

EDWARD E. ELSON

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EDUCATION:

2007 Adobe Illustrator: North Orange County Regional Occupational Program
2002 SolidWorks 3D Design: Orange Coast College, Costa Mesa, CA
1997 Graphics Design: University of California, Irvine, CA
1978 MA Management Peter Drucker School of Management: Claremont Graduate School, Claremont, CA
1968 MS Mechanical Engineering: (Bio-Medical Minor) University of Southern California, Los Angeles, CA
1962 BS Mechanical Engineering (Deans List): Drexel University Philadelphia, PA

ENGINEERING EXPERIENCE SUMMARY:

I have over 40 years of engineering and management experience and have been directly engaged in research, design, development, and manufacturing activities in the aerospace, medical device, toy and consumer product fields. My education includes a BS in Mechanical Engineering, a MS in Mechanical Engineering and a MA in Management. I am the inventor or co-inventor of 30 U.S. Patents.

My responsibilities have ranged from original product conception through high volume manufacturing, including plastic extrusion, injection molding, assembly, decorating, labeling and packaging. I have served on several medical standards committees and have interacted with industry and governmental regulatory agencies. I have intimate knowledge and experience with FDA requirements and Good Manufacturing Procedures (GMP's), producing prototype models, performing computer aided plastic part design (SolidWorks) and failure and hazard analysis including Failure Mode Effects Analysis (FMEA).

IDCO FORENSIC SERVICES EXPERT WITNESS EXPERIENCE SUMMARY:

I have served as an expert witness for more than 17 years working with defense and plaintiff's attorneys and insurance companies in intellectual property, medical and consumer product, labeling, packaging and product liability legal proceedings. In March 2006, I was invited to be the "Expert for the Plaintiff" at the annual Mock Trial sponsored by the California Chapter of the American Board of Trial Advocates.

CASES IN WHICH I HAVE SERVED AS AN EXPERT INCLUDE THE FOLLOWING:

Intellectual property issues including patent infringement, validity and trade secrets related to: needleless connectors; needleless valves; butane lighters; safety syringes and needles; disposable injection molded valves; children's training devices; self-erecting and collapsible structures; gel balls; gel cushioning; Insulated coolers • Design and failure analysis of injection molded plastic components • GMP; product design performance and labeling issues related to medical devices; engineering contract norms; performance standards; trade secrets relative to manufacturing processes • Surgical fluid warmers; hydroculators; moist heat pads; thermal cooling pads and cooling devices; diathermy devices • Laser and thermal hair removal devices; dermal abrasion equipment; surgical laser power cord design reliability • Luggage and costume jewelry • Patient beds; transport gurneys • failure of pilates exercise device • Surgical staplers • Suture failures • Fatigue failure of implanted hip prosthesis; performance and failure of pedicle screw • IV infusion pumps; external and implanted drug delivery devices; test and evaluation of battery powered external insulin pumps; elastomeric drug infusion pumps • Valuation of hundreds of lost toy prototypes • Valuation of toy packaging • Valuation of smoke damage to 25 different types of electronic medical devices; Valuation of Computer imaging systems • Injury potential of chiropractic devices • Bone biopsy needles; Dental burr and drill failures • Thermal injury associated with transbuccal drill and cannula systems • Defective counter stools; chair collapse; stools with castors • Patient walker stability; walker labeling; walker wheel support failures; gait trainer design and labeling; treatment table failure • Drug container packaging integrity • Defibrillator mechanical design issues • Shipping carton package integrity; consumer packaging safety and labeling

SUMMARY OF INDUSTRY POSITIONS HELD AND AREAS OF EXPERIENCE:

1980 TO PRESENT IDCO FORENSIC SERVICES (FORENSIC ENGINEERING CONSULTING AND DESIGN FIRM) - PRESIDENT

Clients have included the following: Gary Frugard & Assoc; AccuLase, Inc TherOx, Inc.; Luther Medical Prod.; Thermometrics, Inc.; ENSOL, Inc.; Dr. John Stevenson; Merlin Technologies; Intern'l Diversified Prod.; Optical Radiation Corp.; X-Technologies, Inc.; Servall Industries; Abbott Laboratories Baxter Healthcare; LifePoint, Inc. Venetec, Inc; Sutura, Inc. N. Gortz Co.; Intertherapy, Inc.

2000 to 2013: Leading Edge Innovations, Inc. - Vice President of Engineering

Joined company as consultant, became a partner in 2003. Developed and patented product line of male urinary management devices (Winner of 2008 Medical Design Excellence Awards). Company has begun nation-wide sales of products that have received FDA approval and earned Medicare reimbursement approval. (www.urinedevice.com)

1991 to 1995: UROHEALTH - Vice President of Research & Development

Joined at company start-up, performed and managed research and development activities, documentation and implemented FDA and GMP manufacturing methods for line of patented products including incontinence pads, disposable diapers, micro-filtration fluid collection systems, programmed centrifuge, urinalysis systems and ambulatory IV drug infusion devices.

1979 TO 1989: BAXTER-EDWARDS DIVISION - DIRECTOR OF CATHETER DEVELOPMENT

Managed 30 engineers, scientists and technicians engaged in the design and development of sterile disposable medical devices, including pressure monitoring, balloon, cardiac pacing, venous and urinary catheters and catheter introducers. I managed the polymer development laboratory and the labeling and sterile packaging groups that serviced all of the division's disposable product lines. Responsibilities included liaison with domestic and Puerto Rico facilities to transfer designs to production. New products introduced during tenure accounted for over \$700,000,000 in sales.

1976 TO 1979: C. R. BARD-INSPIRON DIVISION - NEW PRODUCTS ENGINEERING MANAGER

Managed research and development activities and developed patented line of arterial and venous catheters, respiratory care devices including, humidifiers, nebulizers, heaters and spirometers. I developed production methods and procedures, product labeling, instructions and packaging and managed the prototype machine shop. Developed first low resistance plastic arterial blood collection syringe.

1969 to 1976: Automatic Helium Balloon Systems - Vice President of Engineering

Key player in start-up company where I developed and patented a variety of helium balloon valves and inflation systems which are still being sold in 2012 and was responsible for developing manufacturing methods and assembly equipment to produce company's products.

1962 TO 1963; 1965 TO 1969: AUTONETICS DIV. NORTH AMERICAN ROCKWELL - DESIGN ENGINEER

Responsibilities included conceptual design, testing and development of equipment protocols for space, hospital and medical systems. I designed mobile pharmacy equipment and a chemical agent detector system for the US Army. I helped to develop methods and equipment requirements for extricating trapped accident victims at crash sites.

MILITARY SERVICE:

1963-1965: ENGINEERING COMPANY COMMANDER, 1ST LIEUTENANT, U.S. ARMY CORPS OF ENGINEERS.

ORGANIZATIONS:

Member, Society of Plastic Engineers, Institute of Packaging Professionals; ISTA; Member and former Board Member, Forensic Expert Witness Association (Orange County, CA). Former member of AAMI Standards Sub-Committees: Human Factors for Medical Devices, IV Catheters, Humidifiers & Nebulizers. Contributing editor of AAMI Recommended Practice: *Human Engineering Guidelines and Preferred Practices for Design of Medical Devices*.

U. S. PATENTS EARNED TO DATE:

1. D223,475 Balloon Inflator, Apr. 18, 1972
2. 3,724,516 Gas Dispenser And Inflation Gauge, Apr. 3, 1973
3. 3,728,227 Microorganism Culture Apparatus, Apr. 17, 1973
4. 3,768,501 Inflatable Article Valve, Oct. 30, 1973
5. 3,871,422 Dual Balloon Valve, Mar. 18, 1975
6. 4,170,228 Variable Flow Incentive Spirometer, Oct. 9, 1979
7. 4,202,334 Cap And Stopper, May 13, 1980
8. 4,241,739 Volume Calculator For Incentive Spirometer, Dec. 30, 1980
9. 4,632,125 Right Heart Ejection Fraction And Cardiac Output Catheter, Dec. 30, 1986
10. 4,643,389 Tubing Occlusion Clip, Feb. 17, 1987
11. 4,651,751 Guiding Catheter And Method Of Use, Mar. 24, 1987
12. 4,745,928 Right Heart Ejection Fraction And Cardiac Output Catheter, May 24, 1988
13. 4,759,378 Flexible Tip Cardiac Pacing Catheter, July 26, 1988
14. 5,029,585 Conformable Intralumen Electrodes, July 9, 1991
15. 5,346,476 Fluid Delivery System, Sept. 13, 1994
16. 5,242,370 Centrifuge, Sept. 7, 1993
17. 5,395,590 Valved Container Lid, March 7, 1995
18. 5,409,667 Tube Rack, April 25, 1995
19. 5,466,229 Fluid Collection System, Nov. 14, 1995
20. 5,593,477 Gas and Odor Absorber, Jan. 14, 1997
21. 5,814,018 Needle Point Guard Safety Cap Assembly, Sept. 29, 1998
22. 5,971,957 Through-The-Needle Cannula And Split Needle Plmt. App & Mtd Of Use, Oct. 26, 1999
23. 5,983,460 Bag Closer, Nov. 16, 1999
24. 6,015,397 Needle Point Guard Safety Cap Assembly, Jan. 18, 2000
25. 6,088,889 Clamp Operable As A Hemostasis Valve, July 18, 2000
26. 6,248,096 Male Urinary Incontinence Device Having Expandable Flutes, June 19, 2001
27. 6,248,077 System For Sensing A Characteristic Of Fluid Flowing To Or From A Body, June 19, 2001
28. 6,336,902 System For Sensing A Characteristic Of Fluid Flowing To Or From A Body, Jan. 8, 2002
29. 7,160,277 Male urinary incontinence sheath having gel adhesive and elastic sacrement tape, Jan 9. 2007
30. 7,166,092 Male urinary incontinence sheath system including conformable silicone gel and elastic securement tape, Jan. 23, 2007