



C. R. Bard GmbH · Wachhausstrasse 6 · D - 76227 Karlsruhe

Hospital_Name»

«Users_Name» - «Department»

«Customer_Address»

«Zip_Code» «City» - «Country_name»

**Field Safety Notice
Urgent Medical Device Recall
Bard® Recovery Cone® Removal System**

Date

Dear «Users_Name»,

This letter is to inform you of a voluntary recall initiated by Bard Peripheral Vascular, Inc. (BPV), a wholly owned subsidiary of C.R. Bard, Inc.

Bard® Recovery Cone® Removal System with item number RC-15

Lot numbers affected by this recall:

All lot numbers with expiry dates between May 2008 and February 2011 are affected by this Field Safety Notice. A list of all affected lot numbers is attached to this Field Safety Notice. No other products are included in this recall.

All lot numbers with expiry dates prior to May 2008 are beyond their expiration date. In accordance with accepted medical practice, they should have been discarded and not used. All other lots in your inventory that have an expiry date after February 2011 are acceptable to use.

Reason for Recall:

This action is being taken because the product has a potential for the handle to detach from the purple shaft. The handle detachment may result in the device unable to retrieve the filter or foreign body. Please be advised that this recall only affects the Recovery Cone Removal System and not the Recovery G2 Filter. In 2007, Bard Peripheral Vascular (BPV) experienced an increased rate of handle detachment complaints for Recovery Cone Removal System, as compared to prior year complaints. The failure mode consists of a clean separation of the handle from the catheter material. None of the complaints reported occurred in Europe.

Our records indicate that your facility received some of the affected product. Attachment A provides a complete list of all recalled products.



INSTRUCTIONS:

1. **Please immediately discontinue use of the Bard® Recovery Cone® Removal System with lot numbers listed in Attachment A and remove all of the affected units from your inventory. Segregate the units in a secure place, pending return to Bard.**
2. **Please complete the attached Fax Reply Form even if you do not have any product to return.**
3. **When completed, please fax the Verification Form to +49 721 9445 212.**
4. **If you have products to return, please package them in an appropriate shipping box and send them to:**

**C. R. Bard GmbH
Mr. ..
RGA-# 01-08
Wachhausstr. 6
D - 76227 Karlsruhe**

You will receive a replacement / credit note for all recalled product returned to Bard.

5. **Please pass this notice to any health professional of your organization that needs to be aware and to any organization where the potentially affected devices have been transferred (if appropriate). Please provide Bard with details of any affected devices that have been transferred to other organizations (if appropriate).**

International Competent Authorities will be notified in accordance with country specific regulations.

We regret any inconvenience that this action may cause and we appreciate your understanding as we take action to ensure patient safety and customer satisfaction.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,

C.R. Bard GmbH

Attachments:

Attachment A - Lot numbers affected
Fax Reply Form

**Field Safety Corrective Action - Bard Recovery Cone Removal System
Attachment A - Lot Numbers Affected (Item Number RC-15)**

Lot Number	Expiry Date	Lot Number	Expiry Date	Lot Number	Expiry Date
GFPD1574	2008-05	GFPF4127	2008-07	GFQA3514	2009-02
GFPD1575	2008-05	GFPH0443	2008-08	GFQA3516	2009-02
GFPD1576	2008-05	GFPH0444	2008-08	GFQA3518	2009-02
GFPD2170	2008-05	GFPH0445	2008-08	GFQB1627	2009-02
GFPD2171	2008-05	GFPH0446	2008-08	GFQB1628	2009-02
GFPD2172	2008-06	GFPH0447	2008-08	GFQB1629	2009-02
GFPD4227	2008-05	GFPH0448	2008-08	GFQB1630	2009-02
GFPD4228	2008-05	GFPH0449	2008-08	GFQB1631	2009-02
GFPD4229	2008-05	GFPH0450	2008-08	GFQB3492	2009-03
GFPD4230	2008-05	GFPH0451	2008-08	GFQB3493	2009-03
GFPD4723	2008-05	GFPH0452	2008-08	GFQB3494	2009-03
GFPD4724	2008-05	GFPH0453	2008-08	GFQB3495	2009-03
GFPD4725	2008-05	GFPH0454	2008-08	GFQB3496	2009-03
GFPD4726	2008-08	GFPH0455	2008-08	GFQB3497	2009-03
GFPD4727	2008-06	GFPH0456	2008-09	GFQB3498	2009-03
GFPD4728	2008-06	GFPH0457	2008-09	GFQB3499	2009-03
GFPD4729	2008-06	GFPH0458	2008-09	GFQB3500	2009-03
GFPE3233	2008-06	GFPK2806	2008-12	GFQB3501	2009-03
GFPE3234	2008-06	GFPK2807	2008-12	GFQB3502	2009-03
GFPE3235	2008-06	GFPK2808	2008-12	GFQB3503	2009-03
GFPE3236	2008-06	GFPK2809	2008-12	GFQB3504	2009-03
GFPE3237	2008-06	GFPK2810	2008-12	GFQB3505	2009-03
GFPE3238	2008-06	GFPK2811	2008-12	GFQB3506	2009-04
GFPE3239	2008-06	GFPK2812	2008-12	GFQC4378	2009-04
GFPE3240	2008-06	GFPK2813	2008-12	GFQC4379	2009-04
GFPE3241	2008-06	GFPK2814	2008-12	GFQC4380	2009-04
GFPE3242	2008-06	GFPK2815	2008-12	GFQC4381	2009-04
GFPE3243	2008-06	GFPK4721	2009-01	GFQC4382	2009-04
GFPE3244	2008-07	GFPK4722	2009-01	GFQD0077	2009-04
GFPE3245	2008-07	GFPL4248	2009-01	GFQD0078	2009-04
GFPF2336	2008-07	GFPL4249	2009-01	GFQD0079	2009-04
GFPF4108	2008-08	GFPL4250	2009-01	GFQD0080	2009-04
GFPF4109	2008-08	GFPL4251	2009-01	GFQD0081	2009-04
GFPF4110	2008-08	GFPL4252	2009-01	GFQD0082	2009-04
GFPF4111	2008-08	GFPL4253	2009-01	GFQD2038	2009-05
GFPF4112	2008-08	GFPL4254	2009-01	GFQD2039	2009-04
GFPF4113	2008-08	GFPL4255	2009-01	GFQD2040	2009-05
GFPF4114	2008-07	GFPL4256	2009-01	GFQD3739	2009-05
GFPF4115	2008-07	GFPL4257	2009-01	GFQD3740	2009-05
GFPF4116	2008-07	GFPL4258	2009-01	GFQD3741	2009-05
GFPF4117	2008-07	GFPL4259	2009-01	GFQD3742	2009-05
GFPF4118	2008-07	GFPL4260	2009-02	GFQD3744	2009-05
GFPF4119	2008-07	GFPL4261	2009-01	GFQD3745	2009-05
GFPF4120	2008-07	GFQA3500	2009-02	GFQD3746	2009-05
GFPF4121	2008-07	GFQA3501	2009-02	GFQD3747	2009-05
GFPF4122	2008-07	GFQA3502	2009-02	GFQD3749	2009-05
GFPF4123	2008-07	GFQA3503	2009-02	GFQE4409	2009-06
GFPF4124	2008-07	GFQA3504	2009-02	GFQE4410	2009-06
GFPF4125	2008-07	GFQA3505	2009-02	GFQE4724	2009-06
GFPF4126	2008-07	GFQA3512	2009-02	GFQE4725	2009-06

**Field Safety Corrective Action - Bard Recovery Cone Removal System
Attachment A - Lot Numbers Affected (Item Number RC-15)**

Lot Number	Expiry Date	Lot Number	Expiry Date	Lot Number	Expiry Date	Lot Number	Expiry Date
GFQF0388	2009-06	GFQL2632	2010-01	GFRE4491	2010-06	GFSA2452	2011-01
GFQF0389	2009-06	GFQL2633	2010-01	GFRE4492	2010-06	GFSA2453	2011-01
GFQF0392	2009-07	GFQL4073	2010-01	GFRE4493	2010-07	GFSS0182	2011-02
GFQF4288	2009-07	GFQL4074	2010-01	GFRE4494	2010-07		
GFQF4289	2009-07	GFQL4075	2010-01	GFRE4495	2010-07		
GFQF4296	2009-07	GFQL4076	2010-01	GFRE4496	2010-07		
GFQF4297	2009-07	GFQL4077	2010-02	GFRE4497	2010-07		
GFQG2518	2009-07	GFQL4078	2010-02	GFRE4498	2010-07		
GFQG2841	2009-07	GFRA3887	2010-02	GFRF3639	2010-07		
GFQG3367	2009-08	GFRA3888	2012-02	GFRF3640	2010-07		
GFQG3368	2009-08	GFRA5030	2010-02	GFRF3641	2010-07		
GFQG3369	2009-08	GFRA5031	2010-02	GFRF3642	2010-07		
GFQG3370	2009-08	GFRA5032	2010-02	GFRF3643	2010-08		
GFQG3371	2009-08	GFRB0123	2010-02	GFRF3644	2010-08		
GFQG3372	2009-08	GFRB0124	2010-03	GFRF3645	2010-08		
GFQH2309	2009-08	GFRC0529	2010-03	GFRF3646	2010-08		
GFQH3845	2009-09	GFRC0530	2010-03	GFRF3647	2010-08		
GFQH3846	2009-09	GFRC0531	2010-03	GFRF3648	2010-08		
GFQI0229	2009-09	GFRC0532	2010-03	GFRF3649	2010-08		
GFQI0230	2009-09	GFRC0533	2010-03	GFRG2502	2010-08		
GFQI0231	2009-09	GFRC0534	2010-04	GFRG2503	2010-08		
GFQI0232	2009-09	GFRC0535	2010-04	GFRG2504	2010-08		
GFQI3507	2009-10	GFRC2628	2010-04	GFRG2505	2010-08		
GFQI3508	2009-10	GFRC2629	2010-04	GFRG2506	2010-08		
GFQI3994	2009-10	GFRC2630	2010-04	GFRG2507	2010-08		
GFQI3995	2009-10	GFRC2631	2010-04	GFRG2508	2010-09		
GFQJ0020	2009-10	GFRC2632	2010-04	GFRH4779	2010-09		
GFQJ0432	2009-10	GFRC2633	2010-04	GFRH4780	2010-09		
GFQJ0442	2009-10	GFRC2634	2010-04	GFRH4781	2010-09		
GFQJ0443	2009-10	GFRC2635	2010-04	GFRH4782	2010-09		
GFQJ0444	2009-10	GFRC2636	2010-04	GFRH4783	2010-09		
GFQJ0445	2009-10	GFRC2637	2010-05	GFRH4784	2010-09		
GFQJ0446	2009-10	GFRC2638	2010-05	GFRH4785	2010-09		
GFQJ4114	2009-11	GFRC2639	2010-04	GFRH4786	2010-09		
GFQJ4115	2009-11	GFRD3500	2010-05	GFRJ0045	2010-10		
GFQJ4637	2009-11	GFRD3501	2010-05	GFRJ3372	2010-10		
GFQJ4638	2009-11	GFRD3502	2010-05	GFRJ3373	2010-10		
GFQJ4641	2009-11	GFRE1347	2010-05	GFRJ3379	2010-11		
GFQJ4642	2009-11	GFRE1349	2010-05	GFRJ3380	2010-11		
GFQJ4644	2009-11	GFRE1350	2010-05	GFRJ3381	2010-11		
GFQJ4645	2009-11	GFRE1351	2010-05	GFRJ3382	2010-11		
GFQJ4646	2009-11	GFRE1422	2010-05	GFRJ3383	2010-11		
GFQK3057	2009-11	GFRE1423	2010-05	GFRJ4044	2010-11		
GFQK3788	2009-12	GFRE1424	2010-05	GFRJ4045	2010-11		
GFQL0249	2009-12	GFRE4483	2010-06	GFRJ4046	2010-11		
GFQL0250	2009-12	GFRE4484	2010-06	GFRJ4047	2010-11		
GFQL0322	2009-12	GFRE4485	2010-06	GFRJ4048	2010-11		
GFQL0323	2009-12	GFRE4486	2010-06	GFRJ4049	2010-11		
GFQL0324	2009-12	GFRE4487	2010-06	GFRK3903	2010-12		
GFQL0711	2010-01	GFRE4488	2010-06	GFRK3904	2010-12		
GFQL0731	2010-01	GFRE4489	2010-06	GFRK3905	2010-12		
GFQL2631	2010-01	GFRE4490	2010-06	GFRL0039	2010-12		