

URGENT FIELD SAFETY NOTICE

Argyle™ Single Lumen Polyurethane Umbilical Vessel Catheters

Product Code	Product Description
8888160325	2.5FR URETHANE UMBILICAL CATHETER
8888160333	3.5FR URETHANE UMBILICAL CATHETER
8888160341	5.0FR URETHANE UMBILICAL CATHETER

September x, 2013

Dear Valued Customer:

This safety alert is being issued to notify Covidien customers of an update to the instructions for use for polyurethane single lumen umbilical vessel catheters to include additional information on the care of the device. A copy of the updated instruction insert is attached. We wish to direct your attention to line items 9-12 of the warnings section.

- 9 Do not use alcohol, acetone, or alcohol containing antiseptics **directly** on the catheter. Carefully check antiseptic solutions for alcohol or acetone. These substances may cause irreversible damage to the polyurethane which can lead to a leak or break.
- 10 Ensure gloves or other surfaces which have alcohol on them are completely dry before touching or manipulating the catheter.
- 11 Do not pinch or bend the catheter back to temporarily occlude the catheter. This causes increased stress on the catheter which can lead to a leak or break.
- 12 Do not use instruments with sharp or rough edges directly on the catheter since even a minor cut could tear or break the catheter.

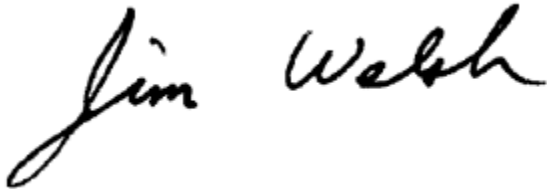
The updates were made to address the increasing use of disinfectants containing alcohol and/or acetone to clean vascular access devices. While we recognize that these materials are now required in many hospital protocols for routine cleaning of vascular access devices, the use of these disinfectants can cause damage to the polyurethane contained in the catheter and make it more susceptible to physical damage, which may ultimately lead to the need to replace the catheter.

Please forward this letter to all colleagues within your organisation who need to be aware of it or to any organisation/persons where the potentially affected devices have been transferred. Please maintain awareness of this notice for an appropriate period.

We know you share Covidien's interest in patient safety and accordingly ask that you review the cleaning methods used in your facility, as well as the guidance for proper care in handling the catheter that is outlined in the attached insert.

Thank you for your attention to this matter. This action is being taken with the knowledge of the [add local Competent Authority]. If you have any questions or concerns, please do not hesitate to contact your Covidien representative at [add local contact number].

Sincerely,

A handwritten signature in black ink that reads "Jim Welsh". The signature is written in a cursive, flowing style.

Jim Welsh
VP, Regulatory Affairs
Medical Supplies
Covidien