Class 1 Recall Of Waste Management System Issued

/PRNewswire/ -- On June 5, 2012, Stryker initiated a Class 1 recall of the Neptune Waste Management System. The devices are being recalled because Stryker has received two reports of serious injury as a result of tissue damage associated with the use of the Neptune 2, including an event in which one customer connected the Neptune 2 System to a passive chest drainage tube post operatively, resulting in a fatality.

The recall includes all serial numbers for the following model numbers:

Product Name	Catalog Number	Manufacture Dates	Distribu
Neptune 1 Gold Rover	0700-001-000	1/11/01 – 12/23/09	3/26/01
Neptune 1 Gold Rover - International	0700-002-000	9/15/05	10/3/05
Neptune 1 Silver Rover	0700-003-000	1/31/02 – 9/3/09	5/31/02
Neptune Bronze	0700-007-000	3/22/04 – 2/22/12	3/31/04
Neptune 2 Rover Ultra (120 V)	0702-001-000	12/3/07 – 8/1/12	12/31/0
Neptune 2 Rover Ultra (230 V)	0702-002-000	10/9/08 – 6/18/12	3/5/09 –

On June 5, 2012, Stryker notified customers that it was recalling the IFUs for the above products. The current IFU did not specifically warn against connecting the Neptune Rover, which is a high vacuum/high flow device, to a passive drainage tube. Customers were instructed to review the revised IFU, distribute to affected departments, and educate users of the Neptune on this warning. Customers must confirm with Stryker via business reply form that they have completed these actions.

Customers who have the Neptune 1 Gold, Neptune 1 Gold International or Neptune 1 Bronze will receive a follow up mailing in October containing warning labels for the device and instructions detailing how to apply them. Customers may continue to use the Neptune 1 Gold, Neptune 1 Gold International, and the Neptune 1 Bronze. Users must be aware of the warning that was added to each device.

On September 18, 2012, Stryker notified customers via letter delivered by FedEx

overnight delivery that it is expanding the recall on the Neptune 1 Silver, Neptune 2 Ultra (120V) and Neptune 2 Ultra (230V) because FDA has also advised Stryker that these devices require, but do not currently have, 510(k) clearance. FDA is therefore unable to determine whether these devices are as safe and effective as their legally marketed predicate, the Neptune 1 (Gold) Waste Management System (510(k) K012992). As such, Stryker has ceased distribution of the Neptune Silver, Neptune 2 Ultra (120V) and Neptune 2 Ultra (230V) devices until FDA clears these devices.

At this time, FDA does not consider the Neptune Silver, the Neptune 2 Ultra (120V) or the Neptune 2 Ultra (230V) to be legally marketed devices because their safety and effectiveness have not yet been determined. As such, FDA advises that the devices not be used. However, customers who do not have an alternative device to use should weigh the risks and benefits associated with continued use of these devices. If customers choose to continue use of the Neptune Silver, Neptune 2 Ultra (120V) or Neptune 2 (230V), they must complete a Certificate of Medical Necessity and return it to Stryker by October 12, 2012.

Customers who submit their signed Certificate of Medical Necessity to Stryker will receive a follow up mailing containing warning labels for the device and instructions detailing how to apply them.

Customers who have questions about this recall should contact Stryker Instruments' Recall Coordinator, Angela Ragainis, Monday – Friday, 8am – 5pm ET, at 269-389-2316 or strykerinstrumentsrecalls@stryker.com.

Healthcare professionals and customers may report adverse events or quality problems experienced with the use of this product to Stryker by calling 1-800-253-3210 or by using the FDA's MedWatch Adverse Event Reporting program either online at http://www.fda.gov/Safety/MedWatch/HowToReport or by phone at 1-800-332-1088.

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