

Academy NEWSLETTER

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The Culprit



Mycobacterium chimaera

Mycobacterium chimaera is part of Mycobacterium avium complex, a group of mycobacteria which are found widely in the environment such as in soil and drinking water and are not harmful to the majority of healthy people. They can sometimes cause respiratory infections, or more serious infections in patients with weakened immune systems.

Cases of invasive cardiovascular infection caused by Mycobacterium chimaera in patients having previously undergone cardiac surgery in Switzerland, the Netherlands and Germany have been reported by the relevant authorities.^{1-3, 5}

Switzerland has reported six Mycobacterium chimaera infections: three cases of endocarditis, one bloodstream infection and two vascular graft infections. Two of the six had fatal outcomes related to the infection.² The clinical manifestations included osteomyelitis and involvement of multiple organs such as the eye and spleen. The Netherlands reported one fatal Mycobacterium chimaera infection in a patient following cardiac surgery.^{1,6} A case has also been reported in Germany. Investigation in Switzerland included microbiological examination of environmental samples that identified Mycobacterium chimaera contamination in heater-cooler units used during cardiac operations, including water samples from the units. Air sampling cultures became positive for Mycobacterium chimaera when units were running but not if they were turned off. Some strains from air and water samples showed

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matching Random Amplified Polymorphic DNA (RAPD)-PCR patterns.^{2,3} This suggests Mycobacterium chimaera-contaminated heater-cooler units as a potential source of infection.² Heater-cooler units are used to regulate the temperature of the blood during extracorporeal circulation and use filtered tap water as a heat exchanger.

A number of control measures have been implemented including placing devices that may spread the bacteria outside of operating rooms.¹

In Switzerland, cleaning and decontamination of the heater-cooler units was followed by recontamination. A new heater-cooler unit that initially tested negative for Mycobacterium chimaera at the hospital tested positive three months after purchase and installation. In a Zurich hospital, a maintenance protocol was applied that included daily water change (using 0.2µm bacterial filters). The hospital also started building customized housing units for these devices inside operating rooms, with high-efficiency particulate air filters connected.²

In the United States, many institutions are following a strict protocol handed-down from industry that includes water changes, disinfecting and testing. These weekly or even daily procedures can require more time and effort from the perfusionist than conducting cardiopulmonary bypass depending on your individual situation.

The Academy will be offering a special panel session at the meeting in Savannah where experts will discuss such topics as the source of the problem, how to deal with the problem and engineering and design of heater/coolers.

You will not want to miss this informative and timely session.

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We're looking for a few good men and women

The Academy is looking for some Fellows or Members interested in serving as co-moderators of Fireside Chats for the upcoming meeting in Savannah. If you are interested, please contact Greg Smigla at gregory.smigla@duke.edu.

2016 Annual Academy Meeting Host Hotel



Hilton Savannah DeSoto

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Area Attractions

To learn more about what Savannah has to offer, please visit http:// www.visit-historic-savannah.com/ savannah-visitor-center.html Abstract Deadline for the 2016 Meeting October 30, 2015

2016 Annual Academy Meeting

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Savannah, Georgia February 4-7, 2016



Thursday, February 4, 2016

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) Emergencies, accidents, common mishaps and how to fix them Human factors, safety and OR design Pediatric ECMO Simulation Students Only Forum
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, February 5, 2016

7:00 AM	REGISTRATION
8:00 AM – 9:30 AM	Scientific Session
9:30 AM – 10:00 AM	Break
10:00 AM – 11:30 PM	Special Scientific Session (Panel) Waterborne Infections and Heater-Cooler Design Waterborne Bugs - TBD Perfusion Related Issues - Richard Walczak, CCP Manufacturer's Perspective - Sorin Group Panel Q&A
11:30 PM – 1:00 PM	Lunch
1:00 PM – 3:30 PM	 Special Scientific Session (Panel) Human Factors, Safety, & OR Design: Empowering the Perfusionist Building a Safe Team Through Standardization: Lessons Learned From The Aviation Industry - Dann Runik Cardiac Surgery (surgical) Flow Disruptions, HFACS, CVOR Performance - Scott Schappel, PhD Technology, Environment, and Team(work) Interaction - Ken Catchpole, PhD Cardiac/Hybrid OR Design Consideration and Tools: Hybrid/OR Design - TBA Getting involved in OR Design, No Room to Complain - TBA Panel Q&A
3:30 PM – 5:30 PM	Fireside Chats (Session #2) Best practices Pediatrics Simulation Transplants, harvests, ex-vivo perfusion

Transporting VADs and ECMOs

The Academy Newsletter	Fall 2015
6:30 PM	Induction Dinner Fellow, Senior, Honorary Members & Guests
Saturday, February 6,	2016
7:00 AM	REGISTRATION
8:00 AM – 9:30 AM	Scientific Session
9:30 AM – 10:00 AM	Break
10:00 AM – 11:30 AM	Memorial Session
	Thomas G. Wharton Memorial Lecture
	Vincent Olshove, President, AACP
11:30 AM – 1:00 PM	Lunch
1:00 PM – 3:30 PM	Special Scientific Session (Panel)
	Congenital Cardiac Surgery - Doing More with Less
	FASE - Ashley Hodge, CCP, FPP
	Patient/Family Perspective - TBD
	Team Communication Tools
	Hand-off - Ken Catchpole, PhD
	Cardiac Team Huddle - Alistair Phillips, MD
	Outcomes
	Evan Zahn. MD
	Use of 3D Modeling in Congenital Heart Disease –
	Evan Zahn, MD Hybrid Approach to Congenital Heart Disease With CPB –
	Alistair Phillips, MD
	Quality of Life after Neonatal Heart Surgery -
	Joseph Sistino, PhD, CCP, FPP The Congenital Perfusion Registry - TBD
Panel Q&A	
3:30 PM – 5:30 PM	Fireside Chats (Session #3)
	Adult ECMO Closing the gap between generations (What the old guts expect from the new guys and
	what the new guys expect from the old guys.)
	Myocardial protection - "What's new" Simulation
	Ventricular assist devices
5:30PM	Closing Business Meeting
	Fellow, Senior and Honorary Members Only
Sunday, February 7, 2	016
8:00 AM – 10:00 AM	Scientific Session
10:30 AM – 12:30 PM	Fireside Chats (Session #4)
	Life outside the cardiac OR
	Simulation
	What are my legal obligations?)



Dane Pratt

Rush University Chicago, IL



Hyperthermic Intraperitoneal Chemotherapy And Its Use in the Treatment of Peritoneal Cancers

Until the early eighties, patients with peritoneal cancers that had metastasized were largely limited to surgery followed by subsequent rounds of chemotherapy. It was not until utilized Spratt et al. existina knowledge on hyperthermia and peritoneal chemotherapy to develop the first Therapeutic Infusion Filtration System (later called HIPEC). Efficacy of hyperthermic peritoneal perfusion with an anticancer drug was subsequently tested in rats and shown to significantly prolong survival compared to controls. HIPEC eventually reached phase III clinical trials in 1985 under Dr. Sugarbaker's landmark study showing diminished incidence of peritoneal carcinomatosis in patients with colon cancer. Much of HIPEC's success is due in part to delivery of chemotherapeutic agents at high local concentrations in the peritoneal cavity. These agents are largely isolated from the systemic circuit by the slow peritoneal clearance. The peritoneal-plasma barrier first described by jacquet et al., is responsible for this isolation to the peritoneal cavity. This is best observed by the area under the concentration (AUC) time curve HIPEC displays compared to other treatment options. According to Moreno et al HIPEC can reach an AUC of 1000 depending on the anticancer drug used and clearance by the liver. This has lead to the use of HIPEC in treatment of several peritoneal cancers. Although initially described in a case report to treat pseudomyxoma peritonei, HIPEC has been shown to treat colon, gastric, colorectal, ovarian cancers, serous carcinoma as well as peritoneal mesothelioma.

HIPEC can be an effective treat-

ment option for many types of cancers when used with appropriate patient selection. Although the criteria used for patient selection varies by institution there are usual preconditions sought before administration of the procedure. For example, the patient must be in adequate condition of health and be absent of haematogenous metastases. In addition, efficacy of treatment is also dependent on even distribution through the peritone-Dissolution al cavity. of intraabdominal adhesions can improve distribution of chemotherapeutic drug through the peritoneum. The chemotherapeutic drug and volume of carrier solution used are also important aspects to be considered for each patient. In addition the drug chosen should lack toxicity after administration and have a well-established activity against the cancer to be treated.

Prior to administration of chemotherapeutic drug, a quantitative assessment of cancer size and distribution is taken. Although other assessments exist, the Peritoneal Cancer Index (PCI) as described by Jacquet and Sugarbaker is commonly used. Evaluation of patient PCI is determined by tumor location within the peritoneal cavity as well as tumor size. Tumor location is divided into 13 independent locations within the abdominal and pelvic region. Each region is then given a separate score based on the largest tumor size recorded in that region. A lesion size (LS) of 0 is given when no tumors are visible. A LS score of 1 refers to tumors present up to 0.5cm, LS 2 is tumors 0.5cm-5cm, while LS 3 is all tumors greater than 5cm. The score of each region is then summed to obtain a final PCI score. Studies have observed



that PCI score significantly correlates to survival. A study done by Elias et al showed that patients with a PCI less than 16 had significantly better survival. In addition, a study done by Sugarbaker displayed a survival of 50% for patients with a PCI less than 10, while patients with a PCI 11-20 had a five year survival of 20%. The PCI is also taken after cytoreductive surgery as a measure of clearance of the peritoneal cavity from visible tumors.

In an effort to maximize the effectiveness of the HIPEC treatment strategy there must be an initial debulking surgery also known as cytoreduction. Preliminary cytoreductive surgery aims to remove all visible cancer from the peritoneal cavity. The necessity of complete cytoreduction was first described by Dr. Sugarbaker in 1995. Dr. Sugarbaker's study demonstrated a 99% survival in patients with complete cytoreduction compared to 20% in patients with incomplete cytoreduction.²⁴ Cytoreduction can be divided into six peritonecomy procedures used to strip the cancer from the peritoneal cavity. The use of one peritonecomy procedure or all of them depends on location and volume of carcinomatosis. The six procedures are greater omentectomy-splenectomy; left upper quadrant peritonectomy; right upper quadrant peritonectomy; lesser omentectomy cholecystectomy with stripping of the omental bursa; pelvic peritonectomy with sleeve resection of the sigmoid colon; and antrectomy. The pelvic peritonectomy is the most frequently utilized procedure; the right and left upper peritonectomy are common among patients with appendiceal, colon or ovarian cancer. Several studies have since affirmed Dr. Sugarbaker's initial findings for the use of preliminary cytoreduction prior to the HIPEC procedure.

After complete cytoreduction of the peritoneal cavity, the HIPEC procedure is initiated. Temperature probes are placed in the peritoneal cavity in addition to core temperature probes placed in the bladder or esophagus. Because the HIPEC procedure utilizes hyperthermic temperatures, seldom the patient is precooled using cooling blankets or packing the patient's head with ice to prevent systemic hyperthermia. The HIPEC procedure is generally preformed by a perfusionist and utilizes a similar circuit to that used in cardiopulmonary bypass. Outflow catheters placed in the peritoneal cavity return the perfusate to a reservoir driven by an occlusive roller pump. The perfusate then passes through a HIPEC machine that maintains the set effusion temperature and provides

feedback regulation of the chemotherapeutic agent. The perfusate is then delivered to the patient by inflow catheters placed inside the peritoneal cavity. The flow rates and target temperature are subject of much debate but generally are 1-1.5 L/Min at 41- 44 °C. Once the desired inflow temperature reached the selected chemotherapeutic agent will be added to the perfusate. The surgical oncologist will periodically manually agitate the abdomen to aid in distribution of the perfusate. The HIPEC procedure generally lasts a total of 90 minutes. After the procedure, the abdomen is flushed with saline and the chemotherapeutic agent is removed by abdominal lavage.

With changes in the chemotherapeutic agents used during HIPEC also brought changes in the technique used to deliver the perfusate. More potent anticancer drugs were sought to be delivered at higher concentrations to improve the efficacy of HIPEC. These chemotherapeutic agents also put the surgical team at greater risk of exposure. The closed HIPEC technique offers a higher level of protection by closing the abdominal skin after placement of temperature probes and catheters. The closed technique is not without its drawbacks, for example the distribution of flow is uneven compared to the open technique. The open technique utilizes a silastic sheet sutured over the abdominal retractor and onto the patients skin covering the incision. An incision in the silastic sheet allows manipulation of chemotherapeutic perfusate and better distribution compared to the closed technique. The open technique of HIPEC however has the disadvantages of higher heat dissipation and exposure to surgical team. A recent study comparing the closed and open HIPEC techniques showed no statistical difference in morbidity or mortality.

Although the technique utilized to administer HIPEC is still the subject of much debate its eminence in the treatment of patients with peritoneal cancers is quickly being realized. Since its introduction in the eighty's HIPEC has quickly risen as a viable treatment option by surgical oncologist here in the United States and Europe. HIPEC was cited in a recent edition of *Anti-Cancer Drugs* to be the most widely accepted treatment for peritoneal surface diseases. The rationale behind the prevalence of HIPEC stems from evidence based practice of its superior results in the treatment of colorectal cancer,

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pseudomyxoma peritonei, Appendiceal Mucinous Adenocarcinoma, peritoneal mesothelioma and ovarian cancer.

HIPEC's acclaim brings about important implications for the perfusion community; the opportunity to expand our profession outside of the cardiovascular setting into another specialty. Although a perfusionist is often the preferred choice for operation of HIPEC equipment, other professions are rising to the challenge. The continued necessity of a perfusionist's role in HIPEC begins with our enthusiasm and commitment to provide exemplary patient care.

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Considerations of Blood Rheology During Deep Hypothermic Circulatory Arrest

Deep hypothermic circulatory arrest (DHCA) is a perfusion surgical adjunct technique that first and foremost serves as a neuroprotective mechanism. Without the development of this approach, aortic arch surgeries, complex congenital repairs, and additional procedures unable to use cardioplegia-induced cardiac arrest would be extremely challenging if impossible. A large portion of the literature pertaining to DHCA is dedicated to the central nervous effects, cooling, rewarming and determining optimal ischemic times tolerated by the various organs. Because of the profound hypothermia induced in these surgeries, further consideration must be focus toward blood rheology at these profoundly reduced temperatures. Aggressive cooling alters the rheological properties of blood, and it is ultimately the perfsuionist's responsibility to adjust to those changes to provide quality patient care.

Although DHCA protocol varies among institutions, common grounds lies in the duration of the procedure committed to patient cooling. In 1997, Geissler et al. demonstrated that the arterial outlet and venous inflow blood temperature gradients should not exceed 10°C upon cooling. This is reported as a Class I, Level C finding (evidence base practice) and warns that exceeding this 10°C gradient is associated this gaseous microemboli formation. In addition slower cooling the patient promotes a more homogenous hypothermia of the neural tissues. Emboli formation not only contribute to impediment flow in the microcirculation but also reduces the velocity of flow compounded by increase in viscosity from deep hypothermia. Surface tension on the bubble increase dramatically during deep hypothermia maintaining the integrity of the bubbles and resiliency to dissolve. External cooling is also implored in order to impede secondary rewarming during DHCA. Total cooling times are accomplished over the period of 30 to 60 minutes. It is during this period of perfusion that the non-Newtonian characteristics of blood are pronounced and is the focus of this article.

Non-Newtonian fluids, such as blood, are different from Newtonian fluids primarily due to changes in viscosity relative to velocity. Because blood is composed of both plasma and formed elements, this fluid demonstrates varying viscosity as a function of fluid velocity. Concomitantly, the viscosity of blood will change according to differing temperature and hematocrit. This is crucially relevant to the perfusion practice as the acceptable cerebral cooling range is between 15-25°C prior to circulatory arrest. As a result, these drastically reduced temperatures will cause an exponential increase in viscosity of the circulating blood volume. The concern that arises with increased blood viscosity at the low temperatures deals with erythrocyte aggregation in the microvasculature. As the red cells aggregate in the microcirculation, this limits the exposed surface area of the cell to deliver oxygen to the tissues. Therefore, clinical technique should consider overcoming this increased blood viscosity. Adding more complication to this scenario is common in practice in some clinical communities is to reduce the flow index during hypothermia . A severe increase in viscosity



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from deep hypothermia should be compensated by an increase in shear force or velocity.

Due to the abovementioned concern of increased blood viscosity at low temperatures, hemodilution during DHCA is widely used. This approach is a dilemma as hemodilution reduces the oxygen-rich hemoglobin content. Moreover, the leftward shift of the P50 curve induced by DHCA further limits oxygen delivery to the tissues. Therefore, it is important to establish an appropriate hematocrit during DHCA. Shin'oka et al. (1996) demonstrated that excessive hemodiltution during DHCA causes insufficient oxygen transport during cooling. The authors compared various degrees of hemodiltuion in their study, and reported that even moderate hemodilution (HCT: 20%) during DHCA is associated with mitochondrial hypoxia. Interestingly the authors addressed previous concerns regarding high hematocrit aggregation in the microcirculation during DHCA and commented that this point may be overemphasized.

The rheological considerations of blood during DHCA are not only limited to cooling, but are very important during the period of rewarming. After DHCA and any adjunctive technique utilized (i.e. antegrade or retrograde cerebral perfusion) are discontinued, a closely monitored period of rewarming occurs. Engelman et al. (2015) reported that the arterial outlet and oxygenator venous inflow gradient should not exceed 10°C upon rewarming. This is stated as a Class I, Level C finding and warns that exceeding this 10°C gradient is associated outgassing. As the circulating blood rewarms, the blood viscosity will decrease. This decrease in blood viscosity is only relative to the state at which the blood was during DHCA. Therefore, the rheological considerations of blood during rewarming can be pursued under normothermic conditions. Under normothermic conditions, hematocrit management is starkly different when compared during cooling. While the degree of hemodilution during cooling is still in debate, the degree of hemodilution during normothermic conditions is wellestablished. Habib et al. (2005) reported downward trends in morbidity and mortality in a cohort of 5,000 patients with hematocrits below 22-23%. Therefore, even if hemodilution was utilized prior to DHCA in the effort to improve microcirculatory floor, techniques such as hem oconcentration are available to increase the hematocrit above this threshold.

Blood rheological considerations during DHCA are a balancing act between Three (3)principles: 1)

avoidance of microvascular sludging, , 2) fastidious hemodilution. 3) adequate flow index to overcome the increase in viscosity and improve the distribution of flow(O2 delivery) in the microcirculation. Additional considerations may include the risk of coagulopathy post DHCA and the effects on patient blood rheology. Ultimately, there are many avenues to consider in the scope of the perfusion practice regarding the physical mechanics and property of blood flow. This cannot be overstated particularly in the case of DHCA where drastic changes in patient and blood temperatures occur. It is the duty of the perfusionist not only to be mindful of neural protection and cooling/rewarming parameters during DHCA, but also to focus on the rheologic changes in the microcirculation during each stages of the cardiopulmonary bypass. The non-Newtonian characteristics of blood are most pronounced in DHCA and the difference s in perfusion techniques will make a impact.

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The Collaboration Continues. Introducing the Medtronic Affinity Fusion® User Channel: A New Channel for Knowledge Sharing. Featuring You.

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Please note that all submissions will be reviewed by Medtronic to determine whether submissions meet requisite guidelines, including but not limited to regulatory guidelines. No videos showing the Fusion System used in an offlabel manner will be accepted. This review process may take up to two weeks, at which time Medtronic will notify you if and when your video is posted.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician. For a list of indications, contraindications, precautions and warnings, please refer to the Instructions for Use which accompany each product. For distribution only in markets where Affinity Fusion Oxygenation System has been approved.

THE ACADEMY TO OFFER LIVE WEBCAST

The American Academy of Cardiovascular Perfusion will again be offering a live webcast of our 2016 Annual Meeting in Savannah.

The General Sessions of the meeting will be broadcast in high quality streaming video. There will also be an opportunity for attendees to ask questions, thus qualifying for Category I CEUs from the American Board of Cardiovascular Perfusion.

Heparin: It's Not What It Used to Be



Colleen Gruenwald, PhD, MHSc, RN, CCP, CPC, a Medtronic consultant, addressed clinicians on the clinical impact of changes made to unfractionated heparin (UFH) at the recent 35th Annual Cardiothoracic Surgery Symposium, held in San Diego.

As reported previously, the U.S Food and Drug Administration (FDA) mandated a change to the heparin monograph in 2009 that brought the USP heparin standard in line with the international standard used by the World Health Organization. Since then, an approximate potency reduction of 10% has been reported by the FDA and in subsequent studies.¹ Heparin remains the anticoagulant of choice to counteract the physiologic response to the non -endothelial surface of the cardiopulmonary bypass (CPB) system.

The need for larger heparin doses to achieve the desired anticoagulation effect has prompted retrospective and prospective studies in both pediatric and adult patients. Authors of recent studies noted that in addition to the 12% increase in the required heparin loading dose, significantly fewer patients in the "new heparin group" achieved an activated clotting time (ACT) > 480 seconds prior to bypass.^{2,3,4}

Gruenwald noted that "with this potency change, there are additional variables that increase the complexity of anticoagulation dosing and monitoring, including:

- evidence that there are brand variations in heparin between manufacturers^{5,6} and variations between and within heparin lots
- known variations between individual patients' responses to heparin (pre-treatment with heparin)
 - coagulation protein levels (including low ATIII)
 - medications and clinical conditions."⁷

Important Recommendations by the FDA and Professional Guidelines^{1,8,9} With the FDA website stressing that, "Heparin dosing is individualized based on patient-specific considerations, given clinical dosing of heparin already varies among patients," Gruenwald reminded clinicians that monitoring anticoagulation should be frequent and individualized for each patient.

The updated guidelines are meant to reduce bleeding and blood product usage in patients undergoing CPB for cardiac surgery. For short routine cases, the guidelines recommend monitoring the anticoagulation state by using at least the activated clotting time (ACT). For longer cases (> 2-3 hours), the guidelines recommend maintaining a higher and/ or patient-specific heparin concentration, which can be achieved by monitoring the heparin dose response (HDR) and the heparin protamine titration (HPT) with the Medtronic HMS Plus Hemostasis Management System.

The guidelines also suggest using the HPT or empiric low dose regimens to lower the total protamine dose, as well as the protamine-to-heparin ratio at the end of bypass. Therefore, these guidelines support using point-of-care HDR and HPT tests during CPB.

Gruenwald underscored the importance of being informed and educated, adding practical reminders such as:

- Talk with the pharmacy department and request that they inform the surgical team if and when heparin brand changes are necessary.
- Document changes among or within heparin lots and be aware of any significant clinical deviations.
- Understand the patient's history and be aware of pre-existing hemostasis conditions, such as low ATIII levels, medications that may affect anticoagulation (previously on heparin), or other medical conditions.

"Enhanced anticoagulation management and monitoring may reduce hemostatic activation, consumption of coagulation proteins, in addition to bleeding and the subsequent need for blood transfusions," observed Gruenwald. "This is an extremely important goal based on recent publications that have shown an increased risk in morbidity and mortality among patients who have received blood transfusion during or following heart surgery."¹⁰

To view Colleen Gruenwald's talk in its entirety and learn more about Individualized Heparin Management and how it can impact your patient, please visit <u>www.medtronic.com/ihm</u>

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1 Francesco Onorati, et al. "Polarizing" microplegia improves cardiac cycle efficiency after CABG for unstable angina. Int J Cardiol, July 2012 ©2014 Quest Medical, Inc. MPS and RetroGuard are registered trademarks of Quest Medical, Inc. 2014-10



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