

Zane Diaz

☎ (617) 555-6194 ✉ zane.diaz@example.com 🔗 linkedin.com/example/zanediaz 📍 Boston, MA 02118

SUMMARY

Principal level **medical device R&D** engineer with 14 years of progressive experience across **systems engineering, electromechanical product development**, connected devices, surgical technology, wound care, digital health, and front end innovation. Leads customer discovery, unmet need definition, architecture exploration, feasibility planning, prototype evaluation, integration testing, technical de-risking, and transition into regulated development. Conducts due diligence on startups, academic innovations, licensing opportunities, and strategic partners, weighing clinical value, feasibility, intellectual property, regulatory pathways, quality, scalability, and strategic fit. Connects hardware, software, sensing, automation, user interfaces, data, and disposable components within medical systems. Communicates evidence, risks, and business tradeoffs with executives, clinicians, engineers, suppliers, and external partners while coaching multidisciplinary teams.

EXPERIENCE

Principal Systems Engineer, Early Innovation

January 2023 - Present

NovaBridge Surgical Systems

Boston, MA

Leads **front end innovation** for surgical and wound care concepts, guiding customer discovery, technology assessment, proof of concept work, and early system architecture. Partners with clinicians, suppliers, engineers, and governance leaders on evidence based portfolio decisions.

- Translated clinical discovery into system requirements, architecture options, and technical risk plans.
- Evaluated startup technologies and academic inventions for feasibility, **intellectual property**, and regulatory fit.
- Integrated hardware, sensing, embedded software, interfaces, and disposables in **proof of concept** builds.
- Applied MBSE and requirements analysis to link user needs, hazards, interfaces, and verification intent.
- Presented **technology landscapes**, business cases, **competitive intelligence**, and risk profiles to governance teams.
- Coached engineers in Design Thinking, Stanford Biodesign, design controls, and **feasibility planning**.

Senior Systems Engineer

April 2020 - December 2022

HelixPoint Medical Devices

Cambridge, MA

Led systems engineering for a connected electromechanical platform, coordinating architecture, requirements, risk management, integration, verification planning, and quality documentation across hardware and software teams.

- Integrated sensors, actuation, embedded **software**, data functions, and clinician controls into one platform.
- Converted workflow research into **user needs, subsystem requirements**, interfaces, and architecture decisions.
- Linked hazards, mitigations, requirements, and verification evidence for regulated design reviews.
- Planned staged integration tests that exposed hardware and software interface issues early.
- Assessed supplier sensing and **automation** technologies, documenting tradeoffs and partner recommendations.
- Supported **design controls**, SQA, SDLC, and lifecycle records with **quality** and regulatory partners.

Systems Engineer

July 2017 - March 2020

Meridian Surgical Innovations

Hartford, CT

Developed system architectures for **electromechanical** surgical devices, connecting **clinical workflows** with mechanics, electronics, sensing, software, disposable interfaces, risk controls, and system level evidence.

- Created architectures spanning **clinical** workflow, mechanics, electronics, sensing, software, and disposables.
- Maintained traceable **system requirements** through design changes and verification planning.
- Planned feasibility experiments for **sensing, actuation**, and control concepts during architecture selection.
- Converted hazard discussions into design actions and testable requirements for engineering reviews.
- Defined use conditions, integration sequences, acceptance criteria, and system evidence needs.
- Summarized competitive technologies and emerging clinical approaches for future platform decisions.

R&D Engineer

June 2014 - June 2017

Pioneer Biomedical Engineering

Providence, RI

Developed electromechanical **medical device** prototypes, test fixtures, engineering records, and supplier solutions under senior guidance within regulated product development programs.

- Developed **electromechanical** prototypes under senior guidance for **regulated product development**.
- Created fixtures and test methods for mechanics, **sensors**, and subsystem interfaces.
- Supported **design controls** through engineering records, reports, requirements updates, and review materials.
- Investigated prototype failures with root cause methods and evidence based design changes.
- Coordinated supplier components, drawings, tolerances, materials, and assembly questions before builds.
- Built scripting tools for data reduction and repeatable test reporting.

Associate R&D Engineer

June 2012 - May 2014

Coastal Biomedical Lab

Worcester, MA

Supported supervised feasibility work for medical instrumentation, including prototype assembly, bench testing, sensor analysis, supplier research, design records, and technical communication across multidisciplinary teams.

- Assembled medical instrumentation prototypes and executed supervised bench tests against engineering objectives.
- Analyzed sensor and mechanical data, identifying repeatability issues for senior engineers.
- Updated drawings, bills of materials, protocols, and laboratory records during design iterations.
- Researched sensors, motors, electronics, and materials for **proof of concept** systems.
- Applied risk analysis and design control concepts during engineering reviews.
- Presented test findings and prototype observations to multidisciplinary **R&D** teams.

PROJECTS

Connected Surgical Platform Feasibility 📅 2022

Assessed sensing, actuation, embedded software, data functions, and clinician controls for a connected surgical platform. Documented architecture options, integration risks, and verification evidence needs.

Wound Care Technology Landscape 📅 2024

Mapped external technologies, clinical needs, supplier capabilities, and competitive approaches for wound care concepts. Prepared evidence summaries and recommendations for early portfolio review.

LEADERSHIP & AWARDS

- Stanford Biodesign Innovation Process Certificate, 2021
- Six Sigma Green Belt, 2019
- Medical Device Innovation Mentor, regional university accelerator, 2024 to Present

EDUCATION

Master of Science in Biomedical Engineering

2014

Boston University GPA: 0

Boston, MA

Coursework: Systems engineering, medical device design, biomechanics, biomedical instrumentation

Bachelor of Science in Biomedical Engineering

2012

Worcester Polytechnic Institute GPA: 0

Worcester, MA

Coursework: Engineering design, electronics, mechanics, biomedical instrumentation

CERTIFICATIONS

- Six Sigma Green Belt 📅 2019
- Stanford Biodesign Innovation Process Certificate 📅 2021

TECHNICAL SKILLS

- **Systems Engineering:** MBSE, requirements analysis, architecture exploration
- **Medical Device Development:** design controls, regulated development, product lifecycle
- **Risk Management:** hazard analysis, risk profiles, design mitigation
- **Verification and Validation:** integration testing, feasibility testing, acceptance criteria
- **Electromechanical Systems:** mechanics, electronics, actuation
- **Connected Devices:** sensors, embedded software, data functions
- **Innovation Methods:** Design Thinking, Stanford Biodesign, TRIZ
- **Quality Engineering:** SQA, quality systems, design reviews
- **Software Practices:** SDLC, scripting languages, software engineering practices
- **Product Lifecycle Tools:** SAP Product Lifecycle Management, requirements records, engineering records
- **Clinical Innovation:** customer discovery, unmet needs, clinical workflows
- **External Partnerships:** startups, academic innovation, licensing opportunities

SKILLS

- Systems Engineering
- Electromechanical Systems
- Automation
- Design Controls
- Technical Due Diligence
- Connected Devices
- Digital Health
- Risk Management

- Front End Innovation
- External Innovation
- Sensors
- Actuation
- MBSE
- Requirements Analysis
- Verification and Validation

PROFESSIONAL AFFILIATIONS

- Medical Device Innovation Mentor, regional university accelerator
- Biomedical engineering and medical device innovation community participant

LANGUAGES

- English (Native)
- Spanish (Proficient)

ADDITIONAL INFORMATION

Work Status : Authorized to work in United States. No sponsorship required.

REFERENCES

AVAILABLE ON REQUEST