



EZ-ECMO: An Expandable Arterial Catheter for Extracorporeal Membrane Oxygenation

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Background

Extracorporeal membrane oxygenation (ECMO) is a type of life support that is performed when the lungs and/or heart are unable to function independently due to cardiac and/or acute respiratory failure. This procedure is used as a last resort treatment when less invasive methods such as mechanical ventilation and medication are ineffective. While on ECMO, a patient's blood is removed from their body, oxygenated by an external device, and then returned to the circulatory system. In most emergency ECMO procedures, catheters are placed in the femoral vein and artery to complete the ECMO circuit [1].

Problem Description

The insertion method for currently used catheters involves numerous dilators, which is time consuming and can cause blood vessel damage [1]. In emergency situations, this wasted time can be life threatening. There is a need for a quicker and less invasive method of inserting an ECMO catheter into a blood vessel.



Figure 1: Serial ECMO dilators with guide wire

This need will be addressed by the designing of an expandable catheter, EZ-ECMO. This novel arterial catheter will expand upon insertion to a specified size and decrease in diameter post-procedure. This will be a safer alternative to insertion using serial dilation, as it will decrease the time and personnel required to establish the ECMO circuit and minimize the risk of mistakes and complications. Ultimately, this will increase the chance of survival for patients.

Manufacturing

Total unit cost: \$79.23/Unit

Material Costs				
Material	Bulk Size	Unit Quantity Required	Bulk Cost	Unit Cost
Polyethylene	20 in x 24 in	5.26 in ²	\$16.26	\$0.18
Polyurethane	50 ft x 1 ft	5.26 in ²	\$322.50	\$0.24
¼ x ¼ in Connector	500	1	\$500.00	\$1.00
Tygon Tubing	50 ft	6 in	\$130.00	\$1.30
Sealant	1 Gallon	60 mL	\$410.11	\$6.51
Labor Costs				
Labor Type	Labor Rate	Quantity	Unit Cost	
Manufacturing	\$15.00/hr	3 hours	\$45.00	
Quality Assurance	\$25.00/hr	1 hour	\$25.00	
Total Labor Cost			\$70.00/Unit	

Need Statement

An expandable femoral arterial catheter would reduce the time required for insertion and the number of steps involved in the initiation of Extracorporeal Membrane Oxygenation (ECMO). EZ-ECMO will expand upon insertion to a specified size and decrease in diameter post-procedure while maintaining appropriate functional parameters required for ECMO treatment.

Final Prototype

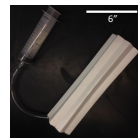


Figure 2: View of the saline bladder attached to the outer sheath

Figure 3: View of the saline bladder alone



Physical Design

- Two layers: inner fluid bladder and outer corrugated layer
- Inner bladder is subdivided into axial channels with radial breaks
- ¼" port connected to Tygon tubing is placed in the end of the bladder
- Saline is pumped into the bladder to expand the catheter using two 140 mL syringes
- Length of the catheter is 12 in
- Outer diameter expands from 2 in to 3.5 in
- Inner diameter of expanded catheter is 3 in

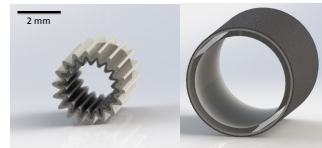


Figure 4: Models of the unexpanded (L) and expanded (R) states of EZ-ECMO

Materials Selection

Corrugated Sheet: Polyethylene	Inner Bladder: Polyethylene Film	Sealant: Polyurethane Epoxy
<ul style="list-style-type: none"> Commonly used in catheters Easy to work with Affordable & easily accessible Maintains corrugations Expands & contracts easily 	<ul style="list-style-type: none"> Commonly used in catheters Easy to work with Affordable & easily accessible Heat seals well Water-proof Withstands higher pressures 	<ul style="list-style-type: none"> Maintains seal under forces in all directions Retains flexibility of bladder and sheet Easy to work with Minimal surface preparation

How Features Avoid Problems

- Corrugated outer layer exerts uniform outward pressure on the vessel
- Outer layer expands to a set diameter so the vessel is not completely occluded
- Bladder is compartmentalized into axial channels to allow for strictly outward, uniform expansion
- All channels meet at the catheter inlet to provide uniform injection of saline
- Using saline as the expansion fluid ensures that the patient will not be harmed if the catheter leaks
- Outer coating of heparin and silver nanoparticles ensures biocompatibility

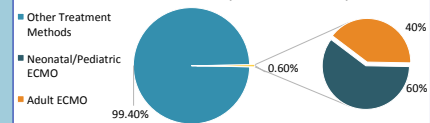
Future Work

- Prepare for and file preliminary patent application
- Determine suitable manufacturing partner to create to-scale product
- Research alternative to epoxy that is a more biocompatible sealant
- Test catheter to evaluate mechanical, biological, and rheological properties

Market

Consumers

- 468,000 cardiac and pulmonary failure cases annually
- Over 1000 emergency ECMO treatments annually
- Average length of ECMO procedure is 9.5 days and the average cost to the hospital is 73,000 USD [2]
- Post operation hospital stays average 51.5 days [2], increasing the cost to 150,000 USD [3]
- With a decreased risk of complications, doctors will be more likely to use EZ-ECMO



Competitors

- SmartCanula is the only major competitor with an expanding catheter for ECMO procedures [4]
- SmartCanula is not available in the US and is not suitable for arterial blood vessels
- Standard ECMO catheters and dilators are the main competitors of EZ-ECMO

Regulation & Insurance

- Approval will be evaluated by the FDA Division of Cardiovascular Devices [5]
- Falls under Class II since existing expandable catheters are Class II devices
- Needs to undergo the 510(k) regulatory process but not the pre-market approval process [6]
- EZ-ECMO reimbursed under existing codes
- Average procedural reimbursement 150,000 USD

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References

- [1] Kaynar, Atat Murat, and Sat Sharma. "Respiratory Failure." *Medscape*. 1 Aug. 2014.
- [2] Mishra, V. et. al. Cost of extracorporeal membrane oxygenation: evidence from the Rikshospitalet University Hospital, Oslo, Norway. *European Journal of Cardio-thoracic Surgery* (2010). 37:339-342.
- [3] D. Lumpkin, personal communication on the Medicaid Handbook Transmittal Letter 3336-09, 14 Feb 2015.
- [4] Segesser, Ludwig K. Von. High Performance Canulas. Corafo Ltd., assignee. Patent US 6626859 B2. 30 Sept. 2003. Print.
- [5] Zeinos, Stefanos, Josh Mackower, and Paul Yock (2010). "Biodesign: The Process of Innovating Medical Technologies." New York: Cambridge University Press.
- [6] "CFR." Code of Federal Regulations Title 21. *The US Food and Drug Administration*, 1 Sep 2014. Web. 14 Feb 2015.