

URGENT: MEDICAL PRODUCT RECALL

March 4th 2016

Dear Valued Customer,

This letter is to inform you of a voluntary Medical Product Recall initiated by Bard Medical Division (BMD), a division of C.R. Bard, Inc. involving the Medivance ARCTICGEL™ Pads.

Reason for Recall:

Bard Medical Division (BMD) has received complaint reports of low flows associated with certain lots of the ARCTICGEL™ Pads. BMD has identified the affected product codes / lot number combinations listed in Attachment 2 that are at risk for causing a restricted/low flow situation. **Only the product/ lot number combinations listed in the attachment are affected.**

Our records show that your facility has purchased at least one of the affected product code / lot number combinations listed in Attachment 2.

Clinical Risk Statement:

The clinical risk associated with the restricted/low flow ARCTICGEL™ Pad(s) is suboptimal therapy delivery. In the event that one or more ARCTICGEL™ Pad(s) do not have sufficient flow, the ARCTICGEL™ Pad(s) may need to be exchanged. This may result in a slight delay in the therapy delivery, which if done in a timely manner is not associated with long-term or residual clinical consequences. If alternate pads are not available, the patient may require therapy delivery by alternate means.

If an ARCTICGEL™ Pad(s) from one of the recalled lots was used on a patient who has had an adverse event related to a low flow event, please report the event to Bard Medical's Customer Service Department by phone at 1-800-526-4455, select option 5 then option 4. In addition, please report the event to the US Food and Drug Administration's ("FDA") MedWatch Program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787, or on line at <http://www.fda.gov/medwatch/report.htm>

Instructions:

1. Check all inventory locations within your institution for ARCTICGEL™ Pad(s)

Our records show that your facility may have received at least one product/lot code combination (Attachment 2) affected by this voluntary recall.

Please refer to the diagram on Attachment 1 to help you locate the product number and lot number of your ARCTICGEL™ Pad(s). Please remove any identified affected product(s) from your shelves and complete steps 2-4 below.

2. Do not further use any affected product(s)

3. If you have unused affected product(s) for return:

- a. Fill out the Customer Recall and Effectiveness Check Form – Write in the product(s) number and affected lot(s) number (found on Attachment 2) in the table provided along with quantities of each, then complete the bottom of the form with your facility's information.
- b. Call or email the recall coordinator (using the contact information on the form) to obtain an RCL number to include on the Customer Recall and Effectiveness Check Form. Return the form to the recall coordinator via FAX: 1-770-784-6469 or E-MAIL: bmd.recall@crbard.com). If you cannot Fax or E-mail the form, please call 1-800-793-8110 and report the required information verbally.
- c. Upon receipt of the Recall & Effectiveness Check Form, the Recall Coordinator will issue you a FedEx shipping label and instructions for the return of the affected product(s). Please mark the outside package as "RECALLED PRODUCT" and include the RCL number. All product(s) should be returned to the following shipping address:

Bard Medical Division
Attn: Recall Coordinator
8195 Industrial Blvd.
Covington, GA 30014

- d. BMD will provide replacement products at no charge for your returned, unused, affected product(s) (Affected Product Code/Lot number combination listed in Attachment 2). Any returned products that are outside the scope of this recall will not be credited or replaced.

4. If you have No Affected Product available for return:

If you have used or distributed all of the affected product(s), complete and return the attached **Recall and Effectiveness Check Form** indicating no product(s) will be returned. (FAX: 1-770-784-6469 or E-MAIL: bmd.recall@crbard.com)

While this is a voluntary recall, it is being made with the knowledge of the Food and Drug Administration.

It is extremely important that we receive this information. Bard Medical Division must document your compliance with this voluntary recall. Facilities that receive this communication must immediately carry out the instructions set forth in this communication and extend the recall to its consignees, as applicable.

We appreciate your cooperation and assistance in dealing with this matter and sincerely apologize for any inconvenience that may result from this action.




Director, Quality Systems
Bard Medical Division

Attachment 1

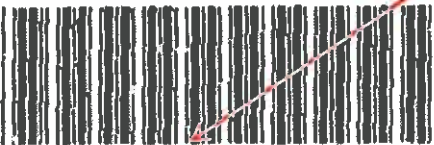
Identifying Product codes and Lot numbers:

Product code

Lot number


+M501317002\$

4 Units
317-00 ARCTICGEL™ Universal Cooling Pads


XXXXXXXX

Manufactured in Mexico

PK7635928 01/2014 0001

Attachment 2
Affected Product Code/Lot Combinations

#	Item Number	Lot Number	Expiration Date
1	31700	NGZB3925	3/31/2016
2	31703	NGZB3926	3/31/2016
3	3170502	NGZB3927	3/31/2016
4	31709	NGZB3928	3/31/2016
5	3170902	NGZB3929	3/31/2016
6	3170004	NGZB3930	3/31/2016
7	31705	NGZB3931	3/31/2016
8	3170702	NGZB3932	3/31/2016
9	31707	NGZB3933	3/31/2016
10	31700	NGZC0490	3/31/2016
11	31705	NGZC0491	3/31/2016
12	3170702	NGZC0492	3/31/2016
13	3170902	NGZC0493	3/31/2016
14	31707	NGZC0527	3/31/2016
15	3170004	NGZC0528	3/31/2016
16	3170502	NGZC0529	3/31/2016
17	31709	NGZC0530	3/31/2016
18	31703	NGZC0531	3/31/2016
19	31700	NGZC2033	3/31/2016
20	31703	NGZC2035	3/31/2016
21	31705	NGZC2036	3/31/2016
22	3170702	NGZC2038	3/31/2016
23	31709	NGZC2039	3/31/2016
24	31707	NGZC2041	3/31/2016
25	3170004	NGZC2042	3/31/2016
26	3170302	NGZC2044	3/31/2016
27	3170502	NGZC2045	3/31/2016
28	3170902	NGZC2046	3/31/2016
29	31707	NGZC2603	3/31/2016
30	3170004	NGZC2604	3/31/2016
31	3170302	NGZC2605	3/31/2016
32	3170502	NGZC2606	3/31/2016
33	31700	NGZC2624	3/31/2016

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#	Item Number	Lot Number	Expiration Date
34	31703	NGZC2625	3/31/2016
35	31705	NGZC2626	3/31/2016
36	3170702	NGZC2641	3/31/2016
37	3170902	NGZC2642	3/31/2016
38	31709	NGZC2661	3/31/2016
39	31700	NGZC3854	4/30/2016
40	31705	NGZC3855	4/30/2016
41	3170702	NGZC3856	4/30/2016
42	3170902	NGZC3857	4/30/2016
43	31707	NGZC3978	4/30/2016
44	3170004	NGZC3979	4/30/2016
45	3170502	NGZC3980	4/30/2016
46	31709	NGZC3981	4/30/2016
47	31700	NGZC4901	4/30/2016
48	31703	NGZC4905	4/30/2016
49	3170502	NGZC4906	4/30/2016
50	31709	NGZC4907	4/30/2016
51	3170902	NGZC4908	4/30/2016
52	31707	NGZC5058	4/30/2016
53	3170004	NGZC5059	4/30/2016
54	31705	NGZC5063	4/30/2016
55	3170702	NGZC5064	4/30/2016
56	3170302	NGZC5065	4/30/2016
57	31705	NGZD1012	4/30/2016
58	3170702	NGZD1013	4/30/2016
59	3170902	NGZD1014	4/30/2016
60	31700	NGZD1081	4/30/2016
61	31707	NGZD1106	4/30/2016
62	3170004	NGZD1107	4/30/2016
63	3170502	NGZD1108	4/30/2016
64	31709	NGZD1109	4/30/2016
65	31700	NGZD2025	4/30/2016
66	31703	NGZD2026	4/30/2016
67	3170502	NGZD2027	4/30/2016
68	31709	NGZD2028	4/30/2016
69	31707	NGZD2134	4/30/2016
70	3170004	NGZD2135	4/30/2016

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#	Item Number	Lot Number	Expiration Date
71	31705	NGZD2136	4/30/2016
72	3170702	NGZD2137	4/30/2016
73	3170902	NGZD2138	4/30/2016
74	31709	NGZD3309	4/30/2016
75	3170004	NGZD3310	4/30/2016
76	31707	NGZD3311	4/30/2016
77	3170302	NGZD3354	4/30/2016
78	3170502	NGZD3367	4/30/2016
79	3170702	NGZD3368	4/30/2016
80	3170902	NGZD3369	4/30/2016
81	31705	NGZD3370	4/30/2016
82	31700	NGZD3459	4/30/2016
83	31707	NGZD4790	5/31/2016
84	3170004	NGZD4791	5/31/2016
85	3170302	NGZD4792	5/31/2016
86	3170702	NGZD4793	5/31/2016
87	31705	NGZD4794	5/31/2016
88	31700	NGZD4883	5/31/2016
89	31703	NGZD4884	5/31/2016
90	3170502	NGZD4885	5/31/2016
91	3170902	NGZD4886	5/31/2016
92	31709	NGZD4887	5/31/2016
93	31707	NGZD4969	5/31/2016
94	3170004	NGZD4970	5/31/2016
95	3170702	NGZD4971	5/31/2016
96	31705	NGZD4972	5/31/2016
97	31709	NGZD4973	5/31/2016
98	31700	NGZD5049	5/31/2016
99	31703	NGZD5050	5/31/2016
100	3170902	NGZD5051	5/31/2016
101	3170502	NGZD5052	5/31/2016
102	31700	NGZE1142	5/31/2016
103	31703	NGZE1143	5/31/2016
104	31705	NGZE1144	5/31/2016
105	31709	NGZE1145	5/31/2016
106	3170502	NGZE1146	5/31/2016
107	31707	NGZE1177	5/31/2016

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#	Item Number	Lot Number	Expiration Date
108	3170004	NGZE1178	5/31/2016
109	3170302	NGZE1180	5/31/2016
110	3170702	NGZE1182	5/31/2016
111	3170902	NGZE1183	5/31/2016
112	31700	NGZE2208	5/31/2016
113	31703	NGZE2209	5/31/2016
114	3170702	NGZE2210	5/31/2016
115	3170902	NGZE2211	5/31/2016
116	3170502	NGZE2212	5/31/2016
117	31707	NGZE2332	5/31/2016
118	3170004	NGZE2333	5/31/2016
119	3170302	NGZE2334	5/31/2016
120	31709	NGZE2335	5/31/2016
121	31705	NGZE2336	5/31/2016
122	3170902	NGZE3433	6/30/2016
123	3170004	NGZE3453	6/30/2016
124	31700	NGZE3454	6/30/2016
125	3170502	NGZE3455	6/30/2016
126	31707	NGZE3606	6/30/2016
127	3170702	NGZE3607	6/30/2016
128	31705	NGZE3608	6/30/2016
129	31709	NGZE3609	6/30/2016
130	31709	NGZEY211	5/31/2016
131	31709	NGZEY212	5/31/2016
132	31709	NGZEY213	5/31/2016
133	3170004	NGZF0202	6/30/2016
134	3170302	NGZF0203	6/30/2016
135	31703	NGZF0330	6/30/2016
136	31707	NGZF0538	6/30/2016
137	3170702	NGZF0605	6/30/2016
138	3170004	NGZF1537	6/30/2016
139	31703	NGZF1538	6/30/2016
140	3170502	NGZF1539	6/30/2016
141	3170702	NGZF1540	6/30/2016
142	31700	NGZF1656	6/30/2016
143	31705	NGZF1658	6/30/2016
144	31707	NGZF1659	6/30/2016

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#	Item Number	Lot Number	Expiration Date
145	31709	NGZF1660	6/30/2016
146	3170004	NGZF3062	6/30/2016
147	3170302	NGZF3063	6/30/2016
148	31705	NGZF3064	6/30/2016
149	31705	NGZF3065	6/30/2016
150	3170702	NGZF3066	6/30/2016
151	3170702	NGZF3067	6/30/2016
152	3170902	NGZF3087	6/30/2016
153	31700	NGZF3088	6/30/2016
154	3170004	NGZF3089	6/30/2016
155	3170502	NGZF3124	6/30/2016
156	31700	NGZF3125	6/30/2016
157	31700	NGZF3126	6/30/2016
158	3170004	NGZF3127	6/30/2016
159	31703	NGZF3128	6/30/2016
160	31705	NGZF3129	6/30/2016
161	31705	NGZF3130	6/30/2016
162	31707	NGZF3131	6/30/2016
163	3170702	NGZF3132	6/30/2016
164	31709	NGZF4439	7/31/2016
165	31707	NGZF4440	7/31/2016
166	31705	NGZF4441	7/31/2016
167	3170004	NGZF4442	7/31/2016
168	3170902	NGZF4460	7/31/2016
169	3170702	NGZF4461	7/31/2016
170	3170502	NGZF4462	7/31/2016
171	31703	NGZF4467	7/31/2016
172	31700	NGZF4468	7/31/2016
173	3170004	NGZG0012	7/31/2016
174	31707	NGZG0013	7/31/2016
175	31709	NGZG0014	7/31/2016
176	31700	NGZG0044	7/31/2016
177	3170302	NGZG0045	7/31/2016
178	3170702	NGZG0046	7/31/2016
179	3170902	NGZG0047	7/31/2016
180	3170902	NGZG0736	7/31/2016
181	3170502	NGZG0737	7/31/2016

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#	Item Number	Lot Number	Expiration Date
182	3170302	NGZG0738	7/31/2016
183	3170004	NGZG0739	7/31/2016
184	3170702	NGZG0944	7/31/2016
185	31705	NGZG0945	7/31/2016
186	31703	NGZG0946	7/31/2016
187	31700	NGZG0947	7/31/2016
188	31709	NGZG1066	7/31/2016
189	3170502	NGZG1123	7/31/2016
190	31707	NGZG2051	7/31/2016
191	31703	NGZG2052	7/31/2016
192	3170702	NGZG2053	7/31/2016
193	3170004	NGZG2054	7/31/2016
194	31709	NGZG2055	7/31/2016
195	31700	NGZG2200	7/31/2016
196	31705	NGZG2201	7/31/2016
197	3170902	NGZG2202	7/31/2016
198	3170502	NGZG2203	7/31/2016
199	3170004	NGZG2696	7/31/2016
200	31705	NGZG2702	7/31/2016
201	31709	NGZG2703	7/31/2016
202	3170702	NGZG3131	7/31/2016
203	3170502	NGZG3139	7/31/2016
204	31700	NGZG3146	7/31/2016
205	3170902	NGZG3147	7/31/2016
206	31703	NGZG3153	7/31/2016
207	31707	NGZG3154	7/31/2016
208	3170702	NGZG3770	8/31/2016
209	31703	NGZG3771	8/31/2016
210	3170502	NGZG3772	8/31/2016
211	31709	NGZG3773	8/31/2016
212	31707	NGZG3891	8/31/2016
213	3170004	NGZG3892	8/31/2016
214	31705	NGZG3893	8/31/2016
215	31707	NGZG3894	8/31/2016
216	3170902	NGZG3895	8/31/2016
217	3170004	NGZH0295	8/31/2016
218	3170502	NGZH0296	8/31/2016

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#	Item Number	Lot Number	Expiration Date
219	31707	NGZH0298	8/31/2016
220	31700	NGZH0299	8/31/2016
221	31705	NGZH0300	8/31/2016
222	3170902	NGZH0301	8/31/2016
223	3170902	NGZH1462	8/31/2016
224	31700	NGZH1463	8/31/2016
225	3170702	NGZH1563	8/31/2016
226	3170902	NGZH2746	8/31/2016
227	3170004	NGZH2747	8/31/2016
228	3170502	NGZH2748	8/31/2016
229	3170702	NGZH2874	8/31/2016
230	31705	NGZH2876	8/31/2016
231	31707	NGZH2877	8/31/2016
232	31709	NGZH3226	8/31/2016