

## URGENT: FIELD SAFETY NOTIFICATION: 8-0 Blue Twisted Silk Suture (specific codes) NOTIFICATION OF SHELF LIFE CHANGE

7-June-2020

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.

**NO OTHER SUTURE CODES ARE IMPACTED AND WE ARE NOT REQUESTING PRODUCT RETURN.**

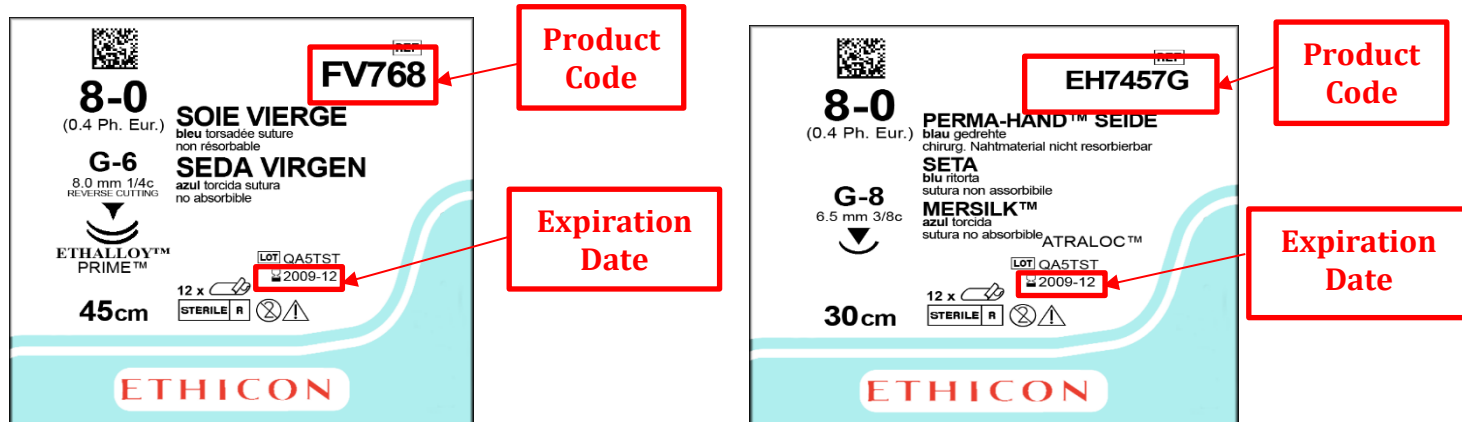
Ethicon has not received any complaints or reports of Adverse Events or Injuries related to this issue, and there is no anticipated patient safety impact. It is not recommended for physicians to provide any non-routine post-surgical care.

Ethicon wants to inform customers that future orders of 8-0 Blue Twisted Silk Suture (Specific codes only) 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 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.

### FRONT OF SALES UNIT CARTON (Representative Sample)



# URGENT: FIELD NOTIFICATION

## 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	LB6583	VIRGIN SILK BLU 45CM M0.4 USP8-0 D/ARM G-6 PRIME
	KDZ665	LBZ323	
	KGK318	MHZ265	
FV769	JKM117	LCM926	VIRGIN SILK BLU 18IN(45CM) USP8-0(M0.4) S/A G-6 PRM
	KGZ428	LJ6781	
FV7771	JK5467	LDM751	VIRGIN SILK BLU 18IN(45CM) USP8-0(M0.4) D/A TG140-8
	KG6391	LGM998	
	KGK122	MLZ444	
U7058	JJH828	KJH714	VIRGIN SILK BLU 18IN(45CM) USP8-0(M0.4) D/A CS140-6
	JJQ472	KKH186	
	JPE958	KKH414	
	JPH660	KKH422	
	JPJ413	KKJ413	
	KDB811	KKQ351	
	KDP880	LAH173	
	KEA813	LAH250	
	KED040	MLQ803	
	KEH484	MLQ983	
U7059	LMH564		VIRGIN SILK BLU 45CM M0.4 USP8-0 DBLE ARMED CS140-6
	MLH118		
W1782	JHH622	KJH581	VIRGIN SILK BLU 12IN(30CM) USP8-0(M0.4) D/A TG140-6
	JKH290	KKJ280	
	JKH291	KMH239	
	JKJ367	LBJ014	
	JMH262	LEH309	
	JMH451	LMB752	
	KCJ065	MCQ954	
	KCJ468	MEB754	
	KGH971	MKH209	
	KGJ788	-	
W1784	KHJ240		VIRGIN SILK BLU 12IN(30CM) USP8-0(M0.4) S/A TG140-6
	LMH575		
	MCH323		

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## 8-0 Blue Twisted Silk Suture

PRODUCT CODE	PRODUCT LOT		PRODUCT DESCRIPTION
W1819	JPE551	KJH266	VIRGIN SILK BLU 18IN(45CM) USP8-0(M0.4) D/A TG140-8
	JPH615	KJH284	
	JPJ120	KJH948	
	KAH393	KJJ285	
	KDB810	KJJ336	
	KDH640	KJJ971	
	KDH719	KKP008	
	KDP776	KKQ042	
	KED059	KKQ106	
	KEE862	MEQ614	
	KEH320	MJH320	
	KEH438	MLA210	
	KEH483	MMH143	
W1820	KCB768	KGJ025	VIRGIN SILK BLU 18IN(45CM) USP8-0(M0.4) D/A TG140-8
	KDE561	LBH039	
	KDE646	MAB866	
	KDH112	MGQ557	
	KDH113	MHB435	
	KDH114	MHB476	
	KDH204	MHH396	
	KDH205	MJH936	
	KDH330	MKH098	
	KDH361	MKH779	
	KDH362	MLH064	
W818	JLJ429	KKP006	VIRGIN SILK BLU 18IN(45CM) USP8-0(M0.4) D/A G-7 PRM
	JLJ813	KLH997	
	JLQ137	KPR661	
	JMJ111	LCJ238	
	JMJ541	LPB629	
	JPH389	LPH954	
	JPH467	MHB548	
	JPH614	MKH419	
	JPJ048	MKH511	
	JPJ119	MKH533	
	JPJ353	MKQ474	
	JPP592	MLH817	
	JPP795	MLJ838	
KJQ327	MMB871		
MMH381	-		
W819	MEQ276	MMH382	VIRGIN SILK BLU 30CM M0.4 USP8-0 DBLE ARM TG175-8
	MJQ277	MPJ283	

# URGENT: FIELD NOTIFICATION

## 8-0 Blue Twisted Silk Suture

PRODUCT CODE	PRODUCT LOT		PRODUCT DESCRIPTION
W870	JJP588	MCH324	VIRGIN SILK BLU 18IN(45CM) USP8-0(M0.4) S/A G-7 PRM
	KGJ148	MEJ543	
	LCJ335	-	

### 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 email it to [[RA-JnJ-MD-FSCARecall@ITS.JNJ.com](mailto:RA-JnJ-MD-FSCARecall@ITS.JNJ.com)] within three (3) business days.

If you have additional questions regarding this Field Safety Notification, please contact us on [[RA-JnJ-MD-FSCARecall@ITS.JNJ.com](mailto:RA-JnJ-MD-FSCARecall@ITS.JNJ.com)]

As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported.

### 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 [[RA-JnJ-MD-FSCARecall@ITS.JNJ.com](mailto:RA-JnJ-MD-FSCARecall@ITS.JNJ.com)] **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: <small>(number used to order J&amp;J product)</small>	Date:
Signed*:  <small>* Your signature provides confirmation that you have received and understood this notification</small>	
<i>Your comments are welcome.</i>	