FDA Safety Communication: Neptune 1 Silver Waste Management System and Neptune 2 Ultra Waste Management System (Neptune 1 Silver and Neptune 2 Ultra)

U.S. Food & Drug Administration

The Neptune 2 Ultra was manufactured from February 2001 through April 2012 and distributed from March 26, 2001 through Aug. 7, 2012. Stryker no longer manufacturers the Neptune Silver; however, they still maintain and support the device.

The Neptune 1 Silver Waste Management System (Neptune 1 Silver) and the Neptune 2 Ultra Waste Management System (Neptune 2 Ultra), manufactured by Stryker Instruments, are intended to collect and dispose of surgical fluid waste in operating rooms and surgical facilities. The Neptune 2 Ultra can also remove smoke generated at surgical sites by electrocautery or laser devices. Both systems consist of a mobile rover unit that can be relocated to a waste disposal area so the waste collection canisters can be emptied through the device's docking station.

(While Stryker recalled three additional Neptune systems -- the Neptune 1 Gold Waste Management System, the Neptune Gold International Waste Management System and the Neptune 1 Bronze Waste Management System -- in August 2012, this safety communication does NOT apply to them.)

Purpose:

To alert health care providers **NOT** to use the Neptune 1 Silver Waste Management System or the Neptune 2 Ultra Waste Management System unless there is no alternative suction device or waste management system available. Facilities should evaluate the risks and benefits of using the Neptune 1 Silver or the Neptune 2 Ultra; if they decide to continue using the device, they must file a Certificate of Medical Necessity with Stryker by Oct. 12, 2012 in order to continue to receive supplies and customer support for this device.

Summary of Problem and Scope:

The FDA and Stryker received one report of serious injury and one report of death as a result of tissue damage resulting from use of the Neptune 2 Ultra Waste Management System.

The patient death and injury reports indicate that the high-flow, high-suction vacuum had been incorrectly applied, and that the instructions for use on the device did not specifically warn against this action. When used incorrectly, the Neptune 1 Silver and the Neptune 2 Ultra can cause hemorrhaging and soft tissue,

muscle, and vital organ damage that can lead to serious injury and/or death.

Stryker issued a recall for these and two other models of its Neptune system [1], and issued revised instructions for use that addressed this warning.

While labeling modifications were sufficient for some of the Neptune models, the FDA determined that the Neptune 2 Ultra Waste Management System and the Neptune 1 Silver Waste Management System contained other modifications compared to prior models that were significant enough to have warranted the submission of a new premarket notification (510(k)) by Stryker for review by the FDA.

However, the FDA has not cleared the Neptune 2 Ultra Waste Management System or the Neptune 1 Silver Waste Management System for marketing. On Sept. 18, 2012, Stryker mailed an updated recall notice [2] [3] to all their customers and advised them of this issue and the steps it would take to respond to the FDA's concerns about the safety of the device and the company's failure to obtain FDA clearance for modifications to the original device.

The FDA is not currently asking Stryker to remove the Neptune 2 Ultra Waste Management System and the Neptune 1 Silver Waste Management System from the U.S. market due to concerns that removal would likely create immediate market shortages.

Facilities without alternatives to these two devices should carefully evaluate the risks and benefits associated with their continued use and submit a Certificate of Medical Necessity [2] [3] to Stryker prior to Oct. 12, 2012 in order to obtain assistance in its continued use and follow the recommendations outlined below.

Recommendations for Health Care Providers:

The FDA and Stryker recommend that facilities with an acceptable alternative to the Neptune 1 Silver and/or Neptune 2 Ultra should transition to that alternative as soon as possible.

If your facility does not have an alternative means for surgical waste disposal during surgery, the FDA advises you to evaluate the risks and benefits before you use this device, then complete and send the required Certificate of Medical Necessity to Stryker. Health care facilities should then ensure that users of these devices follow the recommendations listed below to mitigate the risks of using these devices:

- Ensure all users of these devices are retrained on the proper use of the Neptune 1 Silver and Neptune 2 Ultra devices and are fully aware of the applications for which they are intended to be used and the risks of using them improperly.
- Alwaysconsider the type of tissue associated with the surgical procedure before using this system and adjust suction levels accordingly. Use of

inappropriately high level of suction may result in severe injury or death.

- Ensure that you have each vacuum attached to the correct port because all vacuum ports appear identical making it more difficult to know which port corresponds with the appropriate level of suction.
- Verify that you are using the intended units of measure when setting suction levels to avoid operating the devices at a higher or lower level of suction than you expect and/or need for a specific clinical application. This device uses multiple units of measurement that could be confused leading to errors in suction levels: inches of mercury (in-Hg); millimeters of mercury (mm-Hg), kilopascals (kPa)
    - For example the digital readout may read 21 in-Hg which would be equivalent to 530 mm-Hg.
- Ensure you understand the adjustable vacuum limits and maximum limit for each device:
    - The Neptune 1 Silver vacuum limit is adjustable from 254 – 483 mm-Hg or 11.0 – 19.0 in-Hg and has a maximum vacuum level of 483 mm-Hg or 19.0 in-Hg
    - The Neptune 2 Ultra vacuum limit is adjustable from 50 – 530 mm-Hg, 2.0 – 21.0 in-Hg, or 7.0 – 71.0 kPa. and has a maximum vacuum level of 530 mm-Hg, 21.0 in-Hg, or 71.0 kPa.
- Do **NOT** apply high flow suction or allow extended exposure of suction to tissue associated with procedures that require no suction, low vacuum or low flow suction.
- Do **NOT** use the Neptune 1 Silver in low suction applications that require vacuum levels below 254 mm-Hg or 10.0 in-Hg as this could result in injury to vital anatomical structures, and/or hemorrhage, both of which may result in serious injury and/or death.
- Do **NOT** use the Neptune 2 Ultra in low suction applications that require vacuum levels below 50 mm-Hg, 2.0 in-Hg, or 7.0 kPa as this could result in injury to vital anatomical structures and/or hemorrhage, both of which may result in serious injury and/or death.
- Do **NOT** use these devices for respiratory tract suction.
- Do **NOT** use these devices to provide suction to other suction powered accessories such as Pleur Evac devices.

If you plan to continue using the Neptune 1 Silver and/or the Neptune 2 Ultra devices, you must complete the Certificate of Medical Necessity [2] [3] and send it back to Stryker Instruments at strykerinstrumentsrecalls@stryker.com [4] or fax 866-521-2762 by Oct. 12, 2012. If a Certificate of Medical Necessity is not received by this date, Stryker will not be able to provide any disposable accessories, replacement parts or provide service for your device(s). All facilities that complete the Certificate of Need for the Neptune 1 Silver and Neptune 2 Ultra will receive warning labels to apply to the device.

Customers with questions should contact Stryker Instruments at 269-389-2316 or strykerinstrumentsrecalls@stryker.com for more information.

FDA Activities :

- On August 15, 2012, the FDA issued a Class I recall [5] of the Neptune 1 Bronze, Neptune 1 Silver, Neptune 1 Gold, Neptune Gold International and Neptune 2 Ultra Waste Management Systems, the most serious type of recall. This recall included the following revised Instruction for Use Warning: Do Not apply High Flow suction or allow extended exposure of suction to tissue associated with procedures that require either no suction, low vacuum or low flow suction. All Neptune 1 Bronze, Neptune 1 Gold and Neptune 1 Gold International customers should have received warning labels to apply to the device in an updated notice mailed to customers on Sept. 25, 2012.
- Only customers that complete the Certificate of Medical Necessity can use and will receive warning labels for the Neptune 1 Silver and Neptune 2 Ultra devices.
- Stryker voluntarily stopped selling the Neptune 2 Ultra as of Aug. 7, 2012 and they have informed the FDA that they plan to seek clearance for the currently uncleared devices. They no longer manufacturer to Neptune 1 Silver.
- The FDA will continue to monitor this issue and keep the public informed if new information becomes available.

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect a problem with the Neptune 1 Silver and/or Neptune 2 Waste Management Systems, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program [6]. Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements [7] should follow the reporting procedures established by their facilities. Device manufacturers must comply with the Medical Device Reporting (MDR) regulations. [7]

To help us learn as much as possible about the adverse events associated with Dialysate Concentrates, please include the following information in your reports, if available:

- Product Name
- Lot Number
- Manufacturer
- Relevant events prior and subsequent to the referenced problem
- Concomitant medical products
- Details of the adverse event and medical intervention (if required)

Contact Information:

If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@FDA.HHS.GOV [8], 800-638-2041 or 301-796-7100.

This document reflects the FDA’s current analysis of available information, in keeping with our commitment to inform the public about ongoing safety reviews of medical devices.

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Links:
[1] http://www.fda.gov/Safety/Recalls/ucm320958.htm
[2] http://www.stryker.com/stellent/groups/public/documents/adacct/147939.pdf
[3] http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm
[4] http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/mailto:strykerinstrumentsrecalls@stryker.com
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