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«Hospital_Name»
«Users_Name»
«Department»
«Customer_Address»
«Zip_Code» «City»
«Country_name»

<**Reference: 92970101-FA**> x December 2022

Urgent Field Safety Notice - Urgent Medical Device Recall
ORISE™ Gel Submucosal Lifting Agent

This notification is a follow-up to the previous Product Advisory dated October 10, 2022.

Dear «Users_Name»,

Boston Scientific is conducting a Medical Device Removal of the ORISE Gel Submucosal Lifting Agent.

Boston Scientific became aware that remnant ORISE Gel post-procedure can cause a foreign body reaction, appearing as mass formations and submucosal distortions. The most serious adverse outcome resulting from submucosal distortion and mass formation is unnecessary surgery. The most common adverse outcome associated with submucosal distortion and mass formation is additional surveillance endoscopy, biopsies, further mucosal resections, or additional imaging. Foreign body reaction with granuloma formation, physically appearing as mass formations or submucosal distortions, does not happen at the time of usage of ORISE Gel. There have been no deaths associated with these events.

This information was communicated via a Product Advisory Field Action in October 2022. Since this time, Boston Scientific has become aware of additional events associated with mass formation and submucosal distortion leading to unnecessary medical and surgical intervention. As a result, Boston Scientific now believes the occurrence of these events is potentially higher than anticipated, therefore, this product is being removed from the market globally.

For patients already treated with ORISE Gel, should the user identify submucosal distortions or mass formations in follow-up endoscopy, endoscopic ultrasound, imaging, or surgery, Boston Scientific recommends taking into account prior ORISE Gel use. Review pathology reports from the prior procedure to help determine the most appropriate course of action.

Depending on the pathology present during the initial use of ORISE Gel, and whether it included conditions such as adenoma, high-grade dysplasia, or malignancy, a user may need to do nothing, repeat surveillance, repeat a biopsy, perform further mucosal resection, or plan surgical intervention to rule out any residual lesion.

For each patient treated with ORISE Gel, Boston Scientific recommends appending their medical record with a copy of this letter to maintain awareness of this topic.

Our records indicate that your facility received some of the concerned product. **The table below provides a complete list of all affected products, including Product Description, Material Number (UPN), GTIN, Lot/Batch numbers and expiry date**. Please note that **only the devices listed below are affected. No other Boston Scientific product is involved in this Field Safety Notice**.
Further distribution or use of any remaining product affected by this action should cease immediately.

Product Name	Material Number (UPN)	GTIN	Lot numbers	Expiration Date Range
ORISE™ Gel – Syringe Twin Pack Kit – Box 1	M00519200	08714729974567	All	All
ORISE™ Gel – Syringe Twin Pack – Box 10	M00519201	08714729974574	All	All
ORISE™ Gel – Syringe Twin Pack Kit – Box 1	M00519210	08714729974581	All	All
ORISE™ Gel – Syringe Twin Pack Kit – Box 10	M00519211	08714729974598	All	All
ORISE™ Gel – Syringe Single Pack – Box 1	M00519220	08714729993834	All	All
ORISE™ Gel – Syringe Single Pack – Box 10	M00519221	08714729993841	All	All
ORISE™ Gel –Syringe Single Pack Kit – Box 1	M00519230	08714729993858	All	All
ORISE™ Gel –Syringe Single Pack Kit – Box 10	M00519231	08714729993865	All	All
ORISE™ ProKnife 1.5 mm Electrode - Kit	M00519380	08714729995586	All	All
ORISE™ ProKnife 2.0 mm Electrode - Kit	M00519390	08714729995593	All	All
ORISE™ ProKnife 3.0 mm Electrode - Kit	M00519400	08714729995609	All	All

INSTRUCTIONS:

1- **Please immediately discontinue use of the Boston Scientific product reported in the list and remove all of the affected units from your inventory**, regardless of where these units are stored in your facility. Segregate the units in a secure place, pending return to Boston Scientific.

2- **Please complete the attached Verification Form** even if you do not have any product to return.

3- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of «Customer_Service_Fax_Number» on or before **9 January 2023**.

4- **If you have products to return,** please package them in an appropriate shipping box. **After receipt of the Verification Form, Boston Scientific will contact you to arrange return.**

5- Please pass this notice to any healthcare professional from your organization that needs to be aware and to any organization where the potentially affected devices have been transferred (if appropriate). Please provide Boston Scientific with details of any affected devices that have been transferred to other organizations (if appropriate).

Your Competent Authority is being notified of this Field Safety Notice.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,

Marie Pierre Barlangua
Quality Department
Boston Scientific International S.A.

Attachment: Verification Form

«Sold_to» - «Hospital_Name» - «City» - «Country_Name»

Please Complete the form even if you do not have any affected product & send it to your Local Office:
«Customer_Service_Fax_Number»

Verification Form – Urgent Medical Device Recall
ORISE™ Gel Submucosal Lifting Agent
92970101-FA

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1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated x December 2022.

2. **Boston Scientific records indicate you have received the following affected product** *(additionally please check inventory against complete list of affected product provided)*

Material N° (UPN)	Lot / Batch N° / Serial N°	Customer PO	Qty Sent	Qty to return (Units)

3. We confirm that all areas where affected product could be located have been checked.

4. **TICK ONE OF THESE STATEMENTS***, **SIGN THIS FORM** and send it to «Customer_Service_Fax_Number»

   - ❑ We do not have any affected product.
   - ❑ We have found affected product(s): Please confirm the quantity to return above. *If you are returning product not listed above, please **add the UPN, Lot/Batch/Serial number and the quantity to return.***

TO RETURN PRODUCTS:
1. After receipt of the Verification Form, Boston Scientific will contact you to arrange return.
2. Prepare the package
3. Follow the instructions given by your Local Office about collection of the package

NAME* _____Title _____

Telephone _____ Email _____

Customer' **SIGNATURE*** _____ **DATE*** _____
* Required field dd/mm/yyyy