

## Safety Communication

### Increased risk of death following application of paclitaxel-coated balloons and stents

<b>Device/ Product Name:</b>	Paclitaxel-Coated Balloons and Paclitaxel-Eluting Stents
<b>Lot numbers/Serials:</b>	Not specified
<b>Manufacturer:</b>	Not specified
<b>Problem:</b>	<p>Saudi FDA would like to bring to your attention that the treatment of Peripheral Arterial Disease with Paclitaxel-Coated Balloons and Paclitaxel-Eluting Stents potentially associated with Increased Mortality at two years and beyond in patients treated for a type of peripheral artery disease (PAD) with paclitaxel-coated balloons or paclitaxel-eluting stents compared to patients treated with control devices (non-coated balloons or bare metal stents (You can read the complete Safety Alert that includes recommendations from <a href="#">HERE</a>.</p>
<b>Recommendation/Actions:</b>	<p><b>Recommendations to Health Care Providers:</b></p> <ul style="list-style-type: none"> <li>- Continue surveillance of patients who have been treated with paclitaxel-coated balloons and paclitaxel-eluting stents per the current standard of care.</li> <li>- In clinical decision-making, discuss the risks and benefits of all available treatment options for PAD with your patients.</li> <li>- SFDA will communicate with related physicians to get more clinical data about their patients' who treated with Paclitaxel-Coated Balloons and Paclitaxel-Eluting Stents in order to do further actions if needed.</li> <li>- Report any adverse events or suspected adverse events experienced with the use of paclitaxel-coated balloons and paclitaxel-eluting stents through <a href="#">National Center for Medical Devices Reporting (NCMDR)</a> Or <a href="#">Saudi Vigilance</a> Prompt reporting of adverse events can help the SFDA identify and better understand the risks associated with medical devices.</li> </ul>

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, 2479  
Fax: +966 (11) 2757245

Or

**Saudi Vigilance**

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Sincerely,  
NCMDR Team