Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication

رسالة سلامة

Y-piece and the associated adhesive joint did not conform to specification

Device/ Product Description:	Breathing Circuits, Ventilator		
Affected Products:	 MP00333 VentStar Anesthesia (N) 180 MP00353 VentStar Basic (N) 180 MP00363 VentStar Watertrap (N) 180 MP01327 ID Circuit Basic (N) 180 MP01328 ID Circuit Watertrap (N) 180 		
Manufacturer:	Draeger Medical Systems Inc		
Problem:	The Y-pieces, due to a manufacturing error, can in some cases become disconnected at tensile forces below what is specified. If the Y-piece becomes detached from the hose during use, a leak will be caused that can hinder ventilation of the patient.		
Recommendation /Actions:	 Make sure that this document, with accompanying notice is reached to the end-users. Check the quality of the adhesive joint before use by holding the Y-piece with one hand and then pulling (not twisting) each of the two hoses one after another so that the hose just starts to stretch visibly. Use the hoses with devices that manufacturer has declared compatible in the Instructions for Use or accessories list of the basic device. Contact the authorized representative for required support, and to replace the unused stocks that were manufactured between 01.01.2018 and 13.11. 2020 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 		

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	(19999) unified call center	
Devices/Products photo:		
	AR name:	Draeger Arabia Co Ltd
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