Surveillance study focuses on risk of complications with vascular closure device

A recently published study has examined the risk of vascular complications associated with a novel vascular closure design.

A study published in the New England Journal of Medicine (NEJM) on 9 February 2017 examined the risk of vascular complications arising from the use of the Mynx vascular closure device.\(^1\)

This formed part of a study analysing the benefits of a new active clinical data surveillance system. It was found that, while there was a higher rate of adverse events occurring in those receiving this particular extravascular device, its use and procedural approach was beneficial for femoral artery closure following percutaneous coronary intervention when compared with manual or mechanical compression of the wound.

The intended purpose of the device is to seal access sites within the damaged artery or vein, as well as improve recovery response times following endovascular procedures. It uses a gel compound which attaches to the surface of the blood vessel without using mechanical anchors or clasps. This gel dissolves within 30 days, as the vessel naturally heals and rebuilds itself. Other devices on the market use either anchoring or patch mechanisms to stem the flow of blood around these incision sites. While this study demonstrated a slightly higher incidence rate of adverse events in those treated with this device compared to other devices, the actual difference was less than 1% and not considered a statistically significant outcome. The benefits of this device still lead it to be the preferable option in comparison to manual compression of the wound site, which requires a significant amount of time and human resources in order to achieve the end result of haemostasis.

This device is used extensively throughout the United States and Europe, and there has been no action initiated from these equivalent regulatory bodies following the publishing of the NEJM article.

Australia has had 13 device incident reports involving the Mynx device since its inclusion on the Australian Register of Therapeutic Goods. The majority of these are vascular complications following surgery, and all reports occurred prior to 2013. Since 2013, the device has undergone changes to include use in femoral venous sites, in addition to femoral arterial sites, and alterations to supply and manufacturing processes. No additional concerns have arisen following these developments.

The TGA is not making any changes to the regulatory status of the Mynx vascular closure device. We will continue to monitor adverse event reports and take regulatory action if necessary.

REFERENCE

\(^1\) Resnic FC, Majithia A, Marinac-Dabic D, Robbins S et al. Registry-Based Prospective, Active Surveillance of Medical-Device Safety. NEJM. 2017 Feb 9; 376(6): 526-535.
Disinfectants and detergents can damage medical equipment plastics

Certain disinfectant wipes and detergents can damage medical devices if the cleaning agent is incompatible with the device’s plastic surfaces. *(see clarifications below)*

After investigating reports of damaged or contaminated medical devices, the TGA has found that issues often may have been caused by the cleaning agents used.

**Recent case study**

In one recent case reported to the TGA, one hospital’s technicians servicing infusion pumps found that they had dried material (initially thought to be blood or medication) within the case and internal components.

The report highlighted an affected unit that had never been serviced or opened before, still had the factory tamper-proof seal intact and did not appear to have been dropped or misused.

The problem of internal liquid ingress and/or corrosion appeared to be widespread throughout many similar pumps at the hospital.

**How the TGA investigated the issue**

The first step in the investigation of this report was to determine if the pumps were designed and manufactured in compliance with the relevant standards.

The manufacturer was contacted and provided acceptable evidence to the TGA that the pumps had been tested and met the requirements for fluid ingress protection according to the relevant standards.

The TGA’s next step was to meet biomedical and other staff at the reporting hospital. During this visit the cleaning procedures were demonstrated by the hospital staff and the cleaning agents were identified. The hospital’s biomedical staff also provided one of the pumps to the TGA for further investigation.

The manufacturer was requested to provide the Instructions for Use (IFU) with the associated cleaning instructions. A review of the IFU noted that the cleaning procedures demonstrated during the hospital visit and the cleaning agents used on the pumps were not those recommended by the manufacturer.

A considerable amount of the cleaning agent was being used when wiping down the pumps after use. Cleaning pads were soaked and dripping with cleaning fluid when being used. However, the IFU were vague on this point.

The instructions stated that the user should use mild soap suds on the external surfaces, and they were instructed not to use spray disinfectants at the main power connection and not to spray into openings in the device.

While the IFU stated that the user should not spray into openings in the device, and this was not being done during the cleaning process, excess fluid from the soaked cleaning pads could be having the same effect.

The IFU were also vague when recommending the type of cleaning agent to be used. They stated that it was recommended to use one of the manufacturer’s brands of disinfectant for wiping the surface of the pump, but there was no reference as to what type of disinfectants these were.

There was however, a reference about disinfectants which should not be used: ‘Hexaquart or any other alkyamine containing disinfectants’.
Detergent wipes used by the hospital to clean the pumps contained the ingredient ‘benzalkonium chloride’. This is classed as a quaternary ammonium compound which is a corrosive ingredient and therefore should not be used. **

**Results of the investigation**

While no definitive root cause could be determined, it was likely to be related to the cleaning process. The TGA advised the manufacturer to modify the IFU to more clearly instruct users of the proper cleaning techniques and disinfectants.

**Recommendations for facilities**

When cleaning medical devices the TGA recommends that health facilities: ***

• review all decontamination processes that use a disinfectant wipe or detergent containing quaternary ammonium compounds on a plastic surface ****

• check IFU for:
  - types of disinfectants which may be used
  - warnings regarding agents not to use.

• ensure staff read the ingredients labels of any disinfectants used to confirm the agent is compatible, as per the IFU

• train staff on what may be considered a damp cloth and what may be considered a soaked cloth

• avoid areas of the device which should not come into contact with the agent (for example, some display screens, electrical connections, openings in the case)

• allow adequate drying time, if required.

The issue of cleaning products damaging medical equipment was also recently highlighted in a web statement from the Victorian Managed Insurance Authority.

**Clarifications**

* The TGA considers cleaning agents that contain levels of benzalkonium chloride below 5-10% are safe to use on medical devices. Disinfectants generally use about 0.5% benzalkonium chloride, which is considered noncorrosive at these levels.

** Benzalkonium chloride is unsafe at a concentration above 10% and therefore should not be used without being diluted.

*** Follow the manufacturer’s IFU regarding the type of disinfectant that can be used on the device.

**** Particularly if the surface is made of polycarbonate material.

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**Stryker advice regarding the correct use of V-40 C-taper adaptor sleeve**

Stryker Orthopaedics is undertaking an education strategy to increase surgeon awareness regarding the correct use of the V-40 C-taper adaptor sleeve.

The device sponsor, in consultation with the TGA, has written to surgeons regarding the device after an Australian post-market review revealed incidents of off-label use that contributed to a higher-than-anticipated revision rate in this country.

As there was no device deficiency, action was not undertaken under the TGA’s recall procedures.

This device is a sterile implantable adapter sleeve, fitted intraoperatively to the trunnion of a femoral stem in a hip replacement prosthesis.

The adaptor sleeve (made of titanium alloy – Ti6Al4V) provides for the proper fixation and mechanical function of a C-taper, allowing the fixation of a femoral head with a C-taper to a femoral stem with a V-40 shaped trunnion.

The letter to surgeons was intended to reconfirm that the device could only be used either with a Howmedica Osteonics (Stryker Orthopaedics) Alumina C-taper head or a BIOLOX Delta ceramic femoral head.

The use of any other femoral head is not recommended, and there is evidence that doing so leads to a higher risk of revision.

The Instructions for Use supplied within the carton of each implant contains the Indications, Contraindications, Precautions and Warnings.

If surgeons have any further enquiries, they should contact the local sales representative or Stryker Orthopaedics on 1800 803 601.
Recent safety alerts

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

**Breast implants**: Update – additional confirmed cases of anaplastic large cell lymphoma in Australia, FDA publishes an additional update, and Australia/NZ epidemiological study to be published

**Abbott Vascular Absorb Biodegradable Vascular Scaffold (BVS)**: Safety alert – Increased rate of major adverse cardiac events observed in patients receiving Biodegradable Vascular Scaffold

**EpiPen 300 microgram adrenaline injection syringe auto-injector**: Recall – potential failure to activate or need to apply increased force to activate, four affected batches identified as being supplied in Australia

**Medtronic Strata MR Valves and Shunts**: Hazard alert – potential for under-drainage

**Infections associated with heater-cooler devices**: Additional case confirmed, latest information about the TGA conducting a product safety review into all heater-cooler devices supplied in Australia

**Medtronic Strata II / Strata NSC valves**: Hazard alert – potential for MRI scans to affect valve positioning

**Biolox Forte 36 mm Alumina ceramic heads - used in hip replacements**: Hazard alert – increased risk of requiring revision

**MiniMed 640G insulin pump**: Recall for product correction – potential loss of therapy due to power error

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 Medical Devices Branch on 1800 809 361.

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.

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