Edwards

URGENT FIELD SAFETY NOTICE

PRODUCT RECALL – ACTION REQUIRED

Intro-Flex Automatic Hemostasis Valve Introducer

Reference: FCA-86

cc: Chairman Medical Board and Head of Department

Dear Valued Customer,

As part of our strong commitment to quality, we are always monitoring our products throughout their life cycle to quickly identify and correct issues. We recently discovered an issue with a product and are initiating a recall.

Details on affected devices:
This notice is to inform you of a voluntary removal of the Intro-Flex Automatic Hemostasis Valve Introducer, consisting of model number I300F85 and lot numbers: 60377826, 60377827, 60377828, 60377829, 60385727, 60385728, 60385729, 60393697, 60393698, 60393699, 60393701, 60393702, 60393703.

Description of product:
Intro-Flex 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 recall involves an introducer sheath that was found to be out of specification. If the sheath inner diameter is too small, the clinician may have difficulty in inserting the dilator or catheter into the introducer. This may cause a procedural delay as the clinician would need to change out the device over a guidewire with a minimal delay in treatment.

Advice on action to be taken by the user:
We request that you return all product that is currently in your inventory with the model and lot numbers referenced above. For your convenience, we have pre-populated the attached acknowledgment form with the affected lots you received. Please follow the instructions in the attached acknowledgment form to complete the recall process.

Transmission of this Field Safety Notice:
This notice needs to be passed on all those who need to be aware within your organization. Please transfer this notice to other organizations if the affected devices have been transferred to any other facilities.

Your assistance is appreciated and necessary to ensure that this notice is reviewed and understood. This Field Safety Notice has been communicated by Edwards to the applicable Regulatory Authorities.

At Edwards Lifesciences, we are committed to helping you advance the care and treatment of surgical and critical care patients. This commitment extends to the products, services, and support we provide. We apologize for the inconvenience caused by this action and appreciate your attention to this matter.

If you have additional questions, please call Edwards Customer Service at: +65 83381186 or +65 98192576

Sincerely,

Sunita Das

Digitally signed by Sunita Das
DN: cn=Sunita Das, o=Edwards Lifesciences, ou=Manager Quality GISEA, email=sunita_das@edwards.com, c=IN
Reason: I am approving this document
Date: 2017.12.04 23:02:12 +05'30'

Sunita Das
Sr. Manager Quality

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URGENT FIELD SAFETY NOTICE
PRODUCT RECALL – ACTION REQUIRED
Intro-Flex Automatic Hemostasis Valve Introducer
Reference: FCA-86
Acknowledgment Form

<MM DD, YYYY>
<Customer#>
<Contact Name or Dept.>
<Firm Name>
<Attention: RISK MANAGEMENT>
<Address>>
<City/state/country/zip>

Please follow the instructions below to complete the recall process.

1. Verify your inventory
2. Call Edwards Customer Service at +65 83381186 or +65 98192576 to arrange your return, obtain a Returned Goods Authorization number (RGA#) and learn how to obtain a replacement product
3. Complete this acknowledgment form, indicate "0" if you have no inventory
4. Provide or email the completed form to Edwards Customer Service at hlimtl@singnet.com.sg, within 3 days from receipt of this notification
5. After obtaining an RGA, return the product to:

Edwards Lifesciences
Return Goods/RGA # XXXXXXX
<Address>>
<City/state/country/zip>

Product Model Number	Lot Number	Quantity Shipped From EW	UOM	Order Number	Date Shipped from EW	Number of units to be returned	RGA Number

Name (Print): _____

Telephone Number: _____

Signature: _____

Date: _____

We have notified the medical institutions/ sub-tier dealers below, and summarize the unused and used affected product in above table.

Medical institutions/ Sub-tier dealer	Contact person	Department/ Title	Contact phone	Note