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Medical Plastics and Biomaterials

SPECIAL SECTION

Using Thin-Wall Heat-Shrink Tubing in Medical Device Manufacturing

A reduction in device size is among the advantages of shrink tubing, which has a wide range of applications.

Mark Saab

THE DEMAND for less-invasive medical procedures is a major driving force in today's medical device industry. Smaller and thinner are better—especially in catheters, endoscopes, and other devices that are inserted into the body. Designers are looking for new ways to downsize existing devices and to develop new minimally invasive devices. The industry is also under pressure to build more features into devices without increasing their profile (size). Thin-wall heat-shrink tubing is one product that can help designers meet this demand by reducing diameters and improving production processes. Applications in which this tubing offers advantages include:

- Variable-stiffness catheters.
- Electrical insulation.
- Encapsulation and protective coverings.
- Bundling of components.
- Tube joining and transitioning.
- Marking and printing.
- Catheter tip forming.
- Micro hose clamps.
- Masking for coatings.

This article compares the key properties of thermoplastic materials used in the manufacture of high-end medical shrink tubing—polyolefin, fluoropolymers (PTFE), polyvinyl chloride (PVC), and polyester, specifically polyethylene terephthalate (PET)—and focuses on some of the more interesting product design applications, especially those employing PET.

MATERIALS COMPARISON

Table I compares the properties of the primary materials used in the manufacture of thin-wall heat-shrink tubing. PET polyester is the clear leader in terms of thin walls and high tensile strength. It is 10 to 100 times thinner than any other heat-shrink tubing and more than 10 times as strong. Tube walls of 0.00015 to 0.004 in. can be produced from PET while still maintaining high hoop strength, compared with walls of >0.002 in. for PTFE and >0.005 in. for polyolefin and PVC. Polyester also has superior flex-fatigue properties and the lowest shrink temperature (185°F/85°C) of the commonly used materials, which enables it to be used without being concerned about heat degradation to delicate substrates.

Although PTFE offers outstanding lubricity, a significant drawback is its very high shrink temperature of about 600°F, which precludes its use with plastic catheters and other plastic components. PTFE cannot be sterilized via gamma irradiation, which is a handicap in some market sectors that are moving away from ethylene oxide sterilization. Neither can the walls be

Material	Wall Thickness	Shrink Temp.	Shrink Ratio	Sterilization	Strength	Cost
Polyolefin	>0.005 in.	Medium	2:1 to 3:1	Most	Low	Low/medium
PTFE	>0.002 in.	Very high	1.3:1 to 4:1	No gamma	Low	High
PVC	>0.005 in.	Medium	2:1	Most	Low	Low
PET	0.00015–0.004 in.	Low/medium	1.1:1 to 3:1[a]	Most	High	High

[a]Shrinkage over 20% can be accomplished by drawing while shrinking.

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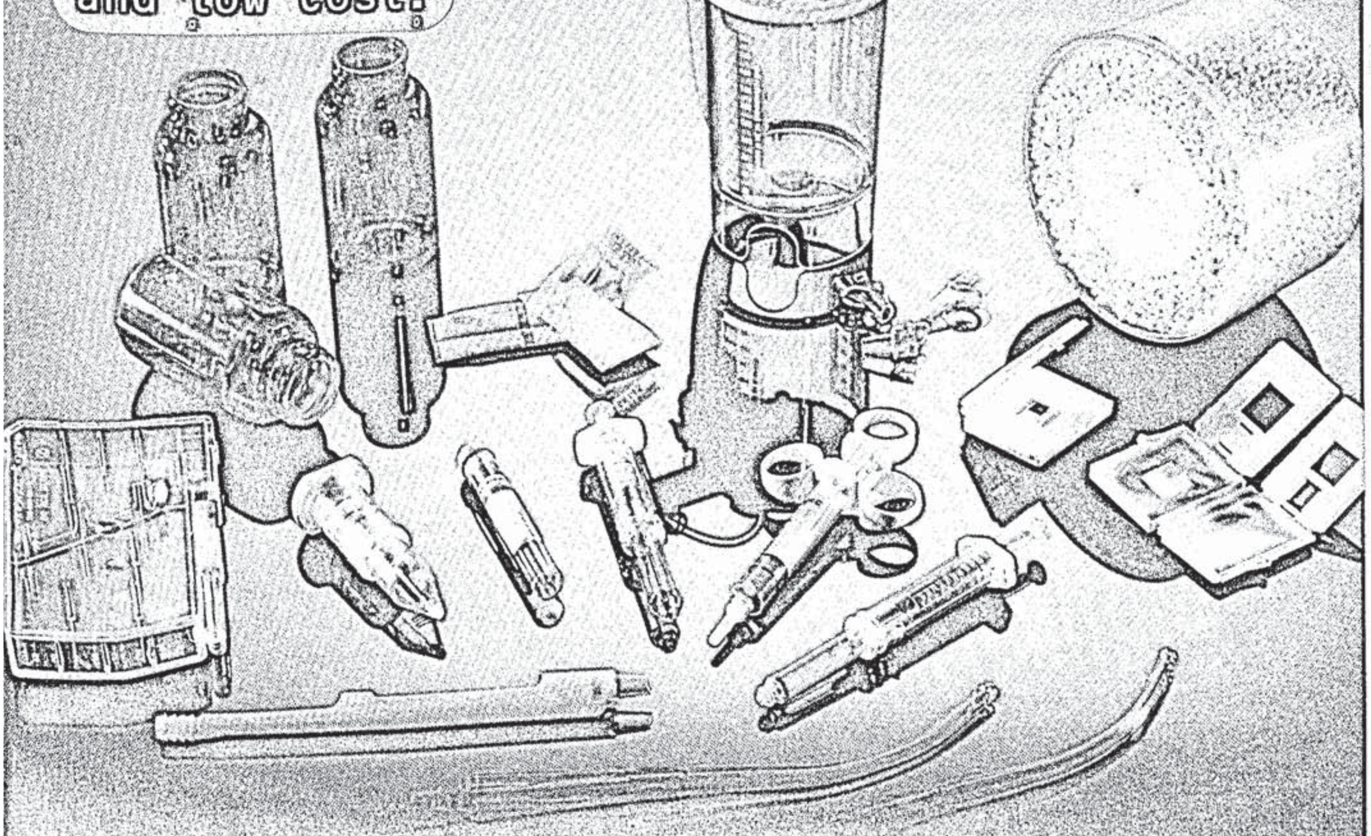

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Wall thickness	Ultrathin wall thickness can be achieved (0.00015–0.004 in.)
Tensile strength	Very high tensile strength can be realized (>20,000 psi).
Electrical insulation	Has one of the highest dielectric strength ratings of any thermoplastic material Dielectric strength: >4,000 V/mil (60 Hz) Dielectric constant: 3.3 Dissipation factor: 0.0025 Volume resistivity: 10^{18} Ω-cm Surface resistivity: 10^{14} Ω/square
Shrink temperature	185° to 374°F (85° to 190°C)
Melt point	High, 455°F (235°C)
Shrink ratio	5–15% typical—up to 70% if drawn or stretched during application
Surface finish	Ultrasmooth, hard, glossy finish
Color/clarity	Optically clear or can be pigmented
Bondability	Can be bonded using a wide range of adhesives (surface treatment recommended)
Flex fatigue	Very high flex fatigue properties
Biocompatibility	Meets USP Class VI requirements

Table II. Properties of polyester (PET) heat-shrink tubing.

made as thin as with polyester tubing and still retain useful strength, and wall-thickness tolerances are generally quite high. PTFE shrink tubing is typically used as a liner inside devices and as a covering for metal components and devices.

PET SHRINK-TUBING PROPERTIES

The key properties of polyester heat-shrink tubing are listed in Table II. With polyester tubing, shrinkage is a function of temperature: the higher the temperature, the higher the shrinkage. PET shrink temperature ranges from approximately 185° to 374°F (85° to 190°C). Unrestricted, the tubing will shrink both radially and axially, and the best overall performance is achieved with minimal shrinkage (less than 15–20%). Whenever a very high radial shrinkage is required (up to 70%), the tubing can be drawn while it is being heated. The ability to draw or stretch the tubing to achieve very high radial shrinkage while maintaining thin walls is unique to polyester.

SHRINK-TUBING APPLICATIONS

Variable-Stiffness Catheters. Because of its ultrathin walls, polyester heat-shrink tubing can be used to add stiffness to catheters without significantly adding to the size of the device. By using different thicknesses of tubing along the length of the catheter, varying degrees of flexibility can be created for improved control of the device. This quick and easy tubing application eliminates the need for joining dissimilar materials or adding braid to sections of a catheter in order to achieve multiple zones of stiffness. For example, some manufacturers use shrink tubing with a wall measuring 1-mil thick at the back end of a catheter, 1/2-mil in the middle, 1/4-mil near the end, and no tubing at all on the tip end. This provides varying degrees of stiffness along the

Electrical Insulation. Virtually every type of heat-shrink tubing is used in electrical insulation. Materials are typically chosen based on temperature, dielectric strength, cost, and wall thickness. High dielectric and resistivity properties make polyester heat-shrink tubing an effective electrical insulation material that adds little dimension because of its ultrathin walls. It can be used over needles, for example, to protect the surface of the skin from being burned during electrical stimulation and has also been employed effectively to cover electrical components or to insulate wiring on catheters and other devices (Figure 1). Some manufacturers are using PET tubing over metal shafts for electrical insulation, replacing a coating process. Application of the polyester greatly reduces the likelihood of the

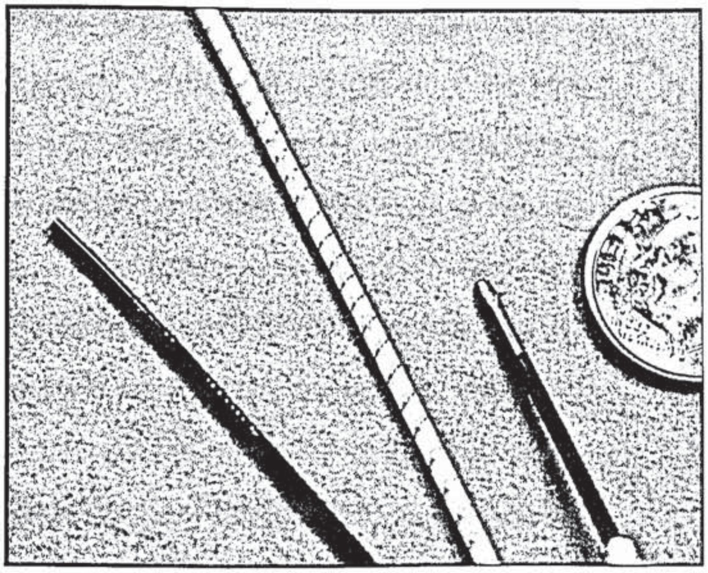

Figure 1. Black polyester shrink tubing covers a needle (right), leaving only the tip exposed. Electrical wires (left and middle) are cov-

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