5900 Optical Court, San Jose, CA 95138 USA | t: 408-754-2000

URGENT MEDICAL DEVICE RECALL NOTIFICATION

STRYKEPROBE SHEATH

September 25, 2019

Attn: Customer
CC: Chairman Medical Board and relevant Head of Department

Table 1: Recalled Part Numbers and Descriptions
0250070450 - PKG. Sheath, 45CM StrykeProbe
0250070460 - Sheath, StrykeProbe

Recalled Lot Numbers of Sheaths: See Attachment A

Table 2: Impacted Part Numbers and Descriptions that shipped with Recalled Part Numbers (listed above):	
0250070441-PKG, StrykeFlow Electrocautery Probe, Spatula Tip 5MM	0250070451-PKG, 5MM X 45CM StrykeProbe Electrosurgical Probe, Spatula-Tip
0250070442-PKG, StrykeFlow Electrocautery Probe, J Tip, 5MM	0250070452-PKG, 5MM X 45CM StrykeProbe Electrosurgical Probe, J-TIP
0250070443-PKG, StrykeFlow Electrocautery Probe, L Tip, 5MM	0250070453-PKG, 5MM X 45CM StrykeProbe Electrosurgical Probe, L-TIP
0250070444-PKG, StrykeFlow Electrocautery Probe, Ball Tip, 5MM	0250070455-PKG, 5MM X 45CM StrykeProbe Electrosurgical Probe, Needle Tip
0250070445-PKG, StrykeFlow Electrocautery Probe, Needle Tip 5MM	0250070446-PKG, StrykeFlow Electrocautery Probe, Spoon Tip, 5MM

The purpose of this notification is to advise you that Stryker Endoscopy is conducting a voluntary recall of the StrykeProbes sheaths listed in Table 1. Attachment A lists all affected sheath lot numbers. The sheaths are also shipped with the part numbers listed in Table 2, and therefore these are also part of the recall. Only the sheath component is affected for the part numbers listed in Table 2. All affected sheaths must be returned to Stryker Endoscopy for replacement.

Reason for the Voluntary Recall:
A complaint was received for a sheath alleging differences in length, caused by manufacturing variation which led to the base of the sheath not being fully seated into the sheath tube.

Risk to Health:
The sheath being too long poses a potential risk for the distal tip of the sheath to melt. If the user does not notice the melting and continues to activate electrocautery, melted portions of the sheath may fall off, compromising the insulation. Compromised insulation leads to the potential risk of unintentional flow of electricity to the patient. While it could not be conclusively confirmed, there have been 36 reports of adverse events or serious injuries with the potential to be attributed to this issue.

Actions to be taken by the Customer/User:

1. Inform individuals within your organization who need to be aware of this device removal.
2. Check all stock areas and/or operating room storage to determine if any devices with the affected **Strykeprobe Sheath** lot numbers from **Attachment A** are at your facility. **RESPONSE REQUIRED BY NOVEMBER 15, 2019**
    a. If you would like a list of all affected probe lot numbers, please email EndoRecall@Stryker.com
3. If affected product is found, segregate the product and call Stryker customer service at 1-800-624-4422 (Option 3) or email endocustomersupport@stryker.com to arrange for product return and issuance of credit or replacement (upon availability).
    a. Remove the affected sheath, quarantine, and discontinue use of the identified non-conforming recalled sheath(s).
    b. When returning units, please enclose Business Reply Form on Attachment B.
4. **If affected product is NOT found:**
    a. Please complete Business Reply Form on Attachment B and return to EndoRecall@Stryker.com

Please forward a copy of this letter to any other personnel within your facility you deem appropriate.

We appreciate your cooperation, and we recognize the inconvenience this may cause your facility. Thank you for your support on this important matter. Please send any questions to EndoRecall@Stryker.com.

[redacted]
Ashley Lower, *Regulatory Compliance Supervisor*

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Attachment A – Recalled Part Numbers and Lots

Catalog# 0250-070-450 - PKG. Sheath, 45CM StrykeProbe

010818-02	010818-05	010818-06	010818-07	010818-08	010818-09	040816-01	040816-02

Catalog# 0250-070-460 - Sheath, StrykeProbe

011819-01	011819-02	011819-03	011819-04	011819-05	011819-06	011819-07	011819-08	011819-09	011819-10
012219-01	012219-02	012219-03	012219-04	012219-05	012219-06	012219-07	012219-08	012219-09	012219-10
012219-11	012219-12	012219-13	012219-14	021018-01	021018-02	021018-03	021018-04	021018-05	021018-06
021018-07	021018-08	021018-09	021018-10	021018-11	021018-12	021018-13	021018-14	021018-15	021018-16
021018-17	021018-18	021018-19	021018-20	022718-01	022718-02	022718-03	022718-04	022718-05	022718-06
022718-07	022718-08	022718-09	022718-10	022718-11	022718-12	022718-13	022718-14	022718-15	022718-16
022718-17	022718-18	022718-19	022718-20	070618-01	070618-02	070618-03	070618-04	070618-05	070618-06
070618-07	070618-08	080818-08	080818-09	080818-10	081518-01	081518-02	081518-03	081518-04	081518-05
081518-06	081518-07	083018-01	083018-02	083018-03	083018-04	083118-02	083118-03	083118-04	083118-05
083118-06	083118-07	083118-08	083118-09	083118-10	091318-01	091318-02	091318-03	091318-04	091318-05
091318-06	091318-07	091318-08	091318-09	091318-10	101018-01	101018-02	101018-03	101018-04	101018-05
101018-06	101018-07	101018-08	101018-09	101018-10	101217-02	110218-01	110218-02	110218-03	110218-04
110218-05	110218-06	110218-07	110218-08	110218-09	110218-10	120617-01	120617-02	120617-03	120617-04

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Attachment B

URGENT MEDICAL DEVICE RECALL
NOTIFICATION ACKNOWLEDGMENT FORM

RESPONSE REQUIRED BY NOVEMBER 15, 2019

<Ship To Customer Name>
<Ship To Address 1>, <Ship To Address 2>
<Ship to City>, <Ship to State>, <Ship to Zip>

Do you have non-conforming units?

☐ No, we have physically checked our inventory and we do not have the affected product(s).

- Return this form to EndoRecall@Stryker.com

☐ Yes, we have the items referenced in the enclosed letter. We will be returning _____ affected unit(s).

- Call Stryker customer service at 1-800-624-4422 (Option 3) or email endocustomersupport@stryker.com to arrange for product return
- Write the **RMA number** on the outside of the box.

Account Number	
Customer Name	
Street Address	
City, State, Zip	
Name	
Title	
Email Address	

_____ _____

Signature Date

By signing this, you are acknowledging you have read and understand the notification from Stryker Endoscopy dated September 25, 2019 stating that they initiated a voluntary Product Recall for the above referenced product.

Return the completed Business Reply Form to Stryker Endoscopy via email (EndoRecall@Stryker.com). Must also include this completed form in box with all returns.