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.

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 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

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.

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

Spray
Manual control for application to larger tissue surfaces

Minimal pressure applied to applicator

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

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.


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.
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 have a history of an allergic reaction to yeast, rHA or other device components.
• 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 of lung parenchyma.
• 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.

• 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.

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.

• 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.

• 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.