

Aspero Medical, Inc.

One-Sentence Summary of What You Do: Aspero Medical, Inc. focuses on improving gastrointestinal endoscopy for both patient and physician with enhanced device performance to improve patient outcomes, all while saving time and money.

Affiliated Institution: University of Colorado Boulder

Have you formed a company yet? Yes

Funding/Financing: Grant Funding, Angel Funding (including Self or Friends/Family), Venture Capital

Please describe your company and the problem you are trying to solve: Aspero Medical (Aspero) focuses on gastrointestinal (GI) diseases which affect approximately 70 million Americans annually. Aspero's differentiated medical products for use in endoscopy procedures result in improved performance, saving time and money, and improved patient outcomes. In balloon endoscopy, the current smooth latex and silicone balloons used have a very low coefficient of friction, especially with the soft, mucous covered wall of the GI tract. This low friction regularly leads to balloon slippage. thus not allowing the scope to properly advance. Aspero's microtexturing technology, when applied to these balloons, dramatically increases friction and balloon anchoring, without increasing the safe pressure operating limit. This technology is designed to maximize anchoring while minimizing adhesion, thereby allowing more effective use of such balloon endoscopy technologies. The technology has been demonstrated in numerous animal procedures and extensive benchtop testing, showing a 3x improvement. Aspero's technology is protected around two issued US patents, with multiple other patents pending. Aspero's international patent strategy is focused on Japan and Western Europe. There is a strong financial benefit for the patient, physician, and hospitals/clinics to use this technology. This invention will save time (20+ minutes per procedure are wasted on balloon slippage and repeated attempts at anchoring), save money (reduced procedure time allows for additional procedures to be performed and billed, plus less patient recovery time postprocedure), and improve patient outcomes (complete endoscopy that is not truncated, and reduced time under sedation with less recovery time).

What is/was your go-to-market strategy? Aspero is focused on the endoscopy market (\$37 billion), of which 30% is accessories (\$11 billion) with CAGR of 7%. Customers include all gastroenterologists as balloon endoscopy is expanding into all areas of upper/lower GI, including colonoscopy and small bowel. Gastroenterologists at all levels of care from teaching hospitals to low-income hospitals, and private practice endoscopy centers, are using these approaches, and all are in need of improved anchoring technology. Aspero will partner with regional distributors for initial sales and marketing.



Aspero may also partner with Olympus or Fujifilm, or companies that are trying to get a stronger foothold into the balloon endoscopy market such as Boston Scientific or Medtronic – active dialogue is ongoing with these strategics. Aspero is also working with balloon and catheter manufacturers, such as Nordson Medical, to explore partnerships that could expand this micro-texturing technology beyond endoscopy. Developing cost-effective methods to manufacture balloon and catheters for a range of medical applications offers tremendous upside. Aspero's go-to-market strategy includes a launch of multiple differentiated products over the next two years. Ancora, Aspero's balloon overtube, will launch in spring 2022 after FDA 510(k) clearance. C-Tube, an intraoperative split overtube for incomplete colonoscopy use, is expected to launch in early 2023. Ancora and C-Tube include Aspero's differentiated patented Pillar micro-texturing balloon technology.

How will/do you generate revenue? The micro-textured balloon overtube is a Class II medical device with predicate and thus is a straightforward 510(k) substantially equivalent application to the FDA. Aspero anticipates 510(k) submission in early 2021. Aspero will contract manufacture and distribute single-use, disposable Ancora balloon overtubes that will be compatible with both Olympus and Fuji endoscopes used for gastrointestinal procedures. Aspero will launch the initial Ancora product offering through independent distributors throughout the U.S. and other geographic markets. As the company expands the product line offering, to include the C-Tube for broader colon applications, consideration will be given to a direct sales strategy. Aspero will stage the introduction and full market launch of Ancora immediately following receipt of the 510(k) for the device. The company intends to focus initially on a small subset of clinical experts within the field of small bowel gastrointestinal endoscopy procedures to develop centers of excellence and referral sites. These clinical champions and their sites may also be developed as training sites for courses on the use of Ancora balloon overtube. The company intends launch outside the U.S. market following the limited product launch period in the U.S. and receipt of all regulatory clearances. The company envisions that Western Europe and Japan will be the initial targets for expansion. Aspero's approach is to provide a superior product compared to current latex and silicon smooth balloons and balloon overtubes. Aspero targets ASP of \$250 (same as current balloon overtubes in the market) with an 80% margin at scale.

How will this showcase benefit your company or technology? Aspero is seeking a \$3M Series A raise to 1) move through commercial launch of the Ancora product and early sales to demonstrate uptake in 2022, 2) complete V&V testing and FDA submission of the C-Tube, and 3) followed by commercialization. Aspero Medical is seeking primarily venture or corporate capital. Aspero has established strong relationships will multiple endoscopy strategics that are interested in strategic investment and distribution partnerships after FDA clearance. Aspero will also be looking for additional team members in early 2022, and Destination Startup will be helpful in making those connections. To date, Aspero Medical has secured \$1M in Series Seed funding, in addition to \$1.8M in Grant funding separate from CU research funds used to developed proof-of-concept and detail device designs. Aspero is continuing to submit NSF and NIH SBIR grants to fund addition product concepts that utilize core intellectual property and that address unmet clinical needs.



Who are the members of your team and why is this the right team to get the job done? Aspero founders include Mark Rentschler (CEO) and Steven Edmundowicz (Chief Medical Officer). Mark (CU Boulder) is a recognized expert in medical mechatronics and device design, while Steven (CU Anschutz Medical Campus) is a former President of the American Society of Gastrointestinal Endoscopy (ASGE, 2019). The founding team is uniquely positioned for success, based on their collaborative history and experience in industry. Mark was previously senior engineer and director of operations for Virtual Incision and works regularly with medical device companies through his research lab, University coursework, and consulting. Steven is also actively involved in endoscopic device and procedure development with a number of medical startup companies. In 2020, Allison Lyle (Director of Engineering) and Jeff Castleberry (Director of Operations) joined Aspero. Allison brings a decade of experience in bringing multiple devices through 510(k) to market and leads all engineering and manufacturing efforts at Aspero. Jeff brings decades of medical device startup experience to the team and leads operations including RA/QA with support from Evergreen Research. Primo Medical Group (Boston, MA) is Aspero's contract manufacturer. Ania Camplin at Richtr Financial Studio serves as Aspero's CFO. Aspero is supported by Wade Johnson and his Polsinelli IP team. Aspero has signed an exclusive IP license with CU. Aspero is continuing to grow relationships with established medical device companies including Olympus, FujiFilm, Pentax, Medtronic and Boston Scientific.