

Omni Arch[®]

Anatomic Wedge System

Optimizing the Gold Standard
for Cotton and Evans
Osteotomies



Overview and Surgical Technique

Pre-Hydrated **X** Pre-Fenestrated **X** Pre-Shaped = Optimized OR Efficiency

EXTREMITY[®]
MEDICAL

Real change *starts* here™

Omni Arch[®]

Anatomic Wedge System

Optimizing the Gold Standard for Cotton and Evans Osteotomies

Engineered to Enhance:

- OR Efficiency
- Osteoconductivity
- Stability of Correction



OR Efficiency: Decreased Preparation Time

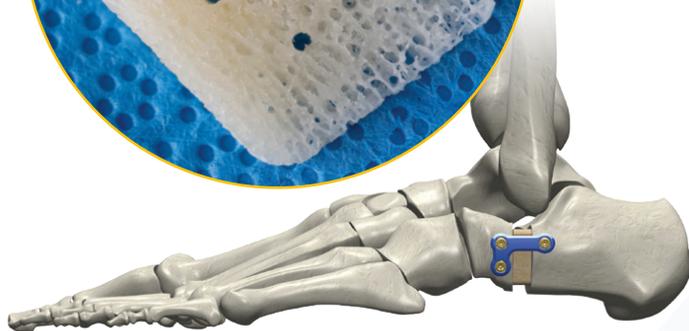
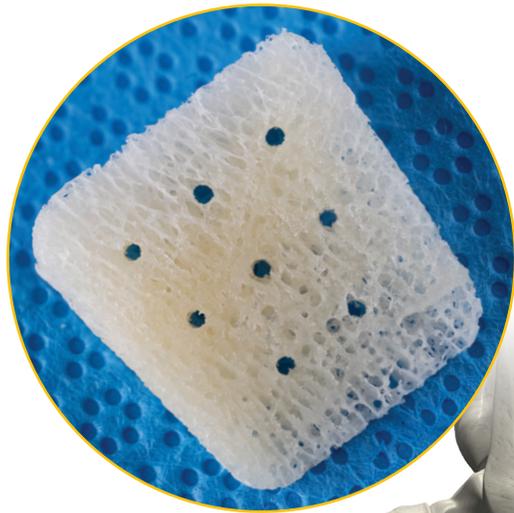
- Pre-hydrated
- Pre-fenestrated
- Pre-sized

Osteoconductivity:

- Pre-fenestrated matrix designed to enhance osteoconductivity, facilitate osteoblast migration, and bony in-growth

Stability of Correction: Low-Profile Osteotomy Plates

- Provide additional stability and protection securing implant height and position
- Pre-hydrated wedges are less likely to crack or flake compared to dry grafts

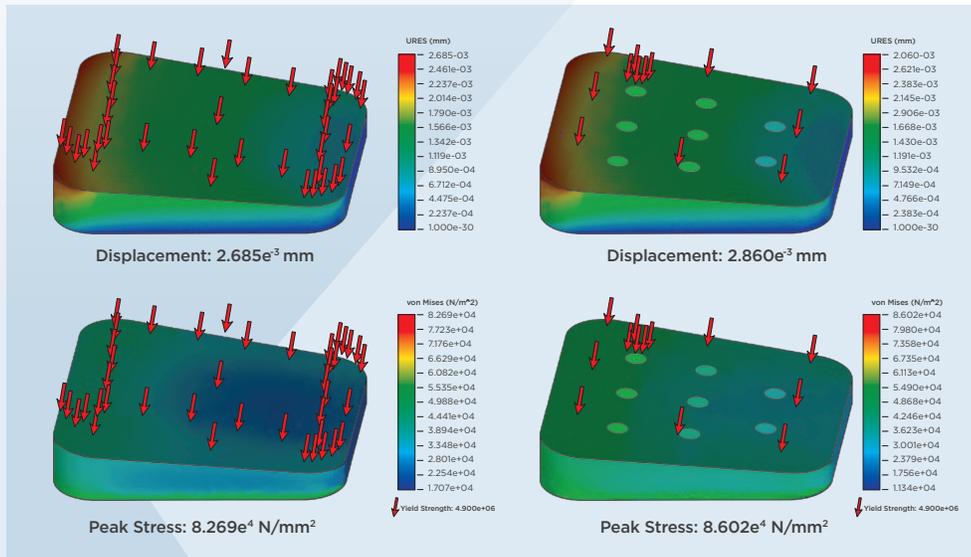


Evans 3-Hole Plate

1.3mm Profile Thickness

chamfered edge designed to decrease soft tissue irritation

Ready to go, from package to patient.
A streamlined approach for Evans and Cotton procedures.



Pre-fenestrated grafts are **designed to enhance osteoconductivity** without compromising implant performance

Illustration of von Mises testing demonstrates that the strategic positioning of the fenestrations for Omni Arch Wedges do not compromise the structural integrity as compared to a standard solid wedge¹.

1. Data on file with Extremity Medical.

Evans Plates	Cotton Plates	Screws
		<p>Screws range 10-30mm in 2mm increments</p>

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Omni Arch Anatomic Wedge System Surgical Technique Guide

The Omni Arch Anatomic Wedge System is comprised of machined, cancellous allograft bone wedges intended for transplant in small bone fusion procedures (e.g., Evans and Cotton procedures). The Omni Arch Anatomic Wedge System allografts are aseptically manufactured using computer numerically controlled (CNC) machining technology for dimensional reproducibility and confirming fit

within the bone space. The finished allograft is hydrated and terminally sterilized.

The Omni Arch Anatomic Wedge System allografts are Human Cellular and Tissue Based Products (HCT/P) per 21 CFR Part 1271. Each allograft is restricted to homologous use for transplant in fusion surgical procedures on a single occasion by a licensed physician or surgeon.



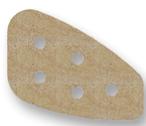
Evans Wedge

	22mm x 22mm, 6mm
	22mm x 22mm, 8mm
	22mm x 22mm, 10mm
	22mm x 22mm, 12mm



Evans Wedge

	18mm x 18mm, 6mm
	18mm x 18mm, 8mm
	18mm x 18mm, 10mm
	18mm x 18mm, 12mm



Cotton Wedge

	15mm x 20mm, 5mm
	15mm x 20mm, 6mm
	15mm x 20mm, 7mm
	15mm x 20mm, 8mm

General Instruments



2.5mm Guide Pin



2.7mm Solid Drill



2.0mm Solid Drill



T10 Driver



3.5mm Drill Sleeve



2.8mm Drill Sleeve



Cotton Wedge Tamp



6mm/8mm Evans Trial/Tamp



10m/12mm Evans Trial/Tamp



5mm/6mm Cotton Trial

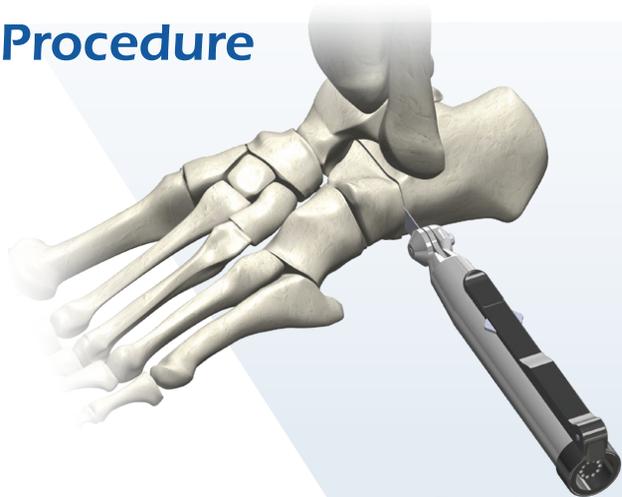


7m/8mm Cotton Trial

Evans Osteotomy (Calcaneal lengthening) Procedure

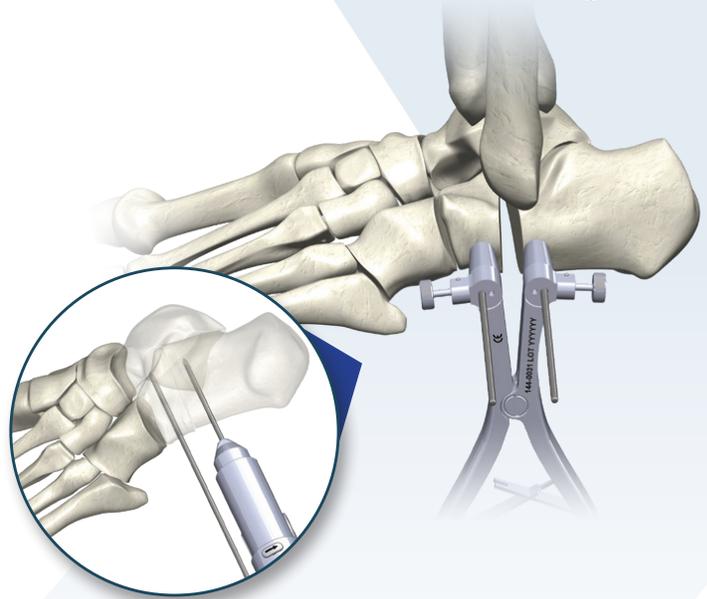
STEP 1. Perform the Osteotomy

The surgeon should access the calcaneus near the Calcaneal-Cuboid (CC) joint using their preferred technique. The calcaneal osteotomy should then be performed approximately 10-20mm from the CC joint.



STEP 2. Distract to Desired Correction

After performing the osteotomy, the calcaneus must be distracted to the desired correction. This can be done in a variety of ways per surgeon preference, such as osteotomes, spreaders, or compressor-distractor instrumentation. The Omni Arch Anatomic Wedge System includes a Compressor-Distractor instrument that can be used with the 2.5mm Guide Pins provided in the set.



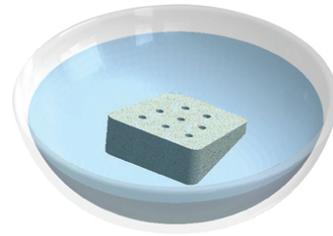
STEP 3. Insert Wedge Trial

Once the space has been distracted to the desired width, the Trial Instruments can be used to determine the required wedge size. Loosen the Distractor and verify the desired forefoot correction with Sizing Trials. If further correction is necessary remove the current Trial, distract the joint and insert a larger Trial.



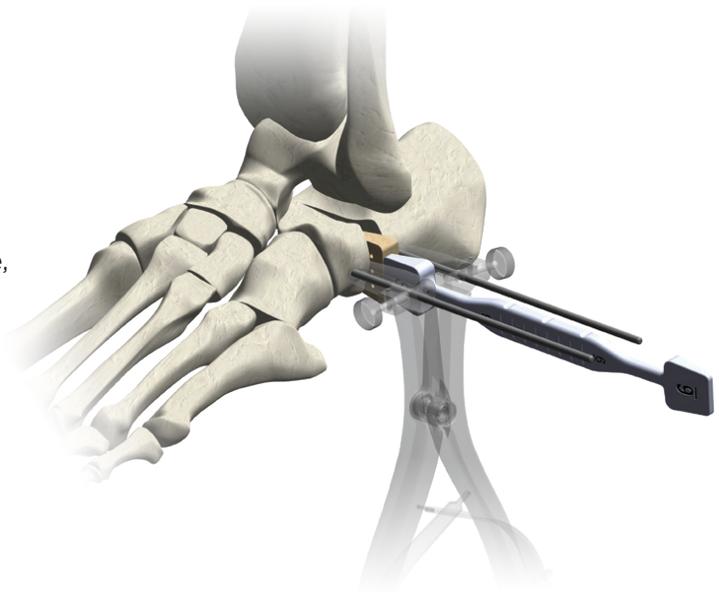
STEP 4. Prepare the Allograft Wedge

Once the desired wedge size has been determined, remove the allograft wedge from the sterile packaging. **The wedge should be rinsed/submerged in warm sterile isotonic solution (or surgeon preferred equivalent) for about 2 minutes.**



STEP 5. Insert the Allograft Wedge

Insert the wedge into the prepared space. This can be done in any way per surgeon preference, such as manually with fingers, using forceps, etc. The Trial can be utilized as a tamp for final positioning, using gentle impactions for insertion. For the Cotton system, the dedicated Tamp instrument can also be used.

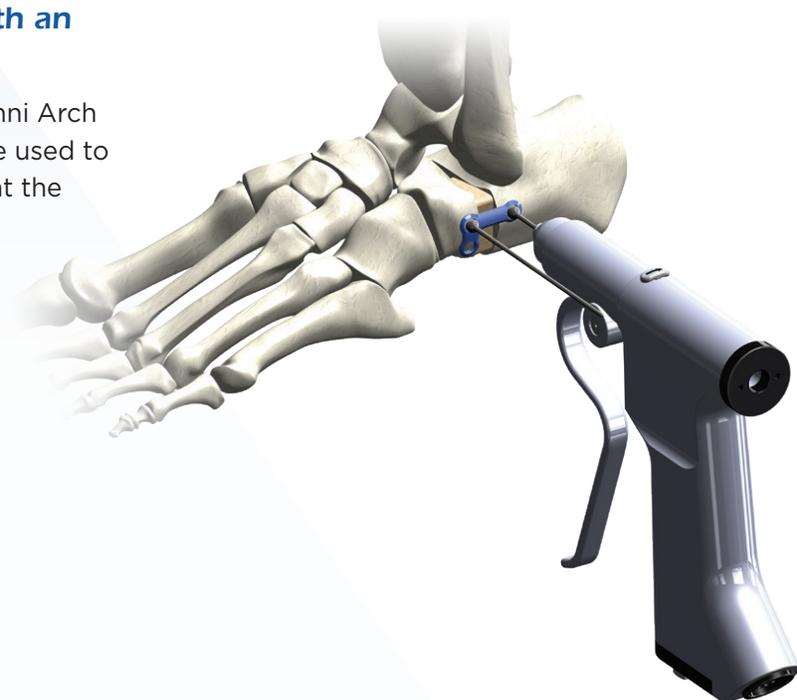


STEP 6. Secure the Wedge with an Omni Wedge Plate

Once the wedge is in place, the Omni Arch System's Wedge Plates can then be used to secure the wedge and osteotomy at the desired correction.

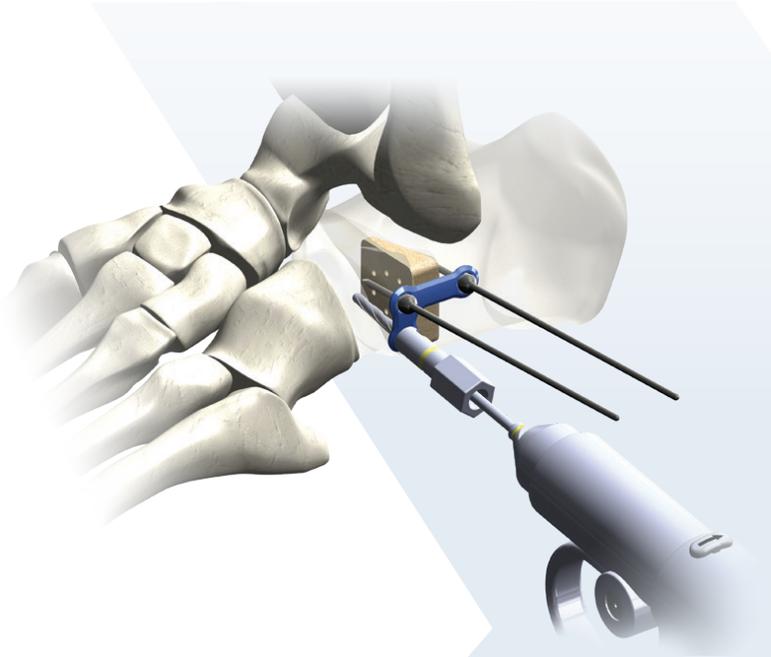
For a 6mm or 8mm wedge, a medium sized L-shaped or straight plate is recommended.

For a 10mm or 12mm wedge, a large sized plate is recommended.



STEP 7. Drill Screw Pilot Hole

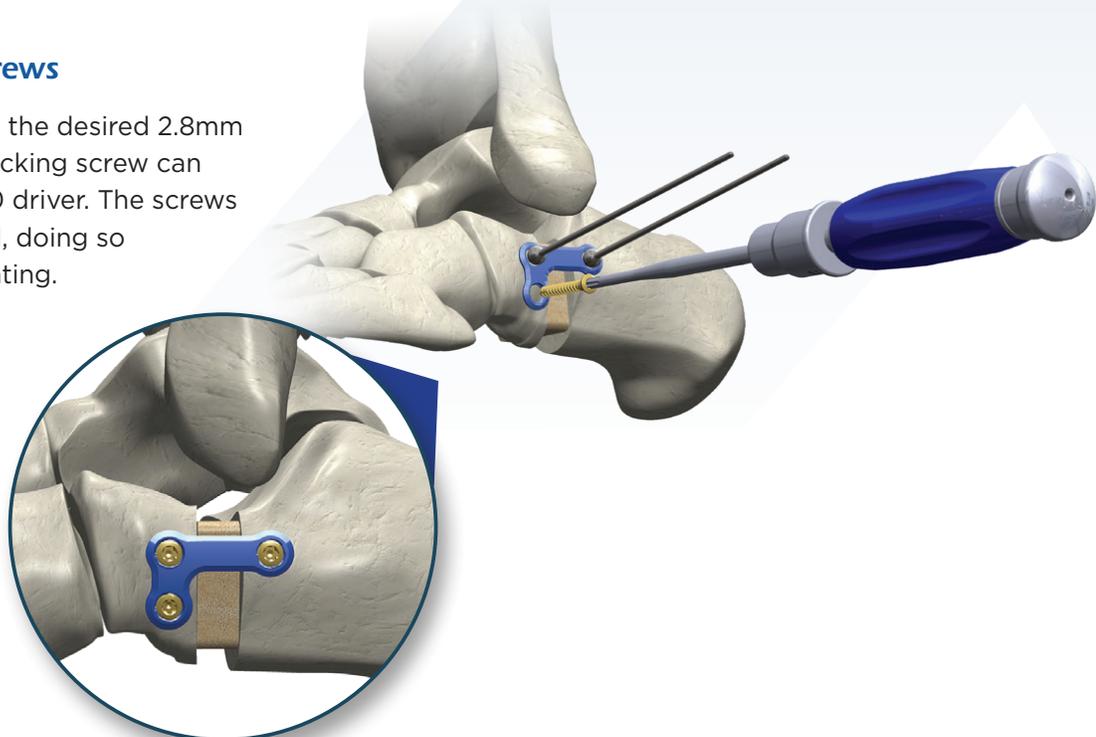
Once secured, thread the locking drill guide into the plate at the desired angle (within the 30° cone). Drill for the screws with the appropriate size solid drill through the dedicated Drill Guide. Measure screw length with the AO-style Depth Gauge. Place the selected screw with the T10 Driver.



Screw Size	Drill Size	Drill Guide and Colors	Driver Size
2.8mm (Locking/Non-Locking)	2.0mm (Solid)	● Yellow	T10
3.5mm (Locking/Non-Locking)	2.7mm (Solid)	● Green	T10

STEP 8. Insert the Screws

After drilling a pilot hole, the desired 2.8mm or 3.5mm locking/non-locking screw can be inserted using the T10 driver. The screws should be fully tightened, doing so carefully toward final seating.



Cotton Osteotomy Procedure

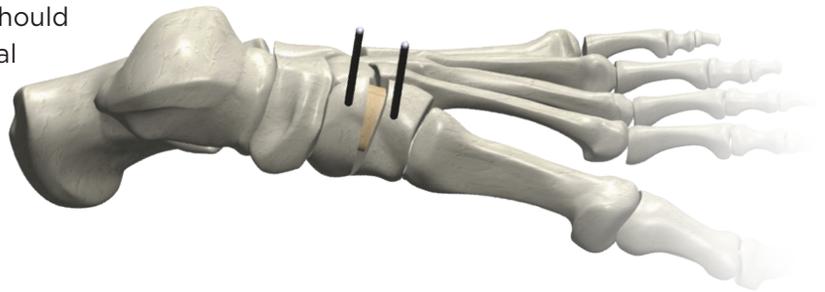
STEP 1. Drill Screw Pilot Hole

For the Cotton osteotomy, the cuneiform bone should be accessed using the surgeon's preferred technique. Then, the osteotomy should be performed in the center of the cuneiform.



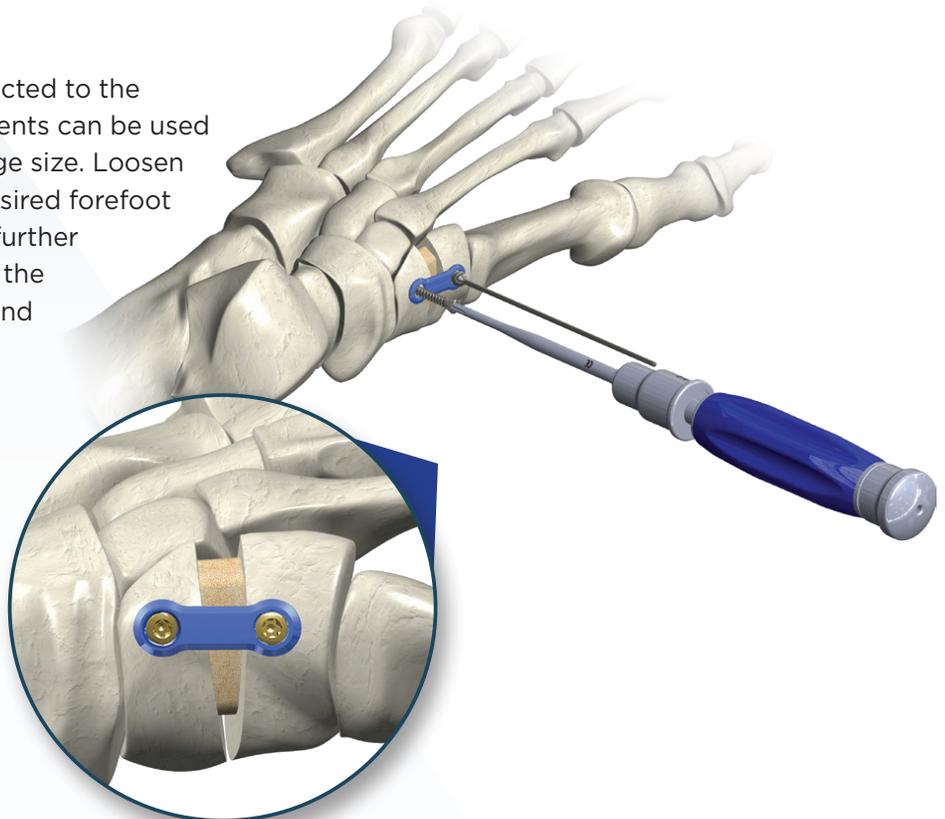
STEP 2. Final Cotton Positioning

Prepare wedge as described on page 5. When fully inserted, the Cotton Wedge should sit approximately 2-3mm below the dorsal tip of the cuneiform. The plate should be placed near the dorsal edge of the cuneiform to allow screw fixation.



STEP 3. Insert Screws

Once the space has been distracted to the desired width, the Trial Instruments can be used to determine the required wedge size. Loosen the Distractor and verify the desired forefoot correction with Sizing Trials. If further correction is necessary remove the current Trial, distract the joint and insert a larger Trial.



Removal Instructions

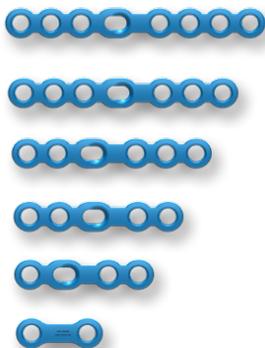
Should removal be required, the plate screws can be removed by using the T10 screwdriver in a counter-clockwise direction. The plate and wedge can then be removed using the surgeon's preferred methods, such as by hand, using forceps, etc.

Compatible with Omni Universal Plating System

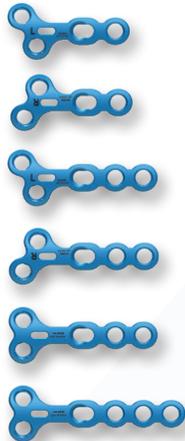
Lisfranc



Straight Plates



T Plates



X Plates



Dog Bone Plates



MTP Plates



Lapidus Plates



Customer Service: 888.499.0079
www.extremitymedical.com

Set Configuration

Part #	Description
Delivery System Components, Tray and Caddy	
144-10004	Omni Foot Plating Implant Caddy 4
System Implants, Plates and Wedges	
150-18006	Evans Wedge, 18mm x 18mm, 6mm
150-18008	Evans Wedge, 18mm x 18mm, 8mm
150-18010	Evans Wedge, 18mm x 18mm, 10mm
150-18012	Evans Wedge, 18mm x 18mm, 12mm
150-22006	Evans Wedge, 22mm x 22mm, 6mm
150-22008	Evans Wedge, 22mm x 22mm, 8mm
150-22010	Evans Wedge, 22mm x 22mm, 10mm
150-22012	Evans Wedge, 22mm x 22mm, 12mm
150-15005	Cotton Wedge, 15mm x 20mm, 5mm
150-15006	Cotton Wedge, 15mm x 20mm, 6mm
150-15007	Cotton Wedge, 15mm x 20mm, 7mm
150-15008	Cotton Wedge, 15mm x 20mm, 8mm
144-12021	Omni 2-Hole Straight Plate, Extra Small
144-12023	Omni 2-Hole Straight Plate, Small
144-12025	Omni 2-Hole Straight Plate, Medium
144-12028	Omni 2-Hole Straight Plate, Large
144-13251	Omni 3-Hole L-Shape Plate, Left, Medium
144-13281	Omni 3-Hole L-Shape Plate, Left, Large
144-13252	Omni 3-Hole L-Shape Plate, Right, Medium
144-13282	Omni 3-Hole L-Shape Plate, Right, Large
System Accessories, Disposable Instruments	
109-00117	Ø2.5mm Guidewire, 6in
System Accessories, Reusable Instruments	
150-01006	Evans Double Ended Trial, 06/08mm
150-01010	Evans Double Ended Trial, 10/12mm
150-02005	Cotton Double Ended Trial, 05/06mm
150-02007	Cotton Double Ended Trial, 07/08mm
144-00031	Hintermann Compressor Distractor
150-00040	Wedge Tamp



All Omni Universal implants and instrumentation are present

Description and Indication For Use

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Delivering

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