Leak-Proof All Round

**Medical Technology.** Balloon dilation catheters used to expand the coronary vessels not only must be leak-proof but are also subject to tight tolerances. A CO$_2$ laser integrated into a welding system ensures the requirements are implemented in series production, while making for a robust process that offers short cycle times.

The term “percutaneous transluminal coronary angioplasty” (PTCA) refers to the technique of widening a constricted coronary vessel from the inside – without open surgery. A PTCA is performed as a planned intervention for chronic coronary heart disease and life-saving emergency surgery in acute myocardial infarction. It involves pushing a balloon dilation catheter bearing a balloon at the end which expands in the vasoconstriction at 8–12 bar (Title picture). The constriction is expanded to restore the blood. The technique primarily exploits the elasticity of the vessels.

**The Correct Method for Joining?**

eucatech AG, Rheinfelden, Germany, produces these PTCA balloon dilation catheters for expanding coronary vessels (Fig. 1). The central element of the catheter is the sophisticated balloon. Its intricate structure imposes special demands on the welding process. Not only must the balloon be leak-tight, but parts tolerances in the range of less than hundred-thousandths of a millimeter must also be guaranteed.

Candidate joining methods were bonding, and laser, hot air and hot-plate welding. Due to its greatly inferior process reliability and the additional footprint necessitated of the aforementioned module, bonding could not be used for the balloon. There were numerous advantages in favor of laser-assisted welding as opposed to the alternatives of hot-plate and hot-air welding. Aside from much shorter cycle times, it is characterized above all by good controllability and high process reliability and stability. Laser welding demonstrably enhances product quality. Scrap due to excessively high energy input is reduced because energy input is localized and kept to a minimum. What is more, there is no contamination of the part.

**Material Bonding with Lasers**

There are several ways to laser-weld plastics. The standard industry method is through-transmission laser welding. It joins one material which transmits the radiation (wavelengths usually between 808 nm and 1,064 nm) to one which absorbs it. The beam is focused through the laser-transparent part directly onto the absorbing adherend, as a result of which the surface melts. The transparent part also becomes plastic due to heat conduction. The two parts are pressed together under a defined force to yield a reliable material bond. This method presupposes, however, that one of the two joined adherends absorbs laser light, usually via an additive. For the present application, therefore, a different solution had to be pursued.

Two undyed plastics can be joined together by lasers which employ longer wavelengths of radiation. This approach exploits the optical property of thermoplastic polymers: the uncolored plastic progressively absorbs radiation from a wavelength ($\lambda$) of about 1.3 $\mu$m, absorbing it almost completely from around 2.7 $\mu$m. One common method for weld-
ing two transparent polymers, for example, employs a laser with $\lambda = 1.5 \, \mu m$. Thin materials, such as PTCA catheters, however, can also be welded with a low-cost CO$_2$ laser system ($\lambda = 10.6 \, \mu m$). A laser beam of this wavelength is absorbed directly in the upper film. Melting and welding to the lower film proceed solely via heat conduction. After a thorough evaluation of the alternative methods, CO$_2$ laser welding was deemed to be the best as regards quality and economics.

**Comparison of Component and Method**

On account of the medical and mechanical requirements, a medically approved specialty polyamide blend was selected. All the components to be joined are used undyed and without addition of additives that would change absorption. The catheter design was modified to suit the requirements of the method, with allowance for the functional and production-specific constraints. Of particular importance is a joining zone that is readily accessible to the laser beam, and the possibility of immobilizing the very delicate components in a fixture.

A system for producing the part was then developed in collaboration with the Plastics Welding Division of LPKF Laser & Electronics AG, Erlangen, Germany. The customized laser-beam polymer welding system uses standard modules supplied by this manufacturer of welding equipment (Fig. 2). All components, such as lasers, coolers, and control unit, are integrated into the system housing, yielding a compact design. The welding system is loaded by hand on account of the manufacturing logistics.

**Precise Positioning**

The core element of the system is the CO$_2$ laser with downstream beam shaping and guidance section. The beam is directed by a special optics construction into a dynamic mirror system (x-y scanner). Downstream of the scanner is an F-Theta optics system, which focuses the beam into the processing plane. Since the circumference of the balloon catheter has to be radially welded without being moved, the laser beam needs to be deflected toward the catheter. This is achieved with a custom-made mirror funnel. It deflects the beam, which emanates from the scanner parallel to the catheter, into the processing zone. The technology for deflecting the beam close to the processing zone is very simple and elegant. It requires a clean environment, but most manufacturing facilities for medical applications would have this anyway.

Another indispensable production module is the unit for positioning the balloon catheter. Since two welds are made at each catheter and the components can vary in line with normal production tolerances, a precision axle with clamping facility is required. The axle employed can hold the part in position not only at the two welding spots, but also allows incremental positioning via camera and tilting. User-friendly, fast operation of the system in every day production is assured by the human-machine interface. The system boasts ProSeT programming software for increased flexibility. This enables the to quickly program the data for welding contour, feed rate and laser power.

**Summary**

Altogether positive experiences have been gained in mass production, both with the laser through-transmission welding of plastics and with the welding equipment. The robust process guarantees high productivity under the given fluctuations in material and component geometry. The system itself is marked by high availability and low downstream costs. This is due in part to the low-maintenance laser and reliable mechanical and electrical components.

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