

A NEW RF SYSTEM

Venclose's new radiofrequency technology outperforms legacy systems

By Larry Storer

The great medical technology companies of our time start and develop in a variety of ways. Some start with a product or idea and build a market around it. Some start as spinoffs from existing successful companies.

But Venclose started by determining the unmet needs of physicians treating venous disorders, and they developed a product adapting proven technology that is more attuned to the needs of physicians using an RF product that hadn't changed in years.

Therefore, in 2014, a group of Silicon Valley medical innovators and consultants formed Venclose to address technology in the marketplace that could be adapted and used to improve the ClosureFast RF product. It was in the mid-1990s when VNUS Medical launched its first generation VNUS Closure system, a truly exceptional RF vein ablation system with the ClosurePlus radiofrequency catheter and began supplanting vein ligation and stripping as the standard of care for chronic venous insufficiency.

But the VNUS Closure system (except for the second-generation ClosureFAST catheter introduced in 2005) is essentially the same technology that was in place when Covidien acquired VNUS Medical in 2009. In 2015, Medtronic bought Covidien and since then they have been utilizing that same second-generation RF technology.

"ClosureFAST is basically a decade or older medical device," Venclose Chairman and CEO Jerry Gibson said. "And for whatever reason, the company [Covidien/Medtronic] chose not to provide any new technology iterations to its original technology, despite the advances in technology and other products available in the market, including technologies available in Europe.

"The premise behind Venclose was to assess the specific needs of the marketplace, understand what the needs were and the frustrations or concerns with the current systems, and develop a product more attuned to today's available technologies and needs of the physician. And that's what we did and that's the foundation of the Venclose RF Ablation System or Venclose System."

Venclose consultants learned from physicians across the country that while many preferred the RF solution to laser therapies, they needed it to be faster, more economical, easier to navigate in the veins, easier to set up and with more responsive customer service.

So, with the needs of the marketplace as their mandate, Venclose set out to build the next-generation endovenous RF ablation system designed to close the damaged vein and restore healthy blood flow in patients with venous reflux disease. Gibson, like those who formed Venclose, brings years of experience in the medical field to the development of Venclose's flagship product.

VENCLOSE'S GREATEST ASSET - ITS PEOPLE

Gibson has held executive positions with medical companies beginning with Siemens Medical Solutions and others, including Nerve Inc. and Critical Perfusion Inc. He also was executive chairman of the board of VenX Medical and on the boards of three other medical companies.

"Our entire team is made up of people who have been in the industry for a number of years and that is one of the reasons how we've been able to accelerate our growth the way we have this past year," Gibson said. "I got involved in the company as the first outside director soon after it was created. The company grew and I took on more responsibilities, the team shifted a little bit and here we are today."

"Our phenomenal growth at Venclose is because of the quality of our people that have driven the innovation and the quality of our product," he explained. "Our philosophy from the day we started hiring people is that we consider our people to be the major asset of our company. The results that we see are a reflection of the effort of our people to develop and sell a quality product."

MARKETPLACE RESPONSE

Venclose initially shipped some systems to a few select accounts in the 4th quarter of 2017 to work through logistics. Last year was the first full year of commercialization, and Venclose treated almost 17,000 patients.

Gibson said the Venclose product is comparable in price to the existing competitive legacy RF device but exceeds it in value, including the value-added of using technology that is expected in this day and age.

"What we do is provide greater value to physicians and their patients, and we do this at a competitive price. Our catheter is comparable in price, but what our product can do in one catheter is half the price what they can do with two."

With the demand for the Venclose RF system growing, Gibson said the company realized they needed a manufacturing partner with the ability to keep pace with future growth and production scale. In the third quarter of this year, Venclose will switch its contract manufacturing to Viant Medical, a contract manufacturing organization specializing in medical devices with about 25 facilities around the globe.

Based on an initial annual production capacity of more than 250,000 catheters and the future ability to triple that volume, Viant ensures that Venclose can meet the accelerating demands of its growing customer base.

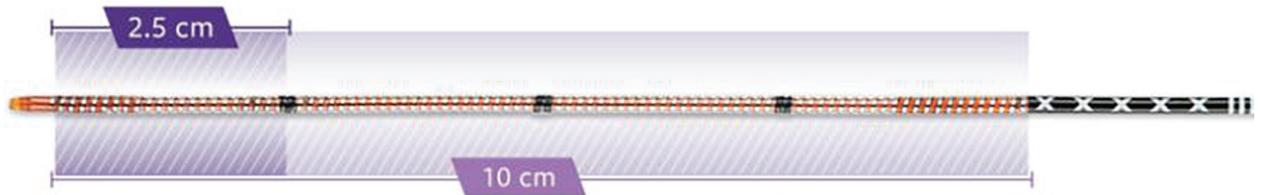
THE NEXT GENERATION RF

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including the ability to easily switch between the 2.5cm and 10cm treatment segments; time of treatment; and audible tones for thermal delivery that allows the physician to focus on the patient and not the display during the procedure.

The Venclose RF ablation catheter has two heating lengths in the same catheter – one at 10cm and one at 2.5cm. This reduces the total in-vein time by up to 30 percent less than the ClosureFAST catheter, simplifies inventory management, and does in one catheter what the ClosureFAST system can only do in two.

The catheter sheath diameter is smaller at 6 Fr than the ClosureFAST at 7 Fr, which minimizes invasiveness and requires a smaller incision to access the vein. The smaller profile offers greater flexibility.

These newly designed technologies are what makes the Venclose System a next-generation product. “There are four main functionalities that clearly separate us from the current existing competitive legacy product,” Gibson said.

“One, is that we have a switchable heating length built into a single catheter. So, we can treat a 10cm or a 2.5cm segment by switching back and forth with the generator’s touchscreen. For our competitors to accomplish that, requires the clinician to pull out one catheter and put in another, which is inconvenient to the physicians, inconvenient to the patient for sure, and increases the cost of the procedure.

“Second, our product is smaller. It is a 6 Fr vs a 7 Fr catheter, which makes it easier to use.

“Third, it has a slightly curved tip that allows you to navigate through torturous veins much easier.

“The fourth significant functionality that distinguishes us from the legacy competitor is an easier system to set up. You can set up the Venclose system up by just inserting one plug versus carefully aligning an eight prong plug that requires some orientation into the legacy competitor system. Our simple catheter connector inserts just like an amplifier jack.”

Gibson said he also believes that Venclose customer service further distinguishes the company from its competitor.

“We focus every day on providing superior customer service. Having spent more than 20 years with large corporations, I know that sometimes as you get bigger that customer service becomes less of a factor for the success of the company – at least within the thought processes of a large company – so we make sure that we support our customers with a customer service department that is focused on addressing their needs in an expeditious manner. And that personal touch, I think, makes a difference as well.”

With a major first year milestone of nearly 17,000 patients treated, Venclose’s direct sales force and marketing plan are also high priorities with Gibson.

“Our plan is to almost triple the direct sales force this year, primarily in the United States,” he said. “Another important part of our program is that we want to make sure we have dedicated, well-trained

individuals to ensure the delivery of professionalism to the physician and ultimately for the benefit of the patient.”

The marketing plan initially was to go after radiofrequency users, and that is still the bulk of the business. Physicians using RF ablation since the early days of VNUS are already sold on the technology.

“Our focus last year was on RF users because that was the low hanging fruit and we had already analyzed the physicians’ needs and wants. But we found out that there were a number of laser users who were older generation RF users that had moved to laser for one reason or another but liked RF better.

“So when it became known that there was an alternative to the older legacy RF competitive product, we started getting business from the laser users that we originally didn’t anticipate. We currently convert new laser users almost every month. But the bulk of our business is from current RF users.”

With all the new technologies on the market, Gibson said the Venclose marketing strategy is that a physician wants and needs multiple tools in his or her toolkit when treating chronic venous insufficiency because every patient condition is unique. But even with a growing number of treatment modalities available, he said they will augment, not replace, thermal therapies like RF.

“The way we think about the development of our product and the way we market it as well, is that RF and laser and all those new modalities are just tools for a physician to have in their procedure room, and physicians are going to use what’s necessary and best for that patient.”

This new RF technology is protected by a pending patents assigned to Venclose by four California Silicon Valley inventors.

A LASER USER’S VIEW

Richard Gitter, MD, a successful cardiothoracic and vascular surgeon for 14 years, returned home to New Orleans in 2013 to open the Gitter Vein Institute, where he had been satisfied using his Dornier laser to close veins for the last six years. Arizona consultant James Heinz, who has a master of health administration degree, subsequently evaluated Dr. Gitter’s practice.

“Man, you’ve got great results and a lot of patients who love you, but you’ve got a lot of bruising. Your patients are in bed for 24 hours and restricted for two weeks, and I just think you would be a lot happier if you tried this new Venclose RF system that just came out,” Heinz told him.

Dr. Gitter said the sales account executive from Venclose came out and he decided to try it, and “it has literally revolutionized my practice. Truthfully, it has revolutionized my practice.”

He has been using the Venclose RF System for almost a year, treating about 120 patients a month.

“I think the biggest thing for me has been patient referrals – they’ve just skyrocketed! And the reason they’ve skyrocketed is because it works, it works beautifully. There is no down time for the patient. They can go to the gym when they leave my office.

“Bruising is almost non-existent compared to what I’ve seen with my laser patents. You know, you get used to it [bruising] and it becomes your normal and then when it went away, it was beautiful. “

He said he used to put his laser patients on ibuprofen every six hours around the clock for two weeks. “They get nothing with the Venclose RF and they don’t want it. They’re happy.

“It’s like ‘frequently wrong but never in doubt.’ You think you know something, like most surgeons. We are frequently wrong, but we’re never in doubt. We thought laser was the end-all because it worked. It closed the vein. But then you see a device like Venclose, and the vein is still closed, but you’ve got none of the side effects.

“You don’t send your patients to bed and you don’t have any bruising and they don’t need any type of nonsteroidal. It’s a win-win,” Dr. Gitter said. “Now, couple that with really good people, an honest company, so that’s just a bonus.”

Dr. Gitter said he preferred his Dornier laser over the Covidien/Medtronic RF Closure system. “I had people trying to sell it to me for six years, but I didn’t want it because it took a lot longer than the laser. The treatment length in the vein was too short and – it was going from a 4 Fr to a 7 Fr change in catheter size, and their ClosureFAST catheter is pretty unforgiving.”

He said the Venclose system is truly new technology. “I like that it has a steerable catheter. It is a 6 Fr instead of a 7 Fr, and it really bounces beautifully off the vein wall; and you can steer it and make it go where you want it to go with just a little twist.

Dr. Gitter said that if you were to compare the tips of a Venclose RF catheter, a Medtronic RF catheter and a laser fiber, you could see how “beautifully user-friendly” the Venclose catheter is with its slight curve compared to the blunt tips of the laser and RF catheters. “That makes it so easy to maneuver. It is really nice.

“It is a bigger catheter than the 4 Fr I was using on my Dornier laser, but the 6 Fr is really short. I think I use a 10cm catheter versus the 35cm I was using on my Dornier, so it only has to go in two inches – it’s really nothing, and then it’s a bareback catheter that you can steer all the way through it.”

Dr. Gitter said that the steerable catheter, a long 10cm heating length to treat at one time and a 20-second treatment cycle added a lot of consistency to his treatments. “Because as precise as I was trying to be with the 1cm per second pullback on my Dornier I would still have some little segmental areas that were still open. “I don’t get that with this catheter.”

Using the Dornier and its catheters were less expensive, and the catheters could be cut and reused, but he said the Venclose system has so revolutionized his practice that it is obvious that price is not the major factor in success.

CORE VALUES AND MISSION

Gibson said the results Venclose has achieved are based on the company’s core values: positive, consistent clinical outcomes; strong physician relationships; and operational excellence.

“These values support our mission, which is to improve the physician and patient experience during chronic venous insufficiency treatment by commercializing the next-generation RF therapy,” the CEO said. “I think we’re right on track.” **VTN**

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