

URGENT MEDICAL DEVICE RECALL NOTIFICATION (Revised)

STRYKER NEPTUNE WASTE MANAGEMENT SYSTEM

ATTENTION: CEO or Designee

CC: RISK MANAGER, OR DIRECTOR, DIRECTOR OF SURGERY

Product Information		
Manufacturer Part Number	Product Description	Serial Numbers Affected
0700-001-000	Neptune 1 Gold Rover	All serial numbers are affected
0700-003-000	Neptune 1 Silver Rover	All serial numbers are affected
0700-007-000	Neptune 1 Bronze Rover	All serial numbers are affected
0702-001-000	Neptune 2 Rover	All serial numbers are affected

February 20, 2013

Dear CEO or Designee:

The purpose of this correspondence is to update you on the status of the Class I recall of the Neptune Waste Management System. Specifically, Stryker would like to provide updates on the following:

- Reported adverse events
- Additional actions to be implemented to continue use of your Neptune device(s)
- Additional actions to be taken by Stryker
- Pre-market status of each device

Reported adverse events

Stryker has received additional reports of serious injury or death in procedures where Neptune 2 was connected to a passive chest drainage tube or closed wound drainage device post-operatively.

Additional actions to be implemented to continue use of your Neptune device(s)

As a result of the additional reported adverse events as well as information suggesting that not all of the recall actions required per the September 19, 2012 Urgent Medical Device Recall Notification for Neptune have been fully implemented at all accounts (specifically it was identified that not all Neptune devices were labeled with the warning labels supplied by Stryker and not all users of the Neptune devices were trained on the risks associated with using the device), Stryker is requiring additional actions to be implemented in order to continue to use your Neptune device(s).

For questions regarding this recall please contact Stryker Instruments:
Monday-Friday 8am-7pm (EST)
Neptune Customer Care Center
855-458-7441 or 269-389-2316
strykerinstrumentsrecalls@stryker.com

Below is a summary of the critical Neptune safety information. This information **MUST** be disseminated to all OR personnel that use Neptune high level suction devices. Please note that surgeons, surgical residents and health profession students on OR assignments must be included in your educational efforts.

Critical Neptune Safety Information

- **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.
- **DO NOT** use these devices to provide suction to other suction powered accessories such as Pleur Evac® devices.
- **DO NOT** use these devices with closed wound drainage systems.
- **DO NOT** use this device for post operative use.
- **ALWAYS** consider the type of tissue associated with the surgical procedure **BEFORE** using this system.
- **ENSURE** that in low level suction applications the appropriate suction device is used. **IT IS RECOMMENDED** that an alternate source of low level suction be available for low level suction applications (e.g. suctioning an airway or near vital anatomical structures).
- **ENSURE** the user has a clear understanding of the units of measure that are displayed. It is recommended that you set your unit to mm-Hg.
- **ENSURE** the level of suction has been checked and is appropriate for the planned procedure.
- **ENSURE** the device control panel can be clearly seen and is not covered by drapes or other objects.
- **ENSURE** that all users of the Neptune device are adequately trained on the appropriate use of the device and are fully aware of the applications for which it is intended to be used and the risks of using it improperly.

FAILURE TO COMPLY COULD RESULT IN INJURY TO VITAL ANATOMICAL STRUCTURES, AND/OR HEMORRHAGE, BOTH OF WHICH MAY RESULT IN SERIOUS INJURY AND/OR DEATH.

The following actions are required to continue use of your Neptune device(s):

1. Ensure all users of the Neptune device, including surgeons, surgical residents and health profession students on OR assignments, are adequately trained, and are aware of the risks associated with the device as detailed above.
2. It is recommended that all facilities keep a master list of all personnel that have been trained on the use of the Neptune. This list should include all users such as surgeons, anesthesiologists, residents, nurses, and technicians.
3. Inform all users of the Neptune device that additional adverse events have been reported.
4. Ensure warning labels previously supplied by Stryker are present on all Neptune device(s). If you require additional labels, please contact Stryker at 855-458-7441 or 269-389-2316.

For questions regarding this recall please contact Stryker Instruments:
Monday-Friday 8am-7pm (EST)
Neptune Customer Care Center
855-458-7441 or 269-389-2316
strykerinstrumentsrecalls@stryker.com

5. On the attached business reply form, identify a training facilitator who will aid in the implementation of the attached Neptune Pre-Use Checklist (for use with Neptune 1 Silver and Neptune 2 devices currently under a certificate of medical necessity) consistent with each healthcare facility's standard protocol. The training facilitator will also partner with Stryker to implement additional training/education.
6. Implement the attached Neptune Pre-Use Checklist within your facility. The checklist must be completed by the circulating nurse prior to every procedure where a Neptune device is in use. Instructions for completing the checklist are listed on the Neptune Pre-Use Checklist. Stryker will be auditing these records to ensure the checklist is being used and that all users have been trained on the device. **Failure of a facility to complete the attached Checklist form prior to each procedure, as noted above, is grounds for revoking the CMN.**
NOTE: The master list and checklist can be computerized electronically and attested by the circulating nurse for each element in each case.
7. Complete the attached business reply form, acknowledging that you completed the above actions.

Additional actions taken by Stryker

In order to ensure that the critical safety information is available to all users of the Neptune device, Stryker will be providing a placard, which includes the critical Neptune safety information listed above. This placard will be applied to each Neptune device by a Stryker Field Service Technician. We have attached a copy of the placard to this notification. In addition to applying this placard to your Neptune device(s), the Field Service Technician will also be conducting a verification check to ensure that previously supplied warning labels have been applied.

Premarket status

Neptune Gold and Neptune Bronze

These are both legally marketed devices. There has been no change to the status of these devices.

Neptune Silver

After careful consideration, Stryker has decided not to submit a 510(k) for this device. Therefore, the certificate of medical necessity is no longer valid and all Neptune 1 Silver devices are now required to be removed from the field. The CMN will expire when the device is returned or on March 1, 2014, whichever is first. Therefore customers need to begin this transition process immediately and should not wait until the last minute. Customers who are affected by this recall will receive a separate notification with specific instructions.

Neptune 2

Stryker Instruments has submitted a 510(k) to FDA for the Neptune 2 device. FDA has made requests for additional information with respect to the 510(k) and we are working quickly to respond to these requests. We do not know when this device will be cleared.

Actions needed:

1. Immediately review this notification and distribute it to all affected departments, including those listed in the header of this letter.
2. Ensure all users of the Neptune device are adequately trained, and are aware of the risks associated with the device as detailed above.
3. It is recommended that all facilities keep a master list of all personnel that have been trained on the use of the Neptune. This list should include all users such as surgeons, anesthesiologists, residents, nurses, and technicians.

For questions regarding this recall please contact Stryker Instruments:
Monday-Friday 8am-7pm (EST)
Neptune Customer Care Center
855-458-7441 or 269-389-2316
strykerinstrumentsrecalls@stryker.com