URGENT MEDICAL DEVICE RECALL NOTIFICATION

PRODUCT: STRYKER® CORE® FOOTSWITCH

ATTENTION: OR DIRECTOR, RISK MANAGER, MATERIALS MANAGER

Cc: Chairman Medical Board and relevant Head of Departments

December 31, 2019

The purpose of this notification is to advise you that Stryker Instruments is voluntarily recalling CORE Footswitches with specific SNs.

Product Number	Description	GTIN	Distribution Dates
5402-007-000	CORE Footswitch	7613327423631	Oct 22, 2019 – Nov 20, 2019

Affected Serial Numbers						
1926000039	1926000059	1926000119	1926000129	1926000139	1926000149	1926000159
1926000169	1926000179	1926000189	1926000199	1926000279	1926000289	1926000319
1926000329	1926000339	1926000349	1926000359	1926000419	1926000429	1926000439
1926000449	1926000459	1926000469	1926000479	1926000489	1926000499	1926000509
1926000519	1926000529	1926000539	1926000549	1926000559	1926000599	1926000619
1926000629	1926000639	1926000649	1926000659			

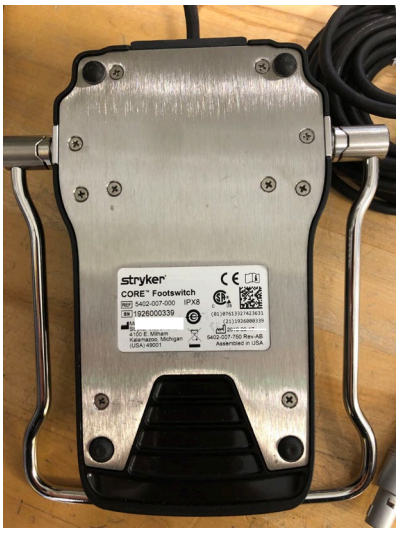
Risk to Health:
There is no risk to health.

Reason for the Voluntary Recall:
The CORE Footswitch may have been programmed incorrectly which could result in an error on the console and the inability to use the footswitch.

Product Description:
The CORE Footswitch is an electronically operated footswitch that connects to the CORE 2 Console. When actuated, the footswitch provides signals to the console for variable speed control of various handpieces. The footswitch is intended for use in a variety of surgical procedures, including but not limited to orthopedic, dental, ENT, neuro, spine and endoscopic applications.

Product photos and location of Product Number (blue) and SN (red) on the underside of the product:

Stryker Instruments
4100 E Milham Ave, Kalamazoo, MI 49001 USA | P 269 800 1336| F 866 521 2762



Actions to be taken:

1. Immediately review this Recall Notification and the Business Reply Form.
2. Immediately check all stock areas, operating rooms, treatment rooms and/or storage for affected products. Quarantine and discontinue use of any CORE Footswitches with SNs listed on page 1 of this notification.
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. Return the completed BRF via fax (866-521-2762) or email to [redacted]

   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 copies of this Notification and the BRF to all affected locations, for each location to complete and return. Even if you have distributed all product to another location, please complete a BRF and indicate each location that received product.
5. If the BRF for your facility indicates that recalled product is currently on hand, a shipping label will be provided which should be used to return recalled product. Upon receipt of the Business Reply Form, replacement(s) will be shipped to your facility.

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.

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

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BUSINESS REPLY FORM

Stryker® CORE® Footswitch

December 31, 2019

Recalled Product Number	Recalled Serial Numbers on hand – Refer to Customer Notification for affected SNs
5402-007-000	

If you don't have any recalled product on hand, please indicate "0" in the "Recalled Serial Numbers on hand" box.
PO# for replacement order, if applicable _____.

Actions to be taken:

1. Immediately review the Recall Notification and this Business Reply Form.
2. Immediately check all stock areas, operating rooms, treatment rooms and/or storage for affected products. Quarantine and discontinue use of any CORE Footswitches with SNs identified on the enclosed Notification.
3. Complete this 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. Fax the completed BRF to Stryker Instruments at 866-521-2762, or email to [redacted].

   Note: Your signature on the BRF indicates that you received and understand the Notification and have followed the instructions in the Notification.
4. If you have further distributed this product, please forward copies of the Notification and this BRF to all affected locations, for each location to complete and return. Even if you have distributed all product to another location, please complete a BRF and indicate each location that received product.
5. If the BRF for your facility indicates that recalled product is currently on hand, a FedEx label will be emailed to you and should be used to return recalled product. Upon receipt of the Business Reply Form, replacement(s) will be shipped to your facility.

Acct name and address: Account #:

Print Customer Name | Customer Title

Contact Phone Number | Customer Signature | Date

Email Address | Fax Number

If you have further distributed any affected product, please indicate to whom below:

Name Address City State Zip

Contact Person and Contact Information Quantities

Instruments

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