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07 Oct 2019

URGENT: FIELD SAFETY NOTICE – VT-RAP-18-10-002

BardPort® M.R.I. Hard Base Implantable Port, BardPort® M.R.I. Implantable Port, BardPort® Titanium Implantable Port, Groshong® 9.5F Dual-Lumen Central Venous Catheter and X-Port® isp M.R.I. Implantable Port

REF & Lot Numbers: Refer to Table 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 BardPort® Ports, Groshong® Catheters and X-Port® Ports due to the potential that the package may contain an incorrect tunneler. 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 combination listed in Table 1 may be at risk of containing a tunneler with a barb tip that is intended to be attached to a 6Fr catheter (Figure 1) instead of the correct barb tip for a 9.6Fr catheter (Figure 2):

Figure 1: Incorrect Tunneler (6Fr Barb Tip)

Figure 2: Correct Tunneler (9.6Fr Barb Tip)

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Users are trained in the placement of these devices, however if an impacted device is used there is the potential that the user would not be able to attach the end of the catheter to the tunneler and would need to get an appropriate tunneler to complete the procedure.

In addition, there is the potential that the catheter could become dislodged from the tunneler during the advancement through the tunnel. In this case, the user would either pull the catheter back out and begin again or, if able, improvise and capture the end of the catheter (with the aid of a surgical clamp or hemostat) and complete the advancement into the port pocket. Overall, this represents a prolongation of the procedure and may have an incremental risk of minor tissue injury. However, this is unlikely to lead to a serious injury and there is no indication that this would lead to a long-term health consequence.

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

Product Name	Product Code (REF)	Lot Number	Expiry Date
BardPort® M.R.I. Hard Base Implantable Port	0604550CE	RECR1431	30-APR-2023
BardPort® M.R.I. Implantable Port	0602680CE	RECR1439	31-MAR-2023
	0602680CE	RECT0078	30-APR-2023
	0602680CE	RECU1067	31-DEC-2019
	0602680CE	RECU2404	31-MAY-2023
BardPort® Titanium Implantable Port	0602230CE	RECR2059	30-APR-2023
Groshong® 9.5F Dual-Lumen Central Venous Catheter	7726950 CE	RECR2195	30-APR-2023
X-Port® isp M.R.I. Implantable Port	0657525 CE	RECU1597	31-MAY-2023

Table 1: Impacted product codes (REF) and Lot Numbers

Advice on actions to be taken by the Customer:

1. Inspect your inventory, locate and quarantine any units of the impacted devices as shown in Table 1. Destroy all impacted product or return to your BD local representative / distributor to be destroyed.

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 4 indicating:
   - the quantities destroyed/returned **OR**
   - that your organisation does not have any impacted units left in inventory

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4. Return the completed customer response form to Ahmed.Shebah@bd.com for replacement product or credit **as soon as possible or no later than October 31st, 2019.**

Contact Reference Person

If you have any questions about this, please contact your local BD representative or the local BD office on +966 11 4554060 or e-mail Ahmed.Shebah@bd.com

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,

Ahmed Shebah [redacted]
Quality Manager KSA
Riyadh, Saudi Arabia

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Customer Response Form - VT-RAP-18-10-002

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REF & Lot Numbers: Refer to Table 1

Please read in conjunction with Field Safety Notice VT-RAP-18-10-002 and return completed and signed form as soon as possible or **no later than the October 31st, 2019** to *Ahmed.Shebah@bd.com FAX +966 11 4555072.*

- **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 Table 1 in our possession.

OR

☐ We have the following units of the affected product as listed in Table 1 in our possession and I confirm that the units have been destroyed/returned *(Please complete the table below with the lot number and the number of units destroyed/returned)*

REF	LOT Number	Quantity Returned	REF	LOT Number	Quantity Returned
0604550CE	RECR1431		0602680CE	RECU2404	
0602680CE	RECR1439		0602230CE	RECR2059	
0602680CE	RECT0078		7726950CE	RECR2195	
0602680CE	RECU1067		0657525CE	RECU1597	

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.