

**MEDICAL DEVICE CORRECTION NOTICE**  
**C-2019-08**

April 10, 2019

Dear Customer:

cc: Chairman Medical Board and relevant Head of Departments

This letter is to inform you that Smith & Nephew, Inc. has initiated a field action to voluntarily provide updates to the NAVIO Surgical System Instrument Kit Cleaning and Sterilization Guide. The affected guide is included with the NAVIO Instrumentation Tray (PFSR02053) and does not contain certain information required by the EN ISO 17664:2004 standard. This standard requires information regarding validated methods for cleaning, disinfection, and sterilization. The affected guides contain validated methods for cleaning and sterilization, but lack validated instructions for disinfection for the NAVIO handpiece (PFSR110137).

Please see product details below:

Product	Description	Shipment Date
PFSR02053	NAVIO INSTRUMENT KIT UK/BE/FR/DE/IT	All products delivered prior to 26 March 2019.
PFSR110137	NAVIO INSTRUMENT KIT UK/BE/FR/DE/IT	All products delivered prior to 26 March 2019.

**Potential Risk with Use of the Product**

In the event an affected device is presented for use, there are no additional risks to use of the product as the device is terminally sterilized prior to each use.

**Actions for Hospital Representatives**

1. Please check your inventory and complete the attached Inventory Correction Certification Form.
2. If you have the NAVIO Surgical System, please maintain awareness of this notice.



## Inventory Correction Certification Form

C-2019-08

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**PLEASE COMPLETE ALL ITEMS AND RETURN WITHIN 5 DAYS OF RECEIPT**

### Acknowledgement of Correction Notification

By signing below, I acknowledge that I have received the notification and I have taken the appropriate actions.

Printed Name: \_\_\_\_\_ Title \_\_\_\_\_

Telephone: (\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_

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

Facility Name:

Account Number:

Signature \_\_\_\_\_

Check One:

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I have checked my inventory and my facility no longer possesses the device

I have checked my inventory, my facility still possesses the device, and I acknowledge the correction notification.

**PLEASE RETURN THIS COMPLETED FORM VIA EMAIL OR FAX TO:**

**Email:** [FieldActions@smith-nephew.com](mailto:FieldActions@smith-nephew.com)

**Fax:** +1-901-566-7975