U.S. Food and Drug Administration

Medical Devices

Medtronic Octopus Nuvo Tissue Stabilizer, Model TSMICS1

Recall Class: Class I

Date Recall Initiated: September 13, 2010

Product: Medtronic Octopus Nuvo Tissue Stabilizer, Model TSMICS1

All Octopus Nuvo Tissue Stabilizer devices are affected. No other models in the Octopus family of products are affected by this recall.

Serial Numbers:

- 201002P030 2010032195 2010032196 2010040103
- 2010032690 2010033377 2010040102 2010061786
- 2010040673 2010041004 2010041500 2010081987
- 2010062722 2010071111 2010081105

This device was manufactured from February 19, 2010 through August 28, 2010 and distributed from March 8, 2010 through September 7, 2010.

Use:

This 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.

Recalling Firm:

Medtronic Perfusion Systems
7611 Northland Drive North
Brooklyn Park, Minnesota 55428-1088

Reason for Recall:

There is a potential that a component of the device could fracture during use. The resulting potential hazards are that fragments of the component could fall into the patient's chest cavity and/or damage the heart tissue. This could lead to serious injury or death.

Public Contact:

Physicians and healthcare facilities can direct questions to their Medtronic representative or contact the CardioVascular Lifeline for technical services, Monday through Friday during business hours (Central time), at 1-877-526-7890.

FDA District: Minneapolis

FDA Comments:

PATIENTS: NO ACTION is required as any adverse event related to this device would have occurred at the time of surgery.

On September 14, 2010, the company sent an "Urgent Medical Device Recall Notice" to its customers. The notice described the issue and identified the affected lot numbers.

The company requested that its customers:

- **IMMEDIATELY DISCONTINUE** use of the device
- **QUARANTINE** all unused devices
- Return unused devices to the company
- FAX the company the recall certificate acknowledging the Recall Notice and quantity of devices to be returned**.**

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.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by FAX.

Useful Links:

- Firm News Release [1]
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program [2]