

Medtronic Statement on the use of Allograft Tissue

According to the American Association of Tissue Banks, allograft tissue (tissue from another person's body) is used by surgeons because of inadequate amounts of available autograft tissue (a person's own bone or soft tissue). Allograft tissues are commonly used in reconstructive surgeries and in cases of bone loss due to trauma or tumors.

We believe the research shows that patients realize significant health benefits from human allograft tissue. The use of allograft tissue has been an important aspect of spinal fusion surgery for several years, actually helping to improve the successful outcomes of thousands of spinal surgery patients. Both the safety and the efficacy of this very important technology have always been and are still very important to Medtronic and our surgeon customers who use it in their spinal surgery cases.

It is important to note, however, that there are inherent disease risks in the use of allograft tissue for implantation into a human recipient, including the risk of latent or emerging infectious agents for which no validated test is approved or recognized. As a consequence there is no foolproof solution to completely eliminate all risk of disease transmission. However, the tissue that we distribute has been processed using a validated cleansing and sterilization methodology designed to eliminate viruses, bacteria, fungi and spores. If we were not entirely confident in these processes and the safety profile of the tissue we distribute, then we would not be providing it to our surgeon customers and their hospitals.

Bert Kelly
Medtronic spokesman