

A Manufacturing Partnership With a Backbone

Product realization success can involve business and technical partnerships.

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When most OEMs outsource a product, the primary focus is to select a core base of key suppliers or an electronics manufacturing services (EMS) provider that can handle the entire process. While this addresses the technological challenges, it may not address all the hidden cost drivers associated with complex projects.

When a small orthopedic instrument company set out to design and manufacture a cutting-edge product for spinal surgery, it turned to an outsourced product development and manufacturing model that leveraged both a strong supply base and biomedical support infrastructure in Singapore.

How it Started

PediGuard, which is manufactured by Paris, France-based SpineGuard, is a disposable, wireless instrument used in spinal surgery. It is a handheld device that is able to detect possible cortex perforation during pedicle preparation for screw placement.

The device, which has been cleared by the U.S. Food and Drug Administration (FDA) and has received a CE Mark in Europe, can alert the surgeon prior to a breach by accurately analyzing the electrical conductivity of the surrounding tissues in real time through audio and visual signals. Accuracy of pedicle screw placement is a critical issue in spine surgery. Published rates of intra-operatively “misplaced” screws range from 10 to 40 percent, some of which result in pathological consequences such as spinal cord damage. Consequently, liability risks for spine surgeons are high.

SpineGuard is a startup, equity-backed company that earlier this year acquired the PediGuard unit from SpineVision. The company was founded by former Medtronic Sofamor-Danek and SpineVision executives Pierre Jérôme and Stéphane Bette.

“Pedicle screw placement is the number one safety challenge today in spine surgery,” said Jérôme, CEO of SpineGuard. “Now, with more than 9,000 spine procedures performed in 25 countries using PediGuard, including the U.S., this innovative device is clearly emerging as the most compelling solution to the significant clinical need for safer pedicle screw placement.”

When SpineVision set out to design its new device, management was seeking a combination of factors: a reasonable cost manufacturing region, a strong supplier that could support both product development and volume manufacturing, and a region that was focused on medical

technology. Singapore appeared to be the best option and Singapore's Economic Development Board (EDB) provided a list of potential suppliers. SpineVision selected Singapore-headquartered Beyonics Technology Limited as its EMS provider to manage the overall manufacturing process. Beyonics, in turn, teamed with Singapore-based design firm PSB Technologies (now Xentiq Pte Ltd.) in the initial development effort under the supervision of SpineVision.

In 2007, the PediGuard was awarded the Singapore President's Design Award. Established in 2006, the award recognizes excellence across all design disciplines, including advertising design and visual communications, architecture and urban design, fashion design, furniture design, interior design, landscape design, product and industrial design.

The Technical Side of the Equation

Close collaboration in the design phase of the project was critical to the development effort. Unlike most EMS companies, Beyonics' manufacturing and assembly capabilities support the requirements of both electronic devices and non-electronic disposable products, giving them strong discipline relative to quality and regulatory issues associated with invasive products. The company is ISO 13485 certified.

PSB Technologies managed the concept development phase and design for testing. Beyonics provided design for manufacturability and collaborated with the design firm on component selection.

This ensured that component selection choices considered both the design team's choice relative to fit,



PediGuard, manufactured by SpineGuard, is a disposable, wireless instrument used in spinal surgery to alert a surgeon prior to a breach by analyzing the electrical conductivity of the surrounding tissues in real time through audio and visual signals. Photo courtesy of SpineGuard.

form and function; and the EMS provider's recommendations relative to quality, availability and price. As Beyonics molded the plastic handle, it participated in that portion of design effort to ensure that the mold gripped firmly to the rod, and that the product finishing was smooth with minimum cosmetic defects.

From a technical standpoint, there were several challenges that needed to be addressed during the development process. Initial clinical trials showed that the speaker volume wasn't always loud enough to be heard over operating room ambient noise. This drove changes to the printed circuit board assembly and a speaker re-design. From a mechanical design standpoint, the cutting edge of the device needed to be sharper. Additionally, the instrument tip required a very precise dimension.

SpineVision's product development team and Beyonic's design transfer team worked closely to address this and other issues. In addition to the testing done in the product development phase, a rigorous functional test needed to be developed for the manufacturing process. The development and regulatory approval process took about 18 months.

From a manufacturing process standpoint, the electronics assembly portion is not complex, and assessing assembly functionality requires a standard in-circuit test. However, several functional tests are required to validate mechanical performance. There is a mechanical test to ensure the device tip can withstand the required level of force.

There also is a functional test that simulates body fluid to ensure the device is sending the correct signals. The device is designed for one-time use and has a limited battery life. This fail-safe mechanism presents a challenge in manufacturing because once the unit is activated, it runs for eight hours. Functional testing needs to be precisely timed, and the battery life is preserved by inserting a plastic tab between the battery and the contact. Currently, the product is shipped to the end customer in Europe. Sterilization and distribution is handled by the customer.

The Business Side of the Equation

Qualified suppliers were only part of the equation in this project. Singapore's strong biomedical infrastructure was also leveraged. Bio*One Capital, a biomedical sciences dedicated investment company and a subsidiary of Singapore's Economic Development Board Investments, led an investor group that funded the device manufacturer's establishment of a Singapore-based subsidiary.

Other attractive aspects of the region included strong intellectual property protection; access to a highly educated workforce combined with access to a number of low labor cost markets within the region; ease of doing business and predictable costs; location as regional logistics hub; and a strong biomedical R&D sector.

In this example, SpineVision found funding for regional expansion, public-private partnerships that supported its expansion into the Singapore medical market and a strong supply base capable of supporting very rigorous requirements for quality and technical solutions in both product development and volume manufacturing.

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