

## Potential patient risk from vented caps on pressure transducer

**Sir,**

The TruWave pressure monitoring kit with TruWave disposable pressure transducer (Edwards Lifesciences LLC, Irvine, USA) is regularly used for invasive monitoring via arterial catheters in the operating theatres, critical care and high dependence units.

Both the transducer port and the four-way stopcock are packaged with protection caps, which are non-occlusive, 'vented', in order to ensure thorough penetration of ethylene oxide gas during sterilization (Figure 1). Packaged separately are two occlusive caps, intended to replace vented caps once the set is readied for use.

One of the authors previously highlighted risk of ventilated caps with intravenous infusion lines, including risk of air entrainment and embolism as a result of the Bernoulli effect (Kapur et al, 2007). Additionally, air bubbles in an arterial line can result in transducer signal 'damping' and, therefore, inaccurate blood pressure readings. The risk of leakage of blood is also potentially detrimental to patient safety.

We have concerns regarding product information provided by the manufacturer informing users of the need to change the caps. First, information provided ('Replace all vented caps on sideports of the stopcocks with non-vented') is easily missed, printed in tiny font lost within a large multi-lingual information leaflet

**Figure 1. Non-occluded 'vented' cap on TruWave pressure monitoring kit.**



(Figure 2). Furthermore, there is only one such leaflet per box of 20 pressure monitoring sets.

The authors believe that the manufacturer could easily address these issues by either removing both ventilated caps completely, providing more information leaflets per box, or by clearly stating on each individual pack the need to change caps appropriately. While this is not the current case, we urge vigilance by the user.

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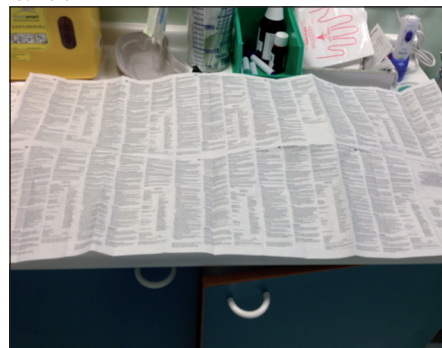
Kapur S, Ahuja N, Moors AH (2007) Air embolism risk from malfunctioning anti-reflux Y-connectors. *Br J Hosp Med* 68(6): 335

**Sir,**

We appreciate the comments from Dr McCormick and colleagues regarding protection caps for the TruWave disposable pressure transducer. Edwards is committed to patient safety and providing the highest quality products to our customers. The TruWave disposable pressure transducers are among an extensive line of Edwards' haemodynamic monitoring tools considered the gold standard in critical care medicine, and have been used safely for over 20 years worldwide.

We strive to make our products and documentation as easy to use as possible and our instructions for use for the TruWave products clearly state: 'Replace all vented caps on side ports of the stopcocks with non-vented caps'.

**Figure 2. Manufacturer's product information leaflet.**



As a technology innovator, Edwards is dedicated to improving product effectiveness for the patient and ease-of-use for the clinician, and will continue to explore ways to improve product education.

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## Single drug regimen for treatment of acute venous thromboembolism in oncology patients

**Sir,**

Venous thromboembolism is the second leading cause of mortality in oncology patients (Noble and Jenkins, 2009; den Exter et al, 2013). The conventional treatment regimen is parenteral anticoagulation with low-molecular weight heparin and concomitant warfarin for non-oncology patients, and low-molecular weight heparin alone for oncology patients (Noble and Jenkins, 2009). While low-molecular weight heparin has better safety and efficacy than warfarin, this regimen is costly, presents challenges with requirement of subcutaneous injections, lacks patient preference, and has a 9% recurrence rate of venous thromboembolism (den Exter et al, 2013).

Agnelli et al (2013a) compared the efficacy of apixaban, a new oral anticoagulant, with the standard regimen in treatment of acute venous thromboembolism (AMPLIFY trial). New oral anticoagulants are given in fixed doses, administered orally and demonstrate predictable effects without need for laboratory monitoring of coagulation unlike the standard regimen (Gonsalves et al, 2013). Indeed, Agnelli and colleagues (2013a) showed that the apixaban regimen was non-inferior for efficacy and superior for safety compared to standard treatment in non-oncology patients.

However, cancer patients with planned long-term treatment with low-molecular weight heparin were excluded, because of the risk of anticoagulant-induced bleeding complications. Evidence of efficacy and