Guidance for manufacturers on reporting adverse incidents involving Inferior Vena Cava (IVC) Filters under the vigilance system

To be read in conjunction with the guidelines on a medical devices vigilance system MEDDEV 2.12/1

Report as individual events (in line with MEDDEV timescales)

- Death that is probably or possibly device-related
- Complications during deployment or placement eg:
  - premature release
  - partial or incomplete expansion
  - deformation (such as crossed or twisted legs or arms)
  - asymmetric deployment (malapposition)
- Partial or multiple fractures
- Device migration/secondary movement with or without embolization
- Recurrent or fatal pulmonary embolism

Can be included in periodic summary reports (PSR)*

	Periodicity
IVC wall perforation / erosion / penetration >3mm	3 monthly
Retrieval difficulties / failure to retrieve	3 monthly
Progressive tilting / angulation	6 monthly

Report at the time the adverse trend is identified

- IVC wall penetration <3mm
- Vascular access and device placement related problems eg:
  - device misplacement / improper placement
  - pneumothorax
  - air embolism
  - haematoma / bleeding / haemorrhage
  - intimal tear
- Inferior vena cava thrombosis / occlusion / restriction of blood flow through the filter or venous insufficiency
- Systemic Infection
- Adverse reaction

Generally not reportable

- Death if there is evidence that it is **not** device related
- Access site thrombosis or stenosis
- Infection at puncture site

* If you can't use PSR, then report these events individually.