

Bidirectional Flow Cannula

Summary

In order to accommodate the high blood flows in veno-arterial extracorporeal membrane circulation (VA ECMO) and

Key Investigator

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Field

- Cardiopulmonary
- Life-support
- Veno-arterial extracorporeal membrane oxygenation (ECMO)

Technology

- Cannula
- Catheter
- Cardiopulmonary
- ECMO

Advantages

- Limb ischemia prevention
- Eliminate need for technically difficult distal perfusion cannula placement

Status

Available for licensing

Patent Status

PCT/US2018/055160

UMB Docket Reference

ZK-2017-057

cardiopulmonary bypass (CPB), large cannulae are inserted into a patient's femoral vein, to drain blood to the system, and into the femoral artery to return the oxygenated blood under pressure. This arterial cannula can obstruct the femoral artery and impair blood flow to the leg. In 10-30% of the cases, this impaired blood flow leads to loss of function or loss of limb, resulting in tremendous financial and personal costs. A novel, bidirectional arterial cannula has been developed that will provide high-volume blood flow to the body like existing cannulae, but will also direct a small but sufficient volume of blood to the leg, ensuring its viability.

Market

Based on the Extracorporeal Life Support Organization (ELSO) registry, which captures ECMO cannulations at 260 U.S. centers, there were approximately 3,000 femoral arterial cannulations performed in 2017, with 108% growth from 2013 to 2017. In addition, the Society of Thoracic Surgeons (STS) database, which captures North American cardiac surgical cases, estimates that there were >7,000 additional femoral arterial cannulations for CPB in 2017 for patients undergoing mitral valve surgery, aortic valve surgery, or repair of an acute aortic dissection. This underestimates the total number of femoral arterial cannulations performed, as preoperative and minimally invasive cardiac procedures are often performed utilizing a femoral arterial cannula as well.

Technology

The novel cannula is a hollow, biocompatible tube that is designed to return blood from an extracorporeal circuit to



a large artery. The unique component of this technology is a hooded side port, which diverts a small but sufficient volume of blood in the opposite direction towards the limb. The hood is located posterior of the cannula tip and is designed to displace the vessel wall. The hood is designed at shallow angle for ease of insertion and removal. The cannula can be made in various diameters (15-21 Fr.) to accommodate a range of patient sizes and flow requirements.



Technology Status

The researcher's medical device laboratory has iterated cannula prototypes using 3D computer-aided design (CAD) and selected a final clinical design. Using externally validated computational fluid dynamics (CFD) analyses, the researchers have demonstrated that under physiologic conditions, the cannula provides satisfactory body (tip) and limb (side port) flows.

Using the CAD drawings several physical prototypes were constructed and currently being tested in the laboratory to confirm CFD analyses.