URGENT FIELD SAFETY NOTICE

FCA # 132

Product: Intro-Flex Introducers

Model Number: I355BF9

Lot Numbers: 61409005, 61409006, 61417169, 61446317, 61446318, 61446332, 61446333, 61468596, 61481228, 61481229, 61481230 and 61494718.

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, we continuously monitor our products throughout their life cycle to quickly identify and correct any potential issues. We've recently became aware of an issue with several lots of IntroFlex Introducers in which the nylon disc is out of specification. The product is being voluntarily recalled by Edwards and the appropriate Regulatory Authorities have been notified.

Details on affected devices and indication of product being recalled:

IntroFlex polyurethane percutaneous sheath introducers are indicated for use in patients requiring access of the venous system or to facilitate catheter insertion (e.g. pulmonary artery or infusion catheter).

Description of the problem:

This non-conformance involves the IntroFlex Introducer in which the nylon disc is out of specification. The nylon disk was too small and therefore, the user was unable to pass the dilator through the introducer. The nylon disk being out of specification does not affect leakage as the nylon disk does not act as a barrier to prevent leakage. Therefore, if the dilator was unable to pass through the introducer, the device can be exchanged with a minimal delay in procedure.

We request that you complete the attached Acknowledgement Form and return to Edwards Lifesciences per the instructions on the form. Additionally, we request that you return any unused units that are currently in your inventory with the model and lot numbers referenced in the Acknowledgement Form. Once returned, replacement product will be shipped to you at no charge.

Edwards

For your convenience, we have prepopulated the attached Acknowledgement Form with the affected lots you have received. Please follow the instructions in the Acknowledgement Form to complete the recall process.

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

If you are a distributor, please ensure your customers are notified of this recall and obtain acknowledgement from each customer. Alternatively, you may provide Edwards with your customer distribution list and we will send this notification to your customers.

If you have any questions, please contact **Edwards Customer Service or Tech Support at <phone>**

Sincerely,

Miledys Santiago
Sr. Manager, Quality

URGENT MEDICAL DEVICE RECALL – ACTION REQUIRED

Field Corrective Action # 132

Product: Intro-Flex Introducers

Model Number: I355BF9

Lot Numbers: 61417169, 61321331, 61134771, 61468596, 61446318, 61446333, 61409005, 60674130, 61148614, 61263595, 61252419, 61409006, 61481229, 61446332

CUSTOMER ACKNOWLEDGEMENT

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

Please follow all instructions below to complete the acknowledgement 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 or Tech Support at XXX-XXX-XXXX to obtain a Returned Good Authorization (RGA) number.
- Fax/e-mail the completed form to Edwards Customer Service or Tech Support at XXX-XXX-XXXX within 10 days from receipt of this notification

Model	Lot Number	PO#	Ship To Date	Quantity Shipped From EW	Number of units to be returned	RGA Number

Name (Print): _____

Title/Dept. _____

Telephone Number: _____

Signature: _____

Date: _____

Please return this form to Edwards Customer Service or Tech Support at: <phone>