George Carlin once stated “Always do whatever’s next”; he also said “I put a dollar in a change machine, nothing changed”. When it comes to health care, no one really knows what is ‘next’ but it is widely accepted that ‘change’ is coming. I picture Mr. Carlin up on cloud 8 (because it’s cheaper, less crowded and has a better view than cloud 9) standing next to a change machine waiting for whatever’s next.

Recently, The Patient Protection and Affordable Care Act was passed by the United States (U.S.) Congress, signed into law by the President and upheld by the U.S. Supreme Court. This law is designed to ensure that all Americans have access to quality health care, affordable health care and to contain health care costs. The concept of health care reform is not new to this country. The reason reform finally gained enough support to be enacted is due to health care costs rising at double the rate of inflation in the 1990’s and the current Medicare system is thought to be unsustainable. The cost of health care in this country is consuming a very large portion of the gross domestic product and is continuing to trend upward. In 2011 U.S. health care expenditures increased by 3.9% from 2010 to $2.7 trillion [1]. The health care industry is increasingly under intense scrutiny from the media. In March of this year Time Magazine featured an entire section to one story, America’s health care costs [2]. This article highlighted some very sobering information for the American public stating “Hospitals and health care providers offer services at prices that very often bear little relationship to costs”. Those of us in the health care industry understand why that is, but this extremely complex accounting system is not intuitive to the average American. The cardiac surgical industry is being affected by these events, following the general economic course of medicine in this country. As hospital personnel, Perfusionists are increasingly being asked to find creative, long term methods of containing the cost of the service we provide. The purchase of capital equipment is increasingly scrutinized and significant justification must be provided when requested. This pressure affects the Perfusion product industry as they endure slimming profit margins. We continue to see companies who specialize in perfusion product development and sales becoming more selective in which organizations they support. Don’t expect this scrutiny to go away soon. One consequence of these facts is that monies for continuing educational endeavors will continue to be a challenge in the foreseeable future for both medical product suppliers as well as attendees of medical conferences.

As bleak as this information seems to be for health care providers, there is optimism to be had. There are individuals and partnerships that have

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found successful ways to address these issues. And, as it just so happens…the AACP is bringing a group of these individuals together at our next Annual Meeting to help us understand some possible strategies and solutions.

The first panel session at the 2014 annual meeting of the AACP (Friday, January 24th, 2014), Quality initiatives: controlling the cost of cardiac care on a local, regional and national level, will include the following speakers: Dr. Michael Culig has published on Toyota production system based methodology to improve patient care [3]. Dr. Richard Prager has published on how a regional collaborative of hospitals and physicians can increase the quality of patient care and reduce cost [4]. Mr. Kenneth Shann will educate the audience on how Perfusionists and Perfusion guidelines can impact in this arena [5]. This session should offer all some very valuable information on these issues we are currently facing and give us some good ideas on how to address them.

The second panel session (Saturday, January 25th, 2014), Trends in Cardiac Care, will feature Bill Harris who will address the enhanced role of Perfusionists outside of the CVOR, Cyril Serrick who will give an update on Ex-Vivo perfusion technologies/techniques, Michael Sobieski who will present an update on heart failure treatment/support options and Dr. Mark Twite who will address the ongoing shortage of pharmaceutical agents used in cardiac surgery.

Please note that the 35th AACP Seminar on CV Perfusion will be at the Buena Vista Palace Hotel and Spa in Lake Buena Vista, Florida January 23 - 26, 2014. I would like to invite all to attend what is shaping up to be another outstanding AACP Annual Meeting. Please visit the AACP website to register and for more information (www.TheAACP.com). The AACP Program Committee (Ed Darling, David Fitzgerald, Bob Groom, Colleen Gruenwald, Bill Harris, Vince Olshove, Kenny Shann, Greg Smiglia, Steve Sutton, John Toomasian and Haven Young) have been hard at work helping to put together an outstanding pro-
Our New 2014 Host Hotel

Buena Vista Palace Hotel & Spa
Orlando, Florida
January 23 - 26, 2014

Single/Double Occupancy—$165.00 per night
Reservations: 866-397-6516

Buena Vista Palace, an official Walt Disney World® Resort, is a contemporary haven offering totally refurbished accommodations, a majestic new lobby and unsurpassed hospitality. Footsteps from the Downtown Disney® area, guests can also enjoy complimentary transportation to the Walt Disney World® Theme Parks. Plus, park tickets are never a problem. Admission is guaranteed for Buena Vista Palace guests, even if the parks are full.
2014 Annual Academy Meeting

Orlando, Florida
January 23 - 26, 2013

Thursday, January 23, 2014
9:00 AM – 1:00 PM    Council Meeting
10:00 AM – 3:00 PM    REGISTRATION
2:30 PM – 4:30 PM    Fireside Chats (Session #1)
4:30 PM – 5:30 PM    REGISTRATION
5:00 PM    Opening Business Meeting
             Fellow, Member, Senior and Honorary Members
6:00 PM – 8:30 PM    Sponsor's Hands-On Workshop & Reception

Friday, January 24, 2014
7:00 AM    REGISTRATION
7:30 AM – 9:30 AM    Scientific Session
9:30 AM – 10:00 AM    Break
10:00 AM – 11:30 PM    Scientific Session
11:30 PM – 1:00 PM    Lunch
1:00 PM – 3:30 PM    Special Scientific Session (Panel)

**Quality Initiatives: Controlling the Cost of Cardiac Care on a Local, Regional and National Level**
Co-Moderators: Robert Groom, MS, CCP and David Fitzgerald, CCP
Experience of UPMC using the Toyota production system based methodology - Dr. Michael Culig
The Quality Movement in Cardiac Surgery: The Michigan Experience - Dr. Richard Prager
Perfusionist’s Perspective - Kenny Shann, CCP
3:30 PM – 5:30 PM  Fireside Chats (Session #2)

6:30 PM  Induction Dinner  
Fellow, Senior, Honorary Members & Guests

Saturday, January 25, 2014
7:00 AM  REGISTRATION
7:30 AM – 9:30 AM  Scientific Session
9:30 AM – 10:00 AM  Break
10:00 AM – 11:30 AM  Memorial Session  
Charles C. Reed Memorial Lecture  
Thomas G. Wharton Memorial Lecture  
D. Scott Lawson, MS, CCP - President, AACP

11:30 AM – 1:00 PM  Lunch
1:00 PM – 3:30 PM  Special Scientific Session (Panel)

**Trends in Cardiac Care**  
Co-Moderators: Edward Darling, MS, CCP and Haven Young, RN, CCP  
Update on Heart Failure - Michael Sobieski II, RN, CCP  
Update on Ex-Vivo Perfusion - Cyril Serrick, MSc, CCP, CPC  
Update on the Perfusionist’s Role in the Cardiac Catheterization Laboratory - William Harris, CCP  
Update on Drug Shortages in Cardiac Surgery - Dr. Mark Twite

3:30 PM – 5:30 PM  Fireside Chats (Session #3)
5:30PM  Closing Business Meeting  
Fellow, Senior and Honorary Members Only

Sunday, January 26, 2014
7:30 AM – 9:30 AM  Fireside Chats (Session #4)
10:30 AM – 12:30 PM  Fireside Chats (Session #5)
PREBYPASS FILTER: THE IMPORTANCE OF FILTERING BEFORE INITIATION OF CARDIOPULMONARY BYPASS

Abstract
The preparation of the Heart Lung Machine for surgery involves priming solutions. The priming solution is kept circulating through the heart lung machine tubing and oxygenator before cannulation, in the attempt to eliminate air bubbles. With the priming solution circulating constantly through the heart lung machine circuit the bubbles are decreased substantially making it safer for the patient to go on bypass. The air bubbles pose a potential threat of emboli to the patient as well as lead to postoperative neurological deficits and even death. But air bubbles are not the only danger lingering within your cardiopulmonary bypass circuit. Endotoxins within the priming solutions have also been found to pose a threat to the patient. The endotoxins found in the priming solutions were concluded to trigger the systemic inflammatory response within patients which can lead to post-operative complications such as respiratory distress. Furthermore, the aggregates and endotoxins formed by priming solutions can be the cause of thrombocytes and fibrin production leading to thrombi and thromboembolization of the microcirculation which can lead to organ failure. They can also lead to the destruction of the endothelium and formation of granules. The use of a prebypass filter can eliminate most of the microemboli before the initiation of cardiopulmonary bypass. This paper will address the effectiveness of using a prebypass filter using a journal article with graft to demonstrate the elimination of microemboli.

Introduction
The postoperative neurological deficits of patients that have undergone cardiopulmonary bypass have been associated particularly with hypo-perfusion caused by air emboli and microemboli. Matter braking and coming off the cardiopulmonary bypass circuit may trigger the activation of inflammatory mediators causing micro circulatory deficiencies and leading to oxygen deprivation of vital organs. This can ultimately lead to the possibility of multior-gan failure. The emboli are mostly noted with transcranial Doppler during the initiation of cardiopulmonary bypass, defibrillation of the heart, manipulation and movement of clamps and during aortic cannulation. But the most startling fact of all is that out of all of these causes of emboli the highest incidences was noticed at the initiation of bypass. Microemboli can be caused not only by gaseous emboli but solid particles are well. For instance linen particles and fibers originating from cloth used to wrap oxygenators before sterilization have been found. In addition particles of iron, silicone and aluminum coming from the oxygenator have been found in postoperative patient’s liver, spleen and other organs. Large numbers of particles have also been found to originate from cardiotomy reservoirs which included fibers, molding materials, plastic particles, and antifoam sponge. In the Udea study discussed in the publication referenced (1) a cardiotomy reservoir was tested and found to have 341.5 particles between 2 and 50 microns. The majority of particles were between 2 and 5 microns.
During the initiation of cardiopulmonary bypass fast arterial infusion of large volumes occurs in a short amount of time. Despite Raping in an attempt to reduce hemodilution of the patient a good amount of priming solutions does make it to the patient and all the potential hazards with it. For this reason it is important to have a filter to reduce these aggregates. Years ago the arterial filter was used and believed to filter out microemboli. The issue with using the arterial filter whose pore sizes consist of 35-40 microns is that the majority of the particles found to come off the cardiotomy reservoir are between 2 and 50 micron and therefore most of the particles pass through the filter and on to the patient. Therefore offering little to no protection for the patient against microemboli coming off the circuit.

Methods
The concept of the pre-bypass filter is to remove any debris left in the perfusion components and tubing. The filter itself is made to be used with non-cellular fluids and therefore should not be blood primed. The concept of pre-bypass filtration prior to connection to cardiopulmonary bypass cannulas was first developed in 1970’s. In the beginning the pre bypass filter sizes were manufactured from 3-8 microns which seems to offer much better protection than the previous method of using the arterial filter with its larger pore size. They were later replaced by filters that ranged from 0.2-0.4 microns the standard sizes used today in most institutions. Then later were designed to filter out bacteria as well. Studies have shown that the filters with 0.2 microns have had the best results in removal of microemboli. The figure below is from an invitro study that was performed in order to determine the quantity and sizes of microemboli found in crystalloid priming solutions and in the CPB circuit. In this study the circuit and priming solutions were tested at different times without pre bypass filters and with filters of different pore sizes.

Results
The study concludes that despite the amount of time the circuit is recirculated with priming solution the presence of the pre bypass filter dramatically and significantly decreases the amount of emboli and aggregates found within the cardiopulmonary circuit. The study demonstrates that the 0.2 micron filter showed a substantial improvement as opposed to the use of no filter at all. The rest of the filters show the same result.

Figure 1
Effect of 0.2-vm PBF on the number of counted particles per milliliter priming solution before and after 1,2,3,4 and 5 minutes of filtration.

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PREBYPASS FILTER

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Discussion
In conclusion we can see the importance of utilizing a pre bypass filter on your cardiopulmonary circuit when recirculating your prime. The marked decrease of endotoxins and microemboli can have a dramatic impact on a patient undergoing cardiac surgery. The importance of having a pre bypass filter can not only improve the overall post-operative outcome of the patient but also serve as a cost effective strategy for the institution. Having a pre bypass filter will mean a lower possibility of neurological deficits, lower incidences of organ failure, lower incidences of respiratory distress syndrome etc. The patients will have a quicker recovery and have a shorter length of stay, which in turn can translate to increased hospital revenue, especially since the cost of your typical pre bypass filter can range as low as 7 -15 dollars.

References


Abstract Deadline for the 2014 Meeting
October 15, 2013

AACP/AmSECT Collaboration

The Council of The Academy recently conducted a conference call to discuss the proposal received from the Editor of the Journal of Extracorporeal Technology to adopt JECT as the official journal of the AACP.

The merits of JECT Editor, Bob Groom’s proposal were discussed by the attendees after reviewing, in detail & prior to the call, the data provided by Mr. Groom, data provided by the Associate Editor & Manuscript Editor of Perfusion, Mark Kurusz, and an internal survey of the AACP membership.

It was generally agreed upon by the attendees that the AACP should not change its affiliation with Perfusion for the following reasons:

- Data from the survey of the AACP membership indicated that the proposed change would result in an approximate 14% loss of AACP membership.
- There is no substantial benefit to changing this affiliation.
- There is value in having two different perfusion journals in competition with each other for journal manuscripts.

The attendees also agreed that the AACP should take advantage of this opportunity to petition Sage Publishing to:

- Increase the number of AACP Fellows on the Editorial Board of Perfusion.
- Create direct electronic access to past Perfusion issues via the AACP website.
- Solidify the relationship between Sage Publishing and the AACP with a formal agreement. The details of this agreement would be worked out at a later date.

Additionally, the attendees suggested that the AACP give the authors of manuscripts the option of choosing to which journal they wish to have their manuscript submitted. It was also proposed that the AACP, as a compromise, suggest to Mr. Groom that only the abstracts from the AACP Annual Meeting be published in JECT.

The group also agreed that we should continue to explore ways to collaborate with AmSECT as well as the ABCP, AC-PE and Perfusion Program Directors’ Council.
Biventricular Replacement With The SynCardia Temporary Total Artificial Heart

Heart Failure Has Reached Epidemic Proportions
Heart failure is a chronic and progressive disease that affects more than 20 million people worldwide, including 5.7 million Americans. An estimated 2 million new cases are diagnosed annually. Heart failure starves vital organs such as the kidneys, liver and brain of the oxygen and nutrients they need to function while allowing waste products to accumulate in the body. If adequate blood flow is not restored in time, organ tissue can die and cause permanent damage that often leads to death.

For people who progress to end-stage heart failure affecting both sides of the heart (biventricular failure), there are two treatment options: an immediate donor heart transplant or the SynCardia temporary Total Artificial Heart as a bridge to transplant.

Shortage of Donor Hearts
Heart transplantation is the current gold standard for end-stage heart failure. However, despite growing demand, the supply of donor hearts has remained flat for the past 20 years. Only approximately 3,500 donor hearts become available each year worldwide, with the U.S. accounting for approximately 2,200 of them. Waiting times vary by country and level of organ donation:

- In the U.S., according to the Organ Procurement and Transplantation Network (OPTN), as of Aug. 17, 2012, nearly half of the people (49%) on the waiting list for a heart transplant had been waiting for a year or more.
- In Europe, according to the Eurotransplant International Foundation, 57% of people listed for a donor heart had been waiting for a year or more, and 34% had been waiting for 2 years or more.

SynCardia temporary Total Artificial Heart
SynCardia Systems, Inc. is the manufacturer of the world’s first and only FDA, Health Canada and CE (Europe) approved Total Artificial Heart. Originally used as a permanent replacement heart, the SynCardia Total Artificial Heart is currently approved as a bridge to transplant for patients suffering from end-stage biventricular heart failure. There have been more than 1,100 implants of the Total Artificial Heart worldwide, accounting for more than 300 patient years of support on the device.

Similar to a heart transplant, the SynCardia Total Artificial Heart replaces both failing heart ventricles and the four native heart valves. Unlike a donor heart, the Total Artificial Heart is immediately available at SynCardia Certified Centers. It is the only device that eliminates the symptoms and source of end-
stage biventricular failure

**Patients Recover Rapidly with the Total Artificial Heart**
Prior to implant, patients who receive the Total Artificial Heart are often the sickest of the sick. According to data from INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support), 90% of patients who receive the SynCardia Total Artificial Heart are in the two sickest categories prior to implant:
- **Level 1** - Critical cardiogenic shock - hours to live (Crash & Burn)
- **Level 2** - Progressive decline - days to weeks to live (Sliding Fast)

The Total Artificial Heart is the only device that provides immediate safe blood flow of up to 9.5 liters per minute through each ventricle. This high volume of blood flow helps speed the recovery of vital organs including the kidneys, liver and brain, which helps make patients better transplant candidates.

During the 10-year pivotal clinical study which resulted in FDA approval, 79% of near-death patients who received the Total Artificial Heart survived to transplantation (NEJM 2004; 351:859-67). This is the highest bridge to transplant rate for any approved heart device.

Additional recovery markers from the clinical study include:
- 1 week after implant: 75% of all Total Artificial Heart patients were out of bed.
- 2 weeks after implant: 60% of all patients were walking more than 100 feet.
- 2 weeks after implant: Liver function had returned to normal and kidney function had improved significantly, trending to normal.

**Unique Design Allows the Body to Determine Blood Flow**
Because of its unique design, the Total Artificial Heart doesn’t require sensors, motors or electronics of any type inside the body. All electronics are safely located outside the body in the pneumatic driver, which powers the Total Artificial Heart with precisely calibrated pulses of air and vacuum. There is never a need to re-operate to repair or replace electronics.

The Total Artificial Heart consists of two polyurethane ventricles. Inside each ventricle is a four-layer diaphragm on the equator of the chamber, and an inflow and outflow valve at the top of each ventricle. Each ventricle is connected to the external driver by a small air tube known as a driveline that exits the patient’s abdominal wall. The driver supplies vacuum to pull the diaphragm to the bottom of the ventricle to allow blood to enter, then produces a precisely calibrated pulse of air that pushes the diaphragm to the top of the ventricle to fully eject the blood.

The unique partial fill/full eject design of the Total Artificial Heart allows the patient’s body to determine the amount of blood flow based on activity level. The Total Artificial Heart is calibrated to accept blood based on the needs of the patient’s body at rest. The ventricles partially fill and then fully eject the amount of
blood returned to the heart by the body. During exercise, increased muscle and body movement causes more blood to return to the ventricles, which can fill with up to 30% more blood. When the patient’s activity level increases, there is no need to adjust the heart rate as the body determines the amount of blood the Total Artificial Heart pumps.

30 Years of Proven Reliability
During 30 years of use, the valves in the SynCardia Total Artificial Heart have never failed. The diaphragm has a failure rate of less than 1% over more than 1,100 implants (2,200+ diaphragms). Currently, the longest a patient has been supported with the Total Artificial Heart is 1,374 days (almost four years) prior to receiving his heart transplant.

Providing Patients with Freedom from the Hospital
In 2010, SynCardia introduced the Freedom® portable driver, the world’s first wearable power supply for the Total Artificial Heart. Weighing 13.5 pounds, the Freedom portable driver allows stable Total Artificial Heart patients who meet discharge criteria to wait for a matching donor heart at home and in their communities instead of waiting in the hospital.

Prior to the development of the Freedom driver, Total Artificial Heart patients in the U.S. were confined to the hospital while they waited for a donor heart because the only FDA-approved driver for powering the Total Artificial Heart was the “Big Blue” hospital driver, which weighs 418 pounds and is the size of a washing machine. Due to the shortage of donor hearts and increasing demand, patients often wait months, sometimes years before a matching donor heart is found.

Life for a stable Total Artificial Heart patient confined to the hospital is emotionally, physically and financially draining for them, their family and the hospital. Recovery at home greatly improves the patient’s quality of life and positively influences their physical, mental and emotional health. Discharge also eliminates most in-hospital costs for this portion of patient care, frees up in-hospital resources to serve additional critically ill patients and reduces the risk of hospital-acquired infections.

In addition, the Freedom portable driver provides increased mobility inside the hospital and on hospital grounds for patients who cannot be discharged home due to medical reasons or because they don’t have an appropriate support system or a full-time caregiver available.

The Freedom driver can be worn by the patient in the Freedom Backpack or Shoulder Bag, allowing many patients to return to normal daily activities such as shopping, going out to dinner, doing housework, going to church and attending social events. Some patients even return to their jobs while they wait for a heart transplant.

To date, more than 130 patients have been supported by the Freedom portable driver worldwide. The Freedom portable driver is CE approved for use in Europe and undergoing an FDA-approved Investigational Device Exemption (IDE) study in the United States. SynCardia Total Artificial Heart patient Chris Marshall hiked 607 miles while waiting for a matching donor heart using the Freedom portable driver. He received his heart transplant on Sept. 12, 2012.
tigational Device Exemption (IDE) clinical study in the U.S. On Feb. 14, 2013, SynCardia submitted the study data to the FDA as part of a premarket approval supplement requesting commercial approval of the Freedom portable driver in the U.S.

Destination Therapy
Patient discharge with the Freedom portable driver has made the Total Artificial Heart a viable option for permanent use, known as destination therapy, which has a much larger patient population than bridge to transplant. In 2012, the FDA approved a Humanitarian Use Device (HUD) designation for the Total Artificial Heart to be used for destination therapy in addition to its current approval as a bridge to transplant. The next step is for the FDA to approve a Humanitarian Device Exemption (HDE) application for the Total Artificial Heart. Once approved, the HDE will allow up to 4,000 U.S. patients annually who are not transplant-eligible to receive the Total Artificial Heart on a permanent basis.

New, Smaller 50cc Total Artificial Heart
The current 70cc SynCardia temporary Total Artificial Heart fits a majority of men and some women and is intended for use in patients with a Body Surface Area (BSA) ≥1.7m². SynCardia is currently seeking regulatory approval for its new, smaller 50cc Total Artificial Heart, which is designed to fit patients of smaller stature, including women and adolescents. It is intended for use in patients with a BSA between 1.2 and 1.79m². Together, the 70cc and 50cc Total Artificial Hearts are intended to fit almost all adult men and women, and many adolescents, including patients with congenital conditions.

Conclusion
Over the years, hundreds of artificial heart designs have been created, tested and ultimately shelved. Only one artificial heart has withstood the rigors of the human body and regulatory approval… the SynCardia temporary Total Artificial Heart.

Today, the opportunity to discharge stable patients using the Freedom portable driver has helped make the Total Artificial Heart a viable option for destination therapy (DT). Approval for DT would make this lifesaving technology available to thousands of patients worldwide who are not eligible for a heart transplant. In addition, once approved, the smaller 50cc Total Artificial Heart will offer a new treatment option to several underserved patient populations: men of smaller stature, most women and many adolescents. These expanding indications are of critical importance because currently these patients have no other treatment options and are often referred to hospice.

CAUTION – The Freedom® portable driver and 50cc Total Artificial Heart are investigational devices, limited by United States law to investigational use.

SYNCARDIA SYSTEMS, INC., Phone: 520-545-1234, Fax: 520-903-1783, Website: www.syncardia.com
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**CASMED MEDICAL**  
Phone: 800-227-4414 or 203-488-6056  
Fax: 203-488-9438  
Website: www.casmed.com

**COVIDIEN**  
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Fax: 303-305-2865  
Website: www.covidien.com

**INVOSURG**  
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Fax: 617-507-6462  
Website: www.invosurg.com

**MAQUET MEDICAL SYSTEMS, USA**  
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Websites: www.medtronic.com  
www.perfusionsystems.com

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Fax: 763-553-0363  
Website: www.nonin.com

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**SPECTRUM MEDICAL, INC.**  
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Fax: 803-802-1455  
Website: www.spectrummedical.com

**SYNCARDIA SYSTEMS, INC.**  
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**TERUMO CARDIOVASCULAR SYSTEMS**  
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Fax: 734-663-7981  
Website: terumo-cvs.com

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**Important Academy Dates**

The ACADEMY ANNUAL MEETING DEADLINES

- **ABSTRACT DEADLINE**  
  October 15, 2013

- **MEMBERSHIP DEADLINE**  
  November 23, 2013

- **PRE-REGISTRATION**  
  January 3, 2014

- **HOTEL REGISTRATION**  
  January 3, 2014

- **2014 ANNUAL MEETING**  
  January 23 - 26, 2014

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**Others Meetings**

**Perfusion Downunder - The Winter Meeting**  
Hayman Island  
Whitsundays, Queensland, Australia  
September 1–3, 2013  
Phone: + 61 3 9799 7444  
Fax: + 61 3 9799 7111  
Website: http://www.perfusiondownunder.com

**Update on Perfusion Devices Workshop 2013**  
Embassy Suites Hotel  
Charleston, SC  
October 24-26, 2013  
Contact: Kristina Hill  
Phone: 843-792-6505  
Website: http://academicdepartments.musc.edu/chp/cvp/conference_2013/index.htm