Edwards

URGENT FIELD SAFETY NOTICE
PRODUCT RECALL – ACTION REQUIRED
Edwards Lifesciences EMBOL-X Glide Protection System, Model codes: *EXGF24, EXGF24LL, EXGF24MM, EXGF24SS, EXGF24XL, EXGF24XS.*
Ref: # FCA-36

September 17, 2013

To: [merge customer name]
Attn: Risk Management and Department of Cardiac Surgery

Details of affected devices:
Edwards Lifesciences EMBOL-X Glide Protection System, models listed below
EXGF24, EXGF24LL, EXGF24MM, EXGF24SS, EXGF24XL, EXGF24XS.

Description of the issue
Through a complaint investigation, Edwards Lifesciences has identified a potential health risk to patients undergoing cardio pulmonary by-pass surgery when using the EMBOL-X Glide Protection System. The reported complaint involved a deformed tip of the cannula that is part of the EMBOL-X Glide Protection System, this was confirmed during product evaluation. As a result, Edwards Lifesciences is recalling all lot numbers of the EMBOL-X Glide Protection System Cannulae that have not expired. The part number with lots involved in the recall are listed below.

Model Number	Lot Number	Expiration Date (m/d/yyyy)
EXGF24	58929648	10/1/2013
EXGF24	59147843	11/1/2014
EXGF24	59176065	12/1/2014
EXGF24	59332287	9/1/2015
EXGF24	59350887	9/1/2015
EXGF24	58929685	10/1/2013
EXGF24	59108308	9/1/2014
EXGF24	59248673	4/1/2015
EXGF24	59079701	7/1/2014
EXGF24	59434428	2/1/2016
EXGF24	59140150	10/1/2014
EXGF24	59220296	3/1/2015
EXGF24LL	59192546	11/1/2013
EXGF24LL	59208534	12/1/2013
EXGF24LL	59271554	2/1/2014
EXGF24LL	59370490	5/1/2014
EXGF24LL	59469785	5/1/2014
EXGF24LL	59278297	1/1/2014
EXGF24MM	59222962	1/1/2014
EXGF24MM	59192551	10/1/2013

EXGF24MM	59322682	2/1/2014
EXGF24MM	59323262	3/1/2014
EXGF24MM	59431975	4/1/2014
EXGF24MM	59491836	9/1/2014
EXGF24SS	59208492	12/1/2013
EXGF24SS	59192554	11/1/2013
EXGF24SS	59271563	2/1/2014
EXGF24SS	59409916	4/1/2014
EXGF24SS	59463380	8/1/2014
EXGF24SS	59523723	9/1/2014
EXGF24XL	59192556	10/1/2013
EXGF24XL	59208493	12/1/2013
EXGF24XL	59271569	2/1/2014
EXGF24XL	59342326	5/1/2014
EXGF24XL	59477823	2/1/2015
EXGF24XL	59278296	1/1/2014
EXGF24XS	59370473	8/1/2014
EXGF24XS	59222968	1/1/2014
EXGF24XS	59342292	1/1/2014

No patient injury has been reported in any of these events with the use of this device. We believe that risk of injury to patients from this issue is possible; if the defect is not noticed during preparation, when force applied to the tip during insertion or removal, it may lead to a separation and embolize.
As patient safety is our highest priority, we are voluntarily recalling all unused Edwards' cannula with the product code listed above.

Action to be taken by user:
Our records show that you received one or more lots of these affected products. Please review your entire inventory for the products listed in this letter. Please, immediately quarantine affected material at your site and ***return this product to Edwards.*** An acknowledgment form is included to assist you in the assessment of your inventory.

Once you have verified your inventory, please complete the attached acknowledgment form and fax it back to Edwards Customer Service at xxx within three days of receipt of this Field Safety Notice. The return of this form allows us to confirm that you have reviewed this notice and have taken appropriate action. Please contact Customer Service at xxx to obtain a Returned Goods Authorization number and replacement product.

Please return affected product to the following address:

Return product to:
Edwards Lifesciences
Attn:
Attention: RECALL, RGA #XXXXXX

The Customer Service organization can answer questions about when replacement EMBOL-X KITS will be available. If you have questions that have not been answered by this letter, please call Edwards Customer Service at xxx from the hours of 9:00AM - 5:00PM or contact your Edwards' sales representative concerning the recall.

Transmission of this Field Safety Notice:
This notice needs to be passed on to all those within your organization, or to any organization where the potentially affected devices have been transferred. Please transfer this notice to other organizations on which this action has an impact.

Edwards has communicated this Field Safety Notice to appropriate regulatory authorities.

We sincerely regret any inconvenience caused by this action and appreciate your immediate attention to this matter.

Sincerely,

Attachments:
Recall response form

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Ship to Number (column B)
«Ship_to_Name» (column D)
Attention: Director O.R./Department Cardiac Surgery
«Add_1», «Add_2»
«City», «State»
«Zip», «Country»

Please call xxx to request an RGA number and if you have any questions.

Please complete the information below and Fax the completed form to xxx,
Attn: Recall Coordinator

Note: Please indicate "NONE" if you do not have any inventory to return.

ModelNumber	Lot Number	Qty shipped from EW	Date shipped from EW	Number of units to be returned	Number of units used or discarded

RGA Number: _____

Hospital / Location: _____

Name Printed: _____

Contact Info./Tel. No/Fax/Email: _____

Signature: _____ Date: _____