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«Users_Name»
«Department»
«Customer_Address»
«Zip_Code» «City»
«Country»

<Reference: 92926415-FA> 10 October 2022

Urgent Field Safety Notice – Product Advisory
ORISE™ Gel Submucosal Lifting Agent

Dear «Users_Name»,

This Field Safety Notice (FSN) provides important information regarding updates that will be made to the Instruction for Use (IFU) for ORISE™ Gel Submucosal Lifting Agent.

Boston Scientific recently became aware of events associated with foreign body reaction which presented as mass formations from remnant ORISE Gel post-procedure, prompting unnecessary surgical intervention at a rate of 0.0019% of units sold (based on known events and total sales to date). There have been no reported deaths associated with these events.

The most serious adverse outcome resulting from submucosal distortions and mass formations is unnecessary surgery arising from a lack of awareness of the foreign body reaction that appears as submucosal distortions and mass formations. The most common adverse outcome associated with submucosal distortions and mass formations is additional surveillance endoscopy, biopsies, further mucosal resections, or additional imaging.

Should the user identify submucosal distortions or mass formations in follow-up procedures, it is advised that the user should take into account prior ORISE Gel use and evaluate whether the distortions or mass formations are the result of that prior use. Users should review pathology reports from the prior procedure to 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, mucosal resection, or surgical intervention to rule out any residual lesion.

Affected products/UPNs are listed in the below Affected Product Table.

Product Description	Material # (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

Summary

- Since commercialization of ORISE Gel in 2018, ORISE Gel inflammatory reaction has been a known adverse event that has been identified and included in the IFU.
- As a result of these events, updates will be made to the product IFUs (please see summary of IFU updates in Appendix 1). The purpose of the updates is to (a) raise awareness that remnant ORISE Gel may elicit a foreign body reaction with granuloma and multinucleate giant cells that can physically appear as mass formations and submucosal distortions, (b) provide new warnings and precautions, and (c) reinforce the existing procedural instructions and the need to document the use of ORISE Gel during the procedure.
- **Boston Scientific is not removing any ORISE Gel devices from the field; devices remain available for use.**

Recommendations

While the occurrence of surgical intervention as a result of mass formations and submucosal distortions remains low (0.0019% of units sold), Boston Scientific is making IFU updates to adequately inform the user of the potential outcomes associated with foreign body reaction to remnant ORISE Gel post-procedure. The IFU updates are intended to help reduce unnecessary medical and surgical intervention due to the presentation of submucosal distortions and mass formations.

This Product Advisory contains the recommended IFU updates, which can be found in Appendix 1 and are intended to:

- Raise awareness that remnant ORISE Gel may elicit a foreign body reaction that could physically appear as persistent submucosal distortions or mass formations.
- Add a new Warning to alert the user that failure to recognize submucosal distortions or mass formations elicited by remnant ORISE Gel may lead to unnecessary medical or surgical intervention.
- Reinforce that the ORISE Gel should be injected into the submucosal layer.
- Reinforce the need to document the use of ORISE Gel during the procedure to bring awareness to future healthcare professionals treating the patient.

Instructions:

1- Please read carefully the Field Safety Notice letter and immediately post this information in a visible location near the product to ensure this information is easily accessible to all users of the device.

2- Please complete the attached Acknowledgement Form even if you do not have any affected product.

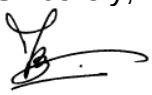
3- When completed, please return the Acknowledgement Form **to your Boston Scientific office** for the attention of «Customer_Service_Fax_Number» **on or before 27 October 2022**.

4- Please pass on this notice to any healthcare professional from your organization that need 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).

Although Boston Scientific is not physically recalling any product, your Competent Authority is being notified of this Field Safety Notice.

Patient safety remains our highest priority and we are committed to transparent communication with our physician customers to ensure you have timely, relevant information for managing your patients. If you have additional questions regarding this information, please contact your local Boston Scientific sales representative.

Sincerely,



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

Attachments: - Appendix 1: IFU updates
- Acknowledgement Form

APPENDIX 1 – Updates to ORISE™ Gel Instructions for Use

Table below provides the updates to the IFU highlighted in blue.

IFU Section	Labeling Updates
Device Description	The ORISE Gel Submucosal Lifting Agent consists of a viscous gel with blue dye in a 10 ml prefilled luer lock syringe. The material is injected into the submucosal layer by means of an 23ga Interject™ Injection Therapy Needle Catheter or ORISE ProKnife Electrosurgical Knife. The gel, when injected into the submucosal layer, creates a cushion in situ that lifts the gastrointestinal mucosa from the muscularis propria, allowing the endoscopist to perform a resection procedure (polypectomy, EMR, or ESD).
User Information	ORISE Gel is for use by or under the supervision of physicians, nurses and technicians trained in endoscopic procedures. A thorough understanding of the technical principles, clinical applications, and risks associated with EMR and monopolar electrocautery is necessary before using this product. The use of ORISE Gel should be documented in procedure reports and communicated to other physicians, including pathologists, involved in the management of the patient. ORISE Gel may appear as amorphous deposits which can resemble mucin upon H&E staining. Remnant ORISE Gel may lead to a foreign body reaction that could physically appear as submucosal distortions, mass formations, or raised lesions upon follow-up. Histologically, this foreign body reaction could appear as granulomas or multinucleated giant cells. In a porcine study, ORISE Gel has not been shown to provide any additional benefit as compared to the use of saline prior to EMR and ESD procedures.
Warnings	The endoscopist using ORISE Gel must be experienced in the administration of submucosal injection fluid.
	Remnant ORISE Gel may elicit a foreign body reaction that could physically appear as persistent submucosal distortions or mass formations, upon follow-up endoscopy or surgery. Failure to recognize submucosal distortions or mass formations elicited by remnant ORISE Gel may lead to unnecessary medical or surgical intervention.

IFU Section	Labeling Updates
Precautions	• ORISE Gel is a single use device provided in a syringe. • ORISE Gel should not be reused after the packaging has been opened. • ORISE Gel syringe contents not injected during the procedure should not be reused in another procedure. • Do not use if the syringe tray is damaged before opening. • Do not use if luer lock on syringe has been damaged. • ORISE Gel should be injected in the submucosal layer.
Adverse Events	• Bleeding • Foreign Body Reaction leading to mass formations or submucosal distortions • Inflammation • Pain • Perforation • Submucosal fibrosis
Procedure	1. Inject ORISE Gel at the desired location in the submucosal layer by depressing the syringe plunger as needed. The amount of gel injected may be determined by the markings on the syringe, which are designated in milliliters (ml). 2. If an additional 10ml syringe of ORISE Gel is needed, disconnect the empty syringe and repeat steps 1-5 to connect another ORISE Gel syringe to the 23ga Interject Injection Therapy Needle Catheter or ORISE ProKnife Electrosurgical Knife. No more than 10 syringes should be administered in a single procedure.

Please complete the form & Send it to:
«Customer_Service_Fax_Number»

«Sold_to» - «Hospital_Name» - «City» - «Country»

Acknowledgement Form – Field Safety Notice

ORISE™ Gel Submucosal Lifting Agent

92926415-FA

By signing this form, I confirm that

I have read and understood
the Boston Scientific Field Safety Notice

dated 10 October 2022 for

ORISE™ Gel Submucosal Lifting Agent

NAME* _____ Title _____

Telephone _____ Email _____

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