Laser Joining Technology Furthers Miniaturization Capabilities

Microwelding provides the medical device industry with yet another manufacturing solution option that enables OEMs to achieve further miniaturization of their products. It can be an ideal alternative to additive joining processes for a number of reasons. This article provides those advantages while also reviewing the technology process itself to illustrate how device makers can best take advantage of it.

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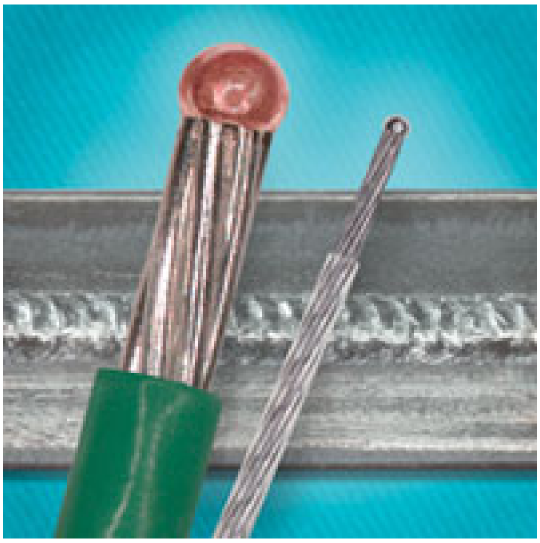

(Ball-welded cable.)

Laser microwelding clearly accommodates the design of medical devices that trend smaller in form and more capable in function. The utilization of microwelding allows for smaller assemblies and can push the limits of component size in these assemblies. Tighter tolerances can be specified and more precise devices can be manufactured. If laser microwelding is done properly, the combination of the two joined metals is very strong-as strong or nearly as strong-as the beginning properties of the starting metal materials and components.

Medical devices that leverage the many advantages of laser-microwelded components can be smaller and less invasive, thereby causing less surgical trauma. They are easier to deploy in the body and can result in shorter and simpler surgical procedures. Ultimately, they help reduce and even eliminate many of the costs associated with surgeries by supporting a shift from in-patient hospital to outpatient clinical procedures.

A medical device which consists of precisely (nearly invisible to the naked eye) microwelded components or subassemblies is aesthetically pleasing to both the surgeon and the patient, and these aesthetic attributes can instill confidence in the device. In addition, they also may enhance the OEM's price point for the device, thereby up-leveling the value of the solution.

The Laser-Microwelding Evolution

Weld-spot sizes are getting smaller; dissimilar materials are being introduced to the discipline; material formats are growing more varied; component pieces are becoming smaller; and the variety and number of applications for laser microwelding is growing. Increasing manufacturing volumes dictate increased manufacturing efficiencies and require more sophisticated material handling and automation.

Furthermore, the discipline is moving beyond single-joint microwelding and the simple joining of two objects. Laser microwelding is evolving toward the joining of multiple components on multiple axes, as well as the integration of different types of welds (seam weld, spot weld, butt weld, etc.) within the same assemblies.

The Laser-Microwelding Process

Laser-microwelding-process equipment is essentially off-the-shelf. Laser-source and beam-delivery components are standard items. However, material-handling automation, tooling, and motion control need to be customized or purpose-built to support the scale of materials and components used in microwelding applications.

A standard inert cover gas is used in laser microwelding. Typically, a small-molecule gas such as Argon is used to create an inert environment to eliminate oxidation and carbon build-up.

The common weld types required to support miniaturization in the medical device industry include ball welds and butt welds in support of catheter guide wires; seam welds and lap welds in support of steerable catheters; and spot welds and tip welds in support of stimulation leads as well as sensing and ablating catheters.

(Tip-welded coils.)

The key to success in all types of welds is understanding the pulse shape (voltage rise, plateau, and fall) of the laser energy used to join the materials. Pulse shape elements include up slope (rise), flash/on-time (plateau), and down slope (fall). There are many variables of flash/on-time that can be explored or combined during the pulse plateau. Once the pulse shape used to join discreet materials is optimized, it can be implemented to create all types of welds (ball, seam, spot, etc.) among those materials. Dissimilar materials and the involvement of particular man-made alloys can complicate the quest for optimized pulse shape in a weld application. Materials and components need to be tightly toleranced. Material thickness must be constant to allow an optimized pulse shape to be pre-set as a stable process input.

Replacing Additive Joining Processes

Additive processes such as brazing, soldering, and gluing introduce additional materials like brazing paste, solder, flux, epoxy, or adhesive. This introduction of additional materials often requires secondary cleaning operations. Conversely, laser microwelding is a clean process with no additive materials, no material-prep time, no post-processing cure or set time, and no secondary cleaning operations. This means chemicals are not present in the process so environmental and material shelf-life concerns are alleviated. Further, OEMs need not design around or mitigate against tolerance stack-up as a result of additive materials.

Additive processes are often manual procedures fraught with variability. Laser microwelding allows for the automated presentation of component parts and materials in a controlled process with pre-set laser parameters. This facilitates stable process inputs, thereby reducing process variability. Therefore, microwelding avoids the scrap and rework associated with manual processes.

The lack of product variability resulting from laser microwelding also allows for the point-of-use introduction (drop-in) of a pre-made precision subassembly, which drives toward the automated manufacturing of complex medical devices. This level of precision improves both the flow and yield of device manufacturing, while facilitating the standardization of quality criteria and inspection methods. These significant manufacturing benefits are difficult to envision with subassemblies produced by a manual additive process.

Laser Microwelding Challenges

Making the transition from an additive joining process (brazing, soldering, gluing) to laser microwelding can present some challenges. For example, two dissimilar metals that were previously joined with the help of additive materials may not be ideally compatible for laser welding. The two metals may have very different material properties. Also, the material formats (component shapes) may not be conducive to the intimate contact necessary for proper laser microwelding. Furthermore, existing component specifications may not be precise enough to facilitate the automated placement desired in a microwelding process.

From a perception standpoint, microwelded components may not appear as strong and robust as components joined with additive processes. Initially, it may require a "leap of faith" to trust that a minuscule weld spot is as strong or stronger than the joints produced by previous generation processes.

Finally, new manufacturing methods often require new quality criteria including benchmarks, metrics, methods, etc. In the event that an existing device subassembly is transferring from additive joining to laser micro-joining the change in appearance or measured values imposes an additional risk-reward justification challenge to an OEM's engineering and marketing departments.

Evolving Toward a Laser-Microwelded Solution

One way for OEMs to ease the responsibility of transitioning to microwelded solutions would be to partner with a contract-manufacturing service provider that offers expertise in the discipline of automated laser welding. OEMs then can let the micro-part handling and welding experts execute on the technical challenges of manufacturing the necessary subassemblies. Within the collaborative framework of outsourcing to laser-microwelding experts, OEMs can realize enhanced solutions along with reduced costs for those solutions.

(Spot-welded wire.)

In all cases, allowing adequate development time and allocating organizational resources assures the validity of the outsourced-component solution. The "leap of faith" problem can be addressed with properly designed and executed process validation and product qualifications, allowing time to fully explore process limits. Also, market testing of new medical devices placed in surgeons' hands generates valuable feedback that can be applied during the development phase of any microwelded solution.

Ultimately, the level of trust at the core of a partnership between an OEM and its preferred service provider has a profound impact on the ultimate effectiveness of the laser-microwelded solution. It is essential that the two parties enter into a project with respect for the collaborative nature of exploratory development, integrating the demands and expectations placed upon the microwelding solution into the needs of the comprehensive device-manufacturing process.

Conclusion

With the inherent advantage of simplifying the manufacturing of catheters and implant devices, laser microwelding facilitates more complex designs and more novel configurations. Partnering with a contract-manufacturing solution provider that specializes in subassembly microwelding allows OEMs to focus on their core purpose of designing devices that are embedded with robust functionality and high performance-devices that have the power to change the medical device and healthcare industries.

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