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URGENT MEDICAL DEVICE SAFETY NOTICE

THIN-FLEX VENOUS CANNULA- TF292902A

Reference : FCA-73

November xx, 2015

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

Attn: Risk Management
cc: Department of Cardiac Surgery

Re: THIN-FLEX VENOUS CANNULA- TF292902A

Dear Valued Customer,

This notice is provided to inform you of a potential safety risk involving the connector size published in Edwards Lifesciences product catalog for the THIN-FLEX VENOUS CANNULA, Model TF292902A.

The connector size for this product is described incorrectly in the product guide as 3/8 inch. The correct connector size is 1/2 inch. The product guide is the only labeling that includes the connector size for this device. A delay in procedure can occur if the correct connector size is unavailable.

16 inch (40 cm) overall length

3/8 inch non-vented connector

TF292902A	29/29/29 Fr. (9.6/9.6/9.6 mm)

Affected Product
All TF292902A lots with a valid shelf life are affected by the product guide error. Actual product is acceptable for use and is not being recalled as part of this field action.

Edwards Lifesciences LLC
One Edwards Way • Irvine, CA USA 92614
Phone: 949.250.2500 • Fax: 949.250.2525 • www.edwards.com

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Customer Instructions

1. Review this field safety notice to understand the potential hazard.
2. Meet and review with appropriate clinical staff at your hospital.
3. Complete and return the acknowledgement form attached to this letter via fax to xxxxx within xx business days of receiving this notice.
4. Distribute this notice within your organization or to any organization where the potentially affected devices have been transferred.
5. Product return is not required. Actual product is acceptable for use and is not being recalled as part of this field action.

Your assistance is appreciated and necessary to ensure that this notice is reviewed and understood.

We appreciate your attention, and apologize for the inconvenience caused by this matter. If you have questions that have not been answered by this letter, please call Edwards Customer Service Monday through Friday at xxxxxx from xxx AM – xxxx PM

Sincerely,

Sherri Robbins
Director, Quality
Edwards Lifesciences

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

Reason for Action: **THIN-FLEX VENOUS CANNULA- TF292902A**

This letter is being returned to confirm that we understand the information in the letter sent to us on November xx, 2015 for the TF292902A product guide error. We have shared this information with all appropriate clinical staff at our site. We have also made the information available to personnel that may be using these devices as part of continuing communication and training.

Hospital / Location: _____

Printed Name: _____

Telephone _____ Fax _____ Email: _____

Signature: _____ Date: _____

Please fax this letter to the attention of:

Customer Service
Edwards Lifesciences
xxxxxxxxx
xxxxxxxxx
Fax: xxxxxxx

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