Mindray DS Initiates Voluntary Recall Affecting Anesthesia Delivery System

Mindray Medical International Limited, a leading developer, manufacturer and marketer of medical devices worldwide, has initiated a voluntary recall affecting the A3/A5 Anesthesia Delivery System. Mindray has initiated this recall due to the possibility of a system leak resulting from improper seating of the CO2 absorbent canister gasket.

Should a system leak occur during use, fresh gas flow may be increased to compensate for any pressure loss resulting from the leak while the absorbent canister is unlocked and locked again to reseat the gasket. If the CO2 absorbent canister gasket is improperly seated, however, a potential leak will likely present itself during the Automatic Circuit Leak and Compliance Test performed at startup and the Manual Leak Test recommended to be performed before each case, at which time the absorbent canister can be unlocked and locked again to reseat the gasket.

The canister gasket subject to this recall may be identified by presence of a small "step" in the gasket surface. A3/A5 units with this gasket may continue to be used. The proper seating of the canister gasket should be confirmed prior to use and after CO2 absorbent is changed.

Customers who have a system(s) subject to this recall were notified by on August 8, 2012 by letter via US Postal Mail, return receipt required. To date, approximately 70% of units affected by this action have been corrected. The issue is corrected through a replacement of the canister gasket by a Mindray Service or authorized representative.

Units with the affected canister gaskets were shipped between May 31, 2011 and July 15, 2012 in the United States, Latin America and Australia.

There have been no reports of injuries associated with this issue. Mindray became aware of the issue when a system leak was reported by a customer. The cause of the leak was determined to be the result of an improperly seated canister gasket.

Mindray has advised the US Food and Drug Administration of this voluntary recall.

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