

Safety Communication

رسالة سلامة

potential leakage in cardioplegia line

Device/ Product Description:	Customized Tubing Set with cardioplegia line “Plegiox”			
Affected Product:	Ref. No.	ITEM	LOT/Artical No.	ITEM DESCRIPTION
	P-0201	701034747	92276770	Blood Cardioplegia Set 4:1
	BO-H 81201	701050628	92273071	Small Adult Perfusion Pack
	BO-H 81201	701050628	92275696	Small Adult Perfusion Pack
	BO-H 81201	701050628	92290456	Small Adult Perfusion Pack
	BO-H 81201	701050628	92290456	Small Adult Perfusion Pack
BO-H 81201	701050628	92290957	Small Adult Perfusion Pack	
Manufacturer:	Maquet Cardiopulmonary GmbH			
Problem Summary:	A missing cable tie in the cardioplegia (Plegiox) line to secure the connection between connector and tubing next to the roller pump. A missing cable tie could lead to a leakage and/or loosening of the tube in the cardioplegia (Plegiox) line. clinical consequences such as air embolism, loss of blood volume, infection, procedure delay or user inconvenience may occur.			
Recommendation /Action:	<ul style="list-style-type: none"> - Make sure that this document, with accompanying FSNs, are reached to the end-users. - Use an affected product only with a cable tie to prevent a potential leakage. - Prime the Plegiox circuit before cardiopulmonary support and not during cardiopulmonary support. - Secure the tubing to the connector with a cable tie in the pump boot section of the Plegiox circuit to prevent a potential leakage. 			

For more information, Please click [here](#).

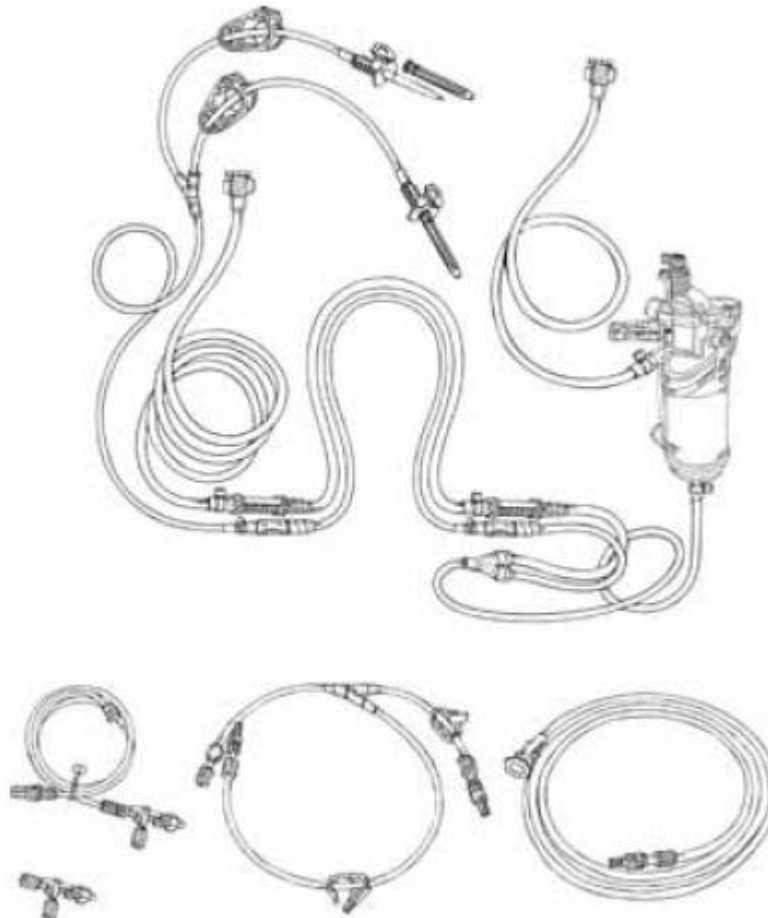
If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through:

[NCMDR](#)

[Vigilance system](#)

19999 unified call center

**Devices/Products
Photo:**



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