

Executive Profile



Alan Crunkleton
San Clemente, CA

EDUCATION

MD

University of Massachusetts Medical School

PhD, Mechanical Engineering

Massachusetts Institute of Technology

MS, Mechanical Engineering

Massachusetts Institute of Technology

BS, Mechanical Engineering

Georgia Institute of Technology



RELEVANT EXPERIENCE

Hardesty – Interim CEO/COO – Technology and AI

- **MayaMD, Inc.** – *Interim CEO* – Commercializing AI technology to engage patients and empower providers to improve quality and reduce cost of care – Established go-to-market readiness and strategy

TriFoil Imaging – *President, CEO* – Private equity owned, preclinical imaging company – Led multiyear turnaround

Correx, Inc. – *Cofounder, President, CEO, Director* – Commercialized heart valve implant for patients with aortic valve stenosis – Led from concept through CE Mark and distribution in 22 countries

Boreas, Inc. – *Cofounder, President, CEO, Director* – Commercialized cryogenic cooling system for MRI magnets – Spun PhD work out of MIT to run VC-backed company until acquired

MateraCor, Inc. – *COO* – Biotech startup developed tissue engineering to enable effective regenerative therapies for congestive heart failure – Participated until acquired by BioVentrix

IOptic, Inc. – *President, CEO, Director* – Commercializing ophthalmic device to measure pressure inside the eyes of glaucoma patients

OPERATIONAL SKILLSET

- Results driven executive with emphasis on go-to-market strategy, turnarounds, and prep for scale
- Medical device and clinical AI expertise
- Persuasive interpersonal and communication skills, an effective negotiator and relationship builder
- Decisive and effective under pressure with leadership and management skills based on a strong ethical foundation
- Drive for Results: Distill big picture strategy into concrete plans, actions, and results
- Able to “deep dive” when needed to solve extremely complex business and technical problems

Executive Summary

An incisive, results-driven executive with an excellent record of building successful businesses and creating investor value based on key strengths in:

Concept to Revenue: Success translating market needs and opportunities into fresh products, rapidly establishing regulatory approvals, reimbursement channels, and global distribution; highly effective business developer and closer

Business Judgment: Demonstrated sound business judgment based on successes in multiple companies, leading high growth and turnaround environments, working with the board and creating investor value

General/P&L Management: Multiyear full P&L management for several businesses ranging from zero to \$10M in revenue

Go-To-Market Strategy: Expert in the nuances of medical device go-to-market strategy with deep understandings of physician behavior and motivation; able to build relationships and communicate effectively with physicians to gain market acceptance

Depth of Understanding: Able to “deep dive” when needed to solve extremely complex business and technology problems

Drive for Results: Distill big picture strategy into concrete plans, actions, and results

Innovation: Bring innovative thinking to opportunities and challenges, developing successful new products, overcoming obstacles with innovative problem solving and building highly innovative organizations

Professional Profile: Persuasive interpersonal and communication skills, an effective negotiator and relationship builder; decisive, effective under pressure with leadership and management skills and a strong ethical foundation

SIGNIFICANT ACCOMPLISHMENTS

Business Turnaround: Turned around a preclinical imaging company with dissatisfied investors by (i) replacing the entire executive team, (ii) discontinuing several unprofitable product lines, (iii) completing development and commercial introduction of an industry-changing new product line, (iv) implementing Objectives and Key Results (OKR), (v) restructuring sales to improve customer engagement and satisfaction, and (vi) overhauling manufacturing processes and quality measures. Company is now on track for favorable acquisition within the next three years.

Business Development: After a successful early adopter strategy, addressed the need for broader adoption by working with surgeons and distributors around the world to understand their perceptions of a new procedure and new product for treatment of aortic valve stenosis; developed effective communication for patient selection, market differentiation, advantages over other new procedures, and

historical perspective. Created scripts and brochures and made personal visits leading to signing on 18 distributors covering 22 countries.

Strategic Partnerships: Booked major partnerships for Boreas and Correx. Established and negotiated partnerships with an international research company and an international MRI provider at Boreas. Established potential private equity and public company partnerships at Correx.

Regulatory Management: Saved Correx several million dollars achieving European regulatory approval. After establishing with FDA that a PMA was required for US market entry, developed a strategy to get European CE Mark. After initial feedback from several notified bodies suggested a 200-300 patient clinical investigation would be required, read and analyzed Medical Device Directives, held further meetings with the chosen Notified Body (BSI), assembled 30 years of clinical history, and prepared a clinical introduction plan which did not require any clinical investigation. After extensive negotiations, the Notified Body (BSI) agreed to allow CE Mark with no clinical investigation.

Reimbursement Approvals: Worked with distributors to obtain timely reimbursement in key target countries, including Switzerland, Italy and Germany. In Germany, the most-influential early adopter, where no reimbursement codes existed for the procedure, identified, selected and worked with expert consultants to prepare a submission for NUB (gap) funding. Achieved Status 1 NUB funding (only about 25 of 600 new applications approved each year) getting the product into the German market with reimbursement within months of CE Mark.

Business Turnaround: Restructured a family-owned business bordering on bankruptcy. Recruited and replaced inherited staff, created a finance and insurance department, computerized inventory and activities of all profit centers, modernized the facility, and repaired damaged vendor, franchise, bank and other key relationships. Eliminated the prospect of bankruptcy, achieved profitability, and returned record sales and profits.

Building Investor Value: Managed all aspects of company development, including product, market, recruiting, regulatory, reimbursement, and HR, building the fastest pathway to sales. Achieved a multimillion-dollar valuation for Series A financing and increased that valuation by over 300% for Series B.

Entrepreneurial Financing: Spearheaded multiple early-stage financing efforts. Raised money for Boreas through SBIR, Seed, Series A and Series B financing with blue chip venture capital firms. For Correx, created an early-stage financing structure that provided 4 ½ years of funding, then led Series A and Series B rounds through family offices and individuals. Led private equity financing for TriFoil.

Risk Management: Developed MRI cooling technology at Boreas. Initiated a venture-funded project to expand into super-cooled/superconducting electronics. When the electronics market did not materialize, sold the technology to another company enabling the investors to recoup their investment.



PROFESSIONAL EXPERIENCE

IOptic, Inc. **President, Chief Executive Officer, Director** Mar 2021 – Present
Lexington, Kentucky (remote)

IOptic is commercializing a permanently implanted sensor to measure intraocular pressure in patients with glaucoma. The technology was spun out of the Univ of Kentucky and developed by a practicing ophthalmologist and a Univ of Kentucky professor primarily under SBIR and state government grants.

MateraCor, Inc. **Chief Operating Officer** Oct 2020 – Jun 2021
Aliso Viejo, California

MateraCor's TCMR – Trans-Catheter Myocardial Restoration – is a one-time procedure performed by an interventional cardiologist to halt and reverse the progression of heart failure that is not responding to drug treatment alone. Acquired by BioVentrix.

Belter Innovations, LLC **Founder** Nov 2019 – Present
San Clemente, California

Belter has provided business development, regulatory, reimbursement and general consulting services in various disciplines, including (i) next-generation nanotechnology for brain computer interface, (ii) easy-to-use and inexpensive mechanical ventilators for adult use in critical care settings, (iii) radiation detection systems for medical imaging, and (iv) medical device using low level germicidal light to treat women with fungal and bacterial vaginosis.

TriFoil Imaging **President, Chief Executive Officer, Director** Apr 2016 – Aug 2019
Chatsworth, California

TriFoil is a private equity owned, preclinical imaging company that develops, manufactures, sells and supports capital equipment for small animal imaging. The company offers a range of products with imaging modalities including CT, optical, PET and SPECT. Joined this turnaround company as a consultant to provide assessment for the private equity investor and to provide leadership advice to officers. Appointed to President and CEO after serving as consultant for four months.

Correx, Inc. **Cofounder, President, Chief Executive Officer, Director** 2004 – 2014
Waltham, Massachusetts

Recruited founders, formed the company, coordinated seed capital funding, and spearheaded Series A and Series B financing to commercialize a novel treatment for patients with Aortic Valve Stenosis. Led product development from conception, devised strategy and obtained CE mark for three Class III devices, and achieved CE mark without a clinical investigation. Recruited 18 distributors covering 22 countries, supervised marketing activities, and enhanced market acceptance.

Mega-Motorsports **Chief Executive Officer, Director** 2003 – 2008
Toccoa, Georgia

Led turnaround of this family-owned motorcycle, ATV, watercraft, and outdoor equipment dealership with >10 major franchises from near bankruptcy to record profitability. Recruited, hired, and trained a general manager, enabling myself to a full-time return to the medical device industry.



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Boreas, Inc. **Cofounder, President, Chief Executive Officer, Director** 1988 – 1996
Billerica, Massachusetts
Developed and commercialized 4.2-Kelvin cryogenic cooler technology for medical MRI and superconducting electronics applications. Founded company with \$550K Small Business Innovation Research (SBIR) Grant from the US Department of Energy, raised over \$6M of venture capital financing, and additional funding from US and international strategic partners. Company's first product was honored as an R&D 100 winner, chosen by R&D Magazine as one of the 100 most technologically innovative products of the year. Facilitated acquisition of the company by a strategy partner in 1996.

EDUCATION

M.D., University of Massachusetts Medical School	2002
Ph.D., Mechanical Engineering, Massachusetts Institute of Technology (Minor Business Administration at MIT Sloan School and Harvard Business School)	1987
M.Sc., Mechanical Engineering, Massachusetts Institute of Technology	1984
B.Sc., Mechanical Engineering, Georgia Institute of Technology Highest Honors	1982

ADDITIONAL INFORMATION

Serves as instructor and mentor for LA BioStart, a Cal State University program for entrepreneurs

Serves as guest lecturer at Cal State University introducing principles of medical device product and business development

List of patents and publications available upon request

Former professional motocross racer; enjoys fitness activities and travel with family



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