

Safety Communication

رسالة سلامة

potential for the unintended use of the Device may harm the patient

Device/ Product Description:	Plasma filter	
Brand:	Bellco MICROPLAS	
Affected product:	Product number:	MPS05
	Batch number:	1506260017; 1506260018; 1601000199
Manufacturer:	Nikkiso Europe GmbH.	
Problem:	Inadvertent use of a plasmafilter instead of a hemofilter during renal replacement therapy could lead to significant hemodynamic compromise, which could be fatal in the acutely ill patient.	
Recommendation /Actions:	<ol style="list-style-type: none">1. Review this notice and ensure that affected personnel are aware of the contents.2. Immediately quarantine and discontinue use of the affected products.3. The manufacturer is requesting that users be observant of the differences between a plasmafilter and a hemofilter.4. Contact the authorized representative for required correction. <p>For more information, Please click here.</p> <p>If you think you had a problem with your device or a device your patient uses, please do not hesitate to report the problem to SFDA through: NCMDR Vigilance system 19999 unified call center</p>	

<p>Devices/Products photo:</p>		
<p>Authorized Representative Details</p>	<p>AR name:</p>	<p>Arabian Health Care Supply Co. (AHCSC)</p>
	<p>Assigned Contact Person:</p>	<p>Fahad Allafi</p>
	<p>Mobile/Phone:</p>	<p>0550103640</p>
	<p>Email:</p>	<p>qara.ahcsc@olayangroup.com</p>

