



**2016** | **TOP 10  
HOSPITAL C-SUITE  
WATCH LIST**

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## About ECRI Institute

ECRI Institute ([www.ecri.org](http://www.ecri.org)), a nonprofit organization, dedicates itself to bringing the discipline of applied scientific research to healthcare to discover which medical procedures, devices, drugs, and processes are best to enable improved patient care. As pioneers in this science for nearly 50 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research. Strict [conflict-of-interest guidelines](#) ensure objectivity. ECRI Institute is designated an Evidence-based Practice Center by the U.S. Agency for Healthcare Research and Quality. ECRI Institute was a contractor to the U.S. Agency for Healthcare Research and Quality for the National Healthcare Horizon Scanning System. ECRI Institute PSO is listed as a federally certified Patient Safety Organization by the U.S. Department of Health and Human Services.

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# 2016 Top 10 Hospital C-suite Watch List

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# Introduction

What does 2016 herald, given that 2015 was another big year in medical technology? A Hospira Symbiq™ infusion pump was hacked. Drug costs soared, not only for novel new drugs, but also for some generics, as meetings convened about high costs and value pricing. Google transformed into Alphabet and extended its reach into various healthcare technology initiatives, including new robotic surgery platforms with real-time imaging and other data, which may soon give the company that has cornered the market for almost 20 years some stiff competition. And hospitals were on the hook again for serious adverse events such as contaminated duodenoscopes and healthcare-acquired infections. New technology offers the promise of reducing organ transplant wait lists by improving the condition of lungs and hearts that are donated for transplantation and keeping them viable longer so they are acceptable for transplanting. New payment models put hospitals in the driver's seat for the entire continuum of care for joint replacements starting in 2016. Hospital C-suite leaders must focus more than ever on creating higher value and excellent outcomes for lower costs.

ECRI Institute again presents its *Top 10 Hospital C-suite Watch List*. It includes both technologies and critical technology use issues we think should be on your radar. This 2016 edition covers a lot of territory, from cybersecurity of medical devices to important new capital equipment decisions; from a new care delivery model through mobile stroke units to new high-cost efficacious cardiac drugs whose cost-effectiveness has yet to be confirmed; from wireless pacemakers to wearable sensors used in disease management. Our *2016 Top 10 Hospital C-suite Watch List* covers topics that will affect workflow, clinical processes, patient outcomes, staffing models, and capital funding needs.

As in years past, ECRI Institute's experts are ready to help guide you through these tough decisions. We also welcome you to post feedback and any questions on our associated LinkedIn group: [Emerging Healthcare Technologies in Patient Care](#). Together, we will be well prepared to face the tsunami of healthcare technology decisions!

## About this Free Resource

The *2016 Top 10 Hospital C-suite Watch List* is produced as an independent collaborative research project by ECRI Institute's [Health Technology Assessment Information Service](#) staff of doctoral-level researchers, medical librarians, and clinical analysts and the organization's [Applied Solutions Group](#), a team of experienced health technology specialists who provide onsite and customized consulting to hospitals, health systems, and ministries of health on a broad range of technology and patient safety-related projects.

# 1

## Mobile Stroke Units:

### Are They More Than a Concierge Ambulance Ride?

A mobile stroke unit (MSU) is a new concept that uses specially outfitted ambulances and a special staff model, telemedicine, and equipment to enable stroke diagnosis and prompt treatment at the patient's location before transport to the hospital. The specially trained onboard team, in teleconsultation with a stroke neurologist, performs blood tests, takes computed tomography (CT) scans, and administers tissue plasminogen activator (tPA), if indicated, before a patient with stroke reaches the hospital. This could be an important change in care delivery because about 87% of strokes are ischemic and stroke is a leading cause of death. Patients with stroke have long been treated with tPA to protect the brain if they meet criteria for tPA's narrow therapeutic window (3.0 to 4.5 hours after symptom onset). But most stroke victims do not present in time for tPA treatment in the emergency department (ED), and fewer than 7% of affected patients receive tPA.

#### The First Step

Four MSU programs are operating in the United States in urban areas, branching out to suburban areas. The first program started in May 2014 led by University of Texas Health Science Center (Houston) in collaboration with Memorial Hermann-Texas Medical Center, CHI St. Lukes' Health, Houston Methodist, and Ben Taub hospitals. The UTHealth Mobile Stroke Unit operates in the greater Houston area 7 days a week, 10 hours a day, every other week. Another program started in July 2014 at the Cleveland Clinic (OH, USA) in partnership with MetroHealth Hospital (Cleveland, OH) and Cleveland Emergency Medical Services ([Cleveland MSU program](#)). It operates from 8 a.m. to 8 p.m. each day every other week within a limited area of Cleveland. The Cleveland Clinic may expand its program to Palm Beach County (FL, USA), where it has a comprehensive stroke center. In mid-October 2015, Mercy Health System (Toledo, OH, USA) launched its [Mercy Life Flight Network MSU](#), which it staffs 24/7. The University of Colorado Health (UCHealth) debuted [its first MSU](#) mid-January 2016, integrating it with its Epic electronic health record. During the initial 10-week pilot period, the MSU will operate Monday through Friday, 8 a.m. to 8 p.m. in Aurora, CO, then split its time between Aurora and UCHealth Colorado Springs. These programs were modelled after programs in Germany at Charite University (Berlin) and the University Hospital of Saarland (Homburg).

An MSU program starts with an emergency response vehicle outfitted with appropriate staff, equipment, medicine, and on-scene and remote clinical personnel who communicate through telemedicine technology. Excellance, Inc., (Madison, AL, USA) built Cleveland Clinic's MSU. The care team must have appropriate knowledge to recognize, distinguish, and treat different types of stroke where the mobile unit picks up the patient. Although MSUs focus primarily on ischemic stroke, they are also equipped to treat other types of stroke.

MSU equipment includes a portable CT scanner, tPA with infusion lines, mobile blood lab, telemedicine equipment with broadband access, and other medical equipment commonly found in an ambulance. MSU staff models include a paramedic, EMS driver, critical care nurse, CT technologist, and vascular neurologist onboard or available through telemedicine communication. The Houston MSU program uses Google Glass (see [2015 Top 10 Hospital C-suite Watch List](#)) worn by onboard personnel to transmit images while MSU staff keep their hands free to tend to the patient.

Using telemedicine, remote stroke specialists can see and hear the patient, consult with first responders, and view test results. If appropriate, tPA is initiated before transport, and infusion continues during the drive. Patients with confirmed strokes are transported to a stroke center, while others may be transported to the closest ED. The receiving hospital then has the opportunity to activate its stroke response team.

MSUs are integrated into a region's emergency dispatch and are sent in addition to EMS after the dispatcher determines that stroke-like symptoms are present. If stroke is excluded as a possible cause, the EMS assumes responsibility for care. The [MSU program in Houston](#) averages 1 tPA treatment per 10 MSU runs. MSU teams may not always administer tPA—it depends on the time from symptom onset and symptom presentation. If symptoms are too mild, the patient is too sick, or if the condition mimics hypoglycemia, seizure, migraine, or psychiatric problems, tPA may not be indicated. If the MSU team determines that the patient is experiencing a warfarin-related intracerebral hemorrhage, the team may give a [warfarin reversal drug](#).





Mobile stroke unit.  
Reprinted with permission from Cleveland Clinic.

## WHAT TO DO

- ▶ Determine whether your health system's current approach to treating stroke is meeting desired cost, quality, and patient and institutional outcomes goals.
- ▶ Determine whether your demographics support use of an MSU.
- ▶ Decide on your staffing model, additional equipment needs, and telemedicine capabilities.
- ▶ Coordinate with your local EMS dispatch services to create a response plan.
- ▶ Develop clinical protocols for use of MSU and how a hospital stroke team will function with an MSU team.

## Evidence Story

The evidence is preliminary so far. In mid-2015 and December 2015, Cleveland Clinic reported some findings from its program. [Results](#) on 155 patients after nearly 5.5 months of MSU operation showed that 5 patients received tPA therapy and were compared to 5 historical controls who had been transferred to the center for tPA therapy. Among the reported results were a median reduction of 20 minutes (12 vs. 32 minutes) in time from the patient entering the ED to taking the initial CT, and a median reduction in time of 83 minutes from CT to tPA therapy (82 vs. 165 minutes). Processing times at the hospital were also shorter. Impacts on patient outcomes have not yet been reported. In December, Cleveland Clinic published [results](#) from 100 consecutive patients in its program and reported that 99/100 patients were successfully evaluated and the time from entering the ED to initial CT was 32 minutes (interquartile range: 24 to 47 minutes) compared to 58 minutes in the control group. The control group consisted of patients with suspected stroke seen in EDs in the Cleveland Clinic between 8 a.m. and 8 p.m. (the same period during which the MSU operated) during the year. All programs are engaged in clinical research to determine the safety and efficacy of this care delivery approach, as well as cost-effectiveness.

## Cost Equation

The programs reported costs for MSUs of \$600,000 to \$1 million for an MSU initial launch. These costs include outfitting the MSU initially and staffing. Broadband coverage for telemedicine components, equipment resupply, technology maintenance, and other costs are ongoing. The Houston program estimated that its five-year fixed and continuing costs for one MSU are \$1.465 million based on two to four runs per day. Cleveland Clinic estimated its costs for the MSU vehicle and equipment at \$1 million, plus \$1.2 million per year for staffing.

## Related ECRI Institute Publication

- ▶ **Healthcare Product Comparison System.** 2013 Telemedicine Videoconferencing Systems Product Comparison.

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# 2

## Medical Device Cybersecurity: When Will Your Pacemaker Be Hacked?

In 2013, the *Washington Post* (among other news outlets) [reported](#) that Vice President Dick Cheney's cardiac pacemaker had its wireless capabilities disabled when implanted in 2007 to eliminate any potential cyberintrusion threat. This old headline, with the more recent [U.S. Food and Drug Administration \(FDA\) cybersecurity alert](#) that the Hospira Symbiq Infusion System was hacked in 2015, has many hospital leaders wondering whether they have the risk of medical device cyberhacking under control. General consensus is they don't.

Many information technology (IT) leaders certainly have many cybersecurity risks under control: passwords are required, servers are secured behind locked doors, policy has been established if any protected health information is sent to a wrong e-mail address or hacked. However, these practices have largely been applied to network infrastructure and the electronic health record (EHR). A medical device, such as a vital signs monitor or an infusion pump, is a cybersecurity threat vector that probably has not been subjected to the same risk-mitigation scrutiny.

To start addressing these issues, FDA is hosting a [public workshop](#) January 20 and 21, 2016, called "Moving Forward: Collaborative Approaches to Medical Device Cybersecurity." FDA, in collaboration with the National Health Information Sharing Analysis Center, the U.S. Department of Health and Human Services, and the Department of Homeland Security, is bringing together diverse stakeholders to discuss complex challenges in medical device cybersecurity that affect the medical device ecosystem. FDA will webcast the workshop for those who can't attend in person.

### Know Where the Threats Lurk

As we know, medical devices are no longer just machines attached to or used by the patient. They are often connected to the EHR—either hardwired or wirelessly. A typical patient in a critical care unit could easily be connected to 10 or more networked devices. While the information on the medical device may not be useful to a hacker, the medical device can be used as a conduit for accessing patient information in the EHR, like home address and social security number, which can be used to perpetrate identity theft or real theft in the patient's home while the patient is hospitalized. Potential threats in medical devices include the physiologic monitor that runs on an outdated operating system, the ventilator with a USB port, and usernames and passwords for the vendor's field service engineers and in-house technicians that are hard-coded. Other industries have largely solved these types of issues years ago.

As a further example, in-house biomedical engineering technicians and vendor field-service engineers typically have administrative rights to access performance records and to apply service diagnostics. These are typically not a managed credential and at many hospitals are the same for everyone with this level of access to the device. What happens if a technician or field-service engineer leaves the hospital or the vendor? The password leaves with the person, with no hospital policy or procedure to update the access codes.

In its [2015 Cybersecurity Survey](#), the Healthcare Information and Management Systems Society (HIMSS) noted that user-access-control security solutions were implemented in just 55% of responding hospitals and mobile device management tools and that access control lists were implemented in only 50% of respondents.

Also, at many hospitals, no clinical engineering or IT staff can tell you which medical devices connect to the EHR, how they connect, or what version of operating software is running on each device. Often, basic security information is nowhere to be found regarding medical devices used in patient care.



Photo courtesy of Shutterstock.

## WHAT TO DO

- ▶ Include clinical engineering, IT, and risk management staff when creating cybersecurity policies and procedures.
- ▶ Proactively assess medical device cybersecurity risks, working with manufacturers as appropriate.
- ▶ Keep up with the latest updates and patches for operating systems and anti-malware software.
- ▶ Limit network access to medical devices through the use of a firewall or virtual LAN.
- ▶ Audit the log-in process to all medical devices to ensure that an access-control method is being followed.
- ▶ Set up a process to monitor and report on cybersecurity threats and events.

## Include the Right Stakeholders to Create Policies and Procedures

In its *Top 10 Health Technology Hazards for 2015*, ECRI Institute recommended that a hospital or health system clinical engineering, risk management, and IT departments jointly take these steps to mitigate cybersecurity threats. Also, medical device security should be thoroughly vetted during the purchasing process of all medical devices and equipment, with a team that includes clinical engineering, IT, and risk management personnel to assess what the vendor has done regarding design and policies for patch and update management. One resource to aid in this process is the Manufacturer Disclosure Statement for Medical Device Security questionnaire developed by HIMSS and the American College of Clinical Engineering, and then standardized during a joint effort between HIMSS and the National Electrical Manufacturers Association. It provides medical device manufacturers with a means for disclosing to healthcare providers the security-related features of the medical devices they manufacture.

### Related ECRI Institute Publications

- ▶ **Patient Safety News.** October 2015, NIST Guide Offers Reference Design to Maintain the Security of EHRs on Mobile Devices.
- ▶ **Health Devices.** October 2015, Top 10 Health Technology Hazards Solutions Kit.
- ▶ **Risk Management.** September 2015, Personal Electronic Devices in Healthcare.
- ▶ **Health Technology News Brief.** August 2015, FDA Warns Hospitals Not to Use Hospira Symbiq Infusion System, Citing Cybersecurity.
- ▶ **Health Technology News Brief.** May 2015, Where Are the Gatekeepers? Cybersecurity Firm Accused of Faking Breaches, Fueling FTC Investigations.
- ▶ **Health Technology Trends.** March 2015, Be Afraid, Digital Health Security Experts Warn Users at Cybersecurity Symposium.
- ▶ **Health Technology News Brief.** January 2015, How FDA Sees Cybersecurity.
- ▶ **Healthcare Risk Control.** August 2014, Hospital Shares Lessons from “Hactivist” Cyberattack.
- ▶ **Healthcare Risk Control.** April 2014, Hospital at Center of Child Custody Case Hit with Cybersecurity Attacks.
- ▶ **Health Devices Journal.** December 2013, Cybersecurity Alerts Highlight Need to Review Precautions.
- ▶ **Continuing Care Risk Management.** June 2013, Health Information Security Standards.

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# 3

## Wireless Wearable Sensors: Data Sense or Data Chaos?

Wellness data collection devices, like FitBit®, AppleWatch®, and other fitness apps, are used daily by consumers to monitor and improve their health. How can health systems put wearable sensors to work to improve cost-effectiveness and safety of patient care throughout the continuum of care?

Wearable sensors hold promise for both outpatient and inpatient monitoring as they continuously monitor health status less obtrusively, capture and provide more data to clinicians, and possibly enable patients to leave the hospital sooner and prevent readmissions. Wearable sensors have potential to cut the cord for inpatient physiologic monitoring and can potentially provide continuous, unobtrusive monitoring pre-, intra-, and postsurgery. In outpatient settings, wearable sensors could have real-world benefits for 24/7 patient monitoring of a wide range of serious and chronic conditions, such as Alzheimer's disease, diabetes, epilepsy, cardiac arrhythmias, heart failure, and pressure ulcer development.

### Wearable Sensors: From High Fashion to Transdermal Patches

Smart wearable sensors are wireless miniature sensing and data collection devices available in several forms, depending on their purpose and maker. Some are integrated into clothing (tight-fitting shirts, vests, shoes), some are worn as accessories (necklace, bracelet, watch, headband, ear probe, ring, belt buckle), and some adhere to the skin (adhesive patch). Sensors communicate wirelessly to a centralized data collection system used for analysis, alerting, and reporting to patients, caregivers, and healthcare professionals. No matter the sensor form, the ultimate goal is to be unobtrusive, passive, and continuously monitor patients in their environment.

Wearable sensors for monitoring serious or chronic illness can be categorized as either movement/activity or physiologic sensors. Movement sensors are mature technologies that entered healthcare from other industries and are worn as clothing or accessories, whereas physiologic sensors measure biologic, chemical, or physical phenomena when in contact with the skin, often as an adhesive skin patch or secured by an elastic band. Often, wearable physiologic sensors use very tiny volumes of fluid to analyze chemicals in tears, sweat, saliva, or urine to indicate a change in patient status (e.g., glucose level, hormones, lipids, enzymes, pH, electrolytes, hydration).

### Novel Applications

Two novel applications include a way to combat pressure ulcers and increase inpatient mobility. Research by the U.S. Agency for Healthcare Research and Quality (AHRQ) shows that pressure ulcers cost the nation's healthcare system more than \$11 billion a year. Chino Valley Medical Center (Chino, CA, USA) reported results from a clinical trial it conducted using Leaf Healthcare, Inc.'s (Pleasanton, CA, USA) wearable, wireless Leaf sensor. Results indicated that sensor use increased compliance with hospital protocols for turning patients from a baseline 64% to 98%. Starting in May 2015, Desert Valley Medical Center (Victorville, CA, USA) is trialing the Leaf wearable sensor in its labor and delivery ward to reposition laboring mothers every 30 minutes. Studies show that labor can be shorter with reduced risk of caesarean birth when mothers are upright and moving during labor.

Movement sensors are also showing some efficacy for early detection, assessment, and monitoring of neurologic function. Uses in this area are benefiting patients with Parkinson's or Alzheimer's disease, dementia, cerebral palsy, poststroke management, and epileptic seizures. By combining data from several motion sensors and computing them through machine-learning algorithms, wearable sensor systems can give detailed insight into gait, falls, tremor, dyskinesia, and limb paralysis. In conjunction with electroencephalogram sensors, the sensors can even distinguish between normal movements and tonic-clonic movements.



Photo courtesy of Shutterstock.

## WHAT TO DO

- ▶ Assess situations in which sensor use might enable your facility to decrease length of stay, improve clinical outcomes, reduce “never events,” or provide high-quality home care.
- ▶ Don’t rely only on vendor demonstrations; establish several use cases and see the technology in action through site visits where you talk with users (health facility and patient).
- ▶ Set goals for how much improvement you seek, and choose outcome measures for clinical factors you intend to improve. Decide in advance how much these metrics need to improve for you to achieve your goals.
- ▶ Consider collaborating with vendors to conduct small-scale pilot studies at sites where you intend to implement. Weigh outcomes against vendor claims.
- ▶ Opt for rental agreements to avoid costly capital investment and being left holding the bag if a vendor goes out of business.
- ▶ Develop robust fail-over protocols for potential technology disruptions to gain clinical acceptance and ensure uninterrupted 24/7 patient care.

A [study](#) at Stanford University Medical Center (CA, USA) demonstrated that a smartwatch device was able to accurately detect seven of eight seizures in patients with epilepsy and transmitted that information to the caregivers. The smartwatch manufacturer [reported](#) that researchers at University of California, San Francisco in 2013 studied a pediatric population in which sensors collected data over 500 hours of testing and reported that the sensors had 100% sensitivity in detecting tonic-clonic seizures and over 90% specificity. This sensor cannot diagnose, predict, prevent, or cure seizures, but it can alert caregivers so they can respond to minimize serious injury or death during a seizure.

Physiologic monitoring wearable sensors often configure multiple sensors to monitor parameters singly or in combination. These sensors include continuous monitoring of heart rate; oxygen saturation; respiration rate; skin temperature; blood pressure; 1-, 3-, or 12-lead electrocardiography; electroencephalography; and electromyography.

Patients with heart disease often face tough self-management routines and frequent readmissions because the conventional markers of weight and symptoms are ineffective at determining the severity of their condition. While an implantable sensor like CardioMEMS™ (St. Jude Medical, St. Paul, MN, USA) has emerged into clinical care, implanting it is an invasive procedure, and externally worn sensors may be preferred. ToSense, Inc. (La Jolla, CA, USA) (formerly Perminova) developed the [CoVa™ Monitoring System](#) as a solution for long-term management of heart failure. FDA cleared it for marketing in May 2015, and the device, worn as a necklace, can be worn for just a few minutes a day to measure thoracic bioimpedance and electrocardiogram waveforms and then calculate thoracic fluid index, heart rate, heart rate variability, and respiratory rate. Next-generation versions of the device firmware are being designed to monitor stroke volume, cardiac output, and blood

pressure. An [ongoing clinical trial](#) is assessing the CoVa necklace for noninvasive remote monitoring of vitals for patients with heart failure or hypertension, who have a pacemaker, implanted cardioverter-defibrillator, or ventricular assist device. The trial is expected to complete in January 2016.

## Implementation Factors

Work with your clinical staff to determine the necessary changes to clinical protocols and workflows that will be required to use wearables in each clinical and patient setting and patient population. Using telemetry as an example, admission and discharge criteria for the new wearable sensors, as well as nursing operating procedures, will need to be developed. Physician, nursing, and support staff should be involved in selecting and customizing devices and software applications to provide a manageable stream of clear and actionable information. Staffing types, numbers, and training will likely need to change to handle the data influx and take appropriate and timely action. Storage, cleaning, disinfection, repair, and replacement of devices must also be considered and will involve staff from nursing, clinical engineering, and supply chain/materials management.

Also, sensors require a dependable wireless infrastructure, which means that health system IT staff must be engaged from the outset. Understanding whether the available infrastructure can support all the new wearable and wireless technology is key to initial implementation in the health system before sensors are given to patients. As with any wireless technology, wearable sensors come with security and privacy concerns as sensors may capture and transmit protected health information, so cybersecurity concerns have to be managed as well.

## Cost Equation

As electronics continue to be miniaturized, costs for wearable devices should also decrease. With FDA clearances and indications for use established for each sensor device, third-party payers may begin to cover use of these devices. For example, the [Zio® Patch](#) (iRhythm Technologies, Inc., San Francisco, CA, USA), cleared by FDA in 2009, is covered by Aetna as an alternative to a 24-hour Holter monitor for detecting cardiac arrhythmias.

Decision makers must also be aware that costs relate not only to wearable devices, but also the hardware and software, including the wireless transmitting infrastructure, IT servers or cloud computing services, and analysis, alerting, and reporting software. The size of the wireless device must also be considered, including the expected number of patients and healthcare providers accessing the system, as this will affect licensing costs.

For inpatient monitoring, hospitals need to weigh the costs, changes to workflow, and staffing levels to use wireless technology against purported benefits of improved patient care and savings from avoiding adverse events like hospital-acquired pressure ulcers or readmissions for heart failure. Evidence supporting these devices must be carefully interpreted because studies often lack control groups, report only short-term outcomes, and may have small sample sizes.

For outpatient applications, reimbursement models, workflow, and staffing changes, in particular, must be considered. The fee-for-service environment is reactive and focused on sick-based care, whereas wearable sensors coupled with wireless data collection are suited to value-based care reimbursement and focused on disease management and preventing new events. Continuous patient data monitoring with transmission to healthcare-provider smartphones and desktops will introduce a deluge of data that will need to be viewed and interpreted. This type of activity is not covered in a fee-based model and may require trained support staff to monitor.

### Related ECRI Institute Publications

- ▶ **Health Technology Trends.** November 2015, Wearables Data in the EHR? Not So Fast.
- ▶ **Health Technology Trends.** August 2015, Mobile Health Apps and Wearables Foster Research, but FTC Mulls Consumer Data Protections.
- ▶ **Health Technology Trends.** August 2014, Wearable, Measurable, Mobile: Vital Signs of the Times from Apple, Google, and Others.
- ▶ **Product Brief.** May 2013, LifeVest Wearable Defibrillator (Zoll Medical Corp.) for Detecting and Treating Ventricular Arrhythmia.

# 4 Miniature Leadless Pacemakers: Will Potential Benefits Make a Difference?

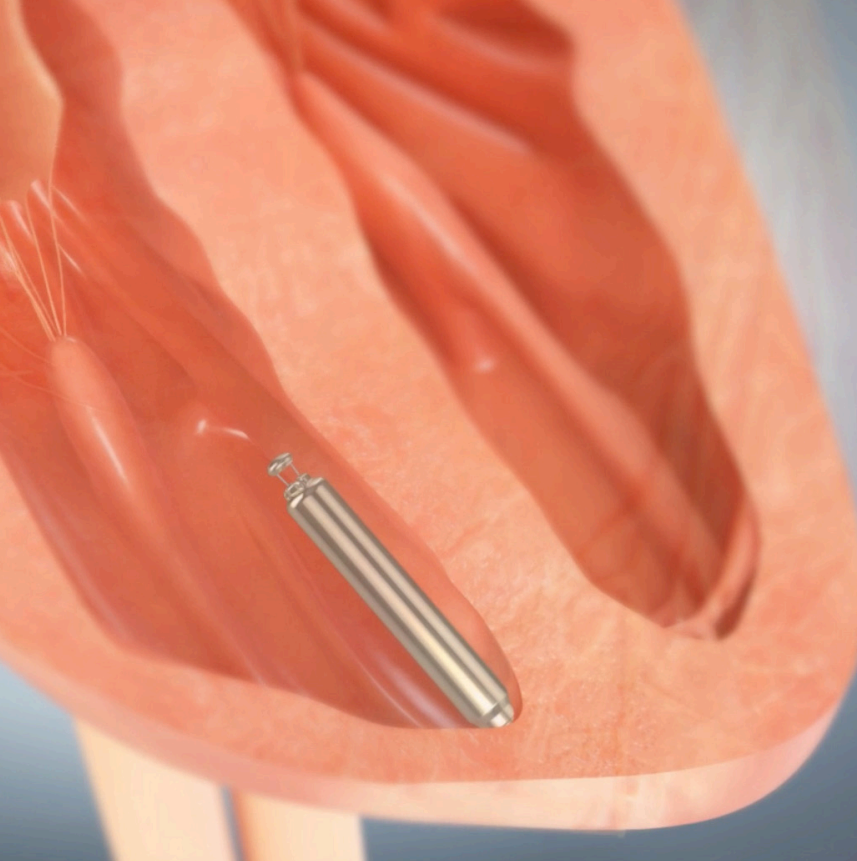
Next-generation pacemakers in development are less than 10% the size of conventional pacemakers, leadless, and do not require surgery to implant. These self-contained devices house a battery, electronics, and electrodes. These devices are able to sense and pace in only one heart chamber, so they are considered appropriate for only about 15% of patients requiring a pacemaker. Nonetheless, the hope is that this new generation of pacemakers will improve safety, comfort, and quality of life for some patients compared to existing devices. Two companies are in the race to the U.S. market with a leadless pacemaker: St. Jude Medical, Inc. (St. Paul, MN, USA) makes the Nanostim™ Leadless Pacemaker, and Medtronic, plc (Dublin, Ireland) makes the Micra™ Transcatheter Pacing System (TPS). Both devices have received the CE mark within the past two years and are commercially available in Europe, but not in the United States, where late-phase clinical trials are ongoing to generate data for premarket approval submissions to FDA.

Nearly 3 million U.S. patients had a pacemaker implanted between 1993 and 2009, with overall pacemaker use increasing by 56% during that period, according to a recently published [article](#) on trends in permanent pacemaker implantation reports. Although pacemaker use in most patients is uneventful, about 4% of patients encounter device-related complications, including lead migration, other lead failure, or implant-related infection, typically in the subcutaneous pocket housing the pacemaker. Also, implanting the pulse generator subcutaneously in the chest can cause a visible lump or scar and somewhat reduce arm mobility. The leadless single-chamber cardiac pacing devices are implanted directly into the right ventricle via a transcatheter approach. Possible candidates for the devices include patients with permanent atrial fibrillation with bradycardia who meet standard pacemaker indications, patients with sinus rhythm with a low level of physical activity or short expected lifespan, and patients with sinus bradycardia with infrequent prolonged pauses or unexplained syncope.

## Procedure

To implant a leadless pacemaker, an interventional cardiologist, typically an electrophysiologist, inserts the steerable delivery catheter at the femoral vein in the groin or jugular vein and advances it to the apex of the right ventricle under fluoroscopic guidance. The device does not have a separate pulse generator and requires no surgical pocket, like a standard pacemaker. The procedure takes about 30% to 60% of the time required for a conventional pacemaker implantation. The pacemaker is attached using a fixation mechanism, and the pacing and sensing system are tested with the device still connected to the catheter. Once deployed and detached from the catheter, the leadless pacemaker can be repositioned or retrieved if necessary. Generally, the patient is observed for 24 hours before discharge. The battery reportedly lasts from about 9.5 years up to 15 years, depending on pacing parameters.





Nanostim Leadless Pacemaker.  
Image provided courtesy of St. Jude Medical.

## WHAT TO DO

- ▶ Meet with the interventional cardiovascular team about whether to be an early adopter.
- ▶ Monitor FDA regulatory decisions expected in 2016.
- ▶ Monitor results of ongoing pivotal trials for both devices.
- ▶ If adopting, plan sufficiently for necessary staff training time.
- ▶ Be alert to individual product warnings regarding patient selection, device repositioning after fixation, and long-term safety.
- ▶ Verify reimbursement status with payers in your geographic area.

## Evidence Story

Nanostim is being tested in a 650-patient, 56-center, single-arm trial (LEADLESS II study) in the United States, Australia, and Canada. In September 2015, Reddy and colleagues published a [report](#) on the 300 patients in this study who had reached the 6-month primary endpoint. The primary efficacy endpoint was acceptable pacing threshold and sensing amplitude through six months. The primary safety endpoint was freedom from device-related serious adverse events through six months. The primary efficacy endpoint was met in 270 patients (90%), and the primary safety endpoint was met in 280 of 300 patients (93.3%). Device-related serious adverse events included device dislodgement with percutaneous retrieval (1.7%), cardiac perforation (1.3%), and pacing-threshold elevation requiring percutaneous retrieval and device replacement (1.3%).

In February 2015, St. Jude Medical temporarily suspended new Nanostim device implants in a postmarket clinical follow-up study in Europe because of incidents of pericardial effusion. After analyzing interim data from clinical trials, the company announced in July 2015 that enrollment in the study could resume at 10 trial sites after approval of amended protocols and retraining of implanting surgeons by St. Jude Medical. Factors identified as possibly contributing to the pericardial effusion events during the implant procedure were related to patient selection and implant technique (e.g., device repositioning after fixation).

A prospective, single-arm, 780-patient, 56-center (30 in the United States) study is evaluating the safety and long-term performance of the Micra TPS. Study completion is expected in 2016. In June 2015, Ritter and colleagues published an interim [report](#) on 140 patients from 23 centers in 11 countries. The primary safety endpoint was >85% freedom from unanticipated serious adverse device events and three-month mean pacing capture threshold. Patients received the implant to treat atrioventricular block or sinus node dysfunction. The safety endpoint was met during mean follow-up of  $1.9 \pm 1.8$  months, and no unanticipated serious adverse device events had occurred.

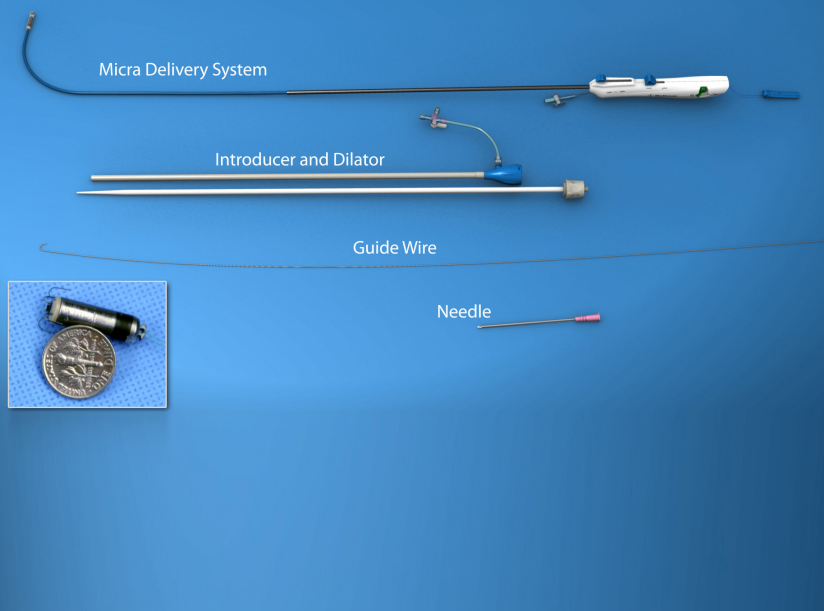


Long-term safety of these devices remains a concern. Authors of an August 2015 [review](#) noted that “although leadless pacemakers are reportedly retrievable at the time of implantation, the ability to remove an implanted device over the longer term remains untested in humans.” Thus, the strategy for device management after battery depletion is unknown.

## Cost Equation

According to ECRI Institute’s PriceGuide™ database, the average price paid for the Nanostim leadless pacemaker, as reported by member hospitals, was \$9,000, and the average price for the Micra TPS was \$9,500. A recent [review article](#) estimated additional procedure implantation costs of about \$4,000/case. In Australia, the Health Policy Advisory Committee on Technology in a July 2015 [report](#) on leadless pacemakers indicated that costs were nearly three times higher than for conventional pacemakers.

A 2014 article by two cardiologists reported that lack of billing codes specific to leadless pacemakers caused many centers participating in U.S. clinical trials to perform procedures at a financial loss. Trial sites reported difficulty securing adequate reimbursement to cover the costs for leadless pacemaker implantation from local Medicare contractors, with many cases reimbursed under a code designated for a conventional single-chamber pacemaker with lead implantation. However,



Micra Transcatheter Pacing System.  
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Micra is investigational and not yet approved for commercial use.

in January 2015, the American Medical Association established specific temporary Current Procedural Terminology (CPT) codes that describe transcatheter insertion or replacement of a leadless pacemaker, transcatheter removal of a leadless pacemaker, and in-person programming and interrogation evaluations. These temporary codes facilitate data collection and set the stage for introduction of permanent codes to facilitate reimbursement if FDA approves leadless pacemakers.

### Related ECRI Institute Publications

- ▶ **Health Technology Forecast News Brief.** September 2015, Good Pacing, Sensing Results Reported for Leadless Cardiac Pacemaker.
- ▶ **Health Devices Alerts.** July 2015, St. Jude Medical—Nanostim Leadless Pacemakers and Delivery System Catheters: Manufacturer Reinitiates Postmarket Clinical Follow-up Study at Select Centers and Updates IFU.
- ▶ **Product Brief.** January 2014, Nanostim Leadless Pacemaker (St. Jude Medical, Inc.) for Managing Cardiac Rhythm.

# 5 Blue-violet LED Light Fixtures: Can the Flip of a Switch Help Prevent Healthcare-acquired Infections?

Maybe. A new light fixture has recently become available that uses continuous environmental disinfection technology to continuously kill harmful bacteria linked to healthcare-acquired infections, including methicillin-resistant *Staphylococcus aureus*, *Clostridium difficile*, and vancomycin-resistant *Enterococcus*. In June 2015, Kenall Manufacturing (Kenosha, WI, USA) introduced Indigo-Clean™, a light-emitting diode (LED) light fixture intended to replace standard overhead LED light fixtures in healthcare settings. Healthcare-acquired infections (HAIs) are a major cause of morbidity, mortality, and increased healthcare costs in the United States, and reimbursement penalties for HAIs continue to make this a top issue for health facilities. According to the U.S. Centers for Disease Control and Prevention, about 2 million HAIs occur each year, resulting in 100,000 deaths and \$28 billion to \$45 billion in excess healthcare costs.

## Continuous Disinfection: A Possible Solution

Current environmental surface disinfection and use of ultraviolet light robots are methods that can miss some surfaces and have short-lasting results. Also, these methods make patient areas unavailable for use during disinfecting procedures. The Indigo-Clean High-Intensity Narrow-Spectrum Light Environmental Disinfection System continuously emits blue-violet light at a wavelength (i.e., 405 nm) that has demonstrated antibacterial and antiviral activity. According to a recent [press release](#), Indigo-Clean operates continuously and requires no operator; it purportedly “kills bacteria in the air and on all surfaces and complies with all internationally recognized standards for patient safety.” Exposure purportedly poses no risk to patients or staff. Three different [product configurations](#) (i.e., Blended White, Indigo-only, Switchable White/Indigo) are available to suit different needs. According to the manufacturer, “Indigo-Clean is especially suited for entryways and waiting rooms, places that are difficult to clean continuously,” and in areas where patients with compromised immune systems are situated.

## Evidence Story

Evidence from a published [report](#) of three studies conducted at the Glasgow Royal Infirmary, Scotland, suggests that Indigo-Clean use reduces bacterial contamination levels in some settings beyond that achieved by standard cleaning and infection control measures. Maclean et al. (2010) carried out 3 studies at the large tertiary referral center’s 13-bed burn unit. They evaluated the technology in the burn unit isolation rooms, assessing efficacy using contact agar plate sampling and enumeration of *Staphylococcal* bacteria on environmental surfaces before, during, and after Indigo-Clean operation. Indigo-Clean use resulted in about 90% reduction of surface bacterial levels when the room was unoccupied and resulted in 56% to 86% reductions when the room was occupied by a MRSA-infected burn patient. Another of these three studies showed that Indigo-Clean reduced surface bacterial levels by 62%, and this reduction was not maintained two days after the system was turned off. Reductions of *Staphylococci* bacteria with use of Indigo-Clean were greater than those achieved by normal infection control and cleaning activities alone.

From the same institution’s burn unit, Bache et al. (2012) published [results](#) of the technology’s use in inpatient rooms and the outpatient burn clinic. For the inpatient study, Indigo-Clean was continuously operated in a patient-occupied room in a burn unit for 14 daylight hours for 2 days and then turned off for 2 days. This cycle was repeated for three weeks. For the outpatient study, Indigo-Clean was continuously operated for eight hours during burn clinic visits. Researchers collected more than 1,000 environmental samples from inpatient isolation rooms and the outpatient burn clinic and compared bacterial contamination levels with and without Indigo-Clean use. Authors reported that the inpatient study found a significant reduction of 27% to 75% in the average number of bacterial colonies after Indigo-Clean use. The outpatient study demonstrated a 61% reduction in bacterial contamination on room surfaces.





Image provided courtesy of Kenall Manufacturing.

## WHAT TO DO

- ▶ Consult with infection control specialists in your organization to weigh the cost-effectiveness of adopting this technology broadly and the patient areas that might benefit most.
- ▶ Test lights in a few patient rooms before wide implementation.
- ▶ Early evidence shows significant reductions in bacteria loads, but no data are available yet on actual reductions in patient infection rates.
- ▶ Monitor results of ongoing trials at facilities enrolled in the company's clinical partners program.

Another [publication](#), by Maclean et al. (2013), reported results of a study conducted during daylight hours in a patient-occupied intensive care unit (ICU) isolation room. Investigators assessed bacterial contamination levels before, during, and after Indigo-Clean use. Authors reported bacterial contamination reductions on almost all contact surfaces during use of the Indigo-Clean system and significant reductions in overall bacterial contamination around the room, with bacterial counts reduced by up to 67%.

## Cost Equation

According to U.S. Healthcare Cost and Utilization Project data, HAIs add an estimated 19.2 hospital days and \$43,000 in costs to care for every affected patient. HAIs also result in significant financial penalties (i.e., lower Medicare reimbursements). A discussion on the [manufacturer website](#) implies that preventing a single HAI by adopting Indigo-Clean could create a positive return on investment for health systems. The company provides a [clinical partners](#) program to assist hospitals in evaluating this technology's performance and cost-savings potential.



## Related ECRI Institute Publication

- ▶ **Health Technology Trends.** January 2016, Seeing the Light: Can Violet-blue Light in Hospital Rooms Reduce Infections?

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# New High-cost Cardiovascular Drugs: Will They Help Your Readmission Rates?

With growing trends to hold health systems responsible for patient care in and out of the hospital and to prevent readmissions, three newly approved cardiovascular drugs intended for use in homecare settings should be on your radar. The three drugs fall into two new drug classes that received FDA approval in mid-2015 with much attention about their efficacy and high costs as they launched in late 2015. One class called PCSK9 inhibitors treats low-density lipoprotein cholesterol (LDLc) that is resistant to the standard statins. The other class—angiotensin receptor neprilysin inhibitors—treats heart failure (HF). Available short-term data for these drugs have been impressive, but some are concerned about their high cost and long-term safety and efficacy.

## Will New PCSK9 Injectables Supplant Statins?

Experts estimate that 10% to 20% of the 34 million Americans with very high cholesterol cannot tolerate the high statin doses they need, and about 620,000 people have 1 of 2 types of inherited familial high cholesterol (either heterozygous familial hypercholesterolemia or the rarer homozygous familial hypercholesterolemia) that does not respond well to statins. These patients need a better option than the familiar statin drugs. The new drugs, known as PCSK9 inhibitors, enable the liver to get rid of bad cholesterol—LDLc—and FDA approved the first two in summer 2015: alirocumab (Praluent<sup>®</sup>, comarketed by Sanofi-Aventis, Bridgewater, NJ, USA, and Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA) and evolocumab (Repatha<sup>™</sup> marketed by Amgen, Inc., Thousand Oaks, CA, USA). The drugs are self-injected using injector pens preloaded with the appropriate dose. Both showed some remarkable results in short-term randomized controlled trials, lowering bad cholesterol by up to 60%. Although rare, allergic reactions (i.e., rash, hives, hypersensitivity vasculitis) that required discontinuing treatment have been reported with their use. FDA also expressed concern about potential neurocognitive adverse events. No completed clinical trials monitored these adverse events as a primary outcome. However, preliminary pooled safety data from about 4,500 patients enrolled in long-term Repatha studies reported that neurocognitive events, including delirium, cognitive and attention disorders, dementia, and memory impairment, were reported in less than 1% of patients. Multiple ongoing trials are assessing long-term safety and effectiveness, but results are not expected until about 2017. An additional PCSK9 inhibitor, bococizumab (Pfizer, New York, NY, USA), is under study in phase II/III clinical trials and could reach market by 2018.

## Will New Oral Heart Failure Drug Supplant ACE Inhibitors?

In July 2015, FDA approved Entresto<sup>™</sup> (Novartis Pharmaceuticals Corp., Basel, Switzerland) for treating patients with New York Heart Association class II-IV heart failure. It is the first HF drug to be approved in 20 years. The drug would be prescribed instead of standard drugs known as angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers for chronic HF. The new drug may offer stiff competition to these long-standing drugs. FDA approved the drug based on data from the [PARADIGM HF](#) trial of 8,442 patients. The drug showed a clear survival advantage over the ACE inhibitor, enalapril. Entresto achieved a 20% reduction in risk of death from cardiovascular causes compared to enalapril, and fewer patients were hospitalized for HF. The drug showed such improvement in patient outcomes, it was stopped early after a median follow-up of 27 months so everyone could receive Entresto.



Photo courtesy of Shutterstock.

## WHAT TO DO

- ▶ Because of the high costs of these drugs, be careful about patient selection and possible financial impact on patients.
- ▶ Cardiac care staff will need to teach patients self-injection techniques and appropriate disposal of injectors.
- ▶ Warn patients to seek immediate medical attention if they experience symptoms of a serious allergic reaction.
- ▶ Watch for results of multiple ongoing trials assessing long-term safety and effectiveness of these agents.

## The Cost Equation

These three new drugs are expensive compared to existing standard-of care-medications. As of November 2015, prices from 11 national pharmacy chains listed 5 syringes (140 mg per syringe) of Repatha at prices ranging from about \$2,700 to \$2,900, for a total annual cost of about \$14,500. Out-of-pocket costs to patients could be substantial depending on insurance status and eligibility for patient assistance. The Institute for Clinical and Economic Review (ICER) (Boston, MA, USA) issued a [report](#) in September 2015 concluding that these drugs would be cost-effective if priced at about 15% of their current price—\$2,180 a year/patient. ICER also concluded that at current pricing, even if only 25% of eligible patients took the drugs, about \$100 billion would be added to U.S. healthcare costs over five years. The high cost has spurred payers to require several conditions and prior authorization for coverage on their formularies.

Entresto will cost about \$12.50 per day (~\$4,500 a year), which is much higher than the \$1-per-day cost of existing HF medications. The *Wall Street Journal* [reported](#) that Novartis is considering providing value-added HF management services to boost uptake of the drug, such as remote patient-monitoring devices. A Novartis spokesperson [told](#) the *New York Times* it may negotiate a risk-sharing agreement with some health plans. But if it provides better control and keeps patients out of the hospital, it might prove cost-effective.

### Related ECRI Institute Publications

- ▶ **Health Technology Forecast Technology Profile.** December 2015, PCSK9 Inhibitors for Treating Hypercholesterolemia.
- ▶ **Health Technology Forecast News Brief.** July 2015, New Heart Failure Drug to Compete with ACE Inhibitors.

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# 7 Changing Landscape of Robotic Surgery: Is a Mainframe to Tablet-type Paradigm Change Coming?

With the upcoming decommissioning of the da Vinci® S model (Intuitive Surgical, Inc., Sunnyvale, CA, USA) and the fact that numerous hospitals' Si models are reaching the end of their useful life, C-suite and surgery leaders are assessing their robotic surgery programs and planning for future growth and technology platforms. The landscape of robotic surgery is changing rapidly—not only with da Vinci's new robotic surgery models and expanding clinical indications, but also with imminent competition expected to enter the market in early 2016, as well as other options in the next couple of years that may make you want to hit the “pause” button on these capital equipment purchasing decisions.

Since Intuitive Surgical introduced its da Vinci Robotic Surgical System more than 15 years ago, robotically assisted surgery use has surged. Now, more than half a million robotic surgeries are performed globally each year, and more than 2,300 da Vinci systems are installed in the United States. Robotic surgery programs have become commonplace at many hospitals. While the technology is not new, planning for it now requires a new approach.

## More Options Than Before

Intuitive Surgical offers three robotic surgery systems: the da Vinci Xi (the newest of the three introduced in 2014), the da Vinci Si, and the da Vinci Si-e. The Xi is the next-generation system following—though not replacing—the da Vinci Si and da Vinci Si-e. These models have distinct differences that play an important role in determining how each model may best suit different robotic surgery programs. When deciding which robot to purchase, surgical program leaders have to consider how it will be used. The following table provides a functional overview of these three available systems.

### Key Features of the Different da Vinci Models

Key Features	Xi	Si	Si-e
Number of robotic arms	4	4	3
Single-site surgery	*	✓	✓
Overhead boom	✓		
Laser targeting guidance	✓		
Compatible instruments		✓	✓
Large surgical field procedures	✓	✓	
Fluorescence imaging	Standard	Optional	Optional

\* Awaiting FDA approval

Table extracted from ECRI Institute's Robotic Surgery Infographic (2015).

No one size fits all. If your hospital is implementing a new robotically assisted laparoscopic surgical program—or expanding with a second or third robot—the intended surgical use is a major consideration in selecting which platform to acquire. Issues such as surgical field of view, required range of motion, single- or multiple-incision laparoscopic surgeries, and image guidance needs are a few of the areas that you will need to evaluate before deciding which system is most appropriate for your surgical needs, as well as what other new systems from other vendors may be able to meet your program's needs.





Photo courtesy of Shutterstock.

## WHAT TO DO

- ▶ If creating or expanding a robotic surgery program, determine whether you can wait to see what the competition brings in 2016.
- ▶ If you have the da Vinci S model, decide whether and when you want to replace it with another da Vinci model or whether to wait for new developments.
- ▶ Identify your potential patient populations for robotic-assisted general surgery indications, including single-site laparoscopic surgeries, and decide whether da Vinci is the way to go or whether to wait for one of the new entrants into this space.
- ▶ Because of the significant capital investment, C-suite and surgery leaders must ensure that costs are managed with a nuanced analysis of the cost-effectiveness of procedures and processes, robotic-specific consumables, staff efficiency, and operating-room-time optimization. Just because a surgery can be done using robotic assistance does not mean it is in the patient's or hospital's best interest to do so!

## The Frontier: Robotic-assisted General Surgery

Prostatectomy and hysterectomy account for nearly 75% of all robotic-assisted surgeries in the United States, according to Intuitive Surgical. However, both procedures are approaching saturation levels. As this has occurred, Intuitive Surgical has shifted its attention to other clinical indications in general surgery and other types of cancer surgery. Procedures being targeted with the new Xi model include colorectal cancer surgery, mitral valve repair and replacement, cardiac revascularization, lobectomy, partial nephrectomy, single-site cholecystectomy, and hernia repair. Accordingly, the number of general surgery cases performed robotically is increasing from 40,000 cases in 2012 to more than 100,000 cases in 2014. This trend is expected to continue as new surgeons emerge from training with experience in robotic-assisted procedures and seek surgery privileges in health systems with robotic surgery machines.

## Near and Far Horizon

For more than 15 years, Intuitive has been the only commercially available multipurpose robotic surgery system vendor. However, competition may finally enter the U.S. market in the next few years. Two of the most likely candidates to challenge Intuitive Surgical's dominance in the near term are Titan Medical, Inc. (Toronto, Ontario, Canada), developer of the SPORT™ (Single Port Orifice Robotic Technology™), and TransEnterix, Inc. (Morrisville, NC, USA), developer of SurgiBot™. Both companies have focused on introducing single-site surgery robotic systems designed to be less expensive alternatives to da Vinci systems. These systems may prove to be viable options for several procedures, including general surgery such as cholecystectomy, appendectomy, as well as ear, nose, and throat procedures.

TransEnterix submitted a 510(k) premarket notification to FDA in June 2015 for the SurgiBot and anticipates clearance in early to mid-2016. The system is intended to be mobile and require fewer staff to operate. TransEnterix also announced in September 2015 that it had acquired the surgical robotics division of Sofar S.p.A., an Italian healthcare company. Sofar has developed the Telelap ALF-X® advanced robotic system for minimally invasive surgery, which has an active CE mark but is not currently available in the United States. Titan Medical targets entering the U.S. market within two years.

In March 2015, Google and Johnson & Johnson's (J&J) Ethicon subsidiary [announced](#) a partnership to develop a new robotic surgery platform that includes real-time imaging, and in December 2015 J&J [announced](#) a new company, Verb Surgical, Inc., an independent surgical solutions company that will work in collaboration with Verily Life Sciences LLC (formerly Google Life Sciences). They intend to leverage Google's analytics to create a next-generation robotic-assisted surgical platform that they assert will be smart, connected to other data sources, have a smaller footprint enabling surgeons to get closer to the patient, and be less costly. J&J's worldwide chairman of medical devices, Gary Pruden, likened the plan to going from a mainframe computer of 50 years ago to an iPad today when [reporting 2015 Q3 results and earnings](#) to investors in October 2015.

Indication-specific surgical robots are also on the market for orthopedic joint replacement (MAKOplasty® Surgical Robot, MAKO Surgical Corp., Fort Lauderdale, FL, USA) and neurosurgeries, which the da Vinci and other general surgery robots in development are not intended for. If your hospital is not in immediate need of a new surgical robot, you may wish to consider waiting a few years to see whether any new additions enter the surgical robot marketplace.

### Related ECRI Institute Publications

- ▶ **Product Brief.** August 2015, MAKOplasty Robotic-assisted Partial and Total Knee Replacement (MAKO Surgical Corp., a Division of Stryker Corp.) for Treating Osteoarthritis.
- ▶ **Health Technology Trends.** May 2015, Google, Johnson & Johnson Partner for Future Robotic Platform.
- ▶ **Product Brief.** February 2015, da Vinci Xi and Si Surgical Systems (Intuitive Surgical) for Minimally Invasive Colorectal Cancer Surgery, Hernia Repair, and Mitral Valve Repair.
- ▶ **Health Technology Forecast.** October 2014, da Vinci Robotically Assisted Surgery for Performing Laparoscopic Procedures.
- ▶ **Health Technology Trends.** October 2014, Move Over da Vinci; Robotic Surgical Competition Is Lining Up at the Gate.

# 8 Spectral Computed Tomography: What's the New Hype About?

Spectral computed tomography (CT) is not new, but people are talking about it more these days because vendors have recently developed specific spectral technology and tools and have often heavily marketed such developments. The technology does not yet have a solid foundation of evidence demonstrating its purported benefits for various clinical applications that lead to improved diagnosis and patient management, despite more than 10 years of availability. Its purported benefits include promise of improved soft-tissue contrast and tissue characterization. Healthcare organizations considering acquiring spectral CT scanners should ensure that the configuration they choose will support a broad range of general CT applications because those other scans may help defray the high procurement and maintenance costs of spectral CT scanners.

## How Does It Differ from CT?

Despite being ubiquitous in healthcare facilities, CT technology capability is limited because it images structural anatomy, not physiologic function. To assess functionality, clinicians turn to magnetic resonance imaging or positron emission tomography (PET). CT vendors have been trying for years to develop cost-effective, clinically effective CT functional imaging capability that improves CT's soft-tissue discrimination and ability to aid diagnosis of small soft lesions. Spectral CT has potential to do this. Instead of using one broad energy band of x-rays, as does conventional CT, spectral CT separates the energy into two or more narrow energy bands. These energy bands are absorbed differently by different tissues. Spectral CT images are reconstructions of two or more sets of spectral absorption values measured during a scan. The absorption values may also be used to provide chemical composition maps of the tissue. The spectral information may be blended over the image data sets to improve soft-tissue contrast. Spectral CT can also improve visualization of contrast-enhanced CT and eliminate metal streak artifacts from CT images.

A conventional CT scanner can perform spectral CT only if two separate scans are performed over the same body part: one scan at a low-energy setting and the other at a higher energy setting. This approach presents problems, however. A notable time elapses between scans; two scans may increase patient radiation dose; and the two scans may not align (coregister) exactly as needed because of patient movement, vascular processes, and the ebb and flow of contrast media.

## Possible Clinical Indications and Purported Benefits

Appropriateness criteria for spectral CT have not yet been established. Therefore, centers using spectral CT should ensure their radiologists have a role in establishing criteria for appropriate use of spectral CT. Many consider much of the current use to be investigational and not routine.

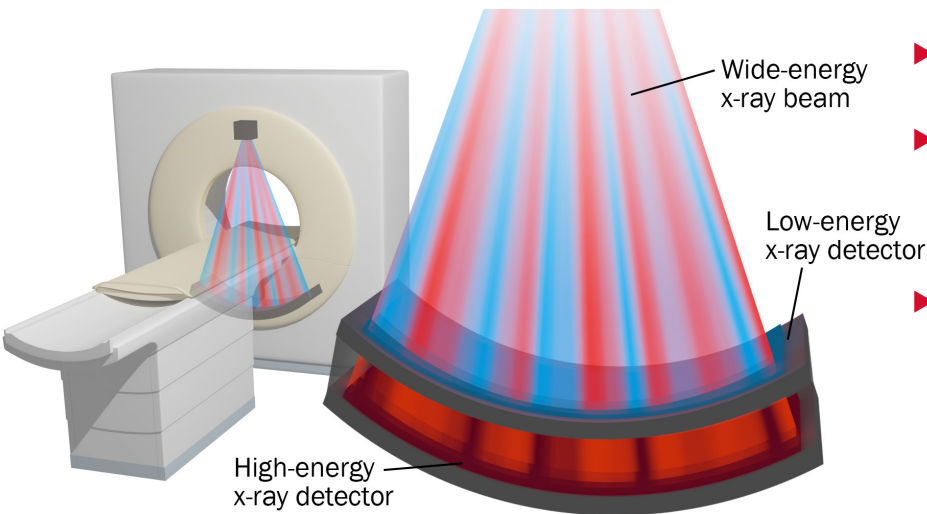
The main purported advantage of spectral CT is that it allows for some tissue differentiation. Also, soft-tissue contrast may improve, which will then allow the use of virtual techniques to remove bone or contrast from tissue of interest; this could potentially eliminate noncontrast imaging from multiphase CT exams.

Abdominal spectral CT imaging is an active area of investigation because suspicious lesions in soft-tissue organs, such as the liver, pancreas, and kidney, may be hard to diagnose and might benefit from use of spectral chemical decomposition. One example is when a clinician needs to distinguish cysts from tumors in the kidney.

Some think dual-source CT scanners for cardiac exams have shown potential for detecting myocardial ischemia and assessing myocardial viability. However, despite more than 10 years of clinical availability, published dual-source CT cardiac clinical studies are few, and traditional, well-established diagnostic tools remain in place, such as echocardiography, single-photon emission computed tomography, PET, and cardiac catheterization.

## WHAT TO DO

- ▶ Spectral CT scanners currently are best suited for facilities performing clinical research activities.
- ▶ No upgrade path is available to add spectral CT capability to existing CT scanners.
- ▶ If interested in spectral CT, consider it as a replacement for aging CT machines.
- ▶ If properly configured, spectral CT affords performance of all advanced CT procedures (e.g., cardiac, brain perfusion) as well as routine CT procedures.
- ▶ No additional reimbursement is provided by payers for spectral CT, so payers must absorb its higher costs.



## Models with Spectral CT Capability

Over the last few years, manufacturers have developed three ways to improve spectral CT capability. The most recent and novel spectral CT capability is the IQon Spectral CT model line (Philips Healthcare, Amsterdam, The Netherlands), which uses a dual-layer (one atop the other) detector. The low-energy band within a broad-energy x-ray beam is absorbed and read in the top layer, and the remaining higher energy band penetrates to and is absorbed and read in the bottom layer. Therefore, the dual-detector (one x-ray tube and one dual-detector array) “creates” the two different energy bands and absorbs them individually during a single coregistered scan.

The CT750 HD and Revolution CT scanners (GE Healthcare, Little Chalfont, U.K.) reuse “Gemstone” detectors, which can rapidly read enough to measure and record the absorption of two or more energy bands in a short interval. A single x-ray tube then switches rapidly between two different energy settings. The switching time is fractions of a millisecond. While the scans are sequential rather than coregistered, the time interval is very short. The CT750 HD also comes in a configuration marketed as a cardiac spectral CT scanner.

Siemens Healthcare GmbH’s (Erlangen, Germany) spectral CT capability is embedded in its dual-source CT scanner model lines, which began with the Somatom Definition Flash CT scanner 11 years ago. Siemens’ modern dual-source CT scanner, the Somatom Force model line, has two x-ray tubes and two separate detector arrays. Therefore, these dual-source scanners generate two different energies simultaneously and detect those two energy absorption values during a single scan. While the original dual-source scanner was primarily designed for cardiac and emergency CT needs, it is also a straightforward implementation of the essential needs for spectral imaging. Of course, the challenge is the need for two CT x-ray tubes with two x-ray generators and two CT detector arrays, which raises costs of procurement and maintenance.

## Workflow and Patient Care Challenges

Current spectral CT scanners allow spectral imaging in one scan, which does not increase exam times or workload for CT technologists. However, using a variety of different CT image sets to reconstruct and read an image may present some challenges for the interpreting radiologists. Also, archiving these spectral CT image sets in the picture archiving and communication system may present a challenge. Certainly, careful patient selection for spectral CT is important and indicated by the clinical condition, as documented in the exam referral, and standardized CT scan protocols would be needed.

## Cost Equation

Spectral CT scanner costs range from \$1.6 million to \$2.2 million, plus the cost of ongoing maintenance. These scanners represent the higher tier of CT scanner technologies, not only because of spectral CT but also because these scanners have large volumetric imaging, fast gantry rotation, advanced dose-reduction features, and advanced image reconstruction and display tools. No additional reimbursement is available for use of spectral CT, so the added costs of its use and maintenance over conventional CT scanners are born by the facility.

## Related ECRI Institute Publications

- ▶ **Healthcare Product Comparison System.** September 2015, CT Scanners Comparison Chart.
- ▶ **Product Brief.** January 2015, Somatom Definition Flash (Siemens AG) for Performing Premium Computed Tomography.
- ▶ **Health Devices Evaluation.** April 2014, GE Healthcare Discovery CT750 HD FREEdom Edition Premium CT System.
- ▶ **Health Devices Guidance.** March 2014, The Latest and Greatest Features for Premium CT.



# 9

## Injected Bioabsorbable Hydrogel (SpaceOAR): An End to Some Radiation Therapy Complications?

A newly approved product may help some of the 220,800 U.S. patients with newly diagnosed prostate cancer in 2015 and beyond. Many patients with prostate cancer undergo radiation therapy, which can damage adjacent tissue and healthy organs, causing lifelong complications. For many years, clinicians have used hydrogel products as sealants and adhesion barriers to protect the most sensitive body parts. Now a new bioabsorbable hydrogel technology called the SpaceOAR® System (OAR stands for “organ at risk”) (Augmenix, Inc., Waltham, MA, USA) is available and intended to protect the rectum of patients with prostate cancer who are receiving radiation therapy. Most prostate cancers arise adjacent to the rectum, and in about 20% of patients, radiation therapy injures the rectum, causing pain, diarrhea, urgency, and bleeding. Until now, the risk of rectal injury has limited use of advanced radiation therapy protocols for prostate cancer, including hypofractionation (more prostate radiation for improved cancer kill rates), dose escalation (fewer radiation treatment sessions), and salvage radiation (radiation therapy given after cancer recurrence).

### Will It Be Coming Soon to Your Cancer Center?

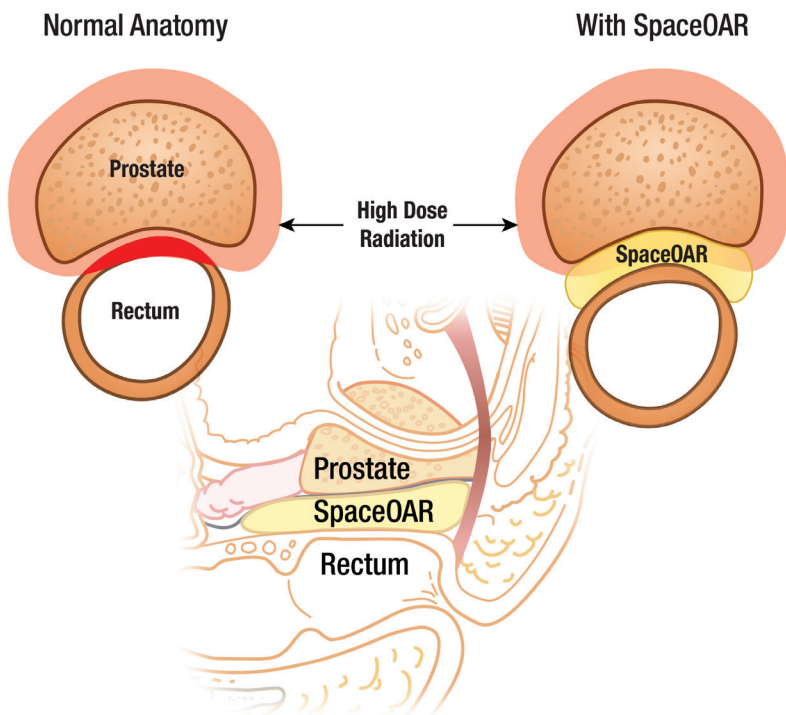
In April 2015, FDA granted a de novo clearance for the SpaceOAR System, and Augmenix announced it planned to train physicians in 20 to 30 centers by the end of 2015. In June 2015, a company [press release](#) cited “overwhelming demand from clinicians to receive training.” The company is attempting to meet this demand while providing support to new customers and enabling much broader adoption in 2016.

The SpaceOAR System temporarily positions the anterior rectal wall away from the prostate during radiation therapy, creating space to protect the anterior rectum from radiation exposure. Patients undergoing the procedure require local or general anesthesia or intravenous sedation. Using transrectal ultrasound for guidance, a urologist or radiation oncologist injects the liquid hydrogel through the perineum. The liquid hydrogel solidifies, creating an expandable soft gel that enlarges the space between the prostate and the rectum, creating a separation of about 1 cm. The spacer maintains separation for up to three months after injection, and then it returns to a liquid state that the body absorbs in about six months and expels through the urine.

### Evidence Story

A multicenter randomized controlled trial at 20 centers enrolled 222 men with T1/2 localized prostate cancer to compare SpaceOAR use during image-guided intensity-modulated radiation therapy (IMRT) with IMRT and no SpaceOAR. Mariados et al. [published results](#) of this trial in August 2015. Of the enrolled patients, 149 were randomly assigned to the spacer group, and 73 were randomly assigned to the control group; 219 (98.5%) completed the required follow-up at 15 months. The primary outcomes assessed were spacer safety and impact on rectal irradiation, toxicity, and quality of life. The study reported a 99% hydrogel placement success rate. Clinicians using the spacer rated its application as “easy” or “very easy” 98.7% of the time. No device-related adverse events occurred, and overall acute rectal adverse event rates were similar between groups. Of patients receiving SpaceOAR, 97.3% had a 25% reduction in the rectal volume that received at least 70 Gray of radiation. The spacer group reported a significant decrease in late rectal toxicity; no spacer patients experienced grade >1 late rectal toxicity. At 12-month follow-up, clinicians performed MRI scans and verified that spacer absorption had occurred. At 15-month follow-up, fewer patients in the spacer group experienced 10-point declines in bowel quality of life than in the control group (11.6% vs. 21.4%).

## Rectum and Prostate Movement



SpaceOAR System.  
Reprinted with permission from Augmenix, Inc.

## WHAT TO DO

- ▶ Despite reported clinician enthusiasm and demand for SpaceOAR, reimbursement is limited at this time, as the company mounts efforts to obtain codes, reimbursement rates, and coverage policies from Medicare and U.S. third-party payers.
- ▶ Cancer centers adopting this technology will need to create protocols for spacer use.
- ▶ Centers will need to include patient education materials about this option.
- ▶ The SpaceOAR application procedure may require an ultrasound technologist and anesthesia professional.

## Cost Equation

SpaceOAR costs in the United States have not been reported yet. SpaceOAR has been commercially available in Europe since 2010 and is also listed in the Australian Register of Therapeutic Goods. In Europe, reported pricing of a single SpaceOAR injection is about €1,700, or \$1,877 (at November 2015 exchange rate). Procedure charges, including those for anesthesia care, add to overall costs of radiation treatment but may be offset by downstream costs of avoided adverse events.

Despite the company's assertion of high demand, reimbursement by private payers is limited in the United States; many private payers make no mention of SpaceOAR in their policies, and others list SpaceOAR as "investigational," although many of those policies predate the FDA clearance. To facilitate reimbursement, the U.S. Centers for Medicare & Medicaid Services (CMS) issued a new HCPCS code describing the procedure (i.e., C9743, injection/implantation of bulking or spacer material with or without image guidance), which became effective October 2015. CMS has established a 2016 national payment rate of \$1,254.53 for this code. Discussions with private payers concerning reimbursement are ongoing.

## Related ECRI Institute Publications

- ▶ **Health Technology Trends.** January 2016, Hydrogel Spacer Offers Rectal Protection During Radiation Treatment for Prostate Cancer.

# 10 Warm Donor Organ Perfusion Systems: Will They Ease the Organ Supply Shortage?

Did you know that about two-thirds of donor lungs and hearts obtained in hospitals are never used? That's because the process of harvesting, preserving, and transporting donor organs can damage organ suitability for transplantation. New technology—the Xvivo Perfusion™ System (XPS) and Organ Care™ System (OCS)—offers the promise of increasing the viability of donated lungs and hearts—and eventually other organs such as the liver—for transplantation. The technology uses machines that provide warm perfusion of donated organs rather than conventional cold storage (i.e., portable cooler with organ on ice) after organ harvesting. The new method, when used on lungs, is called normothermic ex vivo lung perfusion (EVLV). It is intended to mimic the physiologic activity of lungs. If the technology could double the number of donated lungs suitable for transplantation, all patients on U.S. wait lists for lungs might have their needs met.

## Regulatory Story and Diffusion

In August 2014, FDA approved the first of two systems that have been in development—the XPS (XVIVO Perfusion, AB, Göteborg, Sweden) for donor lungs. The system is also in development for preserving donor hearts and livers, according to a recent company [news release](#). XPS is intended to maintain donor lungs in a “near physiologic state” outside the body for four to six hours. As of August 2015, the company reported that 18 U.S. centers had acquired systems; as of October 2015, 3 centers in Europe had acquired the system. Studies are also underway to preserve other organs in a similar way.

The OCS Lung and OCS Heart (TransMedics, Inc., Andover, MA, USA) are commercially available in Europe, and the OCS Heart is expected to be approved in the United States in early 2016. The OCS Heart is being tested at 7 heart transplant centers across the United States and keeps a donor heart functioning (beating) for up to 11 hours, which is about 3 times as long as cold storage. The device is also in development for preservation of livers and kidneys.

## The Procedure

**XPS System:** The XPS is a fully integrated, off-the-shelf cardiac bypass system that includes a centrifugal pump, heater/cooler, ICU-ventilator, gas cylinders, perfusate gas monitor, Steen™ solution pumps, the XVIVO Organ Chamber™ platform, and a touch-screen display and software to monitor the procedure and system as well as capture data. For donor lungs, the XPS continuously flushes the lungs with the solution to evaluate, preserve, and recondition donor lungs that would otherwise not be salvageable for transplantation. The XPS also ventilates lungs, providing oxygen to cells and allowing airway evaluation. Donor lungs can stay in the XPS for up to four hours, allowing the transplant team to evaluate lung function outside the body. Lungs meeting acceptability criteria and passing the transplant surgeon's examination are transplanted into a suitable recipient.

**OCS System:** The OCS Lung consists of a portable, battery-operated console with a wireless monitor, perfusion module, and solution set to deliver nutrients to the preserved donor lungs. Donor lungs are perfused with a solution enriched with two red blood cell concentrates matched to the intended transplant recipient. Clinicians can measure the oxygen concentration in the blood to assess lung function. The OCS Heart is similar, but optimized for preserving donor hearts and keeping them beating until transplantation. It uses an internal oxygen supply and pulsatile pumping system to circulate the proprietary solution containing donor blood through the donor heart to provide oxygen and replenish essential nutrients. A portable console houses all the system components. When physicians harvest the donor heart, they place it in the perfusion module and revive it to a beating state. The self-contained perfusion module maintains the proper temperature and humidity, protects the organ from external contaminants, and allows sterile ultrasound assessment of heart function and sterile blood sampling for laboratory analysis. The wireless monitor allows clinicians to assess the organ's status and control system functions.





XPS System.  
Reprinted with permission from XVIVO Perfusion.

## WHAT TO DO

- ▶ A lung system is now available for donor lungs, and another system is expected to be available for donor hearts in early 2016. Both are also in development for warm perfusion of other donor organs. The technology has potential to double the number of lung and heart transplants, which could increase demands on transplant staff and transplant center infrastructure.
- ▶ The perfusion system costs are high (more than \$200,000) plus disposables and maintenance costs.
- ▶ Consider rental or cost-sharing strategies with other transplant centers.
- ▶ Plan for costs associated with training and ongoing field support.
- ▶ When adopting, time will be needed for training and credentialing of staff to use the systems.

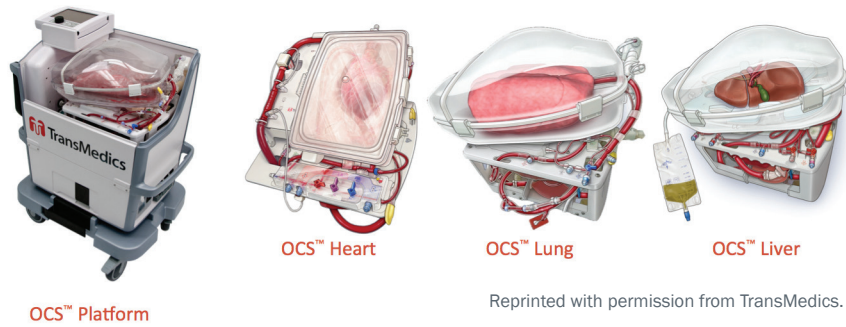
## Evidence Story

**XPS Lung:** In a [single-center trial](#) (NOVEL), 308 patients requiring a lung transplant received lungs preserved with cold storage or XPS, and short-term outcomes were similar between patients. In a [3-center trial](#), 125 donor lungs that were initially deemed unsuitable for transplantation underwent EVLP with XPS. Of these, 103 lungs were subsequently able to be transplanted.

**OCS Lung:** In a [phase III randomized controlled trial](#) (INSPIRE), 320 patients who were registered primary double-lung transplant candidates were randomly assigned to receive a lung from cold ischemic storage or from OCS Lung preservation in a multicenter trial being conducted at 21 U.S., European, and Australian transplant centers. Interim data on the first 136 patients who completed 30-day follow-up showed that patient survival was similar between groups (98% OCS group and 95% cold-storage group). This study also found a 6-month survival benefit in 36 OCS-treated patients (97%) versus 46 standard care patients (87%). No adverse reactions related to OCS Lung use have been reported. The EXPAND lung clinical trial is also ongoing to assess preservation of lungs that may not meet current acceptance criteria.

**OCS Heart:** Two RCTs ([Ardehali et al. 2014](#), [Esmailian et al. 2014](#)) and one uncontrolled comparative study ([Koerner et al. 2014](#)) reported on at conferences or in the peer-reviewed literature indicate that OCS Heart works as well as standard techniques to preserve donor hearts, but definitive data indicating that OCS preservation makes more donor hearts usable or yields better patient outcomes than standard preservation techniques are not available yet. U.S. trials are ongoing. The EXPAND heart trial is ongoing to assess preservation of hearts that may not meet current criteria.

## The OCS™ Platform



### Cost Equation

Costs of system use, per-patient disposables, training, and ongoing support are considerable. ECRI Institute’s PricePaid database indicates that warm donor organ perfusion systems cost between \$225,000 and \$250,000 each. Michigan is an example of one state that shares this cost among several transplant centers. The added per-patient cost for disposables is about \$19,000 for the XPS. In countries where it is commercially available, TransMedics loans OCS Lung preservation equipment to hospitals at no cost if the facility agrees to purchase 10 disposable perfusion sets at \$45,000 each, for a total cost of \$450,000. Hands-on clinical training and support for the OCS Lung is included with the purchase of the system, according to the company. Added costs could eventually be offset by increased revenue from preserving and transplanting more lungs and decreased costs from shorter lengths of stay and reduced complications after transplantation.

### Related ECRI Institute Publications

- ▶ **PricePaid Database.** August 2015, XVIVO Perfusion System (XPS) - Capital Pricing.
- ▶ **Health Technology Forecast News Brief.** August 2014, New Donor Lung Perfusion System Hits U.S. Market, Expected to Increase Useable Donor Lungs.

# There's More than Meets the Eye

The **2016 Top 10 Hospital C-suite Watch List** is just a snapshot of how we can help you keep up with the latest health technology developments in a rapidly changing industry.

Our [Health Technology Assessment Information Service](#) gives you direct access to unbiased evidence-based tools, resources, and consultations from our on-site multidisciplinary staff, and the ability to commission custom rapid reviews on the latest brand-name drugs, health devices, processes, and procedures.

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