

HypoTube Manufacturer Makes Extensive Use of Laser Machines



Case Study

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Manufacturers of medical devices can find success through various business models and approaches to market. Cambus Medical (Galway, Ireland) has become a market leader by targeting and achieving excellence in a very specific area – hypo-tubes and related components (e.g., catheter shafts) for percutaneous transluminal coronary angioplasty (PTCA) catheter manufacturers – supporting a global customer base. Already one of the main suppliers of these components and devices, Cambus has experienced even stronger growth recently, thanks to the worldwide brand visibility and leverage afforded by their merger acquisition by Freudenberg Medical (Gloucester, MA, USA). In addition to their unique PTFE (Teflon®) coating capabilities, Cambus is expert in using a broad range of manufacturing technologies including laser cutting, laser welding, and laser marking, together with traditional technologies such as electrical discharge machining (EDM), passivation, injection molding, etc. According to Barry Comerford, Co-founder and CEO, “Lasers play a key role in everything we make.” In this article, we take a look at some of the ways Cambus uses laser processing for their products.

Why Lasers?

The development and refinement of percutaneous transluminal coronary angioplasty (PTCA) in the 1980's brought about a revolution in the treatment of coronary artery disease (CAD). The founders of Cambus had several years' experience supplying components for this purpose before deciding to start their own company in 2006. Comerford explains, “Our PTFE coating system was certainly the catalyst for starting our business, but from the very beginning laser processing was one of the main enablers. Lasers were just appearing in PTCA work and our first customer wanted a ‘cutting edge laser-made’ product. So we made a bold decision to spend a substantial part of our startup cash on two ROFIN (now Coherent) machines: a StarCut Tube laser cutting machine and a StarWeld* laser welding system. Both machines are still running today. Not only did laser technology give us our first customer. It also gave our fledgling business a credibility for cutting edge products, which older technologies such as EDM could not. Soon we were picking up business in areas ranging from PTCA devices to related components such as pressure sensing guidewires. And today we also have a growing business in the area of structural heart products such as TAVR and TAVI.”

*Today the current generation of these machines are called Select.

“Lasers play a key role in everything we make.”

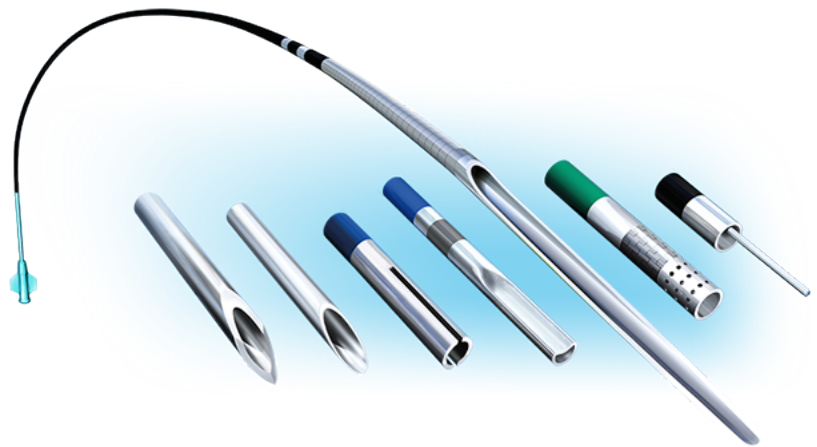


Figure 1. Just some of the diverse microcomponents manufactured by Cambus, thanks to the flexibility and versatility of laser processing. Image courtesy of Cambus Medical.

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Comerford adds that the company has always worked closely with their customers in developing custom and standard products based on delivering the highest levels of performance in terms of torque, trackability, flexibility, lubricity, inflate and deflate times etc. In addition to catheter shafts, Cambus Medical also produces many high-precision, micro component solutions and specialty needles through its Velona program and wire assemblies utilizing the impressive range of laser and non-laser technologies employed within the business.



Figure 2. Cutting slots on a tubular component to enable flexible delivery.

“ We work these machines hard and so we really depend on the super high reliability and prompt quality service we get from partnering with Coherent. ”

Strong Market Growth

Continuous strong growth at Cambus means that today the company has seven (Coherent StarCut Tube series) laser cutting machines, five laser marking systems and six (Coherent Select series) welding machines. Comerford says that Cambus has stayed very loyal to Coherent for three primary reasons, “First, we benefit from having uniform equipment: the same hardware, the same software, and most importantly the same results. We handle contracts from single units up to full volume manufacturing, therefore we need consistent quality and tolerances as well as high yields. Machine reliability is just as important; we typically operate with two four-day 40 hour shifts plus a weekend shift. And we still operate our original 2006 machines! We work these machines hard and so we really depend on the super high reliability and prompt quality service we get from partnering with Coherent. And lastly, these machines are very versatile and user-friendly, enabling Cambus to provide a quite diverse product offering in terms of size and shape, as well as a huge range of batch sizes.”

The StarCut Tube machines are self-contained CNC-style automated systems featuring multiple (up to four) cutting axes and a user-friendly GUI. Today these are available with a choice of a microsecond fiber laser for high throughput or a femtosecond ultrashort pulse (USP) laser for the ultimate surface quality, or even both lasers in a hybrid machine. The use of a granite cutting platform is a key feature that ensures high precision so users can cut struts as thin as a human hair while processing tubes up to 30 mm diameter as well as cutting flat stock.



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The Select series of welding systems are multi-axis (linear and rotary) manual welders that also support semi-automated and automated operation: either joystick control or fully CNC programed. All parameters can easily be adjusted without any special know-how via a multi-functional joystick and large color touch-screen.

The Broad Cambus Product Range

Most of Cambus' products are associated with PTCA delivery systems, imaging, guiding and insertion, and are thus primarily stainless steel: mainly 304 with some 316 and a small amount of 17-7 PH and CoCr. They also handle a few jobs using nitinol. In addition to welding, drilling and cutting, many Cambus products require marking, for functional and/or identification purposes. Since all their products are for single use applications, they don't need black marking based on ultrashort pulse (USP) lasers. Instead they rely on conventional marking with a fiber laser that provides a cost-effective solution for directly marking the metal or for coating removal. Comerford explains an example of a simple functional mark; Cambus removes a small ring of coating at two locations on some of their products to indicate the distance into the body for the surgeon; these marks act as a brachial marker and a femoral marker.



To see how the skills and tools at Cambus come together, let's take a brief look at the smallest and largest products they make. The smallest is a hypotube configured to house a fractional flow reserve (FFR) measurement device; the 304 stainless hypotube has a 0.35 mm OD and a 0.24 mm ID. FFR is defined as the ratio of the coronary pressure distal (Pd) to the lesion, divided by the aortic pressure (Pa) proximal to the stenosis during maximal hyperemia. FFR measurements can help guide the surgeon during the revascularization process. As made by Cambus, the FFR housing is approximately 1.6 meters in length. It includes both a spiral cut to provide the requisite flexibility at the distal end and stiffness at the proximal end for push-ability and steerability. The area which houses the sensor will typically have several special openings to allow the product to work in the disease site.

At the other end of the size spectrum the largest of Cambus' current products is a device for use in transcatheter aortic valve replacement (TAVR) procedures. TAVR is a minimally invasive procedure to replace a narrowed aortic valve that fails to open properly, a condition called aortic valve stenosis. The Cambus device is created from a 10 mm diameter tube of 304 stainless that is 1.5 meters in total length. The distal end is laser cut and the proximal end uses yet another of Cambus' impressive portfolio of laser technologies i.e. welding and marking. The device is completed by other Freudenberg Medical sites in the USA and Ireland.

Summary

In summary, Cambus is a medical device manufacturer that has leveraged a combination of laser and traditional technologies to become one of the market leaders in a major growth niche – hypotubes and related products – all in the space of less than 15 years.

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