URGENT FIELD SAFETY NOTICE: RA2020-2280185

Product: SPY PHI DRAPES

ATTN: Operating Room Director, Risk Manager, Materials Manager

January 2020,

FSCA identification: Field Safety Corrective Action RA2020-2280185
Action type: Product recall

Table 1: Recalled Part Numbers and Descriptions	
HH2020	SPY-PHI Drapes (Pack of 20)
HH2000	SPY-PHI Drape (individual)

Recalled Lot Numbers of Sheaths: See attachment A

The purpose of this notification is to advise you that Stryker Endoscopy is conducting a voluntary recall of the SPY-PHI Drapes.
All units that have a lot listed on Attachment A must be returned to Stryker.
Please note that the SPY-PHI Drapes (HH2000) is a sterile drape pouch that is not sold individually. They are sold as consumables, in a box of 20 individual drapes (HH2020).

Product Description:

HH2020

SPY-PHI Sterile Drape Pack (20 per pack)

HH2000

SPY-PHI Sterile Drape (Individual)

Stryker Endoscopy
5900 Optical Ct, San Jose, California 95138, USA | T: 408-754-2000

Reason for the Voluntary Recall:
Two complaints have been received that the sterile drape pouch was not adequately sealed.

Risk to Health:

The SPY-PHI drape is a sterile product and an incomplete seal on the drape pouch is likely to compromise drape sterility.
When a drape pouch is unsealed, there is a potential hazard of Pathogens/Bacteria on drapes causing a risk of infection to the patient.
To date, there has been no report of an adverse event.

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 SPI PHY Drape lot numbers from Attachment A are at your facility and quarantine all subject devices pending return to Stryker.
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.
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.

Stryker Endoscopy
5900 Optical Ct, San Jose, California 95138, USA | T: 408-754-2000

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

Stryker Endoscopy
5900 Optical Ct, San Jose, California 95138, USA | T: 408-754-2000

Attachment A – Recalled Part Numbers and Lots

Device Description and Part Number: SPY-PHI Drapes (Pack of 20) - HH2020
SPY-PHI Drape (Individual)- HH2000

Impacted Lot Numbers:

1703011	1703261	1704201	1705151	1706091	1707041	1711191	1805251	1808181	1903191	1907221
1703021	1703271	1704211	1705161	1706101	1707051	1711201	1805261	1808201	1903201	1907231
1703031	1703281	1704221	1705171	1706111	1707061	1711211	1805271	1808221	1903211	1907241
1703041	1703291	1704231	1705181	1706121	1707071	1711221	1805281	1808231	1903221	1907251
1703051	1703301	1704241	1705191	1706131	1707081	1711231	1805291	1808241	1903271	1907261
1703061	1703311	1704251	1705201	1706141	1707091	1712021	1805301	1808301	1903281	1907271
1703071	1704011	1704261	1705211	1706151	1707101	1712041	1805311	1808311	1904231	1907311
1703081	1704021	1704271	1705221	1706161	1707111	1712051	1806011	1809011	1904241	1908011
1703091	1704031	1704281	1705231	1706171	1707121	1712061	1806021	1809021	1904251	1908021
1703101	1704041	1704291	1705241	1706181	1707131	1712071	1806041	1809031	1904291	1908031
1703111	1704051	1704301	1705251	1706191	1707141	1712081	1806051	1810041	1905141	1908051
1703121	1704061	1705011	1705261	1706201	1707151	1712091	1806061	1810051	1905151	1908061
1703131	1704071	1705021	1705271	1706211	1707161	1712111	1806071	1810061	1905161	1908071
1703141	1704081	1705031	1705281	1706221	1707171	1712121	1806091	1812051	1905171	1908081
1703151	1704091	1705041	1705291	1706231	1707181	1712131	1806111	1812151	1905211	1908091
1703161	1704101	1705051	1705301	1706241	1707191	1712141	1806201	1902231	1905221	1908151
1703171	1704111	1705061	1705311	1706251	1707201	1712151	1806211	1902241	1905231	
1703181	1704121	1705071	1706011	1706261	1707211	1712161	1807031	1902251	1905241	
1703191	1704131	1705081	1706021	1706271	1707221	1712181	1807061	1902261	1905251	
1703201	1704141	1705091	1706031	1706281	1708221	1712271	1807071	1902271	1906241	
1703211	1704151	1705101	1706041	1706291	1709221	1712281	1807091	1902281	1906251	
1703221	1704161	1705111	1706051	1706301	1710191	1712291	1807251	1903011	1906271	
1703231	1704171	1705121	1706061	1707011	1710201	1712301	1807261	1903021	1906281	
1703241	1704181	1705131	1706071	1707021	1710211	1801031	1807271	1903031	1906291	
1703251	1704191	1705141	1706081	1707031	1710221	1801111	1808171	1903181	1907011	

Stryker Endoscopy
5900 Optical Ct, San Jose, California 95138, USA | T: 408-754-2000

stryker

URGENT FIELD SAFETY NOTICE: RA2020-2280185
BUSINESS REPLY FORM

FSCA identifier: RA2020-2280185

Type of action: Field Safety Corrective Action: Recall

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

Product affected: SPY PHI Drapes

I acknowledge receipt of the Field Safety Notice for RA2020-2280185 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.

Stryker Endoscopy
5900 Optical Ct, San Jose, California 95138, USA | T: 408-754-2000