

# Keep Reaching



If you suffer from debilitating shoulder pain, the Reverse<sup>®</sup> Shoulder Prosthesis may offer you hope for relief.

The Reverse<sup>®</sup> Shoulder Prosthesis is designed specifically for patients with severe shoulder arthritis and irreparable rotator cuff damage. (The rotator cuff is the group of tendons that attach the shoulder muscles to the arm.)

Until now, there have been limited surgical options available for patients with severe deterioration of their shoulder joint. Conventional shoulder implants could not necessarily address both arthritis and rotator cuff damage. As a result, patients often had no choice, but to endure pain with restricted shoulder function.

(CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.)

#### Indications

The Reverse Shoulder Prosthesis is indicated for use in patients with:

- Grossly rotator cuff deficient shoulder joint with severe arthropathy;
- Failed joint replacement with a grossly rotator cuff deficient shoulder joint;
- Evidence of upward displacement of the humeral head with respect to the glenoid;
- Loss of glenohumeral joint space;
- Patients must have a functional deltoid muscle.

While Reverse Prosthesis shoulder replacements are not intended to withstand activity levels and loads of normal healthy bone, they are a means of restoring mobility and reducing pain for many patients.

#### Contraindications

Total joint replacement is contraindicated where there is:

- Non-functional deltoid muscle;
- Active sepsis;
- Excessive glenoid bone loss;
- Pregnancy;
- Muscular, neurological or vascular deficiencies, which compromise the affected extremity;
- Conditions that place excessive demand on the implant (i.e. Charcot's joints, muscle deficiencies, refusal to modify postoperative physical activities, skeletal immaturity);
- Known metal allergy (i.e., jewelry).

#### Precautions and Warnings

This shoulder is a semi-constrained device designed to address irreparable soft tissue, irreparable rotator cuffs, musculature and bony deficiencies. Due to the constraints built into the design, there may be limits to the patient's achievable range of motion. In addition, because of the limit to the range of motion, there may be the possibility of impingement and/ or additional wear.

The ranges of motion below are based on in-vitro testing. Clinical results may vary based on an individual patient's skeletal and soft tissue makeup. Total arcs of motion achieved may be greater or less than the degrees measured in-vitro since these motions are influenced by other body kinematics.

#### Range of Motion

Forward Flexion Adduction Abduction External Rotation Internal Rotation  
No Impingement -9° to 8° 71° to 98° 10° to 30° 26° to 53°

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#### Adverse Effects

1. Accelerated wear of the polyethylene articulating surfaces have been reported following total shoulder replacement. Such wear may be initiated by particles of cement, metal, or other debris which can cause abrasion of the articulating surfaces. Accelerated wear shortens the useful life of the prosthesis, and leads to early revision surgery to replace the worn prosthetic components.
2. Metallosis and osteolysis may be implicated from wear debris associated with the use of orthopedic implants.

3. Peripheral neuropathies have been reported following total joint surgery. Subclinical nerve damage occurs more frequently, possibly the result of surgical trauma.

4. Metal sensitivity reactions in patients following joint replacement have been rarely reported. Implantation of foreign material in tissues can result in histological reactions involving macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to, or during the healing process. In some cases, wear debris can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening of the implant.

5. Dislocation and subluxation of implant components can result from improper positioning of the components. Muscle and fibrous tissue laxity can also contribute to these conditions.

6. Implants can loosen or migrate due to trauma or loss of fixation.

7. Infection can lead to failure of the joint replacement.

8. While rare, fatigue fracture of the implant can occur as a result of strenuous activity, improper alignment, or duration of service.

9. Fracture of the humerus can occur while press-fitting (seating) the humeral stem into the prepared humeral canal.

10. Allergic reactions.

Intraoperative and early postoperative complications can include:

- 1) humeral perforation, or fracture;
- 2) humeral fracture can occur while seating the device;
- 3) damage to blood vessels;
- 4) temporary or permanent nerve damage resulting in pain or numbness of the affected limb;
- 5) undesirable shortening or lengthening of the limb;
- 6) traumatic arthrosis of the shoulder from intraoperative positioning of the extremity;
- 7) cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
- 8) hematoma;
- 9) delayed wound healing; and,
- 10) infection.

Late postoperative complications can include:

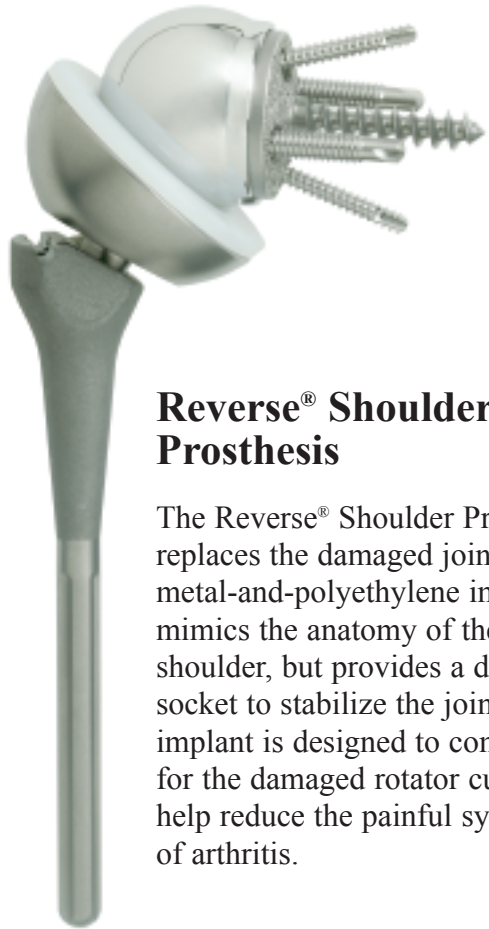
- 1) avulsion as a result of excess muscular weakening;
- 2) non-union due to inadequate reattachment and/or early weight bearing;
- 3) aggravated problems of other joints of the affected limb or muscle deficiencies;
- 4) humeral fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
- 5) periparticular calcification or ossification, with or without impediment to joint mobility;
- 6) inadequate range of motion due to improper selection or positioning of components, by impingement, and calcification.



## Is Shoulder Pain Keeping You from Enjoying Life?

Ask your doctor today about the Reverse<sup>®</sup> Shoulder Prosthesis. Visit [www.encorereverse.com](http://www.encorereverse.com) for more information.

# *New Hope for Severe Shoulder Pain*



## **Reverse® Shoulder Prosthesis**

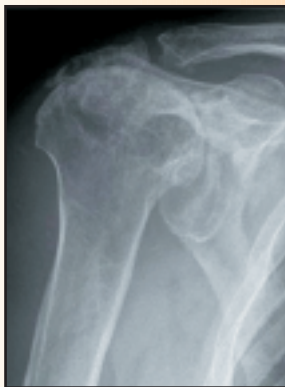
The Reverse® Shoulder Prosthesis replaces the damaged joint. The metal-and-polyethylene implant mimics the anatomy of the natural shoulder, but provides a deeper socket to stabilize the joint. The implant is designed to compensate for the damaged rotator cuff and help reduce the painful symptoms of arthritis.

## **How the Normal Shoulder Works**

The shoulder is a ball-and-socket joint with three main bones: the upper arm bone (humerus), shoulder blade (scapula) and collarbone (clavicle).

In a normal shoulder, the joint is supported by the muscles that surround the shoulder. Shoulder movement is created and controlled by delicate interactions of 30+ muscles, tendons and ligaments. The rotator cuff is a group of muscles and tendons that enables the arm to be lifted, reach overhead and do activities such as throwing and swimming.

In patients with severe rotator cuff damage, the joint can become unstable, severely restricting the patient's range of motion. Over time, the out-of-balance joint can wear down the lubricating cartilage between bones. Bone starts to rub against bone, causing the pain we know as osteoarthritis.



Osteoarthritis



Postoperative Prosthesis

## **Frequently Asked Questions**

### ***Why is this product important news?***

The Reverse® Shoulder Prosthesis provides an innovative surgical alternative to conventional surgical methods. The Reverse® Shoulder addresses both severe shoulder arthritis and irreparable rotator cuff damage.

### ***What makes it unique?***

The Reverse® Shoulder Prosthesis is an exclusive design that reverses the shoulder anatomy in order to effectively resist the pull of the shoulder deltoid muscle. For patients, this could mean greater range of motion and relief from pain.

### ***What are the benefits to the patient?***

With the Reverse® Shoulder Prosthesis, the patient has the potential for greater range of motion compared to conventional shoulder implants.

### ***What is involved in the surgical procedure?***

The surgical procedure is conducted under general or local anesthesia; and generally takes about 1 to 1½ hours to complete.

### ***What is involved in the recovery process?***

Patients will work with a physical therapist to resume daily activities and strengthen shoulder muscles.

### ***How long before the patient can resume activities?***

Most patients are able to return to activities within a few months.