



Karl R. Leinsing, MSME, PE
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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 32 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 bedside blood glucose level analyzer / cartridge, 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, cervical screws/plates, and staplers.
- Developed sleep apnea or CPAP device and trachea tube device.
- Developed catheter dressing for H2L Medical Technologies, LLC.
- Developed trachea tube alarm for Innovations Unlimited, 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



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- Completed locker implant used to plicate the anchors & lock sutures

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



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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
- Published in A-Z Guide to Expert Witnessing by SEAK, Inc. ISBN: 9781892904454

Patents

<u>Patent No.</u>	<u>Issue Date</u>	<u>Title</u>
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

Curriculum Vitae of Karl R. Leinsing, MSME, PE



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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
US 2016/0045693	Feb. 18, 2016	Portable Positive Pressure Apparatus and Method for the Attenuating the Noise Emitted Therefrom



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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
US 2018/0368980	Dec. 27, 2018	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 - (Testimony by deposition, trial, report - last 5 years)

Fisher & Paykel vs. ResMed – No: VID 1356 of 2017 Federal Court of Australia District of Melbourne – Patent litigation case regarding CPAP humidifier tank (Defendant) – Review of devices and patents and affidavits. (September 2018 – February 2019)

Martinez vs. ARCA – Case No: D-101-CV-2018-01440 District Court of New Mexico – Liability case regarding bed rails (Plaintiff) – Review incident, analysis, and report. (June 2018 – Present)

Sanofi vs. Mylan – IPR No: 2018-01670; 2018-01675,6; 2018-01677-9; 2019-00122; 2018-01680,2,96; 2018-01684. US Patent and Trademark Office – Patent litigation case on injector pen (Defendant). Declaration and deposition for IPR petition. (April 2018 – Present)

Stanley Patton vs. Shane Sanders & Covidien – Cause No: 2015-CI-04698 District of Bexar County, TX – Liability case regarding stapler (Plaintiff) – Review medical records, complaints, design & process docs, and wrote report (case settled). (April 2018 – September 2018)

Smith Medical vs. Monaghan & Vice Versa – Case No: 1:17-cv-00712-LPS-CJB District of Delaware – Patent litigation case regarding oscillating positive expiratory pressure (OPEP) device (Plaintiff) – Review patents, claim construction, and declarations. (February 2018 – December 2018)

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 – Present)



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Novo Nordisk vs. Teva – Case No: 17-227-VAC-MPT – District of Delaware – Patent litigation on pen injector (Defendant) – Review of patents/device, claim construction, reports, & deposition. (December 2017 – March 2019)

Custopharm vs. Chemwerth – Case No: D-A-GN-15-003371 & 1101 – Travis County Texas – Breach of Contract Case regarding Sumatriptan and Medroxyprogesterone Injectors (Defense) – Review contracts, documents, report, and jury trial. (November 2017 – April 2018)

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. (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, and jury trial. (April 2017 – July 2018)

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. (May 2016 – November 2017)

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. (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. (January 2017 – Present)

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. (December 2016 - Present)

Boston Scientific vs. Cook – Case No: 15-980-LPS-CJB – District of Delaware – Patent litigation case regarding surgical clip (Plaintiff) – Review patents and documents and reports. (August 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. (July 2016 – September 2017)



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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 two Markman hearings. (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. (January 2015 to May 2016)

In re TVT vs. Ethicon Women’s Health and Urology – Case No. 003470 & Multiple Other Cases – Philadelphia County & Others – Liability case regarding knitted Tension-Free Vaginal Tape (TVT) (Defense) – Expert and report on medical device product development process per FDA CFR Title 21 Subpart C – Section 820.30 and EU 93/42/EEC. (July 2015 - Present)

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, report, and deposition. (June 2015 to August 2015)

Welch Allyn vs. OBP Medical – Civil Action No. 5:14-CV-1122 (TJM/DEP) – US District Court Northern District of NY – Vaginal Speculum Patent Litigation Case (Defense) – Review of patents, products, and declaration. (February 2015 – September 2017)

Terumo vs. Nobel House Group – USPTO Inter-Partes Review of US Pat No. 8,777,921 – IV Blood Set – Review patents, file history, and research prior art and write declaration. Contact: Justin Cruz at Sheridan Ross PC in Denver, CO (303) 863-2984. (July 2014 – December 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. (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. (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. (October 2013 – July 2014)

Shelton vs. North Oaks Health System – Case No: 2013-00421 - 21st Judicial District Court for the Parish of Tangipahoa State of LA - IV Disposables Infection Liability (Plaintiff) – Review of documents and wrote report. (August 2013 – February 2015)



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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. (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. (July 2013 – August 2014)

Baxter vs. Fresenius Medical – Case No: 12-cv-06890 (JL) – US District Court Northern District of Illinois – Peritoneal Dialysis Pump System Patent Litigation (Plaintiff) – Review of documents, submission of infringement contentions, disassembly of pumps, testing, photos, borescope videos, reports. (October 2012 – April 2015)

Declarations in Support or Response of IPR Petitions

Decl. Date	Petition #	Patent(s)	Parties / Type Device
5/8/2009	?	5,380,306	RyMed vs. <u>Vygon</u> / NeedleFree Valve
8/12/2014	2014-01280	8,628,026	<u>Saint-Gobain</u> vs. 3M / Liquid Spray Apparatus
8/12/2014	2014-01281	8,424,780	<u>Saint-Gobain</u> vs. 3M / Liquid Spray Apparatus
7/6/2014	2014-01124	8,647,326	<u>Ivera</u> vs. Catheter Conn. / Disinfecting Caps
11/7/2014	2014-01023	8,777,921	Terumo vs. <u>Nobel House Group</u> / Liquid Sampler
2/2/2015	2015-665	8,647,308	<u>Ivera</u> vs. Catheter Conn. / Disinfecting Caps
2/4/2015	2015-693	8,641,681	<u>Ivera</u> vs. Catheter Conn. / Disinfecting Caps
12/20/2015	2015-361	9,039,395 (6-13)	<u>Baxter</u> vs. DEKA / Pump Cassette
12/21/2015	2015-362	9,039,395 (14-19)	<u>Baxter</u> vs. DEKA / Pump Cassette
6/12/2016	2015-1123	5,601,557	<u>Arthrex</u> vs. Smith & Nephew / Bone Anchor
2/9/2017	2017-0103	9,345,641	<u>EquaShield</u> vs. Teva / Fluid Connector & Valve
7/25/2018	2018-01097	8,033,483	Hyperbranch vs. <u>Confluent</u> / Spray Tip
9/9/2018	2018-01670	8,679,069	<u>Mylan</u> vs. Sanofi-Aventis / Pen Injector (One declaration written for all)
	2018-01675,6	8,603,044	
	2018-01677-9	8,992,486	
	2019-00122	8,992,486	
	2018-01680,2,9	9,526,844	
1/9/2019	2018-01684	9,604,008	<u>Valeritas</u> vs. Roche Diabetes Care / Pen Injector (Two declarations)
	2019-00552	6,736,795	
	2019-00553		

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



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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
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