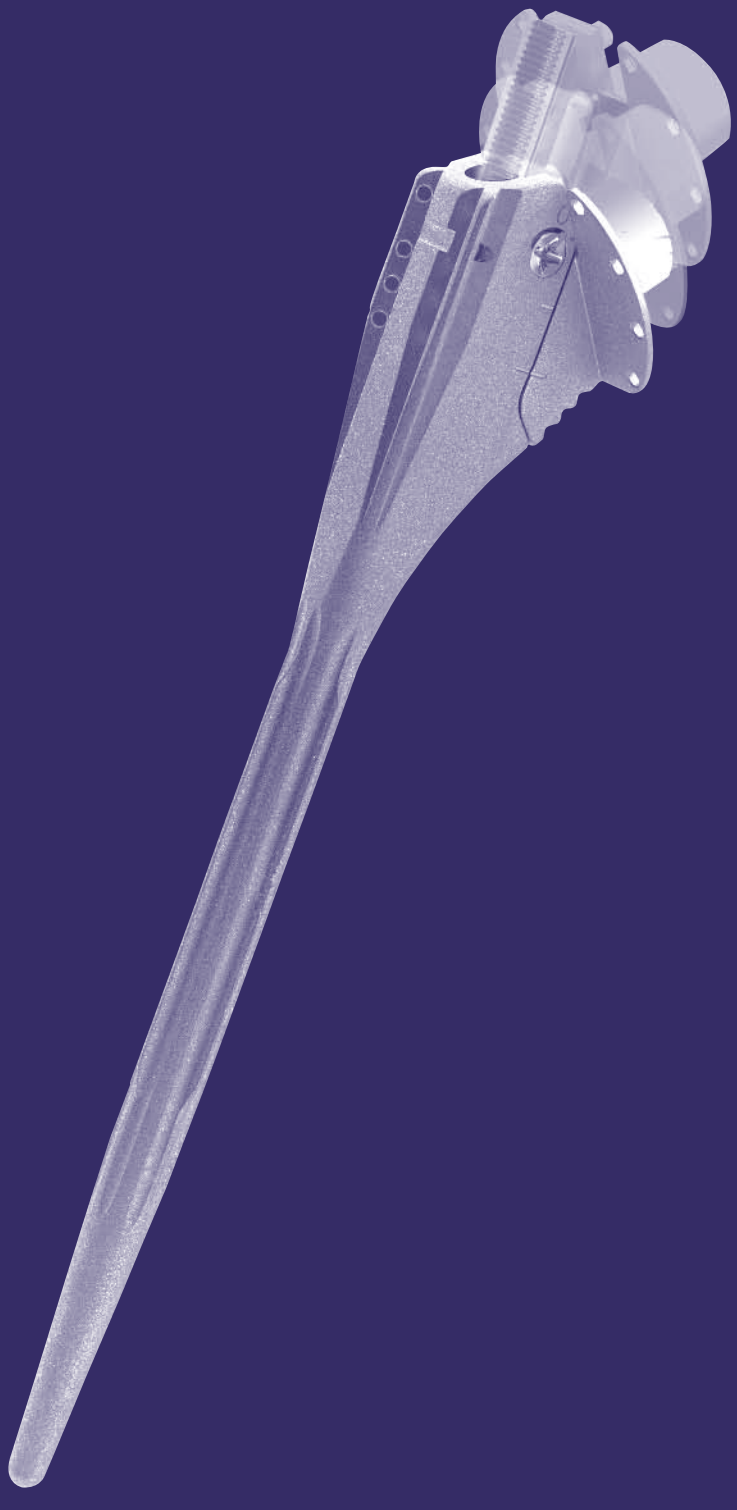
Univers™

SHOULDER FRACTURE SYSTEM

SURGICAL TECHNIQUE



UNIVERS SHOULDER FRACTURE SYSTEM

DESIGN RATIONALE

Conventional shoulder implants are frequently not suitable for optimal reconstruction of proximal humeral fractures because of the loss of anatomic orientation features and the inability to adequately reduce and securely fix the displaced tuberosity fragments. Through the unique design of the implant and instrumentation, the Arthrex Univers Shoulder Fracture System will address all of the issues relating to stabilization of the humeral prosthesis, accurate positioning of the humeral head combined with a straightforward reproducible protocol to accurately reduce and fix the tuberosities.

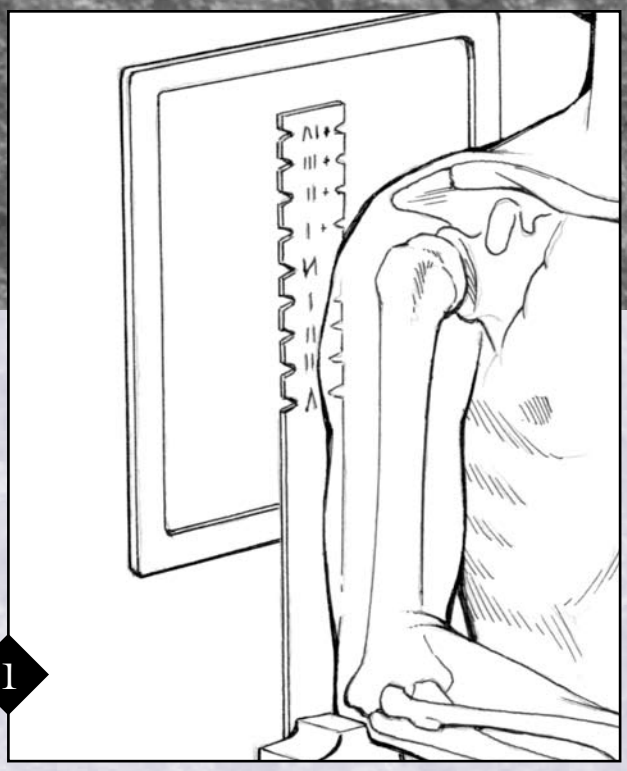
The system includes:

- A preoperative and intraoperative measuring guide to accurately set the humeral head height without the need for technically demanding and complicated fracture jigs.
- Intraoperative adjustable humeral head prosthesis for secondary correction of the implant head height.
- Lateral fin positions with suture eyelets for anatomic reconstruction of the tuberosities.
- Multiple suture eyelets on the Trunion Flange to prevent secondary displacement of the tuberosities.
- Smooth chamfered dimples in the medial aspect of the humeral stem to allow suture fixation of the tuberosities fragments without causing fraying and breakage.
- Variable eccentric adjustment of the humeral head for anatomic reconstruction.

INDICATIONS

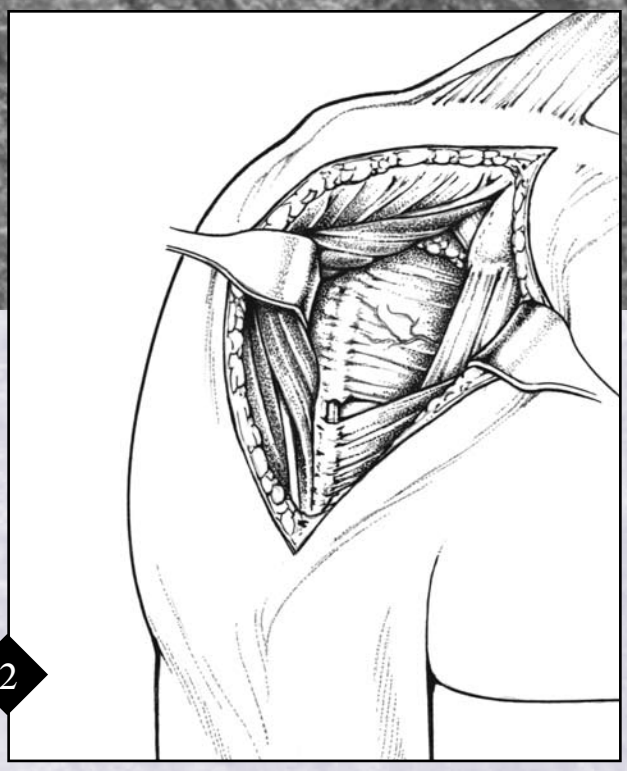
The Univers fracture prosthesis is indicated for treatment of severe pain or significant disability resulting from degenerative, rheumatoid, or traumatic disease or injury of the glenohumeral joint. These indications would include traumatic or pathologic conditions of the shoulder resulting in fractures of the glenohumeral joint, comminuted fractures, humeral head fractures, displaced three or four part proximal humerus fractures, avascular necrosis of the humeral head and fractures of the anatomic neck.

The shoulder humeral fracture prosthesis is designed for cemented or cementless use. This device may be used for hemi or total shoulder arthroplasty using the appropriate Univers Glenoid component, which must be cemented.



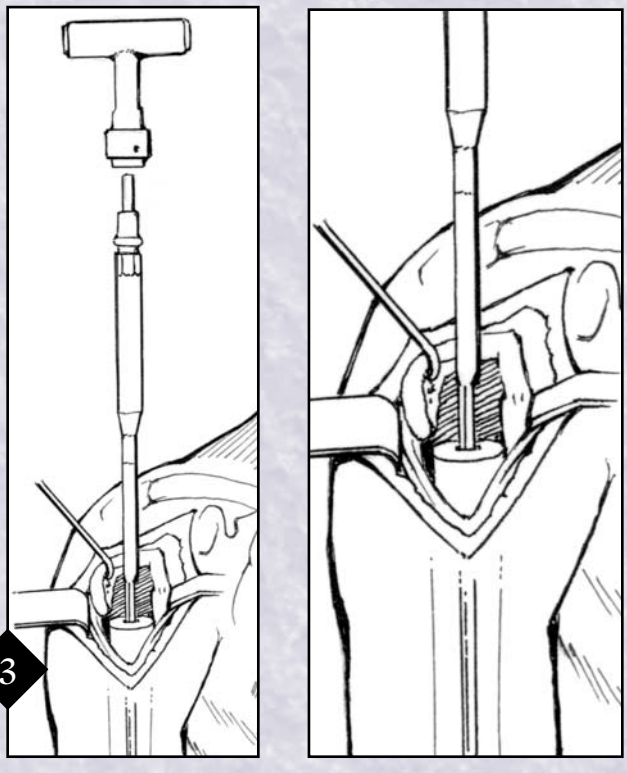
1

The Preoperative Measuring Guide is placed on the contralateral shoulder and a true A/P image of the humerus, in the neutral position, is obtained to determine the appropriate height of the humerus.



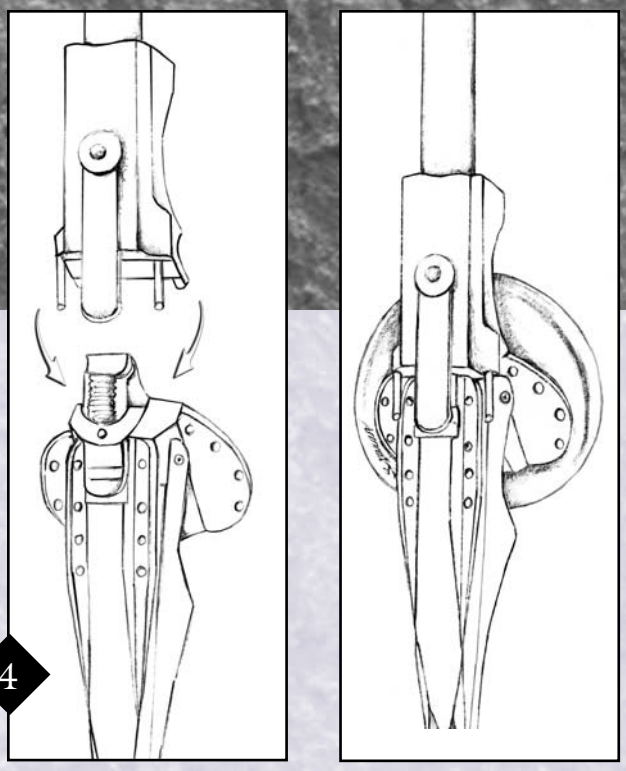
2

The shoulder is prepped to ensure free mobility of the limb including the shoulder and elbow joint. Incision and dissection is carried out through a deltopectoral approach to protect surrounding soft tissues and neurovascular structures from injury. As dissection is carried out to the level of the fracture the subscapularis muscle and tendon attachment to the humerus is identified and a series of #2 FiberWire® sutures are placed into the medial portion of the subscapularis muscle and tendon. Once the subscapularis muscle has been taken down, with or without the presence of a bony component, the arm may be externally rotated further exposing the fracture pattern. Appropriate tag sutures are placed in the respective tuberosity components and the humeral head is removed and sized prior to humeral canal preparation.



3

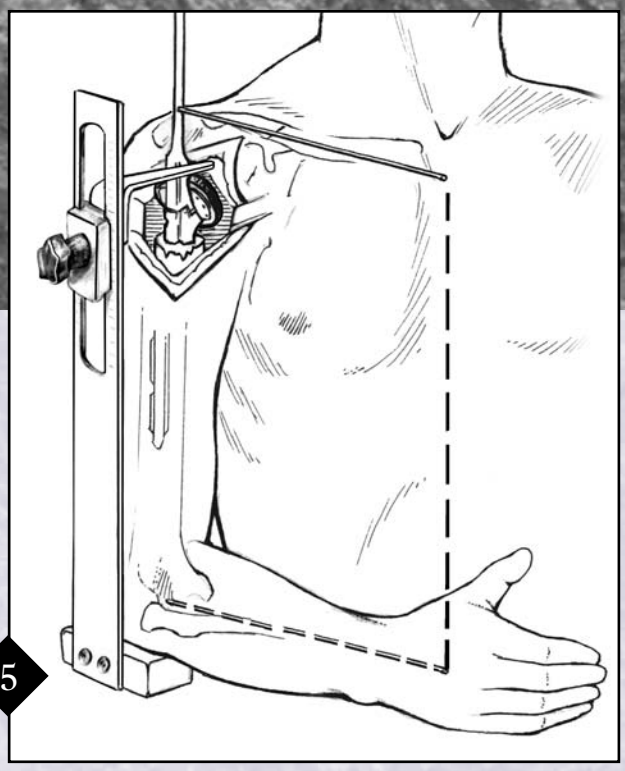
Attach the T-Handle to the 8 mm reamer. Advance the reamer down the humeral canal until the first circumferential groove is even with the shaft fracture line. Continue reaming with progressively larger reamer sizes until resistance is felt from the cortical bone. For noncemented application, select the implant which corresponds to the final reamer size. If cementing the stem is desired, an implant equal to or one size smaller than the final reamer size is recommended. Two holes are drilled in the humeral shaft on either side of the bicipital groove 1 cm inferior to the fracture, accommodating later suture placement and tuberosity repair.



4

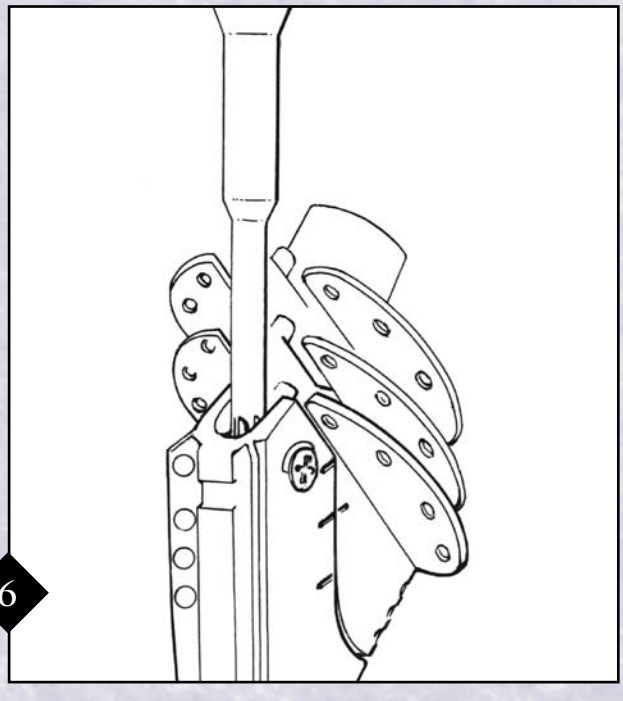
The appropriate size Stem Impactor is attached to the Fracture Stem by aligning the two rod-shaped devices on the Impactor to fit snugly behind the lateral fins of the stem. The Trial Head is now applied to the implant and the Version Rod is attached to the Stem Impactor.

Note: The Trial Heads have offset positions for either the left or right shoulder. The position adjacent to the hash mark results in an average posterior offset. More or less offset may be selected to reproduce symmetrical tension on the rotator cuff.



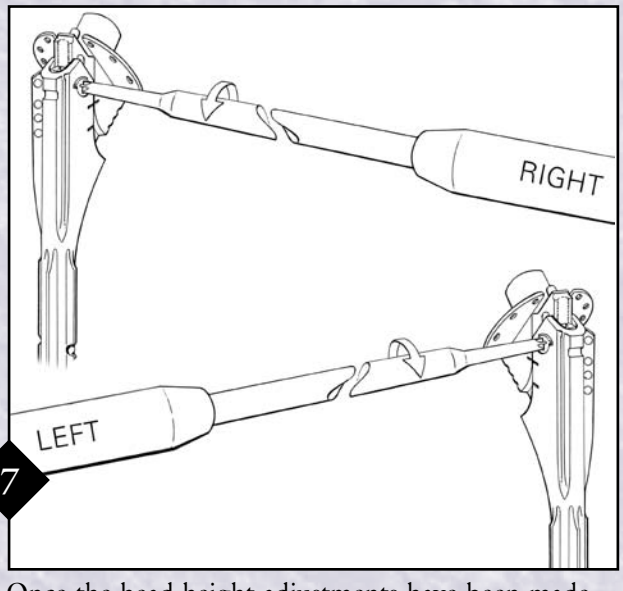
5

The Intraoperative Measuring Guide is assembled and preset to the height taken from the Preoperative Measuring Guide. When the elbow is positioned onto the Interoperative Measuring Guide, the metal pointer will indicate the correct height the implant should be. The Version Rod is aligned with the forearm to establish 20° of retroversion. A mallet is used to fully seat the implant. The implant head height can now be adjusted.



6

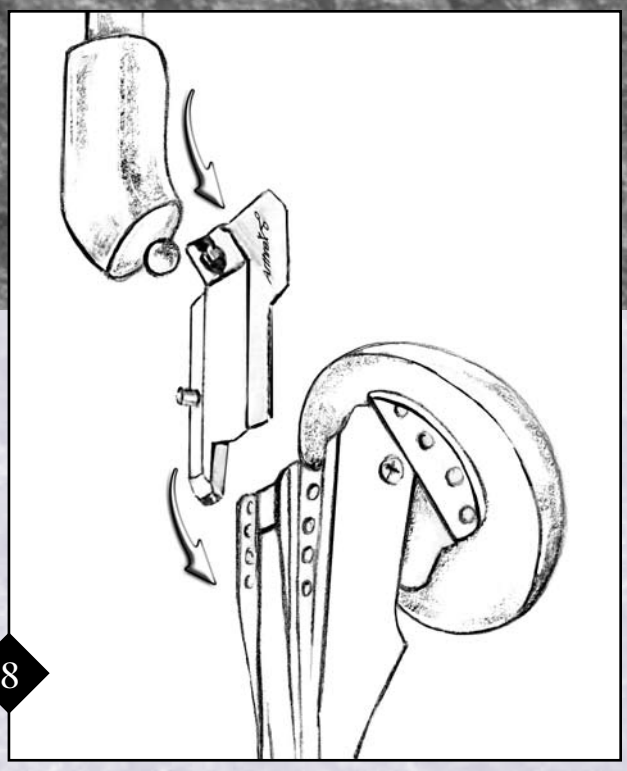
From the initial (middle) position the prosthesis head can be adjusted in a superior and inferior direction, a total of 15 mm (7.5 mm superior and 7.5 mm inferior). This will allow the surgeon to fine-tune the head height from the initial insertion position. The head height is adjusted by rotating the jack-screw located in the proximal portion of the implant using the large screwdriver. Prior to locking the head height, a trial reduction is performed.



7

Once the head height adjustments have been made, the locking screw is tightened to lock the jack-screw mechanism. A side specific locking screwdriver labeled "left" or "right" that corresponds with the operative shoulder is selected from the instrument tray. The design of the uni-directional locking screwdriver prevents rotation of the locking mechanism in a direction contrary to the intended locked position. The appropriate locking screwdriver is inserted into the set screw and rotated until it is tight.

Note: Once the locking screw has been tightened, it may not be possible to unlock for further adjustments.



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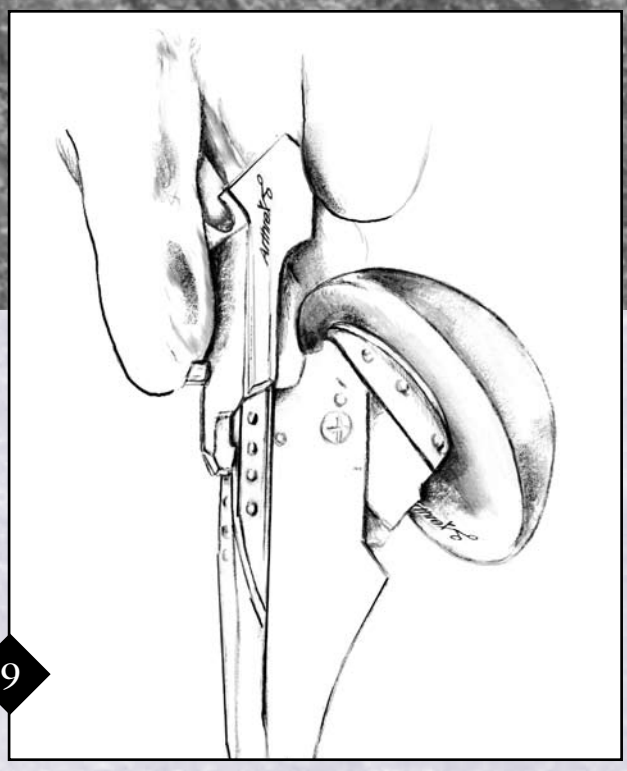
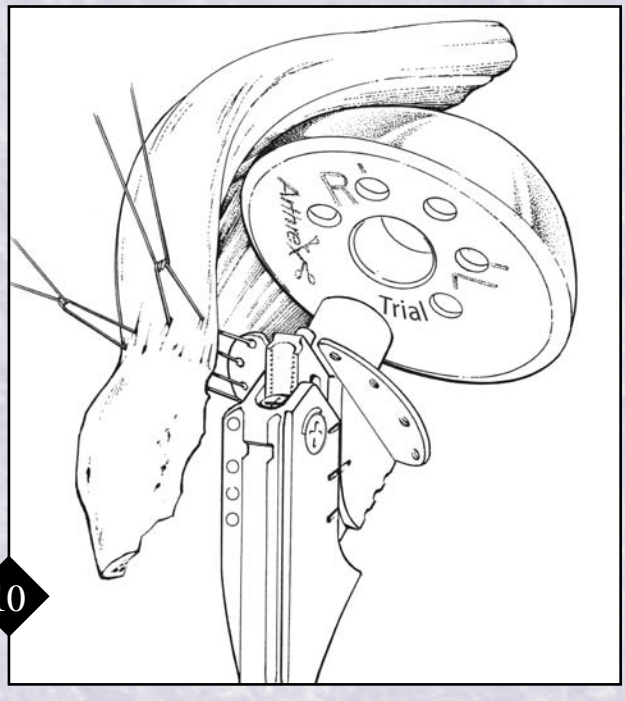
Should the Humeral Stem need to be removed, the Extractor/Adapter is attached to the superior lateral corner of the Stem. The nipple end of the Slap Hammer slides into the receiving slot on the Extractor/Adapter.



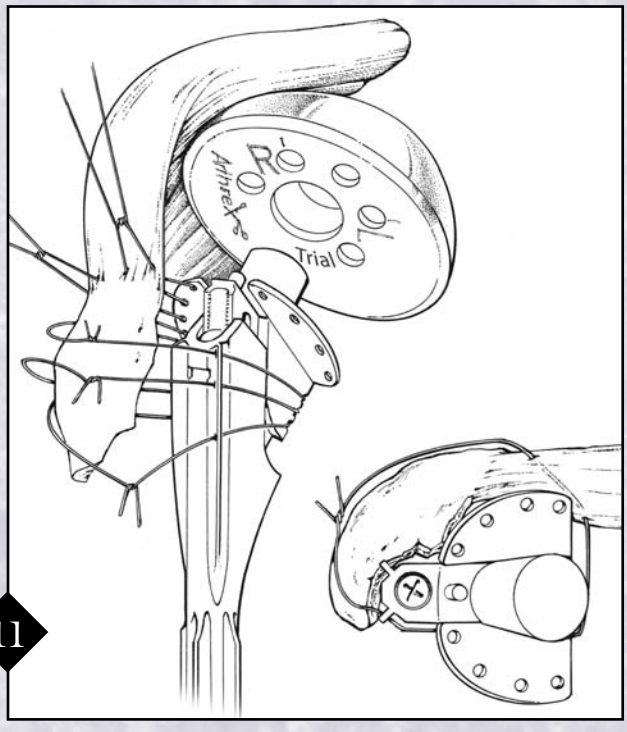
9

The Extractor/Adapter is removed from the stem by depressing the small spring-loaded pin on the side of the Extractor/Adapter.



10

The Trial Head is removed to access the Trunion Flange holes. Two FiberWire sutures are threaded through the posterior Trunion Flange holes and sutured through the bone tendon junction of the major tuberosity. These sutures prevent the tuberosity from moving behind or over the prosthetic head. The Trial Head can be reattached to ensure that the appropriate soft tissue tension is achieved.



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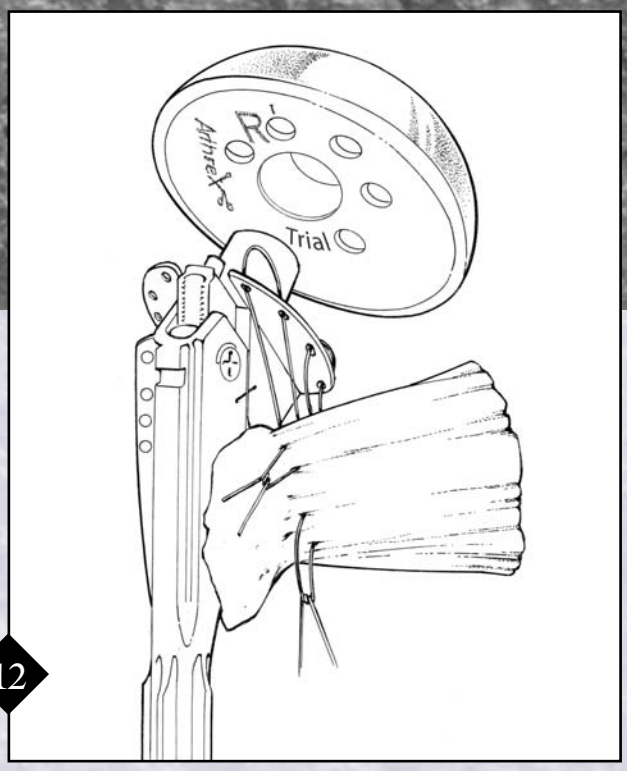
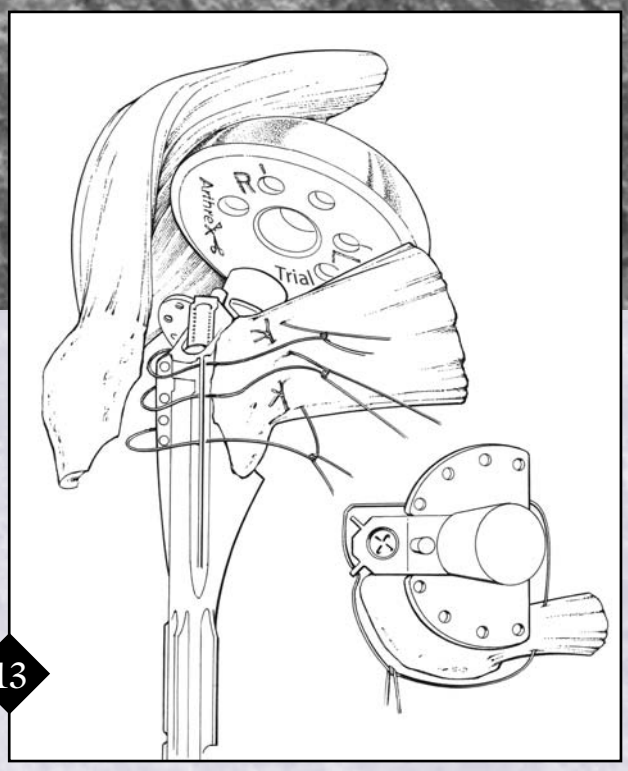
Three FiberWire sutures are positioned through the tendon-bone junction and around the medial prosthesis neck. Each suture is then fed through one of the holes in the lateral fin.



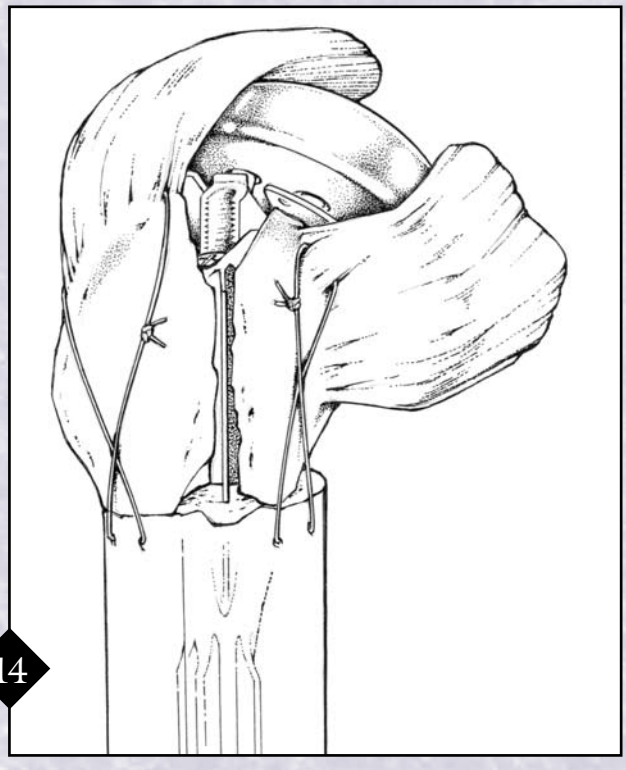
12

The lesser tuberosity is reduced with two FiberWire sutures through the Trunion Flange holes and through the tendon/bone junction. Autogenous bone graft may be taken from the humeral head with a small curette and packed between the humeral shaft, the tuberosity and the implant.



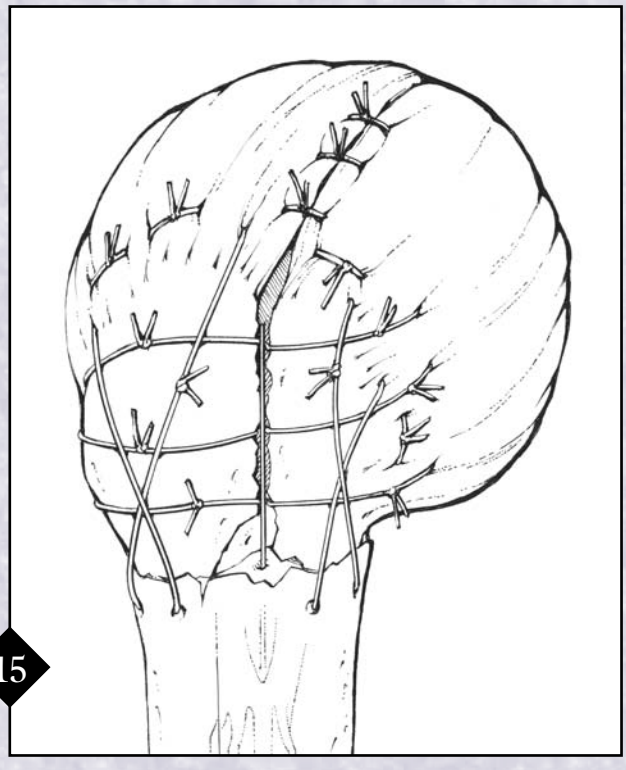
13

The lesser tuberosity is positioned around the prosthesis neck and fixed with three FiberWire sutures through the bone/tendon junction. These sutures are threaded through the lateral fin holes where the major tuberosity is already fixed. Prior to tying all the sutures, the Trial Head is adjusted to the appropriate offset position. The prosthetic head is then opened, poitioned with selected offset and impacted onto the Humeral Stem. Sutures are then tied securely.



14

FiberWire sutures are used to secure the shaft to the tuberosities using a tension band weave. These vertical tension band sutures are used to ensure the tuberosity fragments are mechanically attached to the humeral shaft to prevent proximal migration.



15

The rotator interval is sutured and a biceps tenodesis is performed.

Ordering Information

Univers Fracture Instrument Set	AR-9201S

Accessories:

#2 FiberWire, 38 inches (blue) w/Tapered Needle, 26.5 mm, 1/2 circle, qty. 12	AR-7200
#2 FiberWire, 38 inches w/Reverse Cutting Needle, 36.6 mm, 1/2 circle, qty. 12	AR-7202
#5 FiberWire, 38 inches (blue)	AR-7210
#5 FiberWire, 38 inches w/Conventional Cutting Needle, 48 mm, 1/2 circle, qty. 12	AR-7211
FiberWire Tensioner	AR-1929
FiberWire Suture Kit	AR-7219

Implants:

Humeral Stem, fracture, 8 mm x 158 mm	AR-9100-08F
Humeral Stem, fracture, 9 mm x 173 mm	AR-9100-09F
Humeral Stem, fracture, 10 mm x 180 mm	AR-9100-10F
Humeral Stem, fracture, 11 mm x 187 mm	AR-9100-11F
Humeral Stem, fracture, 12 mm x 195 mm	AR-9100-12F
Humeral Stem, fracture, 13 mm x 204 mm	AR-9100-13F
Humeral Head, fracture, 43 mm x 15 mm	AR-9143-15F
Humeral Head, fracture, 46 mm x 17 mm	AR-9146-17F
Humeral Head, fracture, 48 mm x 17 mm	AR-9148-17F
Humeral Head, fracture, 50 mm x 19 mm	AR-9150-19F
Humeral Head, fracture, 51 mm x 22 mm	AR-9151-22F

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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.

The Univers™ Shoulder Fracture System was designed in cooperation with Professor Peter Habermeyer, M.D., ATOS Clinic, Heidelberg, Germany. This surgical technique has been developed in cooperation with Anthony Romeo, M.D., Rush-Presbyterian - St. Luke's Medical Center, Chicago, IL.

U.S PATENT NO. 6,716,234 and PATENTS PENDING
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