

URGENT FIELD SAFETY NOTICE - UPGRADE NOTIFICATION

STRYKER NEPTUNE 2 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
0702-002-000	Neptune 2 Rover (230V)	All Serial Numbers are affected

Dear Customer:

The purpose of this letter is to advise you of the upgrade to the Neptune 2 Waste Management System. We are sending you this Field Safety Corrective Action to notify you of the following:

1. Immediately check your internal inventory of quarantined Neptune 2 devices.
2. At this time, you should continue to quarantine the Neptune 2 Waste Management System.
3. Maintain awareness of this notice internally until all required actions have been completed within your facility.
4. Inform Stryker if any of the subject devices have been distributed to other organisations. *(Please provide contact details so that Stryker can inform the recipients appropriately).*
5. Complete the attached customer response form and return to the address indicated. *(Please complete this form even if you do not have any product at your facility. This will preclude the need to Stryker to send any reminder notice)*
6. In order to close out this recall, all existing Neptune 2 units in the field will need to be upgraded.
7. A Stryker Representative will contact you to coordinate the upgrade to your Neptune 2 units.
 - o In-servicing on new device features must be completed along with the upgrade.
8. The Neptune 2 Waste Management System can be used again after final signing the UPGRADE COMPLETION FORM by your Facility Representative and a Stryker Representative.

Upgrade Information

A Stryker technician will come to your location to upgrade your units. The upgrade will be scheduled with you in advance. Each unit will take about 90 minutes to upgrade. The upgrade will involve a new top cap, labels and

software package for your units. This will be free of charge to your facility.

Training and In-servicing Information

A Stryker representative will coordinate on-site in-servicing in conjunction with your upgrade. This representative will walk personnel through the new device features and usage. Each facility will need to identify users needing to attend the on-site in-service and receive training. The official training module will be made available via Stryker's NeptuneCustomerCare.com website.

Upgrade Completion

No further action is required at this time; a Stryker representative will contact you for scheduling. Once your upgrade and in-servicing are completed, you will be asked to sign an Upgrade Completion Form (attached), which will close out this recall for your location. Your signature on this form will confirm that you have received the training kit, an on-site in-service on the new features, functions, labels, warnings and cautions and that all units have been upgraded at your location. You will be provided a copy of this form for your records.

Other Information

- This notification is only for the Neptune 2 Waste Management System.
- If you have distributed or moved a Neptune 2 to another location, please contact Stryker Instruments immediately and forward a copy of this letter to the appropriate facility.

For questions regarding this notification, please contact Stryker. Attached are additional Frequently Asked Questions.

We apologize for any inconvenience this action may cause your facility. Please forward a copy of this letter to any other personnel within your facility whom you deem appropriate.

RA2013-186: BUSINESS REPLY FORM

Please respond immediately

Stryker Neptune 2 Ultra Waste Management Device

Please complete and sign this form and send back to Local QAR at XXXX

Manufacturer Part Number	Product Description	Quantity of Neptune 2 Ultra devices on record at your facility
0702-002-000	Neptune 2 Ultra Rover (230V)	

Please indicate all Neptune 2 Ultra serial numbers at your facility:

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Confirm the statements below by checking the corresponding boxes and completing below information:

I have received and understand the attached Field Safety Notice dated XXXX regarding my Neptune 2 Ultra device(s)

On receipt of this completed form a Stryker representative will contact you in order to arrange for your units to be upgraded.

Name (print): _____

Title: _____

Telephone: _____ E-mail: _____

Signature: _____ Date: _____

Account Number and Facility Name: _____

Address: _____

City: _____ State/Land/Province: _____ Country: _____

UPGRADE COMPLETION FORM

PRODUCT: STRYKER NEPTUNE 2 WASTE MANAGEMENT

Please complete this form after the three action items below have been completed at your facility.

[Facility Name]
[Facility Account Number]
[Notification Address]
[City], [State] [ZIP CODE]

Facility Representative: This form must be signed by the facility's designated Training Facilitator, OR Manager, CEO or Designee.

Check and date all boxes to acknowledge completion:

- We have received access to the training on NeptuneCustomerCare.com DATE: _____
- A Stryker representative has provided on-site in-servicing on the upgraded Neptune 2 units, including a review of the new features, functions, labels, warnings and cautions. DATE: _____
- All Neptune 2 units at my facility have been upgraded with the new top cap, software and on-device labels. DATE: _____

Address (location where units will be used post upgrade): _____

Facility Representative's Name (print): _____

Title: _____

Phone Number: _____ Email: _____

Signature: _____ Date: _____

Stryker Representative: By signing this form, you are acknowledging these action items have been completed. This form must be signed by the Stryker representative who performed the on-site in-service. Email or fax the completed form to.

Other Ship-to Locations (if applicable): _____
(Supply Center, Distribution Center and/or Warehouse that orders disposables/accessories on behalf of the facility listed above)

Stryker Representative's Name (print): _____

Title: _____

Signature: _____ Date: _____

Upon completion of the above actions, your facility has met the requirements of this URGENT FIELD SAFETY NOTICE - UPGRADE NOTIFICATION. At this time, all requirements of previous Neptune 2 recall notifications are complete. No further action is required.