



neoSurgical® Begins Postmarket Surveillance Study of FDA-Cleared neoClose® Versus Standard of Care for Closing Port Site Incisions in Lap and Robotic Surgeries

Company also reports commercial milestone of 7000 US procedures using its disruptive technology neoClose®

Three recently published* clinical studies show that hernia incidence is often “grossly under-diagnosed” and “highly prevalent” in port site closures after Lap and Robotic surgeries, which can trigger a vicious cycle of repeat surgical interventions and hernia repairs.

NEWTON, Mass.--([BUSINESS WIRE](#))--neoSurgical Inc. announced today that it has begun a Postmarket Surveillance Study of its FDA-cleared device, neoClose®, at University of Texas Health Sciences Center at Houston. The randomized study will compare neoClose® against the standard of care for closure in a bariatric surgery gastric bypass population of 70 adults aged 18-70 years with BMI > 35.

Principal investigators include: Erik B. Wilson, MD, Professor of Surgery; Peter A. Walker, MD, Assistant Professor of Surgery; and, Shinil K. Shah, DO, Assistant Professor of Surgery. (More about the clinical trial at <https://clinicaltrials.gov/ct2/show/NCT02589171> and neosurgical.com/clinical) “Surgeons in hospitals across the United States are rapidly adopting our neoClose® device. This Postmarket Surveillance Study is intended to build our clinical evidence behind neoClose® and to begin to establish the superiority of neoClose® versus the standard of care for closing port sites — a standard that absolutely must be improved to enhance patient outcomes and safety,” said Barry Russell, CEO of neoSurgical.

Laparoscopic abdominal surgery requires small incisions or “port sites” in the abdomen. The port site must be closed after Lap surgery. While Lap surgery itself is minimally invasive, “herniation,” or protrusion of abdominal tissue through the port site after closure (commonly referred to as “trocar site hernia,” or “TSH,” among doctors), can lead to morbidity due to small bowel strangulation, for example, or nerve and vessel entrapment, resulting in infection, bleeding and pain.

Until 2014, TSH complications were thought to occur at a reported rate of about 1-6% among the six million Lap surgery port sites closed each year. But in a groundbreaking clinical study (Comajuncosas, J, et al. Risk factors for umbilical trocar site incisional hernia in laparoscopic cholecystectomy: a prospective 3-year follow-up study. *Am J Surg.* 2014 Jan; 207(1):-6), nearly 26% of patients were diagnosed with TSHs. Thus, TSHs have been grossly under-diagnosed.

Following the Comajuncosas study, a second published study (Scozzari et al. High incidence of trocar site hernia after laparoscopic or robotic Roux-en-Y gastric bypass. *SurgEndosc.* 2014 Oct; 28(10):2890-8), the total trocar site hernia rate was 39.3% at three years.

Most recently a third, multi-institutional study (Holihan JL et al. Adverse events after Ventral Hernia repair: The vicious Cycle of complications, JACS 2015) revealed that hernia occurrence can lead to a repetitive cycle of repeat procedures and complications. The standard for port site closure has been Closed Loop Suture. Now, there's neoClose®. neoClose® works by the use of a Vector X closure, approximating the tissue together and tying into place for a secure closure with up to 75% less tension compared to standard closed loop suture.

neoSurgical® is a commercial-stage company focused on being a global leader in the development of innovative surgical products. The company's initial product is neoClose®, approved for sale in the US and Europe and designed to be the new standard for Lap surgery port site closure, a potential \$300 million opportunity. The company's neoClose® system for port site closure after Laparoscopic ("Lap") surgery has now been used more than 7000 times in hospitals across the US.

** Comanjuncosas J. et al, Risk factors for umbilical trocar site incisional hernia in laparoscopic cholecystectomy: a prospective 3-year follow up study Am J Surg. 2014 Jan; 207(1):1-6.*

** Scozzari G, et al. High incidence of trocar site hernia after laparoscopic or robotic Roux-en-Y gastric bypass. Surg Endosc. 2014 Oct; 28(10):2890-8*

** Holihan JL et al. Adverse events after Ventral Hernia repair: The vicious Cycle of complications, J Am Coll Surg. 2015*

Source: <http://www.businesswire.com/news/home/20160119006730/en/neoSurgical%C2%AE-Begins-Postmarket-Surveillance-Study-FDA-Cleared-neoClose%C2%AE>

January 19th 2016