

ONE LINERS

Medicines and Healthcare products Regulatory Agency

Eye 2 Eye - Ophthalmology Special

Issued February 2010

MHRA

All ophthalmic medical devices can fail, but a proportion of incidents that result in significant morbidity, or loss of vision, arise from user error or poor practices. Many adverse events reported to MHRA relate to the use of ophthalmic medical devices, including their interactions with medicines. We have therefore dedicated this issue of One Liners to highlighting a number of problems in this area in an attempt to make users more aware of what can go wrong.

WOULD YOU LIKE A FLAKE WITH THAT?

MHRA has received reports of white flakes and deposits appearing on the surface of inserted intraocular lenses while using a viscoelastic not specifically recommended by the lens manufacturer.

Ensure that the correct viscoelastic is used during lens implantation, as recommended in the manufacturer's instructions for use.

STOP, THINK, INJECT!

MHRA has received reports of intraocular lens opacification in association with the off-label intra-cameral injection of recombinant tissue plasminogen activator 'Alteplase' for treatment of post-uveitic fibrosis.

Please ensure all colleagues are aware of this risk and that all cases of intraocular lens opacification, no matter the cause, are reported to the MHRA. Please refer to (MDA/2010/008).

YOU MAY FIRE WHEN READY...

MHRA has been made aware of an ophthalmic surgical laser failing to function, but that this was only discovered after the patient was anaesthetised.

All ophthalmic surgical equipment, including lasers, should be tested at the beginning of an operating list, and prior to any patient being prepped and anaesthetised.

SPEEDY GONZALES?

MHRA has received reports of white deposits on intraocular lenses, which on investigation were found to be scuff marks due to the injector being advanced too quickly during insertion.

Ensure that the speed of insertion of intraocular lenses is appropriate, as recommended in the manufacturer's instructions for use.

WHAT A TURN-OFF

MHRA has received a report of hard drive corruption of a biometry machine due to the incorrect shutting down of the instrument.

Just as a personal computer must be shut down correctly to prevent damage to the hard drive, so do all computer operated instruments, from biometry machines to retinal imaging equipment.

DON'T WASTE AGES, USE OUR WEBPAGES

The MHRA continues to ensure that its ophthalmology specific webpage contains all the up to date safety information regarding medicines and medical devices specifically of interest to ophthalmologists and allied professionals.

Visit www.mhra.gov.uk/ophthalmology and sign up for email alerts that will save you time by automatically informing you when the page is updated.

Safeguarding public health



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