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.

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 dilatation, 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

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<th>Material</th>
<th>Bulk Size</th>
<th>Unit Quantity</th>
<th>Bulk Cost</th>
<th>Unit Cost</th>
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<td>Polyurethane 20 x 24 in</td>
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<td>1/4” In Connector</td>
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<tr>
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<table>
<thead>
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<th>Labor Type</th>
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<th>Unit Cost</th>
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<tbody>
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<td>Quality Assurance</td>
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<td><strong>Total Labor Cost</strong></td>
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</table>

### Materials Selection

- **Corrugated Sheet:** Polyethylene Film
- **Inner Bladder:** Polyethylene Film
- **Sealant:** Polyurethane Epoxy

### 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

### 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 250,000 USD [3]
- With a decreased risk of complications, doctors will be more receptive to using 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 is 150,000 USD

### Final Prototype

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

**Figure 3:** View of the saline bladder alone

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

### 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

### References