

Employee Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

June 28, 2004

- Item:** DeRoyal ReliaFlex™ Suction Canisters with Liners
- General Information:** DeRoyal suction canisters that are used with the ReliaFlex™ suction liner system have violently discharged blood and body fluids when the full liners were removed by clinical staff from the hard outer shell. Unsecured caps on the tandem port and pour spouts along with slight pressure on the flexible suction liner precipitated the discharge. To correct this problem, DeRoyal now manufactures the caps with a ridge inside to ensure a tight fit when minimal pressure is applied by the end user.
- Specific Incident:** Clinical staff at two VA hospitals were splashed with blood and body fluids when removing full suction liners from the hard outer shell.
- Actions:**
1. Review the attached letter from DeRoyal and sequester all affected models and lot numbers.
 - a) 71-9101, canister liner, 1300cc, Lot numbers **lower than 5951**
 - b) 71-9201, canister liner, 1800cc, Lot numbers **lower than 5949**
 - c) 71-9301, canister liner, 3200cc, Lot numbers **lower than 6096**
 2. With the help of your Logistics office or your material management service, contact your local DeRoyal sales representative or distributor to make sure that you have an adequate supply of the redesigned ReliaFlex™ suction liners (those with lot numbers higher than 1a-c) before you ship the affected units back to DeRoyal for free replacement. DeRoyal has agreed to accept returns on partial cases.
 3. In lieu of continuing to use the ReliaFlex™ suction liner system, you may elect to use the DeRoyal Crystalline™ Disposable Canister System.
- Source:** VISNs 11 and 12
- Contact:** Bryanne Patail, Biomedical Engineer, National Center for Patient Safety, (734) 930-5890



3200cc, 1800cc and 1300cc sizes



David Watermeier
Marketing Director
Acute Care

Corporate Offices
200 DeBusk Lane
Powell, TN 37849
U.S.A.
TEL 865.938.7828
FAX 865.938.6655
www.deroyal.com

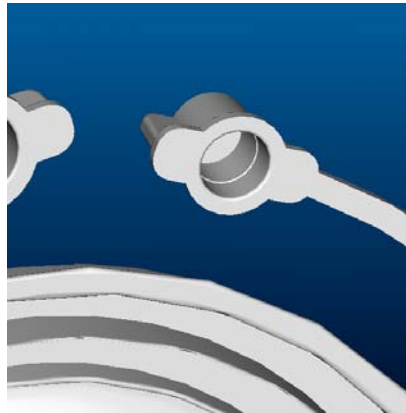
Department of Veterans Affairs
Veterans Health Administration
National Center for Patient Safety
Bryanne M. Patail
24 Frank Loyd Wright Drive
Lobby M
P.O. Box 486
Ann Arbor, MI 48106

June 24, 2004

Dear Mr. Patail,

It has recently come to the attention of DeRoyal that there remains in the market ReliaFlex™ suction liners that were manufactured prior to an upgrade that was made to the tandem port and pour spout caps.

The enhancement made to the port caps was to add ridges inside the caps to ensure a tight fit with minimal pressure applied to the cap by the end user. We feel that the original design, while perfectly safe and effective, was prone to a human factor element in that it required the end user to be more conscientious in ensuring the caps were on tightly and securely. The upgrade of adding the ridges inside the port caps helps to eliminate this human factor by requiring less force by the end user to securely place the port caps. A picture showing this ridge follows:



Nonetheless, DeRoyal is hereby offering to the VA healthcare facilities a global return authorization / product exchange on any old versions of the ReliaFlex Suction Liners. Our normal policy is to accept returns and exchanges on full case quantities only; this policy is being waived for this situation and we will accept partial cases. The procedure to exchange such product is as follows:

1) Exchanges for the products of the below listed lot numbers are eligible for return and replacement product. The lot number can be found printed in black on the lid of the liners. Please go by the lot number printed on the actual product versus the number on the outer case:

- a. 1300cc liners; lot numbers lower than **#5951**
- b. 1800cc liners; lot numbers lower than **#5949**
- c. 3200cc liners; lot numbers lower than **#6096**

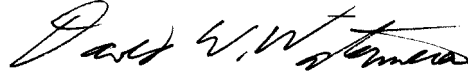
2) Write “**RA# VALINERS01**” on the box and ship the product to DeRoyal’s Distribution Center at:

DeRoyal Distribution Center
ATTN: Returns
1755 Highway 33 South
New Tazewell, TN 37825

3) Upon receipt, replacement product will be shipped out immediately.

Bryanne, I sincerely regret the inconvenience this has caused with any of the VA facilities. Please be assured that the VA’s satisfaction with DeRoyal’s suction system is of utmost importance to us and we will do anything reasonable to resolve any issues.

Sincerely,



David W. Watermeier

cc: Diane Conner Bass, Director of National Accounts, Government Affairs
Jack Payne, Executive Vice President, Acute Care
Chrissy Newton Brooks, Sr. Product Manager
Carla Slone, Manager of Customer Support
Eddie Crockett, Distribution Plant Manger