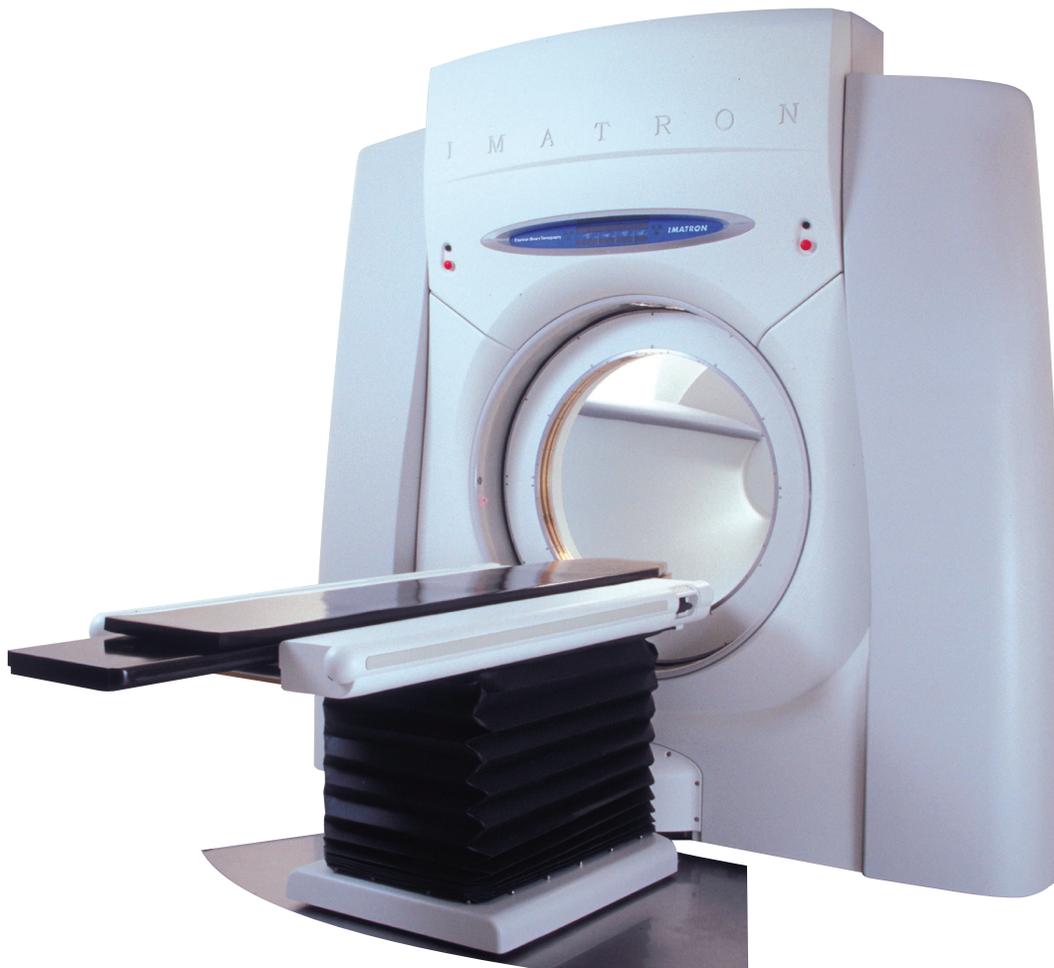


# BRINGING INNOVATIVE MEDICAL PRODUCTS TO MARKET FASTER

White Paper



## OVERVIEW

The medical device manufacturing industry is growing at an incredible pace to keep up with demand. Medical device product designers must not only create innovative medical products but must also navigate an increasingly challenging regulatory environment. This paper will provide an overview of the obstacles medical device designers must hurdle during the product development process, as well as cover the flexible design tools that enable you to foster innovation while supporting regulatory compliance and ultimately bringing your products to market faster.

## INTRODUCTION TO MEDICAL EQUIPMENT MANUFACTURE

Today, medical equipment manufacturers face increasingly demanding regulatory requirements that raise the costs and risks of product development. Stringent federal Food and Drug Administration (FDA) regulations (21 CFR Part 11) require careful and comprehensive documentation of your work, such as maintaining a design history file with the analysis (simulation) results that provided the basis for each design decision. Without the proper data management tools integrated into the early development process, your projects are at greater risk of not meeting FDA requirements.

To manage product development risk, many medical device manufacturers are moving away from high-end point solutions for mechanical and electrical design, analysis (simulation), product data management (PDM), and technical communication and toward integrated product development platforms that address all of these functions. This approach can increase the chances of success because it accelerates validation of innovative design concepts and automates design documentation, providing you with the flexibility and agility you need to comply with regulatory requirements and mitigate risk.

Success in this challenging environment requires a faster process of innovation with shorter design and validation cycles that reduce both time-to-market and engineering costs. You can greatly reduce build-and-test cycles by quickly analyzing the performance of many design concepts in software, then separating out the viable concepts for further testing, trials, and development. Using integrated design analysis tools, you can more efficiently evaluate the performance of a design under a wide range of usage, handling, and storage scenarios, such as determining what will happen when a surgeon drops a surgical instrument on the floor, during early conceptual design.

Many relatively small medical device companies cannot easily afford the high cost of providing the people and infrastructure needed to support high-end design and analysis tools. Yet these companies still need to expand their industrial design and analysis capabilities in order to compete successfully against the increasing number of medical products sold directly to consumers.

The SOLIDWORKS Product Portfolio can help you meet these challenges by delivering a complete, easy-to-use and simple-to-administer solution. Powerful part definition and flexible industrial design tools foster product innovation while integrated software prototyping, validation, and simulation tools help create better products the first time. Comprehensive data and design management capabilities support regulatory compliance while providing collaborative team tools, better communication, and version control. With SOLIDWORKS Inspection, MBD, and Composer you can communicate your designs for medical devices and components more efficiently to manufacturing, allowing you to get your products to market faster than ever.

SOLIDWORKS provides the necessary core product definition, collaboration, manufacturing, and documentation tools to beat competitors to market. In addition, a wide range of powerful, integrated analysis capabilities allow you to evaluate the performance of your design concepts as you create them. Whether you need to evaluate fluid flow, sustainability, frequency analysis, buckling, drop tests, mechanical stresses, or the effects of temperature, the SOLIDWORKS Product Portfolio enables you to analyze designs quickly without ever leaving your familiar modeling environment.

By utilizing the assembly and component configuration management capabilities in SOLIDWORKS Premium, you can develop and manage families of assemblies and parts with different dimensions, materials, capacities, and other properties. SOLIDWORKS software makes it easy to manage the decision-making process. You can store and track each version of a design, along with the analysis results and other details, which document the engineering decision-making process. With SOLIDWORKS software, you also have the necessary surfacing capabilities for developing a modern, stylized design that is as visually appealing as it is functional.

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## PRODUCT DEFINITION AND CONCEPTUAL DESIGN

Using SOLIDWORKS software, you can easily create a feature-based parametric model of your design concept that captures all the information needed to define the product, as well as manage the change and documentation process. Core capabilities include sophisticated solid modeling features, such as lofts, variable-radius fillets, shells, and draft angles. You may need access to these features in order to define the geometry, function, and manufacturability of complex medical devices. With the ability to visualize designs in 3D, you can identify potential problems before investing additional money in the product development process.

Within the same interface and file format, SOLIDWORKS software also provides surface modeling features to help define the flowing, sweeping surfaces that you need to deliver a cutting-edge industrial design. This allows you to work on both aesthetic design and functional design within the same tool, unlike translating your design from software to software to accomplish the same task. For example, the Fill feature offers an n-sided surface path that allows you to fill in a surface patch tangent to a space defined by any number of boundaries. You can also sketch a network of curves and pull any point in a curve to modify the surface, as well as combine both analytical entities and splines into a single feature.

New product designs are often modifications of an existing product, for which no 3D model exists or there is a need to import anatomical objects for design reference. ScanTo3D is an indispensable tool for any medical designer who needs to capture physical concept models, existing OEM parts, or anatomical objects and use these scanned renditions to build SOLIDWORKS software models.

With PhotoView 360™ software, you have the ability to create photorealistic images that rival those produced with more expensive software tools. The software's animation capability goes a step further by helping you create animations from parts and assembly models easily. You can also use this method to capture assembly motion and demonstrate how the moving parts of the medical device operate.

A significant portion of a typical medical device consists primarily of purchased components, such as semiconductors, circuit boards, display screens, valves, and pumps. For each project, you often need to remodel these purchased and commonly used components. SOLIDWORKS software can help you overcome this problem with the help of the Design Library—a central location where you can access a wide range of standard, vendor-specific, and internal company design libraries of finished models. You can use both 3D ContentCentral®, a SOLIDWORKS service including free 3D CAD models of user-contributed and supplier-certified parts and assemblies, or the Design Library to add new parts to a product or assembly simply by dragging and dropping them into the design. Further, you can import printed circuit board (PCB) layouts to integrate electrical and mechanical designs and get complete electromechanical bill of materials (BOM).

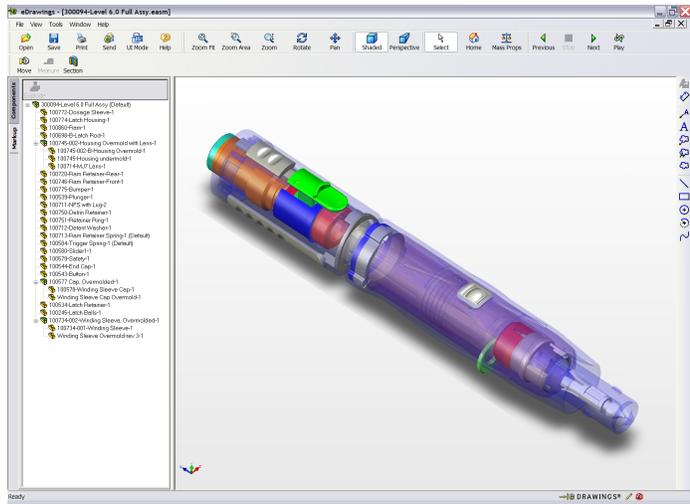
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You can deliver 2D drawings and 3D models to non-CAD users who can view, print, and review them with free viewer software and then provide feedback through intuitive markup tools.

The SOLIDWORKS eDrawings® collaboration and viewing tool allows you to further streamline the product definition process by improving communication with managers, marketers, customers, and vendors via desktop, tablet or mobile phone. You can deliver 2D drawings and 3D models to non-CAD users who can view, print, and review them with free viewer software and then provide feedback through intuitive markup tools. With eDrawings files, everyone who has valuable feedback and input to offer during the product definition and conceptual design phase can directly interact with the design by panning, rotating, and zooming in and out to view the model from any angle. They can view animations of the medical device in operation so they fully understand how the product works and even visualize parts in a real environment using Augmented Reality (AR). This high level of access and insight improves the quality of feedback and input that the design team provides early in the product development process.



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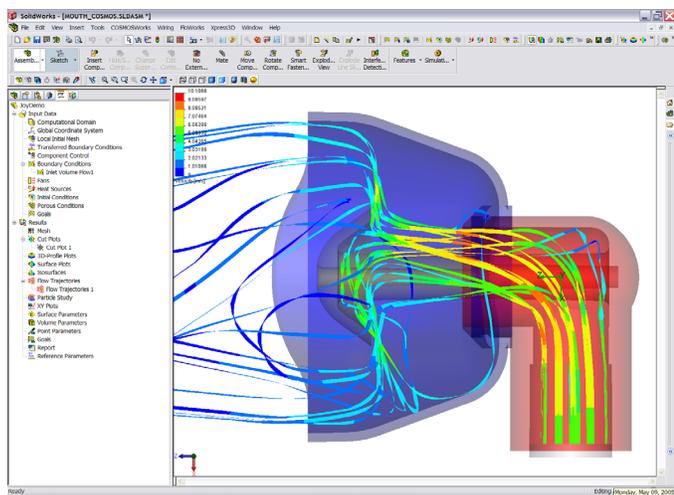
With eDrawings files, you can communicate your design concepts quickly and easily to everyone involved in the design process.

## PRODUCT DESIGN ON AN INTEGRATED PLATFORM

The SOLIDWORKS Product Portfolio automates product design, makes it easy for you to take a design from concept to prototype, and documents every step along the way. Working on a truly integrated design platform will help you to reduce repetitive design tasks substantially, access analysis capabilities within the same environment easily, and create comprehensive design documentation automatically.

Using configuration management capabilities, you can enter dimensional parameters in a spreadsheet and use a design table to automate the creation of hundreds of part or assembly iterations in seconds. You can turn features on or off in different configurations and can assign properties—such as material, part name, and cost—to a configuration. Having the ability to manage multiple configurations from a single document makes it easy to apply changes to all of your configurations or to just those that you select. With these capabilities, you can greatly reduce the amount of work required and time spent to produce and maintain a family of products based on a single technology platform.

Having solid modeling and design analysis, such as finite element analysis (FEA), integrated within a single environment means you can evaluate design performance at a much earlier stage and not waiting until you build a prototype for testing. You can review the results used to refine and optimize the design, rather than performing these tasks as a final validation check prior to prototyping and production. You can use the Simulation tools built into SOLIDWORKS Premium to determine the stress, strain, deformed shape, and displacement of components under operational loads or upgrade to even more capable simulation capabilities with SIMULATION Standard, Professional or Premium. Simulation-based design tools allow you to identify problems quickly and inexpensively and then modify your design to address them early in the process when the cost of change is substantially lower. For example, the Drop Test feature in SOLIDWORKS Simulation allows you to determine the effect of impact on the proposed design when someone drops it from various heights. Another example is a company that used SOLIDWORKS Simulation capabilities to evaluate a concept for a needle-free injection system, using integrated analysis to determine the contact pressure and safety factor.



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SOLIDWORKS Flow Simulation enabled engineers to determine the optimal design for a new oxygen delivery device.

SOLIDWORKS Flow Simulation computational fluid dynamics (CFD) software simulates the flow of liquids and gases through and around a product, while calculating the flow velocity, pressure, temperature, and other relevant variables. Using this tool, a medical device manufacturer evaluated alternative heart valve designs to determine the turbulence of flow, pressure loss, and overall back pressure in the valve. Another company used SOLIDWORKS Flow Simulation software to analyze the oxygen flow concentration from the mouthpiece of an oxygen headset system.

When the products you design will be manufactured using the plastics injection molding process, SOLIDWORKS Plastics helps you optimize your part and mold designs for manufacturability, improving part quality, reducing or eliminating mold rework, and decreasing time to market. SOLIDWORKS Plastics injection molding simulation software can be used to optimize part wall thickness, determine the best gate location, design and analyze mold runner systems, predict and avoid molded part warpage, and even determine the best combination of injection molding processing parameters to produce acceptable quality parts. SOLIDWORKS Plastics can save you tens-of-thousands of dollars, or more, in molds for injection molding.

Another capability included with SOLIDWORKS Premium is SOLIDWORKS Routing software, which helps you route wiring harnesses in closely packed medical device enclosures. With SOLIDWORKS Routing you can import electronic design automation (EDA) data to determine the number and size of wires and cables, as well as other information. Whenever the electronic design changes, new data can be imported to drive the resizing of electrical routes within the product. Electrical wires and harnesses can be designed in SOLIDWORKS Electrical Schematic and included in your 3D models with SOLIDWORKS Electrical 3D.

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Working on a truly integrated design platform will help you to reduce repetitive design tasks substantially, access analysis capabilities within the same environment easily, and create comprehensive design documentation automatically.

SOLIDWORKS Premium includes powerful and intuitive tools for creating enclosures and other sheet-metal components for medical devices in folded or flat states. The software automatically applies all sheet-metal properties, such as metal thickness, bend radius, and bend relief and automates the creation of flanges, tabs, lofted bends, flat patterns, normal cuts, corner cuts, normal treatments, hems, jogs, and more.

After you have used this integrated platform to refine and optimize your design, you can automatically generate design documentation in the form of production-level 2D drawings from your 3D assembly model. By just drawing a line, you can generate section views. SOLIDWORKS software will section the assembly and create the drawing view automatically. You can quickly create exploded views to describe how to operate and maintain the device from your 3D model by selecting sections to define 2D detailed drawing views. You can also easily annotate these views with balloons keyed to your bill of materials, thereby highlighting the components of interest. The 2D drawings and 3D model are bi-directionally associated so any changes made to one will instantly update all others.

## **PROTOTYPING, TESTING, AND MANUFACTURING**

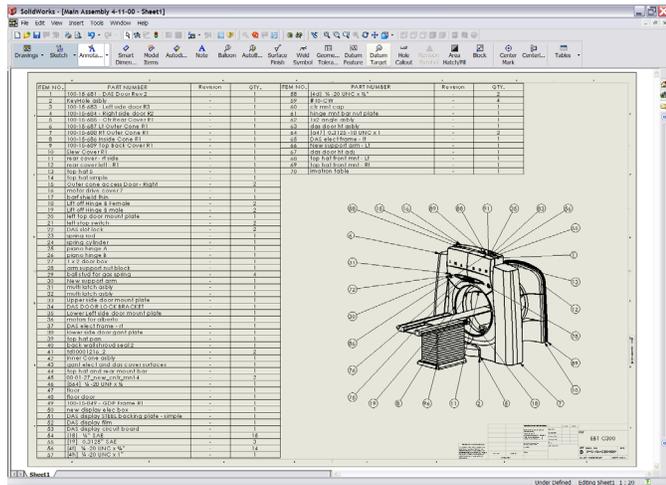
Although advances in display technology have substantially improved its visual prototyping potential, working with an actual physical prototype is still the most intuitive means for reviewing a design. Prototyping and testing prior to trials is also an FDA requirement and medical product developers need access to the latest rapid prototyping technologies to keep development on track. The SOLIDWORKS Manufacturing Network gives you immediate access to the most effective rapid prototyping technologies in the industry, including stereolithography (SLA), fused deposition modeling (FDM), selective laser sintering, rapid injection molding, and 3D printing. By automating prototype development, the SOLIDWORKS Manufacturing Network enables you to order prototypes in minutes instead of hours.

The SOLIDWORKS Manufacturing Network simplifies the process of finding design and manufacturing service providers that use SOLIDWORKS software. By working with native SOLIDWORKS software files, you do not have to worry about converting or re-creating files. You can easily find the right supplier on the network by browsing through any of 21 different categories, such as metalworking, machining, injection molding, and sheet-metal fabrication or by simply searching on keywords.

Engineering changes typically occur at a rapid rate during the product assembly and testing phase. SOLIDWORKS software helps you avoid costly mistakes by ensuring that changes made anywhere in the process automatically update all product documentation, including parts, assemblies, and drawings.

Once you have generated, prototyped, and tested your design, SOLIDWORKS Premium automates production setup and manufacturing. SOLIDWORKS software automatically maintains your bill of materials, so you can export it as an Excel spreadsheet or in other formats for use with material requirements planning (MRP) systems. This information will help you save time and avoid errors during the purchasing process. The software tracks a wide range of information, such as the manufacturer of purchased components, model number, size, and weight. By generating a single bill of materials for multiple projects with numerous parts, quantities, and configurations, you can speed the transition to manufacturing and purchase greater quantities at lower prices.

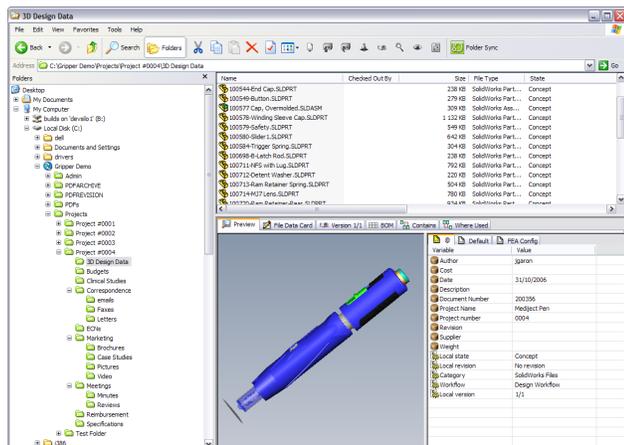
Dassault Systèmes SOLIDWORKS Corp. partners with industry-leading computer-aided manufacturing (CAM) software companies to deliver a variety of powerful CNC programming solutions for milling, turning, and electronic discharge machining. Since Certified CAM Products read native SOLIDWORKS software geometry and are fully associative, your design changes are reflected in the CNC program. Certified Gold Solutions also provide single-window integration with the SOLIDWORKS software model, enabling generation of the CNC program path within the familiar SOLIDWORKS software environment.



With SOLIDWORKS software, you can automatically generate a bill of materials, which you can export as an Excel spreadsheet or in other formats for import into MRP systems.

## REGULATORY DOCUMENTATION COMPLIANCE

Instead of incurring the time and expense required to manage, archive, and track design documentation in either a manual, paper-based, or high-end revision control system, you can cost-effectively automate the documentation function with SOLIDWORKS Enterprise PDM software. SOLIDWORKS Enterprise PDM is an integrated product data management (PDM) solution that securely archives and organizes multiple versions of previous projects. With SOLIDWORKS Enterprise PDM, you can maintain a high level of control and manage the information needed for your medical product design without resorting to an expensive, hard-to-administer, high-end infrastructure. SOLIDWORKS Enterprise PDM helps you manage, track, and document the engineering change process throughout the product development lifecycle. With SOLIDWORKS Enterprise PDM, you can document the reasons for making design decisions, including analysis and test results and track revisions generated at each step of the process. In addition to managing all design documentation, SOLIDWORKS Enterprise PDM maintains a complete audit trail to facilitate FDA compliance including double electronic signature capabilities to meet the required security components of 21 CFR Part 11.



SOLIDWORKS Enterprise PDM manages design revisions and automatically captures the history of all revisions.

## CONCLUSION

The regulatory and competitive challenges facing medical device manufacturers today are tremendous—but so are the opportunities. SOLIDWORKS software can help you meet these challenges and maximize your opportunities while also reducing your initial investment and ongoing expenses. The SOLIDWORKS Product Portfolio provides you with a full range of solid modeling and surfacing tools for designing geometrically complex and stylish medical devices—and turning them into functional, manufacturable products. With powerful, integrated SOLIDWORKS software design visualization and analysis tools in hand, you can evaluate the performance of alternate design concepts long before building physical prototypes.

Robust collaboration, automated rapid prototyping, and integrated manufacturing applications can help you bring validated designs to market faster than the competition. The integrated SOLIDWORKS Premium environment will empower you to design more innovative medical devices faster and at less risk, while at the same time providing you with easy-to-use data management and version control tools for documenting your design process from start to finish, ensuring that your design complies with all applicable regulatory requirements.

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