URGENT FIELD SAFETY NOTICE

FCA #131

Miller Balloon (model 830515F) and Fogarty Dilation (model 830705F)
Atrioseptostomy Catheters

Lot Numbers: All lots within 15 months expiry

MEDICAL DEVICE RECALL

<MM DD, YYYY>

<Customer #>
<Contact name or Dept.>
<Firm Name>
<Attention: RISK MANAGEMENT>
<Address>
<City/state/zip>

Dear Valued Customer:

As part of our strong commitment to quality, Edwards Lifesciences continuously monitors our products throughout their lifecycle to identify and correct any potential issues. We recently identified issues with the Miller and Fogarty® atrioseptostomy catheters that were confirmed following evaluation of complaints received from customers. We ask that you complete the attached Acknowledgement Form and return to Edwards Lifesciences per the instructions on the form. The product is being voluntarily recalled by Edwards Lifesciences and the appropriate Regulatory Authorities have been notified.

Details on affected devices:

Miller catheter: The Miller balloon atrioseptostomy catheter is indicated for enlarging interatrial openings for palliation of several congenital cardiac defects to increase mixing at atrial level or to decompress a hypertensive atrial chamber.

Fogarty catheter: Fogarty dilation atrioseptostomy catheter is indicated for enlarging interatrial openings for palliation of several congenital cardiac defects to increase mixing at atrial level or to decompress a hypertensive atrial chamber.

Description of the problem and indication of product being recalled:

Edwards Lifesciences has identified a potential risk, which may occur during the use of the Miller and Fogarty atrioseptostomy catheters. While the Instructions for Use detail the preparation for use of the product, including inflation and deflation of the balloon to verify functionality, we have received reports regarding difficulty in balloon deflation after deployment, and reports of balloon fragmentation or detachment, which has the potential to lead to additional complications.

This is a voluntary recall notice regarding these products, Models 830515F and 830705F. Edwards Lifesciences is requesting the return of any existing inventory of these models. We are conducting an investigation of the issues.

At this time, we do not have an estimated date as to when replacement product will become available. Accordingly, we urge you to inquire as to the availability of similar products available from:

NuMed; please call customer service at 315-328-4491 for distributors of their Z-5 atrioseptostomy catheters.
Medtronic; please call customer service at 763-514-4000 for information on their Rashkind balloon catheters.

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

If you have any questions, please contact Edwards Technical Support or Customer Service at X-XXX-XXXX.

Sincerely,

This Urgent Field Safety Notice has been communicated by Edwards Lifesciences to the relevant competent authority.

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CUSTOMER ACKNOWLEDGEMENT

<Customer #>
<Firm Name>
<Attention: RISK MANAGEMENT>
<Address>
<City/state/zip>

Please follow all instructions below to complete the recall process.

Complete this acknowledgement form with the following information:

- Verify your inventory
- Complete all sections of the table below, indicate "0" if you have no product to return
- If you have unused product to return, call Customer Service at XXX-XXX-XXXX to obtain a Returned Good Authorization (RGA) number.
- Fax the completed form to Edwards Customer Service at XXX-XXX-XXXX within 10 days from receipt of this notification

Model	Lot Number	PO Number	Quantity Shipped From EW	Number of units to be returned	RGA Number

Name (Print): _____

Telephone Number: _____

Signature: _____

Date: _____