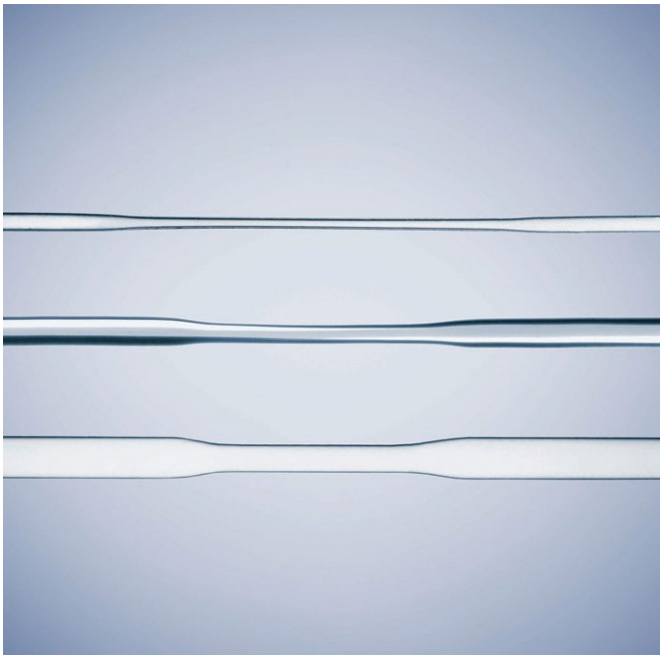
MATERIAL GUIDE FOR MEDICAL GRADE POLYMER TUBING

FLUOROPOLYMERS



Our Production

Our production is performed in an ISO 13485 certified environment providing components for Class II and Class III end-use medical devices. We are dedicated to delivering consistent quality combined with innovation, tight tolerances, traceability and design service.

FEP

(Fluorinated Ethylene Propylene)

At TE Connectivity, we don't just manufacture heat shrink tubing, we design and optimize.
We understand the difference advanced Polymeric Engineering can make to reflowing your complex catheter or protecting and insulating your electrosurgical devices and Laparoscopic instruments.

Profile

- Shrink ratio ≤ 1.6:1
- Full recovery at 210°C (410°F) minimum
- Tight longitudinal change control as low as ± 2%
- Biocompatibility tested
- Custom sizing, finishing options available
- Translucent for high optical clarity

About

FEP is a fluorinated ethylene propylene heat shrink tubing. FEP offers excellent consistency, high dielectric strength, and is chemically inert. FEP is lubricious and semi-rigid with shrink ratios up to 2:1*.

FEP is the industry gold standard for reflowing catheter shafts and bonding joints. For our FEP, we can control longitudinal growth ± 2% ensuring consistency on lot to lot, reducing cost and waste.

*Upper limit offering depends on product size.
Optimal expansion ratio is 1.6:1.

Applications

- Process aid for catheter shaft reflow
- Process aid for reflowing catheter shafts

THERMOPLASTIC EXTRUSION CAPABILITIES

Custom Thermoplastic Extrusions

Single Lumen Development Run (300-500ft) using in house materials and tooling ship in as few as 10 business days.

Custom precision extrusion tubing for medical application capabilities:

- OD: .015” - .510” (0.4-13 mm)
- Wall: ≥.0015” (≥0.04 mm)
- Large assortment of tooling in-stock, braiding, cut to length or spooled, rods, beading, profiles, co-extrusion, multi-layer and multi-lumen.
- ISO 13485 certified – providing components for Class II and Class III end-use medical devices.

TE Connectivity is committed to supplying extrusion needs from development phases to high-volume production runs.

Thermoplastic “In House” Materials

350 resins in stock and stored in a climate controlled environment.

- TPE (thermoplastic elastomers), trade names PEBAX®, Arnitel® and Hytrel®
- Polyolefins, trade names Pellethane®, Tecothane™, Arnitel
- Polyethylenes (LDPE, MDPE, HDPE) and Polypropylenes
- Polyamides (nylon), trade names Vestamid® and Rilsan®
- Polycarbonate

Common Fillers in Medical Applications

Barium sulfate, $BaSO_4$, Bismuth trioxide Bi_2O_3, Bismuth Subcarbonate, $Bi_2O_2(CO_3)$ or Tungsten (W). The level of loading (% by weight) will improve visibility of the component in the body under fluoroscopy (X-ray).

THERMOPLASTIC POLYMERS

Thermoplastic polymers are commonly regarded as “plastics”. They are subgrouped into amorphous and semicrystalline. The crystalline amount of the polymer depends on the original molecules and the thermal history of the polymer. Amorphous polymers are often transparent and semi-crystalline polymers are opaque. Amorphous polymers melt over a wide temperature range contrary to semi-crystalline polymers that have distinct melting temperatures. One characteristic of thermoplastic polymers is that they return to their original physical structure when cooled after melting.

PE (Polyethylene)

PE is categorized by the density of the polymer, LDPE (low density), MDPE (medium density) and HDPE (high density). A higher crystallinity will produce a higher density, higher melt temperature, higher strength, and a lower permeability to gases and moisture. Polyethylene is a relatively inexpensive polymer that is widely used in medical applications.

- Low friction properties (HPDE)
- Good chemical resistance
- Service temperature upto +100°C (HDPE)

PP (Polypropylene)

PP is a semi-crystalline polymer with wide versatility. PP is rather rigid and is frequently used when slightly better mechanical characteristics than HPDE are required.

- High fatigue resistance
- Good chemical resistance
- Service temperature up to +100°C

EVA, EMA, EBA (Ethylene Vinyl Acetate, Ethylene Methyl Acrylate, Ethylene Butyl Acrylate)

Copolymers of ethylene and polar monomers (vinyl-ac-etate, methylacrylate or butylacrylate), are used to produce materials with various properties of stickiness, toughness and impact resistance.

- High fatigue resistance
- Good chemical resistance
- Service temperature up to +100°C

POM (Polyoxymethylene)

POM is a highly crystalline polymer commonly named “acetal”. POM is a very hard, strong, dimension stable, opaque polymer, which is an effect of high crystallinity.

- Low friction properties
- High strength and hardness
- High wear resistance
- Low absorption and permeability of water

PET, PBT (Polyethylene Terephtalate, Polybutylene Terephthalate)

PET and PBT are two of the most commonly used polyesters. PET has a slow crystallization process compared to all other polymers. PBT is more flexible and tougher than PET.

- High strength and hardness
- High dimension stability
- Good chemical resistance

PC (Polycarbonate)

PC is a polyester of carbonic acid that has an amorphous structure to provide transparency. PC is used for its toughness and strength.

- High strength and toughness
- Good transparency
- High dimension stability
- Extreme impact resistance

PA (Polyamide)

PA is a group of semi-crystalline thermoplastics often referred to as Nylon®. The number of carbon atoms between the functional amide groups in PA produces different properties of this polymer with names such as PA6, PA11 and PA12 indicating these numbers. Absorption of water decreases with increasing numbers of carbon atoms.

- High strength, stiffness and hardness
- Good wear resistance
- Service temperature up to +150°C

THERMOPLASTIC ELASTOMERS

Thermoplastic elastomers consist of hard polymer segments in a matrix of soft amorphous polymers. These segments are physically bound to each other, giving the elastic properties. In contradiction to rubber and thermosets, the binding between the molecules is reversible by melting and cooling. Changing the ratio of hard segments in the copolymer will increase or decrease the strength, stiffness, and hardness of the polymer.

TPE-E (Thermoplastic Elastomer Ester)

Ester-based thermoplastic elastomer is a copolymer of polyether-esters or polyesteresters.

- Hardness ranges from Shore 35D to 74D
- Excellent chemical resistance
- High fatigue resistance

TPE-A (Thermoplastic Elastomer Amide)

TPE-A are copolymers of polyamide with either polyether, polyester or polyether ester. The hard segments in the copolymer are formed by the semi-crystalline polyamide segments in the copolymer. PolyEtherBlock-Amide (PEBA), often referred to as PEBAX®, is a commonly used TPE-A in medical applications.

- Hardness ranges from Shore 75A to 75D
- High abrasion resistance
- Good biocompatibility

TPE-U (Thermoplastic Elastomer Urethane)

TPE-U is a group of polymers often referred to as PUR, with a very wide range of properties. The two main types of PUR are polyester-based (aromatic) and polyether-based (aliphatic). The polyether-based TPE-U is more elastic, and has a higher resistance to hydrolysis and micro-organisms. The hard segment in the copolymer is of a crystalline nature.

- Hardness ranges from shore 75A to 75D
- Good biocompatibility
- Softens in vivo
- Excellent abrasion resistance

TPE-O (Thermoplastic Elastomer Polyolefins)

TPE-O is a group of polymer blends mainly comprised of polyethylene, polypropylene and rubber. The TPO is semi-crystalline polymer blend, where polypropylene and polyethylene part constitute the crystalline phase and the rubber for the amorphous phase.

- Hardness from 40A to 62 D
- High impact resistance
- Good chemical resistance

TPE-S (Thermoplastic Elastomer Styrenic Block Copolymer)

TPE-S are compounds based on SBS or SEBS. Styrenebutadienestyrene is based on twophase block copolymer with hard and soft segments. The styrene end blocks provide the thermoplastic properties and the Butadiene midblocks provide the elastomeric properties. SEBS is modified SBS by hydrogenation.

- Hardness from 45A to 65D
- Good scratch resistance

GENERAL SUMMARY OF PROPERTIES

		FLUOROPOLYMERS			THERMOPLASTIC POLYMERS									THERMOPLASTIC ELASTOMERS				
		FEP	PFA	PVDF	LDPE	HDPE	PP	PA 6	PA 11	PA 12	POM	PET/ PBT	PC	TPE-U	TPE-A	TPE-E	TPE-S	TPE-O
Tensile strength at break	MPa	20-28	25-30	35-50	10-20	25-45	20-460	35-80	40-90	38-60	40-70	30-50	70	25-70	30-62	14-25	5-40	
Elongation at break	%	300-325	300	15-50	350-700	50-1000	10-500	40-300	30-400	50-400	10-200	20-350	50-120	160-750	50-700	200-800	400-1000	700-1000
Flexural Modulus	MPa	550-700	590-700	2100	100-600	500-2000	900-2000	500-2900	400-1400	260-1600	1400-3000	1000-2400	2300	70-2300	15-730	40-1200		600-900
Hardness	Shore ID	55-60	55-64	75-78	49-55	58-65	72-81	70	72	72	85	55-65	90	40-75	25-72	35-80	8-62	5-40
Density	g/cm^3	2,15	2,15	1,8	0,91-0,94	0,94-0,96	1,90-1,91	1,03-1,17	1,0-1,05	1,0-1,17	1,3-1,4	1,2-1,3	1,20	1,05-1,20	0,96-1,10	1,12-1,27	0,89-1,04	0,85-0,98
Coefficient		0,25	0,21	0,30	0,60	0,28	0,30	0,40	0,35	0,40	0,35	0,35	0,30	0,22 /0,5	0,55	0,2-0,8		
Transparency	See Note	• • • •	• • • • •	•	• • • •	• • •	• • •	• •	• • •	• • •	•	• • • • •	• • • •	• •	• • • •	• • • •	•	•
Melting Point	°C	257-275	300-310	175	110	125	134-165	220	175-190	170-185	160-175	230-250	240	170-240	135-275	160-215		125-165
Min/ max Service temp.	°C	-200 +200	-200 +260	-60 +150	-30 +80	-20 +100	-10 +120	-40 +150	-50 +100	-50 +100	-40 +100	-40 +140	-40 +120	-50 +80	-40 +130	-40 +130	-50 +125	-40 115
Water absorption	%	<0,01	<0,03	0,04	0,01	0,01	0,01	1-10	0,2-2,0	0,2-1,6	0,2-1	0,1-0,5	0,3	0,1-0,4	0,9-1,2	0,6-2,5		
Chemical Resistance	See Note	• • • •	• • • • •	• • • •	• • •	• • •	• • • •	• •	• •	• •	• • •	• • • •	•	• • •	• • •	• • •	• • • •	• • • •
ETO		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Steam		x	x	x	-	-	x	x	x	x	x	-	-	-	x	x	(x)	x
Radiation		-	-	x	x	x	(x)	x	x	x	(x)	x	x	x	x	x	x	-

Notes:
The property data are taken from different sources and are not necessarily typical for any specific grade. This table is unsuitable for specification, since all values are indicative and for guidance only. TE Medical takes no responsibility for data given in the table. Excellent: • • • • • Poor: •

Capability Highlights

- FEP heatshrink
- Beadings and monofilaments
- Single and multi-lumen extrusions
- Braided shafts
- Secondary operations, tip-forming, flaring, printing, etching, fabricated tubing, etc.

Our experience in polymers Our experiences range from research & development to small, medium, and automated high volume production. We serve markets in the fields of infusion technology, cardiovascular, and delivery devices.

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