

Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	CorVocet™ Biopsy System
Device Model	attached
Lot No.	attached
Manufacturer	Merit Medical Systems Inc.
Country of Origin	USA
Reference	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=17257#:~:text=Merit%20Medical%20Systems%20Inc..pdf
Reason of Recall	NHRA initiates this FSN due to a product defect resulting from incorrect assembly. 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 should be taken	Please stop using the above mentioned medical device and contact the manufacturer to take the necessary action for recall.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh

FSCA-ref: 1721504-08/01/22-004R

12-AUG-2022

URGENT FIELD SAFETY NOTICE (FSN)

Name of Affected Products: CorVocet™ Biopsy System

Action Required: Return Devices to Merit

Merit Medical Systems, Inc. is voluntarily conducting a recall of the CorVocet™ Biopsy System due to 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. The IFU includes the following precaution: “Never test the product by firing into the air. Damage may occur to the device and could result in patient and/or user injury.”

Merit has not received any reports of user or patient harm or injury relating to this issue, however, as of the date of this letter, Merit has received five (5) related customer complaints. This recall affects 523 Merit lots and 50 Merit catalog numbers, as identified in the attached table. Please note that Merit has taken the necessary corrective actions so that all CorVocet™ biopsy product currently being shipped do not exhibit this issue.

Merit has chosen to remove the affected product from the market and requests that you immediately stop using or distributing the affected product and return it to Merit. Our records indicate you have received affected lots, as identified in the attached Customer Response Form.

Actions required of you:

1. Please immediately determine if any of the devices identified in the attached Customer Response Form (CRF) are within your facility, quarantine them, and discontinue use and distribution.
2. Ensure that applicable personnel within your organization are made aware of this field action.
3. If the product has been further distributed to other facilities, institutions, or manufacturers, please ensure this notice is immediately shared with them and note the quantity distributed on the CRF. Additional distribution details may be required by health authorities.
4. Please fill out, scan and email the completed CRF to Customer Service at: CSEEMEA@merit.com within seven (7) calendar days. All affected product shipped to you must be accounted for on the CRF.
5. Please immediately return all affected lots in your possession to Merit, per the instructions in the attached CRF.

Note, the relevant National Competent Authorities have been advised of this field safety corrective action.

If you have any questions concerning this communication, please don't hesitate to contact your Merit Sales Representative or Merit Customer Service at CSEEMEA@merit.com or by phone at 0031 – 43 3588233.

Merit Medical is committed to providing high quality products to you and apologizes for any inconvenience this field action may cause.

Enclosure(s)



Customer Response Form

Merit Medical Systems, Inc.
Merit Sales Rep: MOUSSA, SHERIF

Affected Product: CorVocet™ Biopsy System

MTE - MEDICAL TECHNOLOGY EST. Medical technology/Dar Al Zahrawi Warehouse Abu Ubaidah Ibn Al Jarrah Road - Yaffa str 4278 Yusr Riyadh 14267 Customer Number: 189119	Customer Contact:
	Title:
	Phone #:
	RMA#: 000500

Please provide status on the following:

Lot #	Part #	Qty Merit Shipped to You	Qty You Further Distributed	Qty Used	Qty Unused and Being Returned
I2127448	CORA1615/B	20			
I2170248	CORA1810S/B	10			
I2206888	CORA1410S/B	10			
I2234738	CORA1825/B	10			

Please fill out and sign this Customer Response Form and complete the following steps. Merit may contact you regarding incomplete information. It is very important that you complete these steps in order to assist Merit in complying with applicable government regulations.

1. Scan and email the completed Customer Response Form to Merit Customer Service at CSEEMEA@merit.com within seven (7) days.
2. If you are returning product, place the original completed form with the products to be returned. This form must accompany all products being returned to Merit.

Product Return Instructions

Return the affected products to Merit via UPS Standard Account 7619AE, include the assigned RMA number (see above table) on the outside of the box and ship to:

ATTN: Receiving & Customer Service
Merit Medical Systems, Inc.
Amerikalaan 42, 6199 AE
Maastricht Airport, The Netherlands
RMA# (found in contact information table)

I certify that I received and understood this notice. I certify that the above listed products have been used, distributed, or returned to Merit Medical Systems, Inc. according to the notification instructions. Furthermore, if I have further distributed product listed on this form, I certify that a copy of this notice was provided to said consignee(s).

Signature of Customer Contact

Date



Customer Response Form

Merit Medical Systems, Inc.
Merit Sales Rep: MOUSSA, SHERIF

Affected Product: CorVocet™ Biopsy System

MTE - MEDICAL TECHNOLOGY EST. 2827 SAKHR ST. EXIT 16 AL SULAY RIYADH Customer Number: 189119	Customer Contact:
	Title:
	Phone #:
	RMA#: 000501

Please provide status on the following:

Lot #	Part #	Qty Merit Shipped to You	Qty You Further Distributed	Qty Used	Qty Unused and Being Returned
H1733632	CORA1815S/A	5			
H1743881	CORCA1815SB/A	10			
H1756747	CORA1815S/A	12			
H1762715	CORCA1815SB/A	15			
H1771846	CORCA1810B/A	50			
H1784863	CORA1815S/A	8			
H1815598	CORA1825/A	5			
I1869474	CORCA1810B/B	50			
I1869477	CORA1815S/B	10			
I1874063	CORA1815S/B	5			
I1902603	CORA1810S/B	50			
I1920175	CORCA1615/B	10			
I1958533	CORCA1815B/B	20			
I1958536	CORCA1815SB/B	30			
I1998714	CORCA1610/B	5			
I2114518	CORA1615S/B	10			
I2114626	CORCA1615S/B	5			

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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	I2213361		I2282032	I1869477	I2330668			
CORA1610	I2075805		CORA1810S	I2291981	CORA1815S	I1874063	CORA2015S	H1697709
	I2093969			I2297372		I2075806		H1771823
	I2101330			I2385808	I2114557	H1784884		
	I2124107			I1877912	I2127463	H1795484		
	I2233501	I1877916		I2325902	H1815606			
	I2286703	I1902603		CORA2020	H1375632	I1781880		
I2325899	I1971867	H1382959			I1971845			
CORA1610S	I1998851	H1718587			I2007291			
CORA1615	I2138037	I2033178			H1734004	I2228365		
	I2352845	I2070341			H1739135	H1639707		
	CORA1615S	H1408433	I2075809	H1756748	I2244480			
		H1462686	I2124109	H1762731	I2384730			
		I1863888	I2127455	H1771773	CORCA1410S	I2259093		
		I2127448	I2170248	H1771881	CORCA1410S/CNB	I2305358		
I2170247	CORA1815	I2370120	CORA1820	H1784864	CORCA1415	H1776075		
I2259080		H1733631		H1815597		I2191846		
CORA1615S		H1517631		H1734003		I1823060	I2286700	
		H1715532		H1739133		I1971866	I2318838	
		H1756745		H1756746	I2114564	I2325906		
		H1767115	H1771770	I2137809	CORCA1415S	I2210950		
		H1771762	H1795481	I2170250	CORCA1610	H1428538		
		H1776067	H1800980	I2303053		H1714401		
		H1784861	H1807701	I2385809		I1971855		
		H1800979	I1821113	H1739136		I1998714		
	H1808121	I1838444	CORA1820S	H1790841		I2114620		
	H1825693	I1855417		H1749790	I2170251			
	I1781878	I1920169	CORA1825	H1762724	I2201382			
	I1818817	I1920191		H1808022	I2233505			
	I1837234	I1946564		H1815598	I2318858			
	I1843704	I1952362		I1843706	I2343154			
	I1855418	I1989173		I1958504	CORCA1610/CNB	I2291983		
	I1866359	I1990074	I2234738	CORCA1610S	I1874064			
I1952354	I2033176	I2239042	I2010416					
I1958525	I2070349	CORA1825S	H1790845	CORCA1615	H1703701			
I1971876	I2075808	CORA2010	H1784872		I1845903			
I1990075	I2093995		H1815600		I1888547			
I1998862	I2114555		I1863885		I1920175			
I2043630	I2116111		I2201378		I1962716			
I2070249	I2124110		I2206047		I1998860			
I2075810	I2127456	I2237417	I2103685					
CORA1810	I2093993	I2137805	CORA2010S		H1692834	I2137221		
	I2114550	I2170249			H1776070	I2137223		
	I2116110	I2201366			I2010414	I2170252		
	I2124108	I2233502	CORA2015	H1795483	I2237426			
	I2127451	I2263885		I1823512	I2286696			
	I2137798	I2269827		I1860367	I2297374			

Affected Lots - CorVocet™ Biopsy System

Catalog Code	Lot Number	Catalog Code	Lot Number	Catalog Code	Lot Number	Catalog Code	Lot Number
CORCA1615	I2303056	CORCA1810B	I2286695	CORCA1815B	I2058398	CORCA1820B	H1734019
	I2330680		I2303061		I2061959		H1749803
	I2385810		I2330685		I2062021		H1756754
CORCA1615S	I2114626		I2343157		I2065393		H1762714
	I2246748		I2385811		I2075813		H1771883
CORCA1615S/CNB	I2330683	CORCA1810SB	H1733634		I2075839		H1776084
CORCA1810B	H1718595		H1800986		I2094063		H1790851
	H1734012		I1862927		I2098053		H1807721
	H1749798		I1920180		I2102664		I1827257
	H1756750		I2033140		I2105077		I1845907
	H1771846		I2114634		I2114651		I1902605
	H1776080		I2233507		I2114652		I1902607
	H1782158		I2303065		I2124197		I1920166
	H1790850		I2330686		I2127514		I1946562
	H1800985		CORCA1810SB/CNB		I2127515		I1971929
	H1808042	CORCA1815B/CNB	I2305359	I2150950	I1990094		
	I1814729		H1476238	I2150952	I1998850		
	I1838323		H1608916	I2159275	I1998858		
	I1843705		H1714408	I2159276	I2007294		
	I1845904		H1734014	I2170253	I2094075		
	I1869474		H1734016	I2201393	I2103689		
	I1877911		H1743880	I2217616	I2114708		
	I1888548		H1749800	I2281931	I2124200		
	I1902611		H1749802	I2318869	I2127516		
	I1920161		H1762717	I2330533	I2150980		
	I1946561	H1771848	I2330692	I2159282			
I1946566	H1776082	I2336279	I2159283				
I1958530	H1782159	I2343163	I2233510				
I1962714	H1790847	I2349439	I2286679				
I1990098	H1795487	I2357134	I2343166				
I1990104	H1807720	I2385813	I2352856				
I1998856	I1827256	I2385814	H1733637				
I2025072	I1838326	CORCA1815SB	H1714409	CORCA1820SB	I2137856		
I2070266	I1843709		H1743881		I2325911		
I2070374	I1845905		H1756752		I2170255		
I2093853	I1860329		H1762715	CORCA1820SB/CNB	I2321491		
I2101369	I1860365		I1838328		I2325912		
I2104884	I1877914		I1845906	CORCA1825B	H1718603		
I2114628	I1888549		I1877918		I1946563		
I2114714	I1902608		I1958536		I2137863		
I2114715	I1902609		I2061956		I2201410		
I2116109	I1920165		I2075811		I2265757		
I2124195	I1920186	I2093850		I2325913			
I2127511	I1946560	I2094072	CORCA1825SB	I2156607			
I2150947	I1946567	I2233509	CORCA2010B	H1445217			
I2150948	I1952368	I2325909		H1703705			
I2150949	I1958533	I2330694		H1708690			
I2159264	I1962702	I2399997		H1718606			
I2165513	I1971860	CORCA1815SB/CNB		I2170254	H1718607		
I2165514	I1971861			I2205164	H1749806		
I2201386	I1990097	CORCA1820B		H1718598	H1762738		
I2221444	I1990103			H1733635	H1771884		
	I2007293						

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			
	CORCA2010SB		H1749807	CORCA2015SB	H1662694	
I1874058		H1733642				
I1902604		H1739148				
I1998852		H1771853				
I2122957		H1776087				
I2233511		H1807729				
CORCA2015B	H1624841	CORCA2015SB/CNB	H1815615			
	H1639711		I1827270			
	H1657959		I1845912			
	H1697713		I1862899			
	H1708691	CORCA2020B	I2080472			
	H1714416		I2170257			
	H1718609		I2201414			
	H1733639		I2318903			
	H1734020	CORCA2020B	I2325926			
	H1743882		H1662697			
	H1749810		H1692861			
	H1771851		H1708693			
	H1776086		H1718613			
	H1784915		H1756755			
	H1790853		H1771854			
	H1807727		H1776088			
	I1827258		H1790855			
	I1855420		H1807731			
	I1862900		I1827272			
	I1873128		I1845913			
I1874060	I1869475					
I1888545	I1874065					
I1902614	I1877915					
I1920156	I1971882					
I1952374	I1990071					
I1990072	I2070361					
I1998863	I2075814					
I2070355	I2114712					
I2080473	I2151307					
	I2170259					
	I2201416					
	I2330716					