



نتقدم بثقة  
Moving Forward  
with Confidence



To:

**THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES**  
**Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)**  
**Director General of Engineering Affairs, MOH**  
**Director General of Royal Hospital**  
**Director General of Khoula Hospital**  
**Director General of Medical Supplies (MOH)**  
**Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)**  
**Hospital Director (Al Nahda Hospital)**  
**Hospital Director (Al Massara Hospital)**  
**The Head of Medical Services in SQU Hospital**  
**The Head of Medical Services in Royal Oman Police**  
**The Head of Medical Services in Ministry of Defence**  
**The Head of Medical Services in The Diwan**  
**The Head of Medical Services in The Sultan's Special Force**  
**The Head of Medical Services in Internal Security Services**  
**The Head of Medical Services in Petroleum Development of Oman**  
**The Head of Medical Services in LNG Oman**  
**ALL PRIVATE PHARMACIES & DRUG STORES**

After Compliments,

Please find attached our Circular No 163 dated 25/11/2024 Regarding SFDA Recall of Cordis SELUTION SLRTM 018 PTA 3.0mm X 100mm Balloon Catheters from (mfr: Cordis Corporation).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DSC
- Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information



Circular No. 163 / 2024

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23 -05-1446 H  
25 -11-2024

**Recall of Cordis SELUTION SLRTM 018 PTA 3.0mm X 100mm Balloon Catheters from Cordis Corporation.**

Source	SFDA- Saudi Food & Drug Authority. <a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/181">https://ade.sfda.gov.sa/Fsca/PublishDetails/181</a>
Product	Cordis SELUTION SLRTM 018 PTA 3.0mm X 100mm Balloon Catheters.
Manufacturer	Cordis corporation.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Item/Product Number  Lot Number: SE18030100  L92505 SE18030100  L92835 SE18030100  L93029 SE18030100  L934950
Reason	There is potential for deflation difficulty or "slow deflation" of 4 lots of SELUTION SLRTM 018 PTA 3.0mm X 100mm balloon catheters.
Action	1. Immediately check your inventory to confirm that you do not have any units from the affected lots in your possession. Identify and set aside any units from the identified lots in a manner that ensures the affected product will not be used. Check all storage and usage locations. 2. Return any affected product to the manufacturer's distributor. 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: <a href="mailto:vigilance-md@moh.gov.om">vigilance-md@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie  
Director General

