PATIENT SAFETY BLOG

PATRICK MALONE & ASSOCIATES, P.C.
From Tragedy To Justice - Attorneys For The Injured

Toll Free: 888.625.6635
(888.MaloneLaw)
Local: 202.742.1500

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FDA recalls infusion pump and tissue stabilizer

The Food and Drug Administration has issued Class I recalls of Hospira Symbiq One- and Two-Channel infusers and Medtronic Octopus Nuvo tissue stabilizers.

Class 1 recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

The FDA is recalling Hospira's infusion pump products due to motor encoder failures in the pumping mechanism that causes the infuser to cease operation. Delay or interruption of therapy may result in serious injury or death in: patients receiving critical

Patrick A. Malone
Patrick Malone & Associates, P.C.
1331 H Street N.W.
Suite 902
Washington, DC 20005

pmalone@patrickmalonelaw.com
www.patrickmalonelaw.com
202-742-1500
202-742-1515 (fax)

therapy, pediatric patients, and neonates. The company mailed an “urgent device field correction” to affected customers and issued a recall notification in February 2010. All the affected units were distributed from Dec. 23, 2006 to January 22, 2010.

Medtronic’s Octopus Nuvo tissue stabilizers were manufactured from February 19, 2010 through August 28, 2010 and distributed from March 8, 2010 through September 7, 2010. The device stabilizes and minimizes the motion of selected areas of the beating heart during minimally invasive cardiac procedures while directly visualizing the heart through a small cut in the chest cavity. The FDA ordered the recall because of the possibility that a component of the device could fracture during use and fragments could fall into the patient’s chest cavity and/or damage the heart tissue, causing serious injury or death. Fortunately, no action from patients is required, since any adverse event related to the device would occur at the time of surgery.

Medtronic sent an “urgent medical device recall notice” to its customers on September 14, requesting that they discontinue use of the device, quarantine all unused devices and return unused devices.

Hospira recall source: Bioscience Technology
To view the FDA ruling on Hospira, click here.
Medtronic recall source: Operating Theatre Journal
To view the FDA ruling on Medtronic, click here.

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