Progel™ Pleural Air Leak Sealant

Clinically proven to seal air leaks and reduce length of stay by 1.9 days.¹
Complementing your thoracic technique. Reinforcing your most important work.

Progel™ Pleural Air Leak Sealant (PALS) is a unique option that can help you address postoperative air leak complications. Progel™ PALS is clinically proven to seal pleural air leaks and reduce length of hospital stay. It is specifically designed to complement your surgical technique—reinforcing and protecting the meticulous work you perform.

Adherence
- Flows easily into the tissue's intricate anatomy
- Cross-linking continues at the tissue site
- Direct contact with the visceral pleura for strength in adherence

Strength
- Begins to form a hydrogel within 15–30 seconds
- Reaches adequate strength within 2 minutes
- Supports seal strength during critical postoperative period

Flexibility
- Engineered to be flexible
- Able to expand and contract during respiration
- Provides elasticity with a strong seal

Proprietary science and technology designed to optimize patient outcomes

Progel™ PALS is a specialized sealant comprised of a proprietary combination of human serum albumin (HSA) and polyethylene glycol (PEG). The resulting hydrogel provides strength, flexibility and adherence to the visceral pleura.

HSA: optimal contact and adherence
Human serum albumin (HSA) is a large protein molecule that provides Progel™ PALS with its adhesive strength.

PEG: strength and flexibility
The proprietary polyethylene glycol (PEG) used in the Progel™ PALS formulation is a non-toxic, non-immunogenic molecule which lends the hydrogel its ability to stretch.

The Progel™ PALS sealing cascade
The only FDA-approved product for adjunctive treatment of pleural air leaks, Progel™ PALS forms a highly-flexible hydrogel specifically designed for use on the lung.

2 Progel™ Pleural Air Leak Sealant Instructions for Use. M-00443.
3 Theodore, Pierre, et al. Surgical sealant physical characteristics in vitro comparison to mitigate lung air leaks 2012. Davol Inc. In vitro testing. Data on file. In vitro test results may not correlate to clinical performance. Five samples of each device were included in each in vitro test. The elongation modulus of Progel™ was significantly less than that of BioGlue® (p < 0.05) and comparable to that of COSEAL® and DuraSeal™. Progel™ burst strength at time zero was significantly greater than that of COSEAL®, TISSEEL®, BioGlue® and DuraSeal™ (p < 0.05).
See full product labeling for complete Instructions For Use and important safety information.
The **only sealant** designed specifically for the lung and its unique characteristics

**Variable spray patterns for targeted application**

Our patented spray tips allow for variable spray patterns from a single, easy-to-use device. Customize your Progel™ PALS technique using a stream for targeted application to sutures and staple lines, or increase surface coverage using a fine mist to reinforce where needed.

**Clinically proven to seal leaks**

Evaluated in a prospective, randomized, multi-center trial, Progel™ PALS was also shown to significantly improve clinical outcomes. When used as indicated, Progel™ PALS can effectively seal intraoperative air leaks and significantly reduce the incidence of postoperative air leaks.¹

![Hospital stay comparison chart](chart.jpg)

**Hospital stay**

Shown to reduce the length of hospitalization by 1.9 mean days, potentially minimizing associated complications and cost-of-care.¹

**Extended applicator spray tips**

Progel™ PALS extended spray tip 6” (16 cm)

Progel™ PALS extended spray tip 11” (29 cm)

**Evaluate Progel™ PALS in your next 10 patients**

See firsthand how Progel™ PALS can complement your surgical technique and potentially impact your patient outcomes. We invite you to try Progel™ PALS in your next 10 lung resection cases.

**Talk to a BD sales representative about participating in the Progel™ challenge.**
Indications
Progel™ Pleural Air Leak Sealant is a single use device intended for application to visceral pleura after standard visceral pleural closure with, for example, sutures or staples, of visible air leaks incurred during 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 bronchopleural fistulae, including patients undergoing pneumonectomy, any sleeve resection or bronchoplasty.

Warnings
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.

Adverse Events
In a pivotal clinical trial there were three patients in the Progel™ PALS group with adverse events that were considered by the investigator to be possibly or probably related to the device. The adverse events 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 adverse events, dyspnea and chest pain, were reported as “severe” and “serious,” respectively and occurred in the same patient. All others were reported as mild or moderate. There were also reports of renal dysfunction, urinary system disorders and deaths within the study population. None of these have been confirmed to be associated with Progel™ PALS.

In a subsequent minimally invasive clinical trial there were no device-related adverse events or unanticipated adverse events. The majority of adverse events reported in this study were mild or moderate in severity. The majority of serious adverse events were pulmonary and expected events as part of a lung resection surgery. Two patients died during the course of the study, one due to cardiac arrest and another due to multi-system organ failure; neither was device-related or unanticipated.

The details of these clinical trial adverse events can be reviewed in the Instructions for Use supplied with the product and are also available at bd.com.

To learn more, contact your local BD sales representative or call +1.800.556.6275.

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DAV/PALS/0715/0071