

## Patient safety

# Stryker's Neptune recall raises stakes for compliance

**S**trict requirements needed to comply with a recall for the Neptune brand of roving suction devices are raising questions and concern for ORs whose facilities continue to use the devices.

The recall of the Neptune Waste Management System from Stryker, used to collect and dispose of fluid waste, was initiated in June 2012 after the company received reports of serious tissue damage, including 1 death. Hospitals unable to find a suitable alternative to using the Neptune 1 Silver and Neptune 2 Ultra were required to file a certificate of medical necessity (CMN) if they chose to keep using the affected products.

Since then, further action has been taken by the Food and Drug Administration (FDA) and Stryker. Facilities that continue to use the Neptune 1 Silver and the Neptune 2 Ultra had to file an update to their CMN by March 25.

Under the CMN, these facilities must meet detailed requirements, including a 9-point presurgery checklist, or risk having the CMN revoked.

Though Neptune Gold and Bronze users do not need to use the presurgery checklist, they must agree to conduct training, ensure personnel are informed about the incidents, and make sure their devices have warning labels.

During its investigation, the FDA also advised Stryker that the Neptune 1 Silver and Neptune 2 Ultra lacked the necessary regulatory clearance.

### Adverse events

The requirements come after the reports of injuries and death involving incorrect application of the Neptune's high-flow suction.

Incidents recorded in the FDA's adverse events database show high-flow suction was connected to chest tubes in at least 2 cases and to a Jackson Pratt drain in 1 case (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm>).

In one report cited by the FDA, a patient died after the Neptune was connected to the chest tube during a pneumonectomy, and the suction pulled the heart muscle from its left position in the chest, causing a tear in the aorta.

### Worry about the consequences

OR managers and directors at the facilities that continue to use the Neptune 1 Silver and Neptune 2 Ultra worry about the consequences of meeting the CMN requirements.

One concern is that the Neptune checklist will divert the surgical team's attention from the Joint Commission's Universal Protocol for preventing wrong-site surgery, raising the risk of an error.

Another worry is that reverting to conventional methods for fluid waste disposal could subject OR personnel to the risk of bloodborne pathogen exposure. The Neptune system's rovers collect large amounts of surgical fluids and flush them away through a docking station without exposure to the staff.

### Initial recall

In response to the reports, Stryker in June 2012 recalled the instructions for use (IFU) of the Neptune waste management system.

The IFU did not specifically warn against connecting the high-flow Neptune suction to a passive drainage tube. Stryker revised the IFU and in October 2012 instructed customers to educate users on the revisions and apply warning labels to all Neptune devices, cautioning that the suction is dangerous if not used properly.

### **Requirements raised**

Stryker issued stricter requirements on February 20 after further incidents occurred in facilities that continued to use the Neptune models under the CMN. FDA audits found a number weren't complying with the initial requirements. Among the new requirements are:

- Train all users (ie, surgeons, residents, anesthesiologists, nurses, technicians, health profession students) and make them aware of the risks associated with the device.
- Keep a master list of all personnel who have been trained on the use of the device.
- Inform all users that additional adverse events have been reported.
- Ensure that warning labels are present on each device.
- Implement a 9-point pre-use checklist, which the circulating nurse must complete before every procedure. Stryker will audit these records to ensure use of the checklist. Failure to complete the checklist form is grounds for revoking the CMN.
- Identify a training facilitator for each facility to ensure implementation of the checklist, and partner with Stryker for additional training.
- Complete a business reply form acknowledging these actions have been taken.

In a March 27 update, the FDA acknowledged facilities' concerns about the requirements but simply referred users to the Stryker Neptune website for information to carry them out (<http://neptunecustomer care.com/>).

### **Safety issues**

Though the deaths and injuries that have occurred are tragic, the numbers are low considering the number of Neptune units in hospitals and the years they have been used, notes Chris Lavanchy, engineering director of the Health Devices Group at ECRI Institute, who says he has discussed the recall with both Stryker and the FDA. The nonprofit institute began tracking the recall last year and has issued alerts and special reports for its subscribers.

"These machines have been used since early 2000, and we're just hearing about a few of these incidents in the last 3 years," he says.

### **How did this happen?**

The Silver model, which is associated with several of the events, seems to have a relatively narrow range of vacuum levels (254-483 mmHg), biasing suction toward the high side that could be injurious when applied to tissue, Lavanchy notes.

"Whether that characteristic of the Silver actually was responsible for these incidents, we can't say, but it has been something people have speculated about," he says.

The range for the Gold units is broader (50-530 mmHg), and the vacuum level can be turned down so the suction is not as powerful.

The Ultra model, a newer version of the Gold, has the option of displaying the vacuum level in different units of measure—millimeters of mercury (mmHg), inches of mercury (inHg), and kilopascals (kPa).

In the US, mmHg is commonly used, and inHg is used rarely; kPa, seldom used in the US, is more common in Europe.

A problem could arise, Lavanchy notes, when the Ultra is inadvertently set on a unit of measure other than mmHg, which could cause users to think they are apply-

ing a lower level of vacuum than they actually are. For example, 250 mmHg would be 10 inHg and 33 kPa. Again, it's not known whether this contributed directly to the incidents.

Regardless of the type of suction applied, he says, "It is the responsibility of the person using the suction to verify the level of the suction and whether that is safe for the tissue you're applying it to."

### **Concern about alternatives**

Reverting to conventional wall suction means collecting waste in suction canisters, Lavanchy notes. Rather than having fluids always contained by the rovers, the staff must either apply solidifiers so the canisters can be disposed of as regulated medical waste or dump the canisters manually, potentially exposing them to bloodborne pathogens. This potential for exposure and compliance with Occupational Health and Safety Administration regulations are the reasons many facilities adopted enclosed waste management systems such as the Neptune in the first place.

A major question is whether the risk to patients of using a Neptune system is greater than the risk to staff from emptying canisters of blood and body fluids, he says.

In looking at alternatives, hospitals have questioned whether they should replace their Neptunes with another enclosed waste management system, which might end up having the same requirements down the road.

The FDA has told ECRI Institute that it is not actively looking at other companies at this time, but that doesn't mean it won't in the future, Lavanchy says.

### **Regulatory clearance**

The original FDA clearance was for the Stryker Neptune Gold, he notes. After receiving the adverse event reports and looking into the matter, the FDA determined that because the Silver and Ultra models had somewhat different features than the Gold, they were not equivalent and thus required separate 510(k) clearance. Whether to apply for a new 510(k) when a device is modified can be a judgment call for the company, Lavanchy notes. The company must determine whether the new model entails safety or efficacy issues that warrant a new 510(k) application.

### **Regulatory status**

The Neptune-1 Gold and Bronze devices continue to be legally marketed, and there is no change in their status, although the Gold is no longer being actively marketed, Stryker stated. Regarding the other models:

- Neptune 1 Silver: The company has decided not to submit a 510(k) and will withdraw this model from the market. All support for that device will stop by March 1, 2014.
- Neptune 2 Ultra: Stryker has submitted a 510(k) but does not know when or if the device will be cleared. The FDA has requested additional information. Stryker says it is working to respond to the requests.

Stryker and the FDA recommend that users of the Neptune 1 Silver and Neptune 2 Ultra transition to a legally marketed device as soon as possible. ♦

—Judith M. Mathias, MA, RN