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Hip implants recalled

Three Warsaw companies affected

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WASHINGTON — Hundreds of artificial hips are being recalled because one piece — the joint ball — is made of a ceramic that may suddenly crack.

It's the second major recall of artificial hips in the past year.

Among eight companies that are recalling some artificial hips they manufactured are Biomet Inc., DePuy Orthopaedics Inc. and Zimmer Inc., all of Warsaw.

The Food and Drug Administration announced the recall Friday, warning surgeons not to use the affected implants — and patients to call their doctors if they experience symptoms suggesting the joint has cracked.

The FDA has at least 14 reports so far of Americans in whom the recalled hips have broken.

Patients shouldn't panic: Not all the recalled hips will break, and there's no need for more surgery unless one does. But there's also no way to predict which hip will fracture.

Patients should "be aware this increased risk exists," said FDA medical officer Dr. Dan Schultz. "If they have any symptoms whatsoever, they need to get in to see their physician as quickly as possible. Don't assume ... it's something that is just going to go away."

Symptoms include hip pain, a sensation of grinding or limitation of motion, Schultz said. The fracture sometimes is preceded by an audible pop.

The at-risk hips tend to break between 19 and 28 months after they're implanted, said FDA compliance officer Carol Fedorchak.

The French company St. Gobain Desmarquest recalled nine batches of its ceramic femoral heads — the ball portion of the hip implant — that were manufactured since early 1998.

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The worst batch has an 8 percent breakage rate, well above the one-hundredth of a percent breakage rate expected for such parts, said Fedorchak. The other eight batches had a far lower breakage rate, but were being recalled as a precaution.

Apparently, a change in the manufacturing's heating process left the ceramic more fragile.

In addition to the three Warsaw-based companies, other's using St. Gobain Desmarquest ceramic femoral heads in artificial hips were Apex Surgical of Lakeville, Mass.; Encore Orthopedics Inc. of Austin; Osteoimplant Technology Inc. of Hunt Valley, Md.; Smith & Newphew of Memphis; and Stryker Howmedica Osteonics of Allendale, N.J.

The hip recall is the second in the past year. Sulzer Medica recalled thousands of its artificial hips last December, after a manufacturing change left an oily residue on some that prevented the new joint from bonding with patients' bones. A court is now considering a proposed $700 million class-action settlement for recipients of those joints.