BioSync® Reconstruction Wedge

Patient Information Leaflet

Arthrex®

Helping Surgeons Treat Their Patients Better®

Since its inception, Arthrex has been committed to one mission: Helping Surgeons Treat Their Patients Better. We are strategically focused on constant product innovation through scientific research, surgeon collaboration, and medical education to make less invasive surgical procedures simpler, safer, and more reproducible. Each year, we develop more than 1000 new innovative products and procedures to advance minimally invasive orthopedics worldwide.

Arthrex has always remained a privately held company, which allows for the rapid evaluation of new technologies and ideas. Our economic strength enables us to develop products and techniques that truly make a difference without compromising on quality. Our experienced team of dedicated professionals represents a shared passion and commitment to delivering uncompromising quality to the health care providers who use our products and the millions of patients whose lives we impact.

The medical significance of our contributions serves as our primary benchmark of success and will continue into the future as the legacy of Arthrex.

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Introduction

The bones of the midfoot and forefoot are intricately structured to support weight, absorb shock, and enable complex movements such as walking, running, and balancing. These bones include the metatarsals, cuneiforms, and the calcaneus, among others. When deformities, injuries, or degenerative conditions affect these bones, surgical correction may be necessary to restore alignment and function.

This leaflet contains information about your **BioSync reconstruction wedge implant**. It may not contain all the information related to your specific procedure and if you have any questions, talk to your healthcare provider. All implants have risks and benefits. Follow your healthcare team's advice even if it differs from what is contained within this leaflet. Please read this leaflet carefully and refer to it in the future if needed.

The name and number of your wedge implant can be found on your implant card. If a healthcare professional asks about your implant, please show them your implant card.

Device Description

The BioSync reconstruction wedge is a porous metal wedge used for angular correction of small bones in the ankle and foot. It is offered with varying widths and thicknesses to accommodate a variety of small bone applications.

Material Specifications

The BioSync reconstruction wedge is manufactured from grade 2 chemically pure porous titanium (BioSync-Ti) per ASTM F67 which contains:

- Titanium, (balance)
- Iron, max (0.30%)
- Oxygen, max (0.25%)
- *Other materials may be present at trace levels.

Indications

The BioSync reconstruction 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, except in Canada)
- 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 (tarsometatarsal (TMT) or lapidus)

This device is intended for use with ancillary fixation. The BioSync reconstruction wedge is not intended for use in the spine.

Contraindications

1. Insufficient quantity or quality of bone.
2. Blood supply limitations and previous infections, which may retard healing.
3. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made, and sensitivity ruled out prior to implantation.
4. Any active infection or blood supply limitations.
5. Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
6. The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb, or disrupt the growth plate.
7. Do not use for surgeries other than those indicated.

Risks/Adverse Effects

1. Infections, both deep and superficial.
2. Foreign body reactions.
3. Unwanted soft tissue damage and / or articular surface damage due to improper wedge placement.

Postoperative Care

Postoperative management is patient-specific and dependent on your doctor's assessment. Individual results will vary and not all patients will experience the same postoperative activity level or outcomes. Please be aware that surgery and recovery protocol may vary for each individual and any questions pertaining to the surgical procedure or postoperative protocol should be discussed with your surgeon.

Please call your doctor if:

- You experience loss of function/range of motion
- You develop a fever greater than 100.4 °F (38 °C)
- Drainage continues from the site of your incision
- Your surgical site becomes more swollen, tender, and painful, with increased difficulty performing your exercises.

If you have difficulty breathing or develop severe pain or chest pain, call your local emergency care or report immediately to your local emergency room.

North America emergency services – 911

⚠ Warnings

1. ⚠ Caution: Federal law restricts this device to sale by or on the order of a physician.
2. ⚠ This device is intended to be used by a trained medical professional.
3. ⚠ An internal fixation device must never be re-used.
4. Procedures carried out using these devices may be used on the general population.
5. The clinical benefits associated with the use of these devices outweigh the known clinical risks.
6. There are no unacceptable residual risks or uncertainties associated with the clinical use of these devices.
7. All metallic implant devices used for this surgical procedure should have the same composition properties.
8. Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weight bearing or other unsupported stress. The fixation provided by this device should be protected. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stresses applied to the device.
9. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Device removal should be followed by adequate postoperative management.
10. Detailed instructions and limitations of this device are provided to the surgeon in addition to this patient information leaflet and your patient implant card.
11.  These are single-use devices. Reuse of this device could result in the failure of the device to perform as intended and could cause harm to the patient and/or user.
12. Removal of supplemental fixation after healing. If the supplemental fixation is not removed following the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid re-fracture.
13. Serious incidents should be reported to Arthrex, Inc. or an in-country representative, and to the health authority where the incident occurred.

MRI Safety Information

MRI, or Magnetic Resonance Imaging, is an imaging technique utilizing a strong magnetic field to produce detailed anatomical images. This section details the information that you should be aware of when receiving an MRI scan.

Magnetic Resonance (MR) Conditional

A patient with this device can be scanned safely in an MR system under the following conditions. Failure to follow these conditions may result in injury.

Device Name	BioSync Reconstruction Wedge
Static Magnetic Field Strength (B_0)	1.5-Tesla and 3-Tesla
Maximum Spatial Field Gradient	30 T/m or 3000 Gauss/cm
RF (Radio Frequency) Excitation	Circularly Polarized (CP)
RF (Radio Frequency) Transmit Coil Type	Volume RF body coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR (Specific Absorption Rate)	1 W/kg
Maximum Head SAR	3.2 W/kg
Scan Duration	Under the scan conditions defined, the BioSync Reconstruction Wedge can be scanned continuously for 10 minutes. With 20 minutes wait time, the sequence can be repeated twice in 60 minutes.
MR Image Artifact	The presence of this implant may produce an image artifact.
Patients who have other MR Conditional devices can be scanned as long as all the MR Conditional scan parameters for each of the devices are met. Do not conduct an MRI scan if any conditions for safe scanning for any device cannot be met.	
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

The person with a BioSync Reconstruction Wedge implant can safely undergo an MR exam only under very specific conditions. Scanning under different conditions may result in severe injury. Full MRI safety information is available in the MRI Safety Information section of this patient information leaflet or by calling Arthrex customer service at +1 800 934-4404.

BioSync Reconstruction Wedge

Evans Wedge Implant Models

Consult your BioSync Reconstruction Wedge Implant Identification Card for information on the device type/model of the implant used in your procedure.

Item Number	Product Description
AR-8942W-1806	BioSync Evans Wedge, 18 x 18 x 6.5 mm
AR-8942W-1808	BioSync Evans Wedge, 18 x 18 x 8 mm
AR-8942W-1810	BioSync Evans Wedge, 18 x 18 x 10 mm
AR-8942W-1812	BioSync Evans Wedge, 18 x 18 x 12 mm
AR-8942W-2006	BioSync Evans Wedge, 20 X 20 X 6.5 mm
AR-8942W-2008	BioSync Evans Wedge, 20 X 20 X 8 mm
AR-8942W-2010	BioSync Evans Wedge, 20 X 20 X 10 mm
AR-8942W-2012	BioSync Evans Wedge, 20 X 20 X 12 mm
AR-8942W-2206	BioSync Evans Wedge, 22 X 22 X 6.5 mm
AR-8942W-2208	BioSync Evans Wedge, 22 X 22 X 8 mm
AR-8942W-2210	BioSync Evans Wedge, 22 X 22 X 10 mm
AR-8942W-2212	BioSync Evans Wedge, 22 X 22 X 12 mm

BioSync Reconstruction Wedge

Anatomic Cotton Wedge Implant Models

Consult your BioSync Reconstruction Wedge Implant Identification Card for information on the device type/model of the implant used in your procedure.

Item Number	Product Description
AR-8948W-1645	BioSync Anatomic Cotton Wedge, 16x4.5 mm
AR-8948W-1655	BioSync Anatomic Cotton Wedge, 16x5.5 mm
AR-8948W-1665	BioSync Anatomic Cotton Wedge, 16x6.5 mm
AR-8948W-1675	BioSync Anatomic Cotton Wedge, 16x7.5 mm
AR-8948W-2045	BioSync Anatomic Cotton Wedge, 20x4.5 mm
AR-8948W-2055	BioSync Anatomic Cotton Wedge, 20x5.5 mm
AR-8948W-2065	BioSync Anatomic Cotton Wedge, 20x6.5 mm
AR-8948W-2075	BioSync Anatomic Cotton Wedge, 20x7.5 mm

Contact Information

Any serious incident that occurs in relation to the device should be reported to the manufacturer and to the health authority where the incident occurred.

Region	Contact
Arthrex, Inc.	1370 Creekside Blvd. Naples, FL 34108, USA USA Toll free: +1 800 934-4404 arthrex.com
Arthrex GmbH	Erwin-Hielscher-Strasse 9 81249 München, Germany +49 89 90 90 05-0 arthrex.de

USA – U. S. Food & Drug Administration website: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

The information contained in this patient leaflet is not medical advice and is not meant to be a substitute for the advice provided by a surgeon or other qualified medical professional on the use of these products. You should talk with your physician or healthcare provider for more information about your health condition, and whether Arthrex products might be appropriate for you. The surgeon who performs any surgical procedure is responsible for determining and using the appropriate techniques for surgical procedures on each individual patient. Arthrex recommends that surgeons be trained on the use of any particular product before using it in surgery. A surgeon must always rely on their professional medical judgment when deciding whether to use a particular product when treating a particular patient. A surgeon must always refer to the package insert, product label, and/or directions for use before using any Arthrex product. Products may not be available in all markets because product availability is subject to regulatory approvals and medical practices in individual markets. Please contact Arthrex if you have questions about the availability of products in your area.

Symbols glossary can be found at www.arthrex.com/symbolsglossary.

arthrex.com