

Patient Question and Answer

1. Why has there been a recall of tissue?

The tissue that was used during your surgery is distributed to hospitals by SpinalGraft Technologies, a subsidiary of Medtronic. It was processed and packaged by a Florida company called Regeneration Technologies (RTI).

On October 14, 2005, RTI voluntarily recalled specific lots of tissue due to questions about adequacy of donor documentation. The affected tissue came from Biomedical Tissue Services.

RTI recalled the tissue because they were unable to confirm that the standard donor consent had been properly obtained by Biomedical Tissue Services.

2. Could the tissue implanted during my surgery transmit a disease to me?

To date, the FDA has informed us that it is not aware that any patient has become ill from this recalled tissue. The FDA is continuing its investigation into this matter with our assistance and will issue further public health updates as needed. The risk of you contracting an illness from the implanted tissue is believed to be low, but is not known for sure.

Although all tissue affected by this recall was subjected to a validated sterilization processes prior to distribution, we support the FDA and Centers for Disease Control and Prevention (CDC) recommendation that you be offered access to blood testing.

3. What should I do now? How will I know if the implanted tissue causes me a health problem?

We know this type of news is very unsettling – but the best answers will come from your doctor. Your doctor knows your medical history and is best able to talk with you about your options.

The FDA and CDC “believe the risks from these tissues are low because the tissues were routinely processed using methods that help to reduce the risk of infectious disease; however, the actual infectious risk is unknown.” So, even though the risk of contracting an illness from the tissue is believed to be small, we support the FDA and CDC recommendation that you be offered access to blood testing to make sure you’re okay. We have provided your doctor with information on which tests should be done and how to provide those to you free of charge.

4. Do I have to pay for the blood tests?

You will not have any out-of-pocket expenses related to this testing. Medtronic has made arrangements with two nationally recognized laboratories to perform the blood tests your physician may order. Your physician can assist you in accessing these services. If you or your physician cannot locate a testing site or you have a specific reimbursement question, please call 1-866-825-6158. In addition, you can rest assured that the results of your blood test will only be shared with you and your doctor.

5. Where can I get more information?

We have a toll free number set up so you can call and speak to a registered nurse who can answer your questions about medical issues, testing information and follow-up treatment. This toll-free number is 1-866-825-6158. This line is open Monday through Thursday 7 a.m. – 7 p.m. CST and 7 a.m. – 6 p.m. CST on Friday. You can also visit www.medtronicsofamordanek.com/tissue or www.fda.gov to find more information on the tissue recall.