

SPINE SAFETY NOTICE:

Public Health Notification on Human Tissue Recovered by BioMedical Tissue Services, Ltd. (BTS)

FDA notified healthcare professionals of an update to the October 26, 2005 information paper on human tissues recovered by BioMedical Tissue Services (BTS). The tissue, including human bone, skin, and tendons, was recovered by BTS from human donors who may not have met FDA donor eligibility requirements and who may not have been properly screened for certain infectious diseases. As part of its ongoing investigation, FDA has become aware of additional information regarding the reliability of donor blood samples that is important for health care providers to consider. FDA strongly recommends that health care providers inform their patients who received tissue implants prepared from BTS donors that they may be at increased risk of communicable disease transmission and to offer them testing. While FDA believes the risks from these tissues are low because the tissues were routinely processed using methods to help to reduce the risk of infectious disease, the actual infectious risk is unknown.

The following tissue processors received tissue from BTS:

- LifeCell Corporation of Branchburg, NJ
- Lost Mountain Tissue Bank of Kennesaw, GA
- Blood and Tissue Center of Central Texas in Austin, TX
- Tutogen Medical, Inc., of Alachua, FL
- Regeneration Technologies, Inc., of Alachua, FL

According to MedWatch, these firms have already voluntarily recalled all unused tissue remaining in inventory and are working cooperatively with FDA to ensure that the implanting physicians whose patients may have received the products are properly notified. Physicians who implanted tissue from BTS should have been contacted by the receiving health care facility.

The MedWatch 2006 Safety Summary, including links to the Public Health Notification and previous advisories, is available at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#BTS>

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS Web site at http://www.spine.org/spine_safety_notices.cfm. This information is provided as a service for information and education only.