Cardiovascular Team: Initial Needs Report

EXSU 620 – Surgical Innovation I

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GLOSSARY

INTRODUCTION

Overview

The first physical evidences of surgery were found during the prehistoric era in the Neolithic: contemporary humans practiced trepanation to, it seems, relieve pain in the cranial box and cure mental disease [1]. Since then, surgery, and more specifically surgical techniques, have evolved into something completely different. Safety and maximizing patient survival are at the forefront of priorities. Thanks to medical discoveries, and more recently thanks to technical progress, new technological innovations on the market allow us to constantly move forward and provide the best patient care.

As a heterogeneous team composed of students in medical sciences and in mechanical, computer or biomedical engineering, we too have explored this process of innovation. We visited various departments within the Glen site of the McGill University Health Centre, including: Medical Device Reprocessing; the Pediatric Plastics Clinic; the Cardiovascular and Pediatric operating rooms; and the Emergency Room. With respect to the operating rooms, we witnessed a craniofacial surgery, an emergency coronary artery bypass graft surgery, and a few transcatheter aortic valve implantation procedures in the percutaneous coronary intervention wing. These opportunities provided the basis for our closer observation, in which we looked for places where innovation could be applied to existing practices.

Criteria

By the time these visits were completed, our group had compiled a total of 99 observed needs that were unmet in the hospital. Following the methodology dictated by the course book, Biodesign: The Process of Innovating Medical Technologies (second edition), we narrowed the total down to 35 needs, and then eventually the top five needs. From Chapter 2.5 of the textbook, “Needs Selection”, we used the Needs Screening template found on page 228 as a guide to narrow down our list of needs. In round one of needs screening, the deciding factors were: (1) whether we were passionate about the need, and (2) the need type (blue sky, incremental, mixed). Then a list of 35 needs went through round two, where each need was scored based on five factors and then those scores were ranked. We chose our final top five needs from the highest rankings. We have now been able to focus our attention on gathering background research on these top five needs. In this report, we present what we have found about each need, and will conclude by choosing the one we think will be the best to continue with.

[1] Brothwell, Don R. (1963). *Digging up Bones; the Excavation, Treatment and Study of Human Skeletal Remains*. London: British Museum (Natural History).

NEEDS

Need #1

Need statement:
A way to overcome the lack of wireless charging for medical devices that require an external power source, such as ventricle assist device (VAD), in patients with congestive heart failure, in order to improve convenience, maintenance, portability and quality of life.

Disease state:
Heart failure (HF) is a global pandemic affecting at least 26 million people worldwide, and is increasing in prevalence. Currently, 5.7 million people in the United States have HF, but the projections are worrisome since it is expected that, by 2030, more than 8 million people will have this condition, accounting for a 46 % increase in prevalence [1].

HF is a condition where the heart's pumping power is lower than the healthy level. In heart failure, blood moves at a slower flow-rate and hypertension occurs in the heart. Consequently, the heart is not capable of pumping demanded oxygen and nutrients to the body. The cardiac muscles respond to this situation either by stretching more, or by becoming stiffer and thicker through the remodeling process. In response to this situation, the kidneys retain more fluid (water), and salt; which results in water build-up in the arms, legs, ankles, feet, and lungs. The term congested and congestive heart failure is used to describe the condition. Some of the congestive heart failure risk-factors are high blood pressure, valve disease, thyroid disease, kidney disease, diabetes, and heart defects [2].

Existing Treatment and Problem:
Doctors and healthcare teams may recommend medication or surgery, and may suggest lifestyle changes such as healthy eating and physical activity. Patients take a combination of drugs. Depending on the severity and nature of heart failure, the doctor may also recommend surgery or device therapy to treat the patient's condition. Heart failure may also be treated with bi-ventricular pacing, depending on the clinical condition. The VADs are small implantable devices that act to compensate the pumping function of the heart and assist in circulating blood throughout the body. Patients with VADs can be discharged from the hospital and have an acceptable quality of life. An LVAD pumps blood from the left, whereas RVAD pumps from the right ventricle towards the body [3]. VAD systems consist of a pump, system controller, power source, power leads, batteries and battery clips, as shown in Figure 1.

Currents VADs must always have power, either from batteries or electricity from the wall outlet. A power module or AC adaptor is used when the patient is not active, like when he or she is watching TV. It must be used when the patient is sleeping. Patients can get up and do things away from the power unit by using a pair of rechargeable batteries. Batteries are fully charged within about four hours. During regular activities like reading a book or walking at normal pace, the battery will last four to six hours. By checking an indicator on the controller, the batteries should be exchanged when their charge falls below 25% capacity. Spare, fully charged batteries should always be available. The literature has shown that having a portable wireless charger, which can be carried by patients and doesn't require connection to an electrical outlet, can provide more convenience in daily life. It would also increase the durability of battery charge, which would eliminate the need to carry backup batteries.

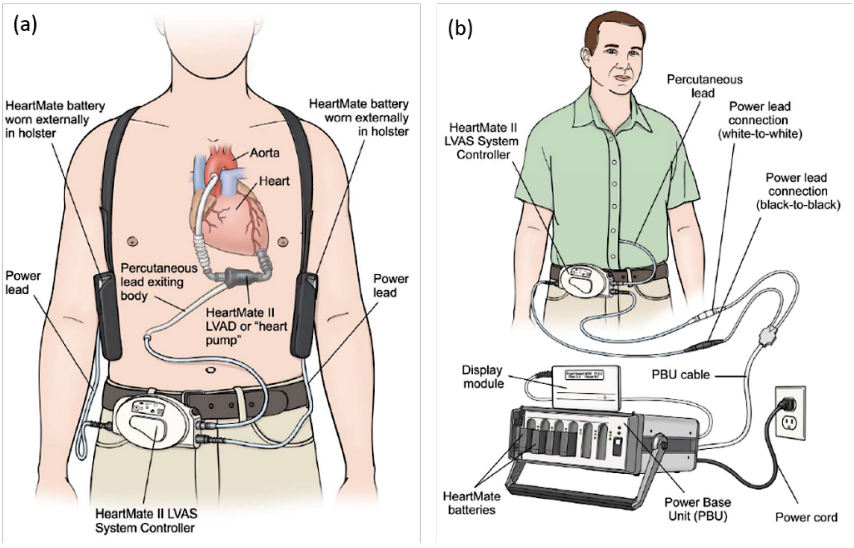
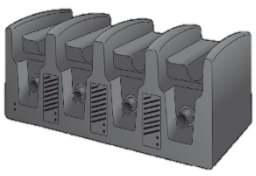


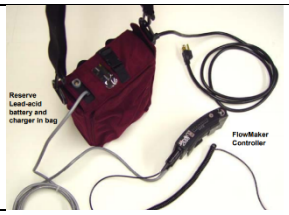
Figure 1. Implanted and worn components of VADs (a) during battery-power operation (b) during tethered operation connected to PBU. (Courtesy of Thoratec Corp., FL, USA)

Current Market:

In 2012 heart failure was responsible for an estimated health expenditure of around $31 billion (£22.5 billion), equivalent to more than 10 % of the total health expenditure for cardiovascular diseases in the United States (US). Projections are even more alarming, however, with total costs expected to increase by 127% between 2012 and 2030 [4]. The global market for cardiac assistive devices is projected to close at 1.4 billion in 2017. Ventricular assistive devices (VADs) are the major segment of the market with 63%. The market has shown a promising compound average growth rate (CAGR) of 8.6% between 2010 and 2017. The reports reveal that the U.S. market composes 55% of the global market of cardiac assistive devices and has expanded with a CAGR of 10.9%. The global CAGR for VAD market segment is reported to be 11.3% between 2010-2017 [5]. There are currently several manufacturers for VADs. As explained before, all current products use battery-charging systems that should be plugged into a wall outlet and charged for at least 4 hours, while keeping backup batteries. Table 1 shows examples of various VADs available in the market, whose batteries and chargers are carried in a backpack [6], [7].

Table 1. Various VADs available in the market, whereby the batteries and chargers are carried in a backpack.

Product	Manufacturer Regulatory status	Image	Battery/Charger	Market Share[10]
HeartMate II® LVAD	Thoratec [8] CE Marked FDA (Bridge to Transplant and Destination Therapy)		Charging time 4 Hours Usage time 8-10 Hours	48%
HeartWare® LVAD	HeartWare [9] CE Marked FDA (Bridge to Transplant)		Charging time 4 Hours Usage time 4-6 Hours	10% Approx.

Jarvik 2000 FlowMaker	Jarvik Heart [10] CE Marked Involved in an FDA-approved phase II clinical pivotal trial		Charging time 5 Hours Usage time 7 Hours	-
Berlin Heart	Berlin Heart [11] CE Marked FDA (Bridge to Transplant)		Charging time 5 Hours Usage time 8 Hours	-

Classification and Applicable Regulations:
The battery chargers have been classified as class 1 by FDA-CDRH in the US. Also, as per EEC/2017/745 and CMDCAS, those are classified as a *class-I* medical device. The applicable regulatory framework in each case is as follows:

FDA	**CE**	**HEALTH CANADA**
Device Classification: I **Product Code:** KRF **Regulation Number**: CFR 870.3670	**Device Classification:** I **Regulation:** EEC/2017/745	**Device Classification:** I **Regulation:** CMDCAS

Need Criteria:
To the best of the author's knowledge, the proposed need is subjected to the following criteria:
1. Lightweight, easy to carry.
2. No need to backpack for reserve battery set.
3. Firmware to track flows and battery charge with phone application.

References:

1. Savarese, Gianluigi, and Lars H. Lund. "Global Public Health Burden of Heart Failure." *Cardiac Failure Review* 3, no. 1 (2017): 7.
2. Hoek, Gerard, Bert Brunekreef, Paul Fischer, and Joop van Wijnen. "The association between air pollution and heart failure, arrhythmia, embolism, thrombosis, and other cardiovascular causes of death in a time series study." *Epidemiology* 12, no. 3 (2001): 355-357.
3. Sen, Ayan, Joel S. Larson, Kianoush B. Kashani, Stacy L. Libricz, Bhavesh M. Patel, Pramod K. Guru, Cory M. Alwardt, Octavio Pajaro, and J. Christopher Farmer. "Mechanical circulatory assist devices: a primer for critical care and emergency physicians." *Critical Care* 20, no. 1 (2016): 153.
4. Mozaffarian D, Benjamin EJ, Go AS et al. American Heart Association Statistics Committee; Stroke Statistics Subcommittee. Heart Disease and Stroke Statistics-2016 Update: A report from the American Heart Association. Circulation. 2016;133:e38–e360.
5. https://www.asdreports.com/news-184/global-cardiac-assist-devices-market-forecast-reach-14-billion-2017
6. Pruijsten, R. V., N. De Jonge, J. H. Kirkels, C. Klöpping, P. A. F. M. Doevendans, A. Oosterom, H. Kemperman, and J. R. Lahpor. "Left ventricular assist device: a functional comparison with heart transplantation." *Netherlands Heart Journal* 16, no. 2 (2008): 41-46.

7. Slaughter, Mark S., Francis D. Pagani, Joseph G. Rogers, Leslie W. Miller, Benjamin Sun, Stuart D. Russell, Randall C. Starling et al. "Clinical management of continuous-flow left ventricular assist devices in advanced heart failure." *The Journal of Heart and Lung Transplantation* 29, no. 4 (2010): S1-S39.
8. www.thoratec.com
9. www.heartware.com
10. www.jarvikheart.com
11. www.berlinheart.de

Need #2

Need Statement:
A way to more accurately determine the size of a heart valve during transcatheter valve replacement, in order to increase the accuracy and efficiency of choosing the proper valve.

Disease State:
Valvular heart disease is becoming an increasing problem, due to higher life expectancy as well as an aging baby boomer population. For example, the elderly population aged 80 years and above has been expected to increase from 6.9 million in 1990 to about 25 million by 2050 in the US. Furthermore, moderate to severe valve disease is prevalent in more than one in eight people aged 75 or older [1].

The four valves of the heart, as depicted in Figure 2, may be affected as a result of congenital birth defects, aging, lifestyle (smoking), injury or related illness. Valve disorders can be classified into the following types: stenosis, prolapse and regurgitation. A stenosis occurs when the valve is sufficiently narrowed or stiffened, mostly due to calcification or plaque build up, which prevents blood from adequately pumping into and out of the heart [3]. A prolapse, also known as floppy valve syndrome, is when the valve leaflets don't close evenly and collapse backward into the chamber that they are supposed to be sealing off [4]. Mitral valve prolapse is the most common abnormality, affecting two to three percent of the population in the United States, and can lead to serious complications including mitral regurgitation [5]. Regurgitation is the backflow of blood into the improper chamber (opposite direction than it is supposed to flow) as a result of defective valves. Those most at risk for valve disorders are people with a history of high blood pressure, coronary artery disease, rheumatic fever, infective endocarditis, heart attack or failure, arrhythmias, birth defects, or those that have undergone mediastinal (chest) radiation therapy for cancer. While some patients do not present with any symptoms, others can have a gradual or severe onset of symptoms such as: chest pain, palpitations, shortness of breath, fatigue, lightheadedness, and swollen feet, ankles, or abdomen. The detection of a heart murmur in patients is a good indication of possible valve problems in the future, and is monitored closely [3].

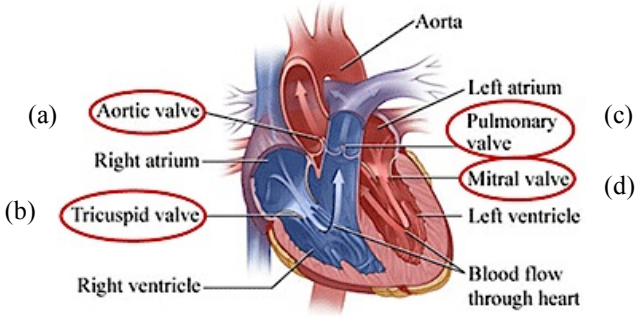


Figure 2. The four valves of the heart: (a) aortic valve, (b) tricuspid valve, (c) pulmonary valve, (d) mitral valve. [2]

Currently, 60 to 70 percent of all valve surgeries performed on the elderly are done to repair aortic stenosis. Patient outcome is largely dependent on age, and higher mortality rates are associated with patients aged 80 and above, as well as those with comordities [1].

Existing Treatment and Problem:
When the defective heart valve starts to hinder the heart's ability to pump blood adequately, it will likely need to be surgically repaired or replaced. Our need is focusing on the replacement of severely affected valves. At the moment, the most trusted diagnostic tool is cardiac Computed Tomography (CT) scans, which uses a series of cross-sectional X-ray images to create a 3D image of the heart. However, this method requires a contrast injection prior to the test, and the intravenous dye can be damaging to the kidneys. For this reason, CT scans aren't used on patients with pre-existing kidney conditions. Other diagnostic tools and imaging that are used include the echocardiogram, cardiac MRI, angiogram, cardiac catheterization, chest X-ray, exercise test, and electrocardiogram [6].

Until recently, open-heart valve replacement surgery was the only treatment option, and the damaged valve was replaced with either a mechanical or bioprosthetic valve. This procedure requires the heart to be temporarily stopped, using the heart/lung machine, and the recovery time takes several weeks [4]. A minimally invasive and non-surgical percutaneous coronary intervention (PCI) is a new option for patients that fit the criteria. A catheter is routed to the heart using a trans-femoral, trans-subclavian, trans-apical, or trans-aortic approach, whereby a stent is inserted in the place where the defective human valve resides. The most common PCI procedure is the transcatheter aortic valve implantation (TAVI; also known as TAVR). This procedure requires pre-operative planning by assessing the dimensions of the aorta and sizing the valve with CT angiography. However, the annulus measurements may vary based on the phase of the cardiac cycle (ie. mid-systole or end diastole) or the amount of calcification. The problem is that when the measurements show variance, the physician is not always choosing the most correct valve size to insert, and this can lead to perioperative or post-operative complications such as paravalvular aortic regurgitation [7, 8].

Current Market:
There is an increased trend in minimally invasive treatments, as it cuts costs and decreases the patient's length of stay in the hospital. The Agency for Healthcare Research and Quality, under the Division of U.S. Department of Health and Human Services, has funded simulation research projects, such as "Using Simulation for Teaching Femoral Arterial Access: A Multi-Centric Approach". This grant supported simulation training for professionals learning PCI, from April 2011 to March 2014 [9]. The two main stent devices for TAVI in clinical use at the moment are the self-expandable Medtronic CoreValve (MCV) (Medtronic, Minneapolis, Minnesota) and balloon-expandable Edwards SAPIEN XT valve (ESV) (Edwards Lifesciences, Irvine, California) [8]. The self-expanding valve allows for slow detachment from the catheter, whereas the balloon valve uses rapid deployment. Both items are depicted in Figure 3 below. Edwards also produces the popular trans-femoral NovaFlex+ catheter. CT scanners are mainly produced and marketed by GE Healthcare, Philips, Siemens, and Toshiba.

Sizing a heart vessel can be approached in the same way that the esophagus and upper gastrointestinal tract are sized. Volumetric laser endomicroscopy (VLE) and tethered capsule endomicroscopy (TCE) are two esophageal imaging techniques already being used. The Nvision VLE Imaging System is produced by NinePoint Medical (Bedford, MA, USA), and the TCE technology was recently developed by the Tearney Lab at Harvard Medical School.

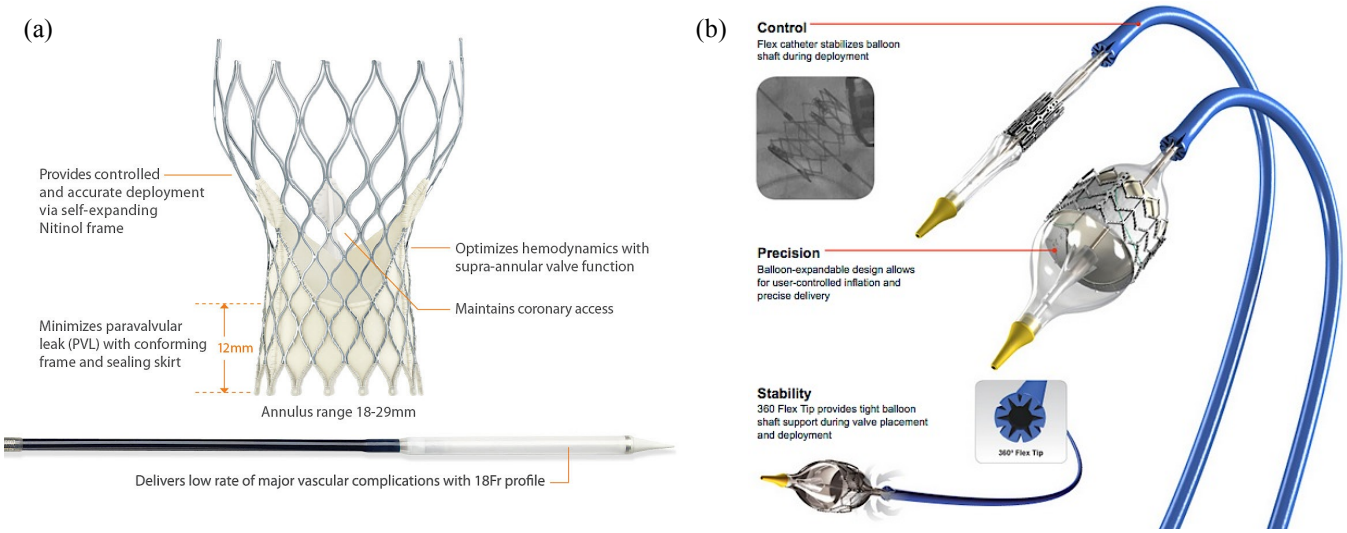


Figure 3. The main products used in PCI procedures, (a) self-expandable Medtronic CoreValve, (b) balloon-expandable Edwards SAPIEN XT valve.

Classification and Applicable Regulations:

The FDA has approved balloon aortic valvuloplasty catheters as Class II, where the product code is OZT and the regulation number is 870.1255. The 510(k) summary for the Nvision VLE Imaging System states that it is a Class II device; the product code is NQQ; the regulation number is 21 CFR 892.1560; and the 510(k) is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf11/k112770.pdf.

Need Criteria:

1. Have to be able to insert a diagnostic tool into a vessel that may be highly calcified.
2. Should be able to take a 360° image of the vessel and determine its diameter for sizing.

Key Opinion Leaders:

The cardiovascular team is fortunate to be able to consult with Dr. Kevin Lachapelle (MDCM, FACS, FRCPSC), as well Dr. Nicolo Piazza (MD, PhD, FRCO(C), FESC). These doctors have collaborated with one another on several publications regarding valve disease and transcatheter heart valve procedures.

References:

1. Mohty, D., and Pislaru, S. 2017. Valvular heart disease in elderly patients. UpToDate. Available at: https://www-uptodate-com.proxy3.library.mcgill.ca/contents/valvular-heart-disease-in-elderly-adults?source=search_result&search=valvular%20heart%20disease&selectedTitle=1~150
2. https://www.cardiosmart.org/heartvalvedisease
3. Understanding Heart Valve Problems and Causes. 2017. American Heart Association. Available at: http://www.heart.org/HEARTORG/Conditions/More/HeartValveProblemsandDisease/Understanding-Heart-Valve-Problems-and-Causes_UCM_450360_Article.jsp#.WfhW_EdrzL8
4. Valve disorders. 2017. Heart and Stroke Foundation. Available at: http://www.heartandstroke.ca/heart/conditions/valve-disorders.
5. Jelani, Q. 2016. Mitral Valve Prolapse. Medscape. Available at: https://emedicine.medscape.com/article/155494-overview.
6. Heart Valve Diagnosis Criteria. 2016. American Heart Association. Available at: http://www.heart.org/HEARTORG/Conditions/More/HeartValveProblemsandDisease/Heart-Valve-Diagnosis-Criteria_UCM_450646_Article.jsp#.WfhxnEdrzL8

7. Mustafa, A. E. et al. Dynamics of the aortic annulus in 4D CT angiography for transcatheter aortic valve implantation patients. PLoS One, 2017; 12(9).
8. Igbal, J., and Serruys, P. W. Comparison of Medtronic CoreValve and Edwards Sapien XT for Transcatheter Aortic Valve Implantation. JACC: Cardiovascular Interventions, 2014; 7(3).
9. Improving Patient Safety Through Simulation Research. 2016. Agency for Healthcare Research and Quality. Available at: https://www.ahrq.gov/research/findings/factsheets/errors-safety/simulproj11/index.html.
10. http://www.corevalve.com/intl/product/index.htm
11. http://www.edwards.com/eu/Products/TranscatheterValves/Pages/novaflex.aspx

Need #3

Need Statement:
A way to reduce the tediousness of counting surgical instruments in every surgery, which will increase the efficiency of medical procedures, lighten the workload of operating room staff, and decrease surgical complications caused by human error.

Problem and Disease State:
Surgeons utilize an array of instruments during every procedure. Before a surgery begins, counting all available surgical instruments such as scissors, scalpels, tubes, sponges and so on is an important standard of practice. At the conclusion of surgery, another count is completed. If the counts are different, it is clear that an instrument has been left behind. Retained surgical instrument (RSI) is any instruments accidentally left inside a patient's body following a surgery. This severe mistake could lead to significant health injuries, repeated surgery, and even death in some cases [1]. Therefore, counting surgical instruments is an indispensable and essential process during a surgery.

At present, the surgical instrument counting process is generally undertaken manually by humans. Thus, mistakes in counting is inevitable, according to a study which reported to the Annals of Surgery that mistakes in instrument counts happened in 12.5% of surgeries [2]. An inaccurate count can occur when nurses are deprived of sleep; when the surgical operation is particularly difficult, long and mentally draining; when the operation is an emergency; or when there are unforeseen changes in the procedure [3]. The Association of Operating Room Nurses published an UpToDate.com policy in 2015, recommending the points below that are widely used in American hospitals [4]. Specifically, counting should be performed at the following time points during the surgical procedure: before the procedure begins (initial count); whenever new additional items are used during the operation; before the surgeon closes the body cavity; when the surgeon begins to close the wound; and when the surgeon closes the skin (final count) [5]. Therefore, counting surgical instruments is tedious work, it requires lots of manpower, and is a heavy burden for nurses.

Existing Solutions:
In order to solve this problem, the Israel RFID (radio frequency identification) medical solution provider, Haldor Advanced Technologies, developed the ORLocate system. Based on passive RFID tags, it can monitor and track the surgical instruments and consumables before, during and at the conclusion of the surgical procedure [6]. The Penelope robot system, designed by Micheael R.T, can also count surgical instruments [7]. However, these two methods are more complex and expensive – the cost of each system is more than $100,000 [8]. Moreover, these systems rely on tags. They need to add tags to the instruments; hence the fabrication process of surgical instruments may be changed. This property prevents these systems from being widely used.

Current Market:
According to data from the National Center for Health Statistics, 48 million surgical inpatient procedures were performed in the United States in 2009 [9]. The number of cases in which surgical instruments were left behind during a procedure in the United States has been estimated at around 1500 cases per year. Approximately 88% of these cases occur in a situation where the surgical instrument counts were declared "correct" [10]. The legal, medical and compensation costs associated with RSI are high, even if there has been little or no harm to the patient. Costs vary from $37,041 to $2,350,000 per incident, with an average cost per case estimated at $95,000 [11]. If a more accurate and efficient surgical counting approach could help hospitals to avoid these losses, it would benefit both hospitals and patients.

Need criteria
1. The aiming approach should not change the fabrication process of surgical instruments.
2. The aiming approach should be more accurate than these existing approaches.
3. The aiming approach should be easy to use.
4. The aiming approach should be low-cost.

References:

1. Nemitz R. Surgical Instrumentation: An Interactive Approach[M]. Elsevier Health Sciences, 2013.
2. Gamble K H. No sponge left behind: Cutting-edge bar coding technologies are being leveraged in an attempt to make foreign bodies left in patients a thing of the past[J]. Healthcare informatics: the business magazine for information and communication systems, 2008, 25(12): 34, 36, 38-9.
3. https://en.wikipedia.org/wiki/Retained_surgical_instruments
4. Denver CA. Guidelines for prevention of retained surgical items. Guidelines for perioperative Practice.
5. Zejnullahu VA, Bicaj BX, Zejnullahu VA, Hamza AR. Retained Surgical Foreign Bodies after Surgery. Open Access Macedonian Journal of Medical Sciences. 2017;5(1):97-100.
6. http://www.haldor-tech.com
7. http://rstautomation.com
8. J. Tan, S. Wang, H. Wang and J. Zheng, "A new method of surgical instruments automatic identification and counting," 2011 4th International Congress on Image and Signal Processing, Shanghai, 2011, pp. 1797-1800.
9. https://stanfordhealthcare.org/medical-clinics/surgery-clinic/patient-resources/surgery-statistics.html
10. Gawande AA, Studdert DM, Orav EJ, Brennan TA, Zinner MJ. Risk factors for retained instruments and sponges after surgery. N Engl J Med. 2003;348(3):229–35. https://doi.org/10.1056/NEJMsa021721. PMid: 12529464.
11. Berkowitz S, Marshall H, Charles A. Retained intra-abdominal surgical instruments: time to use nascent technology? Am Surg 2007; 73: 1,083–1,085.

Need #4

Need Statement:
A way to address the lack of immersive simulations during the training of operating room (OR) staff, students and residents; in order to accelerate their acquaintance with new instruments/sets, and to improve both communication and efficiency in the OR.

Disease State:
During the surgeries that we observed, and in all surgeries in general, the communication between the medical staff in the operating room is essential: there are often more than 10 people in the room, and

many machines that make noise, so it is important that everyone expresses themselves in the clearest possible way. Likewise, it is essential that everyone knows their role and what is expected of them in order to minimize the number of misunderstandings and to limit the general time of the procedure. Given the number of rules regarding hygiene and safety, and the list long of instruments used, the training is often longer for the operating room staff. It is for this reason that surgeons and nurses undergo additional specialized training up to several years to learn the necessities of the operating room. Moreover, advances in medical research cause the evolution of certain operative techniques, or even the appearance of new ones, and the training of surgeons is therefore often continuous throughout their careers, so that they can update their knowledge according to the more recent discoveries. Training is one of the most important aspects for the acquisition of skills to the OR personnel.

Existing Solutions:
With the arrival on the market of new technologies, we realize that the immersive and hands-on aspect of training makes it much more effective. Thus, we have seen the emergence in recent years of a surgical training system using virtual reality in simulation centers. This system is more readily used today so that surgeons can really feel the level of precision needed in a procedure, and can also test the tools on materials with mechanical properties that resemble human tissues. However, apart from these practices reserved for surgeons, the immersive training offered for other operating room staff is quite limited. In the majority of cases, this is limited to theoretical learning followed by practical training. It is therefore completely possible that a health professional arriving the first day in an operating room is lost with all the medical jargon, the names of the instruments used, the procedures to follow, and the hygiene and safety standards.

Current Market:
The contribution margin per hour of operative time is the hospital income generated by a surgical case, when all variable costs of hospitalization and supply are subtracted. Consequently, the economic impact of repeated errors due to the human factor can be estimated: an operating room that supports excessive surgery times can cause the hospital to lose its financial margin. This includes the staff in the operating room not being responsive enough, or the use of too many instruments unnecessarily. On average, every minute in an operating room costs the hospital about $62 US [1]. Poor preparation of surgical instruments, poor communication or lack of staff knowledge are just a few ways that the length of a procedure can be increased, and thus impose additional costs on the hospital. For the moment, there is no training aid for staff other than internships and simulation (with or without virtual reality) for surgeons and anaesthesiologists.

Classification:
Our innovation would take the form of an immersive visual tool that could use augmented reality, for example, or use voice recognition to link the surgeon's demands to what nurses need to do (which machine to check, which instrument to grab and give, etc.). The staff could use it to better identify tools and machines in the OR, apply their knowledge effectively during their training, and allow a more immersive learning without being in internship. Thus, as a non-invasive device that does not come into contact with the patient, it’s the rule 7 that applies: it is therefore a Class I device.

References:

1. Macario, A. (2010). What does one minute of operating room time cost?. *Journal of Clinical Anesthesia*, 22(4), pp.233-236.
2. Wong, J., Joy Khu, K., Kaderali, Z. and Bernstein, M. (2010). Delays in the operating room: signs of an imperfect system. *Canadian Journal of Surgery*, 53(3), pp.189-195.

3. Patient Safety Workshop: Learning from error. (2008). World Health Organization. Available at: http://www.who.int/patientsafety/activities/technical/vincristine_learning-from-error.pdf [Accessed 30 Oct. 2017].
4. Lingard, L., Espin, S., Whyte, S., Regehr, G., Baker, G. R., Reznick, R., Bohnen, J., Orser, B., Doran, D. and Grober, E. (2004). Communication failures in the operating room: an observational classification of recurrent types and effects. *Quality and Safety in Health Care*, 13, pp.330-334.
5. Abelson, J. S., Silverman, E., Banfleder, J., Naides, A., Costa, R. and Dakin, G. (2015). Virtual operating room for team training in surgery. *The American Journal of Surgery*, 210(3), pp.585-590.

Need #5

Need Statement:
A better way to distinguish vessels that need to undergo pre-operative imaging before percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) procedures, in order to speed up diagnosis, and to increase the accuracy of medical professionals in emergency cases.

Disease status:
Coronary artery disease (CAD) is the most prevalent cardiac disease globally. It is related to the build-up of cholesterol in the coronaries that provide blood and nutrients to the the heart muscle [1]. These deposits are called plaques and lead to atherosclerosis. Plaques narrow the coronary arteries and compromise the flow of oxygenated blood to the heart. Coronary artery disease often leads to heart attack (myocardial infarction, MI) or chest pain (angina). If the flow of oxygenated blood to a part of the heart muscle is compromised, a heart attack will occur. Without prompt medical intervention, an MI would lead to serious health risks or even death.

Existing treatments:
Treatment for coronary artery disease aims to improve lifestyle, nutrition, weight control and cholesterol reduction [2]. Some patients, however, will require invasive treatments such as percutaneous coronary intervention (PCI). A thin flexible tube with a balloon at its end is inserted into the vessel to push the clogging plaque against the wall artery, and sometimes a stent can be used [3]. In addition to that, coronary artery bypass graft (CABG) surgery may be the last option when the patient cannot be treated with PCI. CABG is an open surgery performed under general anaesthesia. Blood circulation during the operation is managed by a heart-lung machine, which allows the surgeon to clamp the aorta, and use a vein taken in the leg to bridge the aorta-coronary artery. It is also possible to perform the same surgery without a heart-lung machine (heart-beating surgery), to avoid the technical complications of the machine. This operation lasts typically between 3 and 6 hours [4]. Artery bypass grafts are shown in Figure 4.

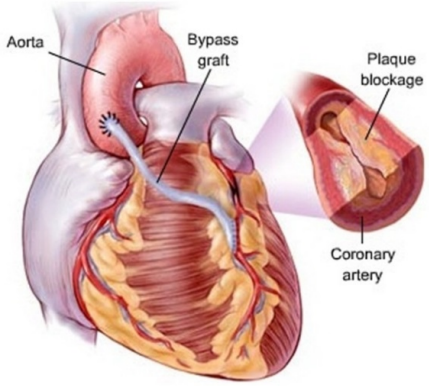


Figure 4. How artery bypass grafts are attached to the heart.

There are many different ways of assessing blockages in the heart arteries. One of the standard ways is cardiac catheterization. A catheter is inserted into the femoral or radial artery up to the heart, and a contrast agent is injected to visualize blockages. The problem of this method is that the diagnosis is not always easy to emit, and repeating these tests carry some risk to the arteries and the kidneys due to dye injection. A CT-angiogram is another modality to gather 3D geometric information on the blood flow in the cardiac vessels. The advantage of CT-angiogram over a PCI is that it is noninvasive, with less risk of heart attack, stroke, or blood vessel damage. However, X-ray exposure and the use of a contrast agent can compromise kidney function [5]. To improve the existing imaging techniques mentioned, and to overcome their limitations, implementing software that could help physicians and emergency responders to more easily locate the blocked vessels would be invaluable. It would be helpful to detect where vessel diameter changes rapidly, as a good indicator of which vessels require a CABG procedure.

Current Market:
CADs are responsible for nearly 1.5 million heart attacks each year in the US alone. This prevalence attributes to an annual health expenditure of $320 billion. Currently, 40 percent of the American population is suffering from a form of cardiovascular diseases. This number is projected to rise to 46 percent by 2035 [7].

Important stakeholders:
The critical stakeholders concerned by this problem and by a potential solution would be all cardiac surgeons, because a significant modification to the pre-operative procedures would affect their protocols and training. Also, the Association of Cardiovascular and Thoracic Surgeons of Quebec could give their opinion on these changes, because they represent every cardiac surgeon in Quebec.

Classification:
Our solution would be to improve existing imaging techniques by using a modified software. The software would be dedicated to an active diagnostic device, where an erroneous reading could represent a risk to the patient. For example, if the software does not locate an artery that deserves a bypass (false negative), we can apply the rule 10 and classify this innovation as a Class II medical device under Health Canada, and a Class 2 device with a specific product code of IZG and regulation number 892.1730 under the FDA.

Need Criteria
The proposed solution shall be compatible with the commercially available fluoroscopic angiography system, so that can be utilized in the determination of the plaque site. Also, it has to be applicable in real-time for emergency patients. Also, the software shall rely only on X-ray fluoroscopic data rather than other imaging modalities.

References:

1. Mullany, Charles J. "Coronary artery bypass surgery." Circulation 107, no. 3 (2003): e21-e22.
2. Gotto AM Jr. Statins, powerful drugs for lowering cholesterol, advice for patients. Cardiology Patient Page. *Circulation.* 2002; 105, 1514–1516
3. Bader, Yousef, Manny C. Katsetos, and Carey Kimmelstiel. "Percutaneous Coronary Intervention." In Cardiology Procedures, pp. 263-274. Springer London, 2017.
4. National Heart, Lung, and Blood Institute. (2017). *What Is Coronary Artery Bypass Grafting?* [online] Available at: https://www.nhlbi.nih.gov/health/health-topics/topics/cabg [Accessed 30 Oct. 2017].
5. Nakamura, Shigeru, Tomoko Kobayashi, Atsushi Funatsu, Tadahisa Okada, Maria Mauti, Yuki Waizumi, and Shinichi Yamada. "Patient radiation dose reduction using an X-ray imaging noise

reduction technology for cardiac angiography and intervention." Heart and vessels 31, no. 5 (2016): 655-663.
6. National Heart, Lung, and Blood Institute. (2017). *Who Needs Coronary Artery Bypass Grafting?* [online] Available at: https://www.nhlbi.nih.gov/health/health-topics/topics/cabg/whoneeds
7. https://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_491543.pdf[Accessed 31 Oct. 2017].

CONCLUSION

To conclude this report, we can therefore recall that, thanks to our different backgrounds, we have been able to notice unmet needs from different perspectives. Our various visits at the McGill University Health Centre allowed us to identify 99 needs. We have edited this list to keep only the five needs that emerged as the most relevant according to the method of the course book, which are the following:

- A way to overcome the lack of wireless charging for medical devices that require an external power source, such as ventricle assist device, in patients with congestive heart failure, in order to improve convenience, maintenance, portability and quality of life.
- A way to more accurately determine the size of a heart valve during transcatheter valve replacement, in order to increase the accuracy and efficiency of choosing the proper valve.
- A way to reduce the tediousness of counting surgical instruments in every surgery, which will increase the efficiency of medical procedures, lighten the workload of operating room staff, and decrease surgical complications caused by human error.
- A way to address the lack of immersive simulations during the training of operating room (OR) staff, students and residents; in order to accelerate their acquaintance with new instruments/sets, and to improve both communication and efficiency in the OR.
- A better way to distinguish vessels that need to undergo pre-operative imaging before percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) procedures, in order to speed up diagnosis, and to increase the accuracy of medical professionals in emergency cases.

After discussion among team members, the need that we are most passionate about and more inspired by is Need #2, the way to more accurately size a heart valve. Our team will now continue researching solutions, regulations, and the marketing process, in order to be able to present a functional prototype by April.

APPENDICES

	Compiled Needs Observations after Round 1, Factor 1 Needs Screening	**Factor 1** Yes = 1 Common=2
1	To mandate personal protective wear which shields the face and eyes from bone fragments and dust as a result of using a bone saw.	1
2	Need to improve the collection of blood and water that overflows off of the surgical table (saw too much dripping onto the floor).	1
3	To automize the distractor technology used in a craniofacial surgery, so that the screw can be turned automatically. This will replace the need for patient's parents to turn the screw manually every day, which will reduce the potential for human error and tool malfunction.	1
4	In MDR, at the assembly station, the OR tools need to be tested on a material that resembles the thickness and texture of human tissue (currently tests surgical scissors on its ability to cut through paper).	1
5	To create a computer system that is compatible and usable by both OR and MDR staff (registry of prepared vs. needed packages, stock of product in storage, etc).	2
6	For the clinics (such as the plastics pediatric clinic), create an app that allows physicians/nurses/staff to pick specifically which forms are needed (choose from template options on screen) and print them rapidly at once. This will decrease the number of forms lying around and taking up space, which will free up patient rooms and office space.	1
7	To create a heart-lung machine that has voice recognition to automatically increase or decrease flow of blood dispensed (would still need a technician to monitor the machine though).	1

8	To create personal protective wear or cushioning devices so that anesthesiologists don't have to continuously kneel in order adjust or administer drugs or to fix tubing. Can possibly create device where all tubing can be controlled through single duct.	2
9	To create an automated pumping system for numerous bags hanging on a single pole. (Control speed and could possibly have all tubes controlled by a single pump).	2
10	To reduce problems that are associated with slippery gloves (due to contact with blood and other bodily fluids), by possibly creating gloves with ribbing for increased grip or by creating gloves with a layer of absorbent powder/absorbent material.	1
11	Creating hanging poles that can be automatically raised or lowered with a foot pedal, so that staff can hang bags on the top of the rack with ease.	2
12	To create a CT scanning software that is able to detect large uneven differences in the vessels of the heart (to make it easier to distinguish where bypass grafts need to be placed). This software could possibly highlight potential areas with coloured imaging (RBG imaging). *Change in vessel diameter*	1
13	To create more comprehensive and precise cardiovascular imaging through 3D reconstruction of 2D imaging. To create cardiovascular imaging that doesn't require the use of CT with contrast.	2
14	To size heart valves without using X-ray imaging (CT/Echo), possibly through a balloon technique (as seen with esophageal sizing). To create a sizing balloon that will not exert too much pressure on surrounding valves and/or will be able to insert into highly-calcified valves.	2
15	To create 3D imaging that allows physicians to see the Z-plane of the heart valve (forward/backward positioning of the catheter and replacement valve). This means to image the leaflet!!	1
16	To create a more compact X-ray machine used during percutaneous intervention.	2
17	Create a catheter with more flexibility but sustained strength.	1
18	To be able to anchor the replacement valve when the existing patient valve has no calcification or when replacing a bicuspid valve.	1
19	Need for percutaneous chronic LVADs, in the case of heart failure and when decompression of the heart is needed (as opposed to traditional open-heart procedures that are done to insert LVAD).	1
20	To create a permanent energy source for an LVAD, such as a wireless charging device.	1
21	Virtual reality glasses that state the name of an instrument (instrument identification)	2
22	There is a board on operation room divided by several stickers to write patient's information by hand; can have updated information displayed on a computer screen.	1
23	They sutured the organ's muscle with a wire then used the stapler. A specific stapler can be used to save time and use for different tissue.	1
24	The head of the C-arm ion X-ray is too close to the surgical site. Surgeons don't have a good space and view to surgical site. Need to create an X-ray that can capture images from a farther distance away.	1
25	X-ray (c-arm) screen and echocardiogram monitors were sometimes in front of each other. Could automate the movement of these machines (instead of having to move them by hand) by voice recognition.	1
26	Nurse had been asked to pump the syringe/baster to clean the surgery area. Can create equipment like in dentistry, which can suction and expel water at the same time.	1
27	Hydraulic bedding to help position patients, specifically those that are undergoing trans-subclavian catheter insertion.	1
28	A kind of holster for scrub nurses/ OR staff to hold their hands while waiting for surgeons to start. (prevent sore limbs)	1
29	During the intervention, surgeons don't know about the type of the blockage (fat or calcification).	1
30	A recording system (hardware and software) that records all the texts, information, voice, etc. in exam room, helps doctor diagnosing, therefore simplifies the whole process of information storage (the paper of diagnostic must be scanned and save in databases). To create an automated note-taking system which eliminates the current practice of hand-written notes and prescriptions.	2
31	A system that can help communicate the orders in operating rooms. (sometimes the voice between doctors and nurses is not clear).	1
32	An automatic check system that can check or help to check the numbers of different medical insurgents in OR, thus release the burden of nurses.	2
33	When medical images have been unauthorized tampered or modified, a technique that can detect tamper and recover the images (Fragile watermarking for medical images). An anti-counterfeit watermark printed in medical certificates of the hospital that let the certificates have some authoritative property and hard to counterfeit.	1
34	An cardiovascular surgery education system based on virtual reality and augmented reality. (specific to TAVI)	1
35	Automate the management of all the green papers used to identify donations of blood and plasma, to avoid human error. (Could have scanner to count all products used)	1