Edwards

URGENT FIELD SAFETY NOTICE
PRODUCT RECALL – ACTION REQUIRED
Edwards Lifesciences QuickDraw™ Venous Cannula, Model code QD22 & QD25
(LOT # attached)
Ref: FCA-27

May 29th, 2013

To:
Arabian Health Care Supply Company
Olayan Plaza PO BOX 8772
Near Pepsi Cola Factory
Al Hasa Street
11492 Riyadh – Saudi Arabia

Attn: Risk Management
cc: Department of Cardiac Surgery

Details of Affected Device:
Edwards QuickDraw™ Venous Cannula

Description of Issue:
Through our routine post market surveillance data review, Edwards Lifesciences has identified new risks associated with specific removal techniques for the QuickDraw™ Venous Cannula product.

- 1. Scar tissue at the incision site may create resistance and increase the withdrawal forces on the cannula.
- 2. When using the percutaneous technique, separation of the cannula may occur during removal if too much compressive force is applied at the incision site. This is in addition to the resistance felt if scar tissue is present.

Edwards has received a total of six reports (2 Germany, 3 USA and 1 Singapore), of cannula separation over the last three years. Four reports involved the QD25, device when used with the percutaneous technique and occurred during the last year. There have been no reports of separation with the QD22 device or when the direct cut down approach is used.

In the reported events when this separation occurred, surgical intervention was required to remove the segment. Based on this occurrence and impact to patients, Edwards is recalling the QuickDraw™ Venous Cannula.

Cautions for these new risks are being added to the IFU for future shipments of the cannula to provide information to users about this potential risk. The caution statements being added are:

1. Placement of cannula and insertion technique must consider scar tissue in the area. Scar tissue may result in higher forces during insertion and withdrawal.
2. ***CAUTION:*** Do not apply excessive pressure to insertion site until the cannula is completely removed from the vessel.

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

Action to be taken by user:
Our records show that you have received one or more lots of these affected products. Please review your entire inventory for any QuickDraw™ Venous Cannula in your inventory that has not expired. Please quarantine affected product from your inventory and return this inventory to Edwards.

An acknowledgment form is included to assist you in the review of your inventory. Once you have verified your inventory, please complete the attached acknowledgment form and fax it back to Edwards Customer Service on +971 4 299 1025 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 Services at Bhagyalakhsmi Shekar to obtain a Returned Goods Authorization number and replacement product.

Please return affected product to the following address:

Return product to:
Edwards Lifesciences
Netherlands

The customer service organization can answer questions about when QuickDraw™ Venous Cannula will be available.

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 greatly appreciate your immediate attention to this matter. If you have any questions that have not been answered by this letter, please call your Edwards representative

Sincerely,

Momchil Blagoev
Director Regulatory Affairs EMEA
Edwards Lifesciences

Edwards

Affected lots QD25 & QD22

Model	Lot#	Model	Lot#	Model	Lot#	Model	Lot#
QD22	59067502	QD22	59296462	QD25	59140133	QD25	59233651
QD22	59074170	QD22	59299605	QD25	59142266	QD25	59246685
QD22	59081626	QD22	59315339	QD25	59145027	QD25	59246703
QD22	59083736	QD22	59320575	QD25	59158524	QD25	59255901
QD22	59091652	QD22	59334652	QD25	59158579	QD25	59268625
QD22	59094887	QD22	59356129	QD25	59163164	QD25	59284781
QD22	59114755	QD22	59365198	QD25	59184252	QD25	59287728
QD22	59117451	QD22	59365199	QD25	59191107	QD25	59296463
QD22	59134508	QD22	59384309	QD25	59201246	QD25	59299610
QD22	59149651	QD22	59390552	QD25	59207044	QD25	59313057
QD22	59154310	QD22	59394166	QD25	59214360	QD25	59320582
QD22	59201243	QD22	59394167	QD25	59214361	QD25	59320583
QD22	59222657	QD22	59421250	QD25	59216991	QD25	59334656
QD22	59233636	QD22	59448841	QD25	59222658	QD25	59344191
QD22	59233637	QD25	59062681	QD25	59222659	QD25	59352608
QD22	59246684	QD25	59069772	QD25	59097289	QD25	59356135
QD22	59246701	QD25	59073141	QD25	59101637	QD25	59374014
QD22	59255899	QD25	59077234	QD25	59106005	QD25	59414791
QD22	59255900	QD25	59079573	QD25	59110720	QD25	59425355
QD22	59269439	QD25	59085168	QD25	59122491	QD25	59437699
QD22	59284780	QD25	59085169	QD25	59126281	QD25	59437700
QD22	59287725	QD25	59131923	QD25	59448853		

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62441175
Arabian Health Care Supply Company
Attention: Director O.R./Department Cardiac Surgery
Olayan Plaza PO BOX 8772
Near Pepsi Cola Factory
Al Hasa Street
11492 Riyadh – Saudi Arabia

Re: Edwards QuickDraw™ Venous Cannula

Dear Recall Coordinator:

This letter is being returned to confirm that we understand the newly identified risks associated with the use of the QuickDraw™ Venous Cannula and have indicated product to be returned. Below are the lot numbers and quantities that we have identified for return:

Model	Lot #	Qty in Inventory	Qty Used	Qty to Be Returned
QD22	59083736	30EA		
QD22	59365199	4EA		
QD22	59390552	16EA		
QD25	59320582	15EA		

☐ There are none of the QD22 or QD25 models with shelf life remaining at the site.

Regards,

Print Name _____ Signature _____

Title _____ Date _____

e-mail address _____ Telephone number _____

Please fax this letter to the attention of:

Customer Service
Edwards Lifesciences

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