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$10,000 "Cure it!" Lemelson-MIT Student Prize Undergraduate Team Winner

Augeo: A cryogel polymer-based embolization solution to treat hemorrhaging patients.

The Challenge: According to the New England Journal of Medicine, hemorrhaging accounts for more than 60,000 deaths per year in the United States and about 1.9 million deaths per year worldwide.[1] A hemorrhage can occur when a blood vessel ruptures, leading to dangerous internal bleeding. To stop the flow of blood, hemorrhages are usually treated with a procedure called embolization in which the blood flow in the affected area is cut off. Most embolizations are permanent to prevent the need for re-surgery, and this is possible as tissues generally have a large network of alternative blood vessels that can provide oxygen and nutrients. Embolizations are typically performed using platinum coils that expand and block the flow of blood after insertion into a blood vessel. But platinum coils are expensive and take between 10 to 20 minutes to expand—critical time when a patient is bleeding. Hospitals must maintain large inventories of these coils because coil sizes are specific to blood vessel dimensions, which can differ throughout the body. Extensive training is required for doctors and nurses to learn coil insertion methods since not all coils are manufactured with the same delivery mechanisms. Finally, these coils can only be visualized through X-ray or other radiography.

The Solution: Team Augeo formulated a novel macroporous cryogel polymer reinforced with nanofibers to act as the first solid, expandable, permanent embolization device. The cryogelation helps the device to act like a sponge—it is small

[1] Cannon, J. W. (2018). Hemorrhagic shock. *New England Journal of Medicine*, *378*(4), 370-379.

enough when dry that it can be injected through a 22G needle, the size of most microcatheters, yet when it comes in contact with blood or liquid, it swells and expands in order to absorb almost 30 times its initial mass within seconds, forming the clotting apparatus that can block blood vessels of a range of sizes. The nanofiber component is used for mechanical strength and Barium is used for radio-opacity so that the device can be seen without X-ray.

Figure 1: Cryogel polymer-based solution

The students used a solid, naturally-derived, polymer-based material because it has been widely studied in living organisms and proven to show little to no harm or negative immune responses. It is also far less expensive than platinum. The gel material that the team created is much simpler to insert into patients than coils. A radiologist only needs to insert a catheter and push the material through with a guide wire, after which it automatically expands, forming the permanent embolus, minimizing waste and the risk for reoperation.

Commercialization: Transcatheter embolization devices form a global market that is expected to be worth $6.86 billion by 2026.[2] Augeo has confirmed with clinicians that their device is far more cost-effective and versatile than platinum coils. Specifically, the device is over 40 times cheaper in raw materials cost than a platinum coil. It is also more environmentally sustainable due to its permanence.

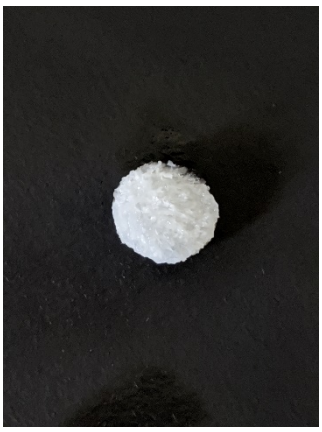

Figure 2: Top view of cryogel polymer-based solution

Manufacturers have already substantiated that the team's chemical synthesis is easily scalable and simpler to produce than minuscule coils from platinum. Discussions with stakeholders such as medical device companies and potential investors, have further reinforced the market potential of this device. Therefore, the cryogel presents a competitive alternative to the platinum coils that currently dominate the embolization market.

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[2] Grand View Research. (2019, April). Transcatheter embolization and occlusion devices market sizes worth $6.86 Bn by 2026. https://www.grandviewresearch.com/press-release/global-transcatheter-embolization-occlusion-market.

The students have initiated patent protection proceedings with Johns Hopkins University's Technology Transfer Office to patent all relevant aspects of the device. They have also presented at business plan competitions and plan to initiate testing in pig models. Afterwards, the team will proceed to clinical trials via the FDA pre-market approval route for Class II medical devices.