

URGENT: MEDICAL DEVICE RECALL NOTIFICATION

STRYKER NEPTUNE 1 SILVER 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
0700-003-000	Neptune 1 Silver	All serial numbers are affected

February 20, 2013

Dear CEO or Designee ,

The purpose of this letter is to advise you that Stryker Instruments is voluntarily recalling all Stryker Neptune 1 Silver devices, part number 700-003-000.

Reason for the voluntary recall:

In the Medical Device Recall Notification dated September 19, 2012, Stryker Instruments notified customers that FDA does not consider the Neptune 1 Silver to be a legally marketed device because the safety and effectiveness have not been determined through the 510(k) process. In this notification, customers were able to continue to use Neptune 1 Silver devices if they determined they have an urgent medical need for the continued use of the Neptune 1 Silver and completed and signed a certificate of medical necessity. This certificate of medical necessity granted the ability for the Neptune 1 Silver devices to remain in use until while the 510(k) submission was under review with FDA.

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 Therefore, the certificate of medical necessity is no longer valid and all Neptune 1 Silver devices are now required to be removed from the field and customers must transition to a legally marketed suction device.

Requirements of the recall:

This recall notice applies to all Neptune 1 Silvers devices; those that are covered under a certificate of medical necessity and those that are quarantined within a facility and not covered under a certificate of medical necessity. Please read the below requirements for each scenario carefully.

Units not covered under a Certificate of Medical Necessity:

- Units that are not covered under a certificate of medical necessity were required by the original recall notification to be removed from use and quarantined at each facility. Due to Stryker's decision to not submit a 510(k), these devices are now required to be removed from the field immediately. Field service technicians will coordinate with your Stryker sales representative to schedule the decontamination and pick up of these devices. Upon receipt of your returned devices, Stryker will work with your facility to issue a refund or credit.

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

Units that are covered under a Certificate of Medical Necessity:

- Customers who signed a certificate of medical necessity were allowed to continue use of their Neptune 1 Silver devices based upon our initial decision to submit a 510(k) for this device. Because a 510(k) will not be submitted, you are required to immediately begin the assessment and planning of a transition to a legally marketed suction option, such as wall suction or another mobile suction device. 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. The timeline for this transition must be indicated on the attached business reply form and returned to Stryker by **March 25, 2013**. Upon receipt of your returned devices, Stryker will work with your facility to issue a refund or credit.

Customers who continue to use the Neptune 1 Silver under the certificate of medical necessity during this transition must do the following:

- Ensure warning labels previously supplied by Stryker are present on all Neptune 1 Silver devices. If you require additional labels, please contact Stryker at 855-458-7441 or 269-389-2316.
- Ensure that all users of the Neptune 1 Silver device are adequately trained on 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.
- Ensure users understand the risks and potential for misuse of the device.

Actions to be taken by the Customer/User:

1. Immediately review this notification.
2. Distribute this notification to all affected departments including those listed in the header of this letter.
3. Customers operating under a certificate of medical necessity must ensure the following:
 - Previously supplied warning labels are present on each device. If you require additional labels, please contact Stryker at 855-458-7441 or 269-389-2316.
 - Users of the Neptune 1 Silver 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.
 - Users understand the risks and potential for misuse of the device.
4. Complete the attached Business Reply Form and email back to strykerinstrumentsrecalls@stryker.com or fax to 866-521-2762.

Once Stryker receives your business reply form:

- If you are operating under a CMN, Stryker will contact you to schedule decontamination and pick-up of your device(s) in accordance with your proposed timeline to transition to an alternate suction option.
- If you are not operating under a CMN, Stryker will contact you to set up a decontamination and pick-up of your device(s) by **March 25, 2013**.
- Upon receipt of your returned devices, Stryker will work with your facility to issue a refund or credit.

Report any serious adverse events or product quality problems to Stryker Instruments: 1-800-253-3210. Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone. Online: www.fda.gov/MedWatch/report.htm Regular Mail: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm and mail to: MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
Fax: (800) FDA-0178 Phone: (800) FDA-1088

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