

ONE LINERS

Medicines

and

Healthcare products Regulatory Agency

MHRA

Interventionalist Special

ALL medical devices can fail but an increasing number of incidents that result in significant morbidity or mortality arise out of user/device interface problems or because of poor practices. The aim of this news sheet is to detail briefly some of these problems in an attempt to make users more aware of what can go wrong – it is all too easy to take equipment for granted.

Spinning Around.....

MHRA has received reports of guide wire tips fracturing after contact with the rotating burr during rotational atherectomy.

Never advance the rotating burr to the point of contact with the guide wire tip as this may result in fracture or distal detachment with embolization of the guidewire tip.

A Test of Strength?

MHRA has noted reports of angioplasty catheter tip breakage, some with balloon separation, after use of excessive force during withdrawal.

If resistance is felt on removal of either the guidewire from the catheter, or the catheter from the introducer sheath, consider removing them as a single unit to prevent damage to the products or the vessel.

Drop Zone?

We continue to receive reports where ceiling mounted ancillary equipment, e.g. operating lights/injector pumps become loose, and in some cases fall down, with the potential for serious staff/patient injury.

Ensure all such equipment is included in regular maintenance schedules.

Location, Location, Location...

MHRA is aware of incidents involving vascular closure devices resulting in vessel occlusion, peripheral ischaemia and pseudoaneurysms.

Always ensure the positioning of the device is optimal according to the instructions for use. This should include confirming location of the femoral bifurcation, checking for local vascular stenosis and ensuring the puncture site is not too proximal.

End-O-Leak?

The MHRA has received reports of deaths associated with the use of long dilators during percutaneous central venous insertions. These fatalities occurred as a result of cardiac tamponade or haemothorax following puncturing of the atrial vessel walls by the dilator tip.

Users should ensure that the dilator is inserted only far enough to create a pathway through the subcutaneous tissues to facilitate entry into the vein. The venous puncture site does not require dilatation and the dilator should NOT be fully inserted into the subclavian or jugular veins.

Tip Off !!!

MHRA has received a number of reports of catheter tips breaking on removal, often requiring surgery for retrieval. Always (visually) check tips of intra-vascular devices, including catheters, guide wires, introducers, etc, after removal, to ensure the tip is intact.

Always use in accordance with manufacturers instructions.