

URGENT: MEDICAL DEVICE RECALL
Polysorb™ Braided Absorbable Suture
Endo Stitch™ Loading Unit with Polysorb™ Suture
Maxon™ Monofilament Absorbable Suture
Biosyn™ Monofilament Absorbable Suture

4 May 2017

Attention: Risk Management Director and O.R. Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific item codes and production lots of Polysorb™ braided absorbable suture, Endo Stitch™ loading unit with Polysorb™ suture, Maxon™ monofilament absorbable suture, and Biosyn™ monofilament absorbable suture.

Issue Description:

This voluntary recall is being conducted due to the potential for an incomplete seal on the inner package, which may result in premature degradation of the suture material. The use of products with this condition may increase the potential for the suture to break. This packaging defect does not impact the sterility of the product. There have been no reports of serious injury associated with these issues.

Medtronic requests that you quarantine and return any unused products of the items/lots detailed below. Unused products from the affected item codes and lots should be returned as described in the Required Actions section below. If you have distributed the Polysorb™ braided absorbable suture, Endo Stitch™ loading unit with Polysorb™ suture, Maxon™ monofilament absorbable suture, Biosyn™ monofilament absorbable suture listed on Attachment A, please promptly forward the information from this letter to those recipients. All unused products from the affected item codes and lots must be returned.

This voluntary recall affects only the item codes and lots listed on Attachment A.

Required Actions:

1. Please quarantine and discontinue use of the affected item code and lots listed on Attachment A.
2. Please complete the attached Recalled Product Return Form in its entirety. If you do not have any units from the affected lots in your inventory, simply tick "No affected inventory to be returned" and revert back to your local Medtronic Representative.
3. Please return affected product as follows:

- **CUSTOMERS WHO PURCHASED PRODUCT DIRECTLY FROM MEDTRONIC**

Please complete the Recalled Product Return Form (attached) and return to your local Medtronic representative together with affected units if any.

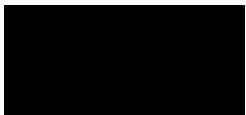
- **CUSTOMERS WHO PURCHASED PRODUCT FROM A DISTRIBUTOR**

Please complete the Recalled Product Return Form (attached) and contact your Distributor directly. All affected product and Recalled Product Return Form must be returned through the Distributor

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations. Please communicate this important information within your facility and or other facilities as required.

Thank you for your attention to this notification. We sincerely apologize for any inconvenience this situation may cause you or your facility.

Sincerely,



Diana Teo
QA Supervisor, SEA
Medtronic

Attachment A

Item Number	Product description	Lots	Item Number	Product description	Lots
170052	ENDO STITCH* POLYSORB* 0 48" VIO DLU SU	J4L1477X	GL67M	POLYSORB 3/0 30" VIOLET V-20 DT	D5A0513GX to D5A0515GX
170053	ENDO STITCH*POLYSORB* 2/0 48" VIO DLU SU	J5A0702X to J5A1207X	GL68M	POLYSORB 4/0 30" VIOLET V-20 DT	D4L0759GX
170056	ENDO STITCH* POLYSORB* 0 48" U/D DLU SU	J4M0853X to J5A0192X	GL69MG	POLYSORB 3/0 18" UNDYED V-20 DT	D5A0171GX to D5B0540GX
170057	ENDO STITCH*POLYSORB* 2/0 48" U/D DLU SU	J5A1097X	GLJ50M	POLYSORB 3/0 18" VIOLET CV-25 DT	D4L0058X to D5A1041X
8886603433	MAXON* 4/0 5X30 GREEN V-20 D*TACH	D4L1156GX	GMJ34M	BIOSYN* 4/0 18" VIOLET CV-25 DT	D4K0010X
8886621933	MAXON 4/0 5X18" GREEN CV-24 D-TACH	D4K0396X to D4M0394X	L14	POLSORB 0 18 VIO PRECUT 226T	D4L1165X to D5A0546X
2CL852	POLYSORB* 2 VIOLET 2X36" BGS-29 (2X90CM)	D4L0467X	L15	POLSORB 1 18 VIO PRECUT 122J	D4L1161X to D5A0096X
3CL812	POLYSORB* 0 30" VIOLET GS-21 REG ATTCH	D5A1024X	L24	POLYSORB 0 18 UNDYED PRECUT	D4L1164X
CL10MG	POLYSORB* 0 18" VIOLET GS-21 DT	D5A0169X to D5B0424X	L25	POLYSORB 1 18" UNDYED PRECUT	D5A0551X
CL11MG	POLYSORB 1 18" VIOLET GS-21 DT	D4J0442X to D5B0263X	L26	POLYSORB* 2 UNDYED 12X18" PRECUT	D4J0736X to D5A0402X
CL13MG	POLYSORB 2/0 18" UNDYED GS-21 DT	D4L1968X to D5B0193X	L27	POLYSORB 0 18" VIOLET PRECUT	D5A0249X to D5A1315X
CL14MG	POLYSORB 0 18" UNDYED GS-21 DT	D4L1756X to D5A1745X	L28	POLYSORB* 2 VIOLET 12X18" PRECUT	D4K2022X to D4L1546X
CL2M	POLYSORB* 0 5 X 30" UNDYED GS-21 DT	D4K1415X to D5A1028X	L34	POLYSORB* 0 24" VIOLET PRECUT	D4K2023X to D4L1547X
CL52MG	POLYSORB 2/0 18" UNDYED GS-10 DT	D4K2361X to D5A1862X	L35	POLYSORB* 1 18" VIOLET PRE-CUT	D4K1272X to D5A0756X
CL60M	POLYSORB* 1 VIOLET 30" GS-26	D4L1131X	L4	POLSORB 0 18 U/D PRECUT 126R	D4K0211X to D5A0876X
CL622M	POLYSORB* 2 VIOLET 5X24" GS-24 D-TACH* (	D4L0692X	L40	POLYSORB* 0 30" VIOLET PRECUT	D4M1190X to D5A0549X
CL64M	POLYSORB 1 30" VIOLET GS-25 DT	D4J1987X	L404	POLSORB 0 30 VIO PRECUT 227C	D4L1545X to D5A0757X
CL659M	POLYSORB* 2 VIOLET 30" GS-26	D4M0542X	L405	POLSORB 1 30 VIO PRECUT 224E	D5A0875X
CL665M	POLYSORB* 2 30" VIOLET GS-25 DT	D4K1044X	L41	POLYSORB* 1 30" VIOLET PRECUT	D4K2024X to D5A0548X
CL6M	POLYSORB 1 30" VIOLET GS-21 DT	D4L1431X	L42	POLYSORB* 2 VIOLET 6X30" PRE-CUT	D5A0098X
CL71M	POLYSORB* 0 VIOLET 5X30" HGS-21 D-TACH	D4M0368X	LL102	POLYSORB 3/0 60 U/D REEL 104R	D5A1291X
CL885M	POLYSORB 1 30" VIOLET GS-22 DT	D4J0841X to D4M0370X	LL104	POLYSORB 0 60 U/D REEL 203G	D4K1537X to D5A1294X
CL886M	POLYSORB* 0 30" VIOLET GS-22 DT	D4K1616X	LL111	POLSORB 4/0 60" REEL VIO 217T	D4L1509X
CL97MG	POLYSORB* 1 5 X 30" VIOLET HOS-12 DT	D4L1159X	LL112	POLYSORB* 3-0 VIOLET 60 REEL	D4L1170X to D5A0811X
CL997MG	POLYSORB* 0 VIOLET 5X30" HGS-20 D-TACH	D4L1563X-D4M1020X	LL113	POLYSORB* 2-0 VIOLET 60 REEL	D4L0065X to D5A0109X
CLT633M	POLYSORB 2 VL 5 X 30" BGST-29 DT	D4K2021X	LL114	POLYSORB* 0 VIOLET 60 REEL	D4L1866X to D5A0869X
GL182M	POLYSORB 3-0 30" VIOLET CV-25 DT	D4K2438X	LL221	POLYSORB* 4/0 98" VIOLET REEL 110T	D4L1169X to D5A1297X
GL223M	POLYSORB 2-0 30" VIOLET V-30 DT	D4L1371X	LL222	POLYSORB* 3-0 VIOLET 98" REEL	D4K2315X to D5A1803X
GL33MG	POLYSORB 3/0 18" VIOLET CV-25 DT	D5A0307X to D5B0844X	LL223	POLYSORB* 2-0 VIOLET 98" REEL	D4K1392X to D5B0302X
GL34MG	POLYSORB 4/0 18" VIOLET CV-25 DT	D5A0410X to D5B0536X	LL224	POLYSORB* 0 VIOLET 98" REEL	D4L0689X to D5A1298X
GL62MG	POLYSORB 2/0 18" VIOLET V-20 DT	D4L1180GX to D5B0427GX	LL225	POLYSORB* 1 VIOLET 98" REEL	D4J0947X to D5A0951X
GL63MG	POLYSORB 3/0 18" VIOLET V-20 DT	D4L1177GX to D5A1039GX	LL226	POLYSORB* 2 VIOLET 98" REEL	D4L0640X to D4L0642X
GL66M	POLYSORB 2/0 30" VIOLET V-20 DT	D4K1263GX	XX2109	MAXON 5/0 5X18 GR CV-23 D-TACH	D4K1485X

**Attachment A
Continued**

Best Practice Kit	Description	Expiration Criteria
00Z2064	Best Practices, Endoscopic Procedure Kit	12/31/2019
00Z2150	Best Practices, Endoscopic Procedure Kit	2/28/2020
00Z2190	Best Practices, Endoscopic Procedure Kit	1/31/2020
00Z2192	Best Practices, Endoscopic Procedure Kit	1/31/2020
00Z2211	Best Practices, Endoscopic Procedure Kit	1/31/2020
00Z2212	Best Practices, Endoscopic Procedure Kit	1/31/2020
00Z2216	Best Practices, Endoscopic Procedure Kit	12/31/2019 to 4/30/2020
00Z2217	Best Practices, Endoscopic Procedure Kit	12/31/2019 to 3/31/2020
00Z2312	Best Practices, Endoscopic Procedure Kit	12/31/2019 and 8/31/2020

Item Code	Description	Lot Number
US1540	CUSTOM SUTURE PACK	A5E0919X
US1614	CUSTOM SUTURE PACK	A5C1345X
US1672	USPACK-SUTURE KIT	A5D0789X
14111316-03	SCHRITTMACHER ANGIO X3	228111X

Attachment B

COVIDIEN™

Polysorb™

Braided Absorbable Suture

3-0 2 Metric

5x18" 45 cm VIOLET

CV-25
TAPER

1/2 • 22 mm



LOT XXXXXXXXXXXXX

Use by YYYY-MM-DD

YYYY-MM-DD



MP 5 x 5
D-Tach

Item #

GL-33-MG

Lot #

Item #

XX-2109

COVIDIEN™

Maxon™

Monofilament Absorbable Suture

5-0 1 Metric

5x18" 45 cm GREEN

CV-23
TAPER

1/2 • 17 mm



LOT XXXXXXXXXXXXX

Use by YYYY-MM-DD

YYYY-MM-DD



MP 5 x 5
D-Tach

Lot #

Item #

170053

COVIDIEN™

Polysorb™

Absorbable Single Stitch Reload

2-0 3 Metric

40" 120 cm

ES-9
TAPER

•
9 mm

12

VIOLET / VIOLETTE / VIOLETT /
VIOLA / MORADO / VIOLETA

LOT XXXXXXXXXXXXX

Use by XXXX-XX

Mfg XXXX-XX

Lot #

RECALLED PRODUCT RETURN FORM

**Polysorb™ Braided Absorbable Suture, Endo Stitch™ Loading Unit with Polysorb™ Suture,
Maxon™ Monofilament Absorbable Suture, Biosyn™ Monofilament Absorbable Suture**

Customer Contact Details	Medtronic Contact Details
Hospital / HCP:	By E-mail:
Address:	By Post:
Telephone no:	
Fax no:	
E-mail:	

Even if you have no affected stock to returned, please complete this form and table; return to your local Medtronic contacts stated above

Please tick (either one) only:

- ☐ No, no affected inventory to be returned.
- ☐ Yes, affected inventory to be returned

Item Code	Product Description	Lot number	QTY (Each)

I have read and understand the instructions provided and acknowledge receipt of the the Polysorb™ Braided Absorbable Suture, Endo Stitch™ loading unit with Polysorb™ Suture, Maxon™ Monofilament Absorbable Suture, Biosyn™ Monofilament Absorbable by signing below.

Name: _____ (print) Signature: _____ Stamp: _____ Date: _____