

NICK ROMCEVICH

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PROFILE

Senior R&D engineer with a Masters of Science in mechanical engineering and over six years of experience in the medical device industry. This experience includes two years of work on spinal surgery products and over four years of work on catheter based arterial and venous products. Looking for opportunities for career growth that include project management, personnel management and technical leadership responsibilities.

EXPERIENCE

SR. R&D ENGINEER, CROSTREES MEDICAL, INC., BOULDER, CO, MAY 2008 TO MAY 2010

CROSTREESMEDICAL.COM

Titled as a Senior R&D Engineer while functioning as a project manager. Managed several product lines from concept phase into market release phase. Responsible for all areas of the project: creating part specification prints, ordering parts, inspecting incoming parts, writing non-conformance reports, designing and executing engineering tests, coordinating sterilization, biocompatibility and packaging validation tests, organizing and performing design verification and validation testing and managing the design history file. Familiar with spinal anatomy and with surgical techniques for vertebroplasties.

Project manager of Bone Void Creator and Access Tool product lines

- Managed the design control of the products via the design history file and document change orders.
- Created required documentation for Essential Requirements for CE marking
- Oversaw design and engineering evaluation of product to meet product requirements
- Worked with vendors to quickly produce product and to lower manufacturing costs

Contributed to the design of the percutaneous vertebral augmentation (PVA) system

- Supported IDE cases and supported various physician training sessions
- Designed and ordered several components for the PVA system
- Planned, coordinated and acted as the operating physician at cadaver studies to evaluate the product design

SR. R&D ENGINEER, FOXHOLLOW TECHNOLOGIES (EV3), REDWOOD CITY, CA, AUGUST 2005 TO DECEMBER 2007

EV3.NET/PERIPHERAL/US/PLAQUE-EXCISION

Worked as a Senior R&D Engineer in the Advanced Technology Group. Led the technical research for a cutting edge catheter that utilized a laser and a .004 in. diameter optical fiber for visualization of the interior of arteries. Regularly presented information to the steering committee, composed of VP level staff. Designed and tested product, developed manufacturing procedures, oversaw the builds of IDE product and supported the IDE clinical study of the device.

Worked on several SilverHawk™ plaque excision systems, including peripheral and coronary disposable catheters

- Technical Lead of the NightHawk platform, which used O.C.T. for real-time visualization of the vessel
 - Managed two R&D technicians (direct reports)
 - Traveled to clinical sites to support IDE cases
- Co-managed the design work and the technical aspects of the Coronary Project
 - Created and analyzed designs ranging from driveshaft design to nose-cone design
 - Proactively evaluated prototypes in sheep models and interacted with physicians to define the product requirements.

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R&D ENGINEER II, BACCHUS VASCULAR, SANTA CLARA, CA, AUGUST 2003 TO AUGUST 2005

BACCHUS-VASCULAR.COM

Worked as an R&D engineer analyzing product performance in the lab, updated and improved manufacturing processes in the clean room, machined prototypes on a three axis manual mill and designed an electronic controller to control the motor of the driveshaft. Operated within the quality and document control system to make the controller ready for production. Installed inspection equipment inside the clean room to perform an in-line inspection of the controller.

Worked on the Trellis-8™ device, which combats deep-vein thrombosis using a dual balloon catheter

- Lead designer of the printed circuit board, which controls the Trellis' rotational speed and stall torque

Designed the Fino™ device, which treats deep-vein thrombosis using a nitinol macerator

EDUCATION

Santa Clara University, Santa Clara, CA — Spring 2006

Leavey School of Business (One Course) - Marketing 551: Marketing Analysis and Decisions

Stanford University, Palo Alto, CA — Masters of Science, August 2003

M.S. Mechanical Engineering (Design Division)

- Cardiovascular Bioengineering and Product Development

University of California, Berkeley, CA — Bachelors of Science, December 2001

B.S. Engineering

- Graduated with Honors in mechanical engineering

SKILLS AND KNOWLEDGE BASE

- Familiar with various materials used to make medical devices
 - Metals
 - 302, 303, 304, 316, 17-4 and 18-8 stainless steel
 - Used in the form of hypodermic tubing, wire and rod stock, coil and braid. Familiar with ASTM 313, 555 and F899 regarding stainless steel.
 - Nitinol coils, shape set
 - Polymers
 - Machinable polymers: Ultem, polycarbonate (Zelux), ABS, Torlon, Delrin, Teflon
 - Injection mold polymers: Lustran ABS and glass filled polypropylene
 - Catheter polymers: Nylon 12, PEEK, Tecothane (PU), polyimide with embedded coil, polyurethane with braided aramid and braided Pebax. PTFE, FEP and PET heatshrink.
- Versed in various machining and manufacturing techniques:
 - CNC machining, wire EDM, media blasting, laser welding, centerless grinding, FDM, injection molding
- Skilled at using SolidWorks™ CAD software to create documents per ANSI Y14.5 using GD&T.
- Familiar with biocompatibility testing per ISO 10993
- Versed in sterilization validation per ISO 11137 (gamma radiation, EtO and steam sterilization)
- Experienced with packaging testing per ISTA 2A
- Comfortable with quality controls and systems per ISO 13485 and ANSI 1.4
- Experienced at providing product support to doctors at live cases during IDE clinical trials
- Partook in discussions regarding FDA filings and CE mark requirements
- Created Instructions for Use and labels per EN 980
- Skilled at inspecting parts using video systems and traditional inspection tools
- Proficient at hitting deadlines and tight schedules and successful at managing people and projects
- Versed in electric motor design and electronic circuitry relating to medical devices

REFERRALS

Referrals available upon request.

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