

# smiths

December 7, 2004

**Smiths Medical MD, Inc.****Medication Delivery  
and Patient Monitoring Division**

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**URGENT: Product Safety & Recall Notification**

**For the Deltec® branded Administration Sets for use with  
Deltec® 3000 and 3100; Graseby 500, 505 and AVI  
Volumetric Infusion Pump Systems (various part numbers).**

**See Attachment 1 for the re-order numbers and lot numbers affected by this notification.**

Dear Risk Manager:

Smiths Medical MD, Inc. ("Smiths Medical") has become aware of incidents of over infusion with use of Deltec® 3000 and 3100; Graseby 500, 505 and AVI Volumetric Infusion Pump Systems. Some Deltec branded Administration Sets which are used with these infusion pump systems may have a defect within the fluid path above the upper chamber of the set cassette which does not always allow the pump valve to close completely and can allow fluid to leak past. This may have the effect of causing an inaccurate infusion rate or allowing fluid flow when the pump is in the hold condition. See the attached Customer Information Bulletin for more detailed information.

In our continued effort to provide our customers with the highest quality of products, and as a precautionary measure, Smiths Medical is voluntarily recalling all unused inventory of the affected products.

In order to expedite this recall, please check your inventory for the affected reorder and lot numbers and contact the Smiths Medical Customer Service Department to make arrangements to have the affected products returned to us. Smiths Medical will replace any returned affected products.

**This recall affects only those products listed. No other lots of Administration Sets are affected by this recall.**

If no Administration Sets from alternative lots are available and the use of the volumetric pump is essential, follow the instructions in the attached Customer Information Bulletin, which describes how to identify a set which does not have the defect. Be vigilant throughout the infusion procedure.

Smiths Medical has informed the U.S. Food and Drug Administration (FDA) of this situation. We would like to take this opportunity to apologize for any inconvenience this situation may cause you.

Sincerely,



Smiths Medical, Inc.  
Russ Davies  
Vice President, Regulatory Affairs & Quality Systems

List of Attachments: Attachment 1 Product Re-order and Lot number Affected  
Attachment 2 Reconciliation Request  
Attachment 3 Customer Information Bulletin

**Deltec** 

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Attachment 1**Product Re-order and Lot numbers Affected by this Customer Notification**

**FEB04T01 thru FEB04T37  
MAR04T01 thru MAR04T36  
APR04T01 thru APR04T29  
AUG04T34, AUG04T35, AUG04T36**

| Reorder    | MODEL    | PRODUCT   |
|------------|----------|---|
|            | NUMBER   | DESCRIPTION   |
| 21-0301-25 | I8C1230J | SET, ADMIN, MDL 8C1230 JPN, 30/CS                           |
| 21-0304-01 | 8C290    | SET, ADMIN, MDL 8C290, 30/CS                                |
| 21-0305-01 | 8C1230   | SET, ADMIN, MDL 8C1230, 30/CS                               |
| 21-0306-01 | 8C1630   | SET, ADMIN, MDL 8C1630, 30/CS                               |
| 21-0308-01 | AK2304   | SET, ADMIN, MDL AK2304, 30/CS                               |
| 21-0309-01 | CC2102   | SET, BLOOD, MDL CC2102, W/PRE-PIERCED INJECTION SITE 30/CS  |
| 21-0313-01 | CJ4303   | SET, ADMIN, MDL CJ4303, W/PRE-PIERCED INJECTION SITE, 30/CS |
| 21-0313-01 | CJ4303   | SET, ADMIN, MDL CJ4303, W/PRE-PIERCED INJECTION SITE, 30/CS |
| 21-0317-25 | I8C290   | SET, ADMIN, MDL 8C290 INT'L, 30/CS                          |
| 21-0318-25 | I8C1230  | SET, ADMIN, MDL 8C1230 INT'L, 30/CS                         |
| 21-0319-25 | I8C1630  | SET, ADMIN, MDL 8C1630 INT'L, W/O FILTER, 30/CS             |
| 21-0323-01 | 8C220    | SET, ADMIN, MDL 8C220, 40/CS                                |
| 21-0324-01 | 8C230    | SET, ADMIN, MDL 8C230, 40/CS                                |
| 21-0325-01 | 8C390    | SET, ADMIN, MDL 8C390, 40/CS                                |
| 21-0327-01 | 8C4209   | SET, ADMIN, MDL 8C4209, 40/CS                               |
| 21-0328-01 | 8C4220   | SET, ADMIN, MDL 8C4220, 40/CS                               |
| 21-0330-01 | AC2029   | SET, ADMIN, MDL AC2029, 40/CS                               |
| 21-0333-01 | CC1201   | SET, ADMIN, MDL CC1201, W/PRE-PIERCED INJECTION SITE, 40/CS |
| 21-0334-01 | CC1301   | SET, ADMIN, MDL CC1301, W/PRE-PIERCED INJECTION SITE, 40/CS |
| 21-0336-01 | CC2204   | SET, ADMIN, MDL CC2204, W/PRE-PIERCED INJECTION SITE, 40/CS |
| 21-0338-01 | CC3217   | SET, ADMIN, MDL CC3217, W/PRE-PIERCED INJECTION SITE, 40/CS |
| 21-0339-01 | CC4203   | SET, ADMIN, MDL CC4203, W/PRE-PIERCED INJECTION SITE, 40/CS |
| 21-0340-01 | CF4203   | SET, ADMIN, MDL CF4203, W/PRE-PIERCED INJECTION SITE, 40/CS |
| 21-0341-01 | LC4203   | SET, ADMIN, MDL LC4203, W/LIFESHIELD, 40/CS                 |
| 21-0344-25 | I820     | SET, ADMIN, MDL 820 INT'L, 40/CS                            |
| 21-0345-25 | I8C230   | SET, ADMIN, MDL 8C230 INT'L, 40/CS                          |
| 21-0346-25 | I8C820   | SET, ADMIN, MDL 8C820 INT'L, 40/CS                          |
| 21-0347-25 | I8C825   | SET, ADMIN, MDL 8C825 INT'L, 40/CS                          |
| 21-0349-25 | I8C4220  | SET, ADMIN, MDL 8C4220 INT'L, 40/CS                         |
| 21-0352-25 | I8C4240J | SET, ADMIN, MDL 8C4240 JPN, 40/CS                           |
| 21-0400-01 | NC4230   | SET, ADMIN, MDL NC4203, NEEDLEFREE VALVE, 40/CS             |
| 21-0402-25 | RC4106   | SET, ADMIN, MDL RC4106, NEEDLEFREE VALVE, 40/CS             |
| 21-0426-01 | NJ4303   | SET, ADMIN, MDL NJ4303, NAC, 30/CS                          |
| 21-0427-01 | NK4303   | SET, ADMIN, MDL NK4303, NAC, 30/CS                          |
| 21-0428-01 | NC1301   | SET, ADMIN, MDL NC1301, NAC, 40/CS                          |
| 21-0433-01 | NJ2304   | SET, ADMIN, MDL NJ2304, NAC, 30/CS                          |
| 21-0441-25 | RC2124   | SET, ADMIN, MDL RC2124, NAC, 40/CS                          |
| 21-0442-25 | RC1201   | SET, ADMIN, MDL RC1201, NAC, 40/CS                          |