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Urgent Field Safety Notice

Sterile Barrier Breach of Breather Pouch in Non-Absorbable Sutures

Recall

Product Name	
Dermalon™ Monofilament Nylon sutures	Monosof™ Monofilament Nylon sutures Monofilament Nylon suture
Novafil™ Monofilament Polybutester Suture	Sofsilk™ Coated Braided Silk Suture
Surgilon™ Braided Nylon suture	Surgidac™ Uncoated Braided Polyester suture
Surgipro™ Monofilament Polypropylene Sutures	Surgipro™ II Monofilament Polypropylene Sutures
Ti-Cron™ Coated Braided Polyester Suture	Custom Suture Packs

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:

	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased directly 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 distributor	Complete all 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 Field Representative directly or via Tel. No: 01 511 1400

Sincerely,

A handwritten signature in black ink, appearing to read 'Bethany Moxon', with a stylized flourish at the end.

Bethany Moxon

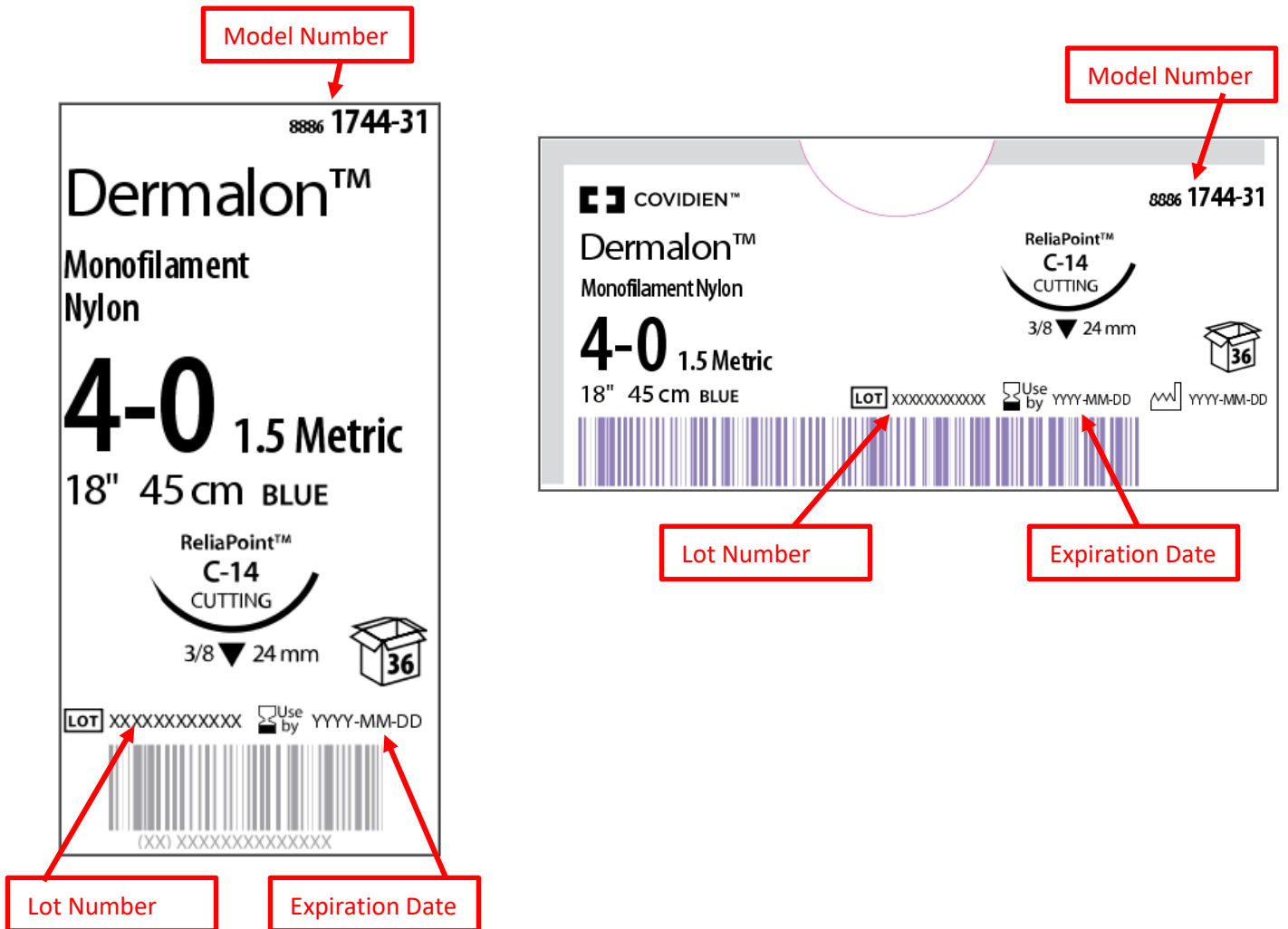
Associate Regulatory Affairs Specialist - UK and Ireland

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:



Custom Suture Pack Product Description	Model Number	Lot #
US1638 CUSTOM SUTURE PACK	US1638	A1K0289Y
US1638 CUSTOM SUTURE PACK	US1638	A1K0291Y
US1756 CUSTOM SUTURE PACK	US1756	A2E0454Y
US1638 CUSTOM SUTURE PACK	US1638	A1K0283Y

Dermalon™ Monofilament Nylon sutures Product Description	Model Number	Lot #
88861741-11 DERMALON* 6-0 BLU 45CM C1	8886174111	D2B0701Y D2E3000Y
88861747-11 DERMALON* 6-0 BLU 45CM C12	8886174711	D1M2315FY D1M2326FY D2F1873FY
88861749-24 DERMALON* 5-0 BLU 45CM P13	8886174924	D2B2781FY
88861756-11 DERMALON* 6-0 BLU 45CM C13	8886175611	D2B1309FY
88861757-41 DERMALON* 3-0 BLU 75CM C13	8886175741	D1J0777FY

Monosof™ Monofilament Nylon sutures Monofilament Nylon sutures Product Description	Model Number	Lot #
CN-724 MONOSOF* 1 BLK 100CM GS25 X36	CN724	D1B2528Y
CN-791 MONOSOF* 2-0 BLK 100CM GCC90X36	CN791	D1L1776Y
CN791-12 MONOSOF* 2-0 BLK 100CM GCC90	CN79112	D1L1776Y
CN-793 MONOSOF* 1 BLK 100CM GCC90 X36	CN793	D1D2772Y
CN-793 MONOSOF* 1 BLK 100CM GCC90 X36	CN793	D2B2754Y
CN793-12 MONOSOF* 1 BLK 100CM GCC90X12	CN79312	D1D2772Y
CN-830-L MONOSOF* 1 BLK 150CM LP GS25	CN830L	D1D2705Y
SUT GNJ-283 MONOSOF 2/0 BLK ST DA 90CM	GNJ283	D1E0555Y D1E0750Y D2D1396Y
N-2781K MONOSOF* 5-0 BLK 45CM SS24 DAX12	N2781K	D1L2330Y
SUT N-59 MONOSOF 2-0 BLK 6X45CM PCT	N59	D2D2350Y
SN-1647 MONOSOF* 7-0 BLK 45CM P16 X36	SN1647	D2E2028FY
SN-1647G MONOSOF* 7-0 BLK 45CM P16 X12	SN1647G	D2B2227FY
SN-247 MONOSOF* 3-0 BLK 90CM C23 X36	SN247	D1D3222FY D2B0043FY
SN-3686 MONOSOF* 7-0 BLK 45CM P10 X12	SN3686	D2E2761FY D2F0402FY
SN-3695 MONOSOF* 5-0 BLK 45CM P10 X12	SN3695	D1G0954FY D1L0957FY D2C1333FY D2E2762FY
SN-3697 MONOSOF* 6-0 BLK 45CM P10 X12	SN3697	D1L1710FY D2C1211FY
SN-3965 MONOSOF* 5-0 BLK 45CM PC11 X12	SN3965	D1E1222Y
SN-5660G MONOSOF* 6-0 BLK 45CM P24 X12	SN5660G	D1L0922FY
SN-5665G MONOSOF* 6-0 BLK 45CM P12 X12	SN5665G	D1L0774FY
SN-5690G MONOSOF* 5-0 CLR 45CM P13 X12	SN5690G	D1M1283FY
SN-5691 MONOSOF* 4-0 CLR 45CM P13 X36	SN5691	D2D0703FY
SN-5694 MONOSOF* 4-0 BLK 45CM P11 X36	SN5694	D1J1230FY
SN-5696 MONOSOF* 6-0 BLK 45CM P13 X36	SN5696	D1M2419FY
SN-5697 MONOSOF* 6-0 BLK 45CM P10 X36	SN5697	D2F0399FY
SN-5767G MONOSOF* 6-0 BLK 45CM P11 X12	SN5767G	D2A0554FY
SN-630 MONOSOF* 4-0 BLK 75CM C22 X36	SN630	D1M1286FY
SN-643 MONOSOF* 5-0 BLK 75CM C13 X36	SN643	D2B0369FY
SN-667G MONOSOF* 6-0 BLK 45CM C1 X12	SN667G	D1L2502FY
SN-694 MONOSOF* 2-0 BLK 90CM C18 X36	SN694	D2C0324FY
SN-871 MONOSOF* 5-0 BLK 45CM C1 X36	SN871	D1K3362FY
SN-872 MONOSOF* 4-0 BLK 45CM C1 X36	SN872	D1K2654FY D1M2450FY
S661GX 5-0 NYLON 18 DS18	S661GX	D1L0912FY
S697GX 6-0 NYLON 18 DSM11	S697GX	D1M2377FY D1M2847FY
S913BX 5-0 NYLON 10 DS12	S913BX	D2D1386FY

Monosof™ Monofilament Nylon sutures Monofilament Nylon sutures Product Description	Model Number	Lot #
S931BX 4-0 NYLON 10 DS12	S931BX	D2B0756FY

Novafil™ Monofilament Polybutester Suture Product Description	Model Number	Lot #		
8886 4002-41 NOVAFIL 3-0 BLU 90CM C14	8886400241	D1G1762FY		
8886 4400-13 NOVAFIL 6-0 BLU 45CM SBE2	8886440013	D2A0461Y		
8886 4400-23 NOVAFIL 5-0 BLU 45CM SBE2	8886440023	D1M0797Y		
8886 440123 NOVAFIL 5-0 BLU 45CM SBE3	8886440123	D1L3389Y		
8886 4402-33 NOVAFIL 4-0 BLU 45CM SBE4	8886440233	D2A0529Y		
8886 4403-33 NOVAFIL 4-0 BLU 45CM SBE6	8886440333	D2C0582Y		
8886 4410-13 NOVAFIL 6-0 BLU 45CM P10	8886441003	D1M1007FY D1M2364FY		
	8886441013	D1M1007FY D1M2364FY		
8886 4410-03 NOVAFIL 7-0 BLU 45CM P10	8886441003	D1M0369FY D1M0796FY		
8886 4422-43 NOVAFIL 3-0 BLU 45CM C14	8886442243	D1D2485FY		
8886 4424-51 NOVAFIL 2-0 BLU 75CM C16	8886442451	D1E1240FY		
8886 4450-41 NOVAFIL 3-0 BLU 75CM V26	8886445041	D2B2109Y		
8886 4452-51 NOVAFIL 2-0 BLU 75CM V20	8886445251	D1D0295Y D1E0843Y		
		8886445961	D1D0529Y	
8886 4470-81 NOVAFIL* 2 BLU 150CM GS26	8886447081	D1D3190Y		
8886 4582-53 NOVAFIL* 2-0 BLU 75CM P14	8886458253	D2B1686FY		
SPB-1213G NOVAFIL* 6-0 BLU 45CM P13X12	SPB1213G	D1L0169FY D2B0773FY D2C0769FY		
		SPB-1233G NOVAFIL* 4-0 BLU 45CM P13X12	SPB1233G	D2E0961FY
		SPB-1623G NOVAFIL* 5-0 BLU 45CM P12X12	SPB1623G	D1D2709FY
SPB-5142G NOVAFIL* 5-0 BLU 45CM P11X12	SPB5142G	D1B2811FY		
SPB-5143G NOVAFIL* 4-0 BLU 45CM P11X12	SPB5143G	D1D2674FY		
SUT SPB-5223G NOVAFIL 5-0 BLU 45CM P13	SPB5223G	D1M1024FY		
SPB-5433G NOVAFIL* 4-0 CLR 45CM P24X12	SPB5433G	D2C1970FY		
SPB-5633G NOVAFIL* 4-0 BLU 45CM P12X12	SPB5633G	D2A0500FY		

Sofsilk™ Coated Braided Silk Suture Product Description	Model Number	Lot #		
CS-211 SOFSILK* 4-0 BLK 45CM CVF21 X36	CS211	D1L1576Y D2B0747Y		
		CS-490 SOFSILK* 2-0 BLK 75CM GS11 X36	CS490	D2C2519Y
CS-562 SOFSILK* 2-0 BLK 75CM GS23 X36	CS562	D1G1928Y		
GS-823 SOFSILK* 2-0 BLK 75CM V30 X36	GS823	D1K1923Y D2D1396Y		
		GS-835 SOFSILK* 1 BLK 75CM V20 X36	GS835	D1E1757Y
S-1172 SOFSILK* 6-0 BLK 45CM C1 X36	S1172	D2C2304Y		
S-1173 SOFSILK* 5-0 BLK 45CM C1 X36	S1173	D2C2305Y D2E1385Y		
		S-1174 SOFSILK* 4-0 BLK 45CM C1 X36	S1174	D1M1794FY D1M2954FY D1M2984FY
S-1750K SOFSILK* 6-0 BLK 45CM HE1 DAX12	S1750K			D2E2348Y
S-176 SOFSILK* 0 BLK 12X45CM PCT X24	S176			D2B1886Y
S-176 SOFSILK* 0 BLK 12X45CM PCT X24	S176	D2C1977Y		
S-1768K SOFSILK* 7-0 BLK 45CM HE6 DAX12	S1768K	D1M1759Y D2B2217Y		
		S-182 SOFSILK* 5-0 BLK 12X45CM PCT X36	S182	D1L1613Y D2B0177Y

Sofsilk™ Coated Braided Silk Suture Product Description	Model Number	Lot #
S-183 SOFSILK* 4-0 BLK 12X45CM PCT X36	S183	D1M1421Y D2E1280Y
S-184 SOFSILK* 3-0 BLK 12X45CM PCT X36	S184	D1L3136Y D1M2895Y D2D0954Y D2D0964Y D2D0967Y D2D0972Y
S-185 SOFSILK* 2-0 BLK 12X45CM PCT X36	S185	D2B2785Y D2B2877Y D2B2878Y D2C1421Y D2D0957Y D2D0968Y D2D0971Y D2D0984Y D2D0985Y D2E2680Y D2E2767Y D2E2769Y
S-187 SOFSILK* 1 BLK 6X45CM PCT X36	S187	D2A1585Y
S-206 SOFSILK* 2 BLK 100CM STDLTH X36	S206	D1L2658Y D1M2896Y D2A1586Y
S-243 SOFSILK* 4-0 BLK 12X60CM PCT X36	S243	D1M1020Y D2D2348Y
S-244 SOFSILK* 3-0 BLK 12X60CM PCT X36	S244	D1M1590Y
S-245 SOFSILK* 2-0 BLK 12X60CM PCT X36	S245	D2A0559Y D2C2036Y D2C2162Y D2D1871Y
S-246 SOFSILK* 0 BLK 6X60CM PCT X36	S246	D2E1375Y
S-2782K SOFSILK* 4-0 WHI 45CM SS24 DA	S2782K	D2F0062Y
S-303 SOFSILK* 4-0 BLK 12X75CM PCT X36	S303	D1M1424Y D2C1472Y D2D1872Y D2D2120Y D2E1496Y
S-304 SOFSILK* 3-0 BLK 12X75CM PCT X36	S304	D2B0173Y D2C2163Y D2C2805Y D2D1991Y D2E1484Y
S-305 SOFSILK* 2-0 BLK 12X75CM PCT X36	S305	D1L3282Y D1L3459Y D2C1280Y D2C1281Y D2C1479Y D2D0959Y D2E0907Y D2E2768Y D2E2772Y
S-316 SOFSILK* 0 BLK 12X75CM PCT X24	S316	D1L3311Y D1M0530Y D2A0555Y D2A0557Y D2A0558Y D2A0866Y D2C2806Y D2D2434Y D2D2436Y
S-317 SOFSILK* 1 BLK 12X75CM PCT X24	S317	D2D2087Y D2E0587Y
S-318 SOFSILK* 2 BLK 12X75CM PCT X24	S318	D1M0153Y D2A1677Y

Sofsilk™ Coated Braided Silk Suture Product Description	Model Number	Lot #
S-346 SOFSILK* 0 BLK 12X60CM PCT X24	S346	D2A0867Y D2B1884Y
S-605 SOFSILK* 2-0 BLK 2X150CM PCT X36	S605	D1L2686Y D2B2244Y
S-607 SOFSILK* 1 BLK 2X150CM PCT X36	S607	D1M2899Y
S-608 SOFSILK* 2 BLK 2X150CM PCT X36	S608	D1L1617Y D1L1619Y D1L1622Y D1M0173Y D1M0635Y D1M0655Y D2E1210Y
SS-523 SOFSILK* 2-0 BLK 75CM SC1 X36	SS523	D2C1971Y
SS-525 SOFSILK* 1 BLK 75CM SC1 X36	SS525	D1G1346Y
SS-5641 SOFSILK* 4-0 BLK 45CM P13 X36	SS5641	D2B2181FY
SS-5641G SOFSILK* 4-0 BLK 45CM P13 X12	SS5641G	D1D2533FY
SS-5678 SOFSILK* 5-0 BLK 45CM P11 X36	SS5678	D1L2430FY
SS-5684 SOFSILK* 3-0 BLK 45CM P14 X36	SS5684	D2B1970FY
SS-623 SOFSILK* 2-0 BLK 75CM SC2 X36	SS623	D1G0960Y D2A1069Y
SS-645 SOFSILK* 4-0 BLK 75CM C12 X36	SS645	D1K2457FY D1L3151FY D1M2526FY D1M2531FY
SS-653 SOFSILK* 4-0 BLK 75CM C13 X36	SS653	D1E2737FY
SS-673 SOFSILK* 5-0 BLK 75CM C12 X36	SS673	D1L0164FY
SS-683G SOFSILK* 4-0 BLK 45CM C13 X12	SS683G	D1L0794FY
SS-685G SOFSILK* 2-0 BLK 45CM C15 X12	SS685G	D2A0503FY
SS-686 SOFSILK* 4-0 BLK 45CM C12 X12	SS686	D1E0201FY
SS-689 SOFSILK* 1 BLK 75CM C16 X36	SS689	D2C0024FY
SS-745 SOFSILK* 3-0 BLK 75CM C12 X36	SS745	D1M2971FY
SS-786 SOFSILK* 0 BLK 75CM C14 X36	SS786	D1E1220FY
SS-787 SOFSILK* 1 BLK 75CM C14 X36	SS787	D1L0032FY
VS-533 SOFSILK* 2-0 BLK 90CM V20 DAX36	VS533	D1M0598Y
VS-845 SOFSILK* 1 BLK 75CM V26 X36	VS845	D2B1779Y
VS-870 SOFSILK* 5-0 BLK 75CM CV23 X36	VS870	D1M2873Y
VS-871 SOFSILK* 4-0 BLK 75CM CV23 X36	VS871	D1L0602Y
SOFSILK 4-0 30 BK CV-23 VS871-2	VS8712	D2C3153Y
VS-872 SOFSILK* 3-0 BLK 75CM CV23 X36	VS872	D1M1837Y D2C2945Y
SOFSILK 3-0 30 BK CV-23 VS872-2	VS8722	D1D3187Y D1M1292Y
VS-882 SOFSILK* 3-0 BLK 75CM CV15 X36	VS882	D1G1139Y
SOFSILK 5-0 30 BK CV-11 VS890-2	VS8902	D2B0364Y
XX-5278 SOFSILK* 3-0 BLK 150CM PCT X36	XX5278	D2B0174Y
XX-5280 SOFSILK* 0 BLK 150CM PCT X36	XX5280	D2E1482Y
XX-5281 SOFSILK* 1 BLK 150CM PCT X36	XX5281	D2B0175Y
XX-5284 SOFSILK* 4 BLK 150CM PCT X36	XX5284	D1L2691Y

Surgidac™ Uncoated Braided Polyester suture Product Description	Model Number	Lot #
D-1764K SURGIDAC* 5-0 WHI 45CM SS24DA	D1764K	D1L2420Y
D-1764K SURGIDAC* 5-0 WHI 45CM SS24DA	D1764K	D1L2428Y
D-1764K SURGIDAC* 5-0 WHI 45CM SS24DA	D1764K	D1M2883Y

Surgilon™ Braided Nylon suture Product Description	Model Number	Lot #
88861883-51 SURGILON* 2-0 BLK 75CM C16	8886188351	D1K1677FY
88861915-71 SURGILON* 1 BLK 75CM GS11	8886191571	D2C3242Y
88861919-31 SURGILON* 4-0 BLK 7X75CMPCT	8886191931	D2B2243Y

88861919-41 SURGILON* 3-0 BLK 7X75CMPCT	8886191941	D1M2553Y
		D1M2561Y
		D2B0169Y
		D1M0915Y
		D2A0560Y
		D2B1245Y
		D2B1537Y
		D2B2751Y
		D2C0267Y
88861919-51 SURGILON* 2-0 BLK 7X75CMPCT	8886191951	D2C0907Y
		D2C1101Y
		D2D2347Y
		D2D2437Y
		D2D2506Y
		D2D2510Y
		D2E0905Y
		D1M1423Y
		D2A0861Y
		D2A0865Y
88861919-61 SURGILON* 0 BLK 7X75CM PCT	8886191961	D2A1709Y
		D2B1349Y
		D2B1350Y
		D2B2727Y
		D1M0640Y
88861919-71 SURGILON* 1 BLK 7X75CM PCT	8886191971	D1M1494Y
		D2C0962Y
88861932-51 SURGILON* 2-0 BLK 75CM GS10	8886193251	D1G1867Y
		D2B0290Y
88861971-71 SURGILON* 1 BLK 75CM GS21	8886197171	D2B0445Y
		D2B0476Y
88861985-71 SURGILON* 1 BLK 75CM SC1X36	8886198571	D1E0626Y
SBS-1884G SURGILON* 4-0 WHI 45CM P12X12	SBS1884G	D1E1212FY
SBS-1928G SURGILON* 5-0 BLK 45CM P13X12	SBS1928G	D2B0707FY
		D2C3247FY

Surgipro™ Monofilament Polypropylene Sutures Product Description	Model Number	Lot #
CP-535 SURGIPRO* 1 BLU 100CM GS24 X36	CP535	D2C1521Y
		D2E1342Y
		D2E1580Y
		D2E2678Y
		D2E2679Y
		D2F0509Y
CP-824 SURGIPRO* 1 BLU 150CM GS26 X24	CP824	D2D0251Y
CP-825 SURGIPRO* 2 BLU 150CM GS26 X24	CP825	D2C3234Y
VP-543 SURGIPRO* 2-0 BLU 120CM V20 DA	VP543	D2B1270Y
		D2D1493Y
		D2E1389Y

Surgipro™ II Monofilament Polypropylene Sutures Product Description	Model Number	Lot #
VP-421X SURGIPRO*II 4-0 90CM V20 DA7P	VP421X	D2C1147Y
VP-435-X SURGIPRO II 4-0 90CM KV5 DA7P	VP435X	D2C1148Y
		D2D0080Y
		D2D0081Y
		D2D1507Y
		D2E1343Y
VP-541X SURGIPRO*II 4-0 BLU 120CM V20DA	VP541X	D2E0506Y
		D2E0507Y
VP-542-X SURGIPRO II 3-0 BLU 120CM V20DA	VP542X	D2E0749Y
		D2E0750Y
VP-735-X SURGIPRO*II 7-0 60CM MV1758DA	VP735X	D0M2060Y
		D0M2061Y

Surgipro™ II Monofilament Polypropylene Sutures Product Description	Model Number	Lot #
		D1A0234Y
		D1A0419Y
		D1A0420Y
		D1A0474Y
		D1A0479Y
		D1A0480Y
		D1A0499Y
		D1A0960Y
		D1A1636Y
		D1B0024Y
		D1B0513Y
		D1B1462Y
		D1B2759Y
		D1B2760Y
		D1B2784Y
		D1B2785Y
		D1G2405Y
		D1G2406Y
		D1H1658Y
		D1H1945Y
		D1H1971Y
		D1H2033Y
		D1H2104Y
		D1H2105Y
		D1H2106Y
		D1H2107Y
		D1J0372Y
		D1J0374Y
		D1J0375Y
		D1J0376Y
		D1J0591Y
		D1J1260Y
		D1J1679Y
		D1J1923Y
		D1J1928Y
		D1J1929Y
		D1J2885Y
		D1K2644Y
		D1L0457Y
		D1L3332Y
		D1M0869Y
		D1M0870Y
		D1M0963Y
		D1M1464Y
		D2B0362Y
		D2C1982Y
		D2C2348Y
		D2D0155Y
		D2D0156Y
		D2D0166Y
		D2D0942Y
		D2D2100Y
		D2E0165Y
		D2E0173Y
		D2E0175Y
		D2E1035Y
		D2E1073Y
		D2E1536Y
		D2E2752Y
		D2F1973Y
		D2F1974Y
		D2F1975Y
		D1B2760Y
		D2D0941Y
VP735X-12 SURGIPRO*II 7-0 60CM MV1758 DA	VP735X12	D1G0407Y
VP-738-X SURGIPRO*II 8-0BLU 60CM CV351DA	VP738X	

Surgipro™ II Monofilament Polypropylene Sutures Product Description	Model Number	Lot #
		D2C1983Y D2F0494Y D2F0495Y D2F0496Y
VP-744-X SURGIPRO*II 8-0 45CM MV1758DA	VP744X	D1G0408Y
	VP744X	D1L0327Y D0M1980Y D1A1635Y D1G1298Y D1H2487Y D1H2488Y D1J0373Y D1J1210Y D1J2362Y D1J2364Y D1J2366Y D1J2541Y D1J2543Y D1K0073Y D1K2317Y D1K2318Y D1K2319Y D1K2326Y D1K2328Y D1K2329Y D1K2642Y D1K2646Y D1K2647Y D1K2648Y D2B0470Y D2B1158Y D2C1984Y D2D0944Y D2D0945Y D2E1923Y D2F0798Y D2F0799Y
VP-745-X SURGIPRO*II 8-0 60CM MV1758DA	VP745X	D1C0229Y D1C0230Y D1C1787Y D1C1849Y D1G0404Y D1G0405Y D1G2408Y D1M1397Y D1M1465Y D2A0334Y D2D0158Y D2E1074Y
VP-747-X SURGIPRO*II 7-0 75CM MV1758DA	VP747X	D2D0641Y
VP-853 SURGIPRO* 2-0 BLU 120CM V26 DA	VP853	D1A1244Y D1E0734Y D1H0909Y D1J1926Y D1K2643Y D1L0605Y D1L2328Y D1M2164Y D1M2165Y D2C0956Y D2E1883Y D2F0936Y
VP-875-X SURGIPRO*II 7-0 75CM MV1759DA	VP875X	D0K3052Y D1H1373Y D1H1374Y
VP-900-X SURGIPRO*II 8-0 45CM MV1355DA	VP900X	

Surgipro™ II Monofilament Polypropylene Sutures Product Description	Model Number	Lot #
		D1H1375Y D1H1457Y D1L0158Y D1L0159Y D1L1321Y D1L2329Y D1L2617Y D1L2618Y D1M1597Y D2A0335Y D2C1926Y D2F0041Y D2F0042Y
VP-902-X SURGIPRO*II 8-0 60CM MV1355DA	VP902X	D1A1236Y D1A1238Y D1A1240Y D1A1242Y D1A1526Y D1B1245Y D1B1246Y D1B1265Y D1B1954Y D1B2137Y D1B2688Y D1C0681Y D1C1270Y D1C2801Y D1C2817Y D1D0141Y D1D0411Y D1D0687Y D1D1498Y D1D1499Y D1D1570Y D1D2580Y D1D2693Y D1D3578Y D1D3629Y D1E0582Y D1E0583Y D1E2328Y D1E3445Y D1F0032Y D1F0519Y D1F0521Y D1F1704Y D1F2371Y D1G3162Y D1H0384Y D1H0411Y D1H0899Y D1H0901Y D1H0902Y D1H0904Y D1H0905Y D1H0906Y D1J0586Y D1J0597Y D1J0598Y D1J0599Y D1J0993Y D1J1258Y D1J1623Y D1J1832Y D1J2361Y

Surgipro™ II Monofilament Polypropylene Sutures Product Description	Model Number	Lot #
		D1J2365Y
		D1J2542Y
		D1K0111Y
		D1K0519Y
		D1K2349Y
		D1K2350Y
		D1K2416Y
		D1K2417Y
		D1K2418Y
		D1K2419Y
		D1K2573Y
		D1K2576Y
		D1K2632Y
		D1K2645Y
		D1L3382Y
		D1L3383Y
		D1M0015Y
		D1M0016Y
		D1M0151Y
		D1M0166Y
		D1M0169Y
		D1M0299Y
		D1M0300Y
		D1M1031Y
		D1M2836Y
		D1M2839Y
		D1M2841Y
		D2A0336Y
		D2A0338Y
		D2A1717Y
		D2A1718Y
		D2B0361Y
		D2B0469Y
		D2B1062Y
		D2B1063Y
		D2B1255Y
		D2B1257Y
		D2C0951Y
		D2C0952Y
		D2C1330Y
		D2C1331Y
		D2C1927Y
		D2C1928Y
		D2C2398Y
		D2C2399Y
		D2C2400Y
		D2C2401Y
		D2C2509Y
		D2C2738Y
		D2D0097Y
		D2D0098Y
		D2D0099Y
		D2D0162Y
		D2D0163Y
		D2D0167Y
		D2D0168Y
		D2D0169Y
		D2D2005Y
		D2E0167Y
		D2E0168Y
		D2E0169Y
		D2E0170Y
		D2E0171Y
		D2E0172Y
		D2E0174Y

Surgipro™ II Monofilament Polypropylene Sutures Product Description	Model Number	Lot #
		D2E1528Y
		D2E1529Y
		D2E1531Y
		D2E1845Y
		D2E1884Y
		D2E1885Y
		D2E1922Y
		D2E2097Y
		D2G0697Y
VP902X-12 SURGIPRO*II 8-0 60CM MV1355 DA	VP902X12	D2C1928Y
		D2G0697Y
VP-904-X SURGIPRO*II 7-0 BLU 60CM MV1355	VP904X	D0M1981Y
		D1B0657Y
		D1C1118Y
		D1D2622Y
		D1G1296Y
		D1G1299Y
		D1G1999Y
		D1J2884Y
		D1M0345Y
		D1M2834Y
		D2A0337Y
		D2B1159Y
		D2E1078Y
VPF-735-X SURGIPRO*II 7-0 60CM MVF1758DA	VPF735X	D1G1297Y
		D1K0520Y
		D1M1046Y
		D1M1557Y
		D2E1079Y
XX-3300 SURGIPRO* II 5-0 BLU 60CM CV1DA	XX3300	D2F2287Y
XX-5224 SURGIPRO*II 5-0 BLU 90CM CV25DA	XX5224	D2D0804Y

Ti-Cron™ Coated Braided Polyester Suture Product Description	Model Number	Lot #
88862775-31 TICRON* 4-0 BLU 75CM CV327DA	8886277531	D1M0276Y
88862880-41 TICRON* 3-0 WHI 75CM Y31DA	8886288041	D1L1698Y
88863012-61 TICRON* 0 BLU 90CM C16 X36	8886301261	D1D3149FY
88863015-61 TICRON* 0 BLU 120CM V20X36	8886301561	D1E1922Y
88863017-51 TICRON* 2-0 BLU 120CM SKX36	8886301751	D2A0889Y
88863026-71 TICRON* 1 BLU 75CM HOS12X36	8886302671	D2C1802Y
88863035-51 TICRON 2-0 BLU 105CM CV305DA	8886303551	D1L0984Y
88863047-41 TICRON* 3-0 BLU 45CM C13X36	8886304741	D1G1844FY
88863048-51 TICRON* 2-0 BLU 75CM C13X36	8886304851	D1G0895FY
88863050-61 TICRON* 0 BLU 75CM C14 X36	8886305061	D2C1969FY
88863054-51 TICRON* 2-0 BLU 75CM C17X36	8886305451	D1D3218FY
88863056-89 TICRON* 5 BLU 45CM GS18X12	8886305689	D2D0199Y
88863059-53 TICRON* 2-0 BLU 45CM P24X12	8886305953	D1M1287FY
88863070-51 TICRON* 2-0 BLU 75CM C15X36	8886307051	D1D2540FY
88863088-51 TICRON* 2-0 BLU 75CM Y5X36	8886308851	D2B2868Y
88863090-51 TICRON 2-0 BLU 75CM GS21X36	8886309051	D2B1332Y
88863092-71 TICRON* 1 BLU 75CM KV37X36	8886309271	D2C2450Y
88863109-43 TICRON* 3-0 BLU 45CM P22X12	8886310943	D2C2451FY
88863111-79 TICRON* 5 BLU 75CM HGS21X36	8886311179	D1D2597Y
88863119-61 TICRON* 0 BLU 75CM KV34X36	8886311961	D1M1166Y
88863154-09 TICRON* 4 BLU 75CM GS11X36	8886315409	D2B2884Y
88863159-31 TICRON* 4-0 BLU 90CM KV5DA	8886315931	D2B0542Y
88863160-41 TICRON* 3-0 BLU 90CM Y31DA	8886316041	D1L1697Y
		D2B0543Y
88863163-61 TICRON* 0 BLU 75CM SC1 X36	8886316361	D1E0506Y
88863185-41 TICRON* 3-0 BLU 75CM CV305	8886318541	D1J1639Y
		D1M2717Y

Ti-Cron™ Coated Braided Polyester Suture Product Description	Model Number	Lot #
88863186-41 TICRON* 3-0 BLU 75CM CV331	8886318641	D1M2851Y D1M2844Y D2A0933Y D2E0947Y D2E1925Y
88863212-51 TICRON* 2-0 BLU 90CM Y5DA7P	8886321251	D2E3008Y
88863226-41 TICRON* 3-0 BLU 60CM CV330DA	8886322641	D2A0451Y
88863280-21 TICRON* 5-0 BLU 75CM CV301DA	8886328021	D1D0290Y
88863280-31 TICRON* 4-0 BLU 75CM CV301DA	8886328031	D1L0721Y D1L2169Y D2B2861Y
88863309-71 TICRON* 1 BLU 75CM GS11X36	8886330971	D2D2188Y
88863369-31 TICRON* 4-0 BLU 90CM CV316DA	8886336931	D2B2738Y D2E0660Y D2F0767Y
88863393-51 TICRON* 2-0 BLU 90CM CV300DA	8886339351	D1M0107Y D1M1299Y
CD-3123K TICRON* 5-0 WHI 45CM SS24 DA	CD3123K	D2B2213Y

CUSTOMER ACKNOWLEDGEMENT FORM

Please email or fax this form back to Medtronic (even if you do not have affected inventory): <rs.regulatoryuk-ire@medtronic.com before 26th January 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"> 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: <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. 			
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)
<input type="checkbox"/> 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.

