

Particulate Contamination in Intravenous Drugs: Coring from Syringe Plunger

Dear Sir,

Particulate matter can be defined as "the mobile, undissolved substances unintentionally present in parenterals."¹ A wide variety of particulates have been reported in parenteral solutions, including asbestos fibers, rubber particles, chemical particles, cellulose fibres, fungi, starch, diatoms, and glass particles.² ("Particulates can enter these solutions in various manners. Many may enter the solutions during processing. There are not universally applicable guidelines, and thus assuming that problem may be of questionable significance.

Colloidal particles of a plasticizer, di-2-ethylhexylphthalate (DEHP) have been identified as being present in solutions contained in polyvinylchloride (PVC) bags. Agitation of the bags increased the amount of DEHP delivered, while the addition of ethanol to the solution in the bags so significantly

increased the amount of DEHP delivered that Corley, et al. recommended that a warning be included with solutions in PVC bags- "not to compound ethanol solutions in the bags".³

Recently we encountered a particulate contamination in freshly prepared thiopentone syringe. Three black particles were floating in the syringe and were grossly visible (Fig.1). After filtering it on the cotton gauge (Fig.2) the particulate matter seemed to be of black rubber which we thought could have cored either from saline bottle seal or thiopentone vial. But when we examined the saline bottle and thiopentone vial, the colour of their seal was grey. Further looking into the cause it was observed that the particulate has sheared off from the syringe plunger. (Fig.1 arrow showing the site). Ideally in a good quality syringe this problem should not occur but recycled goods are pumped into market by spurious manufactures which can cause such problem for which responsibility lies on the anaesthesiologist although ultimate sufferer is patient. As from literature syringe plunger can be a source of silicone contamination⁴ and some time particulate contamination if it is sheared during transfer or aspiration of drug from other syringe with needle.⁵

There are many solutions offered to prevent complication from coring. In-line "final" filtration may be the ultimate answer.

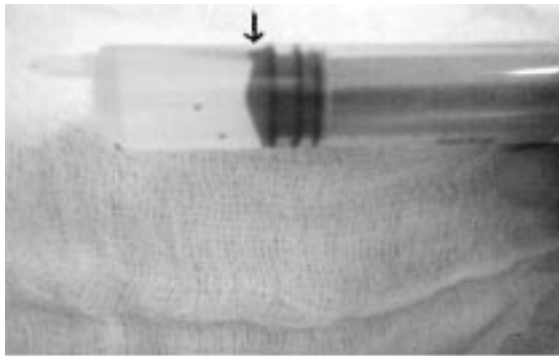


Figure 1

Black particulate matter floating in thiopentone syringe and arrow depicting sheared plunger.

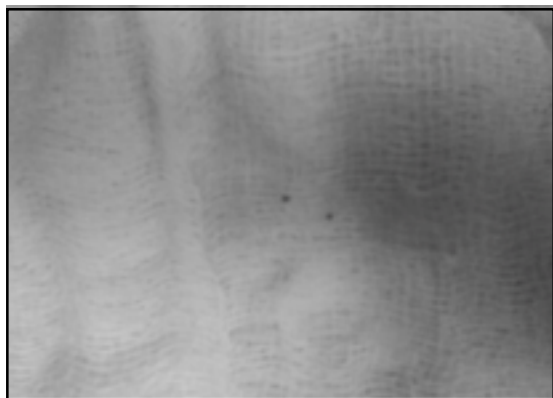


Figure 2

Particulates filtered on cotton gauge piece.

Davis, et al. report that in-line final filtration appears to be 100% effective in the removal of particulates.⁶ There is still some question about the value of these filters under routine clinical conditions. The EmuSiv™ filter (EF; Pall Biomedical Products Co., East Hill, NY, USA) is a filter specifically created for use with lipid emulsion based drugs like propofol. This 0.45 micron rated filter is purported to provide protection from accidental microbial contamination, particulate contamination and entrained air while maintaining the integrity of the emulsion.⁷ For the prevention of glass particle contamination in peripheral intravenous admixtures, the use of pre-filled syringe drugs can be a useful method.⁸

There is no consensus on the problems of and possible solutions to particulate contamination. It is a problem that the anaesthesiologist should be aware of, and exercise reasonable precautions to assure the particulate free drug delivery to patients.

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