

**URGENT: VOLUNTARY MEDICAL DEVICE RECALL
(REMOVAL)
5mm ENDOPATH® XCEL™ Trocars with Optiview Technology
(Product Codes 2B5LT, 2CB5LT, 2B5ST, 2CB5ST, 2B5XT)**

Date: 10 Jul 2018

Dear Operating Room Supervisors, Materials Management Personnel, and Chief of Surgery:

Our records indicate that you have ordered 5mm ENDOPATH® XCEL™ Trocars with Optiview Technology and may have received the product lots subject to this recall. **PLEASE DISTRIBUTE THIS INFORMATION TO ALL PERSONNEL RESPONSIBLE FOR 5mm ENDOPATH® XCEL™ Trocars with Optiview Technology.**

At Ethicon Endo-Surgery, LLC (“Ethicon”), our first priority is to support the needs of our customers and their patients, and that includes the safe and effective use of our products. Recently, Ethicon has become aware of reports from customers related to difficulty removing the obturator from the 5mm ENDOPATH® XCEL™ Trocars with Optiview Technology. **For that reason, we are issuing a voluntary recall of the following products with expiration dates between September 2022 through January of 2023.**

There have been no reported adverse events associated with this issue and it represents a low risk to patient health.

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE FOLLOWING 5mm ENDOPATH® XCEL™ TROCARS WITH OPTIVIEW TECHNOLOGY. THIS RECALL DOES NOT AFFECT ANY OTHER PRODUCT CODES OR LOTS WITH DIFFERENT EXPIRATION DATES.

Table1. Impacted 5mm ENDOPATH® XCEL™ Trocars with Optiview Technology Product Codes

PRODUCT NAME	PRODUCT CODE	Expiration Date Range	DESCRIPTION / SIZE
5mm ENDOPATH® XCEL™ Bladeless Trocars with Optiview Technology	2B5ST	31-OCT-2022 through 31-JAN-2023	Stability sleeve, 5mm diameter (Length 75mm)
	2B5LT	30-SEP-2022 through 31-JAN-2023	Stability sleeve, 5mm diameter (Length 100mm)
	2B5XT	30-NOV-2022 through 31-JAN-2023	Stability sleeve, 5mm diameter (Length 150mm)
5mm ENDOPATH® XCEL™ Universal Sleeve Trocars with Optiview Technology	2CB5ST	31-OCT-2022 through 31-JAN-2023	Stability sleeve, 5mm diameter (Length 75mm)
	2CB5LT	30-SEP-2022 through 31-JAN-2023	Stability sleeve, 5mm diameter (Length 100mm)

Please refer to ATTACHMENT 1 for the full list of impacted lots.

Since there is a low risk to patient health due to this issue, health care practitioners who have treated patients using the 5mm ENDOPATH® XCEL™ Trocars with Optiview Technology should follow those patients post-operatively in the usual manner with no additional action required.

Refer to Attachment 2 for assistance in identifying the product lot subject to this recall.

IDENTIFICATION OF THE PRODUCT LOT SUBJECT TO THIS RECALL:

The products subject to this recall in your inventory can be identified by product code and expiration date (See Table 1 above). The product code and expiration dates can be determined by using the Product Identification Tool within Attachment 2.

ACTION REQUIRED:

1. Examine your inventory immediately to determine if you have any products subject to this recall on hand and quarantine such product(s)
2. Remove the products subject to this recall from your inventory and communicate the issue to all relevant operating room or materials management personnel, or anyone else in your facility who needs to be informed. If any of the devices subject to this recall have been forwarded to another facility, please contact that facility to arrange return.
3. Complete the Business Reply Form (BRF) (Attachment 3) confirming receipt of this notice and return it to your Ethicon sales representative within three (3) business days. **Please return the BRF even if you do not have the product lot subject to this recall.**
4. Customers are required to return all unused 5mm ENDOPATH® XCEL™ Trocars with Optiview Technology subject to this recall that are in their inventory immediately. Only unused 5mm ENDOPATH® XCEL™ Trocars with Optiview Technology subject to this recall returned by July 30, 2018 will be eligible for replacement. Any unused 5mm ENDOPATH® XCEL™ Trocars with Optiview Technology subject to this recall returned after July 30, 2018 will not be eligible for replacement.
5. To return unused 5mm ENDOPATH® XCEL™ Trocars with Optiview Technology or kits subject to this recall, please contact your Ethicon sales representative.

If you require any assistance with returning product, subject to this recall, please contact your Ethicon sales representative.

We recognize disruption to your facility and we apologize for any inconvenience this may cause.

If you have additional questions regarding this recall or to report any customer complaints, please contact your Ethicon sales representative.



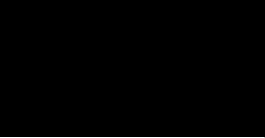
Attachments:

Attachment 1: List of impacted lots

Attachment 2: Product Identification Tool

Attachment 3: Business Reply Form

Yours sincerely,



Lee Ching Hwee
Manager, Regulatory Affairs

cc: Chairman Medical Board
Relevant Head of Departments

ATTACHMENT 1: List of Impacted Lots

Prod Code	Batch	Mfg Date	Expiration Date	Prod Code	Batch	Mfg Date	Expiration Date
2B5LT	P4T58Y	26-Oct-17	30-Sep-22	2B5LT	R4013R	12-Jan-18	31-Dec-22
	P4T59E	26-Oct-17	30-Sep-22		R40172	16-Jan-18	31-Dec-22
	P4T627	28-Oct-17	30-Sep-22		R4017C	17-Jan-18	31-Dec-22
	P4T665	1-Nov-17	30-Sep-22		R4021R	20-Jan-18	31-Dec-22
	P4T66C	1-Nov-17	30-Sep-22		R4021U	20-Jan-18	31-Dec-22
	P4T716	4-Nov-17	31-Oct-22		R4023D	23-Jan-18	31-Dec-22
	P4T71L	4-Nov-17	31-Oct-22		R40267	24-Jan-18	31-Dec-22
	P4T780	9-Nov-17	31-Oct-22		R4026E	24-Jan-18	31-Dec-22
	P4T83K	14-Nov-17	31-Oct-22		R4031V	30-Jan-18	31-Dec-22
	P4T844	14-Nov-17	31-Oct-22		R4036K	1-Feb-18	31-Dec-22
	P4T87R	16-Nov-17	31-Oct-22		R4036V	1-Feb-18	31-Dec-22
	P4T88E	16-Nov-17	31-Oct-22		R40397	6-Feb-18	31-Jan-23
	P4T88G	16-Nov-17	31-Oct-22		R4041C	6-Feb-18	31-Jan-23
	P4T88H	16-Nov-17	31-Oct-22		R4041J	6-Feb-18	31-Jan-23
	P4T927	18-Nov-17	31-Oct-22		R4044A	8-Feb-18	31-Jan-23
	P4T942	21-Nov-17	31-Oct-22		R4044K	8-Feb-18	31-Jan-23
	P4T946	21-Nov-17	31-Oct-22		R4048E	13-Feb-18	31-Jan-23
	P4T94D	21-Nov-17	31-Oct-22	2B5ST	P4T745	7-Nov-17	31-Oct-22
	P4TA19	29-Nov-17	31-Oct-22		P4T88Y	16-Nov-17	31-Oct-22
	P4TA3V	30-Nov-17	31-Oct-22		P4T906	18-Nov-17	31-Oct-22
	P4TA4N	1-Dec-17	31-Oct-22		P4T91H	20-Nov-17	31-Oct-22
	P4TA4R	1-Dec-17	31-Oct-22		P4TA60	2-Dec-17	31-Oct-22
	P4TA9K	5-Dec-17	30-Nov-22		P4TC8M	13-Dec-17	30-Nov-22
	P4TA9R	5-Dec-17	30-Nov-22		P4TD0G	15-Dec-17	30-Nov-22
	P4TC2E	9-Dec-17	30-Nov-22		P4TD2K	21-Dec-17	30-Nov-22
	P4TC2T	8-Dec-17	30-Nov-22		R40015	3-Jan-18	31-Dec-22
	P4TC67	12-Dec-17	30-Nov-22		R4011E	11-Jan-18	31-Dec-22
	P4TC6Z	12-Dec-17	30-Nov-22		R4025E	23-Jan-18	31-Dec-22
	P4TD1M	16-Dec-17	30-Nov-22		R4035E	31-Jan-18	31-Dec-22
	R4000W	3-Jan-18	31-Dec-22		R4042Z	7-Feb-18	31-Jan-23
	R40045	4-Jan-18	31-Dec-22		R4047X	13-Feb-18	31-Jan-23
	R4004G	5-Jan-18	31-Dec-22		R4065E	28-Feb-18	31-Jan-23
R4007H	11-Jan-18	31-Dec-22					

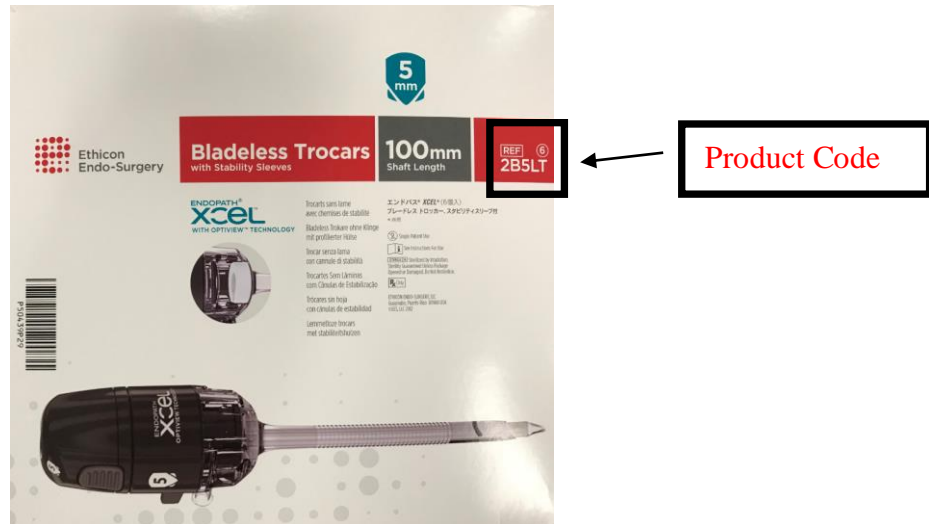
Prod Code	Batch	Mfg Date	Expiration Date
2CB5LT	P4T636	31-Oct-17	30-Sep-22
	P4T63G	31-Oct-17	30-Sep-22
	P4T689	3-Nov-17	31-Oct-22
	P4T708	8-Nov-17	31-Oct-22
	P4T86Z	15-Nov-17	31-Oct-22
	P4T882	16-Nov-17	31-Oct-22
	P4T89N	17-Nov-17	31-Oct-22
	P4T97L	27-Nov-17	31-Oct-22
	P4T994	29-Nov-17	31-Oct-22
	P4TA0T	1-Dec-17	31-Oct-22
	P4TA17	1-Dec-17	31-Oct-22
	P4TA55	1-Dec-17	31-Oct-22
	P4TA70	5-Dec-17	30-Nov-22
	P4TA7R	5-Dec-17	30-Nov-22
	P4TC53	12-Dec-17	30-Nov-22
	P4TC7X	12-Dec-17	30-Nov-22
	P4TC87	13-Dec-17	30-Nov-22
	P4TC8U	14-Dec-17	30-Nov-22
	P4TC93	14-Dec-17	30-Nov-22
	P4TD1Y	21-Dec-17	30-Nov-22
	R4003L	4-Jan-18	31-Dec-22
	R40048	5-Jan-18	31-Dec-22
	R4005Z	9-Jan-18	31-Dec-22
	R4010L	11-Jan-18	31-Dec-22
	R4012F	15-Jan-18	31-Dec-22
	R40142	15-Jan-18	31-Dec-22
	R4020P	18-Jan-18	31-Dec-22
	R4021H	20-Jan-18	31-Dec-22
	R4027N	26-Jan-18	31-Dec-22
	R4042X	7-Feb-18	31-Jan-23
	R4045N	10-Feb-18	31-Jan-23
	R4046X	13-Feb-18	31-Jan-23
	R4054H	17-Feb-18	31-Jan-23

Prod Code	Batch	Mfg Date	Expiration Date
2B5XT	P4TD1E	16-Dec-17	30-Nov-22
	R4001U	4-Jan-18	31-Dec-22
	R4052P	16-Feb-18	31-Jan-23
2CB5ST	P4T686	2-Nov-17	31-Oct-22
	P4T79A	14-Nov-17	31-Oct-22
	P4T99K	29-Nov-17	31-Oct-22
	P4TC30	11-Dec-17	30-Nov-22
	P4TD2D	20-Dec-17	30-Nov-22
	R40191	18-Jan-18	31-Dec-22
	R40223	23-Jan-18	31-Dec-22
	R4045J	9-Feb-18	31-Jan-23
	R4054D	17-Feb-18	31-Jan-23
	R40642	1-Mar-18	31-Jan-23

ATTACHMENT 2: Product Identification Tool for 5mm ENDOPATH® XCEL™ Trocars with Optiview Technology (See Attachment 1 for affected product codes and lots.)

This tool will help customers identify the product lot of 5mm ENDOPATH® XCEL™ Trocars with Optiview Technology subject to this recall. Please refer to the table above for the product expiration dates subject to this recall.

SALES UNIT / DISPENSER CARTON (CONTAINING SIX (6) Trocars)



TOP OF SALES UNIT (WITH LOT AND EXPIRY DATE)



TYVEK POUCH (CONTAINING ONE (1) TROCAR)



ATTACHMENT 3: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete and fax this form to your Ethicon sales representative **within 3 business days, even if you do not have the 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.

Product Inventory – Please check one:

- We have **NO** remaining 5mm ENDOPATH® XCEL™ Trocars with Optiview Technology subject to this recall.

- We have 5mm ENDOPATH® XCEL™ Trocars with Optiview Technology subject to this recall and are returning the following products (Expiration Dates between September 2022 and January 2023):

PRODUCT CODE	LOT # ¹	Quantity Returning (Eaches)

PRODUCT CODE	LOT # ¹	Quantity Returning (Eaches)

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):	
Signed*:	
<i>*Your signature provides confirmation that you have received and understood this notification</i>	
<i>Your comments are welcome.</i>	