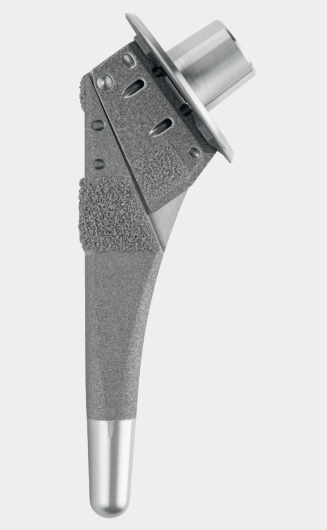
Univers Apex OptiFit™ Total Shoulder System

Surgical Technique

Arthrex®

Implant Design Rationale

With anatomic restoration of the humerus and glenoid, soft-tissue balancing of the rotator cuff is more accurate, allowing for improved functional outcome. Therefore, the Univers Apex OptiFit™ humeral component was designed to account for common anatomical variations of the proximal humerus and allow the surgeon to adapt the humeral stem and articular surface to the position that best represents the patient's normal anatomy. Variable adjustments with respect to the inclination angle, version, and head offset can be made intraoperatively with the implant in the humeral canal.

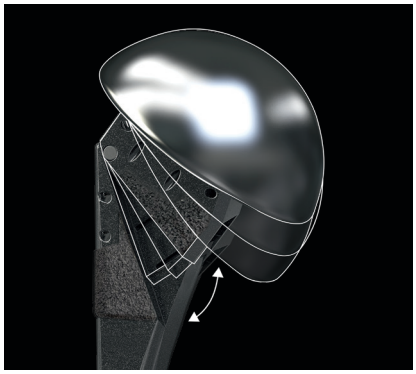


The mid-range stem length in combination with the titanium plasma spray optimizes stability and bone preservation, while the rectangular stem body and removable trunnion optimize revisability. In addition, strategically incorporated suture holes allow for unique subscapularis repair options.

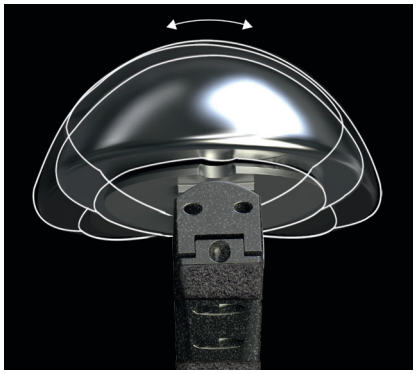
Implant Features

- 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
- Titanium plasma spray for ingrowth fixation
- 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
- Multiple suture eyelets for subscapularis and lesser tuberosity repair techniques
- Removable trunnion for simplified extraction/revision

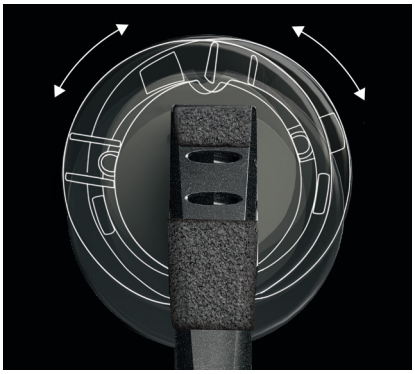
Inclination



Version



Offset



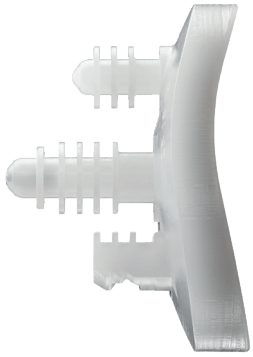
Glenoid Options: VaultLock® Glenoid System

Fluted Central Peg
- Immediate fixation

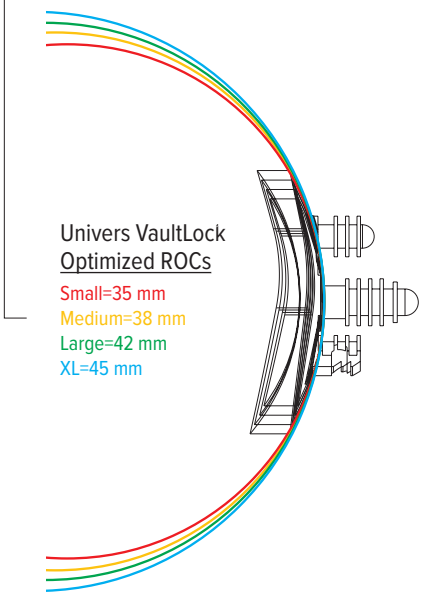
Inferior Keel
- Decreased cortical penetration compared to inferior pegs
- Multiple fixation features, including reverse barbs, flutes, and central cement fenestration

Superior Peg
- Enhanced immediate fixation
- Self-pressurizing design

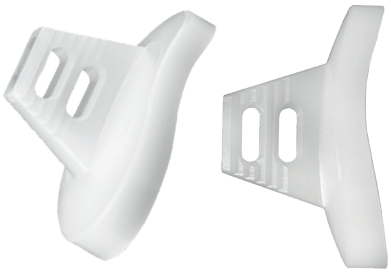
Inline Configuration
- Combines all advantages of pegged and keeled implants including stability and preparation ease



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: Keeled and Universal Glenoid™ Systems



Keeled Glenoid

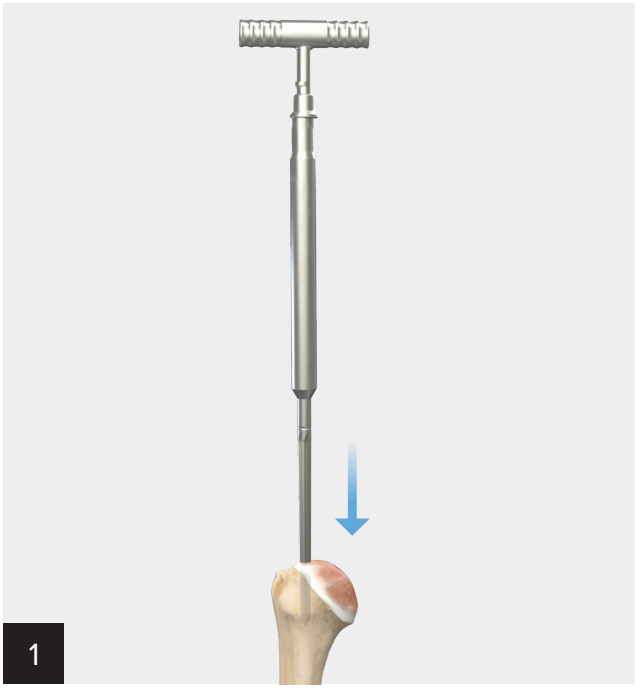
- Dual fenestrations for enhanced anchoring
- Reverse barbs for expansion effect within the glenoid vault

Convertible Universal Baseplate

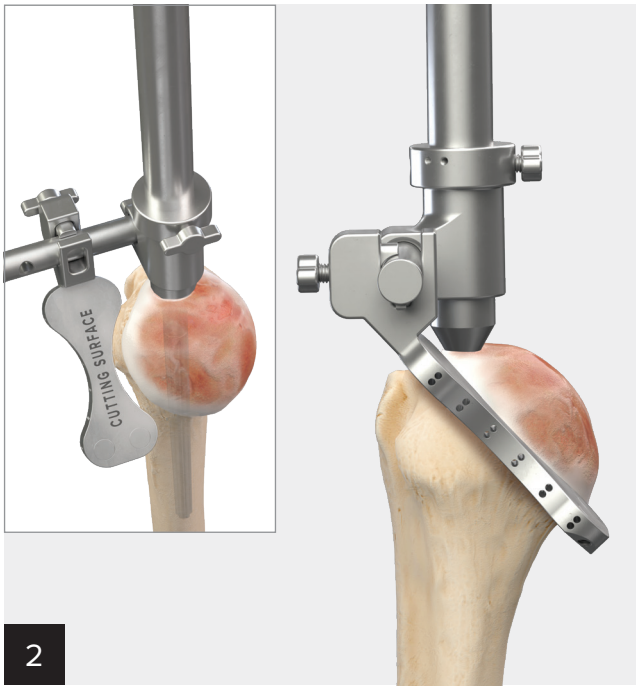
- Combines advantages of polyethylene with the stability of screw fixation, resulting in reduced risk of radiolucent lines
- Three sizes (S, M, L), two polyethylene thicknesses (baseplate + polyethylene = 7 mm or 8 mm), and appropriate glenohumeral mismatch for restoration of anatomic joint kinematics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

Humeral Preparation

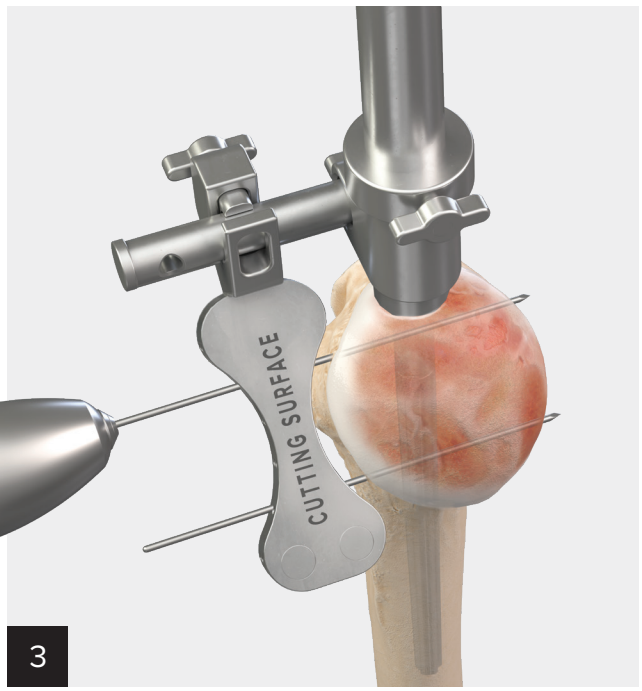
The surgeon should position and expose the shoulder for a standard arthroplasty procedure. Following exposure of the humeral head, including removal of the osteophytes, either an IM resection guide (see step 1), or resection template or freehand resection technique can be used.



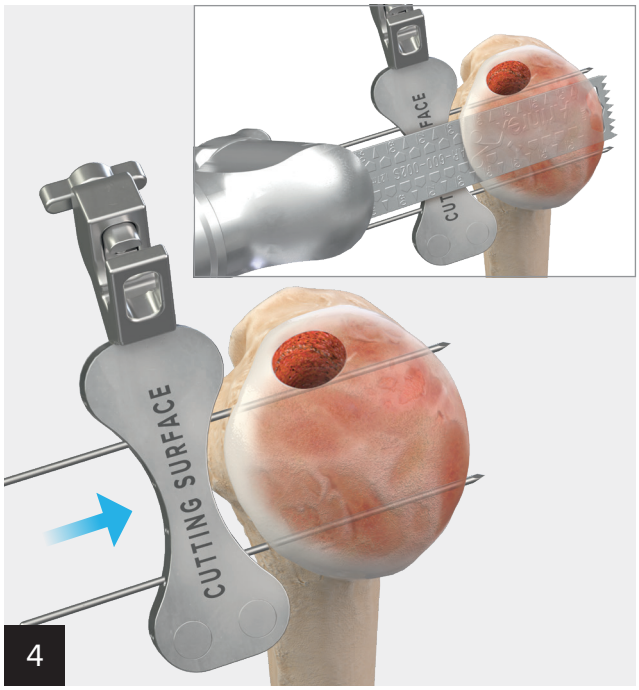
Attach the reamer T-handle to the 5 mm or 6 mm humeral reamer. Advance the reamer down the medullary canal to the first circumferential groove. Repeat with the 7 mm reamer if necessary. Leave the final reamer in place.



Secure the IM guide cutting assembly, cutting surface, and version rods to the reamer.



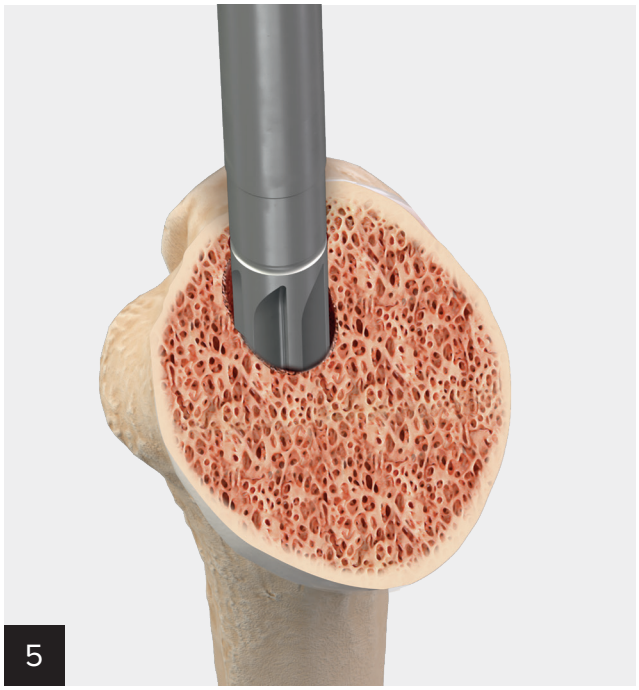
Adjust inclination and version of the IM guide to align the cutting surface with the anatomic neck of the humerus. Secure the cutting surface with two 1.6 mm K-wires.



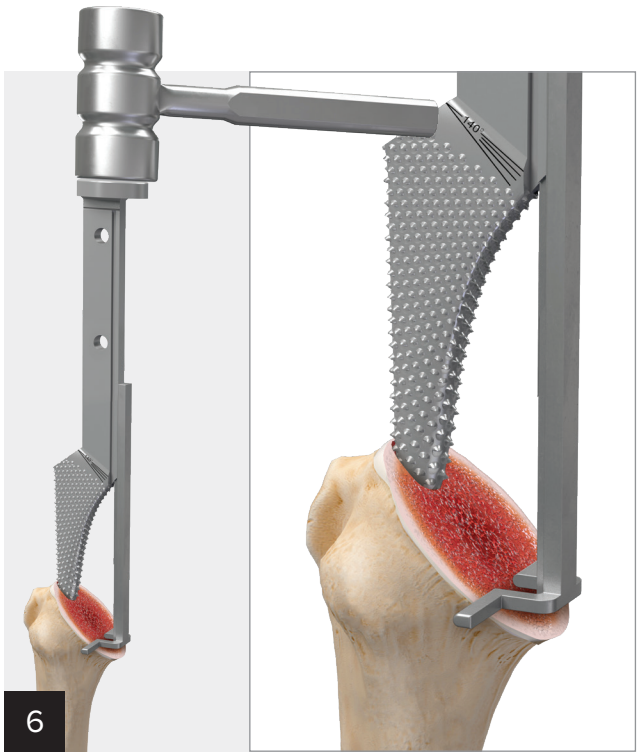
Detach the IM guide cutting assembly from the cutting surface. Remove the cutting assembly and reamer from the humerus.

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 27).

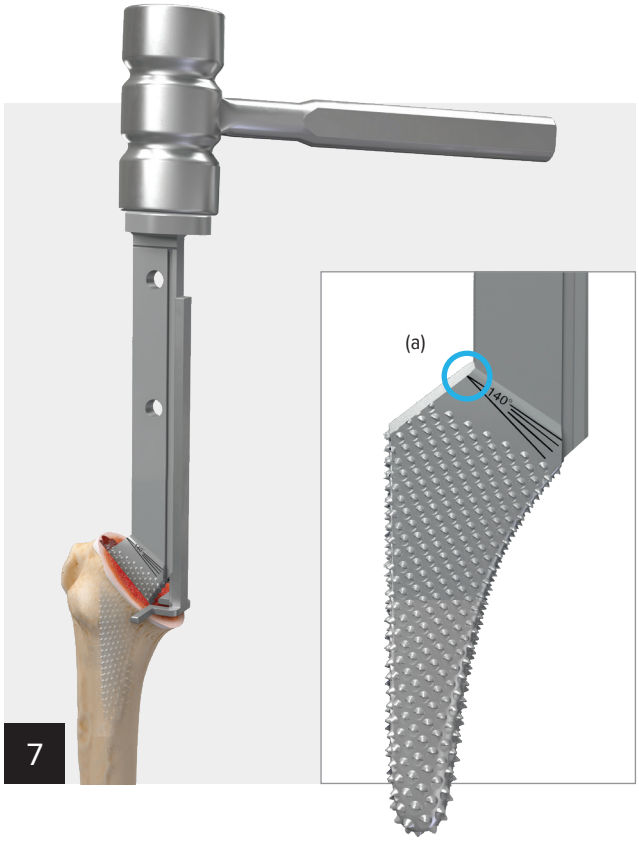


If not used for the humeral osteotomy, attach the reamer T-handle to the 5 mm or 6 mm reamer. Position the tip at the superolateral aspect of the humerus. Advance the reamer down the medullary canal to the circumferential groove adjacent to the cutting flutes. Repeat up to the 7 mm reamer if necessary.



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.

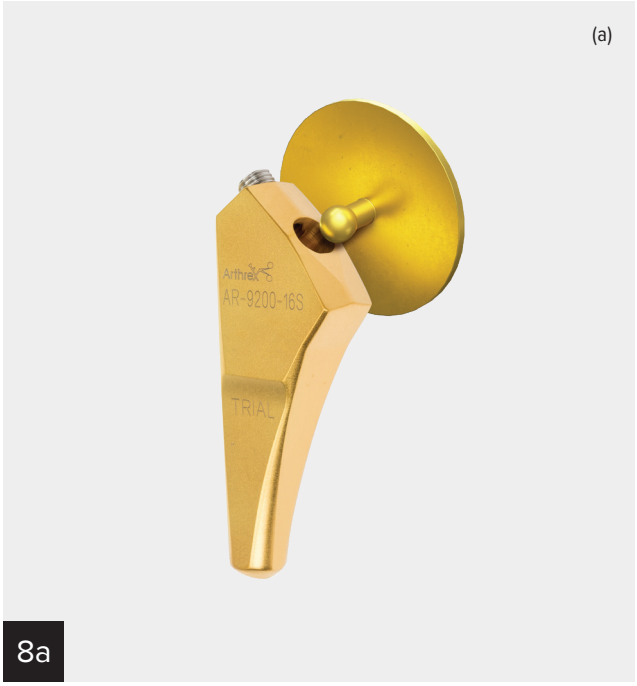


Each broach should be advanced until the lateral hinge point of the laser marks is aligned with the resected surface. Proceed with the next size broach until the appropriate fit is obtained. For noncemented application, select the implant that corresponds to the final broach size.

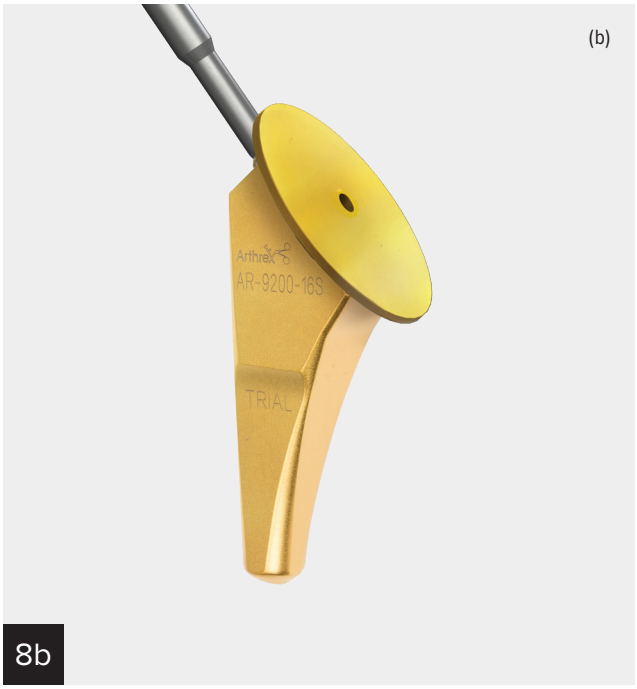
Note: If cementing the stem is desired, an implant one size smaller than the final broach is recommended.

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 **(a,b).** This allows the protector device to rest evenly on the resected surface. Insert the construct into the proximal humerus until the plate comes to rest on the humeral cut **(c,d).**



8a



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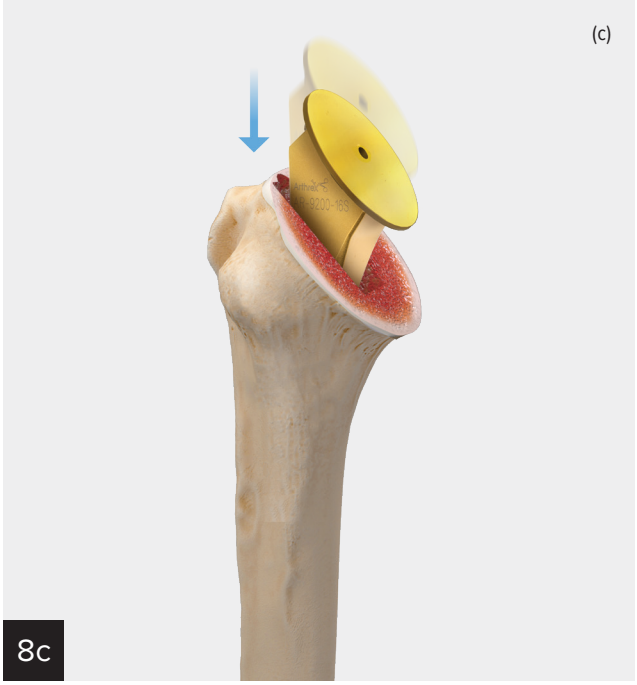

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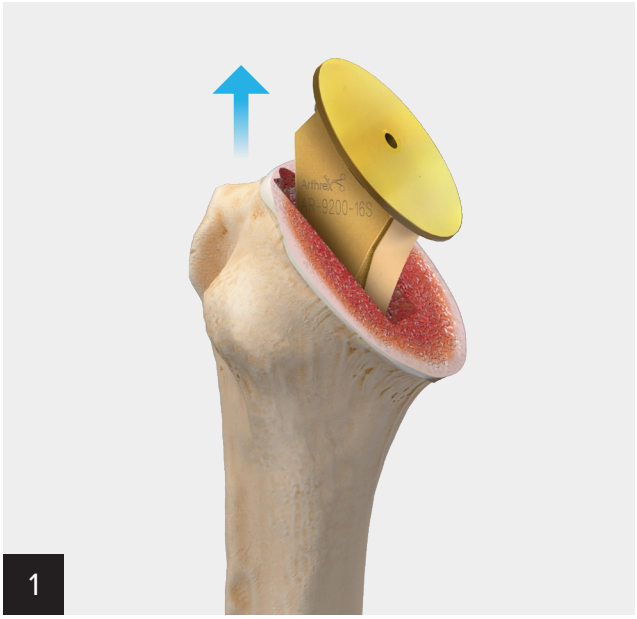
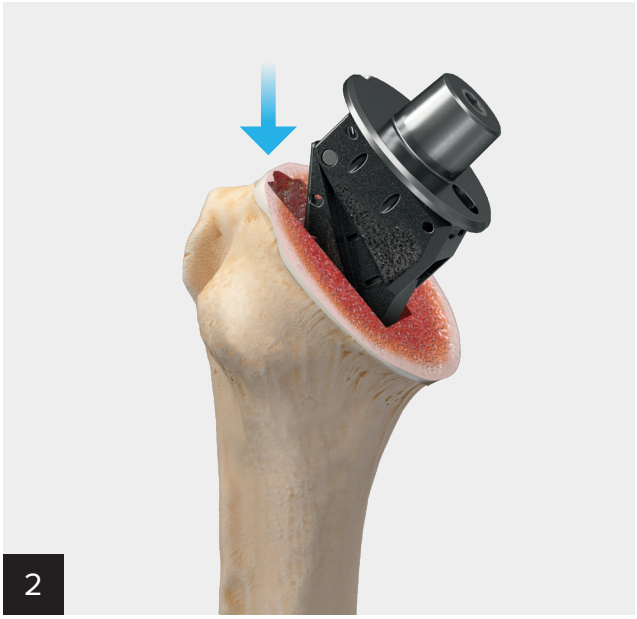
Humeral Stem Implantation (Surgical Technique)

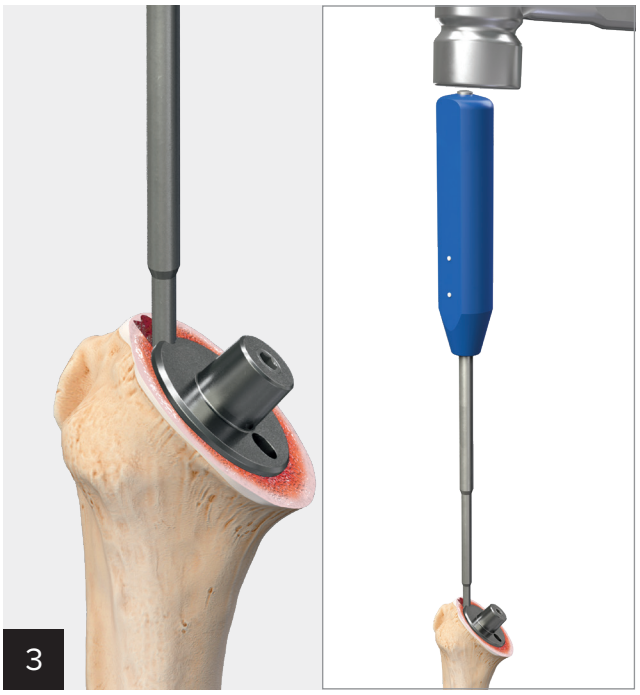


After completing glenoid implantation, remove the resection protector device and post.



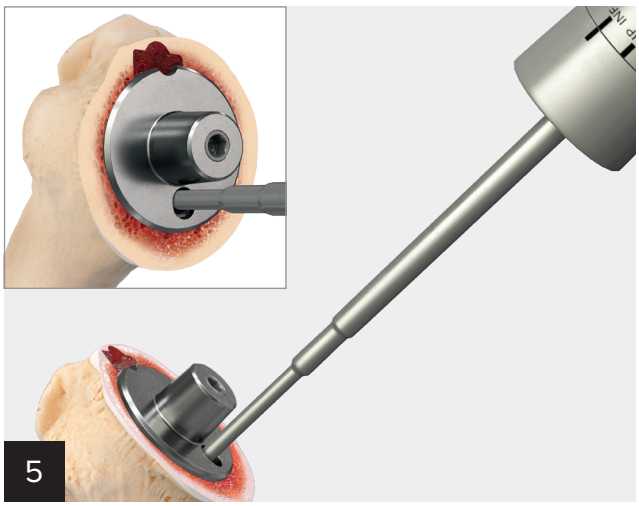
Open the humeral implant in a sterile fashion and insert the stem into the humeral canal.

Note: 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).

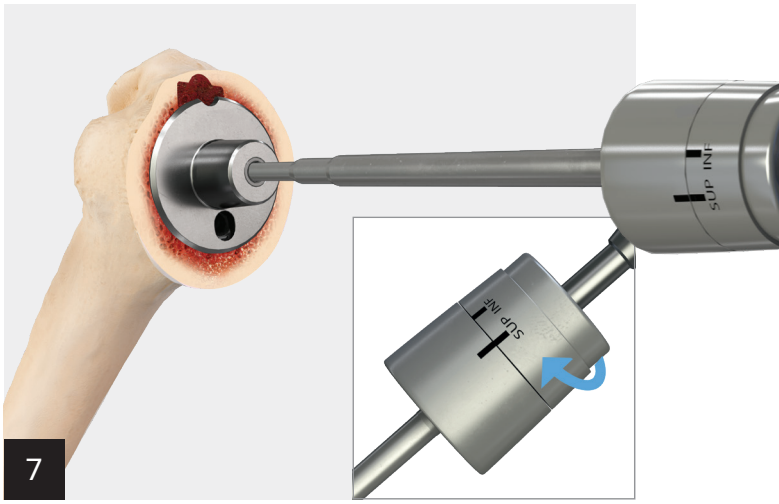
Place the angled Morse taper stem impactor over the Morse taper and complete impaction. Impact the stem into the humerus, keeping the inclination angle free. The inclination angle is established when the flange is in contact with the humeral surface and is fully seated.



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.

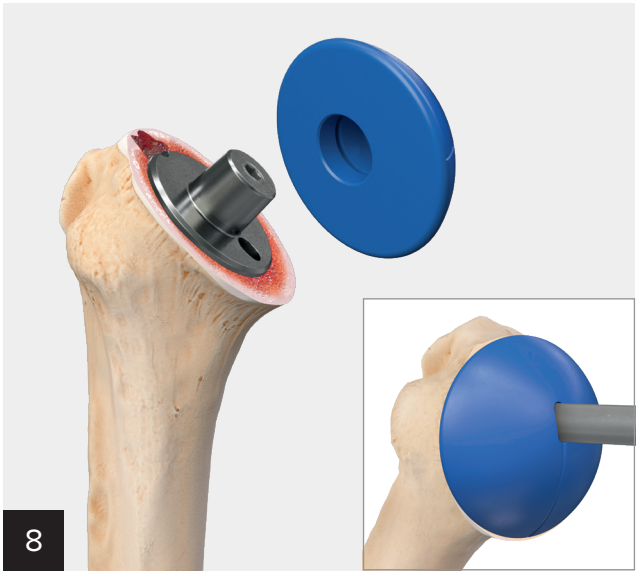
Use the torque driver to lock the inclination (inferior) screw located on the Morse taper of the humeral stem. Properly tighten the set screw by visually confirming that the “INF” mark is rotated to the indicator line on the torque driver.

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.



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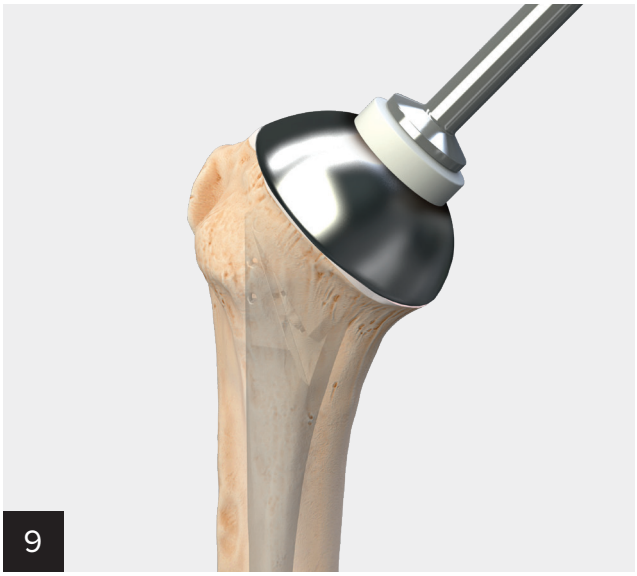
Attach the appropriate trial head and use the trial driver to adjust offset. Perform a trial reduction. The position of maximum offset is designated by a line on the surface of the trial head and corresponds with markings on the implant head.



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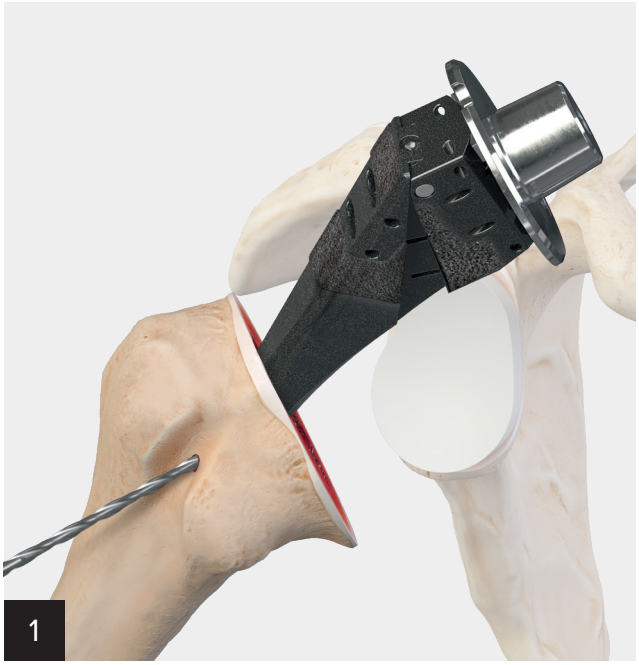
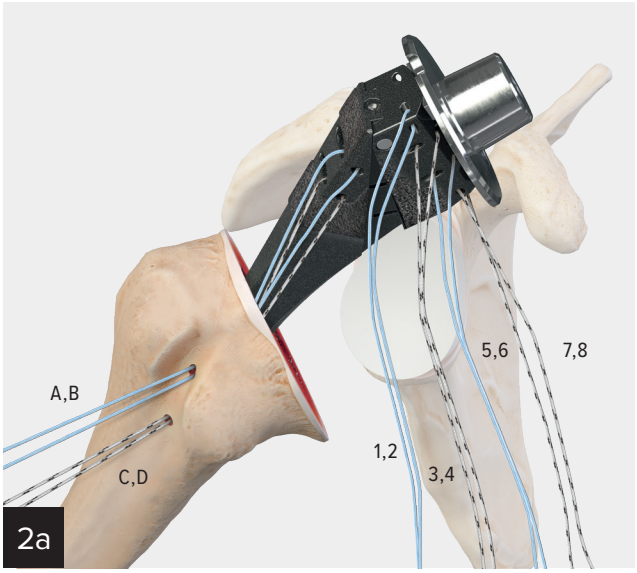
After trial reduction, remove the trial head and clean and dry the Morse taper. Impact the implant humeral head onto the humeral stem using the head impactor.

As described by Evan S. 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 OptiFit™ 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 trunnion in the proximal aspect of the Univers Apex OptiFit 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 below) 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 08).

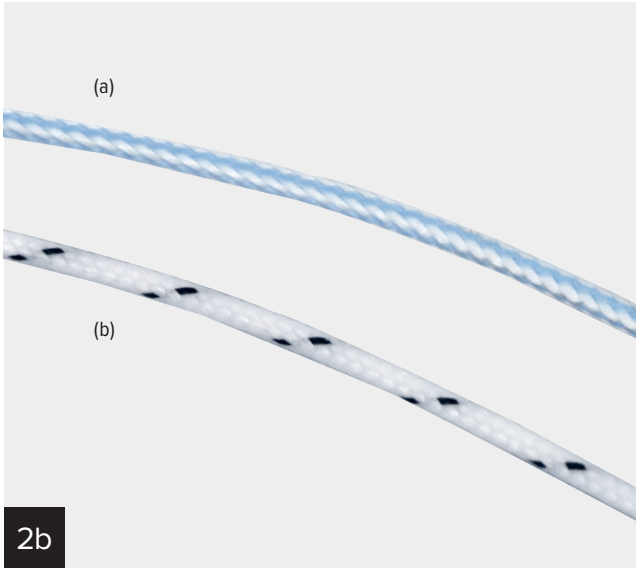


Use a 2 mm drill to place holes in the bicipital groove at the approximate location of the Apex lateral suture eyelets. The implant can be used as a template for targeting drill hole location.

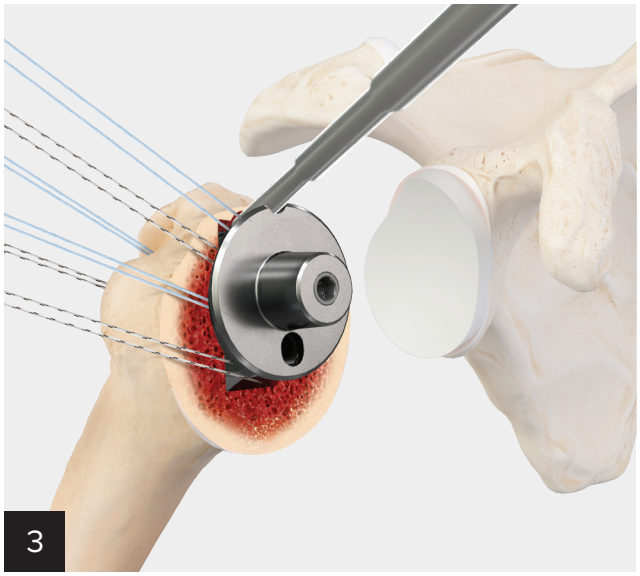


Pass two #2 FiberWire **(a)** sutures through the lateral holes, yielding 4 suture limbs labeled A-D from superior to inferior. FiberWire suture superior/TigerWire suture **(b)** inferior.

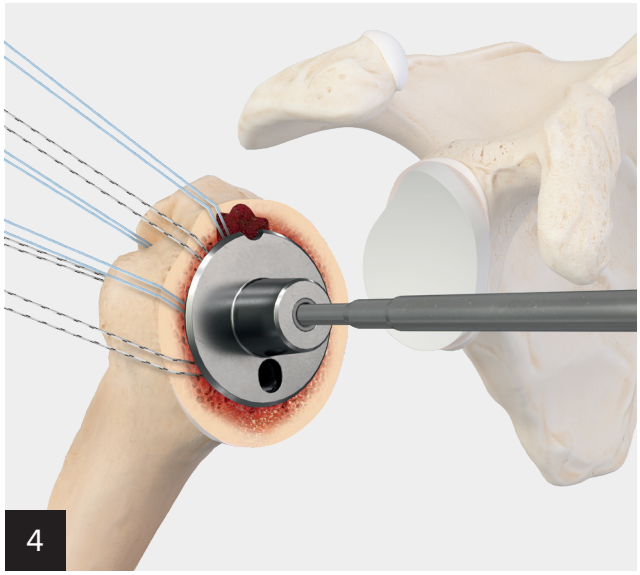
Pass four #2 FiberWire sutures through the holes beneath the trunnion, yielding 8 suture limbs labeled 1-8 from lateral to medial [FiberWire **(1,2)**, TigerWire **(3,4)**, FiberWire **(5,6)**, TigerWire **(7,8)**].



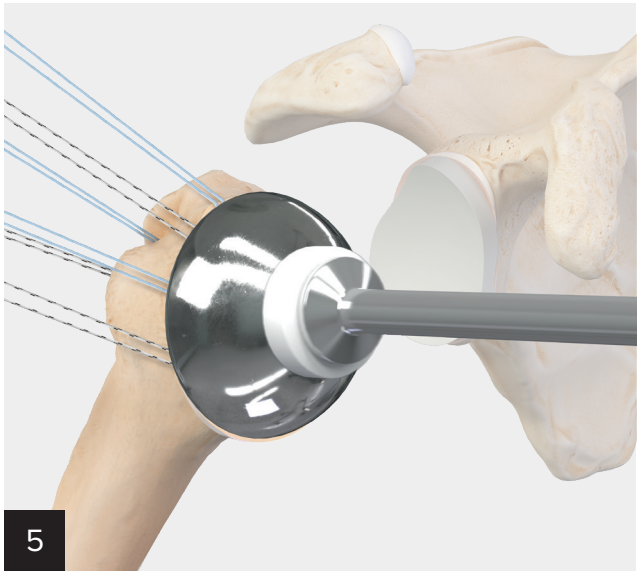
Pass limbs **A** and **B** through the superior hole from the intramedullary canal out. Likewise, pass suture limbs **C** and **D** through the inferior hole from the intramedullary canal out. The Micro SutureLasso™ suture passer simplifies passage.



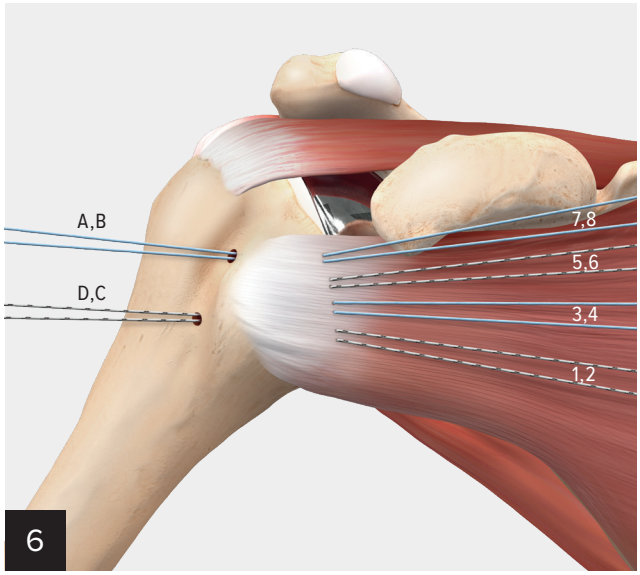
Hold all strands out to length on tension as the stem is implanted and impacted with the pointed stem impactor. Follow by using the angled Morse taper stem impactor, placing the trunnion flush to the osteotomy surface (refer to Humeral Stem Implantation steps 3-4, pages 08-09).



Tighten the inclination (inferior) and version (superior) screws with the torque driver (refer to Humeral Stem Implantation steps 6-7, page 09). The trial head may be used at this point to check stability prior to impacting the actual head component.



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 bony debris. Obtain hemostasis with electrocautery.

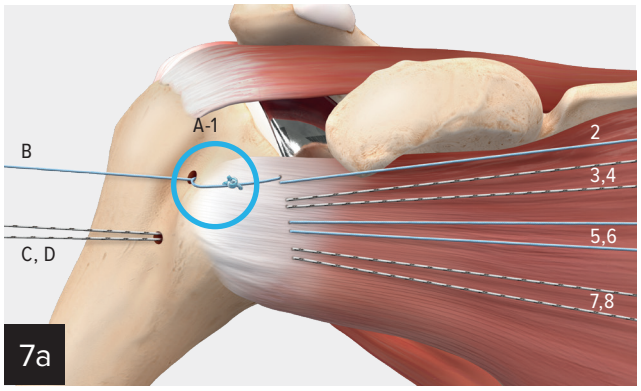


Evenly place suture limbs 1-8 through the medial aspect of the subscapularis tendon from superior to inferior. Proper spacing is key to the final repair. Care must be taken not to cut the sutures when passing through the tendon.

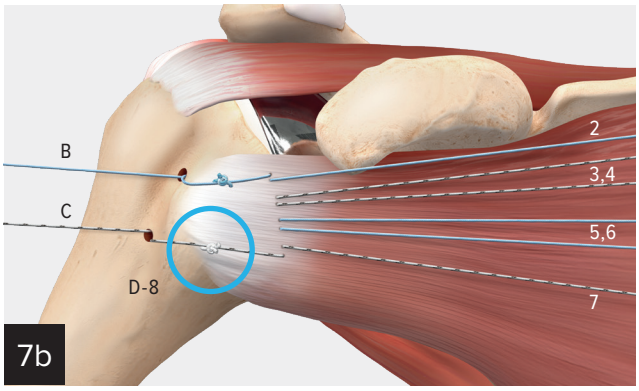
The suture color pattern is such that the first 4 knots are like color to like color and the last 2 knots are different color to different color. In addition, the last knot is tensioned and creates dynamic compression of the subscapularis tendon over the lesser tuberosity. The repair is evaluated by 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 is 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.

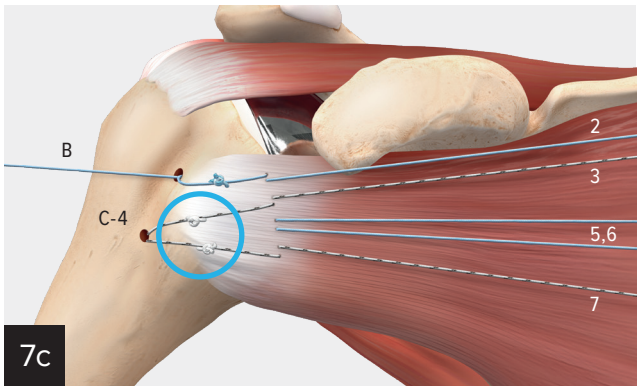
*Do not cut tied limbs until final construct is completed, as limbs can be used as augments if desired.



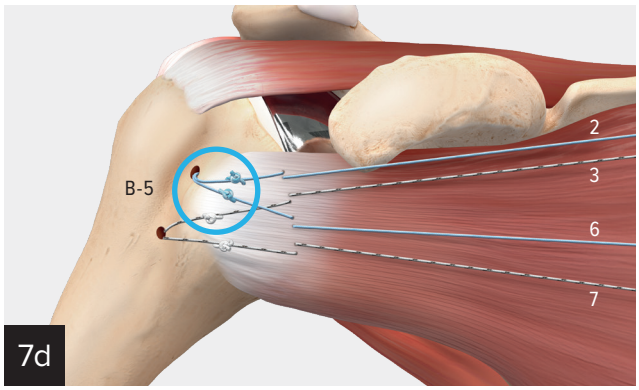
A to 1 (FiberWire® to FiberWire suture).



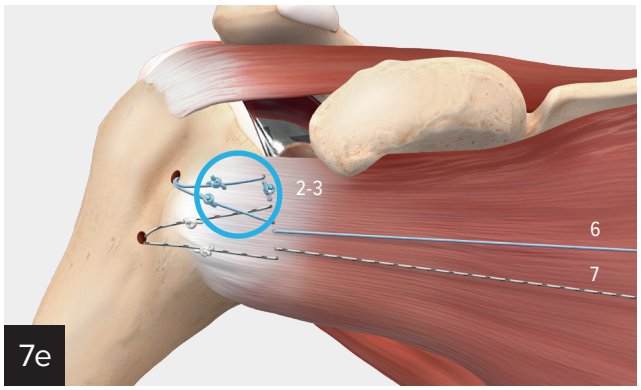
D to 8 (TigerWire® to TigerWire suture).



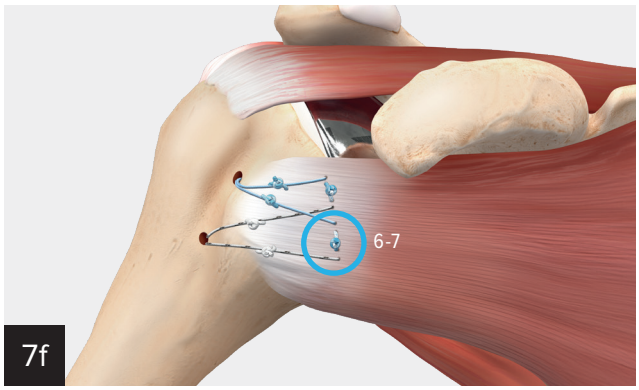
C to 4 (TigerWire to TigerWire suture).



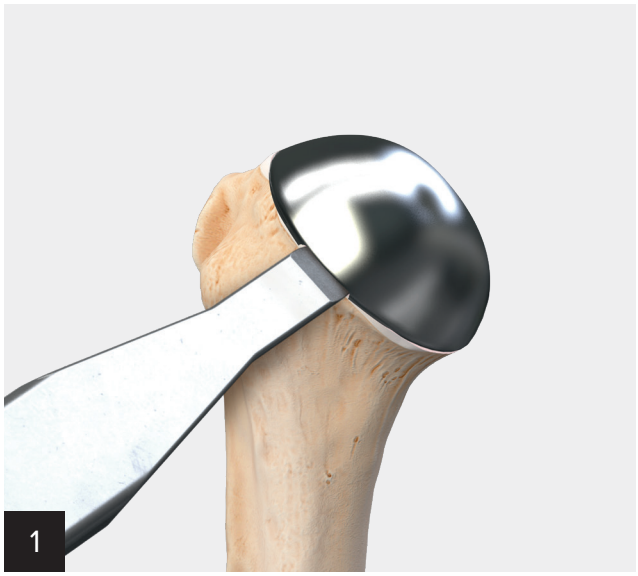
B to 5 (FiberWire to FiberWire suture).



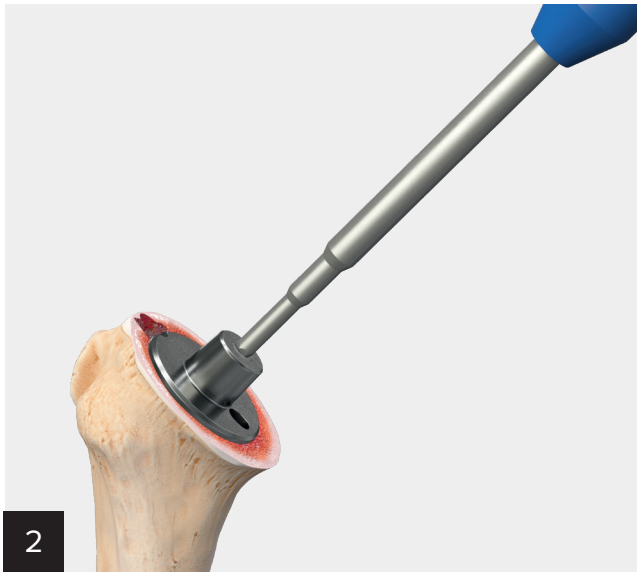
2 to 3 (FiberWire to TigerWire suture). Moderate tension is applied to this knot to initiate tendon compression over the lesser tuberosity.



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



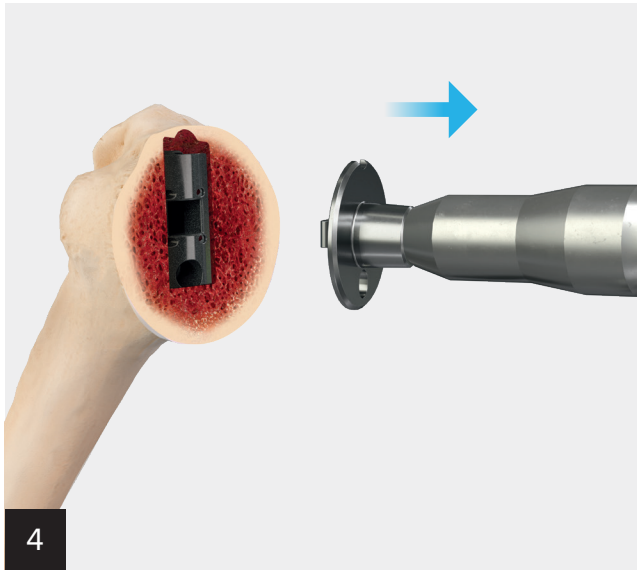
Once exposure is accomplished and the proximal humerus dislocated, disengage the prosthetic head by placing the humeral head extractor into one of the head slots between the head and trunnion. It may be necessary to use more than one slot to accomplish extraction.



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

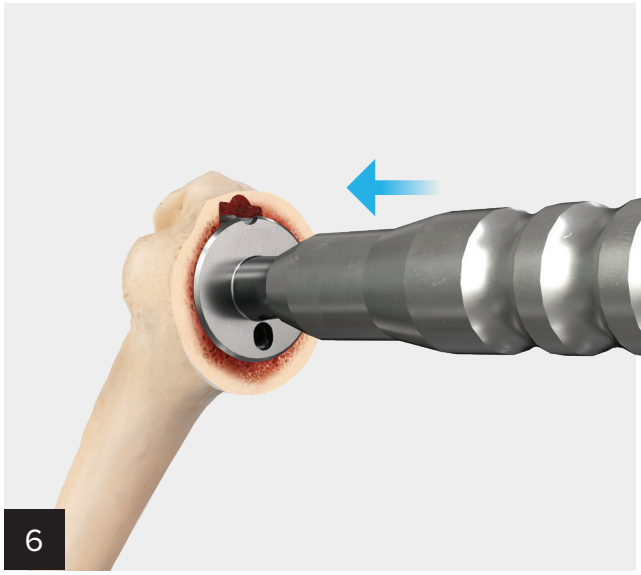
Note: It is important to leave the inferior screw tightened and locked.

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.

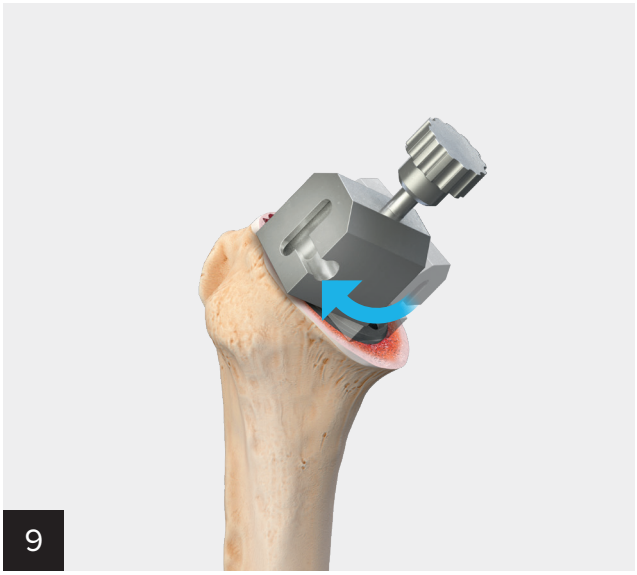
It is essential to first loosen the proximal stem before attempting to use the slap hammer for stem removal. This is accomplished with osteotomes passed between the proximal rectangular body and surrounding bone. Removal of the trunnion allows placement of the osteotome directly along the surface of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

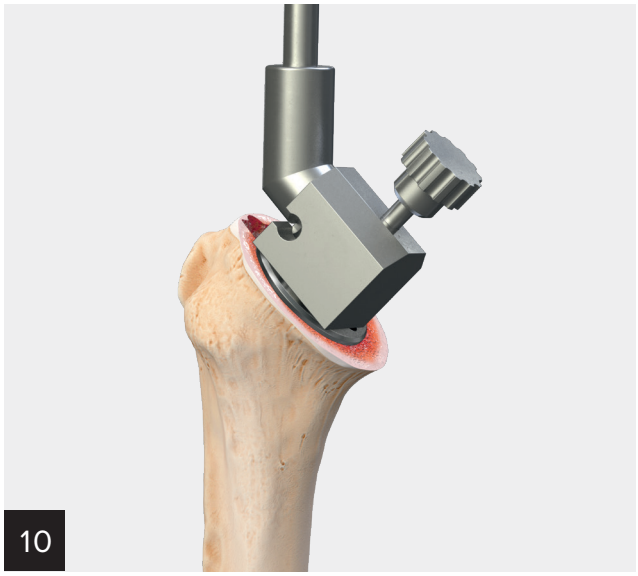
Thread the stem extraction block into the version (superior) screw location on the Morse taper.

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.

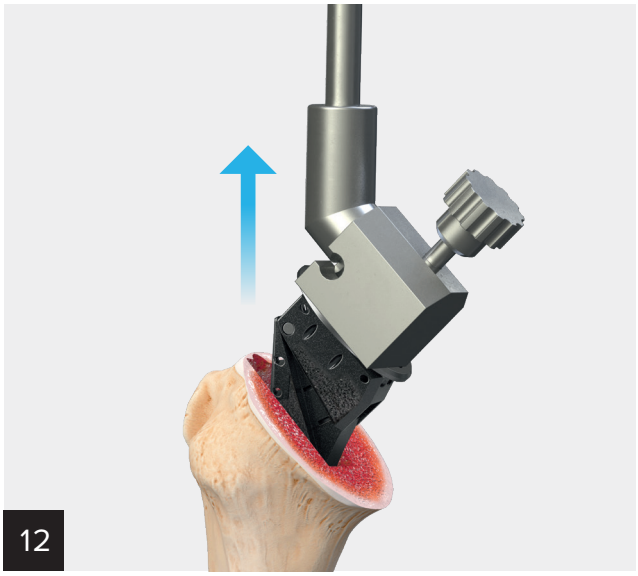


10

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

11

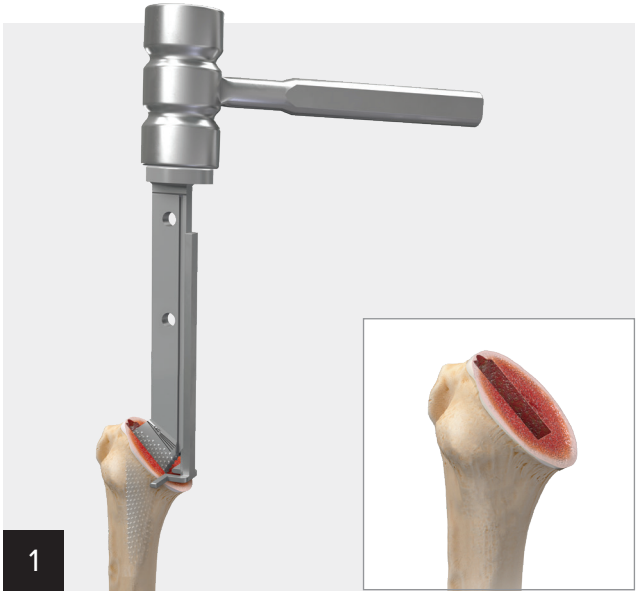
After securing the connection, hold the slap hammer axis in line with the anatomic axis of the humerus and deliver a distracting force.



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.

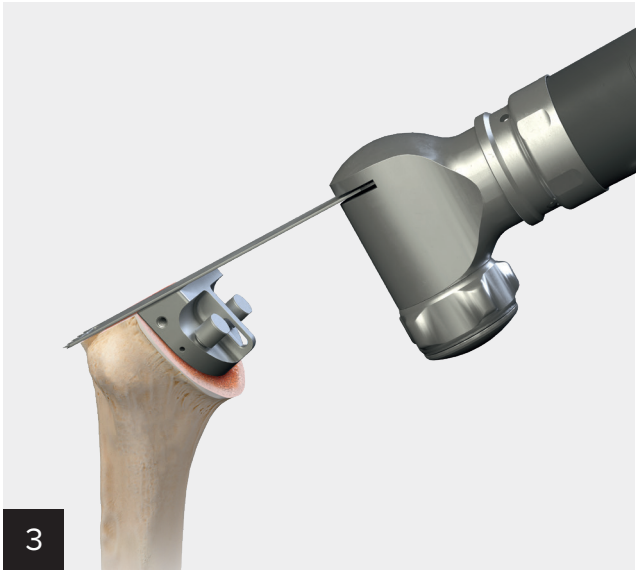
Evaluate the rotator cuff and surrounding soft tissues of the involved shoulder. Upon determining that the rotator cuff tear is irreparable, debride the frayed edges of the remaining cuff and bursa. Do not perform an acromioplasty or release the coracoacromial ligament, since this may compromise postoperative prosthesis stability.



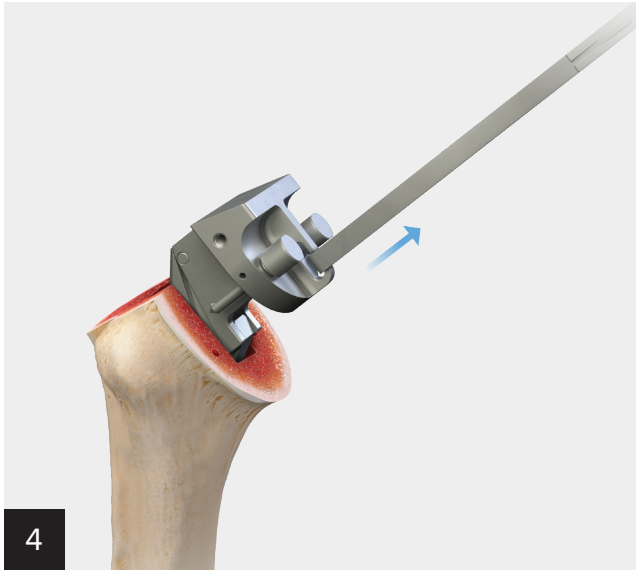
Perform the proximal humeral osteotomy and humeral canal preparation (reaming/broaching) as described in steps 1-7 of the Humeral Preparation technique described on pages 04-06.

Note: The Univers CA humeral head system is not intended for use with glenoid implants.

Place the CA cutting guide in the prepared humeral canal. There is a primary cutting guide that corresponds with each broach size in the Univers Apex Humeral Set. There is no need to downsize the CA cutting guide. Verify that the guide is well seated and aligned with the anatomic axis of the humerus (avoid varus or valgus malalignment). Impact two anchor pegs into the osteotomy surface for stability.

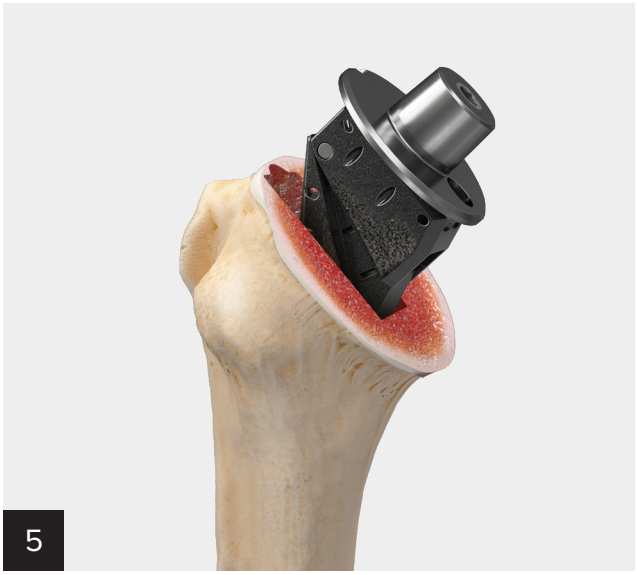


Perform the greater tuberosity osteotomy with an oscillating saw guided by the CA cutting guide.



Remove the cutting guide.

Note: The small window in the cutting guide allows forceps to capture the guide for removal.



5

Place the appropriate-size humeral stem as described in steps 2-7 of the Humeral Stem Implantation technique described on pages 08-09.

6

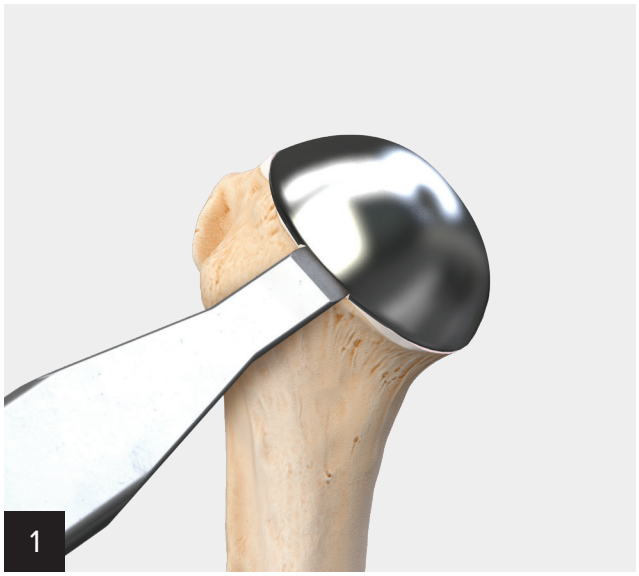
Place the appropriate-size CA trial head on the humeral stem. Reduce the humerus and assess shoulder motion, soft-tissue tension, and stability.

7a

7b

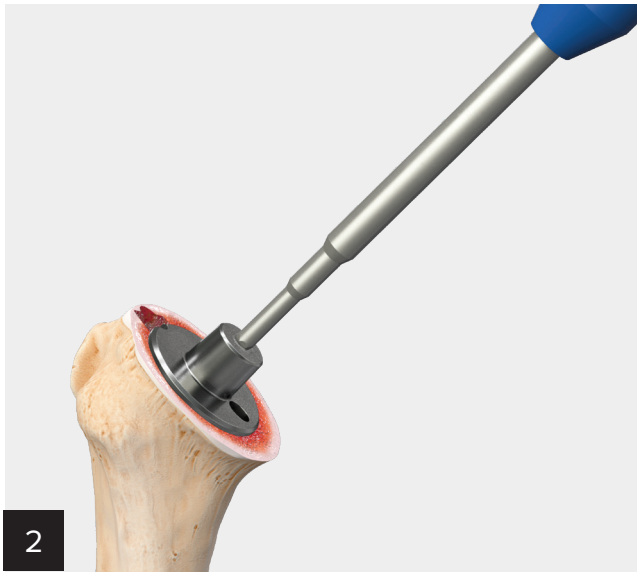
Once the appropriate-size head is determined, dislocate the proximal humerus, remove the trial head, and impact the final implant in place. Reduce the glenohumeral joint and proceed with wound irrigation and closure per surgeon protocol.

Evaluate the rotator cuff and surrounding soft tissues of the involved shoulder. Upon determining the rotator cuff tear is irreparable, debride the frayed edges of the remaining cuff and bursa. Do not perform an acromioplasty or release the coracoacromial ligament, since this may compromise postoperative prosthesis stability.



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.

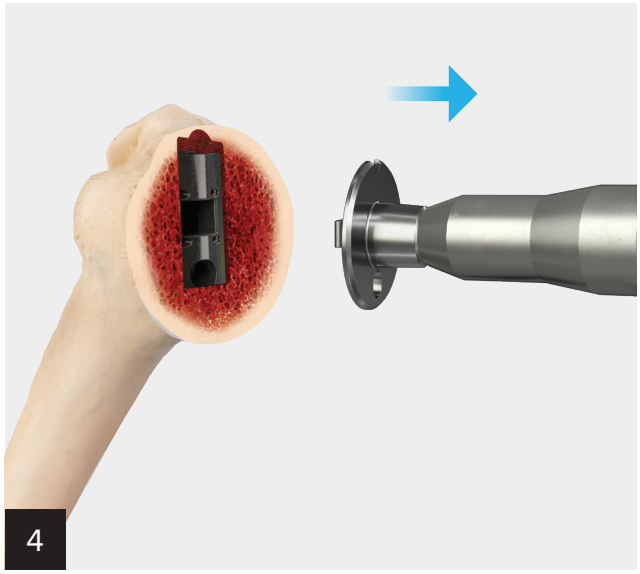
Note: The Univers CA Humeral Head system is not intended for use with glenoid implants.



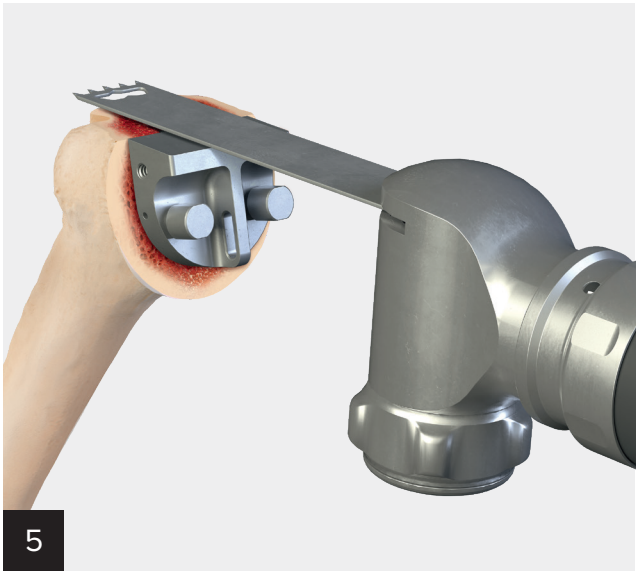
Remove the version-locking (superior) screw to facilitate removal of the trunnion. It may be helpful to use the T-handle torque driver.

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

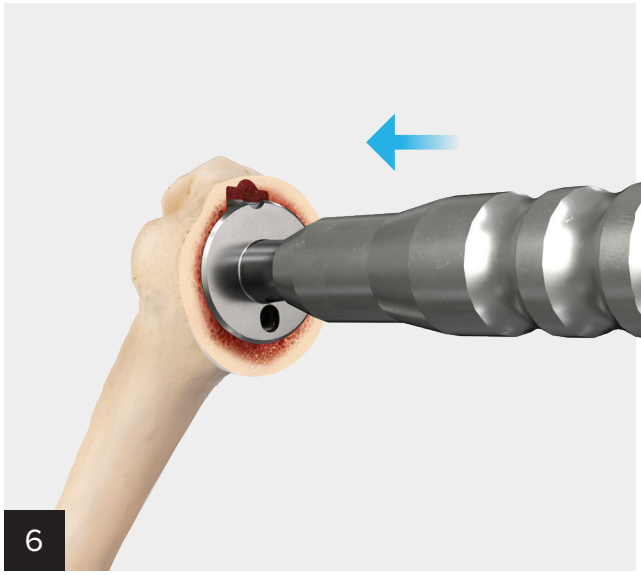
Thread the trunnion extractor into the version (superior) screw location in the Morse taper.



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



Secure the revision CA cutting guide to the rectangular recess of the well-fixed stem. Impact the two anchor pegs into the osteotomy surface for stability. Perform the greater tuberosity osteotomy with an oscillating saw guided by the revision CA cutting guide.



Remove the cutting guide as described in step 4, page 18. Re-engage a new trunnion and new superior locking screw from the Trunnion Replacement Kit as described in step 6 on page 15 and tighten the superior screw.

Remove the guide and place the appropriate-size CA trial head on the humeral stem. Reduce the humerus and assess shoulder motion, soft-tissue tension, and stability.

Once the appropriate-size head is determined, dislocate the proximal humerus, remove the trial head, and impact the prosthetic head in place. Reduce the glenohumeral joint and proceed with wound irrigation and closure per surgeon protocol.

Ordering Information

Instruments

Product Description	Item Number
Univers™ Apex humeral set	AR-**9226ABS**
Univers II/Apex combined tray	AR-**9226CS**

Literature

Product Description	Item Number
Shoulder implant identification card	LC1-0700-EN
Univers Apex Optifit™ surgical technique	LT1-000262-en-US

Implants

Product Description	Item Number
Univers Apex OptiFit stem, size 5 mm	AR-**9100-05M**
Univers Apex OptiFit stem, size 6 mm	AR-**9100-06M**
Univers Apex OptiFit stem, size 7 mm	AR-**9100-07M**
Univers Apex OptiFit stem, size 8 mm	AR-**9100-08M**
Univers Apex OptiFit stem, size 9 mm	AR-**9100-09M**
Univers Apex OptiFit stem, size 10 mm	AR-**9100-10M**
Univers Apex OptiFit stem, size 11 mm	AR-**9100-11M**
Univers Apex OptiFit stem, size 12 mm	AR-**9100-12M**
Univers Apex OptiFit stem, size 13 mm	AR-**9100-13M**
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**

Product Description	Item Number
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**
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

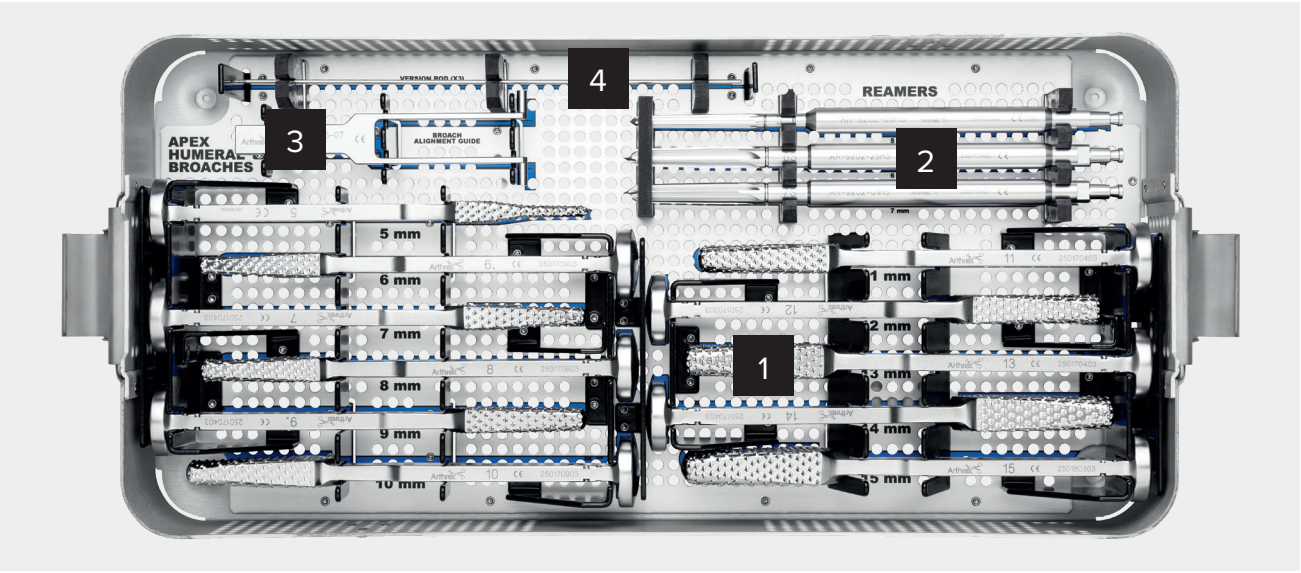
Univers II/Apex Sterile Head Resection Disposables Kit (AR-9207S)

Product Description	Item Number
Steinmann pin, 2.8 mm	AR-**9207**
Kirschner wire, 1.6 mm, qty. 2	AR-**9208**

Univers Apex Suture Kit (AR-7298)

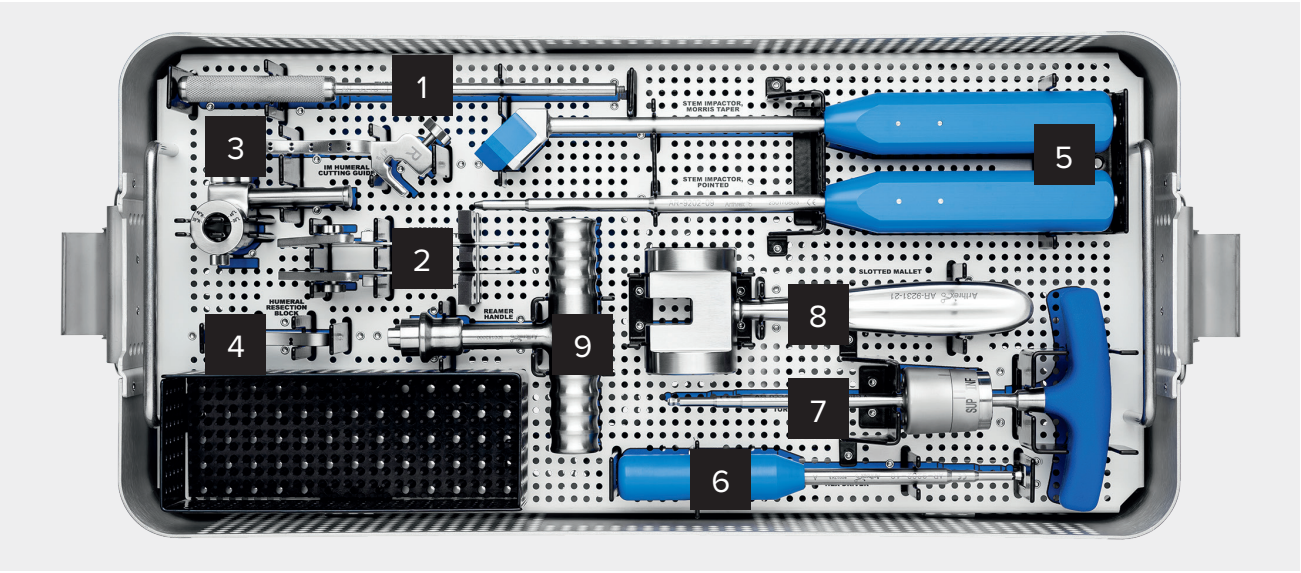
Product Description	Item Number
#2 FiberWire® suture, blue, with tapered needles, qty. 3 #2 TigerWire® suture, with tapered needles, qty. 3 Reverse cutting needles, with nitinol loops, qty. 2 Micro SutureLasso™ suture passer, straight, qty. 1 Drill bit, 2 mm, qty. 1	AR-**7298**

Univers™ Apex Humeral Set (AR-9226ABS)



Pic.	Description	Item Number
1	Univers Apex broaches	AR-**9231-05S/15S**
2	Univers Apex reamer, 5 mm	AR-**9202-25HS**
	Univers Apex humeral reamer, 6 mm	AR-**9202-01HS**
	Univers Apex humeral reamer, 7 mm	AR-**9202-02HS**
3	Univers Apex humeral broach alignment guide	AR-**9506-07**
4	Univers/Eclipse™ orientation pin for resection guide	AR-**9202**

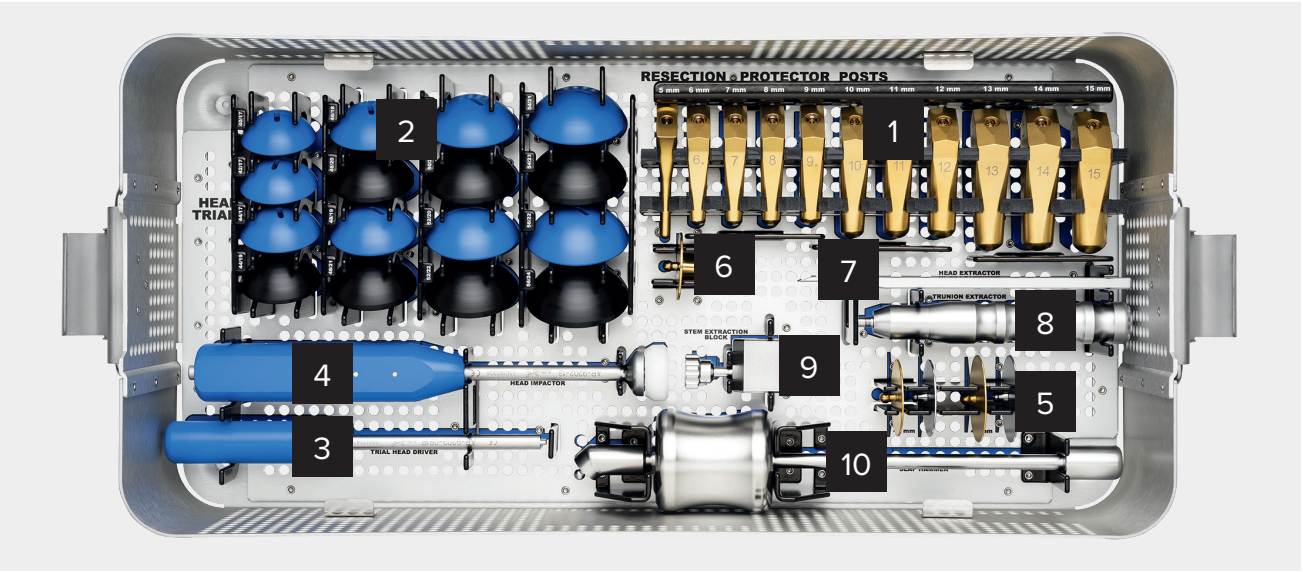
Univers™ II/Apex Combined Tray (AR-9226CS)



Top Tray

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-9226CS)



Bottom Tray

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**

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:
6. Cobalt; CAS No. 7440-48-4
7. European Chemicals Agency Database: https:/echa.europa.eu
8. Failure to achieve the appropriate torque requirements when tightening locking screws may result in the premature loosening of the device.
9. 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.
10. 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.
11. 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.

- 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. 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 Apex OptiFit™ 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.

(Except in Canada) 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.
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.

Glenoid Sizing Matrix - Radial Mismatch in mm

Univers Apex OptiFit 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 Apex OptiFit 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	Effective Length	Total Length
5	85 mm	87.48 mm
6	85 mm	88.38 mm
7	85 mm	88.55 mm
8	85 mm	89.42 mm
9	85 mm	89.91 mm
10	85 mm	90.43 mm
11	85 mm	90.90 mm
12	85 mm	91.14 mm
13	85 mm	91.69 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.

Arthrex Manufacturer, Authorized Representative and Importer information: eIFU - Arthrex

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

arthrex.com