FDA gives Wright Medical approval to market Conserve Plus resurfacing system

By Susan M. Rapp

1st on the web (November 10, 2009)

The Conserve Plus Total Hip Resurfacing System, manufactured by Wright Medical Group Inc., Arlington, Tenn., has been cleared for marketing by the U.S. Food and Drug Administration (FDA), the company announced yesterday.

The Conserve Plus system is the third metal-metal hip resurfacing implant to be approved by the FDA in recent years.

"The approval permits Wright to market Conserve Plus in the original femoral and acetabular component configuration specified in its Premarket Approval (PMA) application and enables the Company to initiate efforts to introduce additional enhancements to the system which are currently only available outside of the United States," according to a Wright Medical's Nov. 9 press release.

The company intends to incorporate these innovative future product options into the Conserve Plus System's femoral and acetabular component offerings via the PMA Supplement pathway, the release said.

Benefits cited

Orthopedics Today Editorial Board member Thomas P. Schmalzried, MD, who implanted 232 Converse Plus implants during the investigational trial, said, "Having Wright Medical and the Conserve Plus in the U.S. market will help train more surgeons in hip resurfacing and increase the proper utilization of this high performance and durable arthroplasty technology;"

Schmalzried, who has used other hip resurfacing systems, reported no femoral neck fractures or loose components in his Conserve Plus series follow-ups, which are now out past 8 years. He said the Conserve Plus has several advantages over the other systems available in the United States, including a sintered, small-bead porous coating on the acetabular component, which has long-term clinical success.

Mid-term results

Wright Medical’s clinical trial leading to FDA approval involved more than 1,300 patients, some of whom were enrolled under Continued Access protocols, according to the release.

"Hip resurfacing represents a valuable alternative to younger, more active patients who desire a hip reconstruction that more anatomically mimics the natural hip," Patrick Fisher, Sr., Wright Medical Director of Hip Marketing, stated in the release. "We have learned this is an excellent option for patients who meet the criteria for hip resurfacing."

The Conserve Plus system is designed to offer pain relief and restore function while retaining as much healthy bone as possible and preserving future surgical options, including a primary total hip replacement.

As part of the U.S. roll-out, surgeon training is expected to begin in the fourth quarter of 2009, a company spokesperson told Orthopedics Today.

Reference:


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Link to FDA approval