

A Sealant Indicated for Pleural Air Leaks

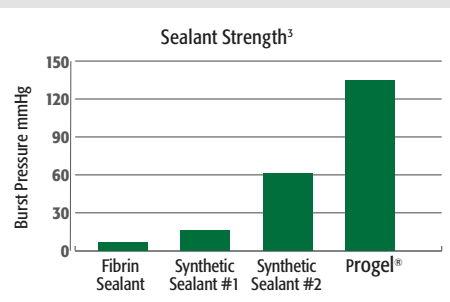
Progel[®] Platinum Surgical Sealant is a resorbable hydrogel designed to seal air leaks incurred during pulmonary surgery. Progel[®] Platinum biocompatible formula combines a unique solution of recombinant Human Albumin (rHA) with Polyethylene Glycol to provide strength, flexibility and unmatched adherence to visceral pleura.

Specifically Designed for Thoracic Surgeons

Progel[®] Platinum is the only sealant chemically engineered for application to the lung in the treatment of intraoperative air leaks:

Key Features

- Forms a **strong, flexible** hydrogel within 15-30 seconds of application.
- Adheres to visceral pleura to maintain seal **strength over time**.
- **Resorbs** within 30 days to promote natural healing.



Clinically Proven to Seal Air Leaks and Reduce Length of Stay in a US PMA Approved Product in a Comparative Clinical Study in the US with Human Serum Albumin.¹

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.

Progel[®] Platinum Surgical Sealant was evaluated in a prospective, randomized, controlled multi-center trial and demonstrated significantly improved clinical outcomes. This was a US study evaluating Progel[®] Pleural Air Leak Sealant (PALS) equivalent to Progel[®] Platinum Surgical Sealant except that Progel[®] PALS includes Human Serum Albumin and Progel[®] Platinum includes a recombinant Human Albumin derived from yeast.

Key Endpoints

- Effectively sealed intraoperative air leaks¹
- Significantly reduced postoperative air leaks¹
- Reduced hospital length of stay by 1.9 days¹
- Minimized associated complications and morbidities^{1,2}
- Provided incidental cost-of-care savings^{1,2}

The information and data shown is based on a Progel[®] formulation that includes Human Serum Albumin (HSA). Progel[®] Platinum uses recombinant Human Albumin in place of HSA.

1. Allen, Mark S. et al, Prospective Randomized Study Evaluating a Biodegradable Polymeric Sealant for Sealing Intraoperative Air Leaks That Occur During Pulmonary Resection. *Annals of Thoracic Surgery* 2004; 77:1792-1801. (Pivotal study. Data on file.)

2. Gremmen, Eric et al. Assessment of the Clinical and Economic Impact of Air Leaks During Post-Operative Pulmonary Surgery. *International Society for Pharmacoeconomics and Outcomes Research* 2010.

3. Campbell, Patrick K., PhD, et al. Evaluation of Absorbable Surgical Sealants: In vitro Testing. © 2005

Intuitive System Makes Set Up and Application Easy

Patented Progel® 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



Minimal pressure applied to applicator

SPRAY

Manual control for application to larger tissue surfaces



Increasing pressure applied to applicator

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.

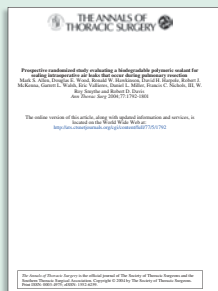
See full product labeling for complete Instructions For Use and important safety information.

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*

Mark S. Allen, Douglas E. Wood, Ronald W. Hawkinson, David H. Harpole, Robert J. McKenna, Garrett L. Walsh, Eric Vallieres, Daniel L. Miller, Francis C. Nichols, III, W. Roy Smythe and Robert D. Davis.

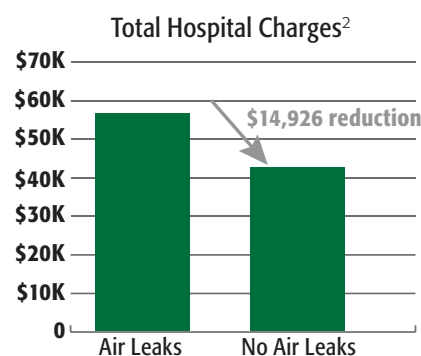
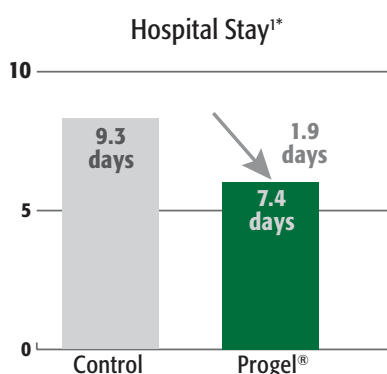
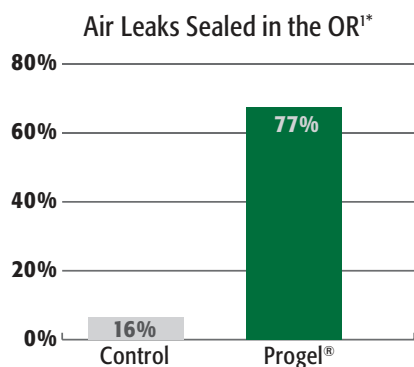


Key Endpoints (Progel® vs. control):

- 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.



Thoracic Surg Clin 20 (2010) 407-411

The Cost of Air Leak: Physicians' and Patients' Perspectives

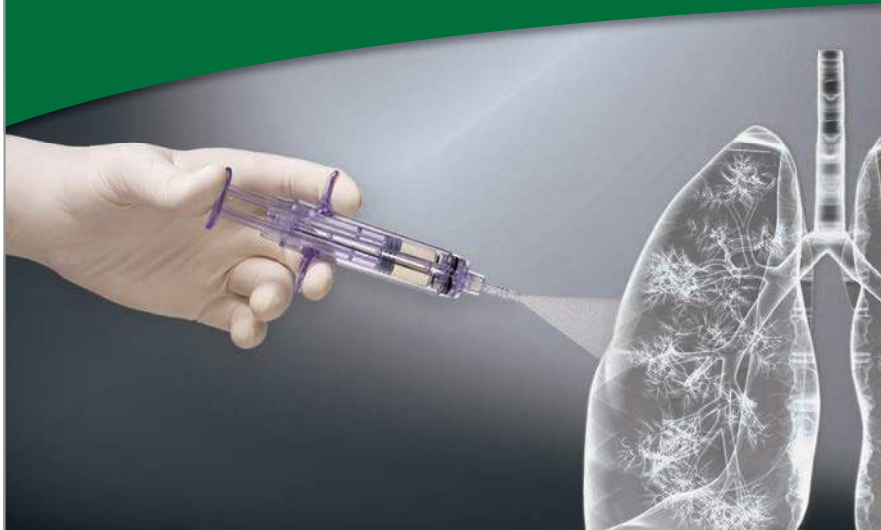
Adam Lackey, MD, John D. Mitchell, MD



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.

*A US study evaluating Progel® Pleural Air Leak Sealant (PALS) equivalent to Progel® Platinum Surgical Sealant except that Progel® PALS includes Human Serum Albumin and Progel® Platinum includes a recombinant Human Albumin derived from yeast.



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Ordering Information

Product Codes:

Catalogue Number	Qty	Description
PGSS008	4/cs.	Progel® Platinum Surgical Sealant (4 ml)
PGST010	10/box	Progel® Applicator Spray Tips
PGEN00516	4/cs.	Progel® Extended Applicator Spray Tip (16 cm)
PGEN00529	4/cs.	Progel® Extended Applicator Spray Tip (29 cm)

INTENDED USE / INDICATIONS FOR USE

Progel Platinum Surgical Sealant is a single use device intended for application to visible air leaks on the visceral pleura after standard visceral pleural closure techniques have been employed during resection of lung parenchyma.

CONTRAINDICATIONS

- Do not use Progel Platinum in patients who have a history of an allergic reaction to yeast, rHA or other device components.
- Do not use Progel Platinum in patients who may have insufficient renal capacity for clearance of the Progel Platinum polyethylene glycol load.
- Do not apply Progel Platinum 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 Platinum 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 Platinum per patient.

WARNINGS

Progel Platinum should be used only as described in these instructions for use.

The Progel Platinum should be refrigerated between 2°C to 8°C (36°F to 46°F).

Do not freeze. Store the Progel Platinum within the recommended temperature range. Failure to do so may result in poor product performance. Do not use Progel Platinum after the expiration date, as sterility or performance may be compromised.

- Inspect the packages before opening. Do not use Progel Platinum after the "Expiration" date, because sterility or performance may be compromised. If package and/or product integrity have been compromised (i.e., damaged package seal, or broken glass), do not use or resterilize the contents. Refer to other 'precautions' in this IFU.

PRECAUTIONS

The safety and effectiveness of Progel Platinum 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.
- In any area or tissue other than the visceral pleural surface as indicated.



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