ISSN 2691-4093
JUNE - 2021

MED TECH OUTLOOK

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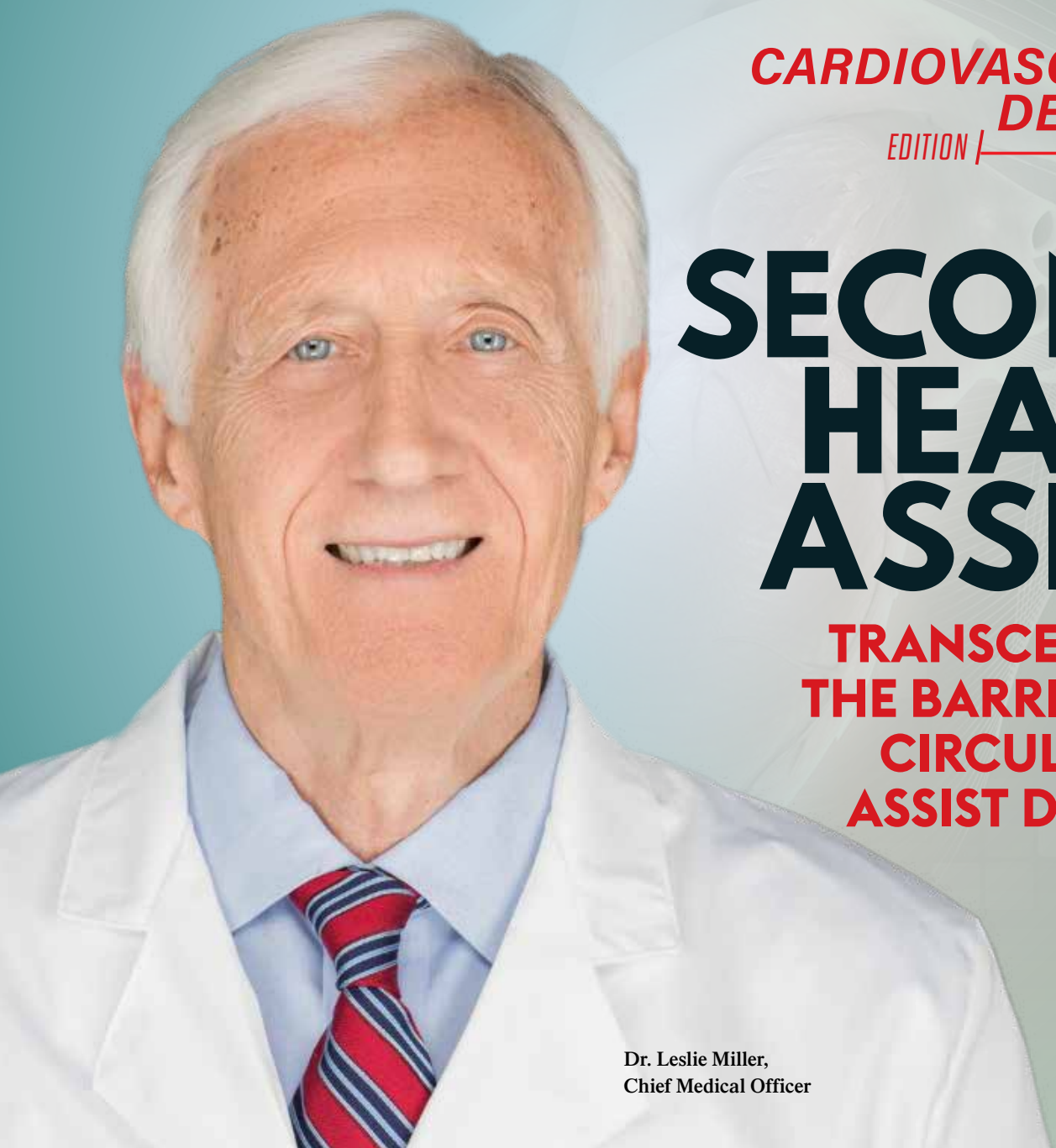
CARDIOVASCULAR DEVICES EDITION

SECOND HEART ASSIST

TRANSCENDING THE BARRIERS OF CIRCULATORY ASSIST DEVICES



Dr. Leslie Miller,
Chief Medical Officer

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MED TECH OUTLOOK TOP 10 EMERGING CARDIOVASCULAR DEVICE PROVIDERS - 2021

SECOND HEART ASSIST

TRANSCENDING THE BARRIERS OF CIRCULATORY ASSIST DEVICES

Howard Leonhardt,
Chairman & CEO

Cardiovascular disease, the number one cause of death worldwide, affects approximately eight million people in the United States and 30 million around the world. These diseases also account for the highest number of readmissions across hospitals due to the lack of effective care, and represent a staggering cost burden to our healthcare system of $70-75 billion annually. Recent findings have indicated that patients diagnosed with heart failure—the primary cause of hospitalization—spend more days in the hospital than any other diagnosis or medical procedure.

For patients suffering from heart failure, there is a dynamic interplay between heart and kidney function that often leads to cardiorenal syndrome, in which the kidney shares the risk factors associated with cardiovascular disease. Currently available circulatory assist devices, despite their general utility, could do more harm than good to the patient. Even after decades of development work, the makers of these devices have failed to address the many attendant problems including: inadequacies in achieving the necessary flow rates, device-specific thrombosis that can result in blockage of blood flow to vital organs, and higher impeller speeds that could potentially lead to hemolysis or pump displacement – three of the more prominent challenges faced by medical professionals. These complications are magnified to a greater degree when medical practitioners must deploy multiple circulatory assist devices within a single patient.

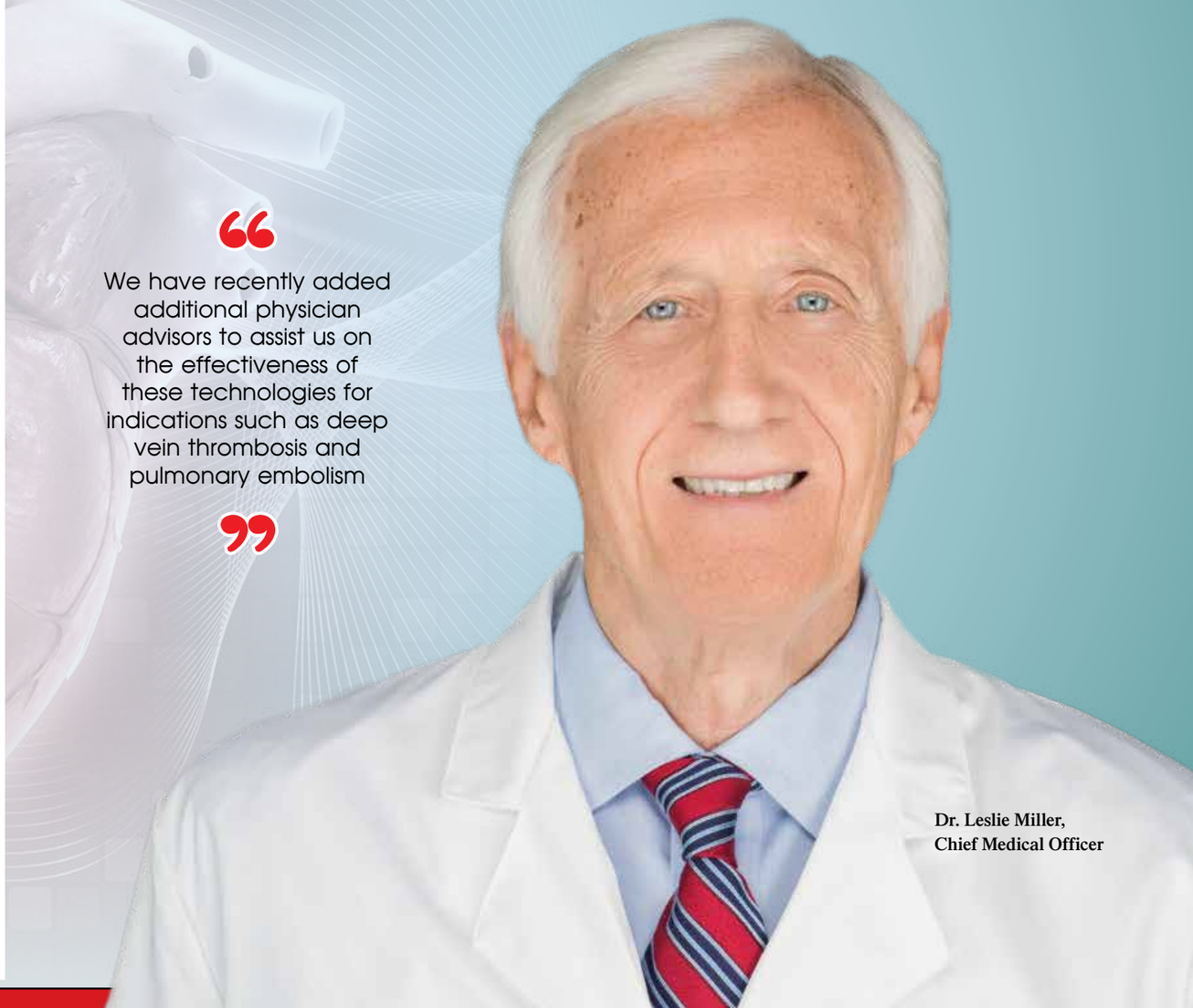
Moreover, essentially all pharmacological approaches have failed to deliver adequate improvement in quality of life or survival — it seems clear that this important medical problem needs a mechanical solution. And while current circulatory assist devices have enjoyed modest success, we believe that the Second Heart Assist device will represent a major step forward.

"More than 12 clinical trials, attempting to improve the outcomes of cardiovascular diagnosis and readmission scenarios have failed, unequivocally describing the current medical problem at hand," begins Dr. Leslie Miller, Chief Medical Officer at Second Heart Assist, highlighting the struggles faced by healthcare professionals in overcoming the above adversities.

The Mechanical Solution to a Medical Problem

"What makes our solution unique is the fact that it is the first truly aortic-stent-based circulatory assist pump; the

> "We have recently added additional physician advisors to assist us on the effectiveness of these technologies for indications such as deep vein thrombosis and pulmonary embolism"



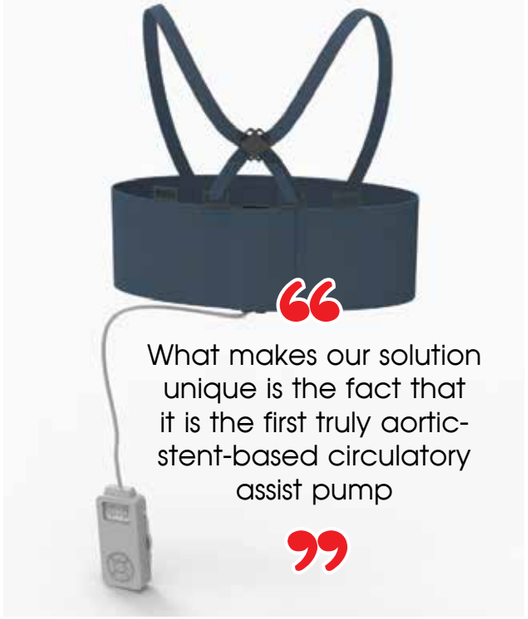
Dr. Leslie Miller,
Chief Medical Officer

device secures its position within the aorta, above the renal arteries," begins Howard Leonhardt, Chairman & CEO of Second Heart Assist. The collapsible stent pump design allows for low profile catheter-based introduction for easy and secure placement in the aorta. The radial force exerted by the device on the aortic wall helps it retain the original placement position without causing stiffness. Our first-generation device will be attached to a catheter used to power it. But importantly, this reliable and secure positioning feature paves the way for our next generation product, a fully implantable, self-contained, wirelessly powered device. Similar to our first-generation device, but without the drive catheter that runs outside the body. This fully implanted wireless device would address a patient population (heart failure) that is four times that of our first-generation product. We cannot possibly overstate the importance that a self-contained implanted assist device would have on a patient's quality of life – the ability to swim and bath freely, with no drivelines and tubes tethering one's body to either portable or bedside equipment. This indwelling device represents a holy grail in cardiovascular therapy. Many have tried, but all have fallen short of developing such a device, one that represents a tremendous benefit to so many patients in need.

Another critical performance feature of the Second Heart Assist device is its ability to improve cardiac output in a general sense, and specifically, because of its mid-aorta positioning, to improve blood flow to the renal arteries. This can improve kidney function by as much as 50% -- which in turn has a salutary impact on heart function. A virtuous cycle. Considering this collection of important performance improvements, Second Heart Assist could potentially be the first company to have an FDA-approved device for temporary percutaneous mechanical support – a breakthrough in the healthcare industry.

Interestingly, not long ago, Second Heart Assist had been working on a technology to deliver muscle stem cells to the damaged heart tissues, which surprisingly led to the development of the aortic-stent-based circulatory assist platform. The original thought for the Second Heart device was to place it in the aorta, above the renal arteries, allowing it to offload the heart's workload, thereby increasing perfusion and reviving the kidneys among cardiorenal patients with heart failure. This setup would keep the patient alive while Second Heart Assist's stem cell technology would provide for a "re-generation" of a heart -- indeed, one could say that the original idea for the company was to "bridge" this regeneration process.

While carrying out the research and development in this endeavor, Dr. Leslie Miller, Chief Medical Officer at Second Heart Assist, and several of the cardiovascular experts discovered the utility of the pump used within the



> What makes our solution unique is the fact that it is the first truly aortic-stent-based circulatory assist pump

platform and reckoned that it could be developed as an independent product. "In addition to serving as a bridge to heart regeneration, the pump allowed us to efficiently conduct transplant or recovery procedures or even help in the removal of excess fluids from the body," adds Leonhardt. This development marked one of the earliest milestones for Second Heart Assist as a company en route to offering a wirelessly powered circulatory assist device.

Achieving the Precise Engineering Equilibrium

Recollecting one of his early interactions with cardiovascular experts, Leonhardt highlights a critical value proposition of Second Heart Assist's solution. One of their advisors showcased a quintessential drawback of the currently available impeller devices to the Second Heart Assist leadership team– that of the displacement/migration of the device from its original position, sometimes within 30 minutes of the placement procedure. Though ultrasound is typically used to reposition the device, the technique does not offer a clear picture, often resulting in damage to the organs or the inaccurate repositioning of the device. Therefore, more often than not, patients are brought back to the laboratory for repositioning; and such realignments can become iterative or repetitive in nature.

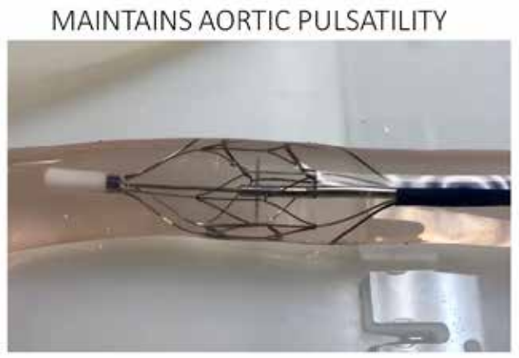
Upon conducting extensive research, animal trials, preclinical and clinical studies at various institutions, the leadership team at Second Heart Assist established two objectives:

1) To generate enough radial force applied by the stent cage in order to prevent the displacement of the device.

2) To prevent any damage to the aorta.

Conventional modalities to solve the displacement issue involved using hooks to anchor the position of the impeller device – a hazardous technique that could rip apart blood vessels. Engineering such a device was a herculean challenge on its own.

"We believe that one cannot interfere with the natural pulsatility (the inherent property of the cardiovascular system) of the aortic wall. Many people are under the misapprehension that the aorta serves only as a passive conduit to carry blood. We disagree with that assessment. We believe that the aorta is a critically important and dynamic organ for the entire health of the patient. In addition to managing the hemodynamics and blood pressure, it releases essential proteins that contribute to overall organ health," says Leonhardt. Upholding this philosophy in its design language, Second Heart Assist developed its proprietary aortic stent pump technology, which achieves the perfect radial balance, generating enough force to remain in its original position without causing any interruptions to the flow of blood or the pulsatility of the aorta. Second Heart Assist achieved this feat without using hooks or other anchoring devices that could very well damage the blood vessels. Such design versatility redefines cardiovascular treatments, thereby ensuring that blood vessels are undamaged, the device does not slip out of position (avoiding patient discomfort and realignment), and finally, allows adequate blood flow through the vessels, which would prevent greater adversities.



The Road to Commercialization

Second Heart Assist upholds a patient-safety first and efficacy second motto in developing products; it has successfully navigated through the preclinical testing and regulatory compliance procedures, succeeded by a series of animal studies as well. These tests were followed by computation fluid dynamics testing of circulatory assist pumps, proof of concept studies, and human trials, further validating the device's merits. All of the above advances indicate a breakthrough in

> This medical problem was in need of a mechanical solution

the healthcare regime that addresses a quintessential but highly critical need for cardiovascular patients.

Alongside the developments above, the capability to transmit power to the device wirelessly offers a long-term solution to patients suffering from chronic heart failure. The Second Heart Assist's system architecture eliminates the need for percutaneous wires or secondary TET (transcutaneous energy transfer) devices and equipment that limits a patient's quality of life and serves as a potential site for infection These merits, combined with Second Heart Assist's expertise in the cardiovascular sciences, have paved the way for an efficient commercialization route for the circulatory assist platform. The company has developed a business model that involves bringing technologies through clinical trials and the early regulatory process to the point where they become extraordinarily valuable to strategic acquirers.

"We have always had a plan that the full commercialization of our product would occur after our company was acquired by one of the larger, broad-based medical device companies. Note that we sold our previous cardiovascular product to Medtronic, at a time when sales were approaching $27 million. This family of products now account for approximately $1 billion in annual sales to Medtronic," explains Leonhardt. He says that the entire team realized the significance of partnering with a large global corporation with all of the necessary resources to make a product successful. The acquisition also reduced the cost involved in manufacturing and improved the device's safety as well, all the while allowing Medtronic to appeal to institutional investors. Second Heart Assist envisions partnering with such a leader in the industry and to ensure a better quality of life for patients through our circulatory assist platform," concludes the chairman.