

Doctor's hired to study safety of Medtronic's Infuse Bone Graft found to have significant financial ties To Company.

Medtronic, Inc., based in Minneapolis, Minnesota, is the world's largest medical technology company. Recently Medtronic came under fire after independent researchers questioned the safety studies surrounding Medtronic's new *Infuse Bone Graft* product.

Infuse Bone Graft is a bioengineered protein used to stimulate the body's natural bone re-growth process to join vertebrae together and reduce back pain. In 2004 doctors hired to study the safety of the Infuse Bone Graft published results from their safety "study" that concluded patients were not harmed by the product. The study acknowledged that excess bone growth was occurring but concluded that patients were not suffering any negative side effects because of it. However, it has been discovered that those doctors had significant financial ties to Medtronic and the results of the study may have been misrepresented. It has also become apparent that excessive bone growth is dangerous and is causing serious medical complications. The U.S. Senate has requested internal documents and communications from Medtronic surrounding the original study to investigate whether the doctors in charge knew about the complications and failed to report them.

A new independent medical study was commissioned to study the side effects of excessive bone growth. The study, which included hundreds of people, had to be stopped because 70% of the patients who had received Infuse Bone Graft had formed excess and damaging bone on their spinal canal. Researchers were only able to administer the product to 34 patients before the study had to be stopped.

Medtronic has now agreed to give \$2.5 million to the Yale School of Medicine to fund and assemble an outside panel of experts. These experts will analyze all of the data collected by Medtronic and their researchers between 2000 and 2009. The fact that Medtronic is giving the independent panel access to both published and unpublished materials surrounding Infuse Bone Graft is important. Usually independent researchers can only review published medical data and what a company chooses to keep secret is often as important, if not more important, than what they decide to tell the public. Allowing independent researchers access to all data is a critical step that is necessary to increase the safety of medical devices and should be the rule, rather than the exception.

What happened with Infuse Bone Graft is unfortunately all too common and easily preventable. Releasing all safety data on medical devices or products to independent researchers is a move in the right direction towards preventing harmful products from reaching the masses.