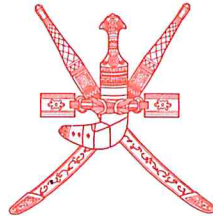


# Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs  
and Drug Control  
MUSCAT



سِلاطَنَة عُومَان  
وَزَارَة الصِّحَّة  
الطَّبِيعِيَّة وَالْعَامَّة لِلصِّدْقِ  
وَالرَّقَابَةِ الدَّوَلِيَّةِ  
مَسَقَط

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...<sup>108/19</sup> dated <sup>23/12/19</sup> regarding  
swissmedic recall of halyard closed suction system for neonates/pediatrics  
(CSC) (Mfr: avanos medical sales)

Copy to:

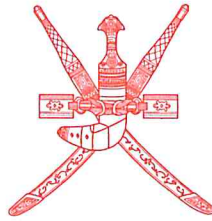
- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central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

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سلطنة عمان  
وزارة الصحة  
الديرة العامة للأدوية  
والرقابة الدوائية  
مسقط

Circular No. 108 / 2019

26 -04-1441 H

23 -12-2019

## Recall of Medical Device

### HALYARD CLOSED SUCTION SYSTEM FOR NEONATES/PEDIATRICS (CSC) Mfr: Avanos Medical Sales LLC

The Swissmedic Recall has recently issued a medical device recall in respect of the following product

**Product** : HALYARD CLOSED SUCTION SYSTEM FOR NEONATES/PEDIATRICS (CSC)  
**Manufacturer** : Avanos Medical Sales LLC  
**Reason for recall** : The central lumen of some 5 Fr Neonate/Pediatric Closed Suction Catheters may be occluded. This may cause the closed suction catheters to not suction secretions and/or saline fluids from the patient's airway to prevent oxygen desaturation. If an occlusion is present, the blockage is NOT visible to the user; however, a blockage is detectable before catheter use by testing suctioning effectiveness. The risk of the blockage to patient's health can be life threatening since catheters not able to suction out any fluids that may obstruct the airway/ET tube.

#### The Affected Products :

Product	Product No.	Catalog No.
5 Fr HALYARD Y-Adapter - Closed Suction Systems for Neonates/Pediatrics	109382303, 109838302	195, 195-5
5 Fr HALYARD Closed Suction Systems for Neonates/Pediatrics with BALLARD Technology	109382803	201
5 Fr HALYARD Elbow Closed Suction Systems for Neonates/Pediatrics	109382903	202

**Action** :

1. kindly check your stock, contact your local agent for remedial action
2. User should confirm that the potentially impacted Products can adequately suction before use on a patient.
3. If the CSC appears occluded, users should not use and immediately replace the product.

Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical Device to:-

Director of Medical Device Control  
Directorate General of Pharmaceutical Affairs & Drug Control  
Ministry of Health, PO Box 393, Muscat, PC-100  
Sultanate of Oman  
Email: dg-padc@moh.gov.om



Dr. Mohammed Hamdan Al Rubaie  
DIRECTOR GENERAL