

Progel[®] Pleural Air Leak Sealant Extended Applicator Spray Tip

The Progel[®] Pleural Air Leak Sealant Extended Applicator Spray Tip package is provided sterile.

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

1.0 DEVICE DESCRIPTION

The Extended Applicator Spray Tip is a single-use medical device that is designed to be used with the Progel Pleural Air Leak Sealant (Progel PALS) Applicator.

Each box includes:

- Four (4) - Individually Packaged Extended Applicator Spray Tips
- One (1) - Instructions for Use (Labeling)

2.0 INTENDED USE/INDICATIONS FOR USE

The Progel Extended Applicator Spray Tip is intended to deliver Progel PALS to visceral pleura during an open thorotomy after standard visceral pleural closure (i.e. with sutures or staples) of visible air leaks ($\geq 2\text{mm}$) incurred during open resection of lung parenchyma in adult humans by bending the malleable tip to direct Progel PALS from the delivery tip in a stream or spray cone pattern that is perpendicular to the target surface.

3.0 INSTRUCTIONS FOR USE

If using the Extended Applicator Spray Tip on a newly assembled kit

Refer to the instructions for use enclosed in the original Progel PALS kit (REF # PGPS002) for proper kit preparation instructions, then follow Step 2 through Step 4 to properly attach the Extended Applicator Spray Tip.

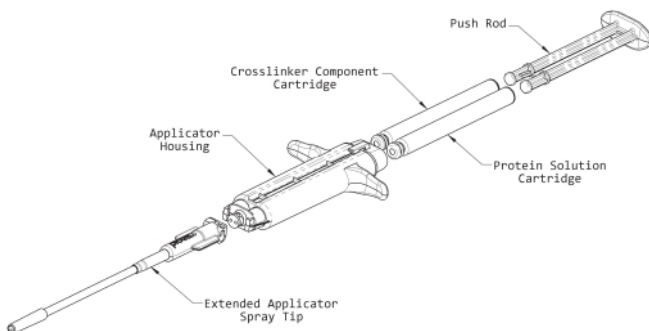
If using the Extended Applicator Spray Tip as a replacement tip:

Refer to the following instructions.

Step 1

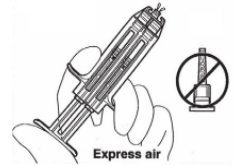
Remove the existing Spray Tip from the Applicator Housing (see Figure 1 below for Spray Tip location).

FIGURE 1 Progel Pleural Air Leak Sealant Delivery System with Extended Applicator Spray Tip



Step 2

With the tip of the applicator pointed upward, express air and a small amount of fluid to verify that the housing is patent and free from clogs. Take care to express as little fluid as possible during this process.



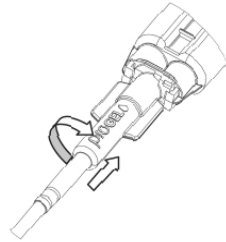
Step 3

Wipe the applicator tip with clean, sterile gauze to remove any liquid that may have been expressed or remains on the nose. Avoid mixing of components: do not wipe from one cartridge opening across to the other - wipe each opening separately.



Step 4

Place an Extended Applicator Spray Tip on the tip of the applicator and rotate Extended Applicator Spray Tip clockwise 1/4 turn until locked.



Step 5

The Progel PALS is ready for application.

Caution: The Extended Applicator Spray Tip is not intended to be used for tissue manipulation. Excessive pressure on the end of the spray tip may cause a leak in material between the spray tip and the applicator housing.

4.0 SYMBOL DEFINITIONS

Symbol	Definition
	Catalogue Number
	Batch Code
	Use By
	Sterilized using Ethylene Oxide
	Prescription use only
	Manufacturer



Neomend, Inc.
60 Technology Drive
Irvine, CA 92618
www.neomend.com
Customer Service: 1-888-776-4351