Dural Patch Recalled

[Ed. Note: *The following is a Press Release From Integra LifeSciences.***]**

PRESS RELEASE PROVIDING UPDATE REGARDING CLASS I RECALL OF SHELHIGH, INC.'S ENDURA™ NO-REACT® DURAL SUBSTITUTE, DISTRIBUTED BY INTEGRA LIFESCIENCES CORPORATION

Integra LifeSciences Corporation ("Integra," d/b/a Integra NeuroSciences) is conducting a recall of all **EnDura™ No-React® Dural Substitute ("EnDura")** products. The EnDura products are manufactured by Shelhigh, Inc. ("Shelhigh") and distributed by Integra. On April 18, 2007, the Food and Drug Administration ("FDA") issued a Public Health Notification regarding products manufactured by Shelhigh, citing sterility and other manufacturing concerns. FDA issued a letter to Shelhigh on May 2, 2007 formally requesting that Shelhigh recall all its medical devices remaining in the marketplace.

Integra is conducting a recall of all EnDura products manufactured by Shelhigh and distributed by Integra to comply with FDA's request. Integra stopped shipping and quarantined all EnDura products on April 18, 2007, the day FDA issued its Public Health Notification. On April 20, 2007, Integra notified hospitals by letter of Integra's stop shipment of EnDura products and FDA's Public Health Notification. Following FDA's May 2 letter to Shelhigh, Integra sent a letter on May 4, 2007 to hospitals requesting the return of all EnDura products in their possession. On the same day, Integra notified FDA regarding its recall plan.

The EnDura products are the only products manufactured by Shelhigh that are distributed by Integra.

On May 18, 2007, FDA notified Integra that it had determined that this recall action constitutes a Class I recall. A Class I recall is the highest priority recall that is assigned when there is a reasonable probability that use of or exposure to the product will cause serious adverse health consequences or death.

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. Only products in the EnDura™ No-React® Dural Substitute product line are affected by this recall. No other products distributed by Integra are included in this recall. The products affected by this recall are as follows:

ENR20210 EnDura™ No-React® Dural Substitute 2cm x 10 cm

ENR20404 EnDura™ No-React® Dural Substitute 4cm x 4 cm

ENR20506 EnDura™ No-React® Dural Substitute 5cm x 6cm

ENR20610 EnDura™ No-React® Dural Substitute 6cm x 10cm

ENR21012 EnDura™ No-React® Dural Substitute 10cm x 12cm

ENR21212 EnDura™ No-React® Dural Substitute 12cm Diameter

The actions taken by Integra reflect the company's commitment to provide timely information to physicians, hospital facilities and patients about the products it distributes. For additional information about the recall of EnDura products, please contact Integra's Customer Service Department at (800) 456-8482.