Advisory Note for Using Intracatheter Devices

Background

The Medical Device Control Office of the Department of Health has received a report of a serious adverse event associated with intracatheter dilators used with central venous catheters.

Description of the Incident

The report was related to the inadvertent cutting of an intracatheter dilator (a device used to facilitate the insertion of catheters) while modifying the length of a central venous catheter at the time of insertion, resulting in a piece of the dilator remaining within the patient's circulatory system. Surgical intervention was needed to retrieve the fragment.

Problem

According to the hospital, the physician was unfamiliar with the insertion procedure for this particular model of catheter and did not realize that the intracatheter dilator had not been removed before cutting the catheter to achieve the desired length. Confusion may be compounded by the fact that the catheter and its intracatheter device may appear to the user as a single unit during insertion: there was a luer lock mechanism with which the intracatheter dilator and the catheter were locked together at the proximal end.

The device fragment can cause local tissue reaction, infection, perforation and obstruction of blood vessels, and even death. Contributing factors may include biocompatibility of device materials, location of the fragment, potential migration of the fragment, and patient anatomy.

The incident described above would not be exclusive to a specific type or model of catheter or intracatheter device such as intracatheter dilators, guidewires and stylets, but could occur with any type or model.

Recommendations

(1) Users unfamiliar with the use of the particular model of catheters should read the manufacturer's instructions for use carefully before application. If there is any doubt, users should contact the supplier for assistance.

(2) There should be very little resistance when the catheter is cut. If there is resistance or difficulty in cutting the catheter, the intracatheter device may be inside the catheter and have been inadvertently cut.

(3) Some catheters are not intended to be cut. Users should not attempt to cut these catheters.

(4) For catheters that can be cut, follow the catheter manufacturer's instructions carefully, taking precautions to ensure that the intracatheter devices have not been inadvertently cut.

(5) For catheters that are intended to be cut prior to the catheter being placed in the patient:
- The instructions for use often direct the user to measure the length required and then trim the catheter at the insertion end.
- The intracatheter device (such as guidewires, stylets, dilators, etc.) must be pulled back at some length (The Therapeutic Goods Administration of Australia recommends that at least 4 cm) more than the length of the catheter to be cut.

- After cutting the catheter, users should check that there is no part of the intracatheter device in the cut catheter portion.

(6) For catheters that should only be shortened after the catheter has been inserted and the intracatheter device removed:

- Users should ensure that the intracatheter device has been removed before the catheter is trimmed.
- Users should pay special attention in these cases where a catheter and its intracatheter device appear as a single unit. Some examples of situations where confusion may arise are:
  - The catheter and its intracatheter device are luer-locked at the proximal end of the catheter; or
  - The catheter and its intracatheter device are of the same colour.

(7) Users should count and check the intracatheter devices at the end of the procedure. Counterchecking the number and integrity of used intracatheter devices should be performed by another staff member. Documentation of the checking procedure in case notes/electronic record system is recommended.