

Urgent Field Safety Notice

Polysorb™ Braided and Biosyn™ monofilament Absorbable Suture

Recall

December 2019

Medtronic reference: FA899

Dear Healthcare Professional:

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific item codes and production lots of

Polysorb™ braided and Biosyn™ monofilament absorbable sutures.

Issue Description:

This voluntary recall is being conducted due to the potential for packaging integrity issues impacting the humidity or sterility barrier of specific production lots of these absorbable sutures. These conditions may result in premature degradation of the suture material or compromise the product's sterile condition. The use of products with an incomplete seal of the humidity barrier may increase the potential for the suture to break. The use of products with a compromised sterile barrier may result in a potentially increased risk for infection. There have been no reports of patient injury associated with these issues.

This voluntary recall affects only the item codes and lot numbers listed on Attachment A of this notification.

Required Actions:

1. Please immediately quarantine and discontinue use of the affected item code and lot listed on Attachment A.
2. Please return affected product as indicated below. All unused products from the affected item codes and lots must be returned.
3. If you have distributed Polysorb™ braided or Biosyn™ monofilament absorbable sutures listed on Attachment A, please promptly forward the information from this letter to those recipients.
4. Complete the Return Verification Form **even if you do not have inventory**.

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please keep a copy of this letter in your file.

Medtronic has notified the Competent Authority of your country of this action.

We request that you contact your Medtronic Representative if you experienced quality problems or adverse events.

	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.

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative at <XXXX>.

Sincerely,

Attachment A

Item Code	Description	Affected Lot Numbers	Expiration Date
CL461	Polysorb™ Braided Absorbable Suture 3/0 VIOLET 30" CV-24 (75CM)	D7H0876X	2022-08-31
CL537	Polysorb™ Braided Absorbable Suture 0 30"" UNDYED HOS-11	A9J0018Y	2024-08-31
CL811	Polysorb™ Braided Absorbable Suture 2/0 30 VIOLET GS-21	A9J0075Y	2024-08-31
CL815	Polysorb™ Braided Absorbable Suture 3/0 30 VIOLET GS-11	A9H1170Y	2024-07-31
CL885	Polysorb™ Braided Absorbable Suture 1 30 VIOLET GS-22	A9H1065Y	2024-07-31
CL892	Polysorb™ Braided Absorbable Suture 3-0 VIOLET 30"" GS-23	A9J0006Y	2024-08-31
CL911	Polysorb™ Braided Absorbable Suture 2 36" VIOLET GS-24	D7H1048X	2022-08-31
CL914	Polysorb™ Braided Absorbable Suture 0 36 VIOLET GS-24	A9H1186Y	2024-07-31
CL914	Polysorb™ Braided Absorbable Suture 0 36 VIOLET GS-24	A9J0015Y	2024-08-31
CL915	Polysorb™ Braided Absorbable Suture 1 36 VIOLET GS-24	A9H0927Y	2024-07-31
CL915	Polysorb™ Braided Absorbable Suture 1 36 VIOLET GS-24	A9H1187Y	2024-07-31
CL915	Polysorb™ Braided Absorbable Suture 1 36 VIOLET GS-24	A9J0383Y	2024-08-31
CL915	Polysorb™ Braided Absorbable Suture 1 36 VIOLET GS-24	A9J0428Y	2024-08-31
CL923	Polysorb™ Braided Absorbable Suture 2-0 VIOLET 36"" GS-21	A9H1189Y	2024-07-31
CL923	Polysorb™ Braided Absorbable Suture 2-0 VIOLET 36"" GS-21	A9J0345Y	2024-08-31
CL925	Polysorb™ Braided Absorbable Suture 1 36 VIOLET GS-21	A9J0014Y	2024-08-31
CL925	Polysorb™ Braided Absorbable Suture 1 36 VIOLET GS-21	A9J0193Y	2024-08-31
CL953	Polysorb™ Braided Absorbable Suture 2-0 UNDYED 36"" GS-21	A9K0004Y	2024-09-30
GL123	Polysorb™ Braided Absorbable Suture 2-0 VIOLET 30"" V-20	A9J0421Y	2024-08-31
GL124	Polysorb™ Braided Absorbable Suture 0 VIOLET 30"" V-20	A9J0053Y	2024-08-31
GL228	Polysorb™ Braided Absorbable Suture 2/0 UNDYED 30" V-30 (75CM)	D7H0794X	2022-08-31
GL323	Polysorb™ Braided Absorbable Suture 2-0 UNDYED 30"" V-20	A9J0384Y	2024-08-31
GLS322	Polysorb™ Braided Absorbable Suture 3/0 30" UNDYED V-20	D7G0387X	2022-07-31
L1742K	Polysorb™ Braided Absorbable Suture 6/0 12"" VL SS-24 D/A	D7H1126X	2022-08-31
L2752K	Polysorb™ Braided Absorbable Suture 6-0 18" UNDYED SS-24 D/A	D7H1092X	2022-08-31
SL1625G	Polysorb™ Braided Absorbable Suture 6/0 18" UNDYED P-10	D7H1214X	2022-08-31
SL5679	Polysorb™ Braided Absorbable Suture UD 3/0 30 P-14	A9H0847FY	2024-07-31
SL5690	Polysorb™ Braided Absorbable Suture UD 4/0 18 P-13	D7G2298X	2022-07-31
SL5690	Polysorb™ Braided Absorbable Suture UD 4/0 18 P-13	D7H0091X	2022-08-31
SL654	Polysorb™ Braided Absorbable Suture 4/0 30 VIO SC-2 124K	D7H0946X	2022-08-31
UL203	Polysorb™ Braided Absorbable Suture 4/0 30 VIOLET CVF23	D7G2301X	2022-07-31
UL203	Polysorb™ Braided Absorbable Suture 4/0 30 VIOLET CVF23	D7H0092X	2022-08-31
UL877	Polysorb™ Braided Absorbable Suture 0 30" VIOLET GU-46	D7H0796X	2022-08-31
UL878	Polysorb™ Braided Absorbable Suture 2/0 30"VIOLET GU-46	D7H0866X	2022-08-31
UM201	Biosyn™ Monofilament absorbable suture 6/0 30" VIOLET CV-23	D7H0404X	2022-08-31

Attachment B

Identifying Affected Product

The diagram illustrates two suture product labels. The left label is for Polysorb™ Braided Absorbable Suture, size 1 4 Metric, 36" 90 cm, VIOLET, with a GS-24 TAPER and a diameter of 1/2" 40 mm. The right label is for Biosyn™ Monofilament Absorbable Suture, size 6-0 0.7 Metric, 30" 75 cm, VIOLET, with a Surgalloy™ CV-23 TAPER and a diameter of 1/2" 17 mm. Both labels include a 'LOT XXXXXXXXXXXX' field, a 'Use by YYYY-MM-DD' field, and a barcode. Red arrows point from a central 'Item code' box to 'CL-915' and 'UM-201', and from 'Lot #' boxes to the 'LOT XXXXXXXXXXXX' fields on both labels.

Item code

Lot #

Lot #