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Laser Welding to the Rescue

A customized welding program fast tracks production of a left ventricular assist system.

SUBHAN KHAN, TAKESHI TSUBOUCHI, AND ELLEN B. MORRISON

Terumo Heart Inc., a medical device subsidiary of Terumo Corp., recently found itself at a crossroads in the production of its left ventricular assist system (LVAS). The company's new DuraHeart LVAS, designed to provide auxiliary pumping power in patients with late-stage heart failure, had earned marketing approval in Europe and completed patient-study enrollment in Japan. With clinical trials under way in the United States, the company was preparing for eventual commercialization in a broader world market.

The anticipated increase in product demand forced the company to reevaluate its manufacturing capabilities to ramp up production. Upgrading the laser welding technology emerged as pivotal in meeting this goal. This article traces the steps Terumo Heart took to identify and customize a laser welding process that would facilitate a fourfold increase in throughput without sacrificing quality or precision of design and function.

The device's 22 distinct seam welds include tiny, curved contours, shown here in a magnified view. These curves require quick, precise changes in laser beam positioning.

Addressing the Intricacies of Design

The original welding process was complicated by the design considerations involved in developing an active, implantable pump. Chief among those complications was the need to use multiple titanium alloys. The specific grade of each alloy was selected to meet a particular requirement such as minimization of residual stress, control of impurities, and achievement of tight tolerances. Further complicating the welding process were the 22 distinct seam welds, many of which include tiny, curved contours that pose difficult laser-beam positioning challenges. One complete pump assembly consists of several welded subassemblies, each requiring its own precise holding fixture. The tight tolerances, some as small as 0.0003 in. (0.00762 mm), present another obstacle to throughput efficiency, requiring operators to perform continuous, section-by-section refinements in motion control to maintain weld integrity.

Most complex of all is the pump's 3-D seam-weld structure, which involves simultaneous rotation of the pump on all axes throughout the welding process. Company engineers liken matching the DuraHeart components to assembling a 3-D jigsaw puzzle as it turns side-to-side and end-over-end. Processes of this complexity often employ multiple robotic arms. However, because of the complicated geometries of the pump design and the restricted environment of the laser glovebox, use of robotics has not been an option.

An expanded view of the DuraHeart LVAS shows the 3-D seam weld structure.

Identifying the System Requirements

The original welding technology, although appropriate for producing small quantities of the pump, lacked sufficient automation for high-volume production. To increase throughput, the new laser system would have to equal the precision and quality of the original welding process while reducing per-unit welding time. Beginning their search, Terumo Heart engineers identified several system requirements the new technology would need to meet.

Increasing Efficiency. Time and steps had to be trimmed to achieve a much leaner process. Many of the welds involved multiple setup changes, with one seam requiring as many as five. The speed and efficiency of fixture changeovers also needed to be improved. Accomplishing these objectives called for a system equipped with a high-performance CNC (computer numerically controlled) motion control subsystem.

Need to Handle a Broad Range of Weld Sizes. The original welding technology called for multiple configuration changes to handle the substantial variations in weld diameters (0.125 in. to 2.84 in.) and penetration depths (0.004 in. to 0.040 in.). Accommodating these differences required a broader range of motion and laser control.

Position-Based Firing Function. The combination of complicated, five-axis motion and simple, straight-line welds along a single contour required the operator to make multiple adjustments in laser firing. The laser had to be coordinated with the path speed to avoid over- or underwelding areas of the contour. If the weld speed was optimized for the straight-line weld, it was too fast for the five-axis movement. Conversely, if the weld speed was optimized for the five-axis motion, it was too slow for the straight-line weld. To improve efficiency and speed, the new system needed a self-adjusting programming feature that matched the firing speed to the location and complexity of the weld.

Minimizing Bulk Heat Effect. Multiple materials with varying degrees of heat tolerance raised concerns about protecting heat-sensitive pump components, particularly in areas involving deep welds. Controlled, pulse-shape programming would ensure precise targeting and containment of the heat-affected zone. Ideally, the system would also incorporate a real-time, closed-loop power feedback control system to ensure consistent laser power throughout the welding process without operator intervention.

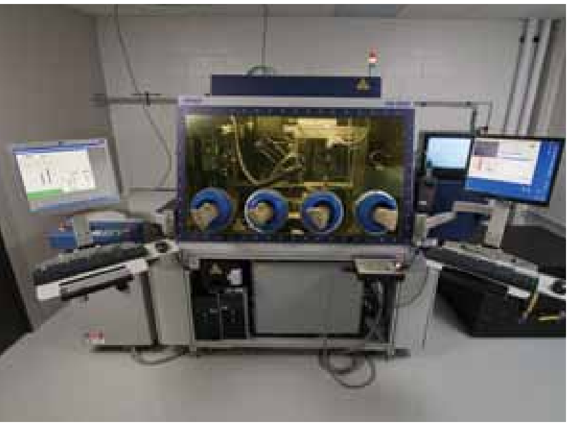
Hermeticity. The new welding technology had to match the original technology in meeting the stringent requirements for hermetic sealing. The pump chamber had to be 100% leakproof to maintain the precise argon-helium mixture necessary to protect the electrical components.

Glovebox Design. Obtaining smooth, high-quality titanium welds required strict control over the glovebox environment. Specifically, moisture, oxygen, and nitrogen, which react with titanium during welding, had to be maintained at ultralow levels. Because conditions are easier to control in a small environment, engineers wanted the glovebox to be as small and compact as the welding process would permit.

Additional features included a recording function to allow the operator to monitor and adjust environmental variables before they exceeded their prescribed ranges, an automatic interlocking function to shut down the laser motion in the event of extreme changes in ambient conditions, and provisions to prevent and detect leakage of the highly combustible titanium dust generated during welding.

Selecting and Customizing the Technology

Using these criteria as a guide, Terumo Heart chose a solid-state, pulsed Nd:YAG (neodymium-doped yttrium aluminum garnet) laser system consisting of a model LW-150A laser with an AX-5000 glovebox and a custom five-axis motion system (Miyachi Unitek Corp., Monrovia, CA). To ensure component compatibility, all elements (laser, glovebox, optics, motion, and software) were obtained from a single supplier.



Shown here is an environmentally controlled glovebox for laser welding.

Although the system met Terumo Heart's selection criteria, it still needed to be customized to meet some of the more specific production requirements of the DuraHeart design. In a circumstance such as this, a medical device manufacturer usually sets goals and then provides the equipment supplier with a set of specifications to meet those goals. However, for this project, because of its complexity, Terumo Heart sought the supplier's guidance in identifying and designing the optimal customized capabilities of the laser technology. The DuraHeart project manager supplied the reasoning behind each detail in the pump assembly, which enabled the laser-system engineering team to select and adapt the best technology features for the pump design.

Successfully incorporating a challenging new technology into a production process with stringent control requirements is difficult enough when all of the engineers work at the same plant. The laser welding project posed the additional obstacle of coordinating operations across a significant geographic distance. Achieving the desired outcome required close collaboration between two companies, calling for shared responsibilities in project oversight, flexible business management styles, and close communication between engineering departments.

This approach to design and development led to several customized features that can significantly reduce welding time, as follows:

- A five-axis, direct-drive laser head improved repeatability, precision seam tracking, and welding speed.
- A five-axis motion control system simplified navigation of complicated 3-D weld curves. The manufacturer produced 3-D CAD files describing each of the contours, and the laser system supplier used a CAD/CAM software package to generate the motion control program.
- A quick-change tooling feature, employing pneumatic controls, addressed the issue of multiple complicated welds. This feature

Meeting the Challenge of End-Stage Left Ventricular Failure

Each year, about 8000 people worldwide are added to lists of heart failure patients waiting for donor hearts. These patients have the most severe form of heart failure—end-stage left ventricular failure (LVF), or what the New York Heart Association defines as "Class IV" disease. In these patients, the left ventricle—the heart's major pumping chamber—is unable to meet the body's requirement for oxygenated blood. With donor hearts scarce (about 3000 worldwide per year), physicians face the challenge of keeping patients alive until a compatible heart becomes available. Treatment options are drug therapy or drug therapy in combination with mechanical pumping support, and research shows the latter to be the better of the two.[1]

The DuraHeart LVAS is designed to provide auxiliary pumping power in patients with late-stage heart failure.

Although some patients have undergone replacement of the native heart with an artificial heart, most physicians opt to leave the diseased heart in place and supplement its pumping strength with a surgically implanted left ventricular assist device (LVAD) or system (LVAS). These systems feature a small, compact pump connected by tubing to an opening in the bottom (apex) of the left ventricle. Blood flows from the left ventricle into the pump, where it is propelled into an outflow conduit attached to the aorta—the pipeline that transports blood to all major arteries in the body. A cable (drive line) tunneled through an exit port in the abdominal wall, links the pump to a portable external monitor and power source.

In the United States, the majority of LVAS manufacturers first seek a bridge-to-transplant indication, meaning that their products are initially approved solely for temporary support in patients awaiting a donor heart. However, the goal of most manufacturers is to demonstrate that their pumps are sufficiently durable for long-term support, or destination therapy, in patients who are not eligible for cardiac transplantation.

Since the first implantation of an artificial pump in the early 1980s, these devices have undergone significant transformation. Large, first-generation pulsatile pumps were followed by second-generation axial-flow pumps. Centrifugal-flow pumps, such as the DuraHeart LVAS, which has a magnetically levitated impeller, represent the latest generation of these devices. This impeller is designed to avoid all mechanical contacts within the pump chamber, thereby reducing wear and tear on the pump components. Even more important, new impeller designs are addressing two of the more common safety issues associated with circulatory support pumps: red blood cell rupture (hemolysis), caused by friction within the pump chamber, and clot formation (thrombosis) due to blood pooling along the sides of the chamber.[2–4] allows a significant reduction in setups per weld (in one instance, from five to one) and improves the efficiency of fixture changes. A single fixture change—including tool changeout, program selection, and calibration—can be accomplished in a matter of seconds with ±0.0005 in. repeatability and accuracy.

- The need to automatically adjust path speed based on weld location and complexity was met by developing a position-based laser firing algorithm to work for multiple types and configurations of axes. This algorithm compensates for skewed axes and tooling offsets, avoiding the need for the operator to make complicated programming adjustments.
- To enhance weld-contour repeatability, engineers modified the specifications for the weld contours and applied a version of a standard teach-mode utility that rotates and translates a fixed weld contour based on a jog-and-click operation (manually positioning the target to match the tracing program, then clicking the start button). The function requires little operator intervention, is adaptable to automatic vision-directed motion, and easily handles 3-D contours.
- To keep the laser lens free of titanium dust, the lens was equipped with a nozzle that continuously recaptures a cross-flow of inert gas and directs it across the lens surface. This feature, which functions like a gas curtain or air knife, reduces downtime required for maintenance.
- In anticipation of a future need for quick access to supplier assistance in troubleshooting, the engineering teams developed a monitoring system that allows resolution of technical issues by remote PC access.

Defining Validation Methodology

Once the equipment design neared completion, engineers turned their attention to defining a comprehensive validation methodology. Validation master plans were developed for facets of production that are verifiable by inspection as well as for those that are not verifiable by inspection, such as process failure modes and effects analyses, installation qualifications, operational qualifications, process qualifications, and product performance qualifications.

> **Successfully incorporating a …new technology into a production process…is difficult enough when all of the engineers work at the same plant.**

Criteria were established for microscopic inspection of weld integrity and morphology. Samples, or coupons, taken before and after welding, can be autopsied and compared for the quality of grain structure, the size of the heat-affected zones, the penetration depth, and the presence of contaminants. A helium mass spectrometer leak detector, capable of detecting as small as one part in 100 million, can be used to validate hermeticity.

This weld cross section shows the weld penetration depth, the quality of the weld, and how the materials have melted together.

Conclusion

Results of feasibility production runs indicate that the new laser technology enables Terumo Heart to reach its goal of a fourfold increase in throughput. Bringing the new technology onboard has improved the quality and precision of the welds, increased welding efficiency, and reduced the requirement for workspace. Moreover, with the customized laser system incorporated into the pump manufacturing process, welding units can be more easily added, thereby positioning the company to keep pace with market demand.

Management predicts that the new streamlined welding process will allow for eventual consolidation of all aspects of DuraHeart manufacturing into a single production facility. Anticipated benefits should include increased cost savings, shortened lead times, quicker response time for process improvements, and faster development of next-generation products.

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