

TMD

For Design, Manufacturing and Assembly of Medical Equipment and Devices

Motion in Review

LASER PROCESSING IN STENT PRODUCTION

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WHEN YOU EXAMINE TODAY'S TECHNOLOGICAL ADVANCEMENTS, they usually fall into one or more of three categories: more features, faster and/or smaller. No doubt we are living in a world where rapid technological change is the norm rather than the exception. Medical devices are not immune to this advancement and, in fact, are pushing the envelope.

As the medical device industry has advanced, it has become extremely

important to improve time to market, throughput, and manufacturing tolerances. An interesting example is the manufacture of stents, where manufacturing tolerances have actually reached the submicron level. In addition, because these devices will be inserted into human arteries, they must be free of grooves and burrs and also must be completely hygienic.

Typical manufacturing requirements of stents include:

- Stents are usually manufactured from stainless steel, nitinol or a cobalt-based alloy.
- Stent design is usually a mesh structure or a coil.
- Stent materials can be as thin as 0.001" (25.4µm).
- Typical diameters of stents are from 0.08" (2mm) to 0.2" (5mm).
- Complex geometries require accuracy and cutting tolerances of ±0.0001" (2.54µm).

To put some of these numbers into perspective, the diameter of a human hair is approximately 100µm, so the entire wall thickness of the material in a stent is 25% the thickness of a human hair. By reviewing these numbers, it is easy to understand the difficulties of ensuring quality manufacturing. But what is the best method of production to meet these tight tolerances?

▼ The Aerotech Automation 3200 1-32 axis, software-based motion controller set.



Due to its unique capabilities, laser processing has become the predominant method of cutting, ablating, and welding materials for stent manufacturing. Compared to other cutting methods, laser processing produces very smooth edges that substantially reduce the finishing process. Another laser processing benefit is the ability to make intricate design cuts with extreme precision and accuracy. These factors allow the system to be more cost-effective to deliver improved throughput.

The ideal laser-machining center will produce the highest quality, be highly repeatable, and will optimize the entire process. When designing the laser-machining center, there are several factors to consider: the laser, motion equipment, the controller and the base structure.

PROCESSING CHOICES

Factors to consider when selecting the laser include laser power, bandwidth, wavelength, operating frequency, spot size, pulse duration and beam quality. The choice of laser, which is usually YAG or fiber, will depend on the type of material being cut, the wall thickness of the tube, and the type and cutting detail that is required.

In general, a stent-cutting machine requires a rotary and a linear axis. In its simplest form, this can be accomplished by bolting individual components together. It is then necessary to add some material handling capability. However, due to the inherent errors in the individual components themselves and the bolting of the axes together, and the addition of a material handling system, it is not possible to assemble a truly optimized system.

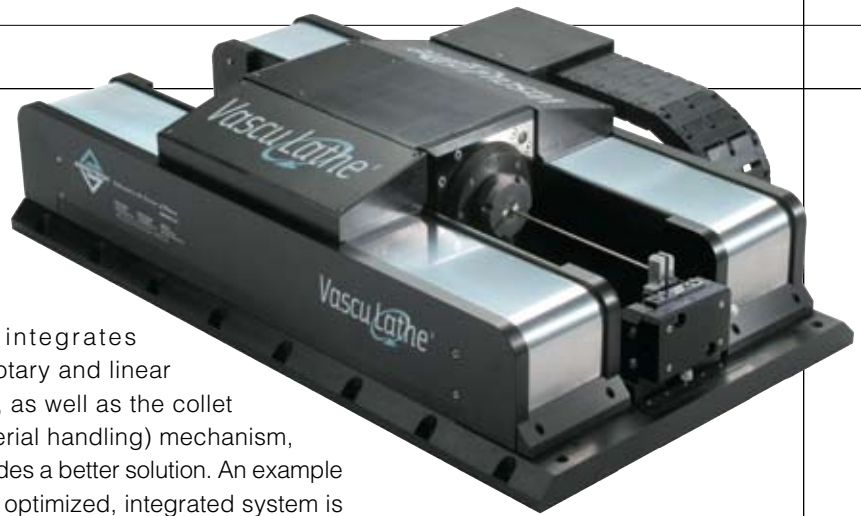
IMPROVED DESIGN

With the push for tighter tolerances and higher throughput, an optimal design

that integrates the rotary and linear axes, as well as the collet (material handling) mechanism, provides a better solution. An example of an optimized, integrated system is the VascuLathe series. The rotary axis has been designed to integrate directly onto the linear axis so that it is in-line with the linear motor and bearings. This design improves overall system stiffness and increases the resonant frequency. The rotary axis also has an integral pneumatic-activated collet mechanism, effectively reducing system complexity and minimizing the total system moving mass. The system also has an optional wet-cutting configuration for applications that utilize fluid to minimize the heat-affected zone and backwall damage, and to assist in the evacuation of waste material.

The cumulative effect of the VascuLathe's optimized design results in throughput improvements from 200% to 500% when compared to traditional component-level manufacturing approaches, while still maintaining submicron tolerances on tight part geometries.

In addition to selecting the proper mechanical stages, it is equally important to choose an appropriate multi-axis motion controller. An example of a feature-rich multi-axis controller that is very good for medical device manufacturing is the Aerotech Automation 3200 (A3200). The A3200 is a software-based controller that offers up to 32 axes of synchronous motion. Key A3200 features used in medical stent manufacturing include contoured motion, PSO laser



▲ Aerotech's VascuLathe integrated, optimized stent-manufacturing platform.

triggering, circumferential units and multi-block look-ahead.

One feature that is extremely useful is the ability to program in circumferential units. So what does this do and how is it useful? By specifying the diameter of the cylindrical part, a program can be written as if it were in XY space. The program then translates the XY coordinates onto the cylindrical part and cuts accordingly.

Another feature that is essential for cutting small circles or arcs on a cylindrical part is contoured motion. Contoured motion refers to motion in which multiple axes are required to work in conjunction with each other. The A3200 is not only capable of providing contoured motion, but also utilizes an advanced feature, "multi-block look-ahead," to optimize cutting velocity as a function of part geometry.

While executing a program, the multi-block look-ahead function is constantly reviewing lines of code that execute later in the program. Acceleration induced by arcs and circles in the part are calculated by the look-ahead function and compared to a threshold acceleration value defined by the user. If the acceleration in an arc is above the allowable threshold, the controller will slow the cutting speed before the part feature is processed to ensure that

the acceleration limit is not exceeded.

Once the feature has been processed, the programmed cutting velocity resumes. By adjusting the acceleration limit in the program, it is possible to directly control the part accuracy and system throughput. Reducing the acceleration limit results in lower position errors and longer processing times. Higher acceleration settings result in increased position error and increased system throughput.

Another key feature is the A3200's ability to trigger and control the laser based on position. Position synchronized output (PSO) uses a combination of hardware and software to allow laser triggering to be based on the actual position of the axes. When used in combination with multi-block look-ahead, the PSO function will ensure consistent laser beam spot overlap as the cutting velocity changes, resulting in improved edge quality and reduced heat-affected zone.

BASE STRUCTURE

The base structure includes the machine base, system base plate and support for the laser optics. If the system is not optimized for stability, significant errors can occur that will affect the quality of the parts produced. Errors are introduced into the process from high system dynamics transferring energy into the system, affecting the system stability and position tracking error during the process. As the axes move, reactive forces are generated within the system. In order to minimize the effects of system dynamics, a stable base structure design is recommended, which may include components such as a granite base plate, elastomeric isolation and a steel machine base.

The other area of concern is the error that can be created in the differential motion between the part and the laser head. This error is not observable within

the control system and thus cannot be corrected through the control loop. The best method for reducing this error is to optimize the stiffness of the structure holding the laser and optics. One recommended method is to provide a solid granite bridge structure to mount the optics and to minimize the length of the unsupported laser head. This design not only provides the necessary support to compensate for the moving axes, but also can support the optics, resulting in improved part quality.

IN SUMMARY


As manufacturing of stents and other cylindrical parts continues to require tighter tolerances, it is becoming exceedingly important to consider all aspects of a laser-machining center. The end result of this optimized machining center is a system that saves money by providing improved throughput and better quality parts. **tmd**

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STENTS, HYPOTUBES, AND CYLINDRICAL MATERIAL PROCESSING

VascuLathe® represents a revolutionary approach to satisfying the demanding requirements of stent manufacturing applications. The fully integrated motion system couples automated material handling functionality with high performance direct-drive linear and rotary motion capability. The integral linear-rotary design increases throughput by 2 to 5 times when compared to traditional screw-based or other manufacturing approaches, while still maintaining submicron tolerances on tight part geometries.

The increased throughput gives much needed flexibility in the extremely competitive stent-manufacturing environment. The higher throughput of the VascuLathe implies that fewer machines are required to produce an equivalent number of stents, resulting in lower total labor costs and reduced floor space requirements. Alternatively, the VascuLathe can be used to meet increased and varied product demand within the existing manufacturing space, saving the costs associated with facility expansion.



- 1 Stainless roll covers protect bearings and feedback from contamination
- 2 Optional wet cutting with coolant return
- 3 Integral frictionless rotary union optimized for stent manufacture provides a lifetime of maintenance-free operation
- 4 Simplified, reliable cable management system ensures trouble-free operation
- 5 Precision ER16, ER25, or ER40 collets support 0.5 mm to 30 mm O.D. tubing, enabling the VascuLathe to support the manufacture of a wide array of peripheral, cardiovascular, and neurovascular stents
- 6 Parallel jaw gripper for automated advance of tubing material
- 7 Manual alignment fixture with precision reference surface and locating pins for rapid replacement of bushing material
- 8 Lower material centerline reduces machine height and fixture sizes giving a lower profile, more rigid system
- 9 Sophisticated machine structure facilitates easy alignment, maintenance, and operation
- 10 Threaded tooling areas located at the front and back of the VascuLathe ease integration of custom material handling features



VascuLathe DS uses a dual spindle configuration to produce twice the output of the standard VascuLathe. For a 10% increase in space (approximate finished machine size) the DS provides a 100% improvement in capacity, further reducing floor space, facility, and manpower requirements. The VascuLathe DS is also very effective at increasing throughput for processes that are intrinsically slow due to laser power or material processing limitations.

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U.S. Patent 7,008,334
U.S. Patent 7,105,956
U.S. Patent 7,420,298

← Specific features of the VascuLathe ACS are shown.

Most Accurate, Highest Throughput, Integrated Systems for Cylindrical Laser Processing



- Three platforms optimized for different price/performance points
- Automatic pneumatic-activated tool holding
- 3-jaw gripper with 25 mm aperture for I.D. or O.D. gripping
- Precision collets support 0.1 mm to 30 mm diameter materials
- Travels up to 300 mm
- 30 mm maximum clear aperture for product feedthrough
- Direct-drive stages with nanometer-level resolution and micron-level accuracy over full travel
- Optional alignment bushing and gripper for complete automated subsystem

The LaserTurn® series of highly integrated motion subsystems dramatically improves your cylindrical laser processing applications. Tightly integrated system elements combined with advanced direct-drive, noncontact motor and directly coupled feedback technology provide maintenance-free operation with the highest level of system accuracy and compatibility over the operating lifetime of your system.

LaserTurn's optimized form factor minimizes system footprint while combining automated material handling functionality with high performance direct-drive linear and rotary motion – creating the most accurate, highest throughput laser machining system available today.

Visit our website for more information on the LaserTurn® series, or contact an Aerotech Application Engineer today to learn how Aerotech motion systems can provide you with a competitive advantage.



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