

# NIAIC MEDICAL DEVICES ONE LINERS

## DEVICES LABELLED “SINGLE USE ONLY”

Some medical devices labelled for “single use only” are reused often because of a lack of understanding of why such a label has been applied. The reuse of such devices can however affect the safety, performance and effectiveness of the devices, exposing staff and patients to unnecessary risk. Such reuse also has legal implications.

The aim of this one-liner therefore is to detail briefly some of the incidents that have occurred as a result of this practice. The majority of these incidents have been reported by the NHS to the Medical Devices Agency (MDA) but the lessons learned are applicable to the HPSS and the wider health and care community in Northern Ireland.

### ENDLESS?

There have been a number of reports of cardiac catheters whose tips have broken off in the patient, with serious consequences. These cases occurred where the catheters had been resterilised and reused.

*Such catheters may be made of a material which embrittles on repeat sterilisation or have design features such as long or narrow lumens, acute angles, coils or specialist surface coatings that could prevent effective cleaning.*

### ONCE IS ENOUGH

There have been reports of inadvertent guidewire advancement used with trauma/orthopaedic guided cannulated screw systems. In one case this resulted in a fatal incident where a cannulated drill became jammed over a screw guidewire which then advanced into the pelvis damaging a iliac vein.

*In the case of guidewires marked “for single use only”, reuse increases the risk of employing a damaged guide wire with possible fatal consequences (NIAIC Safety Notice SN(NI)2001/19).*

### DON'T GET PSEUD!

“Single use” pressure domes, used to cover the pressure transducers in the urodynamic systems for assessing bladder pressure. Several cases have been reported where they have been reused resulting in a number of patients becoming contaminated with *Pseudomonas aeruginosa* and in one case developing severe septicaemia.

*These devices and the catheters linking the transducers to the patient must be used for one procedure only (NIAIC Safety Notice SN(NI)2000/20).*

### RE-ENTRY BRADYCARDIA

We are aware of instances where external pacemakers' extension/adaptor leads packaged as “single use” (sterile and non-sterile) have been reused. Manufacturers have advised that sterilization or reuse may lead to material degradation.

*This degradation can result in poor connections between the lead and pacemaker and a potential for fatal bradycardia or asystole.*

### MAKE A CLEAN BREAST OF IT!

There is a practice of breast implants being used as sizers for measuring the size of implants needed to produce a good cosmetic result.

*Some breast implants do not withstand cleaning, decontamination and sterilization processes, resulting in a potential for cross infection and material degradation. Several different models of breast implant sizers, both reusable and single use, are available.*

### SPECULATION?

“Single use” vaginal speculae are being reused after decontamination by glutaraldehyde.

*Apart from the fact that single use speculae may not withstand the cleaning and sterilization process necessary for effective decontamination to prevent cross infection, glutaraldehyde may be absorbed by certain plastics and leach out during subsequent use, resulting in chemical burns or a risk of sensitisation of the patient*