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Complaints Undermine Hip Device

By BARRY MEIER

Zimmer Holdings, the nation's biggest producer of orthopedic devices, says it will suspend sales of an artificial hip component that some doctors have complained was failing at a high rate.

The company also lowered its earnings outlook as a result of the suspension, and its shares fell sharply Wednesday.

In recent months, some doctors have complained that the device, a hip socket known as the Durom cup, was failing in their patients, who then had to undergo replacement surgery.

Zimmer said its investigation had determined that the product was not defective. But it stated that even some experienced surgeons had found it difficult to implant. The company said it expected to resume sales once specialized training for doctors had begun.

Since it was first sold in the United States in 2006, the Durom cup has been implanted in more than 12,000 patients. Zimmer said it expected the overall need for early replacement in patients would be low. But Zimmer data and interviews with doctors suggest that hundreds of patients might need such procedures in coming years.

Some doctors said their patients had not had problems with the cup.

The company also said the sales halt would cut $20 million to $30 million from its sales estimates. Zimmer said it expected that earnings for the year would be $4.05 to $4.10 a share, down from its earlier forecast of $4.20 to $4.25 a share.

In composite trading on the New York Stock Exchange, shares of Zimmer, which is based in Warsaw, Ind., fell $4.87 a share to close at $66.01 a share. Bruce Nudell, an analyst at UBS who covers medical devices, said that the company had not issued any warnings that sales would be halted.

"They had given hints that there would not be a recall but this came as a surprise," Mr. Nudell said.

The issue with the device surfaced in April when a surgeon in Los Angeles, Dr. Lawrence Dorr, publicly warned other orthopedists about cup failures his patients were experiencing. In response, Zimmer said it would start an investigation but said it saw no reason to take added action like halting sales.

At the time, Zimmer also cited European data showing that the device was doing well there. But the version of the device used outside the United States is slightly different from the one used here. Also, while doctors here use it in traditional hip replacement, surgeons in other countries used it in a relatively new kind of hip surgery known as resurfacing, which involves somewhat different surgical techniques.

Zimmer, which announced the sales suspension late Tuesday, said that its investigation found that using the cup required a higher degree of precision.

Dr. Dorr, who said he had stopped using the device last year, said he did not plan to start reusing it.

“It is a bad design,” he said.

Mr. Nudell, the analyst, said that other doctors were happy with the cup, but he expected that Zimmer might see a 50 percent drop in the product’s use when sales resumed.

As a result of halting sales, Zimmer said that it was also suspending United States premarketing trials of its system for resurfacing, the process that is used in Europe. That decision will put it further behind competitors that already have such products on the American market.