Facilitating Innovation for Medical Device Manufacturing

How laser plastic welding addresses assembly challenges and is helping pave the way for a new era of medical devices

Introduction

It’s simple really. Medical devices are getting smaller. Well, maybe more accurately put, the demand for smaller medical devices is becoming larger.

Trends such as minimally invasive surgery and the rise of microfluidic devices, coupled with the advent of manufacturing technologies that allow for production of such ultra-precise designs, are driving innovation and challenging the status quo in the medical industry.

Laser plastic welding is one such manufacturing technology. Adding a little drama to the typically unexciting world of manufacturing, devices that were no more than working designs a few years ago currently are in use and saving lives thanks to laser welding.

This article explores some of the capabilities that lasers bring to the medical manufacturing industry as well as showcase a few of these life-saving devices.

Laser Plastic Welding

Laser plastic welding is a method of bonding two or more thermoplastic components together. Although there are many methods for joining thermoplastics, laser plastic welding has a few clear advantages for the medical devices industry: cleanliness, precision, hermetic sealing and elaborate quality controls.

Although the picture below is an oversimplified example, and many variations can affect the process, in its essence laser plastic welding is quite simple.

The process relies on passing laser energy through an upper, laser-transmissive layer down to the surface of the lower, laser-absorbing layer where the energy is absorbed. The resulting heat, from absorption, melts the plastics and creates a weld seam.

Changing the Game

Joining and assembly is a critical step in the manufacture of plastics devices. In all cases, devices are designed based on how they are to be assembled. Each joining
method will come married with its own laundry list of design demands and requirements.

Limited by these requirements, device engineers often find themselves trying to put a square peg in a round hole, and innovations are held back based on manufacturing abilities, or lack of.

Laser plastic welding has only been a commercially viable joining method for approximately a decade. Gaining most of its traction in the automobile industry, it has finally laid roots in the medical industry. And there is no turning back.

Before lasers, plastic devices were joined by a myriad of other techniques including adhesives, hot plate welding, ultrasonic welding and friction welding.

Keep in mind that, in most cases, these methods will remain extremely viable and laser welding may never best them.

Each of these methods has its own set of advantages and drawbacks, just as laser welding does. However, lasers have brought a new set of capabilities to the table that previously were unrealized.

Advantages of Laser

Cleanliness, precision, hermetic sealing and quality controls comprise the most significant advantages of laser welding for the medical industry.

1. Cleanliness
It goes without saying that cleanliness is a major factor in the manufacturing of medical devices. Whether it is an intravenous application or a microfluidic device, the smallest contaminates easily could lead to negative results.

Bonding completed by ultrasonic or friction welding processes leave the joint with a scaling effect, caused by what essentially is rubbing two parts together at high speeds.

The scales from the joint break away and become loose, dust-like particulates that can contaminate the device.

This image shows the difference between a clean laser weld (left) and a scaled friction weld (right).

Glues and adhesives also have potential for contamination. Introducing adhesives (which often are toxic) into a device meant to be completely contaminate-free is tricky if not impossible.

Laser welding on the other hand produces tight, clean joints that are particulate-free. There is no relative motion between the joining parts during the process to cause particulates and no additional materials, i.e. glues or extra plastic, are required to complete the weld.

Laser systems are clean room certified and currently in operation in cleanliness class ISO 5 clean rooms.

2. Precision
Small devices require precise welding capabilities. Laser welding systems are capable of producing beam spot sizes as small as 0.07 mm. Therefore, weld seams of relative widths can be realized.

Microfluidic devices are designed to move very small amounts of fluids through highly controlled channels as a means of testing and measuring.

The green device above is one such application. At a total size of roughly 2 ½ x 1 ¾”, this device has 2 m or roughly 6 ½ ft of weld seams within it.

The ultra-small channels are created by precisely placing a weld seam on both sides of the channel without harming the integrity of the channel.
Because the laser beam is only heating the plastic where the beam strikes, the heat affected zone is minimal — there is no worry of damaging or influencing features outside of the weld seam.

Complex patterns are realized by a galvanometric scanning system. Using two high-precision, angled mirrors to guide the laser beam, the most intricate patterns can be traced with superb accuracy.

On a side note, changing the pattern of the weld seam is as simple as loading new data into the system software. This is ideal when manufacturing different products on the same system or for prototyping purposes where changes take place frequently.

3. Hermetic seals
Whether fluids are to be kept in or out, in almost all cases, hermetic sealing of a joint is required for medical devices.

Laser plastic welding is known for producing very strong joints. The nature of the heating process will leave weld seams that are often as strong as or stronger than the parent materials.

The excellent fusion of the two plastics also ensures that the weld seam is entirely sealed. This balloon catheter not only required a perfect hermetic seal, but a high strength weld as well.

The balloon would need to withstand inflation pressures of 8-12 bar to counter the pressure within the artery it is to be inserted, all the while remaining leak-tight.

Due to the ultra-small size of the balloon, part tolerance for this application was specified to the hundredths of a millimeter. Because laser welding produces only localized heating of the plastic, hermetically sealed and strong joints are possible for any size application.

4. Elaborate quality controls
When devices are designed to save lives there is no room for error. Laser plastic welding has unsurpassed quality controls to ensure that any part coming out of manufacturing is held to the highest standards.

Laser welding systems have been proven suitable for the highest risk category, Risk Class III, proven in the manufacture of intracardiac catheters.

Four elaborate process monitoring techniques make up the repertoire for laser welding system quality controls: melt collapse monitoring, pyrometer readings, burn detection and reflection diagnosis. These redundant process monitoring controls ensure accurate quality assurance data can be realized for any type or complexity of weld.

Melt collapse monitoring
Melt collapse monitoring is the most robust process monitoring technique. As the two parts are heated during welding and force is applied, the molten parts will compress into one another. Measuring the melt collapse is a simple, yet sophisticated way of measuring the fusion of the two materials.

Parameters for adequate melt collapse are determined in testing. During production if a part fails to fall within the defined collapse limits, it will be rejected and the data will be stored for later evaluation.

Pyrometer readings
Depending on the type of laser process in use, melt-collapse monitoring cannot always be used; such is the case for radial welds (e.g. balloon catheters).

Pyrometers provide a means of testing quality when no melt-collapse is to take place. A pyrometer measures the amount of heat reflected from the interface of the two parts.

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The picture below shows a sample pyrometer reading. The heat map can help determine weld quality by measuring the consistency of heat distribution at the weld interface.

As you can see in the upper map, there is a small divot. This indicates that there was a lack of heat produced at this section of the weld, and likely will result in a poor weld at this point. Often, this is indicative of a gap between the two joining partners.

Burn detection
A pyrometer measures infrared heat wavelengths from the part. Burn detection is similar in nature, but instead measures heat reflected outside of the infrared range.

Heat outside of the infrared spectrum during laser welding typically is in the form of light that results from the laser striking a contaminate or if the plastic itself is heated to the point of vaporization.

Reflection diagnosis
Designed to ensure that there is no gapping between the joining parts — a laser plastic welding faux pas — reflection diagnosis measures the scattering of light reflected from the surface of the part.

Parts that fit together well have, in essence, only a single surface; the light is reflected in a tight uniform pattern. If there is gapping between the two parts, a second surface at the weld interface will reflect light at alternate angles. The extra scattering is recognized by the system and flagged for review or reject.

More Advantages
Besides the four advantages outlined above, laser welding boasts many more including economic efficiencies, design flexibility, aesthetic welding and new material options.

Conclusion
Laser welding is still the new kid on the block. But there is no doubt that it is making noise in the medical device sector. With so much to offer, the applications that will come from laser assembly will be limited only by the creativity of engineers.

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Check out -> www.laserplasticwelding.com, your laser plastic welding resource.

For general questions or information regarding design and feasibility, please feel free to contact Josh.

Don’t forget to download a copy of LPKF’s Laser Plastic Welding Design Guidelines, a document for engineers and designers in the concept and design stage of an application.

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