The Rescue Stent for Non-Compressible Traumatic Hemorrhage

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Statement of Purpose: Firearm trauma is a reality of our world both in the battlefield due to gunshots and improvised explosive device blasts and noncombatant zones due to terrorism. According to a recent study, more than 12% of military personnel were wounded in action were due to torso vascular injuries [1]. There is a huge burden due to penetrating trauma of large vessels. In this work, we describe a fluoroscopic-free stent that could be placed by any resident or general surgeon without specialized skills in order to reduce mortality and improve quality of life of firearm victims. As a result, hospitals can save close to quarter million for every survivor with early intervention with reduction in blood transfusion, intensive care unit duration and complications.

Technology: It is a well known that present vascular surgery challenges are magnified in our emergency rooms [2]. Today's general surgeons are less trained in vascular proficiency than ever before. Our retrievable stent is placed with the help of a portable radiofrequency monitor (similar to a grocery store scanner) that indicates its exact location in the abdominal aorta. The prototype has been tested in vitro and in a pig model. Time is of the essence with non-compressible hemorrhage as every minute remains crucial. It helps to achieve a four minute hemorrhage control versus current 20 minutes timeframe involving patient transport to hybrid operating room. The device not only disrupts life-threatening bleeding but also allows for continued perfusion of organs until proper personnel and equipment are available. About 4,500 patients, both civilian and military, every year may benefit from our technology. Two PCT applications (US2014/0462 and US2014/068116) have been filed for retrievable stent design and radiofrequency positioning. When compared to current management with resuscitative endovascular balloon occlusion of the aorta (REBOA), Rescue stent would help to effectively counter organ failure and lower limb paralysis due to accurate placement in the aorta.

Market: There are over 440,000 penetrating traumas of large vessels worldwide. Around 42,000 non-compressible torso injuries of the vessel are reported in the US. Out of these, 80% of these people continue to die from rapid blood loss despite modern advances in medical care [3]. Whenever compression is not effective for injuries of the torso, stent repair of large vessel is usually required. This warrants for specialized equipment and special vascular skills. The existing trauma bays are not well suited for vascular injuries and are limited to x-ray imaging and ultrasound. On the other hand, open surgery in the trauma bay poses high risk of complications which is frequently carried out in non-sterile setting under the pretext of inadequate staffing. In addition, other markets for rescue stent are intraoperative emergencies and visceral perfusion for donor organ recovery which would add roughly $1.7 billion dollars in new hospital revenue. This implies expansion to broader product family and further value based pricing.

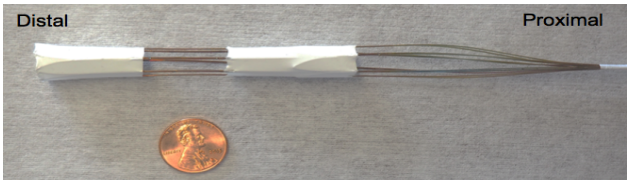

Figure 1. World's first fully retrievable large vessel stent for rapid hemorrhage control in order to allow continued blood perfusion of the vital organs of the body.

Commercialization Strategy: We have recently received $2.5 million in funds from Department of Defense (DoD) for subsequent device development and testing in pigs and human cadavers. Our research has also been supported by Center for Medical Innovation and Coulter Translational research award at University of Pittsburgh. Our Partnership with DoD allows us to conduct clinical trials in military zones with additional funding and encourages trials in civilian centers. Our intended customers are combat casualty cares along with 1154 trauma centers in the US. With a manufacturing cost of $2000/stent and sales price of $30,000/stent, we could anticipate $27 million/year in sales with 20% adoption during first year. We could also assume $90 million/year and $270 million/year in sales win second and fifth years. The stent is a class II device eligible for pursuing 510k pathway with Cook Celect Vena Cava Filter as its predicate which is placed through the femoral access and has a collapsible design. We would move forward with premarket approval pathway for radiofrequency positioning.

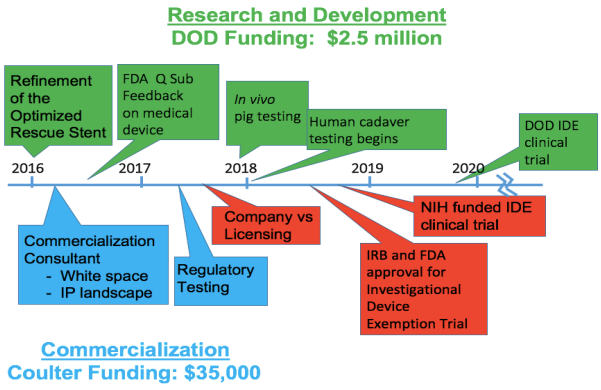

Figure 2. Future Development of Rescue Stent. IP-Intellectual Property, NIH- National Institute of Health, IDE- Investigational Device Exemption

References: [1] Kisat et al. Journal of Surgical Research. 2013;184:414-421. [2] Singh et al. The Vascular Specialist, 2016. [3] Tillman et al. Journal of Vascular Surgery. 2006;43:399-400.