

Novel Emboli Protection Devices for Safer Cardiovascular Procedures



Ravish Sachar, MD - CEO

About Contego Medical

Contego Medical, based in Raleigh, NC, has developed a family of novel emboli protection devices. The main feature of each device is that the treatment portion (i.e., balloon or stent) is on the same catheter as the embolic protection device, thus coupling the two together. This device can act as an angioplasty balloon with an integrated emboli protection device. If a stent is mounted on the balloon, it can serve as a stent with an integrated emboli protection device.

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

CEOCFO: Dr. Sachar, what is the concept at Contego Medical?

Dr. Sachar: The number one cause of death in the US is cardiovascular disease. Blockages in the cardiovascular system are often treated with angioplasty and/or stenting. The blockage could be in the heart, could be in the neck artery, it could be an artery supplying the brain, it could be in the kidneys, it could be in the legs. There could be such blockages anywhere in the body. The goal at Contego is to make existing cardiovascular procedures safer.

The products that we have developed are in the field of embolic protection. During an angioplasty or stent procedure, the physician uses a balloon and stent catheters to open up a blockage in order to reestablish blood flow to the territory that is not getting enough blood flow. What happens though is when you go and you treat these blockages with a balloon or a stent, manipulation of these blockages can cause parts of that blockage to break off. When those small parts break off, they can travel with blood flow downstream and lodge in whatever organ is beyond the blockage. For example, if the blockage is in the neck and you are treating the blockage with a balloon or a stent, any part of that blockage breaks off can go up into the brain and cause a stroke. Similarly, if the blockage happens to be in the heart and it dislodges, it can cause a heart attack. In the kidneys it can cause kidney damage. In the legs it can cause leg damage and increase the risk of amputation of the leg.

CEOCFO: How is this problem being treated currently?

Dr. Sachar: The plaque that is treated with angioplasty or stenting is made up of cholesterol, thrombus and calcium. When part of this plaque breaks off and travels downstream, it is called an emboli particle. The process by which these particles break off and lodge into tissue downstream is called embolization. Currently, this problem is being treated by something called an embolic protection device – a device that is designed to protect against emboli. The first embolic protection device, called the Angioguard®, was invented by Contego co-founder Dr. Jay Yadav. This original device is a wire with an umbrella on the end of it. The use of it involves a multi-step procedure where the device is first advanced beyond the blockage and the umbrella is opened. Once the umbrella is open, then as the second step, the blockage is treated with a balloon or a stent. Then as a third step the balloon or stent catheter is removed, and as final step the umbrella removed. Therefore, there are a number of steps when current embolic protection devices are used.

CEOCFO: What have you figured out at Contego?

Dr. Sachar: The multistep process with currently available embolic protection current devices results in significant limitations. As a result of those limitations, embolic protection devices are currently being used in only about 26% of cases where they should be used. Contego has designed a system where the filter umbrella

is integrated onto the angioplasty balloon or stent catheter. In this integrated system, embolic protection and treatment are on the same platform as opposed to separate platforms. Therefore, anytime a blockage is treated with a balloon or stent, embolic protection can occur at the same time. It becomes a one-step process instead of a multi-step process, allowing embolic protection in a much larger number of patients as compared to current technology.

CEO CFO: *Is there any potential risk?*

Dr. Sachar: The risks are much lower as compared to current procedures with embolic protection because you have a shorter procedure with fewer steps. Shorter procedures with a reduction in the number of times equipment is being taken in and out of the vasculature results in safer procedures.

CEO CFO: *Where are you in the development and commercialization process?*

Dr. Sachar: Contego's first product, PALADIN, is already CE marked and we are currently in the process of commercialization.

CEO CFO: *How will you be marketing? Will you be using distributors or a direct sales force?*

Dr. Sachar: We will be using a distribution model initially.

CEO CFO: *Is there much training involved in using the product?*

Dr. Sachar: No, it is very simple and intuitive. It is just like putting a stent in. Therefore, anyone who trained in cardiovascular intervention can use this product with minimal additional training.

“Contego Medical’s integrated embolic protection platform is poised to revolutionize the field of embolic protection. We address a large market with a significant unmet clinical need in a way that is currently not being done by anyone else. We know that embolization occurs with every vascular intervention, but only the minority of patients can currently benefit from embolic protection. Contego Medical’s platform technology allows embolic protection for every patient. We make existing procedures faster and safer.” - Ravish Sachar, MD

CEO CFO: *Other than the typical reluctance for change and getting in front of people, how could a doctor possibly not want to use it?*

Dr. Sachar: We know that embolization occurs during all cardiovascular interventional procedures. Embolic protection should therefore be offered to all patients. However, current technology does not allow that. The Contego platform **does** enable embolic protection with every procedure.

CEO CFO: *Cost is becoming more and more important, so how do you get the cost down?*

Dr. Sachar: The cost of the Contego integrated platform is less than the cost of two separate devices (a separate stent and a separate embolic protection device).

CEO CFO: *Do you anticipate that cost will be a factor in getting the product utilized, particularly in the US?*

Dr. Sachar: I do believe that in the current economic and healthcare environment, any new product coming to market must not only improve procedural outcomes, but must also have an economic value proposition. The Contego platform does both.

CEO CFO: *You mentioned a number of different uses for this platform. How do you decide what you will be attacking? What is the order?*

Dr. Sachar: The first device we are commercializing, PALADIN, is for use during carotid artery stenting. This device is already CE marked, and addresses a significant unmet need. We will then commercialize other devices in a sequential manner.

CEO CFO: *What have you learned from past experiences that have been most applicable at Contego?*

Dr. Sachar: I think it is very important to address a clinical unmet need. If you have a product that addresses a significant unmet need, the chances of success are much higher.

CEO CFO: Are you funded for the next steps? Will you be seeking investment or funding?

Dr. Sachar: We are in the middle of a Series B raise right now.

CEO CFO: Certain medical conditions are in favor with investors at different points of time. Where do you see what you are offering? Is it an area of interest today from the investor standpoint?

Dr. Sachar: Cardiovascular disease is the number one killer in the western world and it is rapidly becoming the number one killer in the developing world as well. Thus overall cardiovascular procedural volumes are increasing worldwide. In the setting of this growing market, we have developed a platform technology which can be used in multiple vascular beds and allows current procedures to be performed more safely.

CEO CFO: Why should people pay attention to Contego Medical today?

Dr. Sachar: Contego Medical's integrated embolic protection platform is poised to revolutionize the field of embolic protection. We address a large market with a significant unmet clinical need in a way that is currently not being done by anyone else. We know that embolization occurs with every vascular intervention, but only the minority of patients can currently benefit from embolic protection. Contego Medical's platform technology allows embolic protection for every patient. We make existing procedures faster and safer.

BIO: Dr. Ravish Sachar is the founder and CEO of Contego Medical LLC. He is the inventor of the Contego embolic protection platform, and has extensive experience in medical device development. He is an interventional cardiologist with North Carolina Heart and Vascular in Raleigh, NC. He completed his fellowship in interventional cardiology and peripheral vascular intervention at The Cleveland Clinic. His clinical interests include carotid artery stenting, acute stroke intervention, and peripheral vascular disease. He has published extensively and is a frequent lecturer at national and international conferences. He has directed several teaching programs on carotid artery disease and peripheral vascular disease. He has co-authored two textbooks on peripheral vascular intervention. He holds fifteen issued or pending patents.



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