

Urgent Field Safety Notice **Bravo™ Reflux Testing System** **Instructions for Use Outline Important Procedural Steps for Capsule Placement** **Customer Notification**

April 2021

Medtronic Reference: FA956 phase II

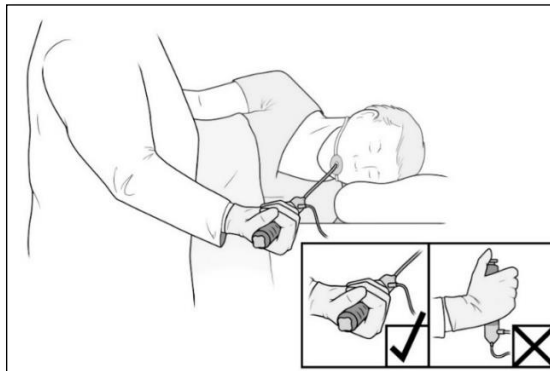
Dear Customer / Risk Manager,

The purpose of this letter is to advise you of an update to our March 2021 communication related to Bravo™ reflux capsule and calibration-free reflux capsules.

As a leading healthcare company, we consider it our responsibility to provide our customers with information related to the safe and effective use of our products. Following our investigation of customer reports of the Bravo™ reflux capsule failing to attach to the esophageal mucosa, we would like to reinforce the information contained in the Bravo™ Reflux Testing System User Guide (DOC-4009-03 December 2019) specific to Placing the Capsule (Section: Performing a Bravo pH Study without (or with) pH Calibration.) In cases where the capsule fails to attach to the esophageal mucosa, the potential exists for aspiration of the capsule resulting in a delay of treatment. Thirteen reports of capsule aspiration have been received in the last 2 years.

Important key elements for clinicians included in the User Guide (pages 25 and 30) include:

- *Carefully advance the delivery device through the mouth (with the capsule facing the patient's tongue) to the desired location in the esophagus.*
Caution - *If lubricants are used to ease placement insertion, **do not cover the suction chamber with lubricant.** This could interfere with the attachment of the capsule.*
- *Holding the delivery device as straight as possible in a relaxed horizontal position, stabilize it by the patient's mouth to make sure that it does not move. See illustration below.*



- *Endoscopically confirm the capsule's attachment.*
Caution - *Avoid contacting the capsule with the endoscope. Contact between the endoscope and capsule may result in the dislodgement of the capsule.*

Please reference and adhere to the instructions for placing the capsule that appear in the User Guides. Following the user guide instructions will reduce the possibility of a procedure in which the capsule does not attach to the esophageal mucosa.

Medtronic has notified the Competent Authority of your country of this action.



If you have any questions regarding this communication, please contact your Medtronic representative.

Thank you for your attention to this notification.

Sincerely,

Medtronic

Acknowledgment and Receipt Form — Response is Required
Bravo™ Reflux Testing System
Instructions for Use Outlines Important Procedural Steps for Capsule Placement

Please complete this form in its entirety.

Date: _____

Name of Person Completing this form: _____

Title: _____

Direct Phone #: _____

Email: _____

Account Name: _____

Account Number: _____

Account Address: _____

City: _____ State: _____ Zip Code: _____

Telephone Number: _____

I have read and understand the instructions provided and acknowledge receipt of the Bravo™ Reflux Testing System Instructions for Use Outlines Important Procedural Steps for Capsule Placement by signing below. I also agree to further distribute and communicate this important information within my facility and to any facility that I have further distributed the Bravo™ Reflux Testing System as required.

Name: (print)

Signature:

Date:

Please fax or this form back to Medtronic within 10 days using the contact details referenced at the top of this form.