



October XX, 2019

URGENT: FIELD SAFETY NOTICE – VT-RAP-19-08-005

Bard® MaxCore® Disposable Core Biopsy Instrument

REF & Lot Numbers: Refer to Attachment 1

Type of Action: Product Removal

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

This letter contains important information which requires your **immediate** attention.

Dear valued Customer,

Bard Peripheral Vascular, Inc. (BPV), a wholly owned subsidiary of Becton, Dickinson and Company (BD) is conducting a Field Safety Corrective Action to remove specific lots of Bard® MaxCore® Disposable Core Biopsy Instrument. The specific product code (REF) / lot number combinations affected by this product removal are outlined in Attachment 1. According to our distribution records your organisation may have received the impacted product.

Description of the Problem

Through customer feedback, it has been identified that the product code / lot number combinations 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.

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.

This product removal is limited to the product code / lot numbers listed in Attachment 1. No other product codes or lot numbers are affected.

Advice on actions to be taken by the Customer:

1. Inspect your inventory, locate and quarantine any units of the impacted devices as listed in Attachment 1.
2. If you have further distributed the product, please identify those facilities, notify them at once of this product removal and have them return the affected product to your facility.
3. Complete the customer response form on page 3 indicating:
 - the quantities returned **OR**
 - that your organisation does not have any impacted units left in inventory



4. Return the completed customer response form to <<insert contact details here>> **as soon as possible or no later than November 29th, 2019.**

Contact Reference Person

If you have any questions about this, please contact your local BD representative or the local BD office on <<insert telephone details here>> or e-mail <<insert contact email address here>>.

We confirm that the appropriate regulatory agencies have been informed of these actions.

BD is committed to advancing the world of health. Our primary objectives are patient safety and user safety and providing you with quality products. We apologise for the inconvenience this situation may cause you and thank you in advance for helping BD to resolve this matter as quickly and effectively as possible.

Sincerely,

William David
Sr. Director, Quality Compliance,
EMEA Quality Compliance
BD Switzerland Sàrl



Customer Response Form - VT-RAP-19-08-005

Bard® MaxCore® Disposable Core Biopsy Instrument

REF & Lot Numbers: Refer to Attachment 1

Please read in conjunction with Field Safety Notice VT-RAP-19-08-005 and return completed and signed form as soon as possible or **no later than the November 29th, 2019** to <insert fax/email address here>.

- I confirm this notice has been read, understood and that all recommended actions have been implemented as required.

Tick the appropriate box below

We do not have any of the affected product as listed in Attachment 1 in our possession. *(Please complete the table below with your contact information and return to the email address listed above)*

OR

We have units of the affected product as listed in Attachment 1 in our possession and I confirm that the units have been returned *(Please complete Attachment 1 with the quantity of units returned. Then complete the table below with your contact information and return both documents to the email address listed above)*

Account/Organisation Name:	
Department (if applicable):	
Address:	
Postcode:	City:
Contact Name:	
Job Title:	
Contact Telephone Number:	Contact E-mail Address:
Signature:	Date:

This form must be returned to BD before this action can be considered closed for your account.



Attachment 1 – Affected Product Code / Lot Number Combinations

REF	LOT	Quantity returned	REF	LOT	Quantity returned	REF	LOT	Quantity returned
MC1410	RECN0753		MC1810	REDQ2499		MC1820	REDP0048	
MC1410	REDR1996		MC1810	REDQ2502		MC1820	REDP1474	
MC1410	REDS0461		MC1810	REDR0676		MC1820	REDP1482	
MC1416	RECP1763		MC1810	REDR1998		MC1820	REDP2160	
MC1610	RECN0756		MC1810	REDS0469		MC1820	REDP3392	
MC1610	RECN1632		MC1810	REDS1610		MC1820	REDP4638	
MC1610	REDN2403		MC1810	REDU2476		MC1820	REDP5040	
MC1610	REDN2448		MC1816	RECZ2179		MC1820	REDP5041	
MC1610	REDP0046		MC1816	RECZ3084		MC1820	REDQ0849	
MC1610	REDQ2463		MC1816	RECZ3178		MC1820	REDQ2461	
MC1610	REDR1997		MC1816	REDN2401		MC1820	REDQ2503	
MC1610	REDS1470		MC1816	REDQ0848		MC1820	REDQ4101	
MC1610	REDS2663		MC1816	REDR0747		MC1820	REDR0677	
MC1610	REDS4214		MC1816	REDR3627		MC1820	REDR2041	
MC1610	REDT1884		MC1816	REDS0421		MC1820	REDR2969	
MC1610	REDT4419		MC1820	RECN0654		MC1820	REDR3028	
MC1616	RECN2119		MC1820	RECN0760		MC1820	REDR3628	
MC1616	RECP2400		MC1820	RECN1633		MC1820	REDR3629	
MC1616	REDN2402		MC1820	RECN1634		MC1820	REDR3690	
MC1616	REDN2447		MC1820	RECN2091		MC1820	REDS0470	
MC1616	REDN3457		MC1820	RECN2120		MC1820	REDS1485	
MC1616	REDP0085		MC1820	RECP1251		MC1820	REDS1612	
MC1616	REDQ2460		MC1820	RECP1252		MC1820	REDS2666	
MC1616	REDQ4100		MC1820	RECP1765		MC1820	REDS3752	
MC1616	REDR0746		MC1820	RECQ0331		MC1820	REDS3866	
MC1616	REDS0420		MC1820	RECQ0592		MC1820	REDS4216	
MC1616	REDS2594		MC1820	RECQ1651		MC1820	REDT0927	
MC1616	REDS2595		MC1820	RECQ1997		MC1820	REDT1881	
MC1616	REDS2664		MC1820	RECZ3012		MC1820	REDT3045	
MC1616	REDS3750		MC1820	RECZ3015		MC1820	REDT4421	
MC1616	REDT0879		MC1820	RECZ3114		MC1820	REDU0931	
MC1616	REDU3571		MC1820	RECZ3132		MC1825	RECN1140	
MC1810	RECN2069		MC1820	RECZ3167		MC1825	RECN1804	
MC1810	REDN0266		MC1820	RECZ3176		MC1825	RECP0227	
MC1810	REDN3443		MC1820	REDN0295		MC1825	REDN1614	
MC1810	REDP2162		MC1820	REDN1613		MC1825	REDN2444	
MC1810	REDP3393		MC1820	REDN2400		MC1825	REDN3461	
MC1810	REDP4637		MC1820	REDN2445		MC1825	REDQ2498	
MC1810	REDQ0871		MC1820	REDN3423		MC1825	REDQ2976	