



## **New Meta-Analysis Presented at American College of Cardiology Strongly Supports RenalGuard Use in Cardiovascular Interventional Procedures**

*RenalGuard Found to Significantly Reduce Rates of Acute Kidney Injury Compared to Standard Urine Volume Expansion; RenalGuard Therapy Also Associated with Significantly Decreased Mortality, Major Adverse Cardiovascular Events, and Need for Dialysis*

MILFORD, Mass. — March 22, 2017 - A new meta-analysis presented this week at the American College of Cardiology further supports the ability of RenalGuard Therapy® to significantly reduce the incidence of acute kidney injury associated with cardiovascular interventional procedures compared to other methods of urine volume expansion. Moreover, findings from the analysis show the use of RenalGuard Therapy to be further associated with reduced risk of mortality, major adverse cardiovascular events, and the need for post-procedure dialysis.

"We are very pleased that independent analysis of the growing clinical data continues to support the potential of RenalGuard Therapy to significantly reduce the serious health risks associated with acute kidney injury related to cardiac interventional procedures," said Andrew Halpert, President of RenalGuard Solutions™. "In doing so, we believe RenalGuard® offers the potential to safely bring the important benefits of such medical interventions to more patients, especially those who have been considered at too high risk due to their reduced kidney function." Mr. Halpert noted that a U.S. pivotal clinical trial of RenalGuard was currently on track to complete at the end of 2017, and if positive, the company planned to seek U.S. marketing approval from the Food and Drug Administration in 2018.

### ***Meta-analysis Results***

The new meta-analysis, presented as a poster by researchers from the University of Texas Health Sciences Center, San Antonio, during the 2017 American College of Cardiology meeting on March 19, included data from nine studies comparing the use of RenalGuard to conventional volume expansion. Six were randomized controlled trials using RenalGuard in the treatment of patients undergoing various cardiovascular diagnostic and therapeutic interventions. Primary outcomes in the analysis included the incidence of contrast-induced acute kidney injury (CI-AKI) and relative risk (RR; the statistical probability that a particular event will occur). Secondary outcomes included the incidence of mortality, major adverse cardiovascular events, and the need for post-procedure dialysis.

The investigators found RenalGuard therapy to be associated with a significant risk reduction in CI-AKI compared to the control therapy (RR: 0.409; 95% CI: 0.282-0.591;  $p < 0.001$ ). The incidence of CI-AKI in RenalGuard-treated patients was 8.7% versus 23% in the control group ( $p < 0.001$ ). Use of RenalGuard was also associated with decreased mortality (RR 0.425, 95% CI: 0.183- 0.987,  $p = 0.047$ ), dialysis (RR 0.197; 95% CI 0.063-0.614,  $p=0.005$ ) and MACCE (RR 0.421, 95% CI: 0.273-0.651,  $p < 0.001$ ) compared to standard hydration.

### ***About RenalGuard Therapy***

RenalGuard measures a patient's urine output and automatically infuses hydration fluid based on that urine output. The system is designed to induce high urine rates, which have been shown to protect the kidney from a range of insults. A number of studies have demonstrated RenalGuard's ability to protect patients from AKI following catheterization procedures when compared to the standard of care, including: [MYTHOS](#), which found RenalGuard to be superior to overnight hydration; [REMEDIAL II](#), which found RenalGuard to be superior to sodium bicarbonate hydration; [Protect-TAVI](#), which reported a significant reduction in post-procedural acute kidney injury (AKI) following transcatheter aortic valve replacement (TAVR) when using RenalGuard during the procedure, compared to standard therapy; and [AKIGUARD](#), which showed significant improvement in long-term outcomes when using RenalGuard vs. standard therapy.

### ***About RenalGuard Solutions, Inc.***

RenalGuard Solutions, Inc. is a medical device company focused on innovative technologies for the cardiac and vascular markets. The company's lead product, RenalGuard, is designed to protect patients from acute kidney injury (AKI), including contrast-induced AKI. Investigator-sponsored studies in Europe have demonstrated RenalGuard's effectiveness at preventing CI-AKI in at-risk patients. RenalGuard is CE-marked and is sold in Europe and certain countries around the world via a network of distributors. The CIN-RG RenalGuard pivotal study is underway in the United States to support a planned Premarket Approval filing with the U.S. Food and Drug Administration. For further information, please visit the website at <http://www.renalguard.com>.

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