

May 16, 2013

Dear Clinician,

As a result of our ongoing efforts to simplify and streamline DePuy Orthopaedics, Inc.'s product portfolio by focusing on fewer, worldwide strategic product platforms to meet patient and clinician needs and ensure long-term growth, we have made the decision to discontinue sales of the metal liner used with the PINNACLE Acetabular Cup System. The metal liner is used in both the ULTAMET<sup>®</sup> Metal-on-Metal Articulation and the COMPLETE<sup>™</sup> Ceramic-on-Metal Acetabular Hip System. Other worldwide product discontinuations will be announced throughout 2013 and 2014.

**This discontinuation does not affect the PINNACLE Cup System, one of the most widely used and clinically successful modular acetabular systems for hip replacement.** The PINNACLE Cup System has among the broadest and most advanced options available on the market today, and it continues to provide surgeons with the choices and options they need to help to reduce pain and restore mobility for patients suffering from chronic hip pain. DePuy remains committed to providing surgeons the choices and options they need to help patients who are candidates for hip replacement surgery. Available options include the ALTRX<sup>™</sup> Altralinked and MARATHON<sup>®</sup> Cross-Linked Polyethylenes for use with metal or ceramic heads, as well as the CERAMAX<sup>®</sup> Total Hip System with BIOLOX<sup>®</sup> *delta* Ceramic-on-Ceramic 28MM and 36MM Large Femoral Heads, which will be fully available this summer.

DePuy made the decision to discontinue ULTAMET and COMPLETE due to low clinician use of these products. In the United States and Europe in 2012, metal-on-metal bearings comprised less than two percent of the bearings implanted.<sup>1</sup> 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 all DePuy bearings sold in these markets.

Another consideration was that clinician preferences have shifted toward metal-on-polyethylene, ceramic-on-polyethylene and ceramic-on-ceramic bearings. An additional factor was the FDA's announcement in January 2013 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<sup>®</sup> was approved 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 it is not a recall. ULTAMET and COMPLETE, which use the same metal liner, are backed by clinical data showing they are safe and effective options for patients who are candidates for hip replacement.

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.

If you have any questions about the discontinuation, please contact Andre Papillon at 574-371-4546. If you have clinical questions, please contact DePuy's Scientific Information Office at 574-372-7401 or visit <http://www.depuy.com/pinnacleclinical> for more information.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew Ekdahl".

Andrew Ekdahl, Worldwide President  
DePuy Orthopaedics, Inc.

**Sources:**

1. Based on multiple sources including ONN, Industry Surveys and Management Estimates