Precision Laser Processing Impacts Medical Device Design Options

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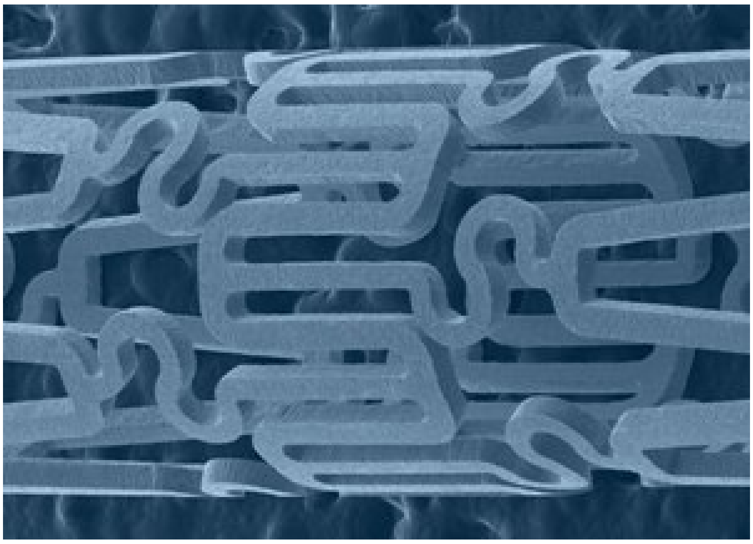
The development of laser technology in the manufacture of medical devices has so exploded in the past 20 years that it is now impossible to fully describe the breadth of applications in anything less than an encyclopedic volume. But a brief recollection of some of the key historical accomplishments and medical devices influenced can help shed light on what we can expect in the next decade.



SEM photo of a typical “as-cut” stent, laser-machined from 0.4 mm wall thickness stainless steel tubing by pulsed YAG.

By 1990, the majority of laser applications used for medical device development and manufacturing utilized flashlamp-pumped Nd:YAG (neodymium doped yttrium-aluminum garnet) laser sources, either directly or fiber-delivered. Ranging from pacemaker/battery/component welding to hybrid resistor trimming, the 25 to 100 micron spot-size, 1.0 micron (infrared) wavelength, and good pulse stability and control were the key factors in selection. Some orthopedic devices were among the first medical cutting applications for both YAG and CO^2 (typically 200 to 300 micron spot size, 10.6 micron wavelength) lasers, with the key factors being edge quality and material absorption. Already in wide use for part marking purposes, during the 1990s CO^2 lasers also found success in key processes of insulation removal (ablation) and spot welding. More technically demanding ablation requirements were met by the excimer laser family (often 25 to 50 micron spot size, 0.2 to 0.4 micron wavelength), generally perceived as expensive but effective task-specific systems.

The start of the 21st century saw a remarkable development initially triggered by the telecom/dot-com phenomenon—the enormous research and deployment of both solid-state and fiber lasers. Although fiber delivery was already well understood, the use of doped optical fiber as the active lasing medium (with high-power diodes as the excitation source) was aggressively developed. Concurrently, solid-state lasers became available at increasing power levels and across the UV to IR spectrum.

Where these developments have brought the industry today is to a very compelling level of process capability. Smaller, more powerful and versatile, more easily-integrated laser sources have therefore opened up an array of new areas and materials with which to work. At the same time, extensive experience with motion control systems, laser-material interaction, and optimal laser source selection have combined to provide custom and standard laser system solutions for many aspects of medical device manufacturing.

Given a specific task and material combination, some form of laser processing is usually possible (although not always at an acceptable cost-benefit ratio). One of the largest volume applications to benefit from this expertise is stent micromachining. Starting with thin-walled stainless steel tubing, laser systems originally used flashlamp-pumped, Nd:YAG lasers operating in either continuous wave or low frequency pulsed single-modes. The rotary and linear axis motion systems were optimized for this process and employed coolant flow through the tubing during the cutting process to provide excellent edge quality. As the material requirements shifted to more Nitinol (nickel-titanium) and cobalt-chrome alloys, the industry sought even better edge characteristics, and the first use of green (0.5 micron, or 532 nm wavelength) and ultrashort-pulse (less than 200 picoseconds) laser sources were created in this market segment. Today and in the near future, the micromachining requirements for both stents and flexible guidewire or other tubular formats will continue to strike a balance of edge quality and cutting speed/cost.

Modern component welding of medical devices and transducers requires extreme control of weld parameters for FDA process validation.

The interest in bioabsorbable materials for stents (predominantly polylactic acid type plastics) has led to the use of both UV and ultra-short pulse laser sources for this micromachining need. One of the largest market segments is the use of UV lasers, both excimer and frequency-tripled YAG sources, for hole drilling, skiving, and general ablation requirements for medical tubing and wire or flex cable insulation. The material absorption characteristics at different laser wavelengths have never been more important than to these applications, and the continued development of new devices using newer materials will imply that the laser process will be a very early factor in the design process. Of course, absorption is a much more significant factor with laser pulses in the nanosecond to millisecond regime. The terms “short pulse” and “ultrashort pulse” are a bit general—typically 200 picoseconds down to femtosecond level durations—but when the pulse length becomes this short, material removal becomes a function of vaporization or sublimation rather than absorption. As so little heat energy is actually absorbed, cut edges can become extremely crisp and heat-affected zones virtually zero. The tradeoff is a relatively slow rate of cut progression, and therefore, process time and cost.

Welding has continued to be one of the big three markets for lasers in medical device manufacturing. The applications are extremely wide-ranging, from pacemaker and battery case components to surgical device assembly to non-metallic catheter components. Once again, the reduction in physical size and increase in performance/flexibility of the lasers has brought more of these processes into cleanrooms and expanded the scope of how devices can be designed. For these scenarios, not only must the laser source and motion parameters be tightly controlled, but the entire system must be process capable and validated for FDA requirements. One of the challenges for the device designer and his/her team is to guarantee the laser welding process validation capabilities of a supplier that may ultimately perform the final assembly.

The next few years will undoubtedly see continued expansion of laser processing for medical devices, based on ever-widening performance of the systems (wavelength/power ranges, materials capability, etc.) and due to better understanding of the strengths and limitations of systems and manufacturers. The driving force behind new applications will always be the designers who press for new solutions to design challenges.

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Links:
[1] http://www.primapower.com/