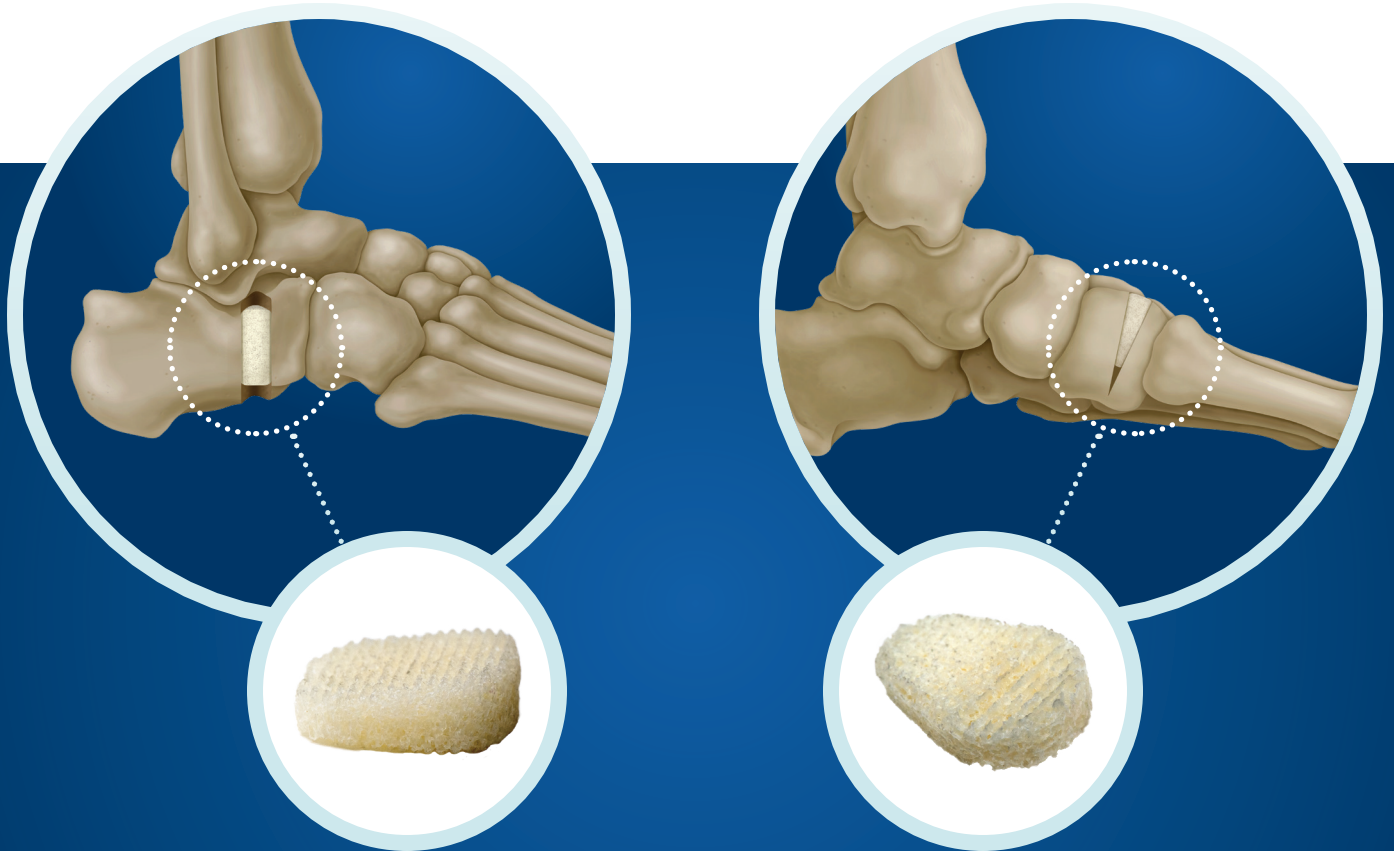


Evans Wedge Osteotomy and Cotton Wedge Osteotomy using

SymALIGN™ Allograft Wedge System



Surgical Technique Overview

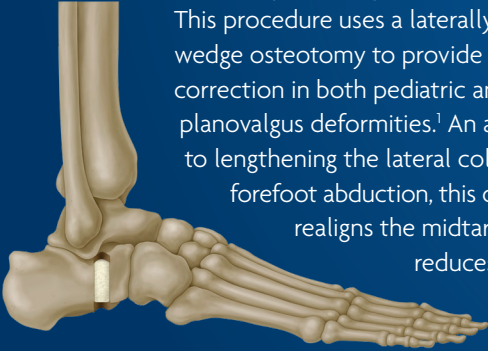
Allograft Osteotomy Wedges

SymALIGN™ Allograft Wedge System

Evans Wedge Osteotomy



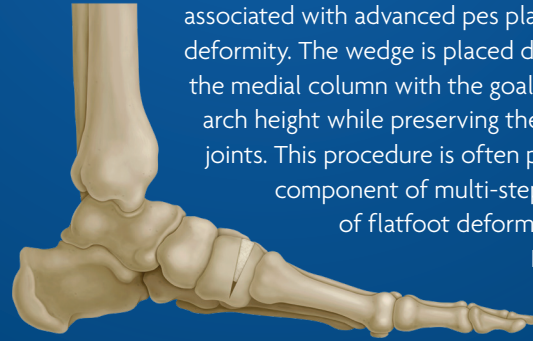
The Evans calcaneal osteotomy is a lateral column-lengthening procedure aimed at preserving the calcaneocuboid joint. This procedure uses a laterally based opening wedge osteotomy to provide multi-planar correction in both pediatric and adult pes planovalgus deformities.¹ An additional benefit to lengthening the lateral column and reducing forefoot abduction, this calcaneal osteotomy realigns the midtarsal joint and reduces calcaneal eversion.



Cotton Wedge Osteotomy



The Cotton osteotomy is a medial cuneiform dorsal opening wedge osteotomy typically used to correct the forefoot varus deformity associated with advanced pes planovalgus foot deformity. The wedge is placed dorsally to plantarflex the medial column with the goal of increasing medial arch height while preserving the medial column joints. This procedure is often performed as a component of multi-step surgical correction of flatfoot deformity (to include an Evans osteotomy).



SymALIGN Foot and Ankle Allograft Wedges

Evans and Cotton Osteotomy Wedge Solutions

SymAlign Evans and Cotton Osteotomy wedges are intended for use in foot procedures. Evans and Cotton allograft wedges are processed and sterilized to a Sterility Assurance Level (SAL) of 10^{-6} using Allowash XG® technology. Preservon® technology, another patented process developed by LifeNet Health, allows for ambient-temperature storage without the need to hydrate the graft. This method of preservation maintains osteoconductive properties and compressive strength when compared to competitive frozen and freeze-dried graft options.¹ The wedges are sourced from cancellous bone from the femoral heads and condyles, talus and calcaneus, which have been determined to have appropriate strength for these procedures.² This, along with specific donor and graft selection criteria, ensures the high density and strength necessary to maintain the deformity correction during impaction as well as throughout the healing/incorporation process.

Unique Texturing

The patent-pending, unique texturing design found on the wedges has been proven to reduce migration while increasing the coefficient of friction between the graft and the bone at the implant site. Bench testing showed the wedge texturing led to an increase in graft surface area from 260 mm² to 564 mm². This increase allows for greater area for cellular attachment and increases the force needed for displacement by nearly 50 percent.³



Features & Benefits

- First and only textured allograft foot wedge designed to resist migration⁴
- Stringent donor and graft selection ensures high density and strength to maintain deformity correction⁵
- Sterility without mechanical compromise protects the graft's inherent osteoconductive properties⁶
- Osteoconductive matrix for cell attachment and proliferation⁷
- Pre-hydrated SymAlign grafts maintain compressive strength and increase intra-operative efficiency¹

Surgical Technique

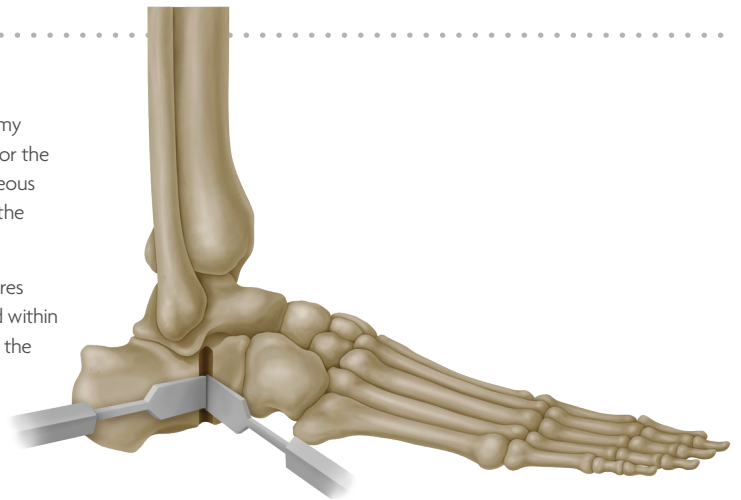
Site Preparation

To prepare the site, a longitudinal incision should be made directly over the planned osteotomy site. Soft tissues are then carefully dissected and retracted to allow for proper visualization. For the Cotton osteotomy, the extensor hallucis longus (EHL) and medial branch of the dorsal cutaneous nerve (superficial nerve) must be carefully protected. The peroneal tendons and branches of the sural nerve must be protected for the Evans osteotomy.

Typically, a k-wire is used to mark the planned osteotomy site with c-arm imaging. This step insures proper placement and angulation of the osteotomy. The Cotton osteotomy should be centered within the long axis of the medial cuneiform, and the Evans osteotomy should be made transversely in the calcaneus, approximately 15 mm proximal to the calcaneocuboid joint.

Begin the osteotomy using a sagittal saw to cut through approximately 80 percent of the bone. Care should be taken not to violate the plantar cortex of the medial cuneiform or through the medial cortex of the calcaneus. The osteotomy is gradually opened with two osteotomes, gently levering each in opposing directions as they are slowly advanced.

Note: The DePuy Synthes distractor can also be used to open the osteotomy bone space.

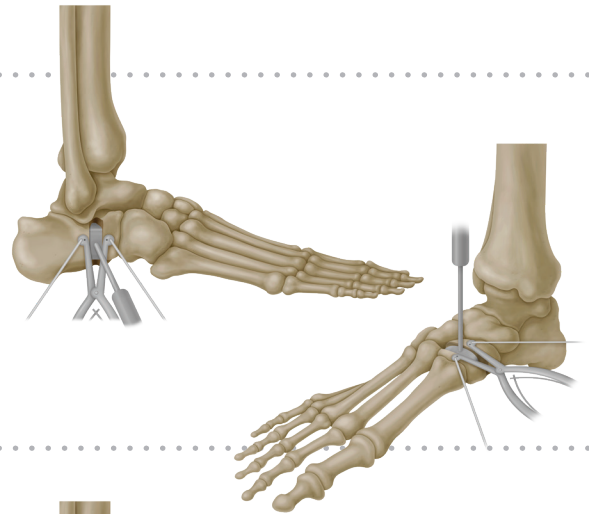


Implant Size Determination

Attach the appropriate size trial to the inline inserter and modular handle. Beginning with the smallest size, sequentially impact trials of increasing size until optimal fit and desired correction is achieved. Ensure that the wedge trial has direct contact with the native bone to ensure for proper reincorporation once the allograft is inserted.

Note: DePuy Synthes trials are offered in identical size configurations as the allograft wedge offerings.

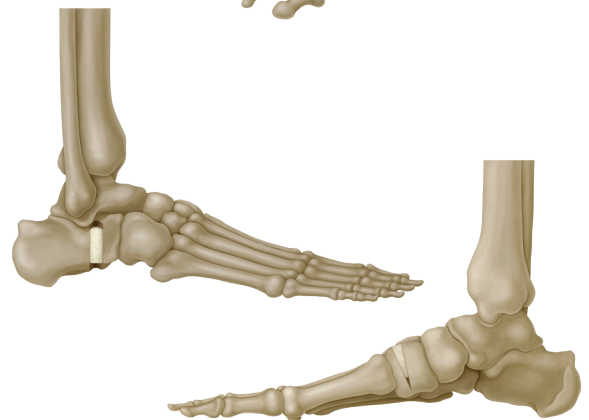
Note: DePuy Synthes trials are not for implantation and must be removed prior to inserting the allograft wedge.



Allograft Implantation

Once the correct allograft wedge size has been determined, carefully insert the wedge into the osteotomy site. The Cotton allograft wedge should be inserted until it sits flush with the dorsal and medial sites of the cuneiform while the Evans wedge should be inserted until flush with the lateral cortex of the calcaneus. Care should be taken to avoid rotation of the graft as it is inserted. If there are remaining gaps between the cuneiform and the allograft or between the calcaneus and the allograft, fill the site with bone graft material. The allograft wedges match the exact size of the trials and should provide interference fit when impacted into the osteotomy.

Note: If needed, using gentle force, the allograft wedge can be impacted into the implant site using the DePuy Synthes "V" tamp. Care should be taken to ensure the surface of the tamp is properly seated against the implant and light force only should be applied. If significant force is required, greater distraction of the osteotomy using the osteotome technique may be required. Using excessive force will increase the chance of damage to the allograft wedge or subsidence of the graft into the cuneiform or calcaneus.



Supplemental Fixation

If desired, fixation can be achieved with:

- DePuy Synthes Plating Systems
- Nitinol Continuous Compression Implants
- Headless Compression Screws

Fixation should be achieved so that it does not come into contact with the allograft wedge. If the second cortex of the cuneiform or calcaneus has been violated with the osteotomy, supplementary fixation is strongly recommended to prevent shift or displacement of the allograft wedge. Care must be taken to avoid violation of the adjacent joints with screw or staple fixation.



SymALIGN™ Allograft Wedge System

Implant Size Offerings

Product Code	Height (mm)	Thickness (mm)	Length (mm)	Evans
FA-EVN-1808	18	8	18	
FA-EVN-1810	18	10	18	
FA-EVN-1812	18	12	18	
FA-EVN-2008	20	8	20	
FA-EVN-2010	20	10	20	
FA-EVN-2012	20	12	20	
FA-EVN-2208	22	8	22	
FA-EVN-2210	22	10	22	
FA-EVN-2212	22	12	22	

Product Code	Height (mm)	Thickness (mm)	Length (mm)	Cotton
FA-CTN-1604	14	4.5	16	
FA-CTN-1605	14	5.5	16	
FA-CTN-1606	14	6.5	16	
FA-CTN-2004	14	4.5	20	
FA-CTN-2005	14	5.5	20	
FA-CTN-2006	14	6.5	20	

References

1. Sohoni, P., Morris, A. Balsly, C., Cotter, A., and Sander, T., The Effects of a New Preservation Method on the Biomechanics and Shelf Life of Allograft Bone. *ORS 2011 Annual Meeting*, 2011.
2. Data on file LifeNet Health, ES-17-051
3. Data on file LifeNet Health, 68-20-198
4. Data on file LifeNet Health, ES-17-108
5. Data on file LifeNet Health, ES-18-031
6. Data on file LifeNet Health, 68-20-010
7. Cornell, C. N. & Lane, J. M. Current understanding of osteoconduction in bone regeneration. *Clinical Orthopaedics and Related Research*, 1998; Number 355S pp S267-273.



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