



**Karl R. Leinsing, MSME, PE**  
77 Spur Rd. Dover, NH 03820-9110  
(603) 926-8216 office / (603) 203-0365 cell / (603) 749-0079 fax  
[kleinsing@comcast.net](mailto: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 30 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 and trachea tube 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](http://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



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**Patents**

<b><u>Patent No.</u></b>	<b><u>Issue Date</u></b>	<b><u>Title</u></b>
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
9,750,907	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)

<b><u>Pub. No.</u></b>	<b><u>Pub. Date</u></b>	<b><u>Title</u></b>
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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