

QUICK FACTS

Sector | Sub-Sector:
Medical Device | Cardiovascular
Devices

Product:
Novel CPR delivery device
specifically designed for
Catheterization Labs

Product Development Status:
MVP complete
Usability study completed at
Sunnybrook

Business Model:
Capital equipment and
consumable sale to Hospital
Emergency Department,
Paramedic Organizations

Regulatory Pathway: Class III
through 510(K)

Patent: U.S. Provisional filed
March 2019 titled "Mechanical
Cardiopulmonary Resuscitation
Device"

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Project Profile

Background: Cardiovascular disease is the number 1 cause of mortality worldwide. The gold standard for treatment of a heart attack is angioplasty and stenting performed in the catheterization lab environment. These patients are at a high-risk of cardiac arrest and requiring CPR.

Current Standard-of-Care: The current guidelines for CPR, provided by the American Heart Association (AHA) and adhered to in Canada by the Heart and Stroke Foundation, is to deliver 100-120 compressions per a minute at a depth of between five and six centimeters¹

- However, chest compressions performed in hospital did not meet the recommended frequency (100-120/min) in 30% of cases and required depth (5cm) in 40%²
- Additionally, weariness started after one minute of manual CPR with a continuous drop in quality during the first three minutes; with adequate compressions (depth and frequency) decreasing from 92% to 67% to 39% during the previously cited timeframe and lowering to 18% after five minutes²

Problem: In spite of the development of mechanical CPR devices, the AHA only advises their use in unfavorable situations, such as the catheterization lab, where it is very difficult to administer high-quality compressions given the proximity of the necessary imaging equipment. The current devices either use a piston positioned directly above the chest cavity or a load-distributing band, both of which greatly interfere with angiographic imaging and the ability of the healthcare professional to complete time-sensitive procedures with every minute being vital for recovery.

The Solution: A mechanical CPR device which is designed so that all necessary angiographic images can be obtained and CPR compressions can be adjusted to the specific patient.

- Radiolucent materials and design to enable the healthcare professional to continue taking angiographic images and complete the necessary stenting without compromising high-quality compressions
- Adjustable compression depth and speed, specific to the patient, while still adhering to the AHA guidelines
- Automatic safety stop mechanism to protect healthcare professionals

Market Opportunity:

- **Device Sales:** In 2001, 1,176 U.S. hospitals were capable of performing percutaneous coronary intervention ("PCI") and over the 5-year period, the number of PCI-capable hospitals grew from 1,176 to 1,695 hospitals, a relative increase of 44%.³ Assuming the same CAGR, an estimated number of hospitals performing in the US alone would be ~4,000. Conservatively, assuming 3 cath labs per hospital, the estimated number of cath lab in the U.S. alone would be ~12,000. If each cath lab purchased a device, conservatively assuming a purchase price of \$10,000, would lead to an estimated market size for the capital device of ~\$360M in the U.S. alone. However, EMEA remains a large untapped market opportunity.
- **Consumables:** According to GlobalData, the U.S. accounts for 33% of cath procedures done by volume, reaching over 1M cardiac cath procedures performed annually in the U.S. and globally this number is estimated at 4M.⁴ If one assumed that 10% of global procedures needed CPR or utilized the device as a safety back-up, consumables per a cath procedure, particularly the active decompression segment, could lead to an additional ~\$120M annually.
- **Expanding Market:** While we have targeted the device for cath lab usage, the device can be used by paramedics or in the general hospital environment, thereby increasing the total market opportunity globally.

¹ American Heart Association

² Brooks SC, Anderson ML, Bruder E, Daya MR, Gaffney A, Otto CW, Singer AJ, Thiagarajan RR, Travers AH. Part 6: alternative techniques and ancillary devices for cardiopulmonary resuscitation: 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation*. 2015;132(suppl 2):S436-S443.

³ A Percutaneous Coronary Intervention Lab in Every Hospital?; Concannon, et al.; *Circ Cardiovasc Qual Outcomes*. 2012 Jan; 5(1): 14-20.

⁴ Daily cardiac catheterization procedural volume and complications at an academic medical center; Slicker et. Al.; *Cardiovasc Diagn Ther*. 2016 Oct; 6(5): 446-452.