

Newly Published Study Demonstrates Safety and Efficacy of Calyxo's CVAC Aspiration System for Patients with Large Kidney Stones

PLEASANTON, CA — November 14, 2023 – [Calyxo, Inc.](#), a medical device company focused on improving care for patients with kidney stones by delivering next-generation treatment solutions, announced this week that results of a new study analyzing the safety and efficacy of the SURE procedure for large kidney stone removal utilizing the company's CVAC Aspiration System have been published in the [Journal of Endourology](#).

This multi-center retrospective study of 43 patients with large renal stones was conducted by Karen Stern, MD of Mayo Clinic Arizona and J. Stuart Wolf Jr., MD of Dell Medical School at the University of Texas at Austin and was titled "*Steerable Ureteroscopic Renal Evacuation (SURE) for Large Renal Stones: A Multi-Institutional Center Study.*"

The study authors concluded that the CVAC Aspiration System is safe and effective for treating large stone burdens, including in high-risk patients (such as those on anticoagulants or with neurologic conditions), and may decrease the need for secondary procedures or more invasive percutaneous nephrolithotomy (PCNL).

In the study, SURE using the CVAC Aspiration System cleared nearly all kidney stones in a single procedure; on average, 96.1% of the stone volume was removed – and 90% of the patients who were expected to need two or more surgeries were successfully treated with a single SURE procedure.

"This study confirms that SURE with CVAC is an excellent option for patients with large stone burdens, especially patients who are high-risk to undergo PCNL or patients who prefer a more minimally invasive alternative to PCNL," said Dr. Stern.

This study builds on a previous safety and feasibility study published in the *Journal of Endourology* in 2022, which demonstrated that the CVAC Aspiration System could safely navigate throughout the kidney, remove significantly more kidney stone volume, and clear a higher proportion of it compared to traditional basket techniques.

"We now have two independent studies demonstrating that the SURE procedure using our novel CVAC Aspiration System is safe and removes a significant amount and proportion of kidney stone volume," said Calyxo President & CEO Joe Catanese, Ph.D. "Providing technology that can lead to a reduction in patient anxiety and the pain associated with passing stone fragments is a significant part of our mission at Calyxo. This new large-stone study is especially encouraging because it indicates patients may also be spared secondary procedures often required in kidney stone care. We are working to further demonstrate such results more broadly in a larger population of patients as we move towards redefining the standard of care for patients suffering from kidney stones."

The study also highlighted the importance of using additional metrics to more accurately measure outcomes of stone removal procedures. Stone-free rate (SFR), a standard binary metric which reports whether there are any residual stones, varied in the study from 33.3% to 45.8%

depending on the criteria for residual stone size, whereas the 96.1% stone clearance (percent stone volume removed) more precisely demonstrated the true effectiveness of the SURE procedure.

The CVAC Aspiration System is a novel technology that uses irrigation and aspiration to remove kidney stones after laser lithotripsy with the goal of a surgically stone-free outcome. Maximizing stone removal is important to decrease the risk of stone regrowth, emergency department visits and surgical retreatment, but complete removal is a challenge that has always been difficult to achieve consistently.

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“CVAC” is a registered trademark of Calyxo, Inc.

About Calyxo, Inc.

Calyxo, Inc. is an innovation-driven medical device company focused on improving care for patients with kidney stones by delivering paradigm-shifting solutions that enable urologists to safely, effectively and efficiently achieve unrivaled clinical outcomes. Learn more at calyxoinc.com.

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