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# CryoLife HeRO can now rescue kidney patients

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**Singapore:** CryoLife, a leading tissue processing and medical device company focused on cardiac and vascular surgery, received US Food and Drug Administration nod for a next generation Hemodialysis Reliable Outflow (HeRO) device.

The device is subcutaneous AV access solution clinically proven to maintain long-term access for end-stage renal disease (ERSD) hemodialysis patients with central venous stenosis. CryoLife expects to launch the next generation HeRO device during the fourth quarter of 2013 following scale up and validation of the manufacturing process.

The newly approved version features an adaptor that provides the option to pair the HeRO device's proprietary venous outflow component with certain other available dialysis access grafts, including early access arterial grafts. The current generation includes a standard ePTFE graft, which requires the placement of a temporary dialysis catheter for approximately two-to-three weeks until the graft incorporates into the surrounding tissue and can be used for hemodialysis access. By design, early access grafts allow access in a matter of days, thus eliminating the need for an accompanying dialysis catheter.

Mr Steven G Anderson, chairman, president and CEO, CryoLife, said that, "We are pleased to receive FDA clearance for our next generation HeRO device, which will provide our customers with the option of using a standard or early access arterial graft in conjunction with the device's proprietary venous outflow component."

"Early access grafts eliminate the need for temporary dialysis catheters, which are associated with increased risk of infection, further enhancing the clinical benefits of the HeRO device. Over the next several months we will work to optimize and validate the manufacturing processes for this next generation system, which includes scaling up our manufacturing supply chain," he added.