

# SIEMENS

*Ingenuity for life*

Medical devices and pharmaceuticals

## Dentsply Sirona

Leading dental manufacturer uses Polarion to unify for all major phases of product development

### Product

Polarion

### Business challenges

Develop a more effective life-cycle management solution

Provide flexibility and adaptability for workflows, scripting, etc.

Make documentation management and traceability easier and more robust

### Keys to success

Make development process more transparent for all parties

Deliver a system that is simple to administer

Leverage Siemens PLM Software professional services and technical support

Provide an affordable solution

### Results

Provided a unified solution covering all major phases of product development

Established traceability to prove compliance

Enabled extensive customization for a variety of processes

**Siemens PLM Software solution enables Dentsply Sirona imaging, CAD/CAM and treatment centers to establish traceability and confirm compliance**

### Seeking enhanced PLM

Dentsply Sirona, The Dental Solutions Company™, is one of the world's largest manufacturers of professional dental products and technologies, empowering dental professionals to provide better, safer and faster dental care with a 130-year history of innovation and service to the dental industry and patients worldwide. Dentsply Sirona develops, manufactures and markets a comprehensive solutions offering including dental

and oral health products as well as other consumable medical devices under a strong portfolio of world-class brands. As The Dental Solutions Company™, Dentsply Sirona's products provide innovative, high-quality and effective solutions to advance patient care.

### The wish list

In the early stages, Dentsply Sirona Project Coordinator Michael Dalpiaz and his team identified several key needs any new life-cycle management tool solution must address.

Most importantly, it needed to be a fully unified end-to-end solution covering all major phases from requirements to testing, not a mere stringing together of point solutions.



**“Many stakeholders were very excited that the Polarion solution is webbased, IT in particular. This saves a lot of work configuring client computers.”**

Michael Dalpiaz  
Project Coordinator  
Dentsply Sirona

In addition, Dentsply Sirona wanted its new solution to provide both documentation management and traceability in an easier and more robust way than what they previously had in place.

Because Dentsply Sirona already had established, proven processes, a restrictive solution based on rigid templates would not be acceptable. The new solution had to deliver flexibility and adaptability in workflows, scripting, etc.

#### **Compliance management**

According to Dalpiaz, in the field of medical engineering in which Dentsply Sirona operates, documentation requirements for the regulatory bodies are less stringent and detailed than for other verticals, such as aerospace. The greater flexibility meant that the company was on its own when it came to devising processes and methods, yet the requirement for regulatory compliance was in no way obviated. The company would still need to document their compliance with safety standards and regulations, including:

- The European Union’s Medical Device Directive standards, such as International Electrotechnical Commission (IEC) 62304, IEC 60601, International Organization for Standardization (ISO) 14971, etc.

- United States Food and Drug Administration (FDA) 510K, which is necessary for any commercialization in North America

As a leading company in its industry, Dentsply Sirona already had processes and systems in place to assure compliance with regulatory and safety standards. Any new lifecycle management solution had to at least support the company’s existing capabilities and, of course, anything it could do to make compliance easier would be a major bonus. For example, if safety requirements could be tracked for compliance reporting separately from functional requirements, it would streamline the process a great deal.

With the importance of embedded software growing throughout their industry, Dentsply Sirona needed a better way to trace source code changes to requirements, and viceversa, while at the same time keeping the code under version control.

#### **The solution**

As a result, Dentsply Sirona Imaging, CAD/CAM and Treatment Centers chose product lifecycle management (PLM) specialist Siemens PLM Software’s Polarion™ software, which is now used extensively in the company’s imaging systems division.

***“Dentsply Sirona uses Polarion solutions not solely to achieve compliance with medical device regulations like FDA or IEC 62304, but to make the development process lifecycle more transparent for all parties involved.”***

Michael Dalpiaz  
Project Coordinator  
Dentsply Sirona

Currently, 20 to 30 people regularly use the Polarion solution, and that is soon to be extended to 40 to 50 people. Siemens PLM Software's professional services were instrumental in rolling out the Polarion solution at Sirona.

"Dentsply Sirona imaging, CAD/CAM and treatment centers use Polarion solutions not solely to achieve compliance with medical device regulations like FDA or IEC 62304, but to make the development process lifecycle more transparent for all parties involved," says Dalpiaz.

"We defined a highly customized configuration with the help of a Siemens PLM Software Polarion consultant, and implemented it together at our Bensheim (Germany) facility. During the implementation, we were supported by another consultant, who prepared custom report pages, scripts and plug-ins. Right after the import of the existing data at the time, we started using Polarion with a limited number of users."

The rollout took five to six months, from the beginning of data import to achieving a fully usable state (for example, when reports were able to be finished).

### The benefits

For Dentsply Sirona, the main benefits include the unified nature of the Siemens PLM Software's Polarion solution, the ease of establishing traceability to prove compliance, the simplicity of administration, the ability to extensively customize it and the general affordability.

"We were looking for an end-to-end solution for both documentation and traceability from requirements to testing," says Dalpiaz. "Traceability is not a unique selling point from our point of view, but since it is very simple to handle in the Polarion product, it was definitely a criterion in our decision."

"The TÜV ISO 26262 certification of Siemens PLM Software's Polarion helps.

Although it is not one-to-one in terms of the standards in the medical engineering, it still helps because ISO 26262 is even stricter.

"The reports and flexibility are also great. The Polarion approach in this regard offers the best solution compared to other tools."

Dentsply Sirona also found that Polarion helped them save considerable time and reduce costs while providing a superior product.

"Many stakeholders were very excited that the Polarion solution is web-based, especially IT," says Dalpiaz. "This saves a lot of work configuring client computers."

"License and maintenance costs were also lower compared with the tools we had, and they were better than what the competitors offered."

"To date, our focus with Polarion software has been on requirements management. We know that it covers testing, and has capabilities for managing variants. We would like to achieve optimum test coverage on different variants. We look to Polarion products to continue to grow support for these areas in the solution."

Michael Dalpiaz  
Project Coordinator  
Dentsply Sirona



## Solutions/Services

Polarion  
[www.siemens.com/polarion](http://www.siemens.com/polarion)

## Customer's primary business

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[www.dentsplysirona.com](http://www.dentsplysirona.com)

## Customer location

Bensheim  
Germany

Dalpiaz also stated that Dentsply Sirona Imaging, CAD/CAM and Treatment Centers benefitted from the assistance of Siemens PLM Software's professional services and technical support: "Their professional services are very competent and we are very satisfied with them."

## Future plans

Dalpiaz sees Dentsply Sirona expanding its use of the Polarion software in the area of testing and test management and variants management.

"To date our focus with Polarion software has been on requirements management," says Dalpiaz. "We know that it covers testing, and has capabilities for managing variants. We would like to achieve optimum test coverage on different variants. We look to Polarion products to continue to grow support for these areas in the solution."

*"The reports and flexibility are also great. The Polarion approach in this regard offers the best solution compared to other tools."*

Michael Dalpiaz  
Project Coordinator  
Dentsply Sirona

## Siemens PLM Software

Americas +1 314 264 8499  
Europe +44 (0) 1276 413200  
Asia-Pacific +852 2230 3308

[www.siemens.com/plm](http://www.siemens.com/plm)

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