

Urgent FIELD SAFETY NOTICE

Device: **Accessory Pack for ROCsafe™ with Flexible Venous Reservoir**
Reference: **FSN903 - EN**
Action: **Product Recall**

Date: 10-02-2010

Attention: Chief of Perfusion, Dept. of Cardiovascular Surgery
-or-
Director of Operating Room Services

Terumo Europe was reported the inversion of the inlet and outlet tubing lines mounted on the Flexible Venous Reservoir (FVR) of the Accessory Pack used in with minimized extra-corporeal circuit Terumo ROCsafe.

Details on affected devices:

Reference code	Description	Affected Lot Numbers
CX-ROCA	Accessory Pack for ROCsafe™ with Flexible Venous Reservoir	0909045 0911044

Description of the problem

Terumo Europe confirms the inverted assembling of the inlet/outlets caused by a specification change of the Venous Reservoir not reflected in the I technical drawing for the tubing pack assembly.

Patient hazard

Blood collected by the vent or sucker line via the left heart vent/intracardiac sucker into the FVR can contain excessive air. This air can be removed by the purge line of the FVR, mounted before the filter of the bag. Inverted inlet with the outlet will no longer allow excess air to be purged out, therefore it might be pushed through the inner FVR filter to the oxygenator.

The bubble trap mounted prior to the oxygenator and arterial filter provided downstream in the arterial line might not stop massive presence of air in unusual situations, establishing a risk of gaseous emboli.

There has been no incorrect line effectively used so far and no patient injury was reported as result of this error.



Customer instructions

- (1) Review this *Field Safety Notice*
- (2) Assure that all involved users are aware of the information in the notice.
- (3) Quarantine the accessory packs of the above listed lot numbers and indicate the number of packs on the enclosed form.
- (4) Please immediately confirm receipt of this communication by completing and faxing the attached "CUSTOMER RESPONSE FORM" to the fax number indicated on the form, even if you no longer have a device listed in this notice. We will contact you to organize the return and replacement as soon as possible.

For any questions or concerns, please contact immediately your local Terumo representative:

Organisation (to be completed by the sales or dealer)
Contact name (function)
Contact phone, mobile, email

We sincerely apologize for any inconvenience this may cause to our customers.

MV Vigilance Manager
Terumo Europe NV
Leuven, Belgium



Field Safety Notice - CUSTOMER RESPONSE FORM

Device: **Accessory Pack for ROCsafe™ with Flexible Venous Reservoir**

Date: 10-02-2010

Please complete, sign and fax this back: To: to whom telefax must be sent back
 Telefax: telefax No

Hospital Name	
City	
Country	

Please provide number of packs you have isolated at your institution in the space below, of the lots that are listed on the Field Safety Notice:

We have no Accessory pack affected by this Notice:

We have the following affected packs:

Reference	Lot Numbers affected	Number of packs isolated
CX-ROCA	0909045	
	0911044	

Please collect the isolated packs, and ship the replacement devices at the following address and contact person: (if other than below)

By completion and return of this form, I am confirming receipt, reading and acting on this Safety Notice.

Person Responding:	<i>[Please Print]</i>		
Title:		Phone Number:	
Signature:		Date:	

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Field Safety Notice - WHOLESALE RESPONSE FORM

Device: **Accessory Pack for ROCsafe™ with Flexible Venous Reservoir**

Date: 10-02-2010

Please complete, sign and fax this back: To: to whom telefax must be sent back
Telefax: telefax No

Company Name	
City	
Country	

Our records indicate that the following devices were delivered to you and are concerned by this Field Safety Notice. Please communicate it to the customers to whom you have sent these devices, obtain customer's response, proceed the return of affected devices if any for exchange with new ones that we will provide you.

Reference	Lot Number	Quantity sent	Dates
CX-ROCA	0909045	40 packs	25/09/2009
	0911044	30 packs	11/12/2009

STEP 1: Notification and reply

By completing and returning this form, I am confirming receipt, reading of this Field Safety Notice and our engagement to diligently issue it to our affected customer(s) with the Customer Response Form A, and organize and consolidate the return of pack with those in our own inventory. I will inform these actions to the local Health Authorities, if required by applicable national legislations.

Person Responding	[Please Print]		
Title		Phone Number	
Signature		Date 1	

STEP 2: Replacement request

We confirm that our customers have no more Accessory Packs affected by this Notice:

We have isolated the following affected packs for return to you:

Reference	Lot Numbers affected	Number of pack isolated
CX-ROCA	0909045	
	0911044	

Person Responding	[Please Print]		
Title		Phone Number	
Signature		Date 2	

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