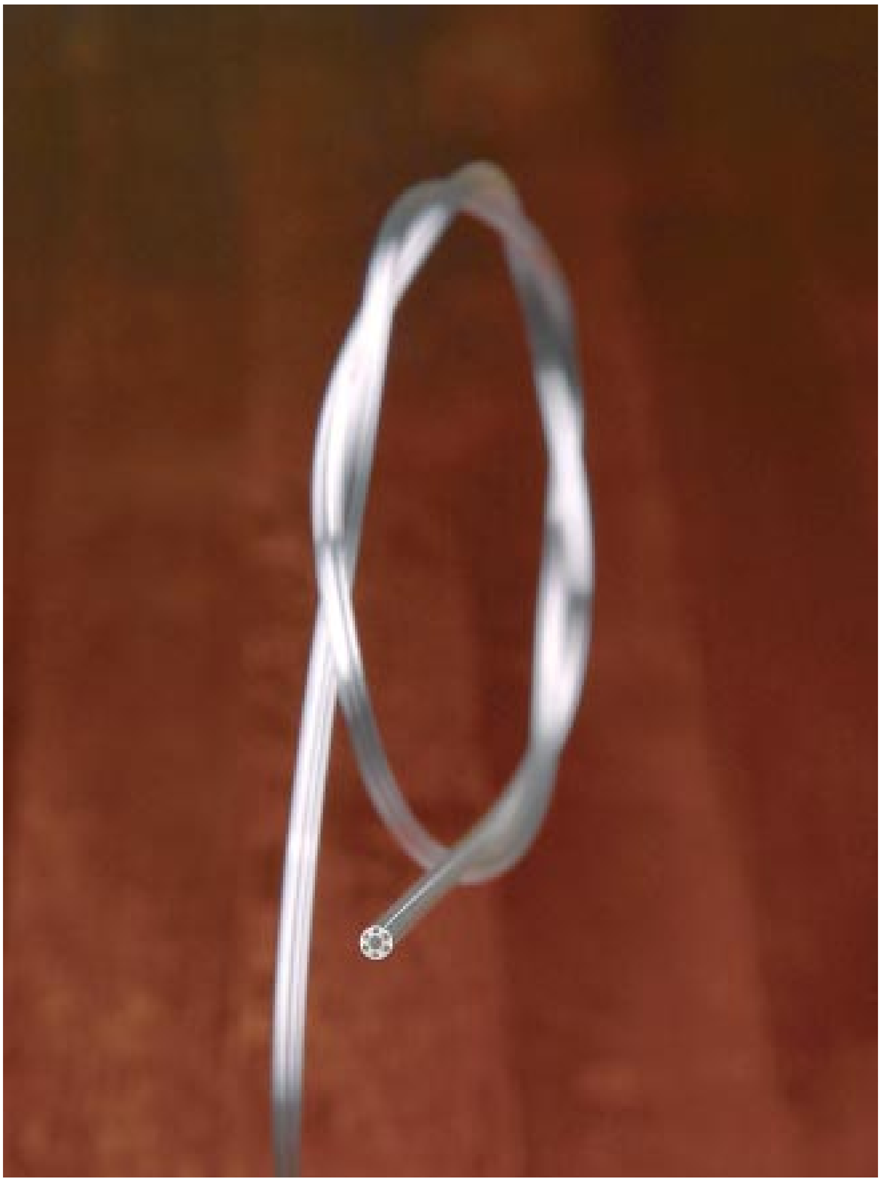
MATERIALS GUIDE FOR CUSTOM EXTRUSION



OPTINOVA AB IS A LEADING COMPANY IN THE PRECISION EXTRUSION OF TUBING FOR MEDICAL APPLICATIONS ACCORDING TO CUSTOMER SPECIFICATIONS. ESTABLISHED IN 1971, OPTINOVA HAS DEVELOPED A WORLD REPUTATION IN FULFILLING CUSTOMER EXPECTATIONS PARTICULARLY IN FLUOROPOLYMERS.

Medical Tubing for World Class Producers

M A T

Our production, in a clean-room environment, is devoted to consistency combined with innovation. Key factors for our business are tight tolerances, traceability, design services and personal customer service.

Optinova operates under GMP guidelines and is certified according to ISO 9001:2000 and ISO 13485:2003.
We offer: Production capacity, experience and knowledge.

PTFE (POLYTETRAFLUOROETHYLENE)

The stability of the carbon-fluorine bond in combination with the very high polarity of the fluorine atom will create the unique properties of the high crystalline PTFE paste fluoropolymer. These properties are unlikely to be beaten by any other plastic material. The physiological inertness of the polymer makes PTFE ideal for medical applications. Since PTFE does not melt, it has to be ram extruded followed by sintering to obtain its final properties.

- Outstanding low friction properties and non-stick characteristics.
- Outstanding chemical resistance.
- Excellent resistance to aging.
- Outstanding continuous service temperature from -200℃ up to +260℃.

THERMOPLASTIC FLUOROPOLYMERS

All thermoplastic fluoropolymers are melt extrudable alternatives to PTFE, and are processed in corrosion-resistant equipment. The various thermoplastic fluoropolymers differ in their molecule structure and number of fluorine atoms. It is this difference that will give them their distinctive properties, whilst still maintaining some of the unique properties of PTFE.

FEP (Fluorinated EthylenePropylene)

FEP is a copolymer of tetrafluoroethylene and hexafluoro propylene with a linear molecule chain. FEP has almost the same characteristics as PTFE and is transparent, even though it is a semi-crystalline polymer.

- Excellent low friction properties and non-stick characteristics.
- Excellent chemical resistance.
- Outstanding continuous service temperature from -200℃ up to +200℃.
- Extremely smooth surface.

PFA (PerFluoroAlkoxy)

PFA is a transparent perfluoroalkoxy copolymer that is considered to be the thermoplastic fluoropolymer with the closest properties to PTFE, whilst being melt processable.

- Low friction properties and non-stick characteristics.
- Outstanding chemical resistance.
- Outstanding service temperatures up to +260℃.
- High light transmission.

ETFE (EthyleneTetraFluoroEthylene)

ETFE is a copolymer of tetrafluoroethylene and ethylene. ETFE is stiff, tough and has a higher resistance to wear than most fluoropolymers.

- Excellent non-stick characteristics.
- Low liquid permeability.
- Good resistance to radiation.
- High light transmission.

PVDF (PolyVinyliDeneFluoride)

PVDF is a polymer of vinylidenefluoride. PVDF is stiffer and has a higher mechanical strength and resistance to wear than ETFE.

- Good chemical resistance.
- Excellent abrasion resistance.
- Excellent aging resistance.
- Smooth surfaces.

THERMOPLASTIC POLYMERS

Thermoplastic polymers are commonly regarded as "plastics". Thermoplastic polymers return to their original physical structure when cooled after melting. They are subgrouped into amorphous and semi-crystalline. The amount of crystalline contained, 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 a distinct melting temperature.

PE (PolyEthylene)

PE is categorised 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 up to +100℃ (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℃.

EVA, EMA, EBA (EthyleneVinylAcetate, EthyleneMethylAcrylate, EthyleneButylAcrylate)

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

- Flexible.
- High impact resistance.
- High toughness.

PA (Polyamide)

PA is a group of semi-crystalline thermoplastics, often referred to as Nylon®. The number of carbon atoms between the functional amid 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℃.

POM (PolyOxiMethylen)

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 (PolyEthyleneTerephtalate, PolyButyleneTerephthalate)

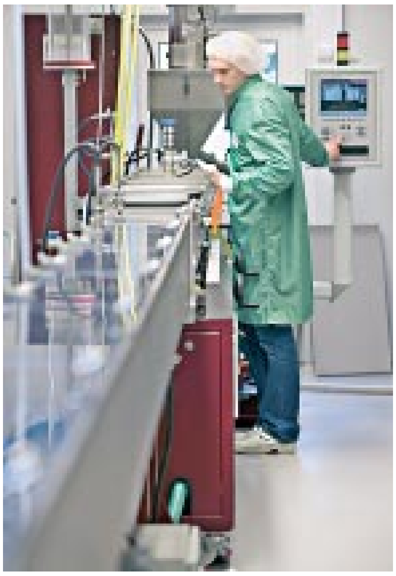
PET and PBT are two of the most commonly used polyesters. PET has a slow crystallisation process compared to all other polymers. PBT is more flexible and tougher than PET.

- 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.



A L S

THERMOPLASTIC ELASTOMERS

This is a group between rubber and thermoplastic polymers, called thermoplastic elastomers. These copolymers 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-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 TPE-U are either polyester or polyether based. The polyether based TPE-U is more elastic, and has a higher resistance to hydrolysis and microorganisms. 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-A (Thermoplastic Elastomer Amide)

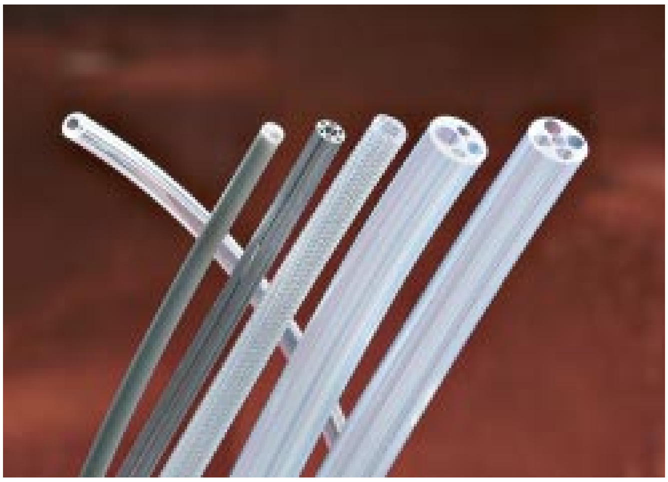
TPE-A are copolymers of polyamide with either polyether, polyester or polyether ester. The hard segments in the copolymer are formed by the semi-crystalline polyamide segments in the copolymer. PolyEtherBlockAmide (PEBA), often referred to as PEBAX®, is a commonly used TPE-A in medical applications.

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

TPE-E (Thermoplastic Elastomer Ester)

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

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



COMPOUND, MASTERBATCH & FILLER

Compound

Compounding is a process used to mix fillers, additives, colour pigments or different polymers or grades of polymers. This process normally consists of dry blending, melting in a single or twin-screw extruder, filtering, homogenising, forming of a strand and pelletising. Compounds are used to obtain good and consistent quality.

Masterbatch

A masterbatch is a concentrated mixture of additives, i.e. colour pigments, in a carrier polymer. A masterbatch is often used instead of a compound to decrease costs, where small volumes are required. However, the consistency may not be as good as with a compound.

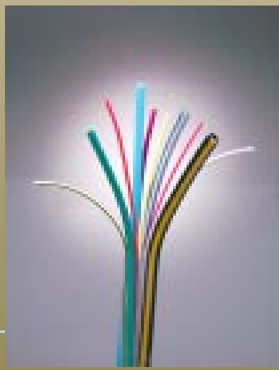
Filler

A filler is compounded with the polymer to enhance the radiopacity, for example. Common fillers in medical applications are barium sulphate ($BaSO_4$), bismuth trioxide (Bi_2O_3), bismuth subcarbonate ($Bi_2O_2CO_3$) or Tungsten (W).

GENERAL SUMMARY OF PROPERTIES

		Fluoropolymers					Thermoplastic Polymers									Thermoplastic Elastomers		
			Thermoplastic Fluoropolymers				Polyolefines			Polyamides								
		PTFE	FEP	PFA	ETFE	PVDF	LDPE	HDPE	PP	PA 6	PA 11	PA 12	POM	PET / PBT	PC	TPE-U	TPE-A	TPE-E
Tensile strength at break	MPa	20 - 34	20 - 28	25 - 30	40 - 47	35 -50	10 - 20	25 - 45	20 -460	35 - 80	40 -90	38 -60	40 -70	30 - 50	70	25 - 70	30 -62	14 -45
Elongation at break	%	200 - 400	300	300	230	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
Flexural modulus	MPa	275 - 620	550 - 700	590 - 700	1200	2100	100 - 600	500 - 1500	900 - 2000	500 - 2900	400-1400	260 - 1600	1400 - 3000	1000 - 2400	2300	70 - 2300	15 - 730	40 - 1200
Hardness	Shore D	55 - 65	55 - 60	55 - 64	63 -75	75 - 78	49 - 55	58 - 65	72 - 81	70	72	72	85	55 - 65	90	40 - 75	25 - 72	35 - 80
Density	g/cm³	2,2	2,15	2,15	1,7	1,8	0,91-0,94	0,94-0,96	0,90-0,91	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
Coefficient of friction		0,10	0,25	0,21	0,23	0,30	0,60	0,28	0,30	0,40	0,35	0,35	0,30	0,22 /0,5	0,55	0,2 - 0,8		
Transparency	See note	* * *	* * * *	* * * * *	* * *	*	* * * *	* * *	* * *	* *	* * *	* * *	*	* * * * *	* * * * *	* * * *	* * * *	* *
Melting point	°C	330	257 - 275	300 - 310	270	175	110	125	134 - 165	220	175 - 190	170 - 185	160 - 175	230/250	240	170 - 240	135 - 175	160 -215
Min. service temp. Max. service temp.	°C °C	-200 +260	-200 +200	-200 +260	-190 +150	-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
Water absorption	%	<0,01	0,004	< 0,03	0,02	<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	* * * * *	* * * *	* * * * *	* * * *	* * * *	* * *	* * *	* * * *	* *	* *	* *	* * *	* * * *	*	* * *	* * *	* * *
Sterilisation,	ETO Steam Radiation	X X -	X X -	X X -	X X X	X X X	X - X	X - X	X X (X)	X X X	X X X	X X X	X 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. Optinova Ab takes no responsibility for data given in the table.
Excellent: * * * * *
Poor: *



Experience, High Quality and Trust

Optinova engineering expertise takes you from idea to product.

Optinova has over 30 years of experience in the precision extrusion of customer-designed components for the medical device industry. Today, our components are incorporated into hundreds of millions of lifesaving devices throughout the world.
Our experience ranges from idea, via choice of material, to the delivery of precise medical device components. This can be achieved through use of our new advanced extrusion techniques and a highly efficient production system.
Optinova is constantly attracting interest as an R & D partner from “World Class Producers”. Our knowledge and long experience is highly valued around the world.

You can turn to Optinova and trust that we will do our utmost to fulfil your expectations. Our integrity is without compromise and we guarantee client confidentiality.

The production equipment and facilities at Optinova are of the latest design. We manufacture under GMP guidelines in a certified clean-room environment with in-process control to ensure the highest consistency and minimum batch-to-batch variation.
Full documentation and traceability are always guaranteed.

Optinova is certified according to ISO 9001:2000 and ISO 13485:2003.

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