

## CERTIFICATE OF MEDICAL NECESSITY FORM

Please respond by **October 12, 2012**

### Provide the following information:

User name (institution or hospital): \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Please indicate which device(s) you have: 0700-003-000 Neptune 1 Rover Silver (120V) \_\_\_\_\_

0702-001-000 Neptune 2 Rover Ultra (120V) \_\_\_\_\_

We are aware that FDA does not consider the Neptune Silver or the Neptune 2 to be legally marketed devices because their safety and effectiveness have not yet been determined.

We are aware of the patient risk in the use of these devices and certify that we have a medical necessity to use either of these devices and feel that the benefit of their use will outweigh the risk for patients and healthcare providers.

After reading the notification, I certify that this medical facility evaluated the relevant risks and benefits and concluded that it has a medical need for the continued use of the Neptune Silver or Neptune 2 and its associated parts, components, and accessories. Furthermore, I certify that all users of the Neptune Silver and/or Neptune 2 at this medical facility have been informed of the contents of this notification and adequately instructed in the risk and benefits of this device and its proper use.

Nature of Medical Necessity: \_\_\_\_\_

Authorized Signature<sup>1</sup>: \_\_\_\_\_

Institution/Hospital: \_\_\_\_\_

Name (print): \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Telephone: \_\_\_\_\_

E-mail (if available): \_\_\_\_\_

<sup>1</sup> The Certificate of Medical Necessity must be signed by one of the following:

**OR Director or equivalent**  
**Surgical Director or equivalent or**  
**Risk Manager**

For questions regarding this recall please contact Stryker Instruments:

Monday-Friday 8am-5pm (EST)

Angela Ragainis

269-389-2316 [strykerinstrumentsrecalls@stryker.com](mailto:strykerinstrumentsrecalls@stryker.com)

General Update  
and Warnings

Recall Letter

Certificate of  
Medical Necessity

Neptune  
Education

Neptune  
Competency Exams

Neptune  
Training Log

Checklist

Appendix