URGENT FIELD SAFETY NOTICE:
RA2019-2187819 – SCOPE EXPANSION
Product: Stryker® STRYKEPROBE SHEATH

ATTN: Operating Room Director, Risk Manager, Materials Manager

December 2019

FSCA identification: Field Safety Corrective Action RA2019-2187819
Action type: Product recall

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 : Recalled Part Numbers and Descriptions that shipped with Recalled Part Numbers (listed above) :	
0250070441	PKG, STRYKEFLOW ELECROCAUTERY PROBE, SPATULA TIP, 5MM
0250070442	PKG, STRYKERFLOW ELECTROCAUTERY PROBE, J TIP, 5MM
0250070443	PKG, STRYKERFLOW ELECTROCAUTERY PROBE, L TIP, 5MM
0250070444	PKG, STRYKERFLOW ELECTROCAUTERY PROBE, BALL TIP, 5MM
0250070445	PKG, STRYKERFLOW ELECTROCAUTERY PROBE, NEEDLE TIP 5MM
0250070446	PKG, STRYKERFLOW ELECTROCAUTERY PROBE, SPOON TIP, 5MM
0250070451	PKG, 5MM X 45CM STRYKEPROBE ELECTROSURGICAL PROBE, SPATULA-TIP
0250070452	PKG, 5MM X 45CM STRYKEPROBE ELECTROSURGICAL PROBE, J-TIP
0250070453	PKG, 5MM X 45CM STRYKEPROBE ELECTROSURGICAL PROBE, L-TIP
0250070455	PKG, STRYKEPROBE ELECTROSURGICAL PROBE, NEEDLE TIP, 5MM X 45CM

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.

The sheath can be sold on its own as listed in Table 1.
The sheath can also be sold together with the electrosurgical probe listed in Table 2.

For the part numbers listed in Table 2 containing a probe and a sheath, ONLY the sheath component is affected and must be returned to Stryker for replacement.
Attachment A lists all affected sheath lot numbers.

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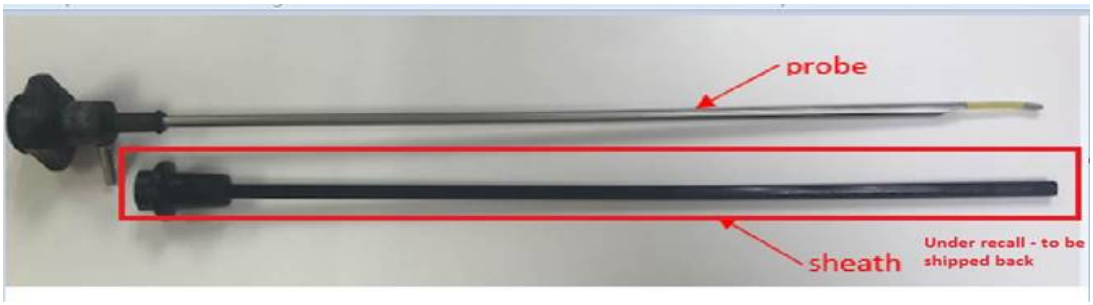
Product Description:



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:

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

We request that you read this notice carefully and complete the following actions:

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.
   Please also make sure to check the devices listed in Table 2 as they may contain affected sheaths.
   a. If you would like a list of all affected probe lot numbers, please email add local contact email adress
3. Maintain awareness of this notice internally until all required actions have been completed within your facility.
4. Inform Stryker if any of the subject devices have been distributed to other organisations.
   a. Please provide contact details so that Stryker can inform the recipients appropriately.
   b. If you are a Distributor, note that you are responsible for notifying your affected customers.

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5. Please inform Stryker of any adverse events concerning the use of the subject devices.
    a. Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.
6. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore please complete even if you no longer have any of the subject devices in your physical inventory.
7. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA
    a. On receipt of the form, a Stryker Representative will contact you to organise any applicable ongoing actions.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Position: email:

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Yours Sincerely,

XXXXXX

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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

***Highlighted lots are impacted by the scope expansion**

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
010318-10	010318-01	010318-03	010318-05	010318-04	010318-02	010318-07	010318-08	010518-05	010318-09
010518-02	010518-09	010518-06	010518-10	010318-06	010518-03	010518-08	010518-01	010518-04	010518-07
120617-05	120617-06	120617-07	120617-08	120617-09	120617-10				

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URGENT FIELD SAFETY NOTICE: RA2019 - 2187819
BUSINESS REPLY FORM

FSCA identifier: RA2019-2187819

Type of action: Field Safety Corrective Action: Recall

Legal Manufacturer: Stryker Endoscopy - 5900 Optical Court, San Jose, CA 95138 USA

Product affected: StrykeProbe Sheaths – Ref: 0250-070-450 and 0250-070-460

I acknowledge receipt of the Field Safety Notice for RA2019-2187819 and can confirm that:

We have not located any of these devices in our inventory: (please delete if not applicable)			
We have located the following devices:			
Catalog number	Description	Lot number	Qty in quarantine
We have further distributed subject devices to the following organizations:			
Facility Name			
Facility Address			
Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE THIS FORM WITHIN 7 CALENDAR DAYS AND RETURN IT BY USING THE EMAIL, XX, OR FAX, XX.

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