

# Eclipse™ Total Shoulder Arthroplasty System

Surgical Technique



## Eclipse™ Total Shoulder Arthroplasty System

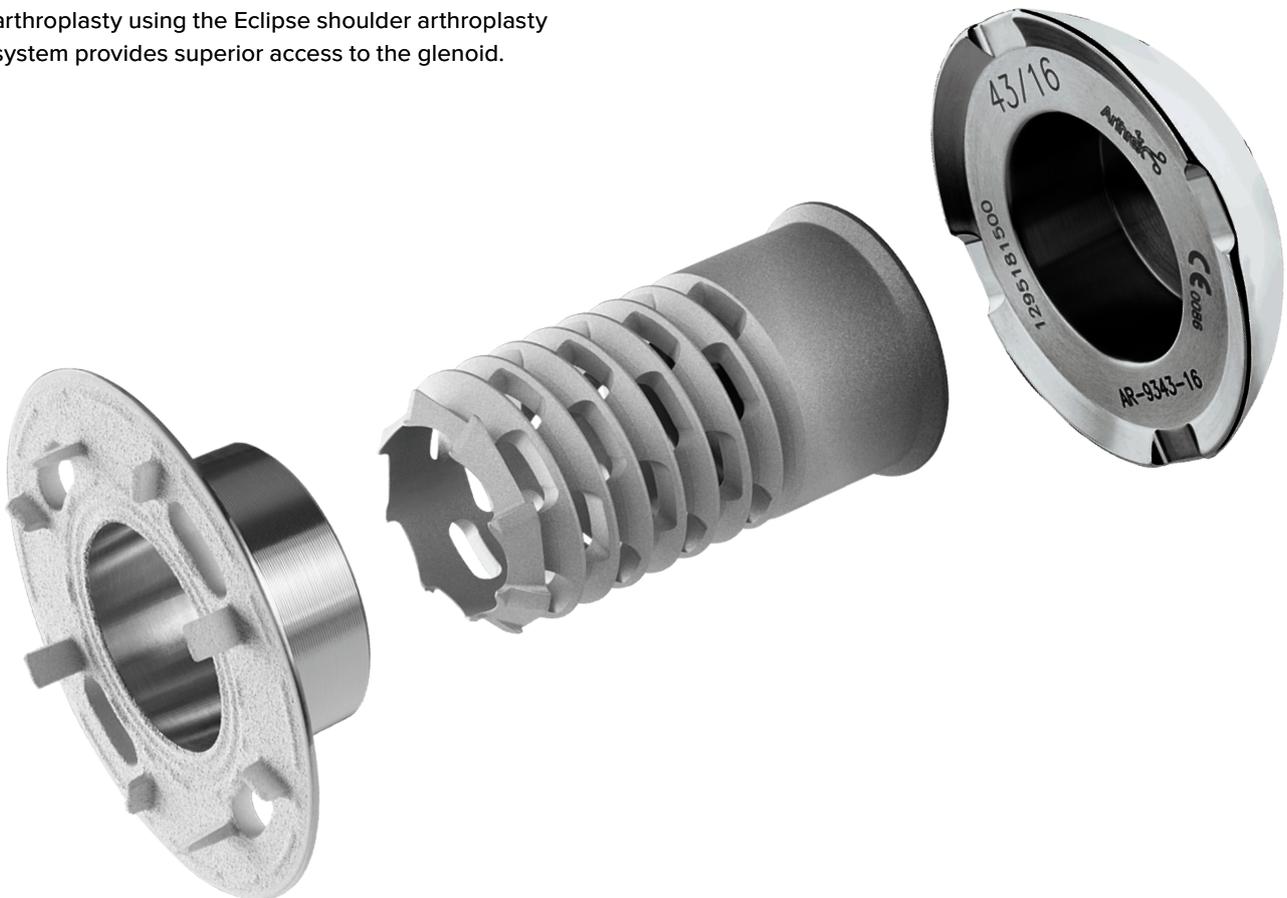
The Eclipse total shoulder arthroplasty system exemplifies a clinically proven design. Its efficacy has been substantiated in various publications spanning a range of short-, mid-, and long-term clinical follow-up.<sup>1-8</sup> In cases of posttraumatic and primary arthritis, the 9-year outcome after shoulder replacement using the Eclipse system has proven to be comparable to that of third- and fourth-generation standard, stemmed shoulder arthroplasty.<sup>7</sup>

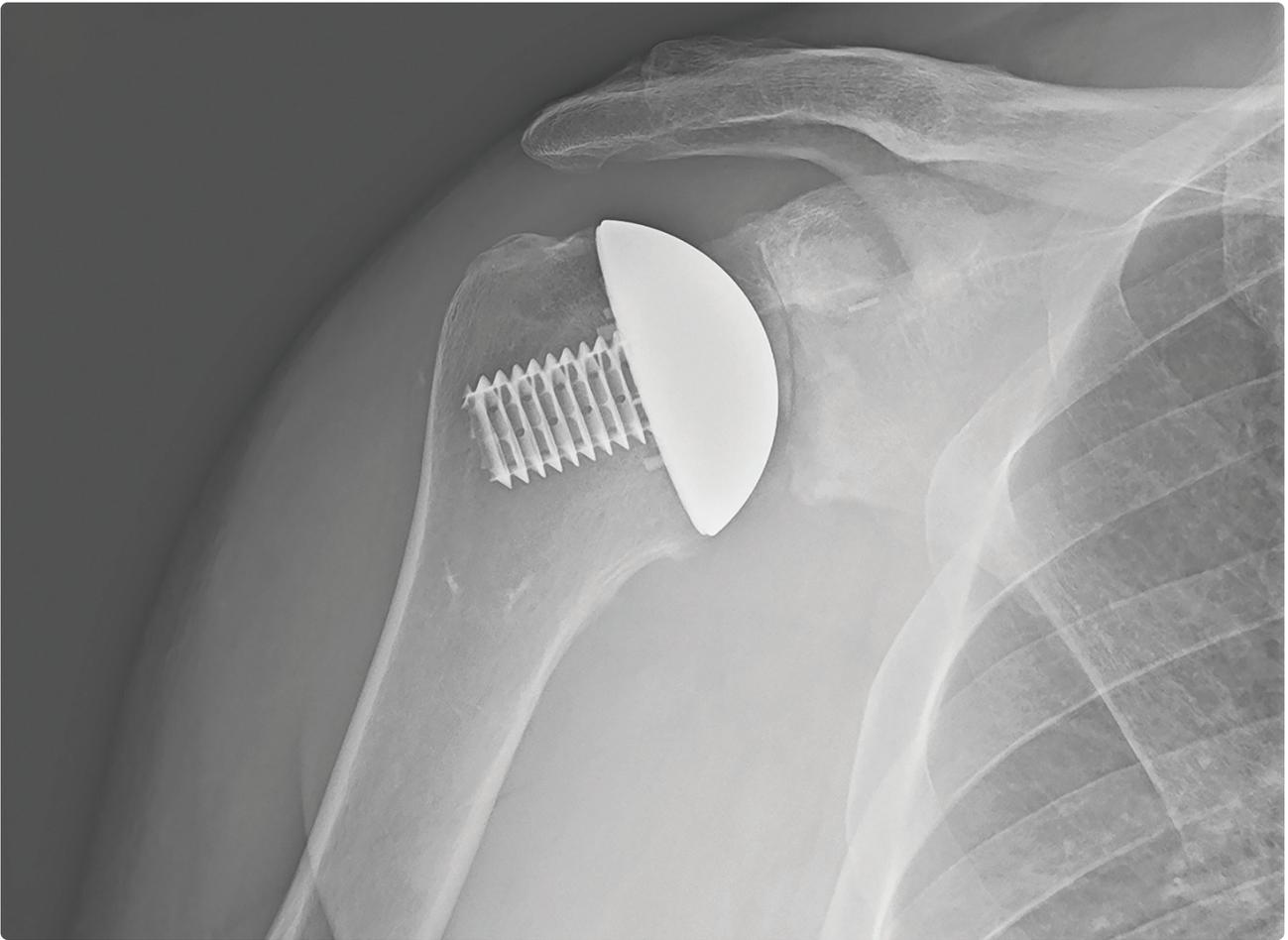
As a result of its design and operative technique, which obviate the need to broach the intramedullary canal, an approximate 20-minute reduction in operative duration has also been noted.<sup>8</sup> Benefits over a traditional stemmed prosthesis include, but are not limited to, reduced blood loss, lower infection rates, and a bone-conserving approach that provides for a primary-like setting in the event of revision arthroplasty.<sup>7,8</sup>

Intraoperatively, the Eclipse system allows for individual anatomic reconstruction of the humeral head based on accurate orientation with the cortical rim of the humeral resection plane. The benefits of this type of anatomic reconstruction, with the ability to place the humeral component independent of the humeral shaft axis, are perhaps most advantageous in post-traumatic cases. In contrast to humeral head resurfacing, total shoulder arthroplasty using the Eclipse shoulder arthroplasty system provides superior access to the glenoid.

In the absence of any published drawbacks associated with the use of a stemless implant versus a traditional long stem when performing primary shoulder arthroplasty, it can be said with confidence that the Eclipse total shoulder arthroplasty system offers several proven advantages for both the patient and surgeon.

Prof. Dr. med. Peter Habermeyer  
ATOS Clinic Munich | Munich, Germany





**Eclipse™ Total Shoulder Arthroplasty System**

|                      |  |
|----------------------|--|
| <b>Humeral Heads</b> | 37 mm-55 mm (2 mm increments)<br>Humeral heads offered in cobalt chrome and titanium (special order) |
| <b>Heights</b>       | Anatomic and Extended (+2 mm)<br><b>Note:</b> Only one head height is available for 37 mm            |
| <b>Cage Screw</b>    | <b>Small:</b> 30 mm<br><b>Medium:</b> 35 mm<br><b>Large:</b> 40 mm<br><b>X-large:</b> 45 mm          |
| <b>Trunnion</b>      | 37 mm-55 mm (sized with humeral head)  |



## Glenoid Options: Univers VaultLock® Glenoid

### Fluted Central Peg

- › Immediate fixation
- › OR efficiency

### Inferior Keel

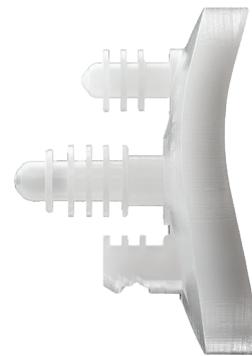
- › Decreased cortical penetration compared to inferior pegs
- › Multiple fixation features, including reverse barbs, flutes, and central cement fenestration

### Superior Peg

- › Enhanced immediate fixation
- › Self-pressurizing design

### Inline Configuration

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

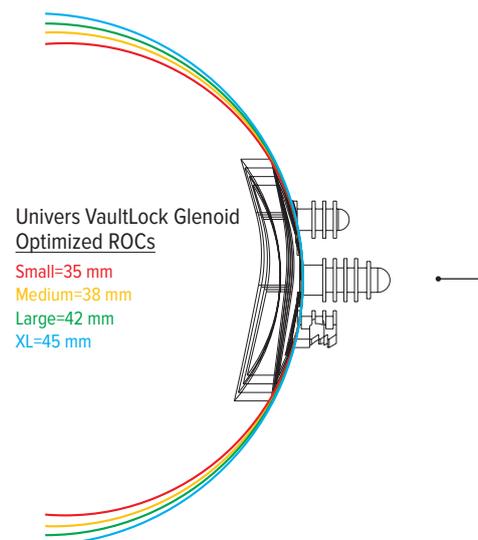


### Anatomic Backside Radius of Curvature (ROC)

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

### Univers VaultLock Glenoid: Optimized ROCs

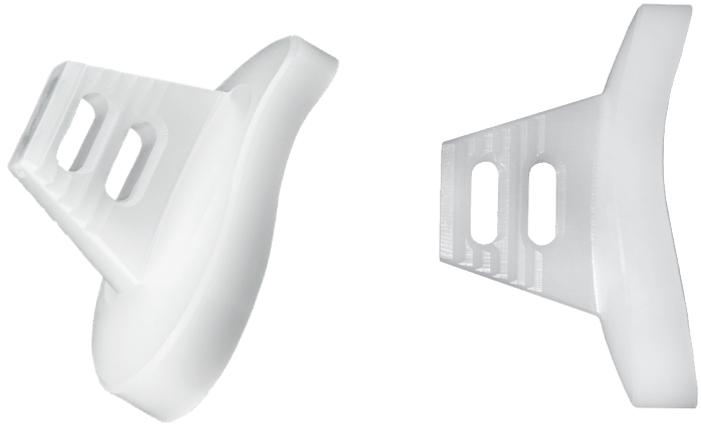
- › Anatomic solution with subchondral, bone-preserving design



## Glenoid Options: Keeled

### Keeled Glenoid

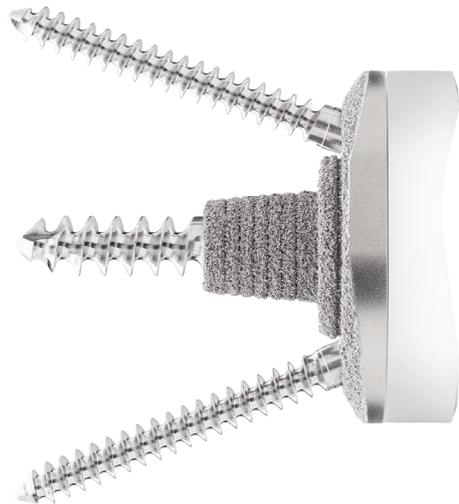
- › Dual fenestrations for enhanced anchoring
- › Reverse barbs for expansion effect within the glenoid vault



## Glenoid Options: Convertible Universal Baseplate

### Convertible Universal Baseplate for Anatomic TSA With Eclipse™, Univers™ Apex, and Univers™ II Implants

- › Combines advantages of polyethylene with the stability of screw fixation, resulting in reduced risk of radiolucent lines
- › Virtual Implant Positioning™ (VIP™) preoperative planning system for appropriate joint-line restoration
- › 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)



# Resection Methods

## Fixed-Angle Cutting Guide



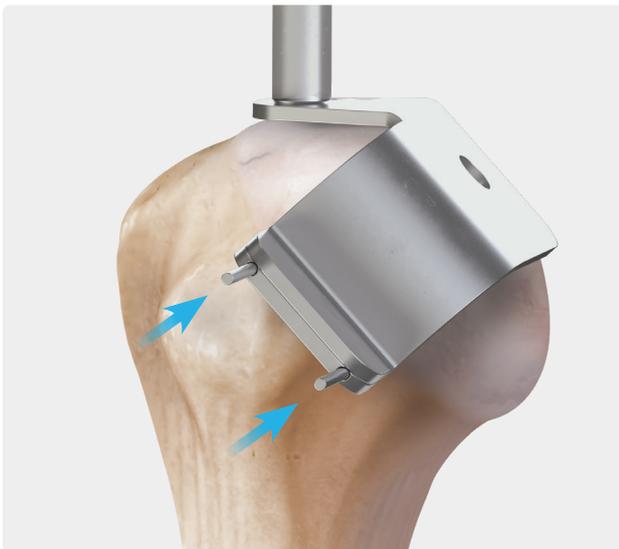
1

Remove osteophytes with a rongeur or small osteotome to identify the anatomic neck. Place the fixed-angle cutting guide (left or right, small or large) on the humeral head. Place version rods in the guide (20° and 40°) and align with the forearm. Typically, the forearm should be visualized between the version rods so that a retroversion of 30° is achieved based on the orientation of the forearm.



2

Using the appropriate guide size and positioning will result in subsequent pin placement across the anatomic neck at an approximate inclination angle of 132.5°. Once the appropriate guide position has been established, advance the 2.8 mm Steinmann pin down the center cannulation of the fixed angle cut guide to secure it to bone.



3

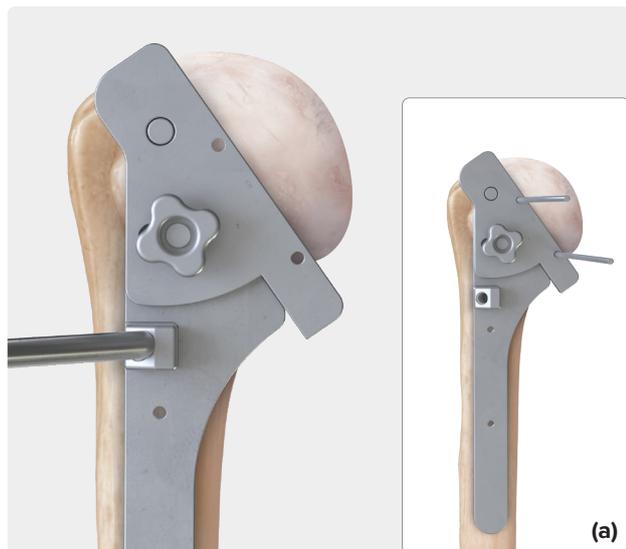
Place 1.6 mm K-wires through the anterior holes of the guide to create the resection plane and remove the 2.8 mm Steinmann pin.



4

Remove the guide and position the cut block on the pins. The humeral head is now resected over the 1.6 mm K-wires and cut block.

## Humeral Resection Template Method



Alternatively, the humeral resection template can be used to guide the humeral head cut. Aligning the handle with the forearm will provide 30° of retroversion. The template can be pinned as shown in **(a)** and the humeral head can be resected over the template.

## Freehand Humeral Resection Method



Following careful removal of osteophytes and exposure of the humeral neck, complete a freehand resection. Care must be taken to follow the humeral neck and to avoid resection of the nonarticular portion of the humerus.

## Bone Quality Test

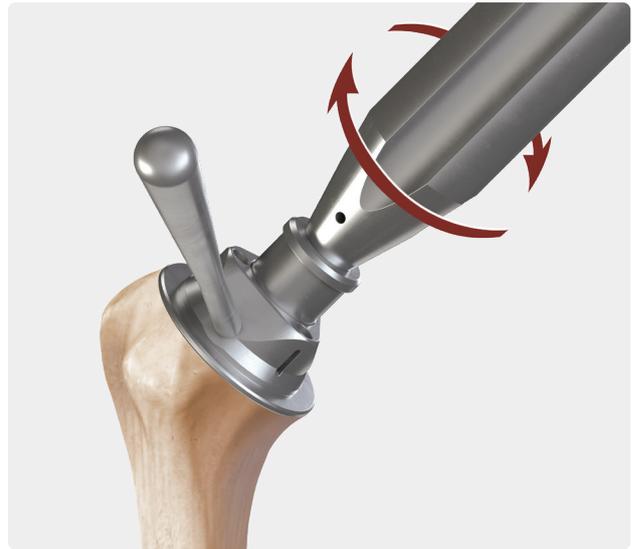
Following humeral resection, assess bone quality by depressing your thumb on the resected humeral surface. If you can depress your thumb into the humeral osteotomy without significant resistance, primary stability of the Eclipse™ prosthesis may be insufficient. In this case, a stemmed prosthesis such as the Univers Apex OptiFit™ or Univers™ II system may provide better fixation.

## Humeral Preparation



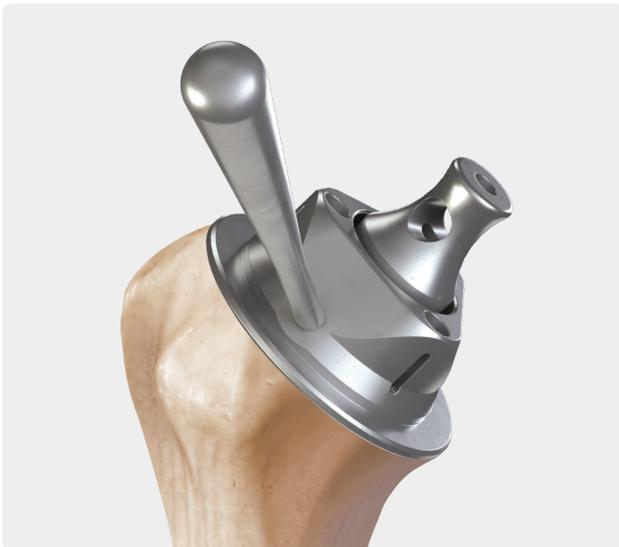
1

Determine the size of the trunnion with the coring templates. The coring template should match the resected plane of the cortical rim as closely as possible without overhanging. When the appropriate size has been determined, impact the coring template fixation pins to secure the template to the humerus.



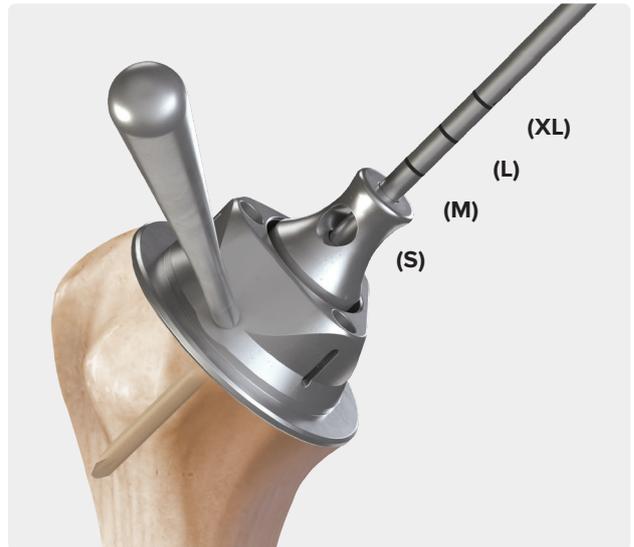
2

Prepare the humerus for the cage screw using the hand coring reamer or secondary coring reamer (if sclerotic bone is encountered). The coring reamer is advanced until the depth stop engages the coring template.



3

Place the centering device into the coring template and advance it into the reamed channel in the humeral osteotomy. Confirm that it is fully seated.



4

To determine the length of the cage screw, drill the graduated sizer through the centering device until it reaches the lateral cortex.

**Note:** Do not puncture the lateral cortex.

The size refers to the laser marking (S, M, L, XL) on the pin and it is referenced off the top of the centering device. If the measurement is between 2 marks, choose the shorter cage screw. Remove the sizer after the measurement has been taken.



5

If glenoid replacement is planned, remove the coring template and protect the resected humeral surface with a resection protector from the instrument set. Proceed to the steps for the chosen glenoid:

- > Univers VaultLock® and Keeled
- > Universal Glenoid Convertible Baseplate (LT1-000000-en-US\_C)

When glenoid implantation is complete, proceed to humeral implantation (step 1).



**Optional:** Humeral head and trunnion sizes (page 8, step 1) can be verified with trial heads and the trial trunnion. The correct size matches the diameter of the cut surface of the humerus, providing cortical support to the implant. The head height is predetermined due to the fixed relationship of the head diameter and height based on normal humeral anatomy. The joint can be reduced and trialed to verify stability and tension.

**Notes:** The resection protector must be removed prior to this optional step. Each humeral head size is offered in an anatomic height and an extended (+2 mm) height. Only one head height is available for the 37 mm humeral head.

## Humeral Implantation



1

Open the trunnion in a sterile fashion (trunnion size predetermined per page 8, step 1). Remove the resection protector and replace the centering device into the reamed channel in the humeral osteotomy. Place the trunnion over the centering device.



2

Seat the trunnion using the trunnion impactor and mallet then remove the centering device.

**Note:** The trunnion should have circumferential contact with the cortical rim.



3

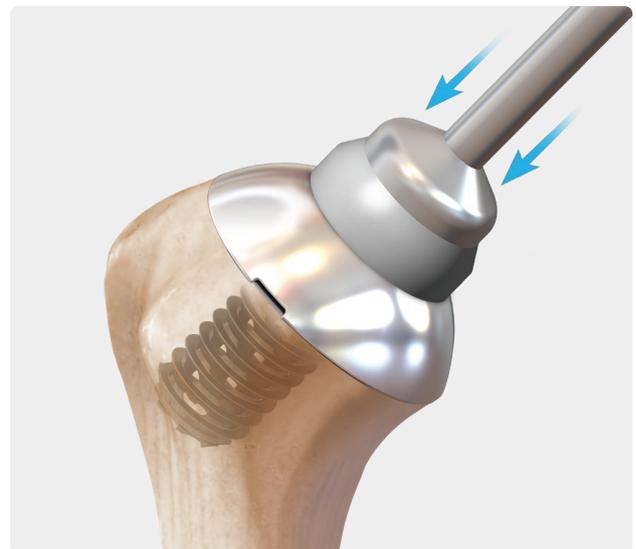
Select the appropriate cage screw according to the previous measurement (page 9, step 2). Advance it through the center of the trunnion while holding the trunnion tightly against the resected surface with the trunnion impactor.



4

Secure the cage screw with the screwdriver until the head of the screw is flush with the neck of the trunnion. Once the cage screw is fully seated, remove the screwdriver and trunnion impactor **(a)**.

**Note:** Do not overtighten the screw, as this could lead to ineffective fixation.



5

Select the appropriate humeral head and impact the humeral head onto the trunnion using the head impactor.

**Note:** The size of the humeral head must correspond to the size of the trunnion.

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

## Eclipse™ SpeedScap™ Implant System and Subscapularis Repair Technique

After performing a subscapularis peel and humeral head osteotomy, and following the final glenoid, trunnion, and cage screw implantation, the technique is as follows:

1. Use the trunnion adapter to determine optimal placement of the 3 medial row FiberTak® DR anchors.
2. Using the trunnion adapter to avoid the cage screw and trunnion, prepare a socket for the first FiberTak DR anchor. Remain parallel or divergent to the trunnion adapter. Implant the FiberTak DR anchor and set. If soft bone is encountered, choose an alternative location. Repeat for the next two FiberTak DR anchors spanning the medial footprint of the subscapularis.
3. Using the trunnion adapter, drill and mark two sockets in the bicipital groove for the 3.9 mm SwiveLock® anchors, but do not implant the anchors.
4. Remove the trunnion adapter and impact the final humeral head.
5. A SutureTape can be passed through the upper border of the subscapularis and the anterior border of the supraspinatus to reapproximate the native footprint of the tissue. Then pass the FiberTak DR LabralTape™ sutures through the subscapularis.

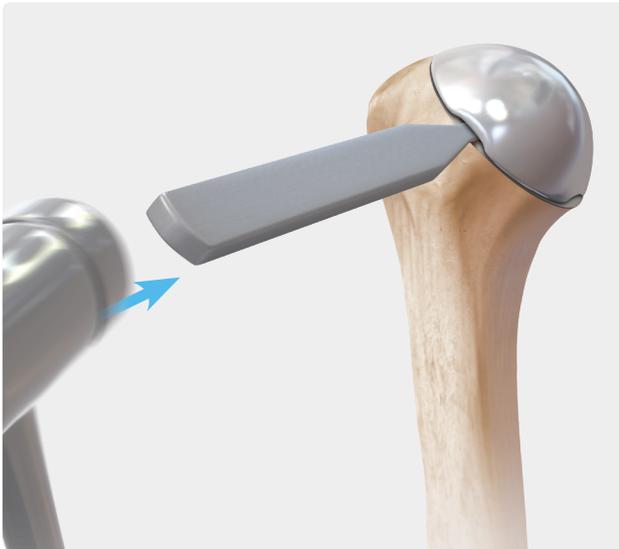
6. Finish the repair by placing one LabralTape™ suture from each FiberTak® DR anchor into a 3.9 mm SwiveLock® anchor. Set the tension of the repair and place the anchor into one of the two bicipital groove sockets. Repeat, placing the final three LabralTape sutures into the final 3.9 mm SwiveLock anchor to finish the repair.

### Pearls

- › Remain parallel or divergent to the silhouette of the trunnion adapter. A convergent trajectory may cause the drill to hit the cage screw.
- › Remain parallel to the hash marks on the trunnion adapter, representing a 5 mm space below the trunnion. A convergent trajectory may cause the drill to hit the undersurface of the trunnion.
- › The trunnion adapter sits in the screw, not on the trunnion itself, so the morse taper is not affected.
- › For more information, animation and technical video, visit [Arthrex.com](http://Arthrex.com).

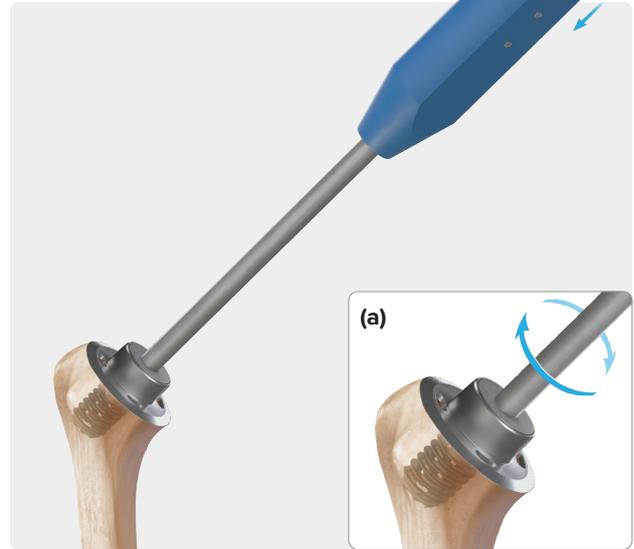


## Extracting the Eclipse™ Shoulder Arthroplasty System



1

Remove the humeral head by placing the head extractor under one of the head slots. Tapping the end of the extractor will disengage the morse taper connection.



2

After engaging the screwdriver to the cage screw, lightly tap the handle. This will assist in detaching the cage screw from the bone. Turn the screwdriver slightly clockwise to fully detach from bone **(a)**. The bone tamp can be used through the handle as shown to provide more torque.



**Optional:** If the cage screw does not readily detach from the bone when performing step 2, an osteotome can be placed down the 4 slots of the trunnion to further assist with extraction.



3

When the cage screw is fully detached, simply turn the screwdriver counterclockwise to remove. After cage screw has been removed, lift the trunnion from the surface using the head extractor or an osteotome.

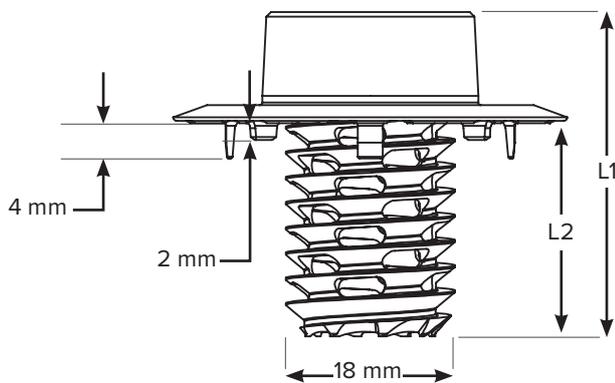
**Note:** If bone is soft, support the humeral neck with a clamp while turning the cage screw.

## Glenoid Sizing Matrix: Radial Mismatch

### Univers VaultLock®, Convertible Universal Glenoid™, and Keeled Glenoids

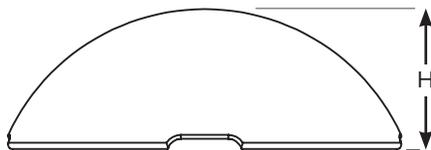
| Eclipse™ Total Shoulder Arthroplasty System | Head Size (mm) | Small       | Medium      | Large      | XL       |
|---|----------------|-------------|-------------|------------|----------|
|   | 37             | <b>9.9</b>  |             |            |          |
|   | 39             | <b>8.5</b>  |             |            |          |
|   | 41             | <b>7.25</b> | <b>8.75</b> |            |          |
|   | 43             | <b>6</b>    | <b>7.5</b>  | <b>9</b>   |          |
|   | 45             |             | <b>6</b>    | <b>7.5</b> | <b>9</b> |
|   | 47             |             | <b>5</b>    | <b>6.5</b> | <b>8</b> |
|   | 49             |             |             | <b>5.5</b> | <b>7</b> |
|   | 51             |             |             | <b>4.5</b> | <b>6</b> |
|   | 53             |             |             |            | <b>5</b> |
| 55  |                |             |             | <b>4</b>   |          |

## Eclipse System: Key Dimensions



### Eclipse Cape and Trunnion

| Cage Size      | L1 (mm) | L2 (mm) |
|----------------|---------|---------|
| <b>Small</b>   | 30      | 18      |
| <b>Medium</b>  | 35      | 23      |
| <b>Large</b>   | 40      | 28      |
| <b>X-large</b> | 45      | 33      |



### Eclipse Humeral Heads

|        |          | Head Size (mm) |    |    |    |    |    |    |    |    |    |
|--------|----------|----------------|----|----|----|----|----|----|----|----|----|
|        |          | 37             | 39 | 41 | 43 | 45 | 47 | 49 | 51 | 53 | 55 |
| H (mm) | Anatomic | 16             | 16 | 16 | 16 | 17 | 18 | 18 | 19 | 20 | 21 |
|        | Extended |                | 18 | 18 | 18 | 19 | 20 | 20 | 21 | 22 | 23 |

## Ordering Information - Eclipse™ Total Shoulder Arthroplasty System

### Implants

|  |               |
|--|---------------|
| Eclipse trunnion, 37 mm, slotted, TPS and CaP coated | AR-9301-37CPC |
| Eclipse trunnion, 39 mm, slotted, TPS and CaP coated | AR-9301-39CPC |
| Eclipse trunnion, 41 mm, slotted, TPS and CaP coated | AR-9301-41CPC |
| Eclipse trunnion, 43 mm, slotted, TPS and CaP coated | AR-9301-43CPC |
| Eclipse trunnion, 45 mm, slotted, TPS and CaP coated | AR-9301-45CPC |
| Eclipse trunnion, 47 mm, slotted, TPS and CaP coated | AR-9301-47CPC |
| Eclipse trunnion, 49 mm, slotted, TPS and CaP coated | AR-9301-49CPC |
| Eclipse trunnion, 51 mm, slotted, TPS and CaP coated | AR-9301-51CPC |
| Eclipse trunnion, 53 mm, slotted, TPS and CaP coated | AR-9301-53CPC |
| Eclipse trunnion, 55 mm, slotted, TPS and CaP coated | AR-9301-55CPC |
| Eclipse cage screw, small, 30 mm                     | AR-9301-01    |
| Eclipse cage screw, medium, 35 mm                    | AR-9301-02    |
| Eclipse cage screw, large, 40 mm                     | AR-9301-03    |
| Eclipse cage screw, x-large, 45 mm                   | AR-9301-04    |
| Eclipse humeral head, 39 mm/16 mm                    | AR-9337-16    |
| Eclipse humeral head, 39 mm/18 mm                    | AR-9339-16    |
| Eclipse humeral head, 41 mm/16 mm                    | AR-9339-18    |
| Eclipse humeral head, 41 mm/18 mm                    | AR-9341-16    |
| Eclipse humeral head, 43 mm/16 mm                    | AR-9343-16    |
| Eclipse humeral head, 43 mm/18 mm                    | AR-9343-18    |
| Eclipse humeral head, 45 mm/17 mm                    | AR-9345-17    |
| Eclipse humeral head, 45 mm/19 mm                    | AR-9345-19    |
| Eclipse humeral head, 47 mm/18 mm                    | AR-9347-18    |
| Eclipse humeral head, 47 mm/20 mm                    | AR-9347-20    |
| Eclipse humeral head, 49 mm/18 mm                    | AR-9349-18    |
| Eclipse humeral head, 49 mm/20 mm                    | AR-9349-20    |
| Eclipse humeral head, 51 mm/19 mm                    | AR-9351-19    |
| Eclipse humeral head, 51 mm/21 mm                    | AR-9351-21    |
| Eclipse humeral head, 53 mm/20 mm                    | AR-9353-20    |
| Eclipse humeral head, 53 mm/22 mm                    | AR-9353-22    |
| Eclipse humeral head, 55 mm/21 mm                    | AR-9355-21    |
| Eclipse humeral head, 55 mm/23 mm                    | AR-9355-23    |

### Special Order Only

|  |             |
|--|-------------|
| Eclipse titanium humeral head, 37 mm/16 mm | AR-9337-16T |
| Eclipse titanium humeral head, 39 mm/16 mm | AR-9339-16T |
| Eclipse titanium humeral head, 41 mm/16 mm | AR-9341-16T |
| Eclipse titanium humeral head, 43 mm/16 mm | AR-9343-16T |
| Eclipse titanium humeral head, 45 mm/17 mm | AR-9345-17T |
| Eclipse titanium humeral head, 47 mm/18 mm | AR-9347-18T |
| Eclipse titanium humeral head, 49 mm/18 mm | AR-9349-18T |
| Eclipse titanium humeral head, 51 mm/19 mm | AR-9351-19T |
| Eclipse titanium humeral head, 53 mm/20 mm | AR-9353-20T |
| Eclipse titanium humeral head, 55 mm/21 mm | AR-9355-21T |

### Consumables

|   |             |
|---|-------------|
| Eclipse SpeedScap™ implant system   | AR-9400-SBK |
| Eclipse and Unvers™ II Total Shoulder System head resection disposables kit | AR-9206S    |
| Eclipse sterile cage screw sizer  | AR-9401-08S |

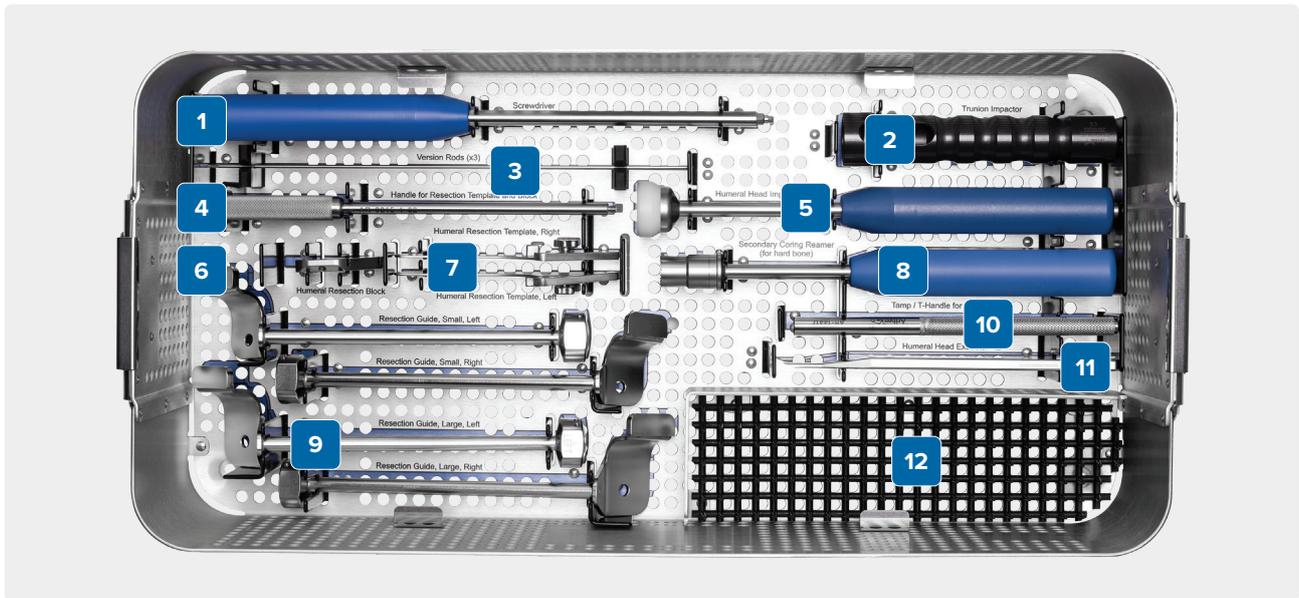
## Ordering Information - Eclipse™ Shoulder Instrument Case (AR-9400S)



### Top Tray

|   |                                |   |                                   |                                 |            |
|---|--------------------------------|---|-----------------------------------|---------------------------------|------------|
| 1   | Eclipse coring template, 37 mm | AR-9400-37  | Eclipse trial head, 37 mm/16 mm   | AR-9437-16                      |            |
|   | Eclipse coring template, 39 mm | AR-9400-39  | Eclipse trial head, 39 mm/16 mm   | AR-9439-16                      |            |
|   | Eclipse coring template, 41 mm | AR-9400-41  | Eclipse trial head, 39 mm/18 mm   | AR-9439-18                      |            |
|   | Eclipse coring template, 43 mm | AR-9400-43  | Eclipse trial head, 41 mm/16 mm   | AR-9441-16                      |            |
|   | Eclipse coring template, 45 mm | AR-9400-45  | Eclipse trial head, 41 mm/18 mm   | AR-9441-18                      |            |
|   | Eclipse coring template, 47 mm | AR-9400-47  | Eclipse trial head, 43 mm/16 mm   | AR-9443-16                      |            |
|   | Eclipse coring template, 49 mm | AR-9400-49  | Eclipse trial head, 43 mm/18 mm   | AR-9443-18                      |            |
|   | Eclipse coring template, 51 mm | AR-9400-51  | Eclipse trial head, 45 mm/17 mm   | AR-9445-17                      |            |
|   | Eclipse coring template, 53 mm | AR-9400-53  | Eclipse trial head, 45 mm/19 mm   | AR-9445-19                      |            |
|   | Eclipse coring template, 55 mm | AR-9400-55  | 8 Eclipse trial head, 47 mm/18 mm | AR-9447-18                      |            |
|   | 2                              | Univers™ and Eclipse handle for drilling template | AR-9203-10                        | Eclipse trial head, 47 mm/20 mm | AR-9447-20 |
|   | 3                              | Eclipse cage screw sizer                          | AR-9401-08                        | Eclipse trial head, 49 mm/18 mm | AR-9449-18 |
|   | 4                              | Eclipse resection protector, small, 40 mm         | AR-9401-40                        | Eclipse trial head, 49 mm/20 mm | AR-9449-20 |
| Eclipse resection protector, medium, 46 mm  |                                | AR-9401-46  | Eclipse trial head, 51 mm/19 mm   | AR-9451-19                      |            |
| Eclipse resection protector, large, 50 mm   |                                | AR-9401-50  | Eclipse trial head, 51 mm/21 mm   | AR-9451-21                      |            |
| Eclipse resection protector, x-large, 55 mm |                                | AR-9401-55  | Eclipse trial head, 53 mm/20 mm   | AR-9453-20                      |            |
| 5   | Eclipse trial trunnion         | AR-9401-18  | Eclipse trial head, 53 mm/22 mm   | AR-9453-22                      |            |
| 6   | Eclipse coring reamer          | AR-9401-02  | Eclipse trial head, 55 mm/21 mm   | AR-9455-21                      |            |
| 7   | Eclipse centering device       | AR-9401-09  | Eclipse trial head, 55 mm/23 mm   | AR-9455-23                      |            |

## Ordering Information - Eclipse™ Shoulder Instrument Case (AR-9400S)



### Bottom Tray

|    |  |                            |
|----|--|----------------------------|
| 1  | Eclipse screwdriver                                      | AR-9401-03                 |
| 2  | Eclipse trunnion impactor                                | AR-9401-05                 |
| 3  | Eclipse and Univers™ orientation pin for resection guide | AR-9202                    |
| 4  | Handle for resection templates                           | AR-9215-1-02               |
| 5  | Univers and Eclipse handle for head impactor             | AR-9203-13                 |
| 6  | Univers II and Eclipse humeral resection block           | AR-9205                    |
| 7  | Humeral resection template, left/right                   | AR-9200-01L<br>AR-9200-01R |
| 8  | Eclipse coring reamer, secondary                         | AR-9401-02L                |
| 9  | Eclipse and Univers II Resection Guide, small, left      | AR-9401-10                 |
|    | Eclipse and Univers II Resection Guide, small, right     | AR-9401-11                 |
|    | Eclipse and Univers II Resection Guide, large, left      | AR-9401-12                 |
|    | Eclipse and Univers II Resection Guide, large, right     | AR-9401-13                 |
| 10 | Bone graft tamp  | AR-13317                   |
| 11 | Eclipse humeral head extractor                           | AR-9401-17                 |
| 12 | Eclipse trunnion adapter (not pictured)                  | AR-9402                    |

# Eclipse™ Shoulder System: Directions for Use

## Indications

The Arthrex Eclipse Shoulder Prosthesis is indicated for severely painful and/or disabled joint resulting from osteoarthritis or traumatic arthritis.

The humeral component is fixated with a hollow screw and the 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 humeral head and/or humeral neck bone stock.
2. A rotator cuff that is not intact and irreparable.
3. Fractures: including irreducible 3- and 4-part proximal humeral fractures and non-union humeral head fractures of long duration.
4. The use of this device is not suitable as a revision from prior shoulder arthroplasty.
5. Metal allergy.
6. Blood supply limitations and previous infections, which may retard healing.
7. Foreign-body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
8. Any active infection or blood supply limitations.
9. Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period, including severe neuro-arthropathy.
10. Do not use for surgeries other than those indicated.
11. 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. 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.
4. Detailed instructions on the use and limitations of this device, the patient leaflet ([www.arthrex.com/patientleaflets](http://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.
5. 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.
6. Preoperative 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 appropriate Arthrex delivery system is required for proper implantation of the device.
7. A stemmed prosthesis is recommended for soft/weak bone.
  - › It is anticipated that up to 33% of total shoulder candidates lack sufficient bone stock to support a stemless device.
  - › If the hollow screw sizer is unstable in the humerus, then this may indicate that the bone is soft/weak.
  - › If you can depress thumb into humerus, then this may indicate that the bone is soft/weak.
8. 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.

9. An internal fixation device must never be re-used.
10. Do not re-sterilize this device.
11. This is a single use device. 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.
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 processed 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. TPS (titanium plasma sprayed)/CaP coated device  
- Fluid contact other than patient's blood should be avoided to achieve best ongrowth results.
20. A titanium humeral head is not recommended for patients who lack a suspected material sensitivity to cobalt alloy. Titanium humeral heads are intended for patients with suspected cobalt alloy material sensitivity. The wear properties of Titanium and Titanium Alloys are inferior to that of cobalt alloy
21. Follow your institutions policy for safe disposal of all needles and other sharps or medical waste.
22. Biohazard waste, such as explanted devices, needles and contaminated surgical equipment should be safely disposed of in accordance with the institutions policy.
23. Serious incidents should be reported to Arthrex Inc., or an in-country representative, and to the health authority where the incident occurred.

## References

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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 or outcomes.



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



US patent information