



## Shape Memory Medical Completes Enrollment in the AAA-SHAPE Early Feasibility Study

August 29, 2022 08:00 AM Eastern Daylight Time

SANTA CLARA, Calif.--(BUSINESS WIRE)--Shape Memory Medical Inc., developer of custom, proprietary shape memory polymers for the peripheral and neurovascular markets, announced the completion of patient enrollment in AAA-SHAPE, the Company's prospective, multicenter early feasibility safety study of the IMPEDE-FX RapidFill® Device when used for abdominal aortic aneurysm (AAA) sac management during elective endovascular aneurysm repair (EVAR).

"We are pleased to reach this critical milestone in our AAA-SHAPE clinical program," said Ted Ruppel, President and Chief Executive Officer of Shape Memory Medical. "We would like to thank the patients, investigators, and clinical study teams for their important contributions, and we look forward to evaluating the follow-up data to come." The AAA-SHAPE study, which enrolled a combined 35 patients across two centers in New Zealand and in three centers in the Netherlands, will follow patients for two years.

IMPEDE-FX RapidFill, the study device, incorporates a proprietary shape memory polymer, which is a high volume, porous embolic material that self-expands upon contact with blood.

AAA-SHAPE is the first prospective clinical trial to evaluate the application of this novel material in AAA patients and its potential to improve aneurysm sac regression rates following EVAR.

"We have been talking for years about the need to directly manage the AAA sac due to the link between aneurysm failure to regress post EVAR and increased mortality risk," said Andrew Holden, MBChB, principal investigator for AAA-SHAPE New Zealand and interventional radiologist at Auckland City Hospital. "IMPEDE-FX RapidFill could be a significant tool for addressing this need, so we could not be more pleased to participate in AAA-SHAPE."

Michel Reijnen, MD, PhD, principal investigator for AAA-SHAPE Netherlands and vascular surgeon at Rijnstate Hospital in Arnhem, the Netherlands added, "Although we are still early in the course of patient follow-up, we are seeing signals of impressive sac shrinkage at six months and one year. We look forward to the ongoing evaluation of these patients and how their aneurysms respond longer-term."

### About Shape Memory Medical

Shape Memory Medical Inc. is dedicated to developing innovative therapeutic solutions with its proprietary shape memory polymers. Neurovascular embolization products include the Trellix® Embolic Coil, which is CE marked for use in the EU. Peripheral embolization products include the IMPEDE® and IMPEDE-FX Embolization Plugs and IMPEDE-FX RapidFill® Device. In countries recognizing CE marking, the IMPEDE and IMPEDE-FX Embolization Plugs and the IMPEDE-FX RapidFill are indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature. In the United States, the

IMPEDE Embolization Plug is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature, and the IMPEDE-FX Embolization Plug is indicated for use with the IMPEDE Embolization Plug to obstruct or reduce the rate of blood flow in the peripheral vasculature. The IMPEDE and IMPEDE-FX Embolization Plugs are PMDA approved in Japan. For more information, visit [www.shapemem.com](http://www.shapemem.com).

## Contacts

Mary Dennehy

[m.dennehy@shapemem.com](mailto:m.dennehy@shapemem.com)

602-908-9812

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