One of the fastest growing fields in medicine is minimally invasive surgery, particularly intravenous procedures. This sector is growing so quickly because these techniques satisfy three important goals in medicine today: reducing costs, improving patient outcomes, and shortening recovery times. The procedures rely on the use of tiny plastic tools and devices. Because of the unusual shapes and small dimensions, these plastic devices are ideally suited to production by ultraviolet (UV) laser micromachining. At the same time, these are disposable products. They are either left in the body for subsequent biodegradation, or if removed, they are too small for easy cleaning and sterilization. Thus, these parts must be fabricated in a cost-effective manner. This article discusses the fabrication of several types of small 3-D devices and shows how they are created easily with an excimer laser.

Micromachining with Pulsed UV Lasers

The function of devices such as stents, embolic protection filters, and balloons depends on their precise, three-dimensional shape. In fact, stents that treat bifurcated vessels can be fabricated to match the precise local anatomy of an individual patient. Traditionally, 3-D shapes have been molded or machined using a CNC mill or lathe. Unfortunately, these older techniques cannot cope with the small size and delicate and flexible materials used in new devices. Hence, there is a pressing need for an alternative processing tool.

Lasers have long been successfully used for micromachining applications, creating cuts, holes, and surface features on the micron-sized scale. The key to laser micromachining is to limit heating effects. In other words, when manufacturers remove target material, they must also avoid allowing significant amounts of heat to flow into surrounding material.

One way to do this is to use very short laser pulses, each one lasting only nanoseconds. Ideally, each laser pulse delivers enough energy to remove material but is short enough so that heat dissipates quickly. The goal is to have a cool part before the next pulse arrives.

Although many types of pulsed lasers can be used for micromachining, pulsed UV lasers are particularly suited for processing plastics. With visible and infrared wavelengths, these lasers essentially melt plastics and push the liquefied material out the back side of the part. But at the deep-UV wavelengths, the laser photons actually break the molecular bonds of the target material, causing the removed material to transition to a vapor. This phenomenon is called photochemical ablation or simply ablation. It enables small features to be created without affecting the surrounding material (see Figure 1).

UV wavelengths are shorter than visible or infrared wavelengths. Fundamental physics tells us that the shorter the laser wavelength, the tighter the laser light can be focused, due to a phenomenon called diffraction. So compared with a visible or infrared laser, a UV laser can deliver a small,
focused spot or project the image of a mask with very high spatial resolution. A mask is a transparent optic that has part of its aperture blocked with a pattern of opaque material. The laser illuminates the mask and the pattern is them reimaged onto the workpiece with focusing optics. The illuminated areas are photomachined and the dark areas are left untouched.

For these reasons, a pulsed UV laser can be the ideal tool for creating tiny 3-D features and shapes in plastic tubes and sheets. When a mask is used, laser machining creates 2-D shapes; the third dimension is provided by tight control of the laser dosage.

Although several types of pulsed UV lasers are available, an excimer laser is often the best solution for high-volume manufacturing. First, it delivers much higher pulse energies than any other laser type, which enables large areas to be processed simultaneously. Second, an excimer can deliver pulses at rates up to several thousand pulses per second. This high power translates into fast processing throughput, which means low-cost manufacturing. Third, an excimer laser can produce several different UV wavelengths, so its output can be optimized to match the specific absorption characteristics of various plastics.

**Optomechanical Tooling**

How do laser beams create specific shapes? There are two ways to micromachine with a UV laser beam. In the **direct-write method**, the laser beam passes through beam-shaping apertures and focusing lenses to produce a concentrated spot on the work surface. Typically this spot has a Gaussian profile that is produced by a diode-pumped UV solid-state laser. A beam with a Gaussian cross section has an intensity peak in the center of the beam. The intensity falls off smoothly toward the edges, creating a bell-shaped, or Gaussian, curve. Such beams are often preferred in direct-write applications because they can be focused to a very small spot. The beam then moves across the object being machined. A computer controls the beam to ensure the material is cut according to a specific pattern. The tight control can be accomplished by using a pair of mirrors that rotate about orthogonal axes to move the laser beam (see Figure 2a). These mirrors are usually powered by high-speed galvanometer coils. The scanning can also be synchronized with movement of the part being machined.

The other approach, the **mask-projection method**, is typically used with excimer lasers. An image of the desired pattern to be machined is first produced on metal or glass. The mask is then illuminated with the laser and projected onto the work surface at some demagnification or reduced size. The mask can contain a pattern of holes, slots, narrow lines, or other shapes. The x-y profile of these shapes will then be machined into the workpiece (see Figure 2b). The mask-projection method is particularly well suited to high-volume production of identical parts.

Mask projection and direct writing determine the x-y characteristics of the machined pattern. The other critical aspect in a 3-D part is depth control. A tool based on a pulsed laser essentially peels the material like an onion—layer by layer. Each pulse removes an amount set by the pulse energy, the focused power (energy density), and the absorption characteristics of the machined material. A typical industrial excimer laser can easily remove material at the rate of 0.1–0.5 µm per pulse. With complete control over laser pulsing, manufacturers can ensure a depth control that simply cannot be matched by any mechanical machining method.

What kind of tasks can be performed? Because of the combination of 3-D control, programmable flexibility, and high spatial precision, excimer-laser processing can be used
The inspection data can be downloaded onto a network, hole diameter and positioning, as the part is laser machined. The inspection data are critical for process validation.

**Turnkey Systems**

How is laser micromachining implemented in practical terms? For small to moderate volumes, medical device makers typically work with a specialty laser contract manufacturer to leverage the contractor’s expertise, reduce costs, and accelerate development schedules. In larger volumes, manufacturers can subcontract or bring the process in-house, depending on economic and other factors. But in all cases, the parts are machined in an integrated laser workstation.

In many ways, an excimer laser workstation can be thought of as a CNC machine tool where the laser beam takes the place of the traditional cutting blade or drill bit. Figure 3. The Laser Lathe workstation combines real-time machine vision with automated focus adjustment and multi-axis substrate motion.

In one company’s Laser Lathe workstation, a pair of programmable collets hold the plastic device in place and a direct-drive system rotates the device. This tooling fixture is mounted on an x-y translation stage to allow three degrees of freedom in positioning the part relative to the laser beam (see Figure 3). A mask-projection or mask-scanning system can produce a line, rectangle, circle, hexagon, or other custom shape on the workpiece. For example, a 300-mm line can produce a line, rectangle, circle, hexagon, or other custom shape on the workpiece. In some stripping or thinning applications, the outer polymer thickness varies and cannot be controlled. In addition, the underlying substrate may be thickness polymer without damaging the sensitive lower layer, an end-point detection scheme can be used. Such a scheme takes advantage of the fact that laser processing produces a small amount of light-emitting plasma with each pulse. Each material produces plasma with a unique emission signature. Special sensors detect the plasma signature and can be used to tell the system to stop machining if the signature starts to change.

**A Range of Applications**

As few as five years ago, the minimally invasive medical device market featured mainly stents and some fairly simple catheters. But today, the breadth of devices includes bioabsorbable or polymer stents, stent grafts, embolic filters, precision drug-delivery devices, electrophysiology devices, neurological devices, many types of catheters, intravascular radiation-delivery devices, angioplasty balloons, and femoral closures—to name a few.

One of the most dynamic areas for such devices is in electrophysiology, particularly to treat cardiac disorders such as arrhythmia. In those cases, ablation catheters or mapping...
catheters are directed to the heart via a femoral entrance. Different technologies can then be inserted, such as cauterization and cryogenic catheters, to selectively kill tissue. Here, excimer-processing tasks may include stripping polymer coating from the metal wires of cauterization devices to provide electrical access to these wires. Laser thinning (outer-layer stripping) is another excimer-based technique used to increase the flexibility of devices to allow them to navigate tortuous arteries (see Figure 4).

Stenting represents another growing field of treatment. More than 2 million stent procedures are performed each year, and that number is increasing. Originally, stents were tubes fabricated as a metal mesh and inserted into a reopened vessel to support the vessel walls during the healing period. But in some cases, the body responds by coating the stent with scar tissue, a process called restenosis. One approach to prevent restenosis has been to coat these stents with a biodegradable polymer impregnated with an antirestenosis drug. This results in the drug being released over time, lowering restenosis rates. Polymer-coated metal stents can remain in the body permanently. However, it is speculated that the stent only needs to be in the body for three to six months as natural regeneration strengthens the vessel wall. That speculation has led to the investigation of bioabsorbable stents. The entire stent would be made of a bioabsorbable material and doped throughout its entire volume with an antirestenosis agent. Such a development would provide a large capacity for the antirestenosis agent to be released over the entire lifetime of the stent—up to several months. Some companies are fabricating these next-generation stents from tubular blanks as well as sheet substrates.

Embolic protection represents another fast-growing device sector. Such devices are often used in conjunction with stents. In fact, the popularity of stenting for carotid artery treatment can be at least partially attributed to the successful development of these embolic protection devices. When fully occluded vessels are being reopened, the very act of intervening and crossing the lesion may cause an embolic event. Devices such as balloon occluders use a balloon to temporarily stop blood flow. A vacuum suction tube removes debris created by a cutting balloon or other atherectomy device. With a partially occluded vessel, there is the potential for small emboli or plaque fragments to break free and pass through the partially occluded artery. In a worst-case scenario, these can reach the brain and cause a stroke. An embolic filter prevents the broken-off pieces from entering the vessels. This device is a small, parachute-like net that crosses the lesion area before the angioplasty is performed. When open, it acts as a trap. The excimer-laser-drilled holes are large enough to allow blood flow, but small enough to catch any potentially dangerous debris. Polymer filters can be laser drilled with 248- or 193-nm excimer lasers (see Figure 5).

Another area where excimer-based fabrication is playing a key role is in the treatment of multibranch lesions in bifurcated vessels—either Y- or T-shaped arteries. Here, the issue is not only treating multiple sites simultaneously, but also dealing with vessels whose diameter varies within the region being treated. Using balloons of different diameters that are deployed side by side addresses the branching. These balloons are introduced into the artery branches via side holes in the main catheter. To shape the plastic devices to match the geometries of the arteries, the programmability of a laser-lathe technique enables the contour of the catheters and balloons to be shaped accordingly (see Figure 6). In essence, the laser beam acts as a virtual lathe bit.

**Conclusion**

Highly miniaturized 3-D devices are key to enabling minimally invasive surgery. As the complexity and sophistication of devices increase, so must the fabrication techniques used to make them. Excimer-laser micromachining, coupled with precision motion and machine vision systems, has proven to be a powerful tool for the microfabrication of intravascular devices. Ongoing developments in all these technologies will continue to support advances in intravascular medicine, as well as new areas such as orthopedics, leading to a host of lifesaving and life-extending devices. ■