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K964769

**Summary of Safety and Effectiveness  
VerSys™ Hip System--Fiber Metal  
Taper Hip Prosthesis**

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- Submitted By:

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- Trade Name: *VerSys™* Hip System--Fiber Metal Taper Hip Prosthesis

- Common Name: Femoral Hip Prosthesis

- Classification Name: Hip joint metal/polymer/metal semiconstrained porous coated uncemented prosthesis

- Predicate Devices for the Femoral Stem:

- Astel F-24 Femoral Hip Prosthesis, manufactured by Zimmer, K901687, cleared September 7, 1990
- *MultiLock®* Hip Prosthesis, K921308, cleared February 22, 1994
- *Zimmer®* Anatomic Hip Prosthesis, K922071, cleared February 22, 1994
- Delta Hip Prosthesis, K961378, cleared October 8, 1996



- **Device Description**

The Fiber Metal Taper Hip Prosthesis is a collarless, modular femoral stem manufactured from *Tivanium*® Ti-6Al-4V Alloy. *Tivanium* Alloy is a high fatigue strength material with a long history of successful clinical use and exceptional biocompatibility. The Fiber Metal Taper Hip Prosthesis is primarily designed for use in patients with a champagne flute (trumpet) type femur but may be used in other patients based upon the surgeon's judgment.

The modular connection of the femoral stem is a Morse-type 12/14 proximal neck taper designed to mate with the corresponding 12/14 bore of a femoral head component. The neck of the prosthesis increments progressively in offset and length with increasing stem size. Progressive offsets and neck lengths are designed to provide restoration of natural joint geometry and kinematics.

The proximal body of the stem features a trapezoidal geometry which optimizes metaphyseal fill of the proximal femur and provides rotational stability. The Fiber Metal Taper Hip Prosthesis will be available in nine sizes (10 through 18) with size increments of 1 mm. Stem sizes 12 through 16 mm are designed with two proximal body options, standard and large metaphysis, to accommodate variations in patient anatomy.

A commercially pure titanium circumferential fiber metal pad is metallurgically bonded to the proximal one-third of the stem. The purpose of the fiber metal pad is to achieve biological fixation to bone without the use of bone cement. The surface of the midstem region features a roughened surface providing for bone ongrowth and implant fixation. The distal shaft is tapered in both the medial/lateral plane and the anterior/posterior plane to encourage proximal fixation and minimize distal stem engagement in the canal.

- **Intended Use**

The Fiber Metal Taper Hip Prosthesis is a femoral stem designed for implantation into the human femur in either total hip or hemi-hip replacement and is indicated for the following:

- **Total Hip Replacement:**

Severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, nonunion of previous fractures of the femur; congenital hip

dysplasia, protrusio acetabuli, slipped capital femoral epiphysis; disability due to previous fusion; previously failed endoprostheses, and/or total hip components in the affected extremity and acute femoral neck fractures.

- Hemi-Hip Replacement:

Fracture dislocation of the hip; elderly, debilitated patients when a total hip replacement is contraindicated; irreducible fractures in which adequate fixation cannot be obtained; certain high subcapital fractures and comminuted femoral neck fractures in the aged; nonunion of femoral neck fractures; secondary avascular necrosis of the femoral head; pathological fractures of the femoral neck; and osteoarthritis in which the femoral head is primarily affected.

• Comparison to Predicate Devices

All hip systems listed above are substantially equivalent to each other and the Fiber Metal Taper Hip Prosthesis in that each is intended for cementless fixation into the intramedullary canal for pathological or degenerative conditions involving the femur and/or acetabulum. All predicate devices feature a porous or roughened surface and are modular in design. Each has a Morse-type proximal neck taper that mates with a femoral head which, in turn, articulates upon the ultra-high molecular-weight polyethylene (UHMWPE) bearing surface of a total hip or hemi-hip acetabular component. All predicate devices and the Fiber Metal Taper Hip Prosthesis are manufactured from metal alloys that have a history of successful clinical use in orthopaedic applications.

• Clinical Data

One current method of hip prosthesis implantation relies upon mechanical fixation through initial implant stabilization with secondary fixation supplied by bone ingrowth or bone ongrowth. The Fiber Metal Taper Hip Prosthesis is an example of a device designed to achieve biologic fixation to bone through bone ingrowth and bone ongrowth. Many studies published in the literature report satisfactory results are obtained through the use of porous coated, cementless hip prostheses.

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