Karl R. Leinsing, MSME, PE
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Professional Summary

Medical device experience since 1992 and mechanical engineering experience since 1988. Areas of expertise include full life cycle medical device product development and consulting from conception through design, manufacturing, testing, qualification, validation, verification, qualification, packaging, labeling, clinical trials, FDA & EU regulatory approval, marketing, and sales training. Granted 41 patents, 7 awards, device published on cover of Life Magazine (May 2000), recognized as one of 100 notable people in the medical device industry by the Medical Device & Diagnostic Industry (MD&DI) in June 2008, recognized by Better Business Bureau and NH Magazine in 2013, and served as chairman of the Medical Device & Manufacturing Conference in 2014, and served on many boards.

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, mitral valve repair (for 3 companies), surgical, intravenous, endoluminal, and percutaneous devices including market analysis.
- Consulting on bedside blood glucose level analyzer / cartridge, glucose sensors, peritoneal dialysis pumps, safety syringes, disinfecting caps, auto-injectors, pen injectors, urinary catheters, insulin pumps, subcutaneous ports & catheters, bed rails, e-cigarettes/pharmaceutical inhalers, bone anchors, bone plates/screws, staplers, device support arms, & walkers/rollators.
- Developed medical textiles, CPAP device for HDM, catheter dressing for H2L, trachea alarm for Innovations Unlimited, urinary incontinence device for a urologist, and stapler/suturing for SubQ It
- Invented and developed Programmable Electrode Array Knitter (6,158,250) to manufacture RF mesh for endometrial ablation device
- Litigation consulting and expert witness (patent & liability cases) in United States, Canada, EPO, USPTO, ITC, and Australia
- Visit www.atechdesigns.com for more information

Sinclair et al v. HydraFacial
IPR2025-00145
HydraFacial Ex. 2002

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

- Developed implants required for percutaneous mitral valve repair
- 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 (project identified as the most successful project in the history of the company)
- Granted many patents for the SmartSite® Needle-Free Valve
- Winner of 5 design awards - 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

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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) / Solarmetrics, Inc.**
To: 1986
Position: *Technician* - Designed automated resistor equipment, inventory management, assembled and tested solar controls and air-wrap systems.

Publications

- 1995 - Thesis: Strength of Medical Thermoplastic Female Luers Exposed to Chemicals
- 2001 - Chemical Compatibility and the SmartSite® Needle-Free Valve
- 2013 - How a Medical Device Expert Witness Can Assist in a Case
- 2015 - A-Z Guide to Expert Witnessing ISBN: 9781892904454 (CV – pp.576 - 580)

Lectures

- 1998 - Lectured MD&M Seminar on “The Science of Successful Product Design”
- 2014 - Chairman of the Medical Device & Manufacturing Conference
- 2014 to 2016 – Webinar Speaker on Medical Device Product Development Process

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Granted US Patents (Foreign filings of same are not included)

Patent No.	Issue Date	Title
12,076,507	09/03/2024	Integrated Sealing and Securing Device for Vascular Catheters
11,826,049	11/28/2023	Devices For Deploying Tissue Fasteners
11,517,437	12/06/2022	Cardiac Treatment System
11,406,500	08/09/2022	Cardiac Treatment System and Method
11,141,552	10/12/2021	Systems For Providing Low-Noise Positive Airway Pressure
10,881,834	01/05/2021	Safety Catheter System and Method
10,695,046	06/30/2020	Tissue Anchor and Anchoring System
10,420,644	09/24/2019	Cardiac Treatment System and Method
10,405,981	09/10/2019	Cardiac Treatment System
10,064,723	09/04/2018	Cardiac Treatment System and Method
RE46,927	07/03/2018	Heart Band W/Fillable Chambers to Modify Heart Valve
9,844,437	12/19/2017	Cardiac Treatment System and Method
9,814,454	11/14/2017	Tissue Anchor and Anchoring System
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)

Pub. No.	Pub. Date	Title
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
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
US 2017/0368315	Dec. 28, 2017	Safety Catheter System and Method
US 2018/0028171	Feb. 1, 2018	Tissue Anchor and Anchoring System

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US 2018/0368980	Dec. 27, 2018	Cardiac Treatment System and Method
US 2019/0247623	Aug. 15, 2019	Integrated Sealing and Securing Device for Vascular Catheters and Methods for Use of Same
US 2019/0343636	Nov. 14, 2019	Cardiac Treatment System
US 2019/0358038	Nov. 28, 2019	Cardiac Treatment System and Method
US 2020/0330088	Oct. 22, 2020	Tissue Anchor and Anchoring System
US 2022/0378579	Dec. 1, 2022	Cardiac Treatment System and Method
US 2023/0285020	Sep. 14, 2023	Devices For Deploying Tissue Fasteners

Education & Licensing

Year	College/University	Degree
1988	University of New Hampshire	B.S. in Mechanical Engineering
1992	NH: 11437	Professional Engineering License
1995	North Carolina A&T State University	M.S. in Mechanical Engineering

Litigation Experience - (Testimony by report, deposition, declaration, or trial - last 4 years)

Arthrex vs. Parcus and Anika - Case No. 2:22-CV-0019-JLB-NPM – Middle District of Florida – Patent Litigation regarding bone syndesmosis (Defense) – Patent and prior art review, testing, analysis, and report. (October 2023 to March 2024)

NJoy vs. Juul – Case No. 337-TA-1372 – Washington, DC – ITC Patent Litigation regarding vaporizer devices (Defense) – Patent and prior art review, claim construction declaration, depositions, invalidity reports, and trial testimony. (September 2023 to June 2024)

Novo Nordisk vs. Teva (Saxenda) – Case No. 21-cv-01782-CFC – District of Delaware – Patent litigation regarding pen injector (Defense) – Patent and prior art review, analysis of accused device, reports, deposition. (January 2022 – September 2023)

Novo Nordisk vs. Dr. Reddy's Lab (Ozempic (Semaglutide)) & [Rio, Sun, Zydus, Alvogen, and Mylan] – MDL No. 22-MD-3038 (CFC) and Case No. 22-cv-294 & 1040 (CFC) – District of Delaware – Patent litigation regarding pen injector (Defense) – Patent and prior art review, analysis of accused device, claim construction declaration. (December 2021 – March 2024)

Microvention vs. Balt – Case No. 8:20-cv-02400-JLS-KES – Central District of California Western Division – Trade secret case regarding catheters and embolization coils (Defense) – Review alleged trade secrets, analysis, report. (June 2022 – December 2023)

Mizuho Orthopedic vs. Allen Medical – Case No. 1:21-cv-10979-NMG – District of Massachusetts – Patent litigation regarding surgical bed (Defense) – Patent and prior art analysis, IPR declaration. (February 2022 – October 2022)

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DNA Genotek vs. Spectrum Solutions - Case No. 21-cv-0516-DMS-LL – Southern District of California - Sample Collection (Defense) – Patent & prior art review, IPR declaration, report, and depositions. (October 2021 – February 2024)

OsteoMed vs. Stryker & Stryker vs. OsteoMed – Case No. 1:20-cv-6821 – Northern District of Illinois Eastern Division – Patent litigation regarding bone plates (Defense & Plaintiff) – Patent and prior art analysis, IPR declaration, deposition. Contact: Scott McBride of McAndrews, Held, & Malloy (312) 775-8131. (May 2021 – Present)

DexCom vs. Abbott and Abbott vs. DexCom – Case No: 6:21-cv-690 in Western District of TX and C.A. No. 21-977 in District of Delaware – Patent litigation regarding glucose sensors (Defense & Plaintiff respectively) – Patent analysis, IPR declaration, attend EPO hearing (parallel Europe case), reports, depositions, and jury trial. (April 2021 – Present)

Altria & US Smokeless Tobacco Co. vs RJR and Modoral Brands – Case No: 1:20-cv-00472-NCT-JLW – Middle District of NC – Patent litigation regarding vaping devices (Defense) – Invalidity analysis, reports, IPR declaration, depositions, trial. (June 2020 – September 2022)

Novo Nordisk vs Sandoz – Case No: 20-747 (CFC) – District of Delaware – Patent litigation regarding pen injector (Defense) – Analysis, report, and deposition. (June 2020 – March 2022)

Earth Animal Ventures, Inc. vs. Sage Fulfillment, LLC. – Case No: 3:20-CV-00444-VAB – District of Connecticut – Metered dispensing syringe w/CBD (Defense) – Testing, report, and deposition. (May 2021 to April 2023)

Anthony Canning vs Medtronic – Case No: CV2019-053458 – The Superior Court of the State of Arizona – Circular Surgical Stapler (Plaintiff) – Report. (November 2020 – April 2022)

Provost vs. Neuro-Rehab Associates, Inc., Elliott Hospital, and Medline Industries, Inc. – Case No: 217-2019-CV-601 – New Hampshire Superior Court – Medline Rollator Liability Case (Plaintiff) – Failure analysis, report, deposition. (July 2020 – November 2021)

Boehringer Ingelheim vs. Lupin Altantis Holdings – Case No: 18-12663 (BRM) (TJB) – District Court of New Jersey – Patent litigation regarding powder inhaler (Plaintiff) – Report and deposition. (January 2020 – October 2021)

Boston Scientific vs. Micro-Tech – Case No: 18-1869-CFC-CJB – District of Delaware – Patent litigation regarding endometrial ablation device (Plaintiff) – Review of patents & products, fracture analysis, reports, deposition. (January 2020 – January 2022)

Novartis vs. Regeneron – ITC No: 337-TA-1207 – Washington, DC – Patent litigation regarding pre-filled syringe (Plaintiff) – Patent review, declarations, Markman hearing. (August 2019 – Present)

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Baxter vs. BD – Case No: 1:17-cv-07576 USDC North IL Eastern Division – Patent litigation on Fluid Reconstitution Device (Plaintiff) – Review patents, declaration, report, & deposition. Contact: Denis Sullivan of Barclay Damon, LLP in Syracuse, NY (315) 425-2828. (July 2019 – December 2023)

Edwards vs. Lindel, MD - Case No: 17 CVS 1936 – Superior Court Division of Surry County, NC – Liability case on endometrial ablation device (Plaintiff) – Review of documents, medical records, deposition. (March 2017 – December 2023)

Hologic vs. Minerva & Minerva vs. Hologic – Case Nos: 15-1031-SLR / 18-217-JFB-SRF / 20-925-JFB-SRF – District of DE & CA - Patent litigation on endometrial ablation (Plaintiff & Defense) – Patents, reports, declaration, depositions, and jury trial. (April 2017 – April 2023)

Dr. Augé vs. Stryker & Howmedica – Case No: 1:14-CV-1089-KG-SMV – District of New Mexico (Santa Fe Division) – Contract case on bone anchors, guides, drills, & inserters (Defense) – Review products, patents, report, deposition, jury trial. (January 2017 – May 2022)

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 MA – Patent litigation on RF & ultrasonic vessel sealing and cutting (Defense & Plaintiff) – Reports, depositions, & trial. (Dec. 2016 – March 2021)

Boston Scientific vs. Cook – Case No: 15-980-LPS-CJB – District of Delaware – Patent litigation case regarding surgical clip (Plaintiff) – Review patents, reports, depositions, and jury trial. (August 2016 – June 2023)

Medline vs. CR Bard – Case No. 1:14-CV-3618 / 1:16-cv-3529 / 1:17-cv-7216 – Northern District of Illinois Eastern Div. – Catheter packaging and trays (Defense) – Claim construction declarations, depositions, testified at two Markman hearings. (January 2016 – Present)

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Declarations in Support or Response of IPR Petitions in Last 4 Years

Decl. Date	Petition #	Patent(s)	Parties / Type Device
10/22/2020	2020-01317 2020-01318	9.220,631	Novartis vs. Regeneron / Pre-Filled Syringe
3/12/2021	2021-00650 2021-00652	10,143,242 10,264,824	Altria Client Services, LLC and US Smokeless Tobacco Company, LLC vs. R.J. Reynolds Vapor Company and Modoral Brands, Inc.
3/31/2021	2021-00744 2021-00745 2021-00746 2021-00747	10,299,517 10,485,269 10,492,541 10,588,357	Altria Client Services, LLC and US Smokeless Tobacco Company, LLC vs. R.J. Reynolds Vapor Company and Modoral Brands, Inc.
07/28/2021	2021-00816	9,220,631	Novartis vs. Regeneron / Pre-Filled Syringe
04/23/2022	2022-00917 2022-00918	10,980,452	Dexcom vs. Abbott / Glucose Sensor
04/22/2022	2022-00919 2022-00920	10,888,481	Mizuho vs. Allen Medical & Hill-Rom / Surgical Table
11/16/2022	2022-01347	11,002,646	Genotek vs. Spectrum / Sample Collection
11/18/2022	2022-00487 2022-00488	9,078,713 10,993,751	Stryker vs OsteoMed / Bone Plates

Note: Underlined party hired me to perform analysis and write declaration.

Affiliations

ASME – American Society of Mechanical Engineers since 1988
National Society of Professional Engineers since 2000
ASM International – American Society of Metals International since 2020
UNH Mechanical Engineering Senior Project Sponsor & Leader - 2022
MDG – Medical Development Group since 2006
Inventors Workshop – Board of Directors since 2006
Eureka Medical – Medical Device Advisory Board since 2006
Big Brothers Big Sisters (BBBS) – Big Volunteer & Contributor – Since 2008
BBB – Better Business Bureau of New Hampshire since 2010
MassMedic – Massachusetts Medical Device Industry Council since 2011
Medical Device & Manufacturing (MD&M) Conferences – Chairman 2014
H2L Medical Technologies, LLC – Catheter Systems – Co-Founder – 2015 to 2018
Neighborhood Community Garbage Cleanup Committee Chairman – Since 2015
UNH STEM (Tech Camp) – Mentor and Contributor – Science, Technology, Engineering, & Mathematics – Since 2016
All Electronic Toll (AET) - NH State Chairman – 2017
NH Bio-Made Industry and State Partnerships Board (ISPB) – Board of Directors - 2018