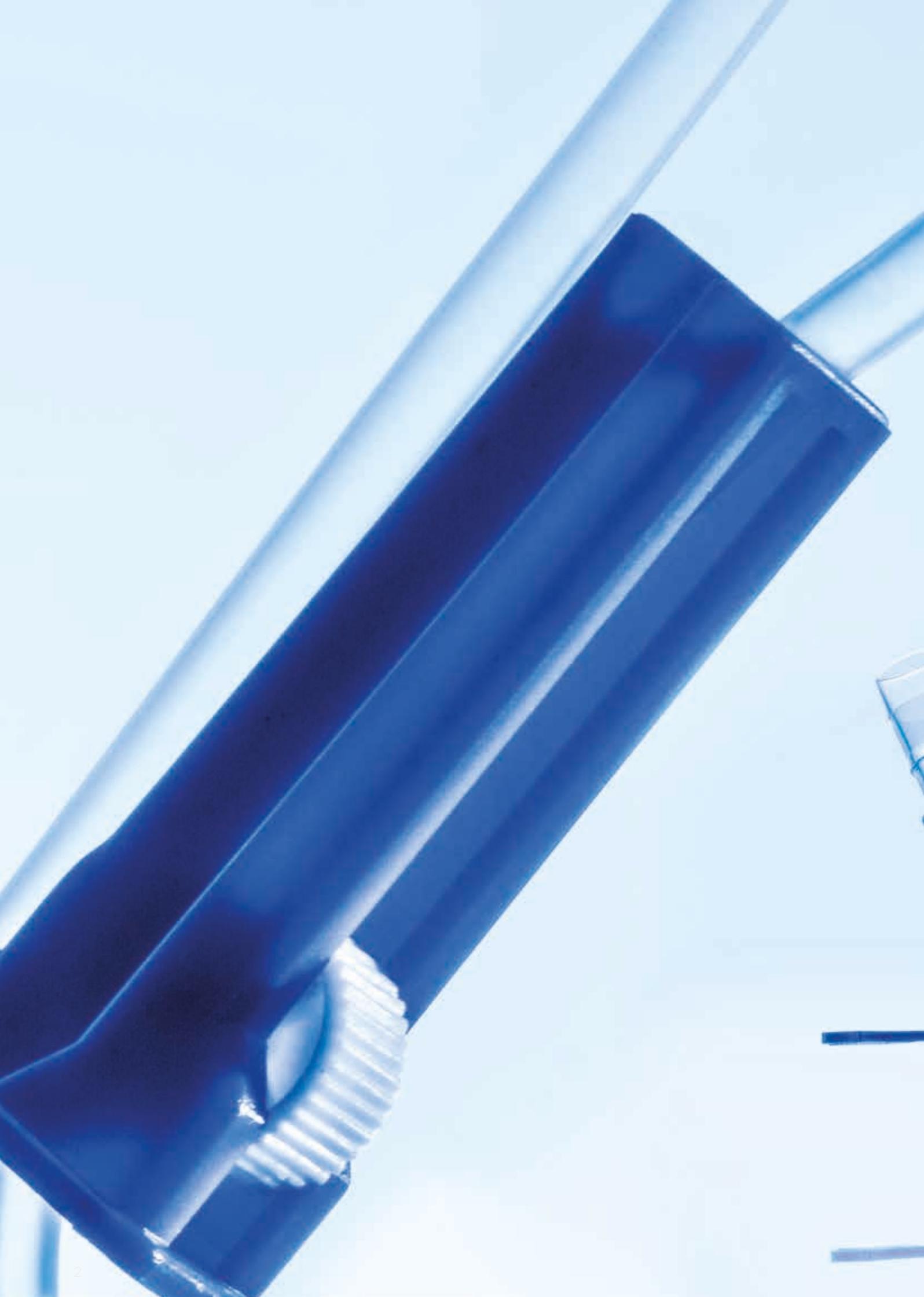




Expertise in Medical Technology



# Expertise in the field of medical technology

**Polymers have become indispensable in the field of medical technology. Their use ranges from simple disposable items, such as syringes or catheters, through to implants and prosthetic devices. Unlike any other material, polymers have the distinct advantage of being adaptable to almost any specific task.**

Medical technology is also one of the most highly regulated industries. Applying plastics in medical technology means adhering to a variety of regulations, which in turn can also require specific tests, certifications and seamless process documentation.

In addition to the material requirements, the medical products and procedures themselves must also go through an extensive certification process to ensure the safety of both patients and users. Clean-room production is an important aspect, as material purity and hygiene are of paramount importance to implants or blood-carrying systems. In many cases, the production process is therefore carried out under strict clean-room conditions.

We pride ourselves developing and manufacturing top-quality tubing, connections and components, as well as modules for challenging applications in the field of medical science. In addition to our extensive know-how on polymers, our long-standing experience in the medical technology industry enable us to provide our customers with unparalleled expertise and benefits:

- We are well versed in the regulatory & procedural requirements
- We support our customers in the approval & certification of medical end-products
- In addition to standard polymers, we also process medically-certified, biocompatible polymers (medical grade)
- Our production takes place in clean-rooms (classes 6 to 8)
- We have certified quality standards (to ISO 9001 & ISO 13485)
- We are a full-service provider for medical standard components & customer projects
- In close cooperation with our customers, we engineer tailor-made medical technology solutions
- Thanks to our own tool-making department, we are able to offer everything from one single source: from tools and individual items through to fully-assembled modules and devices
- Within the Masterflex Group, our teams of experts work closely together to guarantee solutions with unbeatable results
- We stand for medical technology “made in Germany”
- Our range of services covers the entire spectrum from the concept idea through to the sales-ready product

## Masterflex Group - Connecting Values



## Our specialists



We are global leaders and technology drivers in the field of technical tubing, hoses and connection solutions. Our extensive application and material know-how combined with our company history of over 30 years is unique on the world stage. This has enabled us to establish six renowned brands in all industrialized countries throughout the world. We are committed to a consultative approach and provide our customers with individual and tailor-made connection solutions, especially where conventional products are no longer suitable or unable to meet much higher requirements.

As an experienced and financially strong development partner, our objective is to continue our successful creation of sustainable values by top-quality and intelligent products in the future and provide reliability, safety and service to our customers worldwide.

**That's why we're your expert partner for all of your connection tasks!**



Under the Masterflex Group corporation, six specialist companies are united as brands for the most diverse connection requirements: In addition to Masterflex, these are Matzen & Timm, Novoplast Schlauchtechnik, Fleima-Plastic, Masterduct and APT Advanced Polymer Tubing. With further production and sales locations in Europe, the Americas and Asia, the Masterflex Group is represented all over the world.

Our experts in the field of medical technology are **Novoplast Schlauchtechnik** in Halberstadt, Germany and **Fleima-Plastic** in Wald-Michelbach, Germany. The **APT** Advanced Polymer Tubing fluoropolymer specialist based in Neuss, Germany, completes the Masterflex Group portfolio for medical engineering.

The association within the Masterflex Group and the close collaboration of the individual specialist teams provide us with diverse and wide-ranging skills in materials, tool technology and manufacturing processes. Our customers benefit directly from our long-standing experience in the different fields of medical engineering. We pride ourselves in offering the very best in support to our customers throughout the entire development process – from the initial concept idea to the finished medical-technical product.

**Your expert partner in Medical Technology!**



**Founded in 1974**

**Part of Masterflex Group since 2004**

**Specializes in top-quality injection moulding & injection-moulded parts**

- More than 40 years of experience in the production of injection moulds and injection-moulded parts
- Processing of all common thermoplastic polymers
- Certified quality according to ISO 13485 and ISO 9001
- Focus on project business, but a wide range of standard items are offered
- Products include spikes, clamps, drip chambers & injection-moulded items for fields such as ophthalmology, dental technology, cardiology, angiography, packaging and much more
- Clean-room production up to and including Class 8
- Mounting and assembly of multiple components under clean-room conditions up to and including Class 7
- In-house specialist department for moulding and tool design
- Rapid Prototyping (RP), Rapid Manufacturing (RM) & Rapid Tooling are applied, along with feasibility studies and simulations
- Diverse assembly skills including ultrasonic welding, solvents, 2K and UV bonding



**Founded in 1990**

**Part of Masterflex Group since 1990**

**Specializes in the production of intricate polymer tubing & profiles**

- Many years of experience in the field of extruded tubing
- Design & manufacturing of polymer tubing with a diameter of 0.1 to 25 mm
- Processing of thermoplastic materials including PU, PVC, TPE, PE, PP, PA, PVDF
- Certified quality according to ISO 13485
- Certified quality according to ISO 50001 and ISO 14001
- Production clean-rooms of Classes 6 & 8
- Products include tubing for enteral nutrition, hearing aids, infusion, high-pressure applications for the injection of X-ray contrast media, endoscopic applications, and much more
- Cutting-edge production facilities to the most stringent current standards
- Focus on customized solutions



**Founded in 2011**

**Part of Masterflex Group since 2017**

**Specializes in smooth & heat-shrink tubing Fluoropolymer profiles**

- Many years of experience in the processing of fluoropolymers, including PTFE, PFA & FEP
- Specializes in smooth & heat-shrink tubing, such as for catheters or endoscopes
- Fluoropolymers offer a comprehensive chemical resistance & temperature stability at extremely high or low temperatures, and are sterilisable & anti-adhesive
- Certified quality according to ISO 9001:2015 (Quality Management)
- Real-time monitoring of the production process by X-ray, camera and laser measurement technology

# Our materials expertise

**Since the 1960s, polymers and plastics have become more and more important. Depending on the area of application, numerous requirements must be met, such as the mechanical properties of the plastics, biocompatibility, sterilization, and the combination of different materials.**

We process both standard and high-temperature polymers to any known requirements and with or without stringent medical approvals, as required. Combined with a vast application-specific expertise and experience, this provides the basis for success for our customers in the field of Medical Technology.

Due to their mechanical properties and their low price, standard plastics are mainly used for packaging and disposable items. To a limited extent, these plastic materials are also suitable for instrument housings.

Thanks to our brand APT Advanced Polymer Tubing, the Masterflex Group is also able to process high-temperature and advanced plastics, such as fluoropolymers. These are extremely resistant to almost all known types of chemicals, including petrol, solvents, acids or lyes. Furthermore, they are permanently weatherproof and heat-resistant. They offer a high biocompatibility as well as an excellent sliding capacity. Due to these outstanding properties, high-temperature polymers are applied ever more frequently in medical technology, such as for cannula, catheters, or endoscopes.

We focus on the processing of medical-grade materials (MG). This means that the materials used by us are biocompatible. We work together with many renowned raw materials manufacturers. Our products provide almost unparalleled chemical resistance, even compared to high-grade disinfection and cleaning agents. Depending on the material, they can be sterilized using a range of different procedures. We naturally ensure full traceability to the batch of raw material.

Trust in our long-standing material know-how  
- from the raw material to the finished product.



ETFE

THV

FEP

PC

TPEE

LD-PE

TPU

PFA

PTFE

PA 6.12

PC

PA 11

PS

POM

PEBA

PA 6 /  
PA 66

PP-H/C

TPE-S/  
V / O

PA-GV

SBS

PVDF

ABS

HD-PE

SAN

EVA

PP

PMMA

COC

PVC

PSU

ECTFE

PA 12

PBT

# Our manufacturing expertise & development skills

**Precision and hygiene are a must in Medical Technology. With our clean-rooms and certification for DIN ISO 13485, we meet the highest standards of this industry sector.**

## Long-standing experience

For many decades, we have honed our production to the very highest quality level and therefore guarantee the best possible reproducibility of products. Over the years, we have continuously advanced and optimized our processing operations. With our experience and the use of many pioneering technologies, we are well equipped for current and future challenges.



## Passion for injection moulding & extrusion

We provide multifaceted and extensive know-how in the fields of injection-moulding and extrusion united under one roof. According to customer specifications, we process many of our plastic items into modules.

## Injection-moulding

Precision is one of the highest requirements of plastic parts in medical technology. Our advanced injection-moulding production at Fleima-Plastic takes place under strictly controlled processing conditions. We are equipped with over 22

injection-moulding machines together with our own fully-equipped tool construction department and assembly machines. Furthermore, we offer extensive knowledge in various joining and adhesive technologies, including ultrasonic welding and UV bonding.

## We're your experienced development partner

As versatile as the polymer materials themselves – so adaptable and customized can product developments be from these materials. Whether you come to us with an idea, a draft, or a specification sheet, we'll be pleased to take up your requests and wishes and fully dedicate ourselves to the development of a solution.

Today, the time-to-market required is becoming increasingly shorter. Our highly experienced project team actively supports our customers during each phase of the project. In doing this, we also consequently pursue modern design-to-cost approaches. Thanks to their materials expertise and their long-standing experience, our specialists in the development department are able to create initial prototypes within a short timeframe and carry out initial tests. The insights gained from this are integrated into the final development and design of plastic injection-moulded parts. On the basis of the specifications defined for the product, the material design can be started in the following step. For the final mould design and the injection moulding, we create individual tools and moulds on site.

As a reliable development partner, we actively support our customers in the development, manufacturing, testing, and approval processes. This includes services such as: qualification, risk management, monitoring of the product quality (microbiology, endotoxins, and particle contamination) and validation processes.

## Assembly of modules and products

Some injection-moulded parts are processed further in our company and are integrated into a product or a module. For customers in medical

The Development & Production Process of Fleima-Plastic



technology, we also offer assembly (joining, gluing, welding, assembling, etc.) in our class 7 clean-room. Upon request, we also deliver the products readily packaged and labelled.

### Extrusion

Extruded polymers are often the solution in the field of medical technology where optimum flexibility, hygiene and the creation of prototypes are concerned. During the process of extrusion, the respective materials are forced out through a shaped opening continuously and under pressure. The nozzle is responsible for shaping the extrudate. The pressure required is produced via a screw conveyor in which the material is homogenized, compressed, and deaerated. Our know-how in the field of extrusion is tuned to the needs of manufacturers of medical devices.

Our plant comprises:

- Extrusion lines
- Cooling basins
- Cutting units
- PTFE extruders
- Heat-shrink tubing machines
- FEP or PFA extruders

We check and measure the production process via ultrasound, X-ray, and laser measuring technology.

### In-house department for mould & tool design

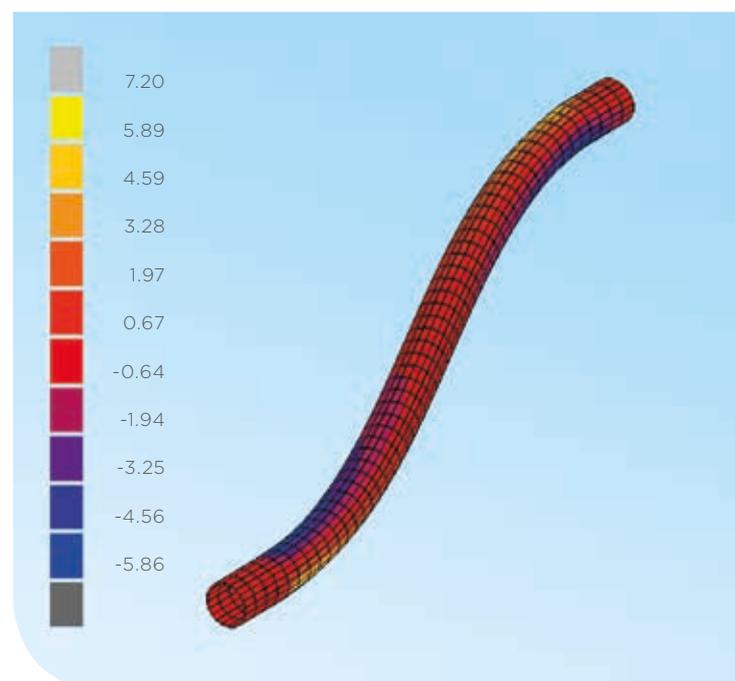
The tool design and construction for medical products made of plastic materials must meet extremely high standards. Here again, the stringent regulations of the industry sector must be observed. This, for instance, concerns special materials or a tool that must be cleaned differently, as it is applied in the clean-room.

We are equipped with our own mould and tool construction department, and therefore able to create the tools and moulds designed quickly and efficiently and test the first injection-moulding samples within a very short time. The tool mechanics and mould makers working in our mould construction department are very experienced and trained at the highest level.

### Qualified supplier for medical devices

We are certified according to the quality standards complying with DIN EN ISO 13485. We therefore not only comply with the legal framework, but we also provide you with additional safety by a certified quality management. We strictly observe the regulations of this standard for our work in all areas of medical production.

FEM analysis of a smooth tube



# Products from the clean-room

**Products in the fields of medical technology, diagnostics and pharmaceuticals must meet extremely high quality standards regarding product purity and hygiene.**

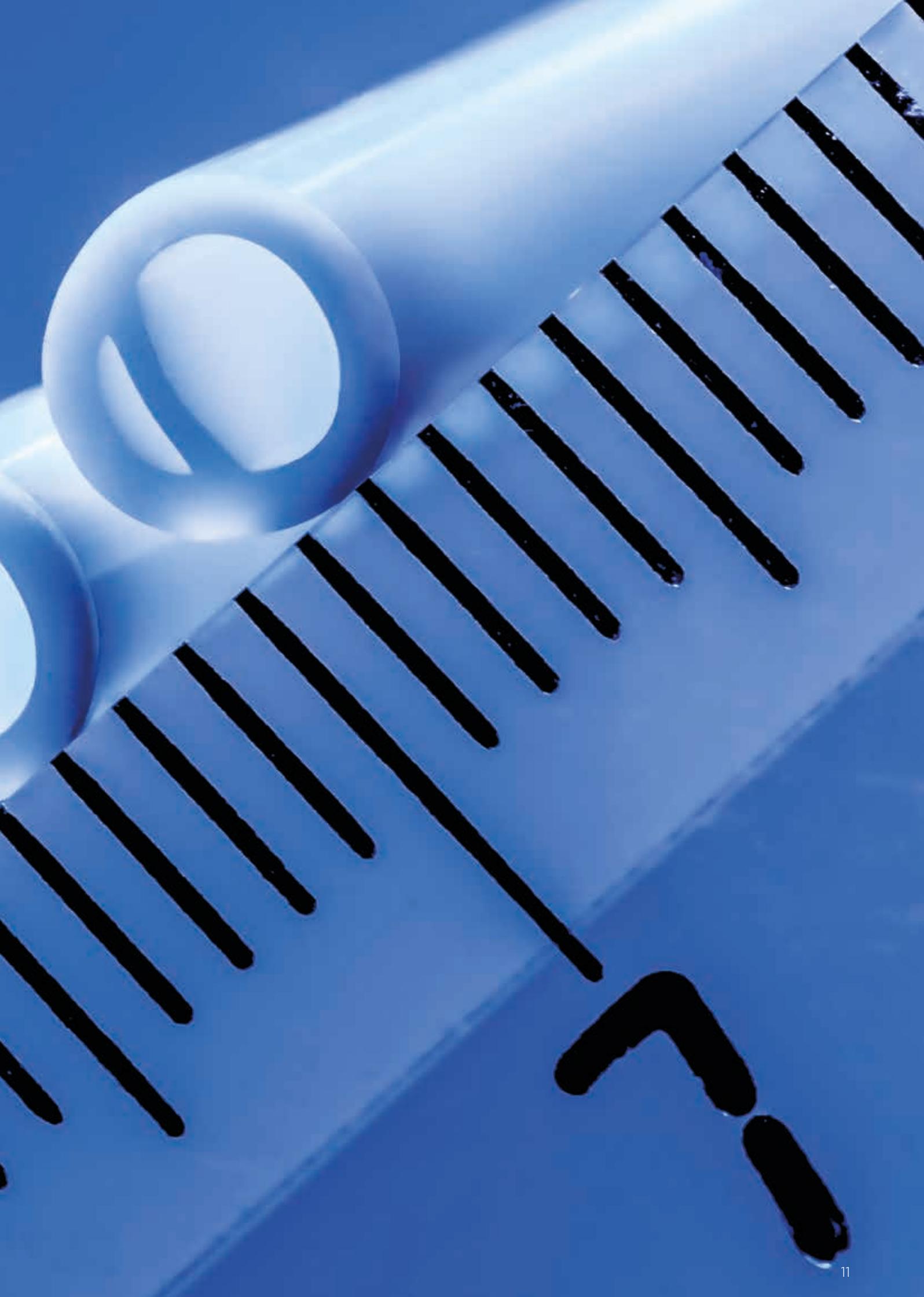
These demands must also be met by the products that we manufacture. The complex and diverse areas of application, in addition to the technical know-how, also require well-founded experience in this field. This also includes the production under “clean conditions” – production in our clean-rooms.

Our production facilities at Halberstadt and Wald-Michelbach in Germany are equipped with clean-rooms of classes 6 to 8 (complying with the specifications according to ISO 14644-1).

In clean-rooms, the concentration of the particles carried in the air is as low as possible. Not only is the supply-air filter controlled, but also the air humidity, air pressure, and the room temperature.

In addition to the actual production in the clean-room, constant monitoring of the clean-room conditions and corresponding training courses for our employees form an important part of our corporate production process. We want to guarantee that the colleagues understand and can relate to the specific demands made in this sensitive field. In addition to training courses, we therefore also carry out internal audits.









# Standard injection-moulded components

In the field of medical standard components, we already provide a huge range of products.

Based on your specific requirements, such as tube diameters or materials, we are more than happy to help you find the right connectors, clamps, caps, or adapters for your applications.

The following items are standard products from our assortment:

- LUER and LUER-LOCK connectors
- Dialysis machine connections
- Protective caps
- Screwcaps, lids, tube clamps
- Connectors from PC (Y and I connectors /HLM connectors)
- T- & Y- connectors and angle-sections
- Adapters & reducers
- Stepped connectors/adapters
- Spikes
- Drip chambers
- Reservoirs
- Tuohy-Borst adapters
- Tube separating diaphragms



# Medical tubing

In the field of medical tubing, we offer the following products to you:

## Monolayers

Monolayers are the simplest type of tubes. They possess the typical tube geometry regarding the inner and outer diameter. Even with this relatively simply cross-section, products can be designed, which have additional benefits. For instance, the anti-microbial equipment of a ureteral stent, the satin-finished surface of an IV tube, or a profiled inner and outer diameter of a protective tube for a cannula.

## Multilayers

Tubes with a multilayer design offer unlimited possibilities. This technology enables advantages of various materials to be combined, even those which are normally incompatible. Examples include infusion tubing and filling tubes for bag systems,

pressure lines for angiography, contrast medium injections of up to 1500 psi, drug administration or highly-flexible operational channels with low kinetic coefficient of friction.

## Multi-lumen tubes

Multi-lumen or multi-chamber tubes provide for a combination of functions. That's why they provide an interesting option for highly specialized areas of application, such as acute dialysis, central venous catheters, liquor drainage, or in urology. This type of tubing is designed in close cooperation with our customers, enabling us to guarantee optimum coordination and therefore excellent results.



## What our customers say

We are fully experienced in handling the specific requirements of the medical technology market. As a reliable quality supplier of standard components and an efficient development partner, we convince our customers with our intelligent solutions, which optimize processes and increase patient safety.

[Learn more about our customized solutions!](#)



### Human Med AG

**The Q-graft® - a globally unique system for the extraction of regenerative cells from body fat**

We manufacture innovative medical products for our long-standing business partner Human Med AG. Here, we perform extensive construction work for the required injection-moulding tools, based on the special requirements for each individual injection-moulded part. Particularly demanding and successful was the cooperation on Q-graft®, a worldwide unique system for the production of regenerative cells from body fat. With this system, the regenerative cells are separated and concentrated directly on the operating table and can then be returned to the patient directly for therapy. For the Q-graft® we developed the extremely complex injection-moulding tools and a process validation for the individual injection-moulded parts. As a special service, we offer the assemblies and final assembly of the Q-graft® under clean-room conditions.

*"We have a very reliable partner. The close cooperation is exceptionally effective and harmonious. We especially appreciate the expertise in substances and materials, as well as the great know-how and quality in tool design and construction. Thank to this, we are able to implement products even more quickly and bring innovations safely to market."*

Konrad Winkler, Design Manager, Human Med AG, Schwerin, Germany



## SOMATEX® Medical Technologies GmbH

SOMATEX® Tumark – the tumour marker which is clearly visible under X-ray and ultrasound diagnosis.



SOMATEX® Medical Technologies GmbH is the specialist for minimally invasive disposable instruments. We have been supplying the company with a combined product for many years now: tube sections made of soft polyethylene LDPE (Low Density Polyethylene) designed by Novoplast Schlauchtechnik and 2-component injection-moulded parts from Fleima-Plastic are assembled in the clean-room to form the SOMATEX® Tumark – a tumour marker with an excellent ultrasound and X-ray visibility.

*“As a specialist of minimally invasive premium single-use products in the medical field, we expect continuously high quality and flexibility from our suppliers. With Novoplast Schlauchtechnik and Fleima-Plastic, we have found long-standing partners who know how to respond to customer needs. Clearly focussed and experts in their fields all specialized departments of the companies work on customized solutions together to provide customized, quality products “made in Germany” at a marketable price level.”*

Nils-Peter Gerlach, Purchasing Department, SOMATEX® Medical Technologies GmbH, Germany

## medwork GmbH

**We support therapeutic endoscopy**

The initial question was that of a suitable material. medwork GmbH is a manufacturer of single-use products in the field of therapeutic endoscopy. The products are used for gastroscopy and colonoscopy operations. In the case of these interventions, flexible endoscopes and HF devices can be used. At the start of our business cooperation, we developed a special combination of materials with optimized friction properties. In addition to the high demands on the material, the dimensions of the tubes in exactly defined tolerances are especially challenging. The dimensions must be exactly coordinated, ensuring that two tubes in the finished product fit into each other perfectly.

**medwork®**  
for mindful people



*“With our innovative single-use products in the field of gastroscopy and colonoscopy, we are constantly setting new standards – all over the world. Manufacturing our products requires concentration, precision, and presence. In Novoplast Schlauchtechnik, we have found a partner who lives up to our high standards just as we do. And who produces, tests and packages its products in Germany, just like we do. This is important to us.”*

Matthias Stirnweiß, Head of R&D at medwork GmbH

# Our locations worldwide



## Germany

**Novoplast Schlauchtechnik GmbH**  
 In den Langen Stücken 6  
 38820 Halberstadt  
 Tel +49 3941 6869-0  
 Fax +49 3941 6869-40  
[www.Schlauchtechnik.de](http://www.Schlauchtechnik.de)

## Germany

**Masterflex SE**  
 Willy-Brandt-Allee 300  
 45891 Gelsenkirchen  
 Tel +49 209 97077-0  
 Fax +49 209 97077-33  
[www.Masterflex.de](http://www.Masterflex.de)

## Czech Republic

**Masterflex Česko s.r.o.**  
 Průmyslová 917  
 34815 Planá  
 Czech Republic  
 Tel +420 374 6294-69  
 Fax +420 374 6310-31  
[www.Masterflex.cz](http://www.Masterflex.cz)

## USA

**Masterduct, Inc.**  
 5235 Ted Street  
 P.O. Box 40727, ZIP 77240  
 Houston, TX 77040, USA  
 Tel +1 713 46257-79  
 Fax +1 713 93984-41  
[www.Masterduct.com](http://www.Masterduct.com)

## China

**Masterflex Hoses (Kunshan) Co. Ltd.**  
 395 Jiande Road  
 Zhangpu Town, Kunshan,  
 Jiangsu Province  
 P.R. China, 215321  
 Tel +86 512 5795-2886  
 Fax +86 512 5795-2787  
[www.Masterflex.cn](http://www.Masterflex.cn)

## Germany

**FLEIMA-PLASTIC GmbH**  
 Neustadt 2  
 69483 Wald-Michelbach  
 Tel +49 6207 92412-0  
 Fax +49 6207 92412-30  
[www.Fleima-Plastic.de](http://www.Fleima-Plastic.de)

## Germany

**Matzen & Timm GmbH**  
 Nordportbogen 2  
 22848 Norderstedt  
 Tel +49 40 853212-0  
 Fax +49 40 8587-23  
[www.Matzen-Timm.de](http://www.Matzen-Timm.de)

## Sweden

**Masterflex Scandinavia AB**  
 Kabelgatan 13  
 43437 Kungsbacka  
 Sweden  
 Tel +46 300 1717-0  
[www.Masterflex.se](http://www.Masterflex.se)

## Brazil

**Masterduct Brasil**  
 Comercio de Dutos LTDA.  
 Rua dos Estados,  
 18-Villa Industrial  
 06516-310- Santana de  
 Parnaíba-SP, Brasil  
 Tel +55 11 415151-00  
 Fax +55 11 415125-96  
[www.Masterduct.com.br](http://www.Masterduct.com.br)

## Asia Pacific

**Masterflex Asia Pte. Ltd.**  
 German Centre for Industry  
 and Trade Pte Ltd.  
 25 International Business Park  
 04-60A German Centre  
 Singapore 609916  
 Tel +65 6897 45-85  
 Fax +65 6897 45-81  
[www.Masterflex.asia](http://www.Masterflex.asia)

## Germany

**APT**  
 Advanced Polymer Tubing GmbH  
 Borsigstr. 13-15  
 41469 Neuss  
 Tel +49 2137 109737-0  
[www.apptubing.de](http://www.apptubing.de)

## France

**Masterflex SARL**  
 Z.A. des 2B  
 01360 Béligneux, France  
 Tel +33 4 780602-02  
 Fax +33 4 780621-56  
[www.Masterflex.fr](http://www.Masterflex.fr)

## UK

**Masterflex Technical Hoses Ltd.**  
 Prince of Wales Business Park  
 Vulcan Street  
 Oldham, OL 1 4ER, Lancashire,  
 Great Britain  
 Tel +44 161 62680-66  
 Fax +44 161 62690-66  
[www.Masterflex-UK.com](http://www.Masterflex-UK.com)

**MASTERFLEX GROUP**

**MASTERFLEX**

**MATZEN & TIMM**

**NOVOPLAST**  
SCHLAUCHTECHNIK

**FLEIMA-PLASTIC**

**MASTERDUCT**

**APT**

[www.MasterflexGroup.com](http://www.MasterflexGroup.com)





 **FLEIMA-PLASTIC**

Fleima-Plastic GmbH  
Neustadt 2  
69483 Wald-Michelbach  
Germany  
Tel.: +49 6207 92412 0  
Fax: +49 6207 92412 30  
[www.Fleima-Plastic.de](http://www.Fleima-Plastic.de)

 **NOVOPLAST**  
SCHLAUCHTECHNIK

Novoplast Schlauchtechnik GmbH  
In den Langen Stücken 6  
38820 Halberstadt  
Germany  
Tel.: +49 3941 6869 0  
Fax: +49 3941 6869 40  
[www.Schlauchtechnik.de](http://www.Schlauchtechnik.de)

 **APT**

Advanced Polymer Tubing GmbH  
Borsigstraße 13-15  
41469 Neuss  
Germany  
Tel.: +49 2137 109737 0  
Fax: +49 2137 109737 98  
[www.ap tubing.de](http://www.ap tubing.de)