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This brochure is presented to demonstrate the surgical technique utilized by the surgeon listed above. DJO Surgical, as the manufacturer of this device, does not practice medicine and cannot recommend this or any other surgical technique for use on a specific patient. The choice of the appropriate surgical technique is the responsibility of the surgeon performing the operation.
Surgical Technique
Foundation® Shoulder System

Foundation Shoulder System

Indications
This total shoulder prosthesis is intended for treatment of patients who are candidates for total shoulder arthroplasty because the natural humeral head and or glenoid has been affected by osteoarthritis, inflammatory arthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis or proximal humeral fracture, and revision arthroplasty where bone loss is minimal. This system includes a humeral stem and head and is to be used with bone cement. These devices are intended to aid the surgeon in relieving the patient of shoulder pain and restoring shoulder motion.

Foundation 4mm Glenoid Component

Indications
The indications for use of total shoulder replacement prosthesis include:
1) noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the humeral head and or glenoid;
2) rheumatoid arthritis;
3) correction of functional deformity; and
4) humeral fracture
5) revision procedures where other treatments where devices have failed.

Contraindications

Absolute contraindications include:
• infection
• sepsis
• osteomyelitis;
• rapid joint destruction or bone absorption apparent on roentgenogram;
• skeletary immature patients and cases where there is a loss of abductor musculature, poor bone stock, poor skin coverage around shoulder joint which would make the procedure unjustifiable,

Relative contraindications include:
• uncooperative patient or a patient with neurologica disorders and incapable of following instructions;
• osteoporosis;
• metabolic disorders which may impair bone formation
• osteomalacia; and
• distant foci infections (which may cause a hematogenous spread to the implant site).
Design Rationale
Stem Diameter and Geometry

The medullary canal of the proximal humerus is shaped like a champagne glass on an anteroposterior radiograph and like a stove-pipe on a lateral radiograph, thereby making it difficult to obtain intimate contact between the humeral component and bone.11 With a prosthesis anatomically shaped in the metaphyseal region of the proximal humerus, the amount of bone-prosthesis contact can be maximized, thereby increasing interface stability and long-term fixation. The cancellous bone beneath the tuberosities often cannot support much in the way of compressive forces because of the osteopenic nature of the bone in patients resulting from inflammatory diseases, disuse or medications such as corticosteroids. More distally, there is good cortical bone where inadequate amount of stem contact can be achieved. To increase stem/bone contact, the design of the Foundation Shoulder Humeral stem incorporates anterior, posterior, and lateral fins on the proximal body. Below the surgical neck level, the diameter of the medullary canal varies 6 to 18mm in diameter. The Foundation Shoulder Humeral stem diameters include 6, 8, 10, 12, 14, and 16mm. A variety of sizes provides stability for the prosthesis, particularly in rotation, and allows the forces transmitted to be dissipated over a larger area.1, 5, 13

Humeral Head Thickness

There is a need for humeral head components with varying thickness because of wear and bone loss from the articular surface, differences in the size of individual patients and the occasional need to alter the head size to balance the musculotendinous rotator cuff after repair of a large tear. The Foundation Shoulder System has five neutral head diameters, each with three head thicknesses along with five offset head diameters, each with two head thickness providing the surgeon with an opportunity to recreate the patient’s normal anatomy. Different head thicknesses also help the surgeon to implant the prosthesis at the proper height with the head slightly higher than the greater tuberosity, thus avoiding impingement, and to recreate the normal center of rotation. The surgeon must be careful not to use a humeral head that is too thick, which would lateralize the center of rotation, put excessive tension on the musculotendinous rotator cuff, and limit motion.1, 5, 13
Surgical Technique
Foundation® Shoulder System

Glenoid Design
Anatomical studies have shown that having the radius of the glenoid slightly greater than that of the humeral head provides the advantage of allowing translation without loading the glenoid rim. Based on these studies, the radius of curvature of the Foundation glenoid component is 6mm larger in the superior/inferior dimension and 12mm larger in the anterior/posterior dimension than the corresponding humeral head.

Hemiarthroplasty Indications
In certain situations, implantation of the humeral component alone is indicated, with the underlying reason being that the surface of the glenoid is judged to be in good condition with minimal deformity or incongruity. The following may be indications for a humeral head replacement alone:

- osteonecrosis of the humeral head;
- recent four-part or head-splitting fractures of the proximal humerus;
- recent three-part fractures of the proximal humerus in the elderly;
- some proximal humeral neoplasms;
- malunions and nonunions of old proximal humerus fractures; or
- insufficient glenoid bone stock to support a glenoid component.

Indications for Cement Fixation
Noncemented, press-fit, humeral components are indicated in younger patients with good bone stock, but they have also been found to work well in older patients with few complications. Indications for cemented fixation may include:

- failure to achieve adequate press fit fixation;
- poor bone stock secondary to the underlying disease process, such as rheumatoid arthritis;
- previous arthroplasty;
- fractures of the proximal humerus in which the tuberosities no longer provide rotational stability; or
- degenerative cysts of the proximal humerus.
Preoperative Care

The patient is made aware of the details of the procedure and the postoperative requirements for physical therapy both as an outpatient and at the time of admission to the hospital. The patient must also understand the necessity of his or her cooperation to complete a full course of postoperative rehabilitative exercises. Starting one week before admission, the patient applies long-acting antiseptic soap to his or her axillary region once a day to reduce skin bacterial counts. At least five minutes before the skin incision, the patient is given prophylactic antibiotics and is continued on them for 24 hours postoperatively.

Templating/Preoperative Planning

Preoperative templates are provided for estimating component size and position. Radiographs should include an A/P view of the glenohumeral joint in both internal and external rotation, and an axillary lateral view. Establish the humeral head osteotomy level by drawing a line on the humeral head starting just medial to the sulcus and just lateral to the articular surface at a 45° angle to the long axis of the humerus. Positioning the bottom of the prosthetic collar on the template at the estimated osteotomy level, select the stem size that best fills the humeral canal. If the stem is to be cemented, the stem should be undersized to the distal canal to allow for the cement mantle.

Once the template of the selected stem size is positioned, note the approximate head height required to reproduce the joint space. In hemi-arthroplasty cases, the humeral head templates are used to determine humeral head size. In total shoulder cases, the glenoid template is used to determine both the glenoid and the corresponding humeral head component size. It is important to note that the prosthetic size of the humeral head and glenoid components must be the same to achieve the designed translation between the two components.

The superior/inferior glenoid bone stock and depth of the glenoid vault are examined on the A/P views. The glenoid template is used to estimate appropriate head coverage. The axillary/lateral radiograph is reviewed for A/P bone stock. In osteoarthritic patients, posterior erosion should be evaluated using computerized tomography as needed. Severe posterior erosion may require augmentation with bone grafting or a custom prosthesis.
Humeral Preparation
Foundation® Shoulder System

Patient Preparation and Positioning

The patient is placed in the beach chair semi-sitting position with the upper part of the body raised 45° to 60° (Figure 1).

The head is supported with a headrest that allows the top portion of the table to be removed and replaced with a board under the nonoperated shoulder. This enables the involved shoulder to lie completely free, and allows the surgeon to adduct and hyperextend the shoulder as needed for adequate surgical exposure. An alternative technique is to use a bean bag so that the upper torso can be brought over the edge of the table, allowing for hyperextension of the shoulder. Care must be taken not to hyperextend the cervical spine.

The legs are parallel to the floor from the knees down to prevent dependency. If the procedure is expected to last longer than 3 hours, a urinary catheter is utilized. The anesthetic of choice is an interscalene block, although endotracheal general anesthesia may be used in patients who, for various reasons, are not candidates for a regional anesthetic. The shoulder and complete upper extremity are prepared with a betadine solution, which is allowed to dry, and then draped completely free, taking care not to decrease the operative field.

Deltoplectoral Surgical Approach

An extended deltopectoral incision is the author's preferred approach because it has the advantage of leaving the origin of the deltoid undisturbed and affords ease of exposure. A 12 to 17 cm skin incision is made from the distal one-quarter of the clavicle lateral to the coracoid and carried down lateral to the axilla toward the insertion of the deltoid (Figure 2).

So that there will be less postoperative edema of the extremity, the cephalic vein is preserved and retracted laterally rather than sacrificed. The medial tributaries are ligated and divided away from the vein to prevent damage to the cephalic vein (Figure 3).
In revisions, the vein may be sufficiently scarred as to require ligation.

**Humeral Exposure**

The deltoid muscle is then retracted laterally and the clavipectoral fascia is divided along the lateral edge of the conjoined tendon from the coracoid inferiorly to the level of the pectoralis major insertion (Figure 4).

A portion of the pectoralis major tendon can be released if additional exposure is required (Figure 5). If more exposure of the supraspinatus tendon is needed, a portion of the coracoacromial ligament may be partially divided (Figure 6). A Darrach elevator is placed in the subacromial bursa beneath the acromion, thereby improving exposure. A second Darrach elevator or deltoid retractor is placed beneath the deltoid muscle to laterally displace the deltoid and increase exposure.
Any thickened or fibrotic subacromial bursa is then excised as the humerus is put through a range of motion with internal and external rotation and flexion. Release the coracohumeral ligament if external rotation is limited (Figure 7). If an acromioplasty is required, it can be performed at this point and the rotator cuff can be assessed.

The humerus is then externally rotated with the arm at the side to displace the axillary nerve medially, protecting it from possible injury, and exposing both the subscapularis tendon and anterior circumflex vessels. The axillary nerve can then be palpated in front of the subscapularis and inferiorly beneath the glenohumeral joint capsule, allowing the surgeon to protect the nerve from damage as the anterior circumflex vessels are divided and ligated with silk sutures.

The subscapularis tendon and capsule are divided longitudinally as a unit 1 cm medial to the subscapularis insertion and the medial edge is tagged with stay sutures for future identification (Figure 8).

The joint capsule is divided anteriorly and superiorly to the level of the long head of the biceps, taking care to avoid any damage to the biceps tendon. A Darrach elevator is then placed next to the humeral neck inferiorly to prevent axillary nerve damage and the capsule is divided inferiorly enough to allow the humeral head to be dislocated anteriorly (Figure 9).

Care must be taken to not to injure the axillary nerve while subperiosteally removing the inferior capsule from the inferior osteophytes that are often present. Externally rotating the arm helps to expose the inferior capsule posteriorly and protects the axillary nerve.
Often the subscapularis muscle is shortened and patients have minimal external rotation, or in fact, an internal rotation contracture. Two methods are available to lengthen the subscapularis tendon and restore at least 30 degrees of external rotation. With both techniques, all adhesions and scarring superficial and deep to the subscapularis muscle must be released to gain as much external rotation as possible. The first method is to perform a Z-plasty lengthening of the subscapularis tendon during the exposure, where the tendon is divided near the lesser tuberosity and the glenohumeral capsule deep to it is divided near the glenoid (Figure 10a).

After division, stay sutures are placed in the divided ends of the subscapularis muscle and capsule to allow for ease of identification. Dividing the capsule medial to the incision of the subscapularis can also assist the closure of larger rotator cuff tears.

The second method of addressing an internal rotation contracture, which is preferred by the author, is to remove the subscapularis tendon from its insertion on the lesser tuberosity and later reattach it to the proximal humerus more medially, thereby gaining relative length and increasing external rotation (Figure 10b & c).

Moderate rotator cuff tears can be repaired at this point, whereas massive tears are mobilized after the humeral head has been removed and are reattached to the greater tuberosity before implantation of the humeral component.

The humeral head is dislocated anteriorly into the wound while a Darrach elevator is placed inside the joint to lever the head forward, taking care to protect the surface of the glenoid fossa if a hemiarthroplasty is to be performed.

Anterior dislocation is performed with a combination of adduction, extension, and external rotation of the proximal humerus to deliver the head out of the glenoid fossa. If difficulty is encountered, often the inferior capsule is still attached and must be completely released inferiorly from the humeral neck. Osteophytes should be removed to help gain the desired exposure. Care must first be taken to avoid forceful external rotation that can fracture the humeral shaft. To further reduce the incidence of a humeral shaft fracture, use an elevator's leverage, not a strong rotatory force on the arm, to dislocate the humeral head. Long-standing subluxation of the humeral head or severe humeral head deformity can make this a tedious step in the procedure.
Humeral Head Osteotomy

The greater tuberosity must be visualized so the proper level of the humeral head osteotomy and seating of the trial prosthesis can be visualized.

The varus-valgus angle of the humeral osteotomy can be determined from the osteotomy guide or the broach face. The surgeon must be careful not to make too vertical an osteotomy toward the inferior humeral neck because this will result in excessive removal of medial bone and no medial calcar on which the humeral component can be seated. The inferior-medial point of the osteotomy often lies medial to the inferior osteophytes. The superior-lateral point of the osteotomy should be at the junction of the anatomic neck and the greater tuberosity (Figure 11). Care must be taken not to carry the osteotomy into the greater tuberosity and risk damage to the rotator cuff tendons.

Humeral head retroversion is determined by using the forearm as a goniometer with the elbow flexed. Recreating the normal 30 to 40 degrees of humeral head retroversion is accomplished by externally rotating the forearm a corresponding amount, and then aiming the humeral osteotomy parallel to the sagittal plane of the body through the proximal humerus (Figure 12).

The biceps and rotator cuff must be protected with a small retractor as the humeral head is osteotomized. The amount of bone removed is often surprisingly small and care must be taken, especially in flattened, deformed or osteophyte-ridden humeral heads, not to remove an excessive amount of the humeral head.

Osteophytes on the humeral head, especially around the inferior neck, are trimmed with a curved osteotome and rongeur until the margins of the articular cartilage or articulating surface can be identified. It is essential that fragments of bone and any exuberant synovial tissue with loose bodies are meticulously removed to improve exposure and prevent complications.
Humeral Canal Reaming

The humerus must be extended and adducted to allow access to the medullary canal. A starting hole is made in the superior-lateral aspect of the proximal humerus, and often a rongeur is used to remove a small amount of lateral cortical bone to allow straight access down the humeral shaft. This can help prevent varus reaming.

A T-handled hand reamer is used to sound the medullary canal (Figure 13).

The canal is then reamed sequentially with larger reamers until cortical chatter is present. Although power reaming can be performed in patients with osteoarthritis, it is recommended to hand ream the medullary canal in patients with rheumatoid arthritis and osteoporosis (Figure 14).

Fat and loose cancellous bone in the metaphyseal region of the proximal humerus are then removed and the canal is irrigated with antibiotic solution.
Humeral Canal Broaching

In preparation for broaching, the patient’s arm should be extended and adducted off the side of the table. An assistant should support the arm and push it upward to prevent stretching of the brachial plexus and to provide a counterforce as the broach is tapped into the medullary canal. As a guide for maintaining proper retroversion, the lateral fin of the broach/implant should lie between the lesser and greater tuberosities just posterior to the bicipital groove. This target can be marked with the electrocautery or methylene blue to assist in alignment (Figure 15).

Broaching is performed in a sequential manner starting with the smallest size and increasing until the correct size is obtained. Excessive force to drive the broach must be avoided. The broach is impacted until it is firmly seated against the humeral neck anteriorly, medially, and posteriorly. A calcar planer is then used to level the humeral osteotomy and ensure circumferential contact with the collar of the prosthesis (Figure 16).

Even if the glenoid surface is determined to be sufficient and not in need of replacement, the glenoid fossa should be thoroughly cleaned of any labrum and/or soft tissue which may interfere with articulation of the prosthetic head.

Should the glenoid surface require replacement, it is recommended to leave the trial broach in the humeral canal while the glenoid fossa is being prepared as this will minimize the risk of deforming or fracturing the proximal humerus.
Pegged Glenoid Preparation

Confirm the size of the glenoid component by sequentially positioning drill guides over the face of glenoid surface until full coverage of the articulating glenoid surface is obtained. With the appropriate sized drill guide centered over the glenoid fossa, drill the center hole with the glenoid center drill bit (Figure 17).

Using the straight glenoid reamer, center the peg into the pre-drilled hole and ream the glenoid surface (Figure 18).

Place the pegged glenoid drill guide over the reamed glenoid surface, aligning the center peg over the pre-drilled center hole. Place the gold anodized lug into the center hole. Push the pegged glenoid drill guide into the center hole (Figure 19).
Surgical Technique
Foundation® Shoulder System

Drill the first peg hole and place a peg lug into the hole for stability, drill the second peg hole and place a peg lug into the hole for stability, drill the remaining peg hole (Figure 20).

The selected glenoid trial provides a line-to-line reference to the final glenoid thickness with the pegs slightly oversized to account for the cement mantle. Occasionally, complete seating of one or more of the pegs is not possible. The pegs of the glenoid component provide easy length customization by cutting along any groove found on the pegs.

The pegs holes are irrigated with antibiotic solution and thoroughly dried, using thrombin soaked gelfoam, if needed. The cement should be in a doughy state when applied and can be injected with a syringe or manually packed. Pressurize the cement several times before the glenoid component is introduced. Excess cement is cleaned away from the component edges, especially posteriorly. The glenoid pusher is used to maintain pressure on the component while the cement cures (Figure 21).
**Keeled Glenoid Peraration**

*Glenoid Drill Guide Placement*
Confirm the size of the glenoid component by sequentially positioning drill guides over the face of glenoid surface until full coverage of the articulating glenoid surface is obtained. With the appropriate sized drill guide centered over the glenoid fossa, drill the center hole with the gold annodized center drill bit (Figure 22).

Using the straight glenoid reamer, center the peg into the pre-drilled hole and ream the glenoid surface (Figure 23).

Align the keel template over the drilled center hole and mark the keel outline with methylene blue (Figure 24).
With a 7mm burr, mill out the keel shape and approximate keel depth (Figure 25). A small curette can be used to undermine the glenoid vault along the axillary border of the scapula and up into the base of the coracoid for cement fixation.

A keel punch is provided to ensure clearance of the keel geometry and an adequate cement mantle (Figure 26).

The selected glenoid trial provides a line-to-line reference to the final glenoid thickness with the keel slightly oversized to account for the cement mantle. Like the pegged glenoid component, the keel is grooved for easy length customization should it be required.

The keel hole is irrigated with antibiotic solution and thoroughly dried, using thrombin soaked gelfoam, if needed. The cement should be in a doughy state when applied and can be injected with a syringe or manually packed. Pressurize the cement several times before the glenoid component is introduced. Excess cement is cleaned away from the component edges, especially posteriorly. The glenoid pusher is used to maintain pressure on the component while the cement cures (Figure 28).
Assessing Mobility and Joint Stability

A humeral head trial component corresponding to the size of the glenoid component used is chosen with an estimated height based on preoperative templating and the amount of bone resected. A trial reduction is then performed.

The height of the humeral prosthesis above the greater tuberosity and degree of retroversion of the head are examined before reduction. The appropriateness of the chosen humeral head thickness is assessed by evaluating the tension present in the rotator cuff and deltoid muscles.

Four criteria for the proper thickness of the humeral head component are helpful in this assessment:

- The articular surface of the prosthetic humeral head must be above the greater tuberosity to prevent impingement.
- The head height of the prosthesis must be long enough to fill the tuberosity-glenoid space or the components will be unstable; conversely, a neck too long will: a) interfere with the closure of the subscapularis tendon, b) overtighten the musculotendinous rotator cuff, or c) limit motion postoperatively.
- The humeral component can be displaced no more than 50% posteriorly and inferiorly.
- Joint reduction should allow full internal rotation and adduction of the arm across the body.

Offset Humeral Head Technique

A humeral head trial component corresponding to the anatomic proximal humeral articular surface is selected. This can be accomplished in several different methods.

1. One method is to trim the osteophytes off the proximal humerus. Prior to the osteotomy, identify the anatomic neck then resection at this level will correspond to a close approximation of the anatomic head size either with a neutral head or an offset head. The cut surface is covered by the trial and if this allows for proper soft tissue balancing, the position of this head will correspond to anatomic restoration of the center of rotation of the shoulder for that individual patient.

2. Another method is to remove osteophytes and make a humeral osteotomy in a fixed retroversion based on an alignment rod referable to the forearm. Then above the rotator cuff insertion and if the neutral trial head provides accurate soft tissue balancing yet there is still exposed head and/or the greater tuberosity is situated higher than the top of the neutral head, then an offset head needs to be trialed. This second method relies on an indirect method of an anatomic restoration; the average top of the humeral head is 8 mm above the tip of the greater tuberosity.

Every offset head has a 4mm offset taper, allowing for rotation of the head into unlimited head positions to provide optimum coverage of the proximal humerus. The height of the humeral prosthesis above the greater tuberosity and degree of retroversion of the head are determined before reduction. The appropriateness of the chosen humeral head thickness is assessed by evaluating the tension present in the rotator cuff and deltoid muscle. When the desired position of the head is found; utilize the medial fin as a point of reference to denote the degree of rotation needed for final implantation.

After the humeral stem component has been cemented/press-fit into the humeral canal, align the offset humeral head into the position found to be the most anatomic during trialing. The offset head is then impacted on the humeral stem using the impactor.
Humeral Implantation
Foundation® Shoulder System

Humeral Cement Technique

A humeral prosthesis one size smaller than the last broach used should be chosen for implantation; this will allow for the desired 2 to 3mm cement mantle. Large nonabsorbable sutures are placed through drill holes in the greater tuberosity in preparation for reattaching the rotator cuff, or through the anteromedial aspect of the proximal humerus to reattach the subscapularis tendon, if necessary. A cement restrictor is gently tapped down the intramedullary canal approximately 1cm distal to the tip of the prosthesis.

The canal is brushed, irrigated with an antibiotic solution using pulsatile lavage, and thoroughly dried. At the same time, two packages of polymethylmethacrylate are vacuum-mixed and loaded into a cement gun. In a doughy state, the cement is injected into the humeral canal in a retrograde fashion and pressurized.

The humeral component is lined up in its proper position with the correct amount of retroversion and gently, but firmly, tapped with a mallet into place down the humeral canal, taking care not to let the component rotate or tilt while being inserted (Figure 28).

Once the component is fully seated, it is held firmly in position until the cement has fully cured. Excess cement is removed. The chosen humeral head is impacted onto the humeral stem (Figure 30). The proximal humerus is reduced and taken through a range of motion, assessing position and stability.
Press-fit Technique

If a press-fit is desired, the proximal humerus is prepared as previously described. However, the stem size chosen will be the same as the last broach size used. The humeral component is slightly larger than the last broach used to help achieve a stable press fit. Once the desired broach is fully seated, it is tested for stability and appropriateness of a press fit fixation. The handle attached to the broach can be grasped and attempts can be made to rotate the broach in the humeral canal. If the broach rotates or deforms the proximal humerus cancellous bone, then the humeral component should be secured with cement fixation.

Once the decision is made to press-fit the component, the canal is irrigated with antibiotic solution, but not with pulsatile lavage. Any sutures that need to be placed for closure are put in at this point. The humeral component is lined up in its proper position with the correct amount of retroversion and gently, but firmly, tapped with a mallet into place down the humeral canal, making sure that the component progresses slightly with each successive tap of the mallet. Once again, care must be taken not to let the component rotate or tilt while it is being inserted because this can compress the proximal cancellous bone and compromise the press-fit fixation. The cancellous bone from the resected humeral head can be used to bone graft any small defects or ensure a tight press-fit. The humeral head is then attached as previously described, and the humerus is reduced into the glenoid.
Closure
Foundation® Shoulder System

Final Reduction

With the humeral component reduced, the wound is copiously irrigated with antibiotic solution and the subscapularis is reattached with nonabsorbable sutures (Figure 32). Care must be taken to avoid injury to the biceps tendon, which is left free in its groove. A medium suction drain is inserted between the deltoid muscle and rotator cuff, and the deltopectoral groove is closed with a running absorbable suture.

Postoperative Management

A sling and swathe is applied in the operating room, and care is taken to place a pillow under the elbow when the patient is lying in bed so that the elbow is kept in front of the coronal plane of the body, allowing the humeral head to fall slightly posterior and not press on the subscapularis repair. Patients are allowed out of bed in a chair with assisted ambulation later in the day and are given a regular diet as tolerated. The suction drain is removed within 24 hours. Early passive motion is begun the afternoon of surgery in the patient's room with the physical therapist.
### Neutral Humeral Head

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### Humeral Stem (primary)

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References
