

HEALTH CAREOC HOMEPAGE

# Turning Doctors Ideas Into Business Products

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JULY 17, 2023

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A Single Pass is inserted into a needle used to conduct a biopsy and cauterizes the area

If you're a doctor with an idea for a medical device, Bill Colone is your guy to turn it into reality.

"We get calls all the time from doctors," Colone, chief executive of Single Pass Inc., told the Business Journal during a visit to his Lake Forest office.

"The deal flow comes through us. Nine out of 10 times, we say 'no' because we don't have the bandwidth or it's not the right market or it's not the right setup."

His latest project is Single Pass, which says it has made “the world’s first disposable bipolar electrocautery device that can cauterize deep tissue through a guide needle.”

The device is for biopsies, which Colone estimated there are 5 million conducted annually in the U.S.

“We learned there literally is no other device that can prevent bleeding after biopsy procedures,” Colone said. “There are no other clinical solutions.”

The product has received clearance in the European Union, where sales are expected to begin this summer. FDA clearance may come in September, he said.

## **Venture Studio**

Colone, who has a degree in chemical engineering from Arizona State University, has been involved in medical device manufacturing for more than 40 years, specializing in vascular grafts and accessories.

He’s served as the CEO of Spinal Singularity and the vice president of R&D for Direct Flow Medical. He was CEO and co-founder of Endomed from 1993 until its sale in 2005 to LeMaitre Vascular.

From 2010 to 2017, he was director of R&D for Endologix LLC, an Irvine-based maker of treatments for aortic disorders that was taken private in 2020 after filing for Chapter 11 bankruptcy.

In 2019, he and two partners began RC Medical LLC, which he calls a “Venture Studio.”

The other two partners are Dave Ferrera, who is acting CEO of Sonorous NV, which has developed a stent that is implanted in a vein behind the

ears to cure pulsatile tinnitus, and Randall Takahashi, a technology expert who has design and development responsibilities for the products in the portfolio companies.

RC Medical also has a third company called Infinity Neuro that makes a neurovascular stent and a neurovascular aspiration catheter that is already on the market in Europe.

The three partners have about 150 patents to their names.

### **Outsource Model**

Ferrera and Colone are the only employees in their companies as they outsource much of the work.

“The nice thing about the model is we don’t have to rent the building,” Colone said. “We don’t have to buy the equipment. I don’t have to pay people when there is downtime because they’re waiting for shipments or orders or test results.

“It’s cheaper than me hiring five people who I’m paying benefits to. We think it’s a better business model. It’s a wiser way to get further and faster with less cash.”

Once the company decides to take on a medical device, it will find investors and provide shares to the physicians.

It employs a contract manufacturer located across the street called M4D LLC, an FDA registered company with a motto of “taking your design from art to part. Together we’ll create it and make it.”

M4D is a 60-employee company that handles the design, the testing and the regulatory submissions; it was founded by Dawson Le.

“We think we can do things faster because the day we start, we already have the team, the facility, the equipment,” Colone said during a tour of the M4D facility.

## **Death From Biopsy**

About 15 years ago, Colone developed an orthopedic product for a hand surgeon in Phoenix and it was sold to Stryker Corp.

“Sometimes when his physician friends have ideas, he’ll call me and say ‘Can you speak to so and so? They have an idea.’”

This time, two interventional radiologists, Peter Sunenshine, chief of Neurointerventional Surgery and Kevin Hirsch, chairman of the Department of Radiology, both formerly of Banner University Medical Center in Phoenix, told Colone that routine biopsies of livers, kidneys, lungs and prostate have some issues that cannot be resolved.

In biopsies, doctors insert a large needle in the patient and snip a tissue for pathology.

About 5% of the time, there might be internal bleeding, Colone said.

Mitigation efforts nowadays include having patients wait in hospitals for hours after their procedures to make sure their vital signs are okay.

The doctors felt they didn’t have control of procedure and were just hoping the patient was okay, Colone said.

The doctors told Colone about one patient who received a biopsy, went home and then later hemorrhaged and died.

“Imagine getting a biopsy to see if you have cancer and then you die from the biopsy,” Colone said.

The doctors' idea was to cauterize the area to seal the tissue after a biopsy procedure.

An intrigued Colone outsourced market research, literature research and physician interviews to discover there was a big problem, especially for biopsies of kidneys.

## **The Exit**

The result is Single Pass, a patented device that contains six to eight wires wrapped to the thickness of half a millimeter.

Before the doctor pulls out the biopsy needle, a Single Pass device is inserted and its tip will heat up to 200 degrees Fahrenheit to cauterize the area.

“It was the doctors' idea. It wasn't simple to make,” Colone said. “The secret sauce is making it this small.”

Each device, which costs customers \$300 a pop, is disposed of afterwards.

The company already has 6,000 orders, including a current batch for 1,000 being made by M4D for shipment to Europe this summer.

It's raised \$4 million to date, including closing a Series A round in February. The original investors have tripled their investments, he said.

He's talking to potential acquirers.

“The best outcome for us is to sell to our strategic partners because they have hundreds of sales reps,” he said.

“What really drives the value is once we’ve removed the regulatory risks with approval in Europe and the U.S.”