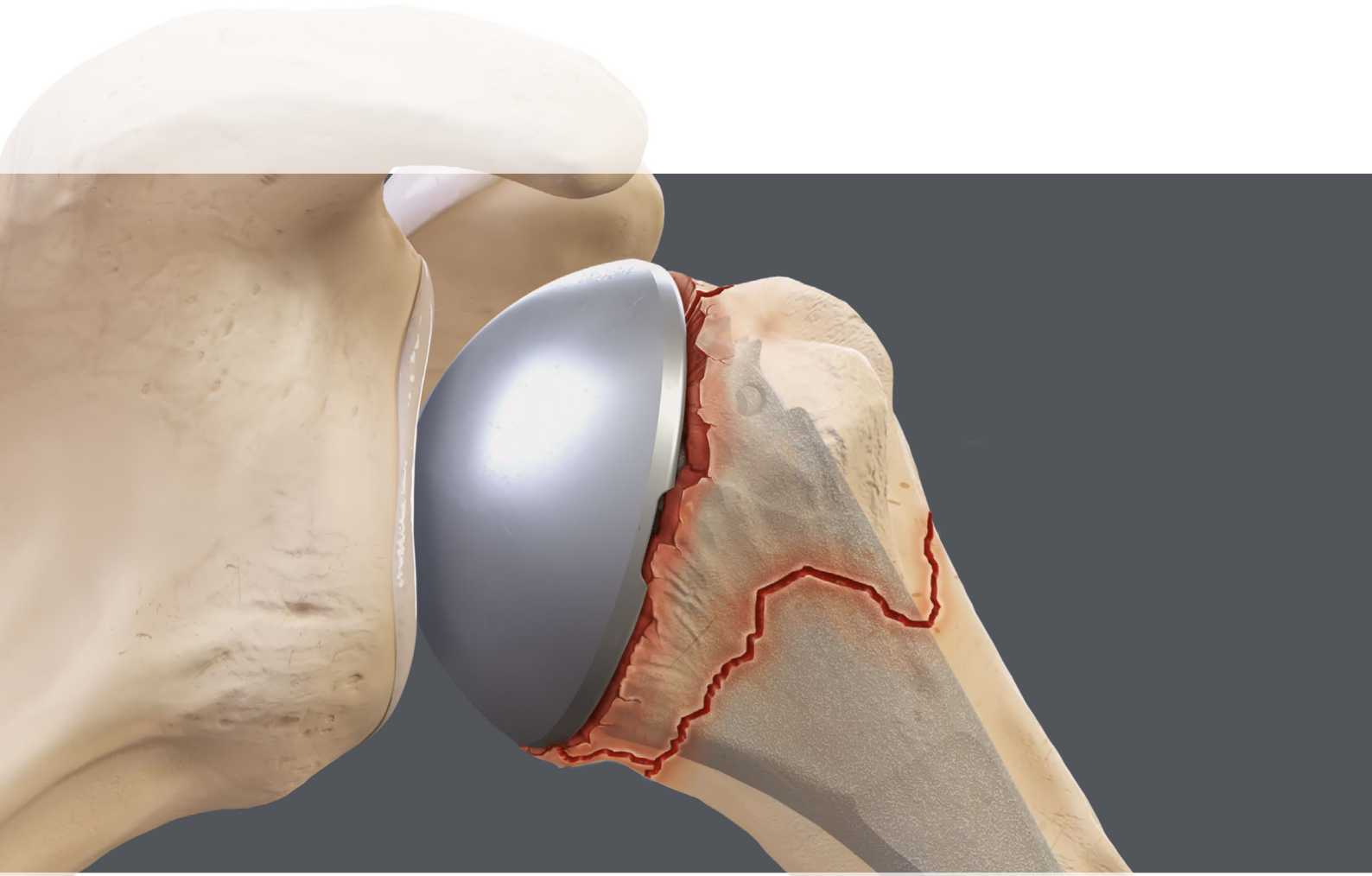
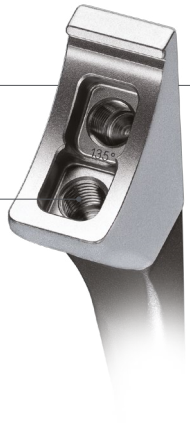
Univers Revers™ Fracture Adapter

Surgical Technique

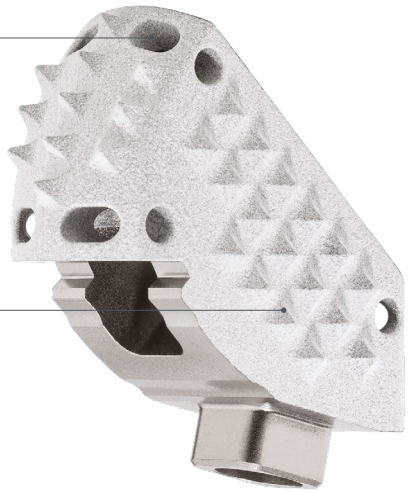


Arthrex®

System Features

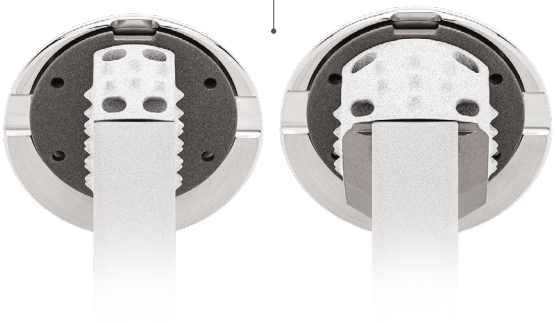


Compatible with all sizes of Univers Revers™ humeral stems



Suture holes for tuberosity fixation

Machine-textured, grit-blasted, and hydroxyapatite (HA)-coated for bony ongrowth



Narrow and wide sizes available:

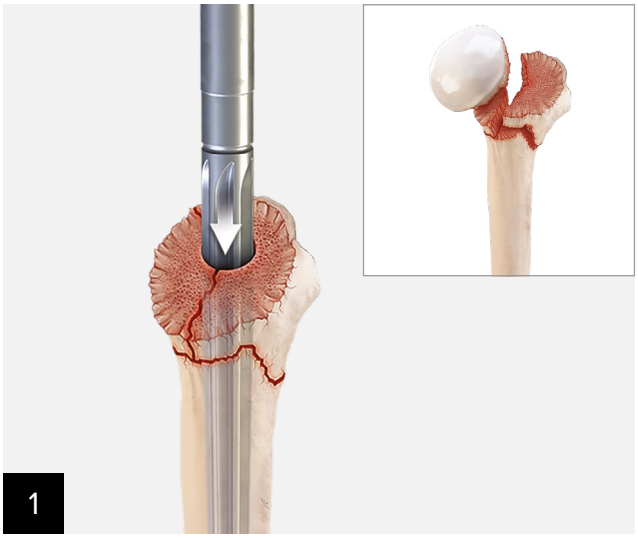
- Size 5: +11 mm
- Sizes 6-9: +9.5 mm
- Sizes 10-15: +7.5 mm

Heights available as standard and +5 mm

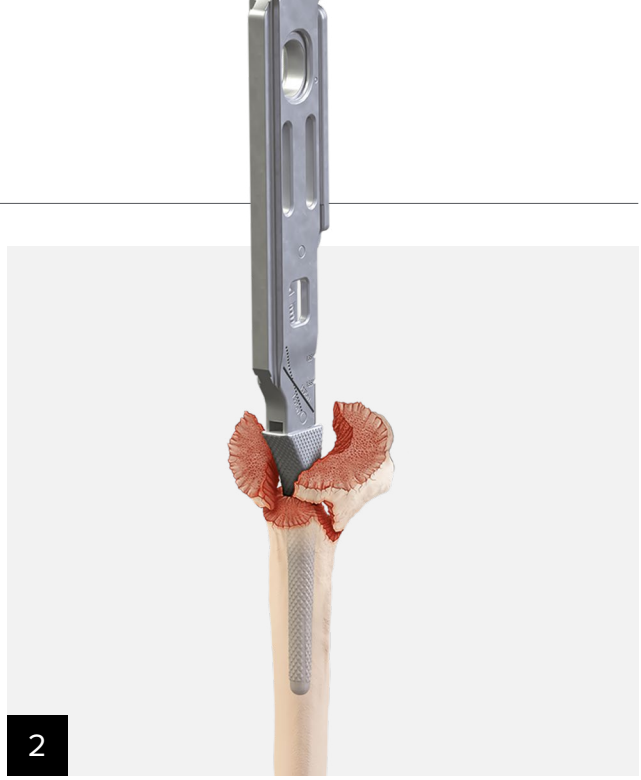
Surgical Approach

- Arthroplasty for proximal humerus fractures is most commonly approached with a deltopectoral incision. Begin the incision at the inferior border of the midsection of the clavicle, proceeding at an angle over the coracoid prominence, and ending at the superolateral aspect of the axillary fold. Incision length varies, depending on the exposure needed for adequate access and visualization of the fracture and glenohumeral joint, and may be influenced by patient-body habitus.
  - The skin incision often lies directly over the cephalic vein, which clearly defines the junction between the deltoid and pectoralis major muscles. If the vein is not readily identified, the prominence of the coracoid marks the deltopectoral interval proximally. Alternatively, the fibrous portion of the superior aspect of the pectoralis tendon at the distal part of the incision can be identified. Although the cephalic vein is typically retracted laterally with the deltoid, it can also be retracted medially based on the number and direction of feeder vessels to the surrounding soft tissue.
- Once the interval is defined, separate the deltoid and pectoralis muscles with a self-retaining retractor, taking care to protect the cephalic vein. Separating the deltoid and pectoralis major muscles so the deltoid muscles is completely free from its origin to its insertion, especially along its deep surface, improves exposures and postoperative motion.
- Identify the conjoined tendon complex, which consists of the short head of the biceps and coracobrachialis muscles just beneath the interval. The muscular portion of the biceps (red) is the most lateral part of the conjoined tendon, with the tendinous portion (white) just medial to the visible muscle.
- Open the clavipectoral fascia just lateral to the “red stripe,” which represents the muscular portion of the short head of the biceps.
- Frequently, the superior 1 cm to 1.5 cm of the pectoralis tendon is released to provide exposure to the inferior aspect of the subscapularis and the anterior circumflex vessels. Carefully identify neurovascular structures potentially damaged by the fracture prior to fracture manipulation.
- Identify and debride fracture fragments and evacuate fracture hematoma. Identify the long head of the biceps and, if necessary, tenodese it to the pectoralis major.
- If the lesser tuberosity is fractured, place sutures medially in the subscapularis tendon. If it is not fractured and in a singular piece with the fractured humeral head, perform a lesser tuberosity osteotomy (LTO) and place 1.3 mm SutureTape in the medial portion of the subscapularis tendon as traction sutures for manipulation and reduction.
  - Alternatively, if the fracture plane of the greater tuberosity is within 1 cm of the bicipital groove, that fragment (lesser tuberosity and small piece of the greater tuberosity) can act as an expanded LTO.
- Additional sutures can be placed in the greater tuberosity for improved control and reduction assistance.
- Retrieve the humeral head through the opening between the supraspinatus/greater tuberosity and subscapularis/lesser tuberosity.
- Carefully evaluate the glenoid and intra-articular space and remove remaining bone fragments before preparing the humerus.

Implantation

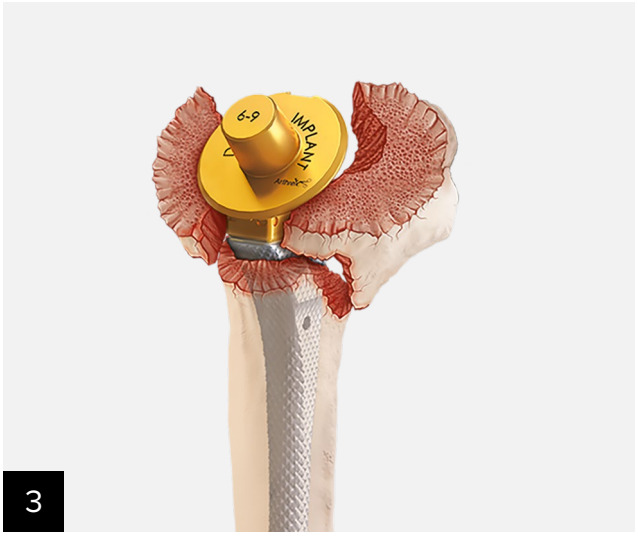


Progressively ream the humeral canal with IM reamers to achieve desired fit.

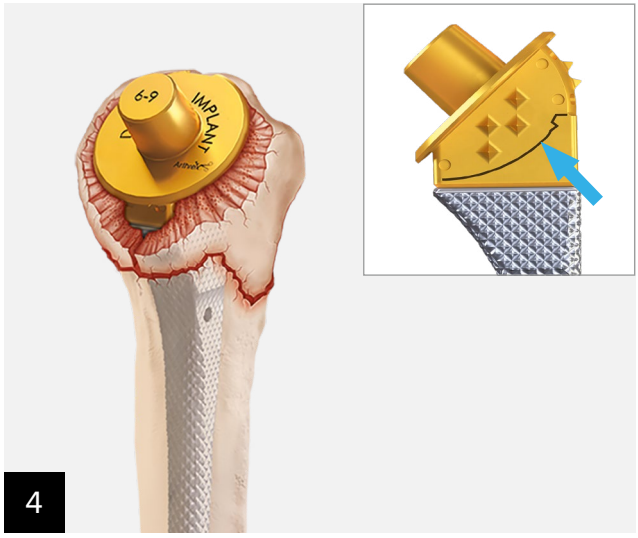


Attach the broach handle to the 6 mm broach. Progressively broach to the desired fit. Version rods may be attached to align with the forearm at 20° and 40° of retroversion. Proper implant fit and height will be determined both with the broach position and fracture adapter selection as shown in steps 3 and 4. Detach the handle and leave the broach in the IM canal to facilitate trialing.

Notes: In smaller patients, a monoblock 5 mm broach should be considered. There are 2 adapter heights available for sizes 6-15.



Attach the fracture adapter trial to the broach.

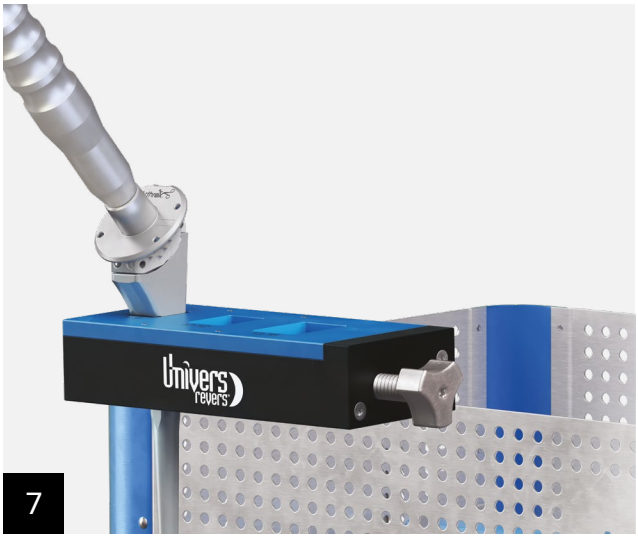


The fracture adapter trial can be used to visualize appropriate stem height and reattachment of the fractured tuberosities. The trial marking shows the top edge of the humeral implant (inset).

Once the proper stem and fracture adapter sizes have been determined, assemble the humeral construct on the back table. Place the stem into the assembly station and clamp it into place. Place the fracture adapter onto the stem.

Tighten the fracture adapter screw in place to the Univers Revers™ humeral stem using the modular screw driver, torque indicator, and ratcheting handle. The screw should be tightened to 3 Nm on the torque indicator.

Note: Do not exceed 5 Nm.
Note: The size 5 fracture adapters (inset) are monoblock such that only one screw needs to be tightened as shown here, so skip steps 7 and 8.

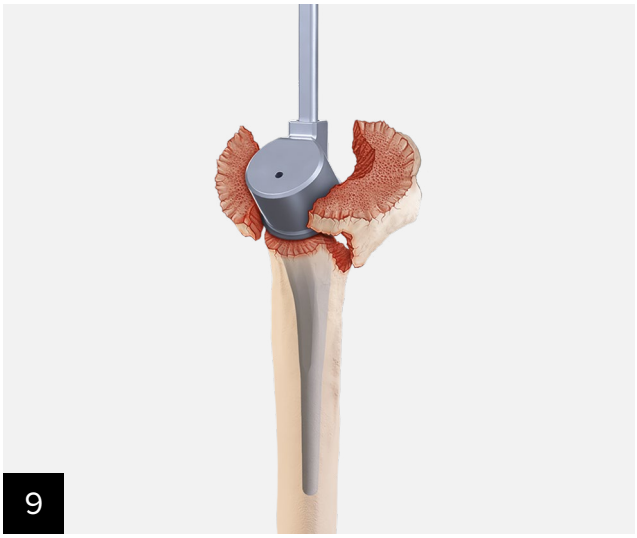


Snap the trunnion into the fracture adapter. This can be done manually or using the instrument as shown.

Note: Do not impact the trunnion into place.

Tighten the trunnion screw with the Univers™ II torque driver to lock the trunnion to the assembly.

Note: The screw should be tightened to the superior screw line, which is labeled “SUP” (see inset).



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Place the humeral construct in the humeral canal. Use the stem impactor to implant the humeral assembly. Version rods can be attached to align with the forearm between 20° and 40° of retroversion.

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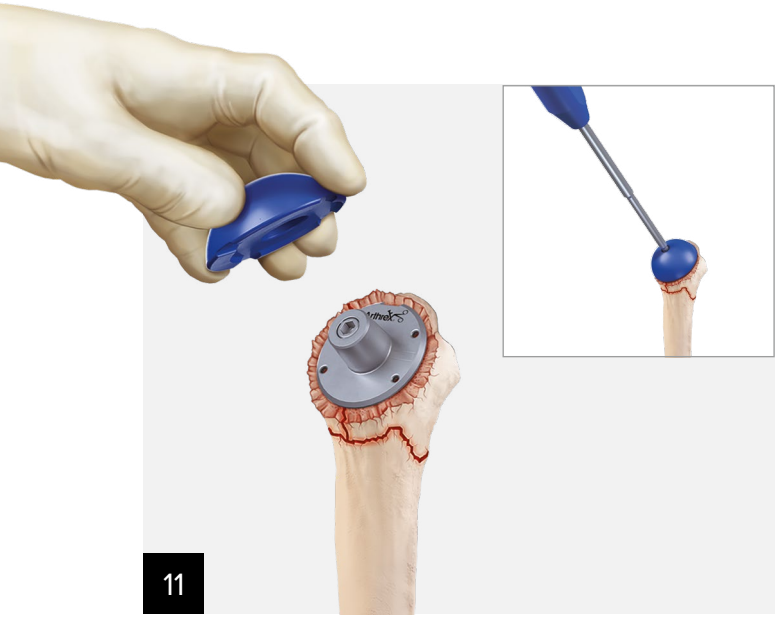
Optional: To compress the tuberosities to the fracture adapter, place the sutures through the trunnion and/or fracture adapter suture holes.

Note: #5 FiberWire® suture is recommended.



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Attach the appropriate Univers™ II trial head and use the trial driver to adjust the 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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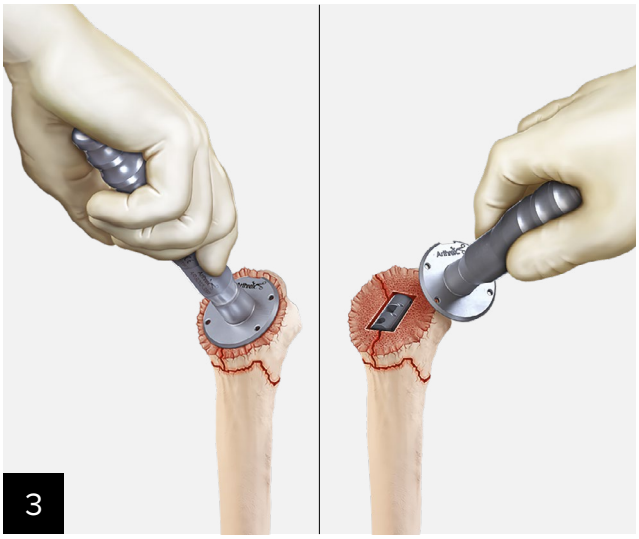
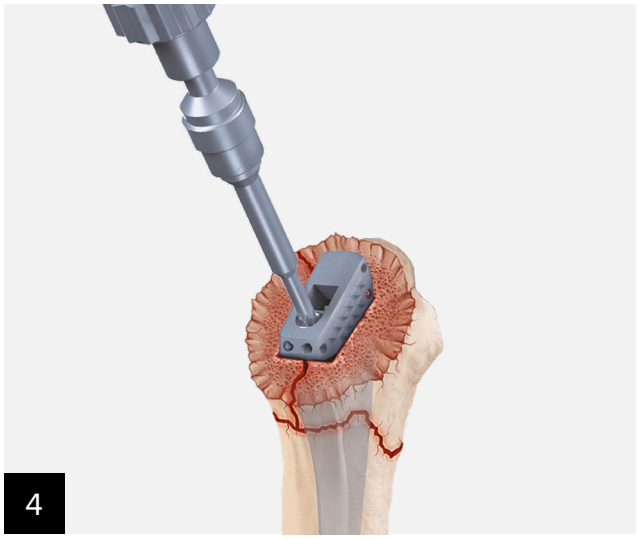
After trial reduction, remove the trial head and clean and dry the Morse taper. Impact the Univers II implant humeral head onto the humeral stem fracture adapter using the head impactor.

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

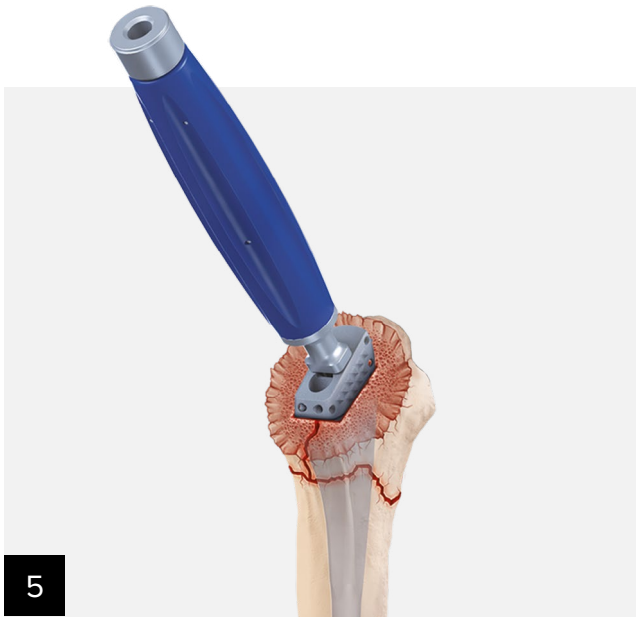
Remove the locking screw to facilitate removal of the trunnion. It may be helpful to use the T-handle torque driver.



Thread the trunnion extractor into the threaded hole. Disengage the trunnion by rolling the wrist in a posterior to anterior motion, releasing the locking connection.

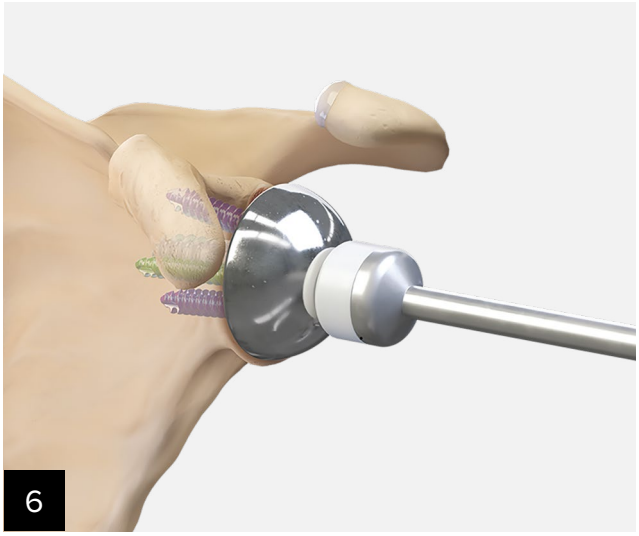


Loosen the fracture adapter locking screw.



Remove the fracture adapter with the extraction device. Osteotomes can be used to break away bony ongrowth, if necessary.

Note: Prior to attaching to the implant, insert the extractor shaft into the extractor, flat end first. Turning the collar will lock the extractor to the implant.



Implant the glenoid implants per LT1-00112-EN (Univers Revers™ Modular Glenoid System Surgical Technique) or LT1-000000-en-US (Universal Glenoid™ Convertible Baseplate Surgical Technique).

Clear any bone that may interfere with required fixation of the SutureCup to the humeral stem. Attach the screw alignment guide into the SutureCup (inset) to ensure the screwdriver is properly aligned with the axis of the screw. Next, insert the post/screw of the SutureCup into the appropriate slot of the stem (135° or 155°). Tighten the screw to at least 3 Nm with the short modular T-15 screwdriver, torque-indicating adapter, and ratcheting handle.

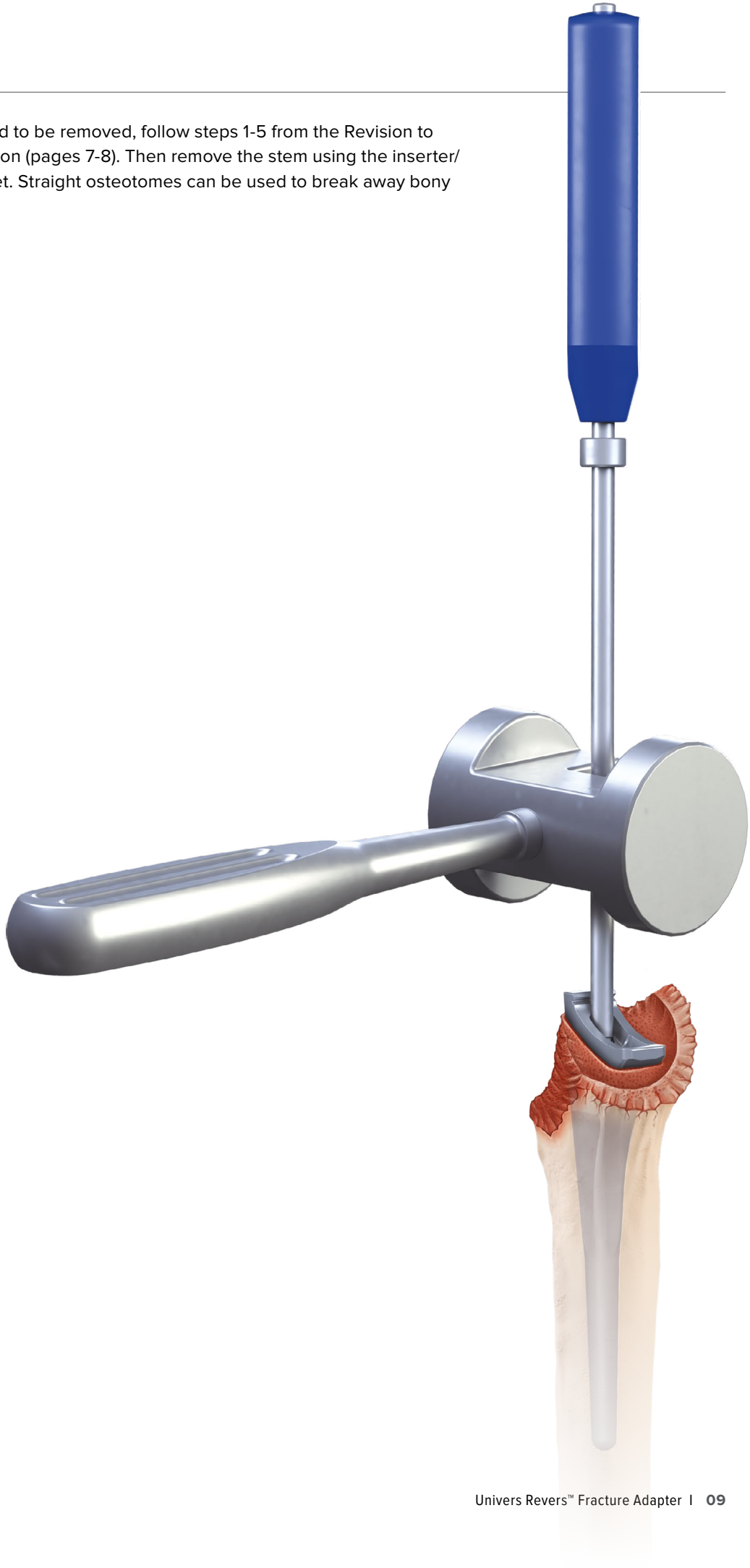
Note: Torque must not exceed 5 Nm.

Perform a second trial reduction with the trial liner, trial spacer (if applicable), and definitive glenosphere. After assessing stability and ROM, connect the definitive spacer (if required) with the short modular T-15 screwdriver, torque-indicating adapter, and ratcheting handle. Tighten the screw to at least 3 Nm. Last, impact the liner (inset).

Note: Torque must not exceed 5 Nm.
Note: Spacers should be used only in combination with +3 mm liners.

Explantation

If all humeral implants need to be removed, follow steps 1-5 from the Revision to Reverse Arthroplasty section (pages 7-8). Then remove the stem using the inserter/extractor and slotted mallet. Straight osteotomes can be used to break away bony growth, if necessary.



Ordering Information

Implants

Product Description	Item Number
Fracture Adapter, sizes 6-9	AR-**9501-FX6N**
Fracture Adapter, sizes 6-9, wide	AR-**9501-FX6W**
Fracture Adapter, sizes 6-9, tall	AR-**9501-FX6NT**
Fracture Adapter, sizes 6-9, wide, tall	AR-**9501-FX6WT**
Fracture Adapter, sizes 10-15	AR-**9501-FX10N**
Fracture Adapter, sizes 10-15, wide	AR-**9501-FX10W**
Fracture Adapter, sizes 10-15, tall	AR-**9501-FX10NT**
Fracture Adapter, sizes 10-15, wide, tall	AR-**9501-FX10WT**
Fracture Adapter, size 5	AR-**9501-FX5N**
Fracture Adapter, size 5, wide	AR-**9501-FX5W**
Fracture Adapter Trunnion	AR-**9501FTK**

Instruments

Product Description	Item Number
Humeral Reamer T-Handle	AR-**9502-15H**
Humeral Broaches/Trial, modular	AR-**9510-XXM**
Lever-Locking Broach Handle	AR-**9510-2**
Humeral Assembly Station	AR-**9532**
Ratcheting Modular Handle	AR-**1999HH**
Torque-Indicating Adapter	AR-**9545-T15H**
T15 Driver Shaft, short	AR-**9545-T15-01**
Humeral IM Reamers	AR-**9202-XXH**
Univers™ II Torque Driver	AR-**9224**

Consumables

Product Description	Item Number
#5 FiberWire® Suture, 38 in (blue)	AR-**7210**
#5 FiberWire Suture, 38 in (white)	AR-**7215**
Spring Eye Needle, 60 mm	AR-**7283**

Products advertised in this brochure/surgical technique guide may not be available in all countries. For information on availability, please contact Arthrex Customer Service or your local Arthrex representative.

Ordering Information

Fracture Adapter Instrument set (AR-9501-FXS)

Product Description	Item Number
Trial, Fracture Adapter, size 5, narrow	AR-**9510-FX5N**
Trial, Fracture Adapter, size 5, wide	AR-**9510-FX5W**
Trial, Fracture Adapter, sizes 6-9, narrow	AR-**9510-FX6N**
Trial, Fracture Adapter, sizes 6-9, wide	AR-**9510-FX6W**
Trial, Fracture Adapter, sizes 6-9, narrow, tall	AR-**9510-FX6NT**
Trial, Fracture Adapter, sizes 6-9, wide, tall	AR-**9510-FX6WT**
Trial, Fracture Adapter, sizes 10-15, narrow	AR-**9510-FX10N**
Trial, Fracture Adapter, sizes 10-15, wide	AR-**9510-FX10W**
Trial, Fracture Adapter, sizes 10-15, narrow, tall	AR-**9510-FX10NT**
Trial, Fracture Adapter, sizes 10-15, wide, tall	AR-**9510-FX10NW**
Fracture Adapter Impactor	AR-**9510-F1**
Fracture Adapter Extractor	AR-**9510-F2**
Fracture Adapter Extractor Shaft	AR-**9510-F3**
Fracture Adapter Instrument Case	AR-**9501-FXC**

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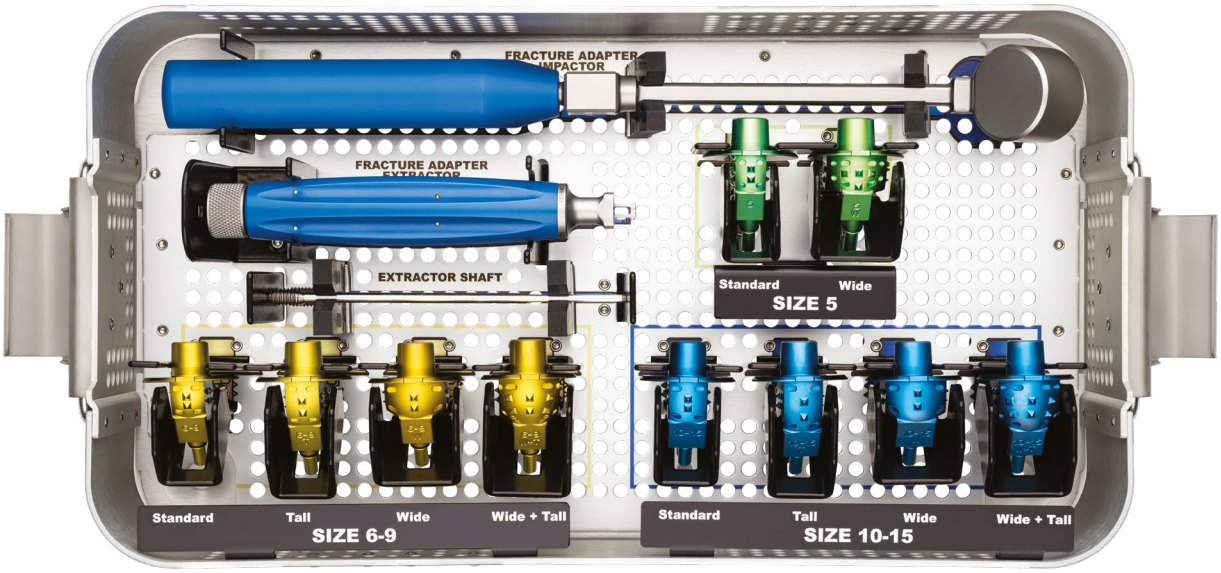


Key Dimensions

Humeral Stem Dimensions (mm)

Stem Size	Length L, L_{Rev}	TØ	A/P	M/L
5 (modular)	99, -	5.5	11.5	23.3
6	111, 180	6.0	12.6	25.4
7	115, -	7.8	12.6	25.4
8	119, -	8.7	12.6	26.4
9	123, 180	9.5	12.6	27.4
10	127, -	10.4	14.5	28.4
11	131, -	11.2	14.5	29.3
12	135, 180	12.0	14.5	30.3
13	139, -	13.0	17.5	31.4
14	143, -	13.8	17.5	32.4
15	147, -	14.6	17.5	33.3

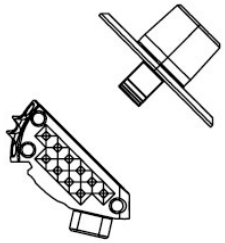
Fracture Adapter Dimensions (mm)

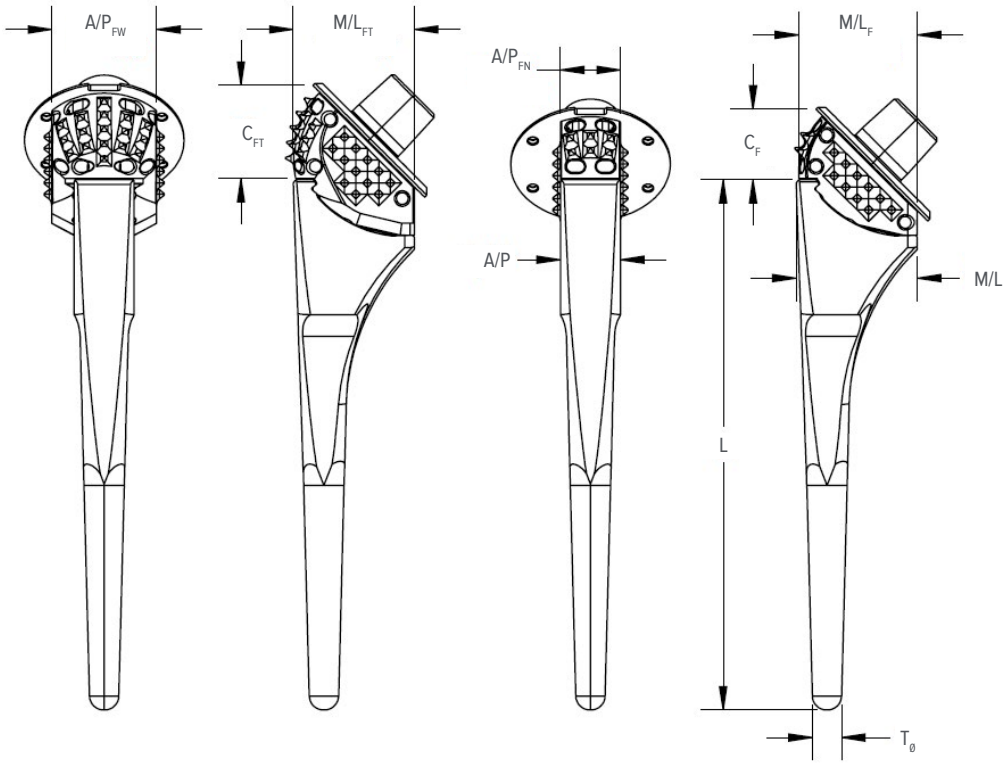
Size	Height C_F, C_{FT}	Width M/L_F,M/L_{FT}	Thickness A/P_{FN}, A/P_{FW}
5	14.5, -	22.8, -	11.5, 22
6-9	14.8, 19.8	24.9, 25.4	12.6, 22
10-15	14.8, 19.8	27.7, 27.7	14.5, 22

Trunnion

Fracture Adapter:

- Sizes 5, 6, and 10
- Standard and tall
- Narrow and wide





Indications

The Arthrex Fracture Adapter Hemi Shoulder Prosthesis is indicated for severe pain or significant disability resulting from degenerative, rheumatoid, or traumatic disease or injury of the glenohumeral joint. This includes traumatic or pathological conditions of the shoulder resulting in fracture of the glenohumeral joint, including impression fractures, comminuted fracture, humeral head fracture, displaced 3-or-4-fragment proximal head fractures, avascular necrosis of the humeral head, and fractures of the anatomical neck.

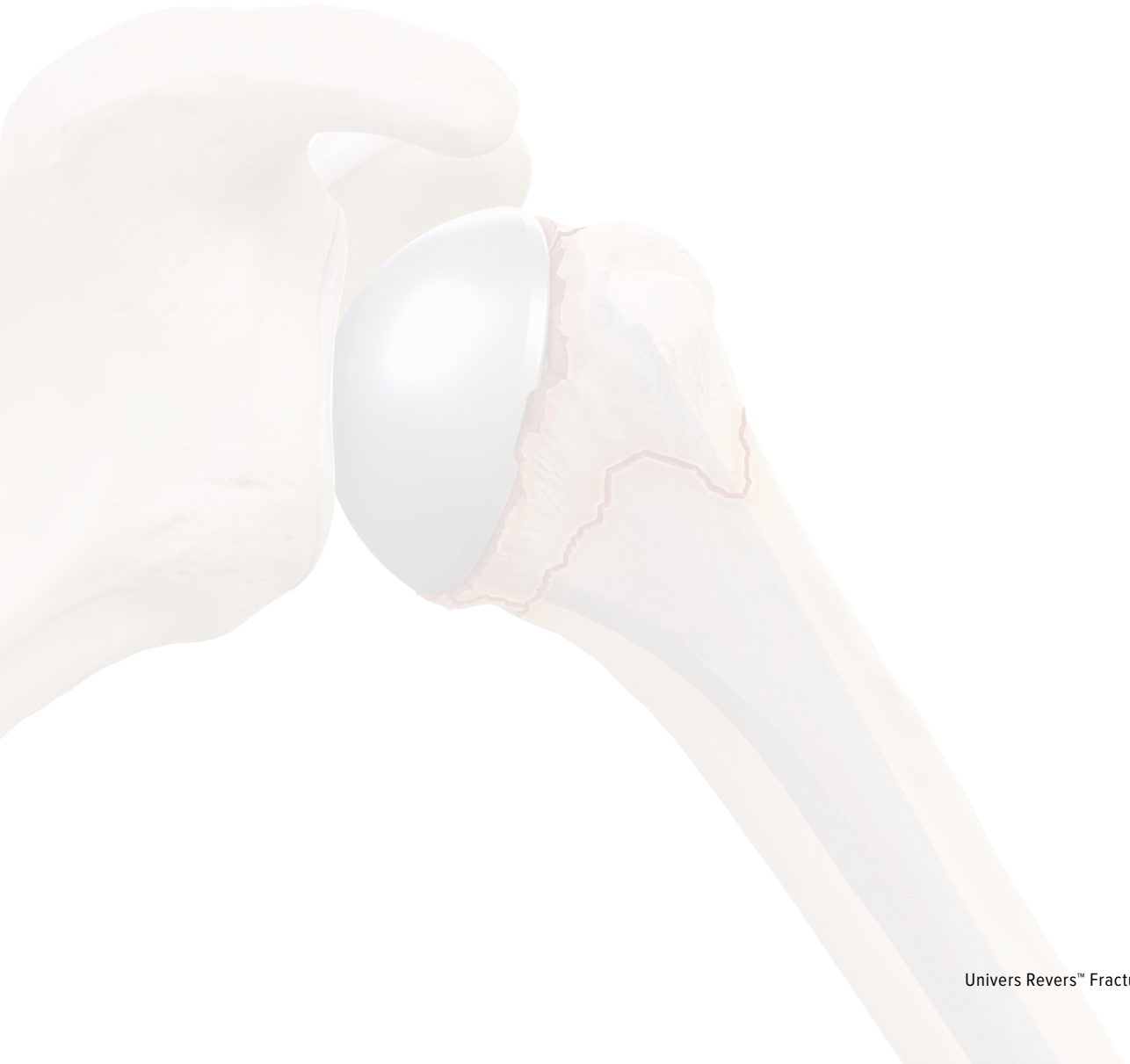
The Arthrex Fracture Adapter Hemi Shoulder Prosthesis is for uncemented use. The device may be used for hemi or total shoulder repair, utilizing the appropriate Arthrex Univers™ Glenoid component, which is to be cemented in place.

Contraindications

- Insufficient quantity or quality of bone.
- Blood supply limitations and previous infections that may retard healing.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
- Any active infection, including severe neuro-arthropathy.
- Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
- 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.
- Do not use for surgeries other than those indicated above.

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. 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.
5. 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.
6. 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.
7. 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.
8. 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.
9. Do not re-sterilize this device.
10. 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.
11. Only Arthrex measuring systems, instruments, and trial prostheses should be used for the implantation procedure.
12. Endoprostheses may not be altered mechanically or changed in any other way.
13. Do not implant any parts that have been altered from their original state, scratched or damaged.
14. 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 the artificial joint.
15. An infection in an artificial joint may lead to implant removal.
16. This device should only be used in conjunction with other implants designed specifically for use with this system.
17. Biohazard waste, such as explanted devices, needles and contaminated surgical equipment should be safely disposed of in accordance with the institutions policy.
18. Serious incidents should be reported to Arthrex Inc., or an in-country representative, and to the health authority where the incident occurred.



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.

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