



PET Heat Shrink

FOR REFLOW APPLICATIONS

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For Reflow Applications

Introduction

Nordson MEDICAL has developed a new application using the currently offered standard Polyethylene Terephthalate heat shrink tubing (PHST) material, with a 3 mil (0.003”) wall thickness, for catheter reflow processing. Reflow processing is a manufacturing application/process that utilizes convection heating to laminate multiple layers of a catheter’s shaft together into one unified piece. These layers can include, but are not limited to, the following: polymer materials, liners, coils, braids, and electrodes.

The heat is applied in a concise and controlled manner, using specific equipment with specialized heater nozzles, to create a layered catheter shaft that is uniform and tailored to the intended application requirements. Various common properties that are sought after through the reflow process include flexibility, durability, lubricity, and strength.

Background

Polyester heat shrink tubing is a high-performance, Per- and Polyfluoroalkyl substances (PFAS) - free alternative to Fluorinated Ethylene Propylene (FEP) heat shrink for reflow applications. Nordson MEDICAL’s 0.003” wall Polyethylene Terephthalate (PET) reflow heat shrink line delivers equivalent lamination results while increasing the line speed of traditional FEP, which assists in a reduction of costs and increased throughput.

The reflow application development is backed by 40 years of Nordson MEDICAL innovation in PET heat shrink tubing. This reflow product is engineered to seamlessly bond common jacket materials, such as PEBAX and Nylon, while offering consistent quality and affordability.

Nordson MEDICAL’s catheter reflow process was developed on a commercially available vertical laminator. The general process steps and outputs of the reflow operation are summarized in the adjacent column.



Reflow Laminator and Clamped 100g Weight

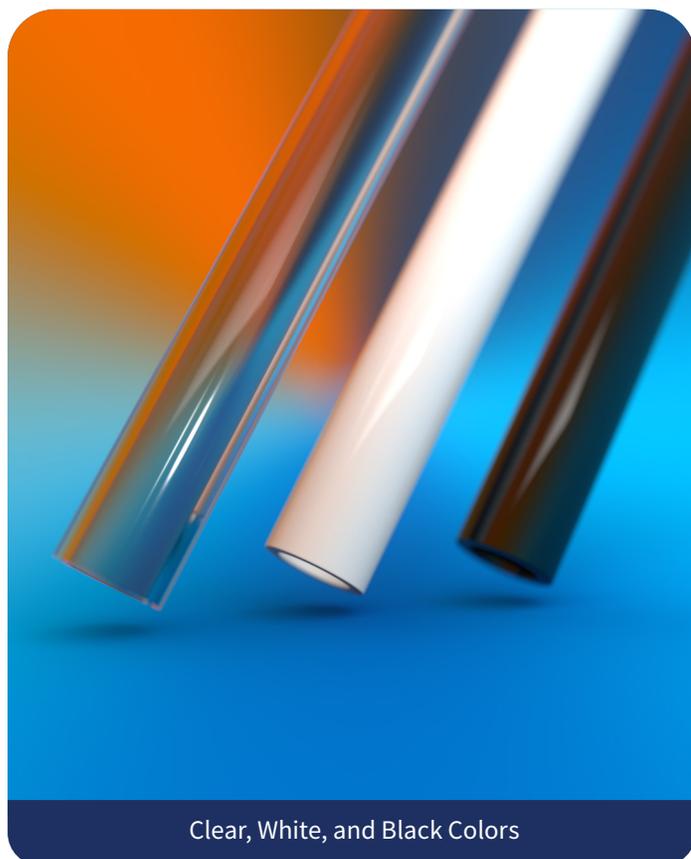
PROCESS STEPS AND FUNCTIONALITY USING REFLOW LAMINATOR

- **Layering:** Common catheter construction involves the layering of materials, typically an inner liner, tie layer (if necessary), and an outer jacket are slid over a mandrel core. Braids or coils can also be added to provide structural support.
- **Heating:** The prepared catheter shaft layers are exposed to heat from the calibrated reflow nozzle and undergo a controlled heating action.
- **Lamination:** The most essential outcome of the reflow process, lamination is achieved when the heat from the reflow nozzle melts and bonds the different layers together.
- **Uniformity:** Utilizing clamps outside of the reflow zone allows the catheter shaft materials to stay in place while the reflow nozzle moves in a controlled manner along the length of the catheter.
- **Shrinking:** The outer heat-shrink layer will shrink down during the reflow process and help compress the layers together during and immediately after lamination.
- **Weighting:** Clamping a 100 gram weight onto the end of the PET heat shrink during reflow ensures optimal shrinkage and lamination.

Purpose - Why use a reflow process for catheter manufacturing?

ADVANTAGES AND BENEFITS OF THE CATHETER REFLOW PROCESS

- **Increased production efficiency:** Reflow machines are available with multiple channels to increase production volume while reducing scrap from manual operations.
- **Customization:** Machines can be customized for specific design requirements, such as different diameters, lengths, materials, or additional features that are needed for unique medical treatments that require catheters.
- **Enhanced catheter performance:** A unified shaft can be laminated with the appropriate flexibility and strength for end use medical applications.
- **Elevated biocompatibility:** Layering materials allows for the combination of various properties to help achieve higher performance and biocompatibility.
- **Process control:** Reflow machines are capable of delivering precise control for the two most important process parameters: temperature and line speed. This results in a more dependable, repeatable, and reliable product compared to the use of traditional ovens.



Scope

PFAS materials are commonly used in many different industries and products. Since Nordson MEDICAL's Salem, New Hampshire, USA facility manufactures medical device components for customers who use PFAS materials such as FEP in their finished devices, the decision was made to focus on PFAS-free alternatives to FEP heat shrink for applications like engineered catheter shafts.

Nordson MEDICAL's Product Innovation (PI) team investigated the commercially available standard PET heat shrink, that is manufactured in-house, to determine if this product could be used for reflow applications specific to building engineered catheter shafts. Due to the thinner-walled (3 mil, 0.003") PET heat shrink, it was paramount to ensure that the proper balance of temperature and line speed could be achieved in order to laminate the inner and outer catheter shaft materials and provide a peel strength that is equivalent to that of FEP heat shrink. See page 4 for the peel strength test results.

In addition to evaluating the peel strength, increased temperatures and line speeds were experimented with for the purpose of determining if PET heat shrink can achieve a higher throughput compared to FEP heat shrink.

Materials

ADDITIONAL MECHANICAL/ELECTRICAL PROPERTIES OF PET HEAT SHRINK REFLOW

- Very high tensile strength up to and exceeding 20,000 psi depending upon tubing design
- Extremely smooth surface finish of ID transfers to process components
- Available in clear, white, and black (other colors may be available upon request)
- Meets USP Class VI and ISO 10993 requirements

OUTER JACKETS USED FOR REFLOW DEVELOPMENT

- PEBAX 35D
- PEBAX 55D
- PEBAX 72D
- Polyamide 12 (Nylon ML24)

COMPATIBILITY

PET Reflow Heat Shrink is PFAS-free and releases easily from most common thermoplastics such as PEBAX and Polyamide 12.

Peel Strength Testing and Results

Goal: To quantify the peel force while separating the inner liner (PTFE/PEBAX 72D) from the outer jacket material (PEBAX 55D) after using two different heat shrink materials: FEP heat shrink and PET heat shrink, to make reflow catheter samples.

REFLOW PARAMETERS

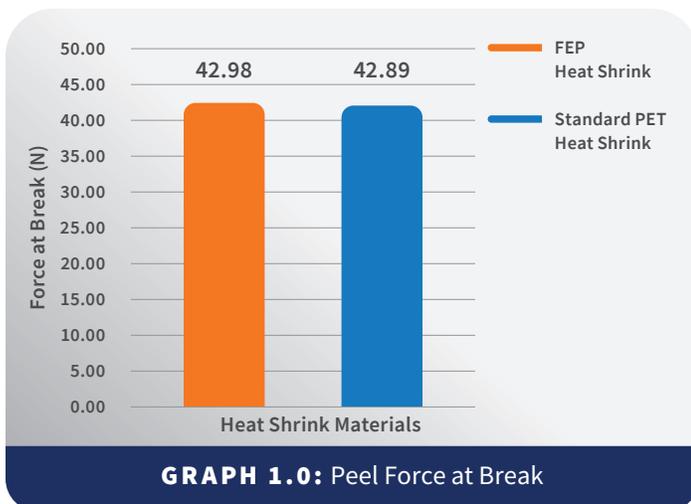
Reflow Temp	Reflow Speed	Heat Shrink Material Used
480°F	1.2 mm/s	FEP
450°F	2.0 mm/s	PET

TESTING PROCESS

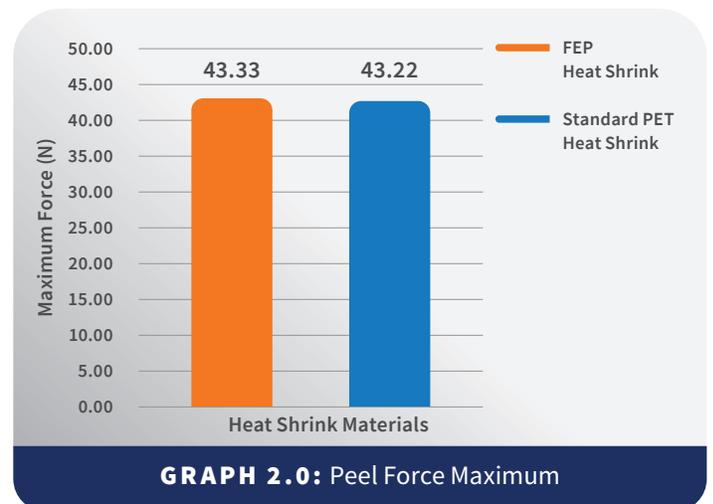
- A total of 10 samples from each heat shrink material were tested.
- After the removal of the heat shrink material, each sample was cut lengthwise.
- Displacement and force values were zeroed before each sample was tested.
- The samples were clamped into the reflow machine's pneumatic grips. The bottom grip clamped the PTFE liner of the sample, while the top grip clamped the outer jacket material (PEBAX 55D) of the corresponding sample.
- The samples did not have slack within the PTFE liner or outer jacket.



Peel Strength Testing Process



GRAPH 1.0: Peel Force at Break



GRAPH 2.0: Peel Force Maximum

Increased Manufacturing Throughput

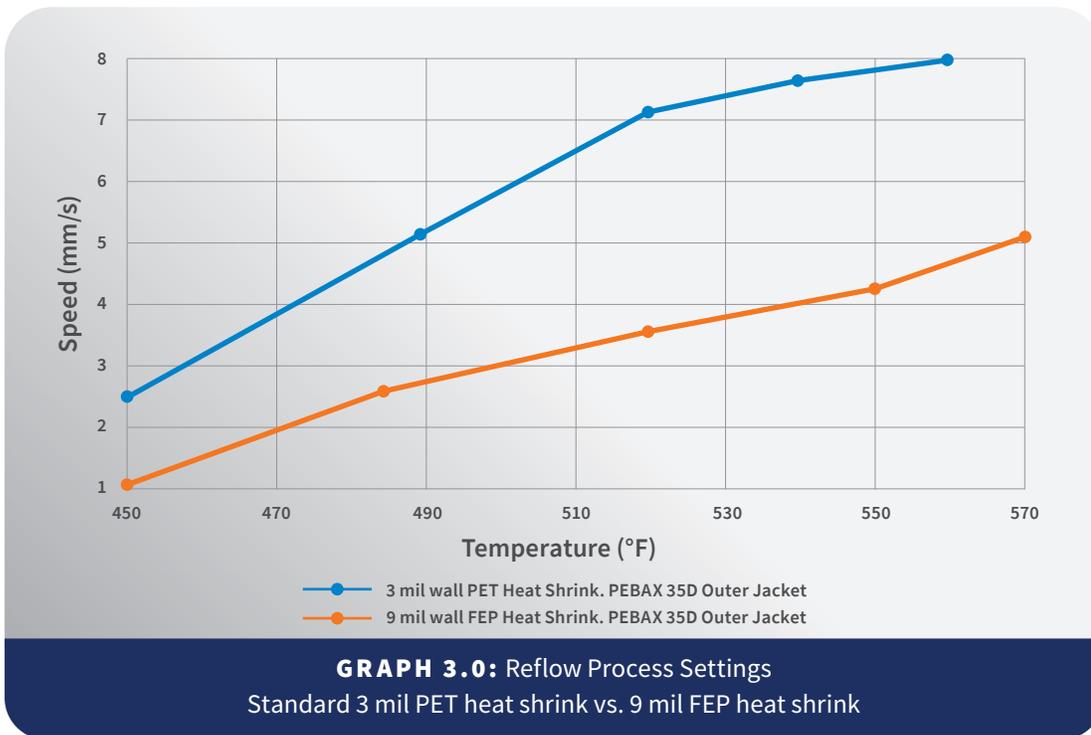
Goal: Create a Design of Experiment (DOE) that will assess the ability of utilizing PET heat shrink to process reflow samples at higher reflow nozzle temperatures and line speeds.

TESTING PROCESS

Samples were prepared to be the same lengths, and coated mandrels were pulled from the same lots. Material variability was minimized by using the same outer jacket polymer shaft (PEBAX 35D).

MATERIAL DIMENSIONS

Material	Inner Diameter (inches)	Wall Thickness (inches)	Outer Diameter (inches)
Outer Jacket PEBAX 35D	0.082	0.0035	0.089
PET Heat Shrink	0.100	0.003	0.106
FEP Heat Shrink	0.098	0.009	0.116



Each data point above represents the speed (mm/s) and temperature (°F) of the reflow process. These parameter combinations resulted in complete reflow of the laminated catheter shaft samples. Reflow parameters shown are for the material dimensions tabulated above. Temperatures and line speeds will vary depending upon the material dimensions.

Removability – Easy Removal After Reflow

PET Reflow heat shrink can be cleanly removed, post reflow processing and recovery, by slitting the tubing with a standard tool, leaving no residue behind.



Slitting Process to Remove PET Heat Shrink

Conclusion

The proposed regulations concerning PFAS are expected to significantly impact various industries in the coming years, including the medical device sector. However, these regulations are still under development, and there is currently no finalized or universally accepted definition of PFAS across regulatory agencies. Consequently, the specific requirements and restrictions that may apply remain unclear, making it difficult to determine how the use of PFAS-containing materials in medical devices might be affected moving forward.

With this shift in material sourcing, Nordson MEDICAL's PET heat shrink stands out as a PFAS-free alternative for reflow applications. The performance of laminated catheter shafts using our PET heat shrink material is on par with current FEP heat shrink product line offerings from Nordson MEDICAL. In conjunction with the equivalent peel strength values, our PET heat shrink reflow product line can be run at higher temperatures and line speeds when compared to FEP heat shrink. This will lead to increased throughput and lower costs for our customers.

About Nordson MEDICAL

Nordson MEDICAL (Nasdaq: NDSN) is a global expert in the design, development, and manufacturing of complex medical device components. As a single-source partner, we enable our customers to save costs, speed time to market, and simplify supply chain management.

We work with companies at any point in the product life cycle, from concept to launch and beyond. With our flexible business model, we can provide a solution that meets the scope and scale of any project to bring innovative ideas to life.

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