

SUPPLEMENTARY ADVISORY

Convenience at a Cost

Changing Catheters Over a Wire

Reports submitted to PA-PSRS from the same hospital within an eight-day period concerned pieces of intravenous catheters being left in patients and embolizing. Two events were discovered following CT scans, with the catheter segments lodged in one patient's inferior vena cava and another patient's hepatic vessels. Subsequent to each occurrence, the retained catheter segments were removed with interventional angiography.

Following root cause analysis, the hospital staff determined that a resident physician was cutting the sheath introducer of single lumen infusion catheters to facilitate change to a new catheter using the Seldinger technique over a wire. The resident did not realize that there was a separate inner catheter inside the outer sheath introducer in the single lumen catheter. When the guidewire was introduced into the cut end of the sheath introducer, it pushed the cut end of the inner catheter into the blood stream without the physician's awareness. The hospital acted quickly to stop the practice of modifying the catheters in this manner and reported the events and their analysis to PA-PSRS.

An intravenous infusion catheter is placed, usually in a large central vein, to administer various intravenous fluids and agents. A percutaneous sheath introducer is used to insert and maintain the catheter placement in a vessel. Figure 1 shows the catheter inserted into the introducer. The side port of the sheath introducer is used to infuse fluids into the bloodstream.

According to the facility, a resident physician was unfamiliar with this particular type of catheter and did not realize that cutting the outer sheath introducer below its hub also cut an inner catheter, freeing it from its hub. Confusion may be compounded by the fact that when the hub of the catheter is positioned against the hub of the sheath introducer; the sheath and catheter may appear as a single device.

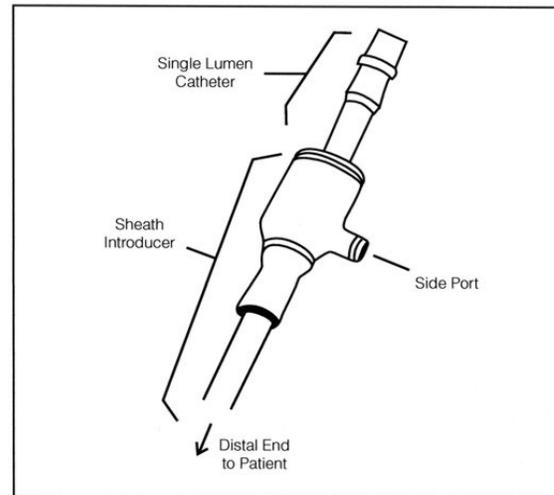


Figure 1. Sheath Introducer and Catheter Assembly

Figure 2 shows the catheter inserted further into the introducer to the point where the catheter hub is resting against the introducer hub.

The sheath introducer hub acts as a stop for the catheter and, on some models, provides a mechanism to lock the catheter to the introducer to prevent unintentional catheter movement. Cutting

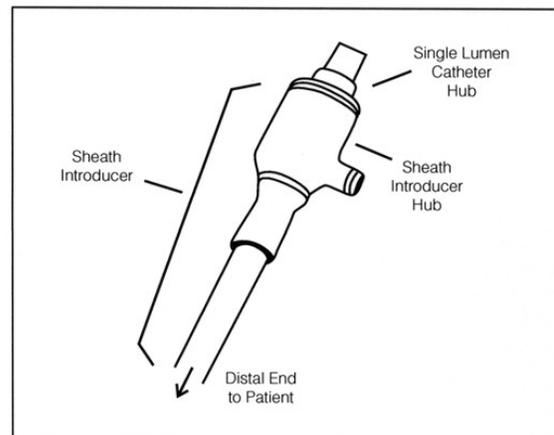


Figure 2. Catheter Hub Positioned against Sheath Hub

Convenience at a Cost (Continued)

below the hub of the sheath introducer removes this anchor. Figure 3a shows where a cut might be made below the hub of the introducer and catheter assembly to introduce a new catheter. A Seldinger guidewire inserted into the introducer to guide the placement of a new catheter into the vein pushes the free-floating original piece of infusion catheter into the patient's bloodstream. The small arrows in Figure 3b show that when the guidewire is pushed

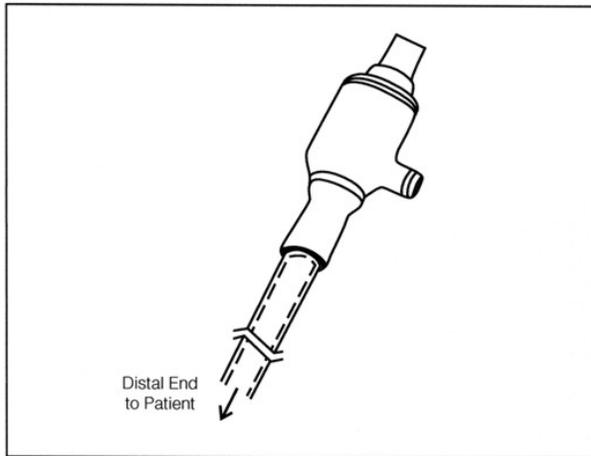


Figure 3a. Sheath Introducer and Catheter Modified (Cut)

further into the sheath introducer, the inner catheter is pushed further distally into the patient's bloodstream.

The cases described above would not be exclusive to a specific style or model sheath introducer and catheter, but could occur with any style or model.

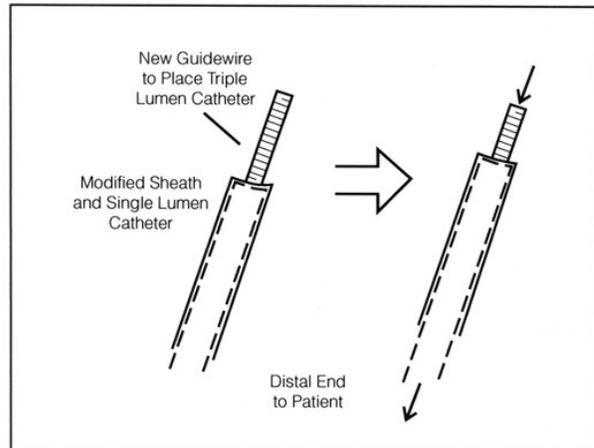


Figure 3b. Single Lumen Catheter Pushed into Bloodstream

Oxygen Flow Selector

Two reports, each from different healthcare facilities, were submitted to PA-PSRS involving unintentional failure to deliver oxygen therapy to patients due to misconfiguration of the oxygen (O₂) flow selector device. In one report, on routine assessment, the patient was discovered with an O₂ saturation level of 83% and with "dusky blue-color" extremities. In the other report, one of the patient's family members notified a nurse that the patient was "a little confused." In both cases, the patients stabilized once O₂ flow was reestablished.

Of the two reports, one identified the manufacturer and model flow selector involved in the incident as Precision Medical Inc Model PM 1000 Flow Selector also marketed as Model MF8025 by Medical Fittings, Inc, a subsidiary of Precision Medical. This particular flow selector has a threaded female connection for a standard O₂ flowmeter. Once connected to the flowmeter, the flow of O₂ can be directed to *only* one of three outflow ports on the device; one DISS outflow and two tubing connections. A label on the flow selector control knob indicates the selected active port with the word "ON" printed

on a green locating arrow pointing at the port. Each of the two inactive ports is indicated with the word "OFF" printed on red locating arrows pointing at each port. The user turns the flow selector control knob to the appropriate outflow port.

According to Precision Medical's marketing literature, the flow selector features allow a humidifier to remain connected during nebulizer treatments and tubing to remain connected when not in use to save time and reduce clutter.

In 1997, Precision Medical Inc and Medical Fittings, Inc., initiated product recalls (FDA Recall Nos. Z-824/825-7, ECRI Health Devices Alerts Action Item No. A3336) on flow selector models PM1000 and MF8025, respectively. The recall was based on FDA's determination that labeling for the flow selectors was inadequate. New labeling was provided by Precision Medical and approved by FDA. Until new labeling was received by healthcare facilities, the products were deemed safe to use, provided users were aware that only one outflow port was active at a time.

Convenience at a Cost (Continued)

A search of FDA's Manufacturer and User Facility Device Experience (MAUDE) database from the year 2000 to the present, using the keyword search "flow selector" revealed 9 reports, for Models PM1000 and MF8025, of improper flow selector setup or failure of the flow selector to deliver O₂ to the appropriate outflow port. Currently, we are unaware of similar flow selector products marketed for sale to healthcare facilities.

The flow selector device does not appear to be designed to provide a clinical benefit for the patient,

but one of convenience for the clinical user. Based on the two PA-PSRS reports, the MAUDE reports, and the 1997 safety recall, convenience still comes at a potential cost to patient safety. To avoid similar occurrences, some hospitals have removed the flow selectors from service or educated clinical staff on the proper operation of the device and on the need to verify that O₂ is flowing to the patient prior to leaving the patient's room.



An Independent Agency of the Commonwealth of Pennsylvania

The Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error (“Mcare”) Act. Consistent with Act 13, ECRI, as contractor for the PA-PSRS program, is issuing this newsletter to advise medical facilities of immediate changes that can be instituted to reduce serious events and incidents. For more information about the PA-PSRS program or the Patient Safety Authority, see the Authority’s website at www.psa.state.pa.us.



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The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit organization dedicated solely to medication error prevention and safe medication use. ISMP provides recommendations for the safe use of medications to the healthcare community including healthcare professionals, government agencies, accrediting organizations, and consumers. ISMP’s efforts are built on a non-punitive approach and systems-based solutions.

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