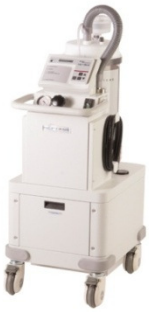

0700-003-000 Neptune Silver

Neptune® 1 Silver

PLEASE REFER TO THE
RECALL NOTIFICATION LETTER
FOR COMPLETE DETAILS

Required Actions

1	Ensure all users of the Neptune 1 Silver device, including surgeons, surgical residents and health profession students or O.R. assignments, are adequately trained, and are aware of the risks associated with the device as detailed in the device recall notification.	☐
2	It is recommended that all facilities keep a master list of all personnel that have been trained on the use of the Neptune 1 Silver. This list should include all users, such as surgeons, anesthesiologists, residents, nurses and technicians.	☐
3	Inform all users of the Neptune device(s) 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.	☐
5	On the business reply form, identify a training facilitator who will aid in the implementation of the Neptune Pre-Use Checklist (for use with Neptune 1 Silver and Neptune 2 devices currently under a certificate of medical necessity CMN) consistent with each healthcare facility's standard protocol. The training facilitator will also partner with Stryker to implement additional training /education.	☐
6	Implement the Neptune Pre-use Checklist within your facility. The checklist must be completed by the circulating nurse prior to every procedure where a Neptune 1 Silver is in use. Instructions of 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 to use this checklist form prior to each procedure, as noted above is grounds for revoking the CMN signed by the facility. 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 business reply form, acknowledging you completed the above actions. If you are not able to sign the business reply, call the Neptune Customer Care Center to log the reason and document the targeted implementation date.	☐
8	The CMN wil expire when the device is returned or on March 1, 2014, whichever is first. Begin your transition process immediately The timeline for this transition must be indicated on the business reply form.	☐