

**The information contained in this document
is intended for healthcare professionals only.**

ReUnion Fracture System

Surgical Protocol



Surgical Protocol for Three
and Four Part Fractures
of the Proximal Humerus

ReUnion Fracture System

Upper Extremity Surgical Protocol

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Stryker would also like to thank the above surgeons for their assistance in the development of this protocol.

Introduction

The ReUnion Fracture System is designed to permit accurate and reproducible implantation of a humeral head replacement for indicated proximal humeral fractures. The Solar Humeral Head patented dual radius design can aid in critical soft tissue tensioning during surgery. The proper height and versioning of the ReUnion Fracture humeral component can be achieved with the use of the patent pending Expandable Trial.



Step 1:

Position the patient in the semi-beach chair upright position.

Image 1a, 1b



Image 1a



Image 1b

Step 2:

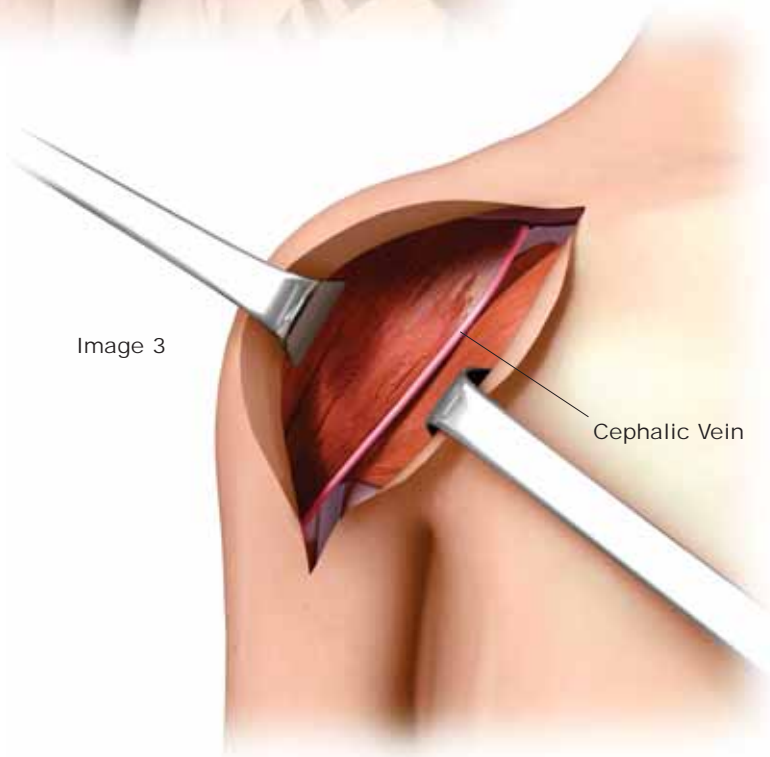
Use a long deltopectoral approach using the coracoid process as a landmark. The cephalic vein is usually retracted laterally with the deltoid, but may be retracted medially with pectoralis major.

Image 2, 3

Image 2



Image 3



Step 3:

The clavipectoral fascia is elevated to coracoacromial ligament at the edge of the conjoined tendon. The coracoacromial ligament is preserved as potential for anterior and superior stability. Retract conjoined tendon medially with Pectoralis major.

Step 4:

Identify biceps tendon/bicipital groove and its course to aid in identifying both orientations of the lesser and greater tuberosities.

Image 4

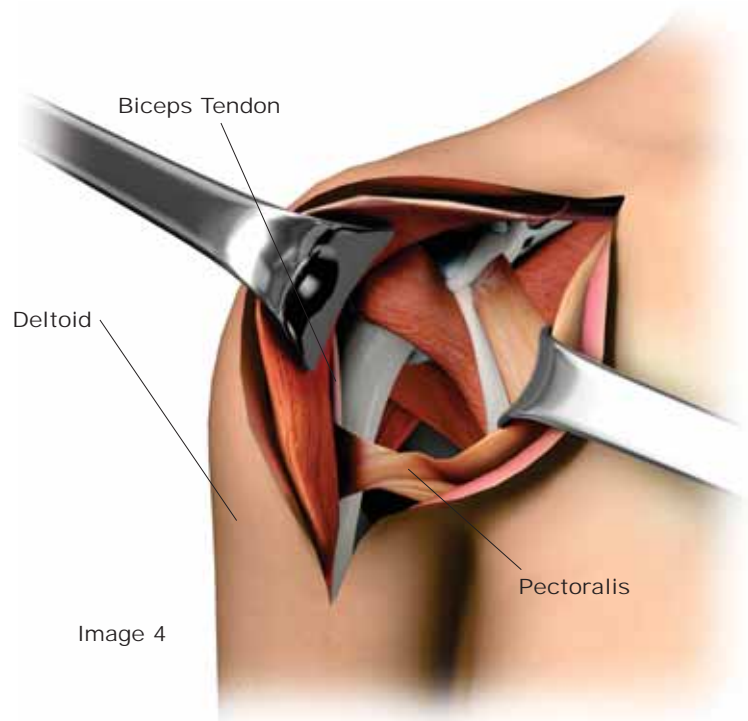


Image 4

Step 5:

The lesser tuberosity is medial to biceps tendon and the greater is superior, lateral, and posterior to biceps.

An osteotome can be used to help mobilize the tuberosities respectively.

Palpate the axillary nerve on anterior / inferior aspect of Subscapularis.

Image 5

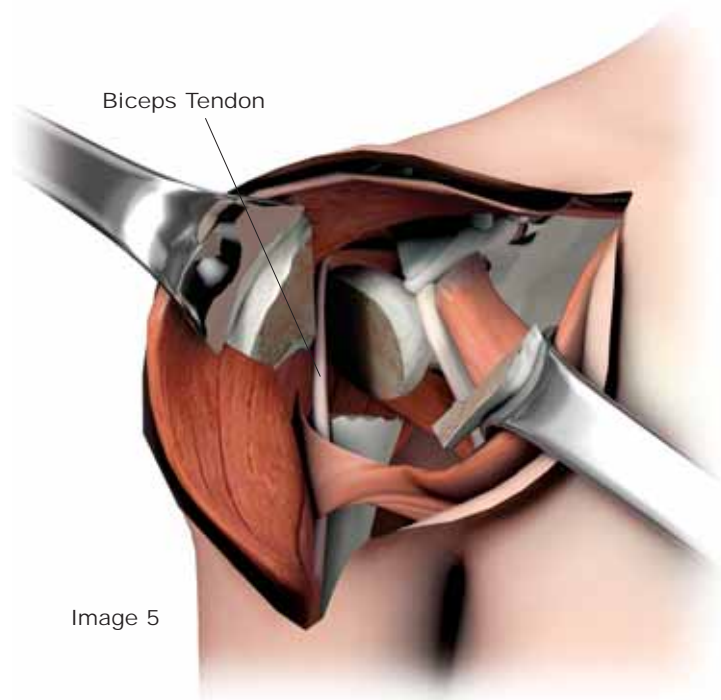


Image 5

Step 5: (Continued)

Mobilize and secure the tuberosities with sutures (Example: 1mm Cottony Dacron) the suture technique is simple (red), mattress (green) and simple (blue) sutures from superior to inferior.

Image 6

Be sure to retract lesser tuberosity medially and greater laterally.

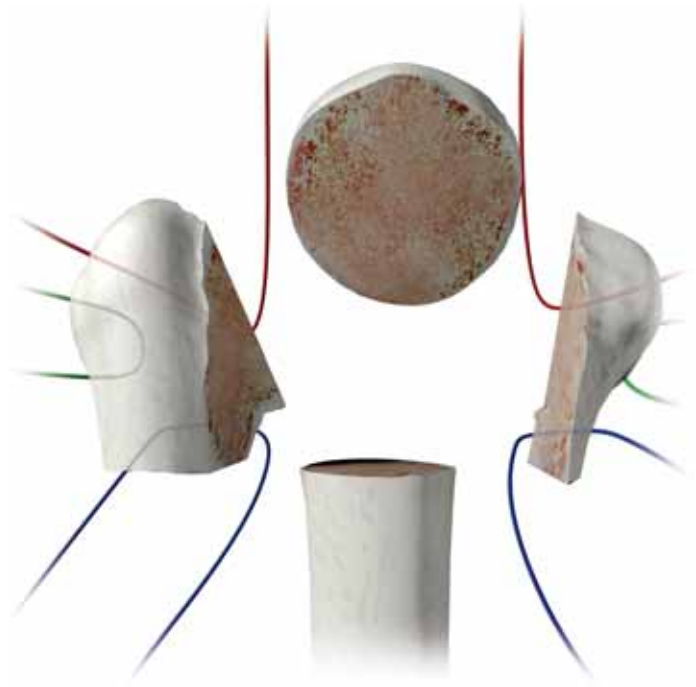


Image 6

Step 6:

Remove humeral head.

Image 7

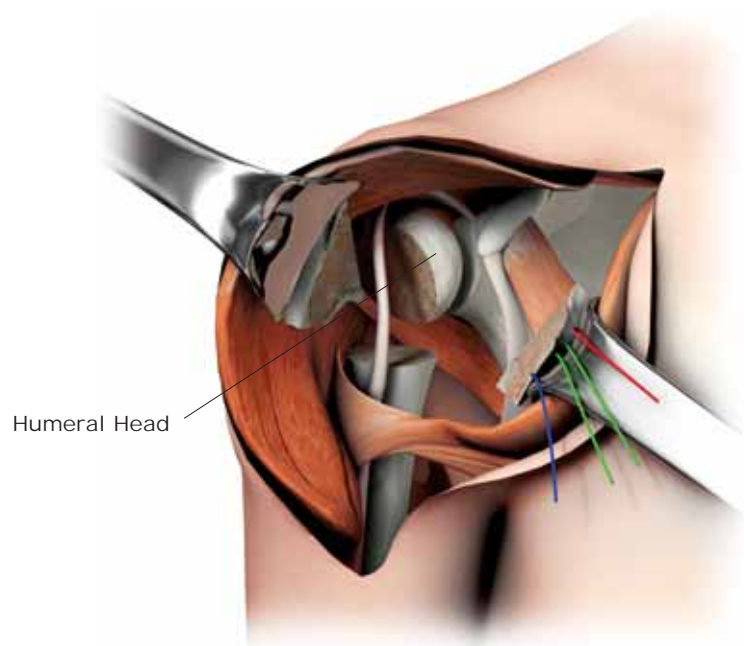
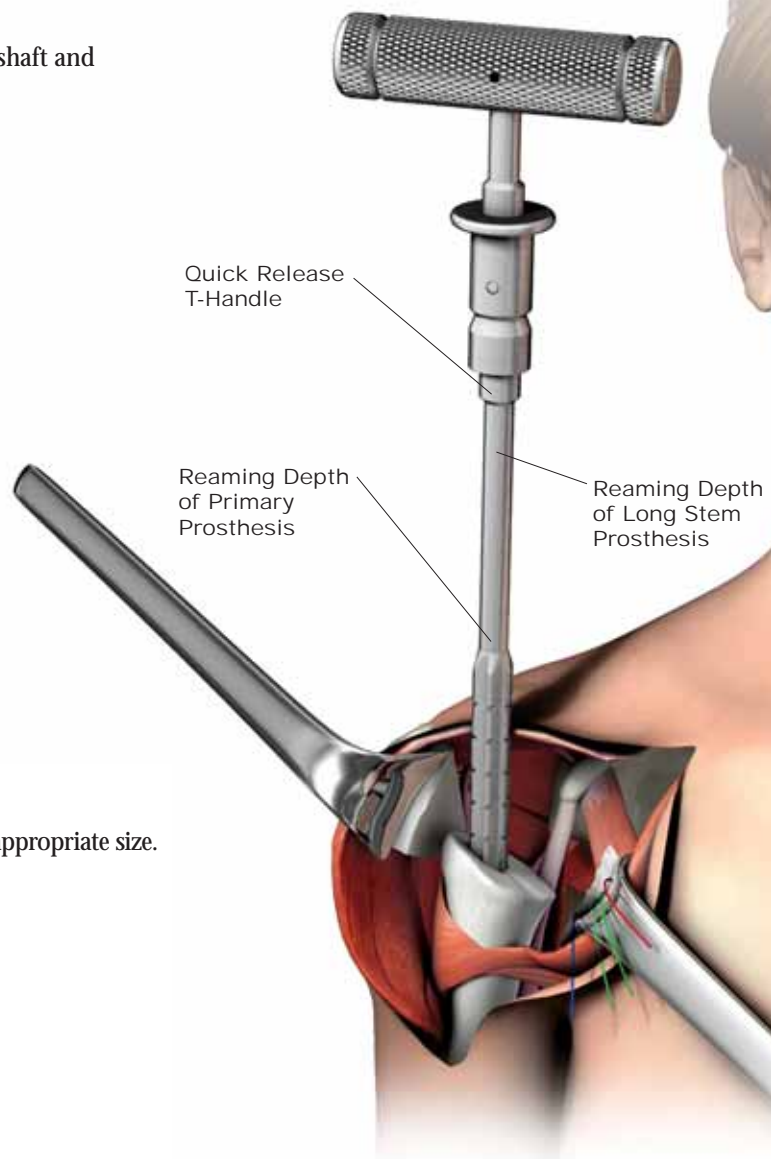


Image 7

Step 7:

Expose proximal humeral shaft and inspect glenoid



Step 8:

Hand ream sequentially to appropriate size.
Image 8

Image 8

Step 9:

Start with the expandable trial that is 2mm smaller than the last reamer used.

For example, with a 12mm reamer, use a size 10 expandable trial. The diameter of the expandable trial will be 12 mm, accounting for 2 mm of cement mantle with a 10 mm diameter stem. The expandable trial will not exceed 2 mm of expansion. (Therefore, the size 10 expandable trial will expand to a maximum of 14 mm.)

Image 9

(See chart on page 17.)

Step 10:

For positioning, insert the version rod into the expandable trial.

Image 9

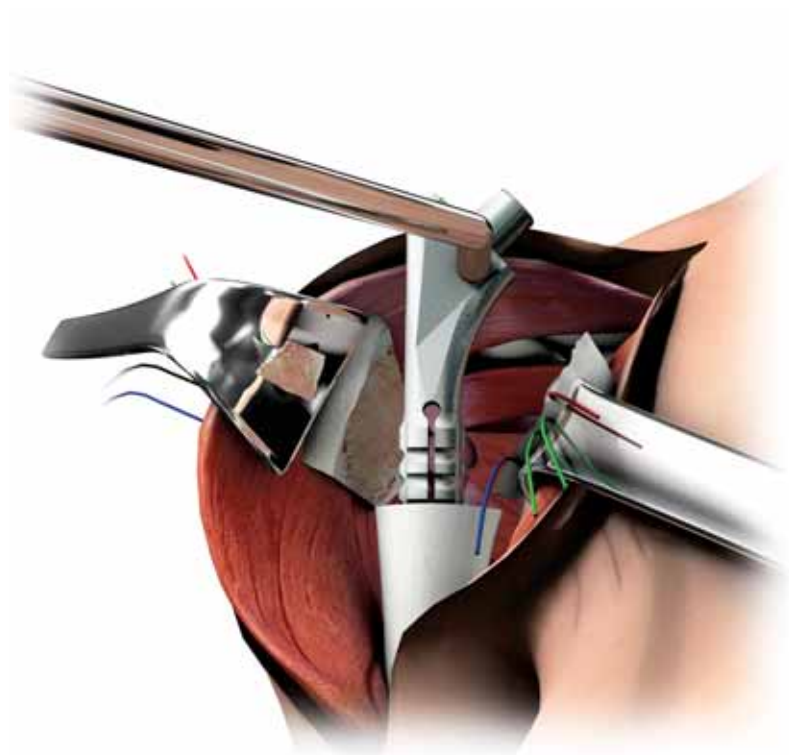


Image 9

Step 10: (Continued)

Place trial humeral head on stem, which most closely matches native humeral head.

Image 10

Arm is held in neutral position.

Slight longitudinal traction is placed on the arm. Elevate the stem until the superior aspect of the humeral head articulates with the top of the glenoid. Also dial the head into the glenoid to establish version.

Mark your height with the 3 laser lines and version with electrocautery on the humeral shaft.

Image 11

You can now remove the trial head.

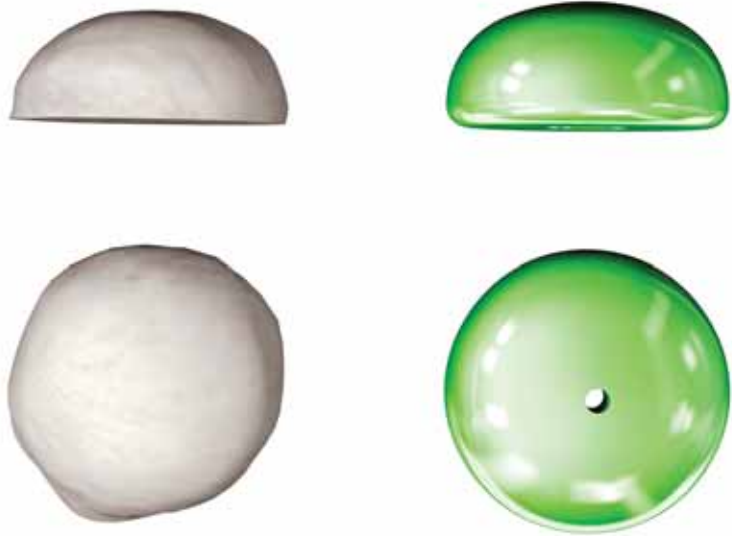


Image 10

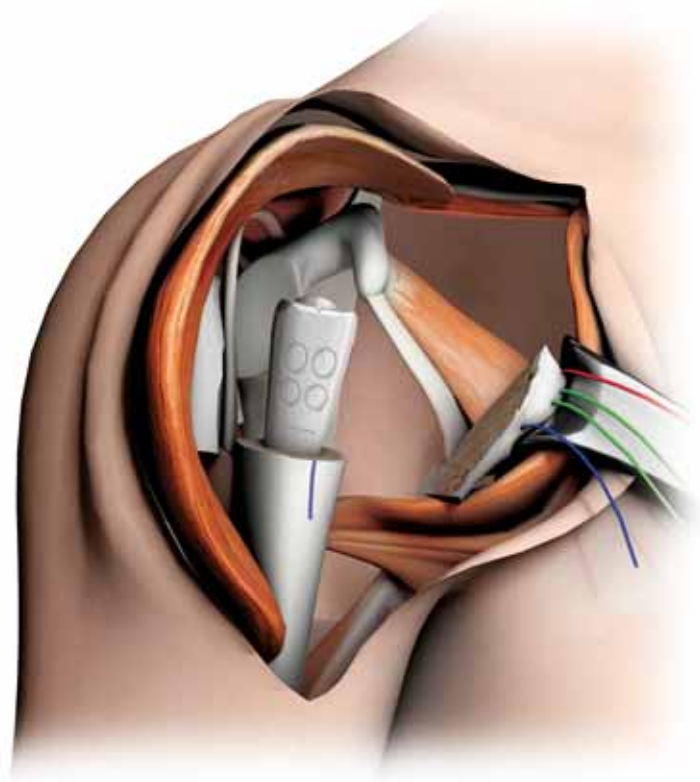


Image 11

Step 10: (Continued)

Place the expandable trial to the previously recorded height and version.

Tighten the T-Handle (approximately half a turn) to lock the expanded trial into the distal humerus at appropriate height and version.

Image 12

See page 17 for Expandable Trial Depth Mark Indications and page 18 for Reaming Chart.



Image 12

Step 11:

To establish reduction:

Begin by placing the humeral head trial on the expandable trial.

Reduce humeral head into glenoid.

Check for 50% translation of humeral head on glenoid.

Image 13

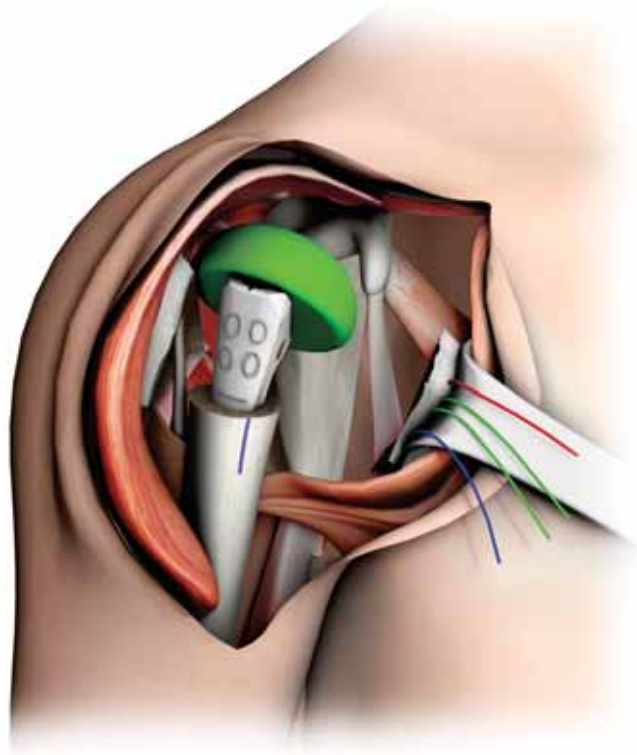


Image 13

Step 12:

Confirm tuberosities and version:

With the trial humeral head reduced, confirm that the tuberosities can be repaired over the prosthesis.

In most cases the humeral component should be set at approximately 30° of retroversion.

To check version, flex the elbow 90°, externally rotate until the prosthesis is in the neutral position. The forearm should be externally rotated approximately 30°.

Image 14

When the forearm is parallel to the version rod, the expandable trial is in 30° of retroversion.

Image 15



Image 14

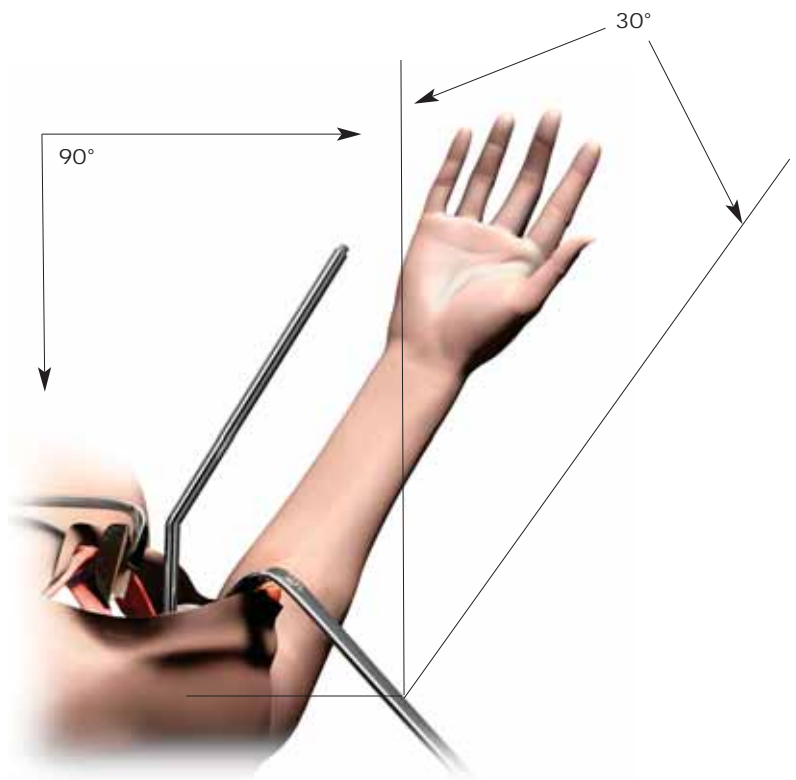


Image 15

Step 13: Cement Prosthesis

Remove trial components.

Clean out humeral canal.

Place two drill holes medial and two drill holes lateral to bicipital groove.

Place sutures (black) through each hole respectively, from inside out (Example: 1mm cotton Dacron).

Irrigate humeral shaft and remove excess fluid with suction.

Insert cement restrictor if preferred.

Inject / hand pack Simplex P or Simplex P *SpeedSet* Bone Cement into proximal humeral canal.

Lower the ReUnion humeral implant into the cement to the appropriate height marked with the 3 laser lines, turn the prosthesis to the appropriate version (previously marked with electrocautery).

Remove excess cement.

Hold at appropriate height and version until cement has hardened.

Image 16

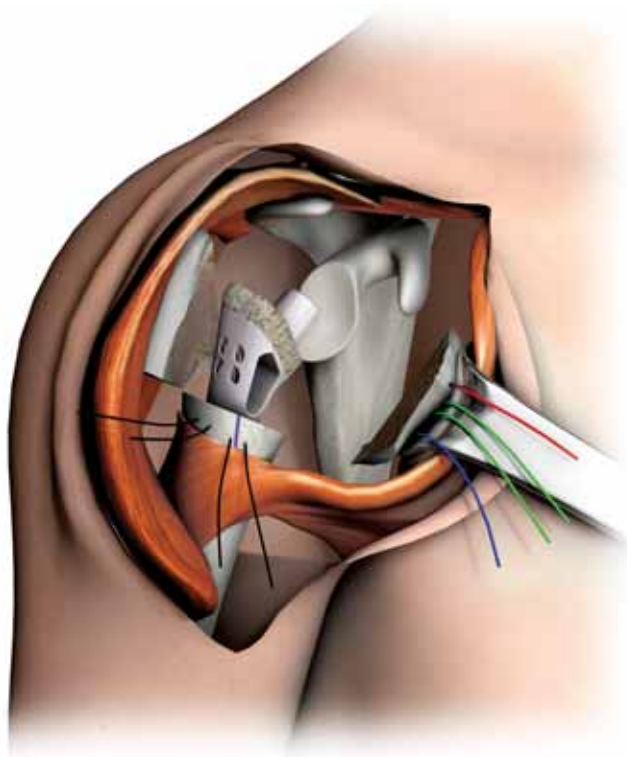


Image 16

Step 14: Humeral Head

Trial head is replaced on humeral prosthesis.

Reduce the head into the glenoid.

Check for ROM, 50% translation anterior and posterior on glenoid.

Check tuberosities once again to make sure they can be repaired to one another over the prosthesis and head easily.

Remove the trial head, then place Solar humeral head implant and impact onto stem.

Image 17

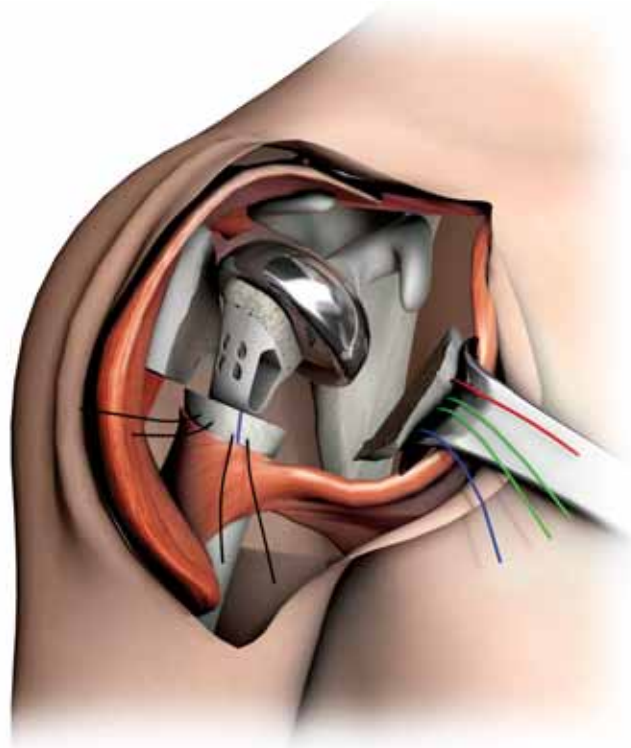


Image 17

Step 15: Bone Grafting

For grafting, place the native humeral head onto bone graft tray that corresponds with chosen expandable trial.

Using a mallet, impact the bone cutter through the humeral head.

Remove the cut out of bone graft using graft remover tool.

Image 18



Image 18

Note: The bone graft cutter blade is not available for implant sizes 7 through 9. This is based on the small geometry of the bone graft window of the implant. For sizes 7 through 9, a rongeur can be used to remove bone graft from the humeral head.

Implant	Size 7-9	Size 10-13	Size 14-15
Bone Graft Cutter Blade	N/A	Medium 5900-8222	Large 5900-8223

Step 15: Tuberosity Repair/
Bone Grafting

Keep prepared bone graft on back table.

Superior simple tuberosity sutures (red) are placed through the prosthesis and then through one another respectively. The inferior simple tuberosity sutures are passed at the bone tendon junction through one another as well (blue).

Image 19a

Insert the previously molded bone graft into the implant fenestration.

Image 19b

Additional cancellous bone graft should be placed on and around the proximal humeral body.

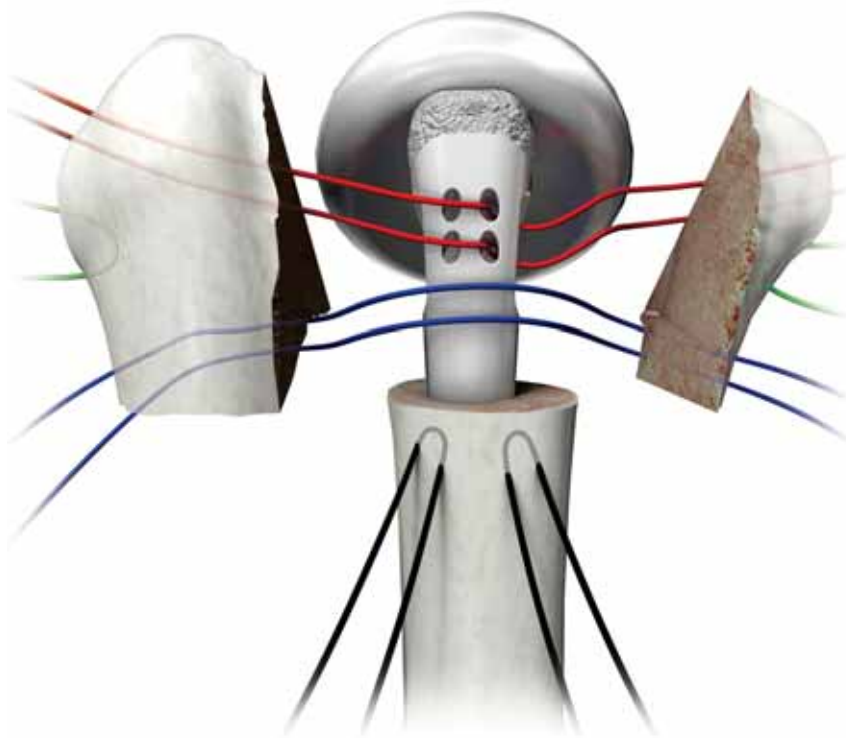


Image 19a

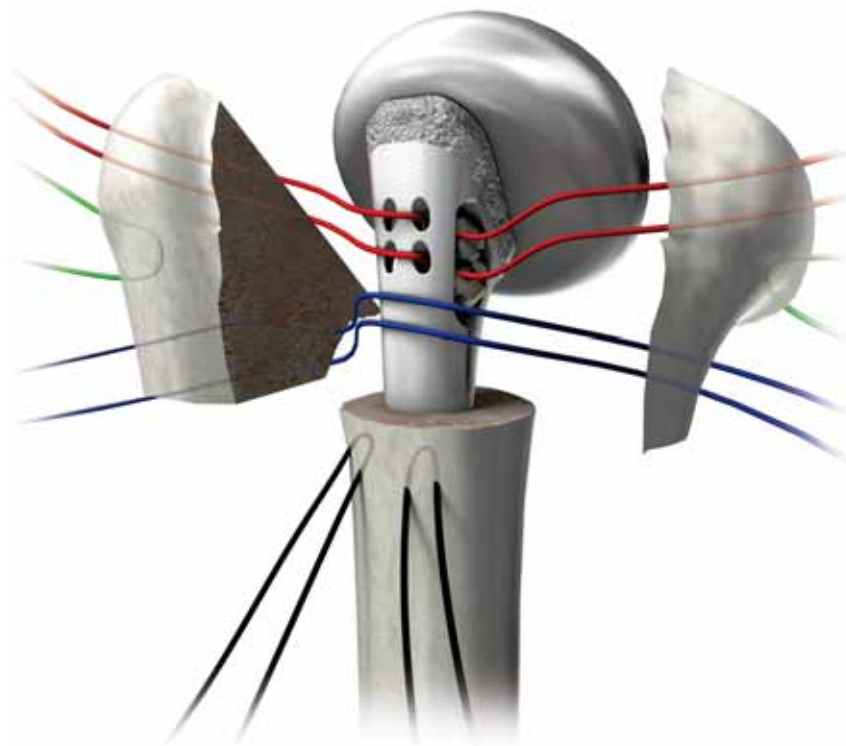


Image 19b

Step 15: (Continued)

Simple tuberosity sutures (red, blue) are tied first, then mattress sutures (green) are tied for tuberosity-to-tuberosity repair.

Image 20 and 21

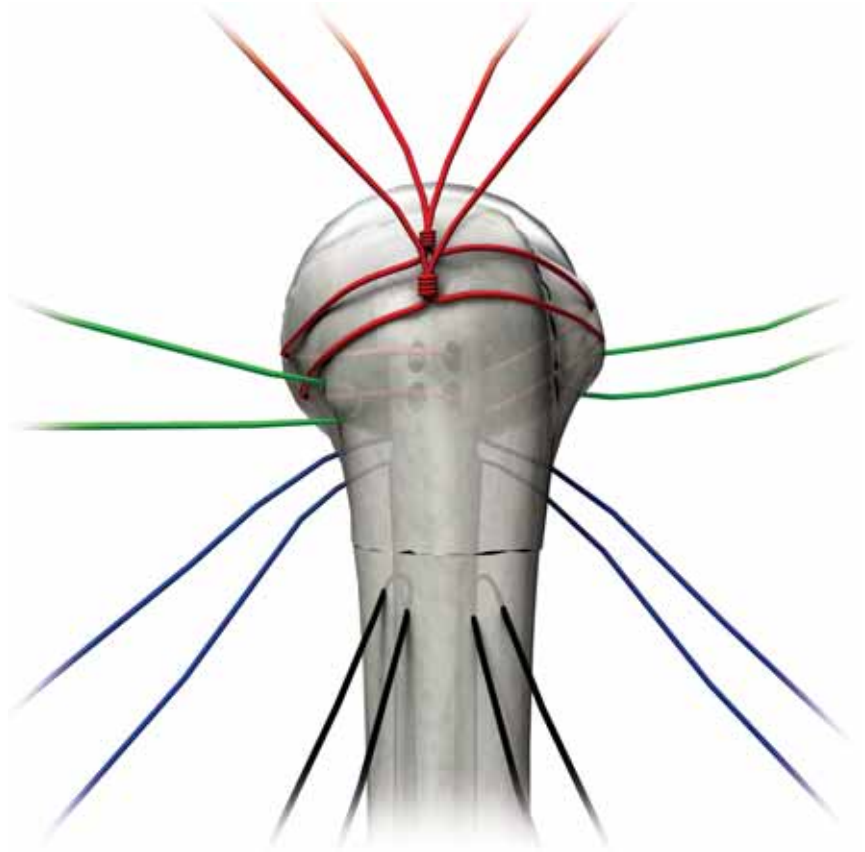


Image 20

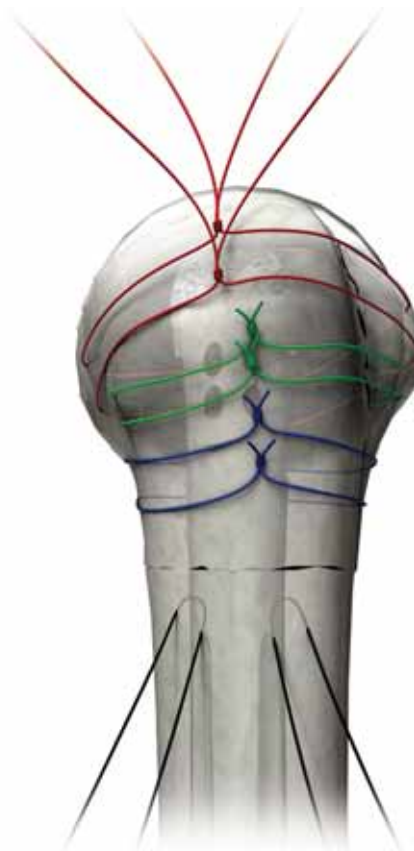


Image 21

Step 15: (Continued)

Tuberosity sutures are then tied to shaft sutures for tuberosity to shaft repair.

Image 22 and 23

Check range of motion; make sure tuberosities and shaft move as one unit.

Step 16:

Biceps Tenodesis – if biceps is ruptured or removed from its anchor during exposure or significant damage to the biceps tendon.

Step 17:

Palpate Axillary nerve.

Step 18:

Irrigate/drain placed deep to deltoid.

Step 19:

Soft tissue and skin closure.

Step 20:

Dressing and Sling.

Step 21:

Intraoperative radiographs to verify tuberosity position and stem position.

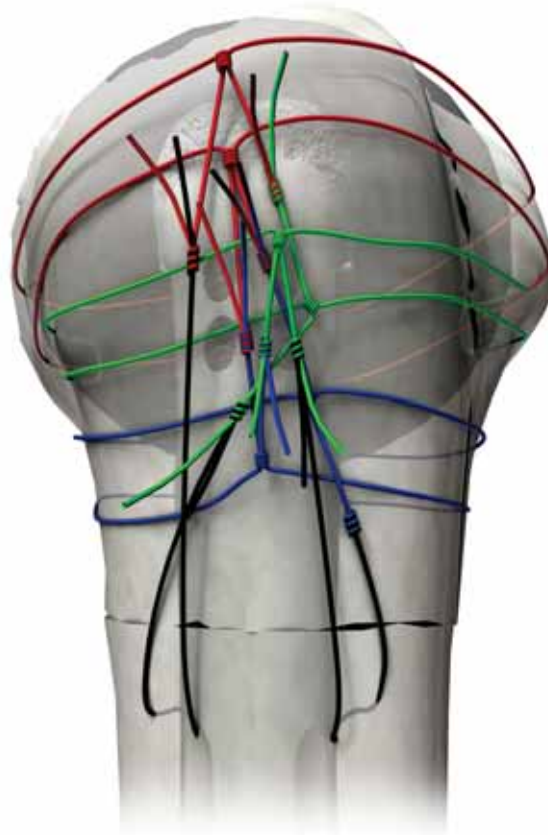


Image 22

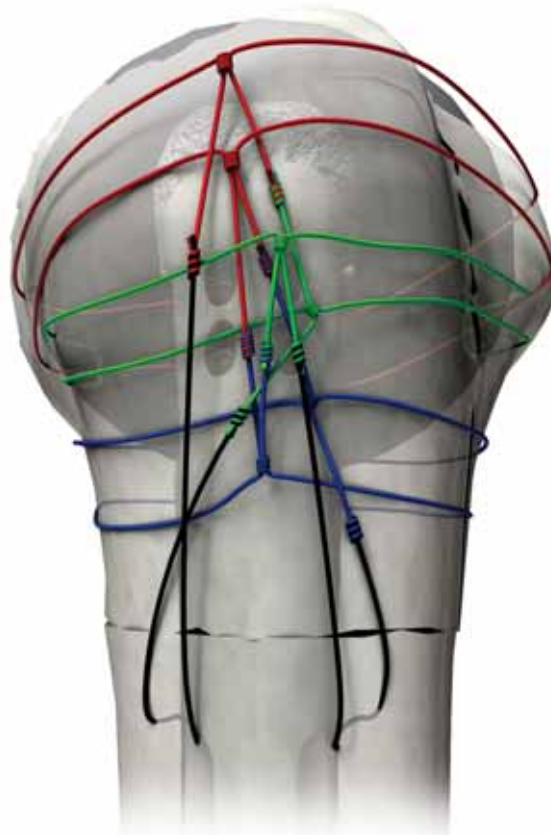
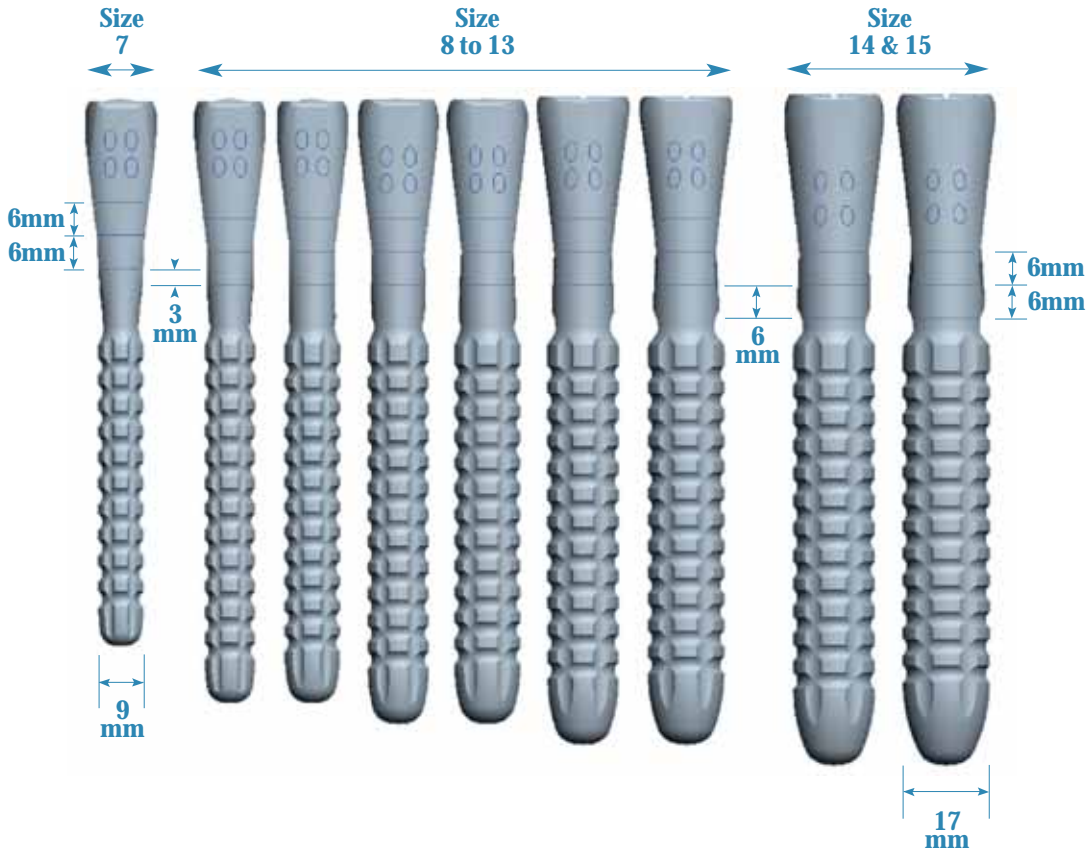


Image 23

Depth Markers

- ▶ There are three depth markers on the trial that correspond to the implant. Each depth marker is 6mm apart.
- ▶ In some cases, the surgeon may decide to use a different size implant than originally trialed.



The above graphic shows the difference in height for the depth markers from size to size.

- ▶ Size 7 is unique to itself
- ▶ Sizes 8 through 13 share the same depth marking pattern
- ▶ Sizes 14 and 15 share the same depth marking pattern

Bolts

Note: There are a total of 3 expansion bolts used across the size range of the expandable trials.

Size 7 has a dedicated bolt
 Size 8 thru 11 share a bolt
 Size 12 thru 15 share a bolt

Expandable Trial	Size 7	Size 8-11	Size 12-15
Expansion Bolt Catalog #	5900-8221	5900-8222	5900-8223

Reaming Diameter Chart

Reaming Diameter	Implant Catalog #	Stem Size	Stem Diameter	Expandable Trial Size	Expandable Trial Distal Diameter	Expandable Trial Maximum Expansion
9mm	5351-4507	7	7 mm	Size 7	9 mm	11 mm
10mm	5351-4508	8	8 mm	Size 8	10 mm	12 mm
11mm	5351-4509	9	9 mm	Size 9	11 mm	13 mm
12mm	5351-4510	10	10 mm	Size 10	12 mm	14 mm
13mm	5351-4511	11	11 mm	Size 11	13 mm	15 mm
14mm	5351-4512	12	12 mm	Size 12	14 mm	16 mm
15mm	5351-4513	13	13 mm	Size 13	15 mm	17 mm
16mm	5351-4514	14	14 mm	Size 14	16 mm	18 mm
17mm	5351-4515	15	15 mm	Size 15	17 mm	19 mm

Expandable Trials not available for canals less than 9mm in humeral diameter.

ReUnion Fracture Instruments

Catalog #	Description
5900-5107	# 7 Expanding Trial
5900-5108	# 8 Expanding Trial
5900-5109	# 9 Expanding Trial
5900-5110	# 10 Expanding Trial
5900-5111	# 11 Expanding Trial
5900-5112	# 12 Expanding Trial
5900-5113	# 13 Expanding Trial
5900-5114	# 14 Expanding Trial
5900-5115	# 15 Expanding Trial
5900-5116	# 8 Trial Long
5900-5117	# 10 Trial Long
5900-5118	# 12 Trial Long
6278-5-100	5 mm Hex Adaptor
5900-8124	Bone Graft Remover
5900-8125	Bone Graft Cutter Blade (Large)
5900-8126	Bone Graft Cutter Blade (Medium)
5900-8128	Bone Graft Cutter Handle
5900-8129	Bone Graft Cutter Seat
5900-8221	Expansion Bolt (Used with # 7 Expanding Trial)
5900-8222	Expansion Bolt (Used with # 8-11 Expanding Trial)
5900-8223	Expansion Bolt (Used with # 12-15 Expanding Trial)
5900-8224	Version Rod
5900-8114	Stryker Case
5900-8115	ReUnion Fracture Specific Tray #1

Existing Solar Instruments used with Fracture Instruments

Catalog #	Description
5900-8114	Stryker Case
5900-8116	New designed Solar General Tray #1
5900-8117	New designed Solar General Tray #2
5900-0020	Humeral Head Impactor
5900-0030	Humeral Head Extractor
5900-0040	Shoulder Mallet
5900-0050	Shoulder T-Handle
5900-4012	40 mm X 12 mm Humeral Head Trial
5900-4015	40 mm X 15 mm Humeral Head Trial
5900-4018	40 mm X 18 mm Humeral Head Trial
5900-4021	40 mm X 21 mm Humeral Head Trial
5900-4512	45 mm X 12 mm Humeral Head Trial
5900-4515	45 mm X 15 mm Humeral Head Trial
5900-4518	45 mm X 18 mm Humeral Head Trial
5900-4521	45 mm X 21 mm Humeral Head Trial
5900-4524	45 mm X 24 mm Humeral Head Trial
5900-5015	50 mm X 15 mm Humeral Head Trial
5900-5018	50 mm X 18 mm Humeral Head Trial
5900-5021	50 mm X 21 mm Humeral Head Trial
5900-5024	50 mm X 24 mm Humeral Head Trial
5900-5028	50 mm X 28 mm Humeral Head Trial
5900-5518	55 mm X 18 mm Humeral Head Trial
5900-5521	55 mm X 21 mm Humeral Head Trial
5900-5524	55 mm X 24 mm Humeral Head Trial
5900-5528	55 mm X 28 mm Humeral Head Trial
5900-5534	55 mm X 34 mm Humeral Head Trial
5910-4015	40 mm X 15 mm Dual Offset Head Trial
5910-4018	40 mm X 18 mm Dual Offset Head Trial
5910-4515	45 mm X 15 mm Dual Offset Head Trial
5910-4518	45 mm X 18 mm Dual Offset Head Trial
5910-4521	45 mm X 21 mm Dual Offset Head Trial
5910-5015	50 mm X 15 mm Dual Offset Head Trial
5910-5018	50 mm X 18 mm Dual Offset Head Trial
5910-5021	50 mm X 21mm Dual Offset Head Trial
5900-6007	Fluted Cylindrical Reamer 7mm
5900-6008	Fluted Cylindrical Reamer 8mm
5900-6009	Fluted Cylindrical Reamer 9mm
5900-6010	Fluted Cylindrical Reamer 10mm
5900-6011	Fluted Cylindrical Reamer 11mm
5900-6012	Fluted Cylindrical Reamer 12mm
5900-6013	Fluted Cylindrical Reamer 13mm
5900-6014	Fluted Cylindrical Reamer 14mm
5900-6015	Fluted Cylindrical Reamer 15mm
5900-6016	Fluted Cylindrical Reamer 16mm
5900-6017	Fluted Cylindrical Reamer 17mm

Description

Stryker shoulder prostheses consist of both humeral and glenoid components. Depending on design, the humeral components may be used in conjunction with a glenoid component for conventional total shoulder arthroplasty or to articulate directly with the anatomic glenoid in a hemi-shoulder application. The components are intended for implantation within the humeral and glenoid fossa preparations in cemented or cementless applications dependent upon device design (consult component package labeling for application restrictions).

Humeral Components: The humeral component is available in modular design. The selection of the appropriate humeral component is dependent upon the type of arthroplasty intended, bone geometry and the type of fixation. The modular humeral design consists of both humeral stem and interchangeable humeral head components. The modular head components are available in diameters ranging from 40mm to 55mm in 5mm increments and in selected thicknesses ranging from 12mm to 34mm.

Glenoid Components: The glenoid component consists of an all-polyethylene design available in an array of sizes. Each size has a thickness of 4mm.

Materials:

- ASTM F-1537 Cobalt chromium alloy
Humeral heads
- ASTM F-90 Cobalt chromium alloy
Glenoid x-ray marking wire
- ASTM F-136 Titanium 6AL-4V ELI alloy
Humeral stem component
- Hydroxylapatite Powder per ASTM F-1185
Humeral stem component
- ASTM F-648 ultra-high molecular weight
Glenoid component polyethylene (UHMWPE)
- ASTM F-1580 CP-Titanium Humeral Stem Component

Indications

- Aseptic necrosis of the humeral head.
- Painful, disabling joint disease of the shoulder resulting from degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis.
- Proximal humeral fracture and/or dislocation.
- Revision of previous unsuccessful total shoulder replacement, resurfacing or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

Contraindications

- Any active or suspected latent infection in or about the shoulder joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Absent, irreparable or non-functioning rotator cuff and other essential muscles.
- Patients whose anticipated activities would impose high stresses on the prosthesis and its fixation.
- Obesity. An overweight or obese patient can produce loads on the prosthesis which can lead to failure of fixation of the device or to failure of the device itself.

Precautions

- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device. Patients should be instructed in the limitations of the prosthesis, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. If the patient is involved in an occupation or activity which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
- Appropriate selection, placement and fixation of the shoulder components are critical factors which affect implant service life. As in the case of all prosthetic implants, these components are affected by numerous biologic, biomechanic and other extrinsic factors, thereby limiting the service life and durability of the product. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize its service life.
- Care must be taken to protect the components and any polished bearing surfaces from being marred, nicked or notched as a result of contact with metal or abrasive objects.

Utilization and Implantation

- The recommended trial components should be used for size determination, trial reduction and range of motion evaluation, thus preserving the integrity of the actual implants and their sterile packaging.
- Radiographic templates are available to assist in the preoperative prediction of component size and style.
- The Stryker Surgical Protocols provide additional procedural information.

Warnings

- Discard all damaged or mishandled implants.
- Never reuse an implant, even though it may appear undamaged.
- Polished bearing areas must not come in contact with hard or abrasive surfaces.
- Bearing areas must always be clean and free of debris prior to assembly.
- Contouring and bending of an implant may reduce its fatigue strength and cause failure under load.
- Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopaedic device.
- Stryker strongly advises against the use of another manufacturer's component with any Stryker shoulder component. Any such use will negate the responsibility of Stryker for the performance of the resulting mixed component implant.
- Removal of an unloosened implant may require the use of special instruments to disrupt the interface at the implant surface.
- Return all packages with flaws in the sterile barrier to the supplier. Do not resterilize.

Adverse Effects

- While the expected life of total shoulder replacement components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices, but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
- Dislocation of the total shoulder prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations.

- Loosening of total shoulder components can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result from trauma, infection, biological complications, including osteolysis, or mechanical problems, with the subsequent possibility of bone erosion and/or pain.
- Fatigue fracture of total shoulder components has occurred in a small percentage of cases.
- Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.
- Serious complications may be associated with any total joint replacement. These complications include, but are not limited to genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli, myocardial infarction or death.
- Wear of polyethylene components has occurred and literature reports have associated its occurrence with bone resorption, loosening and infection.
- With all implant devices, asymptomatic, localized progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to the particulate matter of cement, metal, ultra-high molecular weight polyethylene (UHMWPE) and/or ceramic. Particulate is generated by interaction between components, as well as between components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Secondly, particulate can also be generated by third-body wear. Osteolysis can lead to future complications, including loosening, necessitating the removal and replacement of prosthetic components.
- Metal sensitivity reactions have been reported following joint replacement.
- Adverse effects may necessitate reoperation, arthrodesis of the involved joint and/or amputation of the limb.

Sterilization

- The packaging of all sterile products should be inspected for flaws in the sterile barrier before opening. In the presence of such a flaw, the product must be assumed non-sterile. Special trial prostheses are available to avoid having to open any aspect of the sterile package prior to component use.
- Care should be taken to prevent contamination of the component. In the event of contamination, this product must be discarded.
- If the package is opened, but the product is not used, the prosthesis must not be resterilized and must be discarded or returned to the supplier.

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician.

WARNING: THE GLENOID COMPONENT IS INTENDED FOR CEMENTED USE ONLY IN THE U.S.A.

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A surgeon must always rely on his or her own professional clinical judgment when deciding to use which products and/or techniques on individual patients. Stryker is not dispensing medical advice and recommends that surgeons be trained in orthopaedic implant surgeries before performing any surgeries.

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Literature Number: **LSEXR-ST**
MS/GS 3.5M 01/07

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