



ببمجرد ثقة
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. 162 dated 31/8/22 Regarding NCMDR Recall of CorVocet™ Biopsy System from (mfr: Merit Medical Systems 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



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



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Circular No. 162/2022

04 -02-1444 H

31 -08-2022

بسم الله
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Recall of CorVocet™ Biopsy System from Merit Medical Systems Inc.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=17257
Product	CorVocet™ Biopsy System.
Description	Biopsy kit, soft tissue.
Manufacturer	Merit Medical Systems Inc.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Refer to “Affected Lots” in the attached FSN.
Reason	Merit Medical has become aware of a product defect resulting from incorrect assembly. This assembly error may occur when components are misaligned due to an issue with the manufacturing assembly equipment. In rare instances, the needle may eject from incorrectly assembled CorVocet™ biopsy devices when triggered outside the body, which results in the potential for a user or patient needle stick injury.
Action	1. Return all affected lots in your possession to Merit. 2. Contact the local agent for remedial action.
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 through the E-mail: Med-device@moh.gov.om

Ph. Ahmed Saif Al Harbi
Acting Director General



Affected Lots - CorVocet™ Biopsy System

Catalog Code	Lot Number	Catalog Code	Lot Number	Catalog Code	Lot Number	Catalog Code	Lot Number	
CORA1410	I2206909	CORA1810	I2155289	CORA1815	I2325901	CORA2015	I1962715	
	I2286704		I2206046		I2349440		I2140223	
	I2291980		I2243065	CORA1815S	H1733632		I2243072	
	I2318475		I2263876		H1756747		I2283710	
CORA1410S	I2263877		H1784863		I2303054			
CORA1415	I2282032		I1869477		I2330668			
CORA1610	I2075805		I2291981	CORA1815S	I1874063	CORA2015S	H1697709	
	I2093969		I2297372		I2075806		H1771823	
	I2101330		I2385808		I2114557		H1784884	
	CORA1610S		I2124107	CORA1810S	I1877912	I2127463	CORA2020	H1795484
		I2233501	I1877916		I2325902	H1815606		
I2286703		I1902603	H1375632		I1781880			
I2325899		I1971867	H1382959		I1971845			
CORA1610S	I2138037	CORA1810S	I1998851		H1718587	CORCA1410	I2007291	
	I2352845		I2033178		H1734004		I2228365	
CORA1615	H1408433		CORA1810S		I2070341	H1739135	CORCA1410S/CNB	H1639707
	H1462686				I2075809	H1756748		I2244480
	I1863888				I2124109	H1762731		I2384730
	I2127448				I2127455	H1771773		I2259093
	I2170247			I2170248	H1771881	I2305358		
I2259080	I2370120			H1784864	H1776075			
CORA1615S	I2114518			CORA1815	H1733631	H1815597	CORCA1415	I2191846
	H1517631				H1734003	I1823060		I2286700
	H1715532	H1739133			I1971866	I2318838		
	H1756745	H1756746			I2114564	I2325906		
	H1767115	H1771770	I2137809		I2210950			
	H1771762	H1795481	I2170250		H1428538			
	H1776067	H1800980	I2303053		H1714401			
	H1784861	H1807701	I2385809		I1971855			
	H1800979	I1821113	H1739136		I1998714			
	H1808121	I1838444	H1790841		I2114620			
	H1825693	I1855417	CORA1820S	H1749790	I2170251			
	H1781878	I1920169		H1762724	I2201382			
	I1818817	I1920191	CORA1825	H1808022	I2233505			
	I1837234	I1946564		H1815598	I2318858			
	I1843704	I1952362		I1843706	I2343154			
	I1855418	I1989173		I1958504	I2291983			
	I1866359	I1990074	CORCA1610/CNB	I2234738	I1874064			
	I1952354	I2033176		I2239042	I2010416			
	I1958525	I2070349	CORA1825S	H1790845	H1703701			
	I1971876	I2075808	CORA2010	H1784872	I1845903			
I1990075	I2093995	H1815600		I1888547				
I1998862	I2114555	I1863885		I1920175				
I2043630	I2116111	I2201378		I1962716				
I2070249	I2124110	CORCA1610S	I2206047	I1998860				
I2075810	I2127456		I2237417	I2103685				
CORA1810	I2093993	CORA1815	I2137805	H1692834	CORCA1615	I2137221		
	I2114550		I2170249	H1776070		I2137223		
	I2116110		I2201366	I2010414		I2170252		
	I2124108		I2233502	H1795483		I2237426		
	I2127451		I2263885	CORA2015		I1823512	I2286696	
	I2137798		I2269827			I1860367	I2297374	

Affected Lots - CorVocet™ Biopsy System

Catalog Code	Lot Number	Catalog Code	Lot Number	Catalog Code	Lot Number
CORCA2010B	H1807725	CORCA2015B	I2094083	CORCA2020SB	I2263985
	H1815614		I2114711		I2297377
	I1821093		I2116112	CORCA2020SB/CNB	I2320880
	I1845908		I2124201		
	I1862929		I2127521		
	I1874055		I2137868		
	I1877913		I2159284		
	I1958538		I2191857		
	I1971927		I2246760		
	I1990070		I2263980		
	I2075817		I2287299		
	I2094080		I2303068		
	I2114709		I2352880		
	I2127519		I2370145		
	I2170256		H1662694		
	I2217622		H1733642		
	I2325922		H1739148		
CORCA2010SB	H1749807	CORCA2015SB	H1771853		
	I1874058		H1776087		
	I1902604		H1807729		
	I1998852		H1815615		
	I2122957		I1827270		
CORCA2015B	I2233511		I1845912		
	H1624841		I1862899		
	H1639711		I2080472		
	H1657959		I2170257		
	H1697713		I2201414		
	H1708691	CORCA2015SB/CNB	I2318903		
	H1714416		I2325926		
	H1718609	CORCA2020B	H1662697		
	H1733639		H1692861		
	H1734020		H1708693		
	H1743882		H1718613		
	H1749810		H1756755		
	H1771851		H1771854		
	H1776086		H1776088		
	H1784915		H1790855		
	H1790853		H1807731		
	H1807727		I1827272		
	I1827258		I1845913		
	I1855420		I1869475		
	I1862900		I1874065		
I1873128	I1877915				
I1874060	I1971882				
I1888545	I1990071				
I1902614	I2070361				
I1920156	I2075814				
I1952374	I2114712				
I1990072	I2151307				
I1998863	I2170259				
I2070355	I2201416				
I2080473	I2330716				