For the attention of the operating surgeon

Catalyst Stemmed Anatomic Shoulder System
Instructions for Use

Device Description

The Catalyst Stemmed Anatomic Shoulder is intended for use as a replacement of shoulder joints in primary anatomic or primary 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.

The Anatomic system consists of a humeral stem, adapter, locking screw and articulating head. The humeral stems are manufactured from Ti-6Al-4V with a plasma sprayed CP Titanium coating. The adapters are secured to the stem using a locking screw. The adapters and locking screw are manufactured from Ti-6Al-4V. The Co-Cr-Mo articulating humeral heads are secured to the adapter by a taper lock. The articulating head components have a polished surface for articulation with the glenoid component or the glenoid cavity of the scapula. The compatible Catalyst 3-Peg glenoid components are manufactured from UHMWPE.

The Reverse system consists of a humeral stem, articulating insert, central baseplate, glenosphere, fixation elements and locking components. The humeral stems are manufactured from Ti-6Al-4V with a plasma sprayed CP Titanium coating. The humeral articulating inserts are manufactured from UHMWPE. The central baseplate is a circular disc that rests against the glenoid bone and is secured to the bone using up to four 4.5mm peripheral screws and either a central 6.5mm screw or post. The central baseplate is manufactured from Ti-6Al-4V with a CP Titanium plasma spray on the bone facing surface. The Co-Cr-Mo glenosphere is secured to the central baseplate by a taper lock, with the additional fixation of a locking screw.

Indications for Use

Anatomic Total Shoulder or Hemi-Shoulder

The Catalyst Stemmed Anatomic Shoulder 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 Stemmed Anatomic Shoulder 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 3-peg glenoid implants are intended for cemented use only.
The Catalyst REVERSE Shoulder humeral stems are intended for uncemented or cemented applications.

Reverse Total Shoulder

The Catalyst Stemmed Anatomic Shoulder 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;
- Bone defect in proximal humerus;
- 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

The Catalyst REVERSE Shoulder humeral stems are intended for uncemented or cemented applications.
The glenoid baseplate is intended for uncemented use with the addition of screws for fixation.

Contraindications

Use of the Catalyst Stemmed Anatomic Shoulder 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 Stemmed Anatomic Shoulder surgical technique and use these implants in accordance with the indications and contraindications summarized in this IFU. The Catalyst Stemmed Anatomic Shoulder is not indicated for humeral fractures. The Catalyst EA components are not designed for and should not be used with components from other implant systems or manufacturers. The Catalyst Stemmed Anatomic Shoulder is intended for use only with compatible Catalyst 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 Stemmed Anatomic Shoulder. 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 within the bone as intended.

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 Stemmed Anatomic Shoulder. 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 Stemmed Anatomic Shoulder:

- 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 Stemmed Anatomic Shoulder 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 Stemmed Anatomic Shoulder in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Sterility

The components of the Catalyst Stemmed Anatomic Shoulder are provided sterile and are intended for single use only. Do not use if the sterility of the component 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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