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Rivanna Medical
press release
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Rivanna Medical Receives Health Canada Approval for Accuro Spinal Navigation System

CHARLOTTESVILLE, Va., April 25, 2017—Rivanna Medical, LLC today announced Health Canada approval for its innovative Accuro® automatic spinal navigation system for epidural and related neuroaxial anesthesia guidance. Research has shown that Accuro significantly increases first-attempt anesthesia needle placement, with identification of epidural space matching that of expert radiologists' in almost all cases.*

RIVANNA® Accuro has been in use in major U.S. hospitals since 2015, following its Federal Food and Drug Administration (FDA) 510k clearance. It will be sold throughout Canada by a network of specialized distribution partners.

"Accurate needle placement for epidural and related spinal anesthesia is challenging because physicians are essentially working blind and making assumptions about a patient's spinal anatomy," says RIVANNA Chairman and CEO Will Mauldin. "If incorrect, repeated needle sticks often result in decreased patient satisfaction and quality scores. They also increase costs by prolonging anesthesia procedures and any operating room time involved. Moreover, serious complications due to spinal anesthesia failure cost the healthcare system more than \$1.5 billion annually."

RIVANNA's pocket-sized, portable ultrasound guidance technology provides a highly effective solution to the problem. It is optimized for visualization of bony spinal anatomy, delivering a five- to 10-fold increase in bone-to-tissue contrast compared to traditional ultrasound, which is generally preferred for soft tissue imaging.

Complementing this, Accuro's SpineNav3D™ software uses specialized algorithms to interpret images and detect epidural location and depth measurements in real time. Automated interpretation eliminates the steep learning curve in ultrasound reading and makes the device practical and simple to use for anesthesiologists and other medical professionals who have not undergone training in the modality.

"A large body of research underscores the benefits of ultrasound for neuraxial anesthesia guidance," adds Adam Dixon, Ph.D., RIVANNA Director of Clinical R&D. "Now for the first time, RIVANNA Accuro makes this practical, cost-effective and safe even for expectant mothers, who cannot be exposed to the radiation involved in other imaging procedures."

RIVANNA will launch sales efforts in Canada in May.



ABOUT ACCURO

Accuro, by RIVANNA, is the world's first ultrasound-based system specifically designed to help anesthesia providers effortlessly apply spinal and epidural anesthesia. Accuro's revolutionary image-guidance platform features SpineNav3D™, which automates measurements of the spinal midline, epidural depth and trajectory, and BoneEnhance®, a technology innovation designed to visualize bone landmarks, making it easier and faster (compared to conventional ultrasound) to interpret the underlying image. Accuro supports a sterile environment for optimal patient safety. For anesthesia providers, certainty can be effortless with Accuro.

ABOUT RIVANNA

RIVANNA, located in Charlottesville, Virginia, is the innovative medical device company that imagined, engineered, and commercialized Accuro. Addressing the last frontier of image guidance in anesthesia, RIVANNA's revolutionary application of automated 3D-navigation technology to ultrasound imaging of the spine gives anesthesia providers an intuitive extension of their hands to precisely administer epidural and spinal anesthesia. This proprietary imaging device is FDA 510(k)-cleared for spinal-anesthesia guidance and a variety of additional imaging applications. For information about the easy-to-use Accuro or the medical device company RIVANNA, please visit rivannamedical.com.

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*M. Tiouririne, et al., "Imaging performance of a handheld ultrasound system with real-time computer-aided detection of lumbar spine anatomy: a feasibility study." Investigative Radiology. 2017; 52(8): 1-8.