



Edwards

**URGENT FIELD SAFETY NOTICE  
PRODUCT RECALL – ACTION REQUIRED**  
Edwards Lifesciences QuickDraw™ Venous Cannula, Model code QD22 & QD25

May 14, 2013

To:  
Attn:  
cc:

**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.

- The first is that scar tissue at the incision site may create resistance and increase the withdrawal forces on the cannula.
- The second is 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 six reports of the separation of the device in the last three years on the QD25, four being within the last year. All four in the last year occurred when the percutaneous technique was used in the procedure. There were no reports of separations when the direct cut down approach was chosen or with the QD22 device. There have been over 40,000 devices used during this time period.

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.

**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 800.422.9329 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 800.424.3278 to obtain a Returned Goods Authorization number and replacement product.

Please return affected product to the following address:

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



Edwards

Return product to:  
Edwards Lifesciences  
Attn: Santosh Bhagat  
12050 Lone Peak Drive  
Draper, UT 84020  
Attention: RECALL, RGA #XXXXXX

We sincerely regret the inconvenience caused by this action and greatly appreciate your immediate attention to this matter. The customer service organization can answer questions about when QuickDraw™ Venous Cannula will be available. 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.

**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,

A handwritten signature in cursive script that reads "Suzanne Carpenter".

Suzanne Carpenter  
Sr. Director of Quality, CSS



Edwards

**URGENT FIELD SAFETY NOTICE  
PRODUCT RECALL – ACTION REQUIRED**  
Edwards Lifesciences QuickDraw™ Venous Cannula, Model Code QD22 & QD25

Re: Edwards QuickDraw™ Venous Cannula

Dear Recall Coordinator:

This letter is being returned to confirm that we understand the risks newly identified 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 to be Used	Qty to Be Returned
QD22				
QD22				
QD22				
QD25				

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  
One Edwards Way  
Irvine, CA  
Fax: 800.422.9329