

## **Urgent Field Safety Notice**

**Surgilon™ Braided Nylon Suture**

**Sofsilk™ Braided Silk Suture**

**Monosof™ Monofilament Nylon Sutures**

**Ti-Cron™ Coated Braided Polyester Sutures**

**Steel Monofilament Stainless Steel Sutures**

Recall

January 2024

Medtronic Reference: FA1391

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

Dear Healthcare Professional, Risk Manager,

The purpose of this letter is to advise you of an update to our December 2023 communication related to Medtronic's recall of specific lots Surgilon™ Braided Nylon sutures and Sofsilk™ Braided Silk sutures. Additional lots of Sofsilk™ Braided Silk sutures and specific lots of the Monosof™ Monofilament Nylon Sutures, Ti-Cron™ Coated Braided Polyester Sutures and Steel Monofilament Stainless Steel Sutures have been added to this recall. A comprehensive list of the affected sutures is contained in the Attachment A of this letter.

You are receiving this letter as Medtronic records indicate your facility may have received one of the potentially affected sutures either listed in the initial December 2023 communication or received any of the additional lots listed below in attachment A. The additional models and lots are marked with an asterisk (\*).

Please review the list of affected sutures and complete the customer actions, even if you have previously done so with the prior notification. This letter and confirmation form (January 2024) supersede the December 2023 letter and confirmation form.

Medtronic is initiating this action to prevent the use of potentially affected sutures that may impact patients.

**Issue Description:**

Medtronic determined that specific lots of the Surgilon™ Braided Nylon sutures, Sofsilks™ Braided Silk sutures, Monosof™ Monofilament Nylon Sutures, Ti-Cron™ Coated Braided Polyester Sutures and Steel Monofilament Stainless Steel Sutures were sterilized with gamma doses that exceeded the range approved or were exposed to more than the approved number of Ethylene Oxide- (EO) sterilization cycles. The affected lots were distributed between May 2022 and November 2023. The expected impact on the tensile strength of these sutures will develop overtime throughout their labelled shelf life.

The issue was identified during a recent review of records. Through 10 January 2024, Medtronic has received no complaints or reports of serious patient injury related to this issue.

**Risk to Health:**

The extra gamma levels or additional Ethylene Oxide (EO) cycle have the potential to decrease the strength of these sutures over time which could result in harms such as wound dehiscence, hemorrhage/blood loss/bleeding, tissue breakdown, peritonitis, unspecified infection, malunion of bone (Steel Suture), vision loss (when used in ophthalmic application), and/or prolonged surgery.

**Patient Management Recommendations:**

There are no additional patient management recommendations for patients where potentially affected 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.

**Customer Actions:**

- Identify and quarantine all unused and non-expired affected sutures listed in Attachment A. See Attachment B for guidance on identifying potentially affected devices.
- Return all unused product from the affected lot in your inventory to Medtronic. Please contact your Medtronic Representative for any information regarding Return Good Authorization (RGA).
  - Credit for the returned affected product will be issued based on the RGA number.
  - If purchased from a distributor, contact your distributor directly to arrange for the return of the product back to your distributor.

**Medtronic Limited**

Building 9  
Croxley Park  
Hatters Lane  
Watford, Herts  
WD18 8WW

Tel: 01923 212213

Fax: 01923 241004

[www.medtronic.co.uk](http://www.medtronic.co.uk)

- Please complete and return the enclosed Customer Acknowledgment Form 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 potentially affected sutures have been transferred or distributed.

**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. We regret any inconvenience this may cause. If you have any questions regarding this communication, please contact your Medtronic Sales Representative or via email: [rs.regulatoryuk-ire@medtronic.com](mailto:rs.regulatoryuk-ire@medtronic.com).

Sincerely,

*H. Hussain*

Heidar Hussain

Associate Regulatory Affairs Specialist

Enclosures:

Attachment A: List of Impacted Lot Numbers

Attachment B: Identifying Affected Sutures

Customer Acknowledgment Form

## Attachment A: List of Impacted Lot Numbers

The additional models and lots are marked with an asterisk (\*).

Surgilon™ Braided Nylon suture Product Description	Model Number	GTIN/UDI	Lot Number
88861919-31 SURGILON 4-0 BLK 7X75CMPCT	88861919-31	10884521071728 20884521071725	D1L1929RY
			D2B2243RY
88861919-41 SURGILON 3-0 BLK 7X75CMPCT	88861919-41	10884521071742 20884521071749	D2B0176RY
88861919-51 SURGILON 2-0 BLK 7X75CMPCT	88861919-51	10884521071766 20884521071763  20884521071763	D2D2437RY
			D2E0905RY
			D2E0916RY
88861919-71 SURGILON 1 BLK 7X75CM PCT	88861919-71	20884521071794	D1M0640RY
			D1M1494RY

Sofsilk™ Braided Silk Suture Product Description	Model Number	GTIN/UDI	Lot Number
CS-211 SOFSILK 4-0 BLK 45CM CVF21 X36	CS-211	20884521083629	D1L1576RY
GS-831 SOFSILK 4-0 BLK 75CM V20 X36	GS-831	20884521085203	D2B1216RY
S-176 SOFSILK 0 BLK 12X45CM PCT X24	S-176	20884521085746	D2D0612RY
S-182 SOFSILK 5-0 BLK 12X45CM PCT X36	S-182	20884521085944	D2B0728RY
S-184 SOFSILK 3-0 BLK 12X45CM PCT X36	S-184	20884521085968	D2D0972RY
			D2E2396RY
S-185 SOFSILK 2-0 BLK 12X45CM PCT X36	S-185	20884521085975	D2D0957RY
			D2D0968RY
			D2D0971RY
			D2D0984RY
			D2D0985RY

Sofsilk™ Braided Silk Suture	Model Number	GTIN/UDI	Lot Number
Product Description			
			D2E0900RY
			D2E0902RY
			D2B2878RY*
			D2E2680RY*
			D2E2769RY*
S-245 SOFSILK 2-0 BLK 12X60CM PCT X36	S-245	10884521086197	D2E0674RY
		20884521086194	
		20884521086194	D2D1871RY
			D2E0901RY
S-246 SOFSILK 0 BLK 6X60CM PCT X36	S-246	20884521086200	D2D0980RY
			D2E1488RY*
		10884521086203 20884521086200	D2E1375RY*
S-2782K SOFSILK 4-0 WHI 45CM SS24 DA	S-2782K	20884521086422	D2F2101RY
S-303 SOFSILK 4-0 BLK 12X75CM PCT X36	S-303	20884521086460	D2D1872RY
			D2D2120RY
			D2E1495RY*
			D2E1496RY*
S-304 SOFSILK 3-0 BLK 12X75CM PCT X36	S-304	20884521086477	D2D1991RY
			D2E1472RY*
S-305 SOFSILK 2-0 BLK 12X75CM PCT X36	S-305	20884521086484	D2E0907RY
			D2E2685RY
			D2C1479RY*
			D2E2772RY*
S-316 SOFSILK 0 BLK 12X75CM PCT X24	S-316	20884521086491	D2D2436RY

Sofsilk™ Braided Silk Suture	Model Number	GTIN/UDI	Lot Number
Product Description			
S-317 SOFSILK 1 BLK 12X75CM PCT X24	S-317	20884521086514	D2E0587RY
S-605 SOFSILK 2-0 BLK 2X150CM PCT X36	S-605	20884521086620	D2E0676RY
			D2E1491RY*
S-606 SOFSILK 0 BLK 2X150CM PCT X36	S-606	10884521086630	D2B2638RY
		20884521086637	
		20884521086637	D2D0961RY
S606-12 SOFSILK 0 BLK 2X150CM PCT X12	S606-12	10884521637887	D2D0961RY
S-610 SOFSILK 5 BLK 2X150CM PCT X12	S-610	20884521086675	D2B1535RY
SOFSILK 2-0 30 BK CV-24 GS453-2	GS453-2	20884521758121	D2D0254RY
			D2D1576RY
SOFSLK 4-0 24 BK CV-15 DA VS581-2	VS581-2	20884521757971	D2E1431RY
CS-792 SOFSILK 0 BLK 100CM GCC90 X36	CS-792	20884521084756	D2C0576RY*
S-1172 SOFSILK 6-0 BLK 45CM C1 X36	S-1172	20884521085470	D2J0691RY*
S-1735 SOFSILK 4-0 BLK 30CM C1 DA X12	S-1735	20884521085630	D1L3318FRY*
S-1750K SOFSILK 6-0 BLK 45CM HE1 DAX12	S-1750K	20884521085739	D2E2348RY*
S-1768K SOFSILK 7-0 BLK 45CM HE6 DAX12	S-1768K	20884521085784	D2B2217RY*
S-1789K SOFSILK 4-0 BLK 45CM HE3 X12	S-1789K	20884521085876	D2D0262RY*
S-187 SOFSILK 1 BLK 6X45CM PCT X36	S-187	20884521085982	D2A1585RY*
S-243 SOFSILK 4-0 BLK 12X60CM PCT X36	S-243	20884521086170	D1M1020RY*
			D2D2348RY*
			D2E1492RY*
S-2780K SOFSILK 6-0 BLK 45CM SS-24DA	S-2780K	20884521086408	D2C1916RY*
S-282 SOFSILK 5 BLK 3X60CM PCT X36	S-282	20884521086453	D2E1470RY*

<b>Sof silk™ Braided Silk Suture</b>	<b>Model Number</b>	<b>GTIN/UDI</b>	<b>Lot Number</b>
<b>Product Description</b>			
S-318 SOFSILK 2 BLK 12X75CM PCT X24	S-318	20884521086538	D1M0153RY* D2A1677RY*
S-608 SOFSILK 2 BLK 2X150CM PCT X36	S-608	20884521086668	D1M0173RY* D1M0635RY* D2E1210RY*
SOFSILK 3-0 30 BK CV-23 VS872-2	VS872-2	20884521758060	D2B1783RY*
SS-1694G SOFSILK 4/0 BLK 45CM P24 X12	SS-1694G	20884521176406	D1M0141FRY*
SS-5641 SOFSILK 4-0 BLK 45CM P13 X36	SS-5641	20884521086774	D2B2181FRY*
SS-5649G SOFSILK 6-0 BLK 45CM P13 X12	SS-5649G	20884521086804	D2C1987FRY*
SS-645 SOFSILK 4-0 BLK 75CM C12 X36	SS-645	20884521087580	D1M2531FRY*
SS-675 SOFSILK 3-0 BLK 75CM C16 X36	SS-675	20884521087726	D1K1916FRY*
SS-681 SOFSILK 6-0 BLK 45CM C12 X36	SS-681	20884521087924	D2G0795FRY*
VS-872 SOFSILK 3-0 BLK 75CM CV23 X36	VS-872	20884521090184	D1M1837RY*
XX-5280 SOFSILK 0 BLK 150CM PCT X36	XX-5280	20884521106045	D2E1482RY*

<b>Ti-Cron™ Coated Braided Polyester Sutures*</b>	<b>Model Number</b>	<b>GTIN/UDI</b>	<b>Lot Number</b>
<b>Product Description</b>			
3087-31 TICRON 4-0 BLU 75CM CV-331DA	3087-31	10884521632271	D1M2840RY*
3226-31 TICRON 4-0 BLU 60CM CV330 DA	3226-31	10884521632547	D2G1007RY*

88863026-71 TICRON 1 BLU 75CM HOS12X36	88863026-71	20884521059129	D2C1802RY*
88863070-51 TICRON 2-0 BLU 75CM C15X36	88863070-51	20884521059570	D2C3250FRY*
88863087-31 TICRON 4-0 BLU 75CM CV33DA	88863087-31	10884521059832 20884521059839	D1M2840RY*
88863092-71 TICRON 1 BLU 75CM KV37X36	88863092-71	20884521059990	D2C2450RY*
88863147-83 TICRON 2 BLU 5X75CM KV37X12	88863147-83	10884521060340	D1K0110RY*
88863185-41 TICRON 3-0 BLU 75CM CV305	88863185-41	20884521061191	D2C0774RY*
88863186-31 TICRON 4-0 BLU 75CM CV331	88863186-31	10884521061279 20884521061276	D2G1004RY*
88863226-31 TICRON 4-0 BLU 60CM CV330DA	88863226-31	20884521061634	D2G1007RY*
88863226-41 TICRON 3-0 BLU 60CM CV330DA	88863226-41	20884521061641	D2A0451RY*
88863229-31 TICRON 4-0 BLU 75CM CV307DA	88863229-31	20884521061689	D2G1307RY*
88863271-31 TICRON 4-0 BLU 90CM CV331DA	88863271-31	10884521062177 20884521062174	D2F2152RY*
88863309-71 TICRON 1 BLU 75CM GS11X36	88863309-71	20884521062488	D2D2188RY*

<b>Monosof™ Monofilament Nylon Sutures*</b> Product Description	<b>Model Number</b>	<b>GTIN/UDI</b>	<b>Lot Number</b>
N-63 MONOSOF 3-0 BLK 12X45CM PCT X36	N-63	20884521076607	D2A0862RY*
SN-3695 MONOSOF 5-0 BLK 45CM P10 X12	SN-3695	20884521077994	D2C1333FRY*
			D2H1541FRY*

## Medtronic Limited

Building 9  
Croxley Park  
Hatters Lane  
Watford, Herts  
WD18 8WW

Tel: 01923 212213

Fax: 01923 241004

[www.medtronic.co.uk](http://www.medtronic.co.uk)

<b>Steel Monofilament Stainless Steel Sutures*</b> <b>Product Description</b>	<b>Model Number</b>	<b>GTIN/UDI</b>	<b>Lot Number</b>
88862224-49 STEEL 7 4X45CM SCC X12	88862224-49	20884521 102351	D3B1366RY*

**Attachment B:**

**IDENTIFYING AFFECTED PRODUCT**

**Locate product information on product labels in your inventory.**

8886 1919-31

**Surgilon™**  
Braided  
Nylon

**4-0** 1.5 Metric  
7x30" 75 cm BLACK

Pre-Cut  
pré-coupé  
zugeschnitten  
pre-tagliato  
precortado  
pré-corte

36

LOT XXXXXXXXXXXX Use by YYYY-MM-DD

(XX) XXXXXXXXXXXXXXXXXXXX

**S-246** → **Model Number**

**Sofsilk™**  
Wax Coated  
Braided Silk

**0 3.5 Metric**  
6x24" 60 cm BLACK

Pre-Cut  
pré-coupé  
zugeschnitten  
pre-tagliato  
precortado  
pré-corte

36

LOT XXXXXXXXXXXX Use by YYYY-MM-DD

→ **Lot Number**

(XX) XXXXXXXXXXXXXXXX

## Medtronic Limited

Building 9  
Croxley Park  
Hatters Lane  
Watford, Herts  
WD18 8WW

Tel: 01923 212213

Fax: 01923 241004

[www.medtronic.co.uk](http://www.medtronic.co.uk)

The diagram shows a rectangular label for a Monosof suture package. At the top right corner, the text "N-63" is printed. Below this, the brand name "Monosof™" is prominently displayed, followed by "Monofilament Nylon". The suture size "3-0" is shown in a large font, with "2 Metric" to its right. Below the size, the dimensions and color are listed as "12x18" 45 cm BLACK". A central box contains the text "Pre-Cut" followed by translations in French, German, Italian, and Spanish. To the right of this box is a small icon of a box with the number "36" inside. At the bottom left, there is a "LOT" field with a barcode and a "Use by" field with a date format "YYYY-MM-DD". Two blue arrows originate from the label: one points from the "N-63" text to a box labeled "Model Number", and the other points from the barcode area to a box labeled "Lot Number".

N-63

Monosof™  
Monofilament  
Nylon

**3-0** 2 Metric  
12x18" 45 cm BLACK

Pre-Cut  
pré-coupé  
zugeschnitten  
pre-tagliato  
precortado  
pré-corte

36

LOT:XXXXXXXXXXXX Use by YYYY-MM-DD

(XX)XXXXXXXXXXXX

Model Number

Lot Number

8886 **3309-71**

**Ti-Cron™**  
Coated Braided Polyester

**1** 4 Metric  
30" 75 cm BLUE

GS-11 CUTTING  
1/2 ▼ 37 mm

LOT-XXXXXXXXXX Use by YYYY-MM-DD

Model Number

Lot Number

COVIDIEN™

**Steel**  
Monofilament Stainless Steel

8886 **2224-49**  
MP 4 x 4

7 9 Metric 18 B&S  
4x18" 45 cm

SCC CONV. CUTTING  
1/2 ▲ 48 mm

STERILE R Single use Rx ONLY

Monofilament Stainless Steel 316L Nonabsorbable Suture  
Suture non résorbable monofilament en acier inoxydable 316L  
Monofilament nicht-resorbierbares Nahtmaterial aus Edelstahl, 316L  
Sutura non riassorbibile in acciaio inossidabile monofilamento 316L  
Sutura irabsorbível de aço inoxidável 316L monofilamento  
Sutura não Absorvível 316L de Aço Inoxidável Não Filamentoso

Caution, consult accompanying documents

CE 0123

LOT XXXXXXXXXXXX Use by YYYY-MM-DD

Model Number

Lot Number

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Hatters Lane  
Watford, Herts  
WD18 8WW

Tel: 01923 212213

Fax: 01923 241004

[www.medtronic.co.uk](http://www.medtronic.co.uk)

**Lot Number**