Man sues Johnson & Johnson, subsidiary over drug-coated stent

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WEST PALM BEACH, Fla. – A man has sued Johnson & Johnson and a subsidiary for allegedly failing to warn him of complications that could be caused by drug-coated stents placed in his arteries.

The allegations come as the Food and Drug Administration cited studies this week showing drug-coated stent recipients face a small but significant blood clot risk. The lattice-shaped tubes prop open clogged arteries. Unlike older, bare-metal stents, newer ones use drugs that dissolve into the bloodstream to prevent tissue re-growth.

< Sean O'Shea, 46, alleges Johnson & Johnson was aware of potential complications from the product before it gained FDA approval in 2003, and that the company failed to warn patients and doctors. His lawsuit seeks unspecified damages.

O'Shea had five of the newer stents, made by a Johnson & Johnson subsidiary, Miami-based Cordis Corp., implanted in heart arteries in 2003 and 2004 after suffering a heart attack, according to the negligence lawsuit filed Friday in Palm Beach County state court.

He claims he followed the product's guidelines to stop taking blood thinners after three months, but then began to suffer chest pains again and now may be forced to be on the medications for the rest of his life.

“Had I known there would have been this many complications, I would have chosen other options,” O'Shea said at a news conference Wednesday. “I'm upset that I was deceived. I feel that I was lied to.”
Cordis spokesman Christopher Allman said the company does not comment on pending litigation. But Johnson & Johnson, based in New Brunswick, N.J., maintains there is no significant difference in clotting, heart attack or death rates between its drug-coated stent and bare metal versions.

The FDA, citing studies, said the risk emerges a year or more following surgery once patients stop taking blood-thinning medications.

Some doctors recommend patients should consider taking the blood thinner Plavix indefinitely. The FDA said it was unknown how long patients should remain on the drug to prevent clots. The agency has convened a two-day meeting this week to discuss the clotting risks.

Boston Scientific Corp. and Cordis are the only two companies with U.S. approval to sell the drug-coated versions of the stents, which have been placed in about 6 million people worldwide.

Boston Scientific has acknowledged a slight increase in clotting associated with its version but said it has seen no corresponding increase in heart attacks or deaths.

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