

Professional Summary

Medical device and automation experience since 1986. Areas of expertise include full life cycle product development of medical devices from conception through development including manufacturing, bench testing, verification, validation, packaging, labeling, clinical trials, regulatory approval, marketing, and sales training. Granted 21 patents (others pending), 7 awards, designs published by Life Magazine, was recognized as one of 100 notable people in the medical device industry by the Medical Device & Diagnostic Industry (MD&DI) publication in June 2008, my company has been recognized by the Better Business Bureau and Business NH Magazine in 2013, and recently served as chairman of the Medical Device & Manufacturing Conference in 2014.

Employment History

From: 2006 **ATech Designs, Inc.**
To: Present
Position: *President*

- Medical device product development and consulting since 1998 (formerly Innovative Engineering, Inc. in North Carolina)
- Developed cardiovascular, surgical, intravenous, endoluminal, percutaneous devices including market analysis and benchmarking.
- Consulting on real-time bedside blood glucose level analyzer and disposable cartridge, peritoneal dialysis pumps, safety syringes, disinfecting caps, auto-injectors, urinary catheters, insulin pumps, subcutaneous ports & catheters, bed rails, & sleep apnea devices.
- Failure analysis of hernia mesh stapler and cervical screws & plates
- Developed sleep apnea or continuous positive airway pressure (CPAP) device with patent pending.
- Invented and developed Programmable Electrode Array Knitter (6,158,250) to manufacture RF mesh for endometrial ablation device
- Development of medical textiles and knitting machines.
- Invented & developed minimally invasive mitral valve repair devices for three different companies (8,092,363, D717,954, others pending)
- Litigation consulting and expert witness (patent & liability cases)
- Visit www.atechdesigns.com for more information

From: 2005 **Mitralign, Incorporated**
To: 2006
Position: *Director of Biomedical Engineering*

- Developed implants required for percutaneous mitral valve repair (pat. pending) in 6 months that were selected for final design
- Invented & developed new tissue anchors within 2 months of hire
- Completed locker implant used to plicate the anchors & lock sutures

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From: 2002 **ONUX Medical, Incorporated**

To: 2005

Position: *Manager of Design Engineering*

- Invented, developed, and tested a needlescopic Nitinol fixation device for abdominal aortic aneurysm (AAA) repair in 10 months (patent pending)
- Performed animal studies and trained surgeons on use of device
- Designed a disposable laparoscopic Q-ring fixation device below cost targets and performed market comparison study.
- Design history files were ISO compliant and most organized in the company

From: 1992 **ALARIS Medical Systems** (formerly IVAC (Eli Lilly) & imed)

To: 2002

Position: *Sr. Principal Design Engineer (Director Level Engineer)*

- Worked on development of medical drug infusion products including, but not limited to, disposable sets and components, syringe pump, pump systems, valves, and pump segments, insulin injection system for Eli Lilly, vial adapters, dialysis set components, catheters, and needle-free valves.
- Extensive knowledge of polymer selection, high volume production, IV therapy, chemical resistance, fracture mechanics, measurement equipment, design-of-experiments (DOE) & EtO/Gamma/E-beam sterilization, and packaging.
- Performed market analysis including focus studies.
- Researched and selected injection, compression, injection-compression, transfer, flashless, liquid injection molding (LIM), gum injection, vertical, and rotary molding methods by working closely with molding suppliers
- Designed plastic parts, ultrasonic welding fixtures and processes, decoupled molding processes, high speed leak and flow testing systems, UV adhesive and solvent joints, and automation
- Promoted five times - Product Eng. II to Sr. Principal Design Eng.
- Managed projects throughout product life cycle
- Sole inventor of the \$300 million SmartSite[®] Needle-Free Valve that leads the sales of IV pumps and disposables (this project has been identified as the most successful project in the history of the company)
- Inventor of 17 patents for the SmartSite[®] Needle-Free Valve Technology (5,549,577 / 5,676,346 / 5,839,715 / 6,142,446 / D468016 / 6,706,022 / 6,802,490 / 6,875,205 / 6,971,630 / 7,104,520 / 7,125,396 / 7,184,825 / 7,244,249 / 7,306,199 / 7,497,848 / 8,029,472 / 8,177,768)

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- Winner of 5 design awards for the SmartSite Valve - 1998 Medical Design Excellence Award (MDEA), 1999 NC Governors New Product Award, 2000 NSPE New Product Award, 2001 Prototype Design Award, and 2003 MDEA Gold Winner
- SDRS Master Series 8.0, MARC, AutoCAD 14, and MoldFlow were used for solid modeling, FEA, drafting, and mold filling analysis

From: 1990 **Draper Corporation**

To: 1992

Position: *Mechanical Design Engineer*

- Designed textile loom & knitting machines
- Used knowledge of tribology, cams, gears, bearings, servo motors, electromagnetics, pneumatics, PLC's, PC oscilloscopes, and sensors
- Deflection and stress analysis using own finite element programs
- Electromagnetic analysis using MSC/XL-EMAS

From: 1988 **Harris Graphics Corporation**

To: 1990

Position: *Design Engineer*
Web offset printing press design

From: 1987 **Materials Lab, Incorporated**

To: 1988

Position: *Analyst*
Analyzed and designed plasma arc cutters

From: 1986 **Walker Power, Incorporated**

To: 1987

Position: *Mechanical Designer*
Designed textile wrap-spin machine

From: 1979 **KRL Electronics, Incorporated**

To: 1986

Position: *Technician*
Designed automated resistor equipment

Publications & Lectures

- Thesis: Strength of Medical Thermoplastic Female Luers Exposed to Chemicals
- Lectured MD&M Show Seminar on “The Science of Successful Product Design”
- Published paper on Chemical Compatibility and the SmartSite[®] Needle-Free Valve
- Chairman of the Medical Device & Manufacturing Conference in 2014
- Presenter/speaker at webinars on Medical Device Product Development Process

Curriculum Vitae of Karl R. Leinsing, MSME, PE

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Patents

<u>Patent Number</u>	<u>Issue Date</u>	<u>Title</u>
D717,954	11/18/2014	Heart Treatment Device
8,740,850	06/03/2014	Safety Catheter System & Method
8,177,768	05/15/2012	Vial adapter having a needle-free valve for use with vial closures of different sizes
8,092,363	01/10/2012	Heart band w/fillable chambers to modify heart valve function
8,029,472	10/04/2011	Safety catheter system and method
7,497,848	03/03/2009	Needleless medical connector w/expandable valve mechanism
7,306,199	12/11/2007	Needle free medical connector with expanded valve mechanism and method of fluid flow control
7,244,249	07/17/2007	Needle-free medical connector with expandable valve mechanism and method of fluid flow control
7,184,825	02/27/2007	Needless medical connector having antimicrobial agent
7,125,396	10/24/2006	Safety catheter system and method
7,104,520	09/12/2006	Needle free medical connector with expanded valve mechanism and method of fluid flow control
6,971,630	12/06/2005	Needle free medical connector with expanded valve mechanism and method of fluid flow control
6,875,205	04/05/2005	Vial adapter having a needle-free valve for use with vial closures of different sizes
6,802,490	10/12/2004	Needle free medical connector with expanded valve mechanism and method of fluid flow control
6,706,022	03/16/2004	Needleless medical connector with expandable valve mechanism
D468,016	12/31/2002	Medical fluid connector
6,158,250	12/12/2000	Flat-bed knitting machine and method of knitting
6,142,446	11/07/2000	Medical adapter needleless valve & sharpened cannula
5,839,715	11/24/1998	Medical adapter needleless valve & sharpened cannula
5,676,346	10/14/1997	Needleless Connector Valve
5,549,577	08/27/1996	Needleless Connector

Education & Licensing

<u>Year</u>	<u>College/University</u>	<u>Degree</u>
1988	University of New Hampshire	B.S. in Mechanical Engineering
1989	PADI	Scuba Certification
1992	NH: 11437 and NC: 18508	Professional Engineering Licenses
1995	North Carolina A&T State University	M.S. in Mechanical Engineering
2006	NH Department of Safety	Boating License
2012	FAA	Pilot License – Fixed Wing & Rotorcraft

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Litigation Support Experience - (Deposition and/or Testimony in Last 4 years)

Antares Pharma vs. Medac Pharma – Case No: 1:14-cv-00270-SLR – US District Court of Delaware – Methotrexate Autoinjector Patent Litigation (Defendant) – Review of documents, declaration for PI hearing, and deposition. Contact: Ching-Lee Fukuda at Ropes & Gray, LLP in New York, NY (212) 596-9336. (March 2014 – September 2014)

Medtronic vs. Animas – Case No: 2:12-CV-04471-RSWL-RZx – US District Court, Central District of California – Insulin Pump Patent Litigation (Plaintiff) – Extensive reports, and deposition. Contact: Alex MacKinnon at Kirkland & Ellis LLP in Los Angeles, CA (213) 680-8432. (October 2013 – July 2014)

Ivera vs. Excelsior, Hospira, & Catheter Connections – Case No: 11-cv-1115-H (JMA)/12-cv-1582-H (RBB), 11-cv-1246-H (RBB)/12-cv-1581-H (RBB), 12-cv-0954-H (RBB)/12-cv-1587-H (RBB) each group consolidated – US District Court So. District of CA & Catheter Conn. vs. Ivera – Case No: 14-cv-0070 - US District Court of Utah – Disinfecting Luer Cap Patent Litigation (Plaintiff & Defendant) – Declaration, depositions, reports, & PI Hearing. Contact: Jon Hangartner at X-Patents, APC in La Jolla, CA (858) 454-4313. (July 2013 - Present)

ResMed vs. Apex Medical – ITC Case No. 337-TA-879 – Washington, D.C. – Sleep Apnea Patent Litigation (Defendant) – Review design changes, report, deposition, and hearing. Contact: Jeff Eichen and Joe Bain at Novak Druce Connolly Bove & Quigg, LLP in Wilmington, DE (302) 888-6304. (July 2013 – August 2014)

CareFusion vs. B.Braun – Case No: 8:11-CV-01264 PA (ANx) – US District Court of California – Needle-Free IV Valve Patent litigation (Plaintiff) – Review of documents, testing, reports, technical tutorial for judge at hearing, and deposition. Contact: Atty Scott McBride at McAndrews, Held, & Malloy in Chicago, IL (312) 775-8000. (March 2012 – September 2012)

ICU Medical vs. RyMed Technologies – Case No: 07-468-LPS – US District Court For The District of Delaware – Needle-Free IV Valve Patent litigation (Defendant) – Reports, deposition, & bench trial. Contact: Atty Mark Levine at Bartlit Beck Harman Palenchar & Scott in Chicago (312) 494-4454. (December 2011 – May 2012)

Nance vs. Innovasis – Case No: CIV-11-432D – US District Court for the Western District of Oklahoma – Cervical Screw Failure (Plaintiff) – Review of documents, fracture analysis, SEM analysis, expert report, and deposition. Contact: Atty Michael Atkinson at Atkinson, Haskins, Nellis, Brittingham, Gladd, & Carwile in Tulsa, OK (918) 582-8877. (June 2011 – May 2013)

Dorothy Gove vs. Florida Cancer Institute, P.A. – Case No: 51-2006 CA 2650WS – Circuit Court of the Sixth Judicial Circuit of the State of Florida, in and for Pasco County, Civil Division – Fractured Catheter - Bard Port Liability Case (Plaintiff) – Analysis, testing, reports, two depositions, and trial testimony. Contact: Andrew Wozniak at Mac A. Greco, Jr. Attorneys at Law in Tampa, FL (813) 223-7849. (October 2010 – October 2013)

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Affiliations

ASME – American Society of Mechanical Engineers since 1988
AOPA – Aircraft Owners and Pilot Association since 1999
MDG – Medical Development Group since 2006
Eureka Medical – Medical Device Advisory Board since 2006
BBB – Better Business Bureau of New Hampshire since 2010
MassMedic – Massachusetts Medical Device Industry Council since 2011
BRP – Bombardier Recreational Products - Platinum Owners Club since 2011
NEHC – New England Helicopter Council since 2014