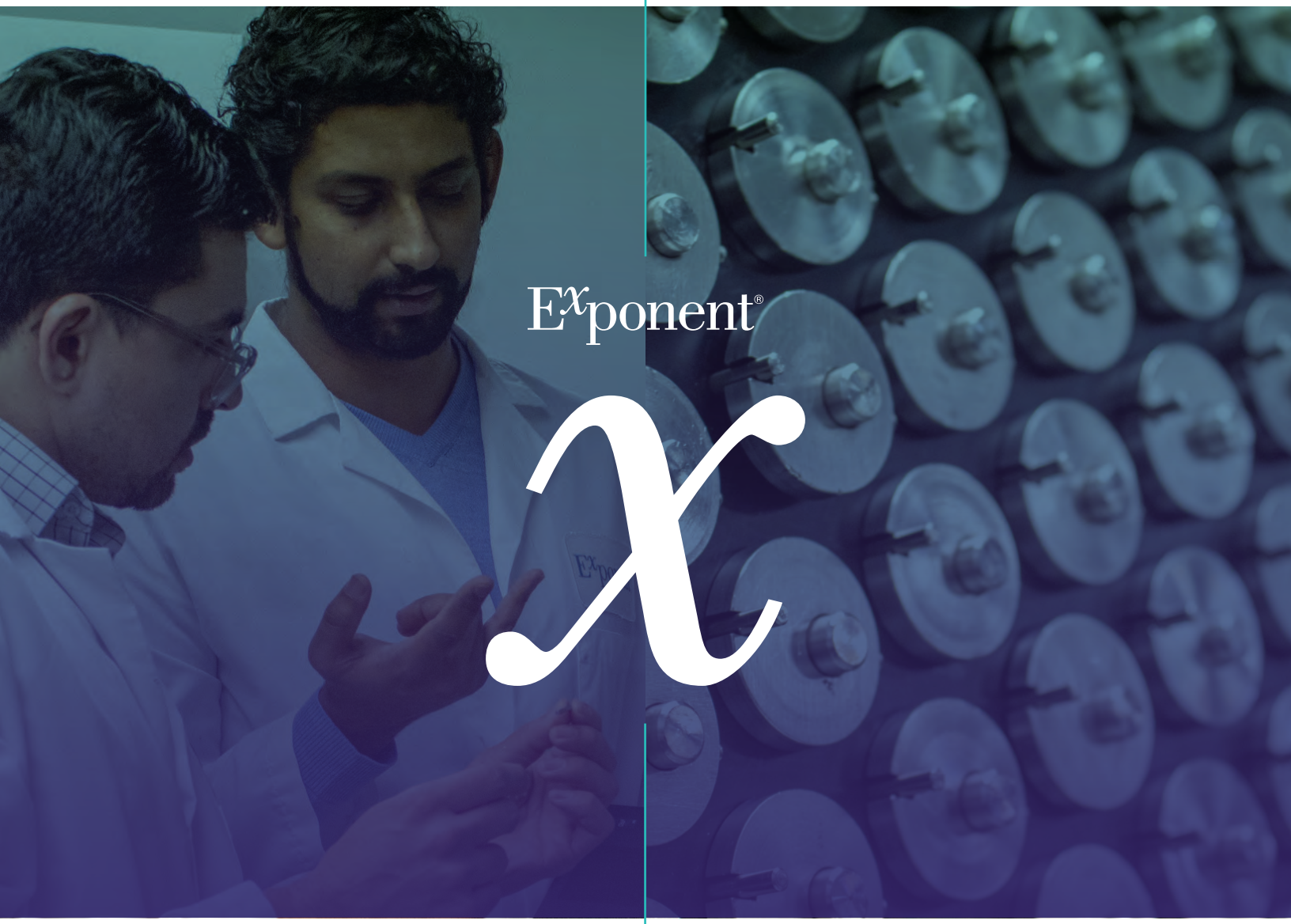
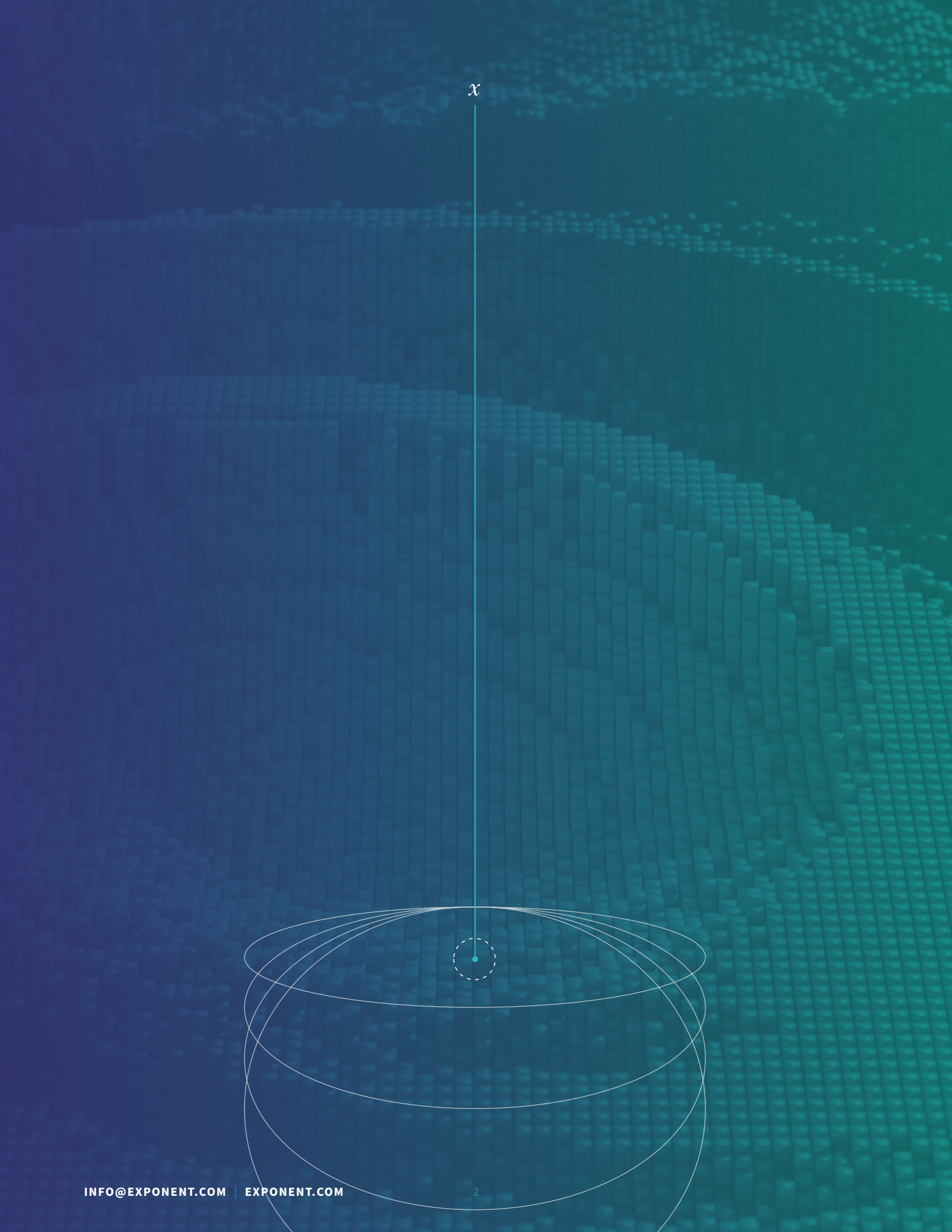


Exponent®

Medical Device Expertise for the Total Product Lifecycle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Transform Science into Life-Changing Impact

In an era of radically-accelerating change, Exponent is the only premium engineering and scientific consulting firm with the depth and breadth of expertise to solve your most profoundly unique, unprecedented, and urgent challenges.

We provide the highest quality technical, regulatory, economic, risk management, epidemiological, and safety assessment services to assist our clients with issues throughout all stages of the medical device product development lifecycle. Our medical device clients face numerous challenges today to get products to market — and Exponent provides the breakthrough insights needed to optimize outcomes, navigate risks and opportunities, and unlock innovation.

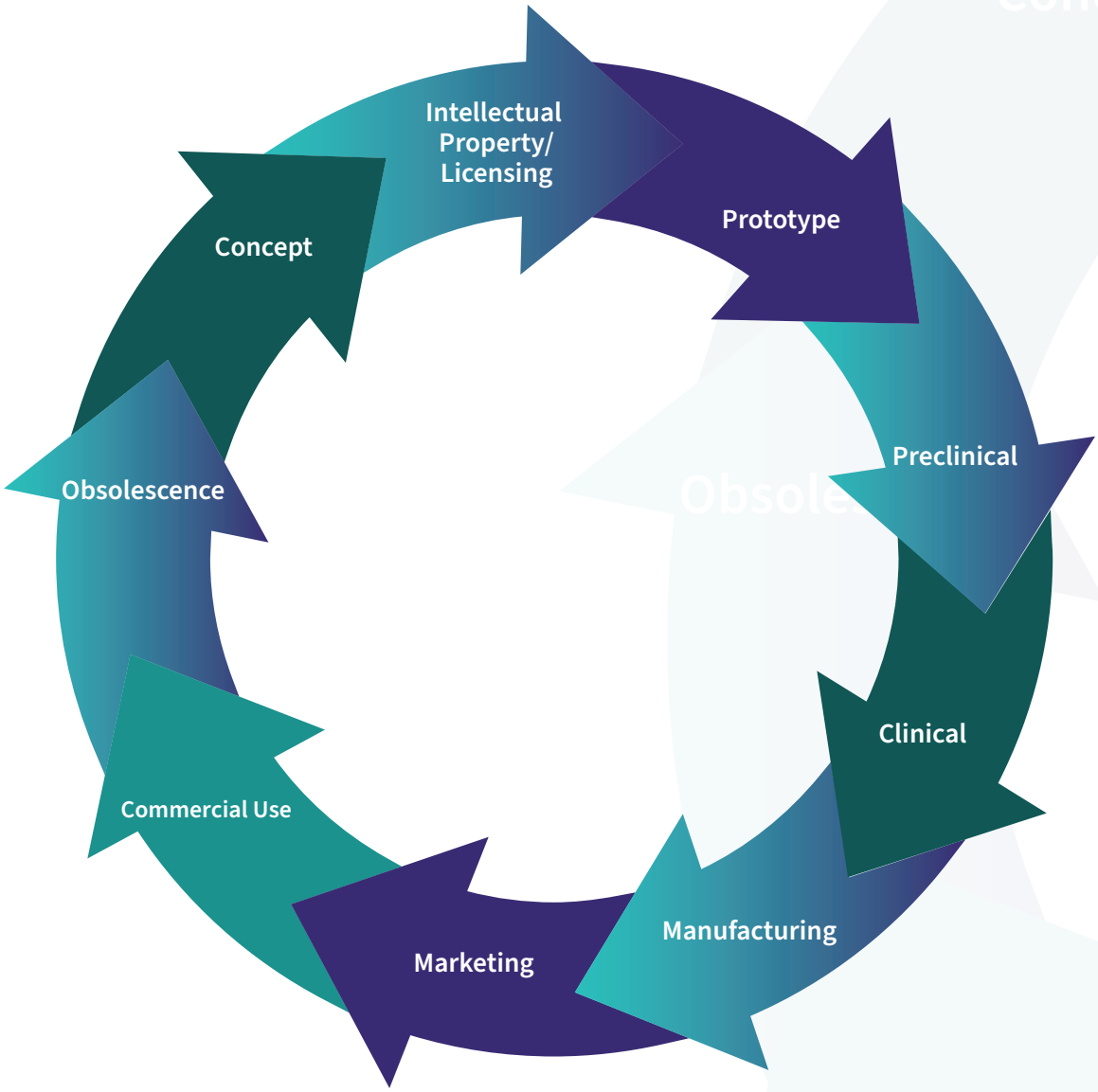
Exponent by The Numbers

90+
Technical Disciplines

30+
Offices Across North America, Europe & Asia

1967
50+ Years of Scientific Excellence

Product Lifecycle



Medical Device Evaluation Services

Medical device design requires knowing how a device will perform under a range of conditions when interacting with the human body. From biocompatibility and corrosion assessments to finite element analysis and MRI compatibility, Exponent provides robust medical device evaluation and analysis expertise to help you develop safer products, meet regulatory requirements, and accelerate time to market. Our expertise is also utilized in product liability and intellectual property litigation, technology acquisition, and due diligence.

CAPABILITIES

- Biocompatiblity & Biological Risk Assessment
- Wear & Biotribology
- Finite Element Analysis
- Retrieved Device & Tissue Analysis
- Medical Device Corrosion
- Biofluid Dynamics for Biomedical Devices & Products
- MRI Compatibility
- Electrical Safety & Compliance
- Clinical Studies
- Real-World Evidence
- Software as a Medical Device

Preclinical Regulatory & Development Strategy

Exponent's multidisciplinary teams have extensive expertise in the medical device product development process, including preclinical test method development and strategy, and experimental and analytical performance evaluations using either custom test methods or standard tests defined by the International Organization for Standardization and ASTM International. We perform mechanical and materials evaluation of implants and delivery instrumentation pertaining to patent evaluation and infringement issues, third-party design reviews, or FDA or international regulatory submissions.

We can also evaluate novel medical device performance characteristics to answer specific questions related to materials, biocontrol and biosignal software (failure analysis, reliability and testing, interaction with hardware), and functionality (fracture, electronic circuit/component failure, functional surface coating integrity, tissue interaction, battery depletion, drug elution).

Biomedical Evaluations

With every advancement in medical device materials and technologies, understanding how they will perform, wear down, and interact with the human body becomes increasingly complex. Engaging our experts early in your product development can help you get ahead of risks, while positioning your devices to achieve FDA and EU compliance.

Exponent's biomedical evaluations include cadaveric models, validated finite element models, and the very latest testing materials, methodologies, and technologies.

Exponent also offers an implant retrieval program that collects explanted devices including orthopedic and spinal implants, neurostimulators, pulmonary devices, pacemakers, implantable cardioverter defibrillators, and their leads, stents, filters, and heart valves. Our custom-made implant retrieval kits also enable us to maintain a broad repository of information to support the assessment of device performance, failure modes of retrieved implants, and the development of analytical and physical test methods and standards.

Exponent's testing and evaluations support global regulatory processes and requirements. Our teams are experienced with regulations in the U.S., EU, UK, and Asia. We are well-versed in CE mark compliance, EN/IEC/ISO standards compliances, and maintain broad knowledge of regulatory agency interactions for product submissions for class I, II (510k), and II (PMA) medical devices. We assist clients in quality systems implementation and compliance improvements for FDA GMP/QSRs, ISO14971 and 13485.

Failure Analysis & 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. Our biomedical, biomechanics, materials, mechanical, and electrical engineers have many years of direct experience evaluating medical device failures and improving product performance, including design and risk analysis and implantation/device deployment investigations. Exponent has broad experience across the medical device industry in conducting root-cause and risk analyses as part of CAPA procedures.

Our experienced consultants can also evaluate the health and safety implications of device failures, including product failure analysis, health hazard evaluations, device history record reviews as part of CAPA, medical and scientific literature reviews, medical device reporting, and “recall readiness” planning.