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



سلطنة عُـمان وزارة الـصحـة الـمديـريـة العامـة للـصيـدلـة والـرقـابـة الـدوائـيـة مسـقـط

Circular No. 23 / 2022

28 -06-1443 H

31 -01-2022

Recall of da Vinci Xi and X 12-8 mm Cannula Reducer (PN 470381-11) from Intuitive.

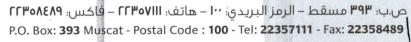
Source	GHC-Gulf Health Council.				
Product	da Vinci Xi and X 12-8 mm Cannula Reducer (PN 470381-11).				
Manufacturer	Intuitive.				
The affected products	470381-11 Cannula Reducer (Box of 6) L10210114, L10210215, L10210305, L10210514, L10210718, L10210807, L10210115, L10210216, L10210308, L10210520, L10210719, L10210808, L10210122, L10210217, L10210309, L10210521, L10210720, L10210809, L10210125, L10210218, L10210316, L10210527, L10210722, L10210812, L10210128, L10210219, L10210317, L10210528, L10210731, L10210813, L10210204, L10210225, L10210318, L10210529, L10210801, L10210819, L10210205, L10210226, L10210321, L10210715, L10210803, L10210924, L10210211, L10210301, L10210322, L10210716, L10210805, L11210111, L10210212, L10210304, L10210513, L10210717, L10210806, L11210316, M10210330, M10210408, M10210415, M10210423, M10210331, M10210409, M10210416, M10210429, M10210405, M10210412, M10210422, M10210430.				
Reason	Voluntary recall from the manufacture due to the potential for the metal tip on the da Vinci Xi and X 12-8 mm Cannula Reducer (PN 470381-11) to get dislodged from the Cannula Reducer plastic shaft. The risk to health to remove a separated tip may include a minor delay in procedure, additional surgery may be required to remove the metal tip from the patient				
Action	 Kindly take the necessary action to Locate all affected lots mentioned-above at your site and return to Intuitive. Contact the local agent for remedial action. 				
Product Picture					
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



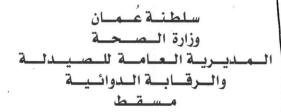






Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat







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.23/.2027. dated 31/.01. 122. Regarding GHC recall of da Vinci Xi and X 12-8 mm Cannula Reducer (PN 470381-11). from (mrf: Intuitive).

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





التاريخ الهجري 15 6 1443 18 18 18 التاريخ الميلادي 2022 18 18 18 المرفقات : 18-01-22 00°5:



تقارير السلامة للأجهزة والمستلزمات الطبية Safety Alerts of Medical Device Products

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

Subject:	تحذير سلامة لمنتج طبي da Vinci Xi and X 12-8 mm Cannula)	الموضوع:		
	(Reducer من انتاج شركة (Intuitive)			
Product Name:	da Vinci Xi and X 12-8 mm Cannula Reducer (PN 470381-11)	اسم المنتج:		
Company:	Intuitive	الشركة :		
Affected product:	470381-11 Cannula Reducer (Box of 6)	المنتجات المتأثرة:		
	L10210114, L10210215, L10210305, L10210514, L10210718, L10210807,			
	L10210115, L10210216, L10210308, L10210520, L10210719, L10210808,			
	L10210122, L10210217; L10210309, L10210521, L10210720, L10210809,			
	L10210125, L10210218, L10210316, L10210527, L10210722, L10210812,			
	L10210128, L10210219, L10210317, L10210528, L10210731, L10210813,			
	L10210204, L10210225, L10210318, L10210529, L10210801, L10210819,			
	L10210205, L10210226, L10210321, L10210715, L10210803, L10210924,			
	L10210211, L10210301, L10210322, L10:210716, L10210805, L11210111,			
	L10210212, L10210304, L10210513, L10210717, L10210806, L11210316,			
	M10210330, M10210408, M10210415, M10210423, M10210331,			
	M10210409, M10210416, M10210429, M10210405, M10210412,			
	M10210422, M10210430			
Product Photo:		صورة المنتج:		
Reg. Status in GHC:	Not registered	وضع المنتج في		
		مجلس الصحة:		
Source of Warning:	MOHAP UAE	مصدر التحذير:		
Reason for	افادة وزارة الصحة ووقاية. المجتمع أن السحب الطوعي من الشركة المصنعة			
Warning:	بسبب احتمالية انفصال الطرف المعدني الموجود على المنتج الطبي المذكور			
	أعلاه من العمود البلاستيكي. والتي قد تتسبب في تأخير في العلاج أو			
	الحاجة لإجراء عملية جراحية إضافية لإزالة الطرف المعذني من المريض.			
Recommendation:	أوصت الوزارة باتذاذ ا لإجراءات اللازمة حيال سحب التشغيلات المذكورة للمنتج	التوصيات:		
	أعلاه، في حال توفرها لديكم، واعادتها للشركة المنتجة.			
Link of Circular	رابط التعميم:			
For inquiries and reporting:	للاستفسارات والإبلاغ:			