Univers Revers™ Shoulder Prosthesis System

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 simple, 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 and the freedom to develop products and techniques that truly make a difference without economic considerations or compromise. Our experienced team of dedicated professionals represents a shared passion and commitment to delivering uncompromising quality to the healthcare 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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Device Description

The Univers Revers™ shoulder prosthesis system

The Univers Revers shoulder prosthesis system has an articular design that is inverted, compared to traditional total shoulder prosthesis. The system is comprised of two main components: the Arthrex Univers Revers shoulder prosthesis and a glenoid baseplate system. The glenoid baseplate system is comprised of either the Universal Glenoid™ shoulder prosthesis or the Univers Revers™ Modular Glenoid System. The Arthrex Univers Revers shoulder prosthesis is comprised of a humeral stem and epiphysis or humeral cup (i.e., SutureCup), a spacer, and a humeral cup liner. The Universal Glenoid shoulder prosthesis consists of a glenoid baseplate, a glenosphere, and screws.

The Univers Revers modular glenoid system consists of a monoblock baseplate or a modular baseplate; both baseplates are available with either a central screw or central post. Modular baseplates are also available with full or half augments that can be obliquely or non-obliquely oriented. The augmented modular baseplates are used with central posts. The baseplates are designed to be used cementless with peripheral screws and a glenosphere. The glenoid system is designed to be used as the glenoid side of the existing Univers Revers shoulder prosthetic system.

The Univers Revers cuff arthropathy system (CA humeral head with adapter) is designed to be used with the existing well-fixated Univers Revers stem, or to convert an existing reversed shoulder prosthesis to a hemi anatomic configuration. The Univers Revers cuff arthropathy (CA) humeral head is designed with a larger area of articulation to allow for articulation with the acromion in patients with gross rotator cuff deficiency.

Material Specifications

The Univers Revers™ shoulder prosthesis system

- The humeral device consists of a stem, cup, screw, and spacer manufactured of titanium. The stem body and cup are partly coated with a calcium phosphate (CaP) or hydroxyapatite (HA) coating and the cup is partly coated with a calcium phosphate (CaP) coating.

- The humeral inlay component is composed of ultra-high molecular weight polyethylene (UHMWPE).

- The Universal Glenoid shoulder prosthesis consists of the baseplate, bushings, a central screw and cancellous screws – all manufactured of titanium. The baseplate is partially coated with calcium phosphate (CaP). The glenosphere is manufactured of cobalt-chromium

- The Univers Revers modular glenoid system consists of a baseplate, central screw or post and cancellous bone screws - all manufactured of titanium. The baseplates and modular posts are partially coated with CP (commercially pure) titanium. The glenosphere is manufactured of cobalt-chromium. The glenosphere is also manufactured of titanium alloy Ti-6AL-4V ELI.

- The Univers Revers CA humeral head is manufactured of cobalt-chromium and the CA head adapter is manufactured of titanium alloy Ti-6Al-4V ELI and UHMWPE.

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 38 °Celsius /100.4 °Fahreheit
- 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 911 or report immediately to your local emergency room.

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.

1. MR Conditional

MRI Safety Information

A person with the Univers Revers™ shoulder prosthesis system may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.	
Device Name	Univers Revers™ shoulder prosthesis system
Static Magnetic Field Strength (B_0 - B subscript zero)	1.5-Tesla and 3.0-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)	0.5 W/kg (Normal Operating Mode)
Maximum Head SAR	N/A
Scan Duration	Under the scan conditions defined, the Univers Revers™ shoulder prosthesis system can be scanned continuously for 60 minutes.
MR Image Artifact	The presence of this implant may produce an image artifact of 60 mm.
Patients who have other MR Conditional devices can be scanned as long 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.	

A person with an Arthrex Univers Revers shoulder system 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, Directions for Use (https://edfu.arthrex.com) or by calling Arthrex customer service at +1 800 934-4404.

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 +1 800 934-4404 arthrex.com
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USA – U. S. Food & Drug Administration website: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

Australia – Therapeutic Goods Administration website: https://www.tga.gov.au

European Union – https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

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

The information contained in this patient information 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.

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