For the attention of the operating surgeon

Catalyst Fracture Shoulder System
Instructions for Use

Device Description

The Catalyst Fracture Shoulder System is intended for use in patients with proximal humerus fractures. The stems can be used in conjunction with the Catalyst Reverse Shoulder humeral articulating poly inserts and glenoid implants for use in reverse shoulder arthroplasty. The stems can also be used in conjunction with the Catalyst Convertible System and CSR System for use in total or hemi-shoulder arthroplasty. The design intent of the Catalyst Fracture Shoulder System is to offer a unique solution for securing and immobilizing the greater and lesser tuberosities in the repair of proximal humerus fractures.

The Catalyst Fracture Shoulder System consists of proximal bodies, distal stems, locking screws and spacers. The proximal bodies have asymmetric, right- and left-sided finned geometry to provide specific locations to reattach the greater and lesser tuberosities for a stable reconstruction of the proximal humerus. The proximal bodies will have a porous titanium structure on the bone engaging regions to enhance the mechanical fixation. The distal stems shall be provided in varying diameters to accommodate varying bone geometries. The distal stems will be offered in press-fit and cemented versions. The press-fit distal stems shall have a tapered, splined proximal geometry with an HA (hydroxyapatite) coating. The cemented stems shall have a smooth stem geometry. The proximal bodies and distal stems shall be secured together using a mechanical taper interface that is supplemented with a locking screw. Spacers shall be provided to offer additional options for restoring the appropriate humeral height.

Indications for Use

The Catalyst Fracture Shoulder System is intended for use as a replacement of shoulder joints in anatomic or reverse arthroplasty. Should the need arise for a conversion from an anatomic total shoulder to a reverse total shoulder, the humeral stem can remain in place, while the articulating surfaces are exchanged.

ANATOMIC TOTAL SHOULDER OR HEMI-SHOULDER

The Catalyst Fracture 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 Fracture 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

REVERSE TOTAL SHOULDER

The Catalyst Fracture Shoulder System is a reverse total shoulder replacement for patients with a functional deltoid muscle and a grossly deficient rotator cuff joint suffering from pain and dysfunction due to:

- Severe arthropathy with a grossly deficient rotator cuff;
- Previously failed joint replacement with a grossly deficient rotator cuff;
- Fracture of glenohumeral joint from trauma or pathologic conditions of the shoulder including humeral head fracture, displaced 3- or 4-part fractures of proximal humerus, or reconstruction after tumor resection;
- Non-inflammatory degenerative disease including osteoarthritis and avascular necrosis of the natural humeral head and/or glenoid;
- Inflammatory arthritis including rheumatoid arthritis;
- Correction of functional deformity

Catalyst Fracture press-fit stems are intended for cementless press-fit applications.
The Catalyst Fracture cemented stems are intended for cemented fixation.
The Catalyst Fracture stem is compatible with the implants from the Catalyst CSR System, Catalyst Stemmed Anatomic Shoulder System and Reverse Shoulder Systems.

Contraindications

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

- Non-functional deltoid muscle
- 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
- Neuromuscular disorders that do not allow control of the joint
- Chronic instability or deficient soft tissues and other support structures (e.g., brachial plexus)
- 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 Fracture Shoulder System surgical technique and use these implants in accordance with the indications and contraindications summarized in this IFU. The Catalyst Fracture components are not designed for and should not be used with components from other implant systems or manufacturers. The Catalyst Fracture Shoulder System is intended for use only with Catalyst Fracture 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 Fracture Shoulder System. Proper size selection, placement, positioning, alignment and/or 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 connection of components and 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 Fracture 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.

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 Fracture 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
- Systemic pain

MRI Safety Information

The components of the Catalyst Fracture Shoulder System have not been evaluated for safety in the MR environment. They have not been tested for heating, or unwanted movement in the MR environment. The safety of the Catalyst Fracture Shoulder System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

Sterility

The components of the Catalyst Fracture 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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