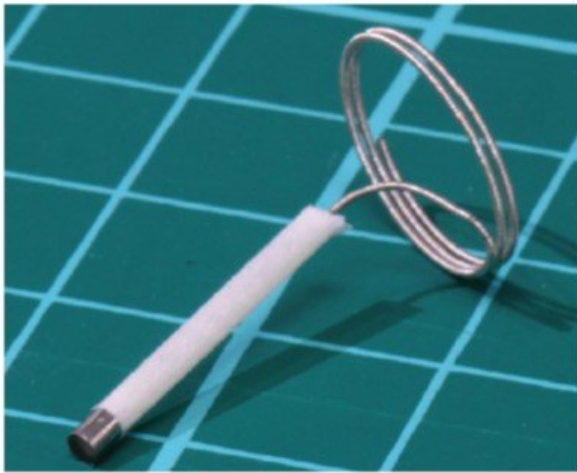


Shape memory foam embolization system deployed in Europe now cleared for U.S. markets

July 20 2018, by Thomas Johnson



Crimped Plug Pre-Implant



Expanded Plug Post-Implant

Left: Compressed shape memory polymer foam on catheter that is thread through blood vessels to treatment site. Right: Foam size and shape when fully expanded at treatment site to induce stable clot formation. Credit: Shape Memory Medical

Shape Memory Medical recently announced FDA clearance for U.S. marketing of their IMPEDE Embolization Plug, a technology funded by the National Institute of Biomedical Imaging and Bioengineering (NIBIB) and created to block irregular blood vessels.

The clearance allows the revolutionary [shape memory polymer technology](#) to be used to improve a variety of vascular complications.

The IMPEDE system received an FDA 510 (k) clearance, which certifies that the product is as safe as current products used for the same procedures, allowing the new IMPEDE system to be marketed in the U.S.

Cleared for use in Europe in 2017, the technology is a new approach to a procedure called embolization. Embolization is a medical procedure for obstructing or reducing the rate of blood flow in the vasculature.

Using a catheter that is threaded through the vascular system, materials that induce clotting in a blood [vessel](#) are guided to the site to be treated. Currently, the most commonly used materials for the procedure are coils of platinum or titanium wires that fill the region and induce a clot that stabilizes the blood vessel. However, the wire coils can have subsequent problems, including inflammation, vessel perforation, and incomplete healing. These complications can result in patients needing additional treatment to once again repair the blood vessel.

The IMPEDE system uses shape memory polymer foam that expands when it reaches the affected area; it fills the vessel more evenly and creates a more uniform [blood](#) clot that has been shown in pre-clinical testing to encourage subsequent healing with a single device as opposed to several metallic coils.

"The shape memory polymer technology was funded by the NIBIB when it was initially conceived in 2003," explained Todd Merchak, a biomedical engineer and Program Officer for the NIBIB Small Business Innovation Research grant program. "After many years of foundational research, further development and commercialization of the technology was aided by several Small Business Innovation Research (SBIR) grants

from the NIBIB. This is a real success story of a product moving from its initial discovery to a commercially available product that promises to improve public health."

This research was funded in part by the National Institute of Biomedical Imaging and Bioengineering (NIBIB) small business grants R43EB022016 and R44EB022016. The company continues to develop the shape memory polymer technology for an expanded range of clinical uses, including neurovascular applications aimed at stabilization of brain aneurysms.

Provided by National Institutes of Health

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