

Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

AL13-01*

October 2, 2012

Item: High vacuum/high flow suction devices, used inappropriately, have resulted in patient injuries and death

NOTE: Many of the sections of this Patient Safety Alert reference a specific manufacturer's high vacuum/high flow suction devices; however, this Patient Safety Alert **APPLIES TO ALL HIGH VACUUM/HIGH FLOW SUCTION DEVICES**, regardless of manufacturer or model.

Specific Incident: Stryker Instruments received a report from a non-VHA facility that a Neptune 2 Rover Ultra Waste Management System (i.e., a high vacuum/high flow suction device) was inadvertently connected to a low suction/passive chest drainage tube post-operatively, while prepping the patient for recovery following a pneumonectomy. A large quantity of blood was aspirated out of the patient's chest into the device. Connecting the patient to a waste management system, instead of to a post-operative low suction/passive chest drainage device, may have resulted in hemorrhage leading to death.

General Information: There are multiple brands and models of high vacuum/high flow surgical waste management systems on the market. Many of them have the potential to be connected inappropriately to chest tubes and low suction drainage systems with the possibility of patient injury or death.

Stryker Instruments issued an Urgent Medical Device Recall Notification (Revised) on September 19, 2012 that addressed the patient death discussed above. In addition, the notice informs customers that the Neptune 1 Rover Silver and Neptune 2 Rover Ultra do not have FDA 510(k) clearance to be marketed, and that the FDA is unable to determine whether the devices are as safe and effective as their legally marketed predecessor, the Neptune 1 Gold Waste Management System.

Neptune Waste Management Systems are high vacuum/high flow suction devices that are intended to be used in surgical environments and special procedure areas for collection of fluid waste and small debris from surgical sites. They are not intended for recovery areas or for use on medical/surgical units. Stryker Instruments' Instructions For Use (IFU) did **not** warn against connecting the Neptune devices

incorrectly to a low suction/passive chest drainage system. To address this concern, for situations where the device was used inappropriately, Stryker Instruments published an Urgent Medical Device Recall Notification on June 5, 2012 and provided customers with new IFUs for each of their Neptune systems which included the following language:

“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, for example, passive chest drainage. ALWAYS consider the type of tissue associated with the surgical procedure BEFORE using this system. Failure to comply may result in severe injury or death.”

The FDA states that the Neptune 1 Rover Silver and Neptune 2 Rover Ultra systems should not be used because they do not have FDA 510(k) approval. However, if facilities do not have alternate devices to use for surgical waste management, they should weigh the risks and benefits of continued use of these devices. If the facility chooses to continue using their Neptune 1 Rover Silver and Neptune 2 Rover Ultra devices, per the FDA they must request a Certificate of Medical Necessity (CMN) from Stryker Instruments by **October 12, 2012**, as outlined in the actions below.

Actions:

1. By Close of Business (COB) October 5, 2012, the following actions must be completed:
 - a. The **Medical Center Director (or designee)** shall ensure that the Surgical Chief, the Operating Room manager, Special Procedures area managers, and the Chief of Biomedical Engineering are made aware of this Patient Safety Alert.
 - b. The **Chief of Biomedical Engineering (or designee)** shall review this Patient Safety Alert and determine if your facility has **any** high vacuum/high flow suction devices, either in use or in storage.
 - c. If your facility does not have any high vacuum/high flow suction devices, the **Patient Safety Manager** shall continue to Action 4 and select “Does Not Apply to this Station” on the VHA Hazard Alerts and Recalls Web site.
2. By Close of Business (COB) October 12, 2012, the following actions must be completed:
 - a. The **Chief of Biomedical Engineering (or designee)** must determine if your facility has any Stryker Instruments devices shown in the following table:

Neptune Model Number	IFU Document Number
0702-001-000 and 0702-002-000 (Neptune 2 Rover Ultra)	IFU 0702-002-700 Rev-H
0700-001-000 and 0700-003-000 (Neptune 1 Rover Silver & Gold Rovers)	IFU 0700-001-700 Rev-W
0700-007-000 (Neptune Bronze Rover)	IFU 0700-007-720 Rev-D

- b. If you have a Stryker Instruments device listed above, the **Chief of Biomedical Engineering (or designee)** must ensure that earlier versions of IFU documents are discarded and replaced with new IFUs shown in the table above. NOTE: If you have not yet received the IFUs listed in the table above, contact Stryker Instruments to obtain them.
- c. The **Chief of Surgery (or designee)** shall complete and return the Certificate of Medical Necessity (CMN) Form (located within Attachment 1) to Stryker Instruments if the facility has no suitable alternative for surgical waste management and needs to continue using the Neptune 1 Rover Silver or Neptune 2 Rover Ultra systems. **NOTE: Stryker Instruments' deadline for requesting the CMN Form is October 12, 2012.**

NOTE: If your facility only has high vacuum/high flow suction devices that are NOT Stryker Instruments devices, consider this Action completed.

3. By COB November 2, 2012, the **Managers of the departments using the devices (or designee)** shall ensure that, **regardless of the manufacturer and model of high vacuum/high flow suction devices in your facility**, additional safety measures are put into place to minimize the chance that a high vacuum/high flow suction device might be connected inappropriately to a patient. Examples include:
- Prior to connection of the waste management system to tubing, add a "Call Out" step for the surgical procedures that use these devices to draw attention to the intended connection.
 - Store the devices in a limited access area and separate them from low flow/low suction devices.
 - Label the devices and/or connections with warnings.
 - Provide refresher staff/user training now and at the facility's standard training intervals.

NOTE: The action to put in place additional safety measures also

applies to those facilities who have requested a Certificate of Medical Necessity from Stryker Instruments.

4. By COB November 9, 2012, the **Patient Safety Manager** must document on the VHA Hazard Alerts and Recalls Web site that medical center leadership has reviewed and implemented these actions or that individual actions are not applicable to your facility.

Source: Stryker Instruments

Additional Information: In deciding whether to request a CMN, facilities can consider using earlier devices and/or methods for surgical waste management and evaluate their risks. Previous devices and methods for surgical waste management had multiple staff safety issues, including splashes and spills of hazardous fluids, pouring disinfecting solidifiers into multiple suction canisters and lifting heavy canisters.

Stryker Instruments has provided a list of customer Frequently Asked Questions (FAQs) dated September 20, 2012.

NCPS has requested Stryker Instruments to pursue an additional safety measure by adding WARNING labels to the disposable supply packages.

Contacts: Alerts and Advisory Team at the National Center for Safety (734) 930-5890