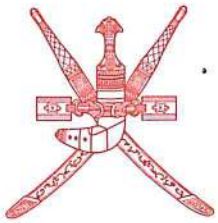
Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

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. 130/2020 **dated** 12/7/2020 **Regarding Gulf Health Council Recall of Langston Dual Lumen Catheter from (mfr: Vascular Solutions, Inc).**

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**

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

Sultanate of Oman
Ministry of Health
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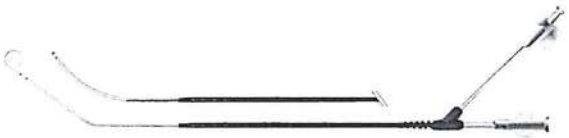
سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

Circular No. 130/ 2020

20 -11-1441 H

12 -07-2020

Recall of/ Langston Dual Lumen Catheter from Vascular Solutions Inc.

Source	Gulf Health Council
Product	Langston Dual Lumen Catheter.
Manufacturer	Vascular Solutions, Inc.
The affected products	651278 651457 651920 652097 652176 652459 652628 652777 653053 653319 653443 653565 653776 653863 654010 654190 654340 654514 654657 654889 654890 655128 655287 655460 655465 655738 655869 656191 656533 656554 656727 656801 657030 657243 657517 657627 657680 657866 658018 658151 658250 658438 658541 658671 658824 658984 659122 659217 659362 659443 659630 659855 660075 660199 660288 660397 660590 660717 660823 660910 661139 661257 661474 662824 Lots distributed between July 12, 2019 and March 10, 2020
Reason	Vascular Solutions, Inc. is recalling the Langston Dual Lumen Catheter because there is a potential the inner catheter may separate during use. If the inner catheter separates, it could cause serious health conditions including additional surgical procedures to remove the separated section, damage to the blood vessel or death. If the inner catheter separates outside of the patient's body, the dye could spray the doctor and lead to an infection that may require the doctor to receive treatment.
Action	Contact the local agent for product recall of all lots mentioned.
Product image	
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 contact E-mail Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

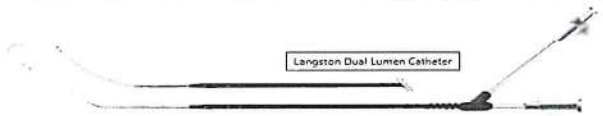
DIRECTOR GENERAL

dg-padc@moh.gov.om : البريد الإلكتروني ص . ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

مجلس الصحة
لدول مجلس التعاون
Gulf Health Council

تقارير السلامة للأجهزة والمستلزمات الطبية
Safety Alerts of Medical Device Products

To: HE / Members of the Executive Committee of the Cooperation Council States Members	إلى: سعادة/ أعضاء الهيئة التنفيذية بدول مجلس التعاون.

Subject:	تقرير سحب تشغيلات لمنتج طبي	الموضوع:
Product Name:	Langston Dual Lumen Catheter	اسم المنتج:
Company Name:	Vascular Solutions, Inc.	اسم الشركة:
Product Photo:		صورة المنتج:
Affected Devices:	651278 651457 651920 652097 652176 652459 652628 652777 653053 653319 653443 653565 653776 653863 654010 654190 654340 654514 654657 654889 654890 655128 655287 655460 655465 655738 655869 656191 656533 656554 656727 656801 657030 657243 657517 657627 657680 657866 658018 658151 658250 658438 658541 658671 658824 658984 659122 659217 659362 659443 659630 659855 660075 660199 660288 660397 660590 660717 660823 660910 661139 661257 661474 662824 Lots distributed between July 12, 2019 and March 10, 2020	الأجهزة المتضررة:
Product Reg. Status in GHC:	None	وضع المنتج في مجلس الصحة:
Source of Recall:	FDA	مصدر السحب:
Reason for Recall:	بسبب احتمالية خطر انفصال جزء من القسطرة أثناء الاستخدام مما قد يتسبب في حدوث حالات صحية خطيرة بما في ذلك الإجراءات الجراحية الإضافية لإزالة القسم المنفصل، أو تلف الأوعية الدموية أو الوفاة. في حالة انفصال القسطرة خارج جسم المريض قد يؤدي إلى رش مادة التباين أو الصبغة على الطبيب وبالتالي انتقال العدوى إليه.	سبب السحب:
Recommendation:	سحب التشغيلات المذكورة أعلاه حال توفرها لديكم.	التوصيات:
Link of Circular	رابط الخبر أضغط هنا	رابط التعميم:
For inquiries and reporting:	pms@ghc.sa	للاستفسارات والإبلاغ:

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