Medtronic
60 Middletown Avenue
North Haven, CT 06473
USA
www.medtronic.com

# URGENT: Field Safety Notice

## Bravo® pH Monitoring System

May 16, 2016

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is issuing a safety notification for Given Imaging Bravo® pH monitoring systems. Medtronic has received three reports from customers related to patients having allergic reactions to the nickel content in the stainless steel trocar needle that attaches the Bravo® capsule to the esophageal mucosa. Allergic reactions can include hives, itching or oral numbness. There have been no reports of serious injury related to this safety notice.

Nickel is a common material found in a number of dental and medical devices and can also be found in a variety of household and personal items including kitchen utensils, earrings and jewelry. This Field Safety Corrective Action (FSCA) affects all lots of the item codes listed below.

| Item Code | Product Description |
|---|---|
| FGS-0312 | Bravo® pH capsule delivery device, 5-pack |
| FGS-0313 | Bravo® pH capsule delivery device, 1-pack |

Medtronic is adding the following statement to the Bravo® pH monitoring system User Manual and product package insert so that physicians are aware of the nickel content and the potential of an allergic reaction in a patient with nickel sensitivity.

*The Bravo capsule contains a trocar needle that is made of stainless steel. Use caution in patients with known sensitivities or allergies to the metals that are contained including chromium, nickel, copper, cobalt and iron. The Bravo® pH test lasts from 48-96 hours.*

If you have products affected by this FSCA, please complete the verification form attached and e-mail or fax it to the contact information provided in the attachment. If you have distributed any of the affected devices listed above, please promptly forward the information from this letter to those recipients.

This action is being taken with the knowledge of the [add local Competent Authority]. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Medtronic is committed to providing you with the most up-to-date and relevant information with respect to the use of our products. If you have any questions, please contact your local Medtronic representative at xxx-xxx-xxx.

Sincerely,

David Cannistraci
Vice President, Regulatory Affairs and Quality Assurance
Early Technologies
Minimally Invasive Therapies Group
Medtronic

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# Medical Device Field Safety Notice

## Verification Form—Response is required

### Bravo® pH Monitoring System

**Please complete this form in its entirety.**

Date: _____

Name of Person Completing this form: _____

Title: _____

Direct Phone #: _____

Email: _____

Account Name: _____

Covidien Account Number: _____

Account Address: _____

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I have read and understand the instructions provided and acknowledge receipt of the Medical Device Field Safety Notice regarding the Bravo® pH Monitoring System by signing below.

I also agree to further distribute and communicate this important information within my facility as required.

| Name: (print) | Signature: | Date: |
|---|---|---|

If you have any questions regarding this Medical Device Safety Alert, please contact your local Medtronic representative.

**PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT (Page 2) TO:**

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**Distinguish affected product**


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