

Medical Devices

Osteonics® ABC System and Trident™ System – P000013

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name(s): Osteonics® ABC System; Trident™ System

Manufacturer: Howmedica Osteonics Corporation, a Stryker Company

Address: 359 Veterans Boulevard, Rutherford, New Jersey 07070-2584

Approval Date: February 3, 2003

Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf/p000013a.pdf

What are these devices? The Osteonics ABC System and Trident System are similar total hip replacement systems surgically implanted to completely replace a diseased or dysfunctional hip joint. The Trident System is newer than the Osteonics ABC System.

How do these devices work? For each of these systems, a stiff rod, called the femoral stem, is first inserted into the shaft of the thigh bone (the femur), and the ball-shaped part of the artificial hip joint, called the femoral head, is attached to this. The cup-shaped part of the joint, called the acetabular cup, is implanted into the cup-shaped space on the outer side of the hip. The femoral head and the acetabular cup fit together and are free to move against each other.

When are these devices used? A doctor uses one of these devices in a patient who needs a total hip replacement because of painful non-inflammatory arthritis. Causes of non-inflammatory arthritis include:

- problems in the joint due to age,
- lack of blood flow to the bone,
- joint damage due to injury,
- the growing end of the bone slipping off the end of the thigh bone,
- a broken hip bone,
- a broken thigh bone,
- a repaired fracture that has broken, or
- an abnormally curved thigh bone.

What will they accomplish? Either the Osteonics ABC System or the Trident System will reduce pain by replacing the painful arthritic hip and allow for increased function in the hip.

When shouldn't these devices be used? Neither the Osteonics ABC System nor the Trident System should be used in a patient who has

- an infection in or near the hip joint,
- a mental or neuromuscular disorder which might make the prosthesis unstable or fail, or lead to complications during postoperative care,
- diseased or infected bones that can't support or fasten to the prosthesis,
- damaged bones from a prior implant that can't support or fasten to the prosthesis, or
- bones that are still growing

Additional information:

- Summary of Safety and Effectiveness and labeling are available at:
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p000013>