

SECTION IX

DEVICES CURRENTLY/PREVIOUSLY AVAILABLE

A. General Availability

Since the advent of the metal-backed, modular acetabular cup in the mid-1980s, constrained liners have been provided to surgeons for patients with a medical need for the device. As a matter of course, orthopedic device manufacturers that produce semi-constrained metal/polymer total hip prostheses have provided constrained cup liners on demand for the benefit of patients with dislocation problems.

Since dislocations occur at a rate of 1% up to 6% following total hip replacement, these devices are rarely used when compared to the usage of semi-constrained liners. As a service to those who need them, it is important that a constrained liner be offered as part of a total hip replacement system. A constrained liner is needed to salvage an otherwise well-fixed prosthesis in a patient with recurrent dislocation of the femoral head. Also it is used rarely in primary surgery for patients at high risk of dislocation. If a compatible constrained liner is not available to stabilize a joint: prosthesis already implanted, that prosthesis might require surgical removal. Polymer liners are not interchangeable from manufacturer to manufacturer, Therefore, in the interest of public health, the manufacturer of the prosthesis must be allowed to provide a constrained liner that fits into that specific acetabular shell.

As a consequence of the regulatory history of this device, manufacturers of total hip prostheses, other than the two listed in "B." below, have been restricted to providing constrained liners on an "emergency use" basis. Otherwise, a patient may have no alternative other than the unnecessary removal of a well-affixed implanted prosthesis to prevent recurrent dislocation.

B. Currently Available Constrained Acetabular CUPS

Since December 1996, there have been only two constrained acetabular components approved for marketing in the United States.

1. Osteonics
Constrained Acetabular Insert
P960047 June 13, 1997

2. Johnson and Johnson Professional, Inc.
S-ROM Poly-Dial Constrained Liner
P960054 June 19, 1997

C. Previously Available Constrained Acetabular Cups

Before December 1996, metal/polymer constrained hip acetabular liners have been commercially available from several orthopedic implant manufacturers. Some of these devices were cleared via the 510(k) premarket notification process, and others may have been provided "on demand" to physicians as "customized" devices to treat patients with chronic dislocation.

1. 5 1 O(k) Cleared Devices

5 1 O(k) Number: K950202
Device: Ringloc Constrained Liner
Applicant: Biomet, Inc.
Date Cleared: 5/15/95

5 1 O(k) Number: K870088
Device: S-Rom **Supercup** Acetabular Cup
Applicant: Joint Medical **Product** Corporation
Date Cleared: 4/22/88

5 1 O(k) Number: **K803 192**
Device: HCL Acetabular Components
Applicant: Osteonics Corporation
Date Cleared: 1/23/81

2. Devices That **May** Have Been Provided For Specific Patients (Custom Use)

When we performed a search of **MDR** and device listing databases, we found that at least five additional manufacturers have provided constrained acetabular cups since the mid-1980s. These constrained cups may have been custom devices, or "customized" versions of existing devices, used to treat specific patients requiring revision due to recurrent or chronic dislocation.