

Urgent FIELD SAFETY NOTICE

Device: **Terumo® Cardiopulmonary Extracorporeal Tubing Set Modular Perfusion Blood Circuit – Pillow Valve Reverse Assembly**

Reference: **FSN 1904 2019-08**

Action: **Return or Replacement**

Attention: Chief of Perfusion; Director of Operating Room Services; Director of Biomedical Services.

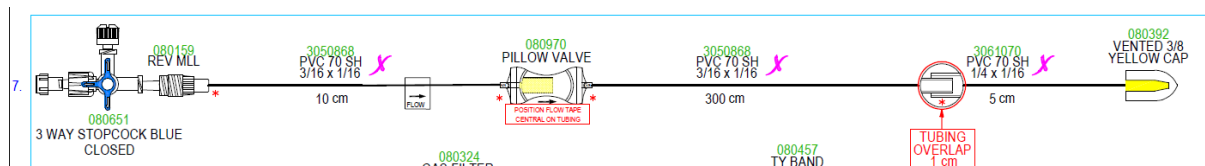
Description of the problem

Terumo Europe has received a complaint related to a pillow valve reverse assembly (see drawing below) in Terumo® Cardiopulmonary Extracorporeal Tubing Set Modular Perfusion Blood code CX-ROCFX25, lot 1901338.

Terumo Europe’s investigation could not rule out the possibility that the concerned pillow valve line in the remainder of this batch has the same issue with wrongly assembled pillow valve.

The pillow valve line is mounted by the user to the circuit and it can be supplied separately.

There is no patient harm reported, therefore, Terumo Europe is voluntarily implementing this Field Safety Corrective Action as a precautionary measure.



Details on affected devices

Product code	Description	Affected lot number
CX-ROCFX25	TUBING SET MODULAR PERFUSION CIRCUIT, PREC.FX25E	1901338

Potential hazard

With the pillow valve being assembled in the opposite direction, there is a possibility of air build-up in the bubble trap. If this issue skipped the operator’s attention, air could further built up in the bubble trap connected to the venous line, increasing the risk for air being passed into the patient circulation with possible serious consequences as a result.

Corrective action

Terumo Europe is alerting its involved customers about the issue, and is asking to immediately identify and segregate the remaining affected units in their inventory prior to sending replacement line(s) or prior to return to Terumo Europe.

Customer instructions

- 1) Review this Field Safety Notice and assure that all users are aware of this notice.
- 2) Immediately identify and segregate the units of the suspected device population.
- 3) Indicate the number of unused units from the referred code/lot on the related reply form and return this form as quickly as possible to the e-mail address or the fax number indicated on the form.
- 4) The company representative will contact you to provide replacement line(s) or to organize pick-up to Terumo Europe.

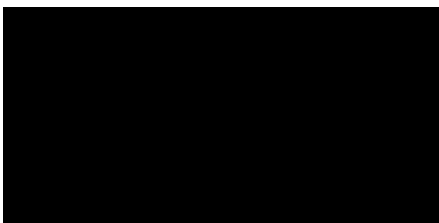
We confirm that this *Field Safety Notice* has also been notified to your national Competent Authority.

We encourage you to contact us or your local Terumo representative with any questions or concerns.

Organisation (to be completed by the sales or dealer)

Contact name (function)

Contact phone, mobile, email



Terumo Europe NV
Leuven, Belgium

Field Safety Notice - CUSTOMER REPLY FORM

Device: **Terumo® Cardiopulmonary Extracorporeal Tubing Set Modular Perfusion Blood Circuit – Pillow Valve Reverse Assembly**

Reference: **FSN 1904 2019-08**

Action: **Return or Replacement**

Please complete, sign and e-mail or fax this back:

To:

E-mail/Telefax:

Hospital/Customer Name	
City	
Country	

Our records indicate that you have received devices from the suspected lot.

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

- We have no physical inventory from the affected population.
- We have ----- unused affected units that need sending replacement for the affected lines.
- We have the following unused affected units ready to return:

Reference	Lot	Number of units ready to return
CX-ROCFX25	1901338	

Person Responding [Please Print]	
Title	
Phone Number	
Signature	
Date	

FSN1904A [EN]