



Bard Access Systems *now* BD
605 N 5600 W
Salt Lake City, Utah 84116
USA
Tel: 800-290-1689

URGENT: MEDICAL DEVICE RECALL

3 Fr. Single Lumen and 4 Fr. Dual Lumen PowerPICC® Provena Catheters

April 11, 2018

For the Attention of:

- Medical Director, Risk Manager, Medical Device Safety Officer, Nurse Manager

Description of the problem and health hazard(s):

Bard Access Systems is expanding its previously executed field correction (customer notification) to a voluntary medical device recall of 3 Fr. Single lumen and 4 Fr. Dual lumen PowerPICC® Provena catheters due to complaints of leaks at the hub. A leak at the hub could result in the following consequences or harms:

- Leakage of infusate
- Disruption/inability to power inject or deliver therapeutic infusates
- Air embolism
- Blood exposure
- Under-dosing of the patient
- Potentially facilitate the ingress of air or pathogenic microorganisms
- Blood loss

A Health Hazard Evaluation has concluded that the most likely severity of harm that could occur with a catheter leak to be negligible to moderate. Moderate risk includes injuries which may cause significant discomfort, minor non-permanent injury and/or temporary disability. Symptoms are temporary and/or reversible.

YOU NEED TO TAKE THE FOLLOWING ACTIONS:

1. See the Attached Table (Attachment A) which lists all product codes and lots impacted by this medical device recall. These products were distributed from February 2017 through March 2018. (An example of the product label is provided in Attachment B to aid you with the identification of the affected product).
2. Immediately examine your inventory for the product code and lot numbers listed in Attachment A. Quarantine any unused product subject to this recall. Immediately discontinue the use and distribution of the affected product. Please share this recall notification with all users of the product to ensure they are also aware of the recall.
3. Please complete the attached Business Recall Response Form and fax to: **801-522-5674** or email to BASD.fieldaction@crbard.com. Bard Access Systems will contact you to provide instructions for returning impacted product for credit upon receipt of the response form.



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4. Please complete the attached Business Recall Response Form and fax to **801-522-5674** or email to BASD.fieldaction@crbard.com. Bard Access Systems will contact you to provide instructions for returning impacted product for credit upon receipt of the response form.

NOTE: If you do not have any of the affected lots in your inventory, please complete the Recall Response Form indicating you have zero (0) quantity and return the completed form so that Bard Access Systems receives an acknowledgement of your receipt of this recall notification.

Actions Taken by Bard Access Systems:

- Bard Access Systems will provide credit for the returned recalled product and will work with you to place orders for alternate devices.

Contact Information:

If you have any questions or require assistance with the return of the recalled product please contact our recall coordinator at 800-290-1689 between 8 AM and 5 PM MST Monday through Friday.

Any adverse health consequences experienced with the use of this product should be reported to Bard Access Systems and may be reported to the to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Web: MedWatch website at www.fda.gov/medwatch
- Phone: 1-800-FDA-1088 (1-800-332-1088)
- Mail: MedWatch, HF-2, FDA, 5600 Fisher's Lane, Rockville, MD 20852-9787

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. Bard Access Systems, *now* BD, is committed to advancing the world of health. Our primary objective is to provide you with quality products that are safe for patients and users. We thank you in advance for helping us to assure this by complying with this medical device recall notification as quickly and effectively as possible.

Sincerely,



Klaus Hoerauf MD
VP Medical Affairs
Medication Delivery Solutions



Gail Griffiths
Sr. Director, Regulatory Compliance
US Region



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**Attachment A- List of 3 Fr. and 4 Fr.
 PowerPICC® Product Codes and Lot
 Numbers**

Part Number	Lot/Serial Number	Expiration Date
CK000114A	REBV2151	11/30/2018
CK000114A	REBZ1268	12/31/2018
CK000114A	RECQ0041	1/31/2019
CK000283A	REBV1203	10/31/2018
CK000759	REBS2133	8/31/2018
CK000759	REBX2038	11/30/2018
CK000759	REBW1228	1/31/2019
CK000759	REBX0457	1/31/2019
CK000765	REBT0255	7/31/2018
CK000765	REBT0843	7/31/2018
CK000767	REBT1889	7/31/2018
CK000767	REBW1216	7/31/2018
CK000767	REBX0441	1/31/2019
ck000770	REBU0664	8/31/2018
CK000770	REBX0460	11/30/2018
CK000770	REBV2233	1/31/2019
S0173108PD	REBR1399	12/31/2017
S0173108PD	REBS2081	1/31/2018
S0173108PD	REBU1224	9/30/2018
S0173108PD	REBY1316	10/31/2018
S0173108PD	RECN2678	2/28/2019
S0274108PD	REBQ1889	11/30/2017
S0274108PD	REBT0697	7/31/2018
S1173108	REBQ1882	12/31/2017
S1173108	REBQ2473	12/31/2017
S1173108	REBU1584	8/31/2018
s1173108	REBT0688	10/31/2018
S1173108	REBX1560	10/31/2018
S1173108	REBY1472	10/31/2018
S1173108	RECP1895	2/28/2019
S1173108	REBY1170	7/21/2019
S1173108D	REBN2329	12/31/2017
S1173108D	REBQ2474	12/31/2017
S1173108D	REBV0536	8/31/2018
S1173108D	REBS1988	9/30/2018
S1173108D	REBT0240	9/30/2018

Part Number	Lot/Serial Number	Expiration Date
S1173108D	REBT1398	9/30/2018
S1173108D	REBU0293	9/30/2018
S1173108D	REBU0690	9/30/2018
S1173108D	REBY0782	10/31/2018
S1173108D	REBY2516	10/31/2018
S1173108D	REBZ0958	1/31/2019
S1173108D	REBY1982	2/28/2019
S1173108D	REBZ0838	2/28/2019
S1173108D	RECN1199	2/28/2019
S1173108D	RECN2175	2/28/2019
S1173108D	RECP0357	2/28/2019
S1173108PD	REBP0948	12/31/2017
S1173108PD	REBQ2479	12/31/2017
S1173108PD	REBS0167	12/31/2017
S1173108PD	REBR1398	1/31/2018
S1173108PD	REBW1843	9/30/2018
S1173108PD	REBX1663	10/31/2018
S1173108PD	REBY0832	10/31/2018
S1173108PD	REBZ1627	1/31/2019
S1173108PD	REBZ0840	2/28/2019
S1173108PD	RECN0088	2/28/2019
s1173108pd	RECN1200	2/28/2019
S1173108PD	RECN2177	2/28/2019
S1173108PD	RECP0594	2/28/2019
S1173108PD	REBY2740	3/31/2019
S1274108	REBQ1883	11/30/2017
S1274108	REBT0682	7/31/2018
S1274108	REBU1047	10/31/2018
S1274108	REBT1846	11/30/2018
s1274108	REBT2073	11/30/2018
S1274108	REBY1004	12/31/2018
S1274108	RECN1068	1/31/2019
S1274108	REBZ1678	5/31/2019
S1274108D	REBN2334	11/30/2017
S1274108D	REBQ1887	11/30/2017
S1274108D	REBR0160	11/30/2017
S1274108D	REBN1883	12/31/2017
S1274108D	REBS0062	4/30/2018
S1274108D	REBS1035	4/30/2018



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S1274108D	REBS1567	4/30/2018
S1274108D	REBR1347	5/31/2018
S1274108D	REBS2562	7/31/2018
S1274108D	REBT0755	7/31/2018
S1274108D	REBS0781	8/31/2018
S1274108D	REBS1033	8/31/2018
S1274108D	REBS2070	8/31/2018
S1274108D	REBT1602	8/31/2018
S1274108D	REBW0268	8/31/2018
S1274108D	REBU0296	10/31/2018
S1274108D	REBU0765	10/31/2018
S1274108D	REBU1271	10/31/2018
S1274108D	REBW1840	11/30/2018
S1274108D	REBX0325	11/30/2018
S1274108D	REBX1581	11/30/2018
S1274108D	REBX2436	11/30/2018
S1274108D	REBX0326	12/31/2018
S1274108D	REBY0835	12/31/2018
S1274108D	REBZ0814	12/31/2018
S1274108D	REBV1690	1/31/2019
S1274108D	REBV2326	1/31/2019
S1274108D	REBW0782	1/31/2019
S1274108D	REBW1841	1/31/2019
S1274108D	REBW1988	1/31/2019
S1274108D	REBX1240	1/31/2019
S1274108D	RECN0085	1/31/2019
S1274108D	REBY0518	3/31/2019
S1274108D	REBY2013	4/30/2019
S1274108D	RECN0938	4/30/2019
S1274108D	RECN2573	4/30/2019
S1274108D	RECP0590	4/30/2019
S1274108D	REBY2739	5/31/2019
S1274108D	REBZ0885	5/31/2019
S1274108D	REBZ1625	5/31/2019
S1274108D	RECN1381	5/31/2019
S1274108D	RECN2461	5/31/2019
S1274108PD	REBP1971	11/30/2017
S1274108PD	REBN2378	12/31/2017
s1274108pd	REBT0146	7/31/2018

Part Number	Lot/Serial Number	Expiration Date
S1274108PD	REBT0146	7/31/2018
S1274108PD	REBT0757	7/31/2018
S1274108PD	REBR1345	8/31/2018
S1274108PD	REBW0728	10/31/2018
S1274108PD	REBV2327	11/30/2018
S1274108PD	REBY0780	12/31/2018
S1274108PD	REBX1122	1/31/2019
S1274108PD	REBY1239	1/31/2019
S1274108PD	RECN0939	1/31/2019
S1274108PD	REBY2518	3/31/2019
s1274108pd	REBZ1718	3/31/2019
S1274108PD	RECN0027	3/31/2019
S1274108PD	RECN2563	3/31/2019
S1274108PD	RECP2482	4/30/2019
S1274118	REBQ1891	11/30/2017
S1274118	REBT0078	7/31/2018
S3173108	REBT1882	9/30/2018
s3173108d	REBQ2592	1/31/2018
S3173108D	REBR1014	9/30/2018
S3173108D	REBT0147	9/30/2018
S3173108PD	REBQ2480	1/31/2018
S3173108PD	REBX1664	9/30/2018
S3173108PD	REBS0171	11/16/2018
S3173108PD	REBZ0960	2/28/2019
S3173108PD	RECN1406	2/28/2019
S3173118	REBV1102	9/30/2018
S3173118	REBY0008	10/31/2018
S3173335	REBP0949	12/31/2017
S3173335	REBQ2587	1/31/2018
S3173335	REBY1941	2/28/2019
S3173335P	REBP1024	12/31/2017
S3173335P	REBT0116	8/31/2018
S3173335P	REBV0052	9/30/2018
S3173355	REBP0950	12/31/2017
S3173355	REBQ2586	1/31/2018
S3173355	REBR1261	8/31/2018
s3173355	REBW1532	10/31/2018
S3173355	RECP2311	2/28/2019
s3173355p	REBP1023	12/31/2017



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s3173355p	REBQ2590	1/31/2018
S3173355P	REBT0101	8/31/2018
S3173355P	REBT0737	8/31/2018
S3173355P	REBT1801	9/30/2018
S3173355P	REBT1948	9/30/2018
S3173355P	REBU0082	9/30/2018
S3173355P	REBU0714	9/30/2018
S3173355P	REBU1265	9/30/2018
S3274108	REBT1884	8/31/2018
S3274108D	REBQ1886	11/30/2017
S3274108D	REBQ1276	12/31/2017
S3274108D	REBQ2476	1/31/2018
S3274108D	REBU0297	11/30/2018
S3274108D	REBY0834	3/31/2019
S3274108D	REBX2246	4/30/2019
S3274108D	RECN2679	4/30/2019
S3274108D	RECQ0417	4/30/2019
S3274108D	REBY2517	5/31/2019
S3274108D	REBZ0839	5/31/2019
S3274108D	RECP0591	5/31/2019
S3274108D	RECN0023	6/30/2019
S3274108PD	REBP1471	11/30/2017
S3274108PD	REBT2364	7/31/2018
S3274108PD	REBR1401	8/31/2018
S3274108PD	REBT0233	11/30/2018
S3274108PD	REBT1403	11/30/2018
S3274118	REBV1104	11/30/2018
S3274335	REBP1580	11/30/2017
S3274335	REBQ1885	11/30/2017
S3274335	REBS0574	7/31/2018
S3274335	REBT0805	7/31/2018
S3274335	REBT1585	8/31/2018
S3274335	REBY0879	4/30/2019
S3274335	RECN0888	4/30/2019
S3274335	REBZ0681	5/31/2019
S3274335P	REBP1583	11/30/2017
S3274335P	REBQ1890	11/30/2017
S3274335P	REBS0534	7/31/2018
S3274355	REBP1581	11/30/2017

Part Number	Lot/Serial Number	Expiration Date
S3274355	REBQ1884	11/30/2017
S3274355	REBR1259	8/31/2018
S3274355	REBT1802	8/31/2018
S3274355	REBU0083	11/30/2018
S3274355	REBU0734	11/30/2018
S3274355	REBV0533	11/30/2018
S3274355	RECP0846	4/30/2019
S3274355	REBZ0494	5/31/2019
S3274355	REBZ1826	6/30/2019
S3274355P	REBP1582	11/30/2017
S3274355P	REBS0026	7/31/2018
S3274355P	REBS1557	7/31/2018
S3274355P	REBS2011	7/31/2018
S3274355P	REBS2550	7/31/2018
S3274355P	REBT0168	7/31/2018
S3274355P	REBT0204	7/31/2018
S3274355P	REBS0843	8/31/2018
S9173108	REBT1883	9/30/2018
S9173108D	REBN2332	12/31/2017
S9173108D	REBQ2475	12/31/2017
S9173108D	REBU1640	10/31/2018
S9173108PD	REBP1020	12/31/2017
S9173108PD	REBT0234	9/30/2018
s9173108pd	REBU2255	9/30/2018
S9173108PD	REBZ0816	2/28/2019
S9173118	REBV1103	9/30/2018
S9274108	REBT1885	7/31/2018
S9274108D	REBN2336	11/30/2017
S9274108D	REBQ1892	11/30/2017
S9274108D	REBQ2477	7/31/2018
S9274108D	REBT0754	7/31/2018
S9274108D	REBU0059	7/31/2018
S9274108D	REBU0691	8/31/2018
S9274108D	REBU1639	8/31/2018
S9274108D	RECP0358	4/30/2019
S9274108D	RECN0084	6/30/2019
S9274108D	RECN1403	6/30/2019
S9274108PD	REBQ1888	11/30/2017
S9274108PD	REBN2379	12/31/2017



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Part Number	Lot/Serial Number	Expiration Date
S9274108PD	REBT1446	7/31/2018
S9274108PD	REBT1340	11/30/2018
S9274108PD	REBU0694	11/30/2018
S9274108PD	REBZ0815	3/31/2019
S9274108PD	RECP1511	5/31/2019

Part Number	Lot/Serial Number	Expiration Date
S9274118	REBU0001	11/30/2018
S9274118	REBU0002	11/30/2018



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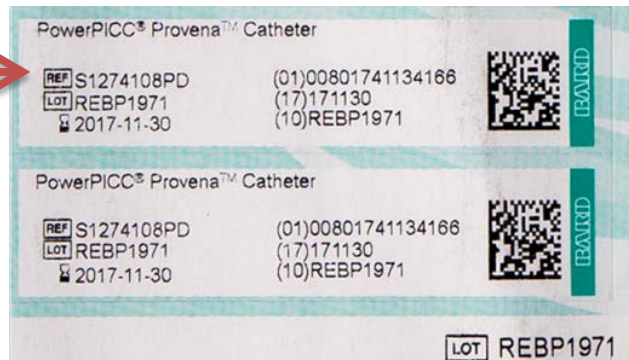
Attachment B

Medical Device Recall Product Code (Ref) / Lot Identification:

Unit Label:



Part Number (Ref)



Lot Number



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Business Recall Response Form

3 Fr. Single Lumen and 4 Fr. Dual Lumen PowerPICC Provena Catheters

Please assist Bard Access Systems by promptly returning this form to:

Bard Access Systems:

- Fax #: 801-522-5674
- Email: BASD.fieldaction@crbard.com

Facility: _____
 Please use full, current facility name. Do not use initials.

Street Address: _____

City: _____ **State:** _____ **Zip:** _____

Contact Person: _____ **Account Number:** _____

Telephone No.: _____ **Email Address:** _____

I have read and understood the attached notice.

Name:	
Title:	
Signature/Date:	

We do not have any of the affected product(s) on hand.

We have the following units and request replacement(s):

Quantity to be Returned	Product Code (Ref)	Lot #

**If needed, attach a list of any additional lots (with quantities) that will be returned.*