

URGENT MEDICAL DEVICE RECALL NOTIFICATION (Revised)

RE: STRYKER NEPTUNE WASTE MANAGEMENT

**ATTENTION: RISK MANAGER, OR DIRECTOR, MATERIALS MANAGER, and
the following areas:**

**DIRECTOR OF SURGICAL SERVICES
DIRECTOR OF ANESTHESIA
DIRECTOR OF SURGERY
DIRECTOR OF OR NURSING
DIRECTOR OBGYN
DIRECTOR OF ORTHOPEDICS
OFFICE MANAGER**

Purpose This letter is a follow-up to the letter dated June 5, 2012 regarding the Neptune Waste Management Instructions for Use. This letter includes additional important information relative to the Neptune Waste Management System. Included in this notification are the warning label(s) that need to be placed on the Neptune device(s). Instructions for applying the label(s) are detailed below.

Date October 9, 2012

Product Recalled Stryker Neptune Waste Management System:

Manufacturer Part Number	Product Description	Corresponding IFU Part Number
0700-001-000	Neptune Gold Rover (120V)	0700-001-700
0700-007-000	Neptune Bronze Rover	0700-007-720

Product Description The Neptune Waste Management System is a high vacuum/high flow device that is intended for use in surgical environments or the physician's office for suction and collection of fluid waste and small debris from surgical sites.

Product Issue Stryker received reports of serious injury and/or death from use of this device in areas where only low suction should be applied. For example, there was one report of a fatality from the use of the Neptune Rover which was connected to a passive chest drainage tube post-operatively. **Use of these products in all low suction applications may result in injury to vital anatomical structures, and/or hemorrhage, both of which may result in serious injury and/or death. In addition, use of these products near vital anatomic structures may injure/damage those structures, which may result in serious injury and/or death.** It is important to note the suction levels for each device. The Neptune 1 device has a maximum suction level of **19 in-Hg which is equivalent to 483 mm-Hg**. These measurements are listed in the Instructions for Use for each device.

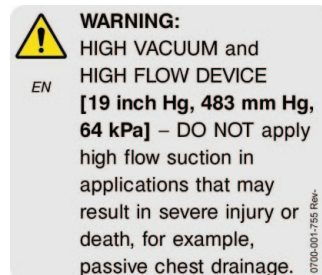
For questions regarding this recall please contact Stryker Instruments:
Monday-Friday 8am-5pm (EST)
Angela Ragainis
269-389-4354
angela.ragainis@stryker.com

The notification dated June 5, 2012 included the addition of the following warning to the IFU:

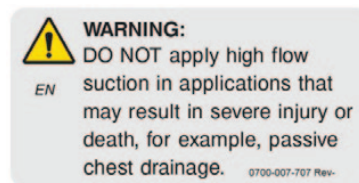
WARNING: DO NOT apply High Flow suction or allow extended exposure of suction to tissue associated with procedures that require either no suction, low vacuum or low flow suction, for example, passive chest drainage. ALWAYS consider the type of tissue associated with the surgical procedure BEFORE using this system. Failure to comply may result in severe injury or death.

The new warning labels will appear as pictured below:

Neptune (Gold)
Part # 0700-001-000



Neptune (Bronze)
Part # 0700-007-000



Actions Needed

1. Immediately review this notification.
2. Distribute the notification to all departments affected and listed above.
3. Please educate all users of the Neptune on this warning and the information contained in this notification.
4. Please attach one of the enclosed warning labels to each Neptune Rover. The placement varies based on the model. Please refer to the instructions and photos in Figures 1 and 2.
5. Replacement Instructions for Use manuals were sent in the initial notification of this recall. If you require additional IFUs please contact Angela Ragainis, Recall Coordinator at angela.ragainis@stryker.com.
6. Complete and sign the enclosed Business Reply Form and fax a copy to: 866-521-2762 or email a copy to Angela Ragainis, Recall Coordinator at angela.ragainis@stryker.com.
7. Keep a copy of this notification and business reply form for your records.

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Figure 1: Part # 0700-001-000/Neptune Rover (Gold)

- Please wipe the surface with Isopropyl Alcohol and allow to dry prior to placing the label.
- Please position and attach label on the flat surface of the unit between the knob and the switch as shown below.

**Figure 2: Part # 0700-007-000/Neptune Bronze Rover**

- Please wipe the surface with Isopropyl Alcohol and allow to dry prior to placing the label.
- Please position and attach label on the exterior side wall of the fluid collection canister cap (next to "Manifold Port" label).
- Please place the label below the rounded top edge of the canister cap as shown in the photo.



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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