Advanced Extrusion Techniques

HOW ENGINEERED EXTRUSION HELPS MEDICAL DEVICE MAKERS IMPROVE DEVICE DESIGNS AND PATIENT EXPERIENCES

WHITEPAPER

Company Introduction

At Trelleborg Healthcare & Medical, we form lasting partnerships with customers to help them negotiate the development process from concept to commercialization. Working alongside our customers, we help to design, develop, manufacture, and bring to market innovative engineered solutions for demanding medical device, biotech and pharmaceutical applications.

Where Trelleborg Healthcare & Medical truly stands out is our ability to partner with customers and solve complex challenges. Our unique combination of capabilities, including molding, extrusion, combination products and more, enables Trelleborg to come to the table with creative solutions to our customers' design and manufacturing challenges.

Our 30+ year track record of offering superior support, reliable supply, and world-class quality, gives customers confidence that they can rely on us for ongoing support and supply once a device is commercialized.

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Trelleborg Healthcare & Medical is a global supplier of medical device components and services.

Dan Sanchez holds a BS in Mechanical Engineering from California Polytechnic State University, San Luis Obispo, and has been in silicone manufacturing for the healthcare and medical industry since 1998. He and the Trelleborg team help medical device designers realize their product concepts through engineered manufacturing solutions and design for manufacturability (DfM) support.

Dan and the global Trelleborg Healthcare & Medical Team invite you to contact them early in your design process to act as an extension of your engineering team, offering design, materials, process development, and manufacturing support to reduce overall costs and time to market.

Introduction

Hoses and tubes are extensively used within the healthcare and medical industry in a wide variety of applications, from wound drains to catheters, from drug delivery to feeding tubes. Technology has moved far beyond the production of single, hollow tubes to multi-lumen extrusions that may incorporate stops, bumps, and varying thicknesses, in one design.

Significant benefits can be achieved by taking advantage of innovative processes and the latest material options to reduce device manufacturers' total cost of ownership while increasing component integrity. At the same time, manufacturing processes can improve patients' quality of life by facilitating reduction in device size and weight, as well as incorporating multifaceted geometries, multiple substrates, and active pharmaceutical ingredients (APIs). This enhances treatment in terms of safety and comfort and makes wearable medical device options more feasible.

To facilitate the specification of these seemingly uncomplicated yet complex extrusions, key factors need to be considered. These will be outlined within this whitepaper along with material options concentrating on silicone extrusion technologies. Applications will be highlighted with actual examples.

ENHANCED DEVICE DESIGN

COMPONENT INTEGRITY

IMPROVING PATIENTS' QUALITY OF LIFE

Market Information

Why is the medical device market growing?

The reasons for a predicted growth in the medical device market are:

- Fast aging populations and increasing life expectancy
- More people looking for a high-quality of life
- Growing incidences of chronic disease
- Rapid increase in the prevalence of infectious diseases
- Rise in obesity
- Growth in surgical procedures and complex surgeries
- Adoption of advanced technologies
- Rising healthcare expenditure globally
- Strong economic growth and increasing access to healthcare facilities in emerging countries

Global market for medical devices

According to 'The Business Research Company', the global medical device market reached a value of nearly 456.9 billion USD in 2019, having increased at a compounded annual growth rate (CAGR) of 4.4% since 2015.*

The market is expected to decline from the figure reached in 2019, to 442.5 billion USD in 2020, equating to a drop of 3.2%.

This is mainly due to lockdowns imposed by governments across the world related to the COVID-19 pandemic, which hindered the supply chain in the medical device manufacturing industry.

Following 2020, the market is expected to grow to 603.5 billion USD in 2023.

*www.thebusinessresearchcompany.com/report/medical-devices-market

Global market for hoses and tubing

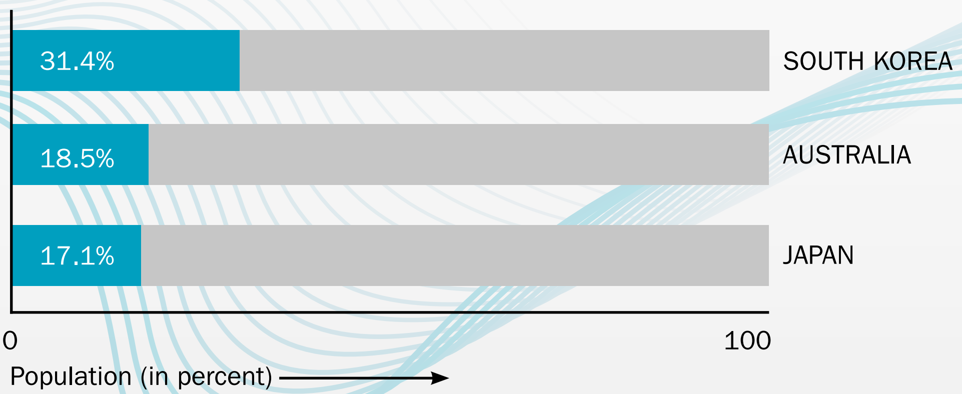
The growth in the medical device market is causing an increase in demand for medical tubing. According to Grand View Research, the global medical tubing market was estimated at 6.4 billion USD in 2018 and has an expected CAGR of 9.2% through 2025 when it will reach 11.9 billion USD. Additionally, growth can be attributed to the availability of cost-competitive medical-grade plastics; a surge in demand for single-use or disposable devices (due to growing awareness of hospital-acquired infections and interest in preventing them) and developing countries having increased access to healthcare supplies.

Market by region and country

By 2050, more than 1.3 billion of the Asia Pacific population will be considered elderly. In South Korea, Australia, and Japan, 31.4%, 18.5% and 17.1% of their respective populations will be considered elderly by 2028. The aging population, driven by increasing life expectancy and declining fertility rates, along with the rise of obesity levels and chronic diseases, is expected to boost medical tubing market growth over the forecast period.

The European market is expected to be driven by the strong healthcare systems in Germany, France, Russia, the UK, and Italy. The product demand is dominated by Germany, which accounted for more than 29.8% of the Europe market share in 2018. The new European Union medical device regulations (MDR) are projected to positively impact the dynamics of the market for medical tubing.**

Population considered elderly in 2028



**www.grandviewresearch.com/industry-analysis/medical-tubing-market;

Key trends

To help detect diseases in the initial stages and mitigate treatment costs, there is a trend toward further development of diagnostic equipment. There is also an increasing emphasis on preventing the spread of infection from one patient to another.

Continuous innovation in drug delivery systems is expanding demand for customizable tubes. In addition, increasing innovations, such as intra cochlear drug delivery and photo-thermally triggered drug delivery, are expected to lead to growth in nano medical tubes.

Less invasive medical procedures have the advantages of a lower cost, as well as quicker recovery times and shorter hospital stays for patients. These are therefore increasing in importance compared to conventional surgical procedures, which in turn is increasing the market for tubing.

The trend toward less-invasive procedures in the tubing market yields better patient outcomes and also places technical demands on the devices to be designed in increasingly smaller and complex ways.

Medical tubing market

In terms of applications, the medical tubing market is categorized into bulk disposable tubing, drug delivery systems, catheters, biopharmaceutical laboratory equipment, and others.

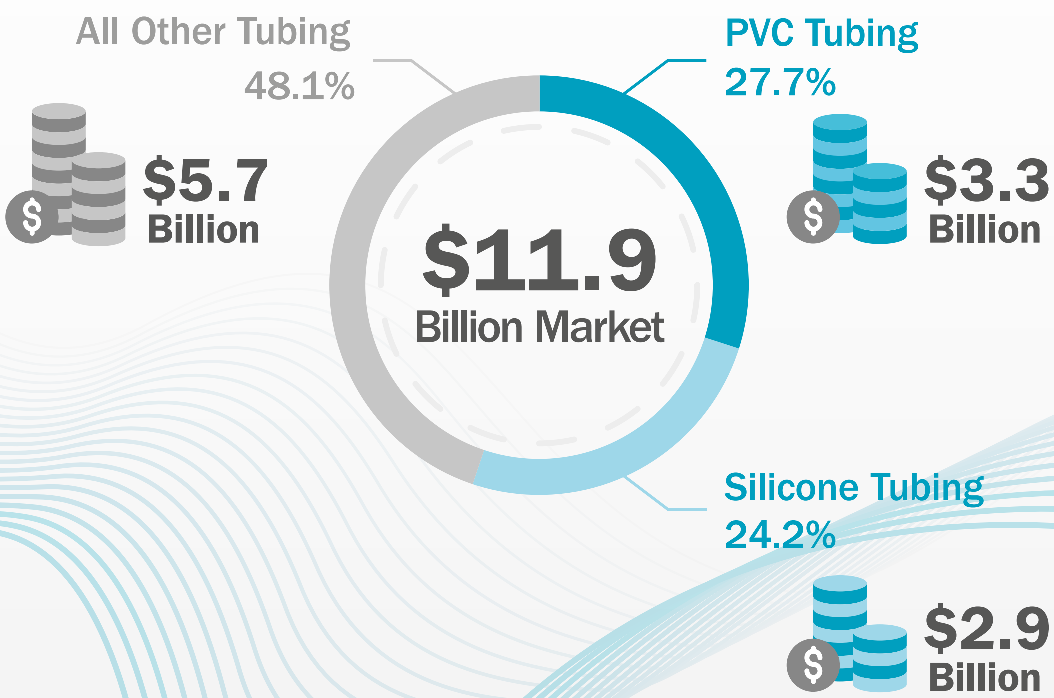
Stent tubes and implant-grade tubes are anticipated to boost market growth, as will wound therapy, in which tubes are used to remove infectious materials and fluids.

Market by material

The medical tubing market is categorized in terms of materials into polyolefins, silicone, polyvinyl chloride (PVC), fluoropolymers, polycarbonates, and others. PVC is the most widely used thermoplastic material in medical tube manufacturing, but silicone is seeing significant growth.

The demand for PVC tubing is anticipated to reach 3.3 billion USD by 2025 owing to the rising demand for single-use pre-sterilized medical devices which are transparent, biocompatible, and offer high resistance to chemicals. This will account for 27.7% of the market for tubing in 2025, while silicone, with its inherent suitability, in particular to implantable devices, will account for 24.2% in revenue terms.

Medical tubing market in 2025



History of Medical Tubing

Use of tubes in medicine is not new. The ancient Chinese used onion stalks, while the Romans, Hindus and Greeks utilized tubes of wood or precious metal.

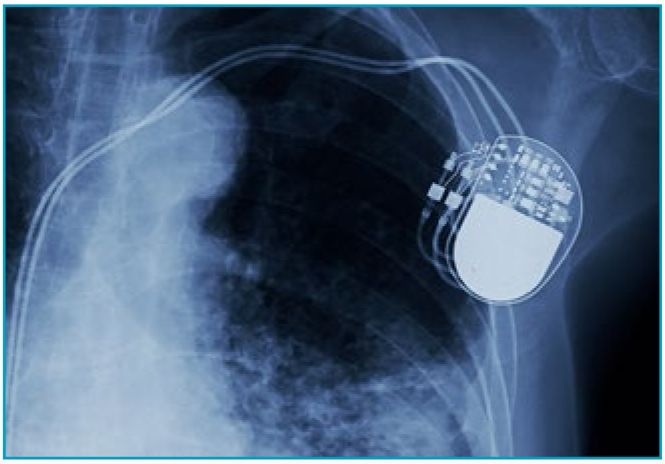
The catheter is probably one of the earliest tubing applications. In 1752, Benjamin Franklin invented a flexible catheter made of metal with segments hinged together and an enclosed wire to provide rigidity during insertion.

David Sheridan, in the 1940s, was credited with inventing the modern disposable catheter. In his lifetime, he started and sold four catheter companies and was dubbed the "Catheter King" by Forbes magazine in 1988.

In 1935, the first slow-drip IV was invented. Early IVs used surgical tubing made from rubber, which was sterilized between uses. It was not until 1945 that any form of plastic material was used in hospital settings, and not until the 1970s that the use of latex and other plastics became widespread in the medical industry.

In 1950, Canadian electrical engineer John Hopps designed and built the first external pacemaker. This was a substantial external device powered by an AC outlet in the wall by the patient.

The commercial availability of the silicon transistor in 1956 was the pivotal event that led to rapid development of practical cardiac pacemakers. In 1958, engineer Earl Bakken of Minneapolis, Minnesota, in the United States, produced the first wearable external pacemaker; a transistorized pacemaker housed in a small plastic box. In the same year, the first clinical implantation into a human was performed.

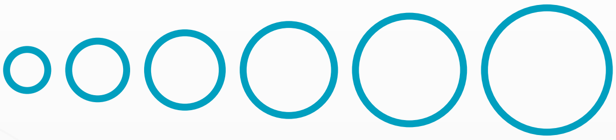


Factors to be Considered Before Specifying Tubing and Hoses

Before designing tubing and hoses for medical devices, engineers should consider factors such as size, hardness, tear strength, elongation, surface friction, transparency, and visibility.

Size

Size is increasingly becoming a critical factor in the design of tubing as medical device developers seek to produce ever-smaller devices and drug delivery systems to be less invasive. Shrinking geometries and tolerances can push the limits of process control, and create down stream challenges with testing, measurement, and assembly.



Hardness

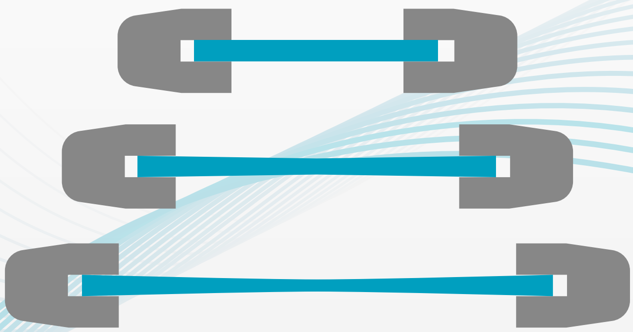
Extruded silicone is commonly available in durometers from Shore A 20 to Shore A 80. As the durometer increases, tensile strength decreases making it an important factor to prevent break failures in wound drains, for instance, which are put under significant tensile load when removed from the body.

Tear strength

Tear strength influences, for example, how difficult it is for a nick in a tube to propagate and is a consideration in situations in which the tube might be exposed to a sharp edge or for geometry with small internal radii. Lower durometer silicones have significantly lower tear strength.

Elongation

Elongation properties relate to the elasticity of the tubing, which is a significant factor for balloon devices, for instance. Lower durometer silicones have higher elongation properties.

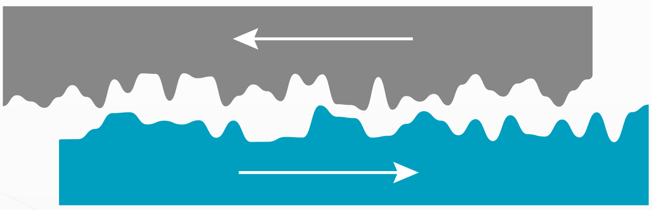


Surface friction

When it is important for a tube to have minimal surface friction, the tube can be coated to decrease the material's inherent "stickiness".

For instance, a coating can reduce the forces required for deployment of an implanted or interventional device, like stents and balloons, or to facilitate assembly of tight fits in devices like pacing leads.

The coating or surface finish must be biocompatible if it is likely to come into contact with the body. Several coatings are available that bond well to silicone and meet compatibility requirements.



Transparency

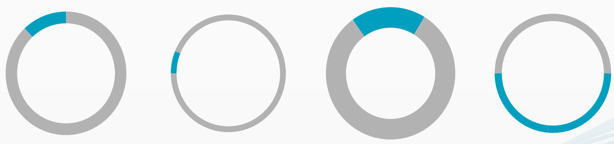
Visibility to verify flow of media through a tube is important for certain types of devices, such as those carrying fluids into or out of the body. Silicone, for instance, is naturally translucent. However, certain silica fillers that increase durometer, as well as barium sulfate ($BaSO_4$) and titanium dioxide (TiO_2), can reduce or eliminate transparency.

Visibility

In some cases, designers may wish to make a tube more visible within the body, for example, to aid in guiding a device through the body when viewing it using an X-ray or fluoroscope.

Barium stripes can be added to a tube to make it visible within soft tissue, while still enabling the fluid to be viewed to verify flow. A higher percentage of barium additive can be used to ensure a tube can be seen through bone, to help a surgeon place a catheter in the spine, for instance.

There is a limit to the amount of radiopaque additive that can be incorporated and still render silicone processable by extrusion. Even a smallest additive amount can make silicone visibly opaque without offering sufficient radiopacity.



Tubing Materials

Depending on the application, medical hoses and tubing are produced in a variety of materials. These include plastics, such as fluorinated ethylene propylene (FEP), Nylon, PVC, polyether ether ketone (PEEK), polytetrafluoroethylene (PTFE) and thermoplastic elastomers (TPE), as well as elastomers, in particular silicone.

Silicone

Silicone is a key material for tubing in medical devices, making it attractive for healthcare applications, especially for implants. The unique characteristics of High Consistency Rubber (HCR) silicones offer an uncured, “Green” strength that allows for a variety of custom and complex processing techniques.

Advantages of Silicone

- Silicone is proven to be inert and bio stable, being the gold standard in terms of biocompatibility
- It is non-reactive with other elements
- It can be platinum-cured for the highest degree of purity
- Durometers can be easily altered
- It allows for extended post cure for lowest level extractables
- It does not utilize leaching plasticizers
- Certain formulations are suitable for long term surgical implant
- It is odorless, tasteless, non-toxic
- It possesses favorable physical and haptic attributes
- It has good tensile strength
- It offers good compression resistance
- It can be made to have a variety of textures
- It can be sterilized by radiation, EtO, steam – 30 psi/2 bar at +123 °C/+253 °F
- It resists temperature extremes with flexibility retention: -54 °C to +204 °C/-65 °F to +400 °F; brittle point: -73 °C/-100 °F
- Processable in a multitude of ways, including molding, overmolding, sheeting, dipping and extrusion in combination with other materials and substrates
- It can include different fillers matched to a specific application
- It offers exceptional permeability, allowing absorption of APIs

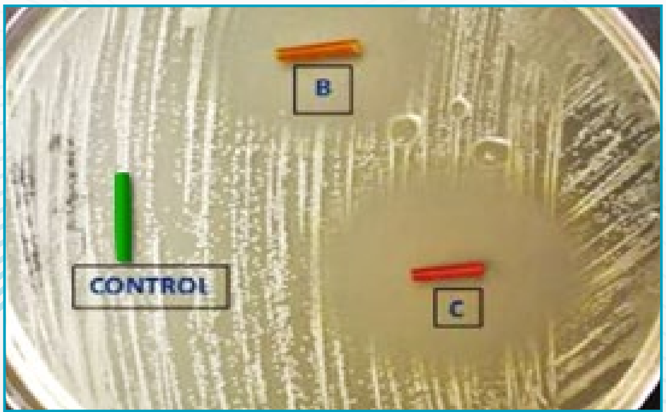
This whitepaper focuses on silicone materials.

Drug-eluting

Silicone is often used for catheters, respirators and implants due to its biocompatibility and biostability benefits. However, silicone is not immune to bacterial colonization.

One option to prevent tubing from transmitting bacteria is to impregnate vulcanized silicone with APIs. The silicone is immersed in the drug solutions, which is absorbed into the material.

The APIs do not interfere with the cure chemistry of the silicone and are uniformly impregnated through the matrix of the silicone. Customizing the API concentration and adding release membranes enables a drug to be released at a constant rate over a longer period of time. APIs can also be used to release a variety of drugs slowly, over longer periods and focused at the site of need. For example, hormones and cancer treatments can also elute through silicone.



Seen above are three samples of extruded silicone. A control with no active ingredient mixed with the silicone, plus samples B and C, each with different loading concentrations. The cloudy areas in the picture depict bacterial growth; however, the areas surrounding samples B and C show varying zones of inhibited bacterial growth.

Platinum-cured silicone

Platinum-cured silicones can eliminate the need for a secondary post-cure process which is required for older peroxide-cured silicone systems. Platinum cure silicone contains fewer volatile organic compounds and can be formulated to have faster cure times at lower temperatures. Platinum-cured silicones can be formulated to bond with metals used in implants, such as titanium, stainless steel and nitinol and such plastics as polycarbonate, polyester, and PEEK.

Tubing Technologies

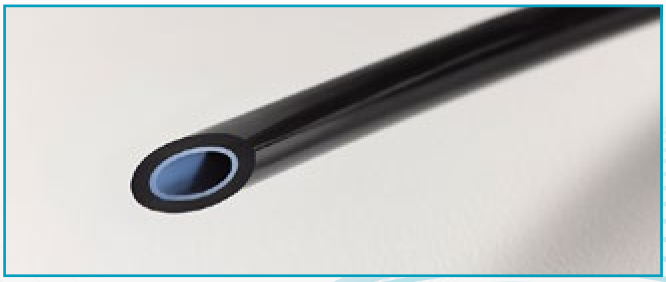
Different processing options have led to ground-breaking ways of producing tubing. When customers partner with medical device component manufactures that utilize the latest capabilities and technologies, they can create solutions that optimize the performance and usability of medical devices.

High-precision, microextrusion, and thin-walled tubing

Microextrusion processing performing below the submillimeter (0.1 mm) range employs modified equipment featuring innovations in extrusion head, tool, and screw designs. This contributes to micro extruded, thin-walled tubing down to 0.05 mm / .002 inches, and outside and inside diameters down to 0.25 mm/ 0.004 inches, potentially for use in minimally invasive surgical (MIS) procedures.

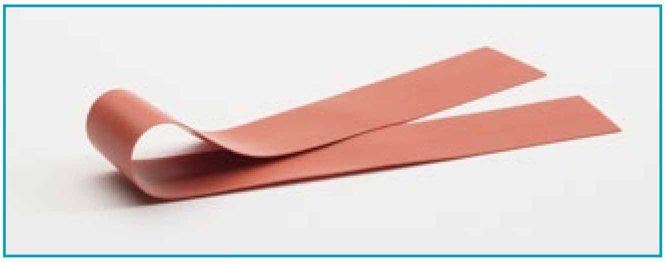
Multicomponent extrusion

Multiple materials can be simultaneously extruded within the same tube to account for differing properties and media interactions. The most common example of this is the inclusion of a radiopaque stripe, which typically incorporates a barium sulfate-loaded silicone as the strip to locate the device in an X-ray or fluoroscope, but it can also be used to vary hardness of specific contact surfaces or to facilitate down-stream assembly through color coding of lumen.



Extruded ribbon and film

Silicone tape, sheet and ribbon can be extruded up to 152 millimeters/6 inches in width with a thickness down to 0.13 millimeters/ 0.005 inches. Such ribbon can be supplied in spools with carriers and slip sheets, or as punched seals or diaphragms to support sealing applications in devices such as pacemaker generator housings.



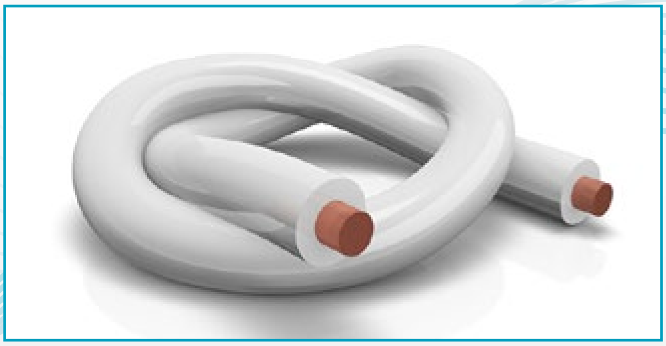
Reinforced and kink resistant tubing

Silicone tubes can be reinforced in a variety of ways, from polyester and stainless-steel braids for expansion-, elongation- and burst-resistance to spiral reinforcement with nylon monofilament for kink- and crush-resistance to keep fluid paths open. Reinforcement is customizable, and tubes can be made to precision tolerances.

Silicone tubing reinforced with polyester braid can also be used to resist abrasion under cyclic loading, such as in pacing leads. The outer covers can be pigmented if required. Care must be taken to verify that the mechanical properties of reinforcing materials are not compromised by the heat required to cure the silicone.

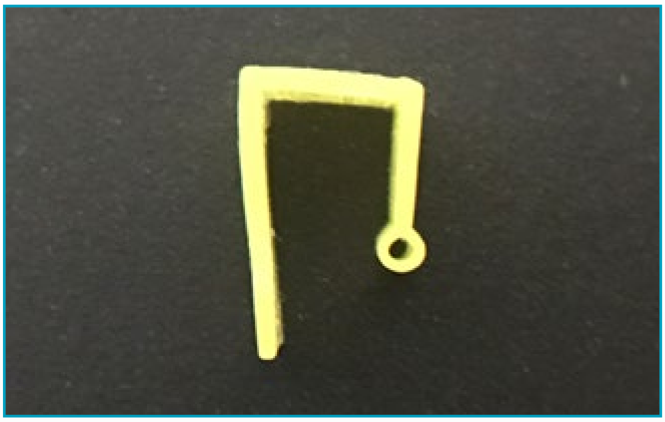
Jacketed wires and cables

Wire and cable assemblies up to 5.08 millimeters/0.2 inches, such as those used to power implantable heart pumps, can be jacketed with one or more layers of silicone to precision tolerances. Such products can be supplied on spools or cut to length. Care must be taken to verify that the mechanical properties of reinforcing materials are not compromised by the heat required to cure the silicone.



Custom profiles

Custom profiles often do not include lumen and are used to seal housing assemblies or in heart valve repair applications. Being non-symmetrical, such cross sections can require longer development cycles and be more difficult to measure while trying to maintain the extrusion's "free-state".



Twisted extrusions

This extrusion process produces continuously twisted tubing for use in applications in which implanted power or sensing cables require strain relief from repeated flexing and bending, as with pacemaker leads.

The tube cross-section typically consists of a center lumen and multiple outer lumen, with the twisting process causing the outer lumen to become spiraled around the center lumen. Due to this, wires fed through the outer lumen are less prone to dynamic flex failures because stresses are distributed more evenly to the multiple wires.

The process does not require the tubing to have a round outer diameter. And features, such as grooves, can be incorporated on the outer surface. Accurate verification of the spiral pitch requires translucent tubing and custom measurement techniques.

Bump tubing

Bump or tapered tubing is created by stretching the tube at a varying rate to produce tubing with a larger diameter at one end and a significantly smaller diameter at the other end. The process can be applied to plastics and elastomers, including silicone. The geometry is limited by the Poisson's ratio of the material during stretching in the green state.

Formed extrusions

Extruded tubing is shaped along its length to create complex paths, such as sinusoid shapes for flex and strain relief and to fit tortuous anatomy, or spiral shapes that might be used to soften contact within the bladder, for instance. Measurement of such geometries in the extrusion's "free-state" can be challenging and require custom methods.

Bonded or over-molded stops

Stops can be bonded or molded onto tubing to lock it in place and keep it from rotating. The stops are typically added to peristaltic pumps for infusion, internal feeding, laboratory equipment, diagnostic equipment, and bioprocessing fluid transfer.

The key advantage of peristaltic pumps is their disposable pump tubing. Only the tubing's inner diameter comes into contact with the fluid; therefore, there is no need to clean or flush the pump in between uses.

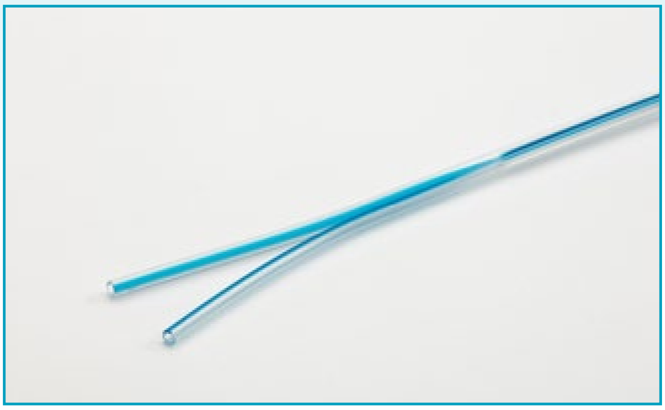
Multi-lumen extrusion

Using this technology, numerous lumens or channels are produced as a single extrusion. More lumen means more dimensions to control and measure, including the inner diameters and the walls between diameters. High precision vision systems with customer programming are often required to ensure quality. Down-stream molding can incorporate over-molded connectors to separate the lumen into individual tubes.

Typical applications include catheters, electronic medical devices, analytical equipment, fluid transfer, drug delivery and medical instrumentation.

Geometric transitioning extrusion

Geometric transitioning, or GeoTrans™ allows for silicone tubing to change cross section during the extrusion process to eliminate molding and secondary bonding steps. Reducing the number of components and the bonding joints between them allows for a more hygienic design.



The technology is applied to custom applications with precision tolerances. To facilitate the development cycle for these highly customized extrusions, it is fastest to identify one cross section as critical and allow flexibility of other cross sections.

Typical changes include:

- Changing the tubing inner diameter, outer diameter, or both to create tubing with two or more different cross sections
- Bifurcation or converting a dual lumen extrusion into two single lumen tubes
- Inclusion of channels to open internal fluid paths at locations along the extrusion length
- Stopping one of multiple lumens to avoid the need for backfilling, such as when the lumen will be used for balloon inflation
- Thinning a tube wall for a short section to drive specific balloon inflation, location, and shape

Geometric transitioning single lumen

This technology, also called "Off-Ratio Bump Tubing", creates two distinct tube cross sections with a near-step transition between them.

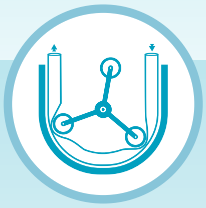
Tubing lengths are available in single transition (cross section A to B) or double transition (cross section A to B to A) options. Applications include custom-end assemblies, such as accommodation of connectors or fittings, and peristaltic pumps.

Foam extrusion

Closed-cell silicone foam offers custom mechanical characteristics by lowering effective durometer and providing additional cushion space. Silicone foam extrusion can be customized in a variety of sizes and cross sections with precision tolerances. Cell pore size and foam density can also be adjusted. Silicone foams are made from medical grade HCR, platinum cured silicone.

Measurement of foam materials can be less precise due to the natural variation of surfaces caused by cell formation that creates the lower density foam.

Application Examples



Bioprocessing Flow Tubing

Application:
Tubing to give a high flow-rate discharge through a large-volume bottom outlet disposable biobag

Issues:
- Desired flow rates were not being achieved
- Tubing was collapsing due to large suction pressure.

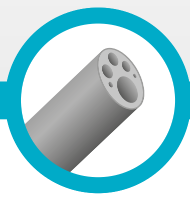
Solution:
Tubing wall was increased to 0.48 mm / 0.188 inch from 0.32 mm / 0.125 inch, while maintaining the same inner diameter.
The thicker wall prevented the tubing from collapsing, and the specified flow rates were met.

Central Vascular Access Catheters

Application:
Multi-lumen tubing and liquid injection over-molding connectors for Central Vascular Access Catheters

Issues:
- Maintaining orientation of feeding lines.

Solution:
Multi-lumen tubing and overmolded connectors utilized a combination of high-precision liquid injection molding and extrusion production techniques.



Orthopedic Tubing

Application:
Extrusion used in an orthopedic additive -eluting medical device

Issues:
- Outer diameter less than 0.012 inch.
- Precisely control a specific elution curve of consistent concentration over a lengthened release time.

Solution:
Close collaboration that started with the elution concept. Using a single material resulted in a narrow two-layer extrusion with the core serving as an eluting rod and an outer concentric layer that precisely regulates elution in MIS procedures. The entire cross section was under 0.012 inches. Customer measurement fixtures were developed and validated with the process.

Implantable Neurostimulator

Application:
Electrical pulses to the brain and spinal cord are used for chronic pain therapy and to treat disorders such as epilepsy, Parkinson's, and Tourette syndrome.

Issues:
- Leads must be very small while maintaining insulation properties to deliver the neurostimulating signals to precise locations.

Solution:
Extremely tight tolerances were met with a micro extrusion. This was possible due to advancements in quality process control and monitoring systems. Diameters of 0.030 inches and less required tolerances of 0.001 inches inner diameter, outer diameter, wall thickness and concentricity to allow for assembly of the conductor, ensure sufficient and consistent insulation along the length of the lead and minimize the overall size.

Pacemaker Lead

Application:
Insulating, biocompatible extrusion carrying multiple conductors for a pacemaker lead.

Issues:
» A strain relief method was needed to mitigate risk of breaking due to dynamic loading.
» The multilumen extrusion design included more that 30 dimensions with tolerances of 0.002 inches or less.

Solution:
Employed continuously twisted tubing process technology with custom tooling and measurement fixtures to validate the process capability of all required dimensions.

Heart Pump

Application:
Cable jacketing.

Issues:
» Provide a biocompatible, protective layer to a cable assembly including several conductors, insulators and strength members.

Solution:
Developed and validated custom extrusion tooling in conjunction with a precise cure parameter window to apply a silicone jacket around the outside of the cable assembly without damage to internal cable components.

Conclusion

Responding to rapid growth in the medical device market, medical device manufacturers are looking to new and innovative processes to enhance their products and meet patients' needs, including miniaturization and wearability.

Hoses and tubing manufacturing techniques are helping to support these new developments and improve patients' quality of life with improved function and integrity and by enabling the incorporation of APIs.

To facilitate the specification of these seemingly uncomplicated yet complex extrusions, it is important to work with an expert in hoses and tubing who will help in considering and weighing up key factors relevant to your application and that can employ progressive technologies and processes to revolutionize medical device design.

Trelleborg is a world leader in engineered polymer solutions that seal, damp and protect critical applications in demanding environments. Its innovative solutions accelerate performance for customers in a sustainable way.

Trelleborg Healthcare & Medical develops, manufactures and supplies innovative engineered solutions for demanding medical, biotech and pharmaceutical applications in thermoplastics, silicone and other elastomers. We focus on meeting the most demanding needs of Healthcare & Medical customers with innovative solutions.

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