4100 E. Milham Avenue
Kalamazoo, MI 49001
269-323-7700
www.stryker.com

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Instruments

URGENT MEDICAL DEVICE RECALL NOTIFICATION

RE: STRYKER NAV3i PLATFORM, POWER BOX

ATTENTION: RISK MANAGER, OR DIRECTOR, MATERIALS MANAGER

May 13, 2014

Dear NAV3i Customer,

The purpose of this letter is to advise you that Stryker Instruments is voluntarily recalling the following NAV3i Platforms and Power Box**:**

Stryker Product Number	Product Description	Stryker Serial Numbers	Dates of Distribution
7700-800-000	NAV3i Platform	15097, 15098, 15099, 15102, 15103, 15104, 15105, 15106, 15107, 15109, 15110, 15111, 15112, 15113, 15114, 15115, 15116, 15117, 15118	12/31/2013 to 3/6/2014
7700-853-000	NAV3i Power Box	10004	3/7/2014

Product Description

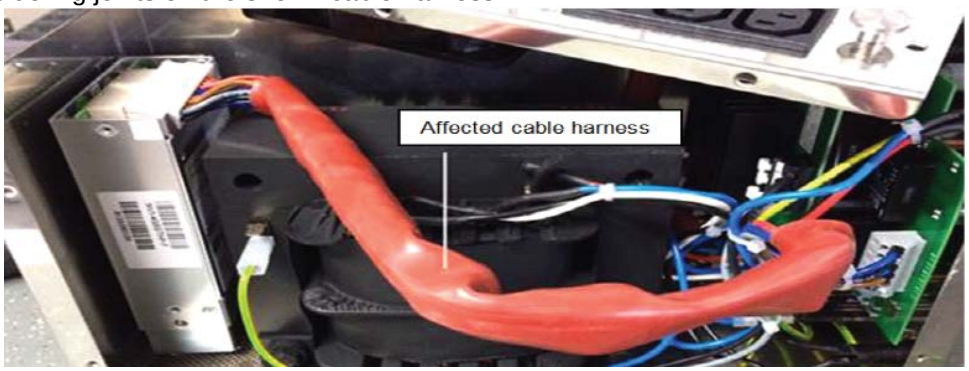
The Stryker NAV3i Platform is a mobile cart platform consisting of the sub-components Stryker Nav3 Graphite Camera, SPC-3 Computer and IO-Tablet (touch screen) as well as the monitor, articulated arms and cart housing. This Navigation system is used in combination with surgical software for cranial, spine, ENT, orthopedic and trauma procedures.

The NAV3i Platform contains a Power Box that supplies the electrical components with power (e.g. Stryker Nav3 Graphite Camera, SPC-3 Computer, IO-Tablet (touch screen) and the monitor).

The NAV3i Platform is a computer workstation that, when used with specific Stryker Navigation surgical software displays patient specific images and/or patient specific anatomical landmark information and tracks the position and movement of surgical instruments in relation to target anatomical site on a patient.

Reason for the Voluntary Recall:

Power Boxes produced between December 9, 2013 and March 7, 2014 may have been assembled without electrical insulation of the soldering joints on the shown cable harness:



For questions regarding this recall please contact Stryker Instruments:

Monday-Friday 8am-5pm (EST)

[redacted]
[redacted]**@stryker.com**

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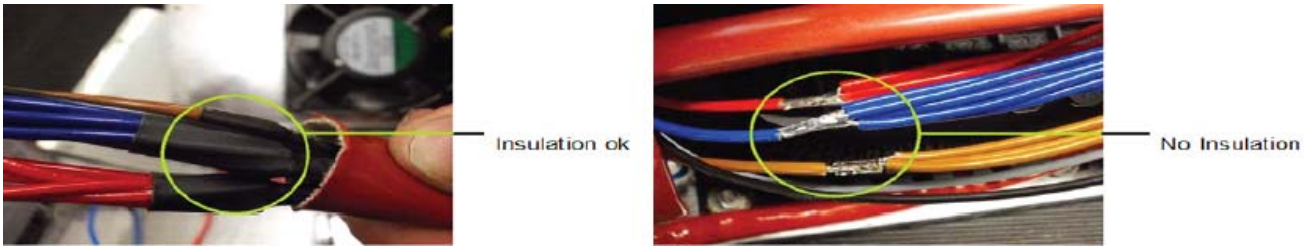

The Monitor and/or the IO Tablet may lose power if non-insulated wires come into contact with each other.

Risk to Health:

There is a potential for a 10-30 minute delay in surgery which could lead to additional time under anesthesia. If the Navigation system stops working and cannot be restored during the initial surgery, surgery may need to be completed without Navigation, or a second surgery may have to be scheduled.

Actions to be taken by the Customer/User:

1. Immediately review this Recall Notification

2. Immediately check all stock areas and/or operating room storage and quarantine all affected equipment found.

3. Complete the enclosed Business Reply Form (BRF) to confirm receipt of this notification and identify Serial Number(s) listed on the BRF is currently at your facility.
   Note: *Your signature on the BRF indicates that you received and understand this Notification and have followed the instructions in this Notification.*

4. If you have further distributed this product, please forward this letter and the attached BRF to all affected locations. Please indicate each location and Serial Number(s) on the BRF.

5. Fax (866-521-2762) or email ([redacted]@stryker.com) the completed BRF to Stryker Instruments Regulatory Department, Attn: [redacted]

6. A Stryker Representative will contact your facility to set up a time to perform the upgrade. The Stryker Representative will be removing the existing power box and will be replacing it with a new power box.

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, or by fax or phone.
Online: www.fda.gov/Safety/MedWatch/HowToReport/default.htm
Fax: (800) FDA-0178 Phone: (800) FDA-1088
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 that you deem appropriate.

For questions regarding this recall please contact Stryker Instruments:

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[redacted]
[redacted]**@stryker.com**