Air leaks are one of the most common complications associated with pulmonary surgery, and when left untreated can lead to additional complications and morbidities that extend inpatient hospitalization and increase healthcare costs.

Clinically Proven to Seal Air Leaks and Reduce Length of Stay

Progel® Pleural Air Leak Sealant was evaluated in a prospective, randomized, controlled multi-center trial and demonstrated significantly improved clinical outcomes:

**Key Endpoints**

- Effectively sealed intraoperative air leaks
- Significantly reduced postoperative air leaks
- Reduced hospital length of stay by 1.9 days
- Minimized associated complications and morbidities
- Provided incidental cost-of-care savings

**Applicator Spray Tips**
- Initiates mixing of hydrogel components
- Allows for variable spray patterns
- Additional Spray Tips now sold separately

**Ergonomic Applicator Design**
- Simple set up in less than 2 minutes
- Easy-to-use
- No spray apparatus required

**Specialized Chemistry Formulation**
- Gel formation < 30 seconds
- Flexible high strength seal within 5 minutes
- Resorption < 30 days*

*Resorption time demonstrated through pre-clinical evaluation testing.

**Variable Spray Patterns**

**STREAM**
Ideal for targeted application along staple lines or sutures

**SPRAY**
Manual control for application to larger tissue surfaces

**Extended Applicator Spray Tips**
- Progel Extended Spray Tip 11" (29 cm)
- Progel Extended Spray Tip 6" (16 cm)
- Progel Standard Applicator Spray Tip

**Applicator Spray Tips NOT shown actual size.**
See full product labeling for complete Instructions For Use and important safety information.
Clinical & Economic Validation

*Annals of Thoracic Surgery* 2004; 77:1792-1801

**Prospective Randomized Study Evaluating a Biodegradable Polymeric Sealant for Sealing Intraoperative Air Leaks That Occur During Pulmonary Resection**


**Key Endpoints (Progel® vs. control):**
- 61% increase in successfully sealed intraoperative air leaks
- 21% increase in successfully sealed patients remaining air leak free at 1 month
- 1.9 days mean reduction in length of stay (1 day median)

**Conclusion:**
This study demonstrates the effectiveness of Progel®, a biodegradable polymer when used in adjunct to standard closure methods for sealing significant intraoperative air leaks that develop from pulmonary surgery. Use of Progel® led to a reduction in POAL, which may have decreased length of hospitalization.

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**The Cost of Air Leak: Physicians’ and Patients’ Perspectives**

Adam Lackey, MD, John D. Mitchell, MD

**Key Points:**
- Total additional hospital costs attributed to persistent air leaks has been reported to be roughly $53,000.
- Presence of prolonged air leaks have been associated with increased incidences of other postoperative complications.
- Use of Heimlich valve or other ambulatory chest drainage burdens patients with additional direct and indirect treatment related costs.
INTENDED USE / INDICATIONS FOR USE
Progel Pleural Air Leak Sealant is a single use device 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.

CONTRAINDICATIONS
• Do not use Progel PALS in patients who have a history of an allergic reaction to Human Serum Albumin or other device components.
• Do not use Progel PALS in patients who may have insufficient renal capacity for clearance of the Progel PALS polyethylene glycol load.
• Do not apply Progel PALS on open or closed defects of main stem or lobar bronchi due to a possible increase in the incidence of broncho-pleural fistulae, including patients undergoing pneumonectomy, any sleeve resection or bronchoplasty.
• Do not apply Progel PALS on oxidized regenerated cellulose, absorbable gelatin sponges or any other surface other than visceral pleura as adherence and intended outcome may be compromised.
• Do not use more than 30 ml of Progel PALS per patient.

WARNINGS
Progel PALS safety and effectiveness was evaluated in 5 patients with FEV1 ≤ 40%, providing limited data about Progel PALS use in patients with FEV1 ≤ 40%. For patients with preop FEV1 ≤ or > 40%, mean (median) chest tube placement duration for patients with FEV1 ≤ 40% was 6.3 (7.0) days for Progel PALS and 5.8 (4.5) days for Control subjects; for patients with FEV1 > 40%, the mean (median) chest tube placement duration was 6.8 (5.0) days for Progel PALS and 6.2 (5.5) days for the Control cohort.

PRECAUTIONS
The safety and effectiveness of Progel PALS has not been established in patients with the following conditions:
• Less than 18 years of age, pregnant or nursing women.
• Contaminated or dirty pulmonary resection cases.
• The presence of an active infection.
• In the presence of other sealants, hemostatic devices or products other than sutures and staples used in standard visceral pleural closure.
• Visceral pleural air leak due to spontaneous pneumothorax, any non resective pulmonary tissue trauma, or malignancy as well as congenital or acquired functional or anatomic defect.
• Patients receiving Progel PALS in more than one application session (surgery) before and/or after resorption of Progel PALS that was applied in any previous surgical session.
• In any area or tissue other than the visceral pleural surface as indicated.

ADVERSE EVENTS
There were 3 subjects in the Progel PALS group with AEs that were considered by the investigator to be possibly or probably related to the device. The AEs reported were: chest pain, constipation, gastroesophageal reflux, nausea, cough, dyspnea, pneumothorax, and subcutaneous emphysema. All were reported as a single occurrence in the Progel PALS group. Two of the AEs, dyspnea and chest pain, were reported as “severe” and “serious”, respectively and occurred in the same subject. All others were reported as mild or moderate.

In a clinical trial there were reports of renal dysfunction, urinary system disorders and deaths within the study population. None of these have been confirmed to be associated with ProGel. The details of these clinical trial adverse events can be reviewed in the IFU supplied with the product and also available at www.neomend.com.

Caution: Federal (USA) law restricts this device to sale by or on order of a licensed physician or properly licensed practitioner.

1 Progel Pleural Air Leak Sealant Pre-Market Approval Study. Davol Inc. data on file.

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