

May 16, 2013

J.&J. Unit Phasing Out All-Metal Hip Devices

By BARRY MEIER

The orthopedic unit of **Johnson & Johnson** said Thursday that it was phasing out production of all-metal replacement hips, a move reflecting an industrywide trend to abandon the once widely used implants because of high early failure rates.

In 2010, the company, DePuy Orthopaedics, recalled an all-metal model known as the Articular Surface Replacement, or A.S.R., because it was failing just a few years after implant. Typically, artificial hips made from materials like plastic and metal last 15 years or more before they wear out and need to be replaced.

But after that recall, the company continued to sell an all-metal version of a popular hip model called the Pinnacle. In doing so, DePuy insisted that the all-metal Pinnacle was safe and performing on par with other hip replacements, a position it reiterated on Thursday.

It is estimated that all-metal replacement hips — in which both the cup and ball of a device are made from metal — once accounted for about one in three hip implants used in the United States. However, the metal components rubbed against each other as a patient moved, creating tiny particles that could damage tissue, muscle and bone.

Johnson & Johnson is facing a wave of lawsuits from patients who say they were injured when all-metal implants sold by the company failed. It faces over 10,000 cases related to the A.S.R. and 3,300 cases related to the all-metal Pinnacle, according to a company filing with the Securities and Exchange Commission

In a statement Thursday, DePuy pointed to two factors behind its decision to drop the all-metal Pinnacle: sharply declining surgeon demand for all-metal devices and a recent ruling by the Food and Drug Administration affecting such products.

In January, the agency told producers of all-metal hips that any models that were cleared for sale through a regulatory route that did not require premarket clinical testing in patients would have to run such studies to continue selling them.

“DePuy has communicated to the F.D.A. its decision not to pursue” such studies for the device, the company said in its statement.

The company said it was also discontinuing sales of a metal component that can be used with a ceramic hip implant called the Complete. Sales of the metal component used in both the Pinnacle and the Complete will end in August, the company said.

