

Urgent FIELD SAFETY NOTICE

Device: **Terumo® Advanced Perfusion System 1 = Roller Pump Tube Clamp**
 Reference: **FSN1105 2011-07 [EN]**
 Action: **Advisory**

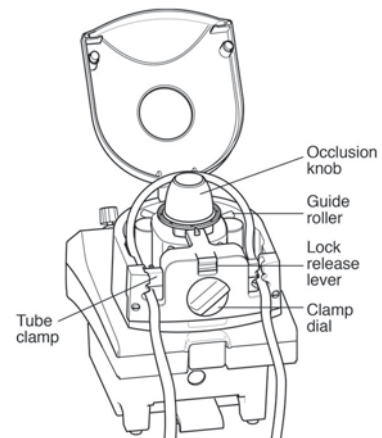
Attention: Chief of Perfusion, Department of Cardiovascular Surgery, Director of Operating Room Services

Description of the problem

Terumo Cardiovascular Systems (Terumo CVS) has received multiple reports of the lower roller pump tube clamp mechanism failing to function in a small population of devices, making it difficult to remove or insert the tubing.

If this failure occurs, the clamp dial will no longer be able to control opening/closing of the tube clamp mechanism.

In response, Terumo CVS is providing the attached addendum to the Terumo Advanced Perfusion System 1 Operators' Manual.



Details on affected devices:

Reference	Description	Lot Numbers
801764	Terumo® Advanced Perfusion System 1 Base 220-240V	0006 to 1394

Patient hazard

If a tubing clamp mechanism fails, the perfusionist needs to replace the roller pump. If this occurs during setup, it might increase the setup time. If, for any reason, the perfusionist needs to change the tubing during bypass, the user will need to replace it with backup equipment. If the pump is used as the arterial or cardioplegia pump, then the act of replacing it during bypass would result in a temporary interruption of blood flow to the patient.

There have been no reports of patient injury as a result of this issue

Corrective Action:

Terumo CVS has created an addendum to the Operators Manual for the Terumo Advanced Perfusion System 1 (provided with notice). The addendum provides additional user instructions regarding the tube clamp mechanism. Please place this addendum in front of your System 1 manual.



Please note that we are not recommending that you stop using your Terumo Advanced Perfusion System 1.

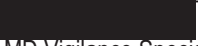
Customer instructions

- (1) Review this *Field Safety Notice*, and assure that all users are aware of this notice.
- (2) Please place the enclosed addendum in front of your System 1 Manual.
- (3) Confirm receipt of this notice, by filling and faxing the enclosed *Customer Reply Form* to the fax number indicated.

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

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


MD Vigilance Specialist
Regulatory Affairs
Terumo Europe NV
Leuven, Belgium

Field Safety Notice - CUSTOMER REPLY FORM

Device: **Terumo® Advanced Perfusion System 1 = Roller Pump Tube Clamp**

File: **FSN1105 2011-07**

Please complete, sign and fax this back:

To:

Telefax:

Hospital Name	
City	
Country	

Our records indicate that you have received one or more affected Advanced Perfusion System 1 (APS1).

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

Please tick-in the appropriate box or add if not listed

Serial Number of the BASE 801764	In Use	NO

Person Responding [Please Print]	
Title	
Phone Number	
Signature	
Date	

FSN1105A [EN]



Advanced Perfusion System 1 Roller Pump Tube Clamp

Addendum

This addendum provides additional information regarding the setup and use of the Terumo® Advanced Perfusion System 1 Roller Pump Tube Clamp. It provides directions to follow in the event of a failure of the tube clamp mechanism during setup or during an unexpected return to bypass that requires the urgent replacement of the perfusion circuit.

This additional information affects the Roller Pump chapter; Installing Tubing section page 5-5 or page 5-7.

Please insert this addendum in the front of the System 1 Operators Manual.

Confirm the Tube Clamp Functionality

1. Load tubing in the roller pump. Confirm the proper operation of the tube clamp mechanism by turning the tube clamp dial half the distance of its travel and observe the sliding movement of the upper and lower tube clamp slides on each side of the tube clamp mechanism. If the tube clamp slides retract, the tube clamp is functioning properly.
2. If the lower tube clamp slide mechanism does not retract, change out the roller pump.
3. To change out the roller pump:
 - a) Remove the tubing from the unaffected side of the tube clamp mechanism as shown in Figure a.

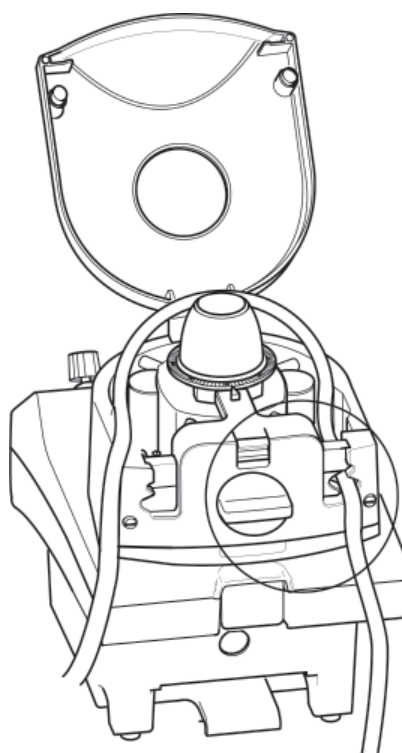


Figure a.



- b) Retract the upper tube clamp slide into the housing on the affected side by turning the tube clamp dial to open as shown in Figure b.

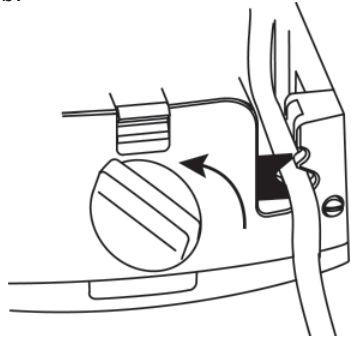


Figure b.

- c) Grasp the tubing on both sides of the broken tube clamp slide and force the tube clamp slide open toward the center of the tube clamp as shown in Figure c.

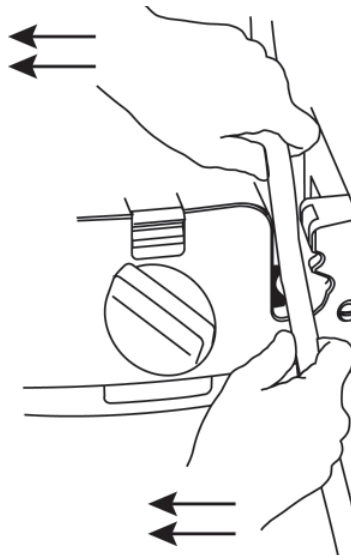


Figure c.

- d) Hold the slide open and apply an upward, twisting force to the tubing in the failed lower tube clamp slide mechanism as shown in figure d. Remove the tubing.

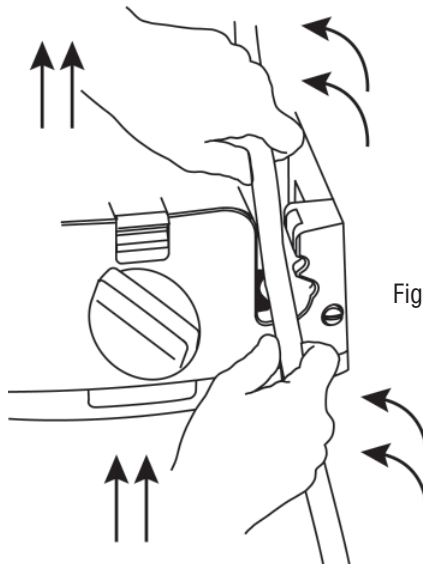



Figure d.

4. Replace and reassign the roller pump. See Emergency Procedures Chapter page 10-3 for instructions. Assure proper operation of all safety connections assigned to the roller pump.
5. Follow the same instructions if the tube clamp failure is observed during unexpected return to bypass that requires the urgent replacement of the perfusion circuit.
6. If a broken tube clamp mechanism is detected, contact your local Terumo Service Representative.



 **TERUMO CARDIOVASCULAR SYSTEMS CORPORATION**
6200 Jackson Road
Ann Arbor, Michigan 48103-9300
(734) 663-4145 or (800) 521-2818

 **Terumo Europe N.V.**
Interleuvenlaan 40
3001 Leuven, Belgium
Terumo Corporation
44-1, 2-Chome, Hatagaya, Shibuya-ku,
Tokyo 151-0072, Japan