

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

ATTENTION: RISK MANAGER/MATERIALS MANAGER
URGENT MEDICAL DEVICE RECALL NOTIFICATION
EQUISTREAM®, EQUISTREAM® XK, and GLIDEPATH® Long-Term Hemodialysis Catheters

21 May, 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 product code / lot number combinations of the EQUISTREAM®, EQUISTREAM® XK, and GLIDEPATH® Long-Term Hemodialysis Catheters are affected as outlined in Attachment 3. Our records show that your facility has purchased one or more units from the affected lots.

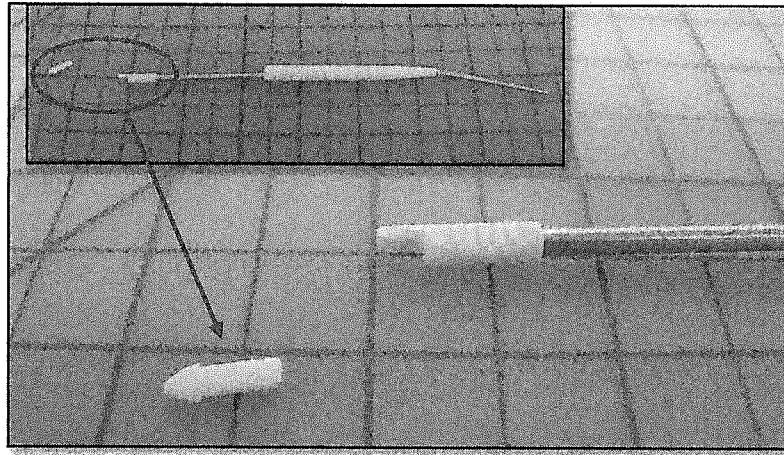
All other product code / lot number combinations not listed in Attachment 3 can continue to be used by your facility as they are safe to use and are not affected by this product recall.

Reason for Recall:

BPV has identified that the product code / lot number combinations listed in Attachment 3 may be at risk of containing a tunneler with a plastic barb tip that is susceptible to breaking, as shown in the figure 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.

Reference: Product Advisory – VT-RAP-19-04-002
Product: EquiStream, Glidepath

Broken Tunneler Barb Tip



Clinical Risk Statement:

The immediate health consequence includes the need to abort the tunneling procedure and retry utilizing a new device. This represents an improvisation or prolongation of the procedure, may have an incremental risk of minor tissue injury or bleeding, however not likely to lead to a serious adverse event.

There is also the potential for the tunneler to break 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.

In addition, if a detached component was small enough, it is possible that the detached component could be flushed 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 interventional/surgical intervention.

Physicians 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 removing and replacing with a new catheter and tunneler.

Required Actions:

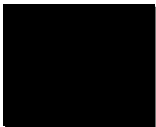
1. Immediately review your inventory for the specific catalog and lot numbers listed in Attachment 03.
2. Share this recall notification with all users of the product within your facility to ensure that they are also aware of this recall.

3. Complete the attached Customer Acknowledgement Form (Attachment 2) and return to the BARD representative whether or not you have any of the impacted material so that BARD may acknowledge your receipt of this notification and process your product replacement.

4. Report any adverse health consequences experienced with the use of this product to BARD.

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,



Melvin Tay
Business Director, BD Interventional



Janet Arul Raj
Customer Quality Manager, Southeast Asia

Attachment 1 – Instructions for Completing Required Actions

Attachment 2 – Customer Acknowledgement Form

Attachment 3 – Affected Product Code / Lot Number Combinations

Attachment 1

INSTRUCTIONS FOR COMPLETING REQUIRED ACTIONS

1. Our records show that your facility has purchased product codes affected by this voluntary recall. Do not use or further distribute any affected product.
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 *Customer 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 **Customer Acknowledgement 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 SEA_Quality@bd.com. Once all information has been verified, BARD will issue a replacement product for your returned product.
7. Email the completed **Customer Acknowledgement Form** to SEA_Quality@bd.com.

Attachment 2

URGENT MEDICAL DEVICE RECALL

CUSTOMER RESPONSE FORM

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

Please read in conjunction with the above Recall Notification and return completed form as soon as possible or **no later than the 21 June 2019.**

Name of Hospital / Facility	
Hospital / Facility Address	
Email Address	
Telephone Number	
Name	
Signature	
Date	

☐	I have read and understood the attached notice.
☐	I have shared this notice with the appropriate personnel within my organization.
☐	We have affected product(s) in inventory and shall return to distributor for destruction.
☐	We do NOT have any affected product(s) in inventory.

Product Name	Catalog (Ref) No.	Lot No.	Product Package Size	Quantities to return to distributor

(Attach a listing if required)

Name:	
Title:	
Signature/Date:	

Reference: Product Advisory – VT-RAP-19-04-002
Product: EquiStream, Glidepath

Attachment 03

Affected EQUISTREAM®, EQUISTREAM® XK, and GLIDEPATH Lot Numbers

	Product Code	Lot Number
1	5393190	RECR1105
2	6393230	RECR1115
3	5397190	RECR1795
4	6905280	RECR2380
5	5903420	RECR2381
6	5393230	RECR2787
7	6393190	RECR2797
8	5393310	RECR2969
9	6393190	RECR2979
10	6903190	RECS0199
11	6905190	RECS0618
12	5905280	RECS0812
13	6905240	RECS0813
14	6393230	RECS0816
15	5393190	RECS0985
16	5903230	RECS1083
17	5393270	RECS1085
18	5397230	RECS1086
19	6393190	RECS1087
20	5903190	RECS1417
21	6903350	RECS1419
22	5397190	RECS1699
23	5903230	RECS1702
24	5904230	RECS1703
25	5903270	RECS1704
26	6905280	RECS1705
27	6903230	RECS1928
28	5397190	RECS2073
29	6903190	RECS2203
30	6903310	RECS2204
31	5903190	RECS2205
32	5397230	RECS2306
33	6903230	RECS2437
34	6903270	RECS2465
35	5903270	RECS2828
36	5393310	RECS2833
37	5396240	RECS3050
38	6903420	RECS3052
39	6393230	RECS3203
40	5393230	RECS3250
41	5393230	RECS3251
42	5397230	RECS3252
43	6393350	RECT0366
44	5393230	RECT0367
45	5393190	RECT0371
46	5905190	RECT0552
47	6396240	RECT0554

	Product Code	Lot Number
48	5397310	RECT0555
49	5393190	RECT0558
50	6903270	RECT0559
51	5393150	RECT0802
52	5903420	RECT0903
53	5393350	RECT0951
54	5397230	RECT0952
55	5913190	RECT0999
56	6913190	RECT1000
57	5913230	RECT1026
58	6913350	RECT1027
59	5397500	RECT1476
60	5913270	RECT1713
61	6903190	RECT1790
62	5913420	RECT2105
63	5915190	RECT2247
64	5915310	RECT2248
65	5903310	RECT2252
66	5393420	RECT2301
67	5397190	RECT2416
68	6903190	RECU0185
69	5913230	RECU0189
70	6903230	RECU0429
71	5915280	RECU0636
72	5393190	RECU0665
73	5397500	RECU0758
74	5905310	RECU0812
75	5397270	RECU0981
76	6913230	RECU0989
77	6903190	RECU1000
78	6903350	RECU1123
79	6915280	RECU1226
80	6903230	RECU1238
81	5393420	RECU1701
82	5396310	RECU2248
83	5397500	RECU2622
84	5397270	RECU2783
85	5915240	RECV0327
86	5905190	RECV0678
87	6905280	RECV0679
88	6905240	RECV0900
89	5903190	RECV0935
90	5903230	RECV1544
91	5913230	RECV1552
92	6905280	RECV1556
93	6393190	RECV1558
94	6393230	RECV1612
95	5397190	RECV1615
96	5903190	RECV1624
97	5393190	RECV1690
98	5393230	RECV2487
99	6903190	RECV2946

	Product Code	Lot Number
100	5393230	RECV2948
101	6905310	RECV3105
102	5913230	RECV3572
103	6903190	RECV3639
104	5393190	RECW0095
105	6393190	RECW0098
106	6905310	RECW0294
107	5393420	RECW0386
108	5397230	RECW0387
109	5397190	RECW0390
110	6393230	RECW0391
111	6903190	RECW0578
112	6903420	RECW0583
113	5903190	RECW0585
114	5913270	RECW0661
115	6913310	RECW0662
116	6903190	RECW0727
117	6913270	RECW0780
118	5903230	RECW0847
119	5393500	RECW0848
120	5397270	RECW0903
121	6903310	RECW0906
122	5397190	RECW0912
123	5903270	RECW0913
124	5393190	RECW0961
125	6903190	RECW0963
126	5903230	RECW0964
127	5397230	RECW0970
128	5913190	RECW1365
129	5393230	RECW1714
130	5397190	RECW1716
131	5397230	RECW1718
132	6903270	RECW1719
133	5393190	RECW1846
134	5396280	RECW1848
135	6903190	RECW1850
136	6913350	RECW2017
137	6903230	RECW2370
138	5393230	RECW2371
139	5396280	RECW2372
140	5903420	RECW2474
141	5393190	RECW2475
142	5397190	RECW2477
143	6913230	RECX0488
144	5903230	RECX0505
145	5393190	RECX0509
146	5393310	RECX0510
147	5397190	RECX0511
148	5397310	RECX0642
149	5393230	RECX0653
150	6913270	RECX0831
151	6903230	RECX0848

	Product Code	Lot Number
152	6905280	RECX0849
153	5393420	RECX0854
154	5396240	RECX0986
155	6393420	RECX0987
156	5393230	RECX0998
157	6903230	RECX1115
158	6903190	RECX1116
159	6393270	RECX1117
160	5397270	RECX1119
161	5393190	RECX1120
162	6393190	RECX1121
163	5393270	RECX1122
164	6393190	RECX1123
165	6393270	RECX1124
166	5393190	RECX1125
167	6393190	RECX1127
168	5393270	RECX1128
169	5397420	RECX1129
170	6913350	RECX1177
171	6903230	RECX1185
172	6903270	RECX1186
173	5903190	RECX1187
174	5903230	RECX1188
175	5396240	RECX1189
176	5393420	RECX1190
177	5393500	RECX1191
178	6393190	RECX1192
179	5393190	RECX1193
180	6393190	RECX1194
181	5393270	RECX1195
182	6393190	RECX1196
183	6393190	RECX1197
184	5393190	RECX1199
185	6393190	RECX1200
186	6903190	RECX1473
187	5903230	RECX1633
188	6393310	RECX1645
189	5393230	RECX1714
190	6393350	RECX1716
191	6396240	RECX1717
192	5903270	RECX2535
193	5396190	RECX2538
194	6396240	RECX2540
195	5397230	RECX2542
196	6903350	RECX2700
197	5393500	RECX2702
198	5393310	RECX2705
199	5396240	RECX2706
200	5397270	RECX2707
201	6915280	RECX2776
202	5397500	RECX2780
203	5913420	RECX2820

	Product Code	Lot Number
204	5905280	RECX2828
205	6903270	RECX2829
206	5905190	RECX2893
207	6905190	RECX2894
208	5393230	RECX2895
209	5913310	RECX3001
210	5913190	RECX3045
211	6913230	RECX3046
212	5903230	RECX3053
213	6903230	RECX3054
214	5905240	RECX3120
215	6903190	RECX3639
216	5913230	RECX3719
217	6913270	RECX3720
218	6913190	RECX3802
219	6913310	RECX3803
220	5393230	RECY7435
221	5397500	RECZ0329
222	5393310	RECZ0610
223	6393350	RECZ0614
224	6913350	RECZ0630
225	6393310	RECZ0632
226	5913270	RECZ0638
227	5393230	RECZ0639
228	5393190	RECZ0651
229	5903350	RECZ0652
230	5903230	RECZ0700
231	6396190	RECZ0702
232	5913350	RECZ0711
233	6903270	RECZ0715
234	5903190	RECZ0716
235	6393230	RECZ0728
236	6903230	RECZ0729
237	5397230	RECZ0753
238	6903270	RECZ1089
239	5903230	RECZ1093
240	5903270	RECZ1097
241	5393230	RECZ1098
242	5393190	RECZ1104
243	6903310	RECZ1111
244	5396240	RECZ1119
245	5397270	RECZ1122
246	6903230	RECZ1124
247	5397190	RECZ1125
248	5913190	RECZ2628
249	6913350	RECZ2629
250	6913230	RECZ2657
251	5393230	RECZ2974
252	5396190	RECZ2975
253	5393350	RECZ2976
254	6903270	RECZ2990
255	6393310	RECZ2995

	Product Code	Lot Number
256	5393270	RECZ2996
257	5393420	RECZ2997
258	5903190	RECZ3009
259	6903420	RECZ3013
260	5904270	RECZ3014
261	6905190	RECZ3018
262	6393420	RECZ3385
263	6396240	RECZ3464
264	6903230	RECZ3478
265	6393230	RECZ3497
266	6903230	REDN0065
267	5903230	REDN0066
268	5397230	REDN0094
269	6396190	REDN0096
270	6903270	REDN0111
271	5397190	REDN0140
272	5393230	REDN0141
273	5393190	REDN0142
274	5915240	REDN1368
275	6903230	REDN1388
276	5905310	REDN1389
277	6905280	REDN1390
278	5393190	REDN1393
279	5397270	REDN1397
280	5397350	REDN1398
281	6905240	REDN1415
282	5393190	REDN1422
283	5393230	REDN1423
284	6393230	REDN1425
285	6393270	REDN1426
286	5903310	REDN2376
287	5396240	REDN2381
288	5397190	REDN2429
289	5393270	REDN2430
290	5903230	REDN2487
291	5393350	REDN2495
292	5393190	REDN2496
293	5903420	REDN2517
294	6903190	REDN3414
295	6905240	REDN3415
296	5905280	REDN3417
297	5903190	REDN3418
298	6903230	REDN3468
299	5903420	REDN4334
300	5903230	REDN4392
301	5905240	REDN4398
302	5903190	REDN4425
303	6903190	REDN4426
304	5903230	REDP0472