Edwards

URGENT – PRODUCT RECALL – ACTION REQUIRED

Fem-Flex II™ Femoral Arterial Cannula
Sizes 8, 10, 12 French

26 March 2015

Attn: Risk Management
cc: Department of Cardiac Surgery

Re: FCA-057: Fem-Flex II™ Femoral Arterial Cannula sizes 8, 10, 12 French, Potential for Released Wire

Dear valued customer,

This is to inform you of a product recall involving Fem-Flex II™ Femoral Arterial Cannula sizes 8, 10, 12 French.

Through post market surveillance, Edwards Lifesciences has identified a potential health risk to patients regarding the use of Fem-Flex II Femoral Arterial Cannula, sizes 8, 10, and 12 French only. Edwards has received one customer complaint regarding a released wire, located at the tip area of the cannula (see Figure 1), which was identified prior to use.

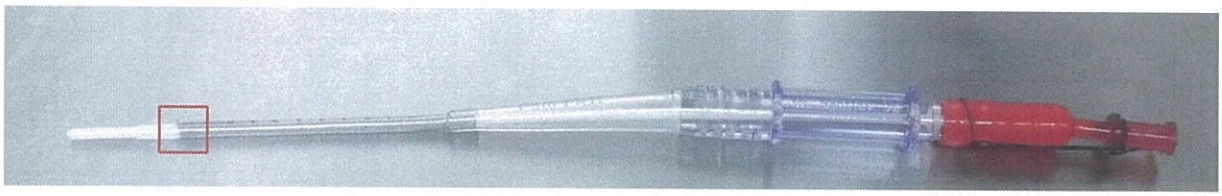

Figure 1

Although the condition does not affect the functionality of the cannula, there is potential patient safety risk if a protruding wire is not detected prior to use. While there have been no reports of injury associated with this, we are taking this action to eliminate the chance of tissue damage caused by a protruding wire.

Edwards has identified the following potentially affected lots:

[redacted]

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Product Code	Lot Number	Expiration Date
FEMII008A	59751073	5/1/2017
FEMII008A	59775775	5/1/2017
FEMII008A	59775776	5/1/2017
FEMII008A	59775777	5/1/2017
FEMII008A	59852930	8/1/2017
FEMII008AT	59807985	7/1/2017
FEMII008AT	59867050	9/1/2017
FEMII008AT	59873263	11/1/2017
FEMII008V	59873250	9/1/2017
FEMII008V	59873251	10/1/2017
FEMII010A	59740468	5/1/2017
FEMII010A	59773806	5/1/2017
FEMII010A	59792415	5/1/2017
FEMII010A	59792416	5/1/2017
FEMII010A	59852934	8/1/2017
FEMII010AT	59747819	5/1/2017
FEMII010AT	59807986	6/1/2017
FEMII010AT	59852935	8/1/2017
FEMII010AT	59890916	11/1/2017
FEMII010AT	59896910	11/1/2017

Product Code	Lot Number	Expiration Date
FEMII010V	59751074	5/1/2017
FEMII010V	59849119	8/1/2017
FEMII010V	59890924	11/1/2017
FEMII012A	59801792	8/1/2017
FEMII012A	59867064	9/1/2017
FEMII012A	59884766	11/1/2017
FEMII012A	59884778	11/1/2017
FEMII012AT	59852940	8/1/2017
FEMII012AT	59867051	9/1/2017
FEMII012V	59723307	5/1/2017
FEMII012V	59796683	6/1/2017
FEMII012V	59849124	8/1/2017
FEMII012V	59873252	11/1/2017

Customer Action Required:
Our records show that you received one or more lots of affected product. Please review your entire inventory for the lots listed in this recall letter. An acknowledgment form is included to assist you in the assessment of your inventory. This form has been pre-populated with the inventory from our records. If you have additional inventory within your control, please add the lot number and quantity to the section on the form provided.

Once you have verified your inventory, please complete the attached acknowledgment form and fax it back to Edwards Customer Service at 800.422.9329 **within three days of receipt** of this Product Recall. 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 800.424.3278 to obtain a Returned Goods Authorization (RGA) number and to obtain credit.

[redacted]

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Please return affected product to the following address:

Edwards Lifesciences
Attn: Cirilo Chaparro
12050 Lone Peak Drive
Draper, UT 84020
Attention: RECALL, RGA #XXX

If you have questions that have not been answered by this letter, please call Edwards Customer Service at 800.424.3278 from the hours of 6:00AM - 4:30PM PST or contact your Edwards' sales representative concerning the recall.

Transmission of this Product Recall:
Please transfer this notice to other organizations if the affected devices have been transferred to any another facilities.

Edwards has communicated this Product Recall to appropriate regulatory authorities. Please also complete and return the enclosed Confirmation Form.

We apologize for the inconvenience caused by this action and appreciate your attention to this matter. If you have questions that have not been answered by this letter, please call Edwards Customer Service at (800) 268-3993 from 8:00AM – 4:30PM Eastern Time.

Sincerely,

Sherri Robbins
Director Compliance

[redacted]

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Fem-Flex II™ Femoral Arterial Cannula
Sizes 8, 10, 12 French

FCA-057

Ship to Number
«Ship_to_Name»
Attention: Risk Management /Department Cardiac Surgery
«Add_1», «Add_2»
«City», «State»
«Zip», «Country»

Please call 800-424-3278 to request an RGA number and if you have any questions. Please complete the information below and Fax the completed form to 800-422-9329, Attn: Recall Coordinator

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

Part Number	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 (Print): _____

Name (Print): _____

Title and Department: _____

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

Signature: _____ Date: _____

Please return this form via fax to Edwards Customer Service: 800.422.9329

[redacted]