Meeting the demand for advanced catheters

Advances in cardiovascular medical technology have led to new, minimally invasive methods for treating various complex conditions.

Many of these procedures require next-generation catheters, which are more challenging for healthcare OEMs and contract manufacturing organizations to design and produce. As cost pressures increase, catheter manufacturers are focused on gaining a competitive advantage by:

- Designing novel devices optimized to treat challenging disease states
- Implementing production processes that maximize operational efficiency

Shifting requirements for catheter materials

Material selection is critical to ensuring catheters are safe and reliable.

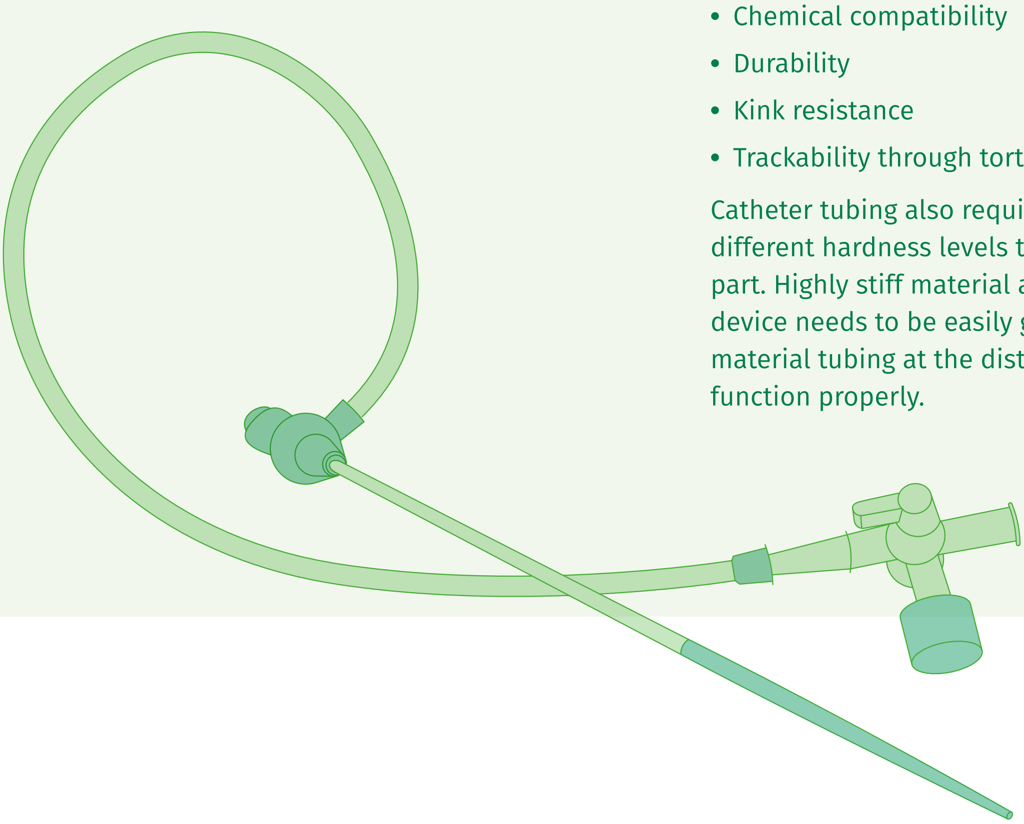
However, traditional solutions – including polyether block amide (PEBA), nylon, silicone, polyurethane (TPU) and latex – come with performance and design limitations and can be difficult or costly to process. Since material delamination, separation or weakness are responsible for the majority of class I catheter recalls[1], materials that can perform in dynamic clinical conditions and not only meet but exceed ever-evolving regulatory requirements must be selected.

Catheter designs include thin-walled single- or multi-lumen tubes that are inserted into body tissue, cavities, or blood vessels to deliver drugs, gases or tools for treating patients. Different types of catheters are used for cardiovascular, neurovascular, urology, intravenous and specialty applications.

To design catheters that can be used effectively in the treatment of various conditions, development engineers need to select materials that balance key property requirements, including:

- Flexibility
- Chemical compatibility
- Durability
- Kink resistance
- Trackability through tortuous vasculature

Catheter tubing also requires multiple materials with different hardness levels to selectively reinforce the part. Highly stiff material at the proximal end of the device needs to be easily glued or welded to soft material tubing at the distal end, to ensure catheters function properly.



Material solutions to improve quality of care

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

1. https://www.medicaltubingandextrusion.com/the-worst-catheter-based-device-recalls-of-2020/10/

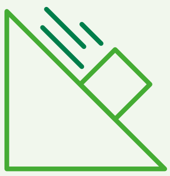
Tested to meet or exceed key global safety and quality standards

DSM's catheter material 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.

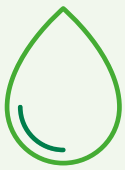
- Unique chemistries tailored to the requirements of various devices
- Compliance with FDA food contact, USP Class VI, ISO 10993-5 and ISO 10993-10 standards
- Outstanding mechanical strength and toughness
- High purity to limit extractables, leachable substances and volatile organic compounds (VOC) 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 DSM's world-class global manufacturing and laboratory network

DSM offers two market-proven material solutions for advanced catheters: Arnitel® Care thermoplastic co-polyester elastomer compounds (COPE) and the Arnitel® family of thermoplastic elastomers (TPE) based on co-polyester chemistries. Co-polyester elastomers are popular material solutions for catheters as they offer:

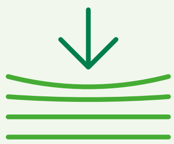
- User-friendly processing windows in extrusion and secondary assembly
- High stiffness independent of moisture absorption – ensuring consistent part behavior in all environments
- Superior snap back performance compared to TPU and PEBA



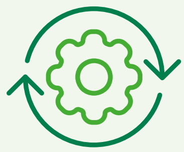
Lower coefficient of friction



Lower moisture sensitivity



Stiffness from 20-1000MPa



Ease of assembly & welding

Proven ease of extrusion & lower scrap

Our Arnitel solutions offer the added benefits of:

- Easy extrusion to reduce scrap
- Easy welding and gluing capabilities – increasing overall part reliability
- Predictable shrinkage and less dimensional change with annealing
- No gels to improve part product quality and strengthen bonding points
- Highest crystallinity and melting point of all TPEs
- Easily compounded to meet strict performance requirements
- Available in multiple low-carbon footprint, bio-based and biomass balanced grades

Arnitel Care combines robust processing capabilities with the characteristics of high-strength rubber. The material has been used to produce various types of vascular catheters for decades. In recent years, its outstanding design flexibility and performance in clinical settings has garnered widespread attention among medical device manufacturers. Arnitel Care's stiffness can be tuned between 20 and 1000MPa, making it ideal for producing medical tubing with stringent mechanical requirements.

Arnitel Care is well-suited for producing medical tubing designed to balance flexibility and toughness. Unlike competing TPE, the material maintains a high tensile modulus and high strength, without compromising elasticity or stiffness. Compared to PEBA, Arnitel demonstrates a much lower coefficient of friction in 55D, 63D and 75D durometer grades. This makes it easier for clinicians to insert and guide tubing, and most importantly, helps keep patients safe by reducing the risk of guidewires puncturing walls during procedures.

Ensuring high reliability in assembly and use

As lifesaving devices, catheters require materials that can withstand and perform under stressful environments, such as high moisture or high-heat conditions. Nylon and PEBA typically absorb moisture, which impacts the dimensions and mechanical strength of parts – leading to decreased performance.

Since Arnitel maintains consistent stiffness after absorbing moisture, testing the material in dry lab setting accurately predicts how catheters will behave in high-fluid clinical settings. Arnitel also remains stable during multiple secondary operations to assemble the final device.

With mounting pressure to reduce costs and improve device sustainability, manufacturers are closely re-evaluating their production processes and supply chains. Arnitel is extremely easy to extrude, resulting in more predictable shrinkage, tighter tolerances and repeatability, and higher throughput. This enables engineers to design gel-free low-profile devices with thin walls.

Many manufacturers opt to leverage several different materials to enhance the quality of individual catheter components. Arnitel offers different durometer grades that are easily welded together, and demonstrate excellent bonding performance with polybutylene terephthalate, polyethylene terephthalate, polycarbonate, acrylonitrile butadiene styrene, and more. This provides manufacturers with greater design and cost flexibility for extrusion processes, as well as secondary assembly operations with injection molded components.

DSM engineering material solutions for medical devices

Arnitel hardness (ISO 868 - Shore D)	Tensile modulus (ISO 527, MPa)	Melting point (ISO 11357, °C)	Humidity absorption (ISO 62, %)	Water absorbtion (ISO 62, %)	Yield stress* (ISO 527, MPa)	Yield strain* (ISO 527, MPa)
25	25	180	0.35	0.8	4	85
40	40	195	0.3	0.75	7	77
46	85	189	0.3	0.70	9	45
55	170	207	0.2	0.65	14	33
63	280	212	0.2	0.60	26	20
74	800	221	0.2	0.55	36	17

* Yield stress and yield strain are derived from theoretical yield points of stress-strain curve for materials with hardness below Shore 50D.

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