



Karl R. Leinsing, MSME, PE
77 Spur Rd. Dover, NH 03820-9110
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kleinsing@comcast.net

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 28 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, and bone anchors.
- Failure analysis of hernia mesh stapler and cervical screws & plates
- Developed sleep apnea or CPAP device.
- Developed catheter dressing for H2L Medical Technologies, LLC.
- 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, Inc.**
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, Inc.**

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 **IVAC/imed/Eli Lilly/ALARIS/Cardinal Health/CareFusion/BD**

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
- SDRC 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, Inc.**

To: 1988

Position: *Analyst*
Analyzed and designed plasma arc cutters

From: 1986 **Walker Power, Inc.**

To: 1987

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

From: 1979 **KRL Electronics, Inc. (Bantry Components)**

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 No.</u>	<u>Issue Date</u>	<u>Title</u>
9,750,907	09/05/2017	Portable CPAP and Method For Reducing Noise Therefrom
9,707,378	07/18/2017	Safety Catheter System and Method
9,421,102	08/23/2016	Cardiac Treatment System and Method
9,375,543	06/28/2016	Systems For Providing Low-Noise Positive Airway Pressure
9,370,425	06/21/2016	Cardiac Treatment System and Method
8,951,286	02/10/2015	Tissue Anchor and Anchoring System
8,951,285	02/10/2015	Tissue Anchor, Anchoring System & Methods of Using
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 With Needle-Free Valve For Use With Vials
8,092,363	01/10/2012	Heart Band W/Fillable Chambers to Modify Heart Valve
8,029,472	10/04/2011	Safety Catheter System and Method
7,497,848	03/03/2009	Needleless Medical Connector W/Expandable Valve
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 with Needle-Free Valve for use with Vials
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 Connector 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



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Published Patent Applications (others pending)

<u>Pub. No.</u>	<u>Pub. Date</u>	<u>Title</u>
US 2002/0133124	Sep. 19, 2002	Needleless Medical Connector Having Antimicrobial Agent
US 2003/0098430	May 29, 2003	Needle free Medical Connector with Expanded Valve Mechanism and Method of Fluid Flow Control
US 2003/0153895	Aug. 14, 2003	Vial Adapter Having a Needle-Free Valve for use with Vial Closures of Different Sizes
US 2003/0199835	Oct. 23, 2003	Needleless Medical Connector w/Expandable Valve Mech.
US 2003/0209681	Nov. 13, 2003	Needle-Free Medical Connector with Expandable Valve Mechanism and Method of Fluid Flow Control
US 2004/0073237	Apr. 15, 2004	Surgical Fastener and Delivery System
US 2004/0127854	Jul. 1, 2004	Safety Catheter System and Method
US 2005/0006614	Jan. 13, 2005	Needle Free Medical Connector with Expanded Valve Mechanism and Method of Fluid Flow Control
US 2005/0148994	Jul. 7, 2005	Vial Adapter Having a Needle-Free Valve for use with Vial Closures of Different Sizes
US 2007/0007478	Jan. 11, 2007	Needle Free Medical Connector with Expanded Valve Mechanism and Method of Fluid Flow Control
US 2007/0010857	Jan. 11, 2007	Tissue Anchor, Anchoring System & Methods of Using
US 2007/0100284	May 3, 2007	Safety Catheter System and Method
US 2007/0276437	Nov. 29, 2007	Lockers for Surgical Tensioning Members and Methods of Using the Same to Secure Surgical Tensioning Members
US 2009/0062596	Mar. 5, 2009	Heart Band w/Fillable Chambers to Modify Heart Valve Function
US 2009/0076547	Mar. 19, 2009	Tissue Anchor and Anchoring System
US 2011/0230810	Sep. 22, 2011	Implantable Anti-Adhesion Three Layer Patch
US 2011/0319827	Dec. 29, 2011	Safety Catheter System and Method
US 2012/0059457	Mar. 8, 2012	Minimally Invasive Surgical Instrument for Delivery of Cardiac Devices
US 2014/0107405	Apr. 17, 2014	Cardiac Treatment System and Method
US 2014/0107406	Apr. 17, 2014	Cardiac Treatment System and Method
US 2014/0107775	Apr. 17, 2014	Cardiac Treatment System
US 2014/0288500	Sep. 25, 2014	Safety Catheter System and Method
US 2014/0299130	Oct. 9, 2014	Portable Positive Airway Pressure Apparatus and Method for Attenuating the Noise Emitted Therefrom
US 2014/0299132	Oct. 9, 2014	Systems and Methods for Providing Positive Airway Pressure in a Tube-Like Structure
US 2014/0299406	Oct. 9, 2014	Systems and Methods for Providing Low-Noise Positive Airway Pressure
US 2015/0173740	Jun. 25, 2015	Tissue Anchor and Anchoring System
US 2016/0015919	Jan. 21, 2016	Systems and Methods for Providing Low-Noise Positive Airway Pressure



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US 2016/0045693 Feb. 18, 2016 Portable Positive Pressure Apparatus and Method for the Attenuating the Noise Emitted Therefrom
 US 2016/0262890 Sep. 15, 2016 Cardiac Treatment System and Method
 US 2016/0331880 Nov. 17, 2016 Cardiac Treatment System
 US 2016/0346085 Dec. 1, 2016 Cardiac Treatment System and Method

Education & Licensing

<u>Year</u>	<u>College/University</u>	<u>Degree</u>
1988	University of New Hampshire	B.S. in Mechanical Engineering
1989	PADI No: 8908122480	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

Litigation Support Experience - (Deposition and/or Court Testimony in Last 5 years)

B.Braun vs. BD – Case No. 1:16-cv-00411-RGA – District of Delaware – Patent litigation case regarding catheters and associated protected needle and flow control technology (Defense) – Review products, patents, documents, report, and deposition. Contact: Alexis Cohen of Wilmer Hale in Washington, DC (202) 663-6864. (October 2016 – Present)

Hologic vs. Minerva – Case No: 15-1031-SLR-SRF – District of Delaware and Civil Action No: 3:17-cv-02013-JD – District of CA. Patent litigation case regarding endometrial ablation device (Plaintiff) – Review of patent and documents, reports, declaration, two depositions. Contact: Ryan Casamiquela of Arnold & Porter, LLP in San Francisco, CA (415) 471-3373. (April 2017 – Present)

Priscilla Zoccole vs. Dr. Liu – Civil Action No. A-15-729004-C – District of Clark County Nevada – Liability case regarding use of Novasure device (Defense) – Medical records, IFU, report, deposition. Contact: Jared Herling of Alverson, Taylor, Mortensen & Sanders (702) 384-7000. (May 2016 – Present)

Custopharm vs. PJW – Case No: NNH-CV-15-6056878-S – State of Connecticut Superior Court – Breach of Contract Case regarding EpiPen (Defense) – Review contracts, report, and bench trial testimony. Contact: Steve Zimowski of St. Onge Steward Johnston & Reens, LLC (203) 541-4558. (November 2016 – September 2017)

Dr. Augé vs. Stryker and Howmedica Osteonics – Case No: 1:14-CV-1089-KG-SMV – District of New Mexico (Santa Fe Division) – Contract dispute regarding confidential disclosure of bone anchors and associated guides, drills, reamers, and inserters (Defense) – Review products, disclosure, patents, write report, deposition. Contact: Beth Larigan of Shook, Hardy & Bacon, LLP (816) 559-2459. (January 2017 – Present)



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Covidien vs. Ethicon & Ethicon vs. Covidien – Case No: 1:11-cv-00871 & Case No: 1:16-cv-00253-SJD – Southern District of Ohio Western Div. & Case No: 1:16-cv-12556-LTS – District of Massachusetts – Patent litigation cases regarding RF & ultrasonic vessel sealing and surgical shears (Defense & Plaintiff) – Review products and asserted patents, reports, depositions. Contact: Jeff Ginsberg of Patterson Belknap Webb & Tyler LLP (212) 336-2630. (December 2016 - Present)

EndoEvolution vs. Ethicon – Case No. 02-15-0006-0013 – Commonwealth of Massachusetts – Trade secret case regarding laparoscopic suturing device (Defense) – Analyze devices, patents, and alleged trade secrets, arbitration. Contact: Ruben Munoz at Akin Gump in Philadelphia, PA (215) 965-1263. (July 2016 – September 2017)

Medline vs. CR Bard – Case No. 1:14-CV-03618 – Northern District of Illinois Eastern Div. – Catheter packaging and trays (Defense) – Review patents, claim construction, declarations, two depositions on claim construction, testified at Markman hearing. Contact: Nicole Smith of Morrison & Foerster, LLP in Los Angeles, CA (213) 892-5582. (January 2016 – Present)

CardiAQ vs. Neovasc – Case No. 1:14-cv-12405-ADB – US District Court of MA – Transcatheter Mitral Valve Replacement (Defense) – Review of trade secrets, search public domain, report, deposition, and jury trial. Contact: Tait Graves at Wilson, Sonsini, Goodrich & Rosati in San Diego, CA (858) 350-2362. (January 2015 to May 2016)

Fontem Ventures vs. CB Distributors – Case No. CV14-1645 GW (MRWx) – US District Court for Central District of CA – E-cigarette / Vaporizer patent litigation case (Defense) – Review of patents, products, and report. Contact: Nicole Smith at Morrison & Foerster, LLP in Los Angeles, CA (213) 892-5582. (June 2015 to August 2015)

3M vs. Saint Gobain – Case No. IPR2014-01281 - US Patent & Trademark Office - Paint Gun (family owned largest group of automobile dealers in the history of NH including a large auto body shop) Petition for Inter Partes Review of Patent (Defendant) – Review of two patents and prior art, claim charts, declaration, deposition. Contact: Desmond P. O’Sullivan at Morrison & Foerster, LLP in San Diego, CA (858) 314-7794. (April 2014 – October 2016)

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 – April 2015)

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)



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Ivera (3M) 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) – 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 – September 2015)

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)

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)

Affiliations

- ASME – American Society of Mechanical Engineers since 1988
- AOPA – Aircraft Owners and Pilot Association since 1999
- MDG – Medical Development Group since 2006
- Medical Device & Manufacturing (MD&M) Conferences – Chairman 2014
- 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
- HAI – Helicopter Association International since 2015
- PD Aviation, LLC – Helicopter Rentals & Pontoon Boat Helipads – Mgr. since 2015
- H2L Medical Technologies, LLC – Catheter Systems – Co-Founder since 2015
- Big Brothers Big Sisters (BBBS) – Big Volunteer & Contributor – Since 2008
- Seacoast Education Endowment Dover (SEED) – Contributor / Fund Raiser – Since 2017
- Community Garbage Cleanup Committee Chairman – Since 2015
- All Electronic Toll (AET) NH State Chairman - 2017