Getting to the Heart of Interconnects

Bernard Cole

The Project: Connect the various subsystems of a left ventricular assist system with a solution that offers reliability and durability.

The Solution: Utilize cable assemblies that enable easy, but not accidental, disconnects, and provide a comfortable feel for patients.

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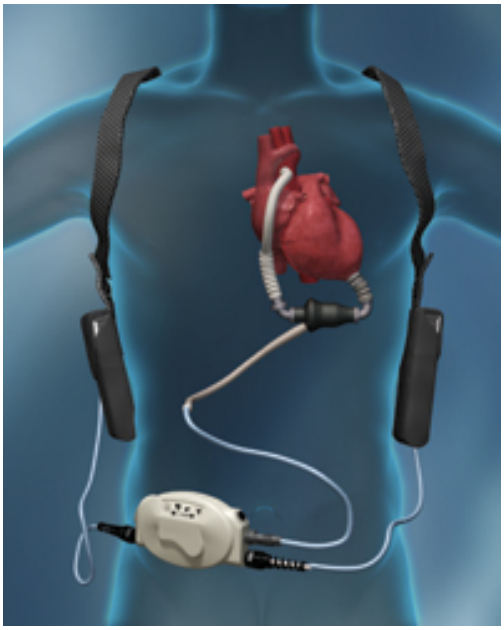
In medical electronic equipment, the elements that connect one component to another are so essential that engineers sometimes take their presence and their functions for granted. If someone asks what the most essential part of a PC is, the likely answer is the CPU. But the CPU is useless without memory, buses, and a hard drive; no single part of a PC can function without all the other parts. It takes a plethora of devices that connect everything.

"A complex medical system, such as our Thoratec HeartMate II left ventricular assist system (LVAS), consists of a collection of intricately interrelated subsystems, each of which is vital to keeping the patient's circulatory system functioning," said Omari Bouknight, business unit manager at Thoratec. "Every component, particularly the connections between the critical elements in the system, should operate without failure for long periods and under demanding conditions. If those interconnects do not perform reliably, the rest of the system will not function reliably."



The HeartMate II is a mechanical circulatory support device intended for a broad range of advanced-stage heart failure patients. It received FDA approval in April

2008. The device is implanted alongside a patient's native heart and takes over the left ventricle's function of pumping oxygen-rich blood from the heart to the rest of the body. It is placed just below the diaphragm in the abdomen and attached to the aorta (the main artery that feeds blood to the entire body), allowing it to propel blood throughout the body's natural circulatory system.

The HeartMate II is connected to an external wearable system that includes a controller and batteries, attached via an external driveline that exits the patient's abdomen. Power cables connect the controller to a small monitor and a power base unit when a patient is stationary. When a patient is on-the-go, the controller and batteries may be worn around the belt and/or in a holster arrangement.

Because the interconnects are so critical to the successful operation of the system, Thoratec turned to Winchester Electronics and its team of engineers and designers to develop the electrical cabling needed.

Important in Thoratec's decision, said Bouknight, was the fact that Winchester has long and extensive experience in supplying interconnect solutions to the medical industry and has expertise in finding solutions for particular kinds of problem environments. Its non-magnetic combination D-subminiature connectors, for example, are designed for medical systems that require non-magnetic coils.

"What we required in the case of the HeartMate II was a supplier who was aware of both the physical requirements of the environment into which the connectors were placed, as well as the human factors involved, especially as it relates to ease of use and maintenance," said Bouknight. "What we also required was a combination of durability and usability, since the system is designed to provide several years of circulatory support to patients without substantially impeding their freedom of movement while performing routine daily activities, traveling, and exercising."

According to John Davies, Winchester's strategic customer manager, the connectors between the external controller unit and the monitor console and the internal assist device, and between the battery and the other electronic components in the system presented a critical challenge. "They needed to be designed so that they could not easily be detached accidentally but, at the same time, when a patient, a doctor, or a nurse need to do so, they have to be able to quickly attach and detach any particular connector when necessary," he said.

Working with Thoratec, Winchester's engineers came up with several patient cable assemblies from the internal pump to the external controller, from the controller to the monitoring device, and from a portable battery back to the controller and monitoring device. Company engineers also designed and supplied some of the cable assemblies used inside each of the system's component units.

In addition to providing custom designs for each connection within the LVAS, much of Winchester's efforts involved building the components to the specific tolerances required by Thoratec and by the FDA. "They have to be reliable and operate properly even after hundreds or thousands of connect/disconnects over the lifetime of the LVAS," Davies said. "They also have to have a good feel, comfortable enough

so that the patient will tolerate their touch on the skin."

Beyond this are the stringent FDA requirements for reliability and traceability. "The FDA requires that each system and subsystem, and each constituent element from which they were built, have a clear chain of traceability back to the suppliers," said Davies. "For Thoratec, this provides information that they can draw on when they are building and testing the system, or if there are problems with the unit after it has been put in the patient's custody."

The FDA also requires such information in case a problem develops and it is necessary to determine how widespread it is, allowing them to quickly determine the source of the malfunction. "Just creating and maintaining the records and chain of traceability for every component and every subassembly and material used in the creation of the LVAS requires a level of expertise that not many companies have," said Bouknight. "Fortunately, Winchester is one of them."

Another bonus is that Winchester has been involved in supplying connectors to the electronics industry and to medical companies since 1941. "During our selection of vendors, we could have gone with a more specialized supplier," he said. "But we also wanted a company that had been in the business for a number of years, and was likely to be there in the future when we needed additional components or when we needed their expertise on some other medical system we were designing."

Companies like Thoratec are fortunate to have suppliers whom they can rely on for quality and dependability. And for patients, who use the HeartMate II where Winchester's connectors provide a critical role, success or failure is a matter of life or death.

Online

For additional information on the technologies and products discussed in this article, see *MDT* online at www.mdtmag.com [2] and the following websites:

•www.thoratec.com [3]

•www.winchesterelectronics.com [4]

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