Intravenous solution bags are for single use only and must not be re-spiked

Health professionals are reminded that intravenous solution bags are designed for single use only and there are no circumstances where they should be reconnected (re-spiked) after first use.

Re-spiking is the process of inserting a giving set into an already used or previously spiked intravenous solution (IV) bag.

IV fluids are administered via a plastic IV solution bag which collapses on itself as it empties.

When a bag is disconnected by removing the giving set spike, air can enter the bag. If it is then reconnected to an IV line, air can potentially enter the patient’s vein and cause a blockage (air embolism).

For this reason, partially used IV bags must never be re-spiked.

Required warning

All IV bags are designed for single use only – for use in one patient and on one occasion only.

All registered large volume injections, including IV bags, are required to have this warning (or words to the same effect) clearly displayed on the labelling.

The TGA has received one report of air embolism associated with an IV bag being re-spiked, which resulted in a death.

While the number of cases is clearly low, the potential risks to patients are serious and it is possible that this issue has been under-reported.

In addition to the potential risk of introducing an air embolus, re-spiking can also result in contamination of the fluid, which may lead to infection and bacteraemia.

Additional safety considerations

In addition to never re-spiking IV bags, health professionals are reminded of the risks of pressurising IV bags to increase flow rates in emergency situations.

If residual air in the bag or infusion set is not removed first, pressurised administration can force the air into the patient’s vein and result in an air embolism.

Do not connect IV bags in series connections, as residual air can be drawn from one container before administration of fluid from a secondary container is completed.

Always ensure that the administration set/line is correctly primed and void of all air before connecting to the patient.

As with any therapeutic product, IV bags should always be used in strict accordance with the instructions for using the products.
Zoll upgrade to counter AED clock drift

The internal clocks on some Zoll AED PRO devices have been identified as having larger-than-expected drift and the sponsor is offering upgrades to address the issue.

During a review of customer reports, Zoll identified that ZOLL AED PROs manufactured within the serial number range of AA14B#### to AA16A#### were experiencing larger-than-expected clock drift.

Automated external defibrillators (AEDs) are portable devices that check the heart rhythm and can send an electric shock to the heart to try to restore a normal rhythm.

The ZOLL AED PRO has an internal 24-hour clock. The clock is used in the device’s non-clinical mode to document the timeline associated with event data stored by the device. Users can subsequently download the data for review.

In a bulletin sent to affected Australian users, ZOLL said it was important to recognise that the clock drift issue did not impact the elapsed time that was displayed to the user during clinical use of the device, and therefore had no impact on the safety or efficacy of the device.

ZOLL said the majority of users would not experience this issue, even on units within the identified range, because when event data was downloaded from the device (for example to a personal computer or personal digital assistant) through the device’s infrared wireless connection, the internal clock would automatically synchronise to the external device’s clock. Users wanting to eliminate the issue can use this feature by regularly connecting the ZOLL devices to an external device that has time synchronisation.

Devices manufactured more recently should not experience the larger clock drift as their electronics had changed. Even so, clock synchronisation would continue to be required to ensure maximum accuracy.

If your facility uses affected ZOLL devices and you would like to take up the offer of a clock upgrade to ZOLL devices in the identified model range, contact ZOLL Technical Support on 1800 605 555.

Hysteroscope cleaning advice updated

Hologic Australia has issued a safety alert updating the Instructions for Use supplied with the MyoSure XL Rod Lens Hysteroscope following reports of contamination.

The TGA had received five device incident reports by 1 June 2017 for the MyoSure Hysteroscope sponsored by Hologic Australia. These reports were submitted for rust/discolouration, corrosion and biological material noted in the internal surfaces of the working channel. Both the TGA and the manufacturer investigated the issue.

Several samples of the device were inspected and assessed by the TGA Biomaterials and Engineering Laboratory. This assessment concluded that there were varying degrees of cleanliness, which indicated the efficacy of cleaning was dependent on practices at each facility.

The TGA’s Microbiology Section evaluated the company’s sterilisation validation data and found that it was considered acceptable to sterilise the device. The TGA determined that the reported incidents could be attributed to cleaning practices.

In order to mitigate these events the manufacturer issued a safety alert updating the Instructions for Use (IFU) supplied with the device. The information added included: not letting the device dry during or after a procedure; suitable dimensions for the cleaning brushes; information about the single use seals; and drying time.

The sponsor will offer training to the central sterilisation services departments at user facilities to review the application of the IFU cleaning instructions. The sponsor routinely provides training to all users in the operation of the device, including its assembly and disassembly for theatre support staff. Follow-up training is also provided six weeks after the initial session. Refresher training will be offered to central sterilisation services departments twice each year.
Mitroflow valves

The UK’s health regulator the Medicines and Healthcare products Regulatory Agency has issued an alert for the Mitroflow LX biological replacement pericardial aortic heart valve due to the risk of early structural valve deterioration with smaller sizes (19 and 21 mm).

The heart valve is manufactured by LivaNova, formerly known as Sorin Group.

The TGA’s Advisory Committee on the Safety of Medical Devices (ACSMD) considered this issue at its meeting on 4 March 2016.

The sponsor cancelled this device from Australian Register of Therapeutic Goods last year but they were implanted in Australians prior to that.

Recent safety alerts

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

- **Philips IntelliVue MX40 wearable patient monitor:** Suspension – safety concerns
- **Meditech ultrasound gel:** Safety advisory - risk of bacterial contamination
- **Medtronic SynchroMed II implantable infusion pump:** Hazard alert – risk of sudden loss of therapy due to reduced battery performance
- **Absorb Bioresorbable Vascular Scaffold System:** Hazard alert - increased risk of heart attack and blood clot

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 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 at the time of publication. The TGA 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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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.

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