

Lawsuit Claims Medtronic Promoted Device for Off-Label Uses

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<u>CourthouseNews.com</u> reports on a lawsuit involving the Medtronic InfuseBone Graft, and alleged "off-label" marketing by Medtronic. Here are excerpts:

Medtronic pays doctors to promote a medical device for off-label uses, and the InfuseBone Graft is "unreasonably dangerous" because its active ingredient can travel from the implant site to the esophagus or trachea, turning soft tissue into bone, a married couple claims in Los Angeles Superior Court.

John and Robin Webb say the U.S. Food and Drug Administration approved Medtronic's InfuseBone Graft only for lumbar, dental and tibial surgeries, but that Medtronic recommends it for cervical spine fusions.

The product allegedly netted \$815 million for Minnesota-based Medtronic in fiscal year ending April 2008.

The Webbs say using the bone graft in cervical spine surgeries is "unreasonably dangerous for the patient" because the active ingredient can travel to the esophagus or trachea, causing calcification, and making it difficult to swallow, breathe or eat.

"While physicians may use FDA-approved medical devices in any way they see fit, companies are not permitted to ... pay doctors inducements or kickbacks to promote off-label uses," according to the complaint.

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