Global provider of medical devices, plastics solutions and pharmaceutical systems

Guide Wires
SP Medical develops, manufactures and provides plastics and surface solutions to the global medical devices and pharmaceutical industries. Our core capabilities are injection molding, surface treatment and processing of plastic products. At our state-of-the-art facilities in Denmark and Poland, we manufacture components, medical devices, single-use devices, and tablets with active pharmaceutical ingredients, and we apply function-enhancing coatings to a number of products.

SP Medical is a company in SP Group A/S, an international plastics group headquartered in Denmark. SP Group is listed on NASDAQ OMX Copenhagen.
Guide Wires and coating
SP Medical is a Danish company with more than 25 years' experience and know-how in the field of development, manufacturing and sales of guide wires for the medical industry. Over the past 40 years, we have built up our know-how of PTFE coated semi-products and medical devices for leading suppliers of for example guide wires on an OEM basis.

It is SP Medical's goal to offer customers a complete guide wire programme of high quality and, if required, of special features.

Vision
SP Medical develops, manufactures and distributes disposable items such as guide wires to the hospital sector focusing on minimally invasive procedures in the field of:
- Angiography use (PTA)
- Cardiology (PTCA)
- Urology use (PTC)
- Gastro-enterology use

Moreover SP Medical contributes to the manufacturing of other companies' medical devices, primarily by applying coating to improve functionality.

Policy
SP Medical's high quality product programme is currently being enlarged with customized special articles by means of structured product development of both process and machinery construction.

SP Medical's articles are manufactured in controlled hygienic environment by a trained staff. The manufacturing is performed with the greatest possible extend of automation to achieve both conform and good quality at competitive prices.

SP Medical's articles are sold and marketed either in bulk or single-packed as OEM articles to manufacturers of medical devices or sterile and single-packed for distribution through our international distributor's network.

Capabilities and core products

From design to distribution
SP Medical has more than 50 years of experience in working with plastics. Our 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.

Medical Devices
SP Medical manufactures medical devices using injection molding as its primary technology.

The company makes individual components, processes semi-manufactured plastic components and manufactures complete devices.

Guide Wires
SP Medical develops and manufactures CE marked guide wires and packing components both as private label products and under its own brand.

These products are aimed at medical fields such as angiography, cardiology, urology, radiology and with a 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 pieces with or without markings.
Global provider of medical devices, plastics solutions and pharmaceutical systems

Accoat™ Standard Guide Wire – Seldinger

Dimensions
Ø 0.018” / 0.46 mm
Ø 0.021” / 0.53 mm
Ø 0.025” / 0.63 mm
Ø 0.028” / 0.71 mm
Ø 0.032” / 0.81 mm
Ø 0.035” / 0.89 mm
Ø 0.038” / 0.96 mm

Length
30 – 450 cm

Surface
Stainless steel
PTFE coated

Distal tip form
Straight tip
J-tip radius: 1,5 – 3 – 6 – 15 mm

Distal flexible length
Standard 4.5 cm flexible tip

Shaft stiffness
Standard
Stiff
Customised

Mode of delivery
Sterile – CE marked
Bulk OEM

Customised products on request

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www.sp-medical.com
Accoat™ Standard Guide Wire – Double ended Seldinger

Dimensions
Ø 0.025” / 0.63 mm
Ø 0.032” / 0.81 mm
Ø 0.035” / 0.89 mm
Ø 0.038” / 0.96 mm

Length
30 – 450 cm

Surface
Stainless steel
PTFE coated

Tip form
J-tip radius: 1.5 – 3 – 6 – 15 mm in one end and straight tip in the other

Flexible tip length
Standard 5 cm flexible tip

Shaft stiffness
Standard
Stiff
Customised

Mode of delivery
Sterile – CE marked
Bulk OEM
Customised products on request

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Global provider of medical devices, plastics solutions and pharmaceutical systems

Accoat™ Standard Guide Wire – Movable

Dimensions
- Ø 0.032” / 0.81 mm
- Ø 0.035” / 0.89 mm
- Ø 0.038” / 0.96 mm

Length
- 30 – 450 cm

Surface
- Stainless steel
- PTFE coated

Distal tip form
- Straight tip
- J-tip radius: 1.5 – 3 – 6 – 15 mm

Shaft stiffness
- Standard
- Stiff
- Customised

Mode of delivery
- Sterile – CE marked
- Bulk OEM
- Customised products on request

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www.sp-medical.com
Accoat™ Standard Guide Wire – Lunderquist PTC

Dimensions
Ø 0.025” / 0.63 mm
Ø 0.035” / 0.89 mm

Length
50 cm
60 cm
70 cm
80 cm
90 cm
100 cm
120 cm
150 cm
260 cm

Surface
Stainless steel
PTFE coated

Distal tip form
Straight tip
J-tip radius: 1.5 – 3 – 6 – 15 mm

Distal flexible length
5 cm
7 cm
10 cm
12 cm
15 cm
17 cm

Mode of delivery
Sterile – CE marked
Bulk OEM

Customised products on request

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www.sp-medical.com
Accoat™ Standard Guide Wire – Schüller PTC

Dimensions
Ø 0.025” / 0.63 mm
Ø 0.035” / 0.89 mm

Length
50 cm
60 cm
70 cm
80 cm
90 cm
100 cm
110 cm
120 cm
150 cm
260 cm

Surface
Stainless steel
PTFE coated

Distal tip form
Straight tip
J-tip radius: 1.5 – 3 – 6 – 15 mm

Distal flexible length
5 cm
7 cm
10 cm
12 cm
15 cm
17 cm

Proximal flexible length
30 cm
33 cm
35 cm
38 cm
40 cm
43 cm
45 cm
50 cm
53 cm
55 cm
60 cm
63 cm
65 cm

Mode of delivery
Sterile – CE marked
Bulk OEM

Customised products on request

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www.sp-medical.com
Poseidon™ Hydrophilic Nitinol Guide Wire

Dimensions
Ø 0.018” / 0.46 mm
Ø 0.025” / 0.63 mm
Ø 0.032” / 0.81 mm
Ø 0.035” / 0.89 mm
Ø 0.038” / 0.96 mm

Length
30 – 260 cm

Surface
Hydrophilic coated - Black

Distal tip form
Angled
Straight
Reshapable

Shaft stiffness
Standard
Stiff

Tip stiffness
Standard
Soft
Floppy

Mode of delivery
Sterile – CE marked
Bulk OEM

Customised products on request

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Global provider of medical devices, plastics solutions and pharmaceutical systems

CHAMPION™ PTCA Guide Wire – For Cardiology use (CAR)

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Ø 0.014&quot; / 0,36 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length</td>
<td>175 cm</td>
</tr>
<tr>
<td></td>
<td>195 cm</td>
</tr>
<tr>
<td></td>
<td>300 cm</td>
</tr>
<tr>
<td>Distal tip form</td>
<td>Straight</td>
</tr>
<tr>
<td></td>
<td>J-tip</td>
</tr>
<tr>
<td>Stent zone stiffness</td>
<td>Standard</td>
</tr>
<tr>
<td></td>
<td>Stiff</td>
</tr>
<tr>
<td>Tip stiffness</td>
<td>Standard</td>
</tr>
<tr>
<td></td>
<td>Intermediate</td>
</tr>
<tr>
<td></td>
<td>Floppy</td>
</tr>
<tr>
<td></td>
<td>Extra Floppy</td>
</tr>
<tr>
<td>Radiopaque length</td>
<td>3 cm</td>
</tr>
<tr>
<td></td>
<td>30 cm</td>
</tr>
<tr>
<td>Coil surface</td>
<td>Uncoated – Stainless Steel</td>
</tr>
<tr>
<td></td>
<td>Hydrophilic coated</td>
</tr>
<tr>
<td></td>
<td>Silicone coated</td>
</tr>
<tr>
<td>Shaft surface</td>
<td>PTFE coated</td>
</tr>
<tr>
<td>Mode of delivery</td>
<td>Sterile – CE marked</td>
</tr>
<tr>
<td></td>
<td>Bulk OEM</td>
</tr>
</tbody>
</table>

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CHAMPION™ PTCA Guide Wire – Stiff tip for highly stenosed lesions (CTO)

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Stent zone stiffness</th>
<th>Coil surface</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ø 0.014” / 0.36 mm</td>
<td>Standard</td>
<td>Uncoated – Stainless Steel</td>
</tr>
<tr>
<td>Length</td>
<td>Tip stiffness (Gram Force)</td>
<td>Hydrophilic coated</td>
</tr>
<tr>
<td>195 cm</td>
<td>3,0gf</td>
<td></td>
</tr>
<tr>
<td>300 cm</td>
<td>4,5gf</td>
<td></td>
</tr>
<tr>
<td>Distal tip form</td>
<td>6,0gf</td>
<td></td>
</tr>
<tr>
<td>Straight</td>
<td>9,0gf</td>
<td></td>
</tr>
<tr>
<td>J-tip</td>
<td>12,0gf</td>
<td></td>
</tr>
<tr>
<td>Radiopaque length</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 cm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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Coating of Medical Devices and Components

SP Medical has developed a wide range of hydrophobic, hydrophilic and UV curable coatings for optimizing different product features.

Typical features are: Low friction, electrical insulation, chemical resistance, markers and scratch resistance.

The coatings are specially designed for devices and components as: Guide wires, needles, electrodes, tubes, coils, cores, displays etc.

Coatings can either be spray- or dip coated in the following colours:

- Blue
- Black
- Green
- Grey
- Transparent

A special feature as Masking or partial coating is available.

Mode of delivery
Bulk OEM

Customised products on request

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SP Medical has developed a very flexible programme of packing materials to supply optimal protection of Guide Wires and Catheters.

**Clipless Dispensers**
The new design – No Clip Penetration – ensures the highest level of sterility during transportation and storage.

- Suitable for Guide Wires from 40 – 200 cm
- Internal Dispenser diameter from 9 to 19 cm
- Standard tubing dimension is Ø 4,0 x 2,75 mm
- Tubing material is PP or PE

**Dispenser with clips**
- Suitable for Guide Wires of any length up to 450 cm
- Internal Dispenser diameter is 14,5 cm
- Standard tubing dimension is Ø 4,0 x 2,75 mm
- Tubing material is PP or PE

**Mode of delivery**
Bulk OEM

**Available packing components**
- J-Straightner in different colours
- Female Luerlock
- 2, 3 and 4 cavity clips
- Peel pouches
- Tip protector

**Customised products on request**
- Variable Dispenser shape
- Variable Dispenser diameter
- Variable tubing dimensions
- Variable tubing material and colour
Being a supplier of both components and complete solutions, we master a wide range of technologies.

**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 utilize multicomponent 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 also perform other work on components such as manual or fully automated assembly, welding, decoration, embossing, gluing and chip cutting.

Our metal processing technologies include chip cutting and chipless processing for purposes such as production of guide wires, complete and ground needles, and cannulas.

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

### Quality and Regulatory

SP Medical’s management system takes into account all the demands on and expectations faced by providers to the global medical devices and pharmaceuticals 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 are authorized to manufacture medicinal products under Eudralex Directive 2003/94/EC.
- We are an FDA-registered contract manufacturer.
- We comply with FDA Part 820 (QSR).
- We have MSA accreditation.
- We build and maintain our cleanroom environments in accordance with ISO 14644 and ISO 14698.

### Quality Activity Plan

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

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 Design History File (DHF), Device Master Record (DMR) and Device History Record (DHR).