ETHICON

PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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

26/03/2018

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	2022-10-31 through 2023-01-31	Stability sleeve, 5mm diameter (Length 75mm)
	2B5LT	2022-09-30 through 2023-01-31	Stability sleeve, 5mm diameter (Length 100mm)
	2B5XT	2022-11-30 through 2023-01-31	Stability sleeve, 5mm diameter (Length 150mm)
5mm ENDOPATH® XCEL™ Universal Sleeve Trocars with Optiview Technology	2CB5ST	2022-10-31 through 2023-01-31	Stability sleeve, 5mm diameter (Length 75mm)
	2CB5LT	2022-09-30 through 2023-01-31	Stability sleeve, 5mm diameter (Length 100mm)

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Table 2 has kit codes and lot numbers that contained trocars subject to this recall.

Table 2. Kit Codes with Trocars Lots Subject to this notification

Kit Code	Kit Lot Number
LSR278	10064703
LSR278	10064715
LSR278	10064728
LSR278	10064749

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 1 for assistance in identifying the product lot subject to this recall.

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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 1. Kit codes and lots that contain trocars subject to this recall can be found in Table 2 above.

ACTION REQUIRED:

1. Examine your inventory immediately to determine if you have any products or kits subject to this recall on hand and quarantine such product(s)

2. Remove the products or kits 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 2) confirming receipt of this notice and fax or email it to MDFieldActionsUKIRL@its.jnj.com, 0113 307 1803 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 or kits subject to this recall that are in their inventory immediately. If you would like a replacement, a sales order would need to be placed with our customer service team seperately. A credit will be issued for all items returned.

5. To return unused 5mm ENDOPATH® XCEL™ Trocars with Optiview Technology or kits subject to this recall photocopy the completed BRF, place it in the box with the subject product(s), and contact the below email address to arrange the collection of the item.

If you require any assistance with returning product, subject to this recall, please contact MDFieldActionsUKIRL@its.jnj.com. Our business hours are Monday through Friday 9am until 5pm We recognize disruptive 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 MDFieldActionsUKIRL@its.jnj.com

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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 the FDA's MedWatch Adverse Event Reporting program online, by regular mail or by fax:

• Online: https://www.fda.gov/Safety/MedWatch/default.htm

• Regular Mail:
Use postage-paid FDA form 3500 available at: https://www.fda.gov/Safety/MedWatch/default.htm
Mail to: MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787

• Fax: 1-800-FDA-0178

Attachments:
Attachment 1: Product Identification Tool
Attachment 2: Business Reply Form

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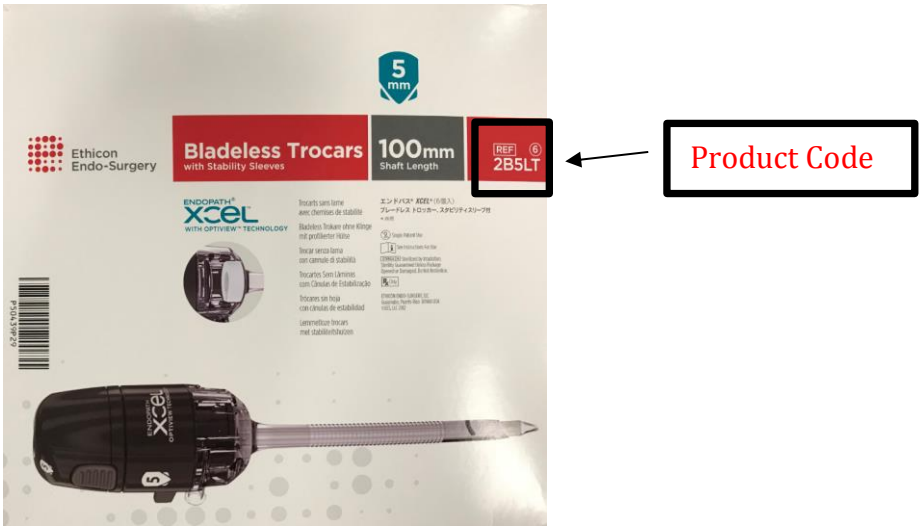
ATTACHMENT 1: Product Identification Tool for 5mm ENDOPATH® XCEL™ Trocars with Optiview Technology (See Table 1 for affected product codes and lots.)

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)

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TYVEK POUCH (CONTAINING ONE (1) TROCAR)

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ATTACHMENT 2: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete and fax/email this form to MDFieldActionsUKIRL@its.jnj.com, 0113 307 1808 **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 or kits subject to this recall.**

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

PRODUCT NAME	PRODUCT CODE	LOT #[1]	Quantity Returning (Eaches)
5mm ENDOPATH® XCEL™ Bladeless Trocars with Optiview Technology	2B5ST		
	2B5LT		
	2B5XT		
5mm ENDOPATH® XCEL™ Universal Sleeve Trocars with Optiview Technology	2CB5ST		
	2CB5LT		

Note[1]: Please include lot number and not expiration date when completing this table.

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Kit Code	Kit Lot Number	Quantity Returning (Eaches)

Print Name of Person Completing Business Reply Form:	Telephone Number:
Email Address:	Date:
Hospital Name & Address:	
Signed*: **Your signature provides confirmation that you have received and understood this notification*	
Your comments are welcome.	