Virtual Product Development in the Medical Device Industry

Enhancing innovation, managing risk, and accelerating products to market
How will you accelerate the delivery of innovative products to your customers while holding to cost targets, ensuring safety, and meeting regulatory requirements?

Medical device manufacturers around the world are working with MSC.Software to improve their product development process, allowing them to become significantly better at concept development, design, engineering, testing, certification, and production activities. MSC.Software is the Virtual Product Development (VPD) technology leader, providing the most complete range of simulation software, engineering expertise, and process improvement capabilities to accelerate innovation.
Medical device manufacturers face significant regulatory, operational, and business challenges in creating and delivering products to the marketplace. Technical, scientific, and medical advances act to increase competition, raise performance and innovation expectations, and shorten product life cycles. At the same time, compliance with governmental regulation increases costs, introduces delays, and imposes specific manufacturing and tracking requirements and processes.

The product development challenges have never been greater for manufacturers of medical devices. Forward-thinking medical device companies are employing new business strategies, new organizational approaches, new business processes and new enabling technology to continually improve their product development process as they constantly search for methods to increase competitiveness, speed time to regulatory approval, improve quality management, and shorten the product development process.

But product development managers, regulatory affairs, and quality assurance personnel face a common challenge: How do we improve innovation, speed the development process, and deliver the products our customers need while maintaining effective methods to meet regulatory requirements, hold cost targets, and maintain safety and reliability?

Whether you are developing hip implants, coronary stents, pacemakers, catheters, wheelchairs, or surgical instrumentation, the Virtual Product Development (VPD) tools and processes from MSC.Software enable you to significantly accelerate the processes of concept design, performance validation, regulatory approval, and production activities.

**Company**
CardioVasc, Inc.

**Challenge**
Predicting fatigue life of a cardiovascular stent is complicated by nature of the geometry.

**Solution**
Examine behavior of stent design using simulation services from MSC.Software.

**Value**
Considerably higher safety factor. Able to predict behavior of the product at an early stage of design.

> “The finite element analysis (FEA) services performed by MSC.Software played a significant role in helping us examine fatigue life predictions, including higher than expected stress concentrations, and ultimately enabled us to design with higher safety factors.”

Leon Rudakov
Director of Engineering
CardioVasc, Inc.
Virtual Product Development is the coordinated application of people, processes, and technology to empower your product development team to confidently accelerate crucial decisions and improve the entire product development process.

VPD enables you to quickly explore innovative new design alternatives while consistently achieving product performance, safety, durability, cost and time-to-market objectives.

VPD provides an efficient, collaborative product development environment across your organization and supply chain for:

- Design, simulation and “virtual testing” of physically accurate product models
- Knowledge capture and process automation
- Simulation data management, material databases, collaboration and design review

The Limitations of Physical Testing

Typically, adequate physical testing of new medical products is at best lengthy and expensive and, at worst, completely cost-prohibitive and often incapable of providing a complete understanding of product performance.

While essential as a final check for certification, correlation, and validation, complete reliance on physical testing is time-consuming, expensive, and not always practical for generating meaningful information about the performance of biomedical devices and their interaction with the human body.

Yet manufacturers spend millions of dollars on test equipment and thousands of hours on product testing – primarily because they see no alternative.

Relying solely on physical testing, even if sophisticated trade studies and design of experiments approaches are used, may not provide all the necessary data. Engineers may not gain enough timely information to make the best product development decisions. Plus, it is often difficult to repeat standard tests and achieve consistent results. With an ever-increasing need to accelerate development, trace design decisions, and optimize design performance within acceptable tolerances, the requirement to leverage design simulation tools has also grown.

Performance Verification of Flow Stop Device
Performance Validation with Virtual Testing

In order to understand product performance attributes, eliminate design problems, and make informed product development decisions, engineers in the medical device field are leveraging Virtual Product Development.

An enterprise business strategy, VPD creates an environment where all phases of the product design process use an integrated combination of simulation software technology and traditional techniques to simulate and correlate product performance and new material.

Using the same software technology relied on by the world’s leading automotive and aerospace manufacturers, biomedical engineers are now able to build detailed, accurate digital models of a wide range of medical devices and products, to evaluate and improve product performance, durability, interaction, and safety characteristics in ways never before possible.

By testing hundreds and even thousands of variations of these virtual prototypes, manufacturers gain a greater quantity of high-quality data with which to make product development and manufacturing decisions, ensure efficacy, and reduce design flaws before the product is submitted for regulatory approval. This product performance and safety information is available earlier in the design process and covers a range of performance attributes and usage scenarios not possible through physical testing.

VPD is accelerating the way manufacturers are moving products through development, manufacture, and regulatory approvals. Simulation with virtual prototypes plays a critical role in design verification and validation, reduces the risk of product failure, and provides a well-managed, traceable product development process. The final result is cost-effective designs with higher levels of reliability being developed and validated in less time.

Company
Guidant Corporation

Challenge
Confidence that soft tissue will respond safely to stent.

Solution
Use simulation methods to understand and visualize stent/soft tissue interaction and performance.

Value
Increased efficiency in stent design and accelerated innovation.

“We need to model the soft tissue to increase our understanding of how the tissue responds and interacts with a device. Finite element analysis (FEA) software provides the evaluation tool to do this.”

Chris Feezor
R&D Engineer
Guidant Corporation
Simulating Functional Performance - Will It Work?

The ‘rule of 10’ suggests that the cost of fixing a design problem increases 10 times if discovered in the testing phase, 100 times if discovered in the production phase, and 1000 times if the problem is discovered by the customer. With the stakes so high, it is imperative for medical device manufacturers to leverage the capabilities of design simulation software in order to answer the most fundamental design questions – will it work and will it last?

The best-in-class simulation solutions from MSC.Software enable you to predict the functional performance of your product during the concept and design phase. Front-loaded analysis helps investigate physically accurate dynamic loads caused by motion or contact, stress behavior due to material properties and dynamic loads, or durability and fatigue due to repetitive loading conditions including vibration.

Design trade-off studies can be performed rapidly to determine the best material to use, how thick or thin to make a part, or if the loads caused during movement and repeated contact will lead to product failure. In the case of a joint replacement device, you are able to study problems such as dislocation, fatigue, or impingement problems early in the development process before physical testing.

Flexible On-Demand Licensing

MSC.Software’s innovative MSC.MasterKey™ License System allows you to take advantage of our world-class simulation software portfolio within a flexible licensing system so you can use the simulation tools you need when you need them. MSC.MasterKey utilizes a token-based licensing method to allow access to a full range of CAE solutions.

With more than 100 different MSC.Software products available, MSC.MasterKey can be tailored to your unique environment to maximize productivity and optimize your VPD investment. Traditional (per seat) software licensing is available if required.
The Broadest Range of Simulation Solutions

Encompassing the broadest range of VPD solutions available from a single vendor, MSC.Software’s product portfolio has evolved into three main product lines, consisting of stand-alone simulation software, CAD-integrated simulation tools, and enterprise data management and collaboration tools.

A Stand-Alone VPD Environment
SimOffice™ incorporates MSC.Software’s major product families – MSC.Nastran™, MSC.Patran™, MSC.ADAMS®, MSC.EASY5™, MSC.Marc®, MSC.SOFY™, MSC.Dytran® and others – into a unified product line of market-leading applications. SimOffice provides a VPD environment to build, test, and review functional virtual prototypes. These products are scalable from a single user to the complete enterprise and enable the evaluation of designs from concept to detail and from system to component, across all functional performance attributes.

A CAD-Embedded VPD Environment
SimDesigner™ delivers VPD technology to the designer’s desktop by embedding MSC.Software simulation solutions into the CAD environment. This enables performance assessment across multiple disciplines, such as linear structures, motion, thermal, nonlinear structures, and more, directly on the CAD model. SimDesigner Gateway products provide CAD users direct access to MSC.Nastran, MSC.Marc, and in-house proprietary systems using the STEP AP209 standard.

Automate & Manage Collaborative VPD
MSC.SimManager™ provides a systematic approach and infrastructure for managing the processes and data required for collaborative virtual product development. MSC.SimManager enables consistent management of all simulation processes, data, and models, ensuring that domain experts have appropriate control of the process, and that all others have appropriate access to the simulation-generated knowledge – including direct access from CAD environments and web environments. It improves productivity by automating processes and reducing manual tasks, and provides the infrastructure to facilitate trade-off studies by integrating multiple simulation domains through a single process.

Company
Zimmer GmbH

Challenge
New joint implants must meet special requirements concerning function and strength before manufacturing begins.

Solution
Design simulation software was used to investigate implant safety and function before physical testing.

Value
Decreased physical test costs by approximately 40%.

“Using simulation, we are able to improve the design of implants prior to manufacturing and decrease costs of physical testing by approximately 40%.”

Daniel Hertig
Computational Biomechanics
Zimmer GmbH

Courtesy of Biomechanics Research Group, an MSC.Software partner
Elliptical Accommodative Intraocular Lens (EAIOL) Concept

Challenge
Determine an acceptable size, shape, and material for new intraocular lens with a range of focal lengths that would be both manufacturable and foldable (nested) for surgical implantation.

Solution
With the use of simulation, the principle behind the design concept was proven before prototypes were made.

Value
50% reduction in time-to-market and 80% reduction in manufacturing costs.

“Simulation helped us refine the design concept, decide on the best material, and prove that the concept works.”

Dr. Mona F. Sarfarazi, M.D.

Planning for Success
When seeking to improve product development processes, business and engineering managers typically have a number of questions to answer: What are our strengths and weaknesses? Is our development process aligned with our strategic objectives? Do we have the appropriate technology and skills? How do we compare with the best in our industry? What benefits can be achieved by implementing new processes and technologies?

To assist in achieving the best return on your technology investment, MSC.Software works with our customers to assess product development processes, define technology and process improvement strategies, and develop a VPD implementation roadmap using the Virtual Product Development Maturity Model (VPDMM). The VPDMM is adapted from the Capability Maturity Model developed by Carnegie Mellon’s Software Engineering Institute.

The VPDMM self-assessment guides a company through more than 30 topics, including quality, risk and opportunity management, decision support, data integrity, customer requirements, cross-functional design integration, the involvement level of management, platform teams, and the supply chain. The results provide an unbiased review of your current product development processes, compares them to industry best practices, and assists in making decisions to define the roadmap needed to reach your product development goals.

Significant return on investment is realized when companies create enterprise-wide change that leverages an integrated and collaborative product development environment to manage simulation and validation techniques to guide design decisions and validate product performance prior to physical testing.

Virtual Product Development Maturity Model (VPDMM)
**Product Development and Simulation Services**

MSC.Software provides professional services to the medical device industry, including project-based design simulation, design process automation, product and simulation data management, on-site training and engineering, as well as enterprise-wide development process assessment and improvement.

One of the most beneficial services we provide our clients is the implementation of a Virtual Product Development framework for integrating all aspects of design and simulation through knowledge capture, process automation, and data management in concert with their existing product development processes.

Our global organization and resources in North America, Europe, and Asia Pacific leverage the state-of-the-art simulation tools in our broad product portfolio and integrate these tools with other products critical to your product development process.

Our broad range of capabilities, years of experience, and global presence differentiates MSC.Software from other companies in today’s product development marketplace.

Using MSC.Software’s professional services, our customers are designing and building products more efficiently and cost-effectively than ever before. The end result is more confidence in delivering superior innovation products to market faster.

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**MSC.Software Simulation Services**

- 3D modeling and design
- Nonlinear materials analysis
- Biomechanics simulation
- Contact interference and structural analysis
- Controlled system simulation
- Deformation/displacement
- Thermal analysis
- Drop test simulation
- Design sensitivity, optimization
- Dynamic load prediction
- Fatigue analysis, material failure, crack initiation
- Linear & nonlinear stress, strain analysis
- Material database development & integration
- Process automation
- Product & simulation data management
- Shape memory material analysis

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**MSC.Software Solutions Framework**
MSC.Software is a trusted partner of leading manufacturing firms worldwide. For more than forty years, we have been developing simulation software, capturing process knowledge, and supporting vital engineering decision-making capabilities.

Today, we provide the world’s most complete portfolio of simulation software technology, engineering expertise, and process improvement capability. We accept the toughest technology and business challenges and deliver excellent return on investment to manufacturing firms worldwide through the use of Virtual Product Development.

Virtual Product Development is focused on enhancing your ability to make informed engineering decisions quickly. By exploring multiple design alternatives during the concept and design phase, your engineering teams are able to consistently achieve the right product performance for safety, motion, durability, and manufacturability, within time and cost constraints.

Our customers rely on VPD as an enterprise business strategy, one with the proven ability to improve the way they invent, design, test, build, and support their products.

By choosing to work with MSC.Software, you are selecting a partner with the resources, knowledge, and experience to assist you in managing product development risks more efficiently and effectively.

“I find that all aspects of our partnership have resulted in solutions to product development requirements which are invaluable in helping us make critical decisions related to stent design and development.”

Leon Rudakov
Director of Engineering
CardioVasc, Inc.
Contact the Virtual Product Development professionals at MSC.Software. You’ll discover the software and services you need to accelerate innovative products to market while maximizing the return on your VPD investment.

http://medical.mscsoftware.com

MSC.Software Corporation (NYSE: MNS) is the leading global provider of Virtual Product Development tools, including simulation software and professional services, that help companies make money, save time, and reduce the costs associated with designing and testing manufactured products.
Whether you're developing airplanes, automobiles, ships, buildings, machine tools, business equipment, medical devices, sporting equipment, or children's toys, MSC.Software's goal is to help you improve your concept, design, test, review, and production activities through the application of Virtual Product Development.