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Sterilization

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		OF AUSTRALIA

President's Report

Welcome to the final issue for 2017 volume 37 no.3.

We had a very productive year, we started the year with our usual planning day so our calendar would be ready for our members to organise their schedules.

We tried bi monthly executive meetings and found it was unsuccessful, mid-year we all agreed it wasn't working and went back to our usual monthly meetings.

We welcomed two new committee members Kim Beard & Sharon Woods. Sharon has been a committee member and an executive committee member in past years.

We decided not to have a conference in 2017 as the FSRACA National is in Sydney in 2018.

We provided 4x workshops all free to our members during the year.

We directed a workshop in Ballina in April which was very well received by our members & Queensland members also. Topics were :

- What standards mean and how to meet them.
- Care &maintenance of ridge scopes and the importance of quality repairs.
- NSQHS the challenges faced by Sterilising Service Departments
- Products /raw products used and associated ISO/EN standards.
- Demonstration of a mobile sterilising unit and the advantages.
- Product families
- We donated 5x national conference registration scholarships

We directed a workshop in June at Hornsby Sydney which was well received topics:

- A detailed explanation of the audit tool for AS/NZS 4187 2014 that was about to be rolled out by CEC NSW Ministry how to complete a self-assessment, gap analysis and a peer review and to risk assess.
- Infection prevention and hand hygiene.
- Workshopped Product families
- We donated 5x national conference registration scholarships

We directed a workshop in Canberra in August again well received topics included:

- Quality systems & we workshopped in groups risk assessment using real sterilising scenarios.
- NSQHS the challenges faced by sterilising services departments.
- How to use the NSW SRACA website.
- We donated 5x national conference registration scholarships

President's Report... continued

We directed another workshop in Hornsby Sydney December and included a Christmas Lunch for our members. The topics included:

- Australian organ & tissue donation program
- Results of the loans survey conducted by Macquarie University.
- Halyard education program for sterilising technicians.
- We donated 5x national conference registration scholarships

We thank all our members for their attendance at these workshops and we sincerely hope you enjoyed them as much as we did. Our presenters have all been world-class and the topics have been on trend with the sterilising business necessities.

At the workshop in December we decided with the members to have our first workshop in the early part of year as an open day so members could bring along a friend or just come along and see what NSW SRACA is all about.

We will again donate another 5 x national conference registration scholarships.

We really are looking forward to seeing you all there.

Thank you to all the NSW SRACA committee members for volunteering your time and the work you put into organising all of the workshops, meetings etc. you are all valuable members of our committee.

From all of us to all of you we wish you a very Merry Christmas and a very happy new year.

Looking forward to seeing you all in the New Year.



Regards George Papadopoulos President NSW SRACA

Canberra Workshop – 16 August 2017

The Belconnen Raiders Club was the venue for the SRACA NSW August workshop. It was a cold and wet day, this was our smallest workshop for 2017 however members and trade travelled from Sydney and the Riverina Region to join our Canberra members for a very interesting and interactive workshop.

SRACA NSW congratulates another five delegates who won scholarships. Christene Oakman (Calvary Riverina); MaryAnn Kelly (Wagga Wagga Rural); Janet Rhodes (Bega); Kym Brown (Calvary John James) & Jimmy Yang (Hurstville Private) will be guests of SRACA NSW at the FSRACA National Conference being held at Luna Park, Sydney in 2018.

SUE GREIG – is the Senior Project Officer for the National HAI Prevention Program, working at the Australian Commission on Safety and Quality in Healthcare. Sue demonstrated a good understanding of the challenges faced by Sterilising Service Departments. Her presentation explained the expectation of the NSQHS (National Safety and Quality Health Service) and Governance of Sterilising Service Departments on behalf of the Australian population, after-all as consumers of health care, we all expect the highest of standards. Advisory no:A16/03 (date of publication May 2017) informs the latest advice for compliance to AS/NZS4187:2014. Evidence for compliance and assessment; risk rating and action plans for non-compliance will be critical for health service organisations undergoing accreditation in the near future. Further information on accreditation and NSQHS can be found on www.safetyandquality.gov.au This was a valuable presentation for Sterilising departments in preparation for upcoming accreditation.

Due to popular demand, Sue Greig has kindly allowed her presentation to be posted on the SRACA NSW website 'Members Zone'. The presentation will assist with preparation for Accreditation and compliance to Standard 3.

NICOLE LAPANAITIS – from 3M Australia provided an interactive exercise on Risk Management in the CSSD. The members and attendees formed small groups and were given scenarios that could be experienced by any Sterilising Services Department. The groups identified the risks, applied risk ratings and strategies for controlling risks in the future.

The interaction of the members and attendees was invaluable and we received very positive feedback. We are pleased to know when workshops benefit the members and welcome all feedback. We also welcome suggestions for future education.

Thankyou to Malcolm Bennett for your words of gratitude-noted below, they are greatly appreciated.

"Thanks heaps for holding the Workshop in Canberra, I am informed it was a great day and great value was gained from the information as well as the opportunity to network. This was my hope that she would start to feel less alone.

If it is at all possible to hold more days where CSSD staff are able to learn as well as Network I would be very interested in supporting this, just putting it out there"!

Malcolm Bennett Sterilising Services Manager



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Certificate III - Sterilisation Services



Certificate III in Sterilisation Services

Course structure and units

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

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



TAFE Western Sydney Institute

Hornsby - Workshop - 5 December 2018

SRACA NSW Xmas Lunch/Workshop 5th December 2017- Hornsby RSL

Welcome from George and General Meeting

Yoni Hope-Hodgetts

Donation Specialist Nurse

Please Note The below summary discusses death and organ donation and may have effect on some readers.

Started the day with a very interesting and informative talk on organ donation in Australia. Learning about the number of Australians waiting for an organ transplant and the amount of organ donors was interesting, there was 503 donors and over 1600 transplants.

I was amazed to hear that you can consent to donate your femoral head from elective hip surgery and the bone can be used by grinding into a dust and used like cement. The example given was a lady that needed a rib made after breast cancer surgery and a donated femoral head was used.

Skin donation is the next big thing for burns victims, the biggest complication for burns patients is infection. Currently we import skin from the USA with as you can imagine a massive expense.

On a personal note I became an organ donor when one-night shift I was working as an orderly and there was a double lung transplant operation booked. When the patient arrived at theatre reception I was amazed it was one of my good mates receiving these lungs. I knew he was on the list because he suffered from cystic fibrosis for most of his life. This was in 2001 and today in 2017 he has recently married and enjoying life.

If organ donation is something you would like to do, please discuss with your family and to register or for more information on organ donation please visit <u>https://register.donatelife.gov.au/</u>

Karen Vickery

Scientific Director of the Surgical Infection Research Group- Macquarie University

A study was contacted by Karen and her team from Macquarie University. The study was focusing on the Reprocessing of loaner surgical instruments and the evaluation of stainless steel surgical instruments at the end of life.

The first part of the study found that bacteria can survive 121 at 20mins when dehydrate under biofilm. To kill the bacteria, they needed to Sterilise the items for 1 hour at 121.

There were 47 participants from Australia and 143 from Brazil. The study compared across the two countries and looked at the staffing profiles of a Sterilising Services Department, instrument traceability, cleaning processes, Sterilisation, autoclave maintenance and storage and distribution.

The aim for the second part of the study was to determine if stainless steel surgical instruments became contaminated with bacteria over the lifetime of use and processing.

All the instruments were all culture negative but found to be covered in Biofilm and this was after being cleaned and sterilised. Instrument damage was found on all instruments with corrosion, bio film and protein. 61% of the instruments were found to have over the accepted amount of protein.

To view the whole study please go to the members only the <u>NSW SRACA</u> website or <u>Facebook Members Page</u>

Donna Am

Education Foundation Halyard

Education for Sterilisation Technicians

The idea behind this program is ongoing online education program developed by Halyard.

Hornsby - Workshop - 5 December 2018... continued

There are short video lessons, test knowledge with quizzes and questions. Is available on any PC or tablet.

There are 4 courses available:

- Keep the bugs out- why have some more bacteria became more aggressive and patients more vulnerable to infection
- Event relate sterility- covers the factors that can compromise the sterility of a wrapped package
- Lint and Practices- how lint can cause severe chronic adhesions and increase the risk of infection by immune distraction
- Sterility Maintenance- evaluate the concern with rigid containers when exposed to a dynamic bioaerosol

There will be more courses added in the future around AS/NZS 4187:2014 and other topics.

The program is available to all Halyard customers for free and departments in the public system would need to seek approval from their districts to use. Others hospitals or staff not a Halyard customers would have a cost involved.

Congratulations to scholarship winners:

- 1. Gail Pengilley Gosford Hospital
- 2. Georgina Rees Royal North Shore Hospital
- 3. Maureen Ward Royal Prince Alfred Hospital
- 4. Johan Piere Bankstown Hospital
- 5. Bella Tong St George Hospital





Hornsby - Workshop - 5 December 2018... continued



		Australia	Brotil	P
Age	20-30	1/45(2%)	25/143 (15%)	10.0001
	Over 50	27/46 (60%)	18/143 (13%)	
Experience in	\$3 years	2/96 (5.5%)	27/197(29%)	\$0,0001
SSU	210 years	23/36(64%)	41/137 (30%)	
Education	Vocational/ High school	14/30 (47%)	6/143 (4%)	\$8.0001
	Higher degree level	16/30 (53%)	137/143 (96%)	

	and the second second	Australia	Brouil	10
Cleaning	Manual+auto	(42/47(89%)	135/141(96%)	1
method	Manual only		6/141 (4%)	10.005
	Auto only	5/47 (11%)		
Pressurised	yes	43/47 (92%)	96/142(68%)	×0.002
system				

		Australia	Benzil	1
Traceability	313	44/46(96%)	97/141(69%)	10.001
system	Company-hospital	33/44 (75%)	37/110 (34%)	\$0.001
	Hospital-patient	41/44 (93%)	81/110 (74%)	=0.013
	Hospital -company	33/44 (75%)	32/76 (42%)	\$0.001
Input functionality	yes	41/44 (93%)	83/106 (78%)	=0.009
Exclusive area	yes	40/47 (85%)	83/140 (59%)	=0.003
for receipt,				

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COSTA 2017

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Infection, Disease & Health (2017) xx, 1-7



Research paper

Evaluation of stainless steel surgical instruments subjected to multiple use/processing

Dayane de Melo Costa ^{a,b}, Lillian Kelly de Oliveira Lopes ^a, Anaclara Ferreira Veiga Tipple ^b, Khalid Johani ^{a,c}, Honghua Hu ^a, Anand Kumar Deva ^a, Evandro Watanabe ^d, Karen Vickery ^{a,*}

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Received 26 May 2017; received in revised form 22 August 2017; accepted 22 August 2017

KEYWORDS Sterilization; Decontamination; Biofilm; Number of re-uses	 Abstract Background: To determine the effect of multiple use and processing cycles on instrument quality over the life of stainless steel, complex designed clinical surgical instruments. Methods: Steam sterilised surgical instruments due to be discarded from Australian hospitals, because of loss of functionality, were assessed for contaminating protein and bacteria using the bicinchoninic acid protein assay and microbial culture, respectively. Biofilm presence and instrument damage were visually confirmed by scanning electron microscopy (SEM). Instruments were categorised into hinged/serrated, screw, cannulated, flexible, and irregular surfaced (but not hinged) according to their design. Results: Protein contamination ranged from 24 µg on the new screw to 3,756,046 µg contamination
	 inating a discarded forceps. The more complex the instrument design the higher the protein contamination. All samples were culture negative, however, biofilm was visually confirmed on 4/8 instruments tested using SEM. SEM also detected soil, holes or black stains on all the instruments. <i>Conclusion:</i> "Ready to use" surgical instruments that underwent multiple uses and processing cycles were contaminated with high amounts of protein, and microscopy revealed the presence of soil, structural damage, black stains and biofilm. While less affected new but multiply processed screws also showed soil and biofilm contamination. These findings highlight the need for further research into determining what is the "life" of stainless steel

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instruments and development of standard criteria for evaluating when to "retire" an instrument.

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Highlights

- Extensive protein deposits were found on multiply processed surgical stainless steel instruments.
- Despite repeated sterilisation by moist heat, biofilm was detected on half the instruments tested.
- Microscopic damage to instruments including pitting was evident.
- The number of times individual instruments can be processed safely needs to be determined.

Introduction

Sterilisation of reusable critical surgical instruments is an essential preventive measure to ensure aseptic surgery and steam sterilisation is the gold-standard option [1,2]. Steam sterilisation is well standardised, with an expected sterility assurance level of 10^{-6} (i.e. 1:1,000,000 viable microorganism) [1]. In addition to killing live infectious organisms, processing of instruments requires patient soil to be removed and, in response to concern for transmission of prions, causing variant Creutzfeldt–Jakob disease, a protein cleaning instruments benchmark has been proposed [3]. This benchmark dictates that instruments be contaminated with a maximum equivalent of 5 µg bovine serum albumin (BSA) protein per instrument side [3].

Incidents associated with failed processing of reusable surgical instruments have been reported [4], and inadequate processing of instruments was rated as one of the top ten health technology hazards by the Emergency Care Research Institute (ECRI) Institute in 2017 [5]. This is no surprise given the number of instruments processed. For instance, in only one large hospital in the USA, approximately 40,000 reusable surgical instruments are processed daily [6].

A reusable surgical instrument can be used in hundreds or thousands of operations, and may potentially infect large numbers of patients if contaminated [7,8]. To date, standards detailing the safe number of uses or processing "life" of reusable medical devices are lacking. Thus, instruments have been commonly used and processed until their integrity and/or functionality is drastically damaged.

The belief that biofilm, a three-dimensional aggregation of sessile microorganisms encased in complex, extracellular polymeric substances (EPS) [9] adhering to a surface [10], will not develop on steam sterilised instruments, irrespective of their number of uses/processing, may be in part due to the belief that steam sterilisation is a "mighty weapon" that kills all organisms [11]. However, biofilms have been demonstrated to contaminate the narrow cannula in stainless steel dental syringes, even though they are subjected to steam sterilisation [12]. Therefore, the aim of this study was to determine if stainless steel surgical instruments became contaminated with bacteria over a lifetime of use and processing.

Methods

Discarded critical surgical instruments that due to be discarded, because of loss of functionality, were donated by healthcare workers from Sterilizing Service Units (SSU) or Surgical theatres of Australian hospitals in New South Wales and Victoria. All the donated sets of stainless steel surgical instruments were processed according to the routine of each SSU, package with surgical grade paper and subjected to saturated steam under pressure sterilization process.

The surgical instruments (n = 27) were divided according to their design into five groups (Table 1):

- Hinged and/or serrated, including nine forceps, two scissors, one bone nibbler and one pin clamp;
- Cannulated, including four suckers, two crown drills and one depth gauge;
- 3) Two sets of unused but multiply processed screws, n = 4;
- 4) Irregular surface two bone rasps (Serenity, OnSite)
- 5) Flexible one flexible drill bit

Instruments from all groups, except screws, were aseptically cut into fragments to enable multiple analyses to be conducted using a sterile Dremel[™] 3000 rotary tool and blade (Robert Bosch Tool Corporation, USA), in a Class II Biological Safety Cabinet (Herasafeks[™], Themo Scientific, Germany).

Determination of contaminating soil and microorganisms

The amount of contaminating protein was determined on 23 samples, including 12 hinged/serrated instruments, seven cannulated instruments, one screw, two irregular surfaced instruments, and one flexible drill, using the Bicinchoninic Acid (BCA) protein assay (PierceTM – ThermoFisher, Waltham, USA), according to the manufacturer's instructions

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Effects of processing instruments until functionality loss

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Table 1 Number of surgical instruments/samples according to the group and tests performed.							
Group design	Number of whole	Number of samples	Number of samples per test				
	surgical instrument	after sectioning into fragments ^a	Residual protein ^b	Bacterial ^c viability	Biofilm/structural damage ^d		
1) Hinged and/or serrated	13	25	12	11	2		
2) Cannulated	7	13	7	5	1		
3) Screws	4	4	1	1	2		
4) Irregular surface	2	4	2	1	1		
5) Flexible	1	2	1	_	1		
Total	27	48	23	18	7		

^a Section under aseptic conditions.

^b Bicinchoninic Acid (BCA) protein assay (Pierce™ - ThermoFisher, Waltham, USA).

 $^{\rm c}\,$ Standard culture in Tryptic Soy Broth after sonication.

^d Scanning Electron Microscopy.

for use. The volume of BCA mix, that instrument samples were incubated in, was adjusted to ensure complete coverage of the samples.

The presence of viable microorganisms was determined by immersion of 18 samples, into tryptic soy broth, and incubating aerobically for up to 48 h at 37 °C, with rotation at 100 rpm (*Incubador Innova 42TM*, *John Morris Scientific*, *Chatswood*, Australia). Instruments subjected to culture included 11 hinged/serrated, 5 cannulated instruments, one screw, and one irregular surfaced instrument. If culture positive, 100 µl from the culture was plated onto horse blood agar and incubated for 24 h at 37 °C. Isolated pure colonies were presumptively identified by using macroscopic features and Gram stain (AccustainTM Gram-stain, Sigma–Aldrich, Inc., USA).

Seven samples, including two hinged/serrated, one cannulated, two screws, one irregular surfaced instrument and one flexible drill bit, were examined by scanning electron microscopy (SEM). Instruments or instrument fragments were fixed in 3% glutaraldehyde, dehydrated through increasing concentrations of alcohol and hexame-thyldisilazane (Sigma—Aldrich Co, USA), coated with 20 nm gold film, and examined in a JSM-6480LA scanning electron microscopy system (JSM-6480LA, JEOL, Tokyo, Japan) as described previously [13]. Samples shown to have bacteria attached to the instrument surface and surrounded by EPS were classified as biofilm positive.

Results

All the instruments were contaminated with more than the suggested 10 μ g protein/instrument and 14/23 samples (61%) had more than 10 times the suggest level of contaminating protein (>1,000 μ g protein/instrument). The median value of protein contaminating instruments classified as hinged/serrated (5,571 μ g) and cannulated (2,171 μ g) was more than 100 times the suggested 10 μ g protein/instrument benchmark. Two needleholders were contaminated with 100,000 times the suggested 10 μ g protein/instrument benchmark. The minimum amount of protein detected was 24 μ g contaminating one screw and the maximum was 3,756,046 μ g contaminating a forceps (Fig. 1).

Of the 27 instruments, 18 were subjected to culture and all were culture negative. SEM was conducted on seven instruments. However, due to the processing required for SEM only one instrument (scissors) was tested simultaneously for culture, protein contamination and presence of biofilm/structural damage. Despite being culture negative, the scissors had evidence of biofilm presence (Fig. 2C, inset). There was extensive physical damage to the instrument, including scratches and pits (Fig. 2C). Biofilm was present in many of the areas of instrument damage.

Biofilm was detected on 6/7 instruments assessed by SEM, the remaining instrument a flexible drill bit had so much contaminating soil it was impossible to ascertain if there was also biofilm (Fig. 2H). Instrument damage, such as scratches, pits or black staining and soil was evident on all instruments as assessed visually by SEM (Fig. 2). Residual protein was determined for three instruments subjected to SEM visual analysis. The scissors and flexible drill bit had over 100 times the recommended amount of contaminating protein (Table 2).



Figure 1 Protein contamination $(\log_{10} \mu g)$ on stainless steel surgical instruments subjected to multiple clinical uses and processing cycles discarded due functionality loss. Horizontal lines are the group median value. Horizontal dotted line is the proposed benchmark of 10 μg of protein/instrument.

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Effects of processing instruments until functionality loss

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Table 2 Scanning electron microscopy and residual protein (µg) analysis of stainless steel surgical instruments subjected to multiple clinical uses and processing cycles discarded due functionality loss. All instruments were culture negative.

Group design	Instrument	Biofilm	SEM ^a findings	Micrograph ^b	Residual Protein (µg)
1)Hinged/ serrated	Scissor	+	Extensive scratching, black staining including pits in metal. Areas of thick biofilm, many of the pits have biofilm associated with them	2C	7609 µg
	Forceps	+	Clumps of organic matter Semi-continuous biofilm, extensive EPS ^c with embedded rod and coccoid shaped bacteria, large metal defects	2A, 2B and 2D	-
2) Cannulated	Sucker	+	Large metal defects with continuous biofilm and contaminating soil	2E	-
3) Screw	2 Screws	+ +	1 Large area covered with biofilm with thick EPS, ^c surface damage (scratching and holes) 2 Large area covered with biofilm with thick EPS ^c	2F	-
4) Irregular surface	Bone rasps (Serenity, OnSite)	+	Surface covered with thin layer of EPS ^c into which rod and coccoid shaped bacteria are embedded	2G	153 µg
5) Flexible	Flexible drill bit		Surface completely covered with organic matter	2H	1,401 μg

^c EPS – Extracellular polymeric substances.

Discussion

We found that all instruments clinically used and processed many times over their lifetime, prior to being discarded due functionality loss, remained soiled despite processing and steam sterilisation. It was not surprising that following steam sterilisation, we failed to detect viable bacteria using standard aerobic culture. However, despite these culture negative results, biofilm (bacteria encased in EPS) was visually confirmed to be present on 6/7 instruments (Fig. 2). The remaining instrument had so much contaminating soil that it was impossible to ascertain if there was also biofilm. This is in agreement with Vickery, Pajkos [12] finding of biofilm on clinically used, processed and sterilised stainless steel dental syringes.

Once formed, biofilm is hard to remove by conventional processing methods [14,15], and is also difficult to detect using conventional culture techniques [16-18], due the small number of cells present on its surface, difficulty in detaching biofilm cells from their substrate, and bacteria in biofilms having low metabolic rate [19]. What we have shown is that bacteria had time to attach to the instruments and survive long enough to form a biofilm and that processing including steam sterilisation, failed to remove this biofilm.

In addition to biofilm, repetitively used and processed instruments were contaminated with large amounts of soil. When exposed to high temperatures, such as those associated with saturated steam sterilization process, contaminating soil over time, can be solidified resulting in insoluble material becoming fixed on the instrument's surface [20], which can act as a physical barrier preventing the sterilising agent from contacting the instrument surface, thus, compromising the sterilisation process and the patient safety.

One major factor interfering with the effectiveness of surgical instruments processing, particularly cleaning, is the instrument design [21,22]. Poorly designed instruments such as those incorporating narrow channels, difficult to clean or visualise areas increase the risk associated with transmission of infectious agents [23], as their design facilitates the harbouring of unwanted debris/microorganisms [1,24,25]. The cannulated and the hinged/serrated instrument groups had an average of 270 and 500-fold more protein per instrument than the recommended benchmark of 5 μ g/instrument side [3] (10 μ g/instrument) as shown in Fig. 1. These instruments were the most complex, but even the screw had more than double the benchmark of contaminating protein [3]. Single-use implants, such as screws, are subjected to multiple processing cycles until

Figure 2 Scanning electron micrographs of stainless steel surgical instruments subjected to multiple clinical uses and processing cycles that would be discarded due functionality loss: hinged - forceps and scissor (A, B, C), serrated - forceps (D), cannulated sucker (E), screw (F), irregular surface - bone rasps (G) and flexible - flexible drill bit (H). Biofilm is shown in panels (B, C, E, F, G), patient soil in panels (A, D, H), pits and holes in panels (B, C, E) and a black stain is shown in panel (C). "Same surgical instrument/ sample.

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+ MODEL

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they are used. Our finding suggests that unused screws are subjected to contamination during procedures or during processing.

SEM confirmed the presence of surface damage and soil on the screws. Similar results were reported by McAuley [26], where corrosion and deterioration on screws was significantly correlated to increased number of times the screw had been processed. A shift to the use of individually packaged screws has been made, however concern about the risk for potential contamination [27,28] and prolonging the surgery time [29] related to this practice has also been raised.

The presence of large amounts of soil (Fig. 2A, D, H) and of instrument structural damage, such as holes or pits, many containing biofilm (Fig. 2B, C and E), were confirmed visually by SEM. Structural damage such as holes and pits can accumulate debris and microorganisms, which promotes biofilm formation and compromises sterilisation.

Thus, capacity for proper processing should be considered when designing a surgical instrument [30]. Regrettably, instruments designers consider only instrument use and frequently do not incorporate cleaning and sterilization considerations [24]. Chemical, thermal and/or mechanical insults may result in surface damage and result in physicochemical changes to the instrument surface [30]. Presence of black stains were detected on stainless steel instruments (Fig. 2C), which may be a consequence of contact with chlorides, which causes corrosion of the instruments and can be visualised as small black dots, and also insufficient rising [30].

In conclusion, "ready to use" reusable critical surgical instruments that had undergone multiple uses and processing, were found to be contaminated with excessive amounts of protein residues, which was substantiated by visual confirmation of contaminating soil and/or the presence of biofilm (bacteria encased in EPS). In addition, the instruments showed structural damage such as holes and pits on their surfaces. The presence of soil, biofilm and instrument damage can compromise sterilisation and threaten surgical patient safety. In this small sample, our findings suggest that instruments discarded due to loss of functionality, will be contaminated with high amounts of protein and are likely to harbour biofilm particularly in damaged areas. Further research into determining what is the "life" of stainless steel instruments and development of standard criteria for evaluating when to "retire" an instrument is needed.

Ethics

Ethics approval for this study was not applicable. There are no human or animal participants.

Authorship statement

The conception and design of the study (Dayane de Melo Costa, Lillian Kelly de Oliveira Lopes, Anaclara Ferreira Veiga Tipple, Khalid Johani, Honghua Hu, Anand Kumar Deva, Evandro Watanabe and Karen Vickery).

Laboratorial experiment (acquisition of data) (Dayane de Melo Costa, Khalid Johani and Honghua Hu).

Microscopy analysis (Dayane de Melo Costa and Khalid Johani).

Analysis and interpretation of data (Dayane de Melo Costa, Honghua Hu and Karen Vickery).

Manuscript preparation — drafting the article or revising it critically for important intellectual content (Dayane de Melo Costa, Lillian Kelly De Oliveira Lopes, Anaclara Ferreira Veiga Tipple, Khalid Johani, Honghua Hu, Anand Kumar Deva, Evandro Watanabe and Karen Vickery).

Manuscript preparation — final approval of the version to be submitted (Dayane de Melo Costa, Lillian Kelly De Oliveira Lopes, Anaclara Ferreira Veiga Tipple, Khalid Johani, Honghua Hu, Anand Kumar Deva, Evandro Watanabe and Karen Vickery).

Conflicts of interest

None.

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Effects of processing instruments until functionality loss

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TGA Medical Devices Safety Update



Australian Government Department of Health Therapeutic Goods Administration

Medical Devices Safety Update

Volume 5, Number 5, September 2017

In this issue

- Requirements when supplying medical device accessories and consumables
- Attention to device design can play an important role in minimising user errors
- Zimmer safety alert reminds surgeons 'once ceramic, always ceramic'
- TGA encourages reporting of incidents involving the use of surgical staplers

Requirements when supplying medical device accessories and consumables

The TGA has noted a rising number of instances of medical device accessories which are being supplied without an appropriate entry in the Australian Register of Therapeutic Goods.

Medical device sponsors are reminded that it is a requirement under the Therapeutic Goods Act 1989 (the Act) to have at all times a current and appropriate entry on the Australian Registry of Therapeutic Goods (ARTG) in order to legally supply a medical device.

Accessories to a medical device, and consumable parts of a medical device system, require their own ARTG entry if they will be supplied on their own.

What is an accessory?

Under section 3 of the Act, an accessory is defined as 'a thing that the manufacturer of the thing specifically intended to be used together with the device to enable the device to be used as the manufacturer of the device intended'. Accessories to medical devices are defined as medical devices under section 41BD(2) of the Act, and thus are required to have an appropriate and current ARTG entry in accordance with section 9A of the Act.

Accessories are designed specifically for a device, and may include consumables, parts, add-ons, and other components for use in conjunction with, or for upgrade, replacement and repair of parts of a medical device. Examples of common accessories may include rechargeable and non-rechargeable batteries that are proprietary in design; filters and cartridges for air, gas and fluid ports; specified disinfectants and cleaning agents; electrical leads/ connectors/ defibrillation pads and even software packages, apps and programs for use with medical devices.

Penalties for not complying

The TGA has noted a rising number of instances of medical device accessories which are being supplied without an appropriate entry. Sponsors are reminded that under section 41MI of the Act, a person who imports, exports, supplies or manufactures medical devices and accessories without inclusion on the ARTG commits an offence, for which imprisonment and/or fines may be imposed as a penalty.

The TGA undertakes post-market surveillance for instances of breaches and illegal supply.

Registering device accessories

Sponsors are urged to review current legislation and legislative requirements along with TGA guidance documents to ensure all devices are correctly included in ARTG and that they continue to comply with conditions of inclusion.

If you have questions device inclusion contact devices@tga.gov.au or 1800 141 144.

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



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TGA Medical Devices Safety Update ... continued

Medical Devices Safety Update

Attention to device design can play an important role in minimising user errors

The TGA's investigations have found that poorly designed devices can often enable and induce user errors, and worsen the consequences associated with user errors.

The TGA has received a variety of adverse event reports regarding the wrong information or incorrect rates being entered into devices such as dialysis machines, infusion pumps and insulin pumps.

In all of these cases it is the user's responsibility to ensure the information entered is correct and to review this before hitting the confirmation button. Users need to be familiar with the Instructions for Use (IFU) and follow them when entering rates into the machines

However, since user error can never be totally prevented and can be exacerbated by device design, the <u>Essential Principles</u> contained within Australia's medical device regulations place a responsibility on manufacturers to mitigate risks.

Manufacturers must select appropriate solutions for the design and construction of medical devices to minimise any risks associated with their use, including foreseeable misuse.

The <u>Essential Principles</u> also require that the measurement, monitoring and display scale of devices must be designed and produced in accordance with ergonomic principles, having regard to the intended purpose of the device.

What are the responsibilities?

While manufacturers are responsible for selecting appropriate design and construction solutions to ensure the quality and safety of their devices in relation to their intended use, the health facilities using these devices also have obligations to ensure effective device management programs are in place.

It is important that the responsible organisations configure their device systems so that operators are not able to compromise them.

Systems issues cannot be solved by any single stakeholder group alone and in working towards effective solutions the TGA believes the following tips can be helpful to reduce user error-related adverse events:

- Health facilities should:
 - set up effective device management programs that involve clinicians, biomedical engineers, hospital management and administrative staff.
 - ensure that responsibilities are clearly assigned to the relevant personnel.
 - ensure all staff carefully read and fully understand the IFU.
- Manufacturers should:
 - apply usability and ergonomic principles in the design and construction of their devices to assure their devices comply with quality and safety requirements.
 - ensure that the IFU is clearly written and that user education is appropriately designed and effectively conducted.

Communication and training vital

Both health facilities and manufacturers have the responsibility to establish effective communication systems to reduce adverse events.

With effective communication and proper user training, users can become familiar with device functionalities and can confidently and competently apply these functions to meet their purposes.

Key points

Medical device users should:

- follow the IFU
- double-check inputs into devices before hitting the confirm/start buttons
- recheck inputs before walking away from the patient
- identify and remedy any issues before hitting a "reset" button
- ensure a device is put back together correctly if it has been dismantled or opened, adhering to the IFU
- if an adverse event occurs that seems to be caused by following the IFU or device prompts, please report it to the sponsor and/or the TGA.

TGA Medical Devices Safety Update ... continued

Medical Devices Safety Update

Zimmer safety alert reminds surgeons 'once ceramic, always ceramic'

A safety alert has reminded orthopaedic surgeons not to replace broken ceramic hip components with metal during revision surgery.

Zimmer has contacted Australia surgeons with the reminder following an article in *The Lancet*¹ which reported severe adverse effects following revision of a Zimmer ceramic-on-ceramic hip implant to ceramic-on-metal due to femoral head breakage.

The purpose of the alert was to provide a reminder about the appropriate hip products/systems to be used after breakage of a ceramic hip component:

Ceramic hip systems have been used in total hip arthroplasty for many years. However, in some cases and due to various factors, revision surgery may be required due to ceramic component breakage.

In these cases of revision, all the ceramic particles must be removed and the wound thoroughly irrigated. The broken ceramic component should be replaced with another ceramic component, resulting in a 'ceramic on ceramic' or 'ceramic on polyethylene' articulation, according to the basic rule 'once ceramic, always ceramic.'

Risks

Because of the risk of ceramic particles remaining in the tissue, the alert advised that use of metal heads for revision after breakage of ceramic components was not appropriate. The potential consequences were:

- pain, joint effusion, progressive or sudden decrease of mobility
- foreign body reaction due to ceramic debris/ particles
- necrosis, pseudo-tumour and aseptic loosening
- revision surgery
- premature tribological wear of the revision component due to abrasion caused by remaining particles of the revised ceramic components.

A limited number of case reports in medical literature had suggested potential for systemic cobalt toxicity leading to severe complications, such as death.

REFERENCES

 Dahms et al, 'Cobalt intoxication diagnosed with the help of Dr. House', JR; The Lancet Volume 383, Issue 9916, Feb 2014

TGA encourages reporting of incidents involving the use of surgical staplers

The TGA encourages health professionals to submit adverse event reports relating to the use of surgical staplers.

The TGA regularly receives Device Incident Reports relating to the use of surgical staplers. The problems reported include: misfiring; failure to fire; device jamming; unusual sounds when firing; and staples not forming properly. These events can lead to adverse outcomes including patient bleeding/ haemorrhage, leaking of anastomosed staple line, and added operating theatre time.

Some recent examples

In one procedure, a laparoscopic sigmoid colectomy was being performed using a powered vascular stapler.

During the operation, the inferior mesenteric artery was ligated using the stapler and an initial bleed from the distal end of the staple line occurred; this was controlled with suture ligation.

In post-operative recovery on the same day, there was difficulty in raising the patient's

TGA Medical Devices Safety Update ... continued

Medical Devices Safety Update

blood pressure and the systolic blood pressure would not raise above 80. The patient was returned to theatre and found to be bleeding (pulsatile) from the proximal portion of the staple line. The surgeon had to proceed with an open operation to control the bleeding into the abdomen.

During a laparoscopic low anterior resection procedure:

The colorectal anastomosis was performed by an experienced surgical assistant firing a 29 mm circular stapler. During firing an audible crunch was reported to have been felt and heard. Upon inspection of the donuts, a complete circular rim of tissue was obtained.

Prior to colonoscopy being performed to check anastomosis, the surgeon noted faecal material in the pelvis. The operation was converted to an open procedure. On inspection of the anastomosis site, there did not appear to be any staples deployed. The colorectal anastomosis was hand-sewn, resulting in a surgical delay of two hours.

During a laparoscopic vascular procedure:

The vascular reload was locked down on the renal artery. The surgeon tried to fire the activation button on the handle and it would not work. He noticed that the blade had deployed about half a centimetre during the reload. It was at this point that the surgeon decided to convert from laparoscopic to open surgery. He then used clips and clamped onto the superior mesenteric artery. Once the bleeding had subsided he opened the stapler and removed it from the renal artery. He also sutured in that area to stop bleeding.

To mitigate adverse events involving surgical staplers, health professionals are advised to always follow the Instructions for Use. Patient selection should be considered. If the device malfunctions, users are encouraged to retain the device and packaging and forward them to the sponsor/ manufacturer for investigation.

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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Deputy Editor: Mr Aaron Hall

TGA Chief Medical Adviser: Adjunct Professor Tim Greenaway

Contributors include: Ms Sharon Bennett Dr Kelly Tsang Mrs Anne Howatt

What to report? Please report adverse events, as well as near misses

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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

- online at www.tga.gov.au (click 'Report a problem')
 - by emailing iris@tga.gov.au

be reported directly to the TGA:

by mail to IRIS, TGA, PO Box 100, Woden ACT 2606

Suspected adverse events or near misses can

• by fax to 02 6203 1713

device interactions

user/systemic errors

For more information about reporting, visit www.tga.gov.au or contact the TGA's Medical Devices Branch on 1800 809 361.

DISCLAIMER

The Medical Devices Safety Update (MDSU) is aimed at health professionals and is intended to provide practical information on medical devices safety, including emerging safety issues. The information in the MDSU is necessarily general and is not intended to be a substitute for a health professional's judgment in each case, taking into account the individual circumstances of their patients. Reasonable care has been taken to ensure that the information is accurate and complete at the time of publication. The Therapeutic Goods Administration gives no warranty that the information in this document is accurate or complete, 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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Call for Abstracts





Sterilizing Research Advisory Council of Australia

Call for Abstracts - National Conference FSRACA 2018

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

Aim:

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

Key Learning Outcomes

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

Key Dates

December 2017 abstract and E – Poster submissions open

May 2018 abstracts submissions closes (oral presentations)

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

July 2018 Preliminary program released & Early Bird registration commencement.

August 11th 2018 abstract submission closes (E Poster)

August 31st 2018 Early bird registration deadline.

Call for Abstracts ... continued



Sterilizing Research Advisory Council of Australia

Call for abstracts

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

JUGGLING PRIORITIES



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

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

Oral Presentations- General Abstract information.

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

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

Call for Abstracts ... continued



Sterilizing Research Advisory Council of Australia

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

Conditions of presenting

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

E Poster presentation

General Abstract information

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

Conditions of presenting an E poster

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

Call for Abstracts ... continued



Sterilizing Research Advisory Council of Australia



Abstract instructions- Oral presentations and e-posters

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

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

Abstract format

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

Maximum 1000 words

Publications

All abstracts will be published in conference proceedings.

Disclaimer

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

Applying for a Research Grant





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.

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

- 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.

Application form (Please circle your title) Title Ms, Miss, Mrs, Mr., Dr		
Surname		
Given Names		
Address		
	Pos	t code
Email address		
Phone number		
Current occupation and years of experie	nce	
Amount of Funding requested \$ I have/have not made application to alte If YES from whom and what support has	rnative sources for fun been requested/grante	ding YES/NO ed:
If funding is granted I Conditions of FSRACA "Guidelines fo SIGNATURE:	agre r Financial Grants"	e to abide by the terms and DATE
OFFICE USE ONLY		
Received by	State SRACA	Secretary on
State SRACA comments regarding eligibil	ity (as per financial gra	nt guidelines)
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Received by FSRACA Secretary on		 DATE:
Presented to FSRACA meeting on		 DATE:
FSRACA Action:		
	POSTION:	DATE:
Attachments Current SRACA Membership Curriculum Vitae 2 x Professional Referees Proposed Project Budget Plan 		

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Applicant_____

- 1= Criteria not met
- 5= Criteria fully met

Criteria Rating Comment

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	1. Documentary evidence.	(Circle correct answer)
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 Oral 1,2,3,4,5 Summary	Current membership and active member State group	YES/NO
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AGM

16th June 2018—Royal Prince Alfred Hospital

General Meeting

10th March 2018 Royal

Prince Alfred Hospita 10th November 2018

National Conference Hornsby RSL

Luna Park Sydney 12-14th September 2018

Executive Committee Meetings

26th February 2018

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- 19th March 2018
- 23rd April 2018
- 16th June 2018
- 25th June 2018
- 30th July 2018
- 27th August 2018
- 24th September 2018
- 29th October 2018
- 26th November 2018

WORLD CSSD DAY

□ 10th April 2018

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

S.R.A.C.A. (NSW) Inc.								
Renewals Due December Annu	ally-NOW	D						
Sterilizing Research & Advisory	Council of Austral	ia (NS	W)					
NEW MEMBERSHIP/RENEWALS								
MEMBERSHIP COMMENCES: 1 st January each year and is valid till 31 st December of the same year								
TITLESURNAMEGIVEN NAME								
HOSPITAL/COMPANY								
POSTAL ADDRESS								
POSTCODESTATEPHONE NO								
EMAIL Please tick Membership Type								
FULL Membership renewal includes Journal	\$50		\$50.00					
NEW Membership includes Journal & Joining fee	\$50 + \$5 Joining fee		\$55.00					
ASSOCIATE Membership includes Journal \$50 \Quad \$50								
SUBSCRIPTION to Journal Only (Overseas incl. postage) \$60								
TOTAL PAYMENT ENCLOSED \$								
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