

ADVANCED MATERIALS FOR MEDICAL DEVICES

Medical manufacturers worldwide need to meet rapidly growing demands for increasingly sophisticated medical devices.

At the same time, regulators in numerous regions, including the United States and the European Union, are implementing stringent measures to mitigate patient safety risks caused by defective medical equipment. In this complex environment, manufacturers require advanced thermoplastics that leverage next-generation material science and address emerging medical industry trends.

Envalior has developed a portfolio of advanced material solutions that respond to the challenges the medical industry needs to overcome.



Industry challenges driving material innovation



Changing regulations



Designed for home medical care



Smart devices & wearables



Safety & comfort for healthcare workers & patients

IMPROVING QUALITY OF CARE

Envalior's Care portfolio is designed for the needs of Class I and Class II medical device manufacturers. Each material is tested to meet or exceed key specifications, as well as standards set by regulatory bodies, including

the U.S. Food & Drug Administration (FDA), International Organization for Standardization (ISO), United States Pharmacopeia (USP) and more.



Tested to meet or exceed key global safety and quality standards

- Unique chemistries tailored to the requirements of various medical products
- Compliance with FDA food contact, USP Class VI, ISO 10993-5 and ISO-10993-10 standards
- Outstanding mechanical strength and toughness
- Superior flow for high-precision molding
- High purity to limit extractables, leachable substances and volatile organic compounds
- Absence of CMR (carcinogens, mutagens and reprotoxic) substances for compliance with new EU regulations
- Excellent resistance to harsh chemicals and repeated sterilization
- Optimized for advanced extrusion and injection molding processing
- Recyclable and reusable materials
- Backed by Envalior's world-class global manufacturing and laboratory network

ARNITEL® CARE TPC

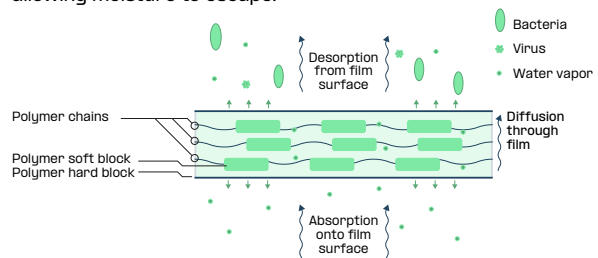
Quality healthcare begins with putting the safety and comfort of patients and healthcare workers first. Envalior has perfected polyester (PBT)-based thermoplastic elastomer compounds (TPC) to develop the Arnitel® Care family of advanced materials for medical supplies. The solution is widely used to manufacture lightweight, durable films that protect users, without sacrificing comfort.

With its proprietary combination of hard crystalline PBT and soft amorphous links, Arnitel Care creates highly breathable monolithic films that provide a 100% effective barrier against bacteria and viruses. Unlike widely-used microporous materials, this solution eliminates any need for microscopic pores that weaken barrier properties.

Breathable monolithic films maximizing protection and comfort

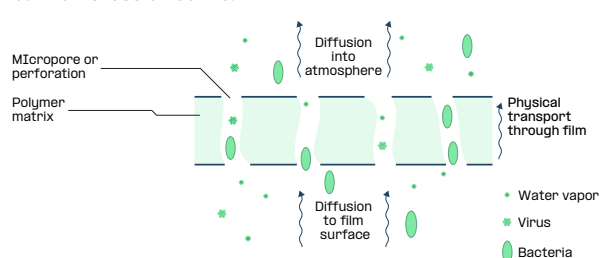
Microporous film

Molecular structure naturally creates a strong but breathable barrier, allowing moisture to escape.



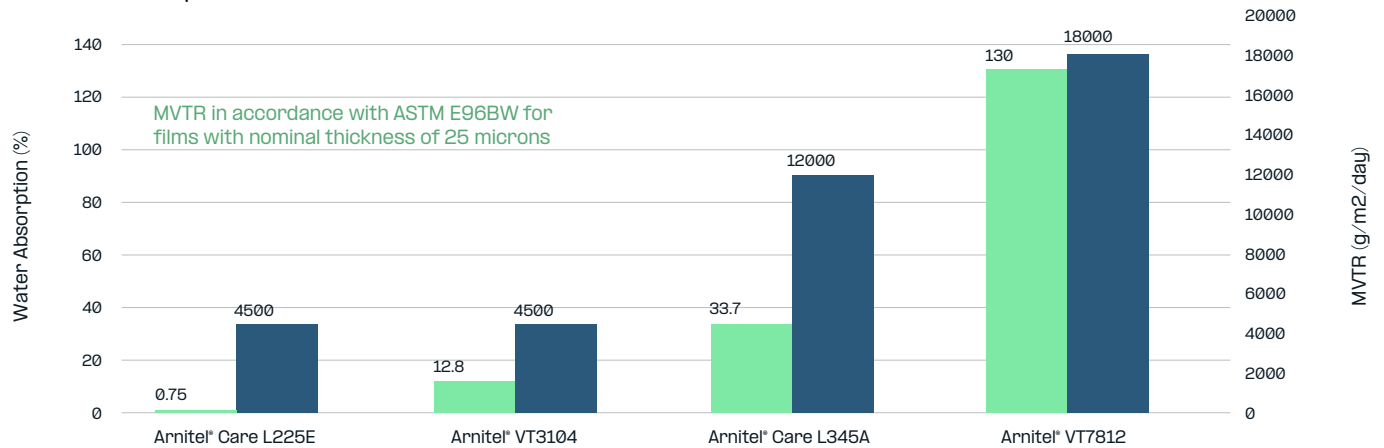
Monolithic film

Microscopic pores added to the material to make it breathable, but the barrier is less effective.



Moisture Vapor Transmission Rate (MVTR) Performance

High to very high MVTR materials, with tunable O2 permeation and water absorption characteristics



A key measurement of breathability is the Moisture Vapor Transmission Rate (MVTR) – a test that assesses material permeability to water vapor. Requirements for MVTR, water absorption, gas permeation to oxygen, and membrane flexibility and softness vary from application to application. Thanks to Arnitel Care and Arnitel VT’s versatile chemistry, membranes can be designed to meet a wide range of property requirements that can’t be achieved through microporous membranes.

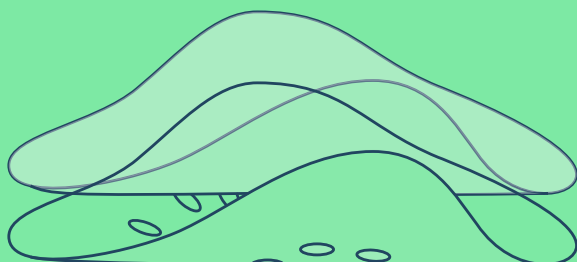
Arnitel Care and Arnitel VT overcome this challenge through a broad range of material grades tailored to the MVTR requirements of various demanding medical applications, including personal protective equipment (PPE), wound care films and medical tubing.

ENHANCING PERFORMANCE WITH ARNITEL

Personal protective equipment (PPE)

Arnitel’s outstanding strength and breathability offers an industry-leading solution for PPE, including medical gowns and surgical drapes. With its proven performance, the material has been used by healthcare workers combatting outbreaks from remote clinics or operating in busy urban hospitals around the world.

- 20+ years of successful use in medical PPE
- Exceeds internationally recognized AAMI Level 4 PPE safety standards
- Superior breathability compared to TPU and microporous materials



Wound care films

Industry-leading medical supply manufacturers trust Arnitel to deliver the right combination of comfort and protection in advanced wound care films. Due to its unique combination of strength, flexibility and breathability, the material provides more value than competing solutions, including TPU.

- Meets or exceeds ASTM 1670/1671 standards
- Long-lasting soft touch and feel.
- High strength, yet flexible and elastic

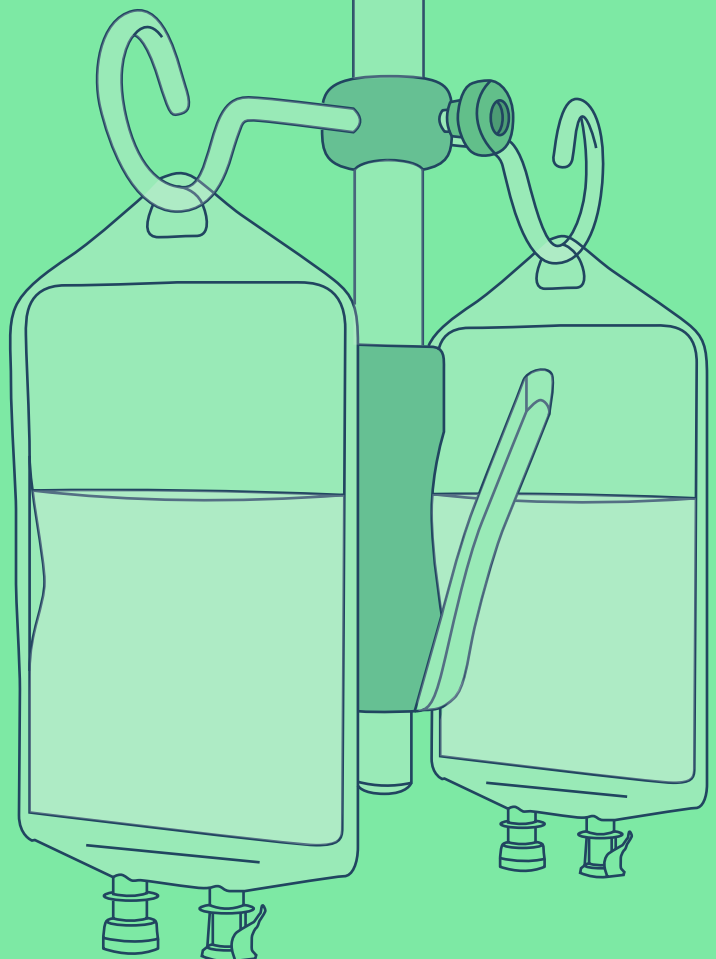
*The following examples are not a complete list of relevant applications. For additional information and case studies, please visit envalior.com.

AKULON® CARE PA6 AND NOVAMID® CARE PA6 AND PA66 COPOLYMER

Our Akulon® Care polyamide 6 materials are well-suited for manufacturing a broad range of medical and drug delivery devices such as pens, autoinjectors, medical clamps and sutures. We develop our PA6 solutions using a very clean process to ensure these materials contain low levels of extractables and leachables.

Envalior is one of the few companies to offer PA6 products that comply with all material safety standards set by medical industry regulators. We also manufacture our PA6 polymers using sustainable raw material sources – which enabled our team to reduce the carbon footprint of Akulon PA6 by over 50% compared to all competing PA6 materials available in Europe. As a result, Akulon Care is the preferred material for producing sustainable, high-quality devices for many demanding medical applications.

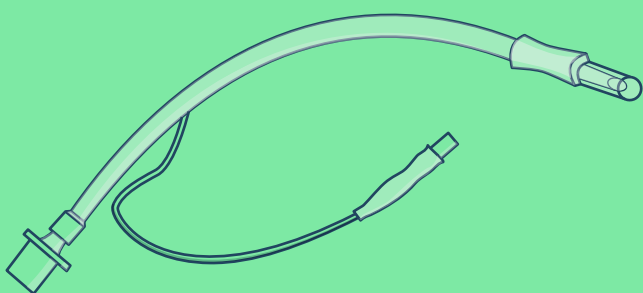
Our Novamid® Care PA6/66 copolymers are widely used to produce various types of primary medical films and packaging products. These materials combine high purity, excellent processing characteristics and strong barrier properties needed to deliver best-in-class large volume parenteral (LVP) medical bags for intravenous (IV) and dialysis fluids.



Soft touch and wearable devices

As demand for wearable medical devices grows, manufacturers require overmolding materials that are comfortable to the touch. With a strong track record of successful use in both medical and consumer electronics industries, Arnitel's easy-to-overmold solution adheres to an array of polar substrates, including PBT, polycarbonate (PC) and acrylonitrile butadiene styrene (ABS). In addition to excellent resistance to abrasive wear, chemicals, UV light and sterilization, the material also provides a silky feel that enhances wearer comfort.

- Easy processing characteristics for overmolding
- Proven performance in wearable devices
- Soft and smooth surface



Medical tubing

Arnitel is an ideal solution for medical tubes, due to its excellent processability in extrusion, as well as its flexibility, strength and resistance to chemicals and sterilization. In respiratory tubing requiring high breathability, the material's excellent MVTR allows moisture to escape — reducing the growth of potentially harmful bacteria.

- Excellent flexibility ensuring kink resistance
- High resistance to repeated sterilization
- Breathable grades for respiratory tubes
- High purity to limit extractables, leachable substances and volatile organic compounds

ARNITE® CARE PBT AND PET

With easy processing characteristics optimized for injection and extrusion molding, Arnite® Care PBT and PET are proven solutions for applications requiring parts with highly precise dimensions, as well as high strength, dimensional stability and durability.

Leading manufacturers of valves and adaptors for high-precision drug delivery devices, such as metered dose inhalers (MDI), have trusted Arnite for more than 10 years to deliver on their requirements.

- Proven performance in drug delivery devices
- Excellent chemical and moisture resistance
- High dimensional stability and strength
- High purity and low extractable levels

Material	Purity (VOC, leachables)	Batch to batch consistency	Processability
Arnite® Care T1U	++	+	+
POM	—*	o	+
PBT supplier 1	+	—	—
PBT supplier 2	o	o	—

* POM contains acetaldehyde, classified as potentially carcinogenic



FORTii® CARE PPA

ForTii® Care polyphthalamide (PPA) offers superior performance in a wide range of demanding non-invasive devices, such as minimally-invasive surgical tools, hand-held instruments, surgical robots and trauma fixation devices. With the ability to withstand mechanical stress at high temperatures (>150°C) and corrosive chemicals (pH 0.5 to 13), the material achieves weight savings of 50% or more when used to replace metal alternatives.

Due to its unique chemistry, ForTii Care outperforms polyacrylamide (PARA) and other high-performance PPA materials, and is more cost-effective than polyetheretherketone (PEEK). The material is also able to undergo more than 100 cycles of steam sterilization without significant impact to its mechanical properties.

ForTii Care can replace metal and ceramics used to manufacture medical rubber gloves, reducing operating costs and environmental impacts from manufacturing.

Material	Medical grade	GF (%)	HDT @1.8 MPa	CTI (V)	Autoclave sterilization (# cycles)
ForTii® Care P1G6 (PA4T)	YES	30	305	600	>100
PPA	YES	35	264	600	>100
PARA	YES	50	230	570	>10

Envalior engineering materials for medical devices

	Polymer	Food Contact (FDA)	ISO 10993-5 / ISO 10993-10	USP Class VI	STERILIZATION CAPABILITY (# OF CYCLES)*		
					Autoclave (120°C, 20min)	ETO (2hrs 48°C, 60% RH, 70mbar)	Gamma radiation (46.1-46.6 kGr)
Arnite® Care L225E	TPC	X	Pass	Pass	100	2	1
Arnite® Care L140E	TPC	X	Pass	Pass	100	2	1
Arnite® Care L146E	TPC	X	Pass	Pass	100	2	1
Arnite® Care L155E	TPC	X	Pass	Pass	100	2	1
Arnite® Care L263E	TPC	X	Pass	Pass	25	2	1
Arnite® Care L274E	TPC	X	Pass	Pass	Not recommended	2	1
Arnite® Care L345A	TPC	X	Pass	Pass	25	2	1
Arnite® Care T1U	PBT	X	Pass	Pass	Not recommended	2	1
Arnite® Care A1U	PET	X	Pass	Pass	Not recommended	2	1
ForTii® Care P1G6	PPA	X	Pass	Pass	100	2	1
Akulon® Care K1U	PA6	X	Pass	Pass	25	2	1
Akulon® Care K1G6	PA6	X	Pass	Pass	100	2	1
Novamid® Care N3U	PA6/66	X	Pass	Pass	100	2	1

*Actually tested to the number of cycles specified. Capability beyond is possible.

Our commitment to patients, healthcare workers and the planet



Envalior's team of material scientists and application development experts continuously collaborate with our customers. Together, we leverage the power of advanced material science to improve the quality of healthcare for patients everywhere. We are also committed to delivering more sustainable alternatives to traditional engineering plastics, and are on track to deliver recycled or bio-based versions of every material we offer by 2030.

To learn more, contact us via Envalior.com.



Envalior is a leading global Engineering Materials company employing around 4,000 people worldwide. With a long track record of customer-focused innovation, Envalior focuses its deep material and application expertise on sustainable and high-performance solutions. The company supplies many of the world's key markets including Automotive, New Mobility, Electronics & Electrical, and Consumer goods. For more information visit www.envalior.com. © Envalior 2023

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