

URGENT: FIELD SAFETY NOTIFICATION: 8-0 Blue Twisted Silk Suture MEDICAL DEVICE VOLUNTARY RECALL (REMOVAL)

[Insert Date]

PLEASE DISTRIBUTE THIS INFORMATION TO THE APPROPRIATE PERSONNEL AT YOUR FACILITY WHO MAY USE THE PRODUCT WHICH IS THE SUBJECT OF THIS RECALL

Dear Distributor, Operating Room Supervisors, and Materials Management Personnel:

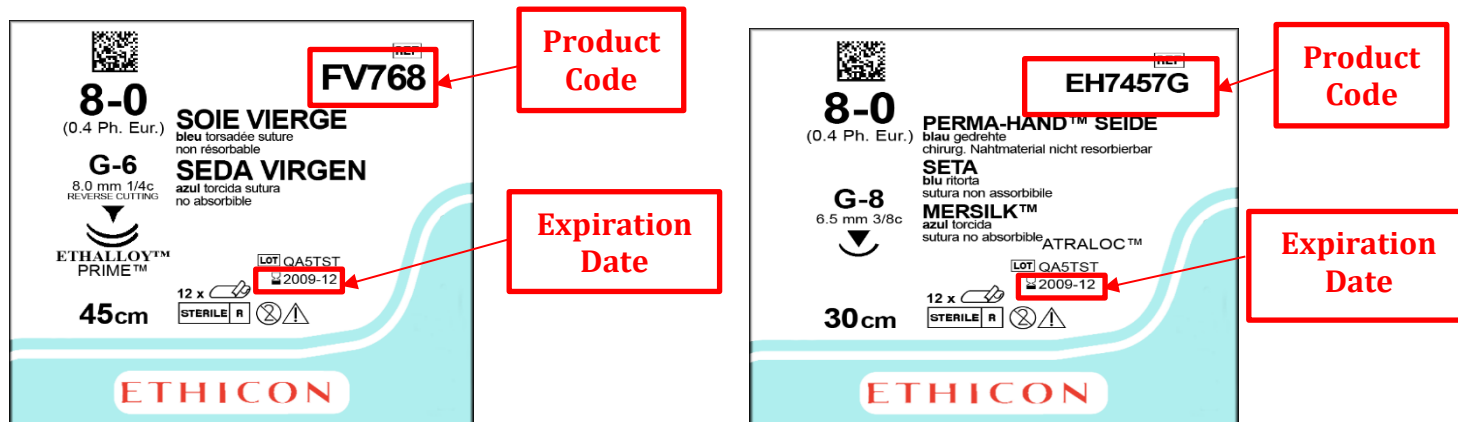
Ethicon is initiating a medical device voluntary recall (removal) of specific product codes and lots of size **8-0 Blue Twisted Silk Suture (listed below)**. Through routine product testing, it has been determined that certain product codes and lots of **8-0 Blue Twisted Silk Suture** may not meet the stringent individual and average requirements for tensile strength through full shelf life. Therefore, we are unable to sustain a 5-year shelf life claim for size **8-0 Blue Twisted Silk Suture**. **8-0 Blue Twisted Silk Suture** with tensile strength below our requirement could potentially result in suture breakage during use.

Ethicon has not received any complaints or reports of Adverse Events or Injuries related to this issue, and there is no anticipated patient safety impact. It is not recommended for physicians to provide any non-routine post-surgical care.

Ethicon wants to inform customers that future orders of **8-0 Blue Twisted Silk Suture** will have a reduced shelf life of 3 years (36 months). We apologize for any inconvenience this may cause in your inventory management.

Product Affected: Any **8-0 Blue Twisted Silk Suture** product received prior to June 2019 labeled with an expiration date of 2024-06-30 or earlier is affected by this recall. Any product received moving forward from this recall will be labeled with a 3-year expiration date and not affected by this recall.

FRONT OF SALES UNIT CARTON (Representative Sample)



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8-0 Blue Twisted Silk Suture

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AFFECTED PRODUCT CODES AND LOT NUMBERS

PRODUCT CODE	PRODUCT LOT	PRODUCT DESCRIPTION
EH7457G	JPM942	PERMA-HAND/MERSILK SILK BLU 30CM M0.4 USP8-0 SGLE ARMED G-8
	KL6991	
	LGM827	
EH7983G	LEZ809	PERMA-HAND/MERSILK SILK BLU 30CM M0.4 USP8-0 DBLE ARMED CS-35C
	MK6383	
	MMZ678	
FV768	JLK294	VIRGIN SILK BLU 45CM M0.4 USP8-0 D/ARM G-6 PRIME
	KDZ665	
	KGK318	
	LB6583	
	LBZ323	
	MHZ265	
FV769	JKM117	VIRGIN SILK BLU 18IN(45CM) USP8-0(M0.4) S/A G-6 PRM
	KGZ428	
	LCM926	
	LJ6781	
FV7771	JK5467	VIRGIN SILK BLU 18IN(45CM) USP8-0(M0.4) D/A TG140-8
	KG6391	
	KGK122	
	LDM751	
	LGM998	
	MLZ444	
U7058	JJH828	VIRGIN SILK BLU 18IN(45CM) USP8-0(M0.4) D/A CS140-6
	JJQ472	
	JPE958	
	JPH660	
	JPJ413	
	KDB811	
	KDP880	
	KEA813	
	KED040	
	KEH484	
	KJH714	
	KKH186	
	KKH414	
	KKH422	
	KKJ413	

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PRODUCT CODE	PRODUCT LOT	PRODUCT DESCRIPTION
	KKQ351	
	LAH173	
	LAH250	
	MLQ803	
	MLQ983	
U7059	LMH564	VIRGIN SILK BLU 45CM M0.4 USP8-0 DBLE ARMED CS140-6
	MLH118	
W1782	JHH622	VIRGIN SILK BLU 12IN(30CM) USP8-0(M0.4) D/A TG140-6
	JKH290	
	JKH291	
	JKJ367	
	JMH262	
	JMH451	
	KCJ065	
	KCJ468	
	KGH971	
	KGJ788	
	KJH581	
	KKJ280	
	KMH239	
	LBJ014	
	LEH309	
	LMB752	
	MCQ954	
MEB754		
MKH209		
W1784	KHJ240	VIRGIN SILK BLU 12IN(30CM) USP8-0(M0.4) S/A TG140-6
	LMH575	
	MCH323	
W1819	JPE551	VIRGIN SILK BLU 18IN(45CM) USP8-0(M0.4) D/A TG140-8
	JPH615	
	JPJ120	
	KAH393	
	KDB810	
	KDH640	
	KDH719	
	KDP776	
	KED059	
	KEE862	
	KEH320	

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PRODUCT CODE	PRODUCT LOT	PRODUCT DESCRIPTION
	KEH438	
	KEH483	
	KJH266	
	KJH284	
	KJH948	
	KJJ285	
	KJJ336	
	KJJ971	
	KKP008	
	KKQ042	
	KKQ106	
	MEQ614	
	MJH320	
	MLA210	
	MMH143	
	KCB768	
	KDE561	
	KDE646	
	KDH112	
	KDH113	
	KDH114	
	KDH204	
	KDH205	
	KDH330	
	KDH361	
	KDH362	
	KGJ025	
	LBH039	
	MAB866	
	MGQ557	
	MHB435	
	MHB476	
	MHH396	
	MJH936	
	MKH098	
	MKH779	
	MLH064	
W1820	JLJ429	VIRGIN SILK BLU 18IN(45CM) USP8-0(M0.4) D/A TG140-8
	JLJ813	
	JLQ137	
W818	JLJ429	VIRGIN SILK BLU 18IN(45CM) USP8-0(M0.4) D/A G-7 PRM
	JLJ813	
	JLQ137	

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PRODUCT CODE	PRODUCT LOT	PRODUCT DESCRIPTION
	JMJ111	
	JMJ541	
	JPH389	
	JPH467	
	JPH614	
	JPJ048	
	JPJ119	
	JPJ353	
	JPP592	
	JPP795	
	KJQ327	
	KKP006	
	KLH997	
	KPR661	
	LCJ238	
	LPB629	
	LPH954	
	MHB548	
	MKH419	
	MKH511	
	MKH533	
	MKQ474	
	MLH817	
	MLJ838	
	MMB871	
	MMH381	
W819	MEQ276	VIRGIN SILK BLU 30CM M0.4 USP8-0 DBLE ARM TG175-8
	MJQ277	
	MMH382	
	MPJ283	
W870	JJP588	VIRGIN SILK BLU 18IN(45CM) USP8-0(M0.4) S/A G-7 PRM
	KGJ148	
	LCJ335	
	MCH324	
	MEJ543	

Indicated Use:

8-0 Blue Twisted Silk Suture is indicated for use in general soft tissue approximating and/or ligation, including use in cardiovascular, ophthalmic, and neurological procedures.

ACTION REQUIRED FOR CUSTOMERS:

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8-0 Blue Twisted Silk Suture
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1. Examine your inventory immediately to determine if you have product subject to this recall on hand and quarantine such product(s).
2. Remove the product subject to this recall and communicate the issue to relevant operating room or materials management personnel, or anyone else in your facility who needs to be informed.
3. If any product subject to this recall has been forwarded to another facility, contact that facility to arrange return. Please consider including a copy of this recall letter when communicating.
4. Complete the Business Reply Form (BRF) (Attachment 1) confirming receipt of this notice and return to **[Insert Affiliate Information]** within three (3) business days. Please return the BRF even if you do not have product subject to this recall.
5. Follow instructions in the letter and immediately return any inventory of **8-0 Blue Twisted Silk Suture** subject to this recall no later than **September 30, 2020** to **[Insert Affiliate Information]**.
6. Keep this notice visibly posted for awareness until all product subject to this recall has been returned to **[Insert Affiliate Information]**. While processing your returns, please maintain a copy of this notice with the product subject to this recall and keep a copy for your records.
7. Customers are required to return unused impacted **8-0 Blue Twisted Silk Suture** subject to this recall that are in their inventory immediately. To receive credit reimbursement, customers must return product subject to this recall no later than **September 30, 2020**. Any non-affected product and any product returned after the date specified will not receive replacement.

If you have additional questions regarding this medical device voluntary recall (removal), please contact **[INSERT AFFILIATE NAME]** at **[INSERT PHONE NUMBER]**.

As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to your Sales Representative, directly to Ethicon, or your National Health Authority. If you have any further questions related to this notice or if you need any additional communications, please contact your local Sales.

ATTACHMENTS:

Attachment 1: Business Reply Form (BRF)

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ATTACHMENT 1: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete this form and fax or email it to [INSERT AFFILIATE NAME] at [INSERT FAX NUMBER] or e-mail the form to [INSERT AFFILIATE EMAIL ADDRESS] within 3 business days, even if you do not have product subject to this recall to return.

If you have product subject to this recall to return, please make a photocopy of your completed Business Reply Form and enclose with your return. Thank you for your cooperation.

[Account Name]
[Account Address]

Print Name of Person Completing Business Reply Form:	Telephone Number:
Account Number: (number used to order J&J product)	Date:
Replacement Product Shipping Address (If different from above) or reference PO for replacement shipment:	
Signed*: <i>*Your signature provides confirmation that you have received and understood this notification</i> <i>Your comments are welcome.</i>	

Product Inventory – please check one

- We have **NO** inventory of product subject to this recall (removal).
 We have product subject to this recall (removal) and are returning the following products:

PRODUCT NAME/CODE	LOT NUMBER	EXPIRATION DATE	RETURNING QUANTITY (Eaches)