

SA-based Bluegrass Vascular eyes expansion to Africa, Middle East

The recruitment of <u>Bluegrass Vascular Technologies</u> Inc. from Kentucky to San Antonio is paying off in a big way as the company's CEO, Gabriele Niederauer, has led an aggressive global expansion strategy that is expected to take its initial product to at least two more continents in the next several months.

Bluegrass, which is still working to obtain the U.S. Food and Drug Administration's approval to sell its Surfacer Inside-Out Access Catheter System in this country, has locked up a presence in several European countries through a distribution deal with <u>Merit Medical Systems</u>. Now, it's pursing opportunities for commercialization worldwide, including Africa and the Middle East.

"We are now selling in seven countries. We are going to be adding additional countries and extending beyond Europe," Niederauer said. "Merit is already looking at Africa, the Middle East and expansion into other territories. We are working on the requirements in those countries so we can make the product available."

The Surfacer system provides what Bluegrass Vascular officials have described as reliable, efficient and repeatable central venous access to the right internal jugular vein — the optimal location for placing a central venous catheter. Those officials said the ability to secure such access more quickly leads to better patient outcomes.

"We are continuing to collect data on the experiences we are having in Europe. We are finding that, in the cases we've done, on average it takes 23 minutes for our system to be used," Niederauer said.

She said some more traditional approaches can take several hours.

"There is a huge economical and clinical benefit to being able to do this so much quicker," said Niederauer, who was in Denmark this week for the Cardiovascular and Interventional Radiological Society of Europe's 2017 annual meeting in Copenhagen, where Bluegrass was scheduled to make a series of presentations.

The expectation among Bluegrass management is that Europe will serve as a launch pad for further international penetration.

"We've been on the market in Europe for just over a year. We are really starting to see momentum and traction there," Niederauer said.

The ultimate goal is for Bluegrass Vascular to be able to bring its technology to market in the U.S. In the next few months, the company plans to launch additional clinical studies for its Surfacer technology. Those trials will support Bluegrass Vascular's planned submission to the FDA for approval to commercialize its product at home.

"We've got some very defined steps that we need to execute for U.S. approval," Niederauer said.

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