



# neoSurgical Limited Expands Indications For neoClose Device

*Closing port site incisions up to 30mm may include bariatric,  
colorectal and cholecystectomy Lap surgeries*

NEWTON, Mass.--(BUSINESS WIRE)--neoSurgical Inc. announced today that it has expanded its neoClose® product offerings to include port site incisions up to 30mm (3cm), which may include bariatric, colorectal and cholecystectomy Lap surgeries. The FDA-cleared neoClose® device may now be used to close port site incisions from 5mm to 30mm (3cm) in length.

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Laparoscopic (“Lap”) 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.

More than three million laparoscopic procedures annually in the U.S. require closure, of which about 25 percent currently use a port site closure device. Unfortunately, 5-50, 1, 2, 3 percent of all laparoscopic incisions herniate. And, there is a 10-45 percent chance of recurrence after a first hernia. With lap surgery in-patient costs as high as \$30,000, herniation and recurring herniation add \$3 billion annually in costs to the U.S. healthcare system.

“Surgeons in hospitals across the United States now have the opportunity to perform the gamut of standard laparoscopic surgeries using our neoClose® device,” said Barry Russell, CEO of neoSurgical. “The reason that neoClose® is being adopted so rapidly by Lap surgeons is because of the demonstrated clinical superiority of neoClose® versus standard of care techniques for closing port sites — a decades-old standard, by the way, that must be recast in order to improve patient outcomes and safety.”

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. Surg Endosc. 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 10,000 times in hospitals across the US.

1 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):1-6.

2 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

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

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