BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 Fax:
+41 21 556 30 99
www.BD.com

June 1, 2016

URGENT: FIELD SAFETY NOTICE – VT-RAP-04-002

EQUISTREAM®, EQUISTREAM® XK, and GLIDEPATH® Long-Term Hemodialysis Catheters

REF and Lot Numbers: See Appendix 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 product code / lot number combinations of the EQUISTREAM®, EQUISTREAM® XK, and GLIDEPATH® Long-Term Hemodialysis Catheters from the market. According to our distribution records your organisation may have received impacted devices as listed in Appendix 1.

Description of the Problem

BD has identified through customer feedback, that the product code / lot number combinations listed in Appendix1 may be at risk of containing a tunneler with a plastic barb tip that is susceptible to breaking, as shown in Figure 1 below. The purpose of the barb tip is to attach to the catheter and create a connection, which allows the catheter to be threaded through the tissue as the tunnel is created.

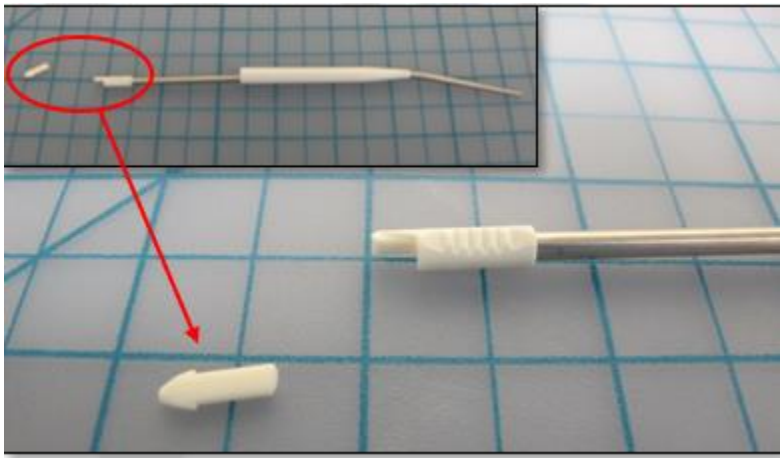

Figure 1: Broken Tunneler Barb Tip

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 Fax:
+41 21 556 30 99
www.BD.com

Clinical Risk

Users are trained in the placement of these devices and it is very likely, given the manner in which these tunnelers have been reported to break, that the breakage would be detected at the time of placement, leading to removal and subsequent replacement with a new catheter and tunneler.

The potential clinical risks if the failure occurs during the procedure are summarised as follows:

- The need to abort the tunneling procedure and retry utilising a new device.
    - This represents a prolongation of the procedure which may have an incremental risk of minor tissue injury or bleeding.

- The tunneler breaks in a manner that leaves a small undetected and detached component within the lumen of the catheter.
    - This could render the catheter unusable as the lumen would be occluded or the flow could be disrupted. This would affect the ability to dialyze the patient as intended and require removal and replacement of the catheter in an urgent manner so the patient could resume dialysis.

- The tunneler breaks in a manner that flushes a small undetected component out of the catheter into the central venous system during dialysis due to the high hemodynamic pressure.
    - The final resting location of the detached component would likely be the pulmonary circulation within a lung. This could lead to long-term health consequences requiring medical or surgical intervention.

This product removal is limited to the product codes / lot numbers listed in Appendix 1; no other product codes / lot numbers are affected.

Advice on action to be taken:

1. Please inspect your inventory and locate and quarantine any unused device/s of any of the impacted lot numbers. Return all impacted devices to your BD local representative / distributor.

2. If you have further distributed the device/s, please identify those users and notify them at once of this product removal.

3. Complete and sign the Customer Response Form on page 4 indicating:
    - the quantities to be returned **OR**
    - that your organisation does not have any impacted units left in inventory

4. Return your completed and signed Customer Response Form to BDUKFieldAction@bd.com **as soon as possible or no later than the June 30, 2019.**

Contact Reference Person

If you have any questions about this, please contact your local BD representative or the local BD office.

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 Fax:
+41 21 556 30 99
www.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,

William David
Sr. Director, Quality Compliance,
EMEA Quality Compliance

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 Fax:
+41 21 556 30 99
www.BD.com

Customer Response Form - VT-RAP-04-002

EQUISTREAM®, EQUISTREAM® XK, and GLIDEPATH® Long-Term Hemodialysis Catheters

REF and Lot Numbers: See Appendix 1

Please read in conjunction with Field Safety Notice VT-RAP-04-002 and return the completed and signed form as soon as possible or **no later than the June 30, 2019 to** BD at fax/e-mail to *BDUKFieldAction@bd.com*

- **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 Appendix 1 in our possession.

OR

☐ We have the following units of the affected product as listed in Appendix 1 in our possession to return to BD *(Please complete the table below with the lot number and the number of units)*

Product Code (REF)	**Lot Number/s:**	**Units to Return** *(insert quantity below)*

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.

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 Fax:
+41 21 556 30 99
www.BD.com

Appendix 1: Affected Product Code / Lot Numbers

Equistream® Long-Term Hemodialysis Catheters	
Product Code (REF)	**Lot Number**
6905190	RECX1473
6905280	RECV0679
	RECX0849
6905310	RECW0294
6903190	RECX1473
6903230	RECW2370
	RECX1115
	RECX3054
	RECZ1124
6903270	RECW1719
	RECX1186
	RECZ1089
6903350	RECX2700
6903420	RECZ3013

Equistream® XK Long-Term Hemodialysis Catheters	
Product Code (REF)	**Lot Number**
6913190	RECX3802
6913230	RECX3046
	RECZ2657
6913270	RECX0831
6913350	RECW2017
	RECZ0630

GlidePath® Long-Term Hemodialysis Catheters	
Product Code (REF)	**Lot Number**
6393190	RECX1123
	RECX1127
	RECX1192
	RECX1196
	RECX1197
	RECX1200
6393230	RECW0391
	RECZ0728
	RECZ3497
6393270	RECX1117
	RECX1124
6393310	RECX1645
6393350	RECX1716
6393420	RECX0987
	RECZ3385
6396190	RECZ0702
6396240	RECX1717
	RECX2540
	RECZ3464