

## Urgent Field Safety Notice

### SmartPill™ SmartBar - Model FGS-0505

Recall

February 2023

Medtronic Reference: FA1313

<For use in countries that follow EU MDR: EU Manufacturer Single Registration Number (SRN): US-MF-000019982>

Dear Risk Manager/Healthcare Professional:

The purpose of this letter is to advise you that Medtronic is initiating a recall of the SmartPill™ SmartBar - model number FGS-0505. This field action only impacts the SmartBar and not other products in the SmartPill™ family.

#### Issue Description:

The SmartPill™ SmartBar - model number FGS-0505 has the potential to be contaminated with tobacco beetles. This contamination may lead to patient nausea, emotional changes, or a delay in the procedure which could lead to a delay in diagnosis.

Through January 25, 2023, Medtronic has received eight complaints related to this issue. No reports of injury have been reported.

There are no additional actions required for patients where a SmartPill™ SmartBar was used during a procedure. These patients should continue to be monitored in accordance with your medical facility's standard care protocols.

#### Product Scope:

Product Names	Model Number	Affected Lot Number	GTIN Number
SmartPill™ SmartBar	FGS-0505	73614B, 74200B, 74800B	04260167482705

#### Actions:

- Immediately identify and quarantine all unused affected SmartPill™ SmartBar, Model FGS-0505 (Refer to Attachment A for identifying affected product).

- Return all unused affected product in your inventory to Medtronic as indicated in the Shipping and Return Instructions below.
- [Please complete the Customer Acknowledgment Form](#) even if you **do not** have unused inventory.
- Pass on to all those who need to be aware within your organization or to any organization where the potentially affected product has been transferred.

## Shipping and Return Instructions:

	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased <b>directly</b> 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.
Purchased from a <b>distributor</b>	Complete <b>all</b> fields on the form and contact your distributor directly to arrange for return of product.	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to your Distributor and to the Medtronic contact provided on the verification form.

## Additional Information:

As indicated in the SmartPill™ Instructions for Use (IFU), an egg-based meal can be substituted for SmartBar. You must have a microwave to prepare this meal. See Ingredients below. Please follow egg-based manufacturer's cooking instructions.

<b>Ingredients</b>	$\frac{1}{2}$ cup (120 g) Egg Beaters®, equivalent to the volume of 2 large egg whites; 60 kcal 2 slices of bread; 120 kcal	1.5 Tbsp. (30 g) strawberry jam; 75 kcal $\frac{1}{2}$ cup (120 ml) water
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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,

[Local / BU Manager](#)

Enclosures:

Attachment A: Product Identification

## Attachment A:

### IDENTIFYING AFFECTED PRODUCT

Locate product information on product labels in your inventory and compare to affected product information below.

SmartPill® SmartBar, 5-pack

REF

FGS-0505

Model Number



GTIN Number

(01)04260167482705(17)999999(10)xxxxxB

LOT xxxxB

Lot Number

YYYY-MM-DD

15°C/59°F  
25°C/77°F  
Storage



Manufactured for: Given Imaging  
15 Hampshire Street,  
Mansfield, MA 02048 USA  
LBL-1703-02