



Edwards

URGENT FIELD SAFETY NOTICE

FCA #177

Product: EndoReturn Kits

Model Number: ER21B

Lot Number: 129488

UDI Code: 00690103191400

MEDICAL DEVICE RECALL

[MON DD, YYYY]

To: <<Customer Number>>
<<Customer Name>>
<<Customer Address>>
<<Customer City, State, Postal Code>>
<<Customer Country>>

Attention: Risk Management Department

Dear Valued Customer:

As a part of our commitment to quality, Edwards Lifesciences is always monitoring our products closely. Through a single complaint, we recently discovered an issue with the expiration date labeling for one manufacturing lot of our EndoReturn kits.

The purpose of this letter is to advise you that Edwards Lifesciences is voluntarily recalling a single lot of EndoReturn Kits, an arterial cannula kit that includes a wire-reinforced cannula, an introducer, a guidewire and a connector hub.

Description of the problem:

The affected kits are labeled with an expiration date of 14 August 2023, however the correct expiration date is 4 April 2023.



Figure 1
Example of where to find the EndoReturn Kit Label Lot Number and Expiration Date

The expiration date on the external kit box is the only information impacted. All other information is correct. While the expiration date on the kit box is incorrect, all items in the kit with expiration dates are correctly labeled. Therefore, the error is easily detectable before the product is used if the expiration dates for each component are verified prior to use.

Advise on action to be taken by the user:

Our records indicate that this product was shipped to your facility. **There is no expected patient safety impact at this time as the product is within valid shelf life until 4 April 2023.**

We request that you return all unused product in your inventory with the model and lot number referenced at the top of this letter. Please contact Customer service at X-XXX-XXX-XXX, or via email: XXXX@edwards.com to request a return kit. Please review your inventory and quarantine any affected product until prepared for return to Edwards Lifesciences.

Please follow the instructions included in the enclosed acknowledgement form and **return within 5 days of receipt of this notification.**



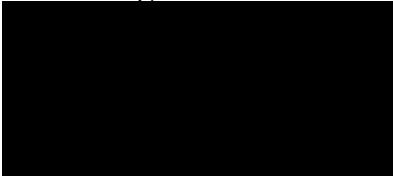
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This notice needs to be passed on to all individuals within your organization who need to be aware of this correction. Please transfer this notice to other organizations if the impacted product has been transferred or distributed to other facilities.

Your assistance is appreciated and necessary to ensure that this notice is reviewed and understood. This Field Corrective Action has been communicated by Edwards to the applicable Competent Authorities.

Edwards Lifesciences apologizes for the inconvenience caused by this action and we appreciate your attention to this matter. If you have any questions, please contact Edwards Customer Service at X-XXX-XXX-XXXX or via email: XXXX@edwards.com.

Sincerely,



Senior Director, Quality
Edwards Lifesciences



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CUSTOMER ACKNOWLEDGEMENT FORM for FCA-177

[MON DD, YYYY]

<<Customer Number>>

<<Customer Name>>

<<Customer Address>>

<<Customer City, State, Postal Code>>

<<Customer Country>>

Reason for Action: Incorrect expiration date on EndoReturn Kits Model ER21B

This letter is being returned to confirm that we understand the information in the letter sent to us regarding the EndoReturn Kits Model ER21B with the incorrect expiration date on the outer label for lot number 129488.

Customer Instruction:

- Review your inventory and quarantine any affected product until it is prepared for return to Edwards Lifesciences.
- Distribute this notice within your organization or to any organization where the potentially affected devices have been transferred.
- Complete **ALL** sections of the table below, indicate the number of units consumed and the number of units to be returned. **All units must be accounted for.**
- If you have unused product to return, call Customer Service at X-XXX-XXX-XXXX, or email: XXXX@edwards.com to obtain a Returned Goods Authorization (RGA) number.
- Email the completed Acknowledgement Form to Edwards Customer Service at XXXX@edwards.com **within 5 days** from receipt of this notification.



CUSTOMER ACKNOWLEDGEMENT FORM for FCA-177

<<Customer Number>>
 <<Customer Name>>
 <<Customer Address>>
 <<Customer City, State, Postal Code>>
 <<Customer Country>>

Please provide status of the following affected product shipped to your facility:

Model No.	Lot No.	PO #	Quantity Shipped from EW	Number of kits consumed	Number of kits to be returned to EW
ER21B	129488	XXXXXXXX	XX		

By signing this Acknowledgment Form, I certify to have followed the instructions listed above.

Name (Print):	
Title/Dept.	
Telephone Number:	
E-mail:	
Signature:	
Date:	