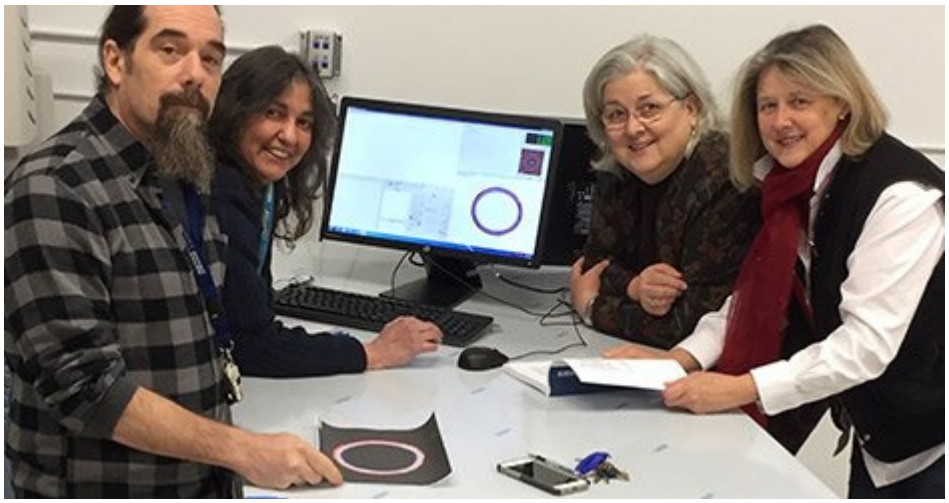
Jaffrey firm advances microcatheter production

Company's tiny extrusions are a first in industry

BY LIISA RAJALA



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Sisters Diane Fukuda and Karen Wirein had been eyeing a vacant industrial park in Jaffrey for years, all the while conceptualizing the type of company they would form.

With over 30 years of experience in manufacturing, Fukuda had served in a variety of roles, including quality control, business unit management, process engineering and new product operations. Likewise, Wirein had nearly 30 years of manufacturing experience in a senior leadership role in the accounting and finance department.

Last year, seeing an opportunity in the extrusion market, they combined forces and in January shipped their first order as Microcatheter Components.

Microcatheter Components' specialty is manufacturing extrusions, or small tubing, that are sold to medical device manufacturers for use in a range of applications, from treating blood circulation problems in the toughest-to-reach areas of the human body to steering through blood vessels of the brain into an aneurysm to pediatric and neonatal care.

"If you've had an IV, that tube that goes into the vessel in your hand is an extrusion," Fukuda explains.

However, Microcatheter Components manufactures tubes with a wall thickness as thin as one ten-thousandths of an inch, or one-third the size of a strand of human hair.

Extrusions with thin-wall qualities had historically been deemed impossible because the walls of the tubes were not strong enough to handle the pressure, says Wirein. Through Microcatheter Components' high-precision manufacturing equipment, the company is able to achieve sufficient wall strength by coextruding multiple layers.

Working for microextrusion manufacturing equipment provider GIMAC, Fukuda realized unmet needs in the area of microcatheter components.

“What Diane observed was a pent-up demand for smaller extrusions manufactured with greater precision,” says Wirein. “The market had been constrained by an existing inability to achieve this level of precision with consistency. With GIMAC, she saw what this technology could achieve, and we saw an opportunity – a gap that, if served, could remove the manufacturing constraint, and open up new possibilities for designers to solve problems with our precision in their products.”

Ultrasonic technology

It took six months for Microcatheter Components to build its extrusion line, consisting of manufacturing equipment from Milan, Italy-based GIMAC. Then Extrusion Engineer Stephen Brumaghim, who had been trained in GIMAC technology, worked with the programming to make the machining sync.

“We produce our products using an engineered, high-precision integrated system designed to control the output,” says Fukuda. “You can think of it as a single organism, in which all of the elements work in harmony to deliver highest-precision components. This is a different approach from a traditional extrusion line where the operator makes their best effort to harmonize a series of non-integrated elements in order to produce the product required.”

Helping maintain Microcatheter Components’ consistency is a laser measurement system that measures the outside diameter of the extrusion as it is being made. The laser measurement system also collects data in real time, providing trend lines that the company can later build into histograms to analyze the process capability.

Jaffrey-based Microcatheter Components purchased extrusion machining equipment from Milan, Italy-based GIMAC. (Courtesy photo)

“That’s the outside,” says Fukuda. “Then we have ultrasonic technology measuring the wall thickness, also as the product runs, and those ultrasonics are also giving us real-time feedback so we can understand at any moment on the line what’s happening with the product we’re producing. The data collected is very valuable to us and to our customers.”

These measurement tools are crucial because dimensional variation can add extra cost and lost time for the customer downstream in the assembly operation, or ultimately affect the reliability of the product, says Fukuda.

“This level of precision is exception, and a key reason for our investment,” says Fukuda. “We could have purchased a much less expensive manufacturing system if we felt the variation that comes with that system would deliver the type of solutions we want to deliver, but we believed the precision would be key to solving our customers’ problems.”

Continual innovation

Dr. Aaron Kaplan, who specializes in cardiovascular medicine at Dartmouth-Hitchcock, is not familiar with Microcatheter Components but praises microcatheter innovation.

“Depending on where the catheters go, I work in the pulmonary arteries, and they have the diameters of a cocktail party straw as opposed to a milk straw, and they’re very sophisticated plastic extrusions,” says Kaplan. “Southern New Hampshire has played a big role in their development.”

Microcatheter development has also lowered mortality rates.

“In the ‘60s, if you had a heart attack, your mortality rate was 30 percent, now it’s below three percent,” says Kaplan. “It used to be a length of stay of six weeks, now it’s three days. It’s all been driven by innovation with the miniaturization of these and the building up hospitals that have that infrastructure to deliver that care.”

When Carmen Ferrara joined Microcatheter Components as quality manager, she also introduced the Kano model, a theory developed in the 1980s by Noriaki Kano regarding product development and customer satisfaction.

“It talks about the voice of the customer and redefining quality in a way that you’re not just meeting the minimum requirements of the customer, but you’re working continuously to understand what will delight them, and, in the best case, delivering it to them before they understand they want it,” says Fukuda.

In order to best serve their customers, Microcatheter Components has fostered collaborative relationships with polymer scientists and material suppliers.

“There are a number of companies in the industry that have polymer scientists in them, and we work with those companies and polymer scientists on next-generation materials,” says Fukuda. “They all have possibilities. We just ran a series of five new materials and we’re sending samples to a number of engineers in the industry so they can give us their feedback.”

The consistency of the materials is important to the medical situations in which multi-layered microcatheters are used.

“If you have an application where you want the outside to be soft because you don’t want it scratching the inside of the vessel, you want the inside to be slippery because you’re going to use that channel to thread something through it, and then you need a strong layer, or an adhesive layer to hold those together, then you’ll have a more higher-performing extrusion than a single layer extrusion,” says Fukuda. “You can also customize mechanical properties with the use of layers.”

The Jaffrey firm has also been working with researchers at the National Institutes of Health in Bethesda, Md., where they are using Microcatheter Components extrusions on ground-breaking designs.

“They’re using us to solve problems they couldn’t historically solve with the suppliers available to them. And specifically, it’s very, very precise dimensional control and very, very thin wall thickness on these tubes,” says Fukuda.

“By combining the materials expertise from the polymer scientists we work with, the best equipment available anywhere in the world, and by having gifted people who can translate the promise into differentiated products, we face the market with synergized capabilities,” says Fukuda. “Working closely and openly with our customers, sometimes elbow-to-elbow in our laboratory, we are building strong and enduring relationships.”