IVD Technology
For In Vitro Diagnostics Development and Manufacturing

The benefits of using laser digital converting

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A novel converting method facilitates the production of features that would be more cumbersome or even impossible to create with die-cutting converting methods.

Early on, when designing microfluidic devices, IVD manufacturers must decide upon a method of manufacturing. This manufacturing decision affects every aspect of the device, from price to performance. With much at stake, it is important for manufacturers to have a firm understanding of the various production solutions that are available.

The use of photolithography processes in glass structures to produce microchannels has been widely publicized. Polymer-based materials, a lower-cost alternative to glass, offer specific advantages over glass structures and can be tailor-made for specific applications. The microfluidic channels can be micromolded or hot-embossed to produce the desired fluid path.[1] Only one viable, cost-effective method is available to produce a polymer-based laminated device. That is, to produce hard tooling and die-cut the individual layers.

These production methods have one similarity: they all require manufacturers to purchase expensive precision tooling before the microarray can be produced. This article will present an alternative approach that is rapidly gaining acceptance by IVD manufacturers for the production of laminated polymer microfluidic devices.

Laser digital converting is a production technology that enables device manufacturers to produce features that otherwise would be problematic or even impossible to die-cut—without the need for tooling. Understanding and exploiting the unique capabilities of laser digital converting can enable device manufacturers to shorten the time to market and produce devices with performance-enhancing features that are not possible with die-cutting technologies.

PHOTOS COURTESY LASX INDUSTRIES

A process engineer monitors the production run of microassay subcomponents on a LaserSharp digital converting system by LasX Technologies.

Design to Production

As a design moves from concept to prototype, and finally to production, the realities and limitations of a manufacturing process can result in substantial design changes and consequently to product performance concessions. When a design moves from functional mock-ups to prototypes, the method used to produce the parts can often change. Production methods can also change when functioning prototypes are produced in preproduction and production quantities.

Production techniques that are both flexible and available on demand are required for the production of prototypes due to frequent design changes and the need to keep development costs in check. Once a design has been validated, production tooling is procured and the focus moves to production efficiencies and cost considerations.

One inherent problem encountered by manufacturers when a production methodology changes is that the new production process must be requalified.

A new production technique may have subtle affects on the accuracy of the part (e.g., burrs on the part edge), consistency in the features produced on the part, and contamination of the part, which can have a detrimental effect on the performance of the finished device.

Laser digital converting offers a solution for these problems. When using laser digital converting, one production process is used throughout the design stage. As a result, the manufacturability of the device remains constant, resulting in decreased time to market with a device that has a robust process window.

Figure 1. A roll-to-roll laser digital converting system. The laser processing module (LPM) is located between the material unwind and rewind modules.

Limitations of Die-Cutting

Product designs are always influenced by limitations in the production methodology. Manufacturers face the challenge of extending the capabilities of production methods while still maintaining part quality to produce a high-performance microassay. When hard tooling is used, whether it is flatbed or rotary tooling, there are certain design criteria that must be maintained.

Because die-cutting is a contact process, manufacturers must address the issue of feature distortion. This distortion can cause both dimensional and edge-quality problems, such as part burring or coining. When die-cutting a transfer adhesive, a top liner is required to keep the tool from picking, in other words lifting, the adhesive as the tool retracts. Also, because die-cutting displaces material, removal of small slugs and the waste matrix can be problematic, especially when an adhesive is part of the laminated structure.

Other issues to consider when die-cutting are tooling wear and the resultant differences in die pressure required for new tools and for tools with a progressively duller cutting edge. In addition, problems can arise from nicks or other damage done to the tooling. The effects of storage and requirements for maintenance of the tooling must also be considered.

When die-cutting polyester, a common drawback is the angel hair, or filaments produced when the die fractures the polyester at the cut edge.[2] This phenomenon can be tolerated in other markets, but this angel hair can be problematic for microfluidic applications because these polyester fragments can break free and deposit themselves on critical areas of a microassay. Laser digital converting does not exhibit this effect because it is a noncontact thermal process. While die-cutting is an established and well-understood method of production, specific limitations associated with its use need to be well understood by device manufacturers.

Laser Digital Converting

Laser digital converting can offer substantial process improvements and overcome many limitations inherent to hard tooling. "Laser digital converting" is a generic term that was coined to define this laser processing method and differentiate it from slower ball-screw or linear-motor laser motion systems. The base component of a laser digital converting system is a laser processing module (LPM) that takes the place of a die-cutting station. LPMs are either stand-alone devices used for sheet-fed production, or they are integrated to web handling systems for roll-fed production (see Figure 1). When integrated to a servo-driven web handling system, the LPM can process material in continuous or indexing format, allowing the converter unmatched flexibility for component production.

Three main components comprise an LPM: a CO_2 laser, a three-axis galvanometer motion system, and process control software. The CO_2 lasers operate in the infrared (IR) spectrum at a wavelength of 10.6 µm, offering good absorption for polyester, polypropylene, polyurethanes, acrylics, and adhesives. These are materials commonly found in polymer-based microarrays.

This technology successfully processes acrylic- and rubber-based adhesives in addition to UV- and IR-curable adhesives. The processing of IR-curable adhesives is possible due to the small spot of the focused laser beam and the short dwell time during processing. For typical processing speeds, the beam traverses the material at a rate that results in a beam exposure of 500 µsec or less along any portion of the cut path. The output beam from the laser is focused by an optical element producing a focused spot size of 150 µm in diameter. The resulting energy density vaporizes the material in its path. The vaporized beam path, or kerf, offers a number of advantages (see Figure 2).

If a section of material needs to be through-cut, to form a 500-µm circle for example, the resulting slug will be smaller than the parent material and

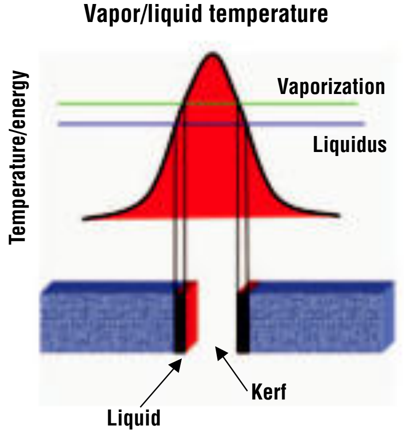

Figure 2. The Gaussian energy distribution of a focused laser beam will vaporize the material being processed, thereby generating a *kerf* where the material in the cut path is removed.

therefore easy to remove from the web. The slug is also easy to remove when the circle is kiss-cut and the waste matrix around the part is then removed, especially if the material is a laminate that includes an adhesive layer. Hard tooling only displaces the laminate, so the adhesive may heal itself before the waste can be removed, making the stripping process problematic. Because the laser produces a kerf, the part and the waste are separated by a significant distance, making waste removal very consistent (see Figure 3).

Lasers that operate in the UV spectrum offer better cut quality and the ability to produce finer detail than CO_2 lasers, but these benefits come at a great expense, both in cycle time and unit cost. This is because a CO_2 laser can produce much higher power levels than a UV laser, resulting in better productivity.[3] In addition, IR CO_2 lasers generate a larger spot size than lasers operating in the UV spectrum. This results in a higher volume of vapors and particulates that will need to be removed from the processing area.

Localized fume exhaust in the processing area is required to eliminate or reduce the vapor condensing on the material surface. The use of sacrificial liners on the material surface will effectively protect the part surface from any debris. Liners can also protect the part from thermal edge damage caused by residual laser energy found at the focused laser beam periphery.

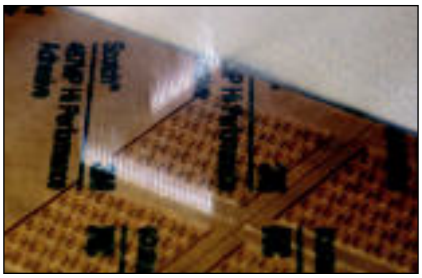

Figure 3. A complex pattern is laser digitally converted in an acrylic adhesive and polyester laminate (by 3M). The plumes are individual pulses from the laser as it microperforates the material at 15,000 mm/sec.

Laser digital converting is set apart from other industrial laser processing systems in use today by its high-speed motion capability and its ability to process materials on a roll. By using two galvanometer motors with lightweight reflective mirrors directly attached to the motor shaft, it is possible to direct the focused laser beam in a two-dimensional plane at processing speeds from 500 mm/sec (20 in./sec) to 5000 mm/sec (200 in./sec) (see Figure 4).

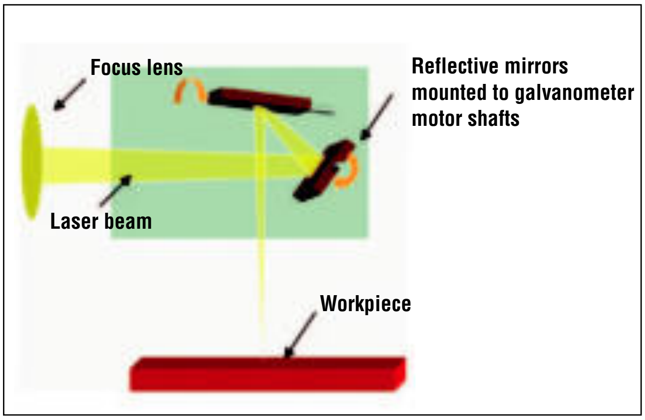

Figure 4. After passing through the focus lens, the laser beam is directed in the x- and y-axis by the galvanometer-mounted reflective mirrors. The focused beam impinges on the workpiece to produce the programmed part.

It is possible to accelerate the beam-directing mirrors up to 50 G due to the low-inertia design of the mirrors, which allows for precision high-speed vector motion. Conventional motion technology, such as servomotors or linear motors, can only accelerate at 0.25 to 1.0 G. Precision components requiring ±50 µm feature or positioning tolerance can be processed at 1000 mm/sec and ±100-µm tolerances can be processed at 2000 mm/sec. The cycle time to produce a part is determined by the average processing speed of the laser beam and the total die-line length to produce the part.

Both high-volume components with common features that make the components easy to die-cut with hard tooling and components with features that are better suited to laser digital converting can be produced on a hybrid web handling system that has a combination of tooling stations and laser digital converting stations. It is readily apparent that laser digital converting can be used as a production tool for process-critical components.

LPMs can process web-based materials in either an indexing mode or a continuous mode. In continuous mode, an encoder is used to monitor the web dynamics regarding velocity and acceleration. This information is input to control software, allowing the laser motion system to track the web movement as the component is being processed.

In order to control the precise movement of the galvanometer motors and the laser power, the laser requires sophisticated control software. This software accepts and directly processes DXF file formats (the most common file output from computer aided design [CAD] software packages), so no tooling is required to produce a part, and most design modifications can be processed simply by updating the DXF (i.e., drawing interchange format) file. This digital control structure can greatly reduce development costs since users do not have to modify or purchase tooling. Once the new design has been loaded, the parts can be processed immediately. This ease of processing initiation can greatly reduce the time to market for the device. Additionally, different processing parameters can be applied to the part features for through cutting, kiss-cutting to a liner, scoring to a depth, or microperforating a part for ease of separation.

When precise part registration is required during multiple-pass laminations, a two-camera vision system is used. On the first run through the LPM, registration holes are programmed adjacent to the feature that is being cut. On subsequent passes through the LPM, the vision cameras are used to find the registration holes and the programmed cut path is re-registered in the x, y, and θ axes. This technique assures precise part registration not only for processing, but also when laminating.

One Company's Experience

BioMicro Systems (Salt Lake City) has benefited from the manufacturing advantages of laser digital converting. BioMicro produces the Maui hybridization system and the Maui Mixer consumable for use in microarray hybridization experiments (see Figure 5). LasX Industries Inc. (St. Paul, MN) developed the LaserSharp brand of laser digital converting technology and offers contract production and equipment sales for the IVD and other markets.

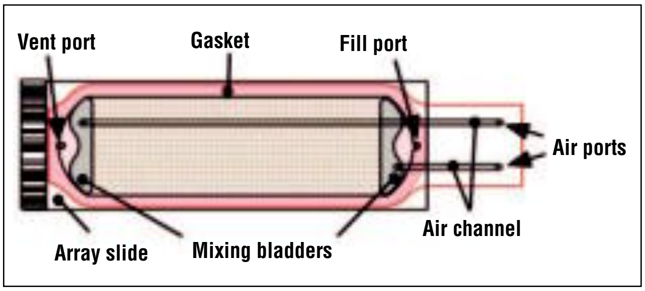

Figure 5. A top view of the six-layer Maui Mixer consumable showing the critical ports and channels that are laser digitally converted in the various layers of the mixer.

BioMicro approached LasX for assistance in manufacturing the Maui Mixer consumable during its product development phase. BioMicro anticipated that laser digital converting could overcome process limitations it was facing with its hard tooling. The multilaminate structure of the Maui Mixer has very tight feature and location tolerances of typically ±50 µm, which are very difficult to hold on a consistent basis using hard tooling. In addition, 6 sets of tools are required, each to process a separate layer of the laminate.

BioMicro encountered great difficulty during the lamination process of all six layers, which required extreme precision. At first, the company was performing the lamination process manually, but an automated lamination process would reduce manufacturing costs and increase production capabilities as the Maui product line moved into production.

The dimensional and laminating tolerances are critical to the functionality of the product, and are essential to achieve correct alignment of the Maui Mixer with the Maui hybridization system. Cleanliness is also a key component in the manufacturing of the consumables to ensure proper performance in the hands of the genetic researchers.

BioMicro's immediate goal in working with LasX was to reduce the laborious hand-laminating process of the 6 layers. The first step toward this goal was determining that two layers, an acrylic adhesive and polyethleneterephtalate glycol, could be laminated and laser digitally converted as a subassembly. Because the subassembly was laminated and both layers were processed at the same time, the critical features were produced in registration, reducing the probability for misalignment often encountered with hand lamination.

Extensive testing at LasX proved that laser digital converting could hold the required tolerances of this subassembly component on a production basis. BioMicro is currently working with LasX on a second subassembly component of the Maui Mixer, and the companies intend to develop of a fully automated manufacturing solution. Laser digital converting has allowed BioMicro to move forward with the commercialization of the Maui product line and the rapid prototyping of new products, having confidence that the parts received are within the specifications of the tight tolerance requirements.

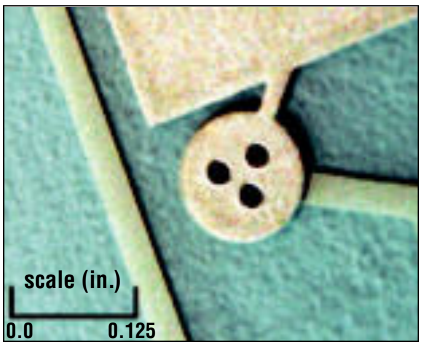

Figure 6. Three 100-µm interconnect holes that were laser drilled in 100-µm polyester. Screen printing both sides of the flexible circuit results in conductive interconnects for a diagnostic device.

Disposable IVDs

Laser digital converting can improve or enable the creation of other disposable products produced in the disposable-IVD market. Biosensors and polyester flexible circuits benefit from the unique capabilities of laser digital converting. These products utilize screen-printed conductive inks on polyester substrates. To reduce the size and cost of these components, manufacturers with products in this market are pursuing double-sided printing of the conductive inks.

This process requires via-hole interconnects between the top and bottom surfaces. Interconnects are through-holes which, when printed with the conductive inks, complete an electrical path from the top surface to the bottom surface of a product. Via holes are 150 µm to 200 µm in diameter, and three holes are produced for each interconnect for redundancy (see Figure 6).

While the holes can be die-cut, the requisite tooling is expensive due to the requirement of small-diameter punches. Additionally, the material between the holes can tear during processing due to the tooling forces of the die. The punches are also vulnerable to breakage resulting in both high maintenance costs and rejected parts caused by interconnect problems. Laser digital converting, which incorporates control software for

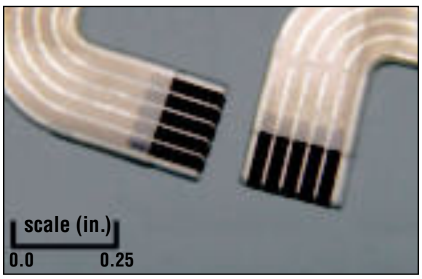

Figure 7. The fine-pitch end connectors of a polyester flexible circuit are laser digitally converted using a two-camera vision system to assure precise registration of the carbon pads to the edge of the polyester.

via drilling, offers a high-speed, consistent production method. The laser will produce via holes at a rate of 100 holes/sec, yielding an ideal interconnect path that can be through-printed with consistent results.

The terminal pads of the device where the device is inserted into the test analyzer are also critical to the performance of a flexible circuit.

One industry trend is to reduce the pitch of the end connectors. This small pitch requires a tight registration of the terminal pads to the device edge to assure proper connection with the test analyzer (see Figure 7). This is further complicated by distortions inherent in the screen-printing process, resulting in die-cuts out of tolerance to the printed terminals. However, if two-camera vision registration is used, a single part or a matrix of parts on the screen-printed sheet can be excised with excellent print-to-cut edge control.

Conclusion

During the development phase of any product, manufacturers must select a manufacturing method that will allow them to maximize product performance, minimize product cost, and reduce the time to market. Understanding the unique capabilities offered by laser digital converting, a microassay manufacturer can make an informed decision regarding the use of this manufacturing technology for its product.

Multilaminate, polymer-based microassays are an ideal candidate for this production technique. As is the case with any production technology, especially when contract production of the product is being considered, it is important to establish a strong partnership with an expert in the production technique selected.

In the case of BioMicro Systems, although its initial production technique, die-cutting, was dropped in favor of laser digital converting, a quick production recovery was realized by developing a strong communication path with its contract-converting services provider. Providing such a partner with the necessary product history and clearly defining the design challenges and production goals should result in a successfully phased-in process development program.

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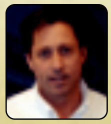


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