SCOTT M. RUSSELL

Santa Cruz, CA 95060
408.813.4866 phone
408.521.1835 fax
scott@benchmarknitinol.com
http://www.linkedin.com/in/scottrussellbenchmarknitinol

OVERVIEW

- Talented medical device generalist with potent combination of business and technical experience, including such diverse areas as executive management, business development, medical device design, strategic planning, process development, testing, clinical research, branding, sales, and marketing.
- Demonstrated medical device startup leadership including business plan development, establishment of infrastructure, staffing, financial management, manufacturing implementation, IP portfolio management, product development, regulatory strategy, clinical trial management, establishment of strategic partnerships, and fundraising.
- Experience with directing medical device development and clinical research activities from concept to commercialization in cardiology, interventional radiology, spine, interventional neuroradiology, venous disease management, stroke, gynecology, minimally-invasive surgery, and pulmonology.
- Proven experience in managing a team of sales personnel and customer service associates.
- Demonstrated capability to build strong, effective, cross-functional partnerships with physicians, clinical researchers, investors, strategic partners, distributors, marketing personnel, sales, business development, manufacturing, quality assurance, regulatory, R&D, and external suppliers.
- World-renowned expertise in the development of Nitinol-based medical devices, alloys and processing.
- Strong sales and marketing experience with demonstrated business results.
- Prolific inventor with 34 issued patents and over 30 pending patent applications (25 published).

EXPERIENCE

Founder and President
Benchmark Nitinol, San Jose, California *2006 to present*
Founded a consulting business to provide product development and business development services to the medical device industry, including medical device invention and prototyping, process development and implementation, device testing and custom test development, process and test method validation, Nitinol technology consulting, educational seminars, clinical and regulatory strategy assistance, estimation of device Cost of Goods (COGS), due diligence on potential Nitinol medical device acquisitions, production of comprehensive business plans for medical device or Nitinol businesses, and development of supply chain strategies.

Co-founder, President and CEO
Emboline, Inc., San Jose, California *2011 to present*
Leading a pre-funding-stage cardiovascular medical device startup to develop a device for embolic protection during transcatheter aortic valve replacement (TAVR). Spearheading initial business establishment, financial/market modeling, proof-of-concept device development and testing, intellectual property development, and fundraising.

Co-founder and CEO
SuperRenal, San Jose, California *2013 to present*
Leading a pre-funding-stage cardiovascular medical device startup to develop novel interventional devices to significantly enhance kidney function for both therapeutic benefit and the prevention of long-term chronic kidney dysfunction. Spearheading initial business establishment, financial/market modeling, proof-of-concept device development and testing, intellectual property development, and fundraising.

President and CEO
SeptRx, Inc., Fremont, California *2008 to 2013*
Led a cardiovascular medical device startup to develop a device for percutaneous repair of *patent foramen ovale*. Directly responsible for all aspects of the operation including device design, clinical trial design, marketing, regulatory strategy, finance, manufacturing process development, packaging, testing, business

planning, intellectual property development and protection, and negotiations/ communications with stockholders, funders and strategic partners. Successfully led the company through final commercial development, including multiple rounds of fundraising, receipt of ethics committee approval from multiple European clinical sites, CalFDB certification, and completion of the pivotal European clinical trial.

Co-founder, General Manager and Chief Technical Officer
Confirmd LLC, San Carlos, California *2007 to 2008*
Co-founded a business to provide medical device testing and characterization services, including corrosion testing, transformation temperature testing, and fatigue testing. Business share sold to co-founder in 2008.

Director, Advanced Device Concepts Group
Nitinol Devices & Components, a Johnson & Johnson Company, Fremont, California *2000 to 2006*
Founded and directed an advanced device concepts group of 21 engineers, scientists, physicians, technicians, and business development personnel to demonstrate the technical and business feasibility of novel medical device solutions. Developed innovative medical device concepts in the areas of cardiology, interventional radiology, spine, neuroradiology, pulmonology, minimally invasive surgery, cardiac surgery, and gynecology. Directed the NDC team for the development and/or launch of the Cordis TrapEase and OptEase *vena cava* filters, the SMARTeR peripheral self-expanding stent radiopacity upgrade, the Aquatrack guidewire, and the Enterprise neurovascular stent. Successfully transitioned three major medical device programs from R&D into Product Development. Successfully spun out two new startup companies based on 1) an innovative pulmonology device concept, and 2) a *patent foramen ovale* repair device.

Director of Sales & Marketing
Shape Memory Applications, Inc., Santa Clara, California *1995 to 2000*
Directed all company sales and marketing efforts with average annual sales growth rate of 20 to 30%. Served as chief technologist for both internal and external Nitinol medical device development projects.

Shape Memory Alloys Product and Sales Engineer
Special Metals Corporation, New Hartford, New York *1993 to 1995*
Served in a combination sales and technical role in the field of Nitinol-based shape memory alloys, including financial modeling, customer service, process development and alloy development.

Materials Engineer/Senior Materials Engineer
Pratt & Whitney, United Technologies, East Hartford, Connecticut *1987 to 1993*
Conducted research in advanced NiAl-based intermetallic materials for aerospace applications. Developed and validated advanced turbine blade repair processes.

EDUCATION

CORNELL UNIVERSITY *B.S. – Materials Science and Engineering, 1987*

UNIVERSITY OF CONNECTICUT *M.S. – Metallurgy, 1996*

SAMPLING OF PROFESSIONAL LEADERSHIP, PATENTS & PUBLICATIONS

Professional Leadership

Lecturer 2010*, Shape Memory and Superelastic Metals: How Nitinol enables novel devices*, MD&M West Conference, Anaheim, CA.

Member 2008–2009, Board of Directors of SMST: The Shape Memory and Superelastic Technologies Society, an Affiliate Society of ASM International.

Worldwide Instructor 2006–2008, *Nitinol for Medical Devices* course, ASM International.
Included instructional modules on basic Nitinol metallurgy, Processing, Device Design, ASTM Nitinol Standards, Corrosion and Biocompatibility (including surface processing and testing), and Fatigue and FEA (including FEA model verification, benchtop testing, and selection of appropriate comprehensive fatigue assessment strategies).

Chairman of SMST-2003: The International Conference on Shape Memory and Superelastic Technologies.

Conference Secretariat of SMST-2000: The International Conference on Shape Memory and Superelastic Technologies.

Participant on the ASTM F04.15.14 Corrosion Task Group for development and maintenance of corrosion testing standards for medical devices

Issued Patents

Stephen J. Kleshinski and Scott M. Russell, *Embolic filtering method and apparatus*, U.S. Patent 8,758,395 (2014).

Stephen J. Kleshinski and Scott M. Russell, *Embolic filtering method and apparatus*, European Patent EP1904217 (2013).

Scott M. Russell, *Orifice device having multiple channels with varying flow rates for drug delivery*, U.S. Patent 8,491,571 (2013).

Lutz Biedermann, Wilfried Matthis, Minh Q. Dinh, Scott Carpenter, Raghuveer Basude, Tracy Lopes, and Scott M. Russell, *Bone anchoring device*, U.S. Patent 8,486,121 (2013).

Scott M. Russell, *Orifice device having multiple channels and multiple layers for drug delivery*, U.S. Patent 8,109,922 (2012).

Lutz Biedermann, Wilfried Matthis, Minh Q. Dinh, Scott Carpenter, Raghuveer Basude, Tracy Lopes, and Scott M. Russell, *Bone anchoring device*, U.S. Patent 8,080,044 (2011).

Minh Q. Dinh and Scott M. Russell, *Shape memory thin film embolic protection device*, European Patent EP185437B1 (2011).

Stephen J. Kleshinski and Scott M. Russell, *Embolic filtering method and apparatus*, Japanese Patent JP4779015 (2011).

Don Tanaka and Scott M. Russell, *Method for treating chronic obstructive pulmonary disease*, U.S. Patent 8,029,492 (2011).

Michelle Bartning, Mari Hou, Raymond J. Hull, Jr., Kirsten Freislinger Luehrs, Scott M. Russell, Paul B. Swick, and Pramod Mavinkurve, *Applicator for intravaginal devices*, U.S. Patent 7,935,098 (2011).

Don Tanaka and Scott M. Russell, *Device and method for creating a localized pleurodesis and treating a lung through the localized pleurodesis*, U.S. Patent 7,828,789 (2010).

Don Tanaka and Scott M. Russell, *Method for treating chronic obstructive pulmonary disease*, U.S. Patent 7,811,274 (2010).

Scott M. Russell, *Orifice device for delivering drugs at low fluid flow rates*, U.S. Patent 7,678,103 (2010).

Lutz Biedermann, Wilfried Matthis, Minh Q. Dinh, Scott Carpenter, Raghuveer Basude, Tracy Lopes, and Scott M. Russell, *Bone anchoring device*, European Patent EP1825826B1 (2008).

Scott M. Russell, *Medical device for fluid delivery having low fluid flow rate*, U.S. Patent 7,211,076 (2007).

Scott M. Russell, *Method for manufacturing an orifice mechanism capable of low fluid flow rates*, U.S. Patent 7,108,762 (2006).

Scott M. Russell, *Implantable device for delivering drugs using orifice mechanism capable of low fluid flow rates*, U.S. Patent 6,976,983 (2005).

Scott Russell, *Releasable and retrievable vascular filter system*, U.S. Patent 6,958,074 (2005).

Scott M. Russell, *Production method of orifice mechanism capable of delivering fluid at low speed,* Japanese Patent JP2005000671A (2005).

Scott M. Russell, *Medicine delivery device for implantation using orifice mechanism capable of delivering fluid at low cost*, Japanese Patent JP2005000670A (2005).

Scott M. Russell, *Medical orifice device for delivering fluid at low speed*, Japanese Patent JP2005000669A (2005).

Scott M. Russell, *Medical device for delivering fluid at low speed*, Japanese Patent JP2005000668A (2005).

Scott M. Russell, *Orifice device having multiple channels between multiple coiled layers for drug delivery*, European Patent EP1600188A2/A3 (2005).

Scott M. Russell, *Orifice device having multiple channels with varying flow rates for drug delivery*, European Patent EP1600187A2/A3 (2005).

Scott M. Russell, *Method for manufacturing an orifice mechanism capable of low fluid flow rates*, European Patent EP1486224A1 (2004).

Scott M. Russell, *Implantable device for delivering drugs using a capillary orifice for low fluid flow rates*, European Patent EP1486223A1/B1 (2004).

Scott M. Russell, *Orifice device for delivering drugs at low fluid flow rates*, European Patent EP1486222A1 (2004).

Scott M. Russell, *Medical device for fluid delivery having low fluid flow rate*, European Patent EP1486221A1/B1 (2004).

Don Tanaka and Scott M. Russell, *Delivery device for localized pleurodesis agent delivery*, European Patent EP1475117A2 (2004).

Don A. Tanaka and Scott M. Russell, *Chemical substance administration for local pleurodesis*, Japanese Patent JP2004344650A (2004).

Scott Russell, *Blood vessel filter system, method and apparatus*, Japanese Patent JP2003230563A (2003).

Scott Russell, *Releasable and retrievable vascular filter system*, European Patent EP1346703A1 (2003).

C. C. Law and S. M. Russell, *Nickel-aluminum alloy*, Japanese Patent JP02213438 (1990).

Chi Chiu Law and S. M. Russell, *Nickel aluminide materials having toughness and ductility at low temperatures*, U.S. Patent 4,961,905 (1990).

Published Patent Applications

Michael Tal, Bob H. Katz and Scott M. Russell, *Intrauterine device with controlled copper ion elution*, U.S. Patent Application US20150101613A1 (2015).

Scott Russell and Amir Belson, *Introducer sheath with embolic protection*, U.S. Patent Application US20150066075A1 (2015).

Scott Russell and Amir Belson, *Integrated embolic protection devices*, European Patent Application EP20130733627 (2013).

Scott M. Russell, Kirsten Luehrs and Alex Nedvetsky, *Thin film tissue repair matrix*, U.S. Patent Application US20130204394A1 (2013).

Scott Russell and Amir Belson, *Integrated embolic protection devices*, U.S. Patent Application US20130178891A1 (2013).

Asia Chang, Scott M. Russell and Don Tanaka, *Devices and methods to create and maintain the patency of an opening relative to parenchymal tissue of the lung*, U.S. Patent Application US20100147295A1 (2010).

Asia Chang, Scott M. Russell and Don Tanaka, *Devices and methods to maintain the patency of an opening relative to parenchymal tissue of the lung*, U.S. Patent Application US20100147294A1 (2010).

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Michelle Bartning, Mari Hou, Raymond J. Hull, Jr., Kirsten Freislinger Luehrs, Scott M. Russell, Paul B. Swick, and Pramod Mavinkurve, *Applicator for intravaginal devices*, European Patent Application EP2106733A1 (2009).

Asia Chang, Scott M. Russell and Don Tanaka, *Methods and devices to maintain the patency of a lumen in parenchymal tissue of the lung*, U.S. Patent Application US20080283065A1 (2008).

Scott M. Russell, Kirsten Luehrs and Alex Nedvetsky, *Thin film tissue repair matrix*, U.S. Patent Application US20080249597A1 (2008).

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Don Tanaka and Scott M. Russell, *Implantable device and method for creating a localized pleurodesis and treating a lung through the localized pleurodesis*, U.S. Patent Application US20080188824A1 (2008).

Don Tanaka and Scott M. Russell, *Device and method for creating a localized pleurodesis and treating a lung through the localized pleurodesis*, U.S. Patent Application US20080188809A1 (2008).

Minh Q. Dinh and Scott M. Russell, *Shape memory thin film embolic protection device*, U.S. Patent Application US20070191877A1 (2007).

Stephen J. Kleshinski and Scott M. Russell, *Embolic filtering method and apparatus*, WO 2007/011353 A2 (2007).

Minh Q. Dinh and Scott M. Russell, *Shape memory thin film embolic protection device with frame*, U.S. Patent Application US20060100659A1 (2006).

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Scott M. Russell, *Implantable device for delivering drugs using orifice mechanism capable of low fluid flow rates*, U.S. Patent Application US20040254565A1 (2004).

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Don Tanaka and Scott M. Russell, *Localized pleurodesis chemical delivery*, U.S. Patent Application US20040225254A1 (2004).

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Publications

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Scott M. Russell, “Design Considerations for Nitinol Bone Staples”, *Journal of Materials Engineering and Performance*, Vol. **18**, Nos. 5–6, 2009, pp. 831–835.

Masao Drexel, Jim Proft and Scott Russell, “Characterization of Transformation Temperatures with the Bend and Free Recovery Technique: Parameters and Effects”, *Journal of Materials Engineering and Performance*, Vol. **18**, Nos. 5–6, 2009, pp. 620–625.

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Scott Russell and Darel Hodgson, “Nitinol Melting, Manufacture and Fabrication”, *Minimally Invasive Therapy and Allied Technologies*, Vol. **9**, No. 2, March 2000, ISSN 1364-5706, pp. 61–66.

A. Pelton, D. Hodgson, S. Russell, and T. Duerig (editors), *SMST-97: Proceedings of the Second International Conference on Shape Memory and Superelastic Technologies*, 1997, ISBN 0-9660508-1-9.

S. M. Russell, D. E. Hodgson and F. Basin, “Improved NiTi Alloys for Medical Applications”, in *SMST-97: Proceedings of the Second International Conference on Shape Memory and Superelastic Technologies*, 1997, pp. 429–436.

Scott Russell, Interview with Martin Sexton, *Acoustic Musician*, December 1996, pp. 8–14.

S. M. Russell, *The Effects of Alloying on the Phase Stability of NiAl*, Masters Thesis, University of Connecticut, 1996.

S. M. Russell and F. Sczerzenie, “Engineering Considerations in the Application of NiTiHf and NiAl as Practical High-Temperature Shape Memory Alloys”, in *SMST-94: Proceedings of the First International Conference on Shape Memory and Superelastic Technologies*, 1994, pp. 43–48.

S. M. Russell, C. C. Law, M. J. Blackburn, P. C. Clapp, and D. M. Pease, *Lightweight Disk Alloy Development*, Air Force Report WRDC–TR–90–4125, 1991.

S. M. Russell, C. C. Law, L. S. Lin, and G. W. Levan, “Mechanical Properties and Microstructure of Certain NiAlCo(Hf) Alloys”, in *Mat. Res. Soc. Symp. Proc.*, Vol. **186**, 1991, pp. 289–294.

S. M. Russell, C. C. Law, and M. J. Blackburn, “The Effect of Cobalt on Martensitic Toughening Parameters in NiAl”, in *Mat. Res. Soc. Symp. Proc.*, Vol. **133**, 1989, pp. 627–632.

D. B. Miracle, S. M. Russell and C. C. Law, “Slip System Modification in NiAl”, in *Mat. Res. Soc. Symp. Proc.*, Vol. **133**, 1989, pp. 225–230.