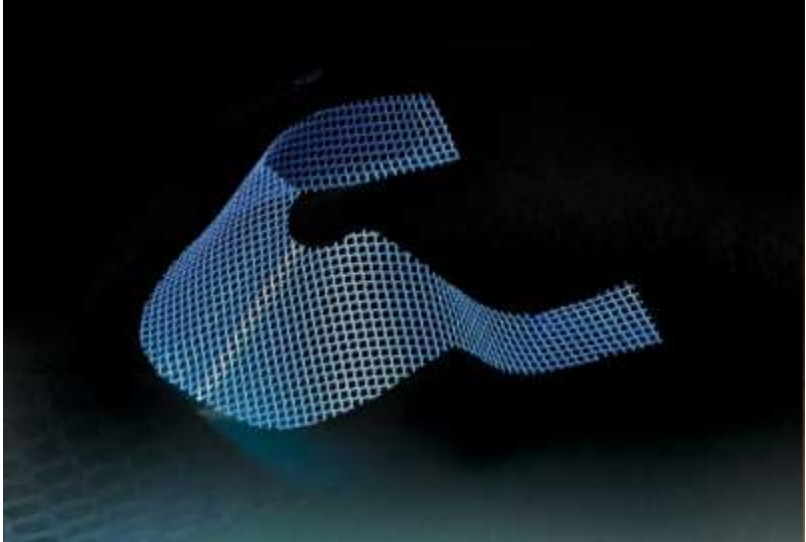


Urgent Safety Communication

Urgent Recall of (Mesh Products) Uphold LITE with Capiro SLIM and Solyx Single Incision Sling System Manufactured by Boston Scientific

Device/ Product Name:	Uphold LITE with Capiro SLIM and Solyx Single Incision Sling System , (Mesh, Surgical)
Lot numbers/Serials:	Catalogue Numbers: M0068318170 and M0068507000
Manufacturer:	Boston Scientific
Problem:	<p>Saudi FDA would like to bring to your attention that the Therapeutics Goods Administration (TGA) decided to remove two transvaginally implanted Boston Scientific mesh products from the Australian Register of Therapeutic Goods (ARTG). The TGA believes there is currently a lack of adequate scientific evidence for it to be satisfied that the risks to patients are outweighed by the benefits of these devices.</p> <p>As a result Boston Scientific is recalling all Uphold LITE with Capiro SLIM and Solyx Single Incision Sling System products from the Australian market.</p>
Recommendation/Actions:	<ul style="list-style-type: none"> • Immediately discontinue use of and segregate affected product. The devices should be stored in a secure location for return to Boston Scientific.

<p>Devices/Products photo:</p>		
<p>Authorized Representative Details</p>	<p>Company name:</p>	<p>Gulf Medical Co.</p>
	<p>Contact Person:</p>	<p>Mohamed Wael</p>
	<p>Phone:</p>	<p>+966 12 6512828</p>
	<p>Email:</p>	<p>regulatory@gulfmedical.com</p>

For further information, please **see the recall by [Click Here](#)**.

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative for corrective action.

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.

Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406, 2412
Fax: +966 (11) 2757245

For latest published Recalls/Alerts, please visit ([NCMDR Website](#))

Sincerely,
NCMDR Team