Class I Medical Device Recall: Mindray A3 and A5 Anesthesia Delivery System

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: August 13, 2012

Product: Mindray Anesthesia Delivery System

Model and Serial Numbers:

- Model A3 Anesthesia Delivery System, serial numbers on the FDA website [1]
- Model A5 Anesthesia Delivery System, serial numbers on the FDA website [2]

Manufacturing Dates: May 2011 to March 2012

Distribution Dates: May 31, 2011 to July 15, 2012

Intended Use: The A3 and A5 anesthesia delivery systems are used to administer continuous or intermittent general anesthesia gases and maintain a patient's breathing during surgery.

These devices are used for both pediatric and adult patients.

Recalling Firm:
Mindray DS USA, Inc.
800 MacArthur Boulevard
Mahwah, New Jersey 07430

Reason for Recall: The affected anesthesia delivery systems may have a gasket leak which could cause an interruption of or inadequate patient anesthesia and ventilation, temporary or permanent patient injury, or death. Facilities should consider having backup equipment to maintain patient ventilation in the event of device failure due to this issue.

The gasket leak could also cause injury to bystanders and operating room personnel due to exposure from leaking anesthesia gases.

The company has identified the cause of the leak as a small step in the gasket surface which may interfere with the full seating of the gasket within the canister. The leak may be identified during the Automatic Circuit Leak and Compliance Test

performed at start up and during the Manual Leak Test recommended before each use.

Public Contact: Consumers who have questions may contact Mindray North America at 1-800-288-2121 extension 5050, Monday through Friday from 8:30-5:30 (EST).

FDA District: New Jersey

FDA Comments: Mindray first informed customers about this recall in a letter, dated August 8, 2012. The letter identified the problem with the device and possible adverse effects on patients.

There have been no reports of injuries associated with this problem. Mindray became aware of the issue when a system leak was reported by a customer.

Mindray is in the process of correcting the leak issue by replacing canister gaskets on affected devices. According to the company, as of November 14, 2012, approximately 70% of units affected by this action were corrected.

Customers who have not already arranged for replacement should contact a Mindray representative at 1-800-288-2121, Monday through Friday from 8:30-5:30.

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 at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm [3], by regular mail, by telephone, or by FAX.

Additional Information:

- Company Press Release [4]

Source URL (retrieved on *06/19/2013 - 4:06am*):
http://www.mdtmag.com/news/2012/11/class-i-medical-device-recall-mindray-a3-and-a5-anesthesia-delivery-system?qt-most_popular=0

Links:
[1] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?start_search=1&recallnumber=Z-0290-2013
[2] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?start_search=1&recallnumber=Z-0291-2013
[3] http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm

[4] http://www.fda.gov/Safety/Recalls/ucm327976.htm