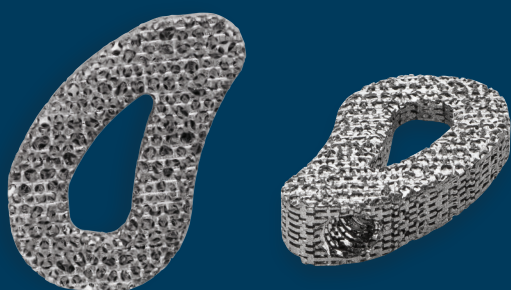
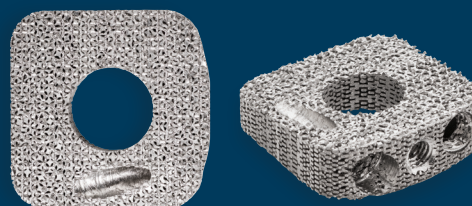
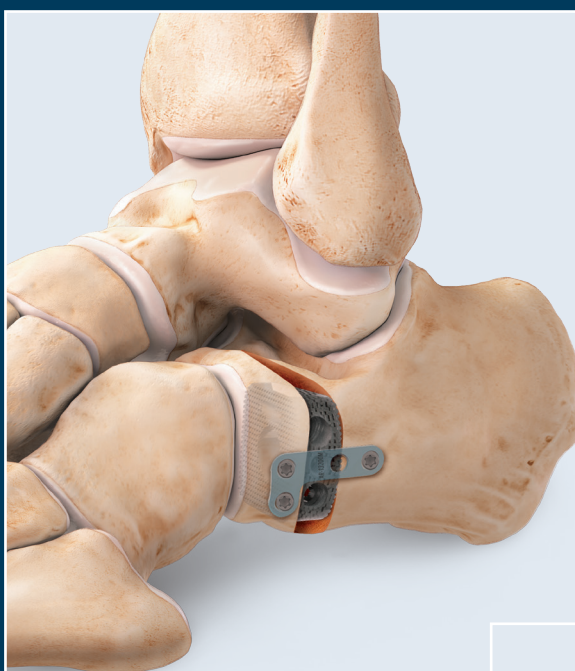




BioSync® Anatomic Reconstruction Wedge

Surgical Technique

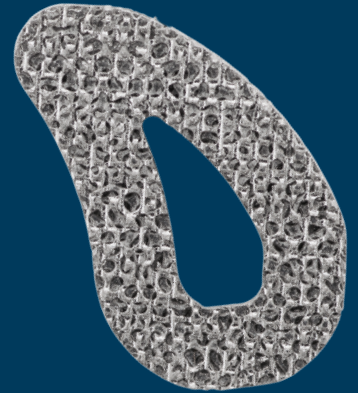


BioSync Anatomic Reconstruction Wedge

BIO SYNC

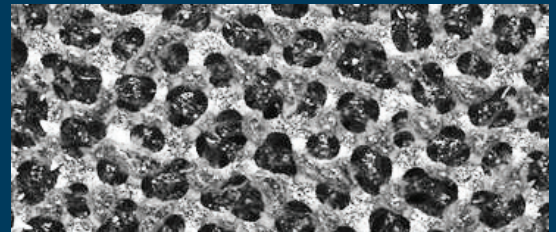
The BioSync® reconstruction wedge system provides an alternative to allograft bone for osteotomies and fusions of the foot. The BioSync reconstruction wedge is an open-celled titanium scaffold. The strong porous scaffold helps minimize any future loss of correction, normally due to allograft incorporation.

Eight anatomically-derived profiles are developed for Cotton Procedures (Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform). Medial (convex) and lateral (concave) shape maximizes bone contact while not violating the intercuneiform joint. Twelve profiles are available for Evans procedure providing reliable and precise correction.



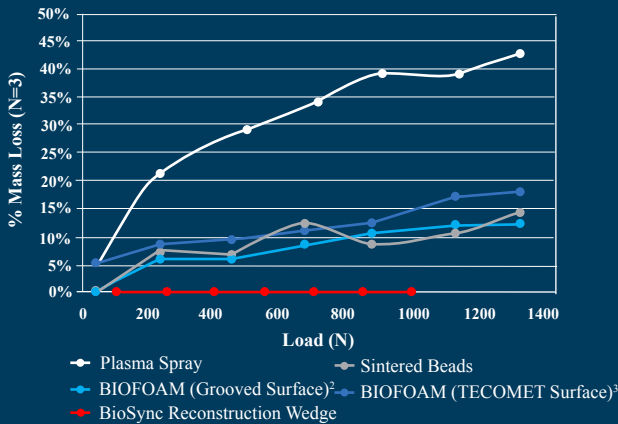
The BioSync Reconstruction Wedge Advantage:

- Maintained strength throughout the remodeling process¹
- 58.8% porous titanium¹
- Sustained stable fixation - high coefficient of friction¹
- Possible shorter OR time vs. non-configured allograft - 20 sterile implant size options
- Optional: Evans wedge has potential for 2.4 mm cortical screws supporting rotational control



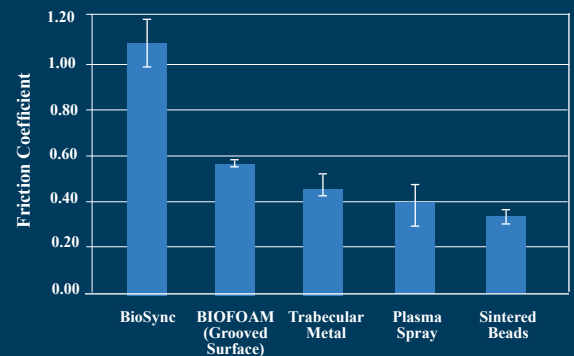
Mechanical Characteristics of BioSync Reconstruction Wedge Arthrex® Whitepaper

Abrasive Wear Analysis



Percent Mass Loss $\% \Delta m$ as a function of applied load. Data points for materials other than the BioSync reconstruction wedge were taken from a graph in the literature and are estimated to be accurate to $\pm 1\%$. At all the loads tested, the BioSync reconstruction wedge's abrasion was negligible and significantly lower than that for the other porous scaffolds.

Friction



Friction coefficient of bone ingrowth materials tested against 10 pcf SAWBONE. Results for materials other than the BioSync reconstruction wedge were taken from Brownhill.

References:

1. Mechanical Characteristics of BioSync Reconstruction Wedge Arthrex Whitepaper
2. Brownhill J, Wong K, Obert R, et al. Biofoam Cancellous Titanium Fixation for Orthopedic Implant Applications: Lateral Column Lengthening. Wright Medical Document FA499-909. 2010.
3. Biofoam Technical Monograph. Wright Medical Document MI023-109. 2009.

BioSync® – Reconstruction Wedge

Anatomic Evans Wedge Surgical Technique



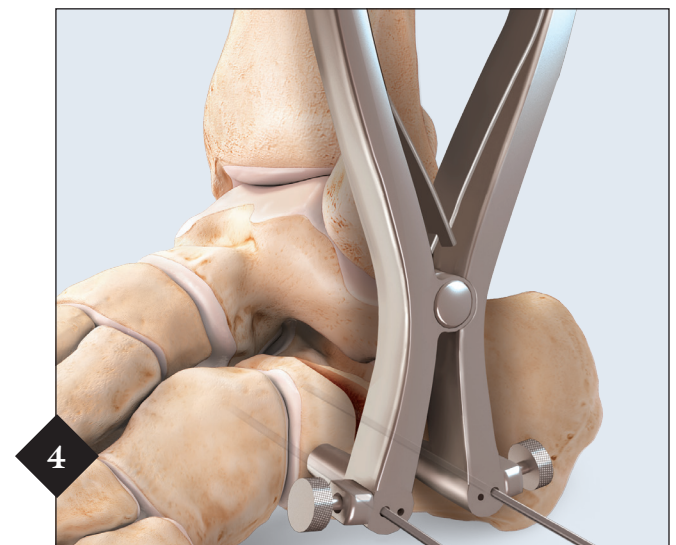
An incision is made just below the sinus tarsi, extending laterally approximately 3 cm proximal to the calcaneocuboid joint.



Carefully reflect the extensor digitorum muscle belly superiorly and retract the peroneal tendons, along with the sural nerves, inferiorly to expose the lateral calcaneal and calcaneocuboid joint.



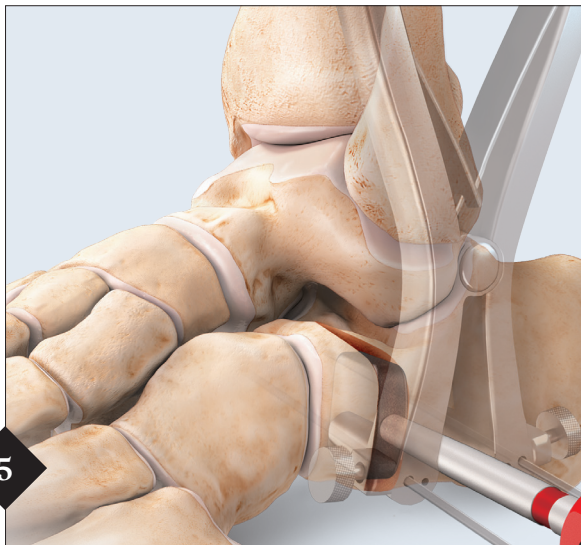
Beginning 10-15 mm proximal to the calcaneocuboid joint, perform an osteotomy with an oscillating saw parallel to the calcaneocuboid joint. Leave medial cortex intact.



Place 2.4 mm or 1.6 mm guidewire on each side of osteotomy and utilize a pin-style distractor to provide controlled distraction and unobstructed access to the osteotomy site. A provisional guidewire may be placed across the calcaneocuboid joint to prevent subluxation of the joint during distraction.

BioSync® – Reconstruction Wedge

Anatomic Evans Wedge Surgical Technique

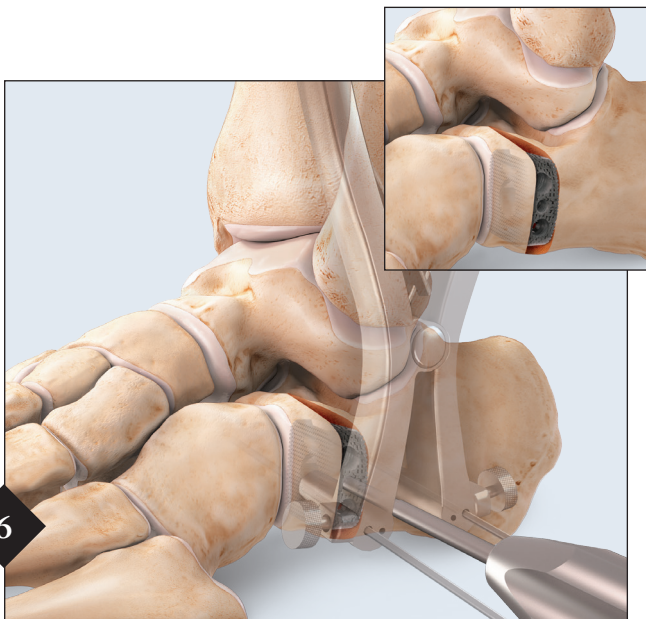
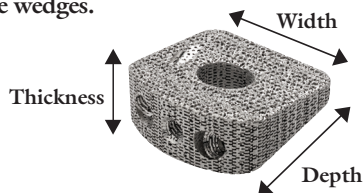


Anatomical correction is performed by distracting the osteotomy site to the surgeon's desired reconstruction between 6.5-12 mm. Start with the smaller trials first and proceed exchanging colored trial inserters with thicker/larger trials. Assess whether desired correction of the talonavicular joint occurs with trial wedge both clinically and fluoroscopically (shape and size). Once the correct footprint and thickness of the wedge are determined, the trial's color and size is recorded.

BioSync Reconstruction Wedge Evans Trial Sizing						
Implant Label and Trial Color	Footprint Image	Implant Part no.	Width (mm)	Depth (mm)	Thickness (mm)	Thickness Image
<ul style="list-style-type: none"> ● Red ● Yellow ● Blue ● Gray 		AR-8942W-1806	18	18	6.5	
		AR-8942W-1808			8	
		AR-8942W-1810			10	
		AR-8942W-1812			12	
<ul style="list-style-type: none"> ● Red ● Yellow ● Blue ● Gray 		AR-8942W-2006	20	20	6.5	
		AR-8942W-2008			8	
		AR-8942W-2010			10	
		AR-8942W-2012			12	
<ul style="list-style-type: none"> ● Red ● Yellow ● Blue ● Gray 		AR-8942W-2206	22	22	6.5	
		AR-8942W-2208			8	
		AR-8942W-2210			10	
		AR-8942W-2212			12	

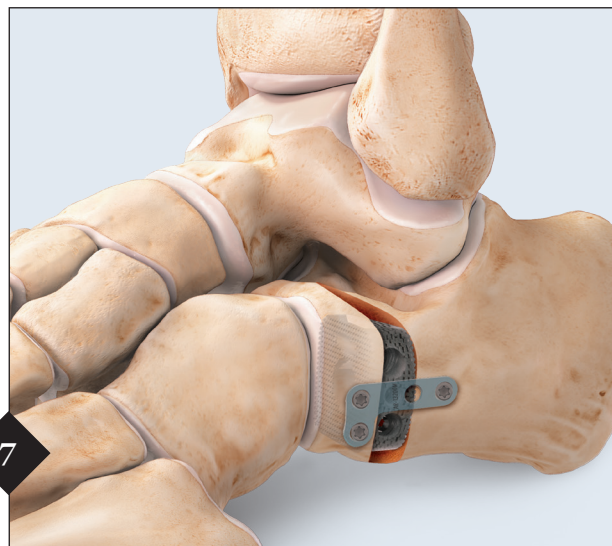
Open the selected size wedge (box has sticker with corresponding color). Prior to inserting the wedge, the center hole may be filled with bone grafting material as per surgeon preference.

Note: Wedges may be used with bone graft such as StimuBlast®* products in combination with other biologics such as PRP or BMC packed in the middle windows of the wedges.



Attach the anatomic Evans BioSync reconstruction wedge by threading the wedge inserter into the center hole. Seat the implant into the osteotomy until flush with bone. Surgeon may choose to slightly recess the implant so that it rests within the walls of the calcaneus. Check final position fluoroscopically: 1) ensure far cortex 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 unthreading counterclockwise.

Note: Utilize the tamp if additional implant positioning is required. Add one or two 2.4 mm nonlocking screws into the Evans wedge as per surgeon preference.



Ancillary fixation is required when using BioSync reconstruction wedges. Refer to the CFS Catalog highlighting various plates which can be used over the BioSync reconstruction wedges. The flat L-plate, medium X-plate or large X-plate are often used for Evans osteotomy. Plate selection is based on the BioSync reconstruction wedge utilized and patient anatomy. Evans: AR-8952XP, AR-8952XM, AR-8952XL or AR-13200M.

*Stimublast® is a registered trademark of AlloSource.

BioSync® – Reconstruction Wedge

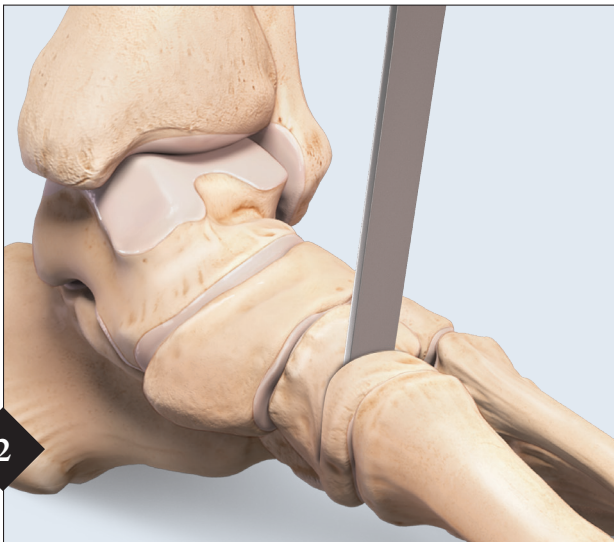
Anatomic Cotton Wedge Surgical Technique

Medial (convex) and lateral (concave) shapes maximize bone contact while not violating the intercuneiform joint that other triangle shaped wedges may. The following surgical technique describes the use of the anatomic Cotton BioSync reconstruction wedges in a Cotton opening wedge cuneiform osteotomy. However, this technique can be applied to other opening wedge osteotomies of the foot requiring wedges of similar size.



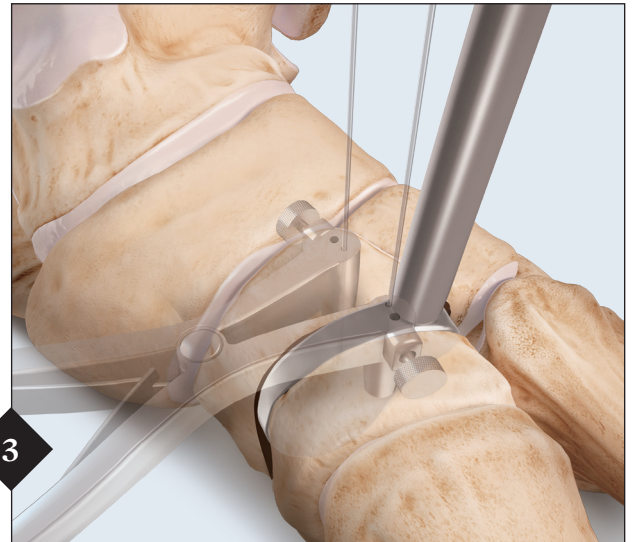
1

An incision is made dorsally over the medial cuneiform. The extensor hallucis longus is retracted, and soft tissues are dissected down to the surface of the medial cuneiform. A transverse osteotomy is made on the dorsal surface of the medial cuneiform.



2

The osteotomy is gently opened with a straight osteotome. The osteotomy may be opened using the stacked osteotome technique or opened using heart osteotomy distractor. The pin-style distractor is optional and utilized based on surgeon preference.



3

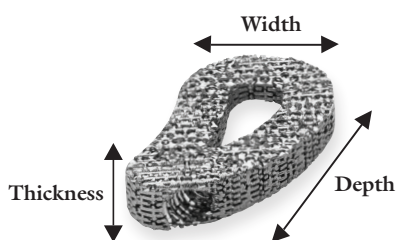
Anatomical correction is performed by distracting the osteotomy site to the surgeon's desired reconstruction between 4.5-7.5 mm. Start with the smaller trials first and proceed exchanging colored trial inserters with thicker/larger trials. Assess whether desired correction occurs with trial wedge both clinically and fluoroscopically (shape and size). Correction is verified under fluoroscopy by assessing the declination of the first metatarsal. Once the correct footprint and thickness of the wedge are determined, the trial's color and size is recorded.

BioSync® – Reconstruction Wedge

Anatomic Cotton Wedge Surgical Technique

Open the selected size wedge (box has sticker with corresponding color). Prior to inserting the wedge, the center hole may be filled with bone grafting material as per surgeon preference.

Note: Wedges may be used with bone graft such as StimuBlast® products in combination with other biologics such as PRP or BMC packed in the middle windows of the wedges.



Cotton BioSync Reconstruction Wedge Trial Sizing					
Implant Label and Trial Color	Footprint Image	Implant Part no.	Depth (mm)	Thickness (mm)	Thickness Image
<ul style="list-style-type: none"> ● Light Purple ● Green ● Light Blue ● Black 		AR-8948W-1645	16	4.5	
		AR-8948W-1655		5.5	
		AR-8948W-1665		6.5	
		AR-8948W-1675		7.5	
<ul style="list-style-type: none"> ● Light Purple ● Green ● Light Blue ● Black 		AR-8948W-2045	20	4.5	
		AR-8948W-2055		5.5	
		AR-8948W-2065		6.5	
		AR-8948W-2075		7.5	



Attach the anatomic Cotton BioSync reconstruction wedge by threading the wedge inserter into the center hole. Seat the implant into the osteotomy until flush with bone. Check final position fluoroscopically: 1) ensure far cortex 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 unthreading counterclockwise.

Note: Utilize the tamp if additional implant positioning is required.



Ancillary fixation is required when using BioSync reconstruction wedges. Refer to the CFS Catalog highlighting various plates which can be used over the BioSync reconstruction wedges. The flat cotton plate or the 2 hole straight plate can be used for Cotton osteotomy. Plate selection is based on the BioSync reconstruction wedge utilized and patient anatomy. Cotton: AR-8952TS-02, AR-8948-00 or AR-13200M.

BioSync® – Reconstruction Wedge

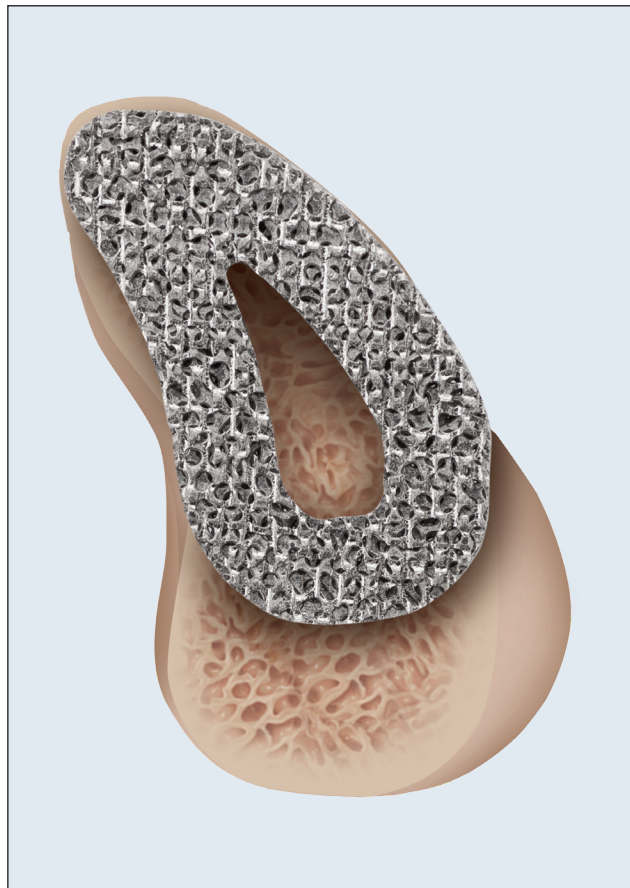
Explant Information

Remove the ancillary plate using the same plate-specific instrumentation used to implant the plate. Wedge inserter can be threaded in or utilize forceps, or other desired general instruments to pull the wedge from its position. It may be necessary to use a saw and a small blade to cut along the surface of the wedge-bone interface to free the wedge from the bone.

Post-op Care

Follow appropriate postoperative protocol based on surgeon preference and all procedures performed.

Anatomic Cotton BioSync Wedge



Ordering Information

BioSync® Reconstruction Instrument Set (AR-8948S) includes:

Wedge Inserter	AR-8948-01
Osteotomy Distractor	AR-13225
Distractor – medium	AR-8948CD
Mallet	AR-8826M
BioSync Reconstruction Wedge Instrument Case	AR-8948C
Cotton Wedge Trial, 16 x 4.5 mm	AR-8948T-1645
Cotton Wedge Trial, 16 x 5.5 mm	AR-8948T-1655
Cotton Wedge Trial, 16 x 6.5 mm	AR-8948T-1665
Cotton Wedge Trial, 16 x 7.5 mm	AR-8948T-1675
Cotton Wedge Trial, 20 x 4.5 mm	AR-8948T-2045
Cotton Wedge Trial, 20 x 5.5 mm	AR-8948T-2055
Cotton Wedge Trial, 20 x 6.5 mm	AR-8948T-2065
Cotton Wedge Trial, 20 x 7.5 mm	AR-8948T-2075
Evans Wedge Trial, 18 x 18 x 6.5 mm	AR-8942T-1806
Evans Wedge Trial, 18 x 18 x 8 mm	AR-8942T-1808
Evans Wedge Trial, 18 x 18 x 10 mm	AR-8942T-1810
Evans Wedge Trial, 18 x 18 x 12 mm	AR-8942T-1812
Evans Wedge Trial, 20 x 20 x 6.5 mm	AR-8942T-2006
Evans Wedge Trial, 20 x 20 x 8 mm	AR-8942T-2008
Evans Wedge Trial, 20 x 20 x 10 mm	AR-8942T-2010
Evans Wedge Trial, 20 x 20 x 12 mm	AR-8942T-2012
Evans Wedge Trial, 22 x 22 x 6.5 mm	AR-8942T-2206
Evans Wedge Trial, 22 x 22 x 8 mm	AR-8942T-2208
Evans Wedge Trial, 22 x 22 x 10 mm	AR-8942T-2210
Evans Wedge Trial, 22 x 22 x 12 mm	AR-8942T-2212
Depth Guide	AR-13120G-2
Driver, T-8 hexalobe, self-retaining	AR-8916-27
Handle, small, w/ AO connection	AR-2001AOT
Holding sleeve, for 2.0 and 2.4 mm screws	AR-8920H
Drill Guide, 1.7 mm, Evans Wedge	AR-8942-03
BioSync Wedge Tamp	AR-8942-01
Screwholding Forceps, self-retaining	AR-8941F
Osteotome, low profile, short, 5 mm	AR-13203-05
Osteotome, low profile, short, 10 mm	AR-13203-10
Osteotome, low profile, short, 12 mm	AR-13203-12

BioSync® Reconstruction Wedge:

Anatomic Cotton BioSync Wedge, 16 x 4.5 mm	AR-8948W-1645
Anatomic Cotton BioSync Wedge, 16 x 5.5 mm	AR-8948W-1655
Anatomic Cotton BioSync Wedge, 16 x 6.5 mm	AR-8948W-1665
Anatomic Cotton BioSync Wedge, 16 x 7.5 mm	AR-8948W-1675
Anatomic Cotton BioSync Wedge, 20 x 4.5 mm	AR-8948W-2045
Anatomic Cotton BioSync Wedge, 20 x 5.5 mm	AR-8948W-2055
Anatomic Cotton BioSync Wedge, 20 x 6.5 mm	AR-8948W-2065
Anatomic Cotton BioSync Wedge, 20 x 7.5 mm	AR-8948W-2075
Anatomic Evans BioSync Wedge, 18 x 18 x 6.5 mm	AR-8942W-1806
Anatomic Evans BioSync Wedge, 18 x 18 x 8 mm	AR-8942W-1808
Anatomic Evans BioSync Wedge, 18 x 18 x 10 mm	AR-8942W-1810
Anatomic Evans BioSync Wedge, 18 x 18 x 12 mm	AR-8942W-1812
Anatomic Evans BioSync Wedge, 20 x 20 x 6.5 mm	AR-8942W-2006
Anatomic Evans BioSync Wedge, 20 x 20 x 8 mm	AR-8942W-2008
Anatomic Evans BioSync Wedge, 20 x 20 x 10 mm	AR-8942W-2010
Anatomic Evans BioSync Wedge, 20 x 20 x 12 mm	AR-8942W-2012
Anatomic Evans BioSync Wedge, 22 x 22 x 6.5 mm	AR-8942W-2206
Anatomic Evans BioSync Wedge, 22 x 22 x 8 mm	AR-8942W-2208
Anatomic Evans BioSync Wedge, 22 x 22 x 10 mm	AR-8942W-2210
Anatomic Evans BioSync Wedge, 22 x 22 x 12 mm	AR-8942W-2212

Low Profile Screws™, Titanium (to be used with Evans Wedge):

2.4 mm Cortex	AR-8724-20 – 40 mm
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Disposables:

Guidewire w/Trocar Tip	AR-8967K
Guidewire w/Trocar Tip	AR-8941K
Drill Bit, 1.7 mm, Evans Wedge	AR-8942-02

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.

