

# Case Study: Actuated Medical, U.S. Seed Funding Create “Good Days” for Patients

## A Medical Innovation Success Story

Burn victims at the University of California, Davis. Critical care patients at Harborview Medical Center, Seattle. Critical care surgical patients at Ohio State University Wexner Medical Center. Veterans in Omaha. A device called the TubeClear system unclogs medical tubes in all those settings.

The first patient ever to use the technology was a 27-year-old soldier in intensive care at Walter Reed hospital in Washington, D.C.

TubeClear would not have been possible without earning highly competitive grant funding from the federal Small Business Innovation Research (SBIR) program, said Maureen L. Mulvihill, PhD, president, chief executive officer, and co-founder of maker Actuated Medical. The central Pennsylvania firm applies electronically controlled motion to medical devices to improve patient outcomes. With 22 employees, the federally certified women-owned business is a member of AdvaMed Accel for start-up companies.



**Maureen Mulvihill,  
President, CEO, Co-  
founder, Actuated  
Medical**

The SBIR and its companion, the Small Business Technology Transfer (STTR), program, encourage high technology domestic research and development to meet U.S. government needs and eventually, benefit the public at large.

Medical tube clogging is a perfect example of a challenge eased using the SBIR seed funding.

An estimated seven million feeding tubes are placed annually in the United States. They clog about 25 percent of the time, requiring nurses and caregivers to deal with 1.8 million clogs, Mulvihill said.

Patients need optimal tube function to receive their medication, nutrition, and hydration therapy.

Nurses are anxious when they cannot clear clogs quickly, as they know it will have a negative outcome for their patients. When a nurse cannot clear the tube, the tube must be replaced. Inserting a new tube through the nasal passages to the stomach is uncomfortable and comes with risks (e.g., mispositioning into the lungs). TubeClear mechanically clears the tube while the tube stays in the patient and works at bedside, filling a critical need for many patients.

"It's a life-sustaining product," Mulvihill said. "If you're not getting your medication, your nutrition and your hydration, you're not going to thrive."

Nurses treating the Walter Reed patient were delighted to see the device work seamlessly. "It didn't cause him any discomfort," Mulvihill said. "It was a really good day for us. Not only did we help a human being, but we also helped someone who was injured fighting for this country."

## What's Next for Actuated Medical

The TubeClear system has Food and Drug Administration clearance for most feeding and decompression tubes and is advancing into an increasing number of hospitals, extended care, and homecare settings. Training clinicians on the device can be done via video, as Actuated Medical learned during the COVID-19 pandemic. The device is in use at a skilled nursing facility, where it reduced the need for tube replacement and thereby hospital transportation for fragile patients for that care. In addition to sparing patients the hardship of hospital transfer, the facility saved \$8,000 in one month using TubeClear.

A second Actuated Medical device, the NeuralGlider inserter, reduces the tissue trauma and improves the placement accuracy of delicate implants to the brain. The device someday will be used to treat Parkinson's disease, for example, Mulvihill said.

Additional products using the same motion technology are progressing. The Baby GentleStick heel stick helper is being clinically tested at two children's hospitals. "You have a fragile baby. If we can reduce that pain at all, it's a good day," Mulvihill said.

Actuated Medical manufactures its products in its Pennsylvania facility that is certified as ISO 13485 (for quality management in medical device manufacturing). Thanks to infrastructure supported through the early federal grants, the company was able to pivot production in seven days to produce and ship 85,000 FDA-compliant protective face shields during the height of the pandemic.

More products are in development, using three-dimensional printing, envisioning the technology in multiple uses and settings. Actuated Medical works with customers to fill specific device needs. The company looks forward to expanding the adoption of its devices via other medical device companies.

## Federal Seed Funding Was Critical

The SBIR program provided the early funding critical to the company's success that otherwise was scarce.

"Investors look for large markets for quickly scalable products," Mulvihill said. The feeding tube clogging market is too small for a venture capital investment but critical in clinical settings, especially during a nursing shortage. The need is incalculable to the family of a tube-dependent patient.

"The federal SBIR/STTR grants are critical to bridge the early gaps between research and development and widespread commercialization and use," Mulvihill said.

"We've helped thousands of patients with the TubeClear system," she said. "It's a reality because of SBIR. The NeuralGlider inserter is helping researchers across the country. Without the SBIR, it wouldn't have been realized."

"There are lots of mothers, parents, whose loved ones have been helped because of SBIR funding's giving innovative, thinking researchers a chance," Mulvihill said. "And there are many more to come after Congress reauthorizes this vital bipartisan program."

### About America's Seed Fund

Known as America's Seed Fund, the federal Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs offer highly competitive grants to stimulate high-tech innovations among entrepreneurs. Numerous federal agencies participate, ensuring a multidisciplinary response for public benefit. Since their establishment in 1982, these programs have provided more than 179,000 awards, totaling more than \$54.3 billion, to U.S. small businesses. A National Academy of Sciences study found a high commercial success rate for these start-ups.

### About Actuated Medical

Company: Actuated Medical  
Founded: 2006  
Location: Bellefonte, Pennsylvania  
Devices: TubeClear, NeuralGlider