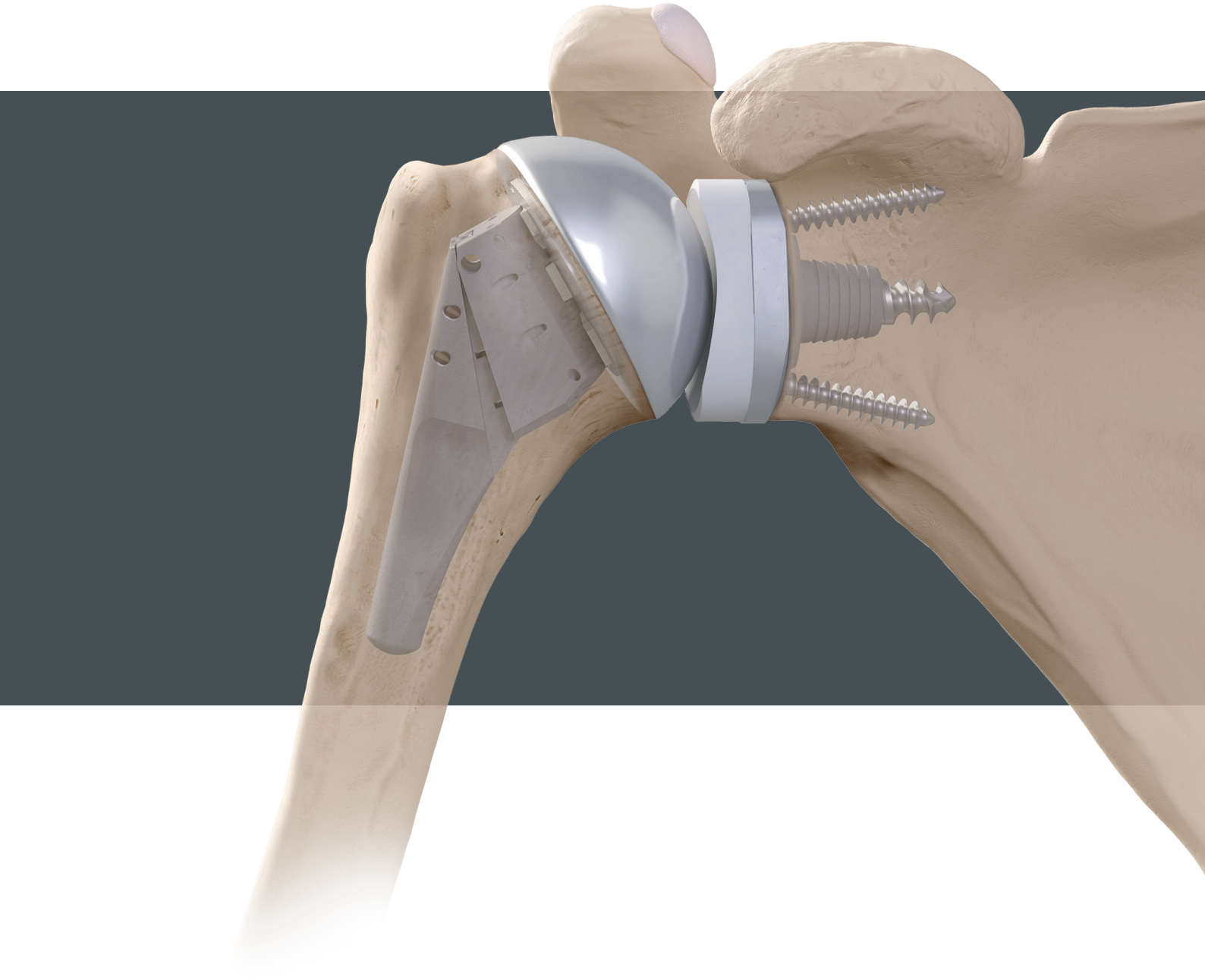
Universal Glenoid™ Convertible Baseplate

Surgical Technique



Arthrex®

Glenoid Preparation and Implantation

Reconstruct the native glenoid during anatomic total shoulder arthroplasty (TSA) or reverse TSA with the Univers Revers™ Universal Glenoid™ convertible baseplate. Its design allows for simplified conversion from anatomic to reverse TSA without removing the baseplate. This instrumentation offers varying angles for baseplate preparation, allowing surgeons to effectively manage patient-specific glenoid wear. Additionally, the Virtual Implant Positioning™ (VIP) System can be used with patients' CT scans.

The Universal Glenoid convertible baseplate is intended to be used with the following Arthrex products:

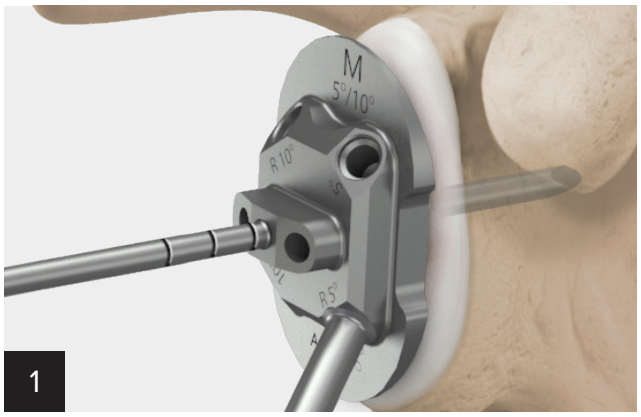
- Univers™ II Total Shoulder System
- Univers™ Apex Total Shoulder System
- Univers Revers™ Total Shoulder System

Detailed information on patient positioning and approach can be found in the Univers™ II Total Shoulder System Surgical Technique (LT1-0701-EN), Univers Apex Total Shoulder System Surgical Technique (LT1-0702-EN), and Univers Revers Shoulder System Surgical Technique (LT1-0703-EN).

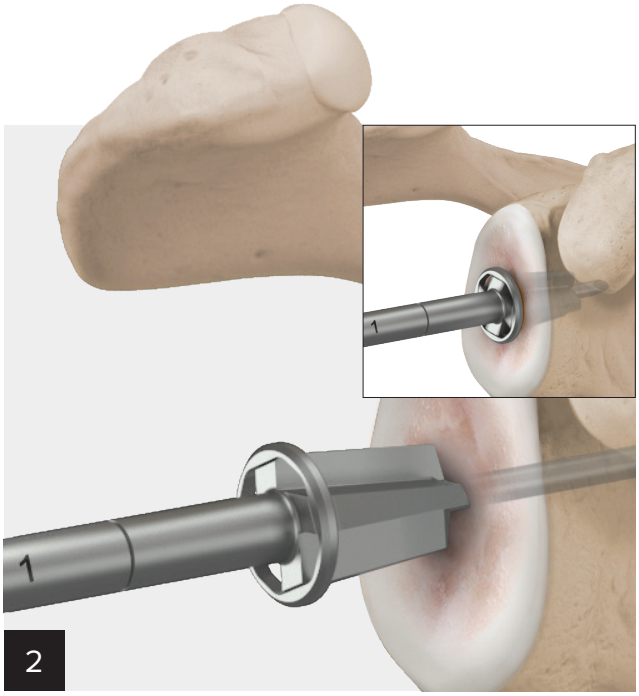
Glenoid Sizing Matrix - Radial Mismatch [mm]

Univers II and Apex Total Shoulder Systems	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	4.0
	56	0.2	1.7	3.2

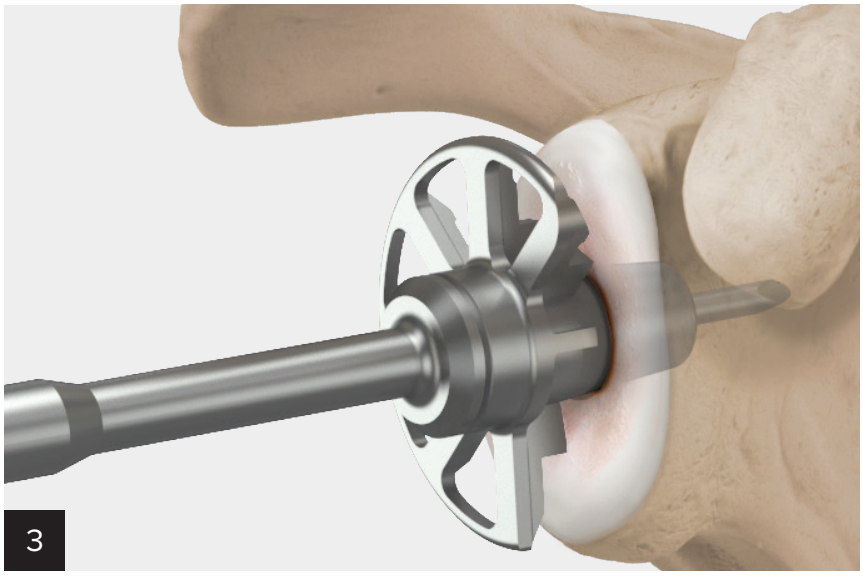
Note: Shaded region represents recommended sizes based on mismatch.



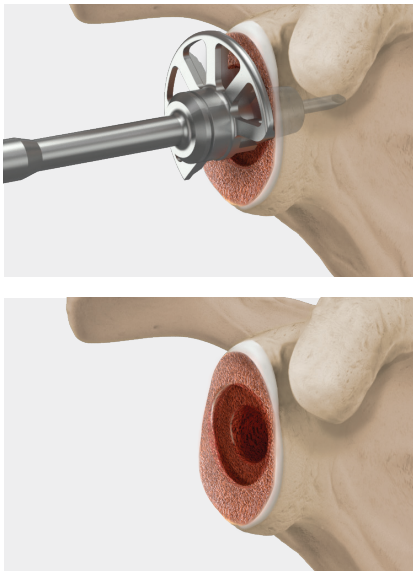
Determine the size of the glenoid drill guide (S, M, L) based on the size of the native glenoid. Before preparing the glenoid, note the diameter of the native humeral head. With regard to radial mismatch, refer to the table on page 2, which provides sizing considerations for the Univers™ II total shoulder system, Univers Apex total shoulder system humeral heads, and the glenoid. Advance the 2.8 mm guidewire through the chosen version hole on the drill guide (0° is shown) to the desired depth. The central screw length can be noted from the laser-marked lines at the drill guide surface. Leave the guidewire in place and remove the guide.



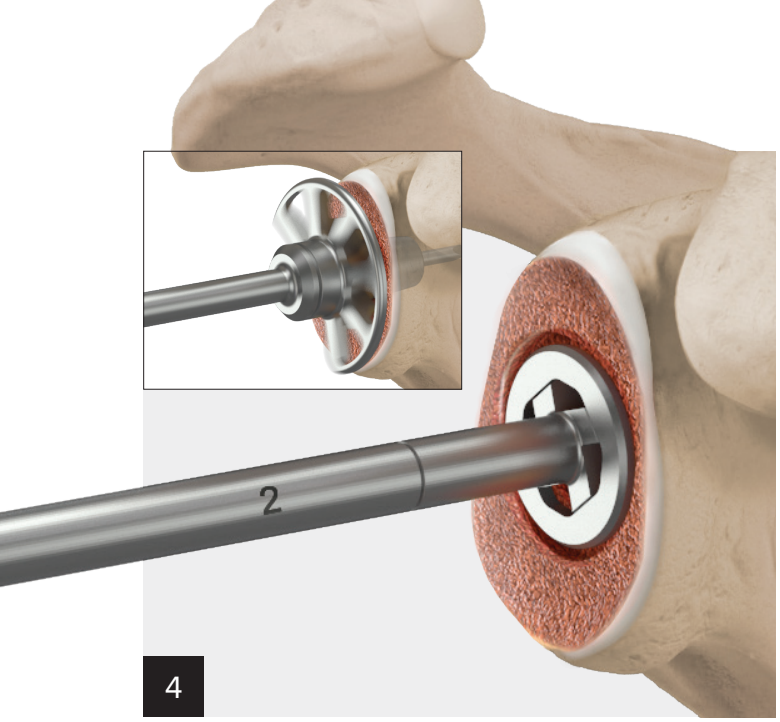
Advance the primary post reamer over the previously positioned 2.8 mm guidewire. Ream until the depth stop contacts the glenoid surface. Remove the primary post reamer, leaving the guidewire in position.



Advance the final reamer (matched to size of the chosen baseplate) over the guidewire. Ream until the reamer no longer advances medially. Remove reamer. Evaluate glenoid surface to determine if entire circumference has been reamed, as shown in the bottom image to the right.

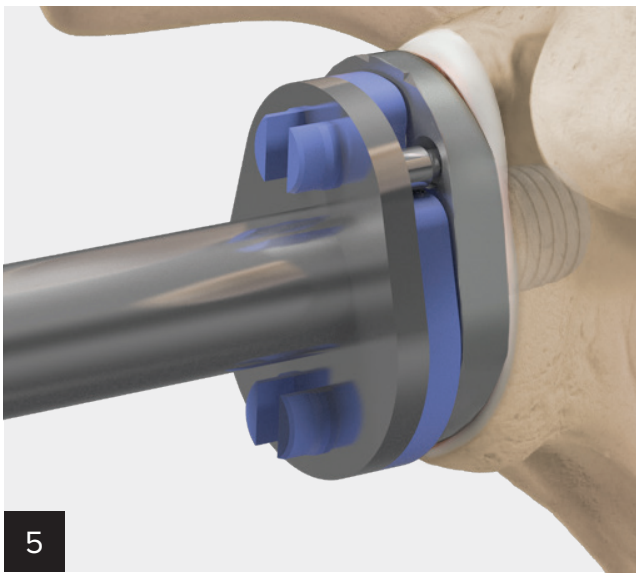


If circumferential reaming has been achieved, as depicted in the bottom right illustration, proceed to Step 5. If not, proceed to Step 4.



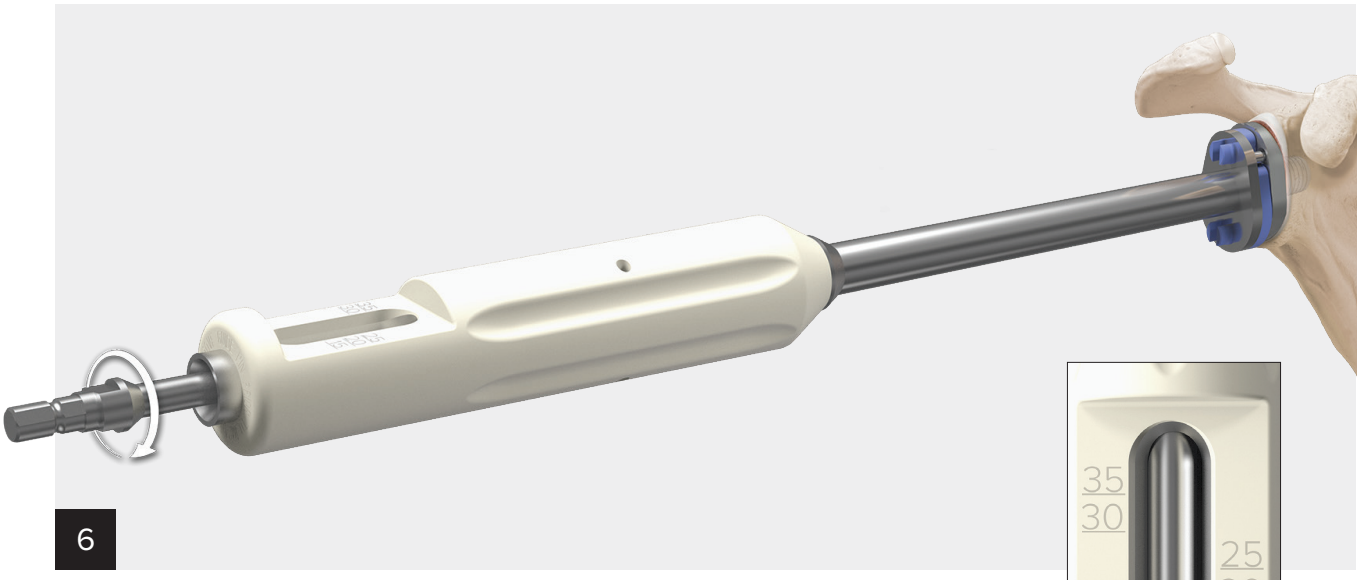
4

If further reaming is required, the correction post reamer will deepen the central post preparation, allowing for additional medialization. This is a controlled process that medializes the glenoid surface 1 mm. After using the correction post reamer, it is important to use the final reamer again (see inset). The correction post reamer may be used additional times for circumferential reaming, however available glenoid bone stock must be considered.



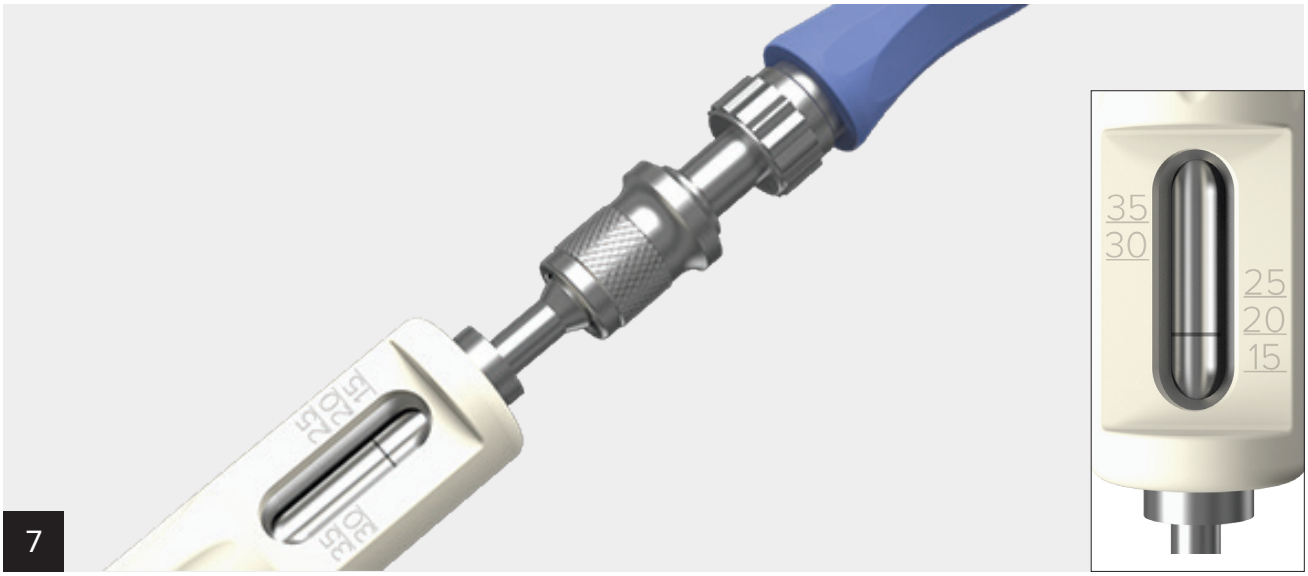
5

Place the baseplate onto the Universal Glenoid baseplate impactor and impact fully onto the prepared glenoid surface. Visually confirm full seating of the baseplate. Hold the impactor in place during preparation and implantation of the central screw as shown in steps 6 through 8.



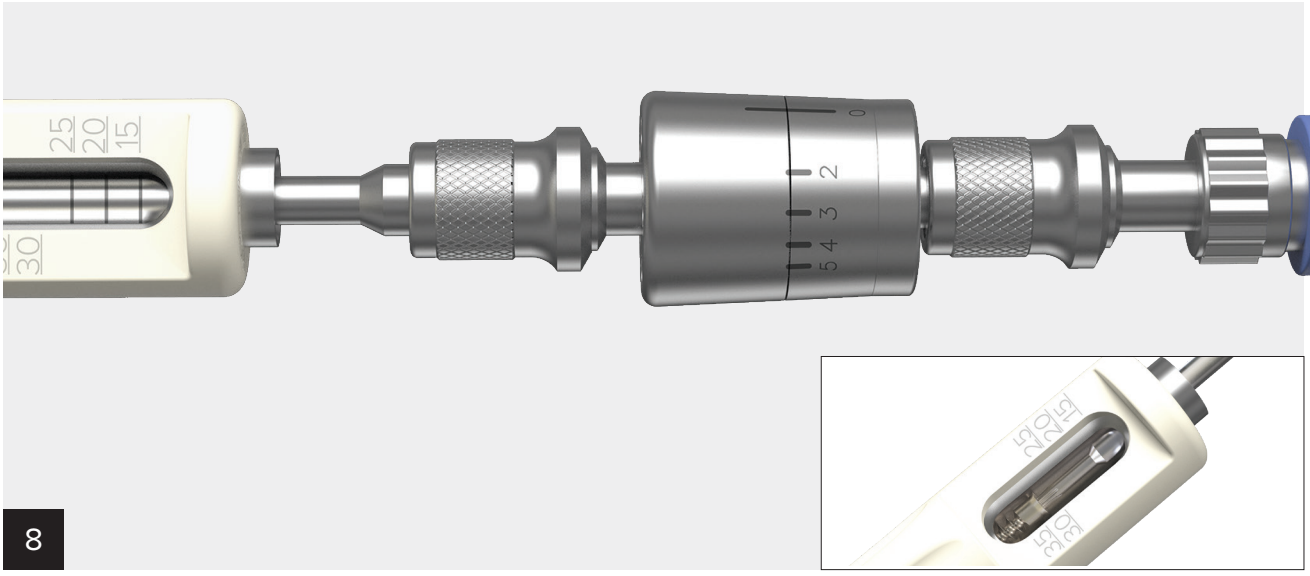
6

To prepare the glenoid for the central screw, insert the drill through the central hole of the impactor. The proximal window of the guide provides depth assessment. The central screw length is determined with the laser-marked line on the drill (inset).



7

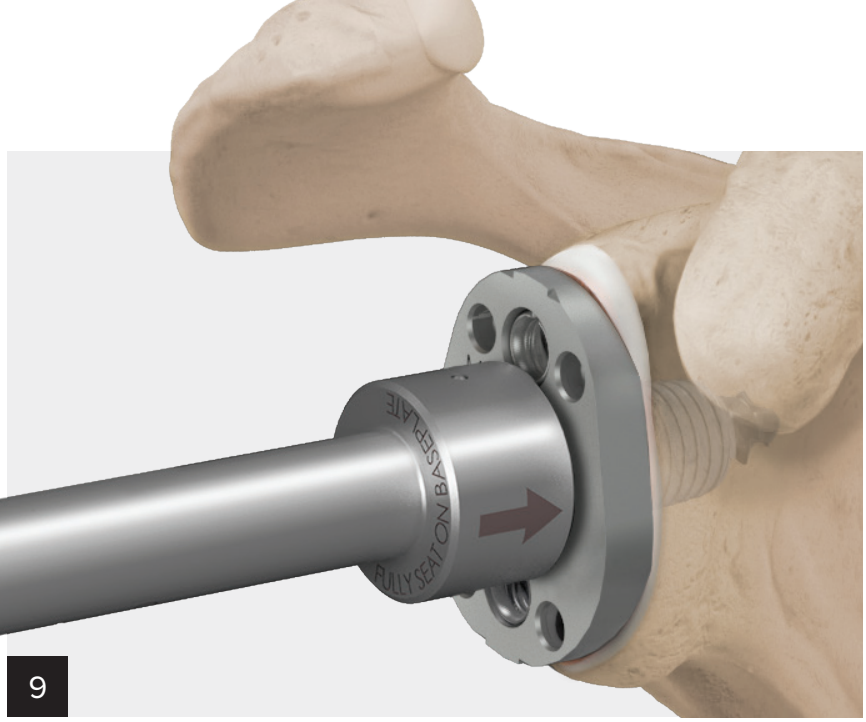
Assemble the tap to the ratcheting handle and insert it into the impactor. Looking into the proximal window of the impactor, the tap should be advanced until the laser-marked line matches same depth that was drilled in Step 6 (inset).



8

The baseplate's central hole accepts both compression and locking screws, depending on surgeon preference and patient bone quality. Once selected, place the central screw directly in the proximal window as shown (inset) and advance it with the long T15 driver. When the screw is fully seated, the 3 laser-marked lines will align with the 15, 20, and 25 markings on the impactor. Remove the impactor from the face of the baseplate.

Note: Torque must not exceed 5 Nm.



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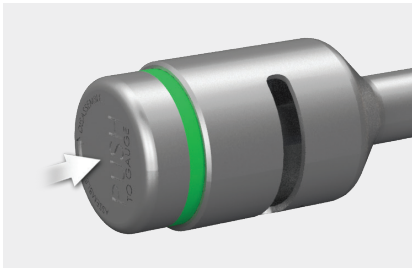
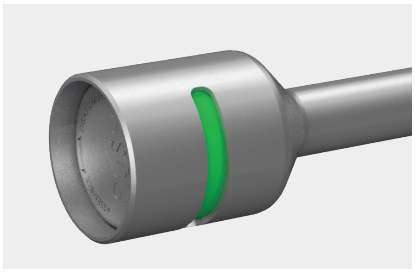
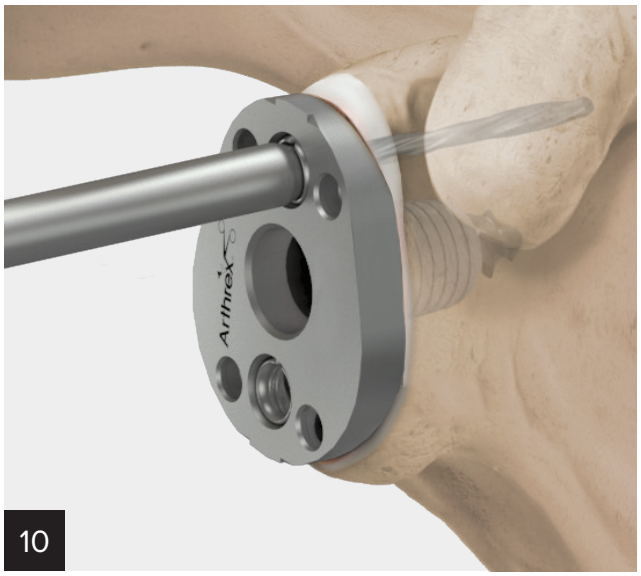




Using the central screw depth gauge, ensure the central screw is adequately seated by confirming green is visible through the gauge window. If any green on the inner shaft is visible in the window, the central screw is deep enough within the baseplate socket for assembling either an inlay poly or a glenosphere.

If no green is visible in the window, the central screw must be driven more medial to ensure it does not interfere with the inlay poly or glenosphere taper engagement.



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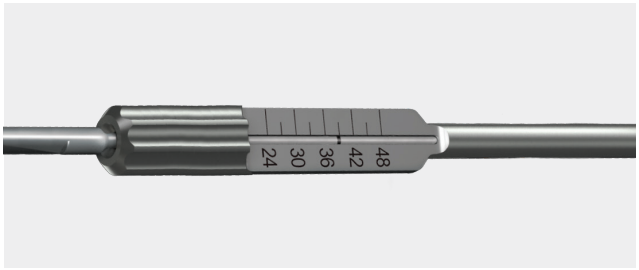
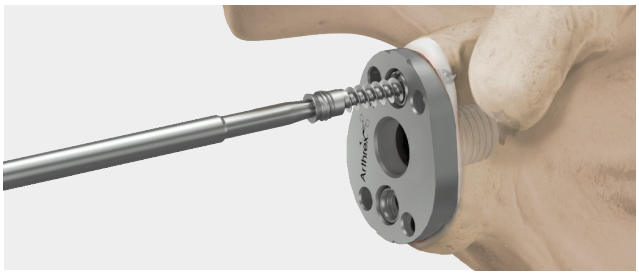
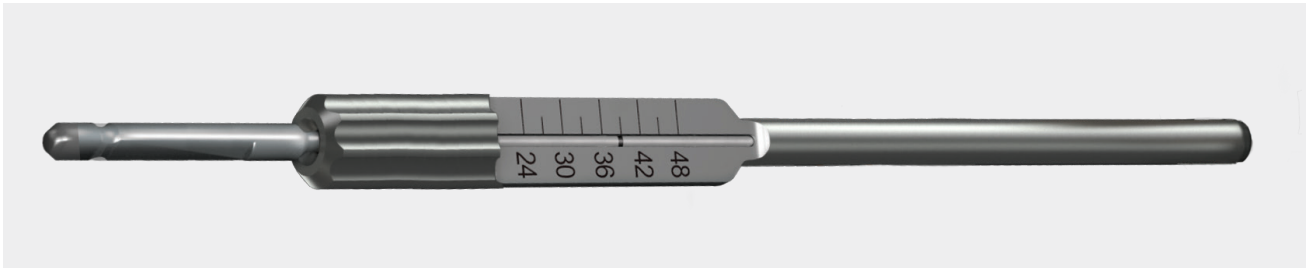
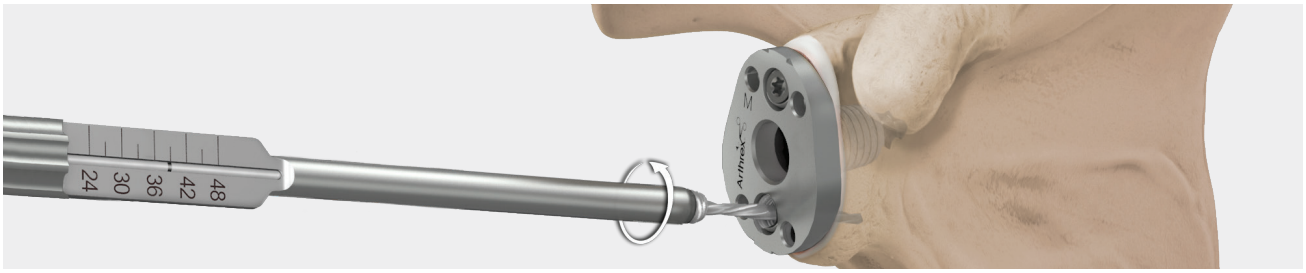


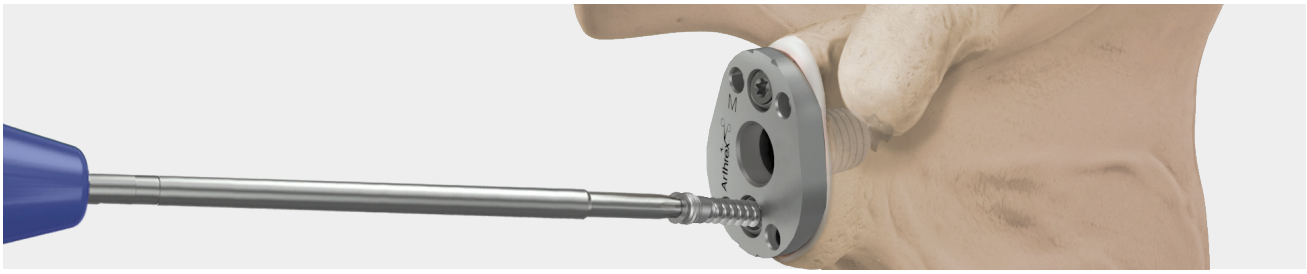


Thread the peripheral screw drill guide into the superior bushing and advance the 2.5 mm drill to the desired trajectory and depth, taking note of the depth marks on the drill guide and drill. Insert and fully seat the screw until completely flush with baseplate surface.

Note: Torque must not exceed 5 Nm.



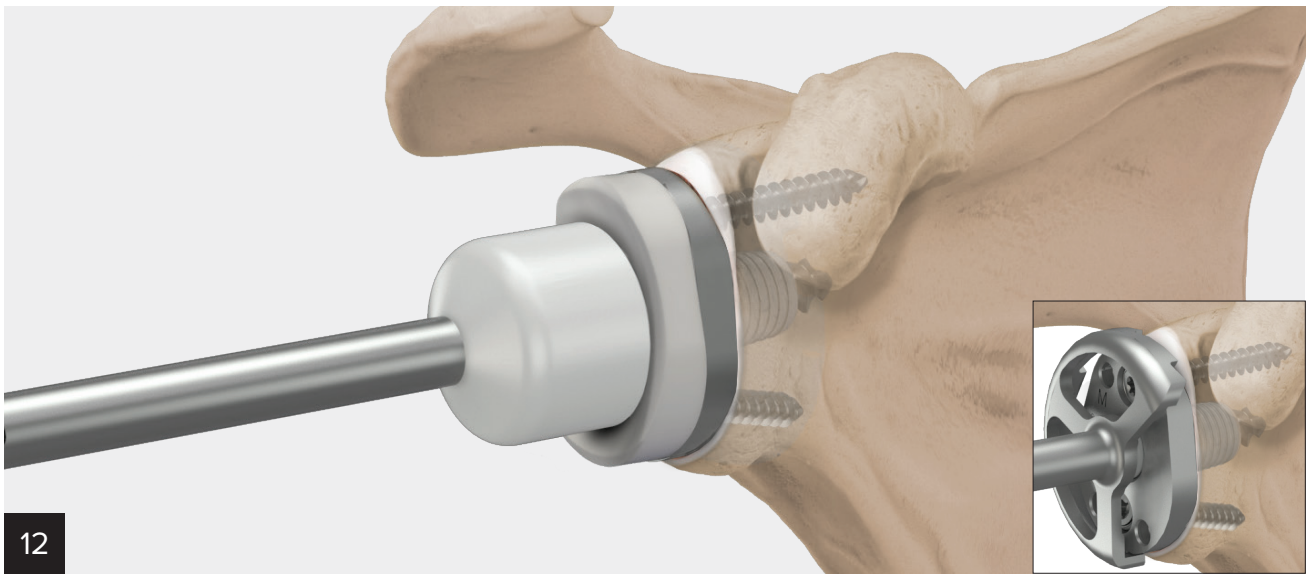




Insert the peripheral screw drill guide in the inferior bushing and drill to the desired depth using the 2.5 mm drill. Insert and fully seat the screw until completely flush with baseplate surface.

Note: Torque must not exceed 5 Nm.

Surgical Pearl: Leave the 2.5 mm drill in place while removing the peripheral screw drill guide. This helps the bushing stay in the trajectory of the drilled hole, which will facilitate peripheral screw locking thread engagement.



Use the coring (peripheral) reamer sized with the baseplate and make one full revolution clockwise and counterclockwise. If the coring reamer contacts the peripheral screw heads in either direction, the screws must be fully seated to ensure proper poly seating and engagement. Position the poly insert onto the baseplate, aligning the 4 locking pegs on the medial side of the poly with the mating holes on the face of the Universal Glenoid convertible baseplate. Impact until seated. Visually confirm full seating of the inlay.

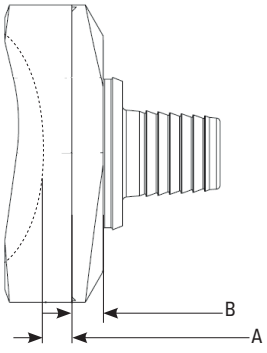
Surgical Pearl: Initial hand placement and engagement of the locking pegs in the superior-inferior plane should be followed by direct, on-axis impaction. Take care in positioning and maintaining the retractors so they do not affect the position of the polyethylene on the baseplate. Additionally, off-axis impaction (often in the anterior-posterior plane), which may occur due to poor exposure, may result in inadequate fixation of the locking pegs, leading to instability of the polyethylene. Confirm polyethylene seating through visual inspection at rest and while performing range-of-motion testing in all planes.

Two options of poly thickness are available to provide desired joint tension. The thickness for both the baseplate and poly components is shown in the following table. This thickness is independent of the glenoid size and radial mismatch chart depicted on page 2.

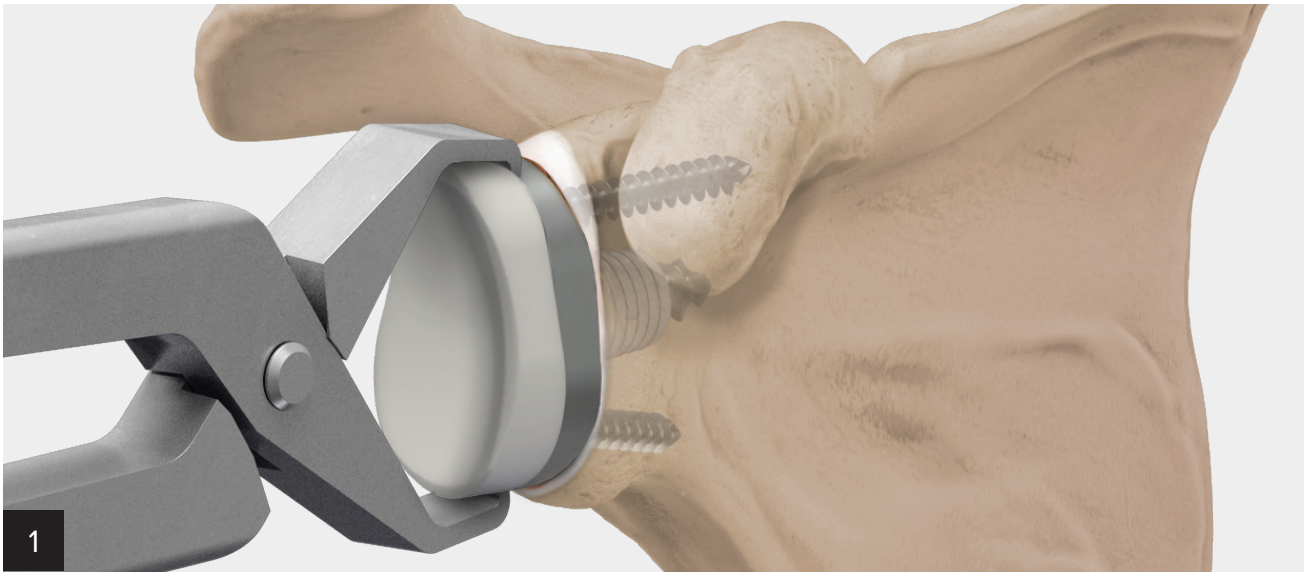
Note: Poly insert size must match the baseplate size.

Now that glenoid implantation is complete, proceed with full humeral implantation.

Poly Insert	**A** Thickness to Center of Curvature	**B** Baseplate Thickness	Total
Small	2.5 mm	4.5 mm	7.0 mm
Small Plus	3.5 mm		8.0 mm
Medium	2.5 mm		7.0 mm
Medium Plus	3.5 mm		8.0 mm
Large	2.5 mm		7.0 mm
Large Plus	3.5 mm		8.0 mm

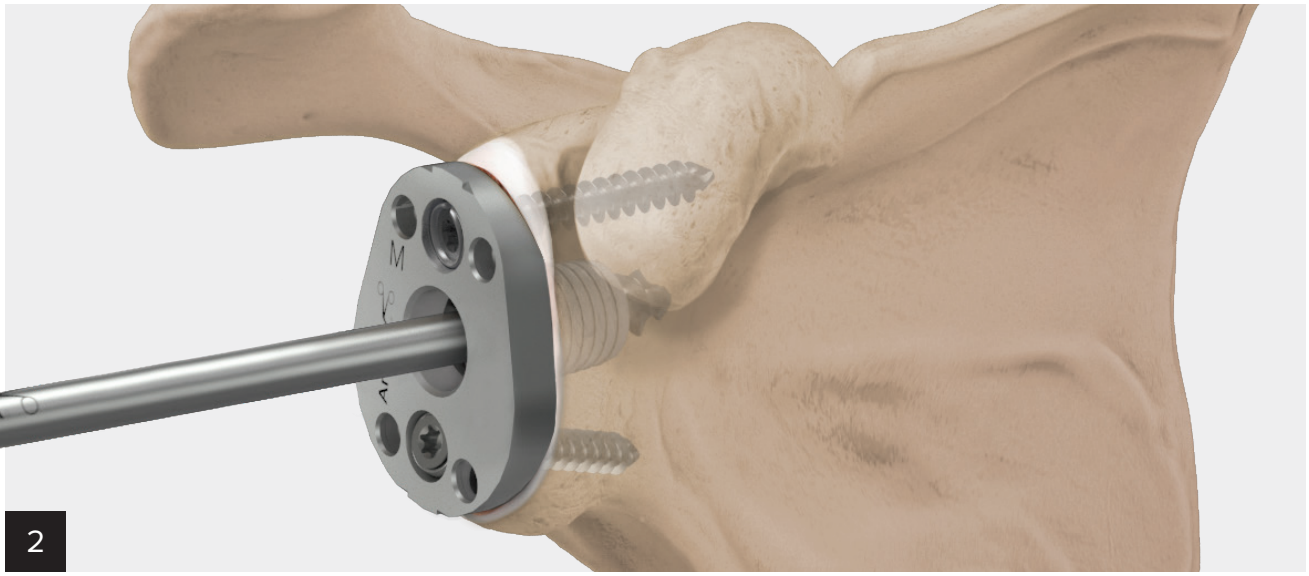


Conversion of Anatomic Poly to Univers Revers™ Glenosphere

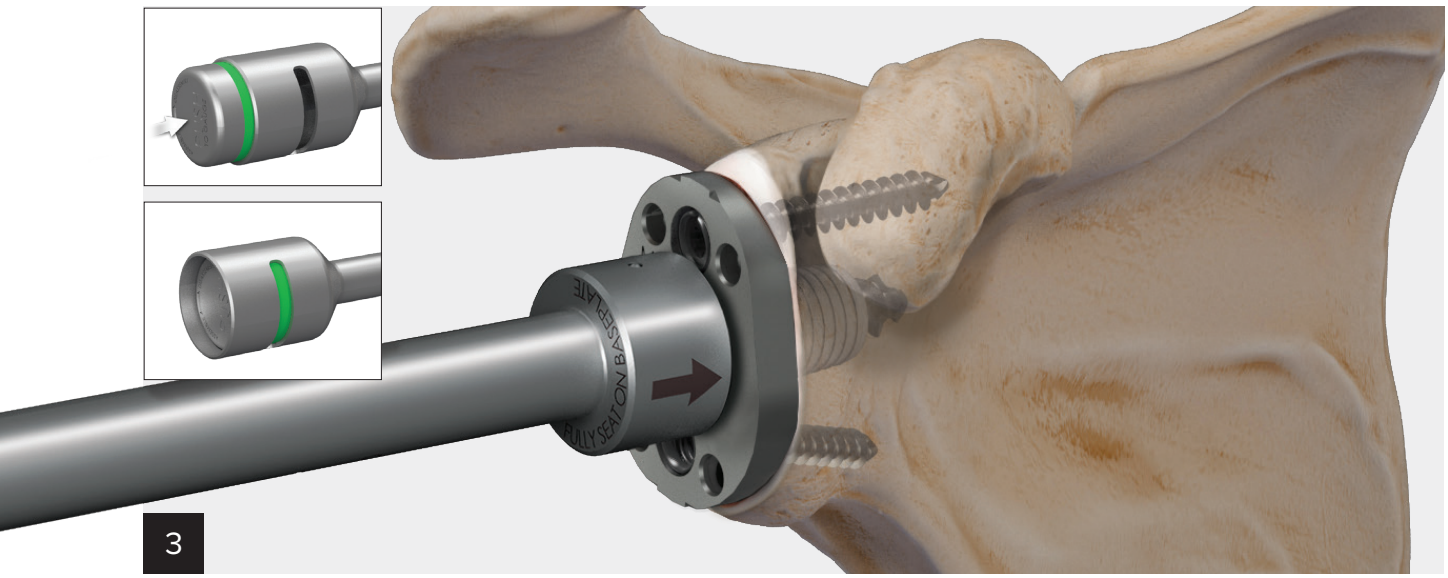


Remove the anatomic poly insert with the extractor. Rest the jaws on the superior and inferior poly with the handle open. Squeeze and pull axially to disengage the poly from the baseplate.

Note: Take care to not grasp the baseplate or medial to the baseplate. Once extracted, discard the poly and never reinsert.



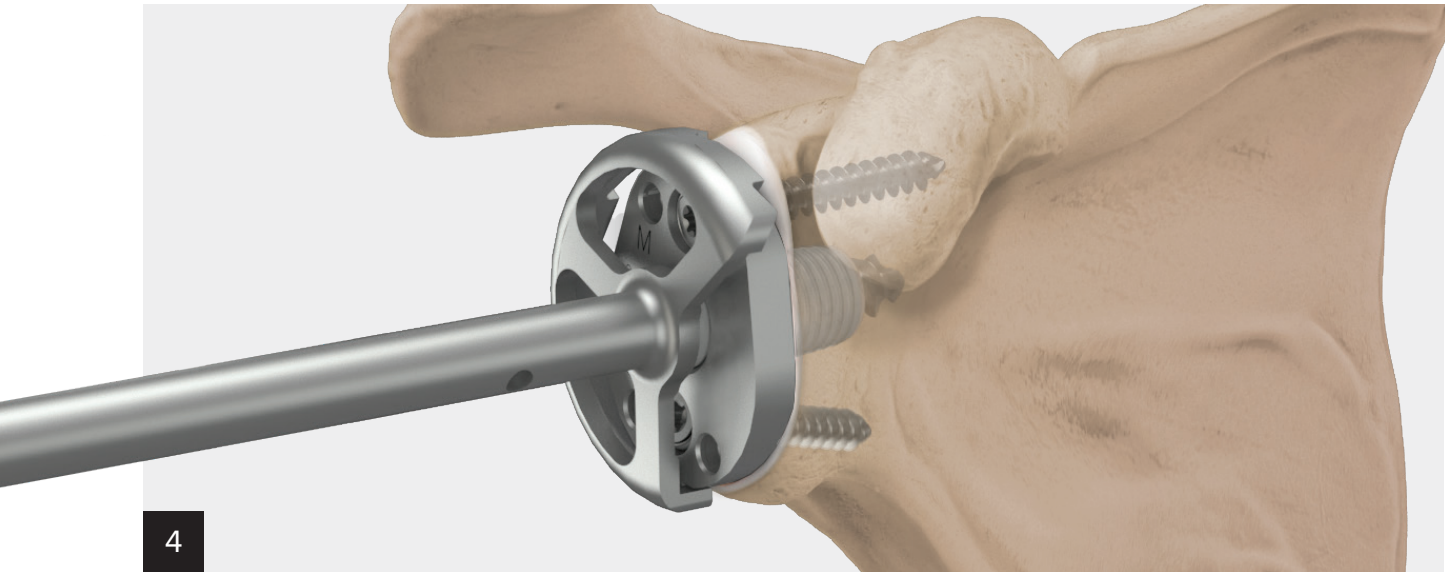
Ensure the center screw is stable. A T15 driver can be used to ensure the screw is fully locked or compressed into the baseplate. Additionally a Freer elevator can be used around the perimeter of the baseplate to ensure that it is well-fixed.



3

Using the central screw depth gauge, ensure the central screw is adequately seated by confirming green is visible through the gauge window. If any green on the inner shaft is visible in the window, the central screw is deep enough within the baseplate socket for secure morse taper engagement. If no green is visible in the window, the central screw must be driven more medial to ensure it does not interfere with glenosphere morse taper engagement.

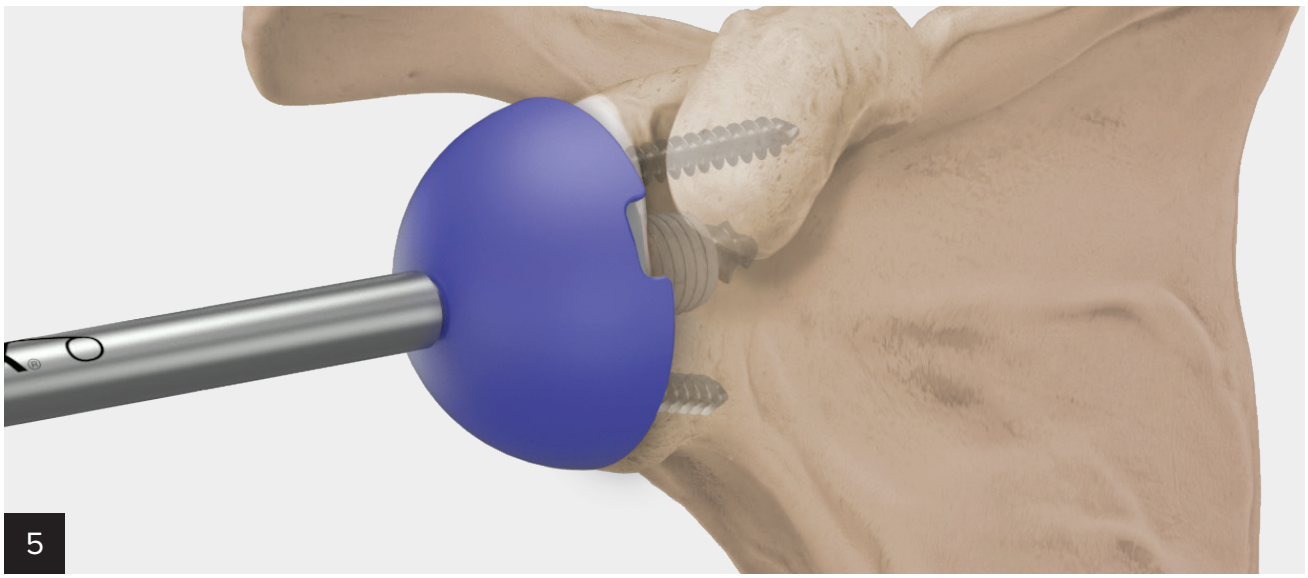
Note: Failure to do so may result in disassociation between the glenosphere and the baseplate.



4

Using the coring (peripheral) reamer of the same size as the baseplate and glenosphere, insert and rotate the reamer clockwise to clear all tissue from the footprint of the glenosphere. After this is completed, perform one full revolution in a counterclockwise direction. If the coring reamer contacts the peripheral screw heads in either direction, the screws must be fully seated to ensure proper glenosphere seating and engagement.

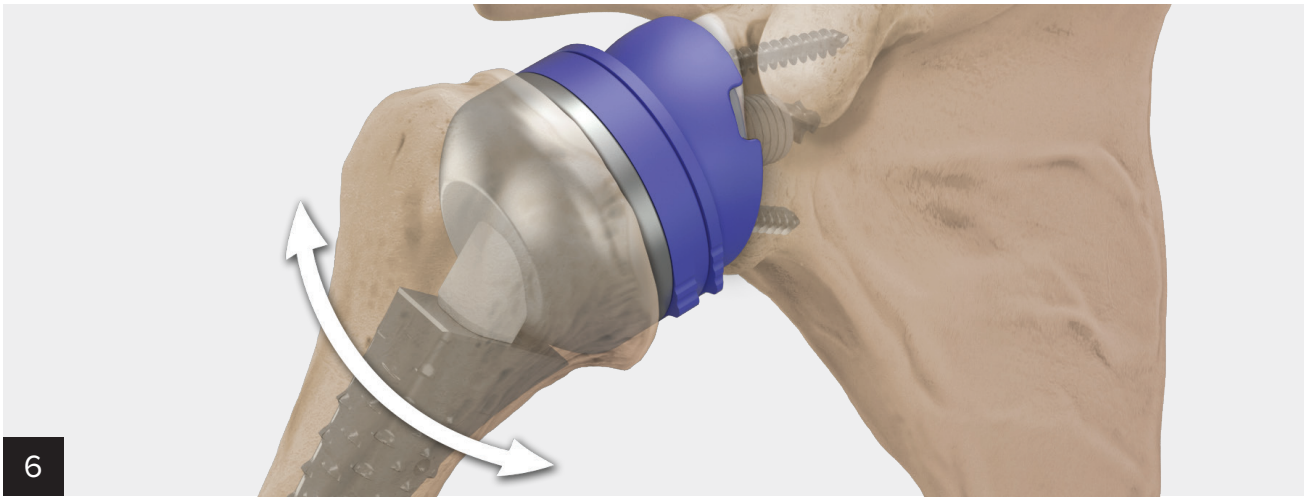
Note: If a glenosphere larger than the baseplate is chosen, it is necessary to ream in a stepwise fashion with multiple coring reamers up to the glenosphere size chosen.



5

Trial glenospheres can be connected to the baseplate using the trial inserter.

Note: Lateralized glenospheres are recommended for 135° and inferiorized glenospheres for 155°. Glenospheres are available in standard, +4 mm lateral, and 2.5 mm inferior offsets.

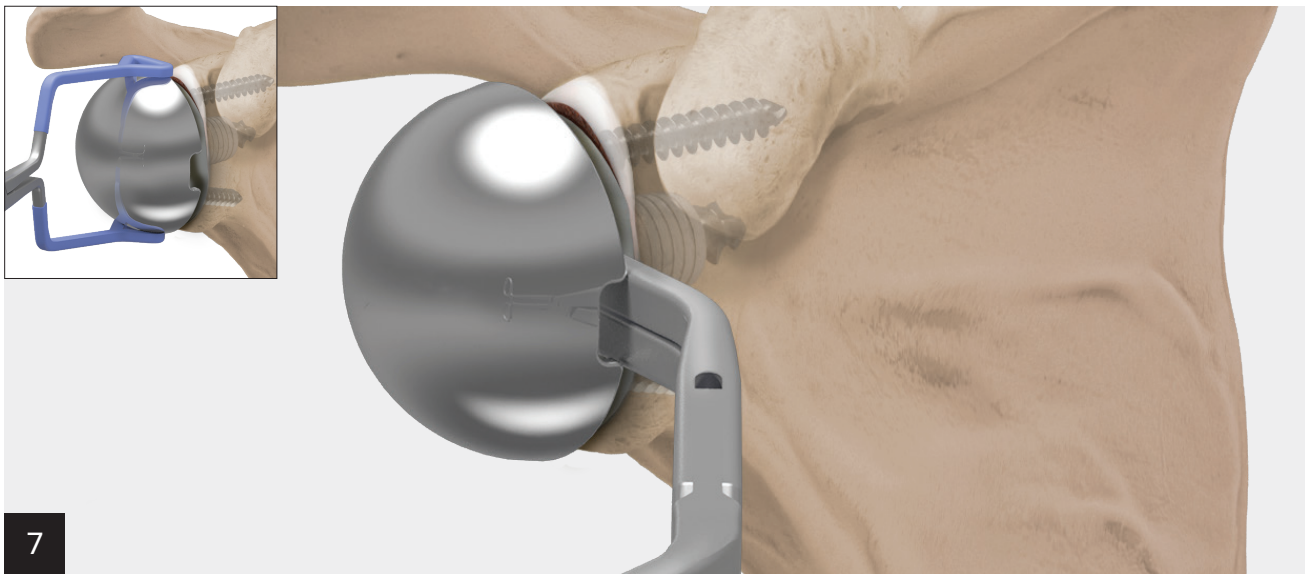


6

Prepare and trial the humeral components in accordance with the Univers Revers™ Shoulder System Surgical Technique (LT1-0703-EN). The baseplate and glenosphere options are shown in the following chart. Use of an inappropriate baseplate/glenosphere combination (eg, 36 mm glenosphere and medium baseplate) will lead to implant dissociation.

Baseplate Size	Glenosphere
Small	36 mm, 39 mm, 42 mm
Medium	39 mm, 42 mm
Large	42 mm

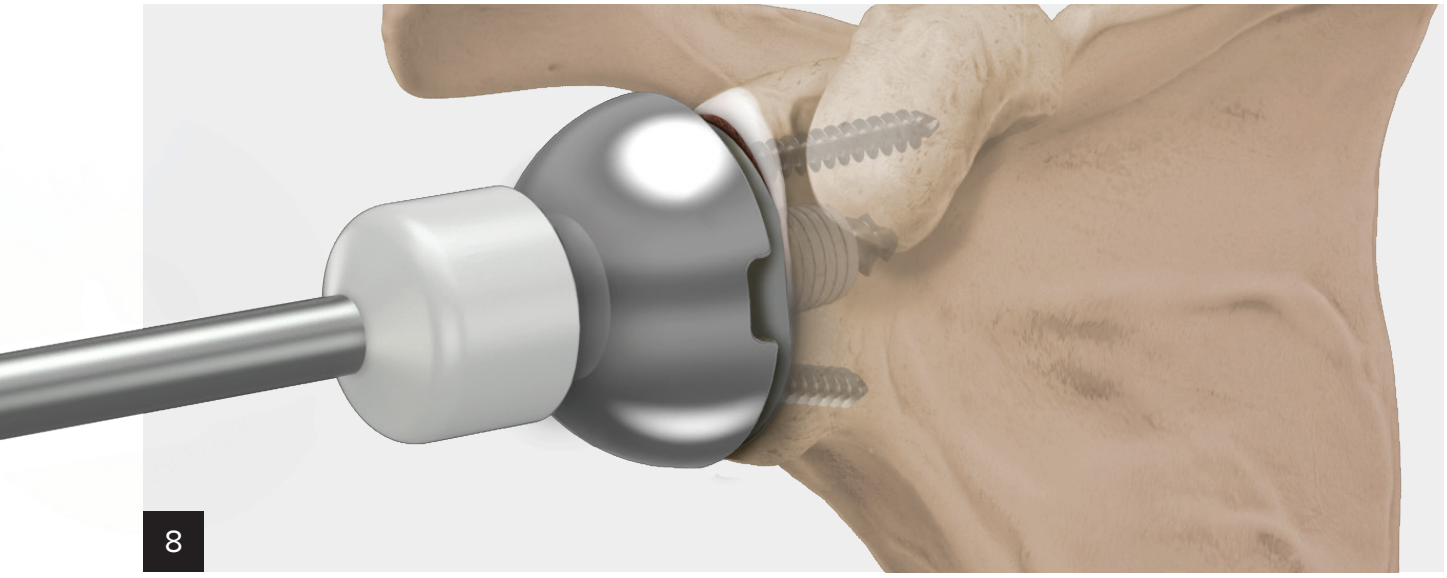
Note: Implanted baseplate size will determine the glenosphere size.



7

Insert the definitive glenosphere into the baseplate. This can be done manually or by using one of two types of insertion instruments, based on surgeon preference. The definitive glenosphere has a male morse taper that connects to the baseplate. The baseplate morse taper must be cleaned and dried.

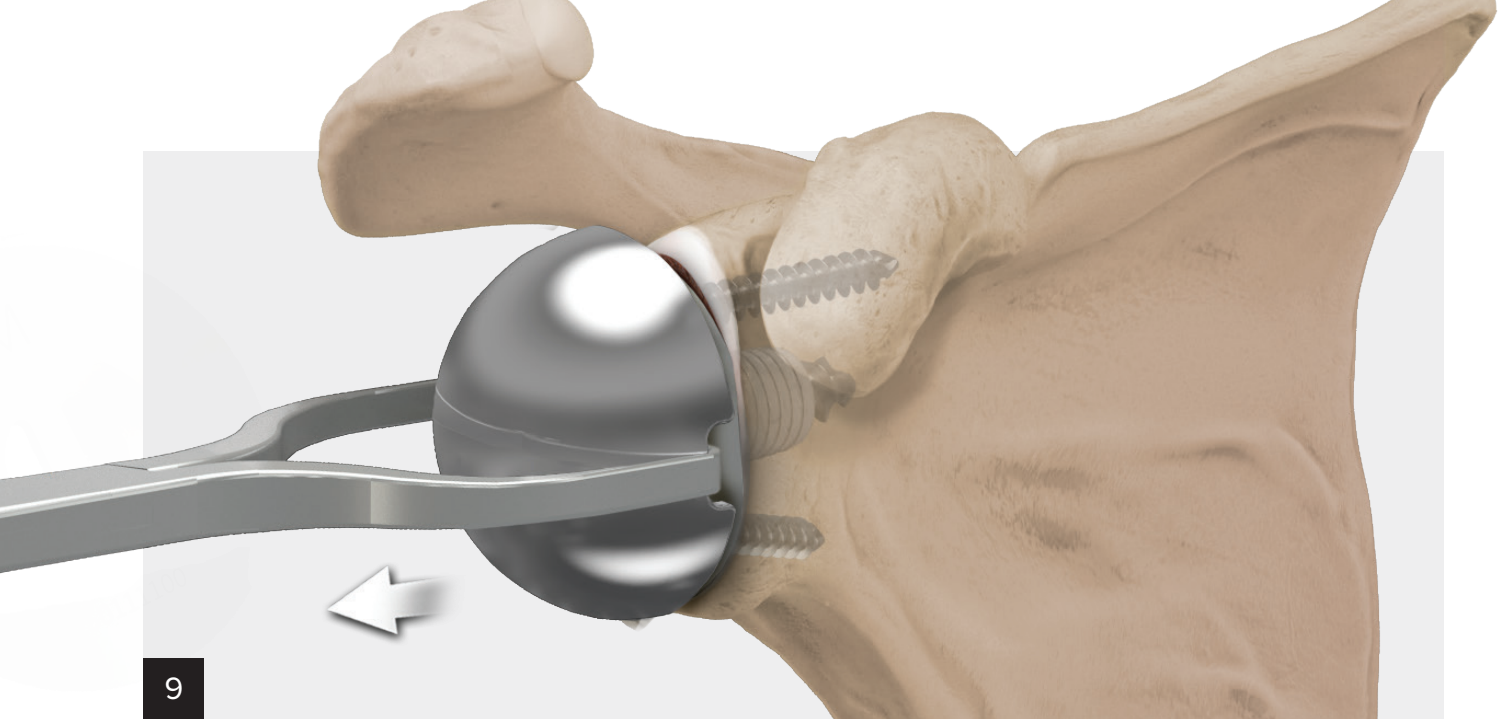
The glenosphere inserter (pictured) and glenoid insertion forceps (inset) are options for guiding the glenosphere morse taper into the baseplate.



8

Once the morse taper junction is aligned, use the humeral liner/glenosphere impactor to apply an engaging force with consecutive mallet strikes to secure the glenosphere.

Note: One of the recesses on the underside of the glenosphere must face anteriorly should future removal be necessary.



9

Use the glenosphere forceps to verify the integrity of the morse taper connection between the glenosphere and baseplate. This required instrument provides a means for securely grasping the glenosphere and applying a distracting force.

Proper technique is to place the tips 180° apart with one tip in one of three glenosphere slots. Once secure, a distracting force is applied in-line with, and evenly distributed across, the morse taper.

10

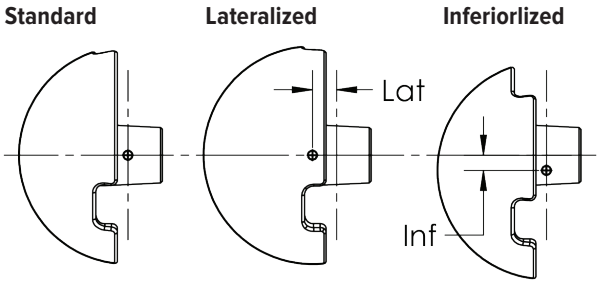
Assemble and implant the definitive humeral components in accordance with the Univers Revers™ Shoulder System Surgical Technique **(LT1-0703-EN).**

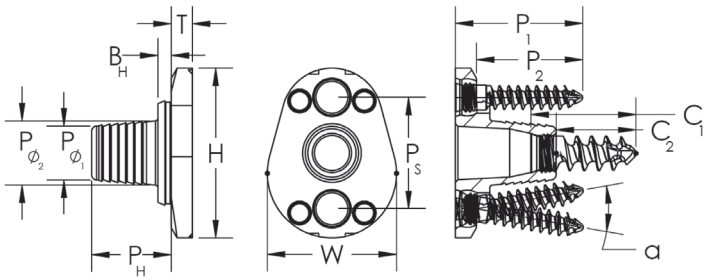
Reduce the shoulder and close the wound.

Univers Revers™ Total Shoulder System Compatibility Matrix

		Stem	Univers Revers (Standard): 5* mm-15 mm Univers Revers Apex (Short): 6 mm-15 mm Revision: 6 mm, 9 mm, 12 mm *5 mm – monoblock stem 135° and 155° options with 36 mm cup only 5 mm modular stem with 36 mm, 39 mm, 42 mm cup								
		Cup Can be fixed at inclination angle of 135° or 155°	**36** Left	**36**	**36** Right	**39** Left	**39**	**39** Right	**42** Left	**42**	**42** Right
Optional		Spacer In combination with +3 mm liners only	**36** **6, 9, 12, 15 mm** (for 5-15 stems)			**39** **6, 9, 12, 15 mm** (for 6-15 stems) 5 mm modular			**42** **6, 9, 12, 15 mm** (for 6-15 stems) 5 mm modular		
		Liner	**36** +3 +6		**36** +3 +6	39 +3 +6		39 +3 +6	42 +3 +6		42 +3 +6
				Constrained			Constrained			Constrained	
		Glenosphere	**36** +2.5 Inf	**36**	**36** +4 Lat	**39** +2.5 Inf	**39**	**39** +4 Lat	**42** +2.5 Inf	**42**	**42** +4 Lat
		Baseplate **S**	●	●	●	●	●	●	●	●	●
		Baseplate **M**				●	●	●	●	●	●
		Baseplate **L**							●	●	●

Univers Revers™ Implant Key Dimensions





Glenosphere Dimensions			
Size	Standard	Lateralized	Inferiorlized
36 mm 39 mm 42 mm	0 mm Lat 0 mm Inf	4.0 mm Lat 0 mm Inf	0 mm Lat 2.5 mm Inf

Baseplate Dimensions			
Size	H (mm)	W (mm)	PS (mm)
S	32.0	24.4	21.0
M	35.0	27.4	22.0
L	38.0	30.4	23.0

Baseplate Dimensions, (Same for All Sizes)				
T (mm)	BH (mm)	PH (mm)	Pø1 (mm)	Pø2 (mm)
4.5	2.5	15.0	10.2	12.1

Baseplate Screw Dimensions				
P1 (mm)	P2 (mm)	C1 (mm)	C2 (mm)	a (°)
24.0	20.0	15.0	10.0	18.0
30.0	26.0	20.0	15.0	-
36.0	32.0	25.0	20.0	-
42.0	38.0	-	-	-
48.0	44.0	-	-	-

Univers Revers Combination Humeral Insert Matrix

SutureCup Glenosphere Matrix

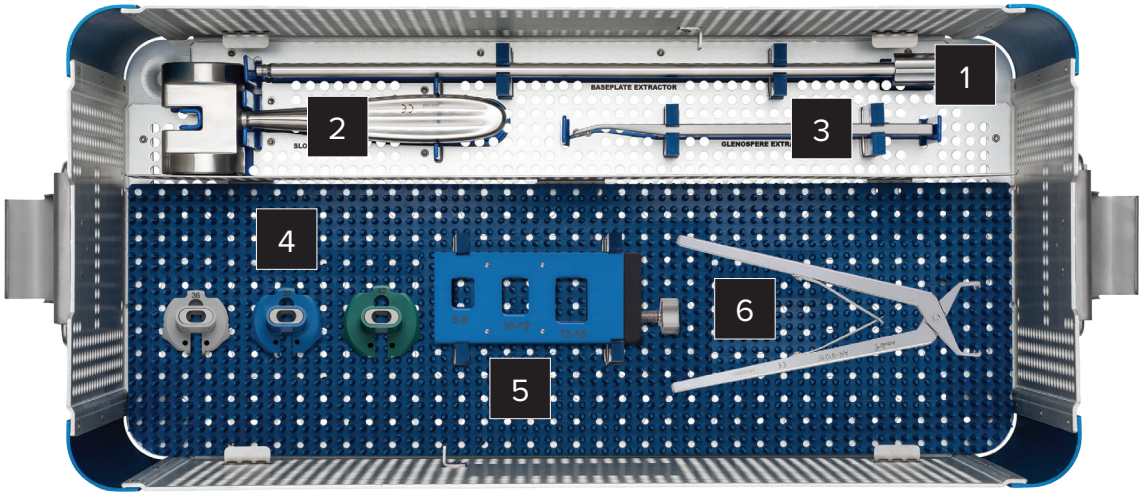
		Glenosphere				
		33 mm	36 mm	39 mm	42 mm	45 mm
SutureCup w/ Insert	36 mm	36 mm 33 mm	36 mm	36 mm 39 mm		
	39 mm			39 mm	39 mm 42 mm	
	42 mm				42 mm	42 mm 45 mm

For use only with the Modular Glenoid System

For use with the Modular Glenoid System and Universal Glenoid™ Convertible Baseplate

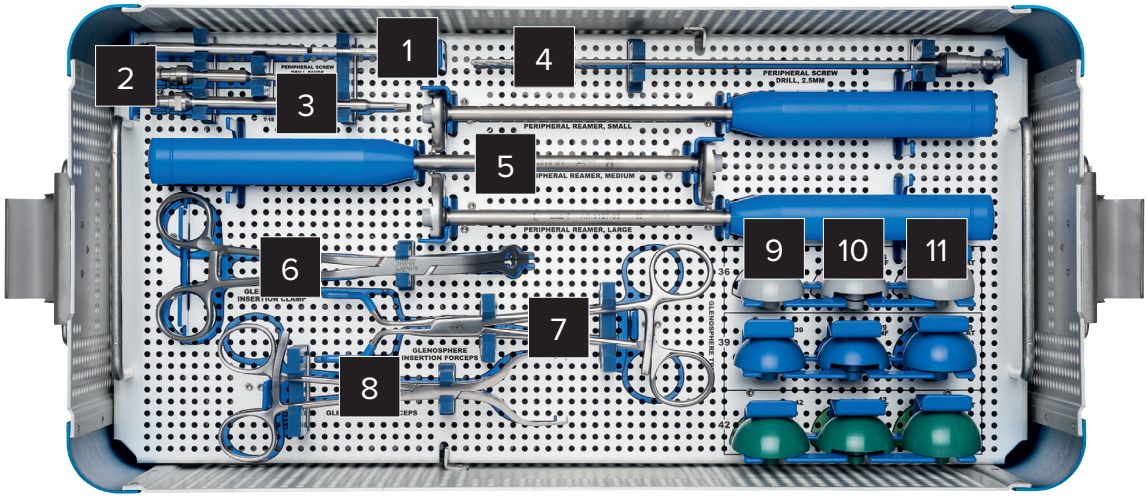
Note: The 36 mm/33 mm and 42 mm/45 mm combo humeral inserts and 45 mm glenospheres are only indicated for use with the Modular Glenoid System.

Glenoid Case (AR-9501GS)



Base Tray

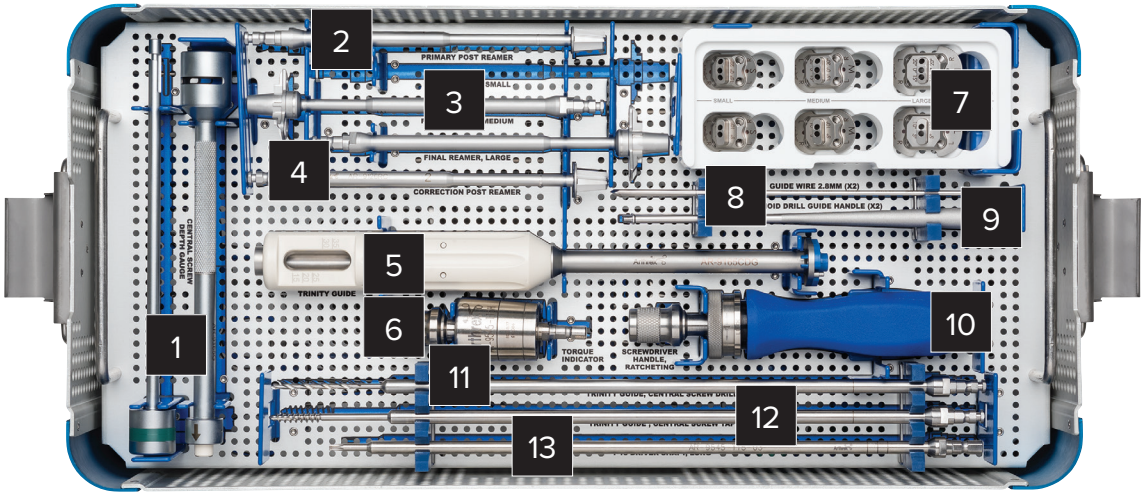
Pic.	Item Number	Qty.	Description
1	AR-**9120E**	1	Baseplate Extractor
2	AR-**9231-21**	1	Slotted Mallet
3	AR-**9123GE**	1	Glenosphere Extractor/Chisel
4	AR-**9532-36/39/42**	1	Cup Alignment Guides
5	AR-**9532**	1	Revers Humeral Assembly Station
6	AR-**9121E**	1	Universal Glenoid Inlay Extractor



Middle Tray

Pic.	Item Number	Qty.	Description
1	AR-**9145DG**	1	Peripheral Screw Drill Guide
2	AR-**9545-T15-01**	1	T15 Driver Shaft, short
3	AR-**9545-T15-02**	1	T15 Driver Shaft, medium
4	AR-**9145K**	1	Peripheral Screw Drill, 2.5 mm
5	AR-**9127-01/02/03**	1	Baseplate Coring Reamers
6	AR-**9542**	1	Glenosphere Inserter
7	AR-**9240**	1	Glenoid Forceps
8	AR-**9544**	1	Glenosphere Forceps
9	AR-**9540SM, AR-9540SM-INF, AR-9540SM-04**	1	Trial Glenospheres, 36 mm
10	AR-**9540MD, AR-9540SM-02, AR-9540MD-04**	1	Trial Glenospheres, 39 mm
11	AR-**9540LG, AR-9540MD-02, AR-9540LG-04**	1	Trial Glenospheres, 42 mm

Glenoid Case (AR-9501GS [Cont])



Top Tray

Pic.	Item Number	Qty.	Description
1	AR-**9165G**	1	Central Screw Depth Gauge
2	AR-**9126RP**	1	Primary Post Reamer
3	AR-**9126-01/02/03**	1	Final Reamers
4	AR-**9126RC**	1	Correction Post Reamer
5	AR-**9165CDG**	1	Universal Glenoid Baseplate Impactor (Trinity Guide)
6	AR-**9545-T15H**	1	Torque Indicating Adapter
7		1	Glenoid Drill Guides
	AR-**9125-1/AR9125-10**	1	Small
	AR-**9125-2/AR9125-20**	1	Medium
	AR-**9125-3/AR9125-30**	1	Large
8	AR-**9165K**	1	2.8 mm Guide Pin, qty. 2
9	AR-**9125H**	1	Glenoid Drill Guide Handle
10	AR-**1999HH**	1	Ratcheting Modular Handle
11	AR-**9165DDG**	1	Baseplate Impactor Drill, 2.8 mm
12	AR-**9165TDG**	1	Baseplate Impactor Central Screw Tap
13	AR-**9545-T15-03**	1	T15 Driver Shaft, long

Ordering Information

Implants

Product Description	Item Number
Porous Coated Baseplate, small	AR-**9120-01PC**
Porous Coated Baseplate, medium	AR-**9120-02PC**
Porous Coated Baseplate, large	AR-**9120-03PC**
Inlay, small	AR-**9121-01**
Inlay, medium	AR-**9121-02**
Inlay, large	AR-**9121-03**
Inlay, small PLUS	AR-**9121-04**
Inlay, medium PLUS	AR-**9121-05**
Inlay, large PLUS	AR-**9121-06**

Univers Revers™ Total Shoulder System Glenoid Implants

Central Screw, 6.5 mm × 15 mm	AR-**9165-15**
Central Screw, 6.5 mm × 20 mm	AR-**9165-20**
Central Screw, 6.5 mm × 25 mm	AR-**9165-25**
Peripheral Screw, 4.5 mm × 24 mm	AR-**9145-24**
Peripheral Screw, 4.5 mm × 30 mm	AR-**9145-30**
Peripheral Screw, 4.5 mm × 36 mm	AR-**9145-36**
Peripheral Screw, 4.5 mm × 42 mm	AR-**9145-42**
Peripheral Screw, 4.5 mm × 48 mm	AR-**9145-48**
Central Screw, 6.5 mm × 15 mm, nonlocking	AR-**9165-15NL**
Central Screw, 6.5 mm × 20 mm, nonlocking	AR-**9165-20NL**
Central Screw, 6.5 mm × 25 mm, nonlocking	AR-**9165-25NL**
Peripheral Screw, 4.5 mm × 24 mm, nonlocking	AR-**9145-24NL**
Peripheral Screw, 4.5 mm × 30 mm, nonlocking	AR-**9145-30NL**
Peripheral Screw, 4.5 mm × 36 mm, nonlocking	AR-**9145-36NL**
Peripheral Screw, 4.5 mm × 42 mm, nonlocking	AR-**9145-42NL**
Peripheral Screw, 4.5 mm 48 mm, nonlocking	AR-**9145-48NL**
Glenosphere, 36	AR-**9504S**
Glenosphere, 36 +2.5 mm inf	AR-**9504S-INF**
Glenosphere, 36 +4 mm lat	AR-**9504S-04**
Glenosphere, 39 mm	AR-**9504M**
Glenosphere, 39 +2.5 mm inf	AR-**9504S-02**
Glenosphere, 39 +4 mm lat	AR-**9504M-04**
Glenosphere, 42 mm	AR-**9504L**
Glenosphere, 42 +2.5 mm inf	AR-**9504M-02**
Glenosphere, 42 +4 mm lat	AR-**9504L-04**

Univers Revers™ Total Shoulder System Humeral Implants

Univers Revers Stem, Size 5, monoblock 135°	AR-**9501-05-135CPC**
Univers Revers Stem, Size 5, monoblock 155°	AR-**9501-05-155CPC**
Univers Revers Modular Stem, Size 5	AR-**9501-05P**
Univers Revers Stem, Size 6	AR-**9501-06P**
Univers Revers Stem, Size 7	AR-**9501-07P**
Univers Revers Stem, Size 8	AR-**9501-08P**
Univers Revers Stem, Size 9	AR-**9501-09P**
Univers Revers Stem, Size 10	AR-**9501-10P**
Univers Revers Stem, Size 11	AR-**9501-11P**
Univers Revers Stem, Size 12	AR-**9501-12P**
Univers Revers™ Stem, Size 13	AR-**9501-13P**
Univers Revers SutureCup, 36 (neutral)	AR-**9502-36CPC**
Univers Revers SutureCup, 36 (+2 mm left)	AR-**9502-36LCPC**
Univers Revers SutureCup, 36 (+2 mm right)	AR-**9502-36RCPC**
Univers Revers SutureCup, 39 (neutral)	AR-**9502-39CPC**
Univers Revers SutureCup, 39 (+2 mm left)	AR-**9502-39LCPC**
Univers Revers SutureCup, 39 (+2 mm right)	AR-**9502-39RCPC**
Univers Revers SutureCup, 42 (neutral)	AR-**9502-42CPC**
Univers Revers SutureCup, 42 (+2 mm left)	AR-**9502-42RCPC**
Univers Revers SutureCup, 42 (+2 mm right)	AR-**9121-04**
Humeral Liner, 42 +3 mm	AR-**9503L-03**
Humeral Liner, 42 +3 mm, constrained	AR-**9503L-03C**
Humeral Liner, 42 +6 mm	AR-**9503L-06**
Humeral Liner, 42 +6 mm, constrained	AR-**9503L-06C**
Humeral Liner, 39 +3 mm	AR-**9503M-03**
Humeral Liner, 39 +3 mm, constrained	AR-**9503M-03C**
Humeral Liner, 39 +6 mm	AR-**9503M-06**
Humeral Liner, 39 +6 mm, constrained	AR-**9503M-06C**
Humeral Liner, 36 +3 mm	AR-**9503S-03**
Humeral Liner, 36 +3 mm, constrained	AR-**9503S-03C**
Humeral Liner, 36 +6 mm	AR-**9503S-06**
Humeral Liner, 36 +6 mm, constrained	AR-**9503S-06C**
Humeral Spacer, 39 +6 mm	AR-**9505-06**
Humeral Spacer, 39 +9 mm	AR-**9505-09**
Humeral Spacer, 39 +12 mm	AR-**9505-12**
Humeral Spacer, 39 +15 mm	AR-**9505-15**
Humeral Spacer, 42 +6 mm	AR-**9550-06**
Humeral Spacer, 42 +9 mm	AR-**9550-09**
Humeral Spacer, 42 +12 mm	AR-**9505-12**
Humeral Spacer, 42 +15 mm	AR-**9505-15**
Humeral Spacer, 36 +6 mm	AR-**9550-06**
Humeral Spacer, 36 +9 mm	AR-**9555-09**
Humeral Spacer, 36 +12 mm	AR-**9555-12**
Humeral Spacer, 36 +15 mm	AR-**9555-15**

Ordering Information (Cont)

Special Implants

Product Description	Item Number
Central Screw, 6.5 mm x 30 mm, nonlocking	AR-**9165-30NL**
Central Screw, 6.5 mm x 35 mm, nonlocking	AR-**9165-35NL**
36+3 / 39 Combination Humeral Insert	AR-**9503-3639-3**
36+6 / 39 Combination Humeral Insert	AR-**9503-3639-6**
36+3 / 39 Constrained Combination Humeral Insert	AR-**9503-3639-3C**
36+6 / 39 Constrained Combination Humeral Insert	AR-**9503-3639-6C**
39+3 / 42 Combination Humeral Insert	AR-**9503-3942-3**
39+6 / 42 Combination Humeral Insert	AR-**9503-3942-6**
36+3 / 42 Constrained Combination Humeral Insert	AR-**9503-3942-3C**
36+6 / 42 Constrained Combination Humeral Insert	AR-**9503-3942-6C**

Instruments

Universal Glenoid Inlay Extractor	AR-**9121E**
Univers Revers Humeral Instrumentation Set	AR-**9501HS**
Univers Revers Glenoid Instrumentation Set	AR-**9501GS**

Directions for Use

Indications

The Universal Glenoid is indicated for use in reverse total shoulder arthroplasty in grossly rotator cuff deficient glenohumeral joint with severe arthropathy or a previously failed joint replacement with a gross rotator cuff deficiency. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

The Universal Glenoid is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency, and is intended to be used with the Univers Revers Shoulder Prosthesis System.

The Universal Glenoid baseplate is CaP (Calcium Phosphate) coated and is intended for cementless use with the addition of screws for fixation.

Outside the US only: The Universal Glenoid is indicated for use in anatomic joint replacement(s) when conditions including severe pain or significant disability resulting from degenerative, rheumatoid, traumatic disease, fracture or injury of the glenohumeral joint; non-union humeral head fractures of long duration; avascular necrosis of the humeral head; neoplastic or dysplastic diseases; or other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable.

For anatomic joint replacement, the Universal Glenoid is indicated to be used as a hemi shoulder replacement, or with the humeral components of the Univers II or ECLIPSE™ system for total shoulder arthroplasty. The Univers Revers Porous Coated Baseplate and Inlay Bearing is designed to be used as the glenoid component of the existing Univers Revers Shoulder Prosthesis System or Univers II Shoulder Arthroplasty System.

The Univers Revers Porous Coated Baseplate and Inlay Bearing is indicated for use in a grossly rotator cuff deficient glenohumeral joint with severe arthropathy or a previously failed joint replacement with a gross rotator cuff deficiency. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

The Univers Revers Porous Coated Baseplate and Inlay Bearing is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency. The Univers Revers Porous Coated Baseplate and Inlay Bearing is porous coated and is intended for cementless use with the addition of screws for fixation.

The Univers Revers Porous Coated Baseplate and Inlay Bearing, and Universal Glenoid Inlay are indicated for use in anatomic joint replacement(s) when conditions including severe pain or significant disability resulting from degenerative, rheumatoid, traumatic disease, fracture or injury of the glenohumeral joint; non-union humeral head fractures of long duration; avascular necrosis of the humeral head; neoplastic or dysplastic diseases; or other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable.

For anatomic joint replacement, the Univers Revers Porous Coated Baseplate and Inlay Bearing, and Universal Glenoid Inlay are indicated to be used with the humeral components of the Arthrex Univers II Shoulder Prosthesis System for total shoulder arthroplasty. The Universal Glenoid Inlay is intended for use with the Univers Revers Porous Coated Baseplate.

Contraindications

1. Insufficient quantity or quality of bone.
2. Blood supply limitations and previous infections, which may retard healing.
3. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
4. Any active infection or blood supply limitations.
5. Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
6. 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 on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb or disrupt the growth plate.

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. 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.
5. 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.
6. 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. Removal of the device should be performed using standard surgical practices for device removal.
7. 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. 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.
8. An internal fixation device must never be reused. Reuse of this device could result in failure of the device to perform as intended and could cause harm to the patient and/or user.
9. Do not re-sterilize this device.
10. The operation is to be planned based on the pre-operative x-rays.
11. The specific Arthrex implantation instruments are to be used both for preparing the bone bed and for adjusting and inserting the joint prosthesis. The appropriate Arthrex delivery system is required for proper insertion of the implant.
12. Only Arthrex delivery systems, instruments, and trial prostheses should be used for the implantation procedure.
13. Endoprostheses may not be processed mechanically or changed in any other way.
14. Do not implant any parts that have been scratched or damaged. Do not implant any parts that have been scratched or damaged. 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.
15. 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.
16. An infection in an artificial joint may lead to implant removal.
17. This device should only be used in conjunction with other implants designed specifically for use with this system.
18. Proper anchoring is of decisive importance for firm, permanent positioning of the prosthesis.
19. In the case of joint endoprosthesis intended for cemented anchoring, the surgeon must comply with the instructions and recommendations of the cement manufacturer when it comes to preparation and cementing techniques. Failure to properly align and completely seat the components together can lead to disassociation. Proper technique must be followed to ensure there is no bony or soft tissue interference between modular components. All screws must be adequately tightened to ensure they are not proud to prevent a mechanical interference between modular components. Thoroughly clean and dry tapers, prior to attachment of modular components to avoid crevice corrosion and improper seating. Glenosphere forceps are required to verify integrity of the Morse Taper connection between Glenosphere and Baseplate.
20. Biohazard waste, such as explanted devices, needles and contaminated surgical equipment should be safely disposed of in accordance with the institutions policy.
21. Serious incidents should be reported to Arthrex Inc., or an in-country representative, and to the health authority where the incident occurred.

MRI Safety Information

1. **MR Conditional**

Non-clinical testing and in-vivo electromagnetic simulations demonstrated that the Arthrex Universal Glenoid is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 3000 Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning in the Normal Operating Mode of operation for the MR system

Under the scan conditions defined, the Arthrex Universal Glenoid is expected to produce a maximum temperature rise of 3 °C after 15-minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the Arthrex Universal Glenoid extends approximately 60 mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.