



May 10, 2011

B. Braun Medical

**MOOG MEDICAL DEVICE GROUP ISSUES URGENT
MEDICAL DEVICE RECALL EXPANSION NOTIFICATION**

Dear Customer,

Please read the enclosed letter from B. Braun regarding the expansion of the Medical Device Recall of listed Moog Curlin Sets. Please review all stock on hand for affected lots and remove them from your inventory. Please Do Not Destroy any Affected product.

If you have any full or partial cases of these affected products and associated lot numbers in your possession, please call B. Braun Customer Support Department at (800) 227-2862 to arrange for shipping and replacement product. A Customer Support Representative will provide you with instructions for handling the affected product and we will arrange for all products to be B. Braun Medical Inc. Should you have any questions or concerns regarding the attached information, please contact B. Braun Customer Support Department at (800) 227-2862 or Moog Medical Devices Group at (800) 970-2337, prompt #7.



B. Braun Medical Inc.

901 Marcon Blvd.
Allentown, PA 18109
Telephone: (800) 227-2862
Fax: (610) 849-1197

May 4, 2011

MOOG MEDICAL DEVICE GROUP ISSUES
URGENT MEDICAL DEVICE RECALL EXPANSION NOTIFICATION

Dear Distributor:

On May 3, 2011, B. Braun Medical Inc. was notified by Moog Medical Devices Group of an expansion to their original medical device recall, which was initiated on January 24, 2011 due to potential false air-in-line alarm that may occur when using the ambulatory administration set. This expansion applies to specific lot numbers of the Curlin model ambulatory infusion administration sets. Please review the attached notice from Moog Medical Devices Group, which provides the necessary information, list of all affected lots, and actions required.

Our records indicate that you have received one or more of these lots. Further distribution of the affected product should be discontinued immediately. **Please contact your customers that have received these lots and inform them of this recall expansion.** Please determine the inventory with your customers and have them return the affected product to B. Braun Medical Inc. to ensure proper credit of returned product. Please do not destroy any affected product. Utilizing the attached "Product Removal Acknowledgement Form" record the number of individual units in your current inventory. If you have no inventory, please enter zero on the "Product Removal Acknowledgment Form." Please return the completed form in the self-addressed envelope provided and fax the completed form to (610) 849-1197 within two weeks of receipt.

Please note that the lot numbers provided on the B. Braun "Product Removal Acknowledgment Form" are the internal lot numbers that B. Braun Medical Inc. utilizes for device identification and traceability. The prefix on some of these lot numbers are indicated as "CF". The attached list of all affected Moog lots (Moog Curlin Infusion Set Recall Notification Attachment A) and the product packaging identifies some Moog lot number with the prefix of "CRF." The "R" is an internal indicator for Moog relating to the manufacturing site. Although the "R" is not utilized by B. Braun as part of our internal lot number provided on the B. Braun "Product Removal Acknowledgement", the lot number provided on attached list of all affected Moog lots is the same manufactured lot. For example, B. Braun lot number CF10125003 is Moog lot number CRF10125003.

To meet regulatory requirements, the attached "Product Removal Acknowledgment Form" must be completed and returned to B. Braun Medical Inc. Quality Assurance Group via the self-addressed envelope provided or fax even if the total inventory in your possession is zero.

If you have any full or partial cases of these affected products and associated lot numbers in your possession, please call our Customer Support Department at (800) 227-2862 to arrange for shipping and replacement product. A Customer Support Representative will provide you with instructions for handling the affected product and we will arrange for all products to be returned to B. Braun Medical Inc. Should you have any questions or concerns regarding the attached information, please contact our Customer Support Department at (800) 227-2862 or Moog Medical Devices Group at (800) 970-2337, prompt #7.

Sincerely,

Kimberly Paris
Director of Quality, PA
B. Braun Medical, Inc.

Enclosures



May 2, 2011

Moog Medical Devices Group
4314 Zevex Park Lane
Salt Lake City, Utah 84128

RE: Expansion of Moog/Curlin Ambulatory Pump Administration Set Recall

ph 801.264.1001
fx 801.264.1051
800.970.2337

Dear Customer,

www.moog.com/medical

Moog is issuing this notification to provide you important information regarding an expansion of the medical device recall for specific lot numbers of Curlin model ambulatory infusion administration sets. The affected administration sets are used with the Moog Curlin Ambulatory Pumps, which includes the 4000 CMS Ambulatory Pump, the 6000 CMS Ambulatory Pump, and the PainSmart® IOD Ambulatory Pump. The decision to expand the original recall dated January 24th, 2011 is due to a potential false air-in-line alarm that may occur when using an ambulatory administration set.



Issue Explanation:

A defect with the resin used in tubing received from a supplier has been discovered. This has resulted in a rough texture on the inner and outer diameter of the tubing segment inserted into the pump. This could lead to the pump sensor registering an air bubble, causing an un-resolvable false air-in-line alarm, even if no air bubble is present.

Patient Impact:

There have been no reported adverse patient events as of the date of this notification.

Necessary Customer Actions:

Moog records indicate you have received ambulatory administration sets that may lead to the false air-in-line alarm. Identification of potentially affected product codes and lot numbers are listed in Attachment A. If you have product from these lot numbers, please follow the process as outlined below:

Product Purchased from a Distributor:

Action	Required Information
1. Remove suspect product code from inventory	See Attachment A to determine lots that are suspect
2. Contact your Distributor to arrange replacement product	Provide lot numbers, quantities of product needing to be returned and a shipping address for replacement product
3. Request a shipping return label as per the distributor's process and ship back to their location.	Box up all suspect product and return via shipping label

Product Purchased Directly from Moog

Action	Required Information
1. Remove suspect product code from inventory.	See Attachment A to determine which lots are suspect
2. Contact Moog Customer Service at 1-800-970-2337, prompt #7.	Provide lot numbers, quantities of product needing to be returned and provide a shipping address for replacement product
3. Moog Customer Service will provide a call tag for convenient product return.	Box up all suspect product and return via the call tag

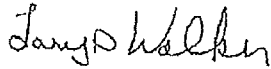
Temporary Clinical Option for Using Pumps:

Until replacement administration sets are shipped, we realize you may need an alternate way in which to provide patient therapy. Following is a suggested temporary solution:

- Clinicians can elect to use the Moog Curlin Ambulatory pump(s) by turning the pump air sensor, located in the options menu, to the "OFF" status. (Reference Attachment B for instructions, or refer to the Curlin Ambulatory Pump Users Manual.)
- Use of an administration set with an air-eliminating filter whenever the Air-In-Line Sensor is set to OFF. (See Attachment C for available product codes with an air-eliminating filter.)
- If you do not currently use sets with "in-line air eliminating filters", contact your account manager to assist you with determining alternative options.

Moog is committed to quickly resolving this issue. We have notified the necessary regulatory bodies of our intent to expand this field action. We apologize for any inconvenience.

Sincerely,



Larry D. Walker
Regulatory Affairs Manager
Moog Medical Devices Group

Attachments for Support:

- A) Product codes and lot numbers
- B) Instructions for air sensor "off" mode
- C) Administration set with filter product codes

Moog Curlin Infusion Set Recall (Expanded)
Attachment A

Model/Lot #
340-4165
CRF10054001
CRF10056001
CRF10077001
CRF10079001
CRF10081001
CRF10166001
CRF10170001

340-4175
CF1022809

340-4125
CRF10173001

340-4128
CF1018003
CF1019017
CF1022207
CF1029503
CF1029504
CRF10138002

340-4128
CF1021808
CRF10082001
CRF10084001
CRF10085001
CRF10089001
CRF10140001
CRF10161002

340-4130
CF1026704
CRF10097001

340-4137
CF1022902

340-4174
CF1022903
CRF10154001

340-4165
CF1022905

340-4168
CF1026006

340-4169
CF1026705

340-4175
CF1025201

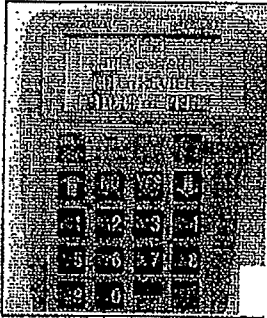
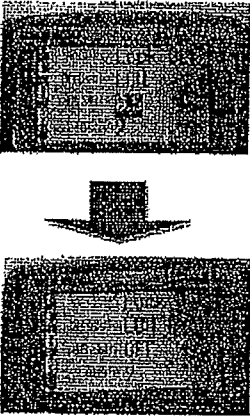
340-4176
CRF1018702



January 24, 2011

ATTACHMENT B

USING THE "OPTIONS" FUNCTION TO TURN OFF THE AIR-IN-LINE SENSOR ALARM

Step	Instructions	Visual
Step 1	Program and verify the therapy.	
Step 2	Upon completion of programming the therapy, select the OPTIONS function. A password will be required if the pump has a set lock level.	
Step 3	Once the Options menu is selected, scroll down (via the arrow or YES key) until AIR SENS is reached. The AIR SENS may show a default of 0.5 mL. Select NO until the OFF mode is on the screen (the pump will offer options of .5 mL, 2mL, and 01.mL). By selecting the NO key, this can be changed to OFF. Select YES to verify your choice.	
Step 4	Select the RUN key to begin the therapy. Answer YES when asked "AIR Sensor OFF, Using an IN Line Filter?"	

ATTACHMENT C		
ADMINISTRATION SETS WITH FILTERS- PRODUCT CODES		
Product Code	Description of substitute sets containing air-eliminating filters	Clinical Considerations
340-4128	Non-vented bag spike, tubing with free-flow protection, slide clamp, 1.2 micron filter, distal male luer lock connector. Latex-free, DEHP-free. Priming Volume: 5.1 mL Length: 94 in (238.8 cm)	1. Free flow protection provided by the "Flow-Stop" device with the break away tab. Set can be gravity primed prior to breaking away the tab or can be pump primed. 2. Note priming volume. 3. Note instructions for priming air filter (hold filter upright).
340-4128-V	Non-vented bag spike, tubing with free-flow protection, slide clamp, 1.2 micron filter, distal male luer lock connector, add-on check valve. Latex-free, DEHP-free. Priming Volume: 5.1 mL Length: 94 in (238.8 cm)	1. Free flow protection provided by the "Flow-Stop" device with the break away tab backed up by the add-on check valve. The valve must be connected prior to connecting to the patient. 2. Set can be gravity primed prior to breaking away the tab and attaching the back check valve. Set can also be pump primed. 3. Note priming volume. 4. Note instructions for priming air filter (hold filter upright).
340-4130	Non-vented bag spike, tubing with free-flow protection, slide clamp, .22 micron filter, distal male luer lock connector, Priming Volume: 5.1 mL Length: 94 in (238.8 cm)	1. Free flow protection provided by the "Flow-Stop" device with the break away tab. Set can be gravity primed prior to breaking away the tab or can be pump primed. 2. Note priming volume. 3. Note instructions for priming air filter (hold filter upright).
340-4130-V	Non-vented bag spike, tubing with free-flow protection, slide clamp, .22 micron filter, distal male luer lock connector, add-on check valve. Latex-free, DEHP-free. Priming Volume: 5.1 mL Length: 94 in (238.8 cm)	1. Free flow protection provided by the "Flow-Stop" device with the break away tab backed up by the add-on check valve. The valve must be connected prior to connecting to the patient. 2. Set can be gravity primed prior to breaking away the tab and attaching the back check valve. Set can also be pump primed. 3. Note priming volume. 4. Note instructions for priming air filter (hold filter upright).
340-4173	Non-vented bag spike, tubing with free-flow protection, 1.2 micron filter, slide clamp, ASV 6 inches from distal end, distal male luer lock connector. Latex-free, DEHP-free. Priming Volume: 7.0 mL Length: 97 in (246.4 cm)	1. Free flow protection provided by the "Flow-Stop" device with the break away tab and in-line anti-siphon valve. 2. Set can only be primed on the pump. 3. Note priming volume. 4. Note instructions for priming air filter (hold filter upright).
340-4174	Non-vented bag spike, tubing with free-flow protection, .22 micron filter, slide clamp, ASV 5 inches from distal end, distal male luer lock connector. Latex-free, DEHP-free. Priming Volume: 7.0 mL Length: 97 in (246.4 cm)	1. Free flow protection provided by the "Flow-Stop" device with the break away tab and in-line anti-siphon valve. 2. Set can only be primed on the pump. 3. Note priming volume. 4. Note instructions for priming air filter (hold filter upright).