



49 Changi South Avenue 2
Singapore 486056
www.medtronic.com

tel 65.6482.0100
fax 65.6482.0300

URGENT Field Safety Notice
Bravo® pH Monitoring System

19th April 2016

Attention: Risk Management Director and O.R. Materials Management
Please forward this communication to all surgeons, surgical personnel and any other potential users of the product.

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 voluntary correction 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.

Actions you should take:

- Complete the attached Acknowledgement form and return it as directed to confirm your receipt and understanding of this information.
- If you are aware of any incidents related to these issues or if you have any questions, please contact our local Medtronic Representative, to provide information regarding those events so regulatory reporting obligations can be fulfilled.

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations. Please communicate this important information within your facility and or other facilities as required.

Thank you for your attention to this notification. We sincerely apologize for any inconvenience this situation may cause you or your facility.

Sincerely,



Gilbert Penaflor
QA Manager, South East Asia
Medtronic

Medtronic

49 Changi South Avenue 2
Singapore 486056
www.medtronic.com

tel 65.6482.0100
fax 65.6482.0300

Field Safety Notice - Bravo® pH monitoring systems

Acknowledgement Form

Customer Contact Details	Medtronic Contact Details
Hospital / HCP:	By E-mail:
Address:	By Post:
Telephone no:	
Fax no:	
E-mail:	

Please tick (either one) only:

☐ No, no affected inventory to be returned.

☐ Yes, affected inventory to be returned (Please fill up the below table if chosen)

Item code	Product Description	Lot number	Expiry Date	QTY (Each)

I have read and understand the instructions provided and acknowledge receipt of the Field Safety Notice regarding the Bravo® pH monitoring systems by signing below. I also agree to further distribute and communicate this important information within my facility as required.

Name: _____ (print) Signature: _____ Date: _____

Distinguish affected product



Given Imaging
3950 Shackleford Road
Duluth, GA 30096 USA
www.givenimaging.com

Bravo® pH capsule
delivery dev, 5-pk

FGS-0312



xxxxxQ

LOT

xxxx-xx/xxxxxQ



xxxx-xx



0123 c us

Rating: — — — 2.7-3.1 V Max 5mA

FCC ID: PHZ-BRAVO100 Rx only

This product is protected under the following US patent:
6,285,897



(01)07290101361695(17)xxxxxx(10)xxxxxQ

Made in Israel

LBL-1112-04