1. Preparation – sterile field

Step 1: Draw 2 mL of sterile water

Step 2: Inject 2 mL sterile water into the white powder cartridge

Step 3: Mix for 1-2 minutes until powder is dissolved

*Note: Progel™ Pleural Air Leak Sealant must be used within 20 minutes of mixing*

Step 4: Load cartridges

*Note: Properly loaded cartridges will sit flush with the end of the applicator housing*

Step 5: Insert locking push rod

*Note: Once inserted, the push rod should not be removed*

Step 6: Express air

Step 7: Wipe applicator tip clean

Step 8: Attach spray tip
2. Application

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.

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

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