

# Second Heart Assist's Whisper Device Poised to Advance AHA CKM Goals with Breakthrough Heart–Kidney Support

*Proven kidney perfusion, heart unloading, and low hemolysis in testing, Whisper sets a new standard in integrated care for heart failure and kidney disease.*

SALT LAKE CITY, CA, UNITED STATES, August 15, 2025 /EINPresswire.com/ -- Second Heart Assist, Inc. is introducing its Whisper percutaneous mechanical circulatory support device as a potential new force in the fight against cardiovascular–kidney–metabolic (CKM) disease. Whisper is designed to enhance kidney perfusion while unloading the heart, supported by low hemolysis results in FDA-requested bench testing.



Jeff Donofrio presenting Whisper at Octane's Annual Cardio Tech Forum in Newport Beach, CA

The American Heart Association (AHA) has declared CKM syndrome a public health emergency, with only 10% of U.S. adults meeting “excellent” CKM health standards. As the AHA expands its CKM initiative to 15 regions and 150 care sites, it is calling for earlier screening and integrated treatment that unites cardiology, nephrology, and metabolic care.

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*Jeff Donofrio, CEO- Second Heart Assist*

Whisper’s dual-organ approach was built to align with that vision.

Performance that benefits both heart and kidney  
Many older-generation devices require extremely high rotational speeds to increase kidney flow, which can also

raise red blood cell damage (hemolysis). Whisper is engineered for low-RPM performance and placed in the descending aorta just above the renal arteries. This position directs blood where

the kidneys need it most while easing the heart's workload.

"The industry has been forced to choose between protecting the heart or the kidney. Whisper proves you can, and must, do both," said Jeff Donofrio, CEO of Second Heart Assist. "We have seen it in our international results and in our hemolysis data. Our focus is on delivering solutions that are fast to deploy, safe for patients, and effective where it matters most."

#### Company-reported OUS results

- 28 patients treated outside the United States
- No device-related adverse events
- Average hospital stay of 48 hours
- Zero readmissions during the initial follow-up period
- Average deployment and initiation of treatment in under 2 minutes

#### Hemolysis advantage

In an FDA-requested in vitro study, Whisper showed approximately 50% less mechanical hemolysis than a comparator device (Impella) under identical conditions, operating at about 10,000 RPM versus more than 44,000 RPM required by the comparator to match flow.

#### Expert perspectives

Leslie W. Miller, MD, Chief Medical Officer, Second Heart Assist

"The CKM initiative will bring needed attention to the important dynamic interaction between the heart and kidney as heart failure triggers adverse responses in the kidneys that secondarily worsens kidney function and patients with intrinsic kidney impairment have a high incidence of secondary cardiac disease. The positioning of the SHA device provides simultaneous benefit to both the heart and kidneys by unloading the heart to increase cardiac output, and significantly increasing blood flow to the kidney to reverse the consequences of heart failure and stimulate the recovery of the function of both organs.

Rob Coronado, MD, Advisor, Second Heart Assist

"For patients with vulnerable kidneys, every moment of optimized perfusion matters. Whisper reflects the priorities of CKM care. It supports kidney health, protect the heart, and make the therapy simple, safe, and fast to deliver."

#### Why this matters

Heart failure readmissions remain among the most frequent and costly events in U.S. healthcare and are often linked to kidney decline. The AHA's CKM initiative emphasizes strategies that protect both organs to reduce complications, improve patient outcomes, and lower costs. Whisper's engineering and early results position it as a powerful candidate for this integrated approach.

#### Next steps

Second Heart Assist is preparing to launch its U.S. Early Feasibility Study, building on OUS

experience and published bench data, with the goal of helping health systems deliver on AHA CKM objectives in real-world care.

#### About Second Heart Assist

Second Heart Assist develops percutaneous and implantable circulatory support systems intended to improve hemodynamics while addressing kidney-relevant flow needs. The company's U.S. patent portfolio includes U.S. Patent No. 11,602,627 and related international applications covering stent-cage pump configurations and renal-adjacent positioning concepts.

Adam Steelwater

Innovative Tech Capital Network

[email us here](#)

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