontal fixation pin, keeping the medial post and the AM tab in contact with bone. This will lower the hinge pin hole away from the tibial plateau.

If the hinge pin hole remains too close to the intra-articular surface, reevaluate the instrumentation size settings and return to the beginning of the biplanar alignment section. Insert a second fixation pin through the anteromedial hole in the base. Remove the alignment handle.



9

Loosen the collet nut and insert the tissue protector. Insert the hinge pin drill and check the location of the drill tip by palpating around the tip. As a general indicator of proper instrument alignment, the tissue protector should lie in a flat spot, which is just distal and slightly medial to Gerdy's tubercle. Make a small skin incision down to bone to allow clearance for the tissue protector. Push the tissue protector into place until it is seated onto the tibial surface. Tighten with the collet nut.

Using a lateral fluoroscopic view, drill the hinge pin drill into the tibia until it reaches the posterior cortex of the tibia. Insert the hinge pin drill stop and advance the drill using the incremental steps, while viewing in the lateral fluoroscopic view.



10

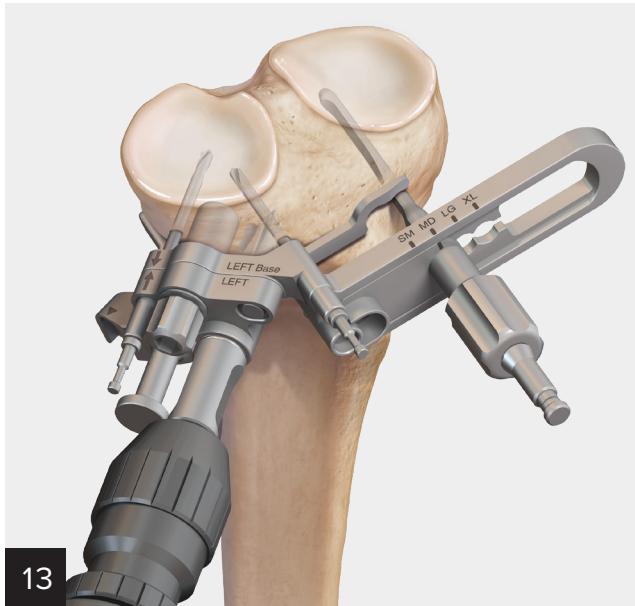
Remove the hinge pin drill, collet nut, and tissue protector. Collect bone material from the drill flutes to be mixed with other bone graft material. Insert the hinge pin until the tab on the hinge pin fully seats into the slot in the adjustable base. Remove the biplanar alignment mount and bar. Secure the hinge pin with the collet nut.



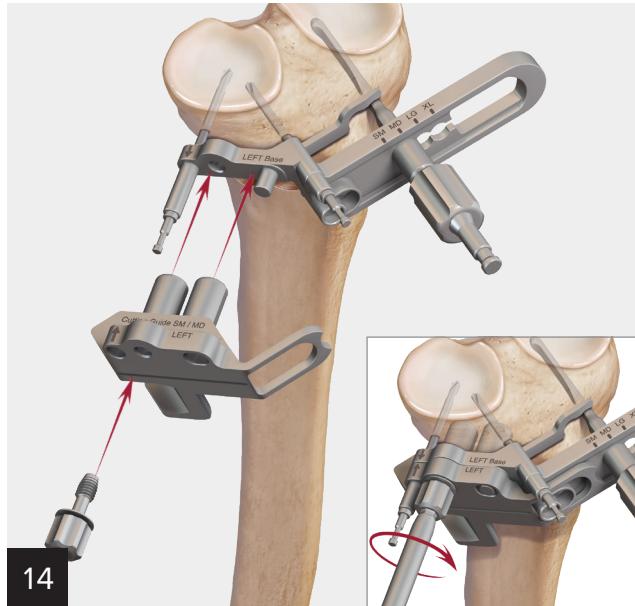
Attach the keyhole reamer to the drill chuck. Insert the keyhole reamer into the posterior hole of the keyhole guide. Drill the keyhole reamer into the tibia until it reaches the depth stop. Remove the keyhole reamer. Carefully collect and save the accumulated bone material for use in bone grafting.



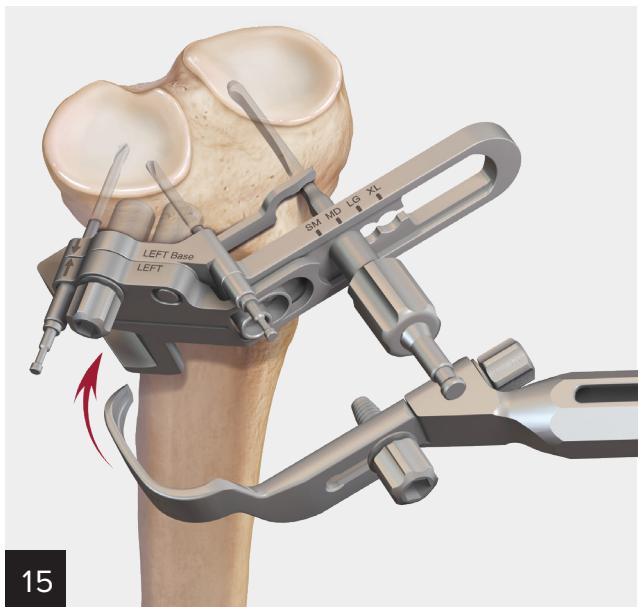
Insert the keyhole provisional pin into the drilled posterior keyhole in order to maintain alignment when drilling the second hole.



Insert the keyhole reamer into the anterior hole in the keyhole guide. Repeat drilling and bone collection steps. Remove the keyhole provisional pin and keyhole guide from the adjustable base. Clean bone debris and soft tissue from the keyholes.

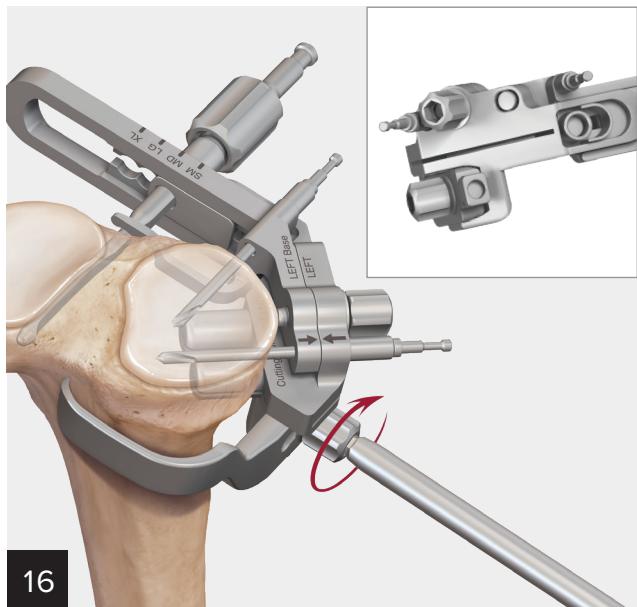


Insert a fastener into the base. Attach the cutting guide to the base by inserting the keyhole extensions on the back of the cutting guide into the drilled keyholes. Firmly tighten the fastener to the base using the hex driver.



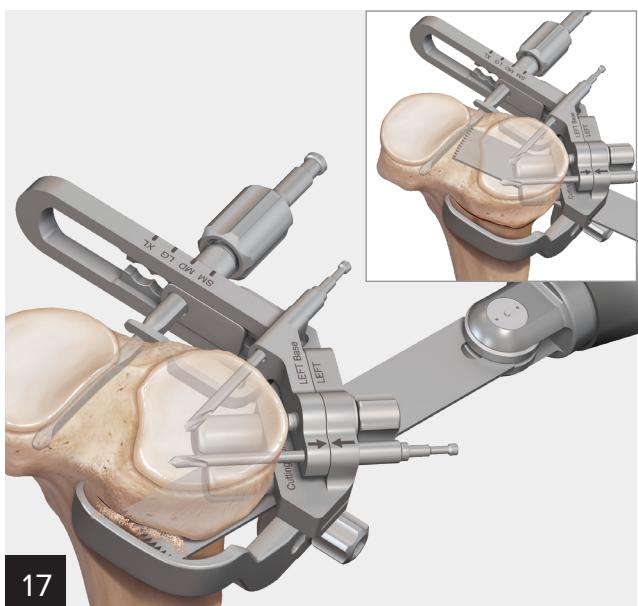
15

Insert the NV shield. Slide the tip of the NV shield along the bone surface, through the subperiosteal sleeve, and around the posteromedial corner of the tibia deep to the popliteus musculature. Aim the NV shield proximally and toward the fibular head.



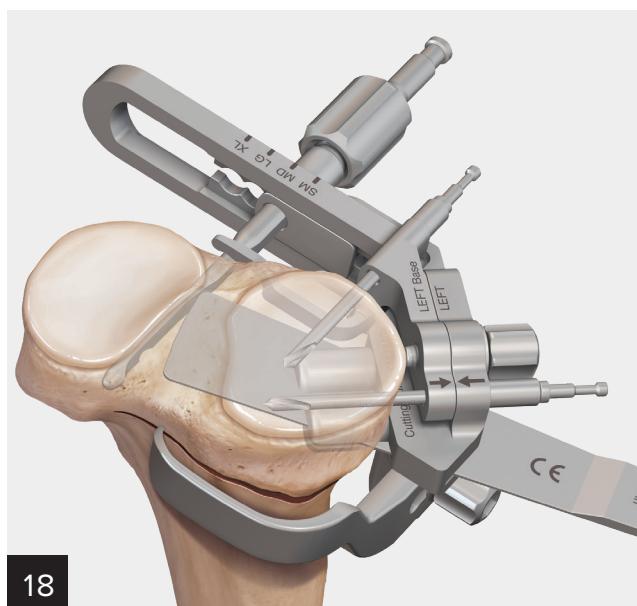
16

Seat the NV shield into the slot on the cutting guide. Attach the NV shield with a fastener into the threaded hole in the cutting guide and firmly tighten with the hex driver. Remove the NV shield handle.



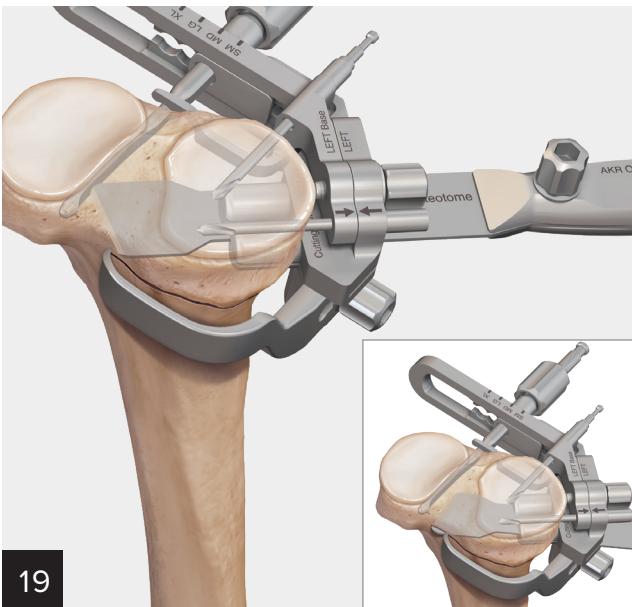
17

Assemble the oscillating saw blade to a large bone oscillating power saw. Insert the saw blade into the cutting guide slot. The saw blade should cut through all cortices and fully contact the medial aspect locator, the NV shield, the hinge pin, and the patellar tendon protector.



18

Insert the tip of the multi-tool through the cutting guide slot. Check for complete cut-through of all the cortices. Reinsert the oscillating saw (or osteotome) and cut as needed.



19

If necessary, insert the osteotome through the cutting guide slot to complete the cut on the posterolateral corner. Align the osteotome with the hinge pin and guide the cutting tip along the hinge pin to the posterolateral corner.



20

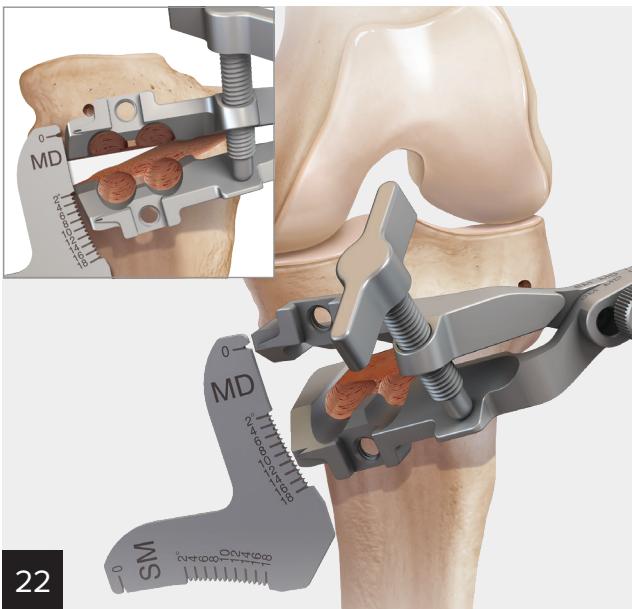
Remove the NV shield and the cutting guide. Check for complete cut-through of the osteotomy. If the osteotomy is complete, remove the collet nut, hinge pin, fixation pins, and adjustable base.

If the osteotomy is not complete, replace the cutting guide and the NV shield and complete the osteotomy. (The completed osteotomy is shown.)



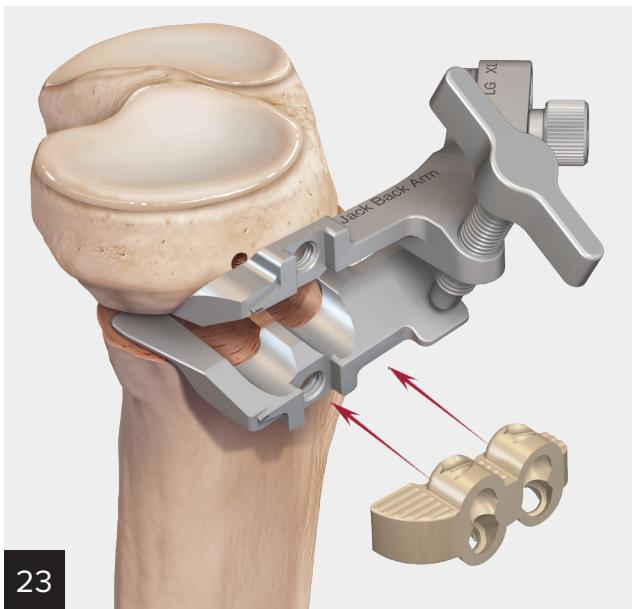
21

Insert the fully closed opening jack paddles into the osteotomy. Align the opening jack to the keyholes using the provisional pin.



Very slowly open the jack by turning the turnkey handle until the planned correction angle is noted on the correction guide. It is important to rotate the turnkey slowly over several minutes to allow for stress relaxation of the lateral cortex.

To allow for compression of graft material, for variation in accuracy, and to permit insertion of the implant, open the jack approximately 1° to 3° more. Press fit the graft material into the osteotomy using the graft tamp. Pack the graft material beyond the opening jack paddles to avoid over filling.



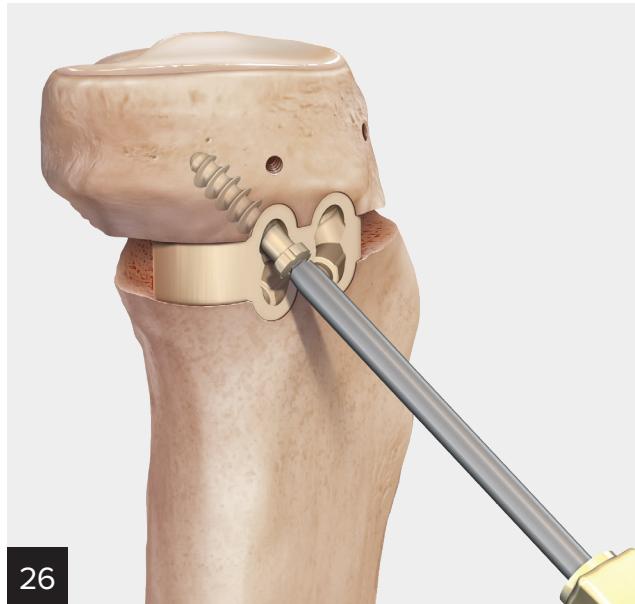
Open the sterile implant package that matches the planned correction angle. Insert the iBalance® HTO implant through the opening jack jaws into the osteotomy and keyholes.



Push in and seat the implant into the wedge and keyholes. Be sure that the implant keys fit cleanly into the drilled keyholes. Check alignment with the anteromedial and posteromedial surfaces. Disassemble and remove the opening jack components from the osteotomy, leaving the iBalance HTO implant in place.



Insert the drill guide into the posterior proximal hole of the implant so that it fits closely and the index marks and numbers are visible. Slide the anchor drill through the drill guide and drill into the tibia ensuring that the drill tip remains below the inferior chondral bone of the tibial plateau. Monitor drilling under fluoroscope imaging.



Slide the anchor depth gauge through the drill guide into the drilled hole until it bottoms out in the drilled hole. Determine the proper cancellous anchor length using the depth gauge.

Use the anchor driver to advance the cancellous anchor through the implant into bone. Tighten the anchor until the entire head just recesses below the implant surface, then advance another quarter turn. Repeat for the other proximal hole of the implant.

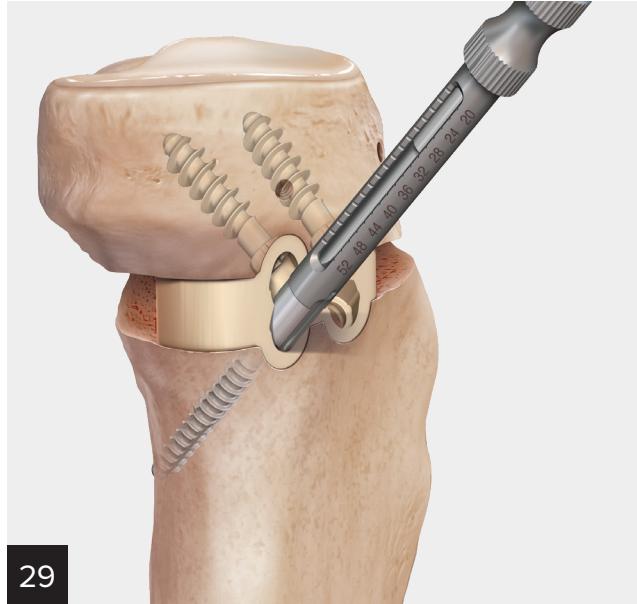


Insert the drill guide into the posterior distal hole of the implant until it fully seats. Adjust the guide until the index marks and numbers are visible. Slide the anchor drill through the guide and drill into the tibia ensuring that the drill tip passes completely through the distal cortex of the tibia.



28

Remove the drill and slide the anchor depth gauge through the drill guide and the drilled hole, hooking the distal cortex. Determine the length of the cortical anchor by selecting the closest aligned index mark on the depth gauge.



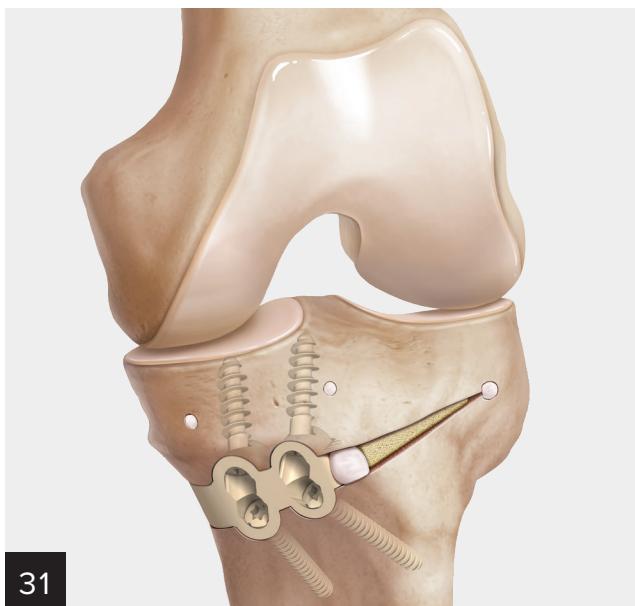
29

Remove the anchor depth gauge. Insert the tap guide into the implant and tap the drilled hole with the cortical tap to the measured depth.



30

Using the anchor driver, insert the cortical anchor through the implant into bone until it engages the far side of the cortex. Tighten the anchor until the entire head is just below the implant surface, then advance another quarter turn. Repeat the above steps for the other distal hole.



Lay the subcutaneous tissue flap over the iBalance® HTO implant and suture in place. Close and dress the knee incision. The remainder of the osteotomy can be filled with OSferion bone void filler, Quickset™* cement, BoneSync™ putty, or AlloSync™ putty.

Postoperative Protocol

- Postoperatively, fit the patient with a post-op hinged knee brace or knee immobilizer.
- The patient should remain non-weightbearing for at least 4 to 6 weeks post-op on crutches.
- Weightbearing should not begin until there is evidence of sufficient bone growth on serial radiographs.

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

Ordering Information

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

| 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 |
| Multi-Tool | 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 Turnkey | 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 |
| iBalance Instrument Case | AR-13400C |

iBalance Instrument Set 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-13400M-14 & 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 Instrument Set 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 |

Suggested Bone Substitute

| 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 |

AlloSync™ DBM Putty

| Product Description | Item Number |
|---------------------|-------------|
| DBM Putty, 1 cc | ABS-2012-01 |
| DBM Putty, 2.55 cc | ABS-2012-02 |
| DBM Putty, 5 cc | ABS-2012-05 |
| DBM Putty, 10 cc | ABS-2012-10 |

BoneSync™ Putty

| Product Description | Item Number |
|---------------------|-------------|
| Putty, 2.5 cc | ABS-3202 |
| Putty, 5 cc | ABS-3205 |
| Putty, 10 cc | ABS-3210 |
| Putty, 15 cc | ABS-3215 |

Arthrex Quickset™ Kits

| Product Description | Item Number |
|---------------------|-------------|
| Kit, 5 cc | ABS-3005 |
| Kit, 8 cc | ABS-3008 |
| Kit, 16 cc | ABS-3016 |

Ordering Information (Cont)

iBalance® Implants

| Product Description | Item Number |
|-------------------------------------|--------------|
| iBalance HTO Implant, SM 12° | AR-13400S-12 |
| iBalance HTO Implant, SM 6°/MD 5° | AR-13400M-05 |
| iBalance HTO Implant, SM 7°/MD 6° | AR-13400M-06 |
| iBalance HTO Implant, SM 8°/MD 7° | AR-13400M-07 |
| iBalance HTO Implant, SM 9°/MD 8° | AR-13400M-08 |
| iBalance HTO Implant, SM 10°/MD 9° | AR-13400M-09 |
| iBalance HTO Implant, SM 11°/MD 10° | AR-13400M-10 |
| iBalance HTO Implant, SM 13°/MD 11° | AR-13400M-11 |
| iBalance HTO Implant, SM 14°/MD 12° | AR-13400M-12 |
| iBalance HTO Implant, SM 15°/MD 13° | AR-13400M-13 |
| iBalance HTO Implant, MD 14° | AR-13400M-14 |
| iBalance HTO Implant, MD 15° | AR-13400M-15 |
| iBalance HTO Implant, LG 5° | AR-13400L-05 |
| iBalance HTO Implant, LG 6°/XL 5° | AR-13400L-06 |
| iBalance HTO Implant, LG 7°/XL 6° | AR-13400L-07 |
| iBalance HTO Implant, LG 8°/XL 7° | AR-13400L-08 |
| iBalance HTO Implant, LG 9°/XL 8° | AR-13400L-09 |
| iBalance HTO Implant, LG 10°/XL 9° | AR-13400L-10 |
| iBalance HTO Implant, LG 11°/XL 10° | AR-13400L-11 |
| iBalance HTO Implant, LG 12°/XL 11° | AR-13400L-12 |
| iBalance HTO Implant, LG 13°/XL 12° | AR-13400L-13 |
| iBalance HTO Implant, LG 14°/XL 13° | AR-13400L-14 |
| iBalance HTO Implant, LG 15°/XL 14° | AR-13400L-15 |

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.



This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Arthrex products. As part of this professional usage, the medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience, and should conduct a thorough review of pertinent medical literature and the product's directions for use. Postoperative management is patient-specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same postoperative activity level and/or outcomes.

View U.S. patent information at www.arthrex.com/corporate/virtual-patent-marking

arthrex.com

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