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**STATEMENT REGARDING FDA RECALL OF BONE IMPLANT TISSUE**

Mayfield Clinic and its physicians, as well as hospitals and other physicians in Cincinnati and around the country, were notified in November 2005 about a Food and Drug Administration (FDA) recall of bone implant tissue used in some spine surgeries. Shortly thereafter, we were notified by Medtronic Corporation, whose subsidiary supplied the bone implant tissue to hospitals, that some of our patients received the recalled tissue in surgeries occurring from early 2004 to September 2005. We have contacted all of the patients affected by the recall.

While the overall risk of infection is low, according to the FDA and the Centers for Disease Control (CDC), the agencies both recommended that healthcare providers contact patients and offer them access to appropriate infectious disease testing, which Medtronic is providing at no charge. We followed the FDA recommendations, and notified all of our affected patients in late November and early December.

Medtronic Corporation has several resources for patients to access for information, including a nurse call line and a web site. We have encouraged our patients who have been affected by this recall to use these resources, and most importantly, access the appropriate infectious disease testing provided through Medtronic.

While Mayfield has no responsibility regarding the selection or sources of bone implant tissue, we regret that some of our patients have been forced to deal with this disturbing issue, and are doing what we can to help ensure that their health has not been compromised.

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