news & press

catch up on our latest news, product launches and company announcements.

company All Divisions year latest go

DePuy Orthopaedics, Inc. Statement on Discontinuation of ULTAMET® Metal-on-Metal and COMPLETE™ Ceramic-on-Metal Hip Systems

DePuy Orthopaedics, Inc. Statement on Discontinuation of ULTAMET® Metal-on-Metal and COMPLETE™ Ceramic-on-Metal Hip Systems

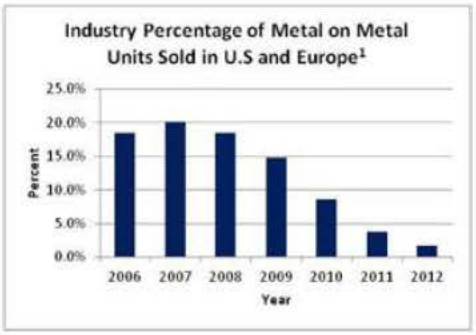
DePuy Orthopaedics, Inc., announced its decision to discontinue sales of its ULTAMET® Metal-on-Metal Articulation and COMPLETE™ Ceramic-on-Metal Acetabular Hip System worldwide. The discontinuation will be effective August 31, 2013. This will allow surgeons to plan accordingly for upcoming surgeries. The ceramic head used in COMPLETE will continue to be available for use in other bearing surface combinations.

The metal liner that is being discontinued is used in both ULTAMET and COMPLETE. The liner is designed exclusively for use with DePuy's PINNACLE® Acetabular Cup System, the PINNACLE Cup is not impacted by this discontinuation. The PINNACLE Cup System is one of the most widely used and clinically successful modular acetabular systems for hip replacement and will continue to be offered with both medical-grade plastic and ceramic liners.

The decision to discontinue ULTAMET and COMPLETE was made in conjunction with an ongoing review of DePuy's product portfolio. Other worldwide product discontinuations will be announced throughout 2013 and 2014 that will simplify and streamline DePuy's portfolio by focusing on fewer, worldwide strategic product platforms that meet patient and clinician needs and ensure long-term growth.

DePuy made the decision to discontinue these products because of low clinician use of ULTAMET and COMPLETE, the availability of other options that meet the clinical needs of patients, and proposed changes in FDA regulation of the entire class of metal-on-metal products, which includes ULTAMET.

Clinician use of ceramic-on-metal and metal-on-metal bearings is extremely low and not expected to increase. In the United States and Europe in 2012, metal-on-metal bearings comprised less than two percent of the bearings implanted.[1]. This represents a 90 percent decline in industry sales since 2007. Industry sales of ceramic-on-metal bearings have been low since their introduction to the market. Consistent with this overall market trend, ULTAMET and COMPLETE brands now represent less than one percent of DePuy bearings sold in these markets.



Advancements in polyethylene bearing technology and the recent approval of next generation options that meet the clinical needs of patients also contr buted to this decision. Physician preferences have shifted toward metal-on-polyethylene, ceramic-on-polyethylene and ceramic-on-ceramic bearings. These options include the newly approved CERAMAX® Total Hip System with BIOLOX® delta Ceramic-On-Ceramic 36MM Large Femoral Head for use with the PINNACLE Acetabular Cup System. Physician use of ceramic-on-ceramic (CoC) bearings is widespread in Europe where, in 2012, CoC represented over one in five bearings used.[2] CoC bearings also have considerable growth potential in the U.S. where new options are coming to market.

Another factor in the decision to discontinue ULTAMET is the proposed regulatory change by the U.S. Food and Drug Administration (FDA), which announced in January that it plans to require all metal-on-metal hip replacements with existing 510(k) clearances to be approved through the Premarket Approval (PMA) process. ULTAMET was first cleared for sale through the 510(k) process in 2000. DePuy will continue to invest in new bearing technologies like ceramic and polyethylene technologies. Investing resources to seek and maintain a PMA in low-use brands like ULTAMET and COMPLETE does not align with this long-term strategy. DePuy has communicated to the FDA its decision not to pursue a PMA submission for ULTAMET.

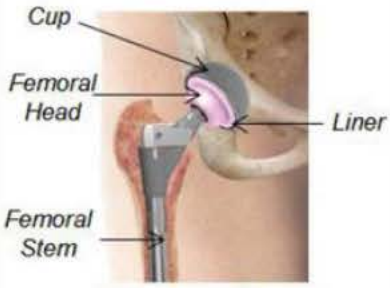
The decision to discontinue these products is not related to safety or efficacy, and is not a recall. ULTAMET and COMPLETE are backed by clinical data showing they are safe and effective options for patients who are candidates for hip replacement. As with all of our products, DePuy will continue to closely monitor the performance of ULTAMET and COMPLETE. DePuy reviews performance data from a variety of sources, including published and unpublished data from national joint registries, published literature, company-sponsored clinical trials and internal complaint data. This includes the FDA's industry wide post-market surveillance of metal-on-metal hip systems.

DePuy is communicating this decision to surgeons, hospitals and other interested parties. Clinicians and patients can learn more by visiting » http //www.depuy.com/pinnacleclinical and » http //www.depuy.com/pinnaclepatient.

Media Contacts
Find media contact information for DePuy and our companies.
» *get contacts*

The ULTAMET and COMPLETE products include two components used during hip replacement surgery: a cup liner and a femoral head. Both products use the same metal liner, which sits in a metal cup that is placed in the pelvis, but each uses different femoral heads. These heads attach to stems that are inserted into the femur during surgery. ULTAMET includes a metal head that rotates inside the metal liner in the pelvis, whereas COMPLETE uses a ceramic head. Only the metal liner used in these products is being discontinued.

DePuy is committed to continuing to provide surgeons the choices and options they need to help patients who are candidates for hip replacement surgery. The PINNACLE Cup System has among the broadest and most advanced options available on the market today and a demonstrated track record of helping to reduce pain and restore mobility for patients suffering from chronic hip pain.



Components of a Hip Replacement

Sources:

1. Based on multiple sources including ONN, Industry Surveys and Management Estimates
2. Source: European Markets For Large Joint Reconstructive Implants. Millenium Research Group: March 2013.

next article