

## Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details			
Device Name	Transvaginal Mesh		
Device information	Manufacturer	Models	
	<b>Boston Scientific</b>	Advantage Single Handle Kit (UPN M0068502000).	
		Advantage Fit – single (UPN M0068502110).	
		Advantage Fit - 5 pack (UPN M0068502111).	
		Lynx Suprapubic Mid-Urethral Sling Sys. (UPN M0068503000);	
		Lynx Suprapubic Sling Syst 5-Pack (UPN M0068503001).	
		Obtryx Curved Single System Device (UPN M0068504000).	
		Obtryx Halo Single System Device (UPN M0068505000).	
		Obtryx Halo System 5-Pack (UPN M0068505001).	
		Obtryx II, Halo, Single unit (UPN M0068505110).	
		Obtryx II, Halo, 5 pack (UPN M0068505111).	
	<b>Coloplast devices</b>	Advantage Single Handle Kit (UPN M0068502000).	
		Advantage Fit – single (UPN M0068502110).	
		Aris (UR3010).	
		Aris kit with Aris mesh (UR3105).	
Supris kit with Aris mesh (519562).			
Aris (UR3010).			

For more information please contact [Medical\\_Devices@nhra.bh](mailto:Medical_Devices@nhra.bh)

	<b>Johnson &amp; Johnson company (Ethicon)</b>	Gynecare Prolift.
		Gynecare Prolift + M.
		Gynecare TVT Secure System.
		Gynecare Prolift.
	<b>Bard</b>	Avaulta Plus.
<b>Reference</b>	<a href="https://www.tga.gov.au/alert/tga-actions-after-review-urogynaecological-surgical-mesh-implants">https://www.tga.gov.au/alert/tga-actions-after-review-urogynaecological-surgical-mesh-implants</a>	
<b>Reason of Recall</b>	<p>NHRA initiated this FSN due to the high risks associated with the use of the above-mentioned brands of the transvaginal mesh which is used for urogynecologic procedures, including repair of pelvic organ prolapse (POP) and stress urinary incontinence (SUI). including:</p> <ul style="list-style-type: none"> <li>• Vaginal mesh erosion (also called exposure, extrusion or protrusion)</li> <li>• Pain, infection, bleeding.</li> <li>• Urinary problems and organ perforation.</li> <li>• Recurrent prolapse, neuro-muscular problems and vaginal scarring/shrinkage.</li> </ul>	
<b>Action should be taken</b>	It is strictly prohibited to import, sell and use the above-mentioned brands of the transvaginal mesh and request all healthcare facilities to report to NHRA in case of having this product.	

**Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.**

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