Univers™ II Total Shoulder System

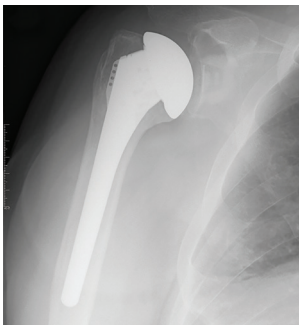
Surgical Technique

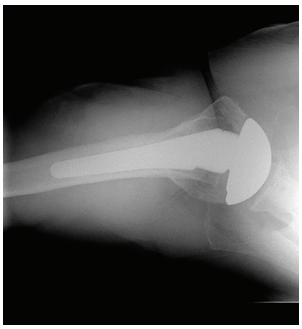
Arthrex®

Univers™ II Total Shoulder System

Implant Design Rationale

The Univers II humeral component was designed to account for common anatomical variations of the proximal humerus. Variable adjustment with respect to the inclination angle, version, and head offset are features critical to reconstruction of the proximal humerus. The simplified design of the Univers II humeral component allows the surgeon to adapt the humeral stem and articular surface to the position that best represents the patient's normal anatomy. All of the adjustments can be made intraoperatively with the implant in the humeral canal. This unique feature allows the surgeon to more accurately recreate the normal anatomical structure of the shoulder joint. With anatomic restoration of the humerus and glenoid, soft-tissue balancing of the rotator cuff is more accurate, allowing for improved functional outcome.

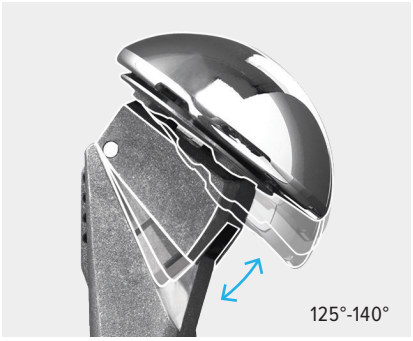




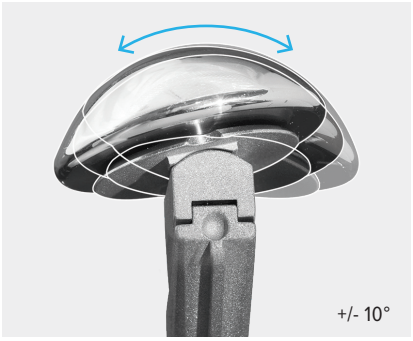
Implant Features

- Variable inclination, version, and offset
- Package-to-canal design: anatomic restoration in situ
- Eccentric humeral heads
- Multiple head diameters and heights for precise anatomic reconstruction
- Humeral heads offered in cobalt chrome and titanium (special order)
- Instruments and trays designed to maximize efficiency in the operating room
- Multiple glenoid options available

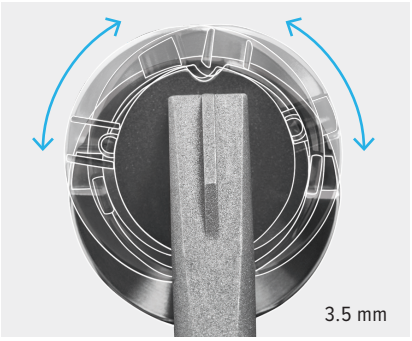
Inclination



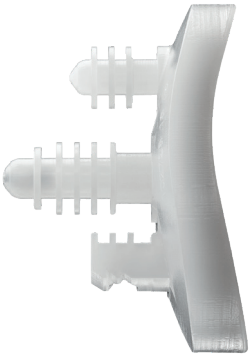
Version

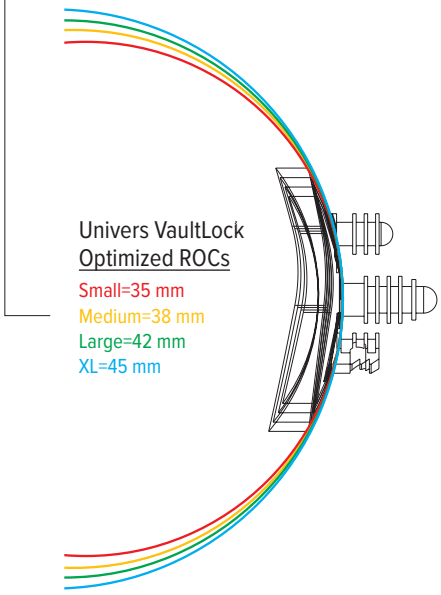


Offset



Univers VaultLock® Glenoid





Fluted Central Peg
- Immediate fixation

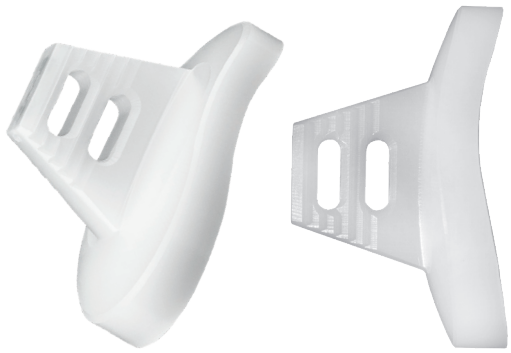
Inferior Keel
- Decreased cortical penetration compared to inferior pegs
- Multiple fixation features, including reverse barbs, flutes, and central cement fenestration

Superior Peg
- Enhanced immediate fixation
- Self-pressurizing design

Inline Configuration
- Combines all advantages of pegged and keeled implants, including stability and preparation ease

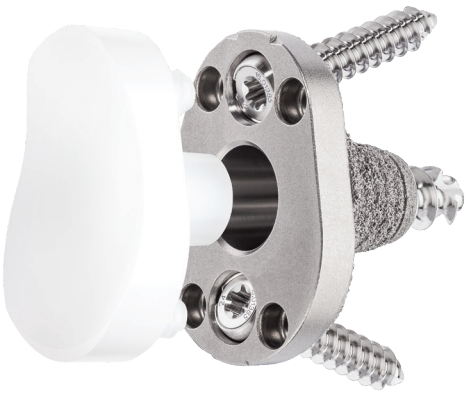
Anatomic Backside Radius of Curvature (ROC)
- Matches glenoid poly to glenoid anatomy
- Bone-sparing reaming
- Simplified decision-making
- Anatomic solution with subchondral, bone-preserving design

Glenoid Options: Pegged and Keeled



Keeled Glenoid

- Dual fenestrations for enhanced anchoring
- Reverse barbs for expansion effect within the glenoid vault

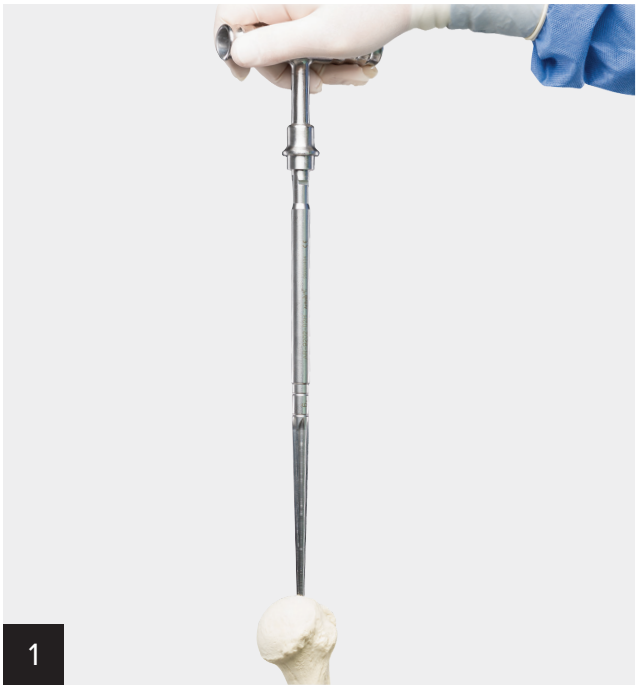


Convertible Universal Baseplate

- Combines advantages of polyethylene with the stability of screw fixation, resulting in reduced risk of radiolucent lines
- Three sizes (S, M, L), two polyethylene thicknesses (baseplate + polyethylene = 7 mm or 8 mm), and appropriate glenohumeral mismatch for restoration of anatomic joint kinematics
- Immediate screw fixation (compression and locking)
- Easily remove poly and add a glenosphere for revision reverse total shoulder arthroplasties

Humeral Preparation

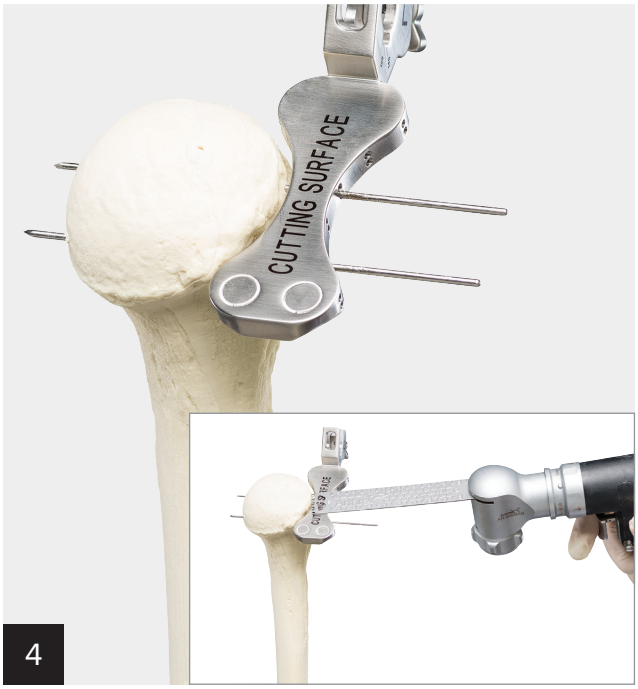
The surgeon should position and expose the shoulder for a standard arthroplasty procedure. Following exposure of the humeral head, including removal of the osteophytes, either a freehand resection technique, Intramedullary (IM) resection guide (see step 1), or resection template can be used. See page 14 for additional resection options.



Attach the reamer T-handle to the 5 mm or 6 mm humeral reamer. Advance the reamer down the medullary canal to the first circumferential grove. Repeat with the 7 mm reamer if necessary. Leave the final reamer in place.

Secure the IM guide cutting assembly, cutting surface, and version rods to the reamer. Refer to the IM Cutting Guide Adjustments (page 16) for usage and adjustment details.

Adjust inclination and version of the IM guide to align the cutting surface with the anatomic neck of the humerus. Secure the cutting surface with two 1.6 mm K-wires.



4

Detach the IM cutting guide assembly from the cutting surface. Remove the cutting assembly and reamer from the humerus.

Perform the proximal humerus osteotomy. Humeral head dimensions should be noted for subsequent glenoid size selection (see Glenoid Sizing Matrix on page 17).

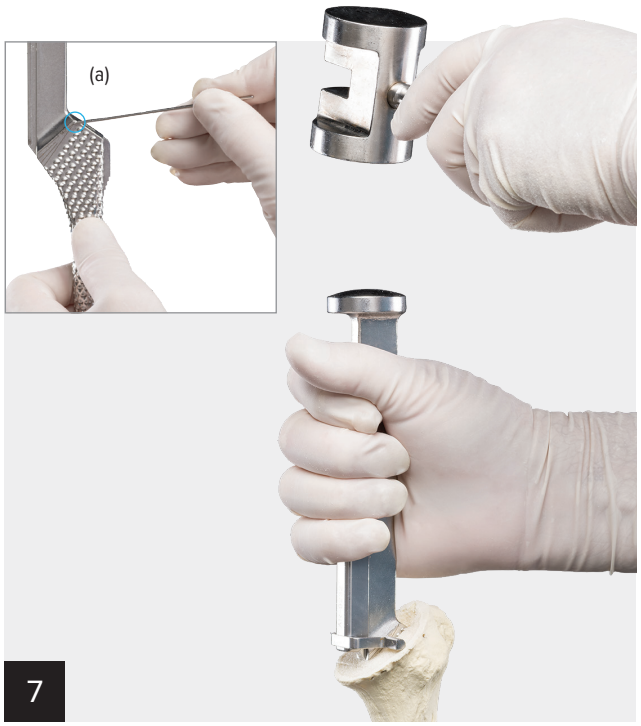
5

If used for the humeral osteotomy, attach the reamer T-handle to the 5 mm or 6 mm reamer. Position the tip at the superolateral aspect of the humerus. Advance the reamer down the medullary canal to the circumferential groove adjacent to the cutting flutes. Repeat up to the 7 mm reamer if necessary.

6

Broaching begins with the 6 mm humeral broach. Position the broach alignment guide onto the 6 mm humeral broach. Gently advance the broach with a mallet until the forks of the guide rest evenly on the medial surface of the resection. The guide assures the broach maintains proper orientation during impaction.

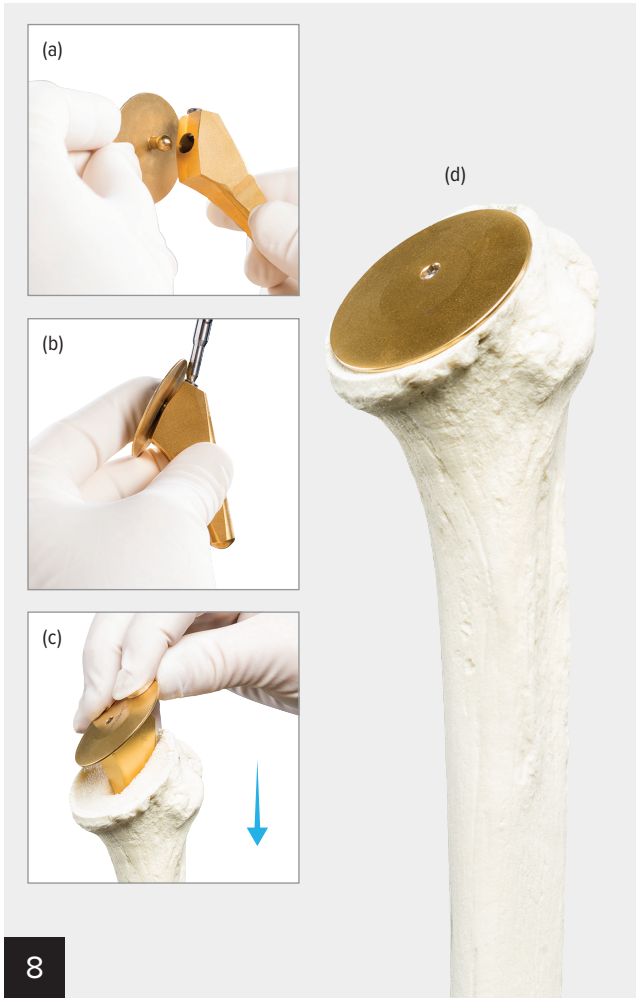
Note: It may be necessary to begin with a 5 mm humeral broach in smaller patients.



Each broach should be advanced until the lateral hinge point of the laser marks (see inset) is aligned with the resected surface. Proceed with the next size broach until the appropriate fit is obtained. For noncemented application, select the implant that corresponds to the final broach size.

Note: If cementing the stem is desired, an implant one size smaller than the final broach is recommended.

The point located on lateral side of broach **(a)** must be flush with the cut both anteriorly and posteriorly.



Assemble a resection Protector™ device of appropriate diameter to a resection Protector post that is one size smaller than the canal preparation. Do not overtighten the set screw. This allows the Protector device to rest evenly on the resected surface **(a,b)**. Insert the construct into the proximal humerus until the plate comes to rest on the humeral cut **(c,d)**.

Humeral Stem Implantation

After completing glenoid component implantation, remove the resection Protector™ device and post.

Open the humeral implant in a sterile fashion and insert the stem into the humeral canal.

Note: It is not necessary to adjust screws prior to implantation.

Note: For cemented application, select a humeral stem one size smaller than the canal preparation. Perform steps 2-7. Remove the stem, place the cement into the canal, and reinsert the stem. It may be necessary to use the stem impactors. Remove any excess cement.

Place the pointed stem impactor into the dimple on the lateral portion of the stem. Impact the stem as far as possible. Change to the angled Morse taper stem impactor (see step 4).

4

Place the angled Morse taper stem impactor over the Morse taper and complete impaction **(a)**. Impact the stem into the humerus, keeping the inclination angle free **(b)**. The inclination angle is established when the flange is in contact with the humeral surface and is fully seated.

5

Tighten the inferior locking screw located on the medial portion of the trunnion. The inferior (inclination) screw should be locked before the superior (version) screw is locked. Place downward pressure on the driver while tightening. It may be necessary to clear debris from the inferior screw hex using a Frazier suction tip or curette if difficulty with driver engagement is encountered.

Note: This screw should be provisionally tightened with the standard hex driver. The torque driver must be used for final tightening (see step 6).

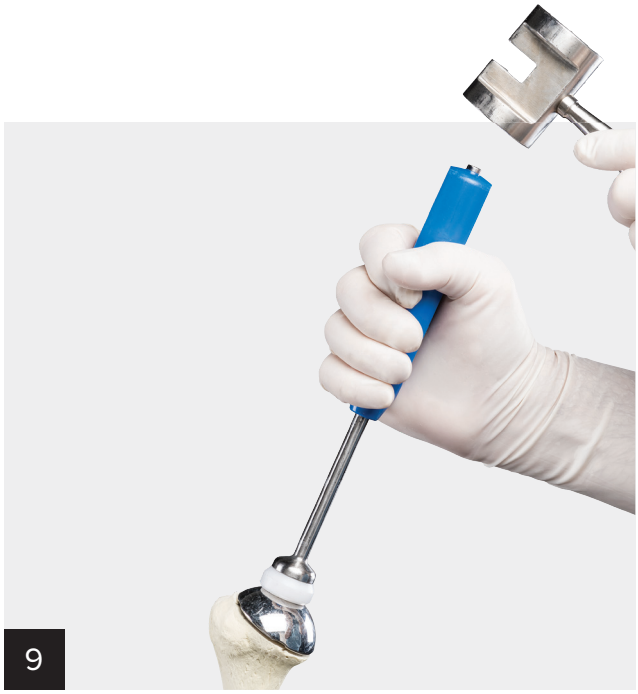
Use the torque driver to lock the inclination (inferior) screw located on the Morse taper of the humeral stem. Properly tighten the set screw by visually confirming that the “INF” mark is rotated to the indicator line **(a)** on the torque driver.

Note: Care must be taken to ensure drivers are completely seated into the locking screws during tightening.

Use the torque driver to lock the version (superior) screw located on the Morse taper of the humeral stem. Ensure that the set screw is properly tightened by visually confirming that the “SUP” mark is rotated to the indicator line on the torque driver.

Note: This screw can be provisionally tightened with the standard hex driver; however, the torque driver must be used for final tightening.

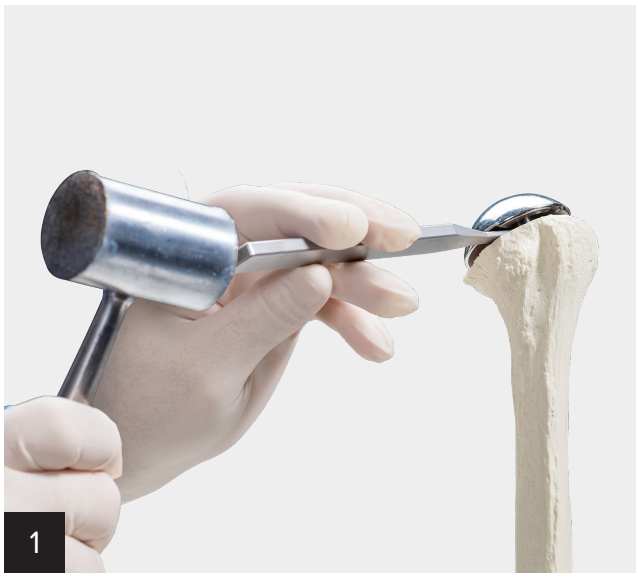
Attach the appropriate trial head and use the trial driver to adjust offset. Perform a trial reduction. The position of maximum offset is designated by a line on the surface of the trial head and corresponds with markings on the implant head.



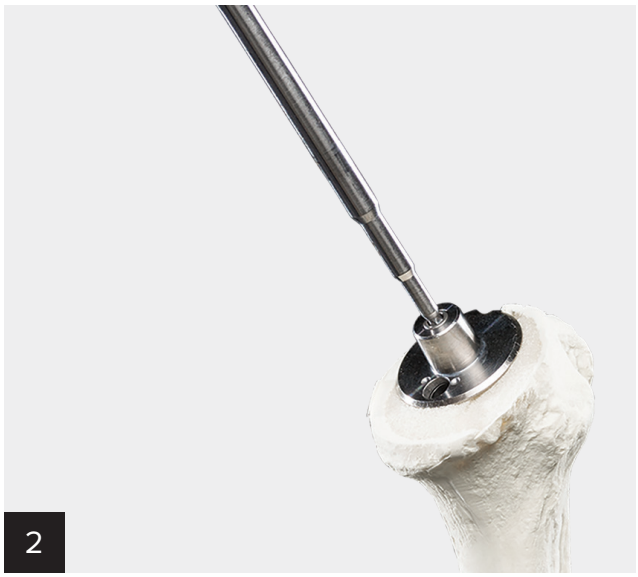
After trial reduction, remove the trial head and clean and dry the Morse taper. Impact the implant humeral head onto the humeral stem using the head impactor.

Univers™ II Implant Removal

Surgical Technique



Once exposure is accomplished and the proximal humerus dislocated, disengage the prosthetic head by placing the humeral head extractor into one of the head slots between the head and trunnion. It may be necessary to use more than one slot to accomplish extraction.



Remove the version locking (superior) screw to facilitate removal of the trunnion. It may be helpful to use the T-handle torque driver.

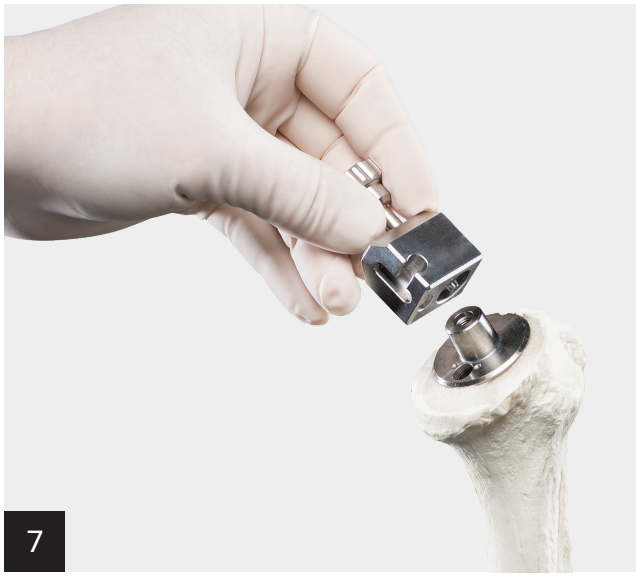
Note: It is important to leave the inferior screw tightened and locked.

Thread the trunnion extractor into the version (superior) screw location in the Morse Taper.

Disengage the trunnion from the stem by rolling the wrist in a posterior to anterior motion, releasing the locking connection.

It is essential to first loosen the proximal stem before attempting to use the slap hammer for stem removal. This is accomplished with osteotomes passed between the proximal rectangular body and surrounding bone. Removal of the trunnion allows placement of the osteotome directly along the surface of the implant, thus minimizing bone loss.

Once the proximal stem has been loosened with osteotomes, replace the trunnion by mating the trunnion male locking connection with the socket on the stem inclination block and applying downward pressure. This pressure is required to fully capture the locking connection. You should feel a “snap” or “click” when connected correctly.



Thread the stem extraction block into the version (superior) screw location on the Morse Taper.

It is essential to fully tighten and completely seat the screw to lock the trunnion to the stem before using the slap hammer (step 10).

9

The extraction block will spin freely even when the locking screw is completely seated.

10

Connect the slap hammer to the dovetail connection slot located on the side of the stem extraction block.

11

After securing the connection, hold the slap hammer axis in line with the anatomic axis of the humerus and deliver a distracting force.

12

Gradually deliver increasing amounts of force until the stem is released and exits superiorly. If the amount of force being applied becomes a concern, remove the extraction block and trunnion. Repeat the osteotome process of loosening the proximal stem.

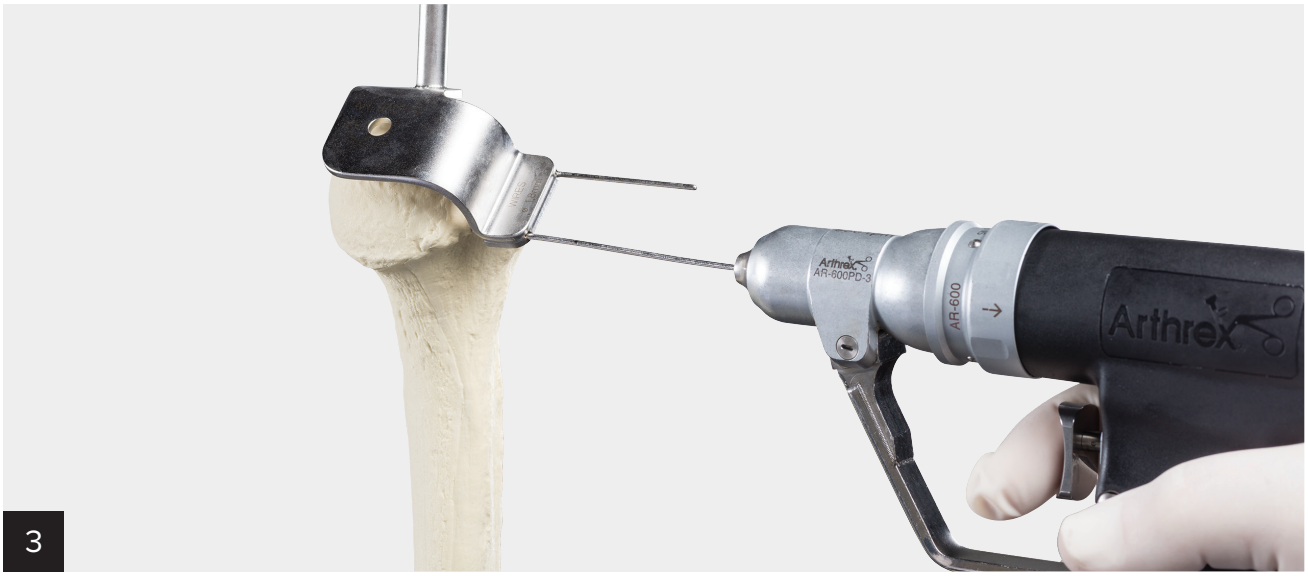
Optional: Humeral Resection Method

1

Remove osteophytes with a rongeur or small osteotome to identify the anatomic neck. Place either the left or right, small or large humeral head resection guide on the humeral head. To determine retroversion, place version rods in the guide at the 20° and/or 40° position and align with the forearm when the elbow is flexed 90°. Typically, the forearm should be visualized between the position of the 2 version rods so that a retroversion of 30° is achieved based on the orientation of the forearm.

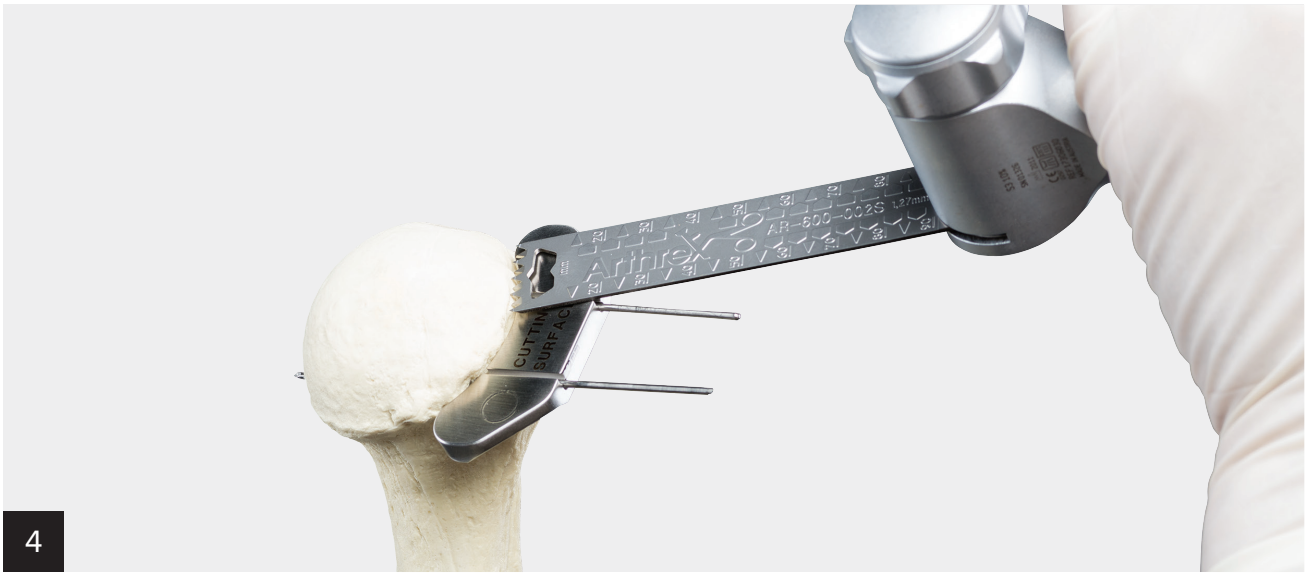
2

The appropriate guide size and position will result in subsequent pin placement across the anatomic neck. Once the appropriate position has been established, advance the 2.8 mm Steinmann pin down the center cannulation of the humeral head resection guide to secure it to bone.



3

Drill two 1.6 mm K-wires through the holes of the humeral head resection guide until they exit the opposite cortex.



4

Remove the Steinmann pin and disengage the resection guide from the K-wires. Resect the head with a saw after placing the cutting block over the K-wires. Compare the resected humeral head or cut surface of the humerus to a trial of corresponding size. The proportions should be noted for subsequent glenoid selection (see Glenoid Sizing Matrix on page 17).

IM Cutting Guide Adjustments

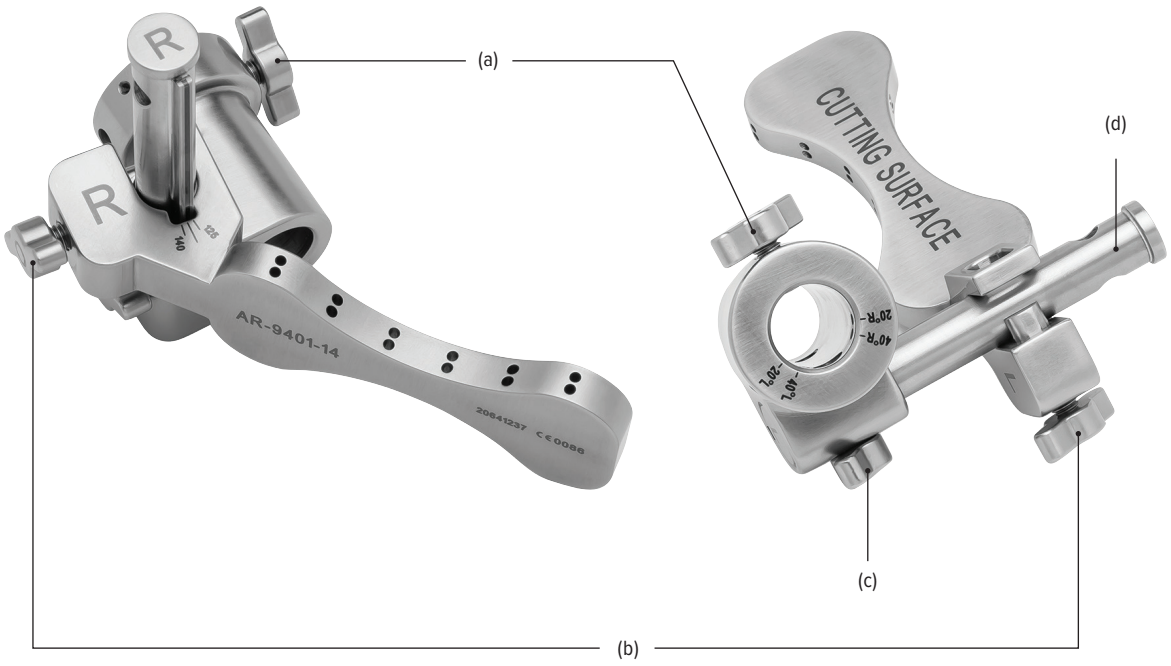
Please refer to the technique video on **Arthrex.com.**

This guide, for use during anatomic shoulder arthroplasty, is designed to attach to any of the proximal humerus reamers in the Univers™ II total shoulder system.

Intraoperatively, leave the final reamer in the proximal humerus intramedullary canal. Adjust and attach the guide to the reamer in the following manner.

There is a central thumb screw **(a)** that secures the guide to the reamer. The guide functions as a left and/or right instrument, and as such has holes along its proximal margin for version guide rod attachment (20°L, 40°L and 20°R, 40°R).

When switching from a left to a right instrument, and vice versa, the cutting surface must be removed from the horizontal support bar **(d)** by loosening the lateral thumb screw **(b)**. Loosen the central thumb screw **(c)** securing the horizontal bar **(d)** to slide the bar left to right, and vice versa. Reattach the cutting surface and tighten the lateral thumb screw **(b)**. The neck/shaft cutting angle and medial/lateral displacement of the cutting surface are also controlled by the lateral thumb screw **(b)**. The height and version of the cutting surface are controlled by the central thumb screw **(a)**, which secures the guide to the reamer.



Glenoid Sizing Matrix—Radial Mismatch in mm

Univers™ II Total Shoulder System	Univers VaultLock® and Keeled Glenoids				
	Humeral Head	Small	Medium	Large	Extra Large
	40	8.5	10	11.5	13
	42	7.5	9	10.5	12
	44	6.4	7.9	9.4	10.9
	46	5.3	6.8	8.3	9.8
	48	4.2	5.7	7.2	8.7
	50	3.1	4.6	6.1	7.6
	52	2.3	3.8	5.3	6.8
	54	1	2.5	4	5.5
	56	0.2	1.7	3.2	4.7

Note: Shaded region represents recommended sizes

Univers II Total Shoulder System	Universal Glenoid™ Convertible Baseplate			
	Humeral Head	Small	Medium	Large
	40	8.5	10	11.5
	42	7.5	9	10.5
	44	6.4	7.9	9.4
	46	5.3	6.8	8.3
	48	4.2	5.7	7.2
	50	3.1	4.6	6.1
	52	2.3	3.8	5.3
	54	1	2.5	4
	56	0.2	1.7	3.2

Note: Shaded region represents recommended sizes

Humeral Stem Lengths

Stem Size	Length
5	105 mm
6	115 mm
7	140 mm
8	143 mm
9	146 mm
10	148 mm
11	151 mm
12	151 mm
13	151 mm
14	151 mm
15	151 mm

Ordering Information

Instruments

Product Description	Item Number
Univers™ II Humeral Preparation Set	AR-**9226UBS**
Univers II/Apex Combined Humeral Preparation Set	AR-**9226CC**

Literature

Product Description	Item Number
Shoulder Implant Identification Card	pBR1-004853-EN
Univers II Total Shoulder System Surgical Technique	LT1-0701-EN

Implants

Product Description	Item Number
Humeral Stem, 5 mm × 105 mm	AR-**9100-05P**
Humeral Stem, 6 mm × 115 mm	AR-**9100-06P**
Humeral Stem, 7 mm × 140 mm	AR-**9100-07P**
Humeral Stem, 8 mm × 143 mm	AR-**9100-08P**
Humeral Stem, 9 mm × 146 mm	AR-**9100-09P**
Humeral Stem, 10 mm × 148 mm	AR-**9100-10P**
Humeral Stem, 11 mm × 151 mm	AR-**9100-11P**
Humeral Stem, 12 mm × 151 mm	AR-**9100-12P**
Humeral Stem, 13 mm × 151 mm	AR-**9100-13P**
Humeral Stem, 14 mm × 151 mm	AR-**9100-14P**
Humeral Stem, 15 mm × 151 mm	AR-**9100-15P**
Humeral Head, 40 mm × 17 mm	AR-**9140-17P**
Humeral Head, 42 mm × 17 mm	AR-**9142-17P**
Humeral Head, 44 mm × 17 mm	AR-**9144-17P**
Humeral Head, 44 mm × 19 mm	AR-**9144-19P**
Humeral Head, 46 mm × 18 mm	AR-**9146-18P**
Humeral Head, 46 mm × 20 mm	AR-**9146-20P**
Humeral Head, 48 mm × 19 mm	AR-**9148-19P**
Humeral Head, 48 mm × 21 mm	AR-**9148-21P**
Humeral Head, 50 mm × 19 mm	AR-**9150-19P**
Humeral Head, 50 mm × 21 mm	AR-**9150-21P**
Humeral Head, 52 mm × 20 mm	AR-**9152-20P**
Humeral Head, 52 mm × 22 mm	AR-**9152-22P**
Humeral Head, 54 mm × 21 mm	AR-**9154-21P**
Humeral Head, 54 mm × 23 mm	AR-**9154-23P**
Humeral Head, 56 mm × 22 mm	AR-**9156-22P**
Humeral Head, 56 mm × 24 mm	AR-**9156-24P**
Univers II/Apex Trunnion Replacement Kit	AR-**9100TK**

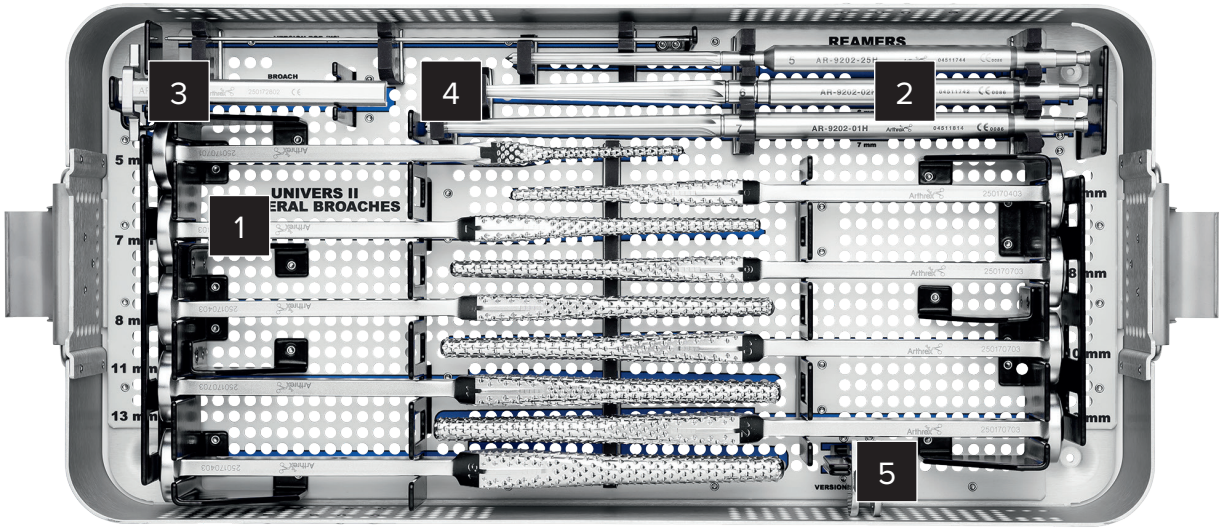
Product Description	Item Number
Titanium Humeral Head, 40 mm × 17 mm	AR-**9140-17T***
Titanium Humeral Head, 42 mm x 17 mm	AR-**9142-17T***
Titanium Humeral Head, 44 mm × 17 mm	AR-**9144-17T***
Titanium Humeral Head, 46 mm × 18 mm	AR-**9146-18T***
Titanium Humeral Head, 48 mm × 19 mm	AR-**9148-19T***
Titanium Humeral Head, 50 mm × 19 mm	AR-**9150-19T***
Titanium Humeral Head, 52 mm × 20 mm	AR-**9152-20T***
Titanium Humeral Head, 54 mm × 21 mm	AR-**9154-21T***
Titanium Humeral Head, 56 mm × 22 mm	AR-**9156-22T***

*Available by special order

Univers II/Apex Disposable Pin Set (AR-9207S)

Product Description	Item Number
Optional Subscapular Repair Kit: FiberTape® Tendon Compression Bridge Kit	AR-**7219**
Univers II/Apex Disposable Pin Set	AR-**9207S**
Steinmann Pin, 2.8 mm	AR-**9207**
Kirschner Wire, 1.6 mm, qty. 2	AR-**9208**

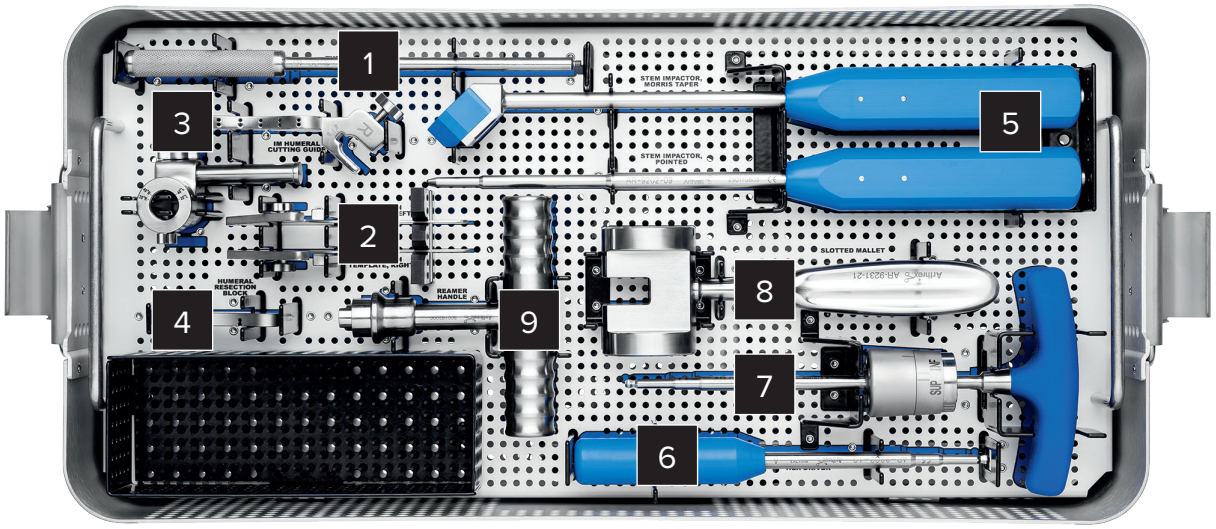
Univers™ II Humeral Preparation Set



Univers II Humeral Preparation Set (AR-9226UBS)

Pic.	Product Description	Item Number
1	Univers II Broaches	AR-**9231-05/13**
2	Univers II Reamer, 5 mm	AR-**9202-25H**
	Univers II Reamer, 7 mm	AR-**9202-01H**
	Univers II Reamer, 6 mm	AR-**9202-02H**
3	Univers II Guide for Humeral Broach	AR-**9232**
4	Univers/Eclipse™ Orientation Pin for Resection Guide	AR-**9202**
5	Univers II Version Rod Bracket for Broach	AR-**9231-20**

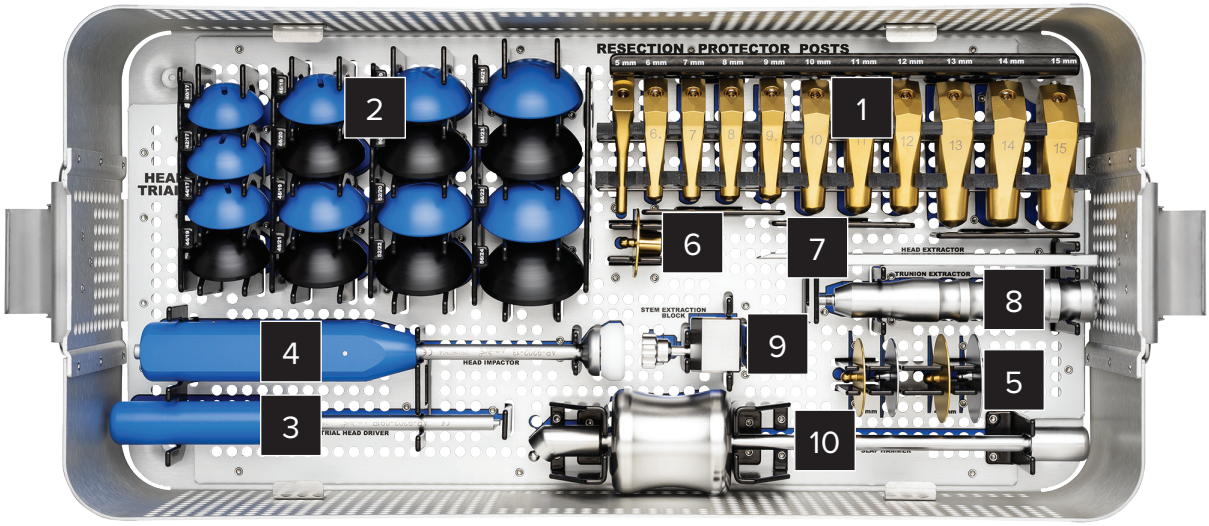
Univers™ II/Apex Combined Humeral Preparation Set



Univers II/Apex Combined Humeral Preparation Set - Top Tray (AR-9266CS)

Pic.	Product Description	Item Number
1	Glenoid Drill Guide Handle	AR-**9215-1-02**
2	Humeral Resection Templates	AR-**9200-01L/01R**
3	Intramedullary Humeral Cutting Guide	AR-**9401-14**
4	Univers II/Eclipse™ Humeral Resection Block	AR-**9205**
5	Univers II Stem Impactors	AR-**9202-09/09P**
6	Univers Screwdriver	AR-**9202-10**
7	Univers II Torque Driver	AR-**9224**
8	Slotted Mallet, shoulder arthroplasty	AR-**9231-21**
9	Univers Reamer T-Handle, Hudson connect	AR-**9202-15H**

Univers™ II/Apex Combined Humeral Preparation Set (Cont.)



Univers II/Apex Combined Humeral Preparation Set - Bottom Tray (AR-9226CC)

Pic.	Product Description	Item Number
1	Univers Apex Protector™ posts, sizes 5-15 mm	AR-**9200-15S**/AR-**9200-25S**
2	Univers II Trial Heads	AR-**9240-17P**/AR-**9256-24P**
3	Univers II Driver, trial heads	AR-**9202-091P**
4	Humeral Head Impactor	AR-**9202-13**
5	Univers II Resection Protector Devices	AR-**9202-40SP**/AR-9202-**45TP**
6	Univers II Trial Trunnion	AR-**9202-27**
7	Humeral Head Extractor	AR-**9401-17**
8	Univers II Trunnion Extractor	AR-**9202-38P**
9	Univers II Stem Extractor	AR-**9202-41P**
10	Univers Slap Hammer	AR-**9202-14**

Optional

Product Description	Item Number
Version Rod Bracket	AR-**9231-20**
Intramedullary (IM) Humeral Cutting Guide	AR-**9401-14**

Directions for Use

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. Do not re-sterilize this device.
5. A cobalt-chromium implant device contains the following substance(s) defined as CMR 1A and/or CMR 1B and/or endocrine-disrupting substances in a concentration above 0.1% weight by weight: Cobalt; CAS No. 7440-48-4. European Chemicals Agency Database: https:/echa.europa.eu
6. Failure to achieve the appropriate torque requirements when tightening locking screws may result in the premature loosening of the device.
7. The Univers Apex total shoulder system stems (lengths 55-65 mm) are not recommended for fractures of the proximal humerus.
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. Detailed instructions on the use and limitations of this device, the patient leaflet (www.arthrex.com/patientleaflets) and the patient implant card should be given to the patient. Guide the patient in deciding what particular treatment is best for them and explain the benefits, risks, and contraindications associated with the treatment.
10. Any decision to remove the device should take into consideration the potential risk to the patient undergoing a second surgical procedure. Implant removal should be followed by adequate postoperative management.
11. Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the device, are important considerations in the successful utilization of this device.
12. The following operative situations may cause premature loosening and complications:

- Extreme weakening of the bone structure in preparing the bone bed;
- Unsuitable selection of the implant size;
- Inadequate cleaning of the bone bed prior to implantation; and
- Excessive use of force in placing or fastening the implant, provoking splintering fractures, or causing the bone to tear.

13. The appropriate Arthrex delivery system is required for proper insertion of the implant.
14. Only Arthrex delivery systems, instruments, and trial prostheses should be used for the implantation procedure.
15. Endoprostheses may not be altered mechanically or changed in any other way.
16. Do not implant any parts that have been scratched or damaged.
17. An artificial joint is subject to wear and/or can loosen over a period of time. Wear and loosening may make it necessary to reoperate on an artificial joint.
18. An infection in an artificial joint may lead to implant removal.
19. This device should only be used in conjunction with other implants designed specifically for use with this system.
20. Biohazard waste, such as explanted devices, needles, and contaminated surgical equipment should be safely disposed of in accordance with the institution's policy.
21. Serious incidents should be reported to Arthrex Inc., or an in-country representative, and to the health authority where the incident occurred.
22. This device is MR (Magnetic Resonance) Conditional. See the DFU for the Univers™ II, Univers Apex, and Univers Apex OptiFit device family (DFU-0131-EO) for the full list of conditions.

Indications

The Univers™ II total shoulder system is indicated in replacement(s) when conditions including severe pain or significant disability resulting from degenerative, rheumatoid, traumatic disease, or injury of the glenohumeral joint; nonunion humeral head fractures of long duration; irreducible 2- and 4-part proximal humeral fractures; avascular necrosis of the humeral head, or other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable.

The polyethylene glenoid components are intended for cemented fixation in the joint and must only be used with appropriate bone cement.

The Arthrex titanium humeral head is indicated for patients with suspected cobalt alloy sensitivity. The wear properties of titanium and titanium alloys are inferior to that of cobalt alloy. A titanium humeral head is not recommended for patients who lack suspected material sensitivity to cobalt alloy.

Contraindications

1. Insufficient quantities 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, including severe neuroarthropathy.
6. Do not use for surgeries other than those indicated.
7. 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.

For a complete listing of instructions, warnings and contraindications, please review the directions for use on Arthrex.com.

This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Arthrex products. As part of this professional usage, the medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience, and should conduct a thorough review of pertinent medical literature and the product's directions for use. Postoperative management is patient-specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same postoperative activity level and/or outcomes.

Arthrex manufacturer, authorized representative, and importer information (Arthrex eIFUs)

US patent information

arthrex.com