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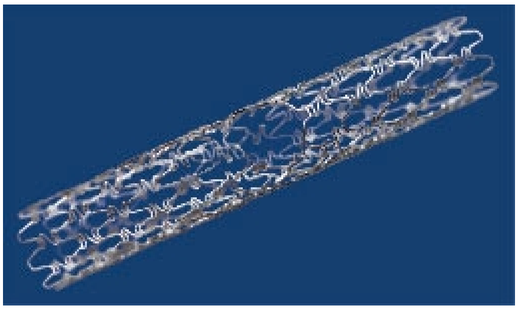
Application Note No. 111

Cutting of stents with SYNOVA Laser-Microjet®

Description of Product

A stent is a wire mesh tube used to prop open an artery that has recently been cleared using angioplasty. The stent is collapsed to a small diameter and put over a balloon catheter. It is then moved into the area of the blockage. When the balloon is inflated, the stent expands, locks in place and forms a scaffold. This holds the artery open. The stent remains permanently in the artery, keeps it open, improves blood flow to the heart muscle and relieves symptoms of stenosis (chest pain)



Description of Material

Stents are frequently made of stainless steel, titanium, or nitinol (NiTi) tubes of varying diameter and thickness. Of these three, 316 L stainless steel, which is also non-ferro-magnetic, is the most commonly used. Diameters typically vary from 1 mm to 5 mm. Tube thicknesses usually vary from 30 microns to 600 microns.

Description of Manufacturing Task

Cutting out slots and similar shapes in tubes.

Description of Conventional Manufacturing Process (State of the Art) and Problem

Metal stents are usually made from small-diameter, stainless steel tubing using an Nd:YAG laser. Other methods used to manufacture metal stents with high precision include electro- discharge machining (EDM) and etch techniques, but these methods have significant drawbacks, and the laser process is the method of choice. [1]

The manufacturing process starts with the cutting out of an intricate pattern in the metal tube to obtain struts. The shape of the struts together with the type of material employed determine the expansion characteristics of the stent.

The tube is cut to exact dimensions using a Nd:YAG laser process. This process will leave an oxide layer on the surface of the stent and remelt on the sides of the struts, as the laser beam becomes more diffuse.

Microblasting can remove both the oxide layer and the remelt. This requires a precise process: too much abrasion will weaken the joints and cause premature device failure. The process is often controlled by measuring the amount of weight, in thousandths of a gram, which is removed from the stent.

The properties of laser processing cause most remelt to occur on the inside of the stent. Often, the most effective means of removing this is to use an extended right-angle nozzle that blasts from the inside of the

[1] *Laser-Manufactured Features in Medical Catheters and Angioplasty Devices* www.devicelink.com

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stent outward. This allows the abrasive to strike the inner diameter of the stent. In most circumstances, the stent is rotating as the nozzle traverses back and forth within it.

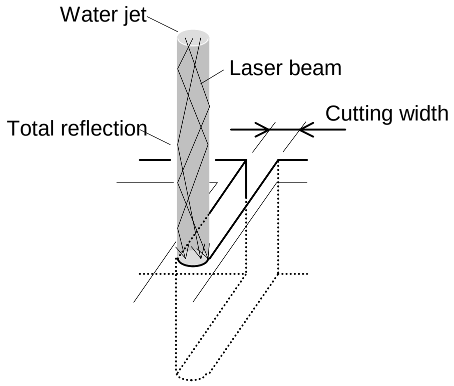
For this application, aluminum oxide has become fairly standard because of its sharp cutting ability. It is able to reach all the nooks and crannies of the stent. Another medium commonly used on stents is silicon carbide, which is more aggressive. Abrasive selection is dependent upon the amount of residue or burrs to be removed.

Factors such as cutting speed, the degree of automation, and the time to convert a design into a cutting program all contribute to throughput in stent cutting.

Problems associated with the conventional manufacturing process include the oxidation and the formation of remelt on cut surfaces, and the weakening of struts during the necessary microblasting process stage to remove oxidation and remelt.

Water Jet Guided Laser Process

In 1993, Scientists at the Institute for Applied Optics at the Swiss Federal Institute of Technology Lausanne succeeded in creating a laser light guiding water jet, called by its inventors Laser Microjet®.
The laser beam is focussed in a nozzle while passing through a pressurised water chamber. The geometry of the chamber and nozzle are decisive to coupling the energy-rich laser beam in the water jet. The low-pressure water jet emitted from the nozzle guides the laser beam by means of total reflection at the transition zone between water and air, in a manner similar to conventional glass fibres. The water jet can thus be referred to as a fluid optical wave-guide of variable length.
Because a pulsed laser is used, the continuous water jet is able to immediately re-cool the cut, resulting in only a very slight depth of thermal penetration. The result is a very narrow, parallel, burr-free, clean cut, without any thermal damage.



Cutting with water jet guided laser

Machining with the Laser-Microjet® Process

Stent materials exhibit excellent absorption of infrared (IR) light, allowing rapid, efficient machining with IR lasers. Using a short pulse IR laser within the water jet, a clean, remelt-free cut of the stent can be achieved. The water jet keeps the stent cool during cutting, thereby avoiding thermal damage and oxidation of the struts.

As no remelt is created during the cutting process, microblasting can be significantly reduced or even eliminated. The laser microjet process thereby eliminates the danger of weakened struts that can lead to stent failure, increases the quality of stent manufacturing, and eliminates potentially crippling product liability issues.

In comparison with the conventional Nd:YAG laser process, the difference in cutting quality is, at the very least, quite remarkable.

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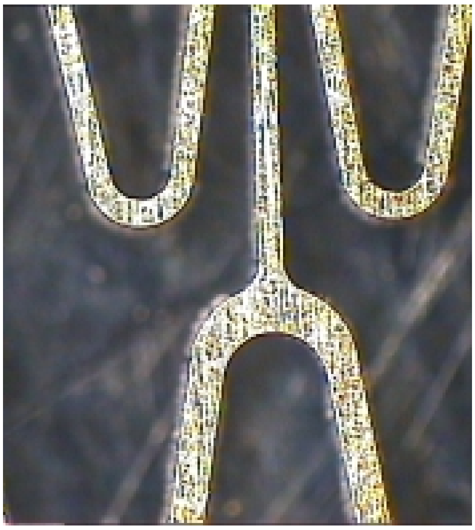
In vivo tests were conducted on stents cut with the Laser Microjet. The tests showed that these stents exhibit significantly higher biocompatibility than stents cut with the conventional process.



Detail of stent cut with Laser Microjet Process, 40 x magnification

Benefits for the Customer

The customer obtains the following advantages:

- High Cutting Speed
- Excellent tolerances and surface finish
- No thermal damage or material changes
- Narrow and parallel cuts (35 ... 60 µm)
- No Remelt inside tubes
- Significantly reduced Post-Processing
- Very low running costs, no tool wear
- Constant results
- Any cutting geometry is possible

Consequence of the Benefits

Because of the significant improvement in quality, productivitiy and biocompatibility compared to conventional YAG laser process, the Laser-Microjet® process will be the future choice for medical stent manufacturing.

Machine for Laser-Microjet® Cutting of Stents

Synova offers a state-of-the-art, clean-room compatible machine, especially adapted for the cutting of stents. Optimum cutting parameters are preloaded. The machine designation is LCS 300.
The machine has a precision of +/- 3 microns, a processing area of 300 X 300 mm and a maximum axis velocity of 1000 mm/s. The system is equipped with CCD camera and fast image treatment software, allowing automatic alignment and inspection. The operation interface is a 15-inch flat color screen with touch panel, the machine software is based on Windows NT®. The operation software is easy to use. The machine can be connected to LAN network for data transmission. The integrated modem allows telediagnostic service. Adapted CAM software can convert all DXF data, fast and easy without special knowledge.

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A complete list of options is available such as a chiller, alternative laser sources, a water treatment system, 2D-reference scales, and transformers.
The CE and S2 certified Synova machines are field proven and used for 24h production.

LCS 300
