

URGENT FIELD SAFETY NOTICE

Retrieval of a Subset of Non-Implanted OmniaSecure™ MRI SureScan™ Defibrillation Leads for Engineering Evaluation

OmniaSecure™ Model: 3930M

Recall

September 2026

Medtronic Reference: FA00006

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

Dear Healthcare Professional/ Risk Manager,

Medtronic's manufacturing quality processes identified a subset of OmniaSecure™ (Model 3930M) defibrillation leads which may have undergone a specific manufacturing sequence that requires the leads to be retrieved for additional engineering evaluation.

Refer to Attachment A for a detailed list of the identified serial numbers associated with your account. No other products in your inventory are affected or being retrieved for this evaluation. If one of the identified lead(s) is implanted, there is no further action required beyond current standard of care.

Up until 27 August 2026, Medtronic has received five (5) complaints associated with leads that underwent this specific manufacturing sequence. In each complaint, difficulty achieving fixation was reported during the implant procedure; none of the leads were implanted. The potential harm is tissue trauma due to implant difficulty. There have been zero (0) reports of patient harm.

Customer Actions:

Medtronic requests that you take the following actions:

- Identify and quarantine **non-implanted** leads identified in Attachment A.
- Return the **non-implanted** leads to Medtronic.
 - Your Medtronic field representative will assist as needed and will work with you on a replacement solution. If one of the identified lead(s) is implanted, there is no further action required beyond current standard of care.
- Please complete and return the enclosed Customer Acknowledgement Form to rs.fsnuiki@medtronic.com **even if you do not** have unused inventory.
- Please share this notification with others in your organization as appropriate.

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. Medtronic will provide additional information to your account, if appropriate, based on the ongoing engineering evaluation. If you have any questions regarding this communication, please contact your Medtronic representative.

Sincerely,



Jasmine Khor

Regulatory Affairs Specialist - UK and Ireland

Enclosed:

- Attachment A: List of identified Serial Numbers
- Customer Acknowledgement Form

Attachment A - List of identified Serial Numbers

GTIN	Serial #
00763000643430	CDD401008V, CDD401100V, CDD401499V, CDD401655V, CDD401951V, CDD402630V, CDD402652V, CDD402658V, CDD402681V, CDD403969V, CDD403996V, CDD404002V, CDD404005V, CDD404010V, CDD404013V, CDD404049V, CDD404050V, CDD404068V, CDD404095V, CDD404096V, CDD404102V, CDD404103V, CDD404104V, CDD404107V, CDD404164V, CDD404177V, CDD408398V, CDD408399V, CDD408405V, CDD408407V, CDD408411V, CDD408414V, CDD408425V, CDD409092V, CDD409098V, CDD409099V, CDD409132V, CDD409134V, CDD409164V, CDD409168V, CDD409220V, CDD409225V, CDD409226V, CDD409890V, CDD409891V, CDD409892V, CDD409894V, CDD409895V, CDD409896V, CDD409909V, CDD409910V, CDD409914V, CDD409937V, CDD409949V, CDD409950V, CDD409951V, CDD409999V, CDD410008V, CDD410574V, CDD410583V, CDD410597V, CDD410602V, CDD410611V, CDD410613V, CDD410614V, CDD410615V, CDD410616V, CDD410617V, CDD410634V, CDD410635V, CDD410641V, CDD410656V, CDD410748V, CDD410749V, CDD410750V, CDD410752V, CDD410753V, CDD410756V, CDD410757V, CDD410758V, CDD410760V, CDD410761V, CDD410762V, CDD410763V, CDD410766V, CDD410792V, CDD410836V, CDD410848V, CDD410875V, CDD410908V, CDD410938V, CDD410958V, CDD410959V, CDD410982V, CDD410983V, CDD410987V, CDD411000V, CDD411007V, CDD411013V, CDD411014V, CDD411016V, CDD411749V, CDD411760V, CDD411780V, CDD411782V, CDD411795V, CDD411805V, CDD412823V, CDD412825V, CDD412829V, CDD412837V, CDD412838V, CDD412839V, CDD412843V, CDD412847V, CDD412851V, CDD412855V, CDD412860V, CDD412868V, CDD412869V, CDD412871V, CDD412872V, CDD412873V, CDD412874V, CDD412876V, CDD412877V, CDD412882V, CDD412883V, CDD412884V, CDD412885V, CDD412888V, CDD412892V, CDD412893V, CDD412894V, CDD412895V, CDD412896V, CDD412897V, CDD412908V, CDD412923V, CDD412926V, CDD412934V, CDD412940V, CDD412941V, CDD412942V, CDD412943V, CDD412944V, CDD412945V, CDD412946V, CDD412947V, CDD412948V, CDD412949V, CDD412957V, CDD412958V, CDD412962V, CDD412963V, CDD412965V, CDD412966V, CDD412968V, CDD412970V, CDD412971V, CDD412973V, CDD412981V, CDD412982V, CDD412983V, CDD412985V, CDD412987V, CDD412992V, CDD412996V, CDD412998V, CDD413011V, CDD413039V, CDD413040V, CDD413049V, CDD413075V, CDD413076V, CDD413077V, CDD413081V, CDD413083V, CDD413084V, CDD413087V, CDD413088V, CDD413090V, CDD413091V, CDD413100V, CDD413101V, CDD413103V, CDD413104V, CDD413105V, CDD413106V, CDD413141V, CDD413142V, CDD413146V, CDD413148V, CDD413149V, CDD413151V, CDD413152V, CDD413154V, CDD413155V, CDD413156V, CDD413157V, CDD413160V, CDD413163V, CDD413164V, CDD413186V, CDD413187V, CDD413188V, CDD413189V, CDD413190V, CDD413199V, CDD413200V, CDD413224V, CDD413248V, CDD413249V, CDD413253V, CDD413254V, CDD414651V, CDD414654V, CDD414668V, CDD414695V, CDD414703V, CDD414706V

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00763000643461	CDD607300V, CDD607301V, CDD607302V, CDD609286V
00199150001170	CDD607327V, CDD607353V

CUSTOMER ACKNOWLEDGEMENT FORM

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

FA00006: Retrieval Non-Implanted OmniaSecure MRI SureScan Defibrillation Leads for Engineering Evaluation

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.