

Key Opinion Leader (KOL) Calls for New Standard to Close Port-Site Hernias in Lap and Robotic Surgeries

Three recently published* clinical studies show that hernia occurrence 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.

"The risk of port-site herniation is really understated. It's a risk that must be addressed because of the potential complication. I am sure through use of neoClose[®] that we are going to see a marked reduction," said Charles E. Miller, M.D., Past President (2007 – 2008) of the AAGL (formerly known as the American Association of Gynecologic Laparoscopists).

NEWTON, Mass.--(<u>BUSINESS WIRE</u>)--<u>neoSurgical Inc.</u> announced today that it will exhibit its FDAcleared neoClose device in Booth #711 at the upcoming "AAGL 2015 Global Congress" in Las Vegas, Nov. 15-19.

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 <u>Vector X closure</u>, approximating the tissue together and tying into place for a secure closure with up to 75% less tension compared to standard closed loop suture.

"neoClose[®] offers a very innovative way of closing the port site, of closing that incision," said Charles E. Miller, MD, Past President (2007 – 2008) of the AAGL, the world's largest organization dedicated to minimally invasive gynecologic surgery; Past President (2011 -2013) of the International Society for Gynecologic Endoscopy (ISGE); Treasurer of the ISGE; Director of Minimally Invasive Gynecologic Surgery and the Director of the AAGL/SRS Fellowship in Minimally Invasive Gynecologic Surgery at Advocate Lutheran General Hospital (Park Ridge, IL.). Dr. Miller is on the Editorial Board of OB/GYN News where he edits the most widely read column in gynecology – The Master Class in Gynecologic Surgery. Dr. Miller is on the Editorial Advisory Board of the Journal of Minimally Invasive Gynecologic Surgery (JMIG). Dr. Miller also is a Clinical Associate Professor, Department OB/GYN, for the University of Illinois at Chicago and the University of Chicago.

"We are extremely pleased that an eminent physician such as Dr. Miller appreciates innovation that enhances patient outcomes and safety," added Barry Russell, CEO of neoSurgical[®].

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 4000 times in hospitals across the US.

NOTE: Dr. Charles Miller received no compensation for his participation in this News Release. For more information, please see his participation in the Video Interview that is accessible through this News Release and posted at <u>www.neosurgical.com</u>.

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