

**Tubes made from
high-performance plastics**

Excerpt: Tubes for Medical
Applications





Tubes that meet the highest demands in medical and laboratory technology, pharmaceuticals, and analytics



As a development partner to internationally leading medical equipment manufacturers, we offer sophisticated solutions. Our products are characterized by their reliability and safety for patients and staff. With our industry orientated sales team specifically trained in medical technology applications, clean room production and manufacturing know-how, we are able to offer creative solutions for new product development opportunities.

From the idea to series production

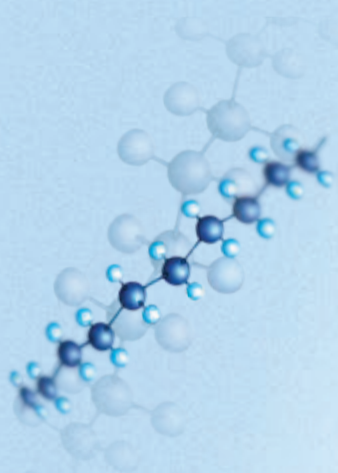
- Application support: technical and commercial
- Specially created prototypes for the first relevant test situations
- Test benches for prototype verification
- Project management and manufacturing conditions in accordance with IATF 16949:2016 and EN ISO 13485
- Production, testing, cleaning, and packaging under controlled conditions
 - Standard production conditions in accordance with GMP (“Good Manufacturing Practice”)
 - Controlled zone (cleanliness class 2)
 - Clean room in accordance with ISO Class 8

- Biological evaluation of products in accordance with EN ISO 10993
- Approved materials for manufacturing medical tubes
- Support for regulatory affairs

Approvals and conformities

- Certificate of compliance with USP Class VI
- Compliance with REACH Regulation (EC) No 1907/2006 (Candidate List of SVHC)
- Conformity with Directive 2011/65/EU (RoHS 2)
- Conformity with FDA 21 CFR 177.1550
- PTFE “Medical Grade”
- Thermoplastic high-performance plastics such as Moldflon™-PFA, -FEP, and -PEEK
- Radiopaque
- For more details, see the material properties chapter

Materials for medical tubes



Need more information?

Give us a call:

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or e-mail:

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Medical tubes for diagnosis and treatment in endoscopy and minimally invasive surgery

Applications

- Gastroenterology
- Laparoscopy
- Proctology
- Gynecology
- Bronchoscopy
- ENT medicine
- Orthopedics

Designs



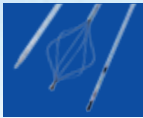
Multilumen tubes, profiles, special shapes

- Design and number of lumens individually configurable
- Good sliding characteristics
- Pressure tested and puncture resistant
- Tempered without shrinkage
- Biocompatible in accordance with EN ISO 10993



Color-coded and labeled tubes

- Individual design (colored rings, logos, measurement scales)
- No color layer on surface
- High wear resistance
- Shade is individually configurable, e.g., in accordance with the RAL or Pantone color scale
- Biocompatible dye in accordance with EN ISO 10993
- UV resistance
- Optimal visual recognition for positioning in the body
- Possible sterilization processes: autoclave, EtO
- Radiopaque



Trocar sleeve for minimally invasive surgery. This device with spiral PTFE tube allows operations to be carried out with a relatively small amount of blood loss.



Colored tubes

- Dielectric
- Insulation
- Thin walls
- Microtubes
- Narrow tolerances
- Shade is individually configurable, e.g., in accordance with the RAL or Pantone color scale
- Biocompatible dye in accordance with EN ISO 10993



Corrugated tubes

- High flexibility thanks to spiral surface
- Kink-resistant
- Individual design
- High dimensional accuracy thanks to a special manufacturing process
- Very good sliding characteristics
- Tempered without shrinkage
- Biocompatible in accordance with EN ISO 10993
- Sterilizable with EtO and superheated steam



Reprocessing of tubes

- Cross section tapering with constant or variable inner diameter
- Expansion and flange shapes
- Processing of tube ends (radii, slants, closures)
- Drilling
- 3D forming
- Surface activation to allow bonding with other materials

Tubes for pharmaceuticals, analytics, and laboratory technology



There is a wide range of possible applications for our tubes in the areas of pharmaceuticals, analytics, and laboratory technology. For example:

- Analysis and measurement devices for chromatography and laboratory technology
- Product lines in miniplant systems
- Dosing lines for reaction vessels
- Applications in dental technology

Applications

- Degassing of liquids, e.g., in liquid chromatography (HPLC)
- Disinfection of liquids
- Water supply and extraction
- Transport of aggressive media such as acids, bases, gases, and solvents
- Dissipation of electrical charge in potentially explosive atmospheres
- Cladding of moving mechanical parts
- Sheathing for measurement sensors and heating elements
- Tempering of liquids

Designs



ESD (Electrostatic Discharge) tube

- Dissipating electrostatic charge
- Transparent design also available
- Small diameters on request



Tube bundles

- Ultrapure PTFE tubes without additives that interfere with analysis (e.g., plasticizers)
- Precise manufacturing
- Small diameters on request
- Small wall thicknesses for defined gas diffusion
- Kink-resistant
- Maximum surface area
- Biocompatible in accordance with EN ISO 10993



Knitted coils

- Linear flow movement created by alternating changes of direction
- Constant, pulsation free reagent flow
- Smoothing of the parabolic velocity curve
- Chemically inert
- Easy to clean
- Different tube variants and sizes available

Modules and assemblies according to customer requirements

Please contact us if you have any questions about additional solutions or modules for medical technology.

Thermoplastic tubes: create the perfect shape with Moldflon™

Thermoplastic extrusion

In contrast to paste extrusion, thermoplastic extrusion involves the use of granulate, which is continuously melted. The dimensions and shape are created during the subsequent calibration and cooling in a water basin. This allows us to manufacture tubes with varying dimensions. The wrapping and guillotine device at the end of the process allows the tubes to be supplied in units or by the meter. This offers the following economic advantages:

- Customized shape
- Large scale production
- Short turnaround times
- More economical use of resources
- Low supervision costs
- High process reliability/stability
- Continuous production

Combination of outstanding properties

Moldflon™-PTFE is characterized by its balanced array of properties. In the fully fluorinated PTFE and thermoplastic products segment, it is positioned between modified PTFE and PFA. With a melting point between 315°C and 320°C, it has very similar properties to modified PTFE.

Application examples

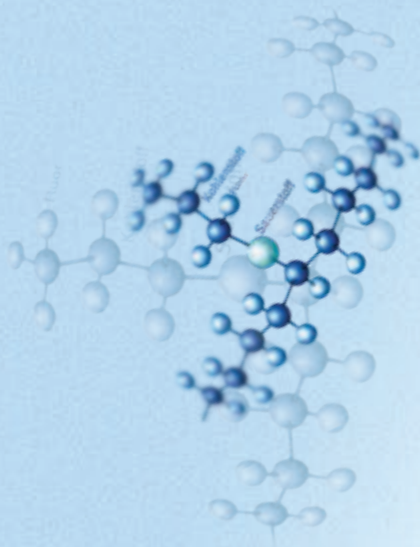
- Automotive
- Medical and laboratory technology
- Analytics
- Electrical engineering
- Chemistry
- Food technology
- Pharmaceuticals
- Biotechnology

Approvals for Moldflon™-PTFE

Moldflon™-PTFE has been given numerous approvals for a wide range of applications. The following certificates are available for natural types, and in special cases also for compounds:

- FDA, EU, BgVV: application in contact with foodstuffs
- In vitro cytotoxicity: no extractable cytotoxic fractions
- USP Class VI: pharmaceuticals and biotechnology
- W270: protection of drinking water from microorganisms

Approvals have also been granted for the other Moldflon™ materials. With these available approvals, users can immediately start development, reduce their own testing costs during product development, and gain time in the development process. We will be happy to assist you in choosing the right material so that you will receive the most functional and economical solution for your specific area of application.



Need more information?

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Advantages of different tube materials

POLYTETRAFLON™-PTFE

- Lowest friction coefficient of any polymer
- Very good sliding characteristics—self-lubricating effect
- No water absorption, water repellent
- Anti-adhesive
- Exceptionally large operating temperature range: –200°C to +260°C
- Almost universal chemical resistance
- Good electrical and dielectric properties
- Resistant to superheated steam
- Light, weather and radiation resistant
- Self extinguishing in acc. with UL 94 V-0
- Physiologically harmless
- Suitable for contact with foodstuffs and medical applications
- UV resistant
- Sterilizable with ethylene oxide and autoclave

POLYTETRAFLON™-modified PTFE (mod. PTFE)

- Comparable properties to PTFE with additional advantages
- Lower permeation and denser, less porous polymer structure
- Reduced pore formation when stretched (stretch void index)
- Higher elongation at break
- Significantly decreased deformation under load
- Smoother surface structure
- Improved weldability
- Higher transparency than standard PTFE

Moldflon™-PTFE

- In contrast to conventional PTFE, can be processed thermoplastically by means of injection molding and extrusion (particularly attractive for large-scale production)
- Continuous operating temperature of up to 260°C
- Significantly better wear behavior than PTFE and mod. PTFE, particularly as an unfilled material
- Optimal sliding and frictional behavior in dynamic applications
- Suitable for contact with foodstuffs

- Biocompatible in accordance with USP Class VI and in terms of cytotoxicity
- Excellent chemical resistance
- Resistant to weather and ageing
- Self extinguishing in acc. with UL 94 V-0

Moldflon™-PFA

- Outstanding purity properties
- Good stress cracking resistance
- Good weldability
- Outstanding thermal resilience
- Very high chemical resistance
- High electrical resistance
- Very high oxygen index
- Self extinguishing in acc. with UL 94 V-0
- Physiologically harmless
- Combines the attributes of PTFE and FEP
- Low gas permeability
- Smoother surface structure than FEP and PTFE
- Can be sterilized with gamma radiation, ethylene oxide, e-beam radiation, and autoclave

Moldflon™-FEP

- Lower gas and vapor permeability than most plastics
- Good stress cracking resistance
- Good weldability
- High purity
- Outstanding thermal resilience
- Very high chemical resistance
- High electrical resistance
- Very high oxygen index
- Self extinguishing in acc. with UL 94 V-0
- Physiologically harmless
- Greater flexibility than PTFE
- Better optical clarity than PTFE
- Better sliding characteristics than PFA
- Excellent UV transmission rates
- Outstanding dielectric strength

Moldflon™-ETFE

- Continuous operating temperature of up to 150°C
- Improved mechanical strength and stiffness
- High chemical resistance to acids/bases and organic solvents
- Resistant to ageing and weather
- Self extinguishing in acc. with UL 94 V-0
- Suitable for contact with foodstuffs
- Can be joined by electron beam welding

Moldflon™ PCTFE

- Continuous operating temperature of up to 160°C
- Outstanding mechanical properties and good machinability
- Suitable for cryogenic applications with temperatures as low as -250°C
- High chemical resistance
- Self extinguishing in acc. with UL 94 V-0
- Physiologically harmless

Moldflon™-PVDF

- Has the best mechanical properties of any unfilled fluoropolymer
- Very good machinability
- Good weldability
- Fulfills the highest purity standards
- Highly resistant to chemicals
- Very good electrical insulation properties
- Resistant to hot water
- Self extinguishing in acc. with UL 94 V-0
- Very high radiation resistance

- Approved in accordance with FM 4910
- Physiologically harmless

Moldflon™-ECTFE

- Continuous operating temperature of up to 150°C
- Optimal permeation resistance
- High chemical resistance
- Outstanding surface quality
- High wear resistance
- Self extinguishing in acc. with UL 94 V-0
- High resistance to UV and gamma radiation
- Good weldability
- Physiologically harmless

Moldflon™-PEEK

- Continuous operating temperature of up to 260°C
- Outstanding mechanical strength and viscosity
- Very good dimensional stability
- High wear resistance and good frictional properties
- Excellent chemical resistance
- Self extinguishing in acc. with UL 94 V-0
- Suitable for contact with foodstuffs and drinking water

Moldflon™-PEI

- Continuous operating temperature of up to 170°C
- High mechanical strength and stiffness
- Creep resistance and dimensional stability over a large temperature range
- Excellent electrical insulator
- Resistant to high energy radiation
- High hydrolysis resistance
- Self extinguishing in acc. with UL 94 V-0
- Low smoke emission in the event of a fire

Overview of technical characteristics of different tube materials

			POLYTETRAFLON™		Moldflon™
General property	Standard	Unit	PTFE	mod. PTFE	PTFE
Density	ISO 1183	g/cm ³	2.14–2.19	2.14–2.19	2.13–2.18
Upper operating temperature, no load		°C	250–260	250–260	250–260
Flammability	UL94	–	V-0	V-0	V-0
Water absorption at 23°C saturation		%	< 0.05	< 0.05	< 0.05
Thermal					
Thermal	Standard	Unit	PTFE	mod. PTFE	PTFE
Melting temperature	ISO 11357	°C	327	327	310–320
Coefficient of linear thermal expansion	DIN 52612	10 ⁻⁵ *K ⁻¹	10–16	10–16	10–16
Thermal conductivity at 23°C	ISO	W/(m*K)	0.23	0.23	0.22
Specific heat at 23°C		kJ/(kg*K)	1.01	1.01	1.09
Oxygen index		%	> 95	> 95	> 95
Mechanical					
Mechanical	Standard	Unit	PTFE	mod. PTFE	PTFE
Tensile strength at 23°C	ISO 527	MPa	29–39	30–42	20–25
Tensile strength at 150°C			14–20	15–24	
Yield stress at 23°C	ISO 527	MPa	10	12	
Tensile strength at 23°C	ISO 527	%	200–500	400–600	330–380
Young's modulus at 23°C	ISO 527	MPa	400–800	500–900	650
Limiting bending stress at 23°C	ISO 178	MPa	18–20	19–22	
Flexural modulus of elasticity	ISO 527	MPa	600–800	650–900	
Ball indentation hardness 23°C	ISO 2039		25–30	26–31	25–30
Rockwell hardness R	ISO 2039		20–30	22–32	25–35
Shore hardness D	ISO 868		55–72	56–75	60–65
Friction coefficient			0.05–0.2	0.05–0.2	0.15–0.25
Electrical					
Electrical	Standard	Unit	PTFE	mod. PTFE	PTFE
Dielectric constant at 100 Hz	IEC 60250		< 2.1	< 2.1	< 2.1
Dielectric constant at 10 ⁶ Hz			< 2.1	< 2.1	< 2.1
Dielectric loss factor at 100 Hz		*10 ⁻⁴	0.5–0.7	0.5–0.7	0.5–0.7
Specific contact resistance	IEC 60093	Ω*cm	> 10 ¹⁸	> 10 ¹⁸	> 10 ¹⁸
Surface resistance	DIN 53482	Ω	> 10 ¹⁶	> 10 ¹⁶	> 10 ¹⁶
Tracking resistance	IEC 60112	CTI	600	600	600
Dielectric strength	IEC 60243-2	kV/mm	> 40	> 40	> 50

PFA	FEP	ETFE	PCTFE	PVDF	ECTFE	PEEK	PEI
2.12–2.17	2.12–2.17	1.71–1.78	2.10–2.16	1.75–1.78	1.67–1.70	1.3	1.27
250–260	200–205	150–180	150–180	150–170	150–180	260	170
V-0	V-0	V-0	V-0	V-0	V-0	V-0	V-0
< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	0.45	1.25

PFA	FEP	ETFE	PCTFE	PVDF	ECTFE	PEEK	PEI
300–310	253–282	265–275	185–210	165–178	240–247	340–350	217
10–16	10–14	8–12	4–8	8–18	4–8	4.7	5
0.22	0.20	0.23	0.19	0.17	0.15	0.29	0.24
1.09	1.17	1.95	0.92	1.38		1.4	2.0
> 95	> 95	30	> 95	43	60	24	47

PFA	FEP	ETFE	PCTFE	PVDF	ECTFE	PEEK	PEI
27–32	19–25	36–48	31–42	38–50	41–54	98	129
15–21	4–6	8–12	1–2	7.5–10.5	3.5–4.5		
14	12	24	40	46	34	98	130
300	250–350	200–500	80–250	20–250	200–300	34	60
650	350–700	500–1,200	1,000–1,200	1,800–1,800	1,200–1,800	3,500	3,200
15		25–30	52–63	55	50	130	140
650–700	660–680	1,000–1,500	1,200–1,500	1,200–1,400	1,700	3,800	3,400
25–30	23–29	34–40	55–70	62–68	55–65	220	165
25–35	20–30	45–55	103–118	100–115	85–95		M 115
60–65	55–60	63–75	70–90	73–85	70–80	85	
0.2–0.3	0.3–0.35	0.3–0.5	0.3–0.4	0.2–0.4	0.65	N/A	0.3–0.4

PFA	FEP	ETFE	PCTFE	PVDF	ECTFE	PEEK	PEI
< 2.1	< 2.1	2.6	2.3–2.8		2.3–2.6	3.2	3
< 2.1	< 2.1	2.6	2.3–2.4			3.1	3
0.5–0.7	0.5–0.7	0.5–0.6				30	0.002
> 10 ¹⁸	> 10 ¹⁸	> 10 ¹⁶	> 10 ¹⁸	> 10 ¹⁵	> 10 ¹⁵	> 10 ¹⁴	
> 10 ¹⁶	> 10 ¹⁶	> 10 ¹⁴	> 10 ¹⁶	> 10 ¹³	> 10 ¹²	> 10 ¹⁶	> 10 ¹³
600	600	600	600	600	600	150	175
> 50	> 50	> 40	> 40	> 40	> 40	19	> 20

This table, intended for guidance only, shows typical values obtained with standard samples. The material properties expressly do not constitute any legal basis for specification or design purposes and may deviate substantially depending on the material, components, and processing and operating conditions.

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GMP



EN ISO 13485

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