

SECTION II

DEVICE INFORMATION

The following describes the devices for which reclassification is being sought.

A. General Device Description and Use

1. General

Total hip prostheses are orthopedic reconstructive devices intended to replace the principal articulating surfaces of the hip joint (i.e. the femoral head and the acetabulum) where these surfaces have been severely damaged by degenerative joint disease or traumatic injury. The main objectives of total hip replacement are relief of pain and restoration of function.

In the above respects, total hip replacement using a constrained acetabular component is no different than standard total hip arthroplasty. Constrained hip surgery involves the use of a commercially available femoral component and a metal polymer, or polymer acetabular component. The difference lies in the use of a polyethylene acetabular component that mechanically captures the femoral head to stabilize the joint and provide resistance to dislocation. Joint stability is afforded by the geometry of the constrained acetabular component for cases where the soft tissue structures are insufficient to provide stability. The constrained cup retains the ball of the femoral component by extending beyond a hemisphere and partially encasing it to provide joint stability. This reduces the travel-distance of the femoral neck, and therefore the range-of-motion is somewhat reduced when compared with a standard semi-constrained acetabular component.

Total hip prostheses generally consist of two components, a femoral component and an acetabular component. Either of these components can be modular in design (e.g. a taper-fit femoral head, and a metal acetabular shell with polymer liner). The femoral component is intended to replace the femoral head, and its stem is inserted into the intramedullary canal of the femur to anchor it. Femoral components are manufactured of alloys such as cobalt- chromium-molybdenum or titanium alloys. Femoral components may be fabricated as a single piece (head-stem) or it may be modular (with separate head and stem components) with a selection of head diameters/neck lengths that can be fitted to a stem of a chosen size. Modular femoral components are generally fitted together by Morse taper connections. Femoral stems may be cemented or press-fit into the intramedullary canal. The spherical femoral head is designed to articulate with the acetabular component that is fixed into the prepared acetabulum. The constrained acetabular component generally consists of a metal shell made from

cobalt-chromium-molybdenum or titanium alloys assembled with a constrained polymer liner fabricated from ultra-high molecular weight polyethylene (UHMWPE). The metal shells come in various styles and sizes to fit the anatomy. Acetabular components are fixed with bone cement, bone screws, and/or porous coating. Certain porous coated metallic femoral and acetabular hip prostheses (and devices determined to be substantially equivalent) for use without bone cement were reclassified from class III into class II in 1994. If bone cement is not used to **affix** the constrained acetabular component, a supplemental method of fixation, in addition to press fitting, is recommended to assure initial stability (e.g. bone screws, spikes, screw threads, fins, etc.)

Hip prosthesis components recommended for reclassification are the class III constrained polymer liners that are implanted in conjunction with standard class II acetabular shells and standard class II hip femoral components, thus making a class III constrained metal/polymer hip joint prosthesis.

B. Specific Intended Use – Constrained Acetabular Cup

This device is indicated for use as a component of a total hip prosthesis in patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intraoperative instability. Nine published articles reporting on 23,731 cases were selected to establish a historical dislocation rate (3.3% average, 1-6% range) following total hip replacement. The nine articles covering the largest number of cases were chosen. The search was conducted in the MEDLINE database using, “dislocation, hip” as the search word combination.

**TABLE II-A (Also See Appendix 2)
Dislocation Rate Following Total Hip Replacement**

Reference Dislocation Rate	
Ali Khan MA, et al (1)	2.1%
Hedlundh U, et al (2)	3.0%
Kristiansen B, et al (3)	4.9%
Madley SM, et al (4)	2.0%
Morrey BF (5)	2-3%
Patemo SA, et al (6)	6.0%
Schulte KR, et al (7)	1.0%
Turner RS (8)	4.5%
Woo RY. Morrey BF (9)	3.2%
Totals	3.3% Average (14% Range)