



بمقدم 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. 95..... dated 22/5/22. Regarding GHC recall of Dragonfly OpStar™ Imaging Catheter from (mrf: Abbott).

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



Circular No. 95 / 2022

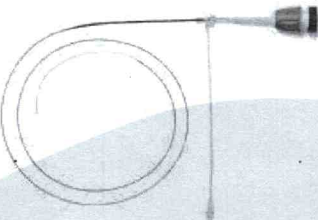
بقدرتك
Go Forward
with Confidence



23-10-1443 H

22-05-2022

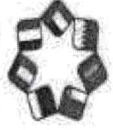
Recall of Dragonfly OpStar™ Imaging Catheter from Abbott.

Source	GHC- Gulf Health Council.
Product	Dragonfly OpStar™ Imaging Catheter.
Manufacturer	Abbott.
The Affected Products	Attached.
Local Agent	Waleed Pharmacy & Stores LLC.
Reason	The proximal marker on devices from these lots may separate from the device. A dislodged marker may require additional intervention, including unplanned additional coronary intervention, or surgery. Potential risks include embolism, cardiovascular injury and myocardial ischemia
Action	1. Immediately stop using devices from affected lots and return to the supplier 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





تقارير السلامة للأجهزة والمستلزمات الطبية
Safety Alerts of Medical Device Products

مرفق 1

Product Identifier/GTIN	Product Description	Model Number	التشغيلات المتأثرة Lot Numbers			
05415067031129	Dragonfly OpStarTM Imaging Catheter	1014651	8010027	8211505	8127934	8257085
			8147191	8127930	8220672	8131370
			8010043	8211506	8131366	8257087
			8153815	8127931	8220673	8147186
			8010047	8211507	8131367	8274128
			8153816	8127932	8220675	8147188
			8010052	8220671	8131369	8294077
05415067031112	Dragonfly OpStarTM Imaging Catheter	1014652	8111644	8211513	8185100	8220686
			8192796	8157505	8211520	8192788
			8131360	8211514	8185101	8256952
			8211508	8157506	8211521	8192789
			8131361	8211515	8192782	8256953
			8211509	8184979	8220680	8192791
			8131362	8211516	8192783	8256954
			8211510	8184980	8220681	8192793
			8131363	8211517	8192784	8274133
			8211511	8184981	8220684	8192795
			8131364	8211518	8192786	8294003
			8211512	8184982	8220685	
			8131365	8211519	8192787	



MOHAP/O/22/003018

التاريخ: 2022/04/14
المرجع: MOHAP/O/22/003018

تقارير السلامة للوسائل الطبية
FIELD SAFETY NOTICE

To : All Healthcare Facilities & Pharmaceuticals All Healthcare Professionals			إلى: جميع المنشآت الصحية والصيدلانية جميع ممارسي الرعاية الصحية						
Subject: URGENT FIELD SAFETY NOTICE			الموضوع: تقارير السلامة للوسيلة الطبية						
Product Name:	Dragonfly OpStar™ Imaging Catheter					اسم المنتج:			
Manufacturer:	Abbott					الشركة المصنعة:			
Product Identifier/GTIN	Product Description	Model Number	التشغيليات المتأثرة Lot Numbers						
05415067031129	Dragonfly OpStar™ Imaging Catheter	1014651	8010027	8211505	8127934	8257085			
			8147191	8127930	8220672	8131370			
			8010043	8211506	8131366	8257087			
			8153815	8127931	8220673	8147186			
			8010047	8211507	8131367	8274128			
			8153816	8127932	8220675	8147188			
			8010052	8220671	8131369	8294077			
05415067031112	Dragonfly OpStar™ Imaging Catheter	1014652	8111644	8211513	8185100	8220686			
			8192796	8157505	8211520	8192788			
			8131360	8211514	8185101	8256952			
			8211508	8157506	8211521	8192789			
			8131361	8211515	8192782	8256953			
			8211509	8184979	8220680	8192791			
			8131362	8211516	8192783	8256954			
			8211510	8184980	8220681	8192793			
			8131363	8211517	8192784	8274133			
			8211511	8184981	8220684	8192795			
			8131364	8211518	8192786	8294003			
			8211512	8184982	8220685				
			8131365	8211519	8192787				
			Source of Alert	Abbott					مصدر التحذير:
			Product Status in MOHAP:	For professional use		لاستخدام ممارسي الرعاية الصحية		الوضع القانوني للمنتج في الوزارة:	
Reason for Alert:	The proximal marker on devices from these lots may separate from the device. A dislodged marker may require additional intervention, including unplanned additional coronary intervention, or surgery. Potential risks include embolism, cardiovascular injury and myocardial ischemia.					سبب التحذير: قد تنفصل علامة المنتج عن الجهاز وقد يستلزم ذلك تدخلاً جراحياً إضافياً. تشمل المخاطر المحتملة الانسداد في الأوعية الدموية وإصابات في القلب ونقص تروية عضلة القلب.			
Recommendation:	Immediately stop using devices from affected lots and return to the supplier.					التوصيات: يرجى عدم استخدام التشغيليات المتأثرة وعودتها إلى المورد.			
Report adverse reaction	http://www.mohap.gov.ae/ar/services/Pages/406.aspx UAE RADR Smart Application					للإبلاغ عن الآثار الجانبية للدواء			
For All Enquiries	pv@mohap.gov.ae					لجميع الاستفسارات			
This circular is for regulatory procedures & should not be used for media publication			هذا التعميم للإجراءات التنظيمية وغير مخصص كمحتوى للنشر الإعلامي						



مع تحيات قطاع التنظيم الصحي
بوزارة الصحة ووقاية المجتمع

لمزيد من التنسيق والمتابعة نرجو منكم الإيعاز لمن يلزم للتواصل على الأرقام التالية :
هاتف: 042301667/042301443/042301523 - البريد الإلكتروني: pv@mohap.gov.ae