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With Warning, a Hip Device Is Withdrawn

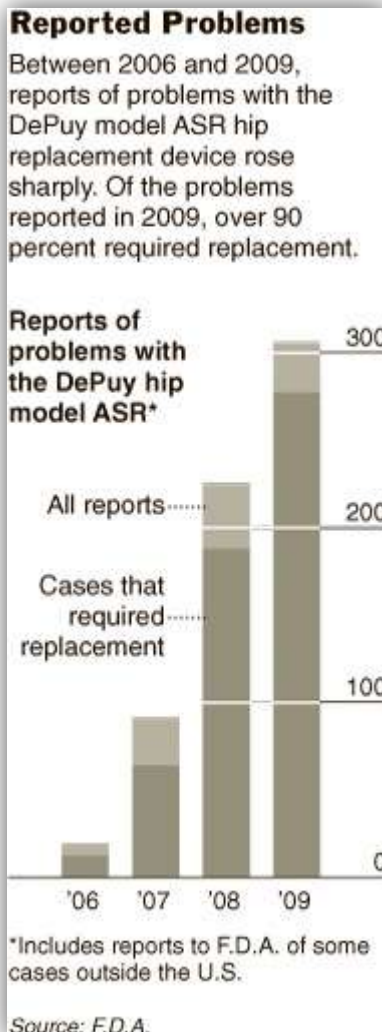
By BARRY MEIER

A unit of Johnson & Johnson, just months after saying it was phasing out an artificial hip implant because of slowing sales, has warned doctors that the device appears to have a high early failure rate in some patients.



DePuy Orthopaedics

A rendering of metallic debris caused by an improperly implanted hip, as shown in instructional material about the proper positioning of a hip socket, sent from DePuy to doctors.



The New York Times

The action by the company, DePuy Orthopaedics, follows more than two years of reports that the hip implant, which is known as the ASR, was failing in patients only a few years after implant, requiring costly and painful replacement operations.

Some orthopedic experts have voiced dismay in recent interviews that DePuy had not halted sales of the device earlier. And some specialists said that they believed the device had a design flaw that made it difficult to implant properly, a claim disputed by DePuy officials, who had said the product had no safety problems. The director of an implant database in Australia, Dr. Stephen Graves, said the data had shown for some time that the ASR had been failing early at a significantly higher rate than some competitors' devices. In December, DePuy voluntarily withdrew the ASR from the Australian market.

DePuy, of Warsaw, Ind., also announced late last year that it planned to phase out sales of the product worldwide by the end of 2010.

"It is way too late," Dr. Graves said.

While the ASR is not widely used in the United States, DePuy officials said recently that it had been implanted in thousands of patients worldwide.

In a letter dated March 6, DePuy told doctors that recently analyzed data from Australia suggested that the ASR had a higher-than-expected failure rate when used in traditional hip replacement on certain types of patients. The letter said that the data shows

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that the risk is highest for patients of small stature, a group that typically includes women, and patients with weak bones.

Asked Tuesday by a reporter why the company was issuing the advisory now, even as it was winding down sales of the device, DePuy said in a statement that it believed that “this is new and important information surgeons who continue to use ASR should have to inform their clinical decision making.”

The ASR, one of several hip models sold by DePuy, belongs to a category of devices known as metal-on-metal implants. Such implants are under increasing scrutiny because they can generate large amounts of metallic debris as they wear. The debris can cause severe inflammatory responses in some patients, damaging muscles and other soft tissues, requiring a follow-up operation to replace the device soon after implant — instead of the 15 or more years artificial hips are supposed to last.

Just last month, in an interview, DePuy officials defended the ASR’s track record, saying its performance equaled that of competing devices. Those officials also said that the company was phasing out sales of the ASR for commercial reasons, not because of any safety issues.

“With declining sales of this particular product in its market segment, we are focusing on newer technologies,” Sally Hunter, DePuy’s worldwide vice president for regulatory affairs, said last month. DePuy sells the ASR for use in hip “resurfacing,” a popular alternative to traditional replacement. The company also separately markets an ASR component — its hip socket, or cup — for use in traditional hip replacement. DePuy’s March 6 alert deals with the ASR’s failure rate in traditional replacements.

While the ASR resurfacing system has been used abroad, the Food and Drug Administration has not approved it for sale in the United States. In 2005, however, the F.D.A. cleared the ASR cup for use in traditional hip replacement. The device was cleared through a regulatory pathway that did not require it to undergo clinical trials. Since the beginning of 2008, the F.D.A. has received about 300 complaints on the ASR involving patients in the United States who received it. A review of those reports indicates that a vast majority of those patients underwent an operation to have the device replaced soon after getting it.

The number of such complaints typically understates a product’s problem, however, because many doctors and hospitals never bother to file reports with the F.D.A. Ms. Hunter said that some problems with the ASR had arisen because doctors were improperly implanting the device’s cup when first using it. To function properly a cup, which resembles a small hollow ball cut in half, must be positioned in the hip at the proper angle.

“With every device, there is a learning curve,” Ms. Hunter said.

Some surgeons, including the ASR’s co-developer, Dr. Thomas P. Schmalzried, an orthopedic specialist in Los Angeles, said they had used the device successfully in their patients. But Dr. Schmalzried said in an interview last month that he and DePuy officials realized within the last two years that the ASR cup might be more of a challenge to implant properly than competing cups.

“The window for component position that is consistent for good, long-term clinical function is smaller for the ASR,” than other cups, said Dr. Schmalzried, who has received \$3.4 million in payments in the last two years from DePuy for his work on the ASR and other devices. Asked last month about Dr. Schmalzried’s comments, DePuy officials expressed surprise that he had made them. They said they would provide a reporter with a statement after consulting with him. But DePuy’s subsequent statement did not refer to Dr. Schmalzried.

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In that statement, DePuy said that while reports had cited “a theoretical potential for ASR cups to be more sensitive to component position,” other data from studies and examinations of explanted devices “does not support the fact that performance is primarily related to design.”

In early 2009, DePuy sent a brochure to doctors on the importance of proper cup positioning for all hip implants. But the information did not address any specific concerns about the ASR. In its recent letter, DePuy emphasized the need to properly position the ASR.

Several orthopedic specialists said that they believed that the design of the ASR cup, which is shallower than some similar devices, was at the heart of the implant’s problems. For example, Dr. Harlan C. Amstutz, an orthopedic surgeon in Los Angeles and an implant designer who is a consultant for Wright Medical Technology, a competing orthopedic company, said that he believed that the design was prone to problems.

“It may not be Toyota, but it is not good,” Dr. Amstutz said.

Andrew W. Lehren contributed reporting.