Medtronic Ireland Limited
T Block 3090-3094
Lake Drive
Citywest Business Campus
Dublin
DN24 XN47
Ireland
Tel: 01 511 1400
Fax: 01 807 7220
www.medtronic.ie

Urgent Field Safety Notice

Everest™ 30 Disposable Inflation Device, Model Number AC3200

Recall

January 2024

Medtronic Reference: FA1395
EU Manufacturer Single Registration Number (SRN): US-MF-000019977

Dear Healthcare Professional,

The purpose of this letter is to advise you that Medtronic is initiating a recall of specific lot numbers of the Everest™ 30 Disposable Inflation Device (Model # AC3200, lot numbers 60435173 and 60435174). You are receiving this letter as Medtronic records indicate your facility may have received product(s) from at least one of the lot numbers identified as impacted. Medtronic has initiated this field action to prevent the use of potentially affected products. There are no actions required for patients whereby impacted devices have been used previously.

Issue Description:
Since the 17th of July 2023, Medtronic has received four (4) complaints for an Everest™ 30 Disposable Inflation Device exhibiting a detached body cap (handle). In all cases, the detachment was noticed either prior to use or during preparation. No patient harms have been reported from these complaints.

The potential for harm has been assessed for all hazardous situations associated with detachment of the body cap. On completion of the patient impact assessment, it was concluded that this issue is not reasonably expected to result in any patient harm.

Product Scope:

Product Name	Manufacturer's Product Number	UDI	Lot Number
Everest™ 30 Disposable Inflation Device	AC3200	00763000338190	60435173
			60435174

Customer Actions:

- Immediately identify and quarantine unused affected Everest™ 30 Inflation Device 30
- Return all unused affected product in your inventory to Medtronic. Your local Medtronic Representative can assist you with the initiation of the return.
- Please share this notice with all those who need to be aware of this issue within your organization or to any organization where the potentially affected devices have been transferred and maintain a copy of this notice in your records.
- Complete and return the Customer Acknowledgement Form enclosed with this letter, acknowledging that you have received this information.

Additional Information:

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 Sales Representative directly or via Tel no: 01 511 1400

Sincerely,

Keith Taverner
Principal Regulatory Affairs Specialist UK & Ireland

Enclosures:

- Attachment A: Identifying Affected Product
- Attachment B: Customer Acknowledgment Form

Attachment A:

IDENTIFYING AFFECTED PRODUCT

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

Product Name	Manufacturer's Product Number	UDI	Lot Number
Everest™ 30 Disposable Inflation Device	AC3200	00763000338190	60435173
			60435174

Lot Number

UDI Number

Manufacturer's Product Number

Medtronic

CUSTOMER ACKNOWLEDGEMENT FORM

Please email this form back to Medtronic (even if you do not have affected inventory):
rs.regulatoryuk-ire@medtronic.com

Urgent Field Safety Notice - Recall

FA1395: Everest™ 30, AC3200 – Detached Body Cap Issue

Customer Contact Details			
Hospital 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/Communication 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)*
	AC3200	60435173	
	AC3200	60435174	
☐ 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. Eg: 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.