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(800) 624-2920 (Canada)
(610) 691-5400 (International)
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July 6, 2010

URGENT- MEDICAL DEVICE RECALL

Dear Medical Professional:

Recently, B. Braun has received reports of particulate matter being generated upon the insertion of the B.Braun addEASE® Binary Connector (N7790 and N7993) into a PAB® container. During this insertion, fragmentation of the PAB container stopper may occur resulting in a small amount of visible particulates in the solution. There is a risk of potential injection of particulates which could result in life-threatening injuries, such as pulmonary embolism, stroke, or heart attack, and/or death.

Due to this issue, B. Braun is initiating a voluntary product recall for the following material:

Catalog #	Lot #	Description
N7990	see attachment	20 mm addEASE® Binary Connector
N7993	see attachment	13 mm addEASE® Binary Connector

Immediately stop use or further distribution of the affected product lots.

Our records indicate that you are in receipt of affected product; please refer to the attached list that details the product that you have purchased. Please utilize the attached "Product Removal Acknowledgement" to record the number of individual units (out of shipping or partial cases) and the number of full-unopened cases you have in your current inventory. If you have no inventory, please enter zero on the form. Please return the completed form in the self-addressed envelope provided or fax the form to (610) 849-1197 within two (2) weeks of receipt. **To meet regulatory requirements, the attached form must be completed and returned to B. Braun even if the total inventory in your possession is zero.**

If you have any full or partial cases of these affected products, please call our Customer Support Department at (800) 227-2862 to arrange for return. Canadian customers may call (800) 624-2920. International customers may call (610) 691-5400. A Customer Support Representative will provide you with instructions for handling the affected product. We will arrange for unopened cases to be returned to B.Braun Medical, Inc. for proper disposal. Individual units (out of shipping cases) may be destroyed at your facility.


B. Braun is currently working to resolve this issue and provide an acceptable alternative to the market. We expect this product to be available in August 2010. In the interim, B. Braun PAB® containers can continue to be used safely with a standard syringe and needle in accordance with the Directions for Use. If you have additional questions regarding this matter, please call our B. Braun Customer Support Department at the number listed above. We apologize for any inconvenience this may have caused and look forward to your continued business.

Should you identify product where this condition has occurred, please report this promptly to B.Braun Medical Inc. by contacting our Clinical and Technical support at 1-800-854-6851. Additionally, any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/Safety/MedWatch.

B. Braun Medical Inc. is committed to assuring our products are safe and effective for both health care professionals and patients.

This voluntary recall is being performed with the knowledge of the United States Food and Drug Administration (FDA).

Sincerely,


Kimberly Paris
Director, Quality

Enclosures

Item N7990

Lots

60888981	60972166	61001972	61034923	61050223	61083703	61103769
60896155	60972167	61001973	61034925	61050224	61083705	61103770
60896156	60972168	61001974	61034926	61054305	61083706	61103771
60896157	60972170	61001975	61034927	61054306	61083707	61103773
60896158	60972171	61001976	61037565	61054307	61083708	61103774
60896159	60972172	61009984	61037566	61054308	61083709	00VL026815
60896160	60972177	61009986	61037567	61054309	61089235	00VL026817
60896161	60972178	61014184	61037569	61054310	61089236	00VL026818
60896162	60972179	61014185	61037570	61054312	61089237	00VL053187
60909722	60972181	61014186	61037571	61054313	61089238	00VL053188
60909724	60972182	61014187	61037572	61062242	61089239	00VL053189
60909725	60984561	61014573	61037573	61062243	61089242	00VL888968
60909726	60984562	61016597	61043243	61062244	61089243	00VL888969
60909728	60984564	61019646	61043244	61062246	61089244	00VL888980
60909729	60984565	61019647	61044023	61062247	61092272	
60929782	60984820	61019648	61044024	61062250	61092273	
60929788	60987936	61019649	61044025	61062254	61093525	
60930263	60987937	61019650	61044778	61062255	61093526	
60930264	60987939	61022786	61044779	61062256	61093527	
60930265	60988418	61022787	61044780	61062258	61093528	
60930266	60988419	61022788	61044781	61074453	61093529	
60930267	60990712	61022790	61044782	61074454	61093530	
60930268	60992400	61022791	61044783	61074455	61093531	
60930269	60993569	61022792	61044784	61074457	61093532	
60930270	60993570	61025398	61047315	61074460	61093533	
60930271	60993571	61025399	61047316	61074461	61093534	
60930272	60993572	61027190	61047317	61074462	61093535	
60930273	60993573	61027191	61047319	61074464	61095666	
60930274	60993574	61027192	61047320	61074465	61095667	
60930275	60994657	61027193	61047321	61079565	61095668	
60930276	60994658	61027194	61050209	61079567	61095669	
60930277	60996549	61028564	61050210	61079568	61095670	
60930278	60996550	61028567	61050211	61079570	61095671	
60930279	60996890	61029635	61050212	61079571	61095672	
60939498	60996891	61029636	61050214	61079572	61095673	
60939499	60996893	61031170	61050215	61079573	61101776	
60939500	60996894	61031171	61050216	61079574	61101777	
60939501	60996895	61031172	61050217	61079575	61101779	
60939502	60997997	61031173	61050218	61079576	61101780	
60939503	60997998	61031175	61050219	61079577	61101781	
60950897	60997999	61031177	61050220	61079578	61103766	
60950898	60998000	61034921	61050221	61083695	61103767	
60968943	61001335	61034922	61050222	61083700	61103768	

Item N7993
Lots
60928513
60936541
60936543
60942059
60950900
60953588
60969534
60972173
60973280
60983742
60997643
61003958
61017469
61027183
61027186
61031167
61031168
61042196
61045157
61056656
61057867
61058745
61073202
61078826
61085625
61096650
61102775
00VL907673
00VL907677
00VL912573
00VL927133
00VL927134
00VL927135