K961571

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SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet, Inc.
Airport Industrial Park
Warsaw, Indiana 46580

Device: CoCr Bi-Angular Humeral Component

Classification Name: Shoulder Joint Non-Constrained Metal/Polymer Cemented Prosthesis

Device Description: The device is composed of a metallic humeral stem which is designed to articulate with a commercially available glenoid component. There is no linkage across the joint.

The tapered collarless stem follows the natural contours of the canal; the tapered geometry loads the cement mantle in compression and promotes evenly distributed stress off-loading. Proximal fins contribute to maximize rotational stability while suture holes in the fins allows for proximal reconstruction of complex humeral fractures. The stem is "grit blasted" for a roughened surface of 200 microinches which provides for an improved fixation between the stem/cement interface.

Stems are available in 7 sizes with diameters ranging from 6.5mm to 15.5mm in 1.5mm increments at a length of 115mm, for primary use. Revision stems are available in a range of diameters of 8.0mm to 14.0mm in 1.5mm increments at a length of 190mm.

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Reaction to bone cement
Fracture of the components
Cardiovascular disorders
Implant loosening/migration
Soft tissue imbalance
Deformity of the joint
Tissue growth failure
Delayed wound healing
Fracture of the cement
Bone fracture
Hematoma
Blood vessel damage
Nerve damage
Excessive wear
Infection
Dislocation
Metal sensitivity

Substantial Equivalence: In function and overall design Biomet's CoCr Bi-Angular Humeral Component is equivalent to almost all shoulder components on the market.

Commercially available shoulder devices include:

Atlas Shoulder, Kirschner, 510(k)# K940537 cleared for marketing 29 August, 1995.
Neer Shoulder, Kirschner, 510(k)# K873073 cleared for marketing 1 October, 1987.
Bi-Angular Shoulder, Biomet, 510(k)# K872454 cleared for marketing 27 August, 1987.

Reported Complication of Total Shoulder Arthroplasty

Complication	Citation
Glenoid loosening	Gristina (1987), Cofield (1984), Brenner, Moor (1982), Barrett (1987), Warren, Thomas, Kelly (1987), Friedman (1989), Roper, Hawkins (1989), Averill, Pahle, Boyd (1991), Wilde (1984), Amstutz (1988), Friedman (1986), Pritchett
Component instability	Gristina (1987), Cofield (1984), Brenner, Moor (1982), Fleega, Barrett (1987), Roper, Hawkins (1989), Averill, Pahle, Wilde (1984), Amstutz (1988), Clayton, Pritchett
Rotator cuff deficiency or tearing	Cofield (1984), Moor (1982), Fleega, Warren, Kelly (1987), Figgie
Humeral component loosening	Gristina (1987), Moor (1982), Barrett (1987), Warren, Boyd (1991), Amstutz (1988)
Infection	Gristina (1987), Moor (1982), Roper, Pahle, Kelly (1990), Wilde (1984), Amstutz (1988)
Bone fracture	Brenner, Moor (1982), Barrett (1987), Warren, Thomas, Kelly (1987), Hawkins (1989), Averill, Pahle, Kelly (1990), Boyd (1991), Amstutz (1988), Pritchett
Humeral Subsidence	Kelly (1990), Boyd (1991)
Impingement	Barrett (1987), Warren, Wilde (1984)
Pain	Barrett (1987), Copeland
Heterotopic bone formation	Wilde (1984)
Superior migration of the humeral head	Brenner, Thomas, Kelly (1987), Hawkins (1989), Averill, Boyd (1991), Amstutz (1988), Pritchett
Tuberosity nonunion	Cofield (1984), Moor (1982)
Excessive bleeding	Warren
Nerve laceration or injury	Gristina (1987), Cofield (1984), Barrett (1987), Warren, Averill, Boyd (1991), Pritchett
Hematoma	Cofield (1984)
Wound healing	Figgie
Muscle weakness	Copeland, Figgie
Reflex sympathetic dystrophy	Cofield (1984)
Pulmonary embolism	Cofield (1984)