

# WHITEPAPER

## Foil Pouch Packaging for Medical Electrodes

### More than Meets the Eye

At first glance, foil pouches may appear to be a simple solution for packaging—merely a metallic enclosure surrounding medical products. However, beneath this unassuming exterior lies a highly engineered structure designed to meet complex functional and regulatory demands. For medical electrodes, which are particularly sensitive to environmental conditions, foil pouches are far more than just containers; they are critical components of the product system itself. This whitepaper summarizes the nuanced construction, functional attributes, and manufacturing considerations that make foil pouches a sophisticated and indispensable choice for electrode packaging.



### Purpose of Foil Pouch Packaging for Electrodes

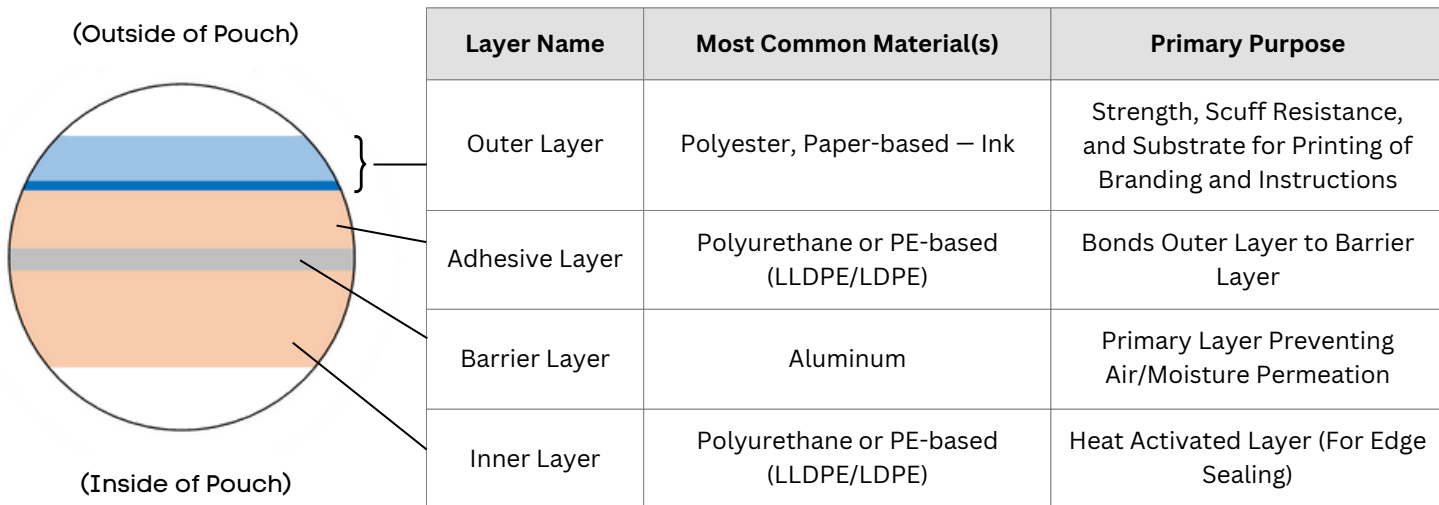
Medical electrodes are sensitive to environmental factors such as moisture, oxygen, light, and contamination. Exposure to these elements can lead to:

- Drying or degradation of hydrogels and adhesives
- Oxidation or corrosion of conductive elements (e.g., silver or Ag/AgCl)
- Reduced adhesion and patient comfort
- Overall, reduced shelf life

Foil pouch packaging provides a robust barrier that protects electrodes from these factors, ensuring consistent product performance up to the point of use.

# BASIC CONTRUCTION OF FOIL POUCHES

Foil pouches used for medical electrode packaging are manufactured by laminating several sub components layers together, each serving a specific function. These sub components can vary by manufacture, however, here is breakdown of the typical layers used and their functionality composed of multiple laminated layers, each serving a specific function:



## KEY FUNCTIONAL PROPERTIES

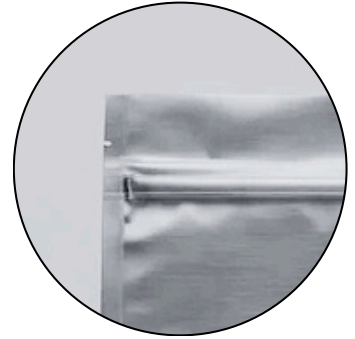
Foil pouches for electrodes must meet several critical functional requirements:

- 1 Barrier Properties:** The aluminum layer is essential for blocking oxygen (OTR: ~0 cc/m<sup>2</sup>/day) and moisture (WVTR: near-zero). This prevents degradation of hydrogels, adhesives, and conductive materials.
- 2 Mechanical Durability:** The pouch must resist punctures, tears, and abrasion during handling, shipping, and storage. Laminates with PET and nylon provide additional strength.
- 3 Heat Sealability:** The inner layer must form consistent, high-integrity seals under controlled heat and pressure. Seal quality is essential for maintaining barrier properties.
- 4 Chemical Compatibility:** The inner sealant must not interact with the electrode materials, particularly hydrogels and conductive gels.
- 5 Printability and Labeling:** The outer layer should support high-resolution printing for labeling, instructions, lot codes, and branding. Reverse printing on PET protects the ink from abrasion.

# VARIATIONS IN FOIL POUCH DESIGN

Foil pouch designs can vary based on specific product needs:

- **Tear Notches:** Allow for easy opening by user.
- **Peelable Seals:** Designed for easy opening by end-users or clinicians without tools
- **Re-closable Features:** Rare in single-use medical electrodes, but may be used for multi-use applications
- **Shaped or Formed Pouches:** Custom dies can create shaped pouches to fit specific electrode geometries



## MANUFACTURING CONSIDERATIONS

**a. Lamination Process:** Inner layer laminations are typically produced using dry-bond lamination with heat-activated or solventless adhesives. The process must ensure even adhesive coverage, no delamination, and stable performance over the product's shelf life.

**b. Pouch Forming and Sealing:** Pouches are formed and sealed using horizontal form-fill-seal (HFFS) or vertical form-fill-seal (VFFS) equipment. Sealing parameters must be tightly controlled to avoid weak or inconsistent seals.

**c. Quality Control Testing:** Routine testing related to foil pouches includes:

- Seal strength and integrity (e.g. peel tests)
- Visual inspection for delamination, seal uniformity, or contamination
- Barrier property testing (OTR and WVTR)

**d. Regulatory and Compliance Aspects:** Foil pouches for medical electrodes must meet applicable regulatory standards:

- **FDA 21 CFR** for materials in contact with medical devices
- **ISO 10993** for biocompatibility (inner layer only)

Lot traceability, labeling, and change control are essential parts of regulatory compliance for medical packaging.

## CONCLUSION

Although they may look like simple metallic envelopes, foil pouches used in medical electrode packaging are thoughtfully engineered items that play a critical role in ensuring product performance and patient safety. Every layer, adhesive, and seal is chosen with precision to deliver moisture protection, oxygen resistance, chemical compatibility, and mechanical strength. These complex requirements must be met without compromising usability or regulatory compliance. More than meets the eye, these packages are a critical component in ensuring the robustness and longevity of a custom medical electrode.