

MSC Solutions for Medical Device Industry Simulation Methods for Reducing Risk and Accelerating Innovation

MSC Software

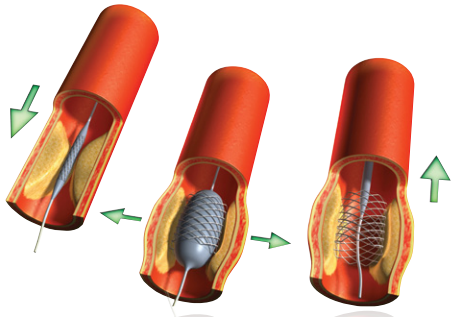


MSC Software Medical Device Industry

Delivering Certainty by Helping You Simulate Real World Behaviors

By optimizing design, medical device corporations can reduce time to market and increase product reliability while meeting budgetary and regulatory requirements.

MSC Software enables the successful adoption of virtual test and simulation methods for medical device manufacturers. Rather than rely on point analysis tools, engineers can now explore a full range of complex simulations when designing medical applications.



MSC solutions offer a suite of integrated productivity tools and techniques for managing the entire simulation process while establishing best practices and standards for virtual testing across the enterprise.

Medical Product Development Challenges

Medical device manufacturers face significant regulatory, operational, and business challenges in creating and delivering products to the marketplace.

Two business drivers are changing traditional product development:

1. Reduced tolerance among shareholders for product recalls
2. The need to reduce time to market and stay ahead of the competition

At the same time, compliance with governmental regulation increases costs and introduces delays. Product development managers and quality assurance personnel must therefore answer the following key questions:

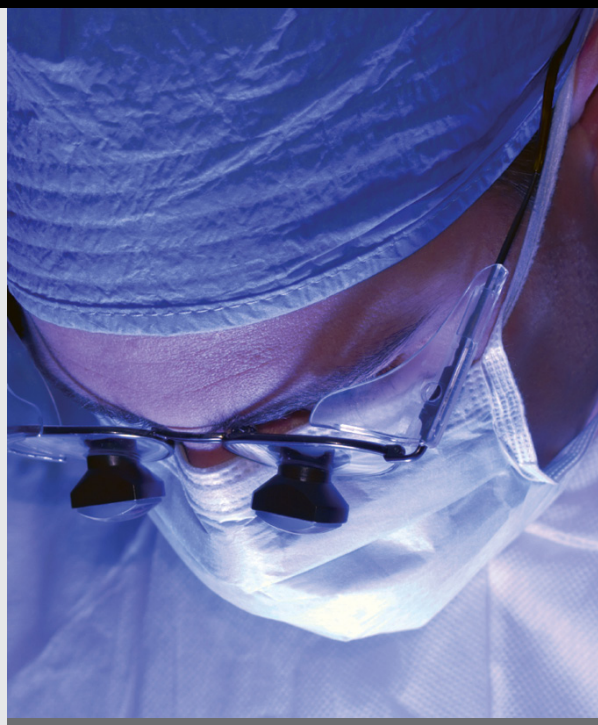
1. How can we optimize the design within a reasonable timeframe?
2. How can we improve product development while still following regulatory processes that maintain safety and reliability?

By relying more and more on computational modeling & simulation, medical device manufacturers can achieve rapid verification with virtual models while reducing reliance on the slow, costly process of physical testing. MSC Software provides simulation solutions and best practices for accelerating the process of concept design, performance validation, and regulatory approval across the medical device industry.

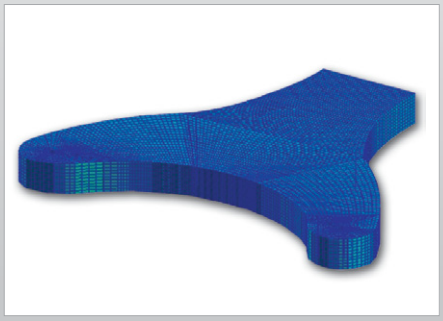
The Limitations of Physical Testing

Adequate physical testing of new medical products is a lengthy and expensive process. At best, it may provide data on failure limits, but does not allow engineers to understand the reasons for each failure. At worst, it can be inconsistent, cost-prohibitive, and incapable of providing any meaningful insight into the interaction between biomedical devices and the human body.

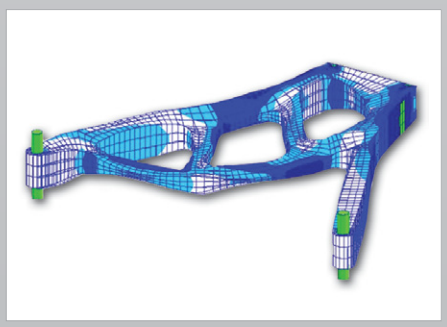
Some manufacturers continue to spend millions of dollars on test equipment and thousands of hours on product testing. However, as more and more product development managers embrace the importance of accelerating development and tracing design decisions, simulation has emerged as an ideal means to achieve major improvements in design processes.



Topology Optimization within Design Process



FE Model



After Optimization



Why Simulation is Important to Medical Product Engineering

Engineers in the medical device field are leveraging computer-aided engineering (CAE) methods to understand performance attributes and make informed product development decisions.

By evaluating multiple variations within virtual prototypes, manufacturers gain more high-quality data, increasing the robustness and reliability of their products prior to submission for regulatory approval. Designs can be verified against required customer specifications and relevant regulatory standards. This enables the efficient development and validation of a reliable, cost-effective design.

Key Success Factors for Simulation

Medical device companies often perform simulation by outsourcing or by purchasing unsophisticated point analysis tools to use on an ad-hoc basis.

However, to gain maximum value from simulation practices, companies must implement proven methods that produce consistently accurate results. These are the five key success factors which help ensure the effective simulation of medical products:

- Optimize design before initiating production
- Capture expert knowledge for repeatability of best practices
- Correlate simulation with physical tests
- Control, manage, and trace simulation methods and processes
- Reuse simulation data across engineering teams

MSC Software Adds Value to Medical Device Product Development

MSC provides a suite of solutions that helps medical device companies address these five key success factors for effective simulation. Our simulation solutions enable manufacturers to complete more virtual testing data throughout the design process, reuse experts' best practices, and control the resulting simulation data across engineering teams.

Simulation solutions which improve medical product testing include:

- Multidiscipline & Multiphysics
- Methods & Best Practices
- Simulation Data & Process Management

Multidiscipline & Multiphysics Simulate Complex Interactions

Simulating Real World Problems

Medical devices are typically subjected to a wide range of complex environmental or biological loading conditions. The variability of these conditions makes the physical testing of all possible scenarios both difficult and time-consuming.

By using MSC Software's leading multidiscipline & multiphysics solutions technology, engineers can study a great number of real-world interactions with higher accuracy. Our solutions provide a methodology for the analysis of complex engineering





systems and subsystems, exploiting the synergism of mutually interacting phenomena such as thermal and structural loading. MSC Software Solutions also enable the chaining of analysis sequences so that the output state of one sequence can be used as the input state for the next.

Multidisciplinary integration allows engineers to use math models that capture dynamic behavior, empowering companies to simulate complex scenarios and anticipate real-world conditions for optimal product performance.

Multidisciplinary Approach Improves Accuracy

Device companies often use point solutions to study scenarios in a serial fashion, but in the real world these phenomena often happen concurrently. For instance, in a dental implant, the device is subjected to chewing conditions which consist of both thermal and mechanical components.

Analysis disciplines that are crucial for studying medical product performance include:

- Structural
- Thermal
- Fluid structures interaction
- Motion-structure-fatigue
- Advanced nonlinear materials
- Motion-structures interaction
- Mechanisms
- Drop testing and packaging analysis
- Fatigue and durability

With our solutions, engineers can simulate these conditions to ensure higher accuracy while increasing the efficiency of the virtual testing process.

SimXpert Establishes Best Practices for Simulation

User-Friendly Simulation

SimXpert delivers a powerful, easy-to-use simulation workspace environment with built-in templating capabilities that provide the tools required to capture and automate complex processes.

Rapid Virtual Testing with Integrated Workspaces

The fully integrated simulation workspaces within SimXpert provide a range of built-in multidisciplinary capabilities for linear and nonlinear structures, motion, thermal conditions, drop testing, and more.
By using common data models across workspaces within a customizable user interface, medical product designers can perform tightly coupled simulations for total flexibility and faster results.

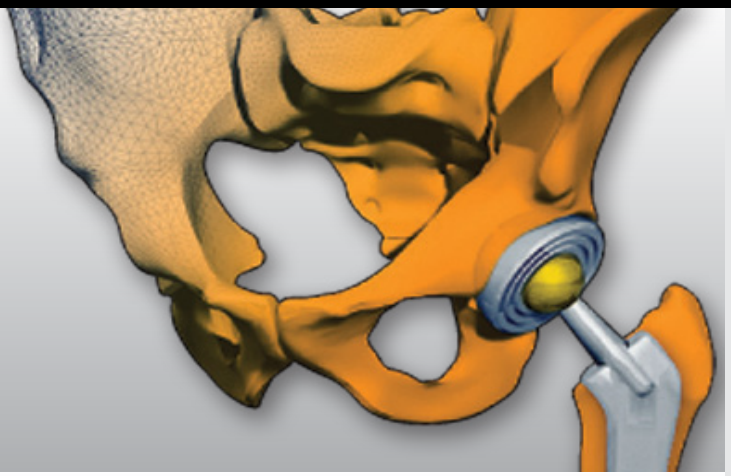
Creating Repeatable Simulation Methods

In order to establish automated processes for simulating medical products, SimXpert offers comprehensive template authoring and execution tools. The templates can automate a single task or string together an entire process for simulating a wide range of product performance characteristics.

For instance, stent designs require a series of testing that includes bending, crimping, expansion, and fatigue. SimXpert can string together this entire process by beginning with the initial geometry, creating the mesh, applying the loads and boundary conditions, running a series of required analyses, interrogating the results, correlating with physical tests, and finally compiling the data for FDA submission reports. By automating these steps, a company can save significant time and provide a repeatable mechanism for the analysis of key applications.

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

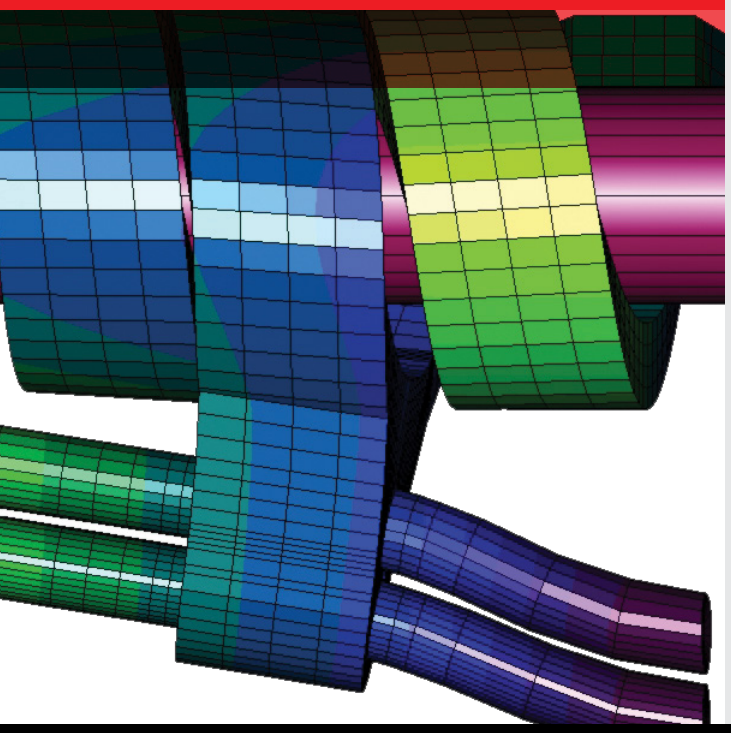
- CardioVasc, Inc.





"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."

- Guidant



SimManager Enables Auditable Simulation Processes

Ensuring Design and Simulation Traceability

Managing and tracking the simulation process is just as important as the simulation process itself. Medical device manufacturers must comply with Good Manufacturing Practice when managing and tracking product development data. FDA submissions require a comprehensive audit trail which includes:

- Records of all simulation data
- Revision management and control
- Correlation with physical test results
- Proven repeatable methods
- Software version tracking

To ensure confidence in the simulation and reliability of the analysis results, medical device manufacturers must ensure that the CAE analyst is using the most current CAD geometry, specify the correct material properties, and apply the appropriate environmental loading conditions. They must also create the proper mesh type and size, record the version of the analysis software, and correlate results with physical test data. These criteria must be preserved and managed for FDA compliance purposes and for the benefit of enhanced enterprise productivity.

Building a Simulation Knowledge Base

SimManager automatically stores all simulation, data files, input data, and results, providing a full history of simulation performance.

SimManager captures the entire simulation process to provide an audit trail for FDA submission reports. Medical device engineers can then locate models and results instantly, tracing and proving the methods which were used to create those results. The audit trail also includes the software versions used to perform the simulation—critical data for FDA compliance purposes.

SimManager also supports global collaboration across engineering teams by enabling anyone with authorization to find, review, and utilize simulation and validation information from a standard Web browser.



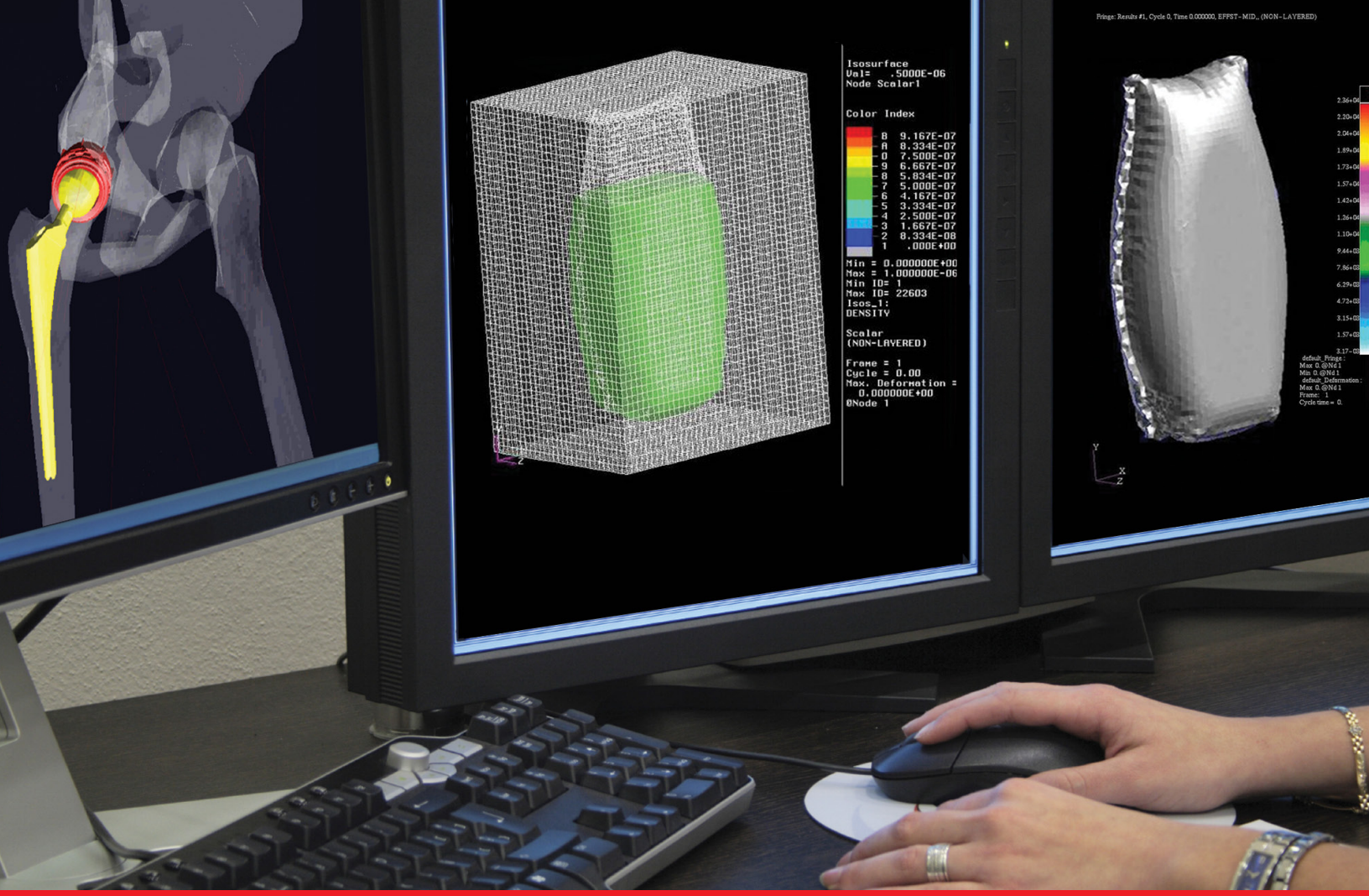
Simulation Confidence

MSC Software Solutions provide the elements needed to achieve successful implementation and utilization of virtual testing throughout the design process:

1. Easy-to-use workspace simulation solutions encourage engineers to integrate simulation into their product development processes.
2. Best practices and templates automate simulations and encourage repeatability and consistency.
3. Multidisciplinary capabilities study real-world complexity for improving simulation accuracy and reducing reliance on physical testing.
4. Management of the simulation process improves knowledge management and complies with FDA regulations for traceable design processes.

Medical device manufacturers around the world work with MSC Software to improve their product development processes, allowing them to improve development, design, engineering, testing, certification, and production.

MSC Software's enterprise simulation solutions use detailed digital product models to simulate and verify every aspect of product performance, track critical design decisions, and coordinate product development, allowing companies to drive product innovation to new and competitively sustainable levels.



Corporate

MSC Software Corporation
4675 MacArthur Court
Suite 900
Newport Beach, CA 92660
Telephone 714.540.8900

www.mscsoftware.com

Europe, Middle East, Africa

MSC Software GmbH
Am Moosfeld 13
81829 Munich, Germany
Telephone 49.89.431.98.70

Asia-Pacific

MSC Software Japan LTD.
Shinjuku First West 8F
23-7 Nishi Shinjuku
1-Chome, Shinjuku-Ku
Tokyo, Japan 160-0023
Telephone 81.3.6911.1200

Asia-Pacific

MSC Software (S) Pte. Ltd.
100 Beach Road
#16-05 Shaw Towers
Singapore 189702
Telephone 65.6272.0082

The MSC Software corporate logo, MSC, and the names of the MSC Software products and services referenced herein are trademarks or registered trademarks of the MSC.Software Corporation in the United States and/or other countries. All other trademarks belong to their respective owners. © 2013 MSC.Software Corporation. All rights reserved.

SMDI*2013SEPT*BR