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ProGEL Lung Surgery Device Gets FDA Approval

Neomend's Sealant Technology Is Only One of Its Kind in the U.S.

IRVINE, Calif. -- [Neomend](#), Inc., an innovator in sealant and adhesion-prevention products for the surgical marketplace, announced it has received premarket approval from the U.S. Food and Drug Administration (FDA) for the company's ProGEL™ Pleural Air Leak Sealant.

ProGEL is a hydrogel polymer sealant consisting of two components: human serum albumin and a cross-linking component of polyethylene glycol. When they are mixed together, a rapid reaction occurs that creates a hydrogel matrix which results in the formation of a strong, adherent and flexible seal.

ProGEL is intended for application to visceral pleura during an open thoracotomy after standard visceral pleural closure with, for example, sutures or staples, of visible air leaks (≥ 2 mm) incurred during open resection of lung parenchyma. ProGEL™ Pleural Air Leak Sealant is the only such product with this specific approved indication in the United States.

“We are very excited to receive this approval and be in a position to provide this unique technology to the surgeons and patients who greatly need it,” said David Renzi, the company's President and CEO. “This technology has also been shown to reduce hospital stay days, a benefit that can significantly reduce the total cost of these procedures to the hospital. Neomend will move quickly to bring this important product to market.”

FDA approval came following a multi-center clinical study on the device that encompassed 161 patients in five institutions: Mayo Clinic, Cedars-Sinai Medical Center, Duke University, MD Anderson Cancer Center, and the University of Washington.

ProGEL was shown to be 77% effective in sealing air leaks intra-operatively, compared to 16% for the control group. The device led to a statistically significant reduction in both intraoperative air leaks and hospital stay of nearly two days.

The newly available device addresses a current, unmet surgical need to seal pleural air leaks incurred during lung surgery. The company estimates approximately 150,000 lung resections are performed in the United States every year. Intraoperative air leaks are a primary complication of lung surgery and can lead to other complications such as infections, pneumonia and extended hospitalization.

Neomend, based in Irvine, Calif., is focused on the design, development and commercialization of surgical sealants and adhesion prevention products derived from the ProGEL technology platform. For more information, visit www.Neomend.com or call 949-916-1630

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