

Peter A. Crosby

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Global leader and serial entrepreneur in the medical device industry with multiple successes in building companies, teams, products and revenues. Experienced at bringing new products to the world market in a high growth dynamic environment. Experienced Board member and Chairman in multiple geographies. Effective expert witness.

Accomplished Senior Executive with broad wingspan and extensive domain experience

- CEO of 6 companies – public and private – in 5 countries
- Member of Board of Directors of 13 companies, including Chairman of the Board of 6 companies
- Broad domain experience including Class III implantable medical devices (cochlear implants, pacemakers & leads, ICD, neuromodulation, LVADs), imaging (ultrasound, X-ray), in vitro diagnostics, software, patient monitoring

Savvy financial manager

- Raised capital (public and private) >\$200M. IPO on Euronext Paris and ESM Dublin
- Built revenues from zero to \$30M annual run rate in 3 years with complex new product
- P&L responsibility from small to >\$30M annual expenditure budget
- Sold three companies, participated in sale of three others

Acknowledged leader and change agent

- Proven team leader from small start up to 160-person public company. Effective mentor.
- Turned around and revitalized struggling company (three times)
- Drove culture change from local to global; from science to market; and from development to profit

Creative Contributor with strategic view

- Inventor or co-inventor on >39 patents and applications, and built intellectual property portfolio of several companies
- Many peer-reviewed scientific publications
- Designed and conducted clinical trials for US (FDA) and European (CE Mark) approval of many medical devices
- Developed and implemented successful global sales and marketing strategies

Education: M Eng Science, B Engineering (University of Melbourne, AU). Graduate of AICD Company Directors course
Citizenship: USA and Australia

Professional Experience

Current Positions

CEO and Managing Partner - Biomedical Business Resources LLC

Jul 95 – Present

A consulting and advisory service in the medical device industry, including board services and expert witness work.

Executive Chairman – ClinNEXUS Inc (Maine)

Oct 2020 – Present

ClinNEXUS is an early-stage health care services company offering a “digital front door” to primary care practitioners for virtual integrated care, particularly for high-risk, high-cost patients. www.clinnexus.com

Executive Chairman – CenSyn Inc. (Irvine, California)

May 2020 – present

CenSyn is an early stage medical device company developing and commercializing an “EEG Pen” to provide quick, efficient and accessible hand-held electroencephalogram (EEG) to monitor brain health during suspected neurological emergencies. The first target application is screening for silent seizures. www.censyn.com

Executive Chairman – Docbot Inc. (Irvine, California)

2018 – present

Docbot is using deep learning artificial intelligence for real-time analysis of HD 60FPS colonoscopy images. First product is for AI assisted polyp detection (currently in clinical trials), followed by optical pathology (polyp identification) with the goal of improved performance of colonoscopy. Multiple publications and patents. <http://www.docbot.ai/>

Chairman of the Board of Directors – SimTutor, Inc (Atlanta, Georgia)

June 2019 - Present

Simtutor is an eLearning company selling simulation and scenario-based training with a primary focus on health care skills training. With authoring tools, bespoke content development, and a large library of existing modules, it has found tremendous demand during the COVID19 pandemic. SimTutor Inc. is the US restructuring of two New Zealand companies which was completed in April 2020. <https://www.Simtutor.com>.

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Member of Board of Directors – Quench Medical (Minneapolis MN)

2018-present

Early stage medical device company with a new technology for delivering chemotherapy via an inhaled route.

<http://www.quenchmedical.net/>

Innovation Advisor – University of California Irvine

2018 – present

Provide guidance and advice to early stage companies in the Wayfinder Seed Program (incubator)

Prior Positions

Chief Executive Officer & Director - Mainstay Medical International PLC, Ireland

Jul 09 – October 2017

A medical device company in the field of neurostimulation therapy for chronic low back pain

Worked for sweat equity refining ideas and raising capital with a \$6M+ Series A financing in 2010. Founded the company, recruited key team, designed Feasibility Clinical Study with encouraging results. Closed over-subscribed \$20M Series B financing in September 2012, and led move of Company's HQ from Minneapolis to Ireland. Led successful IPO in April 2014, with dual listing on Euronext Paris and ESM of Irish Stock Exchange. Closed €30M private placement in June 2016. Designed ReActiv8-A clinical trial which led to CE Marking approval in June 2016 and start of commercialization in 2017. Designed ReActiv8-B Clinical Trial which led to PMA approval in 2020. Planned retirement as CEO in October 2017.

Chief Executive Officer & Director - Ventracor - Sydney Australia, USA and Europe

Jan 2005 – April 2009

An Australian Public Company developing and commercializing an implantable blood pump, the VentrAssist left ventricular assist device as therapy for patients in end stage heart failure.

COO from January 2005, CEO from July 2006. Raised ~\$50M in 2006, and ~\$28M in 2007. Built global sales and marketing organizations from scratch, and grew revenue from zero to ~\$30M annual run rate in three years. Leader of ~160 people worldwide. Repositioned company from a relative unknown to the acknowledged second player in the market. Contributed to design and management of a clinical trial which led to European CE Mark regulatory approval. Developed and completed US clinical trial and prepared for PMA submission. While finalizing a \$40M convertible debt financing in mid-2008, financial crisis triggered withdrawal of lead investors. Placed company into Voluntary Administration in March 2009 with a signed term sheet for acquisition.

Chief Executive Officer & Director - Ischemia Technologies Inc. - Denver, CO

1999-2004

A VC-backed company with an in vitro diagnostic blood test for detecting cardiac ischemia.

Drove product development, clinical trials, regulatory approval, and market launch. Built 35-member team and established a scientific advisory board. Designed and started clinical trials in 1999, obtained CE mark in 2001, Canadian approval in 2002, and FDA clearance in 2003. Expanded patent portfolio from 2 to 10, and drove revenue growth. Raised VC financing of >\$25M in four rounds between 1999 and 2003. Company sold to Inverness Medical Innovations in February 2005.

Chief Executive Officer, Board Chairman - CardioComm Solutions, Inc. - Victoria BC, Canada

1997-2006

A public software development company with products for management of real time ECG and patient data.

Joined as member of Board of Directors (1997) then became interim President & CEO from 1998. Cut costs and turned around company, restructured management team, raised new equity financing. Brought in new CEO and management team in 1999, and remained as Chairman of the Board until June 2006.

Chief Executive Officer & Director - NeoVision Corporation - Seattle, WA

1996-1997

A medical device company commercializing a new product with 3D ultrasound image guidance of minimally invasive breast biopsy for suspected breast cancer. Joined as a consultant early 2006, and later appointed as president and CEO. Obtained 2 term sheets for VC financing, but sold the company to US Surgical for \$42 million, yielding a >4x return to shareholders in approximately 18 months.

Vice President - Teletronics Pacing Systems – Denver, CO

1989-1995

A \$200+ million global company in implantable cardiac pacemakers and defibrillators. Sold to St. Jude Medical in 1996

VP Business Development

1995

Led the development of the overall business strategy; strategic alliances; diversification and consolidation opportunities; coordination with potential investors; and management of the intellectual property portfolio.

VP Research & Technology**1992-1995**

Managed applied research and technology of pacemakers and leads, including IC design, applied research, and biomaterials. Managed patent portfolio and negotiated cross licensing. Managed two major product recalls.

VP Strategic Planning**1992**

Responsibility for forward planning: product strategy, diversification opportunities, and company structure. Organized customer focus groups and Scientific Advisory Board, and developed the strategic plan.

VP International Marketing**1991-1992**

Coordinated global product marketing strategies for regions outside USA. Created sales strategies and provided sales support to sales reps and customers.

VP Tachycardia**1989-1991**

Global project management function, with responsibility for coordination of product development, clinical trial, regulatory strategy, and market launch for the emerging implantable defibrillator business. Forged relationships between the R&D group and customers in major markets. Presented to FDA PMA panel meeting.

Chief Executive Officer & Director - Ausonics Pty. Ltd. - Sydney, Australia**1986-1989**

A \$30M revenue subsidiary of a public company that developed, manufactured, and distributed ultrasound imaging equipment. US distributor of Japanese OEM-sourced X-ray mammography equipment.

Joined as Chief Executive R&D in 1986, promoted to CEO in 1987. Turned around and maintained the viability of the company during a time of cash squeeze, revitalized manufacturing and marketing, removed unprofitable products, improved sales of core products, and cleaned up balance sheet. Negotiated contracts with a Japanese supplier of equipment for U.S. distribution and negotiated to sell the U.S. mammography distribution business to a Finland based company.

R&D Executive - Cochlear Corporation - Sydney, Australia**1981-1986**

World leader in implantable hearing prostheses, dominant market share, major public company.

One of the founding team. Several positions in product development, marketing, and manufacturing. Liaised with University of Melbourne for technology transfer. Developed speech processor and speech processor programming system for cochlear implant. Wrote patents, physician manuals, user manuals, and part of PMA regulatory submissions.

Director, Northern Region Biomedical Engineering Service RNSH Sydney Australia**1978-1981**

Established and managed a Biomedical Engineering Service at a major teaching hospital at the center of a health care region (approx. 3000 beds), with responsibility for procurement and maintenance of medical technology equipment for all departments. Designed and built custom instrumentation for numerous research projects for several specialties.

Researcher Sydney Eye Hospital, Sydney Australia**1976-1978**

Designed and built equipment for the new laboratory for the founding Professor of Ophthalmology including visual evoked potentials, electroretinography, and electrooculography. Participated in several clinics, and ran training programs for ophthalmology fellows in various topics including vitrectomy, ophthalmic electrophysiology, and intraocular lenses.

Other Prior Board Activity**Chairman of the Board - First Medical - Mountain View, CA****1998-2000**

Developer of a point of care immunoassay IVD test platform for biochemical markers of cardiac function. Organized restart and refinancing of the company after original VC investors declined to continue. The Company was sold to Sigma Diagnostics in 2000, yielding approximately 4x return to second round investors in less than two years.

Member of the Board, Chairman of Audit Committee – Cardiac Science, Irvine CA**1997-2005**

A public medical device company (NASDAQ:DFIB) commercializing the PowerHeart Automatic External Defibrillator (AED). Merged with Quinton Cardiology Systems in September 2005.

Chairman, Medical Devices Advisory Board MDS Capital Corp. and CMDF, Toronto, Canada**1998-1999**

Select Expert Experience and Testimony

- Case: 10-CV-0442 DMS (WMC) in the US District Court for the Southern District of California in 2012 involving an IP dispute between Carefusion (Plaintiff) and Sigma (Defendant). Engaged by the attorneys as an expert witness for the defendant. Decided for the defendant.
- Case: 11-0097-CK in the Circuit Court for Kalamazoo County, Civil Division, between Stryker Corporation and Joseph P. Errico, et al. Acted for Stryker through its attorneys, Bartlit, Beck, Herman, Palenchar & Scott LLP. The assignment was to express opinions regarding whether Stryker acted in a manner consistent with a reasonable commercial business in its efforts to achieve U.S. Food and Drug Administration approval and commercial launch of its artificial disc products. Expert report presented in September 2013. Summary Judgement for Stryker.
- Case: 6:09-cv-06041-EAW) in the New York Western District between Bausch and Lomb (Plaintiff) and Dr. Mona Sarfarazi (defendant). Engaged in April 2015 as an expert for the Plaintiff through Plaintiff's attorneys, Nixon Peabody. Expert assignment to provide opinions in an Expert Report as to the usual, customary and routine practices in the medical device industry and whether B+L acted in a manner consistent with a reasonable commercial business in its efforts to achieve the "development milestones." Decided for the Plaintiff.
- A matter between two medical device companies A and B. A acquired certain assets of B and agreed to use "commercially reasonable efforts" to achieve milestones which would trigger milestone payments to B. The milestones were not met, the payments were not made, and B sued A for failure to use "commercially reasonable efforts." Engaged by the attorneys for A, Williams and Connolly LLP. The assignment was to evaluate whether A acted consistently with their obligation to use commercially reasonable efforts to complete the milestones. Appearance before 3 judge panel of the American Arbitration Association in New York in November 2017. Decided for A.
- Case number 2:18-cv-08103 in the District Court for the central district of California between the Securities and Exchange Commission (Plaintiff) and Mr. Hani Zeini, the ex-CEO of Sientra, Inc. regarding adequate public disclosure of potentially price sensitive information. Engaged in May 2019 by the defendant's attorney, Munger, Tolles & Olson LLP., and the case settled through mediation not long after.
- Case: 18-cv-00691-STV, jury trial requested. This is a case between plaintiff Wright Medical, Inc., and Defendant Paragon 28, Inc. Plaintiff alleges misappropriation of intellectual property including trade secrets. Engaged by the attorneys for the plaintiff in June 2019, Duane Morris. The assignment is to opine on what in the medical device industry is considered IP (confidential and/or trade secret information), and how such IP is protected and used. Wrote expert report and rebuttal report, was deposed as a 30b(6) witness, and was deposed as an expert. Case is ongoing.
- Case:1:19-cv-00325-UNA. An intellectual property dispute between Nevro Inc. (plaintiff) and Stimwave Inc. Engaged as a consulting expert by the attorneys for plaintiff, Morrison & Foerster, in 2019. Case settled before trial.
- A case in the US Tax Court Docket number 6944-11 between Medtronic Inc (Petitioner) and the Internal Revenue Service (Respondent). Engaged by the IRS in 2019. Wrote expert report, was deposed, and testified at trial in June 2021.
- Case:19-cv-03140-ECT-DTS in the US District court, District of Minnesota between former members of Caisson Interventional LLC (Plaintiff) and LivaNova PLC (Defendant). Engaged as a consulting and testifying expert in 2019 by the attorneys for the plaintiff, Fox Rothschild, to provide opinions as to whether defendant met its obligations under an acquisition agreement. Wrote expert report, rebuttal report, and was deposed. Case is ongoing.
- Case: 1:20-cv-03214-JPC in the US District Court, Southern District of New York, between INSPIRX Inc. (Plaintiff) and Lupin Atlantis Holdings SA (defendant). Engaged as a consulting expert in September 2020 by the defendant's attorneys, Holland and Knight LLP.
- Case: 1:20-cv-00291-CFC-JLH. An intellectual property dispute between Nevro Inc. (plaintiff) and Nalu Inc. Engaged in March 2021 as a consulting expert by the attorneys for plaintiff, Morrison & Foerster, Case settled before trial.
- Case: 20-cv-01507-NEB-ECW in the US District Court for the District of Minnesota, between Sleep Number Corporation. (Plaintiff) and Steven Young, Carl Hewitt and UDP Labs Inc. (Defendants), in a case involving claims for breach of contract and trade secret misappropriation. Engaged in mid-2021 as a consulting and testifying expert by the attorneys for Plaintiff, Fox Rothschild. Submitted expert report and was deposed. Case is ongoing.

Issued US Patents

11,191,423 Endoscopic System and Methods Having Real-Time Medical Imaging

11,103,706 Systems and Methods for Enhancing Function of Spine Stabilizing muscles associated with spine surgery intervention

- 11,100,373 Autonomous and continuously self-improving learning system
- 10,926,083 Stimulator for Treatment of Back Pain Utilizing Feedback
- 10,925,637 Methods of Implanting Electrode Leads for use with Implantable Neuromuscular Electrical Stimulator
- 10,828,490 Systems and methods for restoring muscle function to the lumbar spine
- 10,661,078 Modular stimulator for treatment of back pain, implantable RF ablation system and methods of use
- 10,471,268 Systems and Methods for Monitoring Muscle Rehabilitation
- 10,471,193 Implantable Medical Devices
- 10,449,355 Systems and Methods for Restoring Muscle Function to the Lumbar Spine and kits for Implanting same
- 10,016,603 Systems and Methods for Restoring Muscle Function to the Lumbar Spine
- 9,999,763 Apparatus and Methods for Anchoring Electrode Leads Adjacent to Nervous Tissue
- 9,950,159 Systems and methods for restoring muscle function to the lumbar spine and kits for implanting the same
- 9,861,811 Electrical Stimulator for Treatment of Back Pain and Methods of Use
- 9,474,906 Systems and methods for restoring muscle function to the lumbar spine
- 9,248,278 Modular stimulator for treatment of back pain, implantable RF ablation system and methods of use
- 9,108,053 Apparatus and methods for rehabilitating a muscle and assessing progress of rehabilitation
- 9,079,019 Apparatus and methods for anchoring electrode leads for use with implantable neuromuscular electrical stimulator
- 9,072,897 Systems and methods for restoring muscle function to the lumbar spine
- 8,876,685 Blood pump with an ultrasound transducer
- 8,858,416 Implantable medical devices
- 7,074,194 Apparatus and method for risk stratification of patients with chest pain of suspected cardiac origin
- 7,063,782 Electrochemical detection of ischemia
- 6,770,487 Bar code readable diagnostic strip test
- 6,217,744 Devices for testing fluid
- 6,106,524 Methods and apparatus for therapeutic cauterization of predetermined volumes of biological tissue
- 6,027,457 Apparatus and method for securing tissue during ultrasound examination and biopsy
- 5,851,180 Traction-inducing compression assembly for enhanced tissue imaging
- 5,820,552 Sonography and biopsy apparatus
- 5,807,234 Myostimulator control using metabolic demand and muscle performance
- 5,720,770 Cardiac stimulation system with enhanced communication and control capability
- 5,693,000 Cardiomyoplasty simulator with feedback control
- 5,476,486 Automatic atrial pacing pulse threshold determination utilizing an external programmer and a V-sense electrode
- 5,458,623 Automatic atrial pacing threshold determination utilizing an external programmer and a surface electrogram
- 5,391,192 Automatic Ventricular pacing threshold determination utilizing an external programmer and a surface electrocardiogram
- 5,311,607 Facsimile machine for printing documents all with corresponding edges aligned but without requiring scanning
- 5,292,340 Physiologically-calibrated rate adaptive, dual chamber pacemaker
- 4,532,930 Cochlear implant system for an auditory prosthesis
- 4,522,209 Cochlear prosthesis test system

Scientific Publications

Russo, M., Deckers, K., Eldabe, S., Kiesel, K., Gilligan, C., Vieceli, J., & Crosby, P. 2018. Muscle Control and Non-specific Chronic Low Back Pain. *Neuromodulation : Journal of the International Neuromodulation Society*, 21(1), 1–9. <https://doi.org/10.1111/ner.12738>

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<https://doi.org/https://doi.org/10.1007/978-1-59259-385-9>
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- Steinhaus, B. M., Smith, R. E., & Crosby, P. 1994. Role of telecommunications in future implantable device systems. *Annual International Conference of the IEEE Engineering in Medicine and Biology - Proceedings*, 16(pt 2)
- Crosby, P.A. 1994 Polyurethane in Cardiac Pacing Leads At 15th Ann Conf of North American Society of Pacing and Electrophysiology, Nashville
- Crosby, P., & Singer, I. 1991 The initial clinical experience with a third generation cardioverter defibrillator/antitachycardia pacemaker. *PACE - Pacing and Clinical Electrophysiology*, 14(10), 1554–1555.
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- Wood, S. L., & Crosby, P. A. 1981 A Real-time On-line digital computer method for monitoring myocardial supply demand ratio. *Anaesthesia Intens Care*, 9(1), 28–33.
- Crosby, P.A. 1981 Rotatable Raster Generator for Visual Research *Med & Biol Eng & Comput* 19:71-74
- Donaghue, K. D., & Crosby, P. A. 1979 Comparison of Recording Methods for Clinical Electroretinography. *Aust J Ophthalmology*, 7, 225–228.

Uren, S. M., Stewart, P., & Crosby, P. A. 1979 Subject cooperation and the visual evoked response. *Investigative Ophthalmology & Visual Science*, 18(6), 648–652.

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Dewhurst, D.J., Crosby, P.A., Cameron, J.D., Shankly, K.H., Kirsner, R.L.G. 1976 Active and Passive Control of Human Limb Movements *Dig 11th In. Conf. On Med & Biol Eng Ottawa*

Other Publications

“Balance of Risks – A Novel” ASIN B08X3YJCXK 21 Feb 2021 (Amazon Kindle)