Sterilization in Australia

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Sterilization in Australia

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

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

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PRESIDENT'S REPORT

Dear Members

Welcome to Journal 38 volume 2 our second edition for 2018.

We recently had our AGM at RPAH in Scot Skirving Lecture Theatre. We had two very informative education sessions presented by Beniot Kergrohen for Gallay Medical Scientific Pty Ltd and Lynn Rapley from Gastroenterological Nurses College of Australia (GENCA).

Beniot presented our members with a new Peracetic Acid (PAA) Chemical Air monitoring Device that allows you to accurately measure PAA Vapours over time or a particular point in time. Data can be recorded and collected over time to track short-term (STEL) and long-term exposure (PEL) via the Steri-Trac DAQ® computer system. This system provides a safe environment for staff working in this area.

Lynn Rapley presented our members with the importance of brushing techniques, and how your brushing techniques if done incorrectly can in fact introduce bioburden to the walls of scopes Lynn had some fantastic slides that had been magnified to show the bioburden on the sides of cleaned scopes. Lynn also spoke about the cleaning of the buttons & accessories and was able to show members some supposedly cleaned buttons that had been sliced open to show the debris still in the channels.

We also had our general meeting the chair and committee was vacated for the elections. President Lynne Noring unopposed. Treasurer position there was 2x nominations therefore a ballot was required. All full financial members present was asked to vote by Ballot. The two nominations were asked to tell the members a little bit about themselves. The voting was organized and counted by our scrutineers Stephan Graham and Beniot Kergrohen. The treasurer elected is Leanne Burns. Congratulations to Leanne.

Tracey Worthington committee member unopposed, David Bellamy committee member unopposed and we welcomed to our committee two new committee members Sonia Jones and Anu Varghese from the floor. We will give you the opportunity to know more our new committee members when they submit their profiles to the journal. Congratulations to you all.

We been exceptionally busy getting ready for the FSRACA National Conference at Luna Park Sydney 12- 14 September 2018. I hope you have all registered it will be a fabulous experience for all those that have anything at all to do with reprocessing reusable medical devices. You will find there is something for everyone. The theme Circus relates to Compliance Innovation Risk Challenges Updates & Standards. There will be keynote speakers that will deliver their story and help to motivate you in your daily life challenges. The conference being circus theme will be a lot of fun and our MC Andrew Baily will be sure to entertain you during the course of the conference. So make sure you don't miss this opportunity in our own state NSW look forward to seeing you all there. I cannot thank our committee enough for their continued support and help in preparation to the National Conference.

Hope to see you all at our next general meeting in November at RPAH. You will receive a flyer with more information soon.

With our new committee changes you will see some new ideas coming your way. Join us at our next General meeting in November and put forward your ideas. You and your ideas will be welcomed with opened arms.

Warm regards,
Lynne Noring
President of NSW SRACA

A CHRISTMAS MESSAGE FROM THE PRESIDENT

To our executive, committee, members, life members and associate members, I thank you for your support & encouragement.

It is truly a privilege for me to lead the NSW SRACA and to represent our members.

I have to say it is at times like this, when we take the time to reflect on what has happened over the last 12 months and the true extent of the work that you all do for your health service organisation and their patients.

It has been an extremely busy year for you and us with our educational workshops, and as you all know it was NSW SRACA's year to organise the national conference here in Sydney.

We had excellent presenters at all our workshops and we can thank Tracey Worthington our education officer for organising the workshops. Thank you to the committee for always being on hand and ready to help out in anyway.

We had a fabulous National conference the feedback back from our delegates was outstanding. We thank our trade representatives for their continued support.

I would like to take this opportunity to wish all our members that are retiring or have retired this year all the very best for a blessed, happy, healthy and relaxed retirement after all you certainly deserve it.

We wish Joe Anne Bendell from the CEC HAI all the very best for her retirement and her new adventures consulting. Joe has been a true inspiration to the sterilising industry for many many years. We cannot thank Joe Anne enough for her continued help and support.

Joe Anne came to the rescue when everyone was screaming for an Audit tool to help identify the gaps from the old version of the AS/NZS 4187 to the revised version.

Joe Anne with members from our sterilising industry was the driving force to ensure this tool would be readily available nationally. Thank you Joe Anne you, and your wealth of knowledge will certainly be missed.

Garry Tucker the face of Getinge has also decided to enjoy some very well deserved rest & relaxation. Garry has been a supporter of the NSW SRACA for over 40 years. Garry has attended our workshops, conferences has been a presenter and taken us under his wing when we have travelled overseas to the world congress. Garry is a true gentleman and always has a smile on his face Garry has been a wealth of knowledge for the sterilisation industry we certainly will miss you Garry.

To all our members I know our job seems thankless at times and we are often in the basements of hospitals without windows poor air-conditioning a huge workload and understaffed. We do what we do because we know and understand how important our job is for the safety of our patients. We need to respect and support each other and lift our profile to ensure that our hospitals have the same understanding as we do. We can achieve this by increasing our members and sticking together as education is power and we need the power to help the sterilising industry move forward into a whole new generation.

We have seen many changes take place over the last 12 months with technology and NSW SRACA has embraced that technology with our website, Facebook, twitter & Instagram. We have recently started to live stream our workshops through social media Facebook.

We have paid tribute to our pioneers for paving the way. We are now seeing a whole new generation joining our committee. We are moving our sterilising organisation into the future I am excited to see what our future holds and I have no doubt that with the new generation on our committee that we are in safe hands.

I would like to finish by offering my personal thanks to our members for the support I have had and our committee has received over the last 12 months. We have seen an increase in memberships and associate members over the last 12 months. Our educational workshops have been superb and our national conference has been labelled as the best one to date. I hope to see more & more members and associate members join us next year to help us keep the sterilising organisation at a professional level.

We can all be proud for making a positive contribution to the health organisation during the last 12 months I know many of you will be working over the Christmas period, but I hope that you all manage to find some time to spend with those people who mean the most to you.

I wish my committee, member's, associate members, and our life members a peaceful Christmas and a wonderful 2019 new year. Take care and be safe.

From the NSW SRACA president

Lynne Noring

S.R.A.C.A (N.S.W.) INC.

Membership Application/Renewal

Renewals Due 1st July Annually

Sterilizing Research & Advisory Council of Australia (NSW)

NEW MEMBERSHIP/RENEWALS

MEMBERSHIP COMMENCES: 1st July each year and is valid till 30th June the following year

NOTE to all Members and potential members

Due to the change in our Membership year from January to now July (the Financial Year) we would like to advise that any Members who renewed or joined from January 1st 2018 to June 30th 2018 will automatically be a Financial Member till **June 30th 2019** when your membership will become due for renewal and there is no need for you to do anything at this point in time.

We will be implementing a process to contact all member from the 1st June annually giving a courtesy reminder that membership is due.

We look forward to your continued support and if you have any concerns or questions, please do not hesitate to ask.

Yours sincerely

SRACA NSW Executive

SRACA AGM

Saturday, June 23, 2018 - Royal Prince Alfred Hospital

Guest Speakers

Lynne Rapley, Nursing Unit Manager RN ACGEN presented on the risks and challenges found in the Endoscopy Unit. Lynne provided information of the 'new consensus statements' and the GENCA Guidelines. The storage requirements for processed endoscopes have changed. Biofilm on the internal surface of endoscopes is a serious risk and is complicated more by the complex design of some endoscopes. The use of alcohol for final drying of the endoscope was also discussed. The ATP for bioburden testing is becoming more popular within the CSSD, however it was emphasised the ATP does not replace the mandatory requirement for routine microbial testing of endoscopes. The AS/NZS4187:2014 audit tool on QARS now incorporates auditing Endoscopy units and can be found on the Clinical Excellence Commission website.

Benoit Kergrohen, Business Development Manager for Gallay Medical & Scientific Pty. Ltd. spoke about GAS Monitoring in the work environment and about the danger of gas fumes in the CSSD. There are many chemical agents from are variety of disinfectants and sterilants that have potential to cause damage or irritation to mucous membranes or eyes by either contact or inhalation. In addition to the correct wearing of ppe, handling and storage of chemical agents, Benoit explained the importance of monitoring the environment and explained how this can be achieved to ensure staff and workplaces are kept safe.

EcoLab, supplied morning coffee and lucky door prize.

Thank you to Lynne Rapley, Benoit Kergrohen and Stephen Graham for contributing to our workshop, your support is greatly appreciated.

Annual General Meeting

Elections

Three positions were vacated due to the terms being completed. Nominations for President, Treasurer and Committee Member were received. The President and Committee Members positions were unchallenged. There were multiple nominations for the Treasurers position. A vote for the Treasurers position was held and counted by Stephen Graham and Benoit Kergrohen. Leanne Burns was successful the nomination for another term as the SRACA NSW Treasurer.

New Committee Members

Sonia Jones from Hawkesbury DHS and Anu Varghese from HNELHD also joined the Committee and were welcomed by all.

FSRACA Conference

The FSRACA conference was discussed and everyone is very excited to show off our beautiful Harbour City from Luna Park. The registrations have been rolling in and the industry trade have provided great support to the conference. Five lucky attendees received scholarships to attend the conference, funded by SRACA NSW.

Treasurers Report

The Treasurers report was tabled and account books were displayed for delegates to review.

2019 Calendar

The delegates were asked to provide ideas for the 2019 calendar. Education is the key focus, and meeting the needs of the delegates is a priority. All suggestions for future learning opportunities will be considered. Suggestions can be e-mailed to info@sracansw.org.au or speak with a Committee member about your ideas.

SRACA NSW will be hosting a state conference in 2019 – venue to be confirmed.

At the conclusion of the meeting, a delicious lunch was enjoyed by all.

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

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

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Australian Government
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Therapeutic Goods Administration

Medical Devices Safety Update

Volume 6, Number 4, July 2018

In this issue

Be aware of cross-reactivity with home-use self-test ovulation kits

Cross-reactivity of human chorionic gonadotropin with self-test ovulation kits may result in false positive results and care is needed when using them in conjunction with some procedures and ovulation inducing agents.

The TGA's laboratories recently tested one ovulation self-test device which passed regarding its sensitivity to luteinising hormone (LH) at 50 mIU/mL, but failed specificity testing at 200 mIU/mL, as it produced a positive result in the presence of human chorionic growth hormone (hCG). The sponsor subsequently cancelled the Australian Register of Therapeutic Goods entry as a result of the test results.

Medical Devices Safety Update discussed issues around sensitivity and specificity in March 2014.

Hormone surge

Self-test ovulation kits monitor changes in LH, with a surge in the hormone indicating the upcoming occurrence of ovulation. This LH surge occurs about 36 hours before ovulation. The LH surge appears in urine about 12 hours after appearing in serum, noting that the surge appears in pulses, rather than as a steady release.

During pregnancy LH is suppressed by oestrogen and progesterone, both of which are increased by human chorionic gonadotropin (hCG; a hormone secreted into maternal circulation after implantation, which occurs 6-12 days after ovulation).

Pregnancy increases the level of hCG which can cross-react with LH self-tests to falsely appear as a surge in LH. Some studies have shown cross reactivity between low levels of hCG and LH in home-use LH detection kits, but this does not appear to be explicitly stated in the Instructions for Use for these kits.

Self-test ovulation kits may be used to increase the chance of conception with the timing of intercourse, or intrauterine insemination (IUI) as an infertility treatment, shortly after the LH surge.

Although the use varies in each setting, if the progesterone level indicates that ovulation occurred, and the women's cycles are regular, there may be a role for the LH tests to assist in timing of intercourse, although most guidelines state that the most reliable way to time intercourse is for intercourse to occur every 2-3 days.

If a woman is engaged with a fertility clinic and undergoing work up for IUI (usually due to male factor infertility) she will either be following her natural cycle or undergoing ovulation induction. Part of a common protocol appears to be the use of daily home ovulation test kits, followed by a confirmatory blood test prior to the final steps before IUI. The confirmatory blood test is likely to be for serum LH, which if suppressed will raise suspicion of early pregnancy.

Don't rely solely on LH tests

Solely relying on home-use LH tests to determine the timing of an IUI procedure or the use of ovulation inducing agents has a potential to add

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additional risks for women who are in early stages of pregnancy, as a test kit's cross-reactivity with hCG could falsely appear to be a surge in the pre-ovulation marker. One such situation was described by US researchers in the journal *Clinical Biochemistry* in 2013:[1]

> *A 37 year old female who was being treated for infertility underwent intrauterine insemination (IUI). Two weeks later the patient thought she began menses and began Clomid (clomiphene citrate; an ovulation inducing agent) and home testing for a luteinizing hormone (LH) surge. Fourteen days after her last menstrual period a home ovulation prediction device (LH device) was positive and she scheduled an appointment for IUI. Nine days later, the patient presented with vaginal bleeding and severe pelvic pain. A quantitative serum hCG test was positive and transvaginal ultrasound demonstrated a 6 week pregnancy with a hemorrhagic cyst. She underwent surgery to stop the bleeding, and subsequently lost the pregnancy ...*
>
> *In the early days of immunoassay, cross reactivity between LH and hCG was a problem. Today however, cross reactivity in quantitative assays is extremely low. This study demonstrates that qualitative LH devices may produce false positive results in women who are very early in pregnancy. Package inserts for some devices contain a cautionary statement which states that "results obtained during pregnancy or administration of certain drugs including hCC may produce misleading results"; however, it is clear that most physicians and laboratorians are unaware of any potential cross-reactivity. Physicians that rely on home LH devices to time IUI should instruct their patients to use devices with minimal hCC cross-reactivity.*

Pregnancy a contraindication

Several ovulation inducing agents list pregnancy as a contraindication in their Product Information and some are known to be embryotoxic, fetotoxic, and associated with birth defects and marked post-implantation loss if used during early pregnancy.

It is important to note that the only time that there is a risk of inadvertently using ovulation inducing agents or IUI during early pregnancy is the first cycle, as subsequent cycles will have a pregnancy test done to assess the success of the cycle prior. This initial cycle is often commenced in the first two days of a normal period, usually indicating that conception has not occurred in the month prior.

As LH tests are available off the shelf, consumers may use them without medical supervision to assist with the timing of intercourse. In this scenario there is no risk of taking ovulation inducing agents or undergoing IUI inadvertently during early pregnancy.

REFERENCE

1 Clin Biochem. 2013 Oct;46(15):1625. doi: 10.1016/j.clinbiochem.2013.07.017. Epub 2013 Jul 27.

TGA undertakes product safety review into intragastric balloon systems

The TGA has conducted a product safety review of two intragastric balloon systems included on the Australian Register of Therapeutic Goods.

The TGA's review follows information published by the USA Food and Drug Administration (FDA) about deaths and serious injuries to patients associated with use of intragastric balloons to treat obesity.

Intragastric balloon systems involve endoscopic insertion of a balloon into the stomach and inflation of the balloon with liquid. The space-occupying fluid-filled balloon aims to achieve temporary weight loss by delaying gastric emptying, which can create a feeling of fullness.

The TGA has received 19 adverse event reports since 2009 regarding the intragastric balloon systems that are currently being supplied in Australia. These reports include three patient deaths.

In conducting the review TGA asked the sponsors of the intragastric balloons to provide:

- post-market safety data

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- the current Instructions for Use
- a clinical evaluation report
- risk assessment documentation.

The information requested has undergone review and the TGA is working with sponsors and manufacturers to ensure clinicians and patients are fully informed of the risks with this type of device.

The FDA has similarly approved new labelling which adds information to the Instructions for Use about certain adverse events and the effects of these events including death.

Advice for health professionals

If you are treating a patient who has an intragastric balloon be alert to symptoms that might indicate there is an issue associated with the device. Adverse events associated with these devices include:

- obstruction
- ulceration
- necrosis
- ischaemia (gastric or intestinal)
- spontaneous hyperinflation of the balloon
- perforation (oesophageal, gastric or intestinal)
- gastritis/gastric erosions
- acute pancreatitis.

The TGA recommends that you ensure the intragastric balloon is not inserted where contraindications exist. Refer to the Instructions For Use for the complete list of contraindications.

Where relevant, patients should be advised to take the necessary precautions to prevent pregnancy prior to placement and throughout the duration of treatment, and be instructed to inform you as soon as possible if pregnancy is confirmed during treatment, so that removal of the device can be arranged.

The TGA recommends that you monitor patients closely during the entire term of treatment with intragastric balloon systems for possible complications. In particular, please be aware that patients with an intragastric balloon who present with severe abdominal pain and have a negative endoscopy and x-ray, may still require a CT scan to definitively rule out a perforation.

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 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 or 1800 809 361

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SRACA NSW CHRISTMAS WORKSHOP

Saturday, Novemeber 17 2018

Saturday 17th, was the final SRACA NSW workshop and for 2018. As always, Events at the Hornsby RSL provided the perfect meeting place with Public Transport close by, and adequate free parking for all attendees. They also supported the workshop with IT equipment and free wi-fi for streaming the presentations to SRACA NSW members. A special thank you to the members who joined us on the SRACA NSW Facebook page. A traditional and delicious Christmas lunch was enjoyed by all, this was supplied with great appreciation by the Committee for the members' support during 2018. on QARS now incorporates auditing Endoscopy units and can be found on the Clinical Excellence Commission website.

Jorge Sigala - DePuy Synthes:

Basic Instrumentation for Trauma Orthopaedics

Wow, hasn't trauma Orthopaedic surgery changed?? Jorge showed a video that made us all appreciate the developments in Orthopaedic surgery over the years to improve patient outcomes (and I suspect survival rates). Jorge explained a graphic definition on Orthopaedic Trauma, how it occurs, the impact it has on the patient and how surgery is used with specifically designed surgical devices.

Tom Webster - Stryker South Pacific:

Orthopaedic Trauma & Extremeties Principals of Fixation

Tom (and Stryker South Pacific) demonstrated how single use consumable Orthopaedic items are used in the Operating Theatre. Tom kindly talked and walked us through the experiences of the Instrument Nurse when assisting Orthopaedic Trauma surgeries. Highlighted, were the challenges experienced including selection correct consumables prior to opening to ensure economical value, maintaining sterility during the opening process &

Henry Biggelaar - Engineering Manager, Spirax Sarco PTY LTD Australia:

Clean Steam to AS/NZS4187:2014

-What does this mean for compliance & instrument Care

Henry presented new requirements for compliance to AS/NZS4187:2014 and associated ISO and EN standards for HSOs, in regards to steam quality and steam purity to the washer/disinfectors and steam sterilisers. A detailed explanation of the difference between the two and the methodology for testing was explained. Henry also spoke about the recent favour of 'clean steam generators', which are compact however are still required to meet the standards for steam quality and purity.

What's Happening in 2019?

SRACA NSW President Lynne Noring spoke to the members with a recap on the FSRACA conference held in Sydney and the positive feedback she received from the FSRACA Committee and the various state representatives, trade representatives and many SRACA members. Everyone is speaking highly about the conference and it appears Sydney has set a new standard for the future. Memberships in 2019 will move to financial year renewals. All new memberships will be due on July 1st, 2019. All new memberships and renewals will be adjusted to reflect the memberships as per the Fair Trade recommendations.

Education is such an important part of our profession, and ongoing development is essential. The members were asked to bring forward any thoughts, ideas or suggestions for topics they would like SRACA NSW to present in 2019.

Finally, wishing all SRACA NSW members a very Merry Christmas and Happy & Safe New Year celebrations. We look forward to seeing you in 2019

Tracey Worthington
SRACA NSW Education Officer

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Medical Devices Safety Update

Volume 6, Number 5, September 2018

In this issue

Case studies in Incident Report Investigations

In the next few issues the team at Medical Device Safety Update will publish a series of case studies. The aim is to highlight the value of reporting of medical device events and problems to the TGA, as the case studies demonstrate that the TGA can often contribute towards significant positive outcomes. We will also be highlighting key lessons that can be learnt from the cases and hope that readers will also find the stories interesting. The issues described are now resolved, so if you are experiencing a problem that is similar, REPORT IT!

Study No. 1: Yellowing of epidural catheters

Our first case study is about an epidural catheter. Three unopened epidural kits were forwarded to us by a nurse. The incident description in the reporting form read simply:

> *"These catheters are yellow. Should be clear blue. Are they safe to use?"*

Incident Report Investigation Scheme (IRIS) standard procedure is to send samples to the sponsor (supplier) of the product in Australia and to ask questions about the device and the reported problem (how often the problem has been reported before, what does the manufacturer believe the root cause to be, what are the intended corrective actions). On this occasion, it was possible to send one of the affected kits to the manufacturer, keeping two. We also asked for new kits for comparison purposes.

The sponsor's reply indicated that the catheter was made of nylon and that "the catheter had been in use for 30 years without any problems". The sponsor speculated that the yellowing was the consequence of subjecting the kits to strong heat or U/V light during transportation or storage, but the IRIS investigator thought that this was not likely ... as only the catheter looked yellow while the packaging and the other kit components appeared to be normal. The TGA investigator decided to have the catheter samples tested at the TGA's Laboratories.

The tensile strength and bending properties of the complaint catheters were the same as those of new catheters, and accelerated ageing under strong light and heat melted and turned the packaging brown – but the kit contents were not affected.

Discovery in the labs

The yellowed catheter recorded the highest cytotoxicity result that the TGA labs had ever witnessed, until they tested the cytotoxicity of the new, unaffected catheter material, which was even higher. The leachate that was poisoning the cytotoxicity test cell lines was later found to be n-butyl benzene sulphonamide – a plasticiser used to make nylon plastics softer and more pliable. Additional research revealed N-butyl benzene sulphonamide to be a powerful neurotoxin.

The TGA argued that the catheter had to be reformulated – as neurotoxins should not be placed

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into close contact with nerve tissue (see Figure 1). The argument was difficult because even though the catheter had been in use for many years there had been no reports of problems directly associated with any form of toxicity or biocompatibility.

A report of our findings was shared with other regulatory agencies and they too exerted pressure for action, so the catheter (there were no others like it) was reformulated.

The investigation did not reveal the cause of the yellowing. It was an isolated incident most likely caused by a contaminant introduced during manufacture.

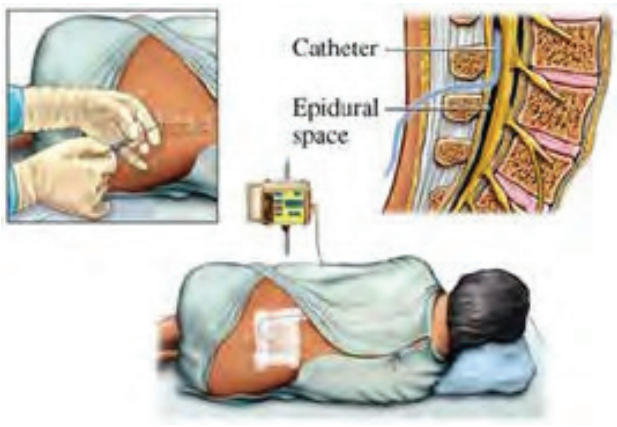

Figure 1: Placement of epidural catheters - The catheter comes into close contact with nerve tissue.

Key ideas and lessons

The TGA has extensive and well-equipped laboratories. They are used for product surveillance and can be a powerful tool when investigating incident reports. Testing is time consuming and resource intensive and so it's used only when a risk assessment indicates that its required.

As it was in this case, serendipity can be a powerful ally during an investigation, but can't always be relied upon to detect problems.

Detection of issues relating to – for example – biocompatibility or the accuracy and specificity of invitro diagnostic devices require other strategies such as premarket assessment and audit, post-market review and testing.

TGA reviews reusable biopsy forceps devices

The TGA is reviewing reusable biopsy forceps devices with a focus on ensuring adequate instructions on cleaning, disinfection and sterilisation.

Any infectious agents introduced into the body can establish an infection.

Medical devices or equipment that requires reprocessing – cleaning, disinfection and/or sterilisation – have the potential to spread infectious agents via ineffective cleaning procedures.

As medical devices have become more complex the issues of how to perform acceptable cleaning, disinfection and sterilisation have become greater in recent years[1]

The TGA's post-market review of reusable biopsy forceps devices was undertaken following concerns being raised about one device that was being supplied in a non-sterile manner but utilised as a re-useable biopsy forcep device.

Specific concerns were expressed regarding the potential risk to patients as the cleaning and sterilisation instructions and procedures were believed to be insufficient.

Reusable biopsy forceps typically have a cleaning port for flushing detergent and rinse water through their internal shaft. However, as the lumen is only open at the distal end, flushing is not entirely effective. An alternative method of flushing and then aspirating cleaning fluid through the single opening has been shown to spread contaminants throughout the device.[2]

Issues identified in this review include investigating whether:

- device design may not facilitate easy and effective cleaning

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- Instructions for Use (IFU) and sterilising instructions are adequate
- IFU lack information regarding the number of times reprocessing of a device can occur, or visual indicators to aid in determining device deterioration and end of service life
- the risk of cross-contamination and spread of infection from a device that is not effectively reprocessed is insufficiently mitigated.

The TGA is reviewing the cleaning and disinfection/ sterilisation procedures for the relevant entries on the Australian Register of Therapeutic Goods (ARTG) to determine their adequacy.

Any updates to cleaning and disinfection procedures will be provided to users of these devices in accordance with the Uniform Recall Procedures for Therapeutic Goods.

There are multiple alternative, single-use sterile devices included on the ARTG and available for use in Australia.

If you have any concerns regarding the reprocessing of a device of this kind, please contact the Australian sponsor of the affected device.

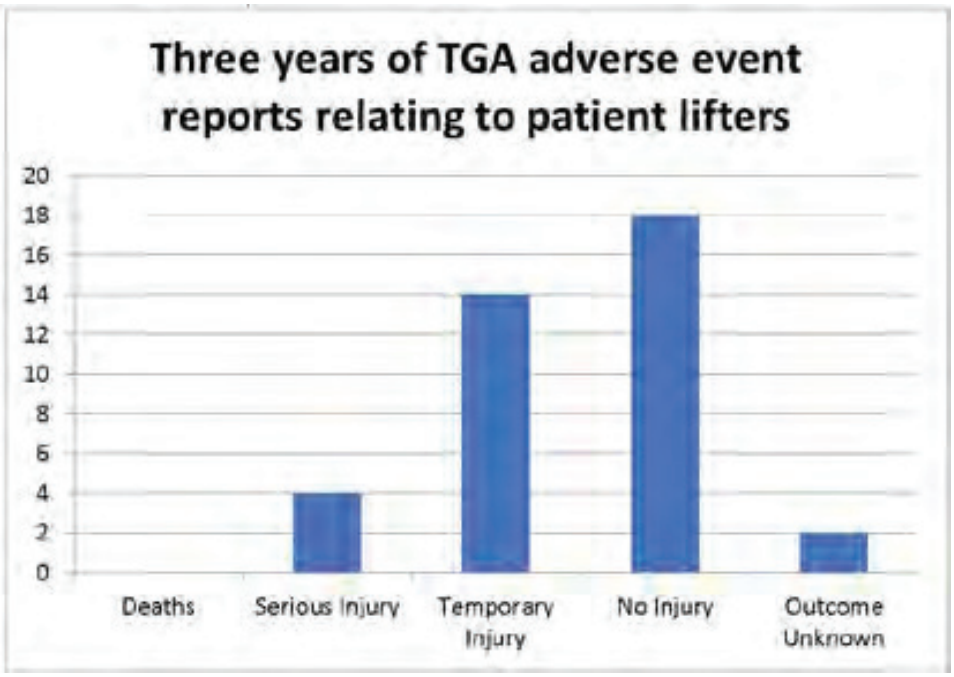
REFERENCES

1. Wade, W et al. 2015. Beyond Traditional Biosafety, Applied Biosafety, vol.20, No.2, 2015
2. Fireman, V. 2006. Biopsy Forceps: Reusable or disposable? Journal of Gastroenterology and Hepatology 21 (7): 1089-1092

Patient lifters save staff from injuries, but care is required

While the widespread introduction of patient lifters has greatly reduced injury rates among health facility staff in recent years, the devices can pose a risk to patient safety if not used correctly.

Back injury is one of the most common causes of time off work among patient care staff and often leads to a loss of staff from the industry. Back injury is a major contributor to the ongoing shortage of nursing staff.[1]



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The issue led to the introduction of 'no lift' policies in many Australian health facilities from 1998 onwards and this move has greatly reduced the rate of staff injury, time off work and worker's compensation claims.1

Facilities have turned to the use of patient lifters as an alternative to manual lifting and these back-saving devices are now commonly used in a wide variety of settings.

There are many models, many styles and methods available, tailored for different patients and patient situations. A variety of patient slings are available to suit different patient conditions and different purposes, e.g. transferring v. showering v. toileting. Different types of slings and models of lifters are suitable for different patient weights, including bariatric lifters for obese patients.

Risk to patient safety if not used correctly

The use of an incorrect lifter or sling, whether due to patient weight or transfer purpose, carries a significant risk of a patient fall and injury. The patient themselves must also be assessed for suitability to be lifted, and mechanised lifting is contraindicated in patients who have dementia or are otherwise uncooperative.

In the three years to 5 September 2018 the TGA has received four reports of serious injury and 14 reports of temporary injury to patients from using patient lifters, predominantly from falls.

Care must be taken to ensure that the lifting components are appropriately and securely attached to the lifter. Failure to do so may result in a component coming loose and a patient fall.

Staff should be reminded to always read and follow the manufacturer's instructions.

REFERENCE

1. Devastating injuries in healthcare workers: description of the crisis and legislative solution to the epidemic of back injury from patient lifting. Edlich RF et al. J Long Term Eff Med Implants. 2005;15(2):225-41

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 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 or 1800 809 361

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

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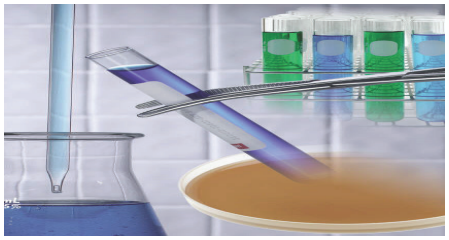
Expression of interest for The Sterilizing Industry

APPLYING FOR A RESEARCH GRANT

Sterilizing Research Advisory Council of Australia



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.

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.

Expression of interest for The Sterilizing Industry

Applying for a Research Grant

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 co nsidered 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
- 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.

Expression of interest for The Sterilizing Industry

Applying for a Research Grant

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 r equest 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.

Expression of interest for The Sterilizing Industry

Applying for a Research Grant

Application form

Title Ms, Miss, Mrs, Mr., Dr (Please circle your title)

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 reques ted/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:_____

Expression of interest for The Sterilizing Industry

Applying for a Research Grant

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

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

_____

_____

_____

_____

_____

_____

Approved/not approved (Circle the correct answer)

Amount granted $_____

Signature_____Date_____

2019 NSW SRACA Calendar of Events

AGM

- 6th May 2019

General Meeting

- 19th September 2019
- 4th December 2019

State Conference

- 18/19/20 September 2019

Executive Committee Meetings

- 18th February 2019
- 4th March 2019
- 1st April 2019
- 6th May 2019
- 3rd June 2019
- 1st July 2019
- 5th August 2019
- 2nd September 2019
- 14th October 2019
- 4th November 2019

WORLD CSSD DAY

- 10th April 2019

January 2019

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

February 2019

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

March 2019

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

April 2019

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

May 2019

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

June 2019

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

July 2019

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

August 2019

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

September 2019

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

October 2019

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

November 2019

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

December 2019

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

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

S.R.A.C.A (N.S.W.) INC.

Membership Application/Renewal

Renewals Due 1st July Annually

Sterilizing Research & Advisory Council of Australia (NSW)

ABN: 85 914 815 703

NEW MEMBERSHIP/RENEWALS

MEMBERSHIP COMMENCES: 1st July each year and is valid till 30th June the following year

TITLE_____SURNAME_____GIVEN NAME_____

HOSPITAL/COMPANY_____

POSTAL ADDRESS_____

POSTCODE_____STATE_____PHONE NO_____

EMAIL_____

Please tick Membership Type

FULL Membership renewal includes Electronic Journal $50 ☐
$50.00

NEW Membership includes Electronic Journal & Joining fee $50 + $5 Joining fee (Admin) ☐
$55.00

(NOTE: New Membership MUST be approved at Executive Meeting prior to be accepted after application made)

ASSOCIATE Membership includes Electronic Journal $50 ☐
$50.00

TOTAL PAYMENT ENCLOSED $_____

TOTAL PAYMENT BANK DEPOSIT $_____

Make cheques payable to:

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

Return with form to

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

PO Box M71

MEMBERSHIPS CAN BE DONE VIA EFT or ONLINE

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

BSB: 032096

Account: 871850

Reference: Company/Member Name

Please send or Email Application Form after payment made


STERILIZING RESEARCH & ADVISORY COUNCIL
OF AUSTRALIA