Caution advised in choosing intravenous catheters if power injection may be required

Health professionals are reminded that care needs to be taken when choosing intravenous catheters for use in patients who may subsequently require high-pressure contrast media injection.

Only catheters, tubing and connectors that are designed to withstand the pressures generated by power injectors should be used when injecting contrast media used in diagnostic scans.

If the catheters, tubing and connectors are not indicated for use with a power injector, the normal pressures produced by a power injector during a diagnostic scan can result in ruptures.

Rupture of a catheter has the potential to cause fragmentation within the patient, which could in turn result in embolisation and/or the requirement for surgical removal. Other potential complications include:

- loss of intravenous (IV) access
- sprays/exposure of blood and contrast media
- delay in diagnosis or treatment
- extravasation of contrast media
- patient distress/pain.

The TGA has received three adverse event reports in the three years to November 2014 involving IV catheters and power injectors used for high-pressure contrast media injection, including one where a critically ill patient’s MRI scan with contrast was delayed as the IV access was for high flow and not for high pressure power injectors.

Preventing problems with incompatibility

Power Injectors must be used with devices that have been pressure tested and deemed suitable to withstand the pressures produced during high-pressure contrast injection.

In general:

- when using a peripheral access site or central venous catheter for power injection, verify that the devices are labelled as compatible with the process
- ensure that you are familiar with your facility’s protocols for the injection of contrast media using power injectors
- consider reviewing the devices available in areas such as resuscitation bays, where a rapid progression to scanning with high-pressure contrast may occur to ensure there are no undue delays.

To assist in the monitoring and investigation of this issue, please report any near misses or adverse events to the TGA.
Acanthamoeba keratitis risk for contact lens users

The TGA urges health professionals to be alert to the risk of Acanthamoeba keratitis, its association with contact lens use, and to report any cases.

Acanthamoeba keratitis is a rare but potentially blinding infection of the eye.

The infection is caused by a genus of ubiquitous, free-living amoeba (Acanthamoeba) found in the environment including water (for example, tap and recreational water), soil and sewerage systems.

The TGA received two reports of Acanthamoeba keratitis in the four years to November 2014, and four reports of keratitis.

Contact lens users are at increased risk of infection, especially if the circumstances involve:

• improper storage, handling or disinfecting of lenses (this includes washing contact lenses in tap water or homemade cleaning solutions prior to insertion into the eye)
• swimming, showering or using spa baths while wearing contact lenses
• wearing lenses for a longer period of time than that specified in the Instructions for Use (IFU) – for example, overnight wear
• people who have damage to their corneas or have had previous trauma to the eye.

Health professionals should remind contact lens users to carefully follow the Instructions for Use document provided with their contact lens cleaning solutions.

Contact lens users should also be advised to discuss with their optometrist or ophthalmologist the correct techniques for cleaning and caring for lenses.

Previous public health actions

Historically, Acanthamoeba keratitis has been the subject of public health notifications internationally.

The US Centres for Disease Control and Prevention undertook an investigation into an increased rate of Acanthomeba keratitis infections from 2005 to 2007.

The increased rate was found to be related to a specific contact lens cleaning solution and the product involved was recalled from the Australian market in May 2007.

TGA urges reporting

In order to more clearly establish the rate and pattern of occurrence of Acanthamoeba keratitis associated with contact lens products, the TGA encourages health professionals and consumers to report these infections when associated with contact lens use.

The following information (if available) should be included in the reporting form:

• the trade names and lot numbers of contact lens solutions
• the contact lens type, trade name and mode of wear (extended or daily wear)
• any potential contributing factors such as issues with lens cleaning process, extended wearing of lenses, exposure to contaminated water.
• results of all cultures taken (for example, corneal, conjunctival, contact lens, care solutions, lens case)
• special patient characteristics, including whether the patient was immunocompromised (for example, used topical or systemic corticosteroids or had diabetes), or had any ocular trauma, surgery, or chronic eye problem
• treatment regimen utilised.

Buying medical devices online

Health professionals are encouraged to educate patients regarding the risks associated with buying medical devices, including contact lenses, over the internet.

The TGA has published information for consumers regarding this issue on its website, including advice to always consult a health professional first.

Consumers are advised not to order medical devices online unless they know how they have been manufactured and that they meet legal requirements for importation and use in Australia.
The TGA thanks you for your medical device adverse event reports

The number of medical device adverse event reports continued to rise strongly in 2014.

The TGA received 4337 adverse event reports relating to medical devices in 2014, a 31% increase from the 2013 total of 3309.

Allied health professionals provided 232 reports (5% of all reports), up from 158 reports the previous year, while nurses provided 167 reports (4%), up from 93.

The majority of reports submitted from allied health professionals are from hospital supply and administration areas.

The remainder of the reports are submitted by a range of allied health professionals, including clinical technicians, pharmacists, biomedical engineers, ambulance officers, laboratory technicians and dentists.

It is important to note that all of these reports were submitted voluntarily and the TGA thanks people for taking the time to submit reports.

The number of reports made by sponsors continued a strong upward trend to a record high of 3697 reports in 2014 (85%), compared with 2456 reports in 2013.

It is mandatory under the Therapeutic Goods Act for sponsors and manufacturers to report adverse events that have led to or could have led to a death, serious illness or injury to a patient, person using the device or others.

Since 1986, the TGA has received more than 36,600 medical device adverse event reports.

Once the TGA identifies a safety concern, it can undertake a range of actions including:

- continuing to monitor the device in relation to the issue
- informing health professionals and consumers via safety alerts, Early Warning System monitoring communications and Medical Devices Safety Update
- requiring the sponsor to undertake product improvement
- requiring changes to the Instructions for Use
- requiring compliance testing
- requiring user education
- suspending or cancelling the registration of the product.
Recent safety alerts

The TGA publishes alerts on its website when there is new safety information regarding therapeutic products.

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

**Riata and Riata ST Silicone cardiac leads**: The TGA published an update to a previous safety advisory. No change to the TGA’s existing advice was needed.

**AK 200 S and AK 200 Ultra S haemodialysis machines**: Gambro issued a recall for product correction to update the Instructions for Use to prevent blood loss if one of these units malfunctions.

**Biomet M2a metal-on-metal total hip replacement implants**: Biomet issued a hazard alert for some components when used in metal-on-metal total hip replacement implants due to higher than expected revision rates.

**Invacare PerfectO2 Oxygen Concentrator**: Invacare Australia undertook a recall for product correction for some units due to the fire risk from a faulty component.

**MiniCaps with povidone-iodine solution (used in peritoneal dialysis)**: Baxter Healthcare initiated a recall for product correction due to the risk of peritonitis from separated, partially protruding or missing sponges.

**Birmingham Hip Resurfacing system**: Smith & Nephew issued a hazard alert advising of additional warnings when used in certain patient groups.

**InterStim and InterStim II neurostimulation devices used for sacral nerve stimulation**: Medtronic Australasia issued a hazard alert due to the risk of premature battery depletion.

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**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

- device interactions
- user/systemic errors

Suspected adverse events or near misses can be reported directly to the TGA:

- **online** at www.tga.gov.au (click ‘Report a problem’)
- **by emailing** iris@tga.gov.au
- **by mail** to IRIS, TGA, PO Box 100, Woden ACT 2606
- **by fax** to 02 6203 1713

For more information about reporting, visit www.tga.gov.au or contact the TGA’s Post-market Surveillance Branch on 1800 809 361.

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**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 is accurate and complete at the time of publication. The Therapeutic Goods Administration gives no warranty 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.

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