SolidWorks

The Standard in 3D

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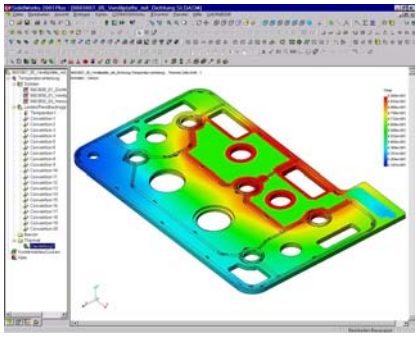


Using COSMOS analysis software during the redesign of this anesthetic unit, engineers at Dräger Medical, Inc. reduced the number of prototypes used in the early stages of product development from 8 to 2.

Analysis Guide for Medical Product Designers

Analysis and simulation software has become an indispensable tool for the development and certification of medical products. In addition to having to meet federal regulatory requirements, medical products manufacturers face greater liability and safety issues than most other manufacturers. In this environment, flawless, reliable product designs have become a competitive necessity.

Dräger Medical, Inc. used COSMOS analysis software in the redesign of this anesthetic unit.

Today's medical manufacturers use analysis software to simulate and assess the performance of a variety of product designs, including implantable surgical devices, artificial limbs and organs, prostheses, orthopedics, and artificial heart valves. Analysis software enables engineers to identify and address potential design problems before prototyping and productions.

This guide describes the key design performance issues facing medical product manufacturers and identifies the benefits of using COSMOS® Analysis software for medical product design.

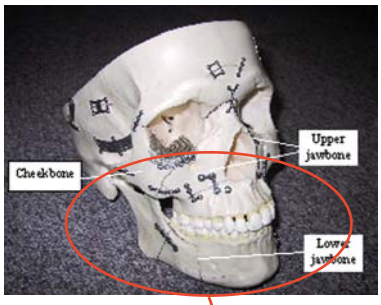
Analysis in the forefront of medical product development

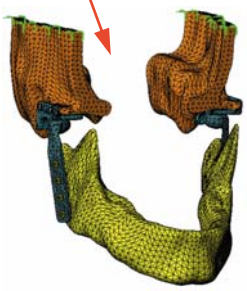
The federal Food and Drug Administration (FDA) has three classification levels for medical products.

- Class I products are passive devices that do not enter the patient's body or contact only the skin.
- Class II products are active devices or devices that are used to administer fluids to the patient's body.
- Class III products are implanted inside the patient's body.

Development cycles for medical products can be quite complex, especially for Class II and Class III devices. The conventional product development process of design, build, test, and rebuild typically involves several trial-and-error-based design iterations prior to full-scale production. These iterations are quite costly and time-consuming, and manufacturers benefit greatly by reducing prototype costs while still producing high-quality products.

Analysis tools help medical product manufacturers reduce the number of expensive prototypes and physical tests by identifying potential problems early in the design cycle. Analysis is most effective when applied early in product development, when engineers are conceptualizing the configuration of the device. At this point, design changes are far easier and less costly to make. Instead of wasting time and money by using numerous prototypes to determine if a design delivers its intended function, manufacturers leverage analysis technology to simulate design performance on the computer, increasing the probability that the final design will require only one round of prototype testing.





Powerful COSMOS™ analysis help product designers optimize SolidWorks 3D models, such as the artificial jaw joints used in this jaw reconstruction. (Design data courtesy of Okayama University)

Application areas

Medical Implants and Surgical Devices

- Cardiovascular devices: anastomoses devices, arterial grafts, endo-luminal stents, balloon catheters.
- Endoscopy and surgical devices: ligation devices, tissue scissors and staples
- Engineered tissue implants: cartilage ligaments, tendons orthopedic implants and devices, joint replacements, inter-medullary devices, fracture fixation devices.
- Dental implants

Medical Packaging and Drug Delivery Systems

- Opto-packaging
- Sterilization effects on material properties
- Material performance — creep, fatigue, stress relaxation
- Shelf life

Scope of design analysis

- Design verification/validation: Does this design work? Does this design behave the way I think it does?
- Relative merit: Which of these candidate designs appears to be the best? How can I weed out the lesser designs?
- Proof of concept: Testing out radical new concepts without "cutting metal"
- Durability and reliability: Failure analysis of implants
- Extending patentability and obtaining regulatory approval

Tight integration with CAD

COSMOS analysis software is tightly integrated with all major CAD systems and is directly integrated with the SolidWorks modeling system, the standard for 3D design. This means that engineers can use COSMOS analysis software directly on the CAD model and do not need to remodel designs to take advantage of analysis technology.

"What if" studies

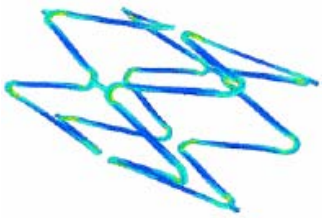
Designing a medical device for a load-bearing application presents unique engineering challenges. Not only does the material have to be biocompatible and FDA-approved, but it also must deliver the appropriate mechanical function within the chosen design envelope.

Using analysis to conduct "what if" studies — what if I tried this material, or what if I used this type of mechanism — can help engineers identify the best material and mechanical design for a particular function. Using a computational model and analysis software to perform "what-if" evaluations saves time and money and can help to improve device performance.

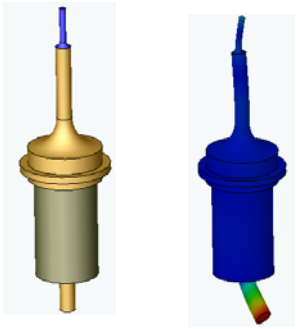
By coupling analysis studies with SolidWorks Configuration Management, the designer can quickly converge on the best-form design solution over many degrees of freedom.

SolidWorks configurations with COSMOSWorks analysis were used in the design of this robotic laboratory equipment to create multiple positions of an assembly. This enables multiple position data to be stored in one file. (Design data courtesy of SAGIAN, a Beckman-Coutler)

Researchers with the Orthopedic Research Group at the University of Western Ontario used COSMOS analysis software to model a hip bone, representing the model with five material properties. After piecing together individual sectors and merging them into a continuous model, the researches used COSMOS analysis software to determine the internal stress distribution within the hip bone.



Because of their critical function, engineers validate designs for endo–luminal stents using advanced methods such as nonlinear analysis.

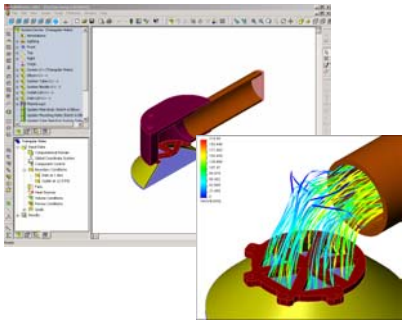


COSMOS vibration analysis can predict natural frequencies of the Ultrasonic resonator shown here.

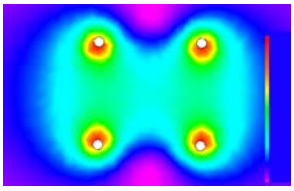
Powerful analysis types — mechanical, thermal, electromagnetic, fluid flow

Reliability is a key requirement for various medical device technologies and designs. Companies that build in reliability at the initial design stage have an advantage over competitors in establishing and maintaining market acceptance. COSMOS analysis software helps to ensure that reliability is established early-on by allowing medical designers to perform a range of analyses and simulations on initial designs. Using a range of analysis technology, COSMOS software helps engineers to ensure that a device's behavior will be within design limits, reliable, and avoid thermal or stress-induced failures.

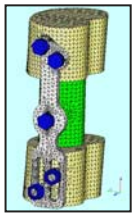
- COSMOS **Static** analysis is a tool that empowers the medical device designer to avoid catastrophic immediate or long-term failure modes and determine if re-design of one or more core elements is necessary. Designers can study the stresses or deflections in the device and compare it against allowable levels to predict failure.
- **Thermal** analysis is critically important in medical packaging. COSMOS analysis software can perform steady-state or transient thermal analysis on parts or assemblies. After meshing the design, the designer sets any relevant constraints, then the designer sets power or heat flux conditions associated with a geometrical feature of the model. Because component material properties include thermal conductivity, coefficient of thermal expansion, and heat capacity, the designer gets a realistic prediction of temperature distributions under prescribed conditions.
- **Nonlinear** analysis gives medical designers the ability to evaluate a medical device's performance within a complex, 3D-simulated environment, giving them a far more accurate determination of the different factors that may cause a device to fail. One product category that benefits from COSMOS nonlinear analysis are endoluminal stents, cylindrical metal mesh tubes that are inserted into blood vessels to counteract the effects associated with vascular diseases, such as narrowing of blood vessels due to plaque build-up. COSMOS nonlinear analysis also allows for the study of bifurcation buckling phenomena such as occur in balloon angioplasty catheter evaluation. Angioplasty is a surgical procedure performed to alleviate stenosed arteries by compressing the calcified plaque that can block the flow of blood. COSMOS nonlinear analysis can also be used in the evaluation of blood vessel ligation clip system conditions.
- **Vibration** analysis is used in the design of certain types of medical devices, such as an ultrasonic resonator. Prediction of the resonator's performance requires an understanding of the natural frequencies at which the resonator will vibrate and the amplitudes and stresses associated with each of these frequencies. After simulating the resonator's performance, the engineer can modify the resonator's dimensions or materials to improve the performance.
- **Fluid flow** analysis is important across a range of medical applications. Whether you're trying to design an artificial heart valve to see blood pumping through it or a needle-free injection system for drug delivery, COSMOSFloWorks™ offers high-powered computa-

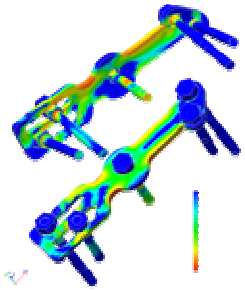


This device is used to remove material from the human body during surgery. COSMOS-FloWorks was used to design the filter screen in this device



COSMOSEMS is playing a vital role in testing certain features of Genetronics's MedPulser®, a device that applies electric pulse technology to cancer cells, making them more permeable to chemotherapeutic agents





tional flow dynamics (CFD) analysis in a straightforward interface. COSMOSFloWorks is the only CFD analysis software completely embedded inside SolidWorks.

- COSMOSEMS™ Electromagnetic analysis software provides powerful electric field strength optimization techniques frequently used in medical product design.

Assembly analysis

Medical components, whether external to the body in the form of external instrumentation and control systems or surgical tools, or internal in the form of pacemakers, sensors or prostheses, generally require a mix of materials, which are connected into an assembly in some way. External instrumentation systems, sensing units and control modules rely significantly on electronics for which a wide range of attachment, interconnection and encapsulation/protection methods exist. These processes, referred to generically as electronics packaging, are also applicable to many internal body sensors, batteries and stimulation devices.

Prosthetic devices, typically hip or knee replacements, rely on a combination of materials to provide the fracture toughness to withstand the mechanical loading, wear resistance and biocompatibility or bioactivity to survive in the body environment. Many hip joints now incorporate 'bonded titanium balls' to roughen the surface and aid mechanical 'fixing' to the bone .

COSMOS analysis software enables engineers to simulate all of these behaviors by allowing for the analysis of small or large CAD assemblies. The software allows engineers to assign different materials to different parts of the assembly and specify how the components will interact with each other. COSMOS assembly gap/contact analysis allows you to simulate various real-life conditions for medical components. For example, the software can simulate the behavior of welded medical components or components that slide against each other, such as is the case with hip joints.

3D results visualization

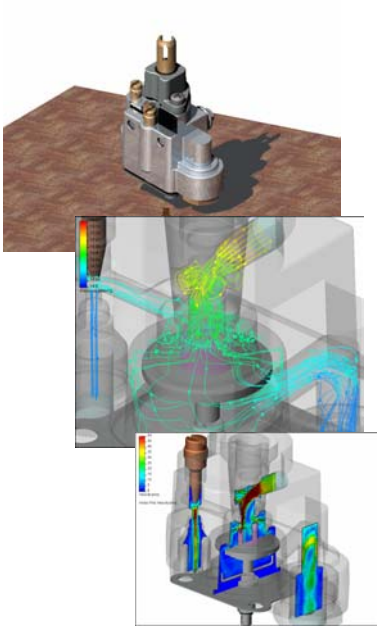
- 3D visualization of analysis results provides a designer with a first check of design intent, proper operation, and aesthetics as the project develops.

- 3D visualization enables the designer to view a product design from all angles and examine the internal parts of the product throughout the design process. This gives designers a clear and accurate review of parts and assemblies early in the design cycle.

- 3D visualization reduces communication and fabrication errors, saving development time by more effectively conveying analysis information so that designers can find problems early in the design cycle. Designers can view the analysis results in he product from all sides and look inside by hiding the outer enclosure or other parts.

- 3D animations of simulations allows you to see how medical devices will bend, move, or function in real life

The ability to visualize designs in 3D and catch potential design problems before going into production saves time and money for product developers.
(Design data courtesy of Medi-Ject Corporation)



- Section plots allow you to see simulation results inside the part and not just on the surface.

Design communication and collaboration tools

- Design collaboration has become an increasingly important part of the product development process, enabling designers to share designs easily with anyone, anywhere.

- Collaboration tools offer new ways for product designers to work more effectively with other members of the development team. The ability to share design resources over the Internet benefits all product designers, from independent consultants to engineers in large multinational corporations.

- COSMOS analysis tools allow designers to share analysis results in various formats such as:
  - HTML reports of analysis results
  - VRML files
  - AVI files

- COSMOSWorks allows users to publish eDrawings for analysis results.

For additional information about COSMOS products, checkout the COSMOS web site http://www.cosmosm.com.

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