Urgent FIELD SAFETY NOTICE

Device: **Terumo® Extracorporeal blood circuits, Tubing sets and Ancillary devices**
Reference: **FSN 2102 -- 2021-05**
Action: **Inspect or Return**

Attention: Chief of Perfusion; Director of Operating Room Services; Director of Biomedical Services; Risk Management

Description of the problem

Terumo Europe has received two complaints for Extracorporeal blood circuits, in which, whilst opening the packaging of the device, the perfusionist detected the outer bag was not sealed.
Further investigation into the seals determined that on a specific sealer for a defined period of time, a full weld had not been obtained between the two films, resulting in a number of units with a seal which can be peeled open if during handling the weight of the product is transferred onto the sealed end of the packaging.

There was no impact on patients as this failure was detected before use, however, Terumo Europe is conducting this voluntary Field Safety Corrective Action (FSCA) as a precautionary measure.

Details on affected devices

Product code	Product Description	Lot Numbers
CX-BE068X	NEONATE PACK WITH FX05RW IN YELLOW BIN	1905120, 1908484
CX-BE093X	TUBING SET WITH FX15RW40C IN YEL BIN	2005151, 2005317
CX-BE094X	ADULT PACK WITH FX25RWC IN YEL BIN	1903203, 1904220, 1905362, 1907097
CX-CH088X	ADULT TUBING PACK WITH FX25E & R400C	1903126, 1903442, 1904341, 2004273
CX-CH094X	ADULT PACK WITH PRECON FX15RE30C	1903224, 1904103, 1905398
CX-CH132X	ADULT PACK XCOAT WITH PRECONNECT FX25REC	1904100, 1905104, 1906111, 1908344, 2004157, 2005231, 2005305
CX-CZ095XA	ADULT SET FX25RWC PACKED IN YELLOW BIN	1904375, 1904377, 1908370, 1908371, 2004022, 2004197, 2004198, 2004211, 2004212
CX-CZ095X	ADULT SET W/ FX25RW PACKED IN YELLOW BIN	1904297
CX-CZ096X	ADULT SET W/ FX25RW PACKED IN YELLOW BIN	1908495
CX-DK098	SMALL ADULT PACK PRECON FX15RW30 YEL BIN	1903171, 1905176, 2005216
CX-GE279	TUBING SET PRECONNECTED FX25REC	1904135, 1905122, 1905211, 2003296
CX-UK484	LARGE CHILD SET WITH FX15RW30 YEL BIN	1905295

CX-UK575	ADULT PACK WITH FX25REC	1903187, 1903271, 1904262, 1905212, 1907040, 1908451, 2005330

Potential hazard

All observations from complaints and testing indicate a clearly identifiable breach of the seal.

It is highly unlikely than an open pack remains undetected during the un-packing process at the hospital; therefore, an open pack is unlikely to be used thereby excluding adverse health consequences to patients.

Corrective actions

The specific sealer was found being used for a defined period of time outside of its validated temperature range and is removed out of service.

Customer instructions

1. Review this communication and ensure that all users have received notice of this issue.
2. This notice needs to be passed on to any organization where the potentially affected products have been transferred.
3. Complete the related reply form and return this form as quickly as possible to the e-mail address indicated on the form.
4. In case, because of medical need, the option for inspection of the devices is chosen, follow the instructions in Annex.
5. Your local Terumo representative will contact you and further follow up depending on your choice for device inspection or device return.

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

Fayez Abou Hamad
MD Vigilance Expert
Terumo Europe NV –
Leuven, Belgium

Annex – instructions for seal inspection

The following instructions below are to be used to remove the tubing sets from within the yellow bins.

1. On receipt of the packs please carefully open the outer packaging.
2. Remove the cardboard interleave and any documentation.
3. Once the cardboard interleave has been removed there will be a tubing set sealed within a gas bag placed within a yellow bin as shown in image 1 below.

Image 1 – Pack when opened

4. Remove the pack carefully by grabbing the plastic insert within the Primary packaging. Place one hand either side and pull by gripping both the product (within the plastic insert) and the packaging together. It is critical that you do not remove the pack by pulling only on the packaging. Image 2 shows how the pack is to be removed.

Remove the pack by placing one hand either side and pull by gripping both the product (within the plastic insert) and the packaging together as shown in image 2.

Image 2 – How to grip packs when removing

5. Once the packs have been removed place on their side and inspect packaging. The seal on the bottom of the pack should be intact as shown in image 3 below. If the pack has been removed by pulling on the gas bag without holding the plastic insert it is possible that the seal has come open (as shown in image 4). In this case the failure of the seal will be a wide opening of 10 – 15 cm.

Image 3 – Pack as seen when removed from yellow bin

Inspection – Inspect the bottom seal on removal: it should be sealed.

In the case that the seal is open the pack is to be discarded. An example of an open seal is shown in image 4 below.

Image 4 – Example of an open seal.

Field Safety Notice - CUSTOMER REPLY FORM

Device: **Terumo® Extracorporeal blood circuits, Tubing sets and Ancillary devices**
Reference: **FSN 2102 -- 2021-05**
Action: **Inspect or Return**

Please complete, sign and e-mail this form back: To:
E-mail:

Hospital/Customer Name	
City	
Country	

Our records indicate that you have received devices from the involved device population.

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

☐ We have no physical inventory of the involved devices

☐ We will inspect the products and further use them in case not affected

☐ We will return the devices and the following devices are ready to return

Reference	Lot number	Number of units ready to return

Person Responding [Please Print]	
Title	
Phone Number	
Signature	
Date	

FSN2102A [EN]