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

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

23

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	1. Kindly take the necessary action to Locate all affected lots mentioned-above at your site and return to Intuitive. 2. 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 & DRUG CONTROL

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
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Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
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.23/2022 dated 31/01/22 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**

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المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control
ISO 9001:2015 CERTIFIED

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

التاريخ الهجري 15/6/1443
التاريخ الميلادي 18/01/2022
المرفقات
رقم 18-01-22 0078

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:	تحذير سلامة لمنتج طبي (da Vinci Xi and X 12-8 mm Cannula Reducer) من انتاج شركة (Intuitive)	**الموضوع:**
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)** 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	**المنتجات المتأثرة:**
Product Photo:		**صورة المنتج:**

Reg. Status in GHC:	Not registered	**وضع المنتج في مجلس الصحة:**
Source of Warning:	MOHAP UAE	**مصدر التحذير:**
Reason for Warning:	افادة وزارة الصحة ووقاية المجتمع أن السحب الطوعي من الشركة المصنعة 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 المعدني من المريض.	**سبب التحذير:**
Recommendation:	أوصت الوزارة باتخاذ الإجراءات اللازمة حيال سحب التشغيلات المذكورة للمنتج أعلاه، في حال توفرها لديكم، واعادتها للشركة المنتجة.	**التوصيات:**

Link of Circular	**يرجى الاطلاع على التعميم المرفق**	**رابط التعميم:**
For inquiries and reporting:	**pms@ghc.sa**	**للاستفسارات والإبلاغ:**