

URGENT FIELD SAFETY NOTICE

FGS-0635 (Bravo™ CF capsule delivery device, 5-pk)

FGS-0636 (Bravo™ CF capsule delivery device, 1-pk)

Recall

August 2026

Medtronic Reference: FA1581

EU Manufacturer Single Registration Number (SRN): US-MF-000019982

Dear Healthcare Professional/ Risk Manager,

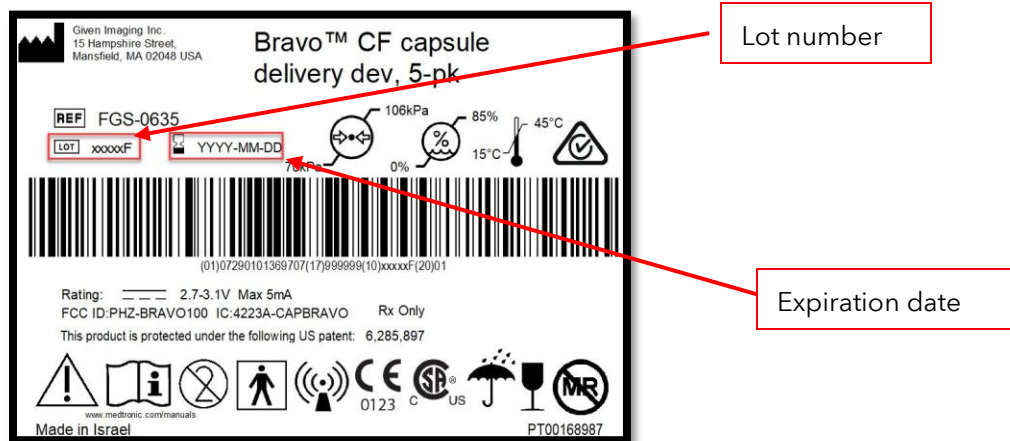
The purpose of this letter is to advise you that Medtronic is recalling specific lots of the Bravo CF capsule delivery device, product codes FGS-0635 and FGS-0636. This recall applies to product with expiration dates prior to and including October 20, 2027 (lot numbers from 64553F up to and including 68912F).

Please note that a subset of these lots was previously included in a recall notification sent to customers and distributors in June 2025. While the issue experienced by customers is the same as that described in the prior recall notification, the underlying cause is different, and this is a separate recall.

Product Scope:

Product Number	Product Names	GTIN	Lot Numbers/Expiration Date
FGS-0635	Bravo CF capsule delivery device, 5-pk	07290101369707 10613994000009	Expiration dates prior to and including October 20, 2027 (lot numbers from 64553F up to and including 68912F)
FGS-0636	Bravo CF capsule delivery device, 1-pk	07290101369714	

The Example Product Label below shows the location of the lot number and expiration date (in red boxes) on the Bravo CF capsule delivery devices.



Example Product Label

Issue Description:

Medtronic has identified an increase in complaints involving the Bravo CF capsule delivery device where the capsule fails to attach to the esophagus or detach from the delivery device. Medtronic's preliminary root cause investigation has identified a potential condition impacting the component that controls the deployment of the capsule, which can then be exacerbated by a failure to keep the delivery device straight as instructed in the User Guide, as a potential cause. Risks associated with this issue include patient aspiration/inhalation, perforation of esophagus, obstruction of the airway, hemorrhage/blood loss/bleeding, laceration of the esophagus, a delay in diagnosis, and foreign bodies remaining in the patient.

From January 1, 2025 – July 7, 2026, Medtronic has received 761 complaints for failure to attach or failure to detach, of which 184 included a patient outcome of serious injury. No deaths have been reported.

Medtronic has implemented corrective actions and lots with an expiration date of December 10, 2027, or later are not in scope of this recall and do not need to be returned.

Customer Actions:

- Immediately identify and quarantine all unused and affected devices described above in the product scope.
- Return all unused, affected product(s) to Medtronic.
- Please complete the enclosed Customer Acknowledgement Form and email to rs.fsnuki@medtronic.com **even if you do not** have unused inventory.
- Pass on this notice to all those who need to be aware within your organization or to any organization where the affected product has been transferred or distributed.
- Please maintain a copy of this communication in your records.

Additional Information:

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

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 Field Representative.

Sincerely,



Jasmine Khor

Regulatory Affairs Specialist - UK and Ireland

Enclosed:

- Customer Acknowledgement Form
- Appendix A: Affected Lot Numbers of FGS-0635
- Appendix B: Affected Lot Numbers of FGS-0636

CUSTOMER ACKNOWLEDGEMENT FORM UK AND IRELAND CUSTOMERS

Please email or fax this form back to Medtronic (even if you do not have affected inventory): rs.fsnuki@medtronic.com

Urgent Field Safety Notice - Recall

FA1581: Bravo Failure to Attach Failure to Detach

Customer Contact Details			
Company name:		Account number (optional):	
Address:		City:	Country:
- I confirm that I have read and understood the Urgent Field Safety Notice - I agree to pass on the Urgent Field Safety Notice to all those who need to be aware within our organization or to any organization where the potentially affected products have been transferred. - I have reviewed our inventory, identified, and quarantined all unused affected products in our inventory, and I declare the following: ☐ No affected products are located at our facility. ☐ Affected products are located at our facility. See below table for details of affected products to be returned to Medtronic.			
Name (print):	Job title:	Date:	Signature:

Please fill-in the section below only if you have affected stock:

Return Details			
Invoice or Delivery Note (if available)	Item Code	Lot # / Serial #	Quantity (please count units inside of the box)
☐ If you have more products to return, tick the box. Please create and send separate attachment with same data.			Total:
Contact Person at Point of Collection:			
Pick-up address / Department (please provide location details. E.g.: collection/accessible area):			
City:			Post code:
Pick-up phone number:		Pick-up email:	
When the product will be ready for pick-up? (Please allow 2 days for handling your request):			
Opening hours of the pick-up location:		Dimension LxWxH (in cm): ... x ... x ...	
# Pallets:	# Parcels:	Number of parcels weighing over 45 kg:	

- 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.
- Please package goods according to packaging instructions that will be provided upon confirmation & remove all labels from the inbound shipment.

Appendix A

FGS-0635 (Bravo CF capsule delivery device, 5-pk) Lot Numbers

68912F	66125F	65917F	65390F	65080F	67112F	68863F	68265F	67839F	67474F	66938F
66657F	66124F	65915F	65391F	65079F	64564F	68864F	68263F	67837F	67196F	67020F
66655F	66123F	65914F	65389F	65077F	64565F	68510F	68264F	67836F	67197F	67019F
66656F	66122F	65913F	65388F	65078F	67111F	68509F	68262F	67835F	67195F	67018F
66654F	66121F	65912F	65386F	65075F	64563F	68508F	68260F	67834F	67194F	66833F
66652F	66119F	65911F	65387F	65076F	67110F	68505F	68261F	67833F	67193F	66832F
66653F	66120F	65910F	65384F	67115F	64562F	68506F	68259F	67831F	67192F	66830F
66430F	66117F	65909F	65385F	64846F	64561F	68507F	68258F	67832F	67190F	66831F
66428F	66118F	65908F	65103F	64845F	67109F	68504F	68256F	67830F	67191F	66828F
66429F	66116F	65680F	65104F	64843F	64560F	68502F	68257F	67829F	67189F	66829F
66427F	66115F	65679F	65101F	64844F	67108F	68503F	68255F	67827F	67188F	66827F
66426F	66114F	65678F	65102F	64842F	64559F	68501F	68253F	67828F	67186F	66825F
66424F	66113F	65677F	65099F	64841F	64558F	68500F	68254F	67826F	67185F	66826F
66422F	66112F	65676F	65100F	67114F	67107F	68499F	68250F	67496F	67184F	66824F
66423F	66111F	65675F	65097F	64839F	64557F	68497F	68251F	67497F	67183F	66823F
66421F	66110F	65674F	65098F	64840F	67106F	68498F	68248F	67495F	67182F	66821F
66419F	66109F	65673F	65096F	64838F	64556F	68495F	68249F	67494F	67181F	66822F
66420F	66108F	65672F	65095F	64836F	64555F	68496F	68247F	67493F	67180F	66819F
66418F	66106F	65670F	65094F	64837F	64554F	68494F	68245F	67491F	67179F	66820F
66417F	66107F	65671F	67117F	64835F	64553F	68492F	68246F	67490F	67177F	
66415F	66104F	65668F	65093F	64834F	68879F	68493F	68243F	67489F	67178F	
66416F	66105F	65669F	65092F	64833F	68878F	68491F	68244F	67488F	67032F	
66414F	66096F	65666F	65091F	64832F	68876F	68489F	67850F	67487F	67030F	
66412F	66097F	65667F	65090F	64830F	68877F	68490F	67849F	67486F	67028F	
66413F	65927F	65664F	65089F	64831F	68874F	68487F	67848F	67485F	67029F	
66411F	65926F	65665F	65088F	64829F	68875F	68488F	67846F	67484F	67026F	
66410F	65925F	65662F	67116F	64828F	68873F	68486F	67847F	67483F	67027F	
66409F	65924F	65663F	65087F	64827F	68871F	68485F	67845F	67482F	67024F	
66407F	65923F	65660F	65086F	67113F	68872F	68484F	67844F	67481F	67025F	
66408F	65921F	65661F	65085F	64826F	68869F	68483F	67842F	67480F	67023F	
66406F	65920F	65395F	65083F	64825F	68868F	68269F	67843F	67478F	67022F	
66405F	65918F	65394F	65084F	64824F	68867F	68268F	67840F	67477F	66940F	
66127F	65919F	65392F	65081F	64567F	68866F	68266F	67841F	67476F	67021F	
66126F	65916F	65393F	65082F	64566F	68865F	68267F	67838F	67475F	66939F	

Appendix B

FGS-0636 (Bravo CF capsule delivery device, 1-pk) Lot Numbers

66426F
66425F
66409F
66096F
65922F
65088F
68252F
67492F
67479F
67198F
67187F
67031F
66819F