CARE MEDICAL MATERIALS

HIGH PERFORMANCE POLYMERS FOR MEDICAL DEVICES

EVONIK
Leading Beyond Chemistry

CONTENT

Evonik is one of the world leaders in specialty chemicals. With more than forty years of experience, Evonik offers customized products for the medical sector.

The product portfolio includes the **MEDICAL CARE SERIES**, special polymers for medical technology such as fluid delivery systems, catheter, surgical instruments and many others.

The application of polymers in medical devices is often challenging. Besides meeting highest quality standards, materials need to withstand aggressive disinfectants, pharmaceuticals and resist different sterilization procedures without sacrificing mechanical performance. Furthermore, it needs to be ensured that no harmful interaction takes place among the material and any bodily tissue or fluids. Moreover, any reaction with pharmaceutical formulation needs to be avoided to prevent changes in the composition and activity of the active ingredients. Not least, materials for medical applications need to exhibit an excellent processability in order to realize delicate geometries for minimal invasive devices or accurate fit of connecting parts.

A proper material selection is a crucial step in the development process of medical devices. Materials need to meet the highest quality standards, resist harsh chemicals & pharmaceuticals, and fulfill critical performance requirements which need to be maintained after sterilization.

We offer a variety of materials under the Care brand – from transparent to translucent, from elastic to strong, from unmodified to stabilized, filled or functional. In addtion to the standard Care product portfolio, Evonik uses its decades of polymer & compound development experience to customize materials fulfilling unmet customer and market requirements.

PRODUCT OVERVIEW

Strong

VESTAMID® Care ML

VESTAMID® Care ML grades cover a range of polyamide 12 (PA12) resins with different viscosities for processing via extrusion or injection molding. In addition to unstabilized base resins, our portfolio contains compounds with heat- and UV-stabilization as well as reinforced compounds. Due to the high dimensional stability, tensile strength and low sliding friction, VESTAMID® Care ML grades are the materials of choice for catheters and tubings. The VESTAMID® Care ML materials meet even highest challenges in applications such as angioplasty balloon catheters. Typical areas of application for reinforced VESTAMID® Care ML grades include housing-parts, monitoring and imaging devices and durable medical equipment.

Flexible

VESTAMID® Care ME

VESTAMID® Care ME materials are polyether block amides, Evonik's flexible polyamide, which is available in various hardnesses. Due to their broad range of flexibility, VESTAMID® Care ME grades are used in different parts of catheter constructions – may it be the distal end, requiring a low modulus for non-traumatic insertion, or the proximal end, needing a high modulus for force and torque transmission. All VESTAMID® Care ME grades are free of plasticizers and stabilized against heat and UV-light.

Bonding

VESTAMID® Care ME-B

VESTAMID® Care ME-B grades cover a range of polyether-block-amides (PEBA) with different flexibility and hardness, which were specially modified to adhere to Daikin's Neoflon® EFEP RP-5101 without the need for any adhesive. The chemical nature of both materials results in the formation of covalent bonds among the polymer chains of VESTAMID® Care ME-B and Neoflon® EFEP at the boundary layer upon processing via coextrusion. Thereby, multilayer tubings can be realized, which combine the individual properties of both EFEP and PEBA, and do not contain any compatibilizer or adhesive, that might migrate out of the device.

Transparent

TROGAMID® Care

TROGAMID® Care grades are based on microcrystalline transparent polyamides. All TROGAMID® Care grades are BPA free. The microcrystalline TROGAMID® Care MX grades exhibit exceptional resistance against chemicals and stress-cracking. Hence, TROGAMID® Care MX is the material of choice for all applications dealing with pharmaceutical formulations, lipids or aggressive disinfectants. Examples include dialyzer parts, housings, covers, dentures, hearing aids, fluid and drug delivery equipment such as cocks and connectors.

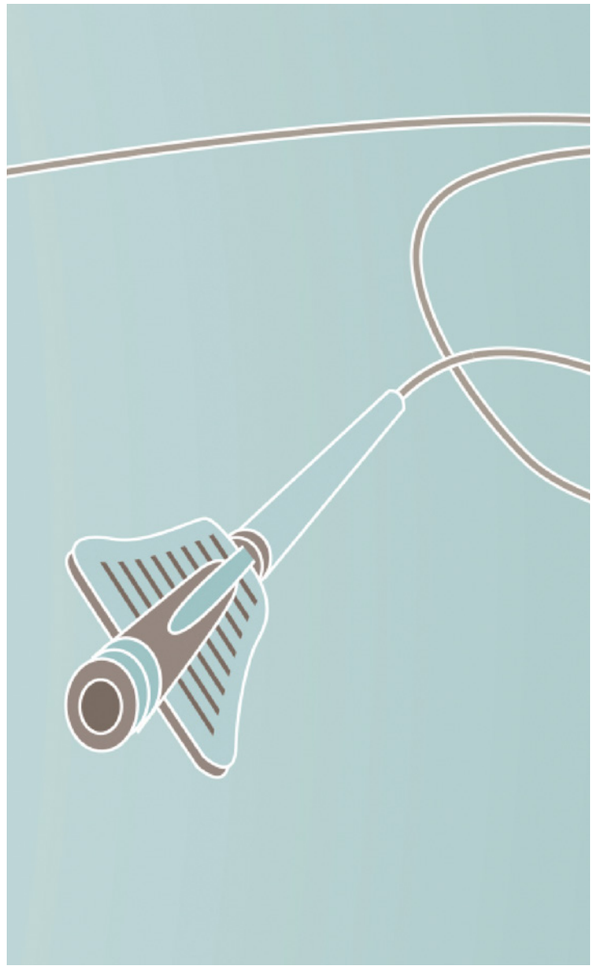
High temperature

VESTAKEEP® Care

When it comes to application conditions involving high temperatures, harsh chemical environments or high mechanical loads, VESTAKEEP® Care grades are the materials of choice. VESTAKEEP® Care polyether ether ketone (PEEK) medical grades are available in different viscosities for processing via extrusion or injection molding and they are also available as stock shapes. VESTAKEEP® Care materials offer higher resistance to heat, chemicals, and hydrolysis. Typical areas of application for VESTAKEEP® Care include parts for housings and surgical instruments, gear wheels and other parts for functional units and durable medical equipment. VESTAKEEP® Care grades retain their properties even after a high number of steam sterilization cycles.

VESTAMID® Care ML

resins are characterized by several outstanding properties, such as high impact & notched impact resistance, dimensional stability, good sliding properties, high abrasion and chemical resistance.



Biocompatibility test reports availability

VESTAMID® Care ML Resins – neat PA12		ML16	ML17	ML18	ML19	ML21
Viscosity number	ISO 307; cm^3/g	120	140	160	180	230
Steam sterilization cycles		5-25	5-25	5-25	5-25	25-50
USP Class VI	Acute systemic toxicity, intracutaneous reactivity, muscle implantation	⊕	⊕	⊕	⊕	⊕
ASTM F756	Hemolysis	⊕	⊕	⊕	⊕	⊕
ISO 10993-5	Cytotoxicity	⊕	⊕	⊕	⊕	⊕
ISO 10993-10	Sensitization: maximization test acc. to Magnusson and Kligman	⊕	⊕	⊕	⊕	⊕
ISO 10993-10	Irritation: intracutaneous reactivity	⊕	⊕	⊕	⊕	⊕
ISO 10993-11	Acute systemic toxicity	⊕	⊕	⊕	⊕	⊕

VESTAMID® Care ML – stabilized PA12 and compounds		ML67	ML94	ML24	MLGB30
Viscosity		Stabilizer	Stabilizer	Stabilizer	Glass beads
Viscosity number	ISO 307; cm^3/g	120	180	225	160
Steam sterilization cycles		5-25	5-25	25-50	25-100
USP Class VI	Acute systemic toxicity, intracutaneous reactivity, muscle implantation	⊕	⊕	⊕	⊕
ASTM F756	Hemolysis	⊕	⊕	⊕	⊕
ISO 10993-5	Cytotoxicity	⊕	⊕	⊕	⊕
ISO 10993-10	Sensitization: maximization test acc. to Magnusson and Kligman	⊕	⊕	⊕	⊕
ISO 10993-10	Irritation: intracutaneous reactivity	⊕	⊕	⊕	⊕
ISO 10993-11	Acute systemic toxicity	⊕	⊕	⊕	⊕

VESTAMID® Care ML

Unfilled VESTAMID® Care ML grades are the materials of choice for catheters and tubing. These materials meet even the most challenging requirements in applications such as angioplasty balloon catheters.

Typical application areas for filled VESTAMID® Care ML grades include housing parts, monitoring and imaging devices and durable medical equipment.

Key features

- → High impact resistance
- → Easy processability & colorability
- → Low sliding friction
- → High toughness
- → High abrasion resistance
- → Density 1.0 g/cc
- → High dimensional stability
- → High chemical resistance
- → Gamma and EtO sterilizable

Biocompatibility

The biocompatibility of VESTAMID® Care ML grades has been tested following the recommendations of ISO 10993-1 for up to 30 days of body contact. Please refer to the results in the table.

Product offering

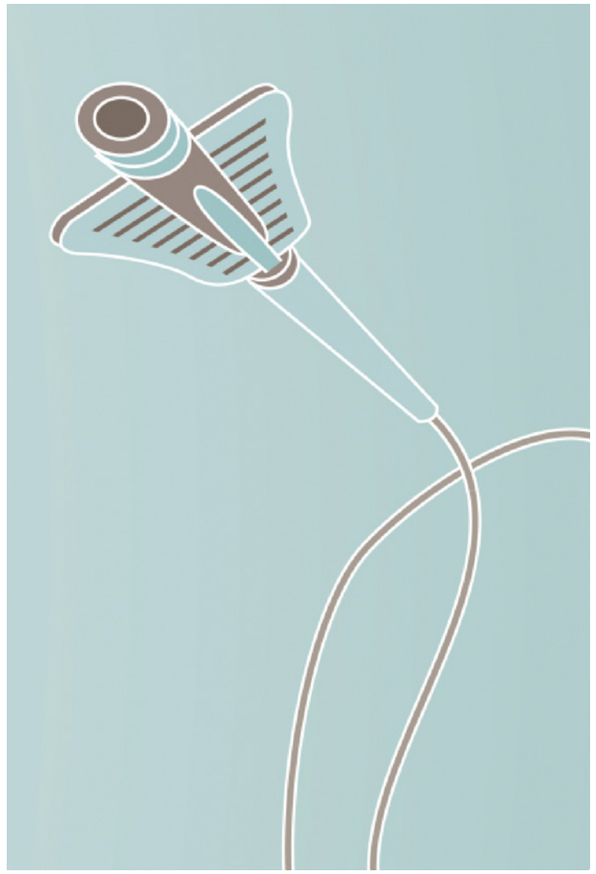
- → Natural color
- → Heat and light stabilized
- → Filled
- → Compounds
- → Pellets packaged in 25 kgs / 55.1 lbs bags

Typical applications

- → Balloons
- → Catheters
- → Medical tubing
- → Housings

VESTAMID® Care ME

grades represent a range of flexible polyether block amide (PEBA) resins of varying hardness levels for processing via extrusion and injection molding.



Biocompatibility test reports availability

VESTAMID® Care ME – impact modified PA12		ME26	ME40	ME47	ME55	ME62	ME71
Shore D hardness		26	40	47	55	62	71
Steam sterilization cycles		n.d.	<5	5-25	25-50	25-50	25-50
USP Class VI	Acute systemic toxicity, intracutaneous reactivity, muscle implantation	⊕	⊕	⊕	⊕	⊕	⊕
ASTM F756-08	Hemolysis	⊖*	⊕	⊕	⊕	⊕	⊕
ISO 10993-5	Cytotoxicity	⊖*	⊕	⊕	⊕	⊕	⊕
ISO 10993-1	Sensitization: maximization test according to Magnusson and Kligman	⊕	⊕	⊕	⊕	⊕	⊕
ISO 10993-10	Irritation: intracutaneous reactivity	⊕	⊕	⊕	⊕	⊕	⊕
ISO 10993-11	Acute systemic toxicity	⊕	⊕	⊕	⊕	⊕	⊕

* In the L929 Neutral Red Uptake Cytotoxicity Test (ISO 10993-5), VESTAMID Care ME26 reveals a viability of 53% and does not meet the test requirement of ≥ 70%. Also ME26 is slightly hemolytic.

VESTAMID® Care ME

VESTAMID® Care ME standard grades have a proven history in catheter applications.

Due to their broad range of flexibility, VESTAMID® Care ME grades are used in different parts of catheter construction – it may be the distal end, requiring a low modulus for non-traumatic insertion, or the proximal end, needing a high modulus for force and torque transmission.

Key features

- → High flexibility & elasticity
- → Good rebound properties
- → High impact resistance
- → Excellent dimensional stability
- → High chemical resistence
- → Easy processability & colorability
- → Plasticizer-free
- → Gamma and EtO sterilization resistant
- → Tough and resilient
- → Low density

Biocompatibility

The biocompatibility of VESTAMID® Care ME grades has been tested following the recommendations of ISO 10993-1 for up to 30 days of body contact including indirect blood contact. Please refer to the results in the table.

Product offering

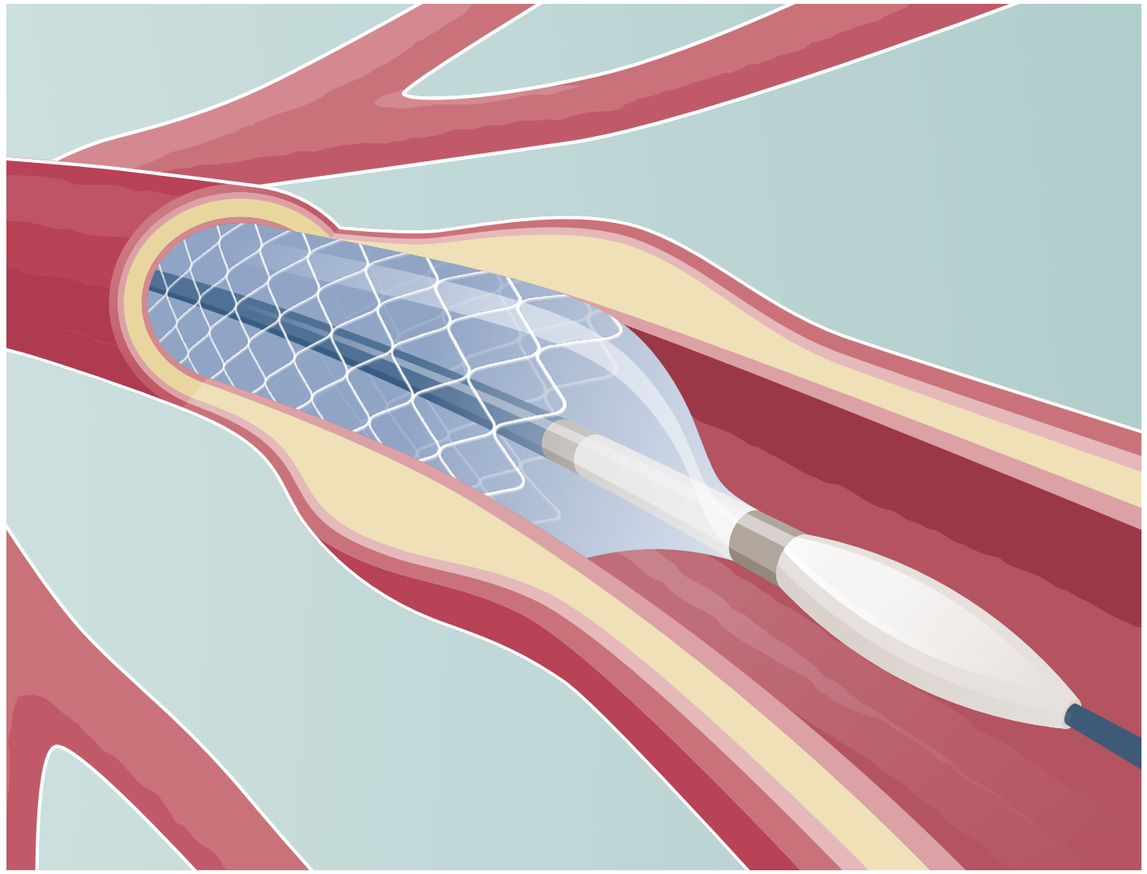
- → Natural color
- → 26 Shore D to 71 Shore D hardness
- → Heat and light stabilized
- → Pellets packaged in 25 kgs / 55.1 lbs bags

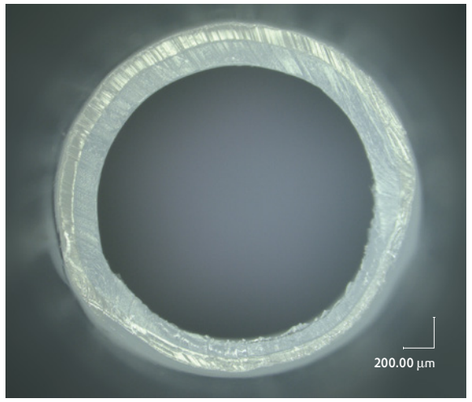
Typical applications

- → Balloons
- → Catheters
- → Medical tubing

VESTAMID® Care ME-B PEBA Bonding Grades

bond directly to fluoro-polymer in a single, one-step co-extrusion. They eliminate burdensome, time and labor intensive multi-step production. No tie layers are required.





Coextrusion process development support

On its in-house, two-layer coextrusion line Evonik supports customer trials for catheter tubings from VESTAMID® Care ME-B bonding grades and EFEP to meet specific customer requirements.

VESTAMID® Care ME-B PEBA Bonding grades

VESTAMID® Care ME-B grades cover a range of polyether-block-amides (PEBA) with different flexibility and hardness, which were specially modified to adhere to Daikin's Neoflon® EFEP RP-5101 without the need for any adhesive. The chemical nature of both materials results in the formation of covalent bonds among the polymer chains of VESTAMID® Care ME-B and Neoflon® EFEP at the boundary layer upon processing via coextrusion.

Thereby, multilayer tubings can be realized, which combine the individual properties of both EFEP and PEBA, and do not contain any compatibilizer or adhesive, that might migrate out of the device.

Key features

- → One step direct coextrusion with fluoropolymers
- → Excellent bonding strength
- → Design flexibilities to offer new catheter structures
- → Elimination of multi-step extrusions
- → Elimination of expensive adhesives
- → Elimination of surface treatment

Biocompatibility

VESTAMID® Care ME-B grades provide an increase in freedom of design without any issues regarding biocompatibility, since no low molecular weight additives are required to connect both fluoropolymer and PEBA.

Bonding strength

Bonding-studies conducted with VESTAMID® Care ME-B bonding grades and unmodified VESTAMID® Care ME grades show a distinct increase in bonding strength. On average, VESTAMID® Care ME-B grades offer a peel strength which is greater by more than one order of magnitude versus the unmodified grades.

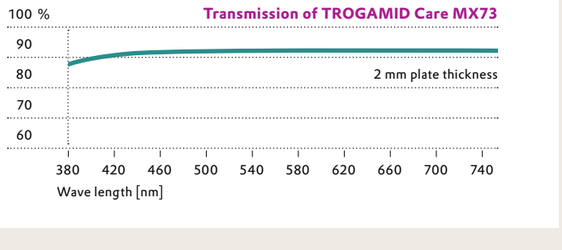
Product offering

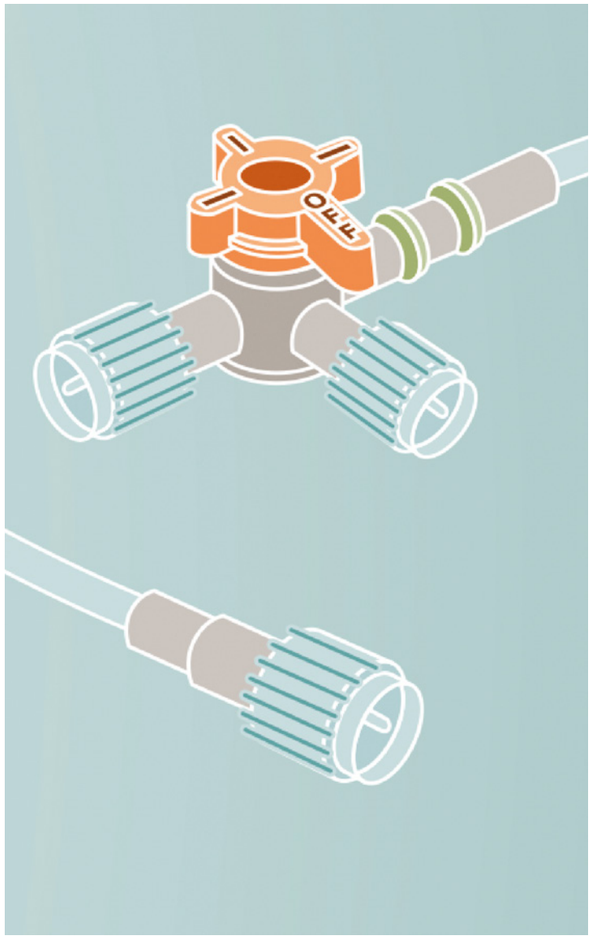
VESTAMID® Care ME-B is available in a wide range of hardnesses:

- → VESTAMID® Care ME40-B
- → VESTAMID® Care ME55-B
- → VESTAMID® Care ME62-B
- → VESTAMID® Care ME71-B

TROGAMID® Care

grades represent micro-crystalline transparent polyamides for processing via extrusion or injection molding.





Biocompatibility test reports availability

TROGAMID® Care		MX73	MX97
Steam sterilization cycles		5-25	5-25
USP Class VI	Acute systemic toxicity, intracutaneous reactivity, muscle implantation	⊕	⊕
ASTM F756	Hemolysis	⊕	⊕
ISO 10993-5	Cytotoxicity	⊕	⊕
ISO 10993-10	Sensitization: maximization test acc. to Magnusson and Kligman	⊕	⊕
ISO 10993-10	Irritation: intracutaneous reactivity	⊕	⊕
ISO 10993-11	Acute systemic toxicity	⊕	⊕

TROGAMID® Care MX73 Stress-cracking resistance

	no cracks		few cracks		many cracks		internal cracks		penetrating cracks		destructive cracks	
Fraction of parts [%]	MX	PC	MX	PC	MX	PC	MX	PC	MX	PC	MX	PC
Cyclosporin	100	18	0	20	0	14	0	34	0	8	0	6
Lipids	100	22	0	64	0	14	0	0	0	0	0	0
Phenytoin sodium	100	52	0	12	0	8	0	20	0	2	0	6
Propofol 1%	100	34	0	32	0	14	0	20	0	0	0	0

MX = TROGAMID® Care MX73
PC = Polycarbonate

TROGAMID® Care MX

Microcrystalline TROGAMID® Care MX is the material of choice for applications dealing with pharmaceutical formulations, lipids or aggressive disinfectants, since it exhibits an exceptional resistance towards chemicals and stress-cracking.

Examples of applications include fluid and drug delivery equipment such as stop-cocks, dialyzer parts, housings, covers or hearing aids.

Key features

- → High transparency
- → High chemical resistance
- → Free of BPA
- → Very good stress-cracking resistance
- → UV resistance
- → Low density
- → High impact resistance
- → Easy processability & colorability
- → Gamma and EtO sterilizable

Biocompatibility

The biocompatibility of TROGAMID® Care MX has been tested following the recommendations of ISO 10993-1 for up to 30 days of body contact. Please refer to the results in the table.

Product offering

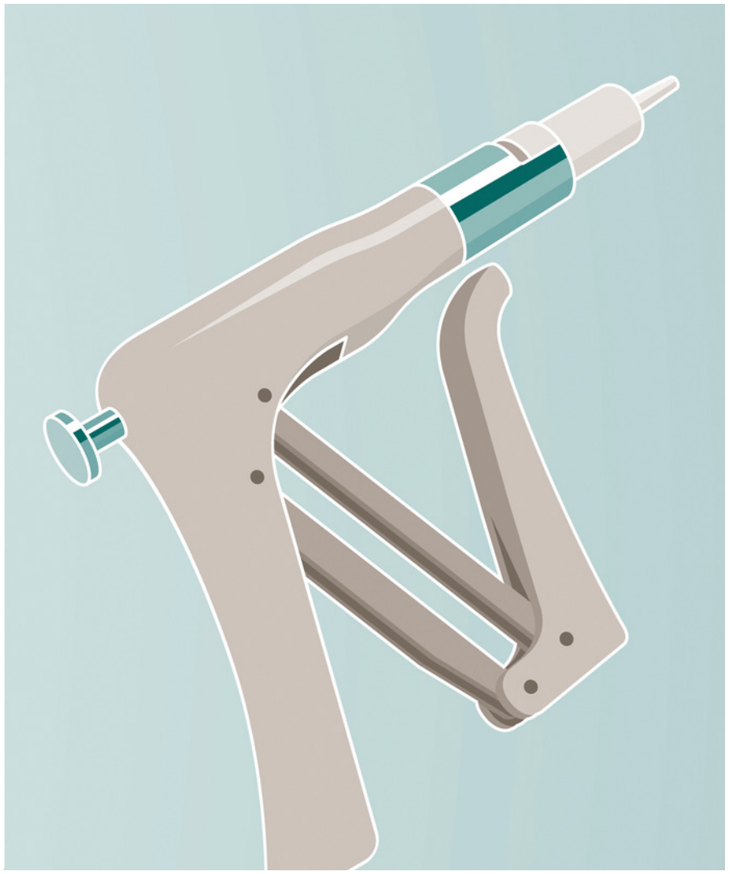
- → Natural color
- → Medium viscosity
- → Transparent
- → Pellets packaged in 25 kgs / 55.1 lbs bags
- → TROGAMID® Care MX97 with an internal mold release agent

Typical applications

- → Stopcocks
- → Lenses
- → Catheters
- → Luers

VESTAKEEP® Care

grades are the materials of choice when it comes to applications requiring metal replacement, dimensional stability and chemical resistance.



Biocompatibility test reports availability

VESTAKEEP® Care		M20 G	M33 G-HP*	M40 G / M40PL / M40 R
Viscosity		Medium	Standard	High
Sterilization autoclave cycles		> 500	> 500	> 500
USP Class VI	Acute systemic toxicity, intracutaneous reactivity, muscle implantation	⊕	⊕	⊕
ASTM F756-08	Hemolysis	⊕	⊕	⊕
ISO 10993-5	Cytotoxicity	⊕	⊕	⊕
ISO 10993-10	Sensitization: maximization test according to Magnusson and Kligman	⊕	⊕	⊕
ISO 10993-10	Irritation: intracutaneous reactivity	⊕	⊕	⊕
ISO 10993-11	Acute toxicity	⊕	⊕	⊕

*melt filtrated, low optical impurity grade

G = granules PL = plates R = rods

VESTAKEEP® Care grades

VESTAKEEP® Care PEEK (polyether ether ketone) products are available in different viscosities for processing via extrusion or injection molding. The ductile materials offer a very high resistance to heat, chemicals, and hydrolysis. Typical areas of application for VESTAKEEP® Care include parts for housings and surgical instruments, gear wheels and other parts for functional units and durable medical equipment. Due to the material's outstanding temperature resistance, parts made out of VESTAKEEP® Care resist steam autoclaving for an extended number of autoclaving cycles.

Key features

- → Resistant to chemicals
- → High temperature resistance
- → Injection molding and extrusion compatible
- → Easy to machine
- → Good processability
- → High strength material
- → Dimensional stability
- → Excellent sterilizability including min 500 steam sterilization cycles

Biocompatibility

The biocompatibility of VESTAKEEP® Care grades has been tested following the recommendations of ISO 10993-1 for up to 30 days of body contact. Please refer to the results in the table.

Product offering

- → Natural color
- → Granules supplied in 25 kg boxes with polyethylene liners
- → VESTAKEEP® Care M40 R rod stock
- → Available as rods and plates, more information on request

Typical applications

- → Parts for housings and surgical instruments
- → Gear wheels
- → Parts for functional units and durable medical equipment
- → Surgical handles and tools

VESTENAMER®

Transpolyoctenamer used as valuable processing aid and polymer modifier for softer rubber seals and stoppers in vial cap applications and production of complex rubber parts for medical applications.

Rubber products for medical applications

VESTENAMER® is a high performance component for rubber formulations. It is a reactive plastiziser and compatibilizer for elastomers of different polarity. It improves the melt flow reducing cycle times in injection or compression molding and also improves the mechanical properties of the final part, including excellent surface quality of complex parts. In many cases, the special capabilities of VESTENAMER® make it possible to successfully combine materials that are typically incompatible.

Key features

- → Reactive plasticizer
- → Compatibilizer between elastomers of different polarity
- → Increased flowability (improved injection and compression molding)
- → Increased throughput
- → Reduced die swell
- → High green strength and dimensional stability
- → Excellent surface finish
- → Increased abrasion resistance
- → Lower reversion of natural rubbers

Product offering

VESTENAMER® is supplied as cylindrical pellets in polyethylene packaging

Typical applications

- → Rubber seals
- → Rubber stoppers

VESTENAMER® TRANS-POLYOCTENAMERS

VESTODUR® is the PBT compound with a wide range of viscosities for extrusion and molding application.

VESTODUR®	GF10	X4621	X9400	X4195	X4159
Viscosity, VZ, ISO 1628-5 (cm^3/g)	app. 105	app. 140	app. 120	app. 120	app. 180

Medical technology

Specialty VESTODUR® polybutylene terephthalate compounds are easy to process and the moldings made of them are dimensionally stable. They feature low sliding friction. Thus, on the one hand, dimensionally stable housings like pipette housings and functional components of inhalers can be made with them. On the other hand, VESTODUR® is also suitable for processing with the melt-blow process, where the structure of the non-wovens produced can be adjusted. They are used as blood filters, for example.

Key features

- → High thermostability
- → High stiffness
- → Good strength
- → Low water absorption resulting in high dimensional stability
- → High hardness
- → Good chemical resistance
- → Good processability

Product offering

VESTODUR® is available in glass filled reinforced forms, non-corrosive, non-bromine flame retardants as well as laser markable technology.

Typical applications

- → Membrane filter housings
- → Pipette housings
- → Inhalers (including housing, rings etc.)

VESTODUR® POLYBUTYLENE TEREPHTHALATES

KEY PROPERTIES TABLE

	TEST METHOD	UNIT	VESTAMID® Care														TROGAMID® Care		VESTAKEEP® Care		
			ML16	ML17	ML18	ML19	ML21	ML67	ML94	ML24	MLGB30	ME26	ME40	ME47	ME55	ME62	ME71	MX73	MX97	M20 G	M33G-HP	M40 G
Density 23°C	ISO 1183	g/cm³	1.02	1.02	1.02	1.02	1.01	1.01	1.01	1.01	1.25	1.00	1.01	1.02	1.03	1.03	1.01	1.02	1.02	1,3	1,3	1,3
Tensile test	ISO 527-2/1A																					
Stress at yield		MPa	45	45	45	45	45	46	45	47	47	-	-	-	-	23	37	60	60	100	98	96
Strain at yield		%	5	5	5	5	5	6	5	5	5	-	-	-	-	42	12	8	8	5	5	5
Strain at break		%	>50	>50	>50	>50	>50	>50	>50	>50	>50	>500	>200	>200	>200	>200	>200	>50	>50	>20	>20	>20
Tensile modulus	ISO 527-2/1A	MPa	1400	1400	1400	1400	1400	1400	1350	1400	2000	22	80	120	230	370	1040	1400	1400	3700	3600	3500
CHARPY impact strength [1]																						
23 °C	ISO 179/1eU	kJ/m²	N	N	N	N	N	N	N	N	160 C	N	N	N	N	N	N	N	N	N	N	N
-30 °C	ISO 179/1eU	kJ/m²	N	N	N	N	N	N	N	N	160 C	N	N	N	N	N	N	N	N	N	N	N
CHARPY notched impact strength [1]																						
23 °C	ISO 179/1eA	kJ/m²	5 C	6 C	6 C	7 C	32 C	4 C	6 C	16 C	6 C	N	N	N	N	120 P	7 C	14 C	14 C	6 C	6 C	7 C
-30 °C	ISO 179/1eA	kJ/m²	5 C	6 C	6 C	7 C	9 C	5 C	6 C	9 C	6 C	N	N	N	22 C	8 C	6 C	11 C	13 C	6 C	6 C	6 C
Heat deflection temperature under load																						
Method A 1.8 MPa	ISO 75-1	°C	50	50	50	50	50	50	50	50	55	-	-	45	45	45	54	108	108	155	155	155
Method B 0.45 MPa	ISO 75-2	°C	110	110	110	110	110	120	120	110	150	-	55	65	90	100	111	122	122	205	205	205
Vicat softening temperature																						
Method A 10 N	ISO 306	°C	170	170	170	170	170	170	170	170	150	74	125	140	160	165	172	137	135	335	335	335
Method B 50 N	ISO 306	°C	140	140	140	140	140	140	140	140	155	-	60	70	100	110	137	130	130	310	305	305
Coefficient of linear thermal expansion																						
23–55 °C	ISO 11359	10-4/K	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.4	1.3	1.7	2.2	2.2	2.0	2.0	1.7	0.9	0.9	0.6	0.6	0.6
Melt volume-flow rate (MVR)	ISO 1133	°C / kg	210/2.16	210/2.16	210/2.16	240/5	275/5	230/2.16	275/5	275/5	275/5	240/2.16	240/2.16	240/2.16	240/2.16	240/2.16	240/2.16	285/5	285/5	380/5	380/5	380/5
		cm³/10 min	46	20	11	27	50	60	110	36	100	110	38	28	24	13	75	20	31	70	20	12
Flammability [2]	IEC 60695		HB	HB	HB	HB	HB	HB	HB	HB	HB	HB	HB	HB	HB	HB	HB	HB	HB	V0/3.2 mm	V0/3.2 mm	V0/3.2 mm
Water absorption																						
23°C, saturation	ISO 62	%	1.5	1.5	1.5	1.5	1.5	1.4	1.5	1.6	1.1	0.7	1.0	1.0	1.1	1.1	1.5	3.5	3.5	0.5	0.5	0.5
23°C, 50% relative humidity	ISO 62	%	0.7	0.7	0.7	0.7	0.7	0.7	0.8	0.7	0.5	0.4	0.4	0.4	0.5	0.5	0.7	1.5	1.5	0.25	0.25	0.25
Mold shrinkage in flow direction	ISO 294-4	%	0.95	0.68	0.85	0.78	0.70	0.9	0.85	0.65	1.2	-	0.49	0.57	0.81	0.81	1.11	0.65	0.65	0.7	0.9	0.9
Mold shrinkage in transverse direction																						
specimen 60 x 60 x 2 mm		%	1.09	1.22	1.03	1.10	1.25	1.1	1.15	1.25	1.2	-	1.13	1.20	1.29	1.35	1.16	0.80	0.80	1.1	1.1	1.1
Melting point, DSC, 2nd heating	ISO 11357	°C	178	178	178	178	178	178	178	178	178	144	151	157	166	171	177	250	250	340	340	340
Shore hardness D	ISO 868		75	75	75	75	75	75	75	75	74	26	40	47	55	62	71	81	81			
Glass transition temperature																						
Tg 10K/min	ISO 11357	°C	45	45	45	45	45	45	45	45	45	-	-60	-50	-20	10	-	140	140	155	155	155

[1] **N** – no break **P** – partial break **C** – complete break; incl. hinge break H
[2] **HB** – horizontal burning

* Test specimen 0.8 mm

For further information please visit our plastics-database and learn more

STERILIZATION **PROCEDURES**

Our Care grades maintain critical mechanical properties after sterilization

	Property	Gamma 50 GY	EtO	Steam cycles 0-5	5-25	25-50	>50
VESTAMID® Care ML	Low viscosity	●	●	●	●	●	●
VESTAMID® Care ML	High viscosity	●	●	●	●	●	●
VESTAMID® Care ME	Low shore hardness	●	●	●	●	●	●
VESTAMID® Care ME	High shore hardness	●	●	●	●	●	●
TROGAMID® Care		●	●	●	●	●	●
VESTAKEEP® Care		●	●	●	●	●	●

Effect on mechanical properties

- ● no or minimal
- ● medium
- ● significant

Medical devices first and foremost need to be safe. From the material point of view, this means that there must not be any kind of harmful interaction with bodily tissue and fluids, may it be via release of harmful substances or deleterious surface effects towards cells. The materials should withstand the necessary disinfection and sterilization procedures without giving in on mechanical stability or performance.

In order to provide a high level of safety throughout the supply chain, our high performance polymers for medical applications are evaluated regarding their performance under common sterilization procedures and tested on their stability to disinfectants and other aggressive liquids such as selected drug formulations.

All Evonik Care grades can be sterilized via ethylene oxide and irradiation (Gamma radiation of up to 50 kGy) without losing mechanical stability. Resistance to steam sterilization of all polyamide-based resins and compounds strongly depends on the individual grade.

In general, high molecular weight extrusion grades can withstand a higher number of steam sterilization cycles compared to the lower molecular weight materials.

VESTAKEEP® Care by contrast withstands a very high number of steam sterilization cycles due to its hydrolysis resistance resulting from the chemical structure of the polymer backbone. The individual performance however needs to be evaluated with the final device under the actually applied sterilization conditions.

Disclaimer

Assessment based on tensile testing of standard specimens according to ISO 527. Suitability and performance always needs to be tested individually for the specific parts and application.

BIOCOMPATIBILITY

All Care grades were tested according to USP Class VI and following ISO 10993 recommendations

In order to support the materials' application in medical devices, Care grades underwent a variety of biocompatibility studies, conducted by independent and certified testing laboratories. The biocompatibility of the materials was tested according to US Pharmacopeia <88> class VI, and also according to several in vivo and in vitro tests from the ISO 10993-series.

Biocompatibility endpoints were selected following ISO 10993 recommendations for up to 30 days body contact. In addition, the blood compatibility of selected grades has been tested.

Regulations oblige manufacturers to evaluate the biological safety of medical devices. The proven biocompatibility of Care grades helps to select appropriate materials and supports the biological safety assessment of medical devices.

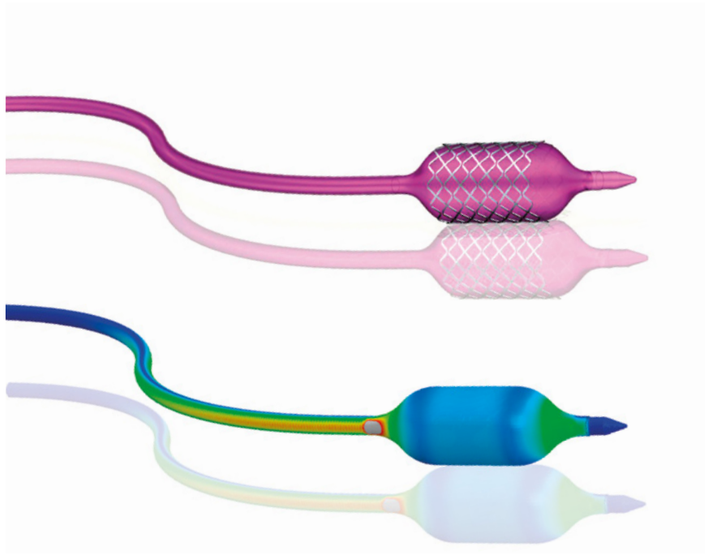
OUR **SERVICE**

Application technology and CAE-Support

Our philosophy is to sell high performance polymers and solutions which address our customers' requirements. The use of CAE methods significantly reduces development risks. Changes at an early stage of development are a fraction of what the costs could be at later stages or during series production – especially in the medical device industry.

Take advantage of our overall application expertise, which includes CAE methods for each type of high performance polymers. Please contact us if you consider building a new component or tool, or face issues with existing tools. Furthermore, we offer comprehensive application technology guidance in order to assist our customers in the development of technologically demanding system solutions, which also includes on-site processing support.

CAD design of a balloon dilatation catheter with a model stent for percutaneous interventions and structural analysis of the balloon deformation behavior upon exposure to internal pressure via CAE.



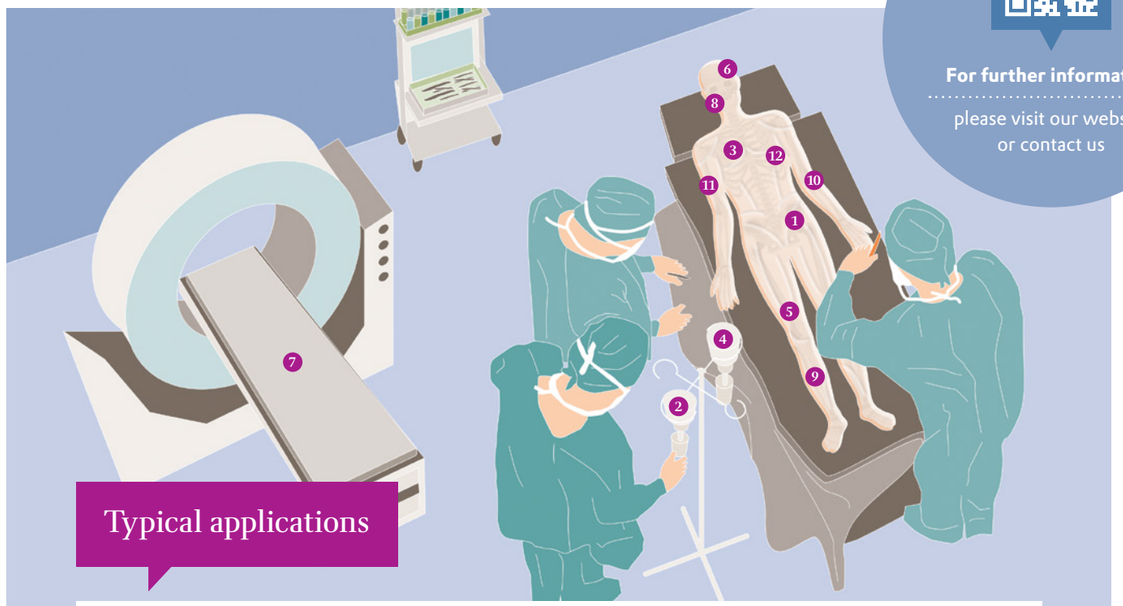
CUSTOMIZED SOLUTIONS

Being a technological leader with more than forty years experience in materials development and design, Evonik offers customized products for the medical sector.

The product portfolio includes specialty polymers for medical technology and biomaterials for long- and shortterm implants as well as non-implant applications.

For further information

please visit our website or contact us



Typical applications

1 VESTAMID® Care
Catheters, surgical instruments, housings

2 TROGAMID® Care
Catheters, hearing aids

3 VESTAKEEP® PEEK
Permanent medical implants, dentures

4 VESTODUR®
Blood filters

5 RESOMER®
Bioabsorbable medical implants

6 VISOMER®
Contact lenses, IOL, bone cements, dental fillings and dentures

7 ROHACELL®
Tables and tops for X-Ray and CT scan machines

8 NANOCRYL®
Dental impressions, composite fillers

9 DEGAPLAST®
Handcrafted orthopedic prothesis

10 Biocellic+
Wound dressings for burns, chronic wounds, edema and burns

11 ENDEXO®
Surface modification for non-implantable and implantable devices

12 VECOLLAN®
Orthopedics, cardiovascular, wound care, ocular care, dental care drug delivery, regenerative medicine

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