Device-specific guidance for manufacturers on reporting adverse incidents under the European vigilance system

**Intraocular lenses**

To be read in conjunction with the European Commission’s guidelines on a medical devices vigilance system [MEDDEV 2.12/1](#)

**What should be reported?**

Manufacturers should notify the relevant competent authority (the MHRA in the UK) if:

- they know of any deterioration or malfunction of an intraocular lens, or any inadequacy in the instructions for use which has led, or might lead, to a serious deterioration in the state of health and/or vision. This would include circumstances where:
  - an intraocular lens related problem results in a clinically relevant increase in the duration of a surgical procedure, as defined by the operating surgeon
  - the cause of the intraocular lens related incident is not well defined, or involves a number of aetiological factors, and the manufacturer is unable to obtain further clarification within the reporting timescale.

- the intraocular lens has been subject to a Field Safety Corrective Action.

Many adverse incidents associated with intraocular lenses will be reportable under the vigilance system. It is the manufacturer's responsibility to judge each incident on its own merit, and to ensure compliance with the statutory reporting requirements contained within the relevant national regulations. The following examples are for illustrative purposes only and do not constitute an exhaustive list:

- lens opacification
- lens explantation due to, for example:
  - decrease in best corrected visual acuity
  - significant halos / glare / starbursts
  - significant induced irregular astigmatism
  - diplopia, or other significant visual disturbances
  - lens dislocation
  - lens opacification
  - lens defect.
- fracture or detachment of the lens haptic
- endophthalmitis
- early cataract formation subsequent to phakic IOL implantation
- intraocular haemorrhage
- incorrect labelling of lens, including lens power
- unexplained poor visual outcome as determined by the clinician
- failure of lens injectors.
**Periodic summary reporting**

Some adverse incidents are appropriate for periodic summary reporting (see MEDDEV 2.12-1). Details of the timing and content of periodic summary reports should be arranged on an individual basis with the competent authority. The following are examples of adverse incidents which may be considered for period summary reporting:

- IOL induced iritis
- post-operative secondary glaucoma
- use errors resulting in serious injury and not falling into any identified categories.

**5 Adverse incident trending**

Some adverse incidents are expected and foreseeable, and as a result may be considered not routinely reportable. These must all be clearly identified in the manufacturer’s labelling, clinically well recognised and quantifiably predictable, well documented in the device master record with an appropriate risk assessment, and clinically acceptable in terms of individual patient benefit. All such incidents should, however, be subject to trend analysis as part of the manufacturer’s wider post-market surveillance process. The expected prevalence or rate of such events should be specified, and if an adverse trend emerges, this should trigger a vigilance report by the manufacturer to the relevant competent authority.

Incidents that are generally only reportable if an adverse trend is identified may include:

- posterior capsular opacification
- posterior capsular tear.