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«Hospital_Name»
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«Customer_Address»
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<Reference: 92825915-FA> 3 March 2022

Urgent Field Safety Notice – Product Advisory
EXALT™ Model D Single-Use Duodenoscope

Subject: Field Safety Notice – Instructions for Use (IFU) Update for EXALT™ Model D Single-Use Duodenoscope, Boston Scientific Field Action Reference 92825915-FA.

Dear «Users_Name»,

Boston Scientific is committed to transparent communication with our physician customers to ensure you have timely, relevant information for managing your patients. This Field Safety Notice (FSN) provides important information regarding updates being made to the Instructions for Use (IFU) for the EXALT™ Model D Single-Use Duodenoscope, as detailed in **Appendix 1**. The affected device information is listed below.

Description	Material Number (UPN)	GTIN Number	Lot/Batch Number	Expiration Date
EXALT Model D Single-Use Duodenoscope	M00542420	08714729983514	All	All
	M00542421	08714729993605	All	All
	M0054242CE0	08714729995746	All	All
	M0054242CE1	08714729995753	All	All

These IFU updates highlight the known risk of perforation and provide best clinical practices related to insertion, advancement, and removal of this device. This information is consistent with standard use of duodenoscopes in endoscopic retrograde cholangiopancreatography (ERCP) procedures.

Boston Scientific is not removing any EXALT™ Model D Single-Use Duodenoscopes from the field; devices remain available for use. There are no changes to the management of patients who have already been treated with EXALT Model D Single-Use Duodenoscopes.

Please distribute a copy of this letter to all physicians and healthcare professionals within your organization who need to be aware of this information.

Description

Although uncommon, perforation, including esophageal perforation, is a known risk for patients undergoing all ERCP procedures, and is a known potential adverse event listed within the current IFU for the EXALT Model D Single-Use Duodenoscope. Since commercial introduction of EXALT Model D, we have received reports of perforation of the esophagus and oropharynx during ERCP procedures from a limited number of facilities, with an occurrence rate of 0.14%.

Boston Scientific conducted a comprehensive investigation of all perforation reports associated with the EXALT Model D Single-Use Duodenoscope. No device malfunctions or patient deaths were identified with any of these events, and it was determined that the EXALT Model D Single-Use Duodenoscope continues to meet design specifications.

EXALT Model D (single use device) has some different characteristics compared to reusable duodenoscopes and opportunities to enhance the IFU have been identified, with the intent of minimizing the occurrence of esophageal perforation and promoting consistent use in all geographies (refer to **Appendix 1**).

After all applicable regulatory approvals are obtained, the updated IFUs will be packaged with EXALT Model D Single-Use Duodenoscopes. An updated IFU will be available at https://www.bostonscientific.com/elabeling in the US.

Clinical Impact

Investigation into this issue has determined that the most common adverse health consequence that is reasonably foreseeable to occur associated with EXALT Model D Single-Use Duodenoscope is perforation of moderate severity managed by either stenting, endoscopic clipping, additional imaging or hospital observation. The most severe adverse health consequence that is reasonably foreseeable to occur associated with EXALT Model D Single-Use Duodenoscope is perforation of severe severity managed by either surgical intervention, intubation or ICU admission. Esophageal perforations do not represent a new harm or higher severity of harm from use of EXALT Model D. The likelihood of encountering an esophageal perforation during use of EXALT Model D is low.

Recommendations

1- Review the content of the IFU updates detailed in **Appendix 1**.

2- Share this information (as appropriate) to provide awareness of this information, particularly with clinicians in your hospital that use the EXALT Model D Single-Use Duodenoscope. Also share this information with any other organization to which these devices may have been transferred.

3- Immediately post this information in a visible location near the product to ensure this information is easily accessible to all users of the device

4- Maintain a copy of this notice in your records.

5- Continue to report all adverse events or quality concerns experienced with use of this device to Boston Scientific (in accordance with all applicable local regulations).

6- Complete the attached Acknowledgement Form and return it **to your local Boston Scientific office** for the attention of «Customer_Service_Fax_Number» **by 25 March 2022**.

Patient safety remains our highest priority. If you have additional questions regarding this information, please contact your local Boston Scientific sales representative.

Sincerely,

Tony Carr
Vice President, Global Quality

Attachments: - Appendix 1: IFU updates
- Acknowledgement Form

APPENDIX 1 – Updates to EXALT™ Model D Single-Use Duodenoscope Instructions for Use

The table below reiterates and provides the updates to the various sections of the IFU for the EXALT Model D Single-Use Duodenoscope. These updates include additional warnings and operational instructions. The updated wording is provided in blue text.

Section	Labeling Updates
Warnings	The Endoscope shaft may feel stiff. Use care during insertion or advancement and move slowly. Do not push through resistance when inserting or advancing the Endoscope, particularly at the upper and lower esophageal sphincters or when the endoscopic view is obstructed. Stop advancing and adjust the position of the Endoscope. Pushing through resistance may cause patient injury such as perforation, bleeding, or tissue damage.
	The articulation section should be controlled solely by the UP/DOWN and LEFT/RIGHT articulation control knobs. Never use force at the distal tip to articulate or straighten this section. Doing so may damage the Endoscope and may cause patient injury such as perforation, bleeding, or tissue damage.
	Articulation control knobs must always be in the neutral position and elevator must be down when inserting the Endoscope into the patient. The articulation control knobs do not naturally return to neutral and must be manually rotated to neutral. Failure to do so may cause patient injury such as perforation, bleeding, or tissue damage.
	During scope removal from the patient, failure to manually return the articulation control knobs to the neutral position or put the elevator in the down position may cause patient injury such as perforation, bleeding, or tissue damage. The articulation control knobs do not naturally return to neutral and must be manually rotated to neutral. If the articulation control knobs cannot be put in the neutral position or the elevator cannot be put in the down position, exercise caution when removing the Endoscope from the patient and do not use excessive force.
Precautions	Use the Endoscope with caution in patients who have surgically altered anatomy for example following a Billroth II reconstruction or with known strictures. These conditions may prevent passage of the scope.

Section	Labeling Updates
Operational Instructions: Preparation and Insertion of the Endoscope	1. Position bite block in patient's mouth.
	2. With the articulation control knobs manually turned to the neutral position and the elevator down, slowly and carefully insert the Endoscope into the patient. Use tactile feedback to detect resistance, particularly at the upper and lower esophageal sphincters or when the endoscopic view is obstructed, adjust the position of the tip of the Endoscope as needed, and advance slowly.
	3. Manipulate the articulation control knobs as necessary under visualization to navigate the Endoscope to the desired location in the digestive tract. Manually return the articulation control knobs toward neutral and keep the tip of the Endoscope midline when navigating past the oropharynx and into the upper esophageal sphincter. Keep the articulation control knobs in neutral position and maintain midline orientation while traversing the esophagus and lower esophageal sphincter. Advancement through the stomach with minimal looping is recommended.
Operational Instructions: Removing the Endoscope from the Patient	1. Release the articulation lock and manually turn the articulation control knobs to the neutral position.
	2. Ensure the elevator is in the down position.
	3. Ensure all accessory devices have been removed from the Endoscope.
	4. Slowly withdraw the Endoscope from the patient while keeping the articulation control knobs in the neutral position.

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

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

Acknowledgement Form – Field Safety Notice

EXALT™ Model D Single-Use Duodenoscope

92825915-FA

By signing this form, I confirm that

I have read and understood
the Boston Scientific Field Safety Notice

dated 3 March 2022 for

EXALT Model D Single-Use Duodenoscope devices.

NAME* _____ Title _____

Telephone _____ Department _____

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