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Siemens PLM Software

Image-to-Implant solution for personalized medical devices

White Paper

A plan to succeed

PLM (product lifecycle management) software enables a regulatory-compliant, cost-effective and streamlined process chain for planning, design and manufacture of patient-matched medical devices.

Answers for industry.

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Executive summary

The demand for more "personalized" orthopedic treatments and therapies is growing rapidly. With the help of today's integrated design, manufacturing and data management software technology, medical device manufacturers are now able to design and produce personalized orthopedic therapies optimized for an individual patient, making "personal" orthopedic medicine more widely accessible.

Patient-matched implants and surgical instruments result in better alignment of implants during surgery and reduced incidence of subsequent corrective surgeries. With the help of an "Image-to-Implant" solution, enabled by Siemens PLM Software, medical device companies can develop personalized products and therapies that automate what is known in traditional manufacturing as an "engineer-to-order" process.
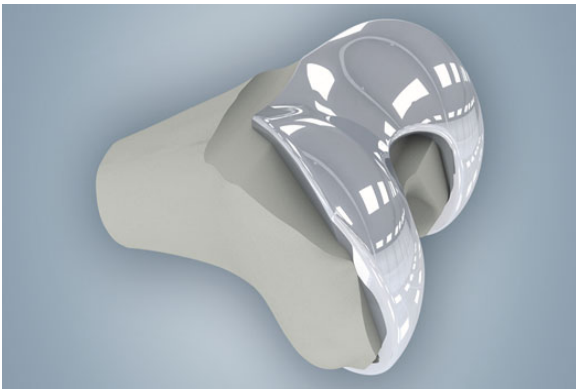

Figure 1: Example illustration shows how the application of "personalized" implants and surgical instrumentation can reduce invasive cutting requirements compared to standard-off-the-shelf therapies.

Until recently, most medical devices (such as surgical instruments or implants) have been designed for mass manufacturing and produced in a limited range of standard sizes and shapes that must be surgically "fit" to the patient. While this traditional approach is well attuned to support standard-off-the-shelf manufacture, it is not flexible enough to support the design and manufacture of personalized medical devices in a "mass customization" mode.

The Siemens Image-to-Implant solution is based on an MRI or CT image of a patient's anatomy, so that the orthopedic implants and instruments are made to fit the patient rather than the reverse. By designing implants and surgical instrumentation (including the various cutting guides, fixtures and attachments needed to perform the surgery) that conform to a patient's anatomy, manufacturers can produce optimized

* EMERGING TECHNOLOGY EVIDENCE REPORT "Total Knee Replacement Using Patient-specific Templates" © 2012 ECRI Institute. Regulatory Clearance for Patient-specific Templating Components.

devices that reduce the need for more highly invasive surgeries, preserve more tissue, simplify surgical procedures, shorten patient recovery times and reduce the occurrence of revision surgeries.

Medical device manufacturers, doctors and patients can all benefit from personalized orthopedic therapies. But to bring these higher-value solutions to market, medical device manufacturers must move beyond conventional engineering practices to a more automated and collaborative engineer-to-order process.

With the help of advanced planning, a surgeon can implant a "template" that precisely fits the patient, according to an Emerging Technology Report on "Total Knee Replacement Using Patient-Specific Templates."* The report lists the benefits of this technology, including:

- Improved alignment

- Decreased operative time

- Increased patient throughput

- Decreased instrumentation

- Reduced risk of fat embolism and intraoperative bleeding due to minimal bone removal (i.e., no intramedullary canal reaming)

- Decreased tissue loss

- Shorter recovery

- Reduced postoperative pain

- Decreased incidence of infection

- Lowered costs

PLM enables personalized solutions

Over the past decade, the medical industry has experienced a dramatic increase in replacement and revision surgeries for hips, knees and other joints. With continuously increasing demand, production of the patient-matched implants and instruments at a sufficient volume and speed to meet market demand is a major challenge to medical device companies. Furthermore, medical device companies face many of the same business challenges as manufacturing companies in other industries – such as improving affordability and value, and managing the increasing costs of stringent regulatory compliance.

Consequently, to realize the most efficient processes for designing and manufacturing personalized orthopedic solutions, medical device manufacturers are adopting the same state-of-the-art product lifecycle management (PLM) software technology used throughout the aerospace, automotive and consumer electronics industries, and applying it to their specific operational requirements.

PLM provides medical device manufacturers with an integrated software platform to support an engineer-to-order process, enabling them to securely manage patient cases from initial submission all the way through to shipment of the patient-matched instruments and implants to the operating room. At the same time, the PLM system facilitates the digital creation and control of required regulatory compliance records.
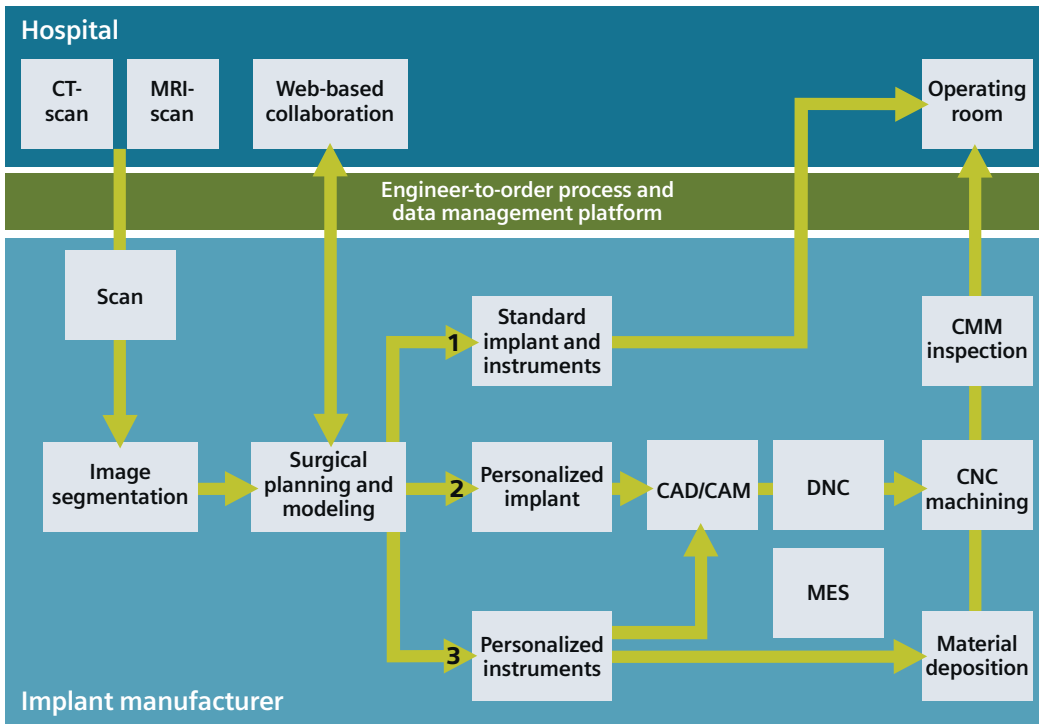

Figure 2: Siemens' Image-to-Implant integrated technology vision automates the complete engineer-to-order process for planning, design and manufacture of personalized medical devices. Personalization can occur with the surgical procedure, implants or instruments; or include all three elements of the therapy.

Engineer-to-order process management

With conventional orthopedic medical procedures – for example, total knee replacement – pre-operative surgical plans are traditionally defined by the surgeon. The pre-operative planning process includes scans of the affected patient's knee to measure the size of the surgical implants and instrumentation required for the operation. The surgeon orders a range of various-sized implants and instrumentation from a catalog, which are delivered to the operating room in time for the scheduled procedure. During the operation the surgeon decides, from the set of pre-selected choices, which implant and which cutting instruments best complement the patient's anatomy and then cuts the patient's bone and tissue to fit the selected implant.

The patient-matched approach to personalized therapy is different. While a standard-sized implant may still be selected for the patient, the surgical instrumentation is custom-manufactured for the individual patient geometry to ensure the best possible fit and placement with minimum tissue removal. In this process the surgeon works upfront with the medical device manufacturer to personalize the instrumentation design. This typically results in a shorter, less traumatic surgery and reduced risk of future revisions.

Figure 3: The physician reviews and approves the surgical plan for an individual patient online via a secure website to help speed the design process.

PLM technology enables device manufacturers and surgeons to collaborate in this way. The personalized surgical planning process is facilitated entirely online, via a secure website to keep the surgeon's time investment to a minimum. The surgeon logs into a medical company's case management website, creates a patient case and uploads the patient's CT or MR scan. The medical company uses the scan data to define the surgical plan and design the personalized components. The surgeon and device manufacturer representative can access the in-progress cases online and participate in reviews. The personalized components are then manufactured to precise specifications for an individual patient. All proposed surgical revisions and designs are approved by the surgeon via the secure website.

Automation speeds design of patient-specific surgical plans

The first step of the Image-to-Implant process, or segmentation, is to analyze and transform the image data of a patient's bones, direct from the CT or MR, into highly accurate digital 3D solid model representations of the bones' exact geometry for use in the precise design of the surgical instruments.
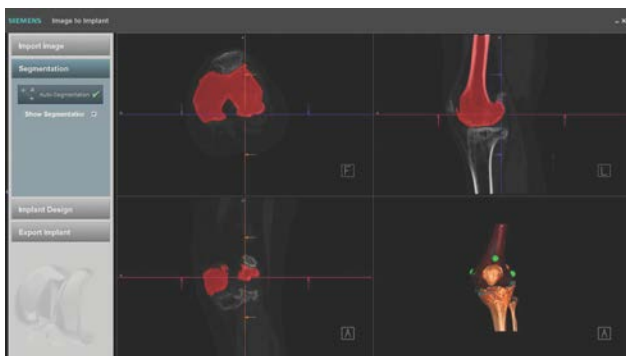

Figure 4: The process of "segmentation" uses MR or CT scan data (left) to create accurate 3D solid model digital representations (right) of a patient's unique anatomy.

Siemens PLM Software's NX™ CAD (computer-aided design) software plays an important role in automating the patient-specific design process. Design templates, driven by proprietary algorithms and widely accepted anatomical landmarks that are identifiable via the digital bone models, can automate digital alignment of the implants and surgical guides to biomechanical axes. This highly accurate alignment ensures that the patient achieves proper range of joint motion post-operation.

Once the proposed surgical plan is completed, it is reviewed online with the surgeon. By enrolling the physician in the automated digital process, PLM technology helps medical manufacturers respond to the fast-paced pressures of personalization.

Advanced CNC and CMM inspection programming capabilities provide the flexibility to manufacture high-quality complex shapes.

Manufacturing planning for personalized orthopedic therapy requires a high degree of precision and advanced capabilities in CNC (computer numerical control) programming and verification to correctly machine the complex surfaces to precisely match anatomical point of measure. NX CAM (computer-aided manufacturing) software technology enables medical manufacturers to tackle these complex shapes by providing the wide range of advanced CNC programming capabilities to fully program 5-axis and multi-function machines.
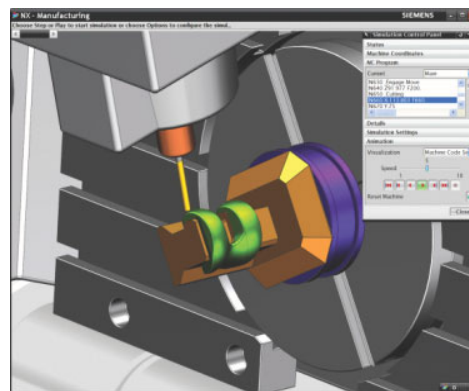

Figure 5: 5-axis machining of hard metals for medical implant applications requires advanced NC programming capabilities.

To effectively machine the hard metals commonly used in orthopedic components (such as titanium and stainless steels) at high speeds and with precision, NX CAM technology provides advanced tool path strategies combined with proven machining parameters for high performance.

To streamline the engineer-to-order process, CNC machine and CMM inspection programming for complex medical device parts can be automated. Machining process templates are used to automatically apply predefined programming methods, setups, machining operations and tool selections to new patient cases. After receiving the surgeon approval for the plan, the CAM software is used to automatically update the shape definitions of the surgical instruments and implant. The CNC programs used to machine the parts are also updated automatically, as well as the CMM programs for quality assurance on the parts.

Program validation saves time on the shop floor with less need for program checking at the machine and also contributes to fewer errors that can waste time and costly materials. Machine tool simulation technologies are applied to provide a complete check of machining and inspection data inside the programming system. For Siemens Sinumerik controlled

machines, the greatest level of accuracy and simulation completeness can be achieved by using G-code driven machine tool simulation with the embedded virtual NC controller kernel (VNCK), which uses the actual Sinumerik controller software to drive the kinematic 3D machine tool model.
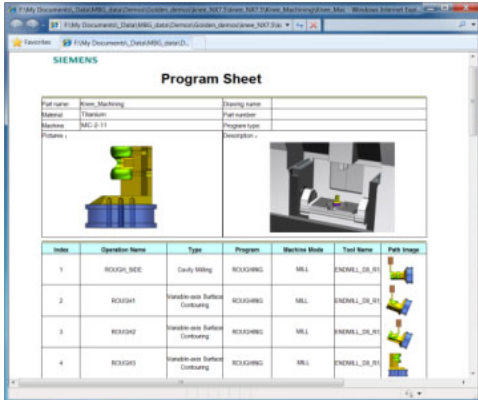

Figure 6: Integrated machine tool simulation enables validation of CNC programs inside the CAM system.

Optimized shop floor connectivity delivers production productivity

In the fast-paced environment of custom medical production, manufacturers must make the most of their manufacturing planning capabilities and advanced shop floor equipment to produce and deliver patient implants to surgery at the required volume and accuracy for the orthopedics industry.
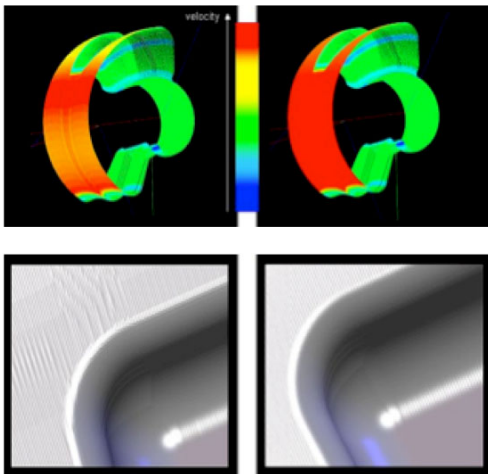
Figures 7: The DNC application enables production staff and equipment to directly access current and released CNC programs and shop documentation in the centralized PLM database.

For best-in-class manufacturing planning, it's essential to obtain the most value from the individual software applications (CAD, CAM, quality) by connecting them within a managed PLM environment such as Teamcenter® software from Siemens PLM Software. The managed environment for design and manufacturing planning is also connected to shop floor systems to synchronize planning and production, enabling use of the right data when and where it's needed. This results in significant error and waste reduction, time-savings and improved traceability for regulatory compliance.

To ensure product orders are efficiently executed, a direct numerical control (DNC) solution delivers the CNC program files from the PLM system directly into the machine controller, with no local data storage. In this way, production staff can access current and released CNC programs, setup sheets, tool lists, drawings, 3D models and other data in the managed environment. This connection to the centralized PLM database avoids data duplication and manages revisions to make sure the correct manufacturing data is used on the shop floor.

Machining by using Sinumerik 840D sl CNC controller

After receiving the NC program from NX CAM, the next step is to machine the orthopedic components effectively with accuracy.

Siemens' Sinumerik CNC controller is highly praised by our customers for its superior capability for 5-axis and multi-function machine tools. Customers not only prefer its advanced and wide range of technological abilities, but also its user-friendly operability. The combination allows you to fully take advantage of the machine tool performance.

Sinumerik 840D sl includes two major features: Sinumerik MDynamics which enables high-speed and high-accuracy machining, and Sinumerik Operate which offers you superior usability.

3D printing as an emerging production alternative

3D printing, or additive manufacturing as it is referred to in certain circles, is increasingly becoming a mature option for product manufacturing in addition to rapid prototyping. 3D printing relieves some of the complexities with manufacturing complicated surface shapes and enables automation of CAM and CMM inspection processes. With 3D printing, you can also create shapes that are impossible to achieve with subtractive (CNC) or formative (casting, molding) methods. For example, you can create internal structures such as lattices that enable the creation of lightweight yet strong parts and surfaces with intricate detail textures that improve part function and ergonomics. Siemens pioneered the use of 3D printing for production of personalized in-the-ear hearing aids.

3D printing is ideally suited for the personalized medical device industry for several reasons. Organic shapes are typically more complicated than engineered parts. The personalization of medical devices results in customized shapes but does not increase the complexity of manufacturing. Patient data derived from CT or MRI images can be used to directly create personalized devices using discrete polygonal mesh surface representations that allow the efficient processing of complicated organic shapes while avoiding the complex problem of converting to NURBS surfaces. The mesh representation can be directly used to derive tool paths for CAM in a simplified and automated manner. This also enables a high degree of automation within PLM systems, helping to integrate the entire engineer-to-order process chain.

Designed surface details can enable better osseointegration of implants. Lightweight latticed implants can reduce additional load on patients. With improvements in equipment, materials and processes, 3D printing has the potential to revolutionize the medical device industry.

Regulatory compliance for medical devices

In addition to helping medical device manufacturers personalize their products, PLM systems are also essential tools for tracking, monitoring and complying with the abundance of regulations imposed on these companies.

Unless medical device companies approach compliance from a holistic perspective, they will continue to spend too much valuable time and resources trying to mitigate the effects of noncompliance. As a result, regulatory compliance must be an integral part of the medical device lifecycle.

Using PLM can help you reduce and even eliminate many of the common causes for FDA nonconformance indications to medical device companies during the regulatory approval process for new product introductions.

Teamcenter enables companies to maintain and manage their product and process knowledge in a globally accessible system. The system's ability to capture audit trails, maintain electronic signatures and facilitate instant information retrieval is closely attuned to the medical device industry's compliance management needs.

Conclusion

In contrast to traditional mass production approaches, personalized – mass-customized – orthopedic solutions are especially designed and manufactured to complement a patient's own unique anatomy. This provides benefits to both patients and surgeons such as less invasive surgical procedures, conservation of patient tissue, simplified surgical processes, shorter patient recovery times and better outcomes.

Beginning with an MRI or CT image of patient anatomy and ending with personalized medical devices (such as surgical instruments or implants), you can automate the entire engineer-to-order process chain for planning, design and manufacture of patient-specific medical devices. To achieve this, a comprehensive PLM system such as Teamcenter and state-of-the-art CAD/CAM software such as NX can be combined into an Image-to-Implant solution that enables medical device companies to economically develop high-quality personalized products and therapies while ensuring full compliance with all government and industry regulations.

Siemens PLM Software has partnered with leading medical device manufacturers to implement its PLM and CAD/CAM technology for the successful design and manufacture of high-quality, personalized orthopedic solutions.

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About Siemens PLM Software
Siemens PLM Software, a business unit of the Siemens Industry Automation Division, is a world-leading provider of product lifecycle management (PLM) software and services with nine million licensed seats and 77,000 customers worldwide. Headquartered in Plano, Texas, Siemens PLM Software helps thousands of companies make great products by optimizing their lifecycle processes, from planning and development through manufacturing and support. Our HD-PLM vision is to give everyone involved in making a product the information they need, when they need it, to make the smartest decision. For more information on Siemens PLM Software products and services, visit www.siemens.com/plm.