

Extrusion
Molding
Assembly



RAUMEDIC®
— Lifeline to Health —

RAUMEDIC

Your development
partner and system
supplier for the medical
and pharmaceutical
industry



The company

RAUMEDIC – your development partner and system supplier for the medical and pharmaceutical industry.



Quality management

We understand the importance of quality, and give you our full support in complying with the regulations.



We are a partner of the worldwide medical and pharmaceutical industry and a leading developer and manufacturer of polymer systems and components. In close collaboration with our customers, we contribute to the development of innovative diagnostic and acute therapy systems.

From the initial idea to serial production, we act as partner and consultant to our customers. With over 70 years of manufacturing expertise in the fields of extrusion, injection molding and assembly, we are ideally equipped to convert your requirements and concepts into mature medical products.



RAUMEDIC headquarters in Helmbrechts

Customer satisfaction and compliance with all relevant statutory, normative and official requirements are the focus of our quality concept. RAUMEDIC has established a comprehensive and certified quality management system for our customers in order to satisfy the demanding requirements for the materials used in medical technology.

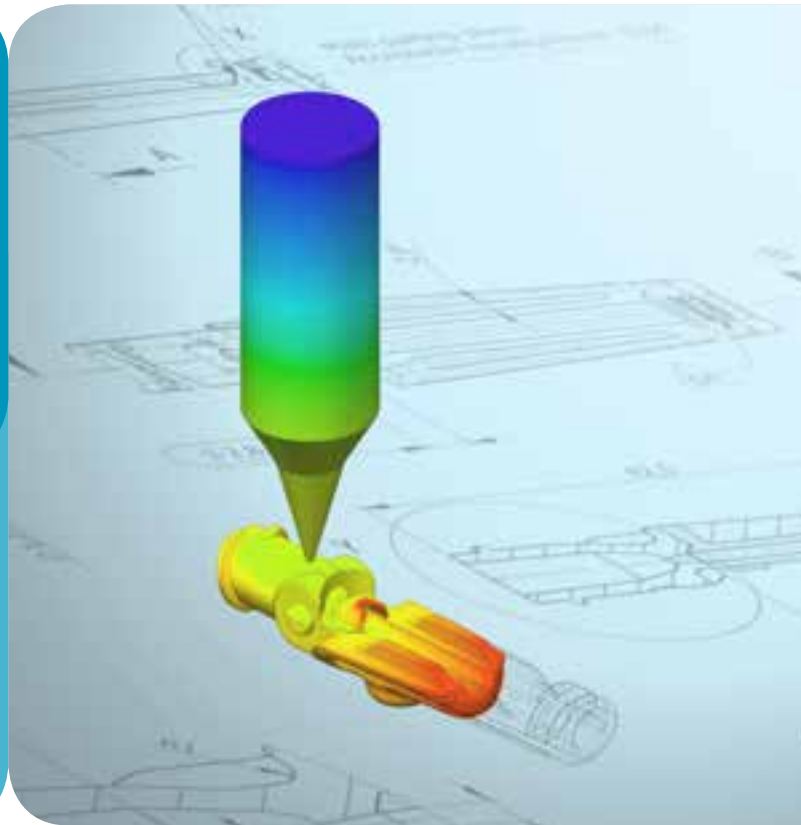
- Certified QM system according to ISO 13485
- Certified according to ISO 15378 (Primary packaging materials for medical products)
- Clean room production according to ISO 14644, Class 7 (=10,000)
- Manufacturing according to GMP standards
- CE approvals for RAUMEDIC medical devices



This means that we ensure compliance with the most important standards and guarantee your complete satisfaction from the design to the finished product.

Development process

Our designers guide the development process of your product from the concept through to production.



RAUMEDIC continually researches new materials, formulations and products, so that we can always ensure the well-being of patients and optimal materials for physicians. Our research and development activities benefit from the many years of experience of our own laboratory staff.

Our engineers will be happy to advise you on design, the selection of materials and production of the first prototypes, through to the finished product and manufacturing concept.

Thanks to modern production equipment and precision work "Made in Germany and the USA", we meet the highest standards of quality and safety.

Individual products require different approaches

RAUMEDIC achieves the best possible functionality with intuitive and ergonomic operation according to the customer's requirements. We attach great importance to production-oriented design and cost-effective manufacturing processes.

We stay in close touch with you all the way from the initial concept through to the finished product. In order to make product development as efficient as possible for our customers, we construct prototypes. This helps us to provide fast and economical solutions for the production of samples and batches.



Material expertise

You know the requirements on your product – we know the appropriate material.



Material formulation

Customized material formulations for processing in extrusion and injection molding.



MATERIAL

The quality of a medical product begins with its raw material

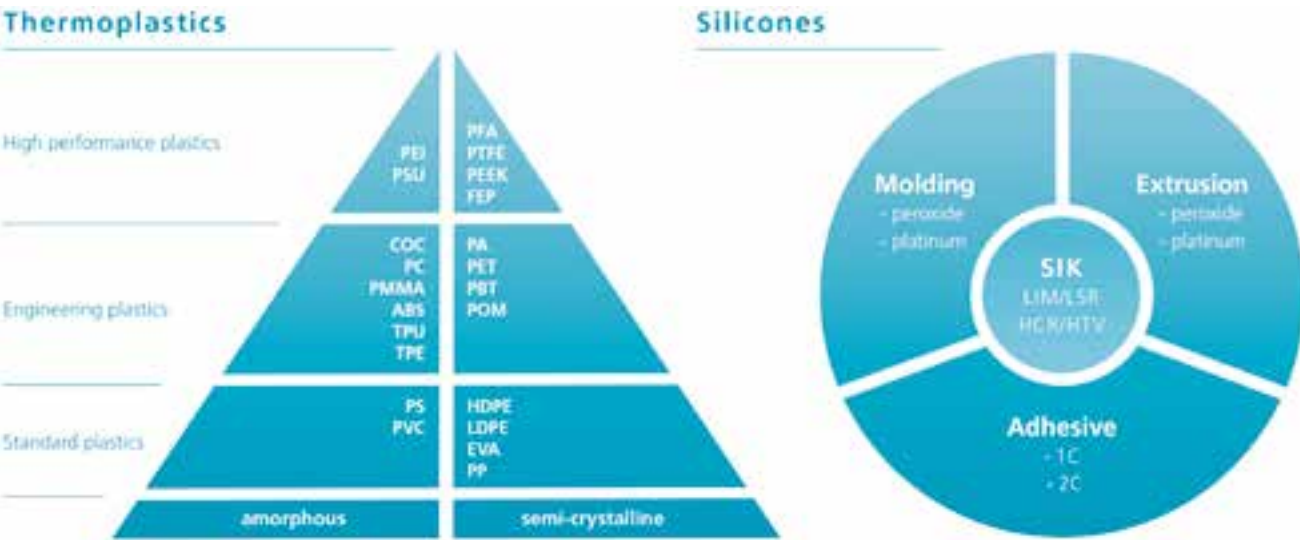
The world of plastics offers us in the medical and pharmaceutical segment endless possibilities for realizing the design requirements for your products. This is why having a diverse range of materials is a top priority for us. Our portfolio of materials ranges from standard thermoplastics (polyolefins) to technical thermoplastics (polyamides) through to high-temperature thermoplastics (PEEK).

A team specifically set up to manage our materials ensures that all material ranges are included when determining the optimal selection for your needs. Whether you have questions regarding biocompatibility or interactions with contact media, such as blood or infusion solutions, we would be happy to consult with you. We can even take aspects such as secondary processing and assembly into consideration during the material selection.

We will find the raw material that is optimally suited for your requirements and your application.

RAUMEDIC processes all thermoplastic polymers and silicones at medical quality.

Here's just one example: We are capable of meeting the challenges associated with the processing of fluoropolymers and can thereby use the optimal sliding properties for the application. Fluoropolymers such as thermoplastic PTFE are therefore exceptionally well-suited for wire coating and thus for our VariCoat® product range.



PVC raw materials and plasticizers

We provide comprehensive and competent consulting in the selection of raw materials and the right plasticizer for your products.



From compounding to a comprehensive PVC solution

Pure-grade compounds – an important step towards a safe PVC product.



Historically, soft PVC is one of the most important plastics in medical technology – this is evident in the wide range of applications in the dialysis and extra-corporeal circulation segment, for instance. For more than 70 years, we have processed and compounded soft PVC in-house and we pay special attention to your requirements with our customized compounds. Drawing on decades of experience in the field of formulating and preparing soft PVC, we are setting new standards for the production of our own compounds. The phthalate-free plasticizer, noDOP®, which has since become established worldwide, is just one example.

Choice of the ideal plasticizer

Choosing the right plasticizer for your application lays the foundation for the product and its suitability for practical application. Please visit our website for more information.

Customized PVC formulations

- Specific sterilization methods
- Good resilience for pump applications
- Customized shore hardness and color
- Suitable for contrast X-rays
- Adapted to all available plasticizers
- Only tested raw materials

Correct processing is the basis for a customized PVC solution

Within the context of compounding, our raw materials are processed on dedicated production lines without contact with the environment, in a process that minimizes wear and tear on the materials. This makes it possible for us to manufacture proprietary compounds that are tailor-made for medical applications.

- Processing in accordance with current state-of-the-art process engineering
- Ensuring quality by means of validated, fully automated process control
- Lot-based quality testing
- Purity ensured by closed material flow from raw material delivery to the finished product
- Several processing systems at two sites ensure supply security, punctuality and customer-oriented flexibility

Tested, documented quality and certified quality system for more product safety

We would be pleased to discuss our alternative materials with you for areas that require a substitute for soft PVC. Replacing soft PVC and its properties is an extensive development task, one which requires special consideration depending on the application. Our solutions comprise thermoplastic elastomers, which combine elastic properties with thermoplastic processing capabilities. This opens up new design possibilities in a wide range of applications, such as in 2-component injection molding. Specially developed thermoplastic elastomers with outstanding pumping properties and excellent transparency and coextruded solutions are available.

Fluoropolymers

Fluoropolymers are used when the product must possess special sliding properties.

Fluoropolymers, such as PFA, FEP and PTFE, are very resistant to almost all chemical compounds and solvents. Their outstanding features are very low slip-page and excellent biocompatibility.

Depending on the intended application, we match the material optimally to your requirements. We also produce spools and cut lengths to the dimensions you specify. In addition, we can incorporate X-ray contrast stripes – variable in number and shape – or offer full-contrast tubing.

With good coating and lubricating properties, fluoropolymers are also ideal for wire coating, e.g. for our VariCoat® product range.

Thermoplastic PTFE

Thermoplastic PTFE is a special fluoropolymer. It provides the perfect combination of PTFE material characteristics and thermoplastic processability. RAUMEDIC has expanded its material expertise to include this unique material. This opens up completely new possibilities for a wide range of medical devices, both for you as a customer and for us as a manufacturer.

- Nearly universal chemical resistance
- Very good sliding properties
- Capacity for further thermoplastic processing
- High temperature resistance

Unlike conventional PTFE, thermoplastic PTFE can be formed and flared without stress cracking or flaking.

Silicone expertise

Scarcely any other material is as versatile in its use or offers such a wide range of beneficial properties.

Silicone is an excellent material for medical applications. Due to its elastomeric nature, it offers unique properties that cannot be achieved with thermoplastic materials.

Advantages of silicone

- Constant material properties within a wide temperature range from -40 °C (-40 °F) to 250 °C (482 °F)
- Excellent pump performance
- High degree of biocompatibility
- Particularly low extractable profile
- All common sterilization methods are possible

Possible areas of application

- Pharma Fluid Handling
- ECC
- Infusion and nutrition
- Drainage
- Pharmaceutical packaging



Extrusion



Injection molding



Assembly

Single lumen tubing

Our range of materials for tubing extrusion includes all common thermoplastics and elastomers.



Multi-lumen tubing

Multi-lumen tubing can be configured according to the customer's requirements, and can therefore be used in a wide variety of applications.



Smallest dimensions for RAUMEDIC extruded tubing

Our products can be adjusted to accommodate the respective requirements.

- Internal diameters starting at 0.002" (0.05 mm)
- Wall thicknesses starting at 0.002" (0.05 mm)
- Micro layers with thicknesses starting at 0.0002" (0.005 mm), can be combined up to four layers
- All common thermoplastics up to high-performance plastics can be selected



Micro extrusion

Thin walled PUR tubing

The wall thickness of thin walled tubing is comparable to the thickness of a human hair. The tubing is therefore very suitable for balloon applications and is used for endotracheal intubation to secure the airways in the areas of anesthesia and emergency medicine.

- Internal diameters from 0.079" (2 mm) to 0.394" (10 mm)
- Wall thicknesses from 0.002" (0.05 mm) to 0.006" (0.15 mm)
- Surface from high-gloss to micro-rough



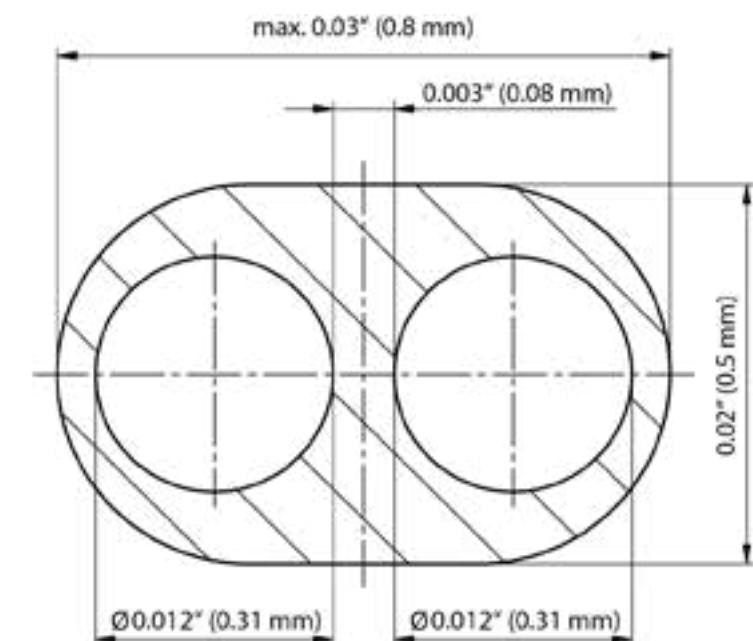
Thin-walled tubing

The material and cross-sectional patterns are tailored to your requirements. This has the following advantages for your application:

- Achieving maximum flow rates
- Delivery of medications via different channels for diagnostic investigations

Typical products are catheters and endoscopes in areas such as:

- Nutrition
- Drainage
- Urology
- Dialysis



Multi-layer tubing

Multi-layer tubing is used when the properties of a single material do not allow us to generate the special characteristics of a product.

Multilayer tubing provides modern, effective and practical solutions for wide-ranging medical applications. Especially in cases when standards and production technology of a medical system require the use of several materials. For example, this is the case if the inside and outside of the tubing must have different properties.

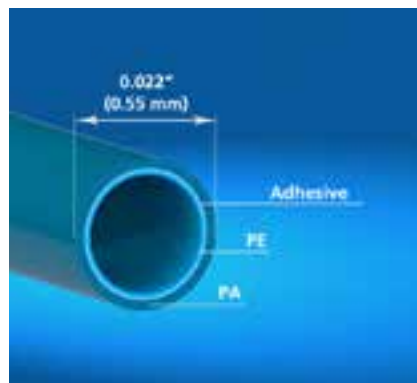
Minimally invasive surgery requires increasingly complex catheters to ensure the patient's well-being during treatment. Even in diagnostics, miniature tubing are used more and more frequently due to sample quantities becoming continually smaller. Up to four different materials can be combined in our multilayer tubing. The smallest inner diameter ever achieved is approximately 0.012" (0.3 mm).

2 Materials



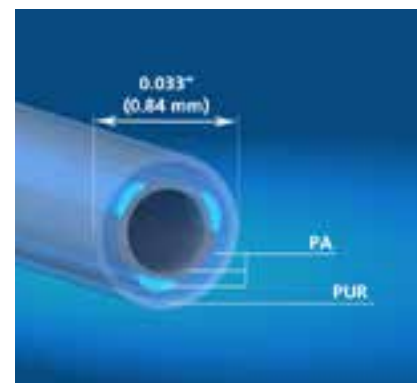
Application: Insulin treatment

3 Materials



Application: Percutaneous transluminal coronary angioplasty (PTCA)

4 Materials



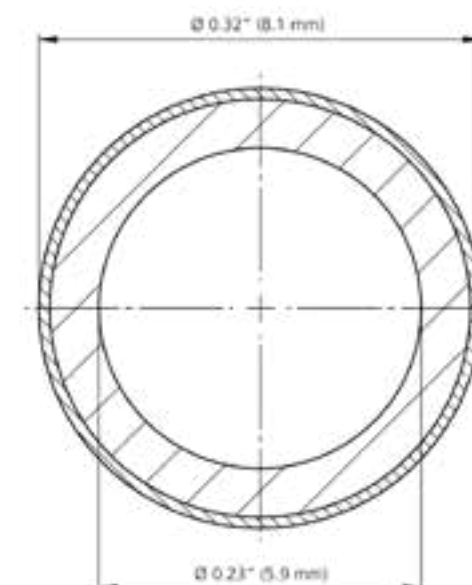
Application: Regional anesthesia

Filling tubing for welding into film bags

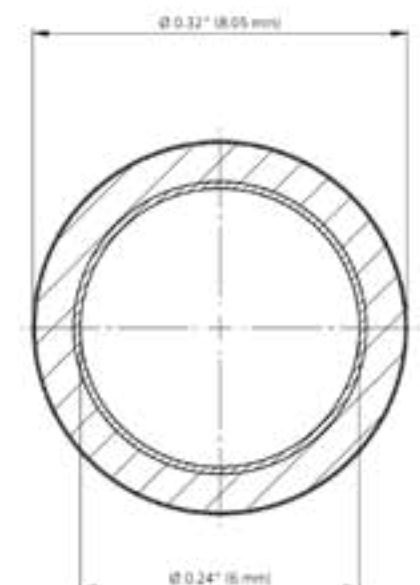
Filling tubing from RAUMEDIC is used, for example, as connector tubing for infusion and dialysis bag applications.

Combination of up to three specially formulated polymer compounds allows targeted adjustment of manual or automated manufacturing processes for optimal further processing in your production facility.

- Secure adhesion of press-fit connectors made of various materials such as PC and ABS
- Optimal weldability using all common types of films
- Processable on different types of machines
- No delamination of individual layers
- No bonding of connectors required due to their secure hold after steam sterilization



2-layer tubing



3-layer tubing

Light protection and drug compatibility

The range of RAUMEDIC tubing for light-sensitive solutions and preventing drug degradation.



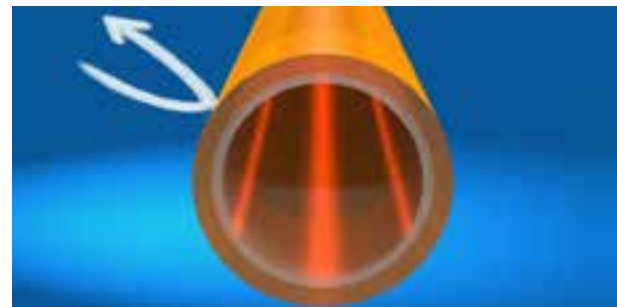
High-pressure tubing

Safety and flexibility through the use of RAUMEDIC high-pressure tubing.



RAUSORB

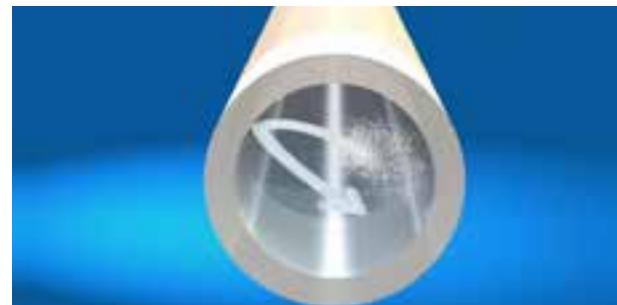
Light-sensitive pharmaceuticals that are destroyed by photochemical reactions play an increasingly important role in therapy. Coloring the outer layer produces a filter that absorbs the harmful wavelengths of light.



For light-sensitive solutions

RAUINERT

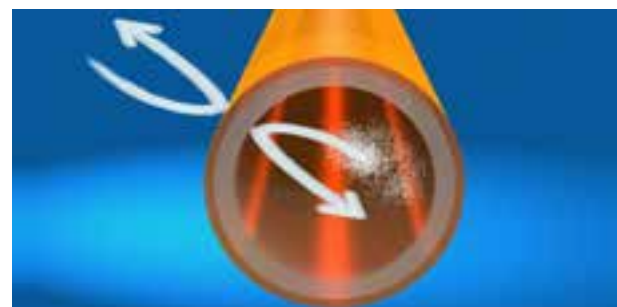
Low dosage rates of modern medications result in higher dwell times in the tubing system. RAUINERT tubing minimizes the risk of unwanted interactions between the drugs and tubing.



For preventing drug degradation

RAUSONERT

Low-dose, light-sensitive preparations place high demands on the transport tubing. RAUSONERT combines all advantages of RAUSORB and RAUINERT in one tubing.



For preventing degradation of light-sensitive solutions

The RAUMEDIC product portfolio offers two versions designed especially for high-pressure applications – reinforced high-pressure tubing and coextruded high-pressure tubing. For both versions, we use exclusively LAL-compliant raw materials. A coreless extrusion process in a class 7 clean room environment results in freedom from particulates as defined in the USP 788 standard.

Reinforced high-pressure tubing

- Outstanding flexibility and optimal kink resistance
- Adjustable transparency
- High-pressure resistance (> 83 bar / 1,200 psi)

Make-up: Spools and cut lengths

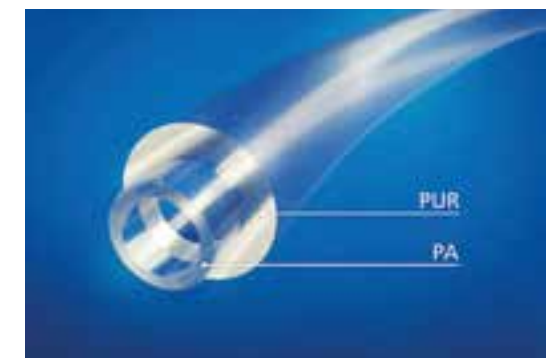


Reinforced high-pressure tubing

Coextruded high-pressure tubing

- Flexibility can be adapted to customer specifications
- Good transparency due to the non-reinforced design
- High-pressure resistance (> 83 bar / 1,200 psi)

Make-up: cut lengths



Coextruded high-pressure tubing

Coated micro cables and wire inlays

Tubing with wire inlays and coated micro cables play an important role in medical products.



Indwelling venous cannulas

As a system supplier, in addition to catheter tubing, RAUMEDIC also has the production know-how for almost all plastic components needed for indwelling venous cannulas.



RAUMEDIC is your skilled development partner for coated micro cables and wire inlays based on customer requirements. With thermoplastic extrusion, we can combine variable support materials, such as wires, braids and synthetic fibers, with a wide variety of polymers. We also process high-temperature thermoplastics such as PFA, FEP, PEEK and thermoplastic PTFE. We attach great importance to the individual needs of our customers.

Coated micro cables and wires

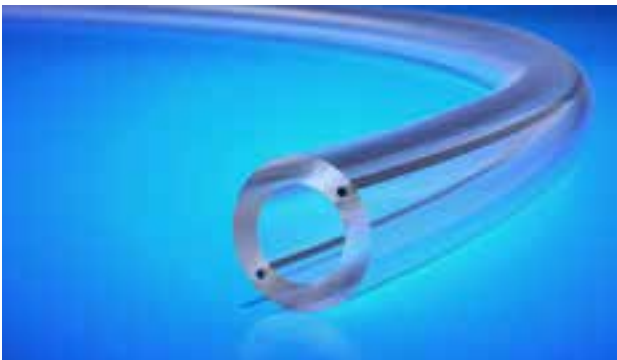
- Customized wire materials such as 304V and nitinol
- Selection of a polymer suited to your requirements
- Layer thicknesses starting at 0.0004" (0.01 mm)
- Wire diameters from 0.001" (0.025 mm) to 0.059" (1.5 mm)

Wire inlay

- Customized wire materials are possible
- Selection of a polymer suited to your requirements
- Wall thicknesses starting at 0.024" (0.5 mm) and inner diameter 0.059" (1.5 mm)
- Wire diameters from 0.002" (0.06 mm) to 0.039" (1 mm)



Coated micro cables and wires



Wire inlay

Examples of RAUMEDIC extrusion expertise include peripheral intravenous catheters, which are available as spools or in cut lengths. Materials used include PUR, FEP, PFA or thermoplastic PTFE for indwelling that is easier on veins and simpler to inject. In addition, coextrusion technology allows us to take advantage of the positive material characteristics of the inner and outer layer together.

We can provide the following components of an indwelling venous cannula for you:

- Intravenous cannula
- Tubing for silicone valve sealing
- Butterfly

Your benefits at a glance

- Excellent blood and biocompatibility
- Number of X-ray contrast stripes can be customized
- Good processing capabilities during tip forming and flaring of the catheter end
- Also with tailored tip geometries implemented by RAUMEDIC



Ranging from zero to maximal contrast - you decide how many X-ray contrast stripes your IV catheter should have.

Lay flat tubing

RAUMEDIC lay flat tubing for enteral and parenteral nutrition.



Gas supply tubing

RAUGAS® – Our tubing is free from BPA and phthalates and complies with European REACH regulations.



Naturally non-PVC materials are explicitly used in manufacturing our lay flat tubing. As such, these materials are very well suited for use as pharmaceutical packaging.

These characteristics make RAUMEDIC lay flat tubing the optimal solution for enteral and parenteral nutrition, as well as for cryopreservation:

- Excellent process capability on high-speed assembly lines
- Flexible film widths from 3.94" (100 mm) to 19.69" (500 mm)
- Variable wall thicknesses from 0.004" (0.1 mm) to 0.016" (0.4 mm)
- Inner surface options include a textured design, longitudinal ribbing or a smooth surface
- Very good transparency due to a special manufacturing process
- Specific transmission characteristics possible through film coloration

Micro lay flat tubing

The micro lay flat tubing manufactured by RAUMEDIC in the clean room is used, for instance, in medical engineering as protective tubing.

- Flat width max. 0.984" (25 mm)
- Wall thickness starting at 0.002" (0.05 mm)
- Material: Polyethylene

Thanks to braiding with polymeric materials between the inner tubing and coating, our gas supply and resuscitation tubing is especially burst pressure resistant. Depending on your requirements, we can also provide electrically conductive versions of the inner layer or special formulations. All DIN EN ISO 5359:2018 requirements for tubing are met. We have tested the following:

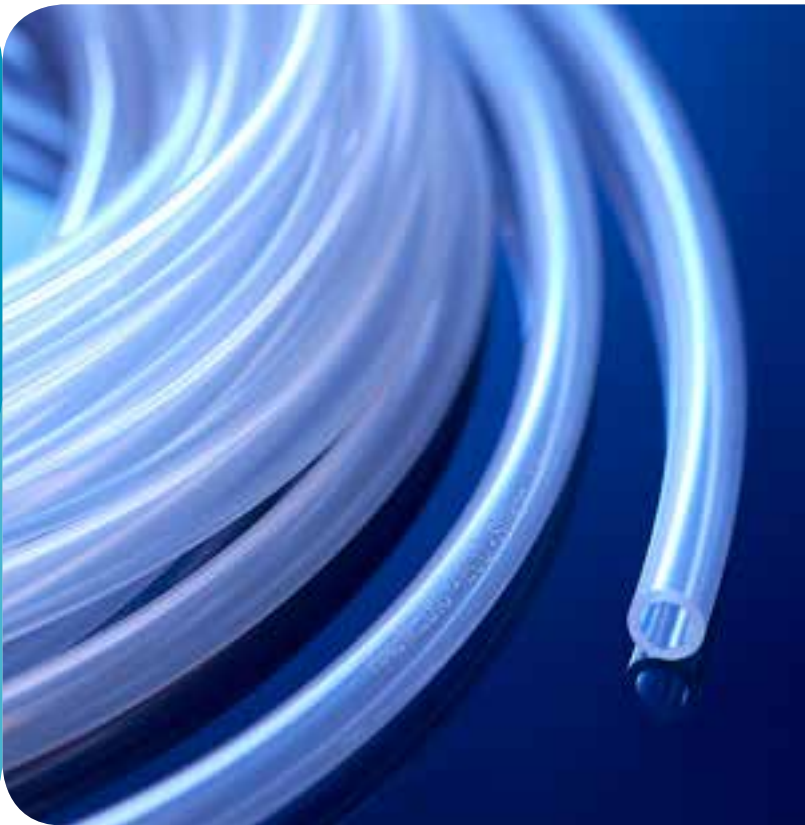
- Axial tensile forces
- Distortion under pressure
- Resistance to occlusion
- Bending radius
- Adhesion of printing

Whether custom manufactured according to your specifications or standard versions off the shelf, we provide the optimal solutions for your respiration, anaesthetic and emergency equipment.



Silicone tubing

RAUMEDIC silicone is the proven tubing for the use in pharmaceuticals and medicine.



Extra-Corporeal-Circulation (ECC)

Our ECC products have proven themselves for over 60 years in many countries. An extensive range in stock enables rapid and reliable delivery.



RAUMEDIC silicone tubing is made of highly resistant, high-quality silicone, which is exceptionally suited for the use in pharmaceutical and medical engineering. Thanks to our years of expertise in production, our silicone tubing has a particularly low extractable content. This ensures outstanding biocompatibility. For selected materials, we can also provide you with comprehensive validation documents for rapid and straightforward customer-specific implementation.

Product portfolio

- Silicone, platinum or peroxide cross-linked
- Shore hardness A 30-80
- Reinforced for high pressure applications
- Full contrast or with X-ray contrast stripes
- Individual printing is possible

Patented surface treatment

- Low-Tack
Reduced tackiness of the surface
- Antimicrobial surfaces
Protection against a variety of clinical germs



RAUMEDIC adhesive and dispersion – safety and protection for your medical devices.

ECC tubing made of noDOP®

RAUMEDIC-ECC-noDOP® tubing is free of DEHP and has a particularly smooth inner surface, which provides outstanding blood compatibility (comparable to that of polyurethane). As a DOP-free material, it is not subject to the labeling requirement for phthalates.

ECC silicone tubing

Maximum reliability and safety as well as tight tolerances are vital, particularly with the ECC roller pump. Our RAUMEDIC ECC pump tubing has set standards in medical technology for many years. Its high transparency and optical quality ensure that bubbles in the blood are detected in good time. ECC silicone tubing is always printed to avoid confusion and document its high quality.

ECC connectors

RAUMEDIC ECC connectors are compact in design in order to minimize the surface area exposed to the patient's blood. They are made of polycarbonate as a single casting and meet the highest mechanical requirements.

Precision injection molding

Our strengths include customized design and manufacture, from complex parts and assemblies through to complete systems.

We manufacture high-precision injection molded parts with part weights from 1 g to 200 g under clean room conditions. Our manufacturing processes have been validated and are guaranteed through application of appropriate statistical methods.



Application system for liquid drugs



Micro injection molding

Injection molding in its smallest size for customized system solutions.

The miniaturization of molded parts and complete groups of components is becoming increasingly important in the medical and pharmaceutical sectors.

In order to meet high customer and quality standards, all phases and processes must be specially designed for micro injection molding.

With micro injection molding, we produce product parts with weights of 0.004 g to 1 g. A wide range of thermoplastics and high-temperature thermoplastics is also used, such as PEEK, PSU and silicones.

We process all thermoplastic polymers up to and including high temperature thermoplastics as well as silicone. A team of specialized engineers and technicians is at your side from the initial idea to series production. Our services include the development and production of molded parts and the assembly of complex groups of components, including customized packaging and sterilization.



Customized dental application in sterile packaging



Complete groups of components and systems from one source

- Micro injection molding
- Micro extrusion
- Micro assembly



PEEK tubing with overmolded tip for stent catheter

Multi-component injection molding

With multi-component technology, various product characteristics can be combined with cost-effective manufacturing options.



Insert molding and overmolding

Insert molding and overmolding of molded parts – the alternative to gluing.



Multi-component injection molding allows us to combine and process a large number of polymers. With this technology, we can implement innovative ideas for products in the areas of medical technology and pharmaceuticals.

Combining hard and soft components in one sub-assembly

The combination of a hard thermoplastic component with a soft elastic component opens up new perspectives in medical technology, such as sealing elements or pharmaceutical dosing systems.

In the cases of insert molding and overmolding, we bundle our expertise in extrusion and injection molding into a single group of components. Even materials that cannot be glued can be successfully joined together with insert molding and overmolding. Furthermore, high tensile loads and pressure tightness can be achieved with injection molding of parts onto metal and plastic cannulas.

The advantages of this process

- Manual, semi- and fully-automated handling of insert parts during the injection molding process
- Optimal bond between the individual components
- Strict requirements on leak tightness



2-component closure cap for syringe system



Catheter coupling for regional anesthesia



Luer cannula for eye surgery



Overmolded connector on a PVC tubing for inhaler applications

Silicone injection molding

Silicone injection molding at RAUMEDIC – true added value. Combine your ideas with our passion for silicone.



Components and systems for the pharmaceutical industry

Together with our customers, we have specialized in the field of pharmaceuticals in the following product groups.



We are specialists in the processing of liquid (LSR/LIM) and high consistency silicone rubber (HCR/HTV). Even 2-component applications in the silicone/silicone or silicone/thermoplastic variants are included in our repertoire. With our many years of experience in medical technology, we support you along the entire value chain of your product.

Competencies

- Sophisticated product and tool design
- Optimal material formulation for your application
- Customized tool technology for your medical and pharmaceutical products
- Qualified and validated processes for maximum process reliability

Possible areas of application

- Pump segments for food and drug pumps
- Silicone plugs for syringe systems
- Insert molded connectors for feeding tubing and catheters
- Seals for the medical and pharmaceutical industry
- Thin-walled molded parts for inhalation systems

Drug delivery systems

Drugs can be fully effective only when their doses are correct. Using our customized solutions, we ensure that drugs are properly dosed.



Disposable patch pump for the treatment of heart failure

Injection systems

We develop intelligent injection systems together with you. In this way, we can ensure the quality and safety of your medications.



Different injection and safety systems

Primary and secondary packaging

Due to our wide range of manufacturing methods we are able to find innovative and customized packaging solutions for your drugs. Thus, your active pharmaceutical ingredient is optimally packaged.



Primary packaging for liquid drugs

Catheter assembly

Our wide range of manufactured items allows us to combine tubing and components into customer-specific, CE-certified and sterile-packaged systems.



Tubing sets

Tubing sets assembled by RAUMEDIC are used, among other purposes, in the areas of ophthalmology, radiology, dialysis and arthroscopy.



Different manufacturing options at RAUMEDIC

- Punching
- Printing (including high-temperature materials)
- Tip forming
- Thermoforming
- Microchip technology
- Integration of electronic components
- Packaging
- Sterilization
- Certification

Manufacturing technologies

- Micro extrusion of multi-lumen tubing
- Precision injection molding of the connector
- Overall assembly of delicate components into the final product



Catheter for microdialysis

We can combine up to 100 components into one tubing set, depending on the customer's individual requirements. Thereby we assemble specially extruded tubing, standard components and customized molded parts.



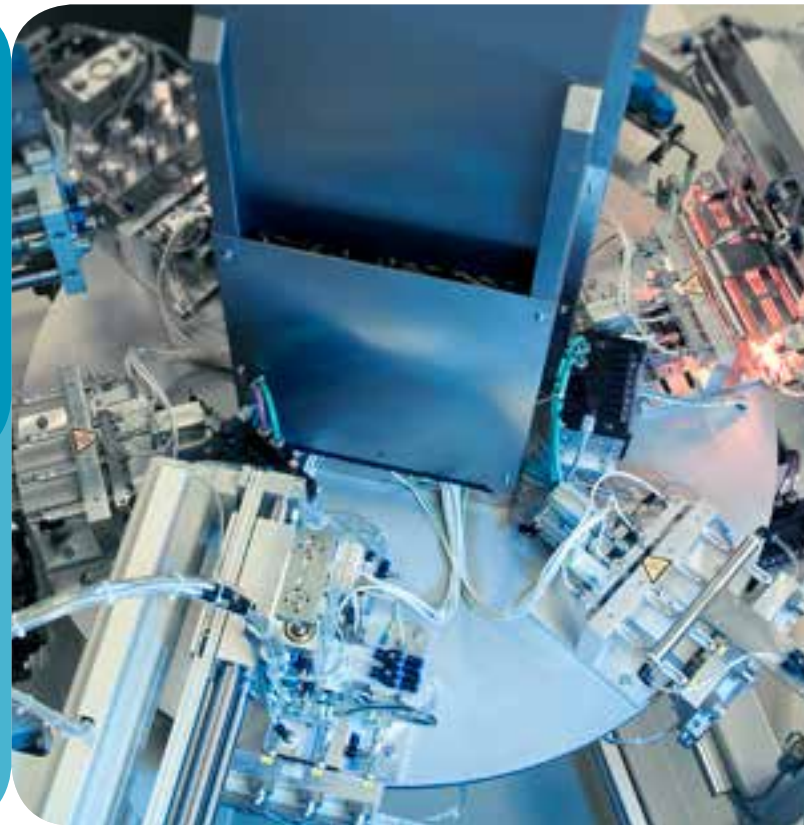
Customized tubing set

Manufacturing technologies

- Application-specific and cost-effective design of the sets
- Semi-automated assembly lines in the clean room
- 100% control of critical characteristics such as leak tightness
- Non-sterile or sterile delivery of the sets

Automation

In whatever quantities you may be planning, RAUMEDIC offers manual, semi-automated or fully automated assembly processes to meet your needs.



Integration of electronic components

With our continuous development of new technologies, we can integrate even the smallest electronic components and cameras into catheter systems.



We have safe and efficient automation solutions, from manual through semi-automatic to fully automatic assembly and production lines. Together with you, we adapt the technical implementation and system concepts according to your wishes and the required capacity.

Micro cannula – an example for RAUMEDIC automation

- Micro extrusion
- Fully automated assembly with tip forming and flaring of the cannula end
- 100% integrated camera inspection of defined quality characteristics



Fully automated UV bonding



Flexible micro cannula for insulin dosing

Due to their generally miniscule size, our catheter systems make minimally invasive procedures possible and can be precisely navigated to the origin of the disease. They are therefore useful in clinical diagnostics as well as in therapy, and reduce the time needed for interventions and, as a consequence, the stress for the patient.



Disposable camera for use in the field of medical endoscopy, among other fields

Manufacturing technologies

- Micro assembly
- Soldering e.g. of wires, cables
- Bonding of microchips
- Assembly of cameras, memory chips, etc.
- Electronic calibration
- Testing of mechanical and optical properties
- Testing of measurement function
- Packaging and sterilization
- Support for CE certification

Implants

RAUMEDIC processes implant-tested materials with advanced manufacturing technology and precise molded parts.



Your system supplier

Together with you, we will develop your product – from the initial idea to series production.



Implants are used in a wide variety of medical disciplines. An example is drainage catheters in urology.

Short-term implants that remain in the body for less than 29 days differ from long-term implants (> 29 days), which must meet particularly high regulatory requirements.

Only certified materials such as silicone and polyurethane are used for these applications. The special feature of these materials is their high purity, which makes them an ideal choice for implants.

Manufacturing technologies

- Silicone and polyurethane extrusion
- Silicone injection molding
- Printing
- Introducing perforations (punching, drilling)
- Assembly of connectors and cuffs
- Biological and toxicological tests and tests according to ISO 10933
- Customized packaging and sterilization
- Support for CE certification

Sophisticated products such as long-term implants, catheter systems, complex tubing sets or other medical devices require many years of experience and extensive knowledge. RAUMEDIC combines these core competencies and offers system solutions from a single source.

RAUMEDIC is your development partner for customized and high-quality product systems in the medical and pharmaceuticals industry. Contact us for your tailor-made solution!

Our experts will advise you on materials and raw material selection, on our production technologies for extrusion and injection molding and the assembly of complex systems. We can also help you with packaging and sterilization.

Global service – what can we do for you?

Thanks to our extensive sales network, you can get personal, on-site support anywhere in the world.

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