URGENT FIELD SAFETY NOTICE: RA2020-2276634

Product: Telescopic Smoke Evacuation Pencils

ATTN: Director, Risk Manager, Materials Manager

Date

FSCA identification: Field Safety Corrective Action RA2020-2276634
Action type: Product recall
Catalogue Numbers: SHK-TSP-CL and SHK-TSPL
Product description: Telescopic Smoke Evacuation Pencils
Lot Numbers: See table below

The purpose of this notification is to advise you that Stryker Instruments is voluntarily recalling specific lots of various Smoke Evacuation Pencils.

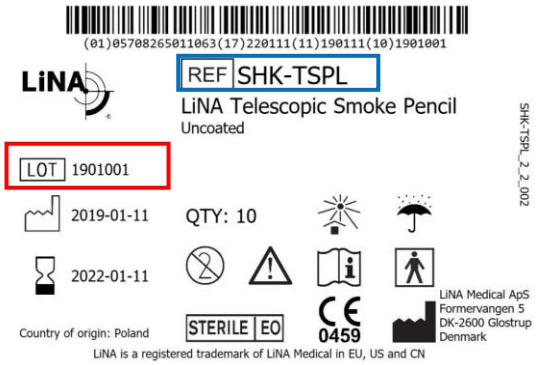
Catalogue Number	Product Description	Affected Lots	Distribution Dates
SHK-TSP-CL	Telescopic Smoke Evac. Pencil, PB, Coated	1923011, 1923050, 1924004, 1924005, 1924015, 1929038, 1929039, 1929055	19-JULY-2019 to 25-SEPTEMBER-2019
SHK-TSPL	Telescopic Uncoated (Push Button)	1922042, 1924003, 1929040, 1929048	23-JULY-2019 To 14-NOVEMBER-2019

Product Description:
Smoke Pencils are designed for general electrosurgical applications and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.

Reason for the Voluntary Recall:
Hairline fractures in a component could allow electrical current to arc out of the Telescopic Smoke Evacuation Pencil.

Risk to Health:
There is a potential for unintended energy delivery resulting in a burn to the patient and/or user.

Location of Product Number (blue) and Lot Number (red) on the labels:



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. Immediately check your internal inventory and quarantine all subject devices pending return to Stryker.
2. Circulate this Field Notice internally to all interested/affected parties.
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. Even if you have distributed all product to another location, please complete a BRF and indicate each location that received product.
    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 FSCA.
    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

CUSTOMER RESPONSE FORM : RA2020-2276634

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I received and understood the Field Safety Notice for RA2020-2276634 have followed the instructions in the Notice.

We have not located any of these devices in our inventory: *(please delete if not applicable)*	

We have located the following devices:		
Catalogue number	Lot Number	Quantity Recalled Product On Hand (Each)

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 Phone No.		E-mail Address	
Date		Contact Signature	

PLEASE COMPLETE AND FAX THIS FORM TO _____
OR EMAIL TO _____