

Please complete form and forward to your site Material Management Dept. and retain any defective products.

SECTION 1: End-user/department to complete with all available information

Section 1A

Supplier: **B. Braun Medical Inc. Supplier**
 Contact: **Donna Bird**
 Phone # **519-404-8125**
 Email Address: **donna.bird@bbraun.ca**

Section 1B *Information will be kept confidential*****

Individual Reporting Problem
 Facility Department
 Phone # Extension
 Email Address
 Date Complaint Form Completed

Problem: Packaging Labeling Defective Product Other (specify)

Product / Service : **B. Braun tubing (IV administration set)**

Supplier Product #

SAP Item #

Lot #

Expiry Date (If known)

Location of Sample: Department or Material Management

Date Problem Occurred:

IMPACT OF PROBLEM

MINOR SERIOUS SEVERE

(economic inconvenience) (potential for harm) (potential for critical incident)

Was an RL Report Submitted? YES NO

Incident #

Health Canada Case# if reported

Person who reported to HC

Is product available for inspection? YES NO

If yes, contact site MM for instructions

Were other devices involved? YES NO

If yes, please describe

Details of Problem and Actions Taken to Date:

Please use checklist on following page for "AIR IN LINE" or "DOWNSTREAM OCCLUSION" alarm complaints. Other problems, please describe:

SECTION 2: Material Management / Pharmacy Department

Section 3A

Material Manager
 Phone #
 Email
 Reviewed and completed by Mat. Man. prior to submission to SCSS
 Comments/Additional Information

Section 3B

Purchase Order #
 Purchased Date
 SAP Item #
 Contract Start Date
 Contract #

Material Management / Purchasing Dept. to send completed form via email to SCSS@sharedhealthmb.ca

To view progress status and resolutions for complaints, please visit the SCSS Complaint Resolution tracker:

[SCM Product Complaints](#)

Please note that additional information may be required to resolve the problem and will be gathered by SCSS following receipt of the complaint form. Please email SCSS@sharedhealthmb.ca should you have any questions.

COMPLAINT #

Use for: "Air in line" alarm.

- Fluid is at room temperature
- Drip chamber is ½ to 2/3 filled
- Tubing is properly loaded
- IV line primed through pump and injection port sites inverted while primed
- ASV in place
- Used prime function to remove the air in the line and infusion restarted (IMPORTANT: DO NOT SELECT "NO" when it asks to prime the air in line. There needs to be an action on the alarm to deactivate it)
- Alarm reoccurs, use prime function again to remove the air in the line and restart infusion
- Open door, remove and visualize tubing, tap the tubing section and observe for bubbles
- No visible bubbles, use Alcohol pad and wipe segment of the tubing between the silicone pump segment and green clamp, reload the tubing and restart infusion
- Alarm re-occurs, fill out Product Vendor Complaint form. Please note the following info:
 - Medication:
 - Rate:
 - Date and time:
 - LOT number of tubing (if possible):
 - Pump Serial Number or asset number:
 - Any other details about the event not already mentioned:

- Change the tubing. If possible send tubing to Biomed (HIPPO to Maintenance).
- Change the pump. HIPPO to Maintenance to send pump to Biomed

Use for: "Downstream Occlusion" Alarm

- IV site patent
- Tubing clamps are open, no kinks in tubing
- ASV in place (no more than 1 ASV in use)
- Pressure adjusted by recommended 1 increment at a time and infusion restarted
- alarm reoccurs, steps repeated, door of pump opened and tubing properly loaded
- alarm reoccurs, change the pump
- alarm reoccurs, change the tubing
- if the problem resolves with changing the pump, fill out Product Vendor Complaint Form. Please note the following info:
 - Medication:
 - Rate:
 - Date and Time:
 - LOT number of tubing (if possible):
 - Pump Serial Number or Asset Number:
 - Any other details about the event not already mentioned:

- Send pump and tubing (if possible) to Biomed (HIPPO to Maintenance)
- If alarm reoccurs, the resistance is most likely caused by IV site or positional IV.