

PHILIP J. HAARSTAD

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PROFESSIONAL EXPERIENCE

Haarstad Engineering Services LLC, Chanhassen, MN

Providing highly skilled project leadership and engineering expertise for medical device endoscopic, catheter based and delivery system technologies.

Owner/ Medical Device Engineering Consultant: May 2008 to Present

Clients Include: Medtronic, Thoratec, EV3, CVRx, Johnson and Johnson/Ethicon's Wound Management Division, InnerPulse and various early stage start-up companies.

EndoMetabolic Solutions, Maple Grove, MN

EndoMetabolic Solutions was an early stage start-up company developing a new device therapy for the treatment of obesity and type 2 diabetes.

Vice President of Research and Development: March 2009 to November 2009

Responsible for leadership of R&D department including: product development, staff, budget, project timelines, prototype lab and machine shop.

InnerPulse, Research Triangle Park, NC

InnerPulse was an early stage medical device company developing a Percutaneous Implantable Cardiac Defibrillator (PICD) that is placed entirely within the vascular system. InnerPulse raised approximately \$85 million.

Principal Engineer: November 2005 to May 2008

Led the development of the implant and retrieval tools for the Percutaneous Implantable Cardiac Defibrillator (PICD). Worked closely with clinicians to develop the implant procedure method in animal studies. Direct Supervisor of 4 engineers and 1 technician.

Velocimed/St. Jude Medical, Maple Grove, MN

Velocimed was a start-up company founded in 2001 that developed three interventional cardiology products simultaneously: The *Premere* PFO Closure System, the *Proxis* Embolic Protection System, and the *Venture* Wire Control Catheter. Velocimed was acquired by St. Jude Medical in April of 2005 for a maximum purchase price of \$262.5 million, depending upon achievement of revenue targets and a product regulatory approval.

PFO Project Leader: February 2003 to November 2005

Led team thru design freeze, GLP animal studies, design verification testing, 1st human use, CE approval, and start of US IDE trial of the *Premere* PFO Closure System. Developed an auxiliary retrieval device that allows the implant device to be recovered in bailout situations. Co-inventor on patent application for the retrieval device and PFO device.

Medtronic Cardiac Surgery Technologies, Brooklyn Park, MN

Medtronic CST was the new technologies division within Cardiac Surgery. It was focused on creating devices for revascularization of diseased coronary arteries, surgical treatment of Atrial Fibrillation, and devices used to treat Congestive Heart Failure.

Principal Engineer and Project Leader: March 2001 to February 2003

Researched, prototyped and developed several devices needed for Endoscopic Multi-vessel Beating Heart Bypass Surgery. Worked with key cardiac surgeons in cadaver and animal studies. Led a development team thru commercialization of the *Starfish NS*. This device allowed Cardiac Surgeons the ability to perform a Multivessel Beating Heart Bypass procedure thru a small thoracotomy incision with out the need for a sternotomy. Primary inventor on patent application for this device.

Worked with other product development teams to solve critical engineering problems with the *Octopus 4* and *Starfish 2* next generation devices. These market-leading products are used for Off-Pump Coronary Artery Bypass Surgery (OPCAB) to stabilize and position a beating heart and made up the majority of revenue for the CST division within Medtronic at that time.

MedtronicAVE, Santa Rosa, CA

MedtronicAVE is the vascular division of Medtronic Inc. and was created by the acquisition of Arterial Vascular Engineering in 1999 for approximately \$4.3 billion. MedtronicAVE develops and manufactures endovascular devices such as stents, balloon catheters, guide catheters and guide wires for coronary and peripheral applications.

Director of Product Development:

August 2000 to March 2001

Responsible for research and development of next generation coronary stent devices and various new concept catheter-based devices. Provided leadership and direction to three technical engineering groups: Stents, Delivery Catheters, and Balloons. Direct supervisor of three technical managers. Entire group consisted of approximately thirty employees.

Led project team through pre-clinical development and IDE clinical trials of the S7 stent delivery system. This next generation device incorporated a stent with improved metal architecture and a more flexible, less radial compliant delivery balloon.

Director of Catheter Technologies:

January 2000 to August 2000

Responsible for research and development of catheter-based technologies. Provided leadership and direction to five R&D project leader catheter engineers and two technicians.

Provided project leadership of an engineering team focused on the development of a new balloon material for coronary stent delivery.

Successfully incorporated a "lead by example" style of management to R&D Engineers.

Supervised project engineer responsible for the design and development of a Chronic Total Occlusion catheter used in coronary arteries. This device has been pursued through successful initial human trials in Japan.

Primary inventor on patent for this CTO device.

Manager of Stent Delivery Systems:

February 1999 to January 2000

Provided leadership and significant engineering contributions to S670 with Discrete Technology stent delivery catheter platforms. In the billion dollar US coronary stent market at that time these products gave MedtronicAVE a 30% plus share that was increased from less than 10% prior to commercial release.

Arterial Vascular Engineering, Santa Rosa, CA

AVE was founded in 1991 and developed balloon catheters and stents for coronary and peripheral artery applications. AVE has been given the title of the fastest growing medical device company ever started. In 1999 it was the market leader in the highly competitive coronary stent market and was sold to Medtronic in the largest medical device acquisition to that date.

Senior R&D Engineer:

August 1998 to February 1999

Project leader of successful development and commercial release of the over-the-wire GFX 2 stent delivery system.

Designed and developed bifurcated stent and delivery system used in successful initial human trials. This product was used in a live case demonstration at a major interventional cardiology conference in Europe. Co-Inventor on patent for this device.

R&D Engineer:

August 1995 to August 1998

Developed an over-the-wire stent delivery catheter that was the basic delivery platform for three generations of stent devices: GFX 2, S670 and S7 stents.

Developed design around rapid exchange stent delivery catheter for competitive patent constrained US market.

Led project through R&D phase and completion of 200 patient US IDE trial. Co-Inventor on patent for this device.

EnVision Surgical Systems, Palo Alto, CA

EnVision was a small start-up medical device company that was developing rigid endoscopes for small joint arthroscopy and a visually guided endotracheal tube system for difficult intubations.

Development Engineer:

January 1994 to August 1995

Developed PVC balloon for endotracheal tube cuff.

Designed endoscope light chord connector with adapters for various brand light chords.

EDUCATION

Bachelor of Mechanical Engineering:

University of Minnesota, Minneapolis, MN
Degree received: June 1993

1989 to 1993

Bachelor of Arts, Physics:

North Park College, Chicago, IL
Degree awarded concurrently with B.M.E. 1993

1985 to 1989

PATENTS

US Issued:

7,976,543, 7,189,231 & 6,960,209, Clague, et al., "Electrosurgical methods and apparatus for making precise incisions in body vessels", July 2011, March 2007 & November 2005
8,734,320, 8,449,449 & 7,494,460, Haarstad, et al., "Methods and apparatus providing suction-assisted tissue engagement through a minimally invasive incision", May 2014, May 2013 & February 2009
8,454,634, Jahns, et al., "Vessel sealing devices", June 2013
8,372,112, Christianson, et al. "Closure devices, related delivery methods, and related methods of use", February 2013
7,338,434, Haarstad, et al., "Method and system for organ positioning and stabilization", March 2008
7,018,400, Lashinski, et al., "Endolumenal prosthesis and method of use in bifurcation regions of body lumens", March 2006
6,533,753, Haarstad, et al., "Apparatus and method for the treatment of an occluded lumen", March 2003
6,520,988, Colombo, et al., "Endolumenal prosthesis and method of use in bifurcation regions of body lumens", February 2003
6,129,738, Lashinski, et al., "Method and apparatus for treating stenosis at bifurcated regions", October 2000
6,071,285, Lashinski, et al., "Rapid exchange folded balloon catheter and stent delivery system", June 2000

US Applications:

20140277419, Garde, et. al., "Anti-Paravalvular Leakage Component for a Transcatheter Valve Prosthesis"
20130282026, Hoarau, et. al., "Engagement device and method for deployment of anastomotic clips"
20130217959, 20090082620 & 20040138522, Haarstad, et al., "Methods and apparatus providing suction-assisted tissue engagement through a minimally invasive incision"
20130184727, 201000121362 & 20080161843, Clague, et al., "Vessel support device and method of vessel harvesting"
20120330330, 20120259350 & 20110144560, Gagner, et al., "Incisionless gastric bypass method and devices"
20120221021, Hoarau, et al., "Coupling System, applicator tool, attachment ring and method for connecting a conduit to biological tissue"
20110152904, 20080161841 & 20100114136, Clague, et al., "Cutting device and method of vessel harvesting"
20110144560, Gagner, et al., "Incisionless gastric bypass method and devices"
20100114136 & 20080161841, Clague, et al., "Cutting device and method of vessel harvesting"
201000174281, 20070073344 & 20050165427, Jahns, et al., "Vessel sealing devices"
20080167669, Clague, et al., "Vessel tensioning handle and method of vessel harvesting"
20070123854, 20050033277, & 20040082945, Clague, et al., "Electrosurgical methods and apparatus for making precise incisions in body vessels"
20060009800, Christianson, et al., "Closure devices, related delivery methods, and related method of use"
20030167083, Lashinski, et al., "Endolumenal prosthesis and method of use in bifurcation regions of body lumens"