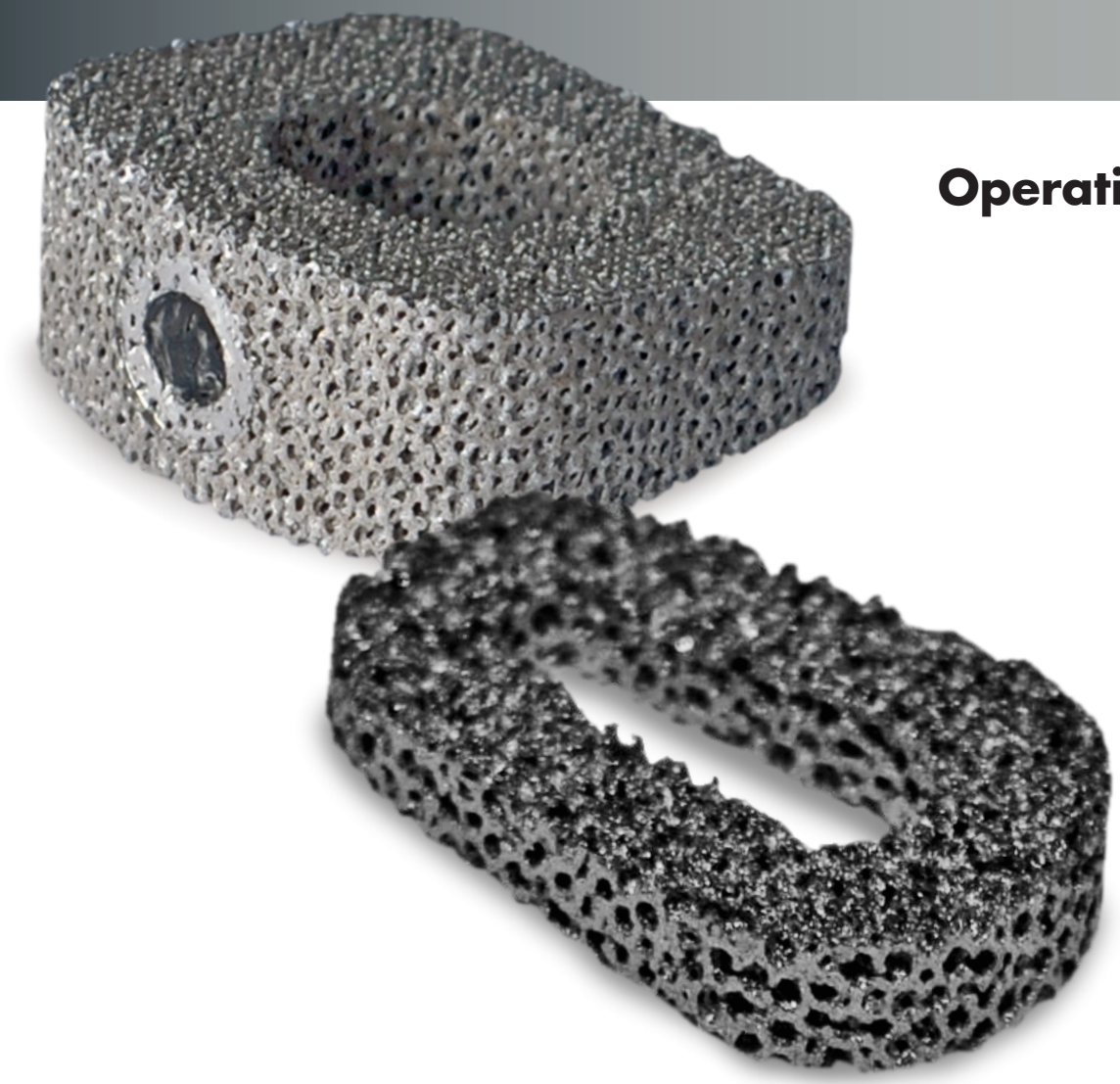
stryker

Biofoam®
Wedge System



Operative technique

Biofoam®
Wedge System

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Operative technique as described by:

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This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

Important

- The patient should be advised that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma and that the device has a finite expected service life.
- Removal or revision of the device may be required sometime in the future.
- Cleaning and sterilization information is provided in the applicable instructions for use.
- Non-sterile devices, including implants and instruments, must be cleaned and sterilized prior to use, in accordance with validated methods.
- Devices that are able to be disassembled should be disassembled prior to point-of-use processing. Additionally, devices with movable components that do not facilitate disassembly should be manually articulated during the point-of-use processing step in order to evacuate additional soils.
- Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.
- Consult Instructions for Use (https://ifu.wright.com) for a complete list of potential adverse effects and adverse events, contraindications, warnings and precautions.
- The surgeon must advise patients of surgical risks, and make them aware of adverse effects and alternative treatments.
- An implant whose packaging is open or damaged or whose expiration date has passed must not be used. Every precaution must be taken to ensure sterility when opening the packaging of the implant and during implantation.

Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience. Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this operative technique and the package insert is available on the website listed.

Biofoam Cancellous Titanium Technology

The proprietary Biofoam Cancellous Titanium technology mimics the strength and flexibility of true cancellous bone by providing a number of important features:

- Ingrowth potential with low risk of an immune response sometimes related to traditional allografts.*
- With a fully interconnected porosity of up to 70%, the titanium matrix provides an environment that mimics cancellous bone to help facilitate potential bone ingrowth and incorporation.*
- Compressive strength that is between that of cortical and cancellous bone should help minimize deformation under dynamic loading conditions.*
- Designed to help facilitate natural transfer of dynamic loads away from the implant to the surrounding bone with a compressive modulus that is close to that of cancellous bone.*
- High surface coefficient of friction facilitates initial stability in the interface between the implant and the bone to help create a stable environment for bone ingrowth and fixation.*

The Biofoam Cancellous Titanium technology thereby combines a microstructure designed to help facilitate ingrowth with continued strength throughout the bone remodeling process to provide an implant material carefully designed for osteotomy corrections of the foot.

While the Biofoam material provides initial stability through a high surface coefficient of friction, ancillary fixation, via a surface plate is required to ensure a stable environment for bone ingrowth. Additionally, the auxiliary hole of the implant or any space near the implant may be filled with autograft chips according to surgeon preference if so desired.

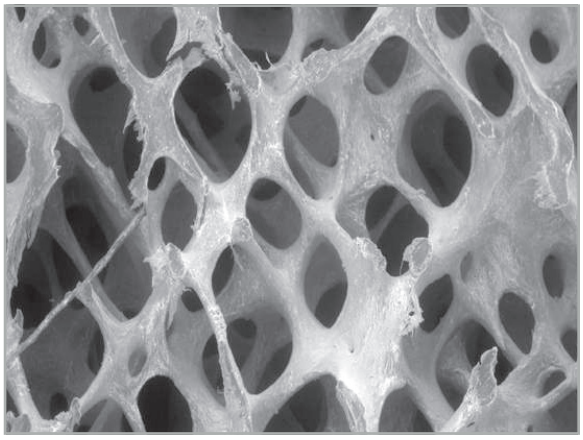


Figure 1A | Cancellous Bone Structure
100x original magnification

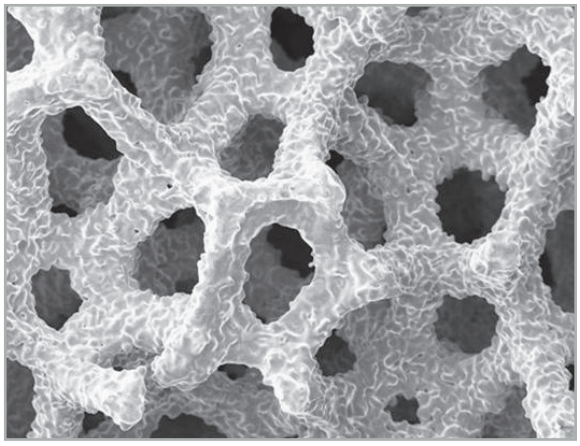


Figure 1B | Biofoam Cancellous Titanium Matrix
100x original magnification

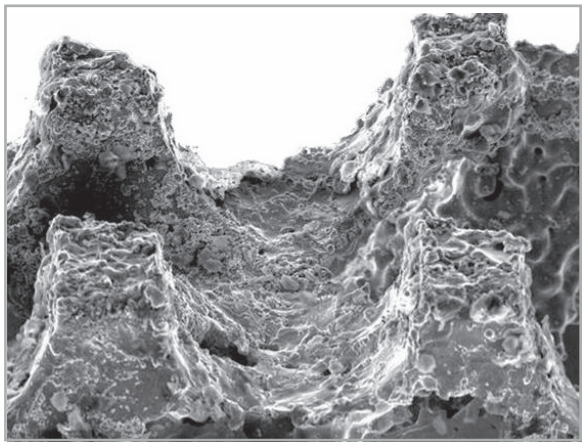


Figure 2 | Surface roughness of the Biofoam Titanium
200x original magnification

*Data on file.

Biofoam Wedge System

The Biofoam Wedge System provides sterile, pre-sized implants for use in a variety of procedures of the foot. With two unique shapes, the system is described for specific use in an Evans Procedure for Lateral Column Lengthening, and in a Cotton Procedure for Plantar Flexion Opening Wedge Osteot omies of the Medial Cuneiform. **| Figure 3A and 3B** Although, the general techniques can be applied to other opening wedge osteotomies of the foot.

While the Biofoam material provides initial stability through a high surface coefficient, ancillary fixation, via a surface plate is required to ensure a stable environment for bone ingrowth. **| Figure 4** Additionally, the auxillary hole of the implant may be filled with a bone void filler or autograft chips according to surgeon preference if so desired.

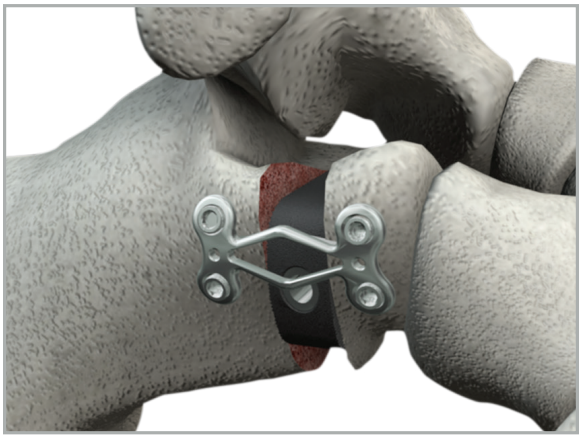


Figure 3A | Lateral Column Lengthening with the Biofoam Evans Wedge

Indications

The Biofoam Bone Wedge is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle and foot, such as:

Cotton and Evans Wedges:

- Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
- Opening wedge of Medial Cuneiform or Cotton osteotomies
- Lateral Column Lengthening (Evans Lengthening osteotomy or Calcaneal Z osteotomy)
- Metatarsal/Cuneiform arthrodesis

Midfoot Wedges:

- Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
- Nonunion of arthrodesis of the Midfoot including Metatarsal/ Cuneiform arthrodesis (TMT or Lapidus)

This device is intended for use with ancillary fixation. The Biofoam Bone Wedge is not intended for use in the spine.

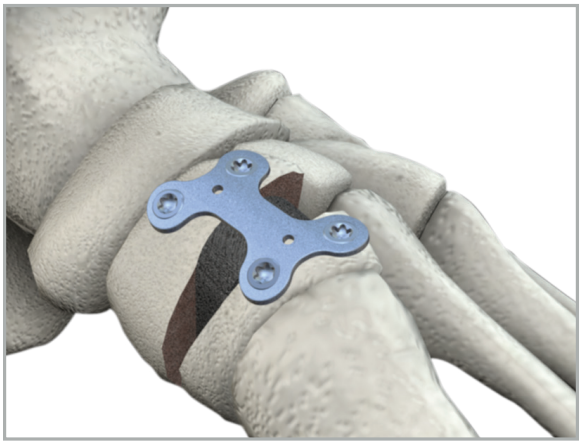


Figure 3B | Medial Cuneiform Opening Wedge Osteotomy with the Biofoam Cotton Wedge

Contraindications

- Infection
- Physiologically or psychologically inadequate patient
- Inadequate skin, bone, or neurovascular status
- Irreparable tendon system
- Possibility for conservative treatment
- Growing patients with open epiphyses
- Patients with high levels of activity

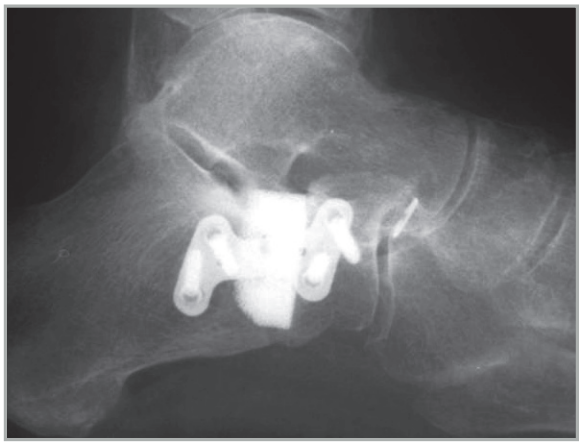


Figure 4 | Biofoam Evans Wedge with a DARCO UPS 3.5mm Plate

Biofoam Evans Wedge System operative technique

Biofoam Evans Wedge

An incision is made just below the sinus tarsi, extending laterally approximately 3cm proximal to the calcaneal-cuboid joint. **| Figure 5**

The peroneal tendons and sural nerves are carefully retracted, and the calcaneal-cuboid joint is exposed. **| Figure 6**

Beginning 10-15mm proximal to the calcaneal-cuboid joint, the osteotomy is made with an oscillating saw, and the cut is finished with an osteotome. **| Figure 7**

A pin-style distractor, with pin placement on either side of the osteotomy, is installed to provide controlled distraction and unobstructed access to the osteotomy site. **| Figure 8**

A provisional K-wire may be placed across the calcaneal-cuboid joint to prevent subluxation of the joint during distraction.

Anatomical correction is performed by distracting the osteotomy site between 8-12mm and inserting the colored trials into the osteotomy site. **| Figure 9** The colored trials are exchanged until the footprint matches the size of the osteotomy site, and the trial's thickness creates the appropriate correction of the talo-navicular joint as determined fluoroscopically. **| Figure 10** Ensure wedge trial is in close contact with the implant-osteotomy interface to provide an optimal environment for bone ingrowth across the entire surface of the wedge.

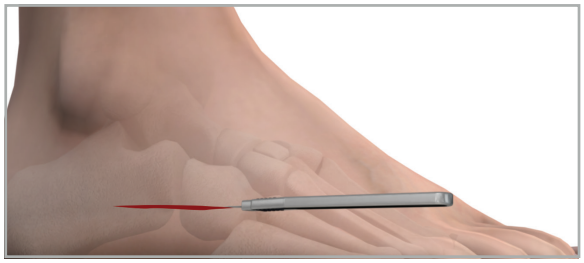


Figure 5

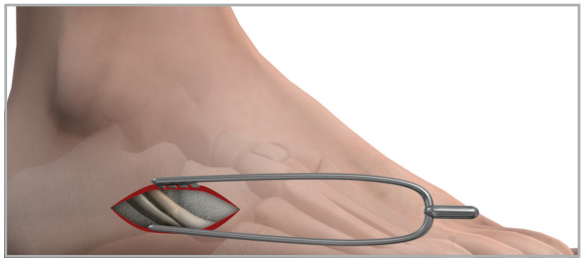


Figure 6

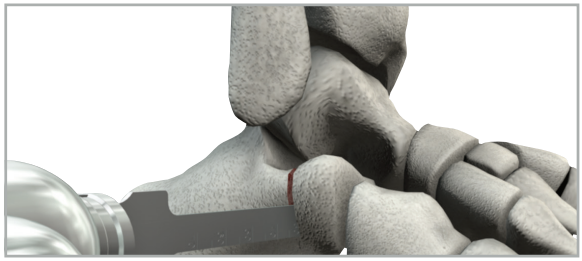


Figure 7

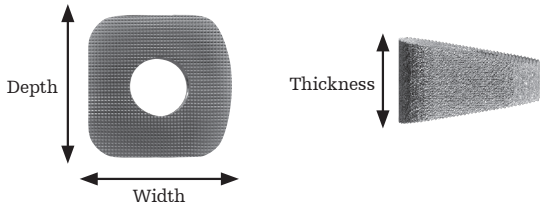
Figure 8

Figure 9

Once the correct footprint and thickness of the wedge are determined, the trial's color and size is noted and the trial is removed. Refer to **Table 1** for trial sizing.

Table 1 | Biofoam Evans trial sizing

Implant part no.	Implant label and trial color	Footprint (width x depth in mm)	Thickness (mm)
47S51808	Purple	18x18	8
47S51810	Bronze	18x18	10
47S51812	Lt. Blue	18x18	12
47S52008	Gold	20x20	8
47S52010	Blue	20x20	10
47S52012	Aqua	20x20	12
47S52208	Green	22x22	8
47S52210	Gray	22x22	10
47S52212	Pink	22x22	12



Prior to inserting the wedge, the center hole of the Biofoam Wedge may be filled with bone grafting material as per surgeon preference. Alternatively, after insertion, a viscous biologic may be inserted through the insertion hole.

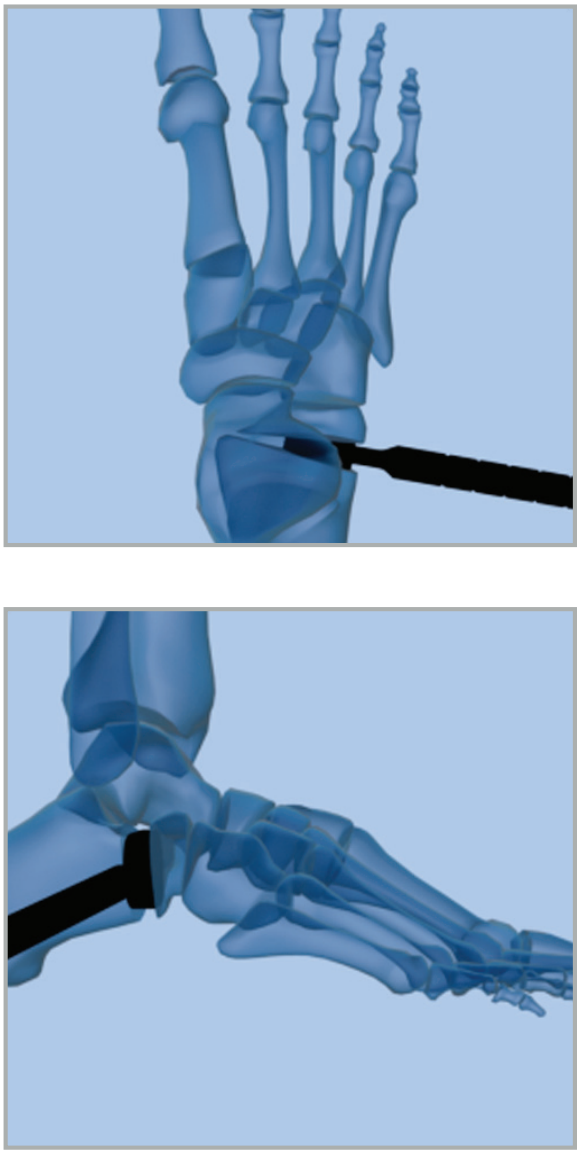


Figure 10

Insert the Biofoam Wedge which corresponds to the trial that provides the desired correction. **| Figure 11** Seat implant with impactor until flush with bone. **| Figure 12** Final correction is checked fluroscopically. Loosen and remove pin-style distractor, ensuring that there is good bone contact with the wedge in both planes.

Claw Plate insertion

Installation of ancillary fixation is required when using Biofoam Wedges. The technique below describes utilizing the Charlotte Claw Plate for fixation, as the plate allows compression to optimally secure the wedge. **| Figure 13** Refer to the Claw Plate Surgical Technique for a detailed surgical technique.

However, any surface plate may be used. If concerns arise involving mixing a titanium implant with stainless steel plate, a titanium Darco Pia Plate (Size 0) or a Darco Ups Plate (Size 16 or 20) may be used. **| Figure 13**

Explant information

Remove the ancillary plate using the same plate-specific instrumentation used to implant the plate. Using foceps, or other desired general instruments, 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

Left to discretion of surgeon.

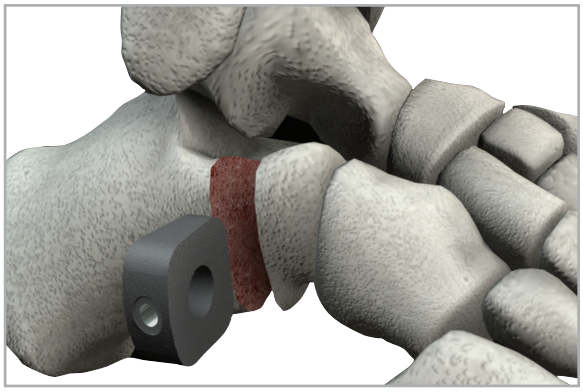


Figure 11

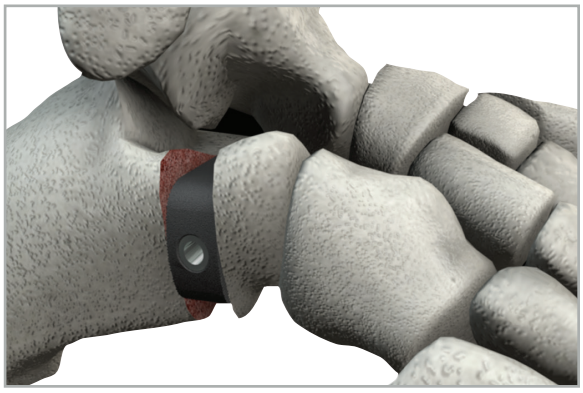


Figure 12

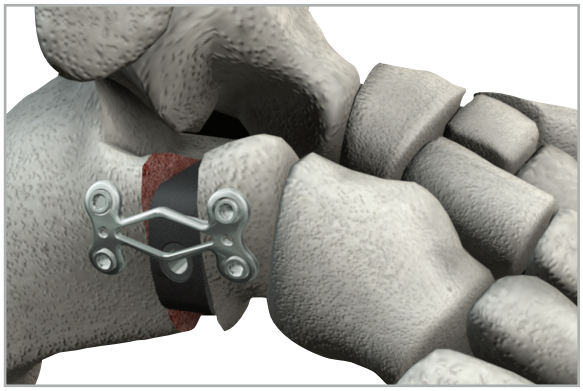


Figure 13

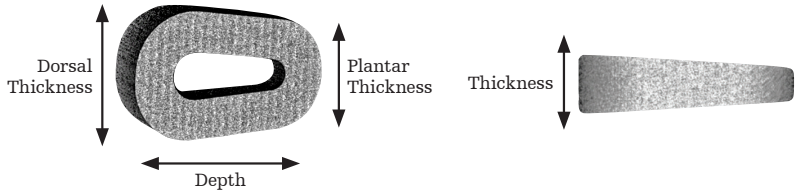
Biofoam Cotton Wedge System operative technique

Biofoam Cotton Wedge

The Biofoam Cotton Wedges are available in two footprint depths – 16mm and 20mm – and three corrective thicknesses – 4.5mm, 5.5mm, and 6.5mm. **| Figure 18 and Table 2** The keystone shape of the implant accommodates the unique geometry of the medial cuneiform. The implant's central auxiliary hole may be used for the addition of biologics or autograft chips according to surgeon preference if so desired.

TABLE 2 | Biofoam Cotton Wedge sizing

Part no.	Depth (mm)	Dorsal width (mm)	Plantar width (mm)	Thickness (mm)
47S01645	16	14	10	4.5
47S01655	16	14	10	5.5
47S01665	16	14	10	6.5
47S02045	20	14	10	4.5
47S02055	20	14	10	5.5
47S02065	20	14	10	6.5



The following surgical technique addresses the use of the Biofoam Cotton Wedges in a Cotton Opening Wedge Cuneiform Osteotomy. However, this general technique can be applied to other opening wedge osteotomies of the foot requiring wedges of similar size.

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, oriented toward the deep plantar cortex. **| Figure 14** The osteotomy is levered open with a straight osteotome. **| Figure 15** The osteotomy may be held open with a pin-style distractor.

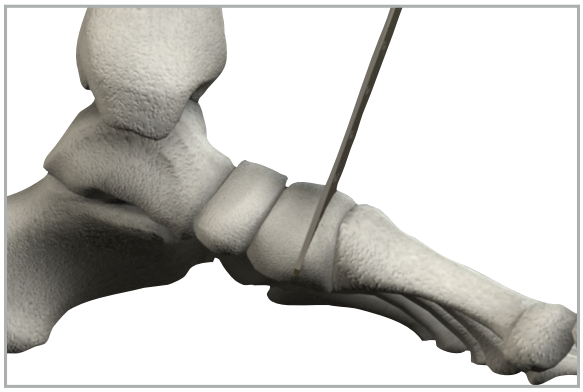


Figure 14

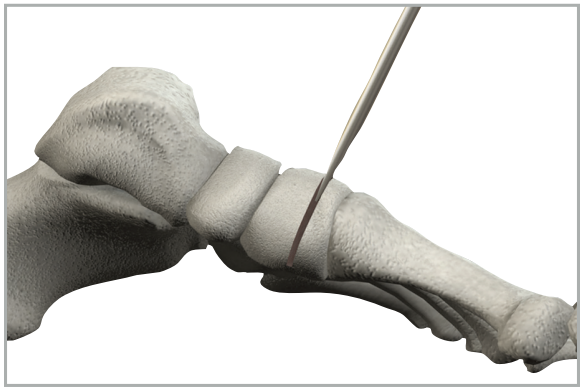


Figure 15

The appropriate size wedge is determined by inserting the colored trials into the ostetomy site. **| Figure 16** Correction is verified under lateral fluoroscopy by assessing the declination of the first metatarsal plantarly. There are three corrective thicknesses of Biofoam Cotton wedges – 4.5mm, 5.5mm, and 6.5mm – to achieve optimal plantar flexion of the first ray. Additionally, the depth of the wedge should be analyzed under fluoroscopy to ensure an interference fit and minimal protuberance of the implant along the dorsal surface. The Biofoam Cotton wedges have two depths – 16mm and 20mm – with trials color coded teal and silver, respectively. Sizing of the trials and implants are outlined in **Table 3**.

Table 3 | Biofoam Cotton trial sizing

Implant part no.	Implant label and trial color	Footprint	Depth (mm)	Thickness (mm)	Dorsal width (mm)	Plantar width (mm)
47S01645	Teal	SMALL	16	4.5	14	10
47S01655	Teal	SMALL	16	5.5		
47S01665	Teal	SMALL	16	6.5		
47S02045	Silver	LARGE	20	4.5		
47S02055	Silver	LARGE	20	5.5		
47S02065	Silver	LARGE	20	6.5		

Insert the Biofoam wedge into the osteotomy, and seat until flush with the dorsal surface of the bone using the Biofoam Impactor. **| Figure 17 and Figure 18** Final correction is checked fluoroscopically.

Installation of ancillary fixation is required when using Biofoam Wedges. The image below shows the use of the Darco Bow2 Size 0 Locked Plate for fixation. **| Figure 19** Please refer to the Darco Bow2 Surgical Technique for a detailed surgical technique. However, any surface plate may be used. If a locked compression plate is desired, a Charlotte 2.7mm Claw plate may be used.

Explant information

Remove the ancillary plate using the same plate-specific instrumentation used to implant the plate. Using foceps, or other desired general instruments, 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

Left to discretion of surgeon.

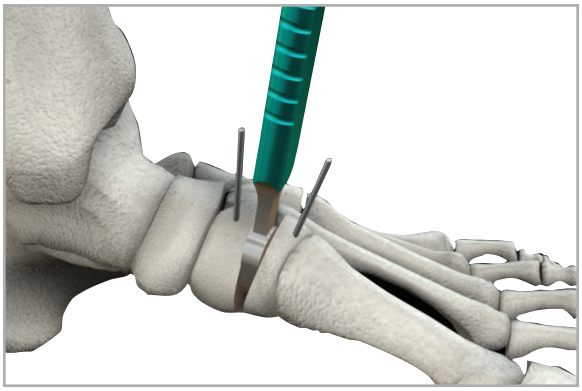


Figure 16

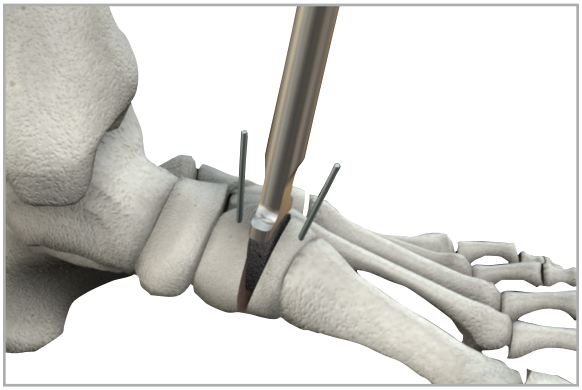


Figure 17

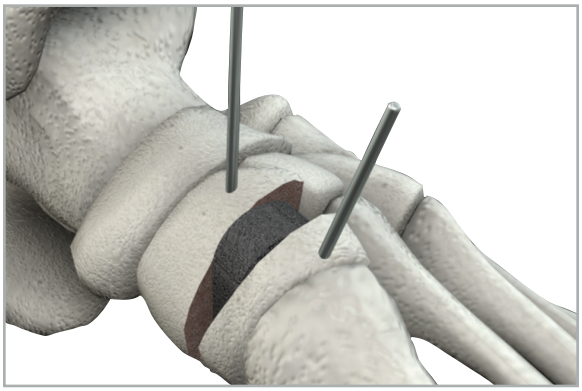
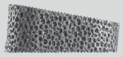
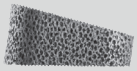
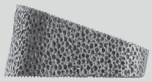


Figure 18

Figure 19

Biofoam Wedge System sizing

Biofoam Evans Wedge sizing

Footprint options	Implant part no.	Depth (mm)	Width (mm)	Thickness (mm)	Thickness options
 18 x18mm	47S51808	18	18	8	 8mm
	47S51810	18	18	10	
	47S51812	18	18	12	
 20 x 20mm	47S52008	20	20	8	 10mm
	47S52010	20	20	10	
	47S52012	20	20	12	
 22 x 22mm	47S52208	22	22	8	 12mm
	47S52210	22	22	10	
	47S52212	22	22	12	

Biofoam Cotton Wedge sizing

Footprint options	Implant part no.	Depth (mm)	Dorsal width (mm	Plantar width (mm)	Thickness (mm)	Thickness options
 16 x 14 x 10mm	47S01645	16	14	10	4.5	 4.5mm
	47S01655	16	14	10	5.5	
	47S01665	16	14	10	6.5	 5.5mm
 20 x 14 x 10mm	47S02045	20	14	10	4.5	
	47S02055	20	14	10	5.5	
	47S02065	20	14	10	6.5	 6.5mm

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for cleaning and sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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