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TransEnterix Names Tammy Barnes Carrea Vice President of Quality and Regulatory Affairs

RESEARCH TRIANGLE PARK, N.C. – TransEnterix has named Tammy Barnes Carrea vice president of quality and regulatory affairs.

At TransEnterix, Carrea is responsible for all operational and manufacturing-related quality and compliance issues, which include product clearances with appropriate U.S. and international regulatory agencies. Quality-related matters concerning pre-clinical trials, vigilance reporting and product design and development also fall under her scope of responsibility.

Carrea directed TransEnterix's two successful clearance applications with the U.S. Food and Drug Administration, which allows the company to begin commercially manufacturing and marketing its SPIDER™ Surgical System, a flexible laparoscopic surgical system.

"Safety and quality absolutely must serve as the foundation of any new medical device," said Todd M. Pope, president and CEO of TransEnterix. "Tammy's robust knowledge of regulatory affairs and quality control has been critical as TransEnterix takes its platform to market."

Carrea brings to TransEnterix more than 20 years of experience overseeing quality, regulatory and clinical affairs within the medical device industry.

Before joining TransEnterix, Carrea served as vice president of regulatory and clinical affairs at Sichel Technologies, a start-up medical device firm. Prior to that, she managed regulatory and quality affairs for new product development at Pharmanetics, a coagulation and drug monitoring diagnostics firm.

Carrea holds a bachelor's of science degree in materials science and engineering from N.C. State University, where she also completed post-graduate studies in materials science-film deposition. She holds a medical devices certificate in regulatory affairs from the Temple University School of Pharmacy. A certified quality auditor with the American Society for Quality, Carrea is regulatory affairs certified by the Regulatory Affairs Professional Society.

TransEnterix partners with world-renowned surgeons to rapidly innovate new treatments and technologies capable of transforming the field of minimally invasive surgery. The company has secured an aggregate of \$75 million in venture capital funding.

TransEnterix is introducing its SPIDER™ Surgical System, which combines the minimally invasive nature of catheter-based surgery with the procedural familiarity of traditional rigid laparoscopic surgery. The innovation promises to create an entirely new category of surgery – flexible laparoscopy.

Flexible laparoscopy features triangulation achieved via single-site access, "true left" and "true right" instrumentation, flexible and articulating instruments, a stable single-operator system, and an open platform with four working channels.