



## Safety Notice 003/18

### Complications Associated with Inferior Vena Cava Filters

19 February 2018

#### Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director Regulation & Compliance Unit
- Healthshare NSW

#### Action required by:

- Chief Executives
- Directors of Clinical Governance

#### We recommend you also inform:

- Directors of Medical Imaging
- Directors of Emergency Departments
- Directors of Medical Services
- Directors of Haematology
- Theatre Managers
- Directors Cardiology
- Vascular Surgeons
- Directors Orthopaedics
- Trauma Surgeons

#### Expert Reference Group

##### Content reviewed by:

- Office of the Chief Health Officer, MoH
- Clinical Director Medical Imaging
- RANZCR

#### Clinical Excellence Commission

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<http://internal.health.nsw.gov.au/quality/sabs/>

#### Review date

February 2019

#### Background

There has been an incident in NSW in which a retrievable Inferior Vena Cava (IVC) filter failed and required removal. On removal it was recognised that parts of the device had fragmented.

Migration, perforation and fracture are known complications with use of these devices and are routinely mentioned in the Instructions for Use (IFU).

IVC filters are used to prevent Pulmonary Embolus (PE) and reduce Venous Thromboembolism (VTE) related mortality. They are indicated mainly for patients who cannot receive anticoagulation due to an acute bleed or a need for surgery, and for patients with chronic recurrent PE where anticoagulation therapy has failed or is contraindicated.

#### Known Complications

Although it is recommended in many guidelines that IVC filters are removed, a large number are not routinely removed once the risk is passed. While there are some filters available that are designed to be permanent, the majority in use are classed as 'optional' (retrievable)<sup>1</sup>.

The TGA has published a safety update on this issue in which they describe 21 adverse reports over 10 years to November 2016 relating to filter complications. The TGA update encourages clinicians to ensure they are familiar with the IFU when using these devices.

In view of the risks, guidelines recommend careful decision making regarding the option to use these devices and removal of the filter when the risk/benefit to the patient favours removal.

#### Prevention

Clinicians responsible for the treatment of patients requiring IVC filters should:

- Be aware of risks associated with long term placement
- Ensure there is a clear indication for the placement of an IVC filter
- Discuss the risks with the patient
- Consider removal as soon as the risk has passed following assessment of the potential risks and benefits to the patient

#### References

1. TGA (Jan 2017) - <https://www.tga.gov.au/publication-issue/medical-devices-safety-update-volume-5-number-1-january-2017>
2. FDA (May 2014) - <https://wayback.archive-it.org/7993/20170722215731/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm396377.htm>
3. FDA (Aug 2010) - <https://wayback.archive-it.org/7993/20170112002302/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm221676.htm>
4. Health Canada (July 2016) - <http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2016/59518a-eng.php>

#### Suggested actions by Local Health Districts/Networks

1. Forward information to appropriate area for action.
2. Review local processes for determining the need for placement and removal
3. Ensure any possible device failure or issues are reported to the TGA and NSW Health Incident Management System (IIMS) in a timely manner
4. Document actions taken.

Made Obsolete May 2024