

Sterilization in **Australia**

Volume 37 No. 2



Print Post Approved
PP255003/01725

Sterilization

in *Australia*

Official Journal of Sterilizing Research & Advisory Council (NSW) Inc.

S.R.A.C.A. NSW Inc. Committee -

President	George Papadopoulos
Vice President	Lynne Noring
Secretary	Cindy Shaw
Treasurer	Leanne Burns
Membership/Journal Subscriptions	Tania Wilcox
Education Officer	Tracey Worthington
Committee Members	Yvonne Emery David Bellamy Ruth Strickland-Ross

Printing & Design

Printed DTP Reflections

Tel: 0400 60 73 83

E: tony@printedreflections.com

Sterilization in Australia is published 3 times per year on behalf of the Sterilizing Research and Advisory Council of Australia NSW Incorporated.

The views expressed in any article are not necessarily those of the S.R.A.C.A. NSW Incorporated, nor are any products advertised given any official backing or endorsement by the Council.

Copyright 1992 is held by S.R.A.C.A. NSW Inc.

Copying or reprinting any of these articles contained herein is strictly forbidden without the prior permission of the Editor.

Sterilization in Australia is Print Post Approved
PP255003/01725

Address all correspondence to

PO Box M71 Missenden Road, Camperdown NSW 2050

Web Address: www.sracansw.org.au

ISSN number 0725.7066

Electronic on-line version ISSN1444-8476

ABN 85 914 815 703

All advertising enquiries to:

David Bellamy

Mob: 0478 138 570

Email: davidsracansw@gmail.com

Contents -

President's Report	3
Kim Beard - Committee Member	4
Certificate III - Sterilisation Services	5
Ballina - Workshop - July 14th, 2017	6
Macquarie University	8
Hornsby Workshop - June 14th, 2017	10
TGA Medical Devices Safety Update.....	12
GENCA	15
National Conference - Luna Park - Sydney	16
Call for Abstracts.....	17
SRACA Christmas Get Together.....	21
Applying for a Research Grant.....	22
2017 Calendar.....	27
Membership Renewal	28



President's Report

Welcome to the second issue of Sterilization in Australia for 2017.

The year has almost ended.

Our postponed workshop at Ballina was a success great work by all involved in getting this workshop up & running & having to rearrange their schedules due to the unfortunate floods.

We also had another workshop at Hornsby, we had Sue Greg from National Standards present to our members this was very informative. Andy Gay carried out the rest of the day with Product Families.

Again I would like to congratulate my team for both of these workshops as they were a success, well attended by our members & received with a positive light by all.

All nominations for our AGM were unopposed, congratulations to all that have been elected. On behalf of our members & committee I would like to thank Yvonne Emery for all of the work she has done for SRACA NSW during the long years of service even after she retired from Sterilising she stayed on the committee to help us out this was greatly appreciated & hope she enjoys her retirement. I would like to congratulate Kim Beard in joining our committee for SRACA NSW & welcome back Sharon Woods to SRACA NSW. Thank you both for joining SRACA NSW.

Like to also congratulate our scholarship winners;

Hornsby workshop:

- Joyce Kenyon- Liverpool Hospital
- Raza Saric- Manly/Mona Vale Hospitals
- Ann Browne
- Debra Carter- Sydney Adventist Hospital
- Savina Chand

Please also check out the website www.sracansw.org.au for information, downloads and copies of the journal. Us as the committee would like to know what our members would like to see, know or add to the site from within the industry that would benefit our members. So please contact us with ideas.

Just a little reminder that memberships are due for 2017

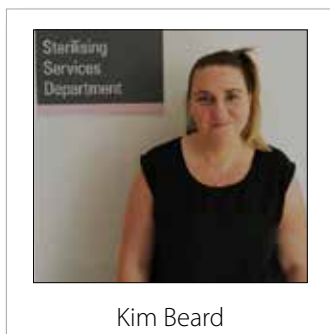
Regards

George Papadopoulos
President NSW SRACA



Kim Beard - Committee Member

Q & A



Q Your role within the industry.

A I am the Sterilising Manager of Gosford Hospital (CCLHD) I have held the position for the past six years. Previous to this appointment I work at Sutherland Hospital and Sydney Eye Hospital in the sterilising departments.
I have always enjoyed working in the sterilising industry and throughout my career I have developed wonderful working relationships with many peers in our industry.

Q Biggest changes you have seen in the world of Sterilising?

A The Sterilising Services at Gosford Hospital is currently undergoing a major refurbishment due to the redevelopment of the hospital. . During this time the unit has been fully operational to enable activity targets to be continued to be achieved. To supplement in house cleaning and disinfection procedures the use of Ultra violet irradiation (UVC) is undertaken daily. The use of this technology in this area has been incredibly effective as it kills a variety of bacterial species including spores. On exposure to UVC the DNA and RNA of the microorganisms are deactivated by the absorption of protons and this stops the organisms reproducing.

Q The one special thing that you are passionate about in the industry?

A I am passionate about making a difference in my unit and building a strong team to provide the best patient care. I am passionate about offering other facility's support and expertise in sterilisation.

Q What do you see being the biggest challenges in the future?

A Working through the Implementation plan from the ASNZS 4187 Gap Analysis to ensure compliance.

Q Best aspect of your job?

A Site visits to other facilities and opportunities to network with others in the industry.

Q Who or what would you want with you if were stranded on a deserted island?

A Endless amounts of Baklava.

Q Favorite song of all time?

A Holiday - Madonna.

Q Hobbies outside of sterilizing?

A Weight Training at my local gym, listening to music and watching old romantic movies.

Certificate III - Sterilisation Services



Certificate III in Sterilisation Services

TAFE NSW Course No: HLT37015-01V01
National Course Code: HLT37015
Nominal Hours: 455

Course structure and units

This course includes 14 units. Use the links below to go to your online learning resources for each unit.

BSBFLM312 – Contribute to team effectiveness

BSBINM301 – Organise workplace information

CHCCOM005 – Communicate and work in health or community services

CHCDIV001 – Work with diverse people

BSBADM311– Maintain business resources

HLTINF001 – Comply with infection prevention and control policies and procedures

HLTSTE001 – Clean and disinfect reusable medical devices

HLTSTE002 – Inspect and pack reusable medical devices

HLTSTE003 – Sterilise loads HLTSTE004 – Manage sterile stock

HLTSTE005 – Care for reusable medical devices

HLTSTE006 – Chemically disinfect reusable medical devices

HLTWHS001 – Participate in workplace health and safety

HLTWHS005 – Conduct manual tasks safely

wsi.tafensw.edu.au

For full details on TAFE NSW
fees and money matters please
visit our website:
wsi.tafensw.edu.au/fees

oten
Open Training &
Education Network

TAFE NSW
Western
Sydney
Institute

Ballina – Workshop – July 14th, 2017

What a beautiful location – Ballina RSL, overlooking the river on a sunny Saturday in July. This workshop was rescheduled from April due to cyclone Debbie which affected the Northern River Region, our thoughts were with you all. SRACA NSW is very grateful for Ruth Strickland-Ross and the presenters, being available and contributing to a successful workshop.

Delegates travelled from as far south as Nowra NSW and north from Toowoomba QLD.

Congratulations to the five delegates who won scholarships to the FSRACA National Conference in Sydney. Karen Brown, Debbie Landers, Jenny Howard, Lawrie McAteer and Joy Carter will be guests of SRACA NSW at Luna Park in 2018.



- **DAVID SALAKTA** presented on 'What the Standards Mean', AS/NZS4187:2014 has sent Sterilising Service Departments into a spin with new terminology and referencing ISO and EN standards as 'normative'. Giving the audience a better understanding of what a standard is and how it is created. David also went on to explain why the ISO standards are important here in Australia and the link with AS/NZS 4187:2014.

Giving an outline of the processes that a sterilizing department follows and how that fits in with standards. In conclusion the standards are trying to bring consistency across the sterilizing industry.

- **ALAN GOLLINGS** – is a qualified medical device repairer from Karl Storz. He spoke about care & maintenance of rigid telescopes and the importance of quality repairs for safety and economical value. Alan had some great examples of substandard repairs performed on scopes and laparoscopic instruments. Some of the repairs were barely noticeable to the naked eye, but with a closer look, the risk was obvious and should have been documented on a risk register. The take home message from this presentation was: check your repairs thoroughly, ensure your repairer is qualified and provides comprehensive information about spare parts and products used for repairs.

Parts and products also need TGA approval and can affect the quality of the medical device. The workshop was informed that replacement programs to Health Service Organisations are available to ensure medical devices remain compliant and safe for patient use.

- **SUE GREIG** – is the Senior Project Officer for the National HAI Prevention Program, working at the Australian Commission on Safety and Quality in Healthcare. Sue demonstrated a good understanding of the challenges faced by Sterilising Service Departments. In particular, she presented on the expectation of the NSQHS (National Safety and Quality Health

Ballina – Workshop – July 14th, 2017... continued

Service) and Governance of Sterilising Service Departments on behalf of the Australian population, after-all as consumers of health care, we all expect the highest of standards. Advisory no:A16/03 (date of publication May 2017) informs the latest advice for compliance to AS/NZS4187:2014. Evidence for compliance and assessment; risk rating and action plans for non-compliance will be critical for health service organisations undergoing accreditation in the near future.

Further information on accreditation and NSQHS can be found on www.safetyandquality.gov.au. This was a valuable presentation for Sterilising departments in preparation for upcoming accreditation.



- **ANDREW BAILEY** – from Halyard Health presented on manufacturers responsibilities to consumers. Andrew spoke about products/raw products used in manufacturing and associated ISO/EN standards required to maintain compliance throughout the sterilisation process. From the products used for cleaning, disinfection, packaging and sterilisation to the equipment used for processes and quality testing, all need to be manufactured to a standard to be valid for use. Non-compliance of equipment or consumables used for sterilisation of medical devices has the potential to adversely affect outcomes and impact on patient safety.

Put simply, for Sterilising Services Departments to comply with AS/NZS4187:2014, the products used to achieve compliance need to also be compliant to Standards. There should be assurance/evidence/certification for consumables and equipment used in the Sterilising department. Manufacturers are aware of their responsibilities and are able to assist with enquiries about their products.

- **LINDA SPARKE** – from Meile Professional showcased a fully functional mobile Sterilising Services Department that was one of the highlights at the World Congress in Brisbane 2016. Meile has fabricated a state-of-the-art unit to assist Sterilising departments during redevelopment. The mobile unit consists of the necessary compartments for a compliant Sterilising Services Department – decontamination, packing and sterile areas. The system is modular; it can be expanded and retrofitted with additional equipment if necessary.

This concept is brilliant and has the potential for a more permanent future in remote areas that require a Sterilising service for reusable medical devices.

- **NARELLE PARFITT AND DEBBIE LANDERS** – from St. Andrews Hospital in Toowoomba, shared their experience on 'Product Families'. What a fantastic outcome for a complex requirement. St. Andrews Hospital has completed the development and validation of product families as required in AS/NZS4187:2014. Instrument trays were tested against the existing steriliser cycle parameters to identify validation non-conformance. Initially, it was thought that many different cycles would be required for the range of medical devices being processed. But small adjustments made a significant difference and four product families requiring 4 different cycle parameters were established to achieve the required SAL (Sterility Assurance Level).

The Sterilising Technicians were involved with the project to enable a good understanding. The instrument tray checklists, tracking and labelling system reflect the cycle types required for sterilisation. This was a great presentation with good practical content, thankyou Narelle and Debbie – well done St. Andrews Hospital Sterilising Services Department.

Macquarie University

FACULTY OF MEDICINE AND HEALTH SCIENCES

Macquarie University
NSW 2109 Australia
T: +61 (2) 9850 2773
F: +61 (2) 9850 3600
medicine.mq.edu.au

ABN 90 952 801 237
CRICOS Provider No 00002J



MACQUARIE
University

Chief Investigators: **A/Professor Karen Vickery and Dr Honghua Hu**

Information and Consent Form

Name of Project: **Evaluation of reprocessing of loaner surgical instruments used in orthopaedic surgery**

You are invited to participate in a study investigating protocols associated with reprocessing of heat resistant surgical instruments used in orthopaedic surgery. As orthopaedic instruments are very expensive, many surgeries are conducted using loaner instruments. The purpose of the study is to determine the role Central Sterile Service Departments (CSSD) play in supply and reprocessing of loaner orthopaedic instruments.

The study is being conducted by Associate Professor Karen Vickery and Dr Honghua Hu of the Faculty of Medicine and Health Sciences. Contact either Karen Vickery on Ph 0422256323, email karen.vickery@mq.edu.au or Honghua Hu on 0423427722, email helen.hu@mq.edu.au.

If you decide to participate, you will be required to fill out an anonymous questionnaire.

Any information or personal details gathered in the course of the study are confidential. No individual will be identified in any publication of the results. All the data will be kept securely in a locked filing cabinet in a locked room at the Faculty of Medicine and Health Sciences, Macquarie University. Only study personnel will have access to the data. A summary of the results of the data can be made available to you on request by contacting either Associate Professor Karen Vickery or Dr Honghua Hu, Faculty of Medicine and Health Sciences, 2 Technology Pl Macquarie University 2109.

Participation in this study is entirely voluntary: you are not obliged to participate and if you decide to participate, you are free to withdraw at any time without having to give a reason and without consequence. You will not be entitled to any financial benefits that might conceivably accrue as a result of this research.

Macquarie University ... continued

FACULTY OF MEDICINE AND HEALTH SCIENCES

Macquarie University
NSW 2109 Australia
T: +61 (2) 9850 2773
F: +61 (2) 9850 3600
medicine.mq.edu.au

ABN 90 952 801 237
CRICOS Provider No 00002J



MACQUARIE
University

Chief Investigators: **A/Professor Karen Vickery and Dr Honghua Hu**

Information and Consent Form

Name of Project: **Evaluation of reprocessing of loaner surgical instruments used in orthopaedic surgery**

You are invited to participate in a study investigating protocols associated with reprocessing of heat resistant surgical instruments used in orthopaedic surgery. As orthopaedic instruments are very expensive, many surgeries are conducted using loaner instruments. The purpose of the study is to determine the role Central Sterile Service Departments (CSSD) play in supply and reprocessing of loaner orthopaedic instruments.

The study is being conducted by Associate Professor Karen Vickery and Dr Honghua Hu of the Faculty of Medicine and Health Sciences. Contact either Karen Vickery on Ph 0422256323, email karen.vickery@mq.edu.au or Honghua Hu on 0423427722, email helen.hu@mq.edu.au.

If you decide to participate, you will be required to fill out an anonymous questionnaire.

Hornsby Workshop – June 14th, 2017

The Hornsby RSL was the venue for the SRACA NSW June workshop. This is a great location, easily accessible by Public Transport and free parking for delegates attending. As usual, the service and facilities exceeded expectation.

- **JOE-ANNE BENDALL** - *HAI Program Manager Governance and Assurance* provided a detailed explanation about the AS/NZS4187:2014 audit tool currently being rolled out to NSW Public Health Sectors. A small but dynamic working party has assisted Joe-Anne with development of the audit tool. It has been trialled at three Health Service Organisations – (large, medium and small rural Hospital) with satisfying results. The audit tool will be featured on the CEC website as a QARS (Quality Audit Reporting System). The Audit Tool consists of 3 components: 1) Self Assessment-completed by Sterilising Services Department Managers/Supervisors; followed by 2) Peer Review-suggested to be completed by an expert peer within the same Local Health District; 3) Questionnaire for Sterilising Technicians-included in the Peer Review.

Audits are electronic, completed on-line and uploaded onto QARS. While the audit tool is not compulsory, the CEC has been given permission by all NSW LHDs' to view entries made into the audit tool. It is intended that monitoring and identification of common non-conformances will enable the CEC to assist NSW Public Health Service Organisations in achieving compliance to AS/NZS4187:2014. The CEC is providing support in the way of workshops across NSW, to demonstrate the audit tool and share the experience of the two hospitals providing the pilot trial.



- **ROBERT ROBINSON** - *Clinical Nurse Consultant, Nepean Blue Mountains LHD Infection Prevention and Control*, spoke about Hospital and community acquired infections and the impact they have on Health Service Organisations. Patient health, extended stay, pandemic outbreaks, resource overload, reputation and financial implications were a few.

Robert highlighted the importance of hand hygiene, validated processes for cleaning, disinfection and sterilisation of reusable medical devices – all can contribute to better outcomes.

It was wonderful to have representation from Infection Prevention and Control attend our workshop to acknowledge and re-enforce the importance of the relationship between the Sterilising Services Department and Infection Prevention & Control to ensure patient safety.



- **ANDY GAY** - continued from his '*Introduction to Product Families*' workshop held in December 2016. Thankyou to the delegates who brought along their example instrument trays. The 'hands on' approach was very useful.

It's obvious that medical devices constructed with varying materials and design, require classification into product families and validation to determine adequate penetration time to ensure sterility. Cannulated devices with silicone and Tufnol handles, in addition to cannulations with insulated coatings have been identified as particularly difficult to sterilise

Hornsby Workshop – June 14th, 2017 ... continued

using the standard 134 degrees @ 3.5 minutes.

ISO17665:3 is the standard for development of product families. In AS/NZS4187:2014 requires each product family to be validated to ensure sufficient holding time at 134 degrees is achieved within the cannulations.

- **DAVID BELLAMY** - *SRACA NSW Committee Member* streamed the workshop on Facebook. Search Facebook for SRACA NSW to see what's new.



Five scholarships to the FSRACA National Conference at Luna Park in 2018 were won by 5 lucky delegates. Congratulations to:

- **Joyce Kenyon**- Liverpool Hospital
- **Raza Saric** - Manly/Mona Vale Hospitals
- **Ann Browne**
- **Debra Carter** - Sydney Adventist Hospital
- **Savina Chand**



TGA Medical Devices Safety Update



Australian Government
Department of Health
Therapeutic Goods Administration

Medical Devices Safety Update

Volume 5, Number 4, July 2017

In this issue

- Intravenous solution bags are for single use only and must not be re-spiked
- Zoll upgrade to counter AED clock drift
- Hysteroscope cleaning advice updated
- Mitroflow valves
- Recent safety alerts

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.

Medical Devices Safety Update
is the medical devices safety
bulletin of the Therapeutic
Goods Administration (TGA)

TGA Health Safety
Regulation

Full text free online at www.tga.gov.au

1

TGA Medical Devices Safety Update ... continued

Medical Devices Safety Update

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.

TGA Medical Devices Safety Update ... continued

Medical Devices Safety Update

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

[Mediatech 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

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



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.

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:
Adjunct Professor
Tim Greenaway

Contributors include:
Dr Jorge Garcia
Mrs Anne Howatt
Dr Clare King

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.

© 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.

GESA-GENCA ICE Consensus Statements CPE

Infection Control in Endoscopy Consensus Statements on Carbapenemase-Producing Enterobacteriaceae

August 2017

Since the 2010 publication of GESA's *Infection Control in Endoscopy Guidelines*, there have been several overseas outbreaks of carbapenemase-producing Enterobacteriaceae (CPE) linked to the use of flexible endoscopes. In response to these outbreaks, the Board of the Gastroenterological Society of Australia (GESA) appointed a multi-organisation expert committee to develop consensus statements addressing this issue. The committee comprises representatives from GESA, the Gastroenterological Nurses College of Australia (GENCA), the Australasian College for Infection Prevention and Control (ACIPC) and the Australasian Society for Infectious Diseases (ASID). The committee examined and assessed the published literature and using the Delphi methodology produced the following consensus statements, which in their expert opinion are considered best practice.

Statement 1 ▶ Endoscopic procedures should only be performed in centres where adequate facilities for safe cleaning and reprocessing are available for appropriately trained staff to reprocess endoscopes.

Statement 2 ▶ The most important component of decontamination is timely and meticulous cleaning prior to disinfection.

Statement 3 ▶ The use of a Therapeutic Goods Administration (TGA)-approved automated flexible endoscope reprocessor (AFER) is mandated for reprocessing in accordance with manufacturers' instructions.

Statement 4 ▶ Quality control is fundamental to the delivery of efficient and safe endoscopic procedures, and incorporates proof of process with adequate staff training (including continuing education, professional development and assessment), documentation and microbiological surveillance cultures.

Statement 5 ▶ Patient-to-patient transmission of carbapenemase-producing Enterobacteriaceae (CPE) by endoscopic instruments can result in serious illness, and its prevention must be a priority of every endoscopic unit.

Statement 5a ▶ Informed consent for patients undergoing endoscopic procedures with duodenoscopes or linear echoendoscopes must include disclosure of the risk of CPE colonisation or infection.

Statement 6 ▶ Reported endoscopic transmission of CPE has been predominantly related to instruments with complex tips (e.g. duodenoscopes and linear echoendoscopes), but all endoscopic instruments may transmit CPE.

Statement 7 ▶ Instrument reprocessing and environmental management protocols need to be augmented in an effort to reduce the risk of CPE.

Statement 7a ▶ All endoscopic instruments, except those in sterile packaging, should be stored in TGA-approved forced-air drying cabinets.

Statement 7b ▶ Endoscopes stored in TGA-approved forced-air drying cabinets may be used for a period of up to 7 days without reprocessing, unless otherwise stated by the manufacturer.

Statement 8 ▶ When endoscopic procedures are performed on known CPE-positive patients, specific environmental and instrument reprocessing protocols should be utilised.

Statement 8a ▶ Following an endoscopic procedure on a known CPE-positive patient, the instrument should undergo microbiological testing and be quarantined until a negative culture result is obtained at 48 hours.

Statement 9 ▶ All cases of suspected CPE transmission related to endoscopic procedures should be investigated by an outbreak management team.

Committee Members:

- Assoc. Prof. Benedict Devereaux (Co-Chair): GESA
- Prof. Rajvinder Singh (Co-Chair): GESA
- Sue Greig: ACIPC
- Prof. Eugene Athan: ASID
- Robyn Brown: GENCA
- Dianne Jones: GENCA
- Dr Henry Cutler: Health Economist (ex officio)
- Fiona Bailey: GESA (ex officio)
- David Wallis: GESA (ex officio)

Endorsed by:

This work is wholly funded by GESA.



© Gastroenterological Society of Australia 2017
This work may not be reproduced in part or in whole without the permission of GESA.
www.gesa.org.au

This document has been prepared having regard to general circumstances, and it is the responsibility of the practitioner to have express regard to the particular circumstances of each case, and the application of this document in each case. Professional documents are reviewed from time to time, and it is the responsibility of the practitioner to ensure that the practitioner has obtained the current version. It is advised that you regularly refer to the GESA website for up-to-date information. Whilst the Society endeavours to ensure that professional documents are as current as possible at the time of their preparation, it takes no responsibility for matters arising from changed circumstances or information or material which may have become available subsequently.

National Conference

LUNA PARK - SYDNEY

Save the date

12-14 September 2018

JUGGLING PRIORITIES



Call for Abstracts



**Sterilizing Research Advisory
Council of Australia**

Call for Abstracts - National Conference FSRACA 2018

The Federation of Sterilising Research & Advisory Council of Australia would like to invite academics of the industry to submit abstracts for the National conference being held in Sydney Luna Park September 12 to 14 2018. Submissions will be considered for oral and E. poster Presentations.

Aim:

The aim of the National conference is to bring colleagues together to expand and exchange knowledge, information and ideas. To learn about new and innovative changes in technology to ensure we are patient focused and ensuring patient and staff safety.

Key Learning Outcomes

- To provide stimulating, motivational and diverse speakers.
- To develop delegate knowledge to enable them to investigate and explore strategies for their working environment.
- To present delegates with new innovative ideas and emerging technologies.
- To assist delegates to share quality initiatives with their peers.
- To keep delegates well informed with National and international standards relating to the sterilising Industry.
- To keep delegates educated with quality management systems and assessing risk factors.

Key Dates

December 2017 abstract and E – Poster submissions open

May 2018 abstracts submissions closes (oral presentations)

June 12018 review of abstracts for oral presentations and abstract acceptance notification.

July 2018 Preliminary program released & Early Bird registration commencement.

August 11th 2018 abstract submission closes (**E Poster**)

August 31st 2018 Early bird registration deadline.

Call for Abstracts ... continued



Sterilizing Research Advisory
Council of Australia

Call for abstracts

The content areas belonging to the following themes can be proposed.

JUGGLING PRIORITIES



C– Compliance
I - Innovation
R - Risk
C - Challenges
U - Up Dates
S - Standards

The program will include the presentation formats of **Oral and E- poster presentation**

Oral Presentations- General Abstract information.

Deadline for submission of Oral Presentation abstracts has been set for May 2018

- All abstracts submitted for consideration of an Oral presentation will be reviewed by the FSRACA committee and those accepted will be published in the conference abstract book. Authors will be notified June 2018
- When submitting an abstract at least one of the authors must commit to present the paper at the conference.
- Present a non –commercial program submit a brief bio and a professional digital photo (for Marketing Materials)
- Please note that only the abstracts selected by the FSRACA Committee will be presented as an oral presentation. All other accepted abstracts will be offered the opportunity to present as an E-Poster.
- Presentation guidelines will be provided on acceptance into program.

Call for Abstracts ... continued



**Sterilizing Research Advisory
Council of Australia**

- All abstracts must be prepared according to the instructions provided below. Submissions will be returned to the author if not in the correct format and must be resubmitted immediately in the correct format to be reviewed and considered for inclusion in the program.

Conditions of presenting

- Presenting authors (oral presentations) will receive complimentary conference registration, economy air flights, one night accommodation pending day and time of presentation on the program.
- All presenters must complete the conflict of interest form, found on the online submission system when submitting their abstract for consideration.
- Standard audio visual is provided for all sessions (microphone, lectern, data projector, screen and Lap top). Any additional requirements must be listed in the online submission system.

E Poster presentation

General Abstract information

- All abstracts submitted for consideration will be reviewed by FSRACA Committee and those accepted will be published in the conference Abstract Book Authors will be notified August 31st 2018
- E poster guidelines will be provided on acceptance of your abstract.
- All abstracts must be prepared according to the instructions provided below. Submissions will be returned to the author without review not in the correct format and must be resubmitted immediately in the correct format to be reviewed and considered for inclusion in the program.

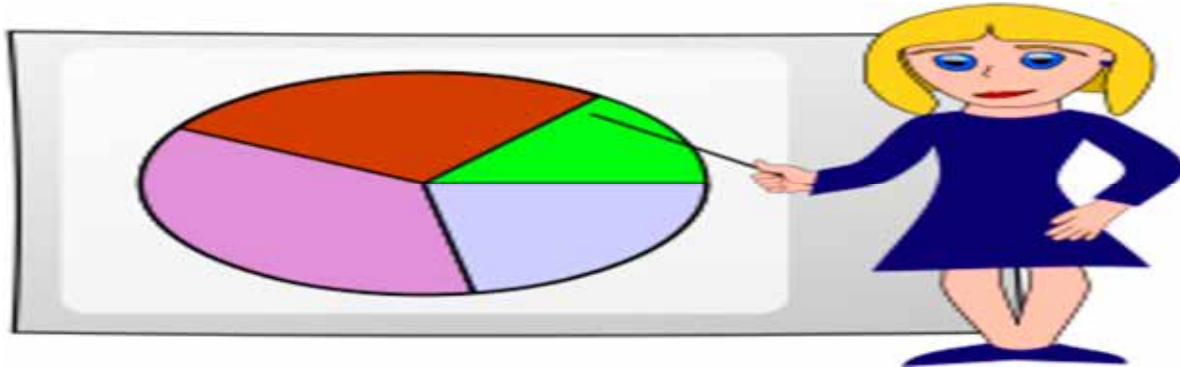
Conditions of presenting an E poster

- All presenting authors must register to attend at least one day of the national conference and must have paid their registration in full prior to the event.
- All authors must complete the conflict of interest form, found on the online submissions system when submitting their abstract for consideration.
- Any e-poster presentation without at least one registered presenter will be withdrawn from the program. Delegate cancellation fees will apply if an e-poster presenter cancels their presentation.

Call for Abstracts ... continued



Sterilizing Research Advisory
Council of Australia



Abstract instructions- Oral presentations and e-posters

All abstracts will be printed as submitted; therefore, all authors must strictly follow the instructions outlined below:

- Abstracts to be submitted only in English.
- The abstract should not exceed 1000 words
- Name, surname, title, institution as well as the city.
- (Street, street number, postal code) is not necessary.
- The name of the presenting author to be mentioned along with other authors and underlined.
- A biography of the presenting author.
- The same team cannot submit more than three papers
- Abstract must be structured as follows; Introduction, Objectives, Results, Discussion, Conclusion.
- The main text may include necessary tables, charts, and typical abbreviations.

Abstract format

Note: It is important that you include the names of all companies where you are employed.

Maximum 1000 words

Publications

All abstracts will be published in conference proceedings.

Disclaimer

The conference organisers will not be held responsible for Abstract submissions not received via the online submissions system

SRACA Christmas Get Together



SRACA NSW CHRISTMAS GET TOGETHER

DATE: Tuesday 5th of December
TIME: 1000am Registration
VENUE: Hornsby RSL
COST: Free for Members
\$80 for non-members
RSVP: Tuesday 28th November

10:30 – GENERAL MEETING

Topics to be discussed:

- Constitution review
- National Conference update
- Education suggestions for 2018

11:15 – OTEN PRESENTATION

12:00 – CHRISTMAS LUNCH

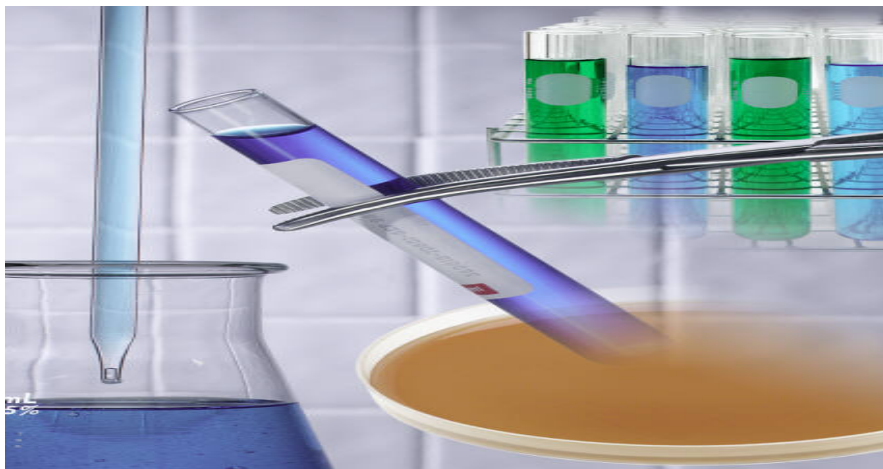
NSW SRACA will award 5 registrations to attend the 2018 National Conference to be held at Luna Park Sydney. You must be a financial member of NSW SRACA to win, you must be in attendance. The scholarship is non-transferrable

New members will be accepted on the day, however subject to approval at the next executive committee meeting

Applying for a Research Grant



**Sterilizing Research Advisory
Council of Australia**



Expression of interest for The Sterilizing Industry

Applying for a Research Grant

FEDERATION STERILIZING RESEARCH ADVISORY COUNCIL OF AUSTRALIA

INVITE ALL FINANCIAL MEMBERS OF SRACA to apply for a research grant of up to \$1400.00

This package includes;

- Information
- Guidelines
- Application form

You can request your package from your State Secretary, or download from your State or Federal website.

Applying for a Research Grant ... continued

Purpose

To provide financial assistance, to promote research and develop skills to ensure the sterilizing industry is contributing to quality patient care.

Value

Maximum \$1,400.00

1. Selection criteria

- Financial assistance will be considered for projects which would be relevant and beneficial to both the applicant and those involved in the field of sterilization.

2. Eligibility

- Highly developed written and oral skills
- State SRACA membership number and proof you are a current active member.
- Be a full member of a state SRACA and have been a member of a state SRACA for a minimum of two years immediately prior to submitting an application
- Be currently employed in the field of sterilization and have been employed in the field of sterilization for a minimum of two years immediately prior to submitting an application
- Has attended SRACA meetings and educational activities during the two years immediately prior to submitting an application.
- Be actively involved in his/her state SRACA. Active involvement is considered to include but is not limited to:-
Willingness to serve on SRACA committee or sub-committee
Promotion of SRACA activities
- Applicants shall submit information about any application for funding from an alternative source/s for the same purpose.
- Only one research grant will be awarded annually.

3. Application Guidelines

- Application forms are available from both FSRACA and SRACA State secretaries
- Applicants should submit a completed type written application form
- Comprehensive Curriculum Vitae, which show details of work and education qualifications.
- Full details of the project, including the objectives, the methodology of the research, the outcome and how the research can enhance sterilization and the estimated or actual budget.
- The proposed project must have commenced within 12 months from receipt of the research grant.
- Within four weeks of completing the research project the recipient will need to submit a type written report outlining the project
- The recipient of a FSRACA grant shall:
Be prepared to speak on the funded project at FSRACA and /or SRACA meetings, conferences or workshops

Applying for a Research Grant ... continued

- The report may be published in the “Sterilization in Australia” Journal or in an appropriate national professional Journal at the discretion of the editor.
- The recipient will submit progress reports to FSRACA if requested to do so.
- Papers and reports shall not be returned to the grant recipient by FSRACA committee.
- Projects involving human bioethics shall show proof of permission by the people and/or organization/s concerned.
- The grant may fund all or part of the project
- The grant will be available only once to any individual.

4. Selection

- Completed application forms together with all supporting documentation shall be submitted to the Secretary of the state SRACA of which the applicant is a member, by 31 December each year.
- The state SRACA committee will determine whether eligibility requirements (as set out in this document) have been met.
- All applications will be forwarded by SRACA to the FSRACA Secretary together with a State committee recommendation.
- The applications shall be assessed at a meeting of the FSRACA committee.
- The decision of FSRACA committee shall be final and binding on all matters.
- Confidentiality of the selection process shall be upheld by all those involved.
- The names of successful applicants, together with an outline of project and funds granted, will be published in the minutes of FSRACA meeting.

5. Publication

- Grant recipients shall retain copyright of all papers/reports submitted to FSRACA

6. Financial Considerations

- Applicant shall submit a statement of proposed expenditure for the proposed project.
- FSRACA committee reserves the right to cancel the grant and request return of any monies granted should the recipient fail to pursue the purpose for which the grant was awarded.

7. Alternative Funding

- FSRACA financial grants are conditioned upon the applicant informing FSRACA at any time should funding received exceed the total cost of the project.
- FSRACA committee reserves the right to request the return of monies over and above full funding.

Applying for a Research Grant ... continued

Application form

(Please circle your title)

Title Ms, Miss, Mrs, Mr., Dr

Surname _____

Given Names _____

Address _____

_____ Post code _____

Email address _____

Phone number. _____

Current occupation and years of experience _____

Amount of Funding requested \$ _____

I have/have not made application to alternative sources for funding YES/NO

If YES from whom and what support has been requested/granted: _____

If funding is granted I _____ agree to abide by the terms and
Conditions of FSRACA "Guidelines for Financial Grants"

SIGNATURE: _____ DATE _____

OFFICE USE ONLY

Received by _____ State SRACA Secretary on _____

State SRACA comments regarding eligibility (as per financial grant guidelines)

SIGNED: _____ POSITION: _____ DATE: _____

Received by FSRACA Secretary on _____ DATE: _____

Presented to FSRACA meeting on _____ DATE: _____

FSRACA Action: _____

SIGNED: _____ POSTION: _____ DATE: _____

Attachments

- Current SRACA Membership
- Curriculum Vitae
- 2 x Professional Referees
- Proposed Project
- Budget Plan

Applying for a Research Grant ... continued

Applicant _____

1= Criteria not met

5= Criteria fully met

Criteria Rating Comment

1. Documentary evidence. (Circle correct answer)

- Current membership and active member State group YES/NO
- Two relevant references supplied YES/NO
- Curriculum Vitae supplied YES/NO
- Project details YES/NO
- Budget Plan YES/NO

2. Essential Qualifications supplied YES/NO

3. Communication skills

- Written 1,2,3,4,5
- Oral 1,2,3,4,5

Summary _____

(Circle the correct answer)

Approved/not approved

Amount granted \$ _____

Signature _____ Date _____

2017 NSW SRACCA Calendar of Events



AGM

- 14th June 2017—Hornsby RSL

General Meeting

- 7th March 2017
Northmead Bowling Club
- 6th December 2017
Hornsby RSL

Workshops

- 1st April 2017—Ballina
- 14th June 2017—Hornsby
- 16th August 2017—
Canberra
- 6th December 2017—
Hornsby

Executive Committee Meetings

- 7th March 2017
- 2nd May 2017
- 5th July 2017
- 5th September 2017
- 8th November 2017

WORLD CSSD DAY

- 10th April 2017

January 2017						
W	S	M	T	W	T	F
1	1	2	3	4	5	6
7						
8	2	8	9	10	11	12
14						
15	3	15	16	17	18	19
20						
21	4	22	23	24	25	26
27						
28	5	29	30	31		

February 2017						
W	S	M	T	W	T	F
5				1	2	3
4						
6	5	6	7	8	9	10
11						
12	7	12	13	14	15	16
17						
18	8	19	20	21	22	23
24						
25	9	26	27	28		

March 2017						
W	S	M	T	W	T	F
9				1	2	3
4						
10	5	6	7	8	9	10
11						
12	11	12	13	14	15	16
17						
18	12	19	20	21	22	23
24						
25	13	26	27	28	29	30
31						

April 2017						
W	S	M	T	W	T	F
13						1
8						
14	2	3	4	5	6	7
8						
15	9	10	11	12	13	14
15						
16	16	17	18	19	20	21
22						
17	23	24	25	26	27	28
29						
18	30					

May 2017						
W	S	M	T	W	T	F
18		1	2	3	4	5
6						
19	7	8	9	10	11	12
13						
20	14	15	16	17	18	19
20						
21	21	22	23	24	25	26
27						
22	28	29	30	31		

June 2017						
W	S	M	T	W	T	F
22				1	2	3
3						
23	4	5	6	7	8	9
10						
24	11	12	13	14	15	16
17						
25	18	19	20	21	22	23
24						
26	25	26	27	28	29	30

July 2017						
W	S	M	T	W	T	F
26						1
1						
27	2	3	4	5	6	7
8						
28	9	10	11	12	13	14
15						
29	16	17	18	19	20	21
22						
30	23	24	25	26	27	28
29						
31	30	31				

August 2017						
W	S	M	T	W	T	F
31		1	2	3	4	5
6						
32	6	7	8	9	10	11
12						
33	13	14	15	16	17	18
19						
34	20	21	22	23	24	25
26						
35	27	28	29	30	31	

September 2017						
W	S	M	T	W	T	F
35					1	2
3						
36	3	4	5	6	7	8
9						
37	10	11	12	13	14	15
16						
38	17	18	19	20	21	22
23						
39	24	25	26	27	28	29
30						

October 2017						
W	S	M	T	W	T	F
40	1	2	3	4	5	6
7						
41	8	9	10	11	12	13
14						
42	15	16	17	18	19	20
21						
43	22	23	24	25	26	27
28						
44	29	30	31			

November 2017						
W	S	M	T	W	T	F
44				1	2	3
4						
45	5	6	7	8	9	10
11						
46	12	13	14	15	16	17
18						
47	19	20	21	22	23	24
25						
48	26	27	28	29	30	

December 2017						
W	S	M	T	W	T	F
48					1	2
3						
49	3	4	5	6	7	8
9						
50	10	11	12	13	14	15
16						
51	17	18	19	20	21	22
23						
52	24	25	26	27	28	29
30						
1	31					

Please note dates and venues are subject to change due to venue availability



S.R.A.C.A. (NSW) Inc.

Membership Application/Renewal

Renewals Due December Annually- **NOW DUE**

Sterilizing Research & Advisory Council of Australia (NSW)

NEW MEMBERSHIP/RENEWALS

MEMBERSHIP COMMENCES: 1st January each year and is valid till
31st December of the same year

TITLE _____ SURNAME _____ GIVEN NAME _____

HOSPITAL/COMPANY _____

POSTAL ADDRESS _____

POSTCODE _____ STATE _____ PHONE NO _____

EMAIL _____

Please tick Membership Type

FULL Membership renewal includes Journal	\$50	<input type="checkbox"/>	\$50.00
NEW Membership includes Journal & Joining fee	\$50 + \$5 Joining fee	<input type="checkbox"/>	\$55.00
ASSOCIATE Membership includes Journal	\$50	<input type="checkbox"/>	\$50.00
SUBSCRIPTION to Journal Only (Overseas incl. postage)	\$60	<input type="checkbox"/>	\$60.00

TOTAL PAYMENT ENCLOSED \$ _____

TOTAL PAYMENT BANK DEPOSIT \$ _____

Make cheques payable to:
S.R.A.C.A. (NSW) Inc.
Return to
S.R.A.C.A. (NSW) Inc
PO Box M71
Missenden Road
CAMPERDOWN NSW 2050

Email: sracansw@gmail.com

**RENEWAL MEMBERSHIPS ONLY CAN BE
DONE VIA EFT:**

S.R.A.C.A. (NSW) Inc.
BSB: 032096

Account: 871850

Reference: Company/Facility Name or
Member Name

Please send or Email Application Form