

Bard Singapore Pte Ltd
1 Harbourfront Avenue, #04-11/13
Keppel Bay Tower, Singapore 098632
Tel: (65) 6250 5988
Fax: (65) 6337 3588
GST Reg No. 19-9901639-R



URGENT MEDICAL DEVICE RECALL NOTIFICATION
MAX-CORE® Disposable Core Biopsy Instrument

24 Oct 2019

Dear Customer,

cc: Chairman Medical Board and relevant Head of Departments

This letter is to inform you of a voluntary product recall issued by Bard Peripheral Vascular, Inc. (BPV), a wholly owned subsidiary of Becton, Dickinson and Company. Specific MAX-CORE® Disposable Core Biopsy Instrument product code / lot number combinations are affected as outlined in Attachment 1. Our records show that your facility has purchased one or more units from the affected lots.

All other product code / lot number combinations not listed in Attachment 1 can continue to be used by your facility as they are safe to use and are not affected by this product recall.

Reason for Recall:

BPV has identified that the product code / lot numbers listed in Attachment 1 may be at risk of having firing issues. An example of a firing issue is where the device does not completely fire, resulting in the inability to obtain tissue samples.

Clinical Risk Statement:

In most cases, the identified issues will lead to a varying degree of user dissatisfaction or may be associated with a prolonged procedure or minor tissue injury or minor bleeding. Most often, a coaxial cannula is used and or the device is being used with ultrasound guidance, minimizing the risk of harm.

Required Actions:

Please find attached instructions detailing the steps we are requesting you take regarding this product.

We appreciate your cooperation and assistance in dealing with this matter and sincerely apologize for any inconvenience that may result from this action. If there is any assistance that you require regarding this action, please do not hesitate to contact your Bard representative.

Yours Sincerely,

A black rectangular box redacting the signature of Melvin Tay.

Melvin Tay
Business Director, SEA
BD Interventional

Attachment 1 – Instructions for Completing Required Actions
Attachment 2 – Acknowledgement Receipt Form

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Attachment 1

INSTRUCTIONS FOR COMPLETING REQUIRED ACTIONS

1. Our records show that your facility has purchased one or more units from the product codes / lot numbers listed in the tables below that are affected by this voluntary recall. Do not use or further distribute any affected product.

Product Code	Lot Number
MC1410	RECN0753
MC1410	REDR1996
MC1410	REDS0461
MC1416	RECP1763
MC1610	RECN0756
MC1610	RECN1632
MC1610	REDN2403
MC1610	REDN2448
MC1610	REDN3426
MC1610	REDP0046
MC1610	REDQ2463
MC1610	REDR1997
MC1610	REDS1470
MC1610	REDS2663
MC1610	REDS3864
MC1610	REDS4214
MC1610	REDT1884
MC1610	REDT4419
MC1610	REDU1687
MC1610	REDU2579
MC1616	RECN2119
MC1616	RECP2400
MC1616	REDN2402
MC1616	REDN2447
MC1616	REDN3457
MC1616	REDP0085
MC1616	REDQ2460
MC1616	REDQ4100
MC1616	REDR0746
MC1616	REDR2055
MC1616	REDS0420
MC1616	REDS1471
MC1616	REDS2594
MC1616	REDS2595
MC1616	REDS2664
MC1616	REDS3750
MC1616	REDT0879
MC1616	REDT2007
MC1616	REDT3043
MC1616	REDU0929
MC1616	REDU3571
MC1616	REDU4536
MC1616	REDV1435
MC1616	REDV2354

Product Code	Lot Number
MC1810	RECN2069
MC1810	REDN0266
MC1810	REDN1612
MC1810	REDN3443
MC1810	REDP0047
MC1810	REDP2162
MC1810	REDP3393
MC1810	REDP4637
MC1810	REDQ0871
MC1810	REDQ2499
MC1810	REDQ2502
MC1810	REDR0676
MC1810	REDR1998
MC1810	REDS0469
MC1810	REDS1610
MC1810	REDS2665
MC1810	REDS3865
MC1810	REDS4215
MC1810	REDT0926
MC1810	REDT1885
MC1810	REDT4420
MC1810	REDU0922
MC1810	REDU2476
MC1810	REDU3498
MC1810	REDU4566
MC1810	REDV1369
MC1810	REDV3016
MC1816	RECZ2179
MC1816	RECZ3084
MC1816	RECZ3178
MC1816	REDN2401
MC1816	REDQ0848
MC1816	REDR0747
MC1816	REDR1989
MC1816	REDR3627
MC1816	REDS0421
MC1816	REDS1484
MC1820	REBZ0283
MC1820	RECN0654
MC1820	RECN0760
MC1820	RECN1633
MC1820	RECN1634
MC1820	RECN2091
MC1820	RECN2120

Product Code	Lot Number
MC1820	RECP0263
MC1820	RECP1251
MC1820	RECP1252
MC1820	RECP1765
MC1820	RECP1988
MC1820	RECQ0331
MC1820	RECQ0592
MC1820	RECQ1208
MC1820	RECQ1651
MC1820	RECQ1997
MC1820	RECZ3012
MC1820	RECZ3015
MC1820	RECZ3114
MC1820	RECZ3132
MC1820	RECZ3167
MC1820	RECZ3176
MC1820	REDN0295
MC1820	REDN1613
MC1820	REDN2400
MC1820	REDN2445
MC1820	REDN3423
MC1820	REDN3424
MC1820	REDP0048
MC1820	REDP1474
MC1820	REDP1482
MC1820	REDP2160
MC1820	REDP3392
MC1820	REDP4638
MC1820	REDP5040
MC1820	REDP5041
MC1820	REDQ0849
MC1820	REDQ2461
MC1820	REDQ2503
MC1820	REDQ4101
MC1820	REDR0677
MC1820	REDR2041
MC1820	REDR2969
MC1820	REDR3028
MC1820	REDR3628
MC1820	REDR3629
MC1820	REDR3690
MC1820	REDS0470
MC1820	REDS1485
MC1820	REDS1612

Product Code	Lot Number
MC1820	REDS2666
MC1820	REDS3752
MC1820	REDS3866
MC1820	REDS4216
MC1820	REDT0927
MC1820	REDT1881
MC1820	REDT3045
MC1820	REDT3146
MC1820	REDT4421
MC1820	REDT4432
MC1820	REDU0923
MC1820	REDU0931
MC1820	REDU1688
MC1820	REDU1693
MC1820	REDU2477
MC1820	REDU2583
MC1820	REDU3499
MC1820	REDU4538
MC1820	REDU4568
MC1820	REDV1370
MC1820	REDV1437
MC1820	REDV2355
MC1820	REDV3017
MC1820	REDV3018
MC1820	REDV3100
MC1820	REDV3791
MC1825	RECN1140
MC1825	RECN1804
MC1825	RECP0227
MC1825	REDN1614
MC1825	REDN2444
MC1825	REDN3461
MC1825	REDQ2498
MC1825	REDQ2976
MC2016	REDT0928
MC2016	REDT1882
MC2016	REDT3150
MC2016	REDT4423
MC2016	REDV1438
MC2016	REDV2329
MC2020	REDV1372
MC2020	REDV2357

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2. Please check all inventory locations within your institution for affected product code / lot number combinations listed in the recall notice. If you have further distributed any of the product code / lot numbers, please immediately contact that location, advise them of the recall, forward these instructions and have them return the affected product to BARD.

3. Please remove any identified product from your shelves.

4. If you have used the affected product, complete and return the attached Acknowledgement **Form** indicating no product will be returned.

Once the product affected by this recall has been removed from your inventory:

5. Fill out the **Acknowledgement Receipt Form**. Be sure to state the quantities and lot numbers of each recalled product that you intend to return. It is extremely important that we receive this information.

6. Please call contact our local BARD representative or email at Customercomplaint@bd.com. Once all information has been verified, BARD will issue a replacement product for your returned product.

7. Email the completed **Acknowledgement Receipt Form** to Customercomplaint@bd.com or hand it to our Bard Sales Representative.