



For the attention of the operating surgeon

Catalyst CSR Shoulder System Instructions for Use

Device Description

The Catalyst CSR Shoulder System is a bone preserving total shoulder prosthesis designed for use in patients where the humeral head, neck and glenoid vault are of sufficient bone stock and there is an intact or reconstructable rotator cuff. The design requires minimal bone resection, thus giving the patient an alternative to other total shoulder designs where more bone is removed.

The Catalyst CSR glenoid components are manufactured from UHMWPE conforming to ASTM F648. Three sizes of glenoid components are available, with standard and posterior augmented options. The augmented implant provides 10° of correction to a posteriorly eroded glenoid. All glenoid components are designed to allow insertion at an angle, in the same orientation as the surgeon's exposure, to reduce the forceful retraction and bone and soft tissue trauma usually required to insert standard glenoid components. Three angled pegs are engineered to match the shape of the glenoid vault and provide implant fixation within the dense cortical and subchondral bone. The three pegs have small prominences to allow for a slight interference fit upon insertion, to minimize micromotion until the cement has hardened.

The Catalyst CSR humeral components are manufactured from cast Co-Cr-Mo alloy conforming to ASTM F75 and have a polished surface for articulation with the glenoid component or the glenoid cavity of the scapula. The humeral components are designed with standard (non-spherical) and spherical geometries. The standard humeral components have seven sizes and the spherical humeral components have six sizes. The humeral components incorporate 4 pegs which assist with alignment and provide rotational stability. The four plane geometry of the back side of the humeral component matches four cut surfaces on the humeral head to recreate the geometry and thickness of the removed bone.

Indications for Use

The Catalyst CSR Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint where hemi- or total shoulder arthroplasty is determined by the surgeon to be the preferred method of treatment. The Catalyst CSR Shoulder System is intended for use in patients with the following conditions where the humeral head, neck and glenoid vault are of sufficient bone stock and the rotator cuff is intact or reconstructable.

- Osteoarthritis
- Avascular Necrosis
- Rheumatoid Arthritis
- Post-traumatic Arthritis
- Correction of functional deformity

The Catalyst CSR humeral and glenoid implants are intended for cemented use.

The Catalyst CSR Press-Fit humeral implants are intended for uncemented or cemented use.

Contraindications

Use of the Catalyst CSR Shoulder System is contraindicated in the following conditions:

- Local or systemic infection, or osteomyelitis of the proximal humerus or scapula; if a systemic infection or a secondary remote infection is suspected or confirmed, joint replacement surgery should be delayed until infection is resolved
- Inadequate or malformed bone that precludes adequate support or fixation of the prosthesis
- Osteoporosis
- Neuromuscular disorders that do not allow control of the joint
- Chronic instability, chronic dislocation or deficient soft tissues and other support structures (e.g., brachial plexus or deltoid muscles)
- Vascular insufficiency
- Patient's age, weight or activity level cause the surgeon to expect early failure of the system
- The patient is unwilling or unable to comply with the post-operative care instructions
- Alcohol, drug, substance abuse or other conditions that would affect or impair the patient from complying with post-operative instructions.
- Patients with known sensitivity to Co-Cr-Mo alloys typically used in prosthetic devices
- Any disease that could adversely affect the function or expected longevity of the implants (e.g., metabolic disorders).

Warnings & Precautions

The orthopedic surgeon must be fully knowledgeable about all aspects of the Catalyst CSR Shoulder System surgical technique and use these implants in accordance with the indications and contraindications summarized in this IFU. The Catalyst CSR Shoulder System is not indicated for humeral fractures. The Catalyst CSR components are not designed for and should not be used with components from other implant systems or manufacturers. The Catalyst CSR Shoulder System is intended for use only with Catalyst CSR Shoulder System instrumentation, unless generic instrumentation is specified (e.g., power saw) in the surgical technique.

Only qualified orthopedic surgeons knowledgeable in anatomy, biomechanics, and reconstructive surgery should utilize the Catalyst CSR Shoulder System. Proper size selection, placement, positioning, alignment and cemented fixation are required to achieve the expected longevity of the implants. The implants must be dry and free of surgical debris to ensure proper fixation with cement.

Patient Selection

As part of the pre-operative, patient selection process; the orthopedic surgeon must ensure that no biological, biomechanical or other factors exist that might prohibit the use of the Catalyst CSR Shoulder System. For example:

- Bone must be of sufficient quality to prevent the prostheses from loosening.
- Patients who are currently smokers are at risk for slower post-operative healing, infection and potential early loosening of the devices.
- The physical size, weight and activity levels of the patient may affect the expected useful life of the implants.

It is recommended to use the largest possible humeral head and glenoid implant that will achieve the desired anatomic and functional outcome in larger patients. The use of prostheses in extremely large, heavy or active patients may result in early failure of the devices (e.g., implant fracture, loosening).

Possible Adverse Events

The following adverse events have been reported after shoulder surface replacement surgery and are possible outcomes with the use of the Catalyst CSR Shoulder System:

- Loosening or instability of the components
- Infection
- Osteolysis
- Reaction due to metal sensitivity
- Fracture of the components or the bone
- Wear and damage to articular surfaces
- Adverse events related to the use of bone cement
- Impingement
- Overstuffing of the joint if the incorrect size of prosthesis is used
- Stiffness
- Myositis ossificans
- Ankylosis

Some adverse events may require revision surgery or fusion of the joint.

In addition, the following adverse events are possible after any shoulder arthroplasty:

- Nerve injury
- Deep vein thrombosis
- Hematoma
- Pneumonia
- Cardiovascular disorders

MRI Safety Information

The components of the Catalyst CSR Shoulder System have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the Catalyst CSR Shoulder System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Sterility

The components of the Catalyst CSR Shoulder System are provided sterile and are intended for single use only. Do not use if the sterility of the components is potentially compromised. Never re-use or re-sterilize any component.

Patient Counseling Information

Patients that are more active, have unrealistic expectations or fail to follow post-operative care may be more likely to have failure or complications associated with their total shoulder prosthesis. Failure of the prostheses can include wear, dislocation, fracture or other complications. The patient must be counseled regarding the total shoulder prostheses and the impact it may have on activities of daily living. Prosthetic joints are not as durable as natural, healthy joints and may not last the lifetime of the patient. The life of the implant may vary greatly depending on many factors and it may need to be replaced during the lifetime of the patient.

Questions or comments regarding the use of this device should be directed to Catalyst OrthoScience Customer Service.

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