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SUMMARY OF SAFETY AND EFFICACY

CATHETER GUIDEWIRE STRAIGHTENER/INTRODUCER

Flexible guidewires are used in the Seldinger technique for central venous catheterization. There are two basic tip configurations: straight and J (a permanent curve). The J-tip is frequently necessary in external jugular cannulations where the wire and catheter must pass around sharp bends in the vein[1,2]. J-type guidewires are usually accompanied by a plastic sleeve which is used to temporarily straighten the J for insertion into the introducer cannula or catheter. This should be done prior to the venipuncture as it usually requires two hands to accomplish.

When advancing the J-guidewire, obstructions are met occasionally and the guidewire must be manipulated. The most successful approach is to rotate the wire between the thumb and forefinger while simultaneously moving the wire back and forth about 1-2 cm.[1,2]

Virtually all currently marketed guidewires are packaged with a simple straight or tapered tube J-straightener. This J-straightener, which must be removed from the guidewire dispenser tube to advance the guidewire, does not securely fit into the introducer needle/ catheter hub, thus it "floats" between the introducer hub and the dispenser tube. The physician must control the introducer needle/ catheter, the guidewire and the dispenser tube within the sterile field.

The device covered by this submission is in the form of a metal cannula attached to one end of the device, and is substantially equivalent to the current J-straightener devices in that it does provide a means to straighten the J-tip of a guidewire. It differs from current devices in that it secures to the introducer needle/ catheter hub, reducing the number of components needed to be controlled by the physician in the sterile field in one hand. It provides access to the guidewire for advancement, retraction, and rotation in the same fashion as other currently marketed J-straighteners.

The risks associated with the use of a J-straightener are few but can be significant. A J-straightener could inadvertently slip off the guidewire after the J-straightener had been disconnected from the dispenser tube to advance the guidewire. Inadvertent over retraction of the J-tip into the straightener, thus pulling the tip out of the straightener, is also possible since most J-straighteners are opaque. Both situations could result in a minor inconvenience or the loss of valuable time in an emergency situation. If either situation were to occur, the physician would (1) use a second guidewire, (2) use the straight end of the guidewire (which may not be preferred), or (3) re-thread the J-end of the guidewire into the straightener.

The risk for loss of the J-straightener is reduced with the device of this submission because the straightened J-tip is held securely within the metal cannula. The risk of inadvertent over-retraction of the J-tip is also reduced since this device is clear or translucent enough to allow visualization of the guidewire tip as it is retracted through the device.

1. Blitt CD: Monitoring in Anesthesia and Critical Care Medicine. Churchill Livingstone, New York, 1985, p.138.

[2] Roberts JR and Hedges JR: Clinical Procedures in Emergency Medicine. W.B.Saunders Company, Philadelphia, 1985, pp.292, 325.

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