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**Device Information:**

proprietary name: Horizon Hip System  
common name: prosthetic, Total Hip System  
classification name: prosthetic, Total Hip System

Femoral component

The Horizon Femoral Stem is manufactured from cobalt chrome and features a collar to distribute stress in a physiological manner. It is available with or without porous coating. The femoral component is available in five sizes: 12mm, 13.5mm, 15mm, 16.5mm, and 18mm.

Acetabular Insert

The Horizon Acetabular Insert is manufactured of UHMWPE. It is designed to snap fit into the acetabular shell. The insert will accept 28mm and 32mm heads. It is offered in sizes ranging from 46mm to 60mm.

Acetabular Shell (cup)

The Horizon Acetabular Shell is manufactured of cobalt chrome. It features three spikes to prevent rotation. It also features a groove on its I.D. to accept the mating acetabular insert. The acetabular shell is porous coated to promote long term fixation. The acetabular shell is available in eight sizes: 46mm, 48mm, 50mm, 52mm, 54mm, 56mm, 58mm, and 60mm.

**Substantial Equivalence:**

The Horizon femoral stems are substantially equivalent to the Depuy AML femoral stems. Both styles have geometries which include a circular distal cross-section and an oval proximal cross-section for anti-rotation. Both styles are manufactured from cobalt chrome and are porous coated at least 5/8 of the way down the stem. The Horizon system also includes a non-porous coated stem option. Although both sets of stems have collars, the angle of the collar varies. The Horizon stems have a collar positioned at 20° from the horizontal, while the Depuy stems have a collar positioned at 45° from the horizontal. The collar positioned at 20° resists the joint loads more efficiently and reduces the shear stresses at the bone/implant interface. The mode of extraction for the stems also differs. The extraction instrument for the Horizon stems fits on the collar; whereas, the Depuy stems contain a hole in the proximal region to allow attachment of an extraction instrument. Additionally, the tapers present on the two stem styles differ. The Horizon taper is designed to accept a Biopro ceramic or cobalt chrome head while a Depuy stem is designed to accept a Depuy head.

The Horizon acetabular cup is substantially equivalent to the AML Plus Depuy cup. Both designs are porous coated on the entire O.D. of the shell and have three spikes projecting from the O.D. for stabilization and anti-rotation. The Horizon cup is manufactured from cobalt chrome and does not have any screw holes in it. This fact makes the joint more resistant to loosening because there is less particulate debris. On the other hand, the Depuy cup is made of titanium and has screw holes. The locking mechanisms for the two cups differ slightly. The Horizon cup has a locking lip around the I.D. to accommodate the insert. The Depuy cup contains rectangular grooves to accommodate its insert.

The acetabular inserts for both the Horizon hip system and the Depuy AML system are manufactured from UHMWPE. They have grooves for dialability and snap into the acetabular cup via their respective locking mechanisms. The Horizon insert is available with a 28mm I.D. or a 32mm I.D. The AML Depuy insert is available with a 26mm, 28mm, or 32mm I.D.

Although there are minor differences between the Horizon and Depuy components, they are substantially equivalent in form and function. Both systems are indicated for treatment of osteoarthritis, rheumatoid arthritis, avascular necrosis, and traumatic arthritis. Contraindications include: excessive bone loss, septic arthritis, periarticular osteomyelitis, and local or systemic infection.