

## **Calyxo Announces FDA Clearance for New, Redesigned CVAC System**

### *New Solution for Kidney Stone Treatment Already Used to Treat More than 50 Patients*

PLEASANTON, CA — March 26, 2024 — [Calyxo, Inc.](#), a medical device company developing innovative solutions for patients with kidney stones, announced that it has received FDA clearance for its new, redesigned CVAC System, which enables a minimally invasive approach to kidney stone treatment. More than 50 procedures have already been completed by 12 urologists with the new CVAC System, yielding strong patient outcomes and consistently positive physician feedback.

Clinical studies have shown that residual stone fragments are associated with a 20%-44% incidence of post-procedure problems including pain, infection, emergency department visits, hospitalization and need for retreatment.

Steerable ureteroscopic renal evacuation (SURE) using the original CVAC Aspiration System has been used to successfully treat more than 1,500 patients in the U.S., demonstrating that vacuum aspiration of stone fragments improves clinical outcomes, with 97% volumetric stone clearance and a high likelihood of avoiding the need for a secondary or more invasive procedure (according to clinical study data collected in patients treated with the device).

Based on learnings from over two years of real-world use, Calyxo reimagined its CVAC System to further enhance the SURE procedure. It is the world's only complete stone clearance solution that integrates ureteroscopy, laser lithotripsy, irrigation and aspiration in one device. By incorporating direct visualization with dedicated irrigation channels and a large aspiration lumen, the new CVAC System enables effective and efficient aspiration of kidney stones.

“Calyxo was founded to dramatically improve care for patients suffering from kidney stones,” said Calyxo’s President & CEO Joe Catanese, Ph.D. “We are excited to introduce the first complete stone clearance solution, which we believe will revolutionize how kidney stones are treated. By enabling the physician to continuously clear stone dust through passive aspiration during laser lithotripsy

and then remove residual fragments through active vacuum aspiration, the SURE procedure with our new CVAC System leads to highly effective stone clearance. We are gratified with the overwhelmingly positive feedback from urologists thus far and we are looking forward to making the technology more widely available in the coming months.”

“The most commonly used kidney stone treatments today do not reliably remove all of the stone fragments and dust,” said endourologist Brian Eisner, MD, Director of Kidney Stone Program, Massachusetts General Hospital (MGH) and founding clinical advisor to Calyxo. “We know that vacuum aspiration of stone fragments during ureteroscopy with laser lithotripsy under direct visualization provides unique advantages to enable better stone clearance for our patients who, in some cases, will experience a less invasive procedure with a decreased need for additional treatments.” Dr. Eisner is a pioneer in the field of kidney stone care and Calyxo has licensed technology from MGH.

Approximately 10% of people in the U.S. will have a kidney stone at some point in their lives, according to the American Urological Association. Kidney stone disease is a painful condition that brings with it significant healthcare costs (Current Urology Reports estimates \$4.1 billion in annual direct treatment costs by 2030).

*“CVAC” and “Calyxo” are registered trademarks 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](http://calyxoinc.com).*

Media Contact: Paul Williams, 310-569-0023,  
[paul@medialinecommunications.com](mailto:paul@medialinecommunications.com)