Improving product reliability and time to market in the medical device industry

Simulation methods for reducing risk and accelerating innovation

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 simulation, medical device manufacturers can achieve rapid verification with virtual models while reducing reliance on the slow, costly process of physical testing.

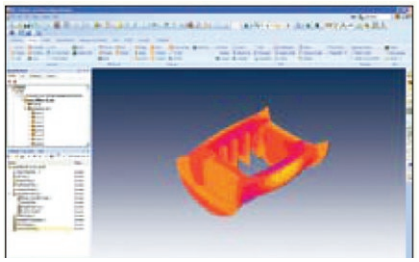
MSC Software provides simulation solutions and best practices for accelerating the process of concept design, performance validation, and regulatory approval across the medical device industry.

Why simulation is important to medical product engineering

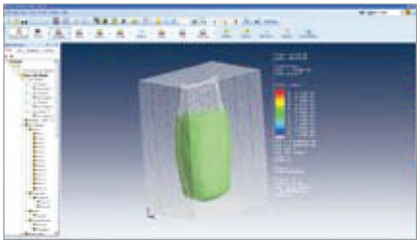
Engineers in the medical device field are leveraging computer-aided engineering (CAE) methods to understand performance attributes and make informed product development decisions.

By evaluating multiple variations within virtual prototypes, manufacturers gain higher quality data, and increase 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.

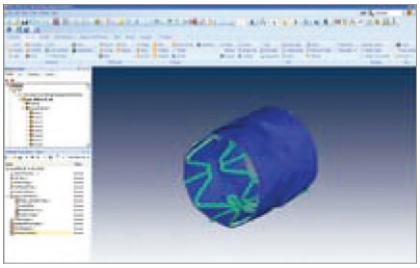
Multidiscipline simulation solutions for medical device tests



Thermal temperature cycling; radiation



Drop test, fluid structure interaction (FSI)



Durability fatigue life

Motion and biomechanics

Key success factors for simulation

Medical device companies often perform simulation by outsourcing or by purchasing functionally limited point analysis tools to use on an ad-hoc basis. However, to gain maximum value from simulation practices, successful companies 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 solutions add value to medical device product development

MSC Software's suite of simulation solutions helps medical companies address the aforementioned key success factors for effective simulations. The solutions enable manufacturers to complete more virtual tests throughout the design process, reuse experts' best practices, and control the resulting simulation data across engineering teams.

Solutions which improve medical product testing include:

1. Multidiscipline & Multiphysics
2. Methods & Best Practices
3. Simulation Data & Process Management

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's multidisciplinary and multiphysics simulation technology or services, engineers can study a greater number of real-world design behaviors with higher accuracy. Multidiscipli-nary simulation provides a methodology for the analysis of complex engineering systems and subsystems, exploiting the synergism of mutually interacting phenomena such as thermal and

structural loading. Multidisciplinary analysis also enables the chaining of analysis sequences so that the output state of one sequence can be used as the input state for the next.

Multidiscipline simulation solutions for medical device tests include:

- Thermal Temperature Cycling; Radiation
- Electromagnetics
- Controls
- Durability Fatigue Life
- Motion and Biomechanics
- Drop Test, Fluid Structure Interaction (FSI)
- Packaging Seal Strength
- Deformation, Contact Material Nonlinearity

Establish best practices for simulation

User-friendly desktop simulation

MSC delivers a powerful, easy-to-use simulation workspace environment with capabilities to capture and automate complex processes. Our customers can cost effectively build customized virtual medical device test solutions which allow the user to focus on the products to test instead of specifics of how to run a simulation.

Rapid virtual testing with integrated workspaces

Fully integrated simulation workspaces provide a range of built-in multidisciplinary capabilities for medical device modeling and simulation including 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.

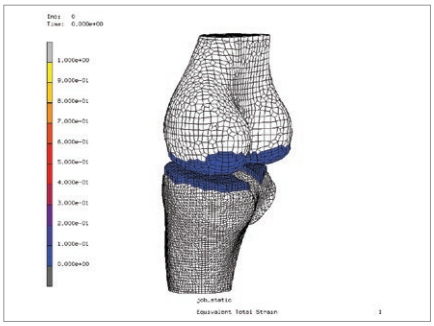
Enable auditable simulation processes

Ensuring design and simulation traceability

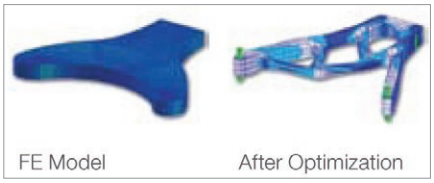
Managing and tracking the simulation process is just as important as the simulation process itself. Medical device manufacturers must comply with Good Manufacturing Practice when managing and tracking product development data. FDA submissions require a comprehensive audit trail which includes:

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

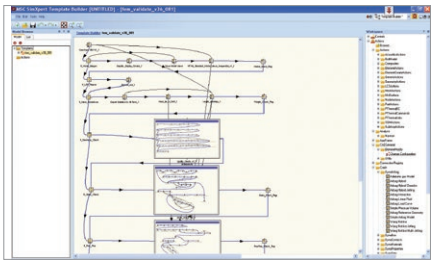
Virtual test automation and process management solutions for medical devices



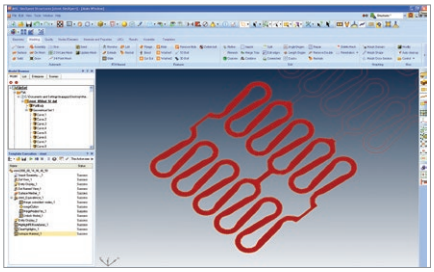
Industry specific application automation



Design optimization



Simulation audit trail and process automation



Best practice capture and deployment

Hexagon is a global leader in sensor, software and autonomous solutions. We are putting data to work to boost efficiency, productivity, and quality across industrial, manufacturing, infrastructure, safety, and mobility applications.

Our technologies are shaping urban and production ecosystems to become increasingly connected and autonomous – ensuring a scalable, sustainable future.

MSC Software, part of Hexagon's Manufacturing Intelligence division, is one of the ten original software companies and a global leader in helping product manufacturers to advance their engineering methods with simulation software and services. Learn more at mscsoftware.com. Hexagon's Manufacturing Intelligence division provides solutions that utilise data from design and engineering, production and metrology to make manufacturing smarter.

Learn more about Hexagon (Nasdaq Stockholm: HEXA B) at hexagon.com and follow us @HexagonAB.