

# ***Sterilization*** in **Australia**

Volume 37 No. 1



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# Sterilization

in **Australia**

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

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## President's Report

Welcome to Volume 37 no.1 Sterilization in Australia for 2017

I would like to thank all the committee & members of SRACA NSW for your enduring support.

Thank you to Ruth Strickland – Ross for organizing our first workshop April 1ST 2017, however cyclone Debbie had other ideas and caused havoc in Lismore and the workshop needed to be rescheduled for July 1st 2017. Same venue and program, the program looks great and very informative with a variety of interesting topics. The workshop is free to all financial members or we are happy for you to join on the day. We hope everyone in Lismore is now safe & dry.



From all NSW SRACA we wish you a very happy Easter and we hope you enjoyed the Easter Break.

April 10th 2017 was our very first World Sterilizing day, many of you celebrated and brought awareness of the sterilizing industry to many Nurses, doctors, visitors and even Executive staff, by opening your department doors or having a stand in your hospital foyer. Some Sydney hospitals even made it on the WFHSS face book page alongside hospitals from around the world great effort. Next year we hope Australia will all support this very important day, we have registered this day on the health calendar.

We understand many are finding the AS/NZS 4187 a little challenging at times, but rest assure NSW SRACA, STIG and the CEC and all trying to help by providing workshops and education sessions.

NSW SRACA have a workshop /AGM scheduled in Sydney at Hornsby RSL on June 14th we have nominations for the following positions:

Vice President - Lynne Noring

Secretary – Cynthia Shaw

Committee members – Ruth Strickland -Ross, Tania Wilcox, Yvonne Emery and a vacant position.

The program for this workshop is about to be released by our education officer Tracey Worthington, Tracey is just working out the final details.

Please remember we are hosting the National Conference in Sydney at Luna Park in September 2018 so start putting together a presentation abstract or a one page poster of a project you have been working on, it can be a team effort.

Please checkout our website [www.sracansw.org.au](http://www.sracansw.org.au) for further information, downloads and copies of the journals. Our Committee would like your ideas & participation for further workshops, education sessions and Journal reports to help our Sterilizing Industry with education requirements to benefit our members.

Thank you and we hope to catch up with you all at one of our up and coming workshops.

Regards

**George Papadopoulos**

President NSW SRACA



## 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](http://wsi.tafensw.edu.au)**

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

**oten**  
Open Training &  
Education Network

**TAFE** NSW  
Western  
Sydney  
Institute

# Gilles Bouillot - Most Outstanding Student of 2016



Gilles Bouillot

## Congratulations – Gilles Bouillot OTEN TAFE – Most outstanding student of 2016

On Thursday 30th March 2017, OTEN TAFE held its' annual awards night at Burwood RSL. Gilles Bouillot studied and earned the award of 'Most Outstanding Student' completing the Certificate III in Sterilisation Services. This award is the result of 12 months of distant learning, made possible by OTEN TAFE NSW, and the dedicated teachers of the Western Sydney Institution located at Kingswood. I asked Gilles some questions to gain insight of his study experience and his intended forward journey new knowledge and education. He was happy to share the following:

Gilles admitted he was surprised, but grateful for the opportunity and honoured to accept the award. Gilles provided the following statements and I hope this will inspire anyone interested in expanding their education and knowledge of the Sterilising industry.

### **Q: What attracted you to the industry of Sterilising?**

**A:** Before I started my course at TAFE OTEN, I was working as a Patient Support Assistant on a casual basis. I was seeking permanent employment in Health and I hoped the successful completion of the Certificate III in Sterilisation Services, would provide me with the knowledge and qualification to gain permanent employment in health and the Sterilising industry.

### **Q: Are you currently working in a Sterilising Services Department? Where & how long?**

**A:** I am currently working full time as an Operating Theatre Assistant. I am convinced the knowledge and qualification I gained through OTEN helped me to secure this position. While I am not working within the CSSD, I have a good understanding how reusable medical devices are processed. I have learned the importance of receiving contaminated medical devices; cleaning and disinfection, preparing and packing, sterilising, transport, control and storage of sterile medical devices. Each step has its' own risks, and correct processing is essential to Infection Prevention and Control and patient safety.

### **Q: Did you utilise the WSI learning centre to assist your studies? What did you think of the facility and the support they offered?**

**A:** I didn't use the WSI at Nepean, instead utilised the Hospital Library for my study. The staffs of CSSD were very helpful. Nevertheless the new infrastructure at OTEN TAFE and access to the teachers for support definitely provided a positive experience.

The opportunity for distance learning through OTEN is very convenient and enables you to work and study. The support documents for the course include a CD and access to online components for assessments.

### **Q: What was the highlight of your learning experience? Has/how has this impacted on your knowledge and understanding of the importance of education for Sterilising Technicians?**

**A:** I am very very grateful to the Teacher, Marina Papadopoulos who made the course very interesting by sharing her experience and knowledge. Her positive energy allows the students to reach their potential.

Altogether I really enjoyed studying Sterilisation Services. I recognised that working and studying would be difficult to achieve but the online solution is great and accessible at any time. Many thanks to OTEN TAFE.



To mark the success of Gilles Bouillot achievement, SRACA NSW has awarded him 12 months membership and the honourable Sam Passfield medallion. Sam Passfield was instrumental in implementing education for Sterilising Technicians through TAFE.

## SRACA Workshop - Ballina

### SRACA NSW MEMBERS WORKSHOP BALLINA PROGRAM



**DATE :** 1ST July 2017  
**TIME :** 8:15am registration  
**VENUE:** Ballina RSL  
240 River street  
Ballina NSW 2478  
**COST:** Free for Financial Members  
\$80.00 for Non Members  
**RSVP:** 27th March 2016  
[Ruth.Strickland-Ross@ncahs.health.nsw.gov.au](mailto:Ruth.Strickland-Ross@ncahs.health.nsw.gov.au)

- 8:15 Registration
- 8:50 Welcome
- 9:00 David Salakta — What the standards mean
- 9:30 Alan Gollings — Care and Maintenance of Rigid Scopes
- 10:00 Morning Tea
- 10:45 Sue Greig — NSQHS Standard3: The importance of governance for sterilising services
- 11:45 Andrew Bailey — Topic to be confirmed
- 12-15 Lunch part sponsored by Miele
- 1:15 Mobile CSSD from Miele Professional State-of-the-art instrument reprocessing during CSSD refurbishment.
- 1:45 Narelle Parfitt & Debbie Landers — Product families
- 2:30 Questions for speakers
- 3.00 Close

*\*New Members will be accepted on the day however will be subject to acceptance at the May 2017 executive committee meeting, as per the NSW SRACA Constitution*



# World Sterilisation Services Open Day



This event was held for the very first time on April 10th 2017 worldwide for all sterilising services departments. ( SSD).

This special event was announced by the President of world Federation for hospital sterilizing Sciences (WFHSS) at the World Congress in Brisbane 2016.

This event is to encourage Sterilizing Departments worldwide to get on board and open their department doors to surgeons, doctors, nurses other support services, executive members and anyone interested to see what happens in our sterilizing departments.

This world day is to recognize the good work our sterilizing departments do, so people can clearly see how intricate and complex our work can be and the technology changes that have occurred over the years.

As we are all aware ,most of our work goes without being appreciated because no one really knows what happens in our departments. Therefore this worldwide day is an opportunity for us to share our departments to any interested parties so our work can be acknowledged and appreciated.

This is a wonderful opportunity for our sterilizing industry as team to ensure this day becomes a major event in the health calendar for our recognition like other important events such as nurses day, midwives day etc etc.

Don't all sit back and expect other hospitals to lead this event, it is important as an industry to be acknowledged and to help make this day work.

CSSD RPAH Sydney opened their doors as did other hospitals.

RPAH have sent these photos to the journal and the world federation to encourage other departments to get on board every year.

RPAH CSSD also had an exhibition stand in the main entrance of the hospital and made ribbons in the WFHSS emblem colours for people to wear in support of our day, we gave out the free ribbons to anyone that visited our stand as well as dough nuts, muffins & small Easter eggs, we had a display of instruments and other RMD'S. The patients visitors, doctors and nurses were all very supportive and stated we certainly are the heart of the hospital.

So we are encouraging and challenging all sterilizing departments to support this world sterilizing open day each year for recognition of the good work we provide to our Health Service Organizations.

Thank you in advance for your support next year 10/04/2018

**Lynne Noring**  
RPAH CSSD Manager



## World Sterilisation Services Open Day ... continued





## World Sterilisation Services Open Day ... continued



# Macquarie University

## FACULTY OF MEDICINE AND HEALTH SCIENCES

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F: +61 (2) 9850 3600  
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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](mailto:karen.vickery@mq.edu.au) or Honghua Hu on 0423427722, email [helen.hu@mq.edu.au](mailto: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**

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

## SRACA NSW Annual General Meeting

### SRACA NSW AGM MEETING AND PRESENTATION



**DATE :** 14 JUNE 2017

**TIME :** 8.00am

**VENUE:** Hornsby RSL  
4 High street  
HORNSBY

**RSVP:** 9th JUNE 2017

Cynthia.shaw@sswahs.nsw.gov.au

Tracey.Worthington@health.nsw.gov.au

### “But Wait – There’s More”

- 8:00** Registration Tea & Coffee served
- 9:00** Andy Gay Developing Product Families & Process Categorization for Steam Sterilisation – **delegates invited to bring along instrument trays/photographs/checklists**
- 12:00** AGM
- 12:30** Lunch
- 13:00** Robert Robinson Infection Prevention and Control (NBMLHD) – Infections – the impact on Hospitals and the CSSD
- 14:00** Andy Gay Conclusion

**Cost will be free for financial members of SRACA and \$80.00 for non-members.**

**Please Notify Tracey Worthington or Cynthia Shaw on the above email of any special dietary requirements.**

## SRACA NSW AGM - Nominations



# S.R.A.C.A. (N.S.W.) Inc.

ABN: 85 914 815 703

P.O. Box M71  
Missenden Road  
CAMPERDOWN NSW 2050  
20<sup>TH</sup> March 2017

NOTICE OF THE ANNUAL GENERAL MEETING TO BE HELD AT 10.00AM ON JUNE  
14<sup>TH</sup> 2017 AT HORNSBY RSL, 4 HIGH STREET HORNSBY NSW.

### AGENDA

1. PRESENT
2. APOLOGIES
3. ACCEPTANCE OF PREVIOUS MINUTES
4. BUSINESS ARISING FROM MINUTES
5. CORRESPONDENCE PERTAINING TO AGM
6. BUSINESS ARISING FROM THE CORRESPONDENCE
7. REPORTS
  - a) PRESIDENT
  - b) SECRETARY
  - c) TREASURER
8. ELECTION OF OFFICE BEARERS FOR 2017-2018
9. NOTICES OF MOTION
10. GENERAL BUSINESS – Pertaining to the AGM

*IN ORDER TO ORGANISE CATERING, MEMBERS ARE REQUESTED  
TO RSVP BY FRIDAY 01/06/2016*

Cynthia Shaw (02) 9515 7304  
[Cynthia.shaw@sswahs.nsw.gov.au](mailto:Cynthia.shaw@sswahs.nsw.gov.au)



## SRACA NSW AGM - Nominations ... continued

### ELECTION OF OFFICERS 2017-2018

The following positions are to be declared vacant and nominations for a period of two years are sought in accordance with the Constitution and By Laws of the association.

Vice President	-	Lynne Noring
Secretary	-	Cynthia Shaw
Committee	-	Tania Wilcox
	-	Yvonne Emery
	-	Ruth Strickland-Ross
	-	Vacant Position

Those members who are vacating Office are eligible and may be available for re-election.

WRITTEN NOMINATIONS MUST BE RECEIVED BY THE SECRETARY 7 DAYS PRIOR TO THE ANNUAL GENERAL MEETING.

**\*\*\*ONLY FULL MEMBERS WHO HAVE CURRENT MEMBERSHIP, (WITH A MINIMUM OF 2 FULL YEARS CONTINUOUS MEMBERSHIP) ARE ELIGIBLE FOR NOMINATION** (AS PER CONSTITUTION \*\*\*

Return completed forms to:

Cynthia Shaw  
The Honorary Secretary  
S.R.A.C.A. (NSW) Inc.  
P.O. Box M71  
Missenden Road  
CAMPERDOWN NSW 2050  
Fax: (02) 9515 8120  
[Cynthia.shaw@sswahs.nsw.gov.au](mailto:Cynthia.shaw@sswahs.nsw.gov.au)

THE NOMINATION FORM BELOW MAY BE PHOTOCOPIED

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### **NOMINATION FORM FOR THE ELECTION OF COUNCIL OFFICERS AND COMMITTEE 2017-2018**

I \_\_\_\_\_ being a fully paid up member of the Sterilising Research and Advisory Council of Australia (NSW) Inc. nominate:

Name \_\_\_\_\_ for the position of \_\_\_\_\_

Signature \_\_\_\_\_ Nomination Seconded by \_\_\_\_\_

Signature of person nominated accepting the nomination \_\_\_\_\_

# GENCA



*Sharing knowledge, sharing learning*

## **Position Statement – March 2017**

### **Infection Control in Endoscopy**

#### **Purpose**

Endoscopic procedures have been linked to serious infections, in particular Carbapenamase-producing Enterocacteriaceae (CPE). Industry guidelines are currently being reviewed to address these potentially catastrophic infections. A specialist Infection Control working party was established by GESA and developed Draft Guidelines addressing CPE which were circulated widely but not adopted by the GESA Board. A second working party has been established by GESA to review the ICE Guidelines in totality. This GENCA Position Statement is to assist all endoscope users in making informed decisions, in the interim, in conjunction with the GESA statement released in August 2016.

#### **Preamble**

Endoscopic procedures have been associated with a worldwide risk of fatal, procedure induced multi resistant infections such as pseudomonas and Gram negative Carbapenamase-producing Enterocacteriaceae (CPE).

Contributing factors:

- Inadequate cleaning of endoscopes
- Design of some types of endoscope eg elevator channel in duodenoscopes
- Inadequate disinfection of all channels
- Failure to dry scopes adequately prior to and during storage
- Inadequate cleaning of reusable endoscopic accessories
- Reuse of single use endoscopic equipment
- Contamination of Automated Endoscope Reprocessor (AER)
- Contaminated Air/water bottle and /or non-sterile water
- Insufficient training of reprocessing personnel
- Lack of regulation of reprocessing procedures

## GENCA ... continued



*Sharing knowledge, sharing learning*

### Position

The Gastroenterological Nurses College of Australasia (GENCA) believes that the nature and complexity of endoscopic procedures and equipment warrants specific precautions to reduce the risk of procedurally transmitted infections.

**Recent FDA TGA ASGE and GESA alerts have highlighted the imperative nature of this risk.**

These include:

1. During the **manual cleaning process**, meticulous attention must be paid to complex endoscopes in particular the elevator channel and recesses surrounding the elevator bridge mechanisms of the duodenoscope. The cleaning adaptors and brushes recommended by the manufacturer of the particular model of endoscope must be used. Strict attention to current manufacturer's manuals and policy must be adhered to.
2. Failure to adequately rinse each channel with bacteria free water following HLD can lead to contamination. Therefore bacteria free water must be used. The final rinse of the endoscope and channels after HLD via an automated reprocessor must pass through filters ranging from 10 microns to 0.2 micron absolute final filter.
3. All endoscopes must be stored in accordance with the National Standards and the GENCA guidelines. Continuous monitored air drying cabinets complying with European Standard EN 16442:2015, or working towards compliance by 2020, in accordance with AS4187:2014, are considered best practice for all endoscopes.
4. Single use accessories are recommended.
5. Microbiological testing of endoscopes as recommended in the GENCA Guidelines with the addition of tip sampling of duodenoscopes.
6. Strict training and assessment of personnel carrying out endoscope reprocessing.

## GENCA ... continued



*Sharing knowledge, sharing learning*

## References

- Infection Control in Endoscopy 3<sup>rd</sup> Edition (2011) GESA, GENCA
- AS/NZS 4187:2014 – Reprocessing of reusable medical devices in health service organizations
- Multisociety Guideline on Reprocessing Endoscopes 2011. Infection Control and Hospital Epidemiology June 2011, Vol 32, No 6
- ASGE Duodenoscope Infection Control Summit 2015
- SGNA ASGE Call attention to CDC Report on ERCP and infections Jan 15 2014
- Design of endoscopic Retrograde cholangiopancreatography (ERCP) Duodenoscopes may impede effective cleaning: FDA Safety Communication February 19, 2015
- Duodenoscope reprocessing: risk and options coming into view, Gastrointestinal Endoscopy Vol 82, No 3 2015
- Olympus Instructions Duodenoscope TJF type Q180V
- GESA Position Statement August 2016

Gastroenterological Nurses College of Australia

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# Medical Devices Safety Update



Australian Government  
Department of Health  
Therapeutic Goods Administration

## Medical Devices Safety Update

Volume 5, Number 3, May 2017

### In this issue

- Surveillance study focuses on risk of complications with vascular closure device
- Disinfectants and detergents can damage medical equipment plastics
- Stryker advice regarding the correct use of V-40 C-taper adaptor sleeve
- Recent safety alerts

## 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.<sup>1</sup>

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.

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

**TGA** Health Safety Regulation



## Medical Devices Safety Update ... continued

### 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.

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.

## Medical Devices Safety Update ... continued

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 alkylamine 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](#).

## 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.

# Medical Devices Safety Update ... continued

## 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 Bioreabsorbable Vascular Scaffold (BVS):** Safety alert – Increased rate of major adverse cardiac events observed in patients receiving Bioreabsorbable 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 StrataMR 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

**Biolog 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](http://www.tga.gov.au) (click 'Report a problem')
- **by emailing** [iris@tga.gov.au](mailto: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](http://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, 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 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](mailto:iris@tga.gov.au) or 1800 809 361

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

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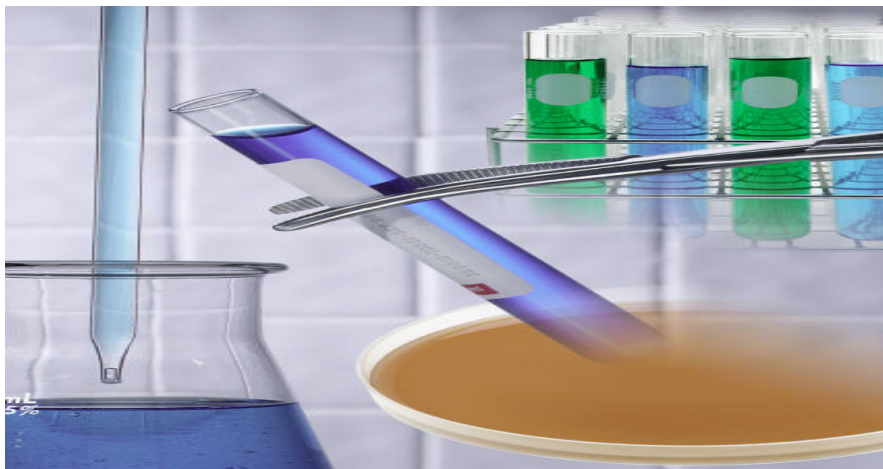
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# Applying for a Research Grant



**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 \_\_\_\_\_

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(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
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15	3	15	16	17	18	19
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February 2017						
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March 2017						
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31						

April 2017						
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May 2017						
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June 2017						
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July 2017						
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August 2017						
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September 2017						
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30						

October 2017						
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28						
44	29	30	31			

November 2017						
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4						
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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
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49	3	4	5	6	7	8
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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: 1<sup>st</sup> January each year and is valid till  
31<sup>st</sup> 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](mailto: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