

URGENT MEDICAL DEVICE NOTIFICATION

STRYKER NEPTUNE 2 WASTE MANAGEMENT SYSTEM

ATTENTION: RISK MANAGER, OR DIRECTOR, DIRECTOR OF SURGERY

June 9, 2015

Dear Neptune2 Customer,

The purpose of this letter is to advise you that Stryker Instruments is voluntarily recalling the following Neptune 2 Ultra diverter valve assemblies:

Manufacturer Part Number	Product Description	Serial Numbers Affected	Distribution or Repair Dates
0702-001-000	Neptune 2 Rover	Serial Numbers ranging from 0803118093 through 1505400223	November 1, 2011 to March 31, 2015

Reason for the Voluntary Recall:

It has been identified during the installation of Rovers, there is a potential for the Neptune 2 Rover's diverter valve assembly to not actuate during docking, preventing the cleaning cycle from occurring and inhibiting prefill water from being supplied to the Neptune Fresh Water System. The diverter valve's material combined with the heat-treating process has the potential to cause diverter valve corrosion when the Rover is allowed to sit for a period of greater than 40 days.

Note: Only Neptune 2 Rovers out of rotation for greater than 40 days have the potential of exhibiting the failure. Neptune 2 Rovers that have been used within the past 40 days are not likely to experience any issue.

Product Description:

The Stryker Neptune 2 Rover is a mobile unit used to suction, collect fluid waste, and evacuate surgical smoke from a surgical site during operation. Fluid waste is removed from the surgical site through suction tubing connected to inlet ports of disposable manifolds installed in the Rover. The Diverter Valve Assembly consists of two diverter valves with three hoses, one inlet and two outlets. The sole purpose of the Diverter Valve Assembly is to direct/divert water from the fresh water inlet to either the large canister or small canister via the pre-fill tank.

Risk to Health:

There is no risk to health as the Rover will be unable to dock either during installation or prior to surgery. Rovers that are in active rotation are not likely to experience any issue related to this diverter valve material issue.

For questions regarding this recall, please contact Stryker Instruments:
Monday-Friday 8am-5pm (EST)
Kelly Jo Davis
269-389-2921
kellyjo.davis@stryker.com

Actions to be taken by the Customer/User:

1. Immediately review this Recall Notification.
2. Check the appropriate box on the Business Reply Form (BRF) indicating if your facility has Rovers that have been out of rotation over 40 days.
3. If you have indicated that your facility has Rovers not used over 40 days a Stryker representative will contact your facility to schedule a repair.
4. If you have further distributed this product, please forward this letter and the attached BRF to all affected locations. Please indicate each location on the BRF.
5. Please complete and return the BRF even if you don't have any affected product on hand. *Note: Your signature on the BRF indicates that you received and understand this Notification and have followed the instructions in the Notification.*
6. Fax the completed Business Reply Form to Stryker Instruments Regulatory Department, 866-521-2762, or scan and email a copy to kellyjo.davis@stryker.com.
7. Please continue to rotate all Neptune2 Rovers. If Rovers are removed from circulation for more than 40 days, it is recommended that you contact Stryker Repair if any issue is experienced putting the Rover back into use.

Report any serious adverse events or product quality problems to Stryker Instruments: 1-800-253-3210 Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, or by fax or phone.

Online: www.fda.gov/Safety/MedWatch/HowToReport/default.htm

Fax: (800) FDA-0178 Phone: (800) FDA-1088

We apologize for any inconvenience this action may cause your facility. Please forward a copy of this letter to any other personnel within your facility that you deem appropriate.

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