

Care Medical Materials

High Performance Polymers for Medical Devices





Product Overview

Evonik, the creative industrial group from Germany, is one of the world leaders in specialty chemicals. With more than forty years 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, catheters or surgical instruments.

The application of polymers in medical devices is often challenging. Besides coping with highest quality standards, materials need to withstand aggressive disinfectants, pharmaceuticals and resist different sterilization procedures without giving in 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 addition to our standard *Care* grades, Evonik can use its decades of polymer & compound development experience and process know how to customize materials which fulfill unmet customer and market requirements.

Bonding grades

Improving and simplifying the manufacturing process of multilayer tubings like catheters

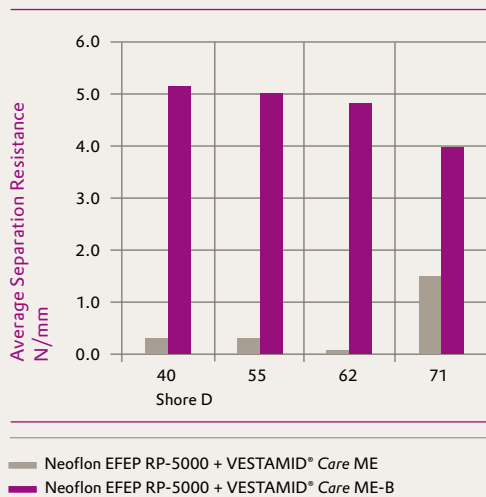
VESTAMID® Care ME-B grades cover a range of polyether-block-amides (PEBA) with different flexibility and hardness (Figure 2), which were specially modified to adhere to Daikin's Neoflon® EFEP RP-5000 without the need for any adhesive. The chemical nature of both materials results in the formation of 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. This offers 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-studies conducted with VESTAMID® Care ME-B bonding

grades and unmodified VESTAMID® Care ME grades show a distinct increase in separation resistance, as depicted in Figure 1. In average, VESTAMID® Care ME-B grades comprise a separation resistance more than 15 times as high compared to the unmodified grades.



Figure 1: Comparison of bonding strengths



Averaged separation resistance among Neoflon® EFEP RP-5000 and VESTAMID® Care ME standard grades compared to VESTAMID® Care ME-B bonding grades. The results shown have been generated from a low number of production lots as well as different specimen geometries; they are not yet the result of a statistical evaluation. Individual adhesion closely depends on device geometry and processing conditions. Please contact us for detailed information.

Figure 2: VESTAMID® Care ME-B – Bonding grades

Product	Autoclaving	Gamma	EtO	USP Class VI	ISO 10993	ASTM F756-08	Shore D
VESTAMID® Care ME40-B	<5 cycles	+	+	+	-5,-10,-11	+	40
VESTAMID® Care ME55-B	5-25 cycles	+	+	+	-5,-10,-11	+	55
VESTAMID® Care ME62-B	50-100 cycles	+	+	+	-5,-10,-11	+	62
VESTAMID® Care ME71-B	50-100 cycles	+	+	+	-5,-10,-11	+	71



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Silver-releasing, transparent materials

Antibacterial capabilities as tested
by the JISZ 2801 & ISO 22196 protocol

The increasing awareness of the safety-issues related to multi-resistant bacteria strains and various efforts to decrease the number of hospital-acquired infections underline the need to protect medical devices from surface bacterial colonization. TROGAMID® Care MX73-A was designed to support this need. While preserving its outstanding resistance to chemicals, stress-cracking, and transparency, the

TROGAMID® Care MX73-A releases silver ions upon contact to moisture or water. The controlled release of silver from a hydrolysable carrier material ensures availability of the ions over time. ISO 22196 & JISZ 2801 tests conducted with *Escherichia coli* and *Staphylococcus aureus* showed a reduction of the viable cell count within 24 hours of more than 99.99 percent, each.

Furthermore, the silver ion release was confirmed with analytical methods. Areas of application for TROGAMID® Care MX73-A include monitoring and imaging devices, durable medical equipment, surgical instruments, fluid and drug delivery systems.

Figure 3: Silver-releasing, transparent grade

Product	Autoclaving	Gamma	EtO	USP Class VI	ISO 10993	ASTM F756-08	<i>E.coli</i> reduction*	<i>S. aureus</i> reduction*
TROGAMID® Care MX73-A	5-25 cycles	+	+	+	-5,-10,-11	+	> 99,99%	> 99,99%

* As tested by the JISZ 2801 & ISO 22196 protocol

Transparent materials for laser welding and laser marking

Durable labeling and reliable welding

TROGAMID® Care MX73-L is a transparent specialty grade for applications involving laser welding and laser marking. TROGAMID® Care MX73-L contains nano-sized oxide particles, which absorb laser energy without scattering light due to their small diameter. Hence, the material still appears transparent and colorless but can nevertheless be used as laser-absorbing component.

Thereby, the combination of TROGAMID® Care MX73-L and TROGAMID® Care MX73 enables the connection of two transparent parts via laser-welding, omitting exposure of the materials to extensive heat treatments and the usage of adhesives.

Additionally, surface or sub-surface labeling of devices can be realized straightforwardly via laser marking of TROGAMID® Care MX73-L.

The distinct advantage of this type of labelling is the resistance against removal of labeling during exposure to disinfectants, chemicals, etc. and again the avoidance of further chemicals being used.

Areas of application for TROGAMID® Care MX73-L include housings, micro-fluidic devices, fluid and drug delivery systems, monitoring and imaging devices.

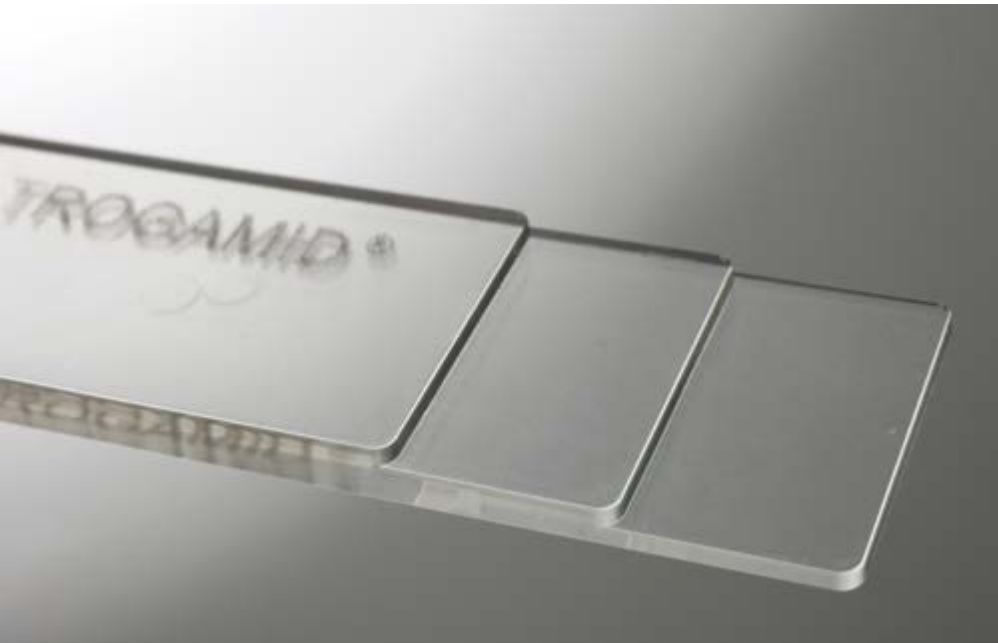


Figure 4: Transparent grade for laser welding and laser marking

Product	Autoclaving	Gamma	EtO	USP Class VI	ISO 10993	ASTM F756-08
TROGAMID® Care MX73-L	5-25 cycles	+	+	+	-5,-10,-11	+

Product Overview

The proper polymer for each application



Strong grades

VESTAMID® Care ML grades cover a range of polyamide 12 (PA12) resins with different viscosity for processing via extrusion or injection molding. In addition to un-stabilized 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 for example 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. Due to their low water uptake, filled VESTAMID® Care ML grades resist steam autoclaving for more than 500 cycles.

Flexible grades

VESTAMID® Care ME materials are polyether block amides, Evonik's flexible polyamide, which is available in various durometers. 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.

Transparent grades

TROGAMID® Care grades include both amorphous and microcrystalline transparent polyamides. All TROGAMID® Care grades are BPA free. Amorphous TROGAMID® Care MT50 comprises one of the highest moduli compared to other transparent polyamides and the microcrystalline TROGAMID® 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, hearing aids, fluid and drug delivery equipment such as stop-cocks and connectors. The high mechanical stability of TROGAMID® Care MT50 predestines the material for applications requiring a high modulus but retained impact resistance; this includes dentures, parts for monitoring and imaging devices or durable medical equipment.

High temperature grades

When it comes to application conditions involving high temperatures, VESTAMID® Care M30-HT and VESTAKEEP® Care grades are the materials of choice.

VESTAMID® Care M30-HT is a semi-crystalline PA10T based polyphthalamide (PPA), which partly consists of monomers derived from renewable resources. It exhibits high long-term temperature resistance, high chemical resistance and very good creep resistance. VESTAKEEP® Care polyether ether ketone (PEEK) medical grades are available in different

viscosities for processing via extrusion or injection molding. These ductile grades offer even higher resistance to heat, chemicals, and hydrolysis. Typical areas of application for VESTAKEEP® Care and VESTAMID® Care M30-HT include parts for housings and surgical instruments, gear wheels and other parts for functional units and durable medical equipment. Due to their low water absorption, parts made out of VESTAKEEP® Care grades resist steam autoclaving for an extended number of autoclaving cycles.

Figure 5: VESTAMID® Care ML – Polyamide 12 grades and compounds

Product	Autoclaving	Gamma	EtO	USP Class VI	Relative viscosity	Additives
VESTAMID® Care ML16	5-25 cycles	+	+	+	1.6	none
VESTAMID® Care ML17	25-100 cycles	+	+	+	1.7	none
VESTAMID® Care ML18	25-100 cycles	+	+		1.8	none
VESTAMID® Care ML19	25-100 cycles	+	+		1.9	none
VESTAMID® Care ML21	100-250 cycles	+	+		2.1	none
VESTAMID® Care ML67	5-25 cycles	+	+	+	1.6	Stabilizer
VESTAMID® Care ML94	25-100 cycles	+	+	+	1.9	Stabilizer
VESTAMID® Care ML24	100-250 cycles	+	+	+	2.1	Stabilizer
VESTAMID® Care ML-GB30	500 cycles	+	+	+	1.8	Glass beads

Figure 6: VESTAMID® Care ME – PEBA grades

Product	Autoclaving	Gamma	EtO	USP Class VI	ISO 10993	ASTM F756-08	Shore D Hardness
VESTAMID® Care ME40	<5 cycles	+	+	+	-5,-10,-11	+	40
VESTAMID® Care ME47	5-25 cycles	+	+	+	-5,-10,-11	+	47
VESTAMID® Care ME55	25-50 cycles	+	+	+	-5,-10,-11	+	55
VESTAMID® Care ME62	25-100 cycles	+	+	+	-5,-10,-11	+	62
VESTAMID® Care ME71	25-100 cycles	+	+	+	-5,-10,-11	+	71

Figure 7: TROGAMID® Care – Specialty grades

Product	Autoclaving	Gamma	EtO	USP Class VI	Microstructure
TROGAMID® Care MX73	5-25 cycles	+	+	+	Microcrystalline
TROGAMID® Care MX97	5-25 cycles	+	+	+	Microcrystalline
TROGAMID® Care MT50	n.d.	+	+	+	Amorphous

Figure 8: Polyphthalamide and polyether ether ketone grades

Product	Autoclaving	Gamma	EtO	USP Class VI	ISO 10993	ASTM F756-08	Polymer
VESTAMID® Care M30-HT	n.d.	+	+	+	-5,-10,-11	+	PPA
VESTAKEEP® Care M20G	>500 cycles	+	+	+	-5,-10,-11	+	PEEK
VESTAKEEP® Care M40G	>500 cycles	+	+	+	-5,-10,-11	+	PEEK
VESTAKEEP® Care M33G-HP	>500 cycles	+	+	+	-5,-10,-11	+	PEEK



Sterilization procedures

Our *Care* grades maintain critical mechanical properties after sterilization

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 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 and reinforced compounds can withstand a higher number of autoclaving

cycles compared to the lower molecular weight and unfilled counterparts.

VESTAKEEP® *Care* in contrast can be steam sterilized for an extended number of autoclaving cycles due to its hydrolysis resistance resulting from the chemical structure of the polymer backbone.

Figures 2-8 summarize the number of autoclaving cycles at 134 °C, at which the tensile bars utilized in the study retained their mechanical properties.

The individual performance however needs to be evaluated with the final device under the actually applied sterilization conditions.

Biocompatibility compliance

Our *Care* grades are tested according to USP Class VI and partly to ISO 10993

In order to confirm the materials suitability for medical applications, the *Care* grades underwent a variety of biocompatibility studies, conducted by independent and certified testing laboratories. The materials were tested via *in vivo* studies on their biological reactivity according to the United States Pharmacopeia <88> class VI test. Additionally, different *in vivo* and *in vitro* tests according to ISO 10993-1 – biological evaluation of medical devices – were con-

ducted. Thereby, the chosen tests relate to medical devices which are applied inside the body for up to 30 days. Although the approval needs to be completed with the final device, the provided certificates for the raw materials enable a higher level of safety from the beginning, during the material selection process. Figures 2-8 display the biocompatibility studies conducted and the compliance attained, respectively.



Our Service

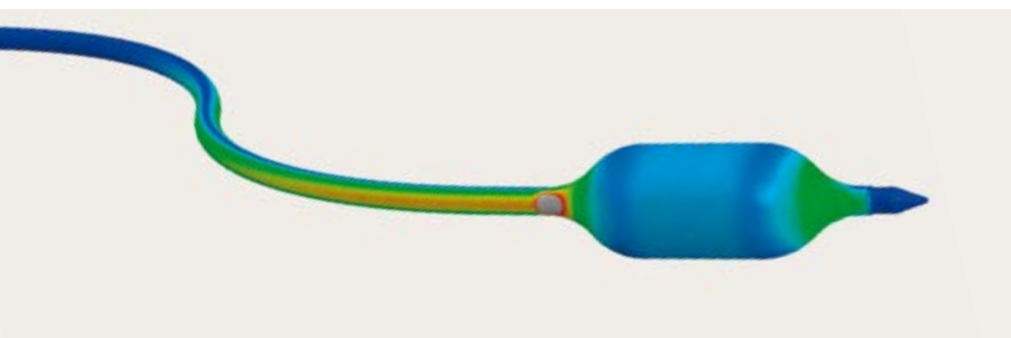
Application Technology and CAE-Support

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.



A materials toolbox for Medical technology

Beyond the medical *Care* series, Evonik's product portfolio includes additional specialty polymers and biomaterials for short & long term implant applications as well as non implant applications.

For further information please visit our website:

www.evonik.com/medical

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