

URGENT: FIELD SAFETY NOTIFICATION:

8-0 Blue Twisted Silk Suture NOTIFICATION OF SHELF LIFE CHANGE

[Insert Date]

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

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

NOTIFICATION ONLY: Ethicon is notifying customers of the following information about certain product codes (listed below) of size **8-0 Blue Twisted Silk Suture**. Through routine product testing, it has been determined that certain 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.

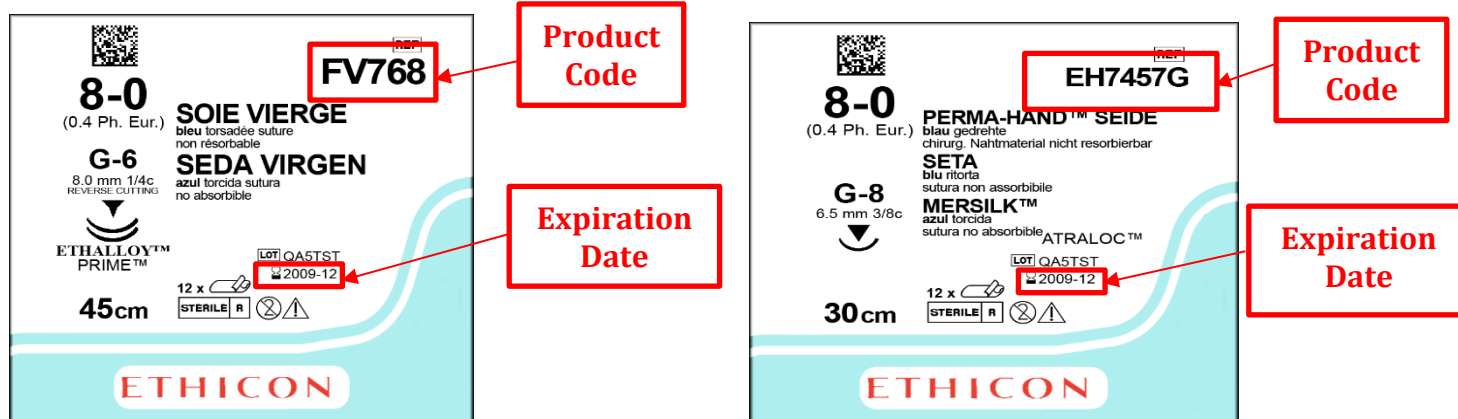
Ethicon has not received any complaints or reports of Adverse Events or Injuries related to this issue, and there is no anticipated patient safety impact. It is not recommended for physicians to provide any non-routine post-surgical care.

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 product received prior to June 2019 labeled with an expiration date of 2024-06-30 or earlier is affected by this Field Safety Notification. Any product received moving forward from this Field Safety Notification will be labeled with a 3-year expiration date and not affected by this Field Safety Notification.

NO OTHER SUTURE CODES ARE IMPACTED AND WE ARE NOT REQUESTING PRODUCT RETURN.
FRONT OF SALES UNIT CARTON (Representative Sample)



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8-0 Blue Twisted Silk Suture

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	
	KKQ351	
	LAH173	

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PRODUCT CODE	PRODUCT LOT	PRODUCT DESCRIPTION
	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	
	KEH438	
	KEH483	
	KJH266	
	KJH284	

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PRODUCT CODE	PRODUCT LOT	PRODUCT DESCRIPTION
	KJH948	
	KJJ285	
	KJJ336	
	KJJ971	
	KKP008	
	KKQ042	
	KKQ106	
	MEQ614	
	MJH320	
	MLA210	
	MMH143	
W1820	KCB768	VIRGIN SILK BLU 18IN(45CM) USP8-0(M0.4) D/A TG140-8
	KDE561	
	KDE646	
	KDH112	
	KDH113	
	KDH114	
	KDH204	
	KDH205	
	KDH330	
	KDH361	
	KDH362	
	KGJ025	
	LBH039	
	MAB866	
	MGQ557	
	MHB435	
	MHB476	
	MHH396	
	MJH936	
	MKH098	
	MKH779	
	MLH064	
W818	JLJ429	VIRGIN SILK BLU 18IN(45CM) USP8-0(M0.4) D/A G-7 PRM
	JLJ813	
	JLQ137	
	JMJ111	
	JMJ541	
	JPH389	
	JPH467	
	JPH614	
	JPJ048	

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PRODUCT CODE	PRODUCT LOT	PRODUCT DESCRIPTION
	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:

1. Ethicon is requesting that you acknowledge this notification using the Business Reply Form (BRF) contained below in **Attachment 1**. Please fax or email it to **[Insert Affiliate Information]** within three (3) business days.

If you have additional questions regarding this Field Safety Notification, please contact **[INSERT AFFILIATE NAME]** at **[INSERT PHONE NUMBER]**.

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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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8-0 Blue Twisted Silk Suture

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 correction.

Please complete the following information:

We hereby acknowledge receipt of this medical device Field Safety Notification letter from Ethicon regarding 8-0 Blue Twisted Silk Suture. We have distributed this information to all staff within our facility that use the affected product and will maintain a copy of this notice with the identified product.

[Account Name]

[Account Address]

Print Name of Person Completing Business Reply Form:	Telephone Number:
Account Number: (number used to order J&J product)	Date:
Signed*: <small>* Your signature provides confirmation that you have received and understood this notification</small>	
Your comments are welcome.	