Whitepaper

Envalior
Imagine the Future

ADVANCED MATERIAL SCIENCE FOR RESPIRATORY TUBING

Globally, increasing rates of respiratory infections and chronic lung conditions are driving up demand for highly sophisticated respiratory tubing.

As hospitals and caregivers require more of this equipment, medical device manufacturers will be expected to supply differentiated products that meet the needs of patients experiencing severe or long-term respiratory issues.

At the same time, manufacturers must ensure medical devices comply with evolving safety regulations set in numerous regions, including the United States (U.S.) and the European Union (EU). Products that fail to meet these standards can lead to costly recalls and put the health of patients at risk. To balance these considerations, Envalior Engineering Materials offers advanced thermoplastics that leverage next-generation material science and address emerging medical industry trends.

Industry challenges driving material innovation

- Changing regulations
- Enhancing comfort
- Improving safety
- Reducing infection risks

MATERIALS TO IMPROVE QUALITY OF CARE

Envalior's Care portfolio is tailored to the needs of Class I and Class II medical device manufacturers worldwide. Each material is tested to meet or exceed key performance requirements for various medical applications.

Our solutions meet standards set by trusted 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 devices, including respiratory tubing
- Compliance with FDA food contact, USP Class VI, ISO 10993–5 and ISO 10993–10 standards
- Outstanding mechanical strength, toughness and breathability
- High purity to limit extractables, leachable substances and volatile organic compounds (VOC) per ISO–18562 requirements
- Absence of carcinogenic, mutagenic and reprotoxic (CMR) substances to ensure 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 FOR RESPIRATORY TUBING

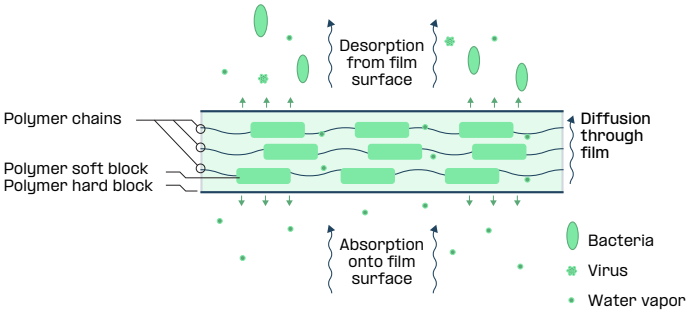
Envalior's Arnitel® Care materials are polyester–based thermoplastic elastomer compounds (TPC) that offer the performance characteristics of high–strength rubber combined with robust processing capabilities.

These materials are well suited for producing medical tubing that requires a balance of flexibility and toughness. Unlike competing thermoplastic elastomers (TPE), TPC maintains a high tensile modulus and high strength, without compromising flexibility or toughness. Arnitel Care's stiffness can also be tuned between 20 and 1000MPa, making it an ideal solution for producing medical tubing with strict performance requirements.

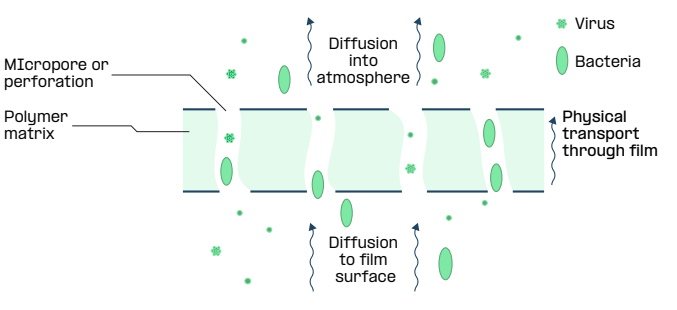
Enhanced breathability

Arnitel Care's unique combination of hard crystalline polyester and soft amorphous links creates a highly breathable film, which allows excess moisture to escape while preventing pathogens from penetrating the material's surface. By comparison, microporous competitors contain microscopic pores that make the material breathable, but weaken its barrier properties.

Arnitel® Care TPC film

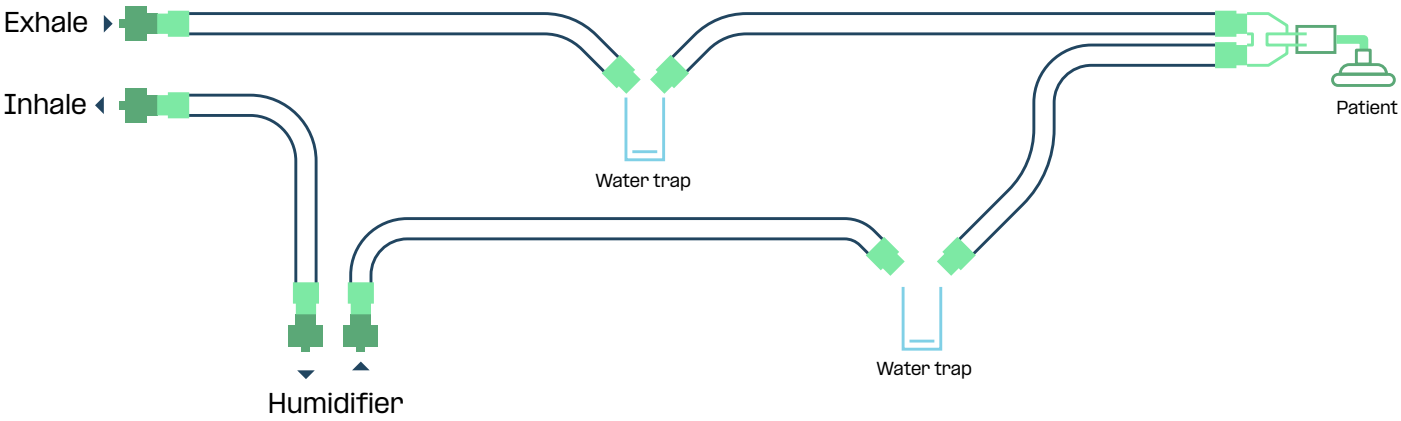


Microporous film



Typical ventilator tubing

Breathable Arnitel Care materials have the potential to reduce design complexity by potentially eliminating the need for water traps commonly used in respiratory tubing.

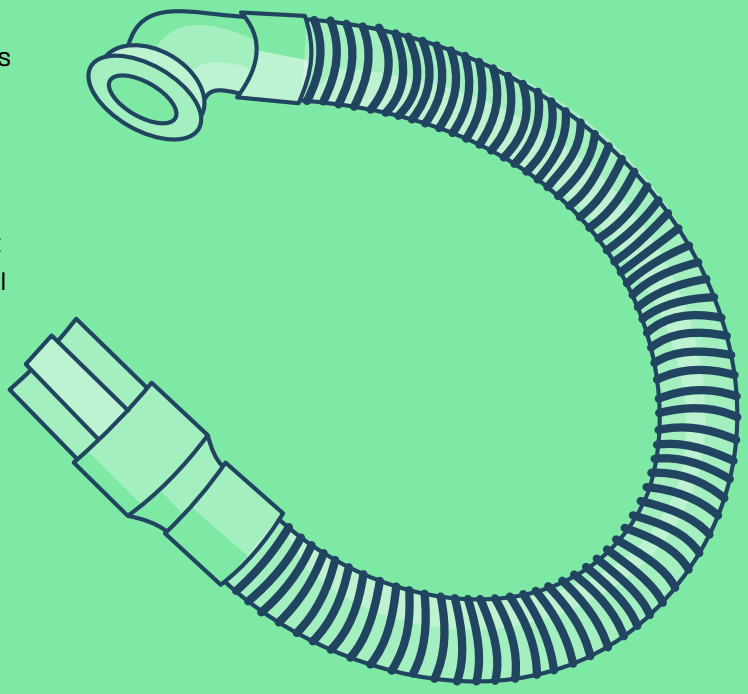


High breathability is essential for respiratory tubing, as too much moisture inside the tube creates a warm environment that accelerates bacteria growth – resulting in the equipment needing to be drained and cleaned more often. In clinical settings, such as intensive care units (ICU) with ventilators, excess moisture inside respiratory tubes creates additional work for healthcare workers, who must follow stringent procedures to safely drain and clean the equipment. If the condensation is not regularly drained, this can reduce the efficiency of the ventilator and even increase the risk for hospital acquired infections (HAI). Envalior conducted extensive moisture vapor transmission rate (MVTR) testing to verify Arnitel Care's best-in-class breathability. Due to the material's unique chemistry, its breathability can be customized to the precise specifications of specialty tubing applications. This additional breathability enables hospital staff to perform manual draining procedures less frequently, and avoids the need for common design modifications, such as adding heating elements to the respiratory tubes.

REMOVING SUBSTANCES OF CONCERN

Recently introduced EU Medical Device Regulations (MDR) underscore the importance of replacing materials that contain unsafe levels of extractables and leachable substances. And in 2017, the ISO announced new standards to limit the use of plastics that emit VOC and other substances that can create gas stream contamination.

Envalior proactively addresses these growing concerns by incorporating standardized best practices throughout our material manufacturing processes. As a result, Arnitel Care offers clean chemistry with ultra–low extractables and leachables.



Engineered for high performance

Arnitel Care is designed, engineered and tested to provide robust design flexibility that is critical to manufacturing best–in–class medical tubing. High strength, lightweight final parts offer:

- Excellent flexibility ensuring kink resistance
- A clear view of tube interiors
- Rheology optimized for high throughput during extrusion
- Reduces design complexity and maintenance (moisture reservoir draining)

Arnitel Care for respiratory tubing

Grade	Key Material Properties	Shore D Hardness (3s)	Moisture Vapor Transmission Rate (ASTM E96BW, 1mm film) g/m2/day	Stiffness (E modulus) MPa
Arnitel® Care L345A	Highest MVTR with a good balance of mechanical properties, medium viscosity	45	12,000	110
Arnitel® Care L225E	Good MVTR, high elasticity, low viscosity	25	5,000	25
Arnitel® Care L140E	Fair MVTR, a good balance of mechanical properties, low viscosity	33	2,700	40
Arnitel® Care L155E	Lower MVTR, high strength and toughness, medium viscosity	55	800	175

To learn more, contact us via Envalior.com.

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