

## Urgent Field Safety Notice

### Sterile Barrier Breach of Breather Pouch in Non-Absorbable Sutures

Recall

Product Name	
Monosof™ Monofilament Nylon sutures Monofilament Nylon suture	Sofsilk™ Coated Braided Silk Suture
Surgidac™ Uncoated Braided Polyester suture	Ti-Cron™ Coated Braided Polyester Suture

December 2022

Medtronic Reference: FA1286

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

Dear Risk Manager/Healthcare Professional/Distributor:

The purpose of this letter is to advise you that Medtronic is voluntarily initiating a recall for specific lots of non-absorbable sutures. You are receiving this letter as Medtronic records indicate your facility may have at least one of the potentially affected non-absorbable sutures as listed in Attachment A. Medtronic is initiating this action to prevent the use of potentially affected non-absorbable sutures that may impact patients.

#### Issue Description:

Medtronic has determined manufacturing errors in the packaging of the listed non-absorbable sutures may cause a gap or wrinkle in the breather pouch seal resulting in a sterile barrier breach. The potential harm(s) of a sterile barrier breach include infection or vision loss for ophthalmic procedures in cases where there is direct patient contact.

Through 1 November 2022, Medtronic has received no complaints of packaging integrity defects or reports of serious patient injury related to this issue.

There are no additional patient management recommendations for patients where potentially affected non-absorbable sutures in scope of this recall were used during a procedure. These patients should continue to be monitored in accordance with your medical facility's standard care protocols with consideration to the specific use.

#### Actions:

- Identify and quarantine all unused and non-expired affected non-absorbable sutures as listed in Appendix A.
- Please complete the Customer Acknowledgment Form even if you **do not** have unused inventory.
- Return all unused and non-expired affected product in your inventory to Medtronic as indicated in the Shipping and Return Instructions below.
- Pass on this notice to all those who need to be aware within your organization or to any organization where the potentially affected product has been transferred or distributed.

**Shipping and Return Instructions:**

	<b>Customer with inventory</b>	<b>Customer with zero inventory</b>	<b>Where to send the completed form</b>
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:**

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,

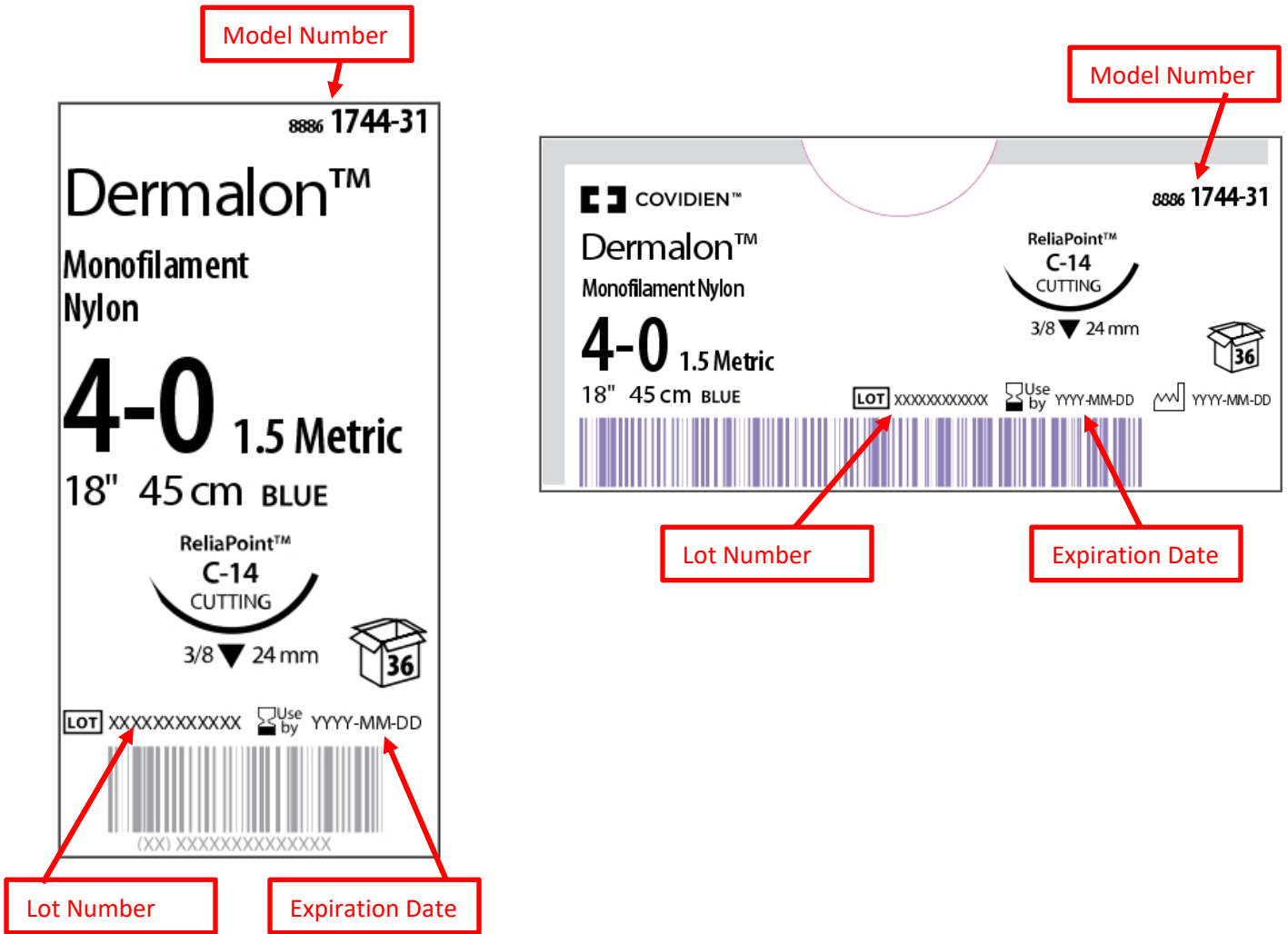
Local / BU Manager

Attachment A:

IDENTIFYING AFFECTED PRODUCT

Locate product information on product labels in your inventory (see example in diagram A) and compare to affected product information in applicable table - organized alphabetically by product name.

Diagram A:



<b>Monosof™ Monofilament Nylon sutures</b> <b>Monofilament Nylon sutures</b> <b>Product Description</b>	<b>Model Number</b>	<b>Lot #</b>
SN-5696 MONOSOF* 6-0 BLK 45CM P13 X36	SN5696	D1M2419FY

<b>Sofsilk™ Coated Braided Silk Suture</b> <b>Product Description</b>	<b>Model Number</b>	<b>Lot #</b>
SS-5641 SOFSILK* 4-0 BLK 45CM P13 X36	SS5641	D2B2181FY
SS-5641G SOFSILK* 4-0 BLK 45CM P13 X12	SS5641G	D1D2533FY

<b>Surgidac™ Uncoated Braided Polyester suture</b> <b>Product Description</b>	<b>Model Number</b>	<b>Lot #</b>
D-1764K SURGIDAC* 5-0 WHI 45CM SS24DA	D1764K	D1M2883Y

<b>Ti-Cron™ Coated Braided Polyester Suture</b> <b>Product Description</b>	<b>Model Number</b>	<b>Lot #</b>
88863035-51 TICRON 2-0 BLU 105CM CV305DA	8886303551	D1L0984Y
88863088-51 TICRON* 2-0 BLU 75CM Y5X36	8886308851	D2B2868Y
88863092-71 TICRON* 1 BLU 75CM KV37X36	8886309271	D2C2450Y

# Medtronic

## CUSTOMER ACKNOWLEDGEMENT FORM

Please email this form back to Medtronic (even if you do not have affected inventory):

[rs.ranordic@medtronic.com](mailto:rs.ranordic@medtronic.com) before **31 March 2023**

### Urgent Field Safety Notice - Recall

#### FA1286: Non-Absorbable Sutures Sterile Barrier Breach

Customer Contact Details			
Company name:		Account number (optional):	
Address:		City:	Country:
<ul style="list-style-type: none"><li>I confirm that I have read and understood the Urgent Field Safety Notice.</li><li>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.</li><li>I have reviewed our inventory, identified, and quarantined all unused affected products in our inventory, and I declare the following: <input type="checkbox"/> No affected products are located at our facility. <input type="checkbox"/> Affected products are located at our facility. See below table for details of affected products to be returned to Medtronic.</li></ul>			
<b>Name (print):</b>	<b>Job title:</b>	<b>Date:</b>	<b>Signature:</b>

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)
<input type="checkbox"/> If you have more products to return, tick the box. Please create and send separate attachment with same data.			<b>Total:</b>
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.