

«Hospital_Name»

«Users_Name»

«Department»

«Customer_Address»

«Zip_Code» «City»

«Country»

<**Reference: 92926415-FA**>

10 October 2022

Cover letter for Distributors – Urgent Field Safety Notice ORISE™ Gel Submucosal Lifting Agent

Dear «Users_Name»,

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

You are kindly requested to follow the below instructions:

- 1- Please read this notice and the instructions attached to this Cover letter
- 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 Boston Scientific office** for the attention of «**Customer_Service_Fax_Number**» on or before **27 October 2022**.
- 4- **Please notify all your customers that have received affected product of this notification.** To effectively manage this notification, your accounts are to communicate directly with you, not Boston Scientific. If any of your customers are distributors, please notify them that they must communicate this notification to their own customers.

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

Although Boston Scientific is not physically recalling any product, your Competent Authority is being notified of this Field Safety Notice, unless per local regulation, this task is to be performed by you as a Distributor.

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

Yours sincerely,



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

Attachment: - Acknowledgment Form
- Field Safety Notice

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

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

Distributor's Acknowledgement Form – Field Safety Notice

ORISE™ Gel Submucosal Lifting Agent
92926415-FA

I acknowledge receipt of the Boston Scientific Field Safety

Notice dated 10 October 2022 for

ORISE™ Gel Submucosal Lifting Agent

and will disseminate this information to our customers.

NAME* _____ **Title** _____

Telephone _____ **Email** _____

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