Intravitreal syringes and injection packs: Are the quality standards and testing optimum?

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INTRODUCTION

Anti-vascular endothelial growth factor (anti-VEGF) intravitreal injections have transformed the management of macular degeneration, diabetic macular oedema and retinal vein occlusion. Manufacturers must follow strict quality checks to minimise risks of complication including endophthalmitis, a sight-threatening condition.

METHODS

This prospective observational review was conducted following an unusual cluster of three patients with sterile endophthalmitis post anti-VEGF injections. Injectors were instructed to follow strict visual inspection and report any issues with syringes and/or injection packs. Each incident was formally logged using trust electronic incident report system, local investigation including photographic evidence, manufacturer investigation and MHRA reporting.

RESULTS

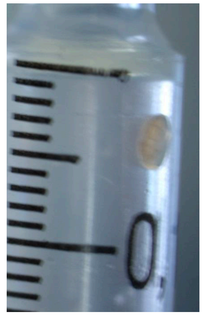
Between September 2018-2019, 4620 intravitreal injections were performed. 7 issues (0.15%) of foreign bodies/particles, noted in 4 syringes and 3 hand towels, were reported. All packs were quarantined. Syringe manufacturer was switched from BD to B.braun and issues were reported with both. Foreign particle nature and origin was investigated. Manufacturer BD reported the particles as polypropylene material from the moulding and transport process of the syringe. B.braun conducted spectrometric investigation and revealed that the particle in the last incident originated from cellulose fibres, matching the sealing paper.

IMAGES

Syringe incident number 1 (September 2018)



Syringe 1 (view a)



Syringe 1 (view b)

Syringe incident number 2 (November 2018)

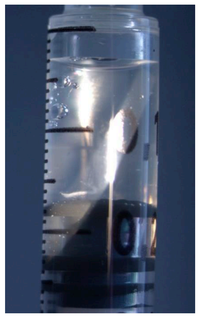


Syringe 2



Syringe 3

Syringe incident number 3 (April 2019)



Syringe 4 (view a)



Syringe 4 (view b)

CONCLUSIONS

Visual inspection of packs is recommended before injection. 7 issues (0.15%) from two different manufacturers over one year is a significant concern and triggered escalation to the Royal College. Syringes are produced in a clean room according to ISO 14644-1 class 9 in operation. The companies suggested that these were isolated incidents, with complaint rate within the accepted limits. Is this an under-reported problem? “Are the quality standards and testing methods truly optimum?”.

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Salisbury Foundation Trust stopped the use of BD syringes for Intravitreal Injections in 2018

Royal College of Ophthalmologists issued alert on 3 July 2019



Safety Alert – particulate matter discovered in syringes for intravitreal injections

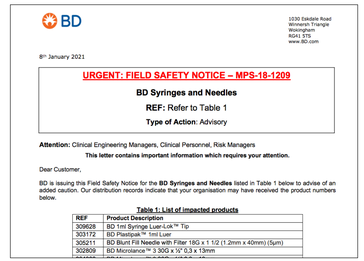
3 July 2019

The College has been approached by a unit concerned about particulate matter discovered in syringes for intravitreal injections. The literature reports that silicone oil droplets have been implicated in the past but this set of cases appears to be linked to particles of syringe plastic material. There are also concerns of a small number of cases of sterile endophthalmitis in the same unit and whether this could be in any way linked to the particles seen but there is so far no evidence of such a causative link.

It is recommended that a visual inspection of the syringe and contents is undertaken prior to any intravitreal injection and that, if there is a suspicion of contamination or particulate matter, the device is quarantined and returned to the manufacturer for investigation. In addition, clinicians should document any issues via local governance routes and always alert the MHRA where appropriate (https://yellowcard.mhra.gov.uk/).

The College is also interested in collating information about this matter in order to inform its guidance. Therefore we would be grateful if, when reporting cases via the usual channels, members would also share anonymised data with beth.barnes@rcophth.co.ac

BD alert on 8 January 2021 Intraocular use is not validated by BD



BD

8th January 2021

URGENT: FIELD SAFETY NOTICE – MPS-18-1209

BD Syringes and Needles

REF: Refer to Table 1

Type of Action: Advisory

Attention: Clinical Engineering Managers, Clinical Personnel, Risk Managers

This letter contains important information which requires your attention.

Dear Customer,

BD is issuing this Field Safety Notice for the BD Syringes and Needles listed in Table 1 below to advise of an added caution. Our distribution records indicate that your organisation may have received the product numbers below.

Table 1: List of impacted products

REF	Product Description
309628	BD 1ml Syringe Luer-Lok™ Tip
303172	BD Plastipak™ 1ml Luer
305211	BD Blunt Fill Needle with Filter 18G x 1 1/2 (1.2mm x 40mm) (5µm)
302909	BD Microlance™ 3 30G x ½" 0.3 x 13mm