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Summary of Safety and Effectiveness

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Trade Name: Foundation® Porous Press-fit Acetabular Component

Common Name: Press-fit Porous Shell

Classification Name: Hip joint metal/polymer semi-constrained non-cemented prosthesis

Description: The metal shell is fabricated from wrought/forged or cast Ti-6Al-4V. The outside surface of the shell is porous coated with commercially pure titanium beads to provide a porous surface for enhanced press-fit fixation.

The metal shell is hemispherical in shape and is available with and without screw holes. The screw holes are for the use of 6.5 mm cancellous bone screws for adjunct fixation. The geometry of the screw holes is such that a 12° angulation of the screws is possible.

The poly liners are manufactured from ultra high molecular weight polyethylene and are available in a neutral and 10° hooded design. The hooded design is intended for those patients prone to subluxation because of soft tissue laxity.

Intended Use: The Press-fit Porous Acetabular Component is intended for treatment of patients who are candidates for total hip arthroplasty because the natural femoral head and neck and/or acetabulum have been affected by osteoarthritis, inflammatory arthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis or femoral neck fracture, and revision arthroplasty where bone loss is minimal. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.

Comparable Features to Predicate Device(s): The spherical shape, titanium substrate and beaded coating, indexability of liners in shell and bone screw holes are features that are comparable to other devices in commercial distribution.

Test Results: Testing on this device included porous coating, tensile and shear strength, and attachment strength of liners to shell. All results are sufficient for *in-vivo* loading.