

# Roivios announces first patient enrolled in feasibility trial for JuxtaFlow® Renal Assist Device (RAD)

*The BIPASS-AKI trial is testing the use of JuxtaFlow in patients with renal impairment undergoing on-pump cardiac surgery*

ROSWELL, GEORGIA, US, October 10, 2023 /EINPresswire.com/ -- [Roivios](#) Ltd., a medical device company pioneering a revolutionary treatment to reduce poor surgical outcomes associated with Acute Kidney Injury (AKI), today announces the first patient has been enrolled in the [BIPASS-AKI](#) early feasibility study for the JuxtaFlow Renal Assist Device (RAD). Insertion of the proprietary JuxtaFlow catheters was overseen by principal investigators Prof. Slobodan Micovic and Dr Dragana Kosevic from the Institute for Cardiovascular Diseases Dedinje in Belgrade, Serbia. "This is an exciting moment for patients with renal insufficiency who undergo cardiac surgery," said Prof. Micovic "These individuals frequently develop post-surgical complications and become some of our most challenging and complex patients, so I am proud to be the first to offer this novel therapy in the study."

Cardiac surgery-associated AKI (CSA-AKI) occurs in up to 73% of patients who have preexisting renal insufficiency documented as part of their standard pre-surgical workup<sup>1</sup>. This type of AKI then impacts a patient's ability to recover from surgery, leading to a longer and more costly hospital stay, a higher risk of morbidity and mortality, and a more frequent need for chronic dialysis treatment 2-5. The JuxtaFlow RAD is used in the hospital setting where it enables the kidneys to function optimally and thereby improve overall patient outcomes. "Patients who develop AKI after cardiac surgery have few options. This unmet clinical need has driven the team at Roivios to design an innovative solution that enhances the kidneys' own natural ability to function without altering the patient's hemodynamic status in any way.", said John Erbey, PhD, Chief Executive Officer of Roivios. "We are incredibly excited about the opportunity to apply this novel therapy to at-risk patients and serve as the bridge to their successful recovery. We look forward to partnering with hospitals, surgeons, and critical care teams around the world who share our vision for reducing this all-too-frequent adverse event of surgery."

The BIPASS feasibility trial is being conducted pursuant to Medicines and Medical Devices Agency of Serbia (aka ALIMs) regulations. Ten patients will be enrolled across two hospitals in Serbia, one located in the capital of Belgrade and the other in the city of Sremska Kamenica. The JuxtaFlow RAD is not commercially available in any geography. The system is limited by United States law to Investigational Use Only and is not available for sale in the United States. For more

information about the JuxtaFlow RAD system, please visit [www.roivios.com](http://www.roivios.com)

For more information about BIPASS-AKI, see <https://clinicaltrials.gov/study/NCT05990660>

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#### About Roivios

Roivios is a medical device company pioneering a novel renal assist device designed to reduce or eliminate acute kidney injury (AKI) in patients who are at elevated risk.

Initially focused on meeting an unmet need of cardiac surgery associated-acute kidney injury (CSA-AKI) in the coronary artery bypass and surgical valve population, our pioneering renal assist device has the potential to address a range of poor outcomes.

Our first product, the JuxtaFlow Renal Assist Device, is the world's first negative pressure renal assist device, featuring a patented catheter and unique energy delivery system.

John Erbey

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