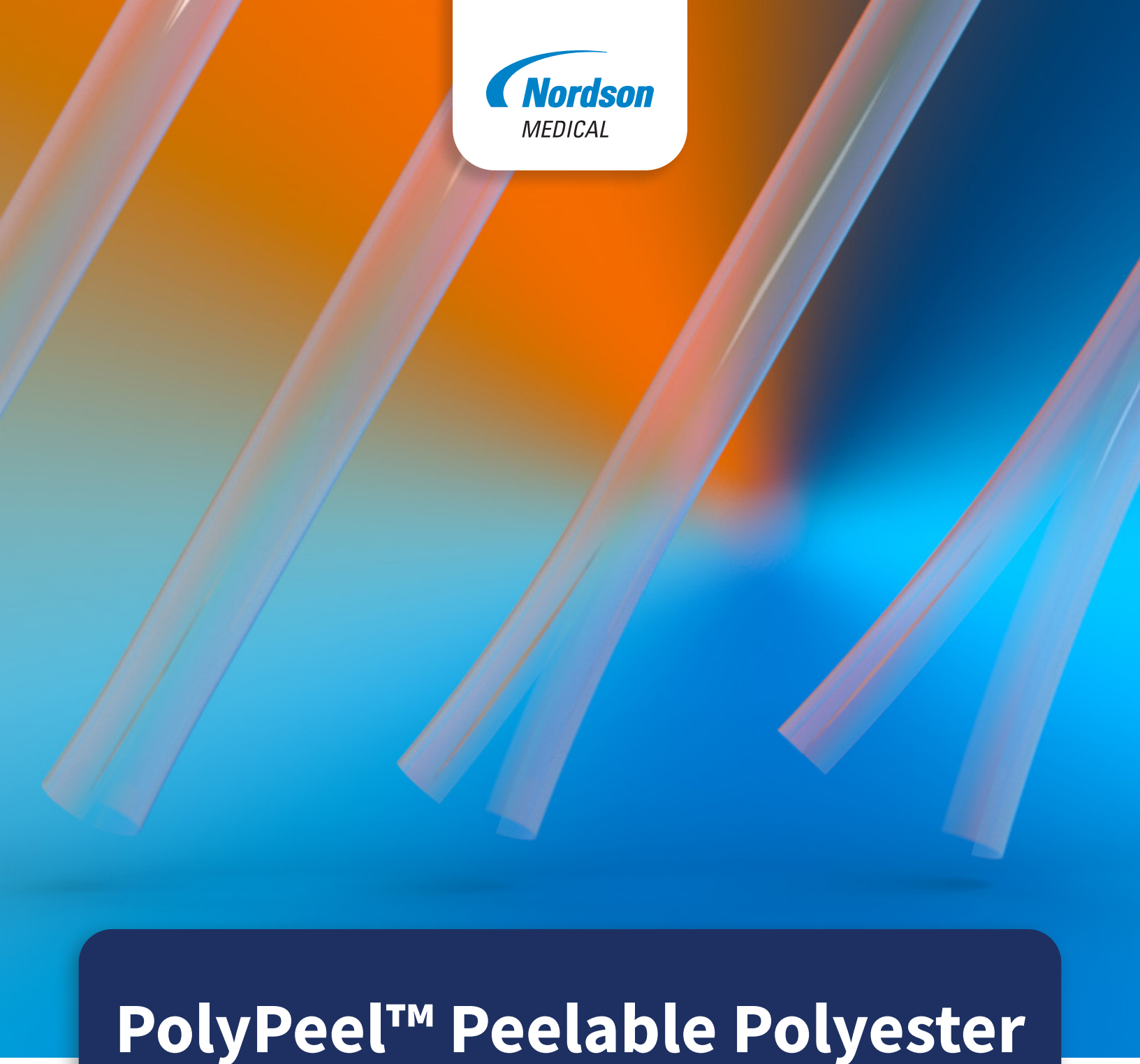


Nordson MEDICAL

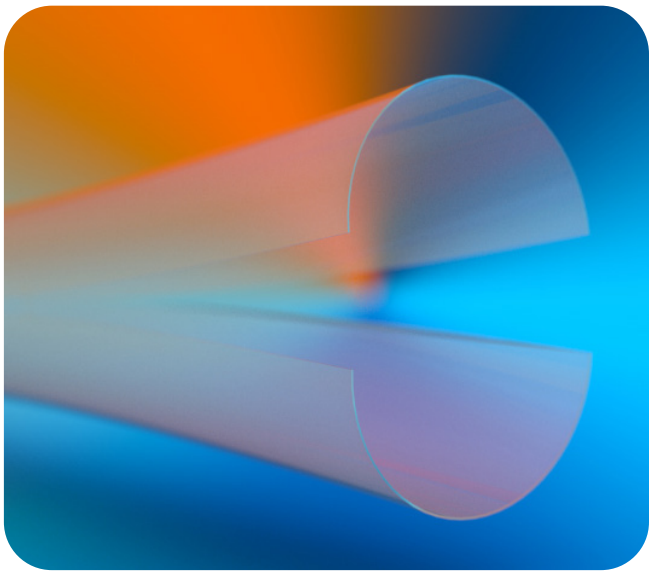
PolyPeel™ Peelable Polyester Heat Shrink Tubing:

SOLVING A FOUR-DECADE PROBLEM

PolyPeel™ Peelable Polyester Heat Shrink Tubing:

Solving a Four-Decade Problem

Introduction



Introduced more than four decades ago, polyethylene terephthalate (PET) heat shrink is a highly effective protective barrier for medical devices. More recently, PET heat shrink's application as a disposable manufacturing aid have multiplied exponentially.

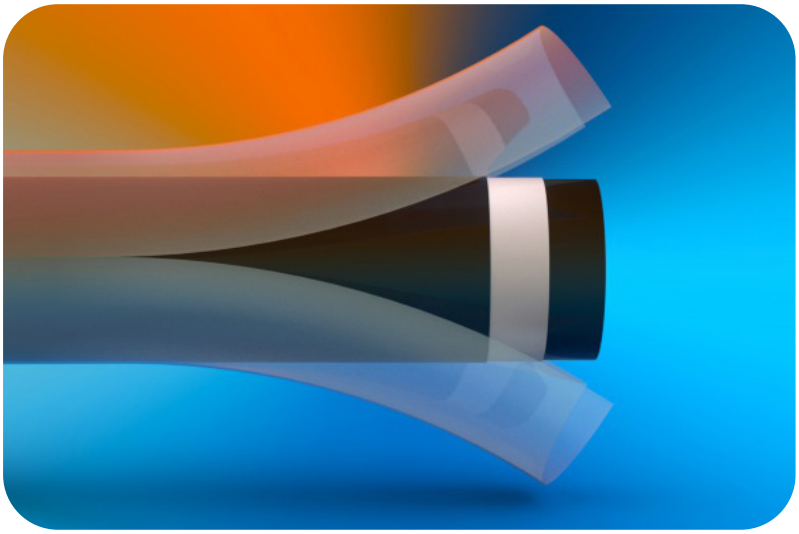
However, because PET is naturally strong, yet thin, it can be difficult to remove during manufacture or from finished medical devices. It often comes off in pieces or operators on the manufacturing line must carefully skive it for removal. This adds to manufacturing time, diminishes throughput, and increases the risk of damage to the sensitive substrate underneath — in some cases, the damage is severe enough that the device must be discarded.

PET That Peels Back With No Drawbacks

To address these shortcomings, Nordson MEDICAL developed PolyPeel™ Peelable Polyester Heat Shrink Tubing. As the industry's premier provider of medical-grade PET heat shrink, we are committed to helping with issues experienced by customers and better serving current and future PET applications in manufacturing.

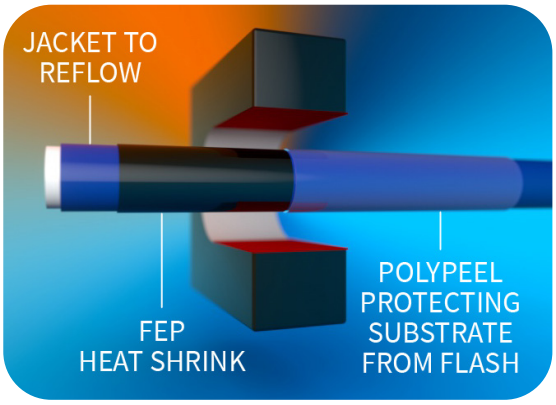
PolyPeel's patent-pending design easily releases from common thermoplastic jacket materials, such as Pebax® and nylon. Removal is as simple as holding the PET heat shrink in two places while pulling them apart in different directions.

We developed PolyPeel to offer the same reliable performance our customers expect from our standard PET heat shrink tubing. PolyPeel is free of per- and polyfluoroalkyl substances (PFAS) and meets ISO 10993 requirements. It also exhibits the same tolerances, wall thicknesses, and inner diameter (ID) ranges as our standard PET heat shrink tubing.



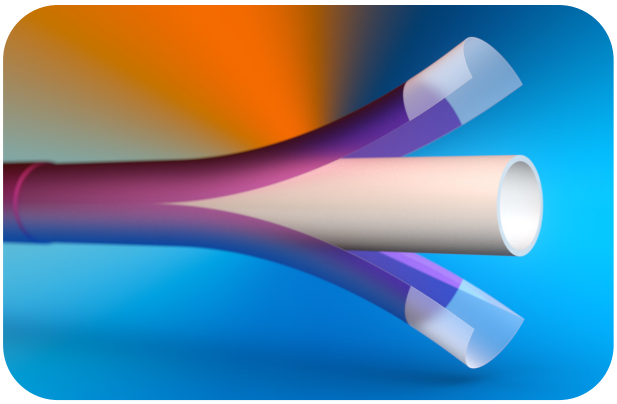
This consistency is critical because many customers have used standard PET heat shrink for decades, and its dependable performance is integral to their applications. This includes the ability to achieve ultra-thin walls and to enable significantly lower-temperature recovery of PET heat shrink tubing versus fluorinated ethylene propylene (FEP). While these attributes make PolyPeel heat shrink ideal for an ever-expanding number of purposes, four primary applications are most prominent:

1. WRAPPING



Wrapping applications are among PET heat shrink tubing's most common uses and benefit from the material's low temperature recovery (shrink ratios of at least 1.1:1). FEP tubing requires nearly double the heat to recover versus PolyPeel, whose heat shrink recovery range is 185°F to 374°F. This range enables safer usage in existing applications and offers opportunities for new uses by reducing the risk of heat damage to temperature-sensitive substrates. PolyPeel's peak melt temperature is 489°F.

Consider, as an example, a stent mounted on a balloon with a tight wrap. Device engineers must maintain or improve the wrap's low profile when updating materials. The low profile enables a smaller hole at the puncture site, reduces the risk of puncture site complications, and makes it easier to navigate the device through the vasculature. Additionally, the wrapping material must maintain a tight wrap during storage. If that product sits on a shelf waiting to be finished, sterilized, and/or packaged before being sent to a hospital, a material that relaxes over time will increase the profile, perhaps even enough to draw the product out of spec for use.

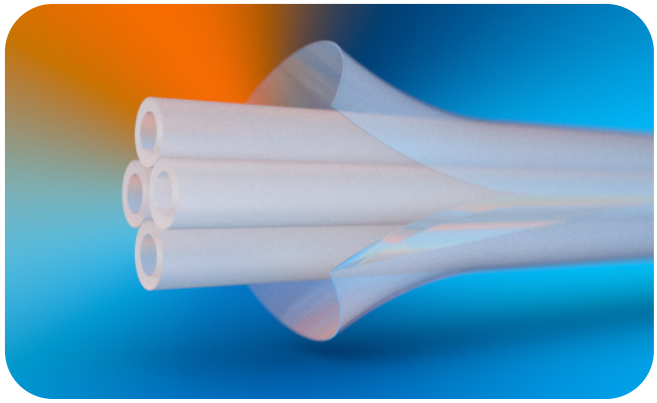


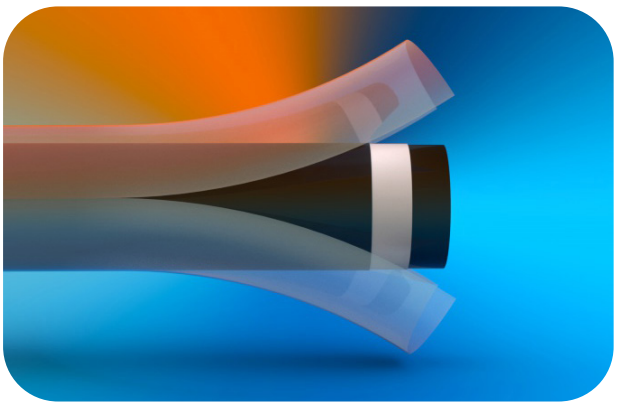
2. MASKING

Thin-wall PET heat shrink tubing allows for all-but-seamless transitions between coated and uncoated catheter sections in masking applications. For example, PET heat shrink is applied over the area to be protected, the coating is applied, the heat shrink is removed, and a smooth transition is created between the coated and uncoated surfaces. A thicker coating, like FEP (about 0.01" thick), might cause coating to build up at the edge of that wall, creating a bumped transition in the catheter. PolyPeel is available in wall thicknesses from 0.00025" to 0.001" and IDs ranging from 0.080" to 0.300".

3. BUNDLING

Ultra-thin walls also enable tight-tolerance bundling of various wires and catheters. For example, a catheter may comprise tubing, electrical wires, and/or a complex, articulating tip. Thin-walled PET heat shrink or PolyPeel enable the operator to insert that bundle into a tight-tolerance outer jacket, push it all the way through, and then remove the heat shrink from the other end. The result is a low-profile outer jacket with a tight tolerance wrap around all the various components inside. Again, FEP heat shrink would create a thicker outer wall and thus a larger outer diameter (OD) on the jacket, as well as potentially a larger profile.





4. REFLOW

Currently, almost all reflow laminating processes use FEP heat shrink, which contains PFAS. However, our PET heat shrink and PolyPeel provide a PFAS-free alternative. Recommended reflow temperatures range from 185°C to 235°C, depending upon jacket material, but much higher temperatures can be used by increasing reflow run speeds. This is possible because heat transfers through the PET's thin walls more quickly and efficiently. So, the same temperature heat can be used to laminate multilayer catheters in a reflow process, but run at a much faster speed, increasing throughput and reducing manufacturing costs.

Time's Up For "Forever Plastics"

The FDA acknowledges that PFAS materials, particularly polytetrafluoroethylene (PTFE), are valuable substances that not only support but also often enable the functionality of medical devices. However, the FDA also has stated the use of PTFE should be avoided in food-contact applications, paving the way to curtailed use in medical applications.

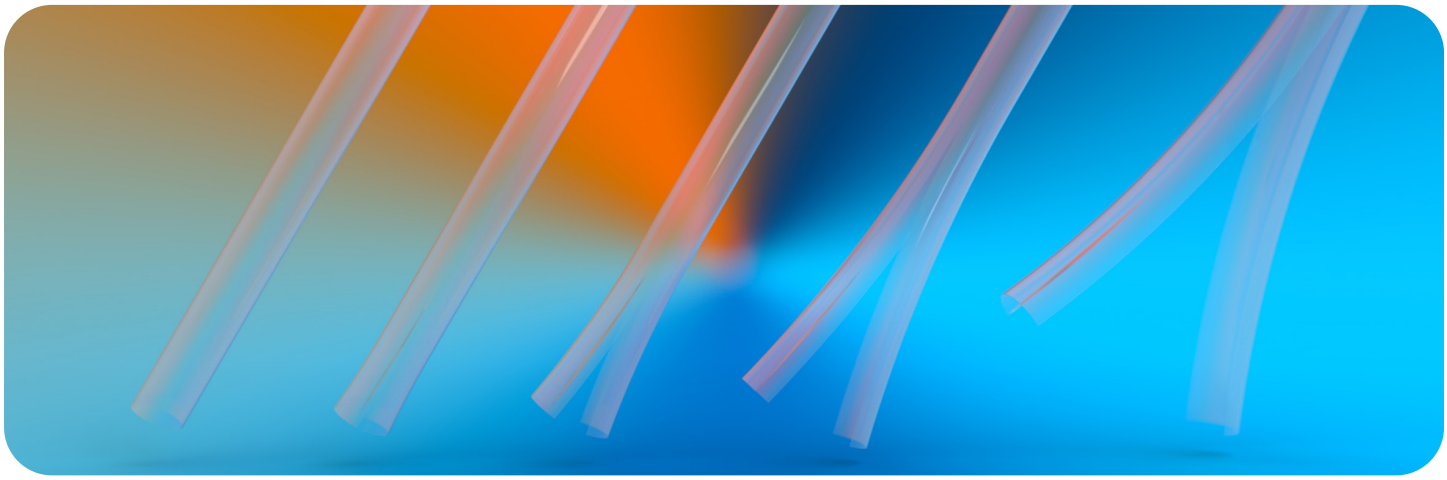
Moving away from the use of PFAS — dubbed "forever chemicals" or "forever plastics" because of their high resistance to breakdown — is environmentally responsible and minimizes humans' exposure risk, as some PFAS have been determined to be toxic. If a defective device is discarded wearing a PTFE liner, as many catheter-based devices do, the operator or user is throwing away a PFAS material. This also applies to hospitals discarding single-use devices.

Additionally, device materials and components typically are cleaned during manufacture, and the resulting wastewater is tainted with microplastics that contaminate drinking water. The European Commission has proposed adding numerous PFAS to its lists of water pollutants (in addition to PFAS like PFOA, already on that list), as well as releasing a chemicals action plan that includes the creation of an EU-wide PFAS monitoring system. Therefore, reducing this scrap is imperative for both sustainability and regulatory compliance.

A Novel Product Informed By Industry Heritage

Over Nordson MEDICAL's decades of operation, hundreds of customers have discovered the benefits of PET heat shrink across a multitude of applications and thousands of different part specifications. Usage has increased so steadily that we now supply nearly all the PET heat shrink used in the global medical device market, amounting to 20 to 30 million feet annually.

In fact, we recently doubled the production capacity of our Salem, NH, facility — our PET Heat Shrink Center of Excellence — meaning we have ample capacity to support future growth in service of new and existing customers. This capability extends to PolyPeel, which is available in high-volume production, empowering Nordson MEDICAL to support significant market demand or growth.



In addition to 40+ years of technical experience, Nordson MEDICAL customers benefit from the trust we have earned and industry relationships we have established during that time. We regularly consult with customers to understand their needs and to resolve challenges they encounter, both in product development and on the manufacturing line.

Providing solutions can mean modifying PET heat shrink's dimensions, tweaking processing parameters, changing how the heat shrink is manipulated during use, or, with the advent of PolyPeel, making polyester heat shrink tubing removal easier and safer. Nordson MEDICAL's knowledge of polyester's morphological structure, during manufacture and use, enables us to "dial in" these specifications with precision.

We encourage and support our customers' innovation in how they use heat shrink, and we look forward to breaking new ground with PolyPeel's implementation into existing applications and use in novel operations. To learn more, contact the authors and visit https://interventional-solutions.nordsonmedical.com.

Conclusion

Jiunn-Yow "Jerry" Chen is an inventor/co-inventor holding 15 US Patents and several international patents, including the PCT Patent Application of the Peelable Polyester Heat Shrink Tubing. Jerry holds a Ph.D. in Fiber and Polymer Science from North Carolina State University.

Gordon Brooks is Senior Director of Product Management for Nordson MEDICAL with a career spanning nearly 30 years in the medical device sector. After 15 years with Boston Scientific in sales, marketing and portfolio management, he helped lead a small balloon catheter company to acquisition before joining Nordson MEDICAL, where he has served in various product line management roles since 2020.

About Nordson MEDICAL

Nordson MEDICAL (Nasdaq: NDSN) is a global expert in the design, development, and manufacturing of complex medical devices and component technologies. 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 lifecycle, 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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