

Univers™ Apex Total Shoulder System

Surgical Technique

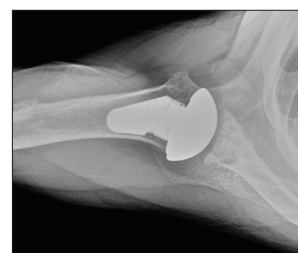
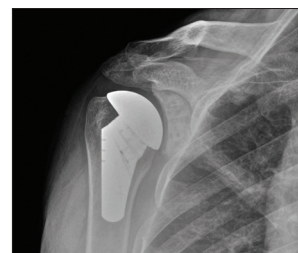


Univers™ Apex

Implant Design Rationale



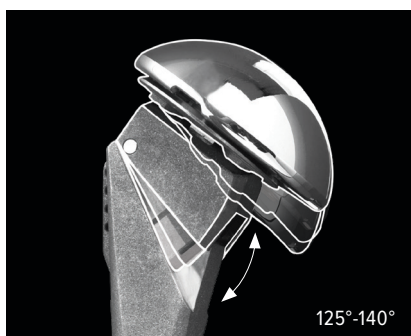
The Univers Apex system represents the evolution of Arthrex total shoulder arthroplasty systems. While maintaining all of the in situ variable adjustment capabilities of the Univers II total shoulder system (inclination, version, head offset), the Apex introduces advanced features important in the treatment of all total shoulder patients. The reduced diaphyseal stem length, rectangular stem body, and removable trunnion optimize stem removal and therefore revisability. In addition, strategically incorporated suture holes allow for unique subscapularis repair options. The system is compatible with Univers VaultLock®, pegged, keeled and Universal Glenoid™ glenoid systems, as well as with the Univers II humeral head options. In keeping with the Arthrex focus on intraoperative adaptability, the Apex restores normal patient glenohumeral anatomy in a stable, press-fit solution while allowing for bone-conserving stem revision.



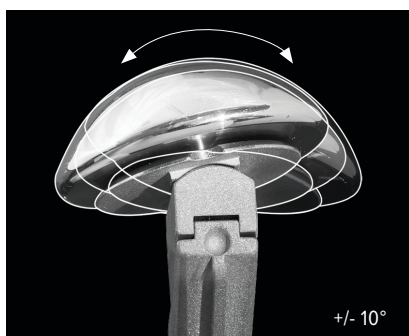
Implant Features

- Variable inclination, version, and offset
- Package-to-canal design: anatomic restoration in situ
- Instruments and trays designed to maximize efficiency in the operating room
- Multiple head diameters and heights for precise anatomic reconstruction
- Multiple suture eyelets for subscapularis and lesser tuberosity repair techniques
- Removable trunnion for simplified extraction/revision
- Eccentric humeral heads
- Humeral heads offered in cobalt chrome and titanium (special order)
- Multiple glenoid options available

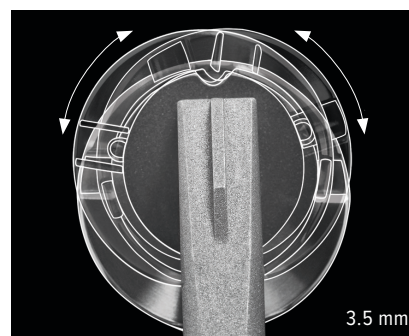
Inclination

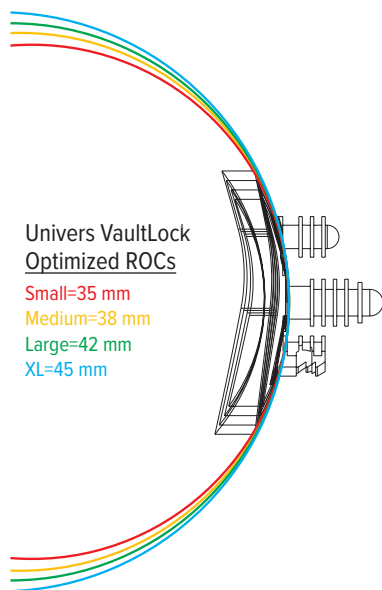
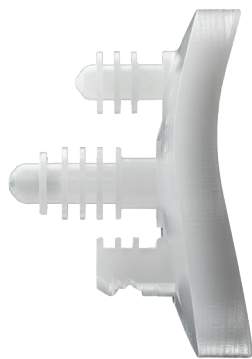


Version



Offset





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

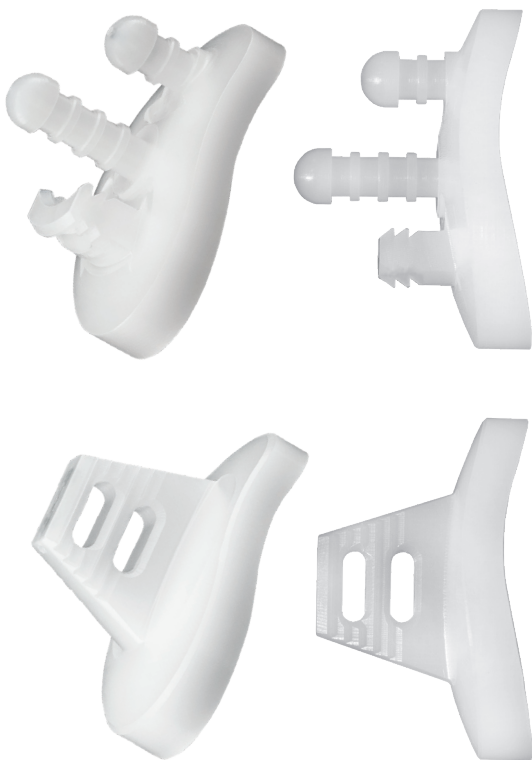
- Combines all advantages of pegged and keeled implants including stability and preparation ease

Anatomic Backside Radius of Curvature (ROC)

- Matches glenoid poly to glenoid anatomy
- Bone-sparing reaming
- Simplified decision-making

Univers VaultLock Glenoid System Optimized ROCs

- Anatomic solution with subchondral, bone-preserving design



Pegged Glenoid

- Unique, 2-peg design features a curved keel with reverse barbs and large fenestration for vault fixation

Technique for pegged glenoids detailed in LT1-0701-en

Keeled Glenoid

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

Technique for keeled glenoids detailed in LT1-0701-en

Surgical Approach

Patient Positioning

Following general anesthesia, the patient is placed in the beach chair (semi-sitting) position. Typically the angle is 30° to 45° of elevation with respect to the operating room floor. The head and neck are secured using a ring headrest, which is helpful in maintaining the head and neck position throughout the procedure. The endotracheal tube and intravenous lines are positioned on the contralateral side of the affected shoulder. The upper body is brought to the edge of the operating room table to allow full extension of the arm, which is essential for the exposure of the proximal humerus. A folded towel is placed behind the medial border of the scapula to stabilize the position of the glenoid throughout the procedure. A sterile preparation and draping are performed on the shoulder and arm to allow full exposure and free movement of the entire limb.

Incision and Exposure

The deltopectoral incision begins at the inferior border of the midsection of the clavicle, proceeds at an angle past the medial aspect of the coracoid prominence, and ends at the superior aspect of the axillary fold. The skin incision often lies directly over the cephalic vein, and therefore the interval between the deltoid and pectoralis major muscles.

The cephalic vein clearly defines the junction between the deltoid and pectoralis major muscles. If the vein is not readily identified, the prominence of the coracoid also marks the deltopectoral interval, or the surgeon can identify the fibrous portion of the superior aspect of the pectoralis tendon at the distal part of the incision. The vein can be mobilized medially or laterally.

The conjoined tendon complex consisting of the short head of the biceps and the coracobrachialis muscle is identified. The muscular portion of the biceps (red) is the most lateral part of the conjoined tendon, with

Surgical Approach

the tendinous portion (white) just medial to the visible muscle. The approach through the clavipectoral fascia is just lateral to the “red stripe” representing the muscular portion of the short head of the biceps. The deltoid muscle is carefully mobilized laterally and protected. The coracoacromial ligament is maintained (not released). A thin retractor (eg, Hohmann or Darrach) is placed under the coracoacromial ligament to provide exposure to the superior aspect of the subscapularis and humerus. Retraction of the deltoid and pectoralis major is maintained with a self-retaining retractor. Frequently, the superior 1 cm to 2 cm of the pectoralis tendon is released to provide exposure to the inferior aspect of the subscapularis and the anterior circumflex vessels. The arm is then externally rotated to further expose the boundaries of the subscapularis muscle and tendon insertion.

The superior aspect of the subscapularis tendon is at the level of the coracoid tip and can be clearly identified by excising part of the subcoracoid bursa and rotator interval capsule.

The inferior border of the subscapularis tendon is at the level of the anterior circumflex vessels. This group of vessels includes the anterior circumflex artery bordered by 2 anterior circumflex veins and is commonly referred to as the “Three Sisters.” The lateral border of the subscapularis tendon is identified just medial to the bicipital groove. Two tag stitches using #2 FiberWire® suture are placed into the medial aspect of the subscapularis tendon in preparation for the subscapularis release.

Subscapularis Release

The subscapularis tendon is released during exposure by tenotomy or tendon peel-off. While technique is surgeon-dependent, the subscapularis tendon is entirely released beginning at the rotator interval, over the biceps tendon, and inferior to the level of the anterior circumflex vessels. The humerus is externally rotated to facilitate the release of the capsule from the humerus to the 6-o’clock position on the humerus.

Note: It is not advisable to perform a complete lesser tuberosity osteotomy as this could compromise fixation of the final implant.

Glenohumeral Capsule Release

Once the subscapularis tendon is released from the humerus, the surgeon has an opportunity to release the anterior and inferior capsule with direct visualization. This capsular release is a routine part of shoulder arthroplasty for patients with a loss of external rotation,

most commonly seen in osteoarthritis patients. A ring retractor (Fukuda) is placed across the glenohumeral joint and hooked on the posterior glenoid. The retractor is used to sublax the humerus, posterior and lateral, placing tension in the inferior capsule. The junction between the muscular portion of the subscapularis (red) and the capsule (white) is clearly identified. The axillary nerve is generally just inferior to the muscular portion of the subscapularis or less than 1 cm from the capsule.

The nerve should be identified and protected. With tension in the capsule, it is released from lateral to medial, ending at the 6-o’clock position on the glenoid. The anterior capsule is bluntly separated from the subscapularis and sharply incised (capsulotomy). Finally, the fibrous attachments from the lateral aspect of the coracoid to the subscapularis are released, completing mobilization of the subscapularis when combined with the anterior/inferior capsulotomy. The release should remain lateral to the coracoid process to avoid injury to the nerve of the subscapularis and the brachial plexus. This step will be necessary for improved range of motion. The lack of bone preparation at this stage of the procedure provides visualization of all involved structures, particularly the capsule and its relationship to the axillary nerve. The subscapularis tendon is displaced medially under the coracoid process and held away from the surgical site with the self-retaining retractor, for preparation of the humerus.

Glenoid Exposure

Glenoid exposure begins with a complete anterior/inferior capsulotomy, which is described in the Glenohumeral Capsule Release section above. This not only improves the motion postoperatively, but helps with visualization and exposure of the glenoid.

Following the identification and release of the capsule from the anterior/inferior aspect down to the 6-o’clock position, it is not unusual to have to continue the release further posteriorly, along the glenoid margin. Once the axillary nerve is identified, the release of the capsule may continue unimpeded until complete visualization of the glenoid is possible.

If the glenoid remains poorly visualized after the release of the anterior, inferior, and posterior capsules, additional steps may assist in achieving a direct approach to the glenoid. Full release of the deltopectoral interval should be confirmed. Additional release of the pectoralis major tendon can be included with repair of the tendon at the end of the procedure. On the deltoid side, the anterior attachment of the deltoid on the deltoid tubercle of the humerus can also be partially released.

Surgical Approach

Once a direct view of the glenoid is possible, a glenoid neck retractor is placed along the anterior glenoid neck, as medial as possible. This will help the surgeon with respect to the orientation of the glenoid, especially in cases where significant posterior erosion has occurred. The important principle is to have direct visualization of the glenoid face in order to avoid malposition of the glenoid implant.

Humeral Head Resection

The humerus is dislocated from the glenoid using a flat retractor (eg, Darrach) as a shoehorn to gently guide the humerus out of the glenoid. The arm is externally rotated until a direct view of the entire humeral articular surface is achieved. This can be facilitated by using a flat retractor medially, as well as a retractor placed just behind the superior rotator cuff. The arm is held in greater than 90° of external rotation, 20° to 30° of extension, and adduction against the operating room table. If complete exposure of the humeral head articular surface cannot be accomplished, further capsulotomy may be necessary.

Following exposure of the humeral head, osteophytes are removed with Rongeur or osteotome. Careful removal of osteophytes will properly expose the anatomic humeral neck allowing for more accurate visualization and resection along the anatomic neck and will therefore facilitate anatomic replication.

Three humeral head resection options are available and can be selected based on surgeon preference

- **Freehand Resection:** Identify the exposed anatomic neck and resect the head using a saw. Care must be taken to follow the anatomic humeral neck and to avoid resection of the nonarticular portion of the humerus.
- **Fixed-Angle (132.5°) Cutting Guide:** This guide is available for surgeons who prefer this resection method.

Note: Using this guide (steps 1-4) will create an appropriate humeral osteotomy and will avoid excessive varus placement of the final implant.

Anatomic Humeral Resection Templates

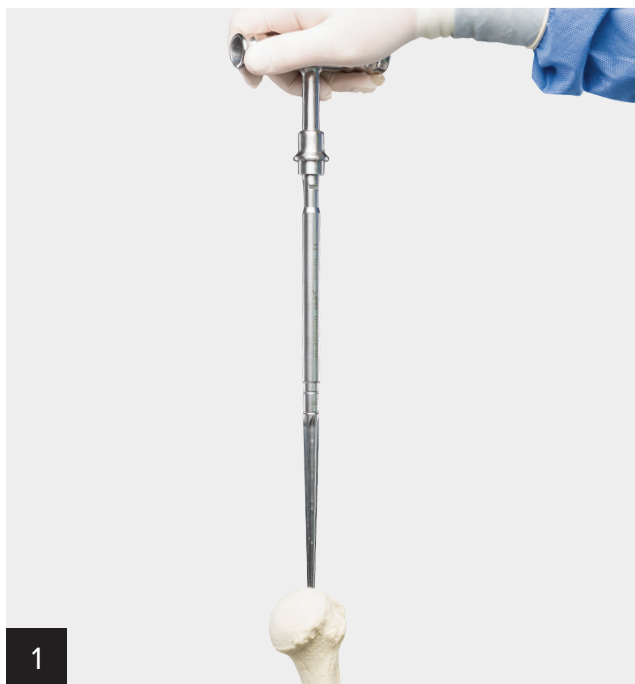
- The Anatomic Humeral Resection Templates enable the surgeon to accurately resect the humeral head along the anatomic neck without the use of intramedullary or extramedullary devices (page 10). Of note, the template handle projects from the template at 30° and creates an additional version “check” when referencing with the patient’s forearm.

Intraoperative Considerations

- To achieve the desired outcome, the patient must have adequate bone stock to support the fixation of the implant. It is anticipated that up to 33% of total shoulder candidates lack sufficient bone stock to support a stemless device.⁹ If there is any doubt about bone quality affecting the stable fixation of the Eclipse™ implant, you must use a stemmed shoulder prosthesis. The Univers™ II or Univers Apex systems may offer the appropriate solutions. Because inadequate metaphyseal bone quality assessment is not possible until the humeral head has been resected you should always be prepared with a back-up stemmed system.
- Intraoperative fluoroscopy can be used to verify proper anatomic osteotomy. This will offer additional visual confirmation that the final implant will be properly and anatomically positioned.

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, IM Resection Guide (see Step 1), or resection template can be used. See page 33 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 groove. 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 48) 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 Guide cutting assembly from the cutting surface. Remove the cutting assembly and reamer from the humerus.

Note: The glenoid guide handle may be used to stabilize the cutting surface (see arrow).

Perform the proximal humerus osteotomy. Humeral head dimensions should be noted for subsequent glenoid size selection (see Glenoid Sizing Matrix on page 50).



5

If a freehand cut was 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.

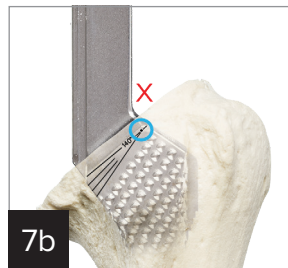
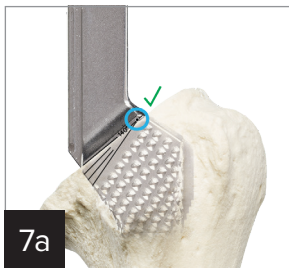
Note: It may be necessary to begin with a 5 mm humeral broach in smaller patients.



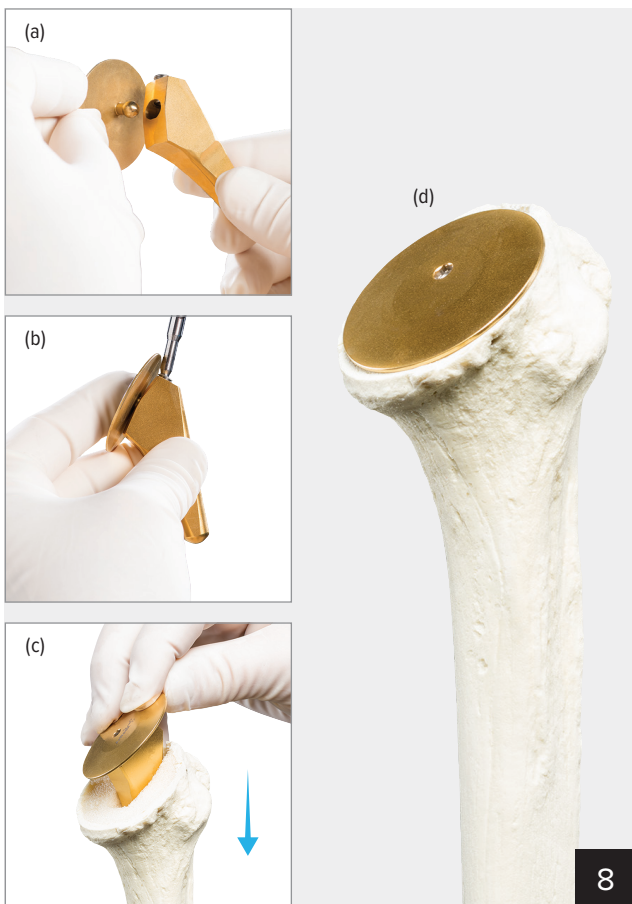
Each broach should be advanced until the lateral hinge point of the laser marks (see inset) is aligned with the resected surface. Proceed with the next size broach until the appropriate fit is obtained. For noncemented application, select the implant that corresponds to the final broach size.

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.



Note: Do not broach past the lateral hinge point. This may result in improper implant fit.



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)**.

Univers VaultLock® Glenoid System Surgical Technique

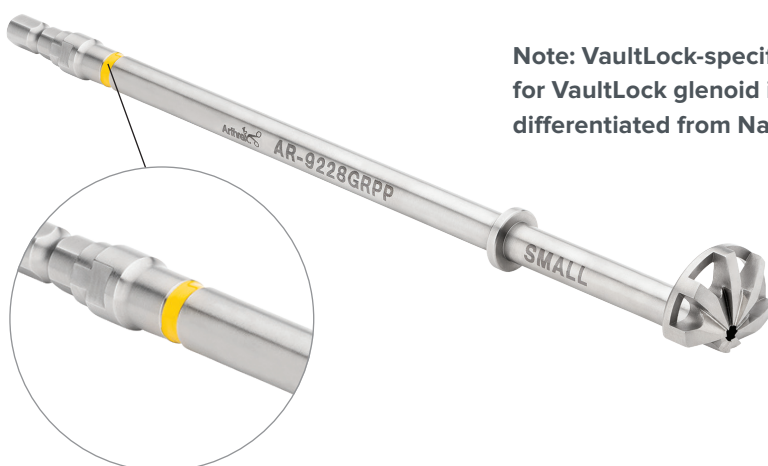
The Univers VaultLock Glenoid System consists of a low-profile, cannulated reaming system similar to the Univers™ Nautilus Reaming System. The VaultLock Glenoid System consists of reamers, guides, and trials with variable backside radii of curvatures to match the implant size of choice.



Obtain complete exposure of the glenoid articular surface. Assemble the glenoid guide handle to the VaultLock pin guide (S, M, L, XL) that best matches the glenoid surface area. Drive the pin through the glenoid vault until it reaches the medial vault cortical bone. Note vertical laser lines, which differentiate VaultLock guides from standard Nautilus guides.



Remove the guide and verify central glenoid pin placement as well as appropriate pin version and inclination.



Note: VaultLock-specific reamers must be used when preparing for VaultLock glenoid implantation. VaultLock reamers are differentiated from Nautilus reamers by a yellow ring on the shaft.



3

Select the VaultLock reamer size matching the pin guide used in the previous step. Place the cannulated reamer over the guide pin. Carefully ream the glenoid surface to remove any remaining cartilage and the minimum amount of subchondral bone necessary to conform to the surface geometry of the final glenoid component.

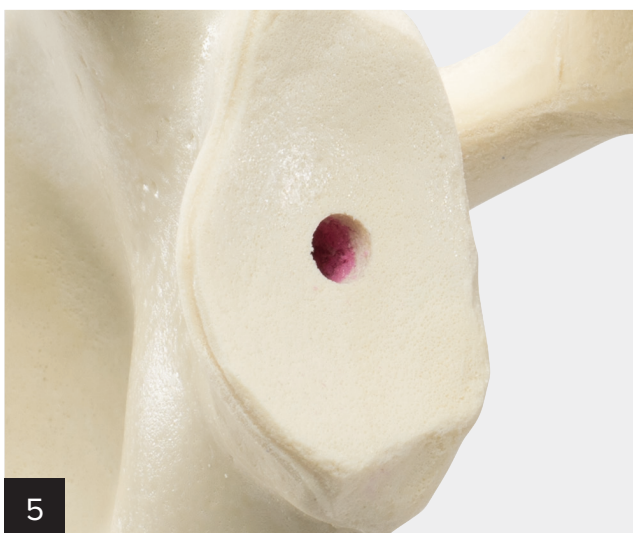
Note: Initiate reaming before contacting the glenoid surface.



4

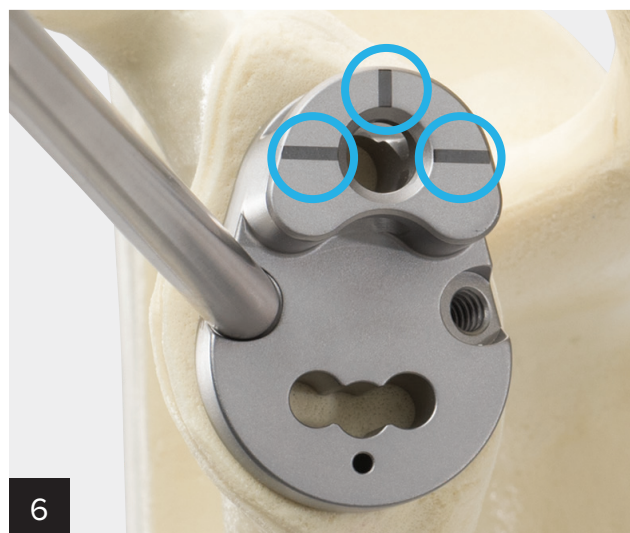
Prepare the central peg hole by placing the 6 mm drill over the guide pin. Advance the drill until the positive stop reaches the glenoid surface, taking care to maintain alignment of the pin to the trajectory of the drill.

Note: The 6 mm cannulated drill is designed to prepare only the central hole when using the VaultLock cannulated system. The noncannulated 6 mm drills from the standard Univers™ II Glenoid Instrument Set must be used to prepare the superior peg site through the VaultLock drill guide (see step 7).



5

Remove the guide pin.



6

Move the VaultLock drill guide into position by engaging the peg into the previously drilled central peg hole in the glenoid. Note laser lines (circled), which differentiate VaultLock guides from standard Nautilus guides.

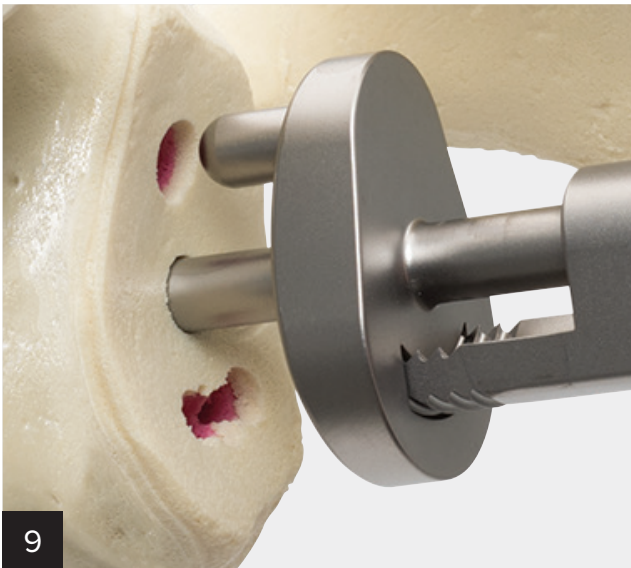


7
Position the 6 mm noncannulated drill into the reamer quick connect adapter and drill the superior glenoid hole. Detach the drill and keep it in place to hold guide orientation.

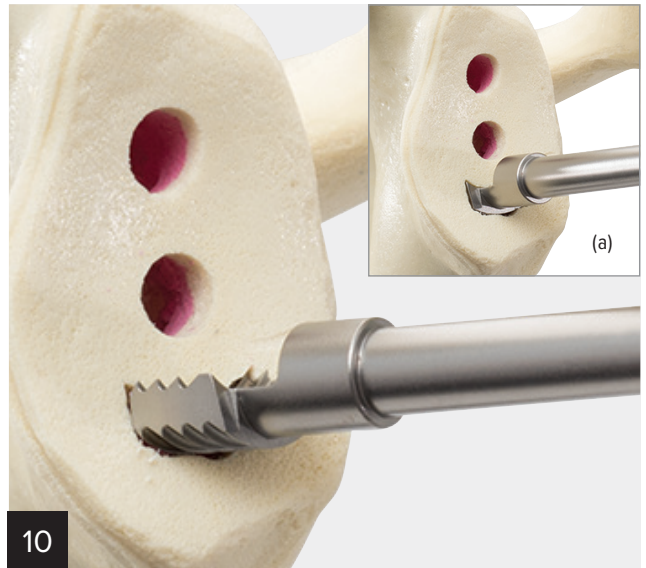


8
Use the 4.5 mm quick release drill to prepare the 3 inferior holes.

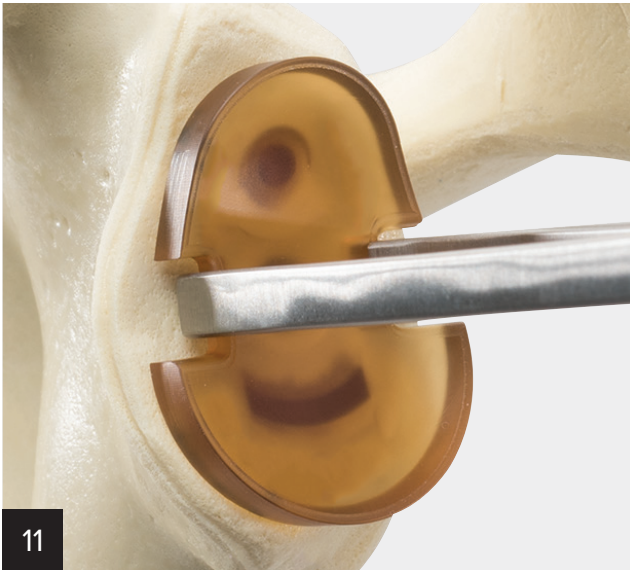
Note: Insert drill into guide before activation. There is a mechanical stop on the drill for depth control. Remove the guide.



9
Engage the pegs on the glenoid broach into the previously drilled holes. Use a mallet to advance the glenoid broach into the roughly prepared slot.



10
Optional: Alternatively, use the pegged glenoid punch to prepare the keel slot in place of the glenoid broach. Advance the punch until the shoulder of the punch is flush with the bone surface **(a)**.



11

Insert the VaultLock glenoid trial by hand or with the glenoid trial forceps.

Note: Verify the trial is fully seated to ensure proper fit of the actual glenoid implant.



12

After preparing of the peg holes/keel slot, perform meticulous irrigation and suctioning to remove bone and soft-tissue debris from the area. Hemostasis should be achieved before placing the cemented glenoid. Once the glenoid has been fully prepared, open the appropriate size glenoid implant and press bone cement into the fenestration on the implant keel and around the superior peg.



13

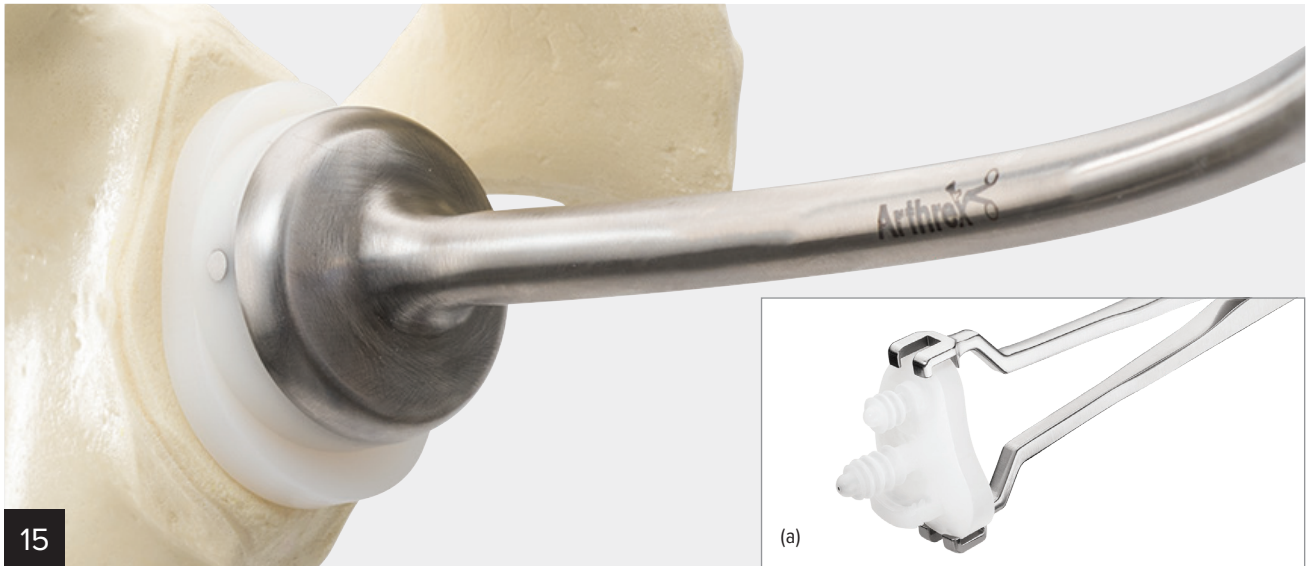
Optional: Bone graft from the humeral head or recovered from the drills can be placed around the central fluted peg by hand or with the graft compression tool.

Note: Bone slurry taken from the humeral head or drills is preferred over bone chips.



14

Pack the keel slot and superior peg hole with cement using a syringe or finger. Use the cement pressurizer to impact cement into the keel slot and peg holes and to create good cement interdigitation within the glenoid vault. Alternate between cementing and pressurization until a sufficient quantity of cement has filled the glenoid vault. Prior to step 15, the superior hole and inferior keel slot should be filled again with cement.



15

Implant may be introduced manually or with the VaultLock Forceps **(a)**. Once in central fluted peg is initially fixed in the prepared hole, push and impact the implant into the cement-filled glenoid vault. Remove excess cement and verify complete seating of the implant. Firmly hold the glenoid component in place until the cement has cured.

Note: Once complete, proceed to Humeral Stem Implantation step 1, page 24.

Nautilus Reamer Surgical Technique

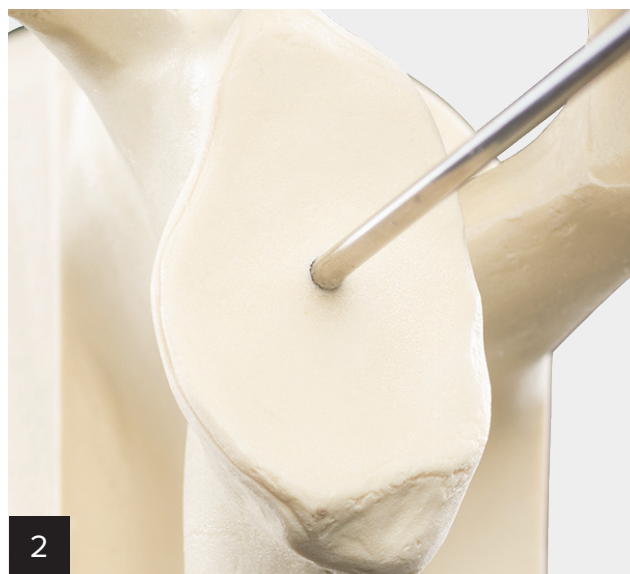
The Univers™ Nautilus Reamer System is a low-profile cannulated option for initial glenoid surface preparation prior to placing keeled or pegged glenoids with the standard Univers #2 drill guides. The cannulation allows precise and stable glenoid surface preparation and version correction when necessary.



Note: If noncannulated option is desired, please refer to surgical steps depicted in steps 1 and 2 on page 23.



1
Obtain complete exposure of the glenoid articular surface. Assemble the Nautilus Guide (S,M,L,XL), which matches the glenoid surface to the glenoid guide handle. Drive the 2.8 mm pin through the glenoid vault until it reaches the medial vault cortical bone..

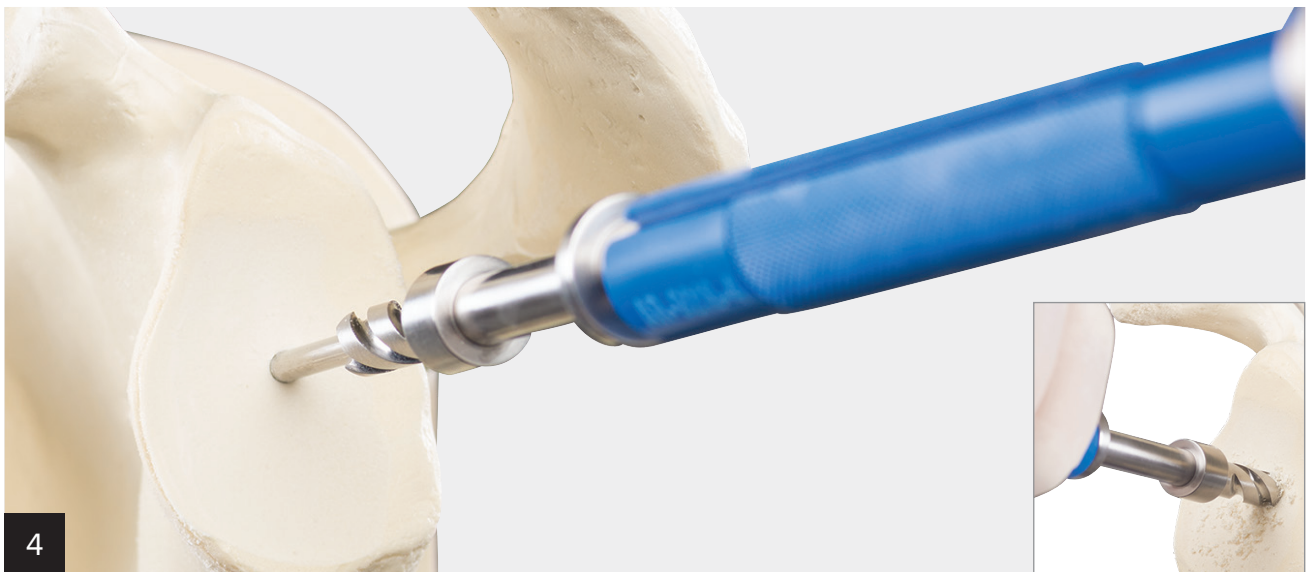


2
Remove the guide and verify central glenoid pin placement as well as appropriate pin version and inclination.



3
Select the reamer size matching the guide used in the previous step. Place the Nautilus cannulated reamer over the guide pin. Carefully ream the glenoid surface to remove any remaining cartilage and the minimum amount of subchondral bone necessary to conform to the surface geometry of the final glenoid component.

Note: Initiate reaming before contacting the glenoid surface.



Prepare the keel/central peg hole by placing the 6 mm drill over the guide pin. Advance the drill until the positive stop reaches the glenoid surface, taking care to maintain alignment of the pin to the trajectory of the drill.



Remove the pin. To complete glenoid preparation, proceed to: Step 1 on page 15 for Keeled or Pegged.

Note: The 6 mm cannulated drill is designed to prepare only the central hole when using the Nautilus cannulated system specifically. The noncannulated 6 mm drills from the standard Univers™ II Glenoid Instrument Set must be used to prepare the keel and superior peg sites through the keel or peg drill guide #2, respectively.



Keeled Drill Guide #2. Continue to step 1 below.



Pegged Drill Guide #2. Continue to step 1 on page 20.

Keeled Glenoid Preparation and Implantation



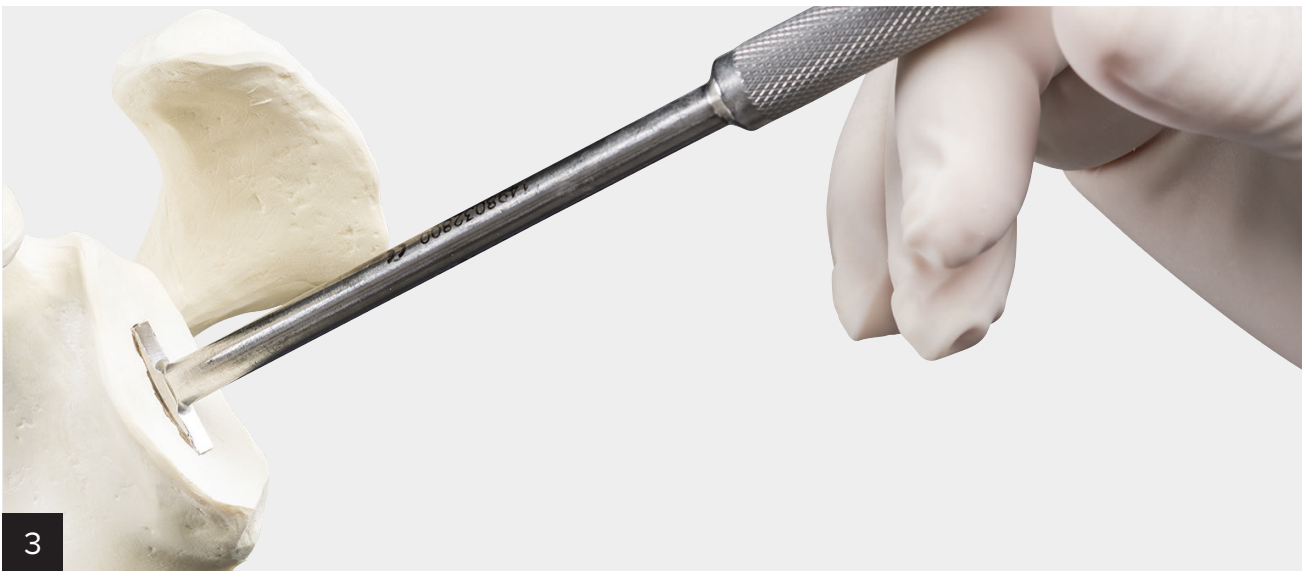
The Uniers VaultLock Glenoid System consists of a low-profile, cannulated reaming system similar to the Uniers™ Nautilus Reaming System. The VaultLock Glenoid System consists of reamers, guides and trials with variable backside radii of curvatures to match the implant size of choice.



Select the small, medium, large, or extra large glenoid guide #2 (with 2 holes and peg) and thread in the handle. The handle is oriented 65° to the face of the glenoid matching the normal anatomic slope of the anterior glenoid neck. Engage the peg on the back of the guide into the previously drilled peg hole. Use the noncannulated 6 mm drill to drill through both holes in the guide. If desired, the short drill bit can be disconnected and left in the first drill hole to function as an antirotation peg during drilling of the final hole.



Use a small rongeur to remove the bone bridge between the 3 drill holes, resulting in a roughly prepared glenoid slot.



Use the glenoid punch to make the final preparation for the keel of the glenoid implant. Position the punch perpendicular to the glenoid surface. Use a mallet to advance the punch into the roughly prepared slot. The punch should be advanced until it is flush with the bone surface. The bone slot for the keel should closely match

the geometry of the keel. Therefore, it is important to prepare the slot with the punch. Cement fixation will be enhanced by this method and with preservation of the cancellous bone of the glenoid vault.



After preparing the glenoid for the keeled glenoid implant, perform meticulous irrigation and suctioning to remove bone and soft tissue debris from the area. If desired, use a keeled glenoid trial to evaluate component stability. Hemostasis should be achieved prior to proceeding with cemented glenoid placement.



Open the appropriate glenoid size and press bone cement into the fenestrations on the implant keel. Insert cement into the glenoid slot and pressurize with the glenoid punch. Alternate cementing and pressurization until a sufficient quantity of cement has filled the glenoid vault. Prior to step 6, the slot should be filled again with cement.



Push and impact the keel of the implant into the cemented glenoid vault. Excess cement should be removed. Firmly hold the glenoid component in place until the cement has cured.

Note: When complete, proceed to Humeral Stem Implantation step 1, page 24.

Pegged Glenoid Preparation and Implantation

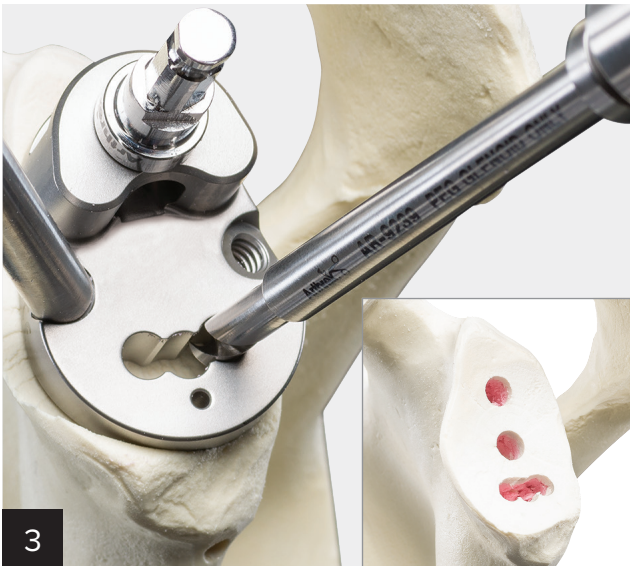


Move the pegged glenoid drill guide #2 into position by engaging the peg into the previously drilled central peg hole in the glenoid.

Note: If significant glenoid reaming has been performed and the pegged glenoid drill guide #2 does not sit flush against the glenoid surface, it may be necessary to redrill the central peg hole.

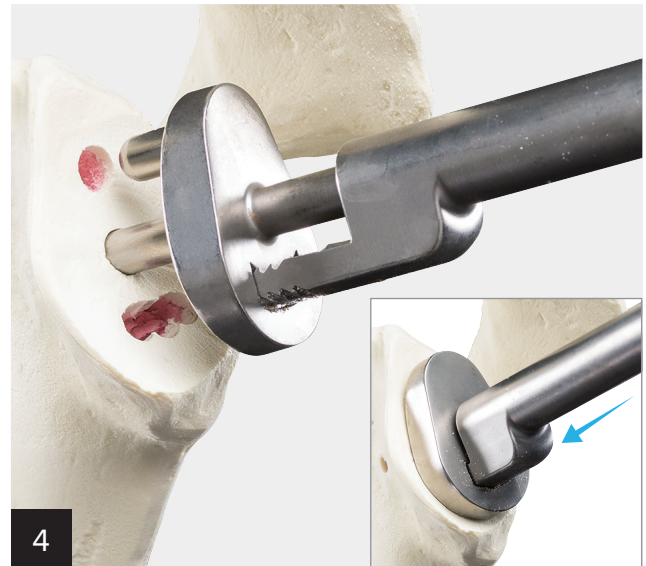


Position the 6 mm drill into the reamer quick connect adapter and drill the superior glenoid hole. Detach the drill and keep it in place to hold guide orientation.

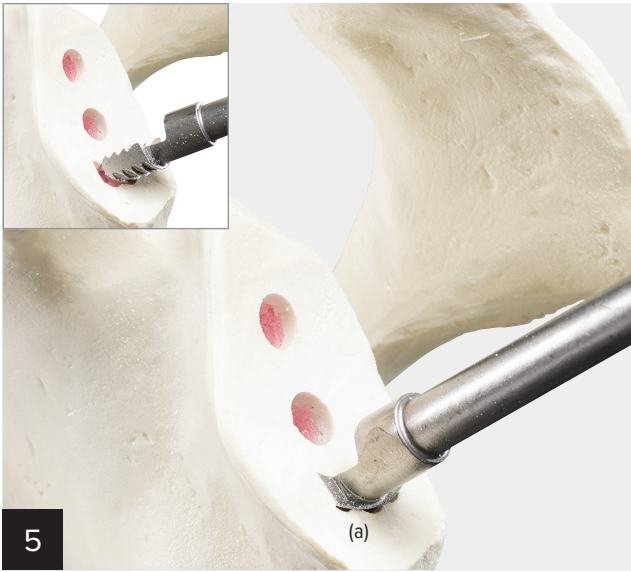


Use the 4.5 mm quick release drill to prepare the 3 inferior holes.

Note: Insert drill into guide before activation. There is a mechanical stop on the drill for depth control. Remove the guide.



Engage the pegs on the glenoid broach into the previously drilled holes. Use a mallet to advance the glenoid broach into the roughly prepared slot.



Optional: Alternatively, use the pegged glenoid punch to prepare the keel slot in place of the glenoid broach. Advance the punch until the shoulder of the punch is flush with the bone surface **(a)**.



Insert and impact the pegged glenoid trial by hand or with the glenoid trial forceps.

Note: Verify the trial is fully seated to ensure proper fit of the actual glenoid implant.



After preparation of the peg holes/keel slot, perform meticulous irrigation and suctioning to remove bone and soft-tissue debris from the area. Hemostasis should be achieved before placing the cemented glenoid. Once the glenoid has been fully prepared, open the appropriate size glenoid implant and press bone cement into the fenestration on the implant keel and around the pegs.



Pack the keel slot and all peg holes with cement using a syringe or finger. Use the cement pressurizer to impact cement into the keel slot and peg holes and to create good cement interdigitation within the glenoid vault. Alternate cementing and pressurization until a sufficient quantity of cement has filled the glenoid vault. Prior to step 9, both holes and slot should be filled again with cement.



Push and impact the implant into the cement-filled glenoid vault. Remove excess cement and verify complete seating of the glenoid. Firmly hold the glenoid component in place until the cement has cured.

Note: When complete, proceed to Humeral Stem Implantation step 1, on page 24.

Noncannulated Reaming Option: Pegged and Keeled Only



Select the small, medium, large, or extra large glenoid guide #1 (with single, central hole) and thread a handle to the anterior side. Place the guide on the central axis of the exposed glenoid face. The handle of the guide is 65° to the orientation of the surface of the glenoid, which corresponds to the relatively fixed 65° anatomic slope of the anterior glenoid neck. This may help identify the proper orientation of the glenoid version. Use the 6 mm drill to drill a hole through the guide. There is a mechanical stop on the drill bit for depth control.



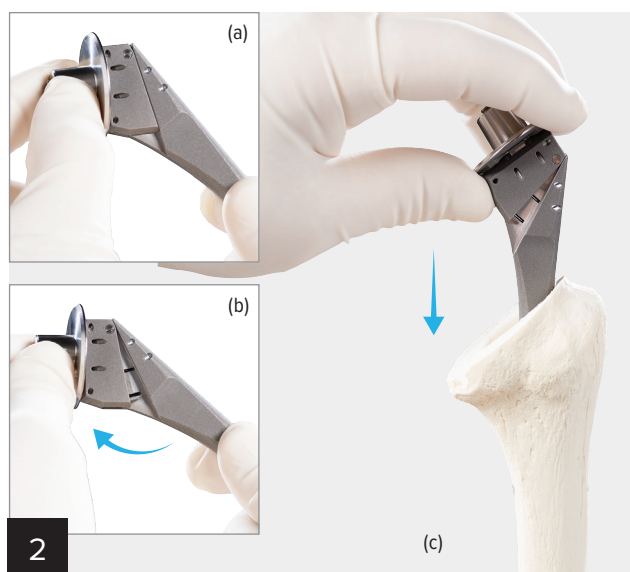
Assemble the appropriate size glenoid reamer to the reamer shaft to prepare the glenoid surface. The reamer shaft may be driven by either the reamer T-handle or a powered handpiece with a Hudson-style fitting. Insert the nipple end of the reamer into the central glenoid drill hole and initiate reaming. Ream the glenoid until the superior to inferior surface is made congruent to the mating implant component. For keeled glenoid vault preparation, continue to step 1 on page 17. For pegged glenoid vault preparation, continue to step 1 on page 20.

Note: Based on variable backside radii of curvature, full-radius reamers are not compatible with the Univers VaultLock® glenoid system.

Humeral Stem Implantation



Remove the resection Protector™ device and post.



Open the humeral implant in a sterile fashion. Manually open the inclination angle to its maximum position **(a,b)** and insert the stem into the humeral canal **(c)**.

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



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)**.



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.

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.



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.

Note: For patients sensitive to cobalt alloy, titanium humeral heads are available as special order.

Surgical Approach

As described by Anthony Romeo, MD, Rush University Medical Center, Chicago, IL

Prior to closure, stability and mobility should be assessed with the final implants in place. This can be accomplished intraoperatively using the “40-50-60” method: a stable 40° of external rotation with the arm in neutral position, 50% posterior translation with good “bounce-back,” and 60° of internal rotation with the arm in abduction.

Wound closure begins with thorough irrigation, removing any remaining soft tissue or bone debris. Hemostasis is obtained with electrocautery. The initial focus of wound closure is the repair of the subscapularis tendon. To ensure that the subscapularis tendon is repaired to its anatomic position, the first step of the repair is reattaching the superior lateral edge of the subscapularis to the anterior lateral edge of the supraspinatus directly over the bicipital groove. This is performed with #2 FiberWire® sutures. By securing the superior lateral edge of the subscapularis at the beginning of the repair, the tendon is held in an anatomic position.

Four braided #5 FiberWire sutures that were placed at the rim of the osteotomy site are individually passed through the subscapularis tendon separated by approximately 1 cm.

The sutures can be passed with a Mason-Allen configuration to improve security of the suture in the tendon. The sutures are tied beginning superiorly and proceeding inferiorly. Additional #2 FiberWire sutures are placed in between each of the #5 FiberWire sutures for a tendon-to-tendon repair, reattaching the subscapularis tendon to the remaining fibers in the lesser tuberosity. A total of eight sutures, four #2 FiberWire sutures for the tendon-to-tendon repair, and four #5 FiberWire sutures for a tendon-to-bone repair are used for a secure subscapularis repair. This will allow for an early range of motion and minimize the risk of subscapularis rupture. Alternatively, the Apex subscapularis repair technique can be used as described on page 29.

Hemostasis is assessed at this time and if excessive bleeding is found, a single Hemovac®* wound drainage device is placed into the deep layer. The deltoid and pectoralis major muscles are repaired with a side-to-side closure using a #1 absorbable suture. The subcutaneous layer is repaired with 2-0 interrupted absorbable suture and finally, a 3-0 suture is used for the skin closure. The skin closure is supported by Steri-Strip™† skin closures. If used, the Hemovac drain is secured and suction is initiated. The drain is usually removed on the first postoperative day.

*Hemovac is a trademark of Zimmer Biomet.

†Steri-Strip is a trademark of 3M.

Univers™ Apex Suture Kit

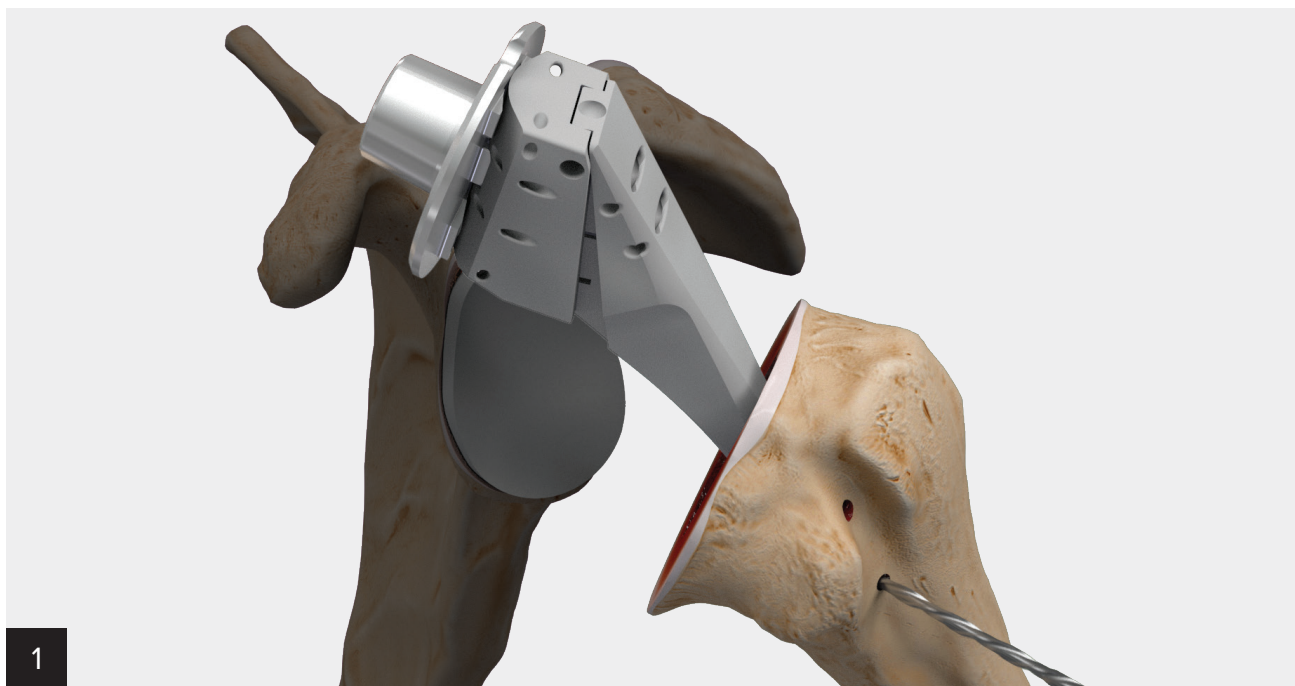
Subscapularis Repair Technique

As described by Evan Lederman, MD (Phoenix, AZ) and Reuben Gobezie, MD (Cleveland, OH)

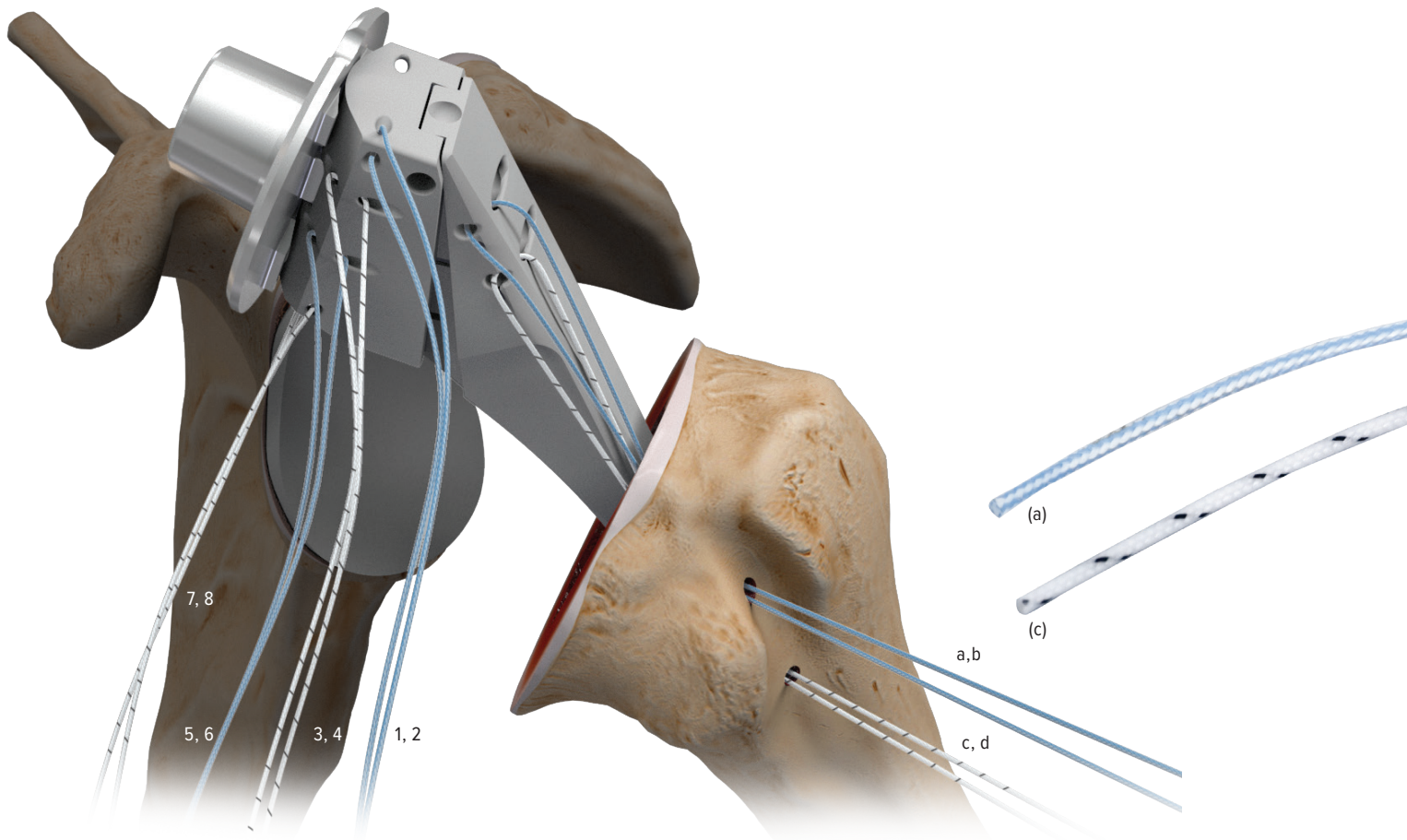
The initial focus of wound closure is the repair of the subscapularis tendon. The Univers Apex proximal stem has suture eyelets to aid in soft-tissue repair, specifically the reattachment of the subscapularis to the lesser tuberosity. There are 2 to 3 eyelets laterally and 4 inferior to the trunion in the proximal aspect of the Apex stem. The Apex subscapularis repair technique is a suture technique for stable subscapularis suture repair using the suture eyelets. This is a double-row tendon repair that applies dynamic compression over the tendon as the final sutures are tightened and tied.

The recommended subscapularis release technique for this repair is the “peel-off” method, although the technique is compatible with subscapularis tenotomy and lesser tuberosity osteotomy techniques. Specific colored sutures (#2 FiberWire® and TigerWire® sutures) and suture pattern (see figures on following page) are described to simplify the technique.

Note: If using the Apex subscapularis repair technique, sutures must be passed through the suture eyelets prior to implanting the humeral stem and impacting the prosthetic head as described in the humeral stem implantation section (page 27).



Use a 2 mm drill to place holes in the bicipital groove at the approximate location of the Apex lateral suture eyelets. The implant can be used as a template for targeting drill hole location.

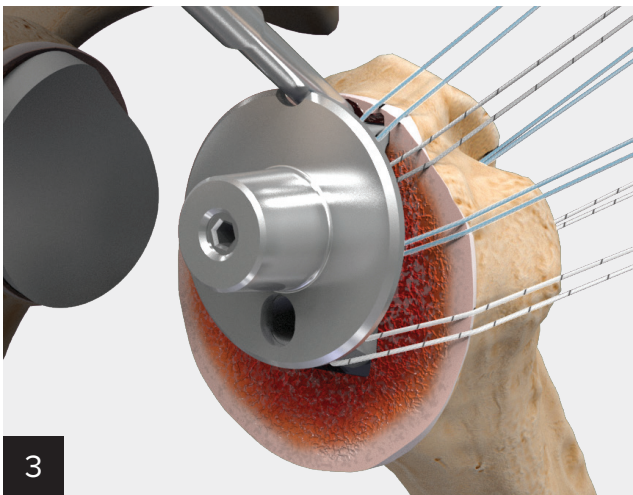


2

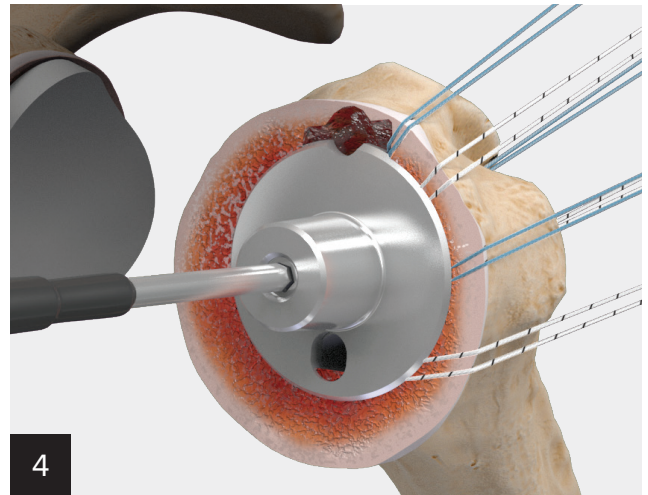
Pass two #2 FiberWire sutures through the lateral holes yielding 4 suture limbs labeled **a-d** from superior to inferior. FiberWire suture superior/TigerWire® suture inferior.

Pass four #2 FiberWire sutures through the holes beneath the trunnion yielding eight suture limbs labeled **1-8** from lateral to medial [FiberWire (**1,2**), TigerWire® suture (**3,4**), FiberWire® suture (**5,6**), TigerWire suture (**7,8**)].

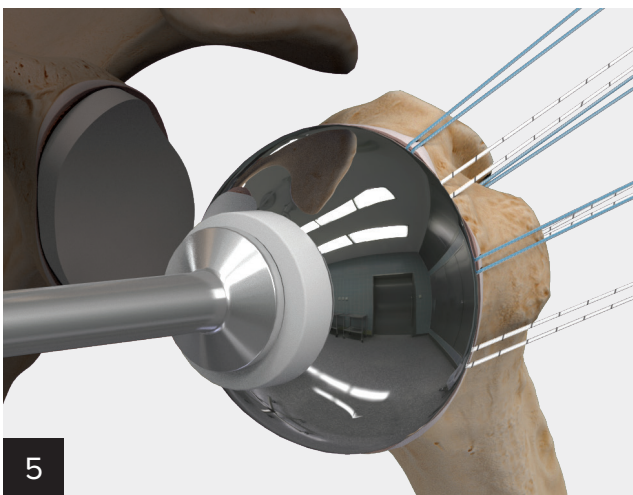
Pass limbs a and b through the superior hole from the intramedullary canal out. Likewise, pass suture limbs c and d through the inferior hole from the intramedullary canal out. The Micro SutureLasso™ suture passers simplifies passage.



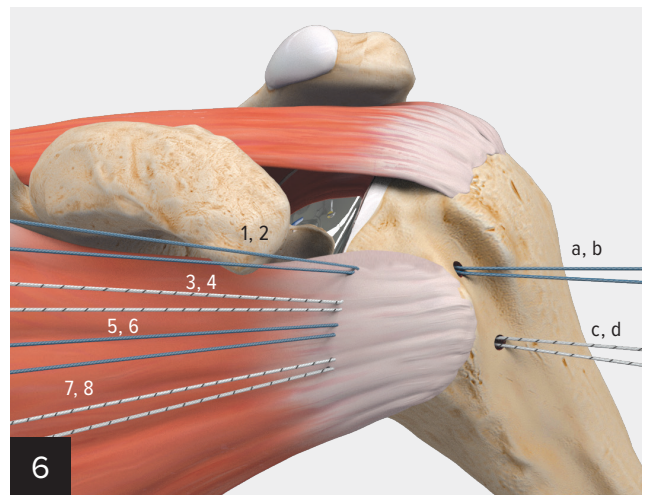
Hold all strands out to length on tension as the stem is implanted and impacted with the pointed stem impactor. Follow by using the angled Morse taper stem impactor, placing the trunnion flush to the osteotomy surface (refer to humeral stem implantation steps 3-4, on pages 24-25).



Tighten the inclination (inferior) and version (superior) screws with the torque driver (refer to humeral stem implantation steps 6-7, on page 31). The trial head may be used at this point to check stability prior to impacting the actual head component. This can be accomplished intraoperatively using the “40-50-60” method: stable 40° of external rotation with the arm in neutral position, 50% posterior translation with good “bounce-back”, and 60° of internal rotation with the arm in abduction.



With stability achieved, clean and dry the Morse taper and impact the humeral head on the Morse taper. Begin wound closure with thorough irrigation, removing any remaining soft-tissue or bone debris. Obtain hemostasis with electrocautery.

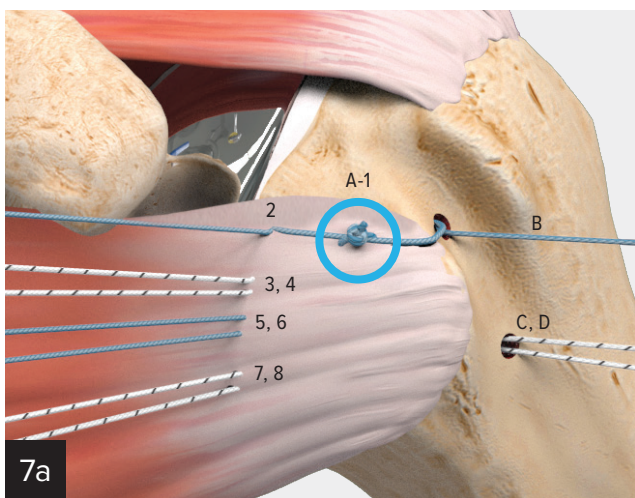


Evenly place suture limbs 1-8 through the medial aspect of the subscapularis tendon from superior to inferior. Proper spacing is key to the final repair. Care must be taken not to cut the sutures when passing through the tendon.

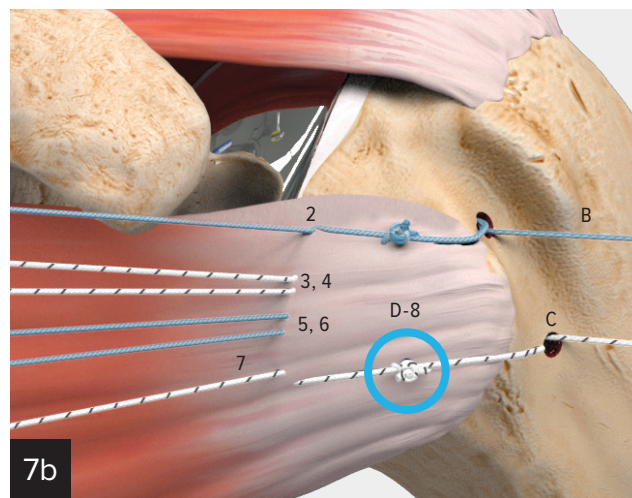
Subscapularis Repair Technique

The suture color pattern is such that the first 4 knots are like color to like color and the last 2 knots are different color to different color. In addition, the last knot is tensioned and creates dynamic compression of the subscapularis tendon over the lesser tuberosity. The repair is evaluated by externally rotating the arm with the arm adducted. The degree of external rotation achieved without stressing the repair is noted for postoperative therapy limitations. Superficial wound irrigation and closure are performed according to the surgeon's preference.

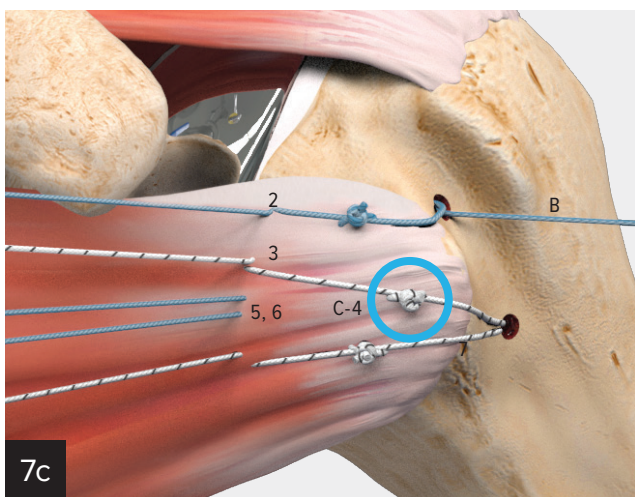
Note: The first 5 knots are between different suture strands. Therefore, these knots are tied without applying tension and should not be sliding knots. Otherwise, there may be a risk of knot failure when the repair is stressed postoperatively with external rotation of the arm. Do not cut tied limbs until final construct is completed, as limbs can be used as augments, if desired.



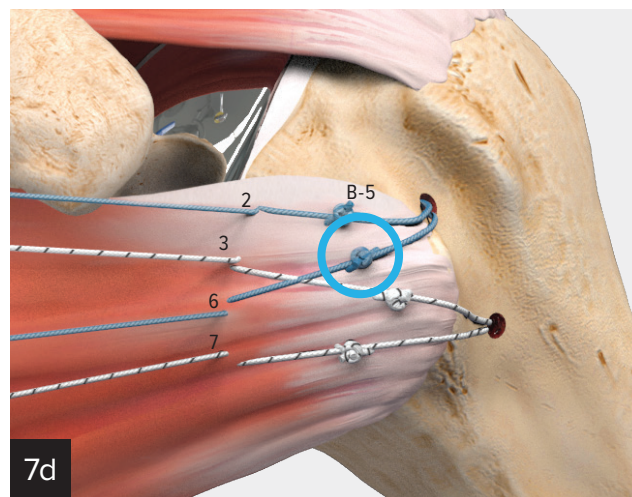
A to 1 (FiberWire® suture to FiberWire® suture).



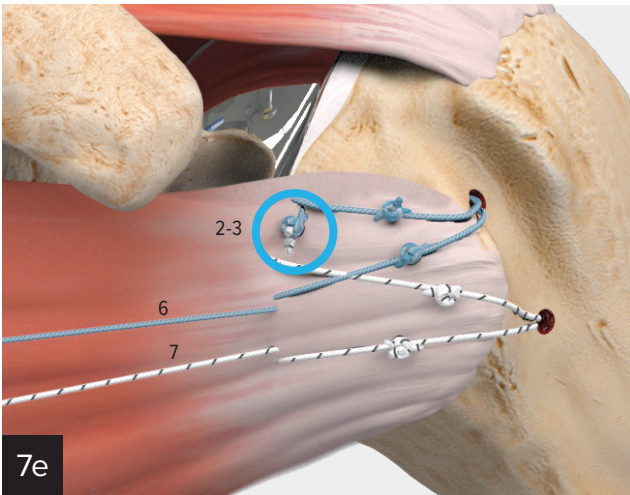
D to 8 (TigerWire® suture to TigerWire® suture).



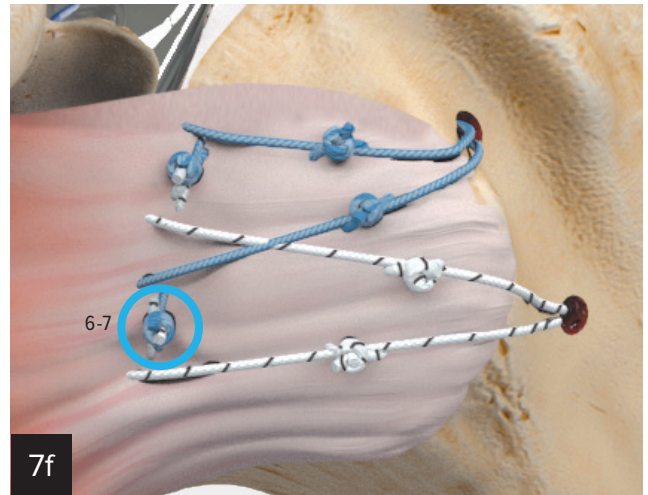
C to 4 (TigerWire® suture to TigerWire suture).



B to 5 (FiberWire® suture to FiberWire suture).



2 to 3 (FiberWire® suture to TigerWire® suture). Moderate tension is applied to this knot to initiate tendon compression over the lesser tuberosity.



6 to 7 (FiberWire® suture to TigerWire® suture). Full tension is applied to this final knot to complete compression of the tendon repair over the lesser tuberosity.

Optional: Humeral Resection Method



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 two version rods so that a retroversion of 30° is achieved based on the orientation of the forearm.



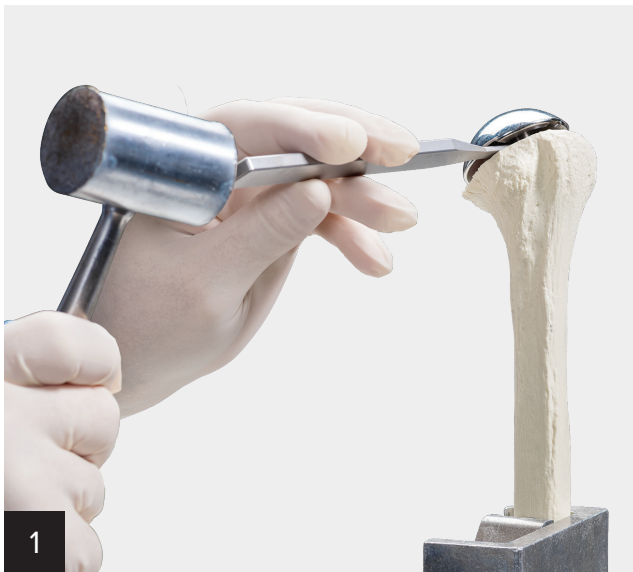
The appropriate guide size and position will result in subsequent pin placement across the anatomic neck. Once the appropriate position has been established, advance the 2.8 mm Steinmann pin down the center cannulation of the humeral head resection guide to secure it to bone.



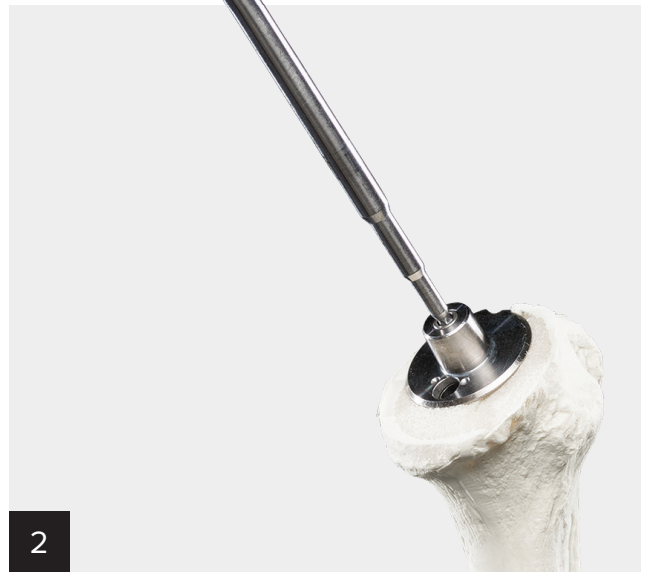
Drill two 1.6 mm K-wires through the holes of the humeral head resection guide until they exit the opposite cortex.



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 50).

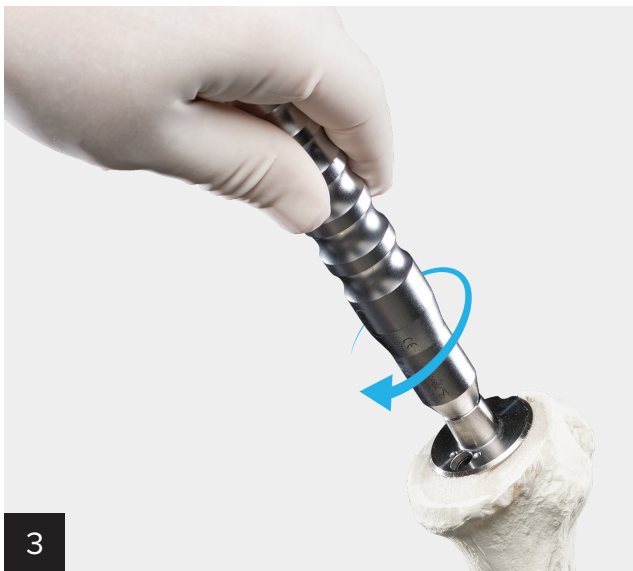


Once exposure is accomplished and the proximal humerus is dislocated, disengage the prosthetic head by placing the humeral head extractor into one of the head slots between the head and trunnion. It may be necessary to use more than one slot to accomplish extraction.

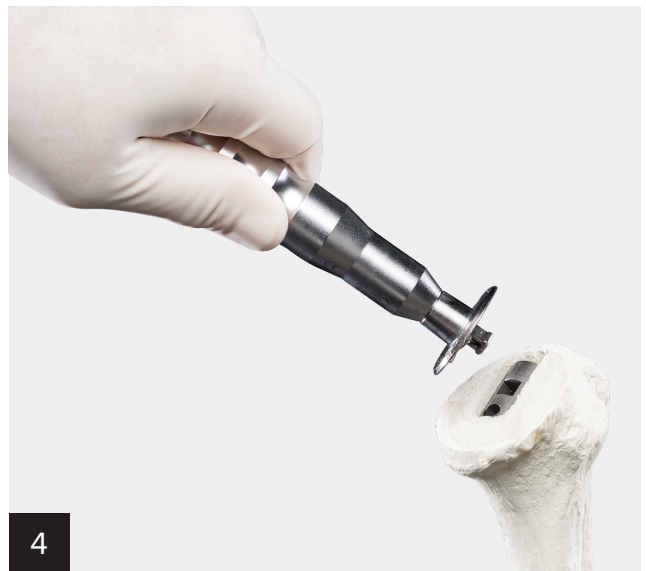


Remove the version locking (superior) screw to facilitate removal of the trunnion. It may be helpful to use the T-handle torque driver.

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.

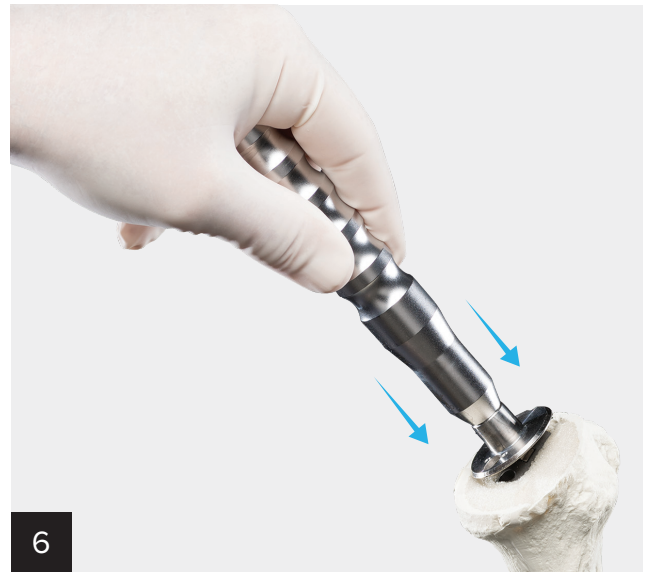


Disengage the trunnion from the stem by rolling the wrist in a posterior to anterior motion, releasing the locking connection.



5

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.



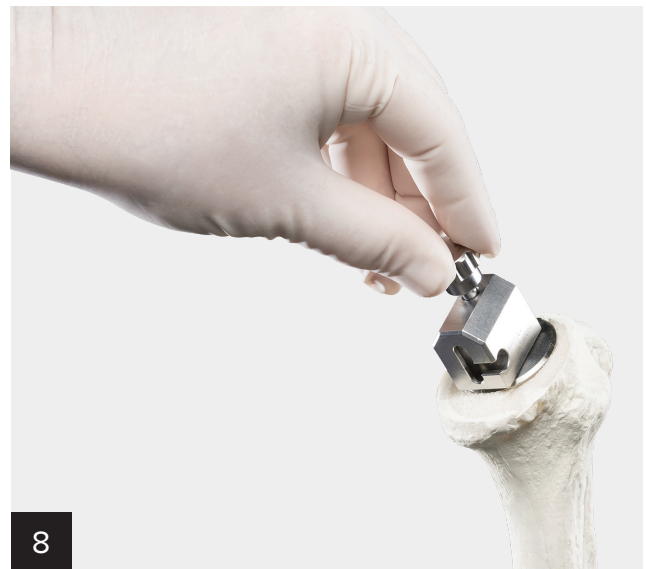
6

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.



7

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



8

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**).



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



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



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



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.

Postoperative Management

As described by Anthony Romeo, MD, Rush University Medical Center, Chicago, IL

Postoperative care is patient- and surgeon-dependent. Please review the Directions For Use for a full listing of instructions and warnings.

The arm is placed in a sling supported by a form-fitting pillow with a waist strap, which immobilizes the upper extremity. Wrist, hand, and finger range of motion and grip strengthening begin on the evening of surgery. On the first day after surgery (postoperative day 1), passive and active-assisted range-of-motion exercises are started. These activities will include pendulum exercises in a standing position, as well as assisted forward elevation exercises in a supine position with a limitation of 90°, which may be adjusted based on the intraoperative assessment by the surgeon. Active-assisted external rotation exercises in the supine position are allowed up to 20° of external rotation and again adjusted based on the surgeon's evaluation at the completion of the subscapularis repair. The focus of the rehabilitation program is to teach patients exercises that they can perform on their own 3 to 4 times daily. Assisted devices such as a pulley or a physical therapy baton can be valuable.

The patient is typically discharged 48 hours following the surgical procedure. Younger patients and patients undergoing a hemiarthroplasty alone may be comfortable and independent within 24 hours. The rehabilitation goals upon discharge include a minimum of 90° of forward elevation and 20° of external rotation and successful education of the patient regarding their home exercise program.

Upon discharge, an outpatient physical therapy program is initiated. Active exercises are started 10-14 days after the surgical procedure. The major restriction to physical therapy, within the first 6 weeks, is prohibiting resisted internal rotation or other activities that would put stress on the subscapularis repair such as passive, unprotected, external rotation performed by the physical therapist. If the patient is allowed independent active-assisted external rotation, the subscapularis repair will not be jeopardized.

For the first 6 weeks the focus is on stretching and improving active range of motion. Once the subscapularis tendon has had adequate time to heal, at approximately 6 weeks, all range of motions including internal rotation are advanced as tolerated.

Furthermore, the strengthening program is balanced to include both the anterior rotator cuff (subscapularis) and posterior rotator cuff (primarily supraspinatus and infraspinatus). Deltoid strengthening, as well as scapular muscle strengthening (shoulder shrugs, scapular protraction, scapular retraction, rows, front pull downs), can be gradually incorporated into the patient's rehabilitation program. By 3 months, the patient should be independent with the rehabilitation program. In the first year following the shoulder procedure, the patient should be encouraged to pursue both the stretching and the strengthening program.

The final result for an uncomplicated total shoulder arthroplasty when treating osteoarthritis should be an average forward elevation of greater than 140°, active external rotation of greater than 45°, and active internal rotation up behind the back to the T12 level or above. Strength should allow all activities of daily living as well as light recreational activities, such as golf, light fitness training, household chores, gardening, and swimming in select patients. The final weight-restriction based on theoretical concerns of prosthetic loosening includes no repetitive lifting activities greater than 20 lb and no repetitive work activities at shoulder level or above on a routine basis.

Ordering Information

Instruments

Product Description	Item Number
Univers™ Apex Humeral Tray	AR-9226ABC
Univers II/Apex Combined Tray*	AR-9226CC
*Required for Apex surgical cases	

Literature

Product Description	Item Number
Shoulder Implant Identification Card	LC1-0700-EN
Univers Apex X-ray Templates	AR-705
Univers Apex Surgical Technique	LT1-0702-EN

Implants

Product Description	Item Number
Apex Humeral Stem, 5 mm × 60 mm, 132.5° fixed	AR-9100-05S
Apex Humeral Stem, 6 mm × 60 mm	AR-9100-06S
Apex Humeral Stem, 7 mm × 60 mm	AR-9100-07S
Apex Humeral Stem, 8 mm × 60 mm	AR-9100-08S
Apex Humeral Stem, 9 mm × 60 mm	AR-9100-09S
Apex Humeral Stem, 10 mm × 60 mm	AR-9100-10S
Apex Humeral Stem, 11 mm × 60 mm	AR-9100-11S
Apex Humeral Stem, 12 mm × 60 mm	AR-9100-12S
Apex Humeral Stem, 13 mm × 65 mm	AR-9100-13S
Apex Humeral Stem, 14 mm × 65 mm	AR-9100-14S
Apex Humeral Stem, 15 mm × 65 mm	AR-9100-15S
Keeled Glenoid, small	AR-9104-01
Keeled Glenoid, medium	AR-9104-02
Keeled Glenoid, large	AR-9104-03
Keeled Glenoid, extra large	AR-9104-04
Pegged Glenoid, small	AR-9105-01
Pegged Glenoid, medium	AR-9105-02
Pegged Glenoid, large	AR-9105-03
Pegged Glenoid, extra large	AR-9105-04
VaultLock Glenoid, small	AR-9106-01
VaultLock Glenoid, medium	AR-9106-02
VaultLock Glenoid, large	AR-9106-03
VaultLock Glenoid, extra large	AR-9106-04

Product Description	Item Number
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

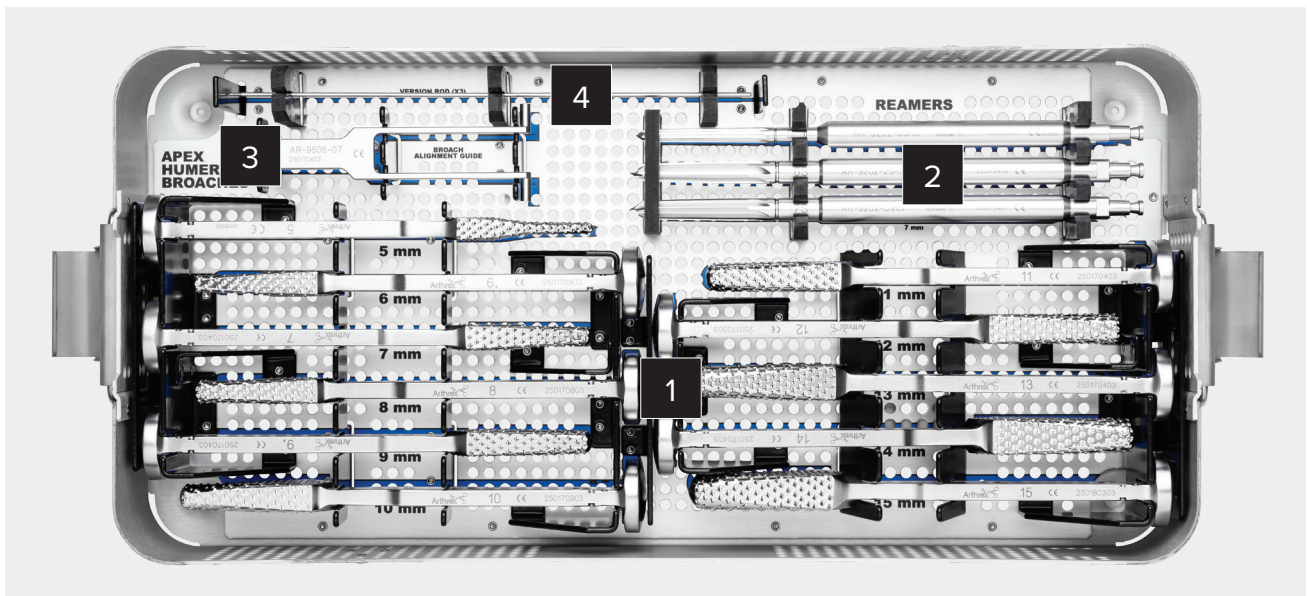
Product Description	Item Number
Titanium Humeral Head, 40 mm × 17 mm	AR-9140-17T*
Titanium Humeral Head, 42 mm × 17 mm	AR-9142-17T*
Titanium Humeral Head, 44 mm × 17 mm	AR-9144-17T*
Titanium Humeral Head, 46 mm × 18 mm	AR-9146-18T*
Titanium Humeral Head, 48 mm × 19 mm	AR-9148-19T*
Titanium Humeral Head, 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*

*Special order only

Univers II/Apex Sterile Head Resection Disposables Kit (AR-9207S)

Product Description	Item Number
Steinmann Pin, 2.8 mm	AR-9207
Kirschner Wire, 1.6 mm, qty. 2	AR-9208

Univers™ Apex Humeral Set (AR-9226ABC)

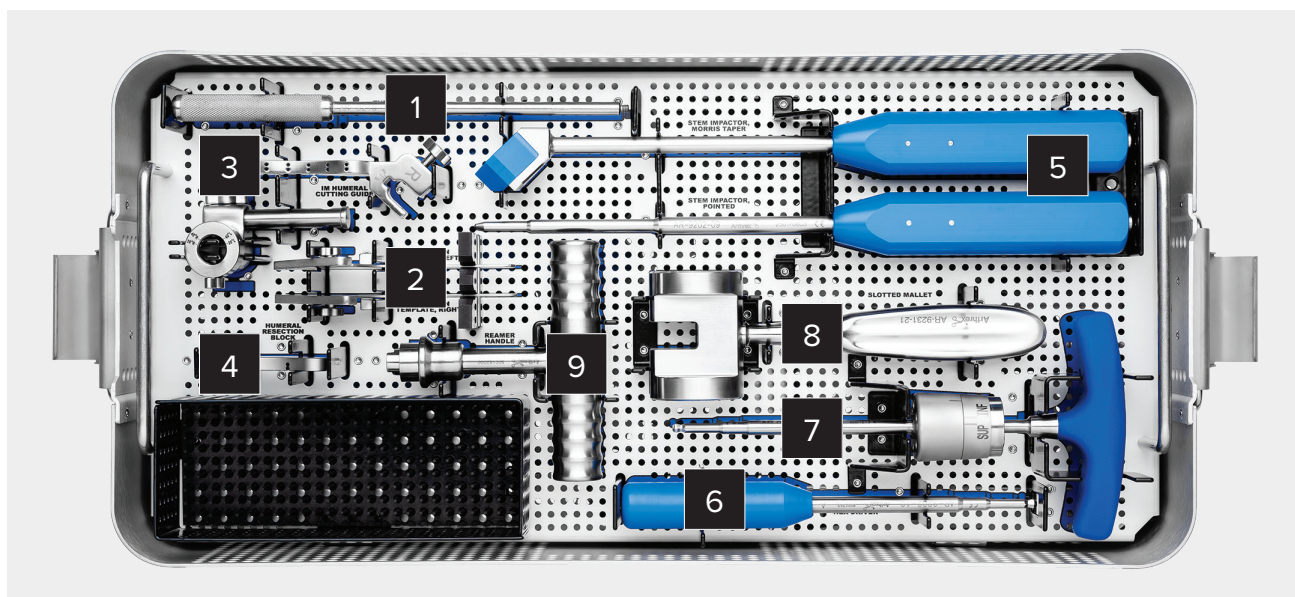


Pic.	Description	Item Number
1	Univers™ Apex Broaches	AR-9321-06S/15S
2	Univers Apex Reamer, 5 mm	AR-9202-25S
	Univers Apex Humeral Reamer, 6 mm	AR-9202-01S
	Univers Apex Humeral Reamer, 7 mm	AR-9202-02S
3	Univers Apex Humeral Broach Alignment Guide	AR-9506-07
4	Univers/Eclipse™ Orientation Pin for Resection Guide	AR-9202

Univers Apex Suture Kit (AR-7298)

Product Description	Item Number
#2 FiberWire® Suture (Blue) w/ Tapered Needles, qty. 3 #2 TigerWire® Suture w/ Tapered Needles, qty. 3 Revers Cutting Needles w/ Nitinol Loops, qty. 2 Micro SutureLasso™ suture passer, straight, qty. 1 2 mm Drill Bit, qty. 1 Univers Apex Subscapularis Repair Surgical Technique	AR-7298

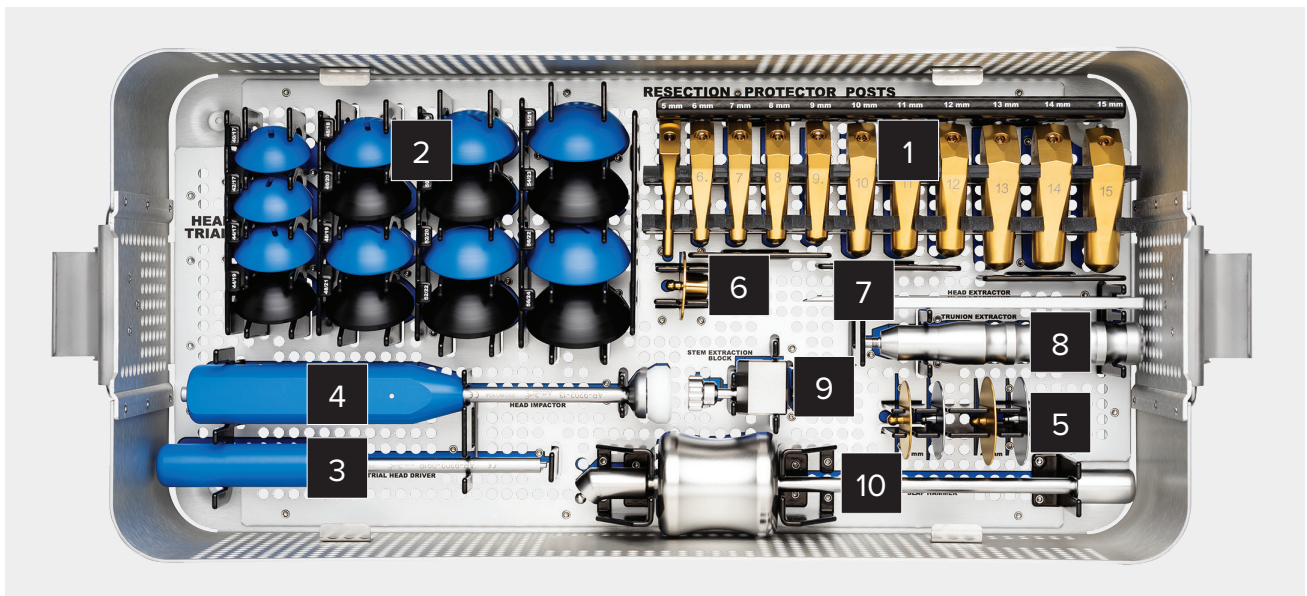
Univers™ II/Apex Combined Tray (AR-9226CC)



Top Tray (AR-9226CC)

Pic.	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 Tray (AR-9226CC)



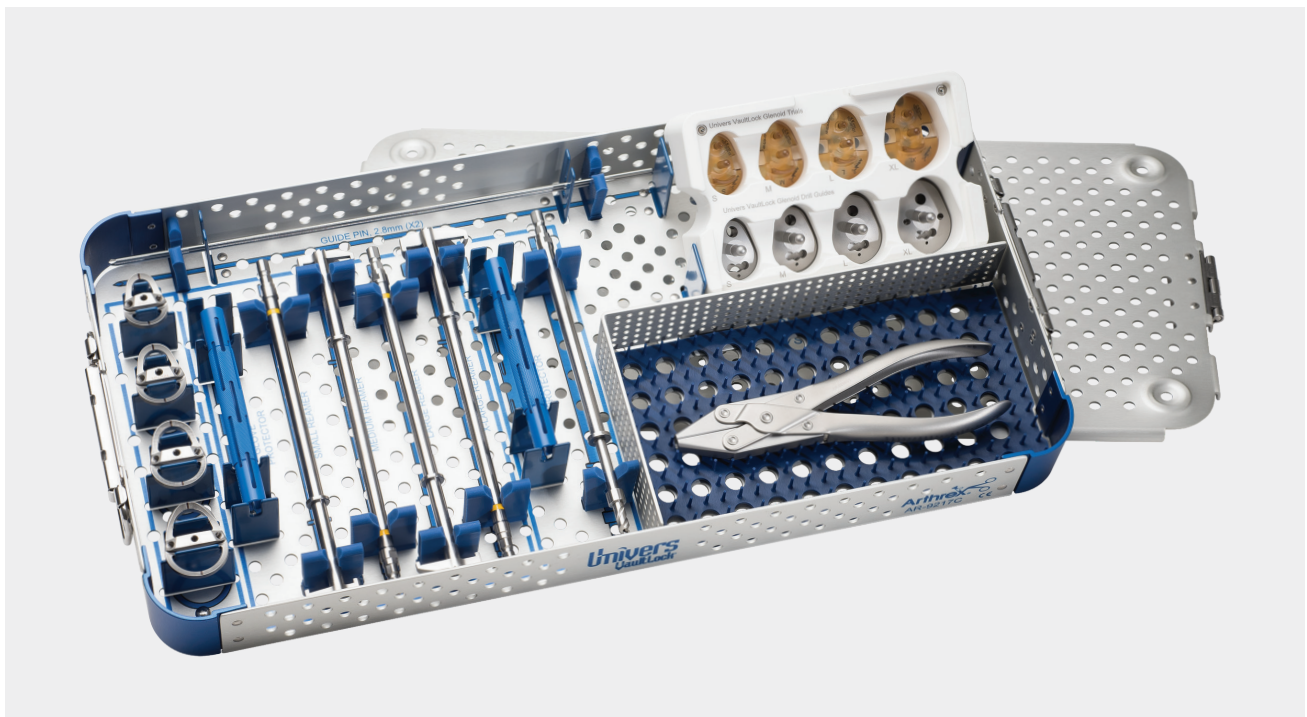
Base Tray (AR-9226CC)

Pic.	Description	Item Number
1	Univers™ Apex Protector Post Sizes 5 mm - 15 mm	AR-9200-15S/26S
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 Protectors	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

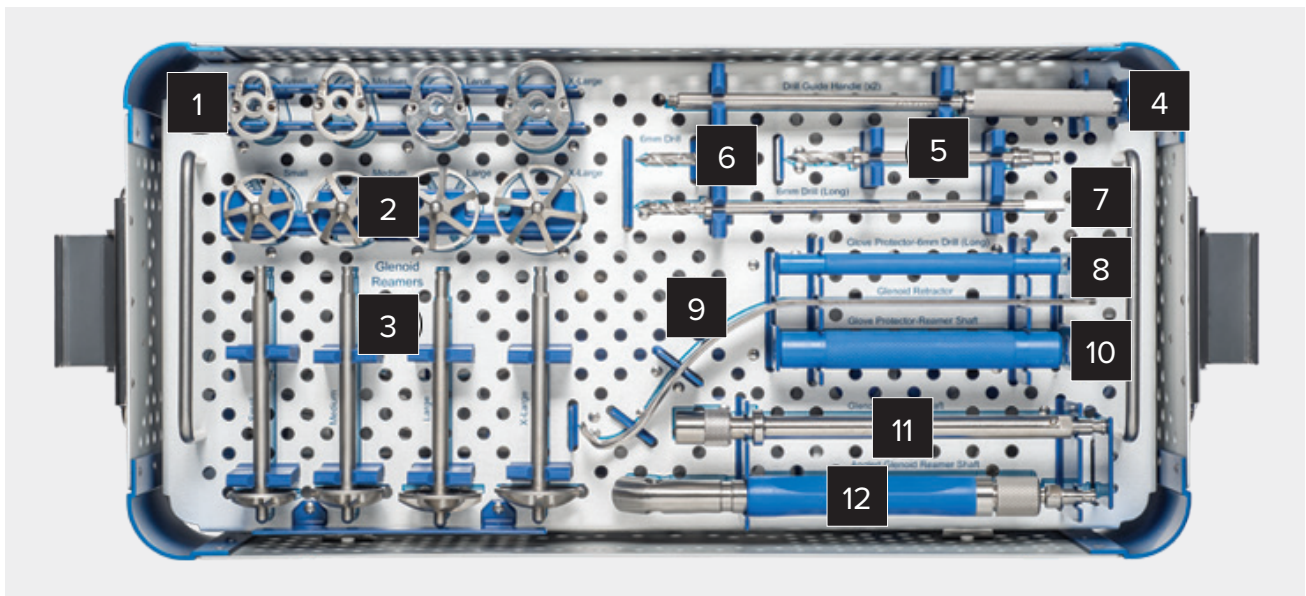
Product Description	Item Number
Version Rod Bracket	AR-9231-20
Intramedullary (IM) Humeral Cutting Guide	AR-9401-14

Uniers Vaultlock® Glenoid Instrument Set (AR-9217S)



Product Description	Item Number	Product Description	Item Number
Steinmann Pin, 2.8 mm, qty. 2	AR-9207	Drill Guide, Uniers VaultLock Glenoid, small	AR-9231-01PP
Pin Guide, Uniers VaultLock Glenoid, small	AR-9215-2CGPP	Drill Guide, Uniers VaultLock Glenoid, medium	AR-9231-02PP
Pin Guide, Uniers VaultLock Glenoid, medium	AR-9215-4CGPP	Drill Guide, Uniers VaultLock Glenoid, large	AR-9231-03PP
Pin Guide, Uniers VaultLock Glenoid, large	AR-9215-6CGPP	Drill Guide, Uniers VaultLock Glenoid, extra large	AR-9231-04PP
Pin Guide, Uniers VaultLock Glenoid, extra large	AR-9215-8CGPP	Uniers VaultLock Glenoid Trial, small	AR-9236-01PP
Drill, 6 mm Cannulated	AR-9216-3	Uniers VaultLock Glenoid Trial, medium	AR-9236-02PP
Nautilus Reamer/Drill Glove Protector, qty. 2	AR-9216-4	Uniers VaultLock Glenoid Trial, large	AR-9236-03PP
Instrument Case, Uniers VaultLock Glenoid	AR-9217C	Uniers VaultLock Glenoid Trial, extra large	AR-9236-04PP
Uniers VaultLock Glenoid Reamer, small	AR-9228GRPP	Uniers VaultLock® Glenoid System Graft Compression Tool	AR-9236GT
Uniers VaultLock Glenoid Reamer, medium	AR-9229GRPP		
Uniers VaultLock Glenoid Reamer, large	AR-9230GRPP		
Uniers VaultLock Glenoid Reamer, extra large	AR-9231GRPP		

Glenoid Instrumentation (AR-9225S and AR-9225KS)

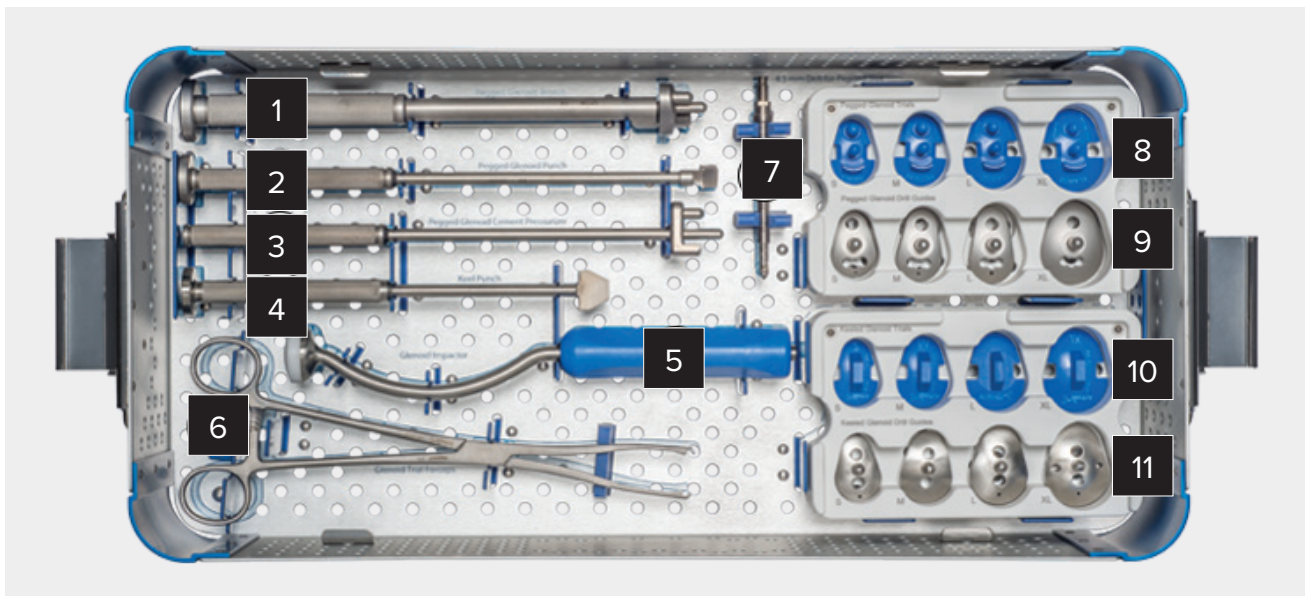


Top Tray (AR-9225C)

Pic.	Description	Item Number
1	Glenoid Drill Guides #1 - S, M, L, XL	AR-9215-2/4/6/8
2*	Glenoid Reamers - S, M, L, XL	AR-9220/AR-9213 AR-9210/AR-9206
3	Glenoid Reamers, Long Shaft - S, M, L, XL	AR-9228/29/30/31
4	Drill Guide Handle	AR-9215-1-02
5	Quick Release Drill, 6 mm, long	AR-9227
6	Quick Release Drill, 6 mm, short	AR-9221
7*	Drill, 6 mm, long	AR-9216-1
8*	Drill Glove Protector, 6 mm	AR-9216-2
9	Posterior Glenoid Retractor	AR-9203-25
10	Glove Protector - Glenoid Reamer Shaft	AR-9211
11	Glenoid Reamer Shaft	AR-9211
12*	Angled Glenoid Reamer Shaft	AR-9222

*Items not included in AR-9225KS

Glenoid Instrumentation (AR-9225S and AR-9225KS)

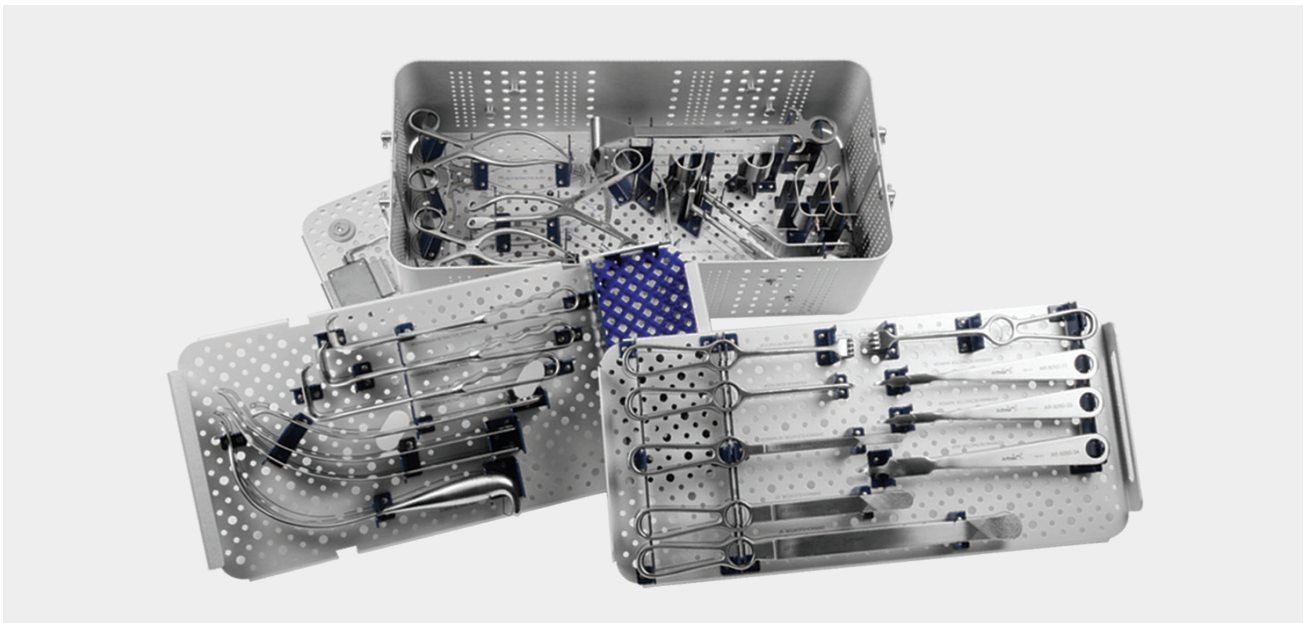


Base Tray (AR-9225C)

Pic.	Description	
1	Pegged Glenoid Broach	AR-9233
2	Pegged Glenoid Punch	AR-9234
3	Pegged Glenoid Cement Pressurizer	AR-9235
4	Keel Punch	AR-9214
5	Genoid Impactor	AR-9223
6	Glenoid Trial Forceps, VaultLock® Forceps	AR-9238, AR-9241
7	Quick Release Drill, 4.5 mm	AR-9239
8*	Pegged Glenoid Trials, S-M-L-XL	AR-9236-01/02/03/04
9*	Pegged Glenoid Drill Guides, S-M-L-XL	AR-9231-01/02/03/04
10	Keeled Glenoid Trials, S-M-L-XL	AR-9217/AR-9218/AR-9219/AR-9219-1
11	Keeled Glenoid Drill Guides, S-M-L-XL	AR-9215-3/5/7/9

*Items not included in AR-9225KS

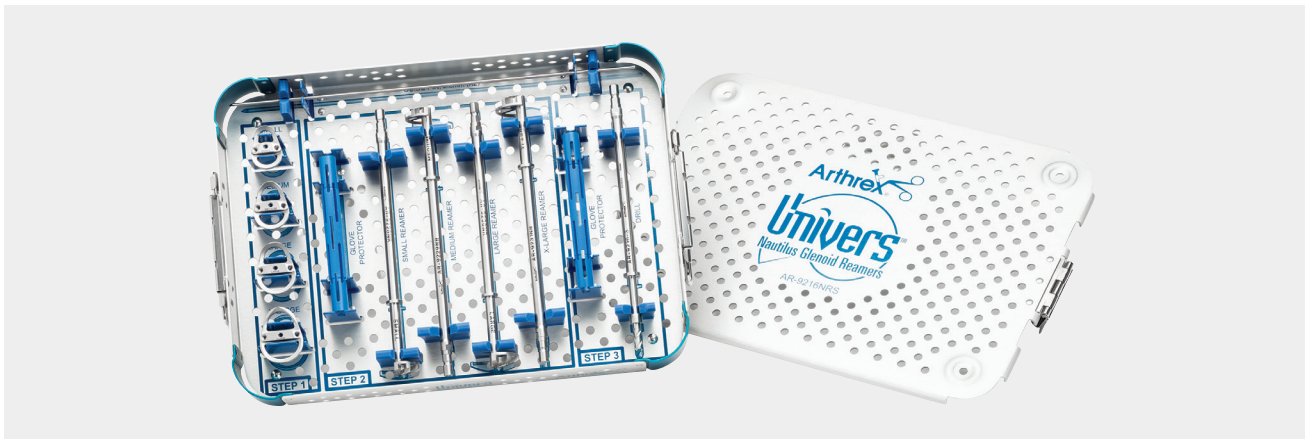
Shoulder Arthroplasty Retractor Set (AR-9260S-53)



This comprehensive retractor set consists of more than 25 standard and specialty retractors. The set is the most extensive shoulder arthroplasty-specific retractor grouping on the market and includes Fakudas, Darrachs, Hohmanns, Gelpis, Richardsons, Kolbels, anterior/posterior glenoid retractors, Cobras, a Browne Deltoid Retractor, and much more. Perfect for use with the Univers™ II, Univers Revers™, Univers Fracture, and SuturePlate™ systems.

Product Description	Item Number	Product Description	Item Number
Thin Glenoid Retractor, narrow tip	AR-9260-30	Richardson Retractor, narrow, 9.5 in long × 1 in wide × 1.5 in deep	AR-9260-40
Thin Glenoid Retractor, wide tip	AR-9260-31	Richardson Retractor, wide, 9.5 in long × 1.5 in wide × 1.5 in deep	AR-9260-41
Fukuda Retractor, large, 7.5 in × 38 mm × 81 mm, T-handle	AR-9260-32	Richardson Retractor, deep, 9.5 in long × 3/4 in wide × 2 in deep	AR-9260-4
Fukuda Retractor, small, 7.5 in long × 32 mm × 81 mm, T-handle	AR-9260-52	Gelpi Retractor, 7.5 in, blunt tip	AR-9260-43
Hohmann Retractor, narrow, 8.5 in long, 10 mm blade, qty. 2	AR-9260-33	Gelpi Retractor, 7.25 in, sharp tip	AR-9260-44
Hohmann Retractor, wide, 9.5 in long, 17 mm, pointed	AR-9260-34	Kolbel Retractor, 8 in long, ring handle	AR-9260-45
Hohmann Retractor, curved, 10.5 in long × 24 mm blade, round	AR-9260-35	Kolbel Retractor Blades, small, 36 mm × 36 mm, blunt, qty. 2	AR-9260-46
Hohmann Retractor, bent, 9.75 in long × 19 mm wide blade	AR-9260-48	Kolbel Retractor Blades, large, 36 mm × 68 mm, blunt, qty. 2	AR-9260-47
Darrach Elevator, 10 in long × 5/8 in wide, blunt with serration	AR-9260-36	Cobra Retractor, 11.5 in blunt, serrated	AR-9260-49
Darrach Elevator, 14 in long × 1 in wide, blunt with serrations	AR-9260-37	Browne Deltoid Retractor	AR-9260-50
Darrach Elevator, narrow, 10 in long × 3/8 in wide, blunt with serrations	AR-9260-51	Shoulder Arthroplasty Retractor Case	AR-9260C-53
Volkman Bone Hook, 9 in long × 20 mm deep, sharp	AR-9260-38		
Volkman "Rake" Retractor, 8.5 in long, 4 prong semi sharp, qty. 2	AR-9260-39		

Univers™ Nautilus Glenoid Reamer Instrument Set (AR-9216NRS)



Product Description	Item Number
Glenoid Reamer, small	AR-9228NR
Glenoid Reamer, medium	AR-9229NR
Glenoid Reamer, large	AR-9230NR
Glenoid Reamer, extra large	AR-9231NR
Cannulated Drill, 6 mm	AR-9216-3
Glove Protectors, qty. 2	AR-9216-4

Product Description	Item Number
Glenoid Pin Guide, small	AR-9215-2CG
Glenoid Pin Guide, medium	AR-9215-4CG
Glenoid Pin Guide, large	AR-9215-6CG
Glenoid Pin Guide, extra large	AR-9215-8CG
Steinmann Pin, 2.8 mm, qty. 2	AR-9207
Reamer Instrument Case	AR-9216NRC



Optional

Product Description	Item Number
Univers™ II Glenoid Version Correction System	AR-9215S
Univers II Congruent Glenoid Reamer Set	AR-9200RRS
Univers Cuff Arthropathy (CA) Humeral Head Instrument Set	AR-9200CAS

IM Cutting Guide Adjustments

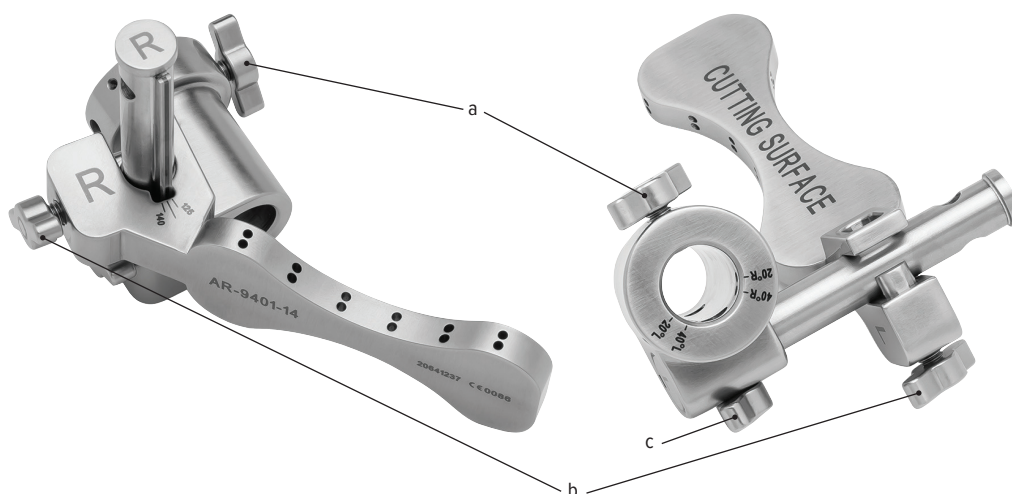
Please refer to the technique video on arthrex.com.

This guide, for use during anatomic shoulder arthroplasty, is designed to attach to any of the proximal humerus reamers in the Univers™ Apex 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 respectively (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.



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. Failure to achieve the appropriate torque requirements when tightening locking screws may result in the premature loosening of the device.
4. The Univers Apex Total Shoulder System stems (lengths 55-65 mm) are not recommended for fractures of the proximal humerus.
5. Postoperatively, until healing is complete 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 implant.
6. 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. Your surgeon will guide you in deciding what particular treatment is best for you and explain the benefits, risks, and contraindications associated with the treatment.
7. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Implant removal should be followed by adequate postoperative management.
8. Pre-operative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implant, are important considerations in the successful utilization of this device.
9. 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.
10. An internal fixation device must never be re-used.
11. Do not re-sterilize this device.
12. The appropriate Arthrex delivery system is required for proper insertion of the implant.
13. Only Arthrex delivery systems, instruments, and trial prostheses should be used for the implantation procedure.
14. Endoprostheses may not be altered mechanically, or changed in any other way.
15. Do not implant any parts that have been scratched or damaged.
16. An artificial joint is subject to wear and/or can loosen over a period of time. Wear and loosening may make it necessary to re-operate on an artificial joint.
17. An infection in an artificial joint may lead to implant removal.
18. This device should only be used in conjunction with other implants designed specifically for use with this system.
19. Biohazard waste, such as explanted devices, needles and contaminated surgical equipment should be safely disposed of in accordance with the institutions policy.
20. Serious incidents should be reported to Arthrex Inc., or an in-country representative, and to the health authority where the incident occurred.

Indications

The Univers™ Apex 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. **US Only:** 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. 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.

Glenoid Sizing Matrix - Radial Mismatch in mm

Univers™ Apex Total Shoulder System	Univers VaultLock®, Keeled, and Pegged 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 Apex 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	60 mm
6	60 mm
7	60 mm
8	60 mm
9	60 mm
10	60 mm
11	60 mm
12	60 mm
13	65 mm
14	65 mm
15	65 mm



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.

View U.S. patent information at www.arthrex.com/corporate/virtual-patent-marking

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