Medtronic

URGENT FIELD SAFETY NOTICE

Surgipro™, Surgipro II™, Dermalon™, V-Loc™ 90 and 180 Suture Products
Perforation of Suture Breather Pouch

Recall

July 2026

Medtronic Reference: FA1570
EU Manufacturer Single Registration Number (SRN): US-MF-000028763

Dear Risk Manager/ Healthcare Professional,

The purpose of this letter is to advise that Medtronic is initiating a recall for specific lots of the Surgipro™, Surgipro II™, Dermalon™, V-Loc™ 90 and V-Loc™ 180 suture products listed in Attachment A.

Issue Description:

Medtronic identified a manufacturing nonconformance in affected lots through internal inspection that could result in product containing a perforation or tear in the sterile barrier packaging. The affected product's sterile barrier not meeting specifications may result in biocontamination of the sterile sutures. Internal inspections have found a perforation rate of 0.008% on V-Loc ™ 90 and V-Loc™ 180, and 0.264% on Dermalon ™, Surgipro ™ and Surgipro II ™ for the affected product lots.

Variation in manufacturing equipment performance, which contributed to inadequate sterile barrier formation, has been mitigated through additional actions and products currently being distributed are unaffected.

Until June 8, 2026, there have been no customer complaints or patient harm reported in relation to this action.

Risk to health:

While there have been no reports of patient harm in relation to this action, risks of compromised packaging integrity and sterile barrier performance include, but are not limited to, infection, loss of vision if in ophthalmic utilization, or prolonged surgery.

Patient Management:

If products in scope of this field action have been used in patients under your care, please monitor for signs of infection or vision issues due to the possibility of biocontamination.

Customer Actions:

Our records show that your facility has received impacted products. Medtronic requests you take the following actions:

- Immediately identify, cease use, and quarantine all unused impacted product. See Attachment A.
- Return all unused impacted products listed in Attachment A to Medtronic.
- Please complete the enclosed Customer Acknowledgement Form and email to rs.fsnuki@medtronic.com **even if you do not** have unused inventory.
- This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

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- 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:
Attachment A: Affected lots
Customer Acknowledgement Form

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Attachment A: Affected lots

Product Name	Product Description	Model #	Lot #	GTIN
Dermalon™	88861757-31 DERMALON* 4-0 BLU 75CM C13	88861757-31	D6A3020FY	20884521070919
				10884521070912
	88861799-31 DERMALON* 4-0 BLU 75CM C14	88861799-31	D6A2861FY	20884521071060
Surgipro II™	S8698GX SURGIPRO II BL 5/0 18 P-13	S8698GX	D5M3438FY	20612479214716
Surgipro™	SP-623 SURGIPRO* 2-0 BLU 75CM SC2 X36	SP-623	D6A2963Y	20884521037073
V-Loc™ 180	VLOCL0013 V-LOC* 180 4-0 CLR 30CM P12	VLOCL0013	A5M1176VFY	20884521130361
	VLOCL0014 V-LOC* 180 3-0 CLR 30CM P12	VLOCL0014	A6A0972VFY	20884521130378
	VLOCL0023 V-LOC* 180 4-0 CLR 45CM P12	VLOCL0023	A5M1175VFY	20884521130408
	VLOCL0024 V-LOC* 180 3-0 CLR 45CM P12	VLOCL0024	A5M1224VFY	20884521130415
	VLOCL0306 V-LOC 180 DEVICE 0 15CM GS-21	VLOCL0306	A6A0996VY	20884521130941
				10884521130944
	VLOCL0316 V-LOC* 180 0 GRN 30CM GS21X12	VLOCL0316	A5M1060VY	20884521131313
				10884521131316
			A6A0994VY	20884521131313
	VLOCL0345 V-LOC* 180 2-0 GRN 23CM GS21	VLOCL0345	A5M1165VY	20884521131047
	VLOCL0436 V-LOC* 180 0 GRN 60CM GS25X12	VLOCL0436	A5M1036VY	20884521131085
	VLOCL0604 V-LOC* 180 3-0 GRN 15CM V20	VLOCL0604	A5M0869VY	10884521131132
				20884521131139
			A5M1179VY	10884521131132
				20884521131139
			A5M1180VY	20884521131139
			A5M1181VY	10884521131132
				20884521131139
			A5M1182VY	10884521131132
				20884521131139
	VLOCL0615 V-LOC* 180 2-0 GRN 30CM V20	VLOCL0615	A5M1245VY	20884521131160
	VLOCL0625 V-LOC* 180 2-0 GRN 45CM V20	VLOCL0625	A6A1000VY	20884521131238
	VLOCL0644 V-LOC* 180 3-0 GRN 23CM V20	VLOCL0644	A5M1163VY	20884521131269
	VLOCL0804 V-LOC 180 3-0 GRN 15CM CV23	VLOCL0804	A5M1064VY	20884521131283
				10884521131286
			A5M1205VY	20884521131283
				10884521131286
			A6A1004VY	20884521131283

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	VLOCL2105 V-LOC* 180 2-0 GRN 15CM GS22	VLOCL2105	A5M1183VY	20884521131535
			A6A1003VY	20884521131535
				10884521131538
	VLOCL2145 V-LOC* 180 2-0 GRN 23CM GS22	VLOCL2145	A5M1164VY	20884521131542
			A6A1001VY	10884521131545
				20884521131542
	VLOCL2246 VLOC180 0 GRN 9 GS-22	VLOCL2246	A6A0998VY	20884521762494
V-Loc™ 90	VLOCM0003 V-LOC* 90 4-0 CLR 15CM P12X12	VLOCM0003	A5M1022VFY	20884521131603
				10884521131606
			A5M1166VFY	20884521131603
	VLOCM0013 V-LOC* 90 4-0 CLR 30CM P12X12	VLOCM0013	A5M1023VFY	20884521131641
			A5M1024VFY	10884521131644
				20884521131641
	VLOCM0024 V-LOC* 90 3-0 CLR 45CM P12X12	VLOCM0024	A5M0860VFY	10884521131699
				20884521131696
	VLOCM0123 V-LOC* 90 4-0 CLR 45CM P14X12	VLOCM0123	A5M1169VFY	20884521132235
	VLOCM0315 V-LOC* 90 2-0 VIO 30CM GS21	VLOCM0315	A6A1005VY	20884521132464
	VLOC 90 0 VL 22 GS-21	VLOCM0336	A5M0917VY	20884521132501
	VLOC 90 0 VL 22 GS-25 VLOCM0436	VLOCM0436	A5M1035VY	20884521827513
	VLOCM0603 V-LOC* 90 4-0 VIO 15CM V20X12	VLOCM0603	A5M1246VY	20884521132532
				10884521132535
	VLOCM0604 V-LOC* 90 3-0 VIO 15CM V20X12	VLOCM0604	A5M1014VY	20884521132549
			A5M1062VY	10884521132542
				20884521132549
	VLOCM1203 V-LOC* 90 4-0 VIO 15CM CV15	VLOCM1203	A6A1063VY	10884521132757
				20884521132754
	VLOCM2115 V-LOC* 90 2-0 VIO 30CM GS22	VLOCM2115	A5M1155VY	20884521133003

Kit Description	Model #	Lot #	GTIN
BOX ZESTAW DO RYGB	WEJRYGB3	0233547345	00763000975326
BOX LAP HERNIE INGUNIAL RIGHT	BOX00051V4	0233560350	00763000967765
		0233570153	
		0233584284	
		0233606897	

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BOX BYPASS CARDON	BOX01056V2	0233484641	00763000593711
BOX BYPASS DR LAGAE	BOX01482V2	0233607201	00763000457990
BOX GASTRIC BYPASS SIGNIA	BOX02191V11	0233514888	00199150038022
		0233586164	
		0233586169	
		0233587200	
		0234047180	
BOX BEDSIDE STAPLING IS KING	BOX06614V4	0233506453	00199150037902
		0233506454	
		0233506455	
		0233506456	
BOX GASTRICBYPASS KIT V4	BOX06863V4	0233560359	00763000991654
		0234087501	00763000991654
BOX BY PASS FINAL	BOX07405V1	0233617676	00763000960186
BOX GBP SIGNIA	BOX08506V2	0234121845	00199150028627
		0234122488	
		0234122495	
		0234122500	
		0234122505	
		0234122509	
BOX BYPASS KIT NEU BOX 003	BOX08767V1	0233598575	00199150034338
BOX BYPASS KIT DEZEMBER 2025	BOX09222V1	0233577301	00199150066636
BOX GASTRIC BYPASS	JAWBYPASS2	0233608008	00763000931988
		0233608009	
BOX KIT COLON IHS	KIT00625V1	0233646102	00199150033874
BOX KIT HERNIA HIATO IHS	KIT01026V1	0233646101	00199150033867
BOX NEW GBP KIT	PST03130V2	0233628870	00763000911096
BOX GB BOX MET LHOOK	PST04884V3	0233514943	00763000523954
		0234035336	
BOX GB ZONDER ENDOHERNIA EGIA	PST04884V6	0233476937	00763000646820
		0233550564	
		0233609032	
BOX ZESTAW DO BARIATRII GB	UCKGB5	0233600730	00763000910549

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CUSTOMER ACKNOWLEDGEMENT FORM UK AND IRELAND CUSTOMERS

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

Urgent Field Safety Notice - Recall

FA1570: Perforation in Suture Breather Pouch SurgiPro™, Surgipro II™, Dermalon™, V-Loc™ 90 and V-Loc™ 180 Suture Products

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.