Class I Medical Device Recall: Lumenis Limited, Lumenis VersaCut Tissue Morcellator

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: January 2, 2013

Product: Lumenis VersaCut Tissue Morcellator

Trade Name: VersaCut Morcellator

Model Numbers:

- 0637-245-01 (starter kit)
- 0636-470-01 (Control Box)

Affected Serial Numbers: All VersaCut Morcellators manufactured since May, 1998.

Use: These devices break up and remove dissected tissue during surgical procedures when access to the surgical site is limited.

Recalling Firm:
Lumenis Limited
6 Hakidma Street, POB 240
Yokneam Industrial Park
Yokneam 20692
Israel

Reason for Recall: Lumenis Limited is recalling certain models of VersaCut Morcellator devices to correct its labeling. There is a potential for air embolisms to occur if the aspiration tubing is hooked up backwards to the aspiration control box housing. This product may cause serious adverse health consequences, including death.

Public Contact: For questions, users can contact the VersaCut Morcellator field correction administrator by either Cell: +972-(54)-9599196, Tel: +972-(4)-9599296 or by email at: VersaCutMorcellator@lumenis.com [1].

FDA District: Denver District Office

FDA Comments:

Lumenis placed an immediate internal quarantine on all affected products within its possession. The firm will re-label these devices and replace the current Operator's Manual with the revised Manual.

On Jan. 2, 2013, Lumenis sent an Urgent Safety Advisory Notice letter to all affected customers. The letter identified the affected product, problem and actions to be taken. The letter instructed customers to:

- re-label the device with the two labels provided;
- remove and destroy the existing Operator’s Manual and replace it with the current revised Manual;
- complete the information requested on the confirmation card provided; and,
- return the confirmation card using the enclosed, pre-paid UPS shipping label.

The firm will send follow-up notices to customers who do not respond in 30, 60, and 90 days.

Class I 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 MedWatch: The FDA Safety Information and Adverse Event Reporting Program [2] either online, by regular mail or by FAX.

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http://www.mdtmag.com/news/2013/02/class-i-medical-device-recall-lumenis-limited-lumenis-versacut-tissue-morcellator

Links:
[1] http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/mailto:VersaCutMorcellator@lumenis.com
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm