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Britain Extends Monitoring for People With Metal Hips

By BARRY MEIER

British health regulators said Tuesday that patients in Britain who received a specific type of all-metal artificial hip — one that was also used widely in the United States — should undergo annual examinations for as long as they have the device to make sure they are not suffering tissue damage or other problems.

Previously, regulators in Britain urged that patients with “metal-on-metal” hips — in which a joint’s ball and cup are both made of metal — be monitored for five years to detect damage caused by metallic debris generated as the implants wear.

But on Tuesday, officials increased the monitoring period, apparently out of concerns that debris-related problems could occur for as long as a patient had an implant, a period that could last 15 to 20 years.

“By monitoring patients every year, any complications will get picked up earlier and more complex surgery on the patient can be avoided,” said Dr. Susanne Ludgate, the clinical director of the Medicines and Healthcare Products Regulatory Agency.

The British advisory does not affect patients in the United States. But the type of all-metal hip covered by it, which used larger ball components than traditional implants, was widely used in the United States for years.

While precise figures are not known, it is estimated that many, if not most, of the half a million patients in the United States who received an all-metal hip over the last decade got such devices. While the use of all-metal hips has plummeted in recent years because of high failure rates, surgeons often used the larger ball components because they believed that doing so provided the joint with more rotation and reduced the likelihood of a dislocation.

In recent years, data from orthopedic registries in Australia and England has shown that all-metal hips are failing prematurely at two to three times the rate of those made from metal and plastic.

Thousands of patients in the United States who received the implants have also been forced to undergo second surgeries to have them replaced within a few years of getting the devices. Hundreds of patients have also suffered crippling injuries because the metallic debris can destroy tissue and muscle surrounding the hip.

The debris can come from several sources, including one that appears common to all-metal devices regardless of the model.

Studies have indicated, for example, that the use of the larger ball component increases the amount of torque and motion at the point where that ball and cup are joined, generating debris.

In addition, some specific designs produce more debris because of the way the joint's ball strikes against the implant's cup.

As the metal-hip episode has unfolded in recent years, regulators and surgeons outside the United States have typically been ahead of their counterparts here in addressing the risks of the implants.

In a statement, an official with the American Academy of Orthopaedic Surgeons said the organization agreed with "the clinical assessment" made by British regulators.

Asked about the British action, a spokeswoman for the Food and Drug Administration, Erica Jefferson, said the agency was maintaining its existing recommendations. Ms. Jefferson said it was not clear if one way to assess tissue damage, testing patient blood for the presence of metallic ions, accurately reflected damage.

"We continue to recommend that hip replacement patients undergo regular follow-up with their physicians," she said.