

Global provider of medical devices,
plastics solutions and pharmaceutical systems



SP Medical

About SP Medical

Mission

Our Name and Logo

Strategy

Corporate Values

Customers

SP Medical A/S develop, manufacture and provide plastic solutions to the global medical devices and pharmaceutical industries.

SP Medical A/S is a company in SP Group A/S, an international plastics group headquartered in Denmark. SP Group A/S is listed on OMX The Nordic Exchange Copenhagen

Mission

Formed in 1934, SP Medical A/S has focused on plastics since 1950. Having been in the business since plastic was born, so to speak, we have more than 50 years of experience in developing and manufacturing plastic products and systems.

Our mission today is to develop, manufacture and provide plastic solutions to the global medical devices and pharmaceutical industries. In addition to customized solutions, standardized products and own-brand products, we offer systems and logistics solutions.

SP Medical A/S has state-of-the-art production facilities in Denmark and Poland



Our Name and Logo

Our name and logo reflect our mission and skills.

Our core competencies – **s**urfaces and **p**lastics – provide the letters “**SP**” in our name.

Our market is the medical devices and pharmaceuticals industries, which is where the “**Medical**” part of our name comes from.

The colors of our logo illustrate the colorful plastic materials.

The logo for SP Medical features the letters 'SP' in a large, bold, black sans-serif font. A small blue square is positioned above the letter 'P'. To the right of 'SP', the word 'Medical' is written in a smaller, black, sans-serif font. A thin red horizontal line runs beneath the entire logo.

SP Medical



Strategy

Our strategy is based on growth and on expanding our international scope.

We also intend to stand out as a business partner by continuing to develop our know-how in raw materials, processes and design, to provide solutions that add value for our customers.

We aim to build long-term partnerships with our customers, and to achieve this, the constant improvement of our skills, performance and flexibility is a vital part of our strategy.

Corporate Values

Our organization builds on four basic corporate values, each one describing a characteristic we want every single member of our staff to possess.

- **Responsible**
We keep our promises and do things properly.
 - **Performance-Driven**
We constantly strive to do things better and in a more rational way.
 - **International**
We listen to our customers and find solutions together with them in an open dialog, regardless of where they are in the world.
 - **Ready for Change**
We must be at the forefront of developments to continue to be a strong partner to our customers and business partners.
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Customers

Our customers are located throughout most of the industrialized world. Exports account for more than 75% of our business.

Our clients include some of the world's largest manufacturers of diagnostics equipment, medical devices and pharmaceutical products. We also have smaller biotech and medical-devices companies as our partners.



Technologies

Injection Molding
Surface Treatment
Assembly and Finishing
Metal Fabrication
Packing and Sterilization
Automation
Production Environments

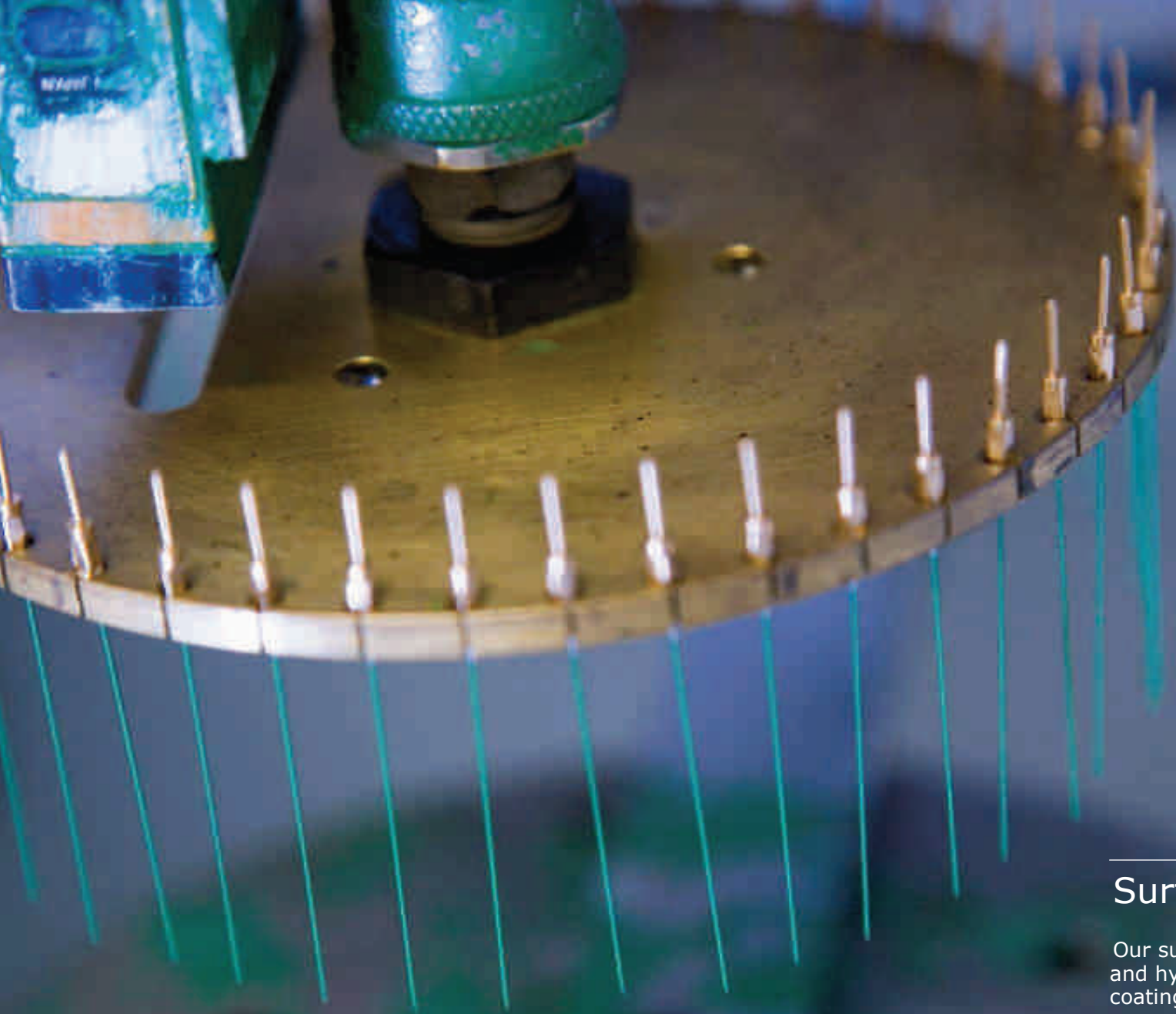
SP Medical A/S have more than 50 years' experience in working with plastic. Our core capabilities are injection molding, surface treatment and processing of plastic products.

Injection molding

Our machinery includes injection-molding machines with a clamping force ranging from 25 to 1250 metric tons.

Among the injection molding technologies we use are multi-component molding, air molding and insert molding.





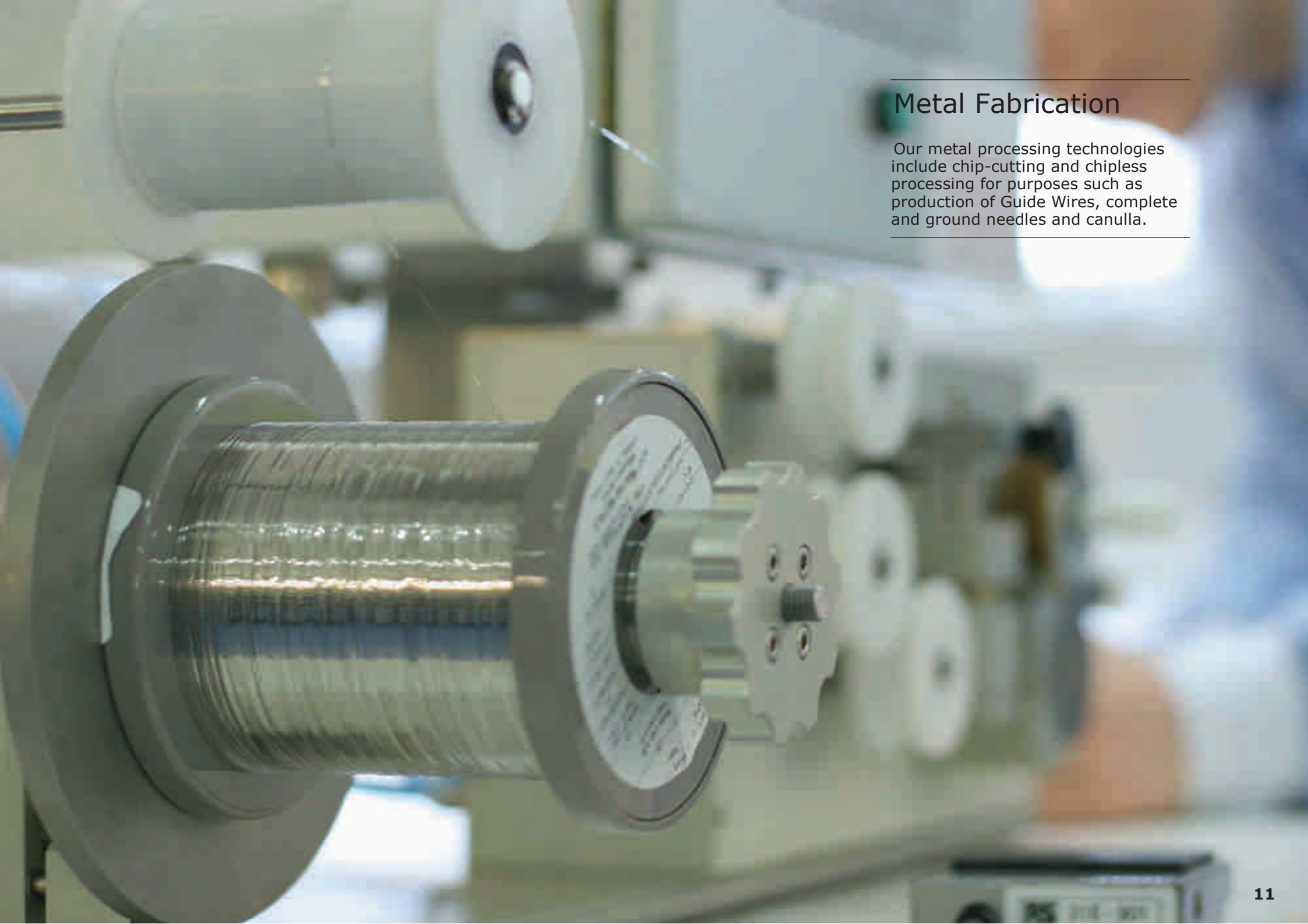
Surface Treatment

Our surface treatment technologies include PTFE and hydrophilic spray and dip coating, PVD coating, plasma coating and hard coating.

Assembly and Finishing

We perform other work on components such as manual or fully automated assembly, welding, decoration, embossing, glueing and chip-cutting.





Metal Fabrication

Our metal processing technologies include chip-cutting and chipless processing for purposes such as production of Guide Wires, complete and ground needles and canulla.

Packing and sterilization

We offer manual and fully automated packaging and labeling of components and complete devices to be delivered either sterile individually packed or bulk.

We also have an extensive network of regular business partners in technologies such as metal finishing, punching and bending services, x-ray sterilization and gas sterilization.

Medtronic
Disposable Concentric
Needle Electrode, 25 mm x 0.30 mm (30G)

USE BY 2009-11

LOT 36019



Attention: use
instructions for use
Sterile until packaging is damaged
or opened. Do not re-sterilize.

STERILE

Medtronic

Disposable Concentric
Needle Electrode, 25 mm x 0.30 mm (30G)

USE BY 2009-11

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STERILE

Medtronic



Automation...

is a natural part of the manufacture of plastic products and surface coating.

We have extensive experience in production automation, such as robotic handling of parts, materials handling and in-line quality control, including vision control and functional tests.

Production Environments

Our production environments include monitored Class 7 and 8 cleanrooms as well as controlled environments.

Our cleanroom environments are built and maintained in accordance with ISO 14644 and ISO 14698.



Capabilities

Quality

Logistic solutions

Tools


Project Management

Design

Development

Performance

SP Medical A/S' capabilities cover a large part of the value chain – from design and development to production and distribution of complete devices, including the necessary documentation for regulatory approval of the products.



Quality

SP Medicals management system takes into account all the demands on and expectations faced by providers to the global pharmaceuticals and medical devices industries:

- We are certified to the ISO 9001, ISO 13485 and ISO 14001 standards.
- We have CE mark certification under the Medical Device Directive (93/42/EEC) as amended by 2007/47/EEC
- We comply with FDA Part 820 (QSR).
- We comply with the Global Harmonization Task Force Process Validation Guidance SG3/N99-10.
- We have MSA accreditation.
- We build and maintain our cleanroom environments in accordance with ISO 14644/ISO 14698.

Logistic solutions

Our organization and systems are designed to handle high-level global sourcing. Sourcing and vendor management are integral parts of our management system.

We have extensive experience in the large-volume purchase of plastic raw materials and, being a manufacturer of complete devices as well, we also have skills in sourcing components we do not make ourselves, such as metal and electronics components, cables, packaging and other items. In addition, we also purchase services such as finishing and sterilization.





Tools

SP Medical sources tools from all over the world.

Our tools suppliers are carefully selected on the basis of our many years of experience and collaboration with them. We make high demands with respect to quality, reporting, documentation and delivery precision, and we maintain a close dialog with and follow up on our tools suppliers.

All tools are tested, subjected to trial runs and documented locally before being approved and delivered to us for final validation.

Project Management

SP Medical have extensive experience in managing complex projects using our standardized project management model.

We have experience in both large and small outsourcing projects and in the development of new components as well as complete devices.

Our project management model includes a Quality Activity Plan (QAP) that defines requirements for the relevant project.

Our QAP complies with the requirements set out in EU-GMP/GLD/GDP, FDA Part 820 (QSR) and the Medical Device Directive 93/42/EEC as amended by 2007/47/EEC.

This means that we prepare documentation in the form of a Design History File (DHF), a Device Master Record (DMR) and a Device History Record (DHR).



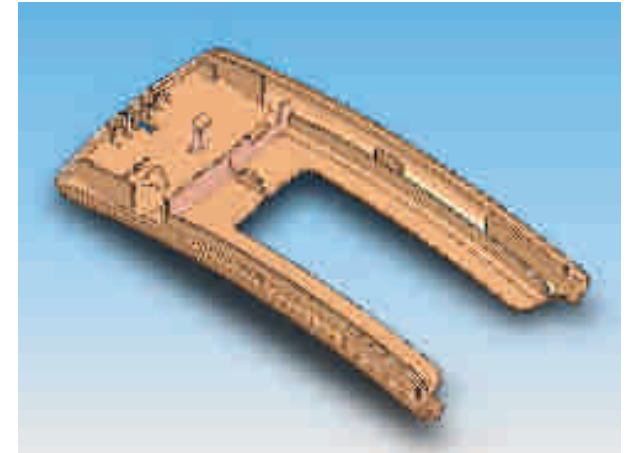
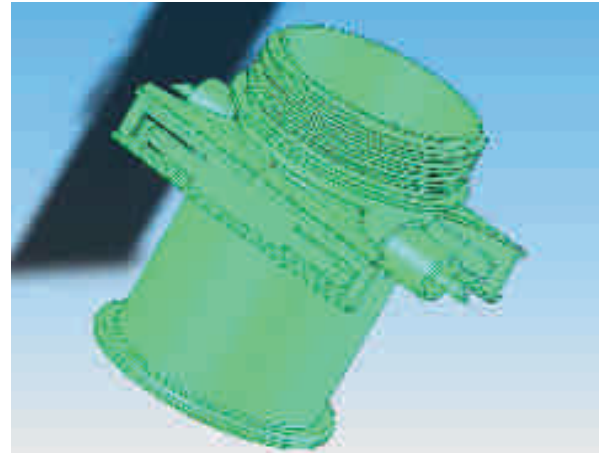
Design

SP Medical can help ensure the optimal product, from initial concept to finished design and complete devices.

Our many years of experience and our standardized methods provide solutions that optimize quality and production price.

We use different types of computer modeling, risk analysis and prototyping to optimize solutions and shorten the development process.

We use different kinds of computer modeling in designing plastic components, including Moldflow analysis, visualization, digital prototyping and 3D CAD modeling, which we employ directly in the manufacture of production tools, fixtures, etc.



Development

Our in-house product development and participation in research projects are factors that continually help improve our plastics and surfaces capabilities. We aim to be at the forefront when it comes to know-how and the practical application of materials and production technologies.

We develop materials and production technologies in an international partnership with suppliers, universities and other research institutions.

Performance

Two of our strategic goals are to ensure high performance and develop our competencies on a continual basis.

Our management system is designed to optimize performance and service level in all the services we provide.

Our management system ensures that any deviations are corrected and employs a large number of benchmarks to constantly monitor and improve our performance.

Management By Objectives (MBO) is an integral part of our management system.

Our efforts both in the short term and the long term are primarily guided by the needs and requirements of our clients.

Key Figures

Delivery Performance

SP Medical A/S



Claims



Product Areas

Medical Devices

Guide Wires

Coatings

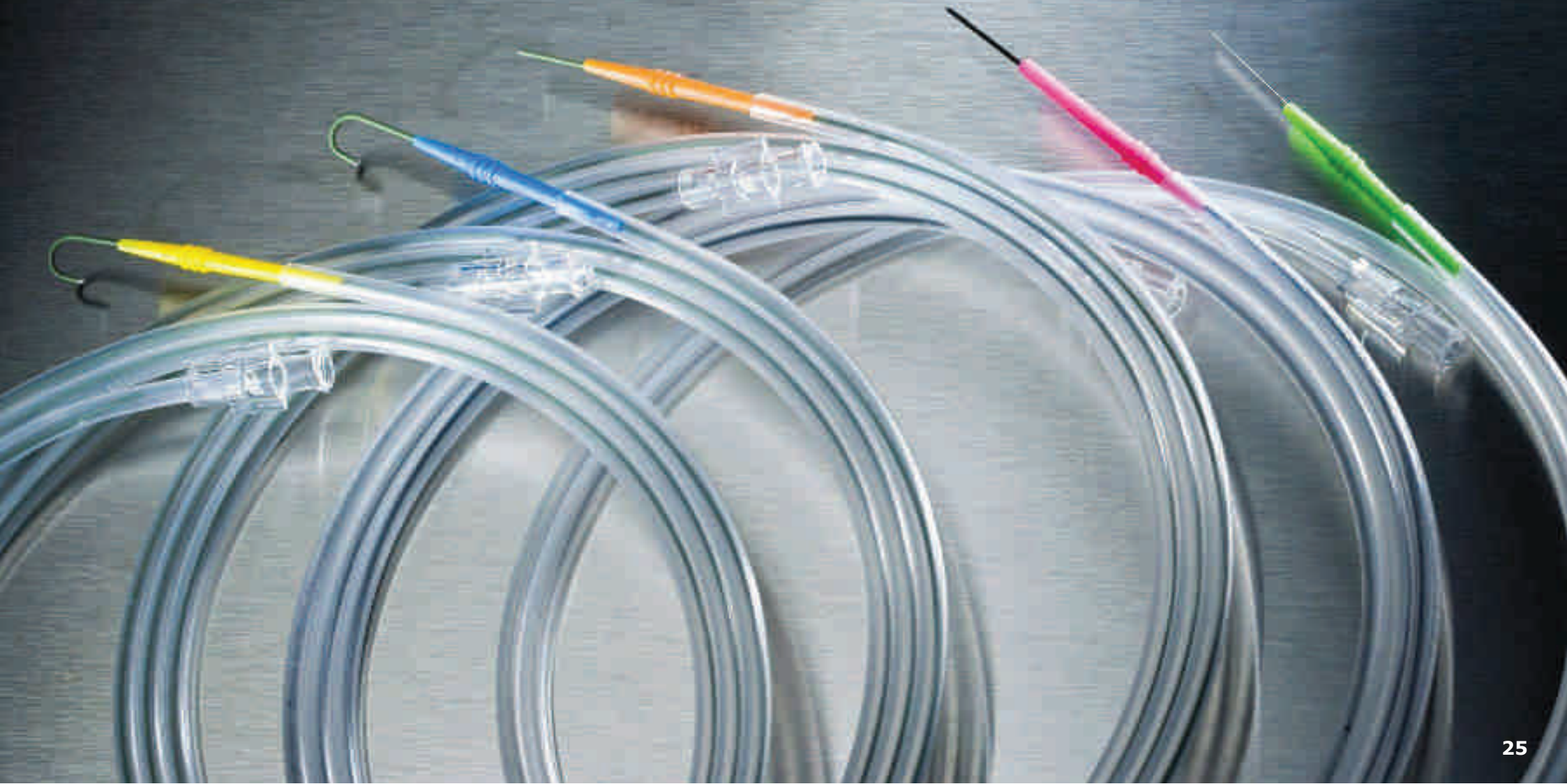
SP Medical A/S manufacture components, medical devices and single-use devices, and we apply function-enhancing coatings to a number of products.

We offer customized solutions, standardized products and own-brand products

Guide Wires

SP Medical develop and manufactures CE marked Guide Wires and packing components both as private label products and under our own brands. We are among the largest manufacturers in this field in Europe.

These products are aimed at medical fields such as angiography, cardiology, urology, radiology and with focus on minimally invasive procedures.



Coatings

SP Medical surface treats medical devices with performance improving coatings such as PTFE and hydrophilic coatings.

We can spray coat or dip coat parts with or without markings. Coatings of down to 3 μm may be applied to plastic and metal surfaces.

We also offer hard-coated, scratchproof surfaces and PVD coating of plastic surfaces, i.e. coating plastic with gold or other metals.

Typical coated devices include:

- Catheters
 - Canulla
 - Guide Wires
 - Cores
 - Spirals
 - Thread
 - Springs
 - Needles
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www.sp-medical.com

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