Medtronic

Urgent Field Safety Notice

Bravo™ reflux capsule and calibration-free reflux capsules

Recall

March 2021

Medtronic Reference: FA956

Dear Customer / Risk Manager,

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific production lots of its **Bravo™ reflux capsule and calibration-free reflux capsules.**

Issue Description:

This voluntary recall is being conducted following customer reports of the Bravo™ reflux capsule failing to attach to the esophageal mucosa. In cases where the capsule fails to attach to the esophageal mucosa, the potential exists for aspiration of the capsule. In the event of capsule aspiration, immediate intervention to remove the capsule is required. Potential outcomes following capsule aspiration include low oxygen saturation, intervention to retrieve the capsule, potential need to intubate the patient, extended hospital stay and a delay of treatment. Thirteen reports of capsule aspiration have been received in the last 2 years. Manufacturing process improvements have been implemented to address this issue.
This voluntary recall affects only the item codes and lots listed on Attachment A.

Required Actions:

1. Please immediately quarantine and discontinue use of affected item codes and lots listed on Attachment A.
2. Please return affected product as indicated below. All unused products from the affected item codes and lots must be returned.
3. If you have distributed the Bravo™ capsules listed on Attachment A, please promptly forward the information from this letter to those recipients.
4. Complete the Return Verification Form **even if you do not have inventory**.

	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased **directly** from Medtronic	Please complete the attached Returns Verification Form in its entirety. Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products. You will receive credit for unused device(s) that you return	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to the Medtronic contact provided on the verification form.

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

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic representative.

Sincerely

MEDTRONIC DANMARK A/S

Panu Lauha
Country Director Nordic Countries

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Attachment A

Item Code	Description	Affected Lot Numbers				
FGS-0312 FGS-0313	Bravo™ pH Capsule Delivery Dev 5-PK Bravo™ pH Capsule Delivery Dev 1-PK	49349Q	49801Q	50393Q	50497Q	50871Q
		49350Q	49809Q	50492Q	50615Q	50872Q
		49351Q	49849Q	50493Q	50616Q	50873Q
		49352Q	49850Q	50494Q	50868Q	50875Q
		49799Q	49851Q	50495Q	50869Q	50877Q
		49800Q	50392Q	50496Q	50870Q	
FGS-0635 FGS-0636	Bravo™ CF Capsule Delivery 5-pk Bravo™ CF Capsule Delivery 1-pk	46966F	48438F	49080F	49387F	50374F
		47358F	48439F	49081F	49388F	50375F
		47359F	48440F	49082F	49663F	50376F
		47360F	48441F	49083F	49664F	50377F
		47361F	48442F	49084F	49665F	50378F
		47362F	48443F	49366F	49666F	50379F
		47363F	48444F	49367F	49667F	50380F
		47364F	48445F	49368F	49668F	50489F
		47365F	48446F	49369F	49911F	50490F
		47366F	48447F	49370F	49912F	50595F
		47367F	48448F	49371F	49913F	50596F
		47368F	48449F	49372F	49914F	50597F
		47369F	48781F	49373F	50197F	50598F
		47370F	48782F	49374F	50198F	50599F
		47371F	48783F	49375F	50199F	50600F
		47783F	49068F	49376F	50285F	50601F
		48082F	49069F	49377F	50286F	50602F
		48083F	49070F	49378F	50287F	50603F
		48084F	49071F	49379F	50297F	50604F
		48085F	49072F	49380F	50298F	50606F
		48086F	49073F	49381F	50299F	50607F
		48087F	49074F	49382F	50300F	50848F
		48088F	49075F	49383F	50301F	50849F
		48090F	49076F	49384F	50370F	50850F
		48091F	49077F	49385F	50371F	50853F
		48092F	49078F	49386F	50372F	51188F
		48437F	49079F			

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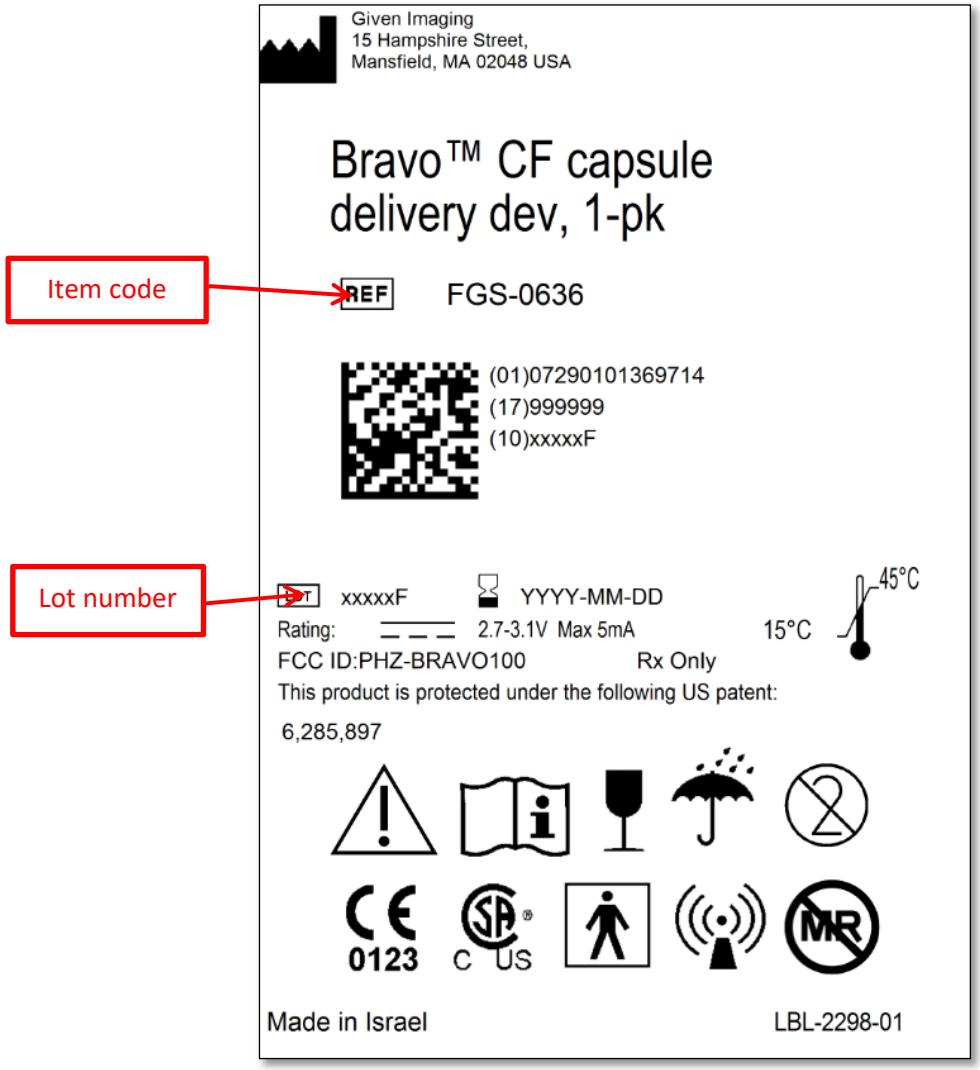
Identifying Affected Product



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RETURN VERIFICATION FORM

FA956: Bravo™ reflux capsule and calibration-free reflux capsules

Please complete this form and return it to Medtronic even if you do not have affected inventory

[Please insert date the form was sent]

Customer Contact Details	**Medtronic Contact Details**
Hospital Name: **Covidien/Medtronic Account Number:**	**To:** [*please insert name*]
Account Address: Street: Postal Code: City: **Department:** Contact Person at Point of Collection: Opening Hours: **Name of person completing this form:**	**Address:** [*please insert Medtronic address*]
Telephone:	**Telephone:** [*please insert Medtronic telephone number*]
Fax:	**Fax:** [*please insert Medtronic fax number]*
E-mail:	**E-mail:** [*please insert contact e-mail address*]

Please list the quantity of affected product at your facility, if you have **no** inventory, please tick the box below.

No Inventory (Please tick): ☐

Item Code	**Invoice or Despatch Note (if available)**	**Lot number**	**Quantity (Eaches or Cases) Please specify**

Information for the courier:

Number of parcels to collect: _____

Number of these parcels that weigh more than 45 KG: _____

By signing this form, I confirm that I have read and understand the communication from Medtronic regarding Bravo™ reflux capsule and calibration-free reflux capsules dated March 2021.

I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of the Bravo™ pH and CF capsules noted in this letter.

_____ _____ _____

Name: (print) Signature: Date:

- Please fax or email this form back to Medtronic within 10 days using the contact details referenced at the top of this form.
- Customer Service will contact you directly to organise return of affected products and credit will be given for returned products.
- Please don't send the goods back before having received the return documentation.