In this issue

- TGA encourages formal strategies for inferior vena cava filter removal
- ECRI lists infusion errors as top 2017 hazard
- Recent safety alerts

TGA encourages formal strategies for inferior vena cava filter removal

Health workers and facilities undertaking implantation of removable inferior vena cava filters should ensure they have formal strategies to address the issue of removal once the risk-benefit profile warrants it.

An inferior vena cava (IVC) filter is a small cone- or umbrella-shaped device that is implanted in the inferior vena cava just below the kidneys.

The filter is designed to capture an embolism, a blood clot that has broken loose from one of the deep veins in the legs on its way to the heart and lungs, while still allowing blood to flow past.

Implantation of IVC filters has become a common part of clinical practice despite the lack of good quality evidence supporting their use, especially in patients deemed to be at high risk of developing a pulmonary embolism.

Although it is recommended in various guidelines that vena cava filters are retrieved, in practice this does not occur routinely.

Some of the IVC filters listed on the Australian Register of Therapeutic Goods (ARTG) are designed to remain in-situ permanently; however the majority are classed as ‘optional’ (retrievable).

In the 10 years to November 2016 the TGA had received 21 adverse event reports relating to complications noted with IVC filters.

These complications were mostly related to migration and fracture of the wire-like ‘limbs’ in these devices. A migration or fracture can lead to complications such as vein perforation.

Most reports (16) have been classed as causing a serious injury to the patient, with the rest being marked as temporary.

There were no reports of deaths in Australia, although there have been reports of deaths overseas.

Known complications

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

There have been seven recalls for these products – most relating to manufacturing issues, but some have been for movement of the filter.

Both the US Food and Drug Administration and Health Canada have published statements relating to these issues in recent years:

- FDA statement
- Health Canada statement

Be alert to the IFU

The TGA encourages clinicians to ensure they are alert to the IFU when using IVC devices.

We encourage each health facility to identify all patients who have a retrievable IVC filter placed and to develop a formal strategy to assess these patients for filter removal to reduce the known risks.
ECRI lists infusion errors as top 2017 hazard

Infusion errors have been named as the top health technology hazard worldwide, followed by inadequate cleaning of complex reusable instruments.

Infusion errors pose the number one health technology hazard worldwide for 2017, according to ECRI Institute (formerly known as the Emergency Care Research Institute).1

ECRI Institute publishes a list each year detailing what it believes to be the top 10 health technology hazards for the coming year.

Clinical alarm hazards had topped the ECRI Institute list in 2012, 2013, 2014 and 2015 and were listed second in 2016. ECRI Institute has listed ‘missed ventilator alarms’ as the third most pressing hazard in 2017.

The full list
The ECRI Institute’s top 10 hazards list for 2017 is:

1. Infusion errors can be deadly if simple safety steps are overlooked (an MDSU article discussed this issue in July 2014)
2. Inadequate cleaning of complex reusable instruments can lead to infections (MDSU articles discussed this issue and related issues in September 2014, November 2015 and May 2016)
3. Missed ventilator alarms can lead to patient harm (an MDSU article discussed this issue in May 2014)
4. Undetected opioid-induced respiratory depression (an MDSU article discussed this issue in November 2016)
5. Infection risks with heater-cooler devices used in cardiothoracic surgery (an MDSU article discussed this issue in May 2016)
6. Software management gaps put patients, and patient data, at risk (an MDSU article discussed software-related issues in September 2016)
7. Occupational radiation hazards in hybrid operating rooms
8. Automated dispensing cabinet setup and use errors may cause medication mishaps
9. Surgical stapler misuse and malfunctions
10. Device failures caused by cleaning products and practices.

ECRI Institute said the list did not enumerate the most frequently reported problems or the ones associated with the most severe consequences, although such information fed into the analysis. Rather, the list reflected its experts’ judgment about which risks should receive priority now.

The list focused on ‘generic hazards’, problems that result from the risks inherent to the use of certain types or combinations of medical technologies.

To create the list, ECRI Institute engineers, scientists, clinicians, and other patient safety analysts nominated topics for consideration based on their own expertise and insight gained through:

• investigating incidents
• testing medical devices
• observing operations and assessing hospital practices
• reviewing literature
• speaking with clinicians, clinical engineers, technology managers, purchasing staff, health systems administrators and device suppliers
• analysing thousands of health-technology-related problem reports.

All the items on the list represented problems that could be avoided or risks that could be minimised through the careful management of technologies.

Focus on solutions
The TGA advises health professionals to consider ways to mitigate risks within the clinical settings in which they work. A good place to start would be to consider the MDSU articles listed above and other safety communications published by the TGA.

Health facilities should:

• set up effective risk management programs that involve clinicians, biomedical engineers, hospital management and administrative staff
• ensure that responsibilities are clearly assigned to the relevant personnel
• ensure all staff carefully read and fully understand the Instructions for Use for devices they use and are responsible for.

REFERENCE

Recent safety alerts

Below are TGA safety alerts relating to medical devices published since the last edition of Medical Devices Safety Update.

- **balanSys UNI convex PE inlays x/5**: Hazard alert - higher than expected rate of PE inlay breakage
- **Microport Orthopedics metal-on-metal hip implant components**: Hazard alert - revision rate increasing
- **Medtronic SynchroMed II implantable infusion pump**: Update - additional information
- **Nanostim leadless cardiac pacemaker**: Hazard alert - potential for loss of telemetry and pacing due to battery malfunction
- **ASR XL total hip replacements**: Alert - TGA advice regarding potential association with heart failure
- **Advance HA coated tibial bases**: Hazard alert - potential for implant failure due to loosening
- **Nellix EndoVascular Aneurysm Sealing System**: Hazard alert - risks of leaks, stent movement and aneurysm enlargement
- **Medtronic model 37751 recharger - used with neurostimulators**: Recall for product correction - risk of loss of therapy due to the recharger not functioning
- **Orchestra and Orchestra Plus programming devices when used with Reply and Esprit pacemakers**: Update - new software update and inclusion of Kora pacemakers
- **Infections associated with heater-cooler devices**: Alert - updated advice for health professionals and facilities
- **Active Total Knee Replacement System**: Hazard alert - higher than expected revision rate when used without patella resurfacing

What to report? Please report adverse events, as well as near misses

The TGA encourages the reporting of any suspected adverse event or potential adverse event relating to a medical device. Adverse events can involve actual harm to a patient or caregiver, or a near miss that may have resulted in harm.

Some issues relating to medical devices that may lead to adverse events and prompt you to report include:

- mechanical or material failure
- design issues
- labelling, packaging or manufacturing deficiencies
- software deficiencies

For the latest information from the TGA, subscribe to the TGA Safety Information email list via the TGA website.

For correspondence or further information about Medical Devices Safety Update, contact the TGA’s Medical Devices Branch at iris@tga.gov.au or 1800 809 361.

Medical Devices Safety Update is written by staff from the Medical Devices Branch.

Editor: Ms Pamela Carter
Deputy Editor: Mr Aaron Hall
TGA Principal Medical Adviser: Associate Professor Tim Greenaway
Contributors include: Mrs Sharon Bennett

Disclaimer

The Medical Devices Safety Update (MDSU) is aimed at health professionals and is intended to provide practical information on medical devices safety, including emerging safety issues. The information in the MDSU is necessarily general and is not intended to be a substitute for a health professional’s judgment in each case, taking into account the individual circumstances of their patients. Reasonable care has been taken to ensure that the information in this document is accurate or complete, and does not accept liability for any injury, loss or damage whatsoever, due to negligence or otherwise, arising from the use of or reliance on the information provided in this document.

© Commonwealth of Australia 2017

This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the Copyright Act 1968 or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to tga.copyright@tga.gov.au.