

Medical device manufacturers need to accelerate the development of innovative, high-quality products that are easy for both medical professionals and patients to use safely, and that fully comply with all relevant government regulations.

Using Solid Edge® software from Siemens PLM Software, medical device and equipment manufacturers can speed product development and perform virtual testing and analysis of designs to ensure that new products meet customer needs and regulatory requirements for high-quality, easy-to-use devices. They can also communicate better with suppliers, customers and regulatory bodies during the product development process, reducing the errors and



delays that can prevent getting new products to market in a timely manner. Faster introduction of high-quality products to the market results in increased cash flow and higher profit margins.

Using Solid Edge improves product development performance for medical device manufacturers in these key process areas:

Communicate new designs to potential customers

Medical device manufacturers can significantly improve how they communicate designs to potential customers and regulatory bodies during the product development process, and sales staff can quickly convey the innovative features and ease-of-use of your designs. Using Solid Edge makes that possible with the creation of rich 3D product information, including photorealistic images and animations.

Manage customer requirements

Medical devices need to be developed to meet both customer requirements and specifications mandated by regulatory authorities. Using integrated design management capabilities, requirement documents and specifications can be

The Solid Edge advantage:

- Combine the speed and simplicity of direct modeling with the flexibility and control of parametric design that is made possible with synchronous technology
- Use integrated Solid Edge Simulation analysis capabilities to ensure high performance, safety and product durability
- Model complex shapes using Solid Edge surface design capabilities
- Use advanced assembly design techniques to model equipment enclosures around electromechanical components and other subassemblies
- Integrate electrical and electronic components into equipment using Solid Edge XpresRoute software cable routing capabilities

Solution focus

The Solid Edge advantage: continued

- Demonstrate compliance with government regulations with secure document vaulting and electronic workflow management with signoffs
- Create attractive product images and animations that communicate innovative designs to potential customers

managed as an integral part of the design project and can easily be made available to designers.

Speed 3D design and changes

Designers and engineers are under pressure to work faster as well as produce accurate 3D part models, assemblies and 2D drawings. Solid Edge provides a complete software portfolio that speeds design and helps to eliminate errors before manufacturing begins. Design changes can be implemented faster so new medical devices can be delivered on time and on budget.

Model complex shapes

Medical devices often involve the creation of complex shapes, such as equipment housings that feature complex surface designs and products that incorporate organic design elements to fit the human body. Designers need to be able to model these components quickly and accurately, and package other components alongside these designs.

Integrate electrical wiring and components

Many medical devices incorporate electrical and electronic components so routing electrical wiring and housing electronic components is becoming an important part of the design process. Solid Edge helps by enabling accurate modeling of electrical wiring, connections and housings. Wire routings can be optimized, correct cable lengths calculated and accurate bill-of-materials (BOM) created for electrical components.



Develop sheet metal enclosures

Medical equipment, including electromechanical components, needs to be securely and attractively housed for safety and hygiene. Solid Edge includes capabilities that enable rapid design of these components and the creation of accurate flat patterns that simplify and speed manufacturing.

Optimize design for human factors

Medical devices are used daily by patients and medical professionals and must be designed for ease-of-use, fail-safe operation and rapid learning. By creating 3D parts and assembly models, human factors can be taken into consideration as an integral part of the design process. Photorealistic images and animations can also be created for assessment of designs for human factors and to aid the training of users and physicians.

Design for manufacture

Improving the design to minimize manufacturing costs and understand suitable tolerances is important for medical device manufacturers. Siemens PLM Software helps manufacturers overcome these challenges by providing standard geometry linked with available tooling, and making design data easily accessible to manufacturing. Designs are optimized for production capabilities, and manufacturing errors are reduced.

Prototype for safety and quality

Typically, design engineers have to wait until a device is built to identify engineering problems. However, by creating 3D models of devices, engineers can investigate different solutions and refine functionality. Integrated capabilities, including Solid Edge Simulation, facilitate motion and stress analysis, and the result is a significant drop in costs and timeto-delivery as engineers solve problems before manufacturing begins.

Ensure compliance with government regulations

Significant time and effort may be required for quality assurance and to demonstrate compliance with government regulations. Solid Edge enables you to work efficiently in this area by managing regulatory requirements and required documentation,

Key solution components

- Solid Edge design for 3D part and assembly modeling using synchronous technology accelerates equipment design, speeds revisions and improves the re-use of proven components in new designs
- Solid Edge Simulation for digital validation of products reduces the need to create physical prototypes, lowers material and testing costs and improves reliability and safety
- Solid Edge manufacturing for defining accurate machining processes that improve manufacturing efficiency and product quality
- Solid Edge for design management improves the overall efficiency of design processes and projects, and ensures that accurate product data, specifications and compliance documents are easily accessible

creating print files of designs to ensure released versions cannot be changed, and implementing electronic workflows for controlled, consistent process completion. As a result, you have reliable audit results and a reduced risk of litigation.

Manage design projects and engineering change

Manufacturers need to retrieve data quickly, optimize resources and manage engineering changes efficiently. Solid Edge helps by providing visual design management tools that include preconfigured workflow capabilities, enabling your team to access and track design projects and engineering change information.

Installation and service

Medical device manufacturers must support installation and ongoing service for customers who have purchased their devices and equipment. Solid Edge can be used to create documentation that includes 3D graphics to effectively communicate installation, operation and maintenance procedures.

Realizing significant benefits

Designers and engineers in medical device and equipment manufacturing firms report significant benefits using Solid Edge. Some examples from published case studies include:

- Cut design project by almost 60 percent from 12 to 5 months
- Reduced number of physical prototypes required
- Increased design productivity by 40 percent
- Reduced design changes by 50 percent
- Achieved up to three times faster design-through-manufacturing process
- Reduced product development time by 50 percent
- · Less rework in manufacturing
- Improved customer satisfaction



For more information on this offering and to read customer case studies, please visit www.siemens.com/solidedge