



**URGENT MEDICAL DEVICE PRODUCT REMOVAL
IMMEDIATE ACTION REQUIRED
*ORISE™ Gel Submucosal Lifting Agent***

February 22, 2023

Dear Health Care Professional/Risk Manager/Materials Manager:

We would like to bring to your attention information regarding the ORISE Gel Submucosal Lifting Agent as you may have utilized this product or may treat a patient in whom this product has been used. On December 15, 2022, Boston Scientific initiated a Medical Device Product Removal for the ORISE Gel Submucosal Lifting Agent and a recall letter was sent to Risk/Materials Management teams advising them of this removal from the market. Similar information was also shared via a Product Advisory communication in October 2022. We are now broadening our direct communication to additional members of the healthcare community. Due to this, you may receive repetitive field action communications.

Boston Scientific initiated the product removal as there is potential for remnant ORISE Gel post-procedure causing a foreign body reaction, appearing as mass formations and submucosal distortions, which may be interpreted as neoplastic tissue. The most serious adverse outcome resulting from submucosal distortion and mass formation that has been reported to date 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. As of January 30, 2023, there have been a total of 75 reports of foreign body reactions, 30 of which were reports of mass formation/submucosal distortion that led to unnecessary interventions. BSC is not aware of any deaths related to these events. Boston Scientific 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.

Use and distribution of any remaining unused ORISE Gel Submucosal Lifting Agent products affected by this removal must cease immediately.



This removal affects all lot numbers of UPNs listed in Table 1 (below).

Table 1: Affected Products

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

In response to this communication, please do the following:

- **Share this communication with all Endoscopists at your facility.**
- Immediately examine your inventory to identify and segregate affected product. Return product to Boston Scientific in accordance with the enclosed removal instructions. If you are a distributor, this notification must be forwarded to your customers to ensure notification is carried out to the end user level. If you are a facility that has sent products to another hospital or facility within your network, ensure that this notification is forwarded to them.
- No further action is required if you have already provided response to the previous product removal communication.

Your local Sales Representative can answer any questions that you may have regarding this notification.



We appreciate your understanding as we take action to address patient safety and customer satisfaction. We are committed to continuing to offer products that meet the quality standards that you expect from Boston Scientific Corporation.

A handwritten signature in black ink that reads "Tony Carr".

Tony Carr
Vice President, Global Quality

Encl: Removal Instructions
Reply Verification Tracking Form

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to Boston Scientific by calling 1-800-811-3211 and to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

Online: www.fda.gov/MedWatch/report.htm

Regular Mail: use postage-paid FDA form 3500 available at www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, 5600 Fishers Lane, Rockville, MD, 20852-9787

Fax: (800) FDA-0178

Phone: (800) FDA-1088



Removal Instructions

The Reply Verification Tracking Form (RVTF) enclosed with this Removal Notice must be completed and returned even if you do not have any affected units.

1. Immediately discontinue use and segregate affected product.
2. Complete and return the RVTF to get a Return Goods Authorization (RGA) number.
 - Indicate the quantity of SINGLE units you will be returning for credit
 - If you have product that is listed in Table 1 (Affected Products) that is not included on your RVTF, provide the material number, batch number and quantity to return on your RVTF
 - Return the RVTF via:
 - Email: BSCFieldActionCenter@bsci.com
 - or
 - Fax: BSC Field Action Center 1-763-415-7708
3. Once Boston Scientific receives your completed RVTF, you will be contacted within 2 business days and provided an RGA number for product return.
4. Package and ship affected product:
 - Write the RGA number in large print on the enclosed (red/white) return address label
 - Affix the return address label to the outside of box
 - Use our Federal Express account number: 9205-2515-6 to return package via second day delivery
 - Seal box and return to:
 - Boston Scientific Corporation
 - US Distribution Center
 - 500 Commander Shea Blvd
 - Quincy, MA 02171
5. If you have responded to this Removal Notice to anyone other than Boston Scientific, we would not have received your response. Please ensure response is sent to email or fax indicated above.
6. Credit will be issued for all affected product once received and confirmed by Boston Scientific.
7. Reach out to your local Boston Scientific representative with any questions.