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SUMMARY OF SAFETY AND EFFECTIVENESS

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

Device: Fenning Femoral Component

Classification Name: Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis.

Device Description: Biomet's Fenning Femoral Component is composed of a metallic femoral stem which is designed to articulate with a commercially available acetabular component. The device limits translation and rotation via the geometry of the articulating surface. There is no linkage across the joint.

The stem has a 30° collar with plasma sprayed porous coating circumferentially on the underside of the collar, including the cone; the porous coating extends to the proximal lateral 1/4 of the stem: 1.5 inches from the top laterally to below the collar medially. Porous coating is to achieve biological fixation to the surrounding bone by tissue, either bone or soft tissue, without the use of bone cement. The porous coating on the underside of a collar and the extended proximal lateral porous coating provide areas of potential tissue ingrowth in crucial regions of cortical bone.

The conical collar design provides a larger contact surface for stress transfer to the proximal femur via the collar wedging into the bone. The wedging of the implant into the canal allows the entire collar to sit on cortical bone occluding the proximal canal while providing rotational stability of the stem. There is no lateral collar eliminating the need to resect the greater trochanter.

The stem is tapered, following the natural contours of the canal. The stem below the porous coating to the middle portion is "grit blasted" for a roughened surface of 200 microinches. The distal half of the stem is smooth and fluted. The flutes provide additional rotational stability. There is a distal coronal slot to minimize distal stem stiffness.

The device will be available in 5 stem sizes of diameters 9mm to 17mm at 2mm increments with corresponding stem lengths of 145mm to 165mm at 5mm increments. The stem is straight eliminating the need for left and right configurations.

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

Substantial Equivalence: In function and overall design Biomet's Fenning Femoral Component is equivalent to almost all hip components on the market. These stems include:

PSL Total Hip (BioPro) 510(k) K922500
Conical Collar Hip (Kirschner) 510(k) K854046
C₂ Osteocap Hip (Kirschner) 510(k) K861450