Univers II™, Univers Apex, and Univers Apex OptiFit™ Total Shoulder 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 II™, Univers Apex, and Univers Apex OptiFit™ Total Shoulder System** consists of a stem for fixation within the humerus, a spherical head for replacing the humeral head, and a trunion to connect the head to the stem. The stems and heads are available in a variety of sizes. The Univers™ Apex total shoulder system consists of a stem for fixation within the humerus, a spherical head for replacing the humeral head, and a trunion to connect the head to the stem. The Univers Apex OptiFit Humeral Stem is a component of Univers II total shoulder system. The stems and heads are available in a variety of sizes. The Univers Apex stem and Univers Apex OptiFit humeral stem are identical to the existing Univers II stem, except for the overall length. The Univers Apex and Univers Apex OptiFit stems length has been shortened to optimize bone conservation. The stem and trunions in the Univers II, Univers Apex and Univers Apex OptiFit systems are comprised of titanium. The heads are available in cobalt alloy or titanium alloy.

The Univers VaultLock® keeled and pegged glenoids are comprised of ultra-high molecular weight polyethylene (UHMWPE) and available in a variety of sizes. The Univers VaultLock may include a half wedge augment.

Material Specifications

Univers II, Univers Apex and Univers Apex OptiFit Total Shoulder System

- The device consists of a stem body manufactured of titanium and may be partly coated with titanium plasma spray coating (TPS), a metal head support of titanium alloy, and a head manufactured of cobalt-chromium (Co-Cr) alloy. Humeral heads are also offered in titanium alloy 6L-4V Eli. The glenoid component is composed of ultra-high molecular weight polyethylene (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° Fahrenheit
- 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 Arthrex Univers II, Univers Apex, and Univers Apex OptiFit Total Shoulder System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.	
Device Name	Univers II, Univers Apex, and Univers Apex OptiFit Total Shoulder 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 Arthrex Shoulder 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 II, Univers Apex, and Univers Apex OptiFit Total 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
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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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