

## SPINE SAFETY NOTICE:

### **Information for Healthcare Professionals: Class I Recall of Integra LifeSciences EnDura No-React Dural Substitute**

According to MedWatch, Integra LifeSciences (Integra) informed healthcare professionals and patients of a recall of all EnDura No-React Dural Substitute (EnDura) products. The products are manufactured by Shelhigh, Inc. and distributed by Integra. The recall is pursuant to an April 18, 2007, FDA Public Health Notification regarding products manufactured by Shelhigh, citing sterility and other manufacturing concerns and FDA's request that Shelhigh recall all of its medical devices remaining in the marketplace. Integra is recalling all Endura products that may be in the field from the date of the first shipment by Integra in 2003 to present. On May 18, 2007, FDA classified the recall as Class I. A Class I recall is assigned when there is a reasonable probability that use of or exposure to a product will cause serious adverse health consequences or death. See the attached manufacturer's press release for a list of products affected by this recall.

The complete MedWatch 2007 Safety Summary, including a link to the manufacturer's press release which includes a list of products affected by this recall, is available at:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Integra>

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 website at [http://www.spine.org/spine\\_safety\\_notices.cfm](http://www.spine.org/spine_safety_notices.cfm). This information is provided as a service for information and education only.