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

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URGENT MEDICAL DEVICE RECALL NOTIFICATION

RE: STRYKER Navigation System II-Cart, Articulated Arm Camera

ATTENTION: RISK MANAGER, OR DIRECTOR, MATERIALS MANAGER

May 18, 2015

Dear Customer,

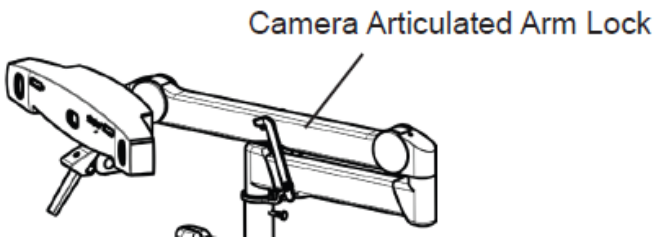
The purpose of this letter is to advise you that Stryker Instruments and Stryker Leibinger GmbH & Co. KG are voluntarily recalling the following Navigation System II-Cart, Articulated Arm Camera:

Stryker Product Number	Product Description	Stryker Serial Numbers	Dates of Distribution
7700-100-000	Navigation System II-Cart	See enclosed list	12/23/2011 to 8/3/2012
7700-103-001	Articulated Arm Camera	Refer to serial numbers for Navigation System II-Cart	12/23/2011 to 8/3/2012
7700-103-001U	Articulated Arm Camera (refurbished)	Refer to serial numbers for Navigation System II-Cart	12/23/2011 to 8/3/2012

Product Description:

The Navigation System II is a computer aided surgery platform which supports surgeons by providing navigational information during procedures. The Navigation System II-Cart is a component of the Navigation System II; it contains a computer workstation which runs Stryker Navigation application modules used to display the calculated position and/or navigation information.

One of the components to the Navigation System II-Cart is the Navigation System Camera; the camera communicates the coordinate location of the navigated instruments to the system. The camera is attached to the Articulated Arm.



For questions regarding this recall please contact Stryker Instruments:

Monday-Friday 8am-5pm (EST)
Kelly Jo Davis
269-389-2921
kellyjo.davis@stryker.com

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Reason for the Voluntary Recall:

Additional inspection is required because there is a potential that the weld seam between the main stud and the two flaps on the Articulated Arm was not welded in the correct location, which may result in a potential failure of the arm joint.

Risk to Health:

A change in the position of the camera will not impact the accuracy of navigation. A failure in the weld joint could result in the interruption or discontinued use of the Navigation system.

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 for affected equipment found.
   Note: *The serial number of the Navigation System II-Cart is located on the base between the wheels.*

3. Complete the enclosed Business Reply Form (BRF) to confirm receipt of this notification and identify how many affected items are currently in your inventory. Please complete and return the BRF even if you don't have any affected product on hand.
   Note: *Your signature on the BRF indicates that you received and understand this Notification and have followed the instructions in the 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 (kellyjo.davis@stryker.com) the completed BRF to Stryker Instruments Regulatory Department, Attn: Kelly Jo Davis.

6. A Stryker Representative will contact your facility to set up a time to perform the additional inspection of the weld seam on the Navigation System II-Cart, Articulated Arm Camera.

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.

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