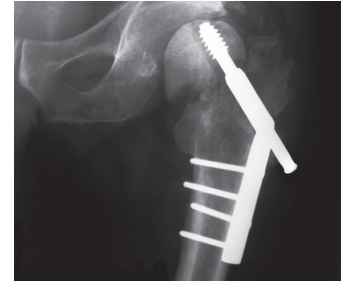
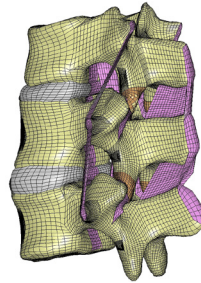
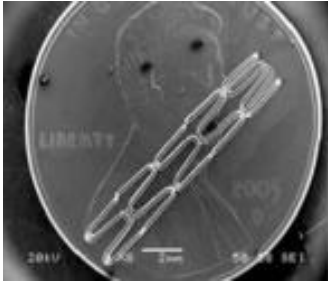




Engineering and Scientific Consulting

## Medical Devices & Biomedical Engineering



**Exponent provides the highest quality technical, regulatory, safety assessment, epidemiological, and health economics services to assist our clients with matters related to medical devices.**

**We specialize in providing rapid, focused, market-sensitive solutions to complex topics.** Medical device clients face numerous challenges today to get products to market, including developing appropriate preclinical and clinical plans to evaluate safety and effectiveness and preparing compelling regulatory submissions. From a business standpoint, it is important that our clients understand the market and reimbursement strategies for their products under development.

Once a product is on the market, there are many other factors to be addressed as part of postmarketing strategies, such as ensuring compliance with FDA Good Manufacturing Practices and appropriately documenting, evaluating, and communicating reports of medical device adverse events. In addition, although no company markets a product with an expectation of having to recall it, it is imperative that contingency plans are in place when the product hits the market.

Exponent's team of scientists, engineers, physicians, and other professionals hold advanced degrees in more than 90 disciplines. We bring a multidisciplinary approach to the continuum of medical device new product commercialization, applying expertise in biomechanics, biomaterials, biostatistics, electrical engineering, epidemiology, exposure assessment, health economics, human factors, materials science, mechanical engineering, medicine, regulatory affairs, and toxicology.

Our capabilities and experience include the following:

### Technology Acquisition

We assist with technology and regulatory due diligence, assessment of intellectual property, patent reviews, identification of "fatal flaws," and assessments of potential product safety issues.

### Safety, Risk, and Exposure Assessments

Exponent's scientific and medical staff has extensive expertise in assessing toxicological safety and risk from chemical exposures, and in comparing actual exposure levels to safe levels, including assessments for California's Proposition 65.

### Design and Testing

Exponent's scientists perform materials characterization and selection; tissue/device interaction and biocompatibility evaluations; finite-element and stress analyses; engineering and fracture mechanics and fatigue evaluations; fluid-flow analysis; vibration and acoustic testing; biomechanical and ergonomic assessment; physical, mechanical, chemical, and corrosion testing; and reliability testing. We also have extensive experience in test technology development. While all of our practices, policies, and procedures uphold the basic principles of good laboratory procedures, a select group of our procedures are specifically A2LA accredited.

### Regulatory Compliance

Exponent supports the regulatory process at both the state and federal level in the U.S. Our scientists also have experience with international regulations, CE mark compliance, and EN/IEC/ISO standards compliance. We also have successful experience in regulatory agency interactions for product submissions, clinical and technical development plans, and postmarketing issues, such as medical device reporting and recalls.

### Failure Analysis

Our biomedical, biomechanics, materials, mechanical, and electrical engineering consultants have many years of direct experience evaluating medical device failures and improving product performance, including design and risk analysis and implantation/device deployment investigations. Our experienced medical staff can also evaluate the health and safety implications of device failures.

### Medical and Economic Assessment

Exponent has expertise in outcomes, economic, and clinical research for medical devices and other health-care interventions. We have used modeling and simulation studies to evaluate the clinical and cost effectiveness of health-care interventions and have used national health-care surveys and other sources of medical claims data to evaluate factors that influence decision making among physicians, patients, and health-care administrators.

### Clinical Evaluation

We have experience in the design, execution, and analysis of controlled clinical trials and epidemiology studies, including Good Clinical Practices, medical monitoring, biostatistics, and data analysis.

### Postmarketing Research

We have experience conducting long-term performance assessments, including large-scale clinical and epidemiology studies.

### Product Recalls

Our experience includes product failure analysis, health hazard evaluations, root-cause analysis, and device history record reviews (DHRs) as part of Corrective and Preventive Actions (CAPA) programs, medical and scientific literature reviews, and "recall readiness" planning.

### Medical Device Reporting (MDR)

Exponent's physicians and epidemiologists have experience in the medical evaluation of adverse events and trend analysis. We also have experience in evaluating the effectiveness of internal systems and SOPs for MDR.

### Patent/Intellectual Property Evaluations

Exponent has many years of experience evaluating the scientific basis for patent prosecutions and in conducting technical evaluations for patent infringement and validity disputes concerning medical devices.

### Risk Management

Exponent has experience in risk management and in performing design reviews using techniques such as fault-tree and failure modes and effects analysis (FMEA).

### Manufacturing

Exponent provides manufacturing operations support, manufacturing process analysis, trouble-shooting and process FMEA, as well as process verification, validation, and statistical process control.

### Scientific and Medical Litigation Support

Our scientists and engineers are well versed in the technical and confidential issues surrounding product liability disputes. This knowledge base can be applied early on in product development to minimize costs associated with failures and litigation.

### Quality Assurance

Exponent has expertise in quality systems implementation and auditing for compliance with Good Manufacturing Practices, as well as manufacturing procedures analysis.

Our experience includes evaluations of numerous types of medical devices, including:

- » Breast implants
- » Cardiovascular-assisted pumps
- » Catheters
- » Contraceptive devices
- » Drug delivery systems and i.v. and biopsy devices
- » Gynecologic devices
- » Implantable cardioverter defibrillators (ICDs)
- » Implant delivery systems
- » Implantable hearing devices
- » Intra-aortic balloon pumps
- » Needle destruction devices
- » Needleless injection devices
- » Orthopedic implants (e.g., total hip, total knee, shoulder, elbow replacements, anchors)
- » Pacemakers
- » Spine implants (e.g., posterior and anterior instrumentation, total disc, vertebral augmentation, nucleus replacements, dynamic stabilization)
- » Surgical tools and instruments
- » Tissue biomaterial scaffolds
- » Urologic devices
- » Vascular and intra-cardiac closure devices
- » Vascular grafts, stents and shunts