



20-Year Path from Concept at a DOE NNSA Lab Through Texas A&M University to Commercialization

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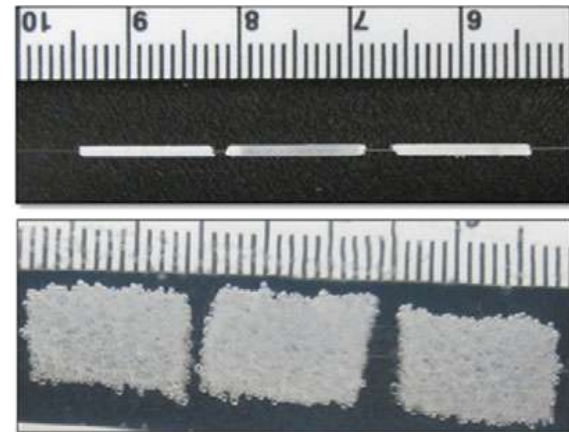
Project Manager, R&D

November 6, 2019

Technology Development

- First medical use of shape memory polymers (SMPs): Lawrence Livermore in 1996, neurovascular aneurysms (Dr. Duncan Maitland)

- SMP foams conceptualized as better occlusion scaffolds by Maitland and Thomas Wilson in 1999



- Dr. Maitland brings technology to Texas A&M in 2008
- Shape Memory Medical founded in 2009 as “Shape Memory Therapeutics, Inc.”

Initial Funding



LLNL LDRD – Started in 1995 with Strategic Initiative in treating Stroke



DOE Office of Biological and Environmental Research: “Shape Memory Polymer Microactuator for Treating Ischemic Stroke,” 2000



R01: “Shape Memory Polymer Devices for Treating Stroke,” 2002-2015



Texas Emerging Technologies Fund (first dilutive funding in 2009)

Follow-On Funding

Friends & Family and Angel seed rounds of dilutive funding



National Institute of Biomedical Imaging and Bioengineering
Creating Biomedical Technologies to Improve Health

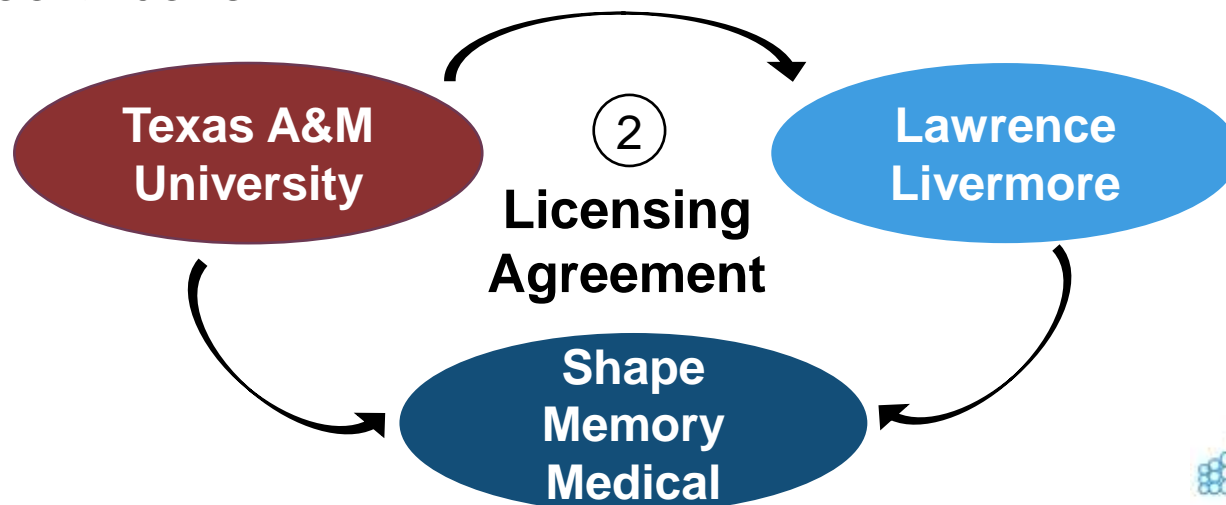
SBIR Phase I and II: “Shape Memory Polymer Foam Vascular Occlusion Device for the Treatment of Chronic Venous Insufficiency”

Venture Capital and Institutional Investments

Institutional Agreements

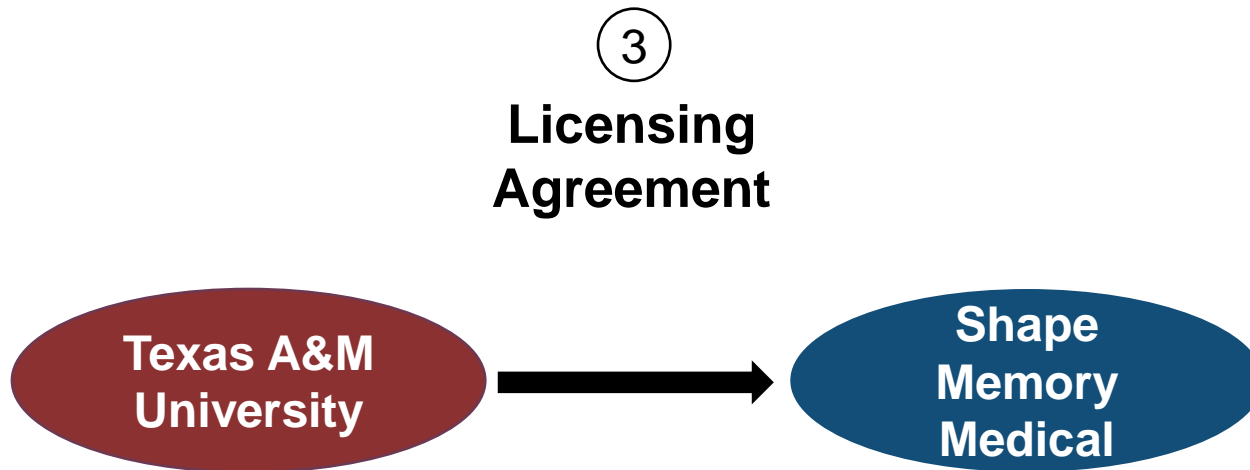
- 1) License agreement with Johnson & Johnson fell through, other negotiations stalled as SMP was too risky
- 2) Inter-Institutional Agreement put in place between TAMU, SMM, and LLNL to make commercialization easier

SMM founded in 2009 to continue the pursuit of improving healthcare



Institutional Agreements

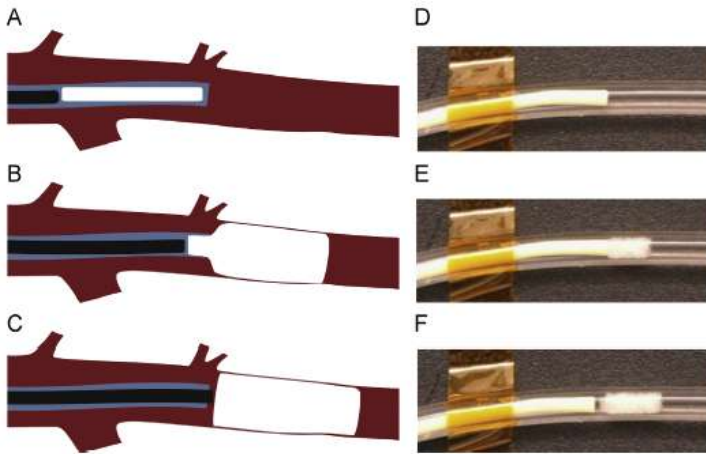
3) Shape Memory Medical and TAMU exclusive license agreement if no LLNL inventors are involved



Translation to Commercialization

IMPEDE[®] Embolization Plug

1st Prototype



Rodriguez et al. 2014

Commercial Product



www.shapemem.com

Over 200 patients treated worldwide

Commercializing National Lab and Academic Technology

Hurdles

- Communication
- Differing priorities
- Transparency
- Personalities/Ego

Advantages

- Additional licensing options for labs
- Unique expertise for both parties
- De-risk technology for investors

SMP Commercial Translation Timeline

First SMP used in humans



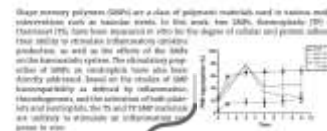
NIH BRP: SMPs for Stroke



Publications document function and biocompatibility

Polyurethane Shape-Memory Polymers Demonstrate Functional Biocompatibility In Vitro

Marcel Colarik, Thomas Haffner, Thomas Wilson, Scott Stone, Theodor Wu, M. Eric Gestblom, July Van de Walle



NIBIB SBIRs: Peripheral Occlusion



TrelliX FIH

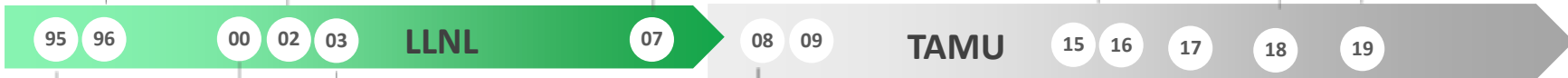


IMPEDE FDA 510k



FDA and CE Mark

- IMPEDE
- IMPEDE-FX



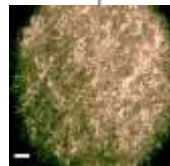
LLNL LDRD Stroke Project



DOE Embolectomy Device



Sierra Interventions NINDS SBIR First SMP Foams



NIBIB BRP Renewal: SMP Foams



SMM Founded



NINDS U01 Foam-over-coil



IMPEDE • First in Human (FIH) • CE Mark

NIH – National Institutes of Health
DOE – Department of Energy
TAMU – Texas A&M University

LLNL – Lawrence Livermore National Laboratory
NINDS – National Institute of Neurological Disorders and Stroke
NIBIB – National Institute of Biomedical Imaging and Bioengineering



References

1. Rodriguez, Jennifer N., et al. "Reticulation of Low Density Shape Memory Polymer Foam with an in Vivo Demonstration of Vascular Occlusion." *Journal of the Mechanical Behavior of Biomedical Materials*, vol. 40, 2014, pp. 102–114, doi: 10.1016/j.jmbbm.2014.07.037.