URGENT FIELD SAFETY NOTICE: RA2019-2137735

Product: LINA Smoke Pencils and LINA Telescopic Smoke Pencils

ATTN: Director, Risk Manager, Materials Manager

Date

FSCA identification: Field Safety Corrective Action RA2019-2137735
Action type: Product recall

Catalogue Number	Product Description	Affected Lots
SHK-TSP	Telescopic Uncoated (Push Button)	All lots 1652003-1826901
SHK-TSP-C	Telescopic Smoke Evac. Pencil, PB, Coated	All lots 1652007-1823905
SHK-TSP-CL	Telescopic Smoke Evac. Pencil, PB, Coated	All lots 1643002-1912108 and lot 1912901
SHK-TSPL	Telescopic Uncoated (Push Button)	All lots 1643003-1848027
SHK-VS	Smoke Evac. Pencil non-coated, push button pencil	All lots 1626060-1851902
SHK-VS-C	Smoke Evac. Pencil coated, push button pencil	All lots 1626065-1834900
SHK-VS-CL	Smoke Evac. Pencil coated, push button pencil	All lots 1817036-1906002
SHK-VS-C-NP	Smoke Evac. Pencil, PB, Coated, NO PVC	All lots 1645019-1804053
SHK-VS-C-NPL	Smoke Evac. Pencil, PB, Coated, NO PVC	All lots 1823030-1851014
SHK-VS-C-RS	Smoke Evac. Pencil, RS, Coated	All lots 1726039-1733034
SHK-VS-C-RSL	Smoke Evac. Pencil, RS, Coated	Lot 1821014
SHK-VS-C-SPT	Smoke Evac. Pencil, RS, Coated, NO PVC	All lots 1627011-1810041
SHK-VS-C-SPTL	Smoke Evac. Pencil, RS, Coated, NO PVC	All lots 1824010-1837014
SHK-VSL	Smoke Evac. Pencil non-coated, push button pencil	All lots 1818001-1905044
SHK-VS-NP	Smoke Evac. Pencil, PB, Uncoated, NO PVC	All lots 1646011-1806034
SHK-VS-NPL	Smoke Evac. Pencil, PB, Uncoated, NO PVC	All lots 1823031-1850041
SHK-VS-SPT	Smoke Evac. Pencil, PB, Uncoated, Split Tubing	All lots 1626022-1841905
SHK-VS-SPTL	Smoke Evac. Pencil, PB, Uncoated, Split Tubing	All lots 1817035-1902025

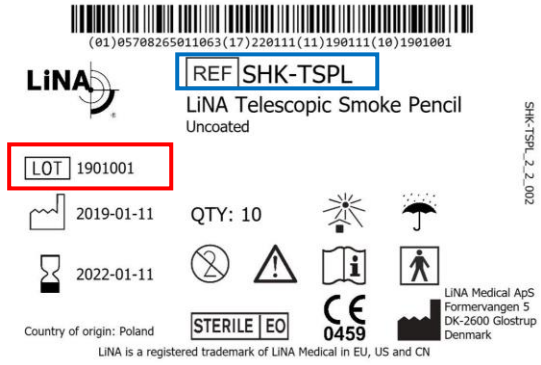
The purpose of this notification is to advise you that Stryker Instruments is voluntarily recalling various Smoke Pencils which were sold and shipped by LINA, prior to Stryker's acquisition of the products.

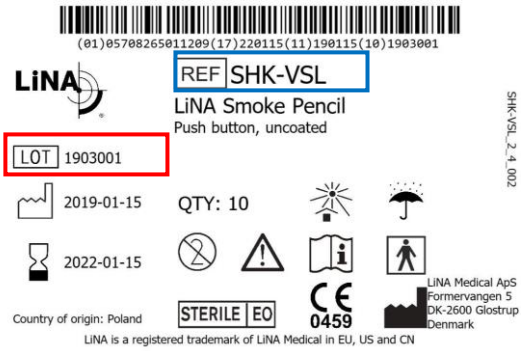
Product Description:
Smoke Pencils are designed for general electrosurgical applications and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output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

Reason for the Voluntary Recall:
There is a potential for the Smoke Pencil to pierce the packaging, creating pinholes resulting in a breach in sterility.

Risk to Health:
Use of a product with a breach in sterility could potentially lead to an infection requiring medical intervention.

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.
   If you have further distributed this product, please forward copies of this Notification to all affected locations, for each location to complete and return. Even if you have distributed all product to another location, please complete a reply form and indicate each location that received product.
   Distributors: If you'd prefer that Stryker notifies your end users, please contact your nominated Stryker Representative (indicated below).
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.
   If the form indicates that recalled product is currently on hand, a Stryker representative will contact you to organize the return of the product. Upon receipt of the recalled product, a replacement product will be provided if it is currently available in your country. Otherwise you will be offered a similar product, if available, or a credit.

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 : RA2019-2137735

LINA Smoke Pencils and LINA Telescopic Smoke Pencils

FSCA identification: Field Safety Corrective Action RA2019-2137735
Action type: Product recall
Catalogue Numbers: See table page 1
Product description: Smoke Evacuation Pencil
Lot Number: See table page 1

I received and understood the Field Safety Notice for RA2019-2137735 and 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 1	
Facility Address 1	
Facility Name 2	
Facility Address 2	

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 _____