

Global provider of medical devices,
plastics solutions and pharmaceutical systems



Guide Wires

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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 radiology, urology, gastro and cardiology.

At our state-of-the-art facilities in Denmark and Poland, we manufacture components, medical

devices, single-use devices, 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.

A Brief Guide Wire Introduction

Guide Wires and coating

SP Medical is a Danish company with more than 30 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.

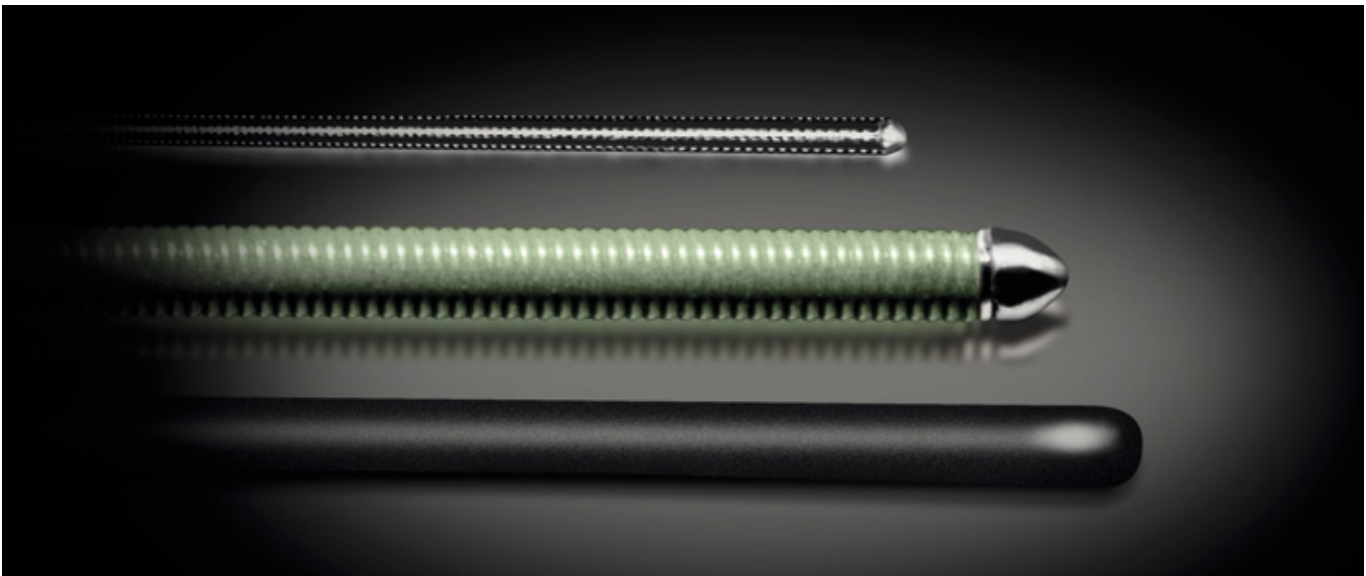
SP Medical's articles are manufactured in controlled hygienic environment by a trained staff. The manufacturing is performed

with the greatest possible extend of automation to achieve both conform and good quality at competitive prices.

SP Medical A/S develops and manufactures own branded CE marked Guide Wires as well as OEM and private label products.

The articles are sold and marketed either to manufacturers of medical devices or through our international distributor's network.

Core products and features



Champion™ PTCA Guide Wire:

- Platinum Tip for excellent radiopacity.
- One core construction with superior torque ability.
- PTFE coated shaft for smooth surface.
- Various tip coatings for reduced friction.
- For both Cardiology and CTO.

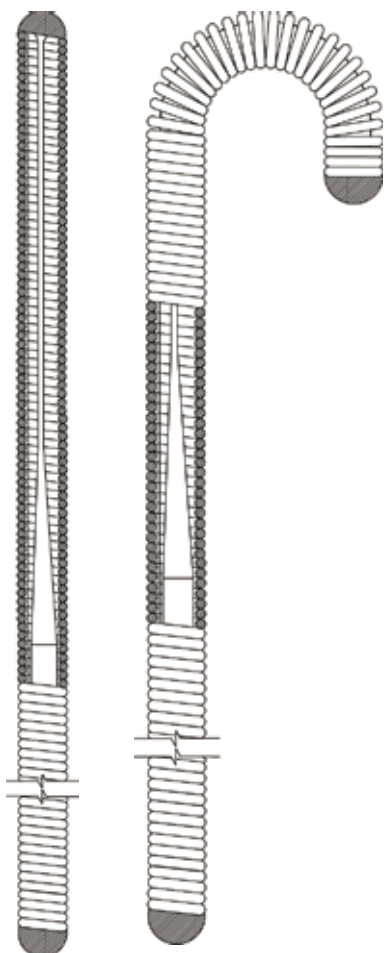
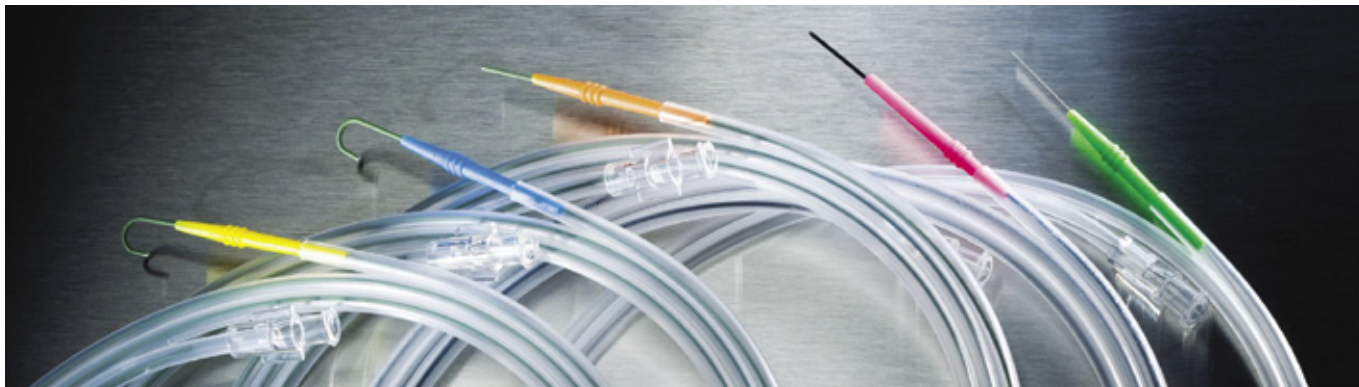
Accoat™ Guide Wire:

- Complete and functional coating from distal to proximal end.
- Polished and 100% inspected in both ends.
- No possibility for drainage of blood due to special coating method.
- Smooth surface due to homogeneous coating.

Poseidon™ Hydrophilic Nitinol Guide Wire:

- Excellent radiopacity.
- Reduced friction due to superior hydrophilic surface features.
- Different tip flexibilities.
- Kink-resistant nitinol core.

Accoat™ 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

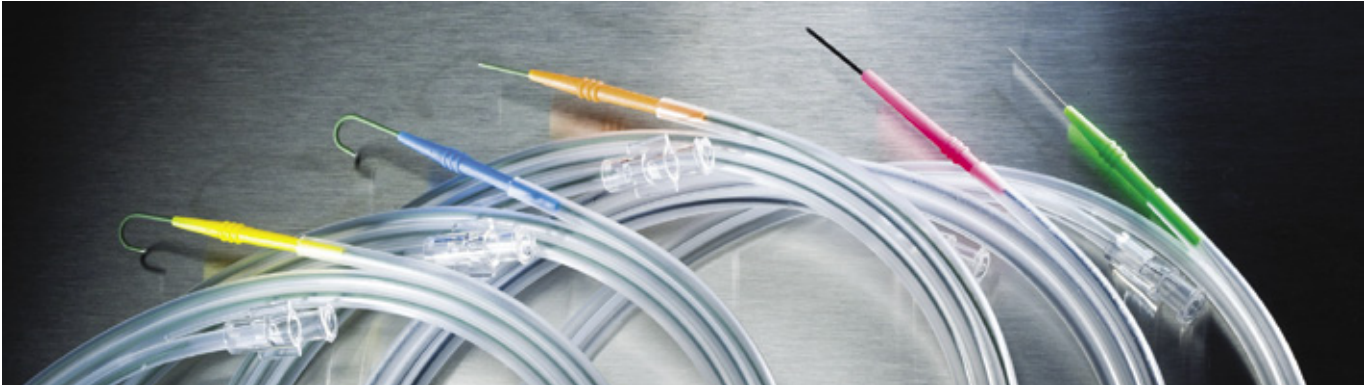
Customised products on request

**Description of item code for
Seldinger guide wires**

(H/X/X)-S/Jx-(C)-0xx-L
(example: J3-C-035-150)

H	Stiff Guide Wire
H-X	Extra Stiff Guide Wire
H-X-X	Super Stiff Guide Wire
S	Straight tip
Jx	J-tip radius J1.5 mm J3 mm J6 mm J15 mm
C	PTFE coated
Without C	stainless steel
0xx:	Diameter of the guide wire 0.018" (0,46 mm) 0.021" (0,53 mm) 0.025" (0,63 mm) 0.028" (0,71 mm) 0.032" (0,81 mm) 0.035" (0,89 mm) 0.038" (0,96 mm)
L:	Length of the guide wire (from 30 – 450 cm)

Accoat™ 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

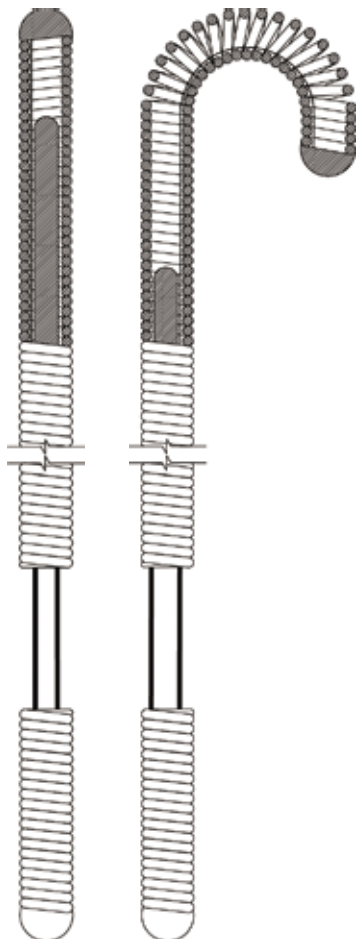
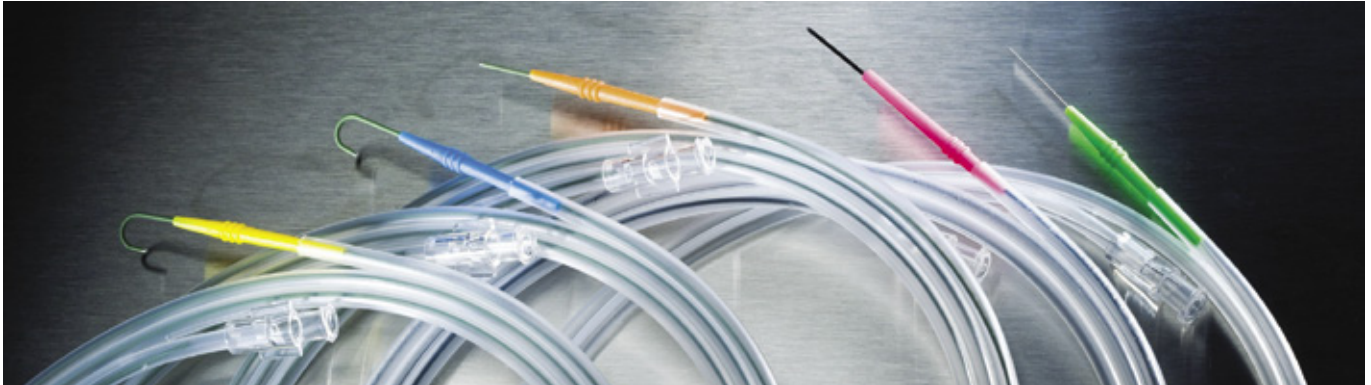
Customised products on request

**Description of item code for
Double-ended Seldinger guide wires**

D-S-Jx-(C)-0xx-L
(example: D-S-J3-C-035-150)

D	Double ended (flexible tip in both ends)
S	Straight tip (one end)
Jx	J-tip radius (the other end) J1.5 mm J3 mm J6 mm J15 mm
C	PTFE coated
Without C	stainless steel
0xx:	Diameter of the guide wire 0.025" (0,63 mm) 0.032" (0,81 mm) 0.035" (0,89 mm) 0.038" (0,96 mm)
L:	Length of the guide wire (from 30 – 450 cm)

Accoat™ 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

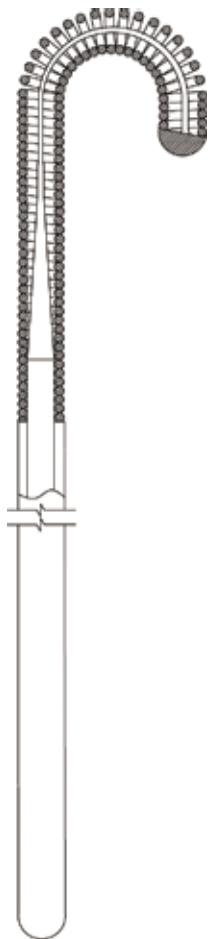
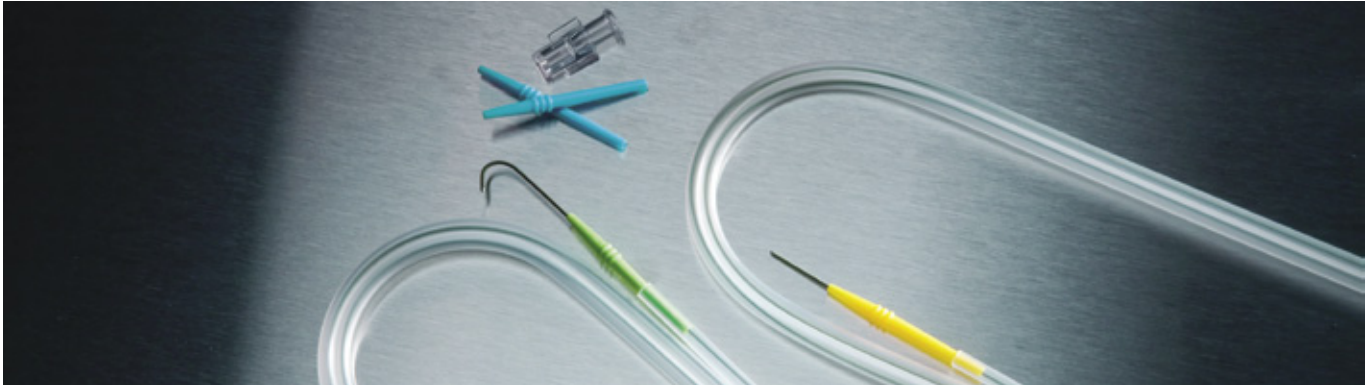
Customised products on request

**Description of item code for
Movable guide wires**

(H)-M-(X)-S/Jx-(C)-0xx-L
(example: M-S-C-035-150)

M	Movable Guide Wire
H-M	Stiff Movable Guide Wire
H-M-X	Extra Stiff Movable Guide Wire
S	Straight tip
Jx	J-tip radius J1.5 mm J3 mm J6 mm J15 mm
C	PTFE coated
Without C	stainless steel
0xx:	Diameter of the guide wire 0.032" (0,81 mm) 0.035" (0,89 mm) 0.038" (0,96 mm)
L:	Length of the guide wire (from 30 – 450 cm)

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 mm

Distal flexible length

- 5 cm
- 7 cm
- 10 cm
- 12 cm
- 15 cm
- 17 cm

Customised products on request

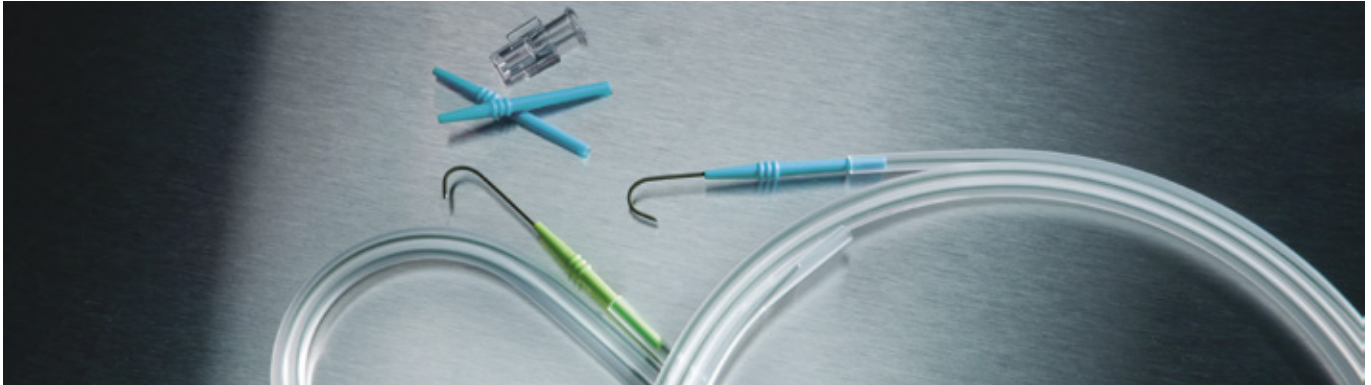
Description of item code for Lunderquist PTC guide wires

PTC-S/Jx-C-Fx-0xx-L

(example: PTC-S-C-F5-035-150)

S	Straight tip
Jx	J-tip radius J1,5 mm tip J3 mm tip J6 mm tip
C	PTFE coated
Without C	stainless steel
Fx	Distal Flexible length F5 - 5 cm flexible tip F7 - 7 cm flexible tip F10 - 10 cm flexible tip F12 - 12 cm flexible tip F15 - 15 cm flexible tip F17 - 17 cm flexible tip
0xx:	Diameter of the guide wire 0.025" (0,63 mm) 0.035" (0,89 mm)
L:	Length of the guide wire 50, 60, 70, 80, 90, 100, 120, 150 and 260 cm

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 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

Customised products on request

Description of item code for Schüller PTC guide wires

PTC-SCH-S/Jx-C-Fx-yy-zz-0xx-L

(example: PTC-SCH-S-F5-40-55-035-100)

S	Straight tip
Jx	J-tip radius J1,5 mm tip J3 mm tip J6 mm tip
C	PTFE coated
Without C	stainless steel
Fx	Distal Flexible length x = cm ex. F5 = 5 cm Available in 5, 7, 10, 12, 15 or 17 cm
yy	Shaft length - cm
zz	Proximal Flexible length - cm Available in 30, 33, 35, 38, 40, 43, 45, 50, 53, 55, 60, 63 or 65 cm
0xx:	Diameter of the guide wire 0.025" (0,63 mm) 0.035" (0,89 mm)
L:	Length of the guide wire (Sum of Fx+yy+zz) Available in 50, 60, 70, 80, 90, 100, 110, 120, 150 or 260 cm

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

Special product with double ended flexible tip

One end angled standard tip, other end straight soft tip. Stiff shaft stiffness. Available in two lengths: 150 and 180 cm.

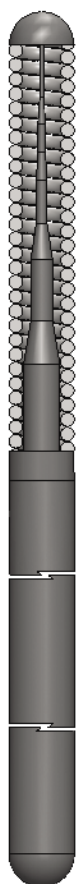
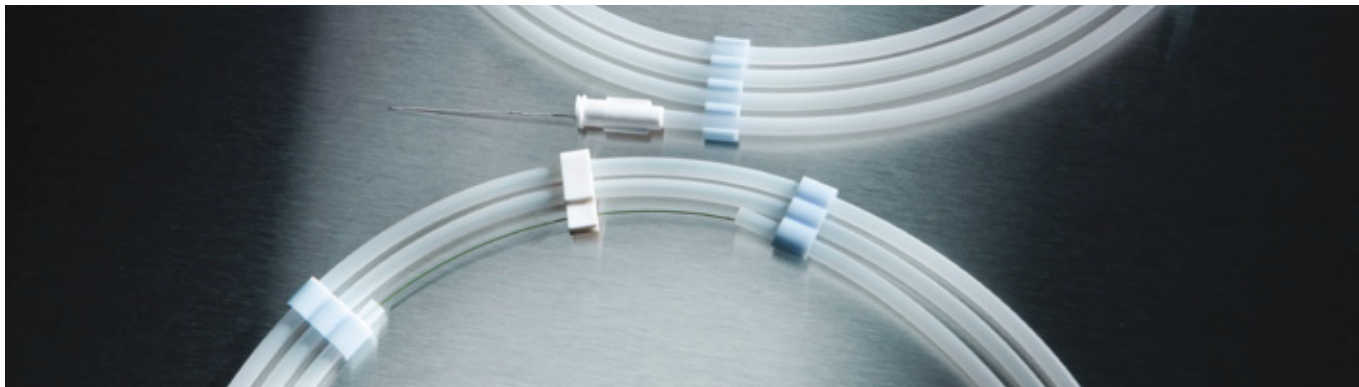
Customised products on request

Description of item code for Hydrophilic guide wires

Hy – N – S/R/A – ST/SO/F – 0xx – D/H – L
(example: Hy-N-A-ST-035-D-150)

HY	Hydrophilic coating
N	Nitinol core
S	Straight tip
A	Angled tip
R	Reshapable tip
ST	Standard tip stiffness
SO	Soft tip stiffness
F	Floppy tip stiffness
0xx	Diameter of the guide wire 0.018" (0,46 mm) 0.025" (0,63 mm) 0.032" (0,81 mm) 0.035" (0,89 mm) 0.038" (0,96 mm)
H	Stiff shaft
D	Standard shaft
L	Length of the GW (from 30 – 260 cm)

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



Dimension
Ø 0.014" / 0,36 mm

Length
175 cm
195 cm
300 cm

Distal tip form
Straight
J-tip

Stent zone stiffness
Standard
Stiff

Tip stiffness
Standard
Intermediate
Floppy
Extra Floppy

Radiopaque length
3 cm

Coil surface
Uncoated – Stainless Steel
Hydrophilic coated
Silicone coated

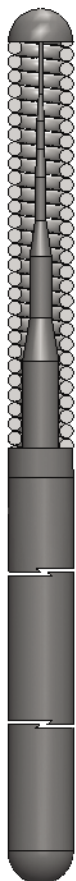
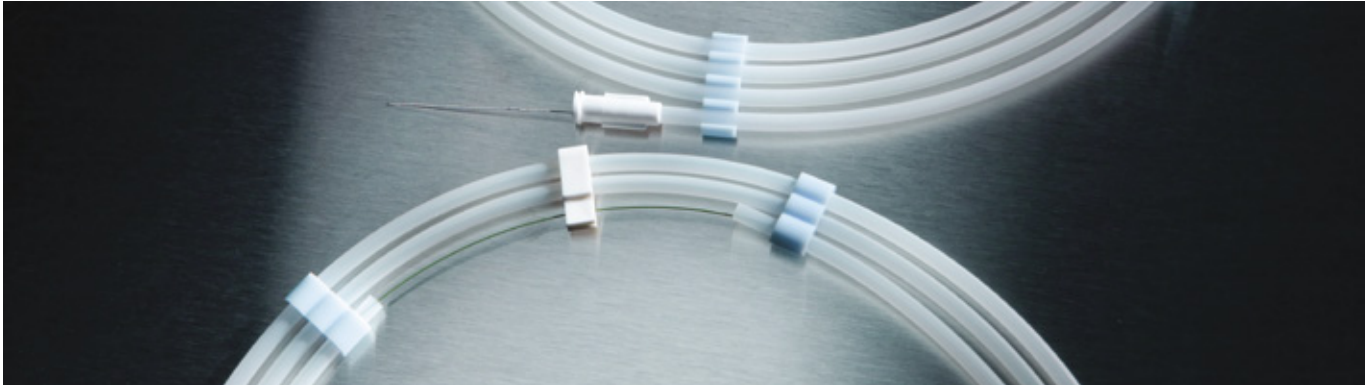
Shaft surface
PTFE coated

Description of item code for PTCA guide wires (CAR)

PTCA-CAR-S/J-M/HY/SI-EF/F/I/ST-D/H-014-L
(example: PTCA-CAR-S-HY-F-D-014-175)

CAR	For cardiology use
S	Straight tip
J	J-tip
M	Coil surface uncoated – stainless steel
HY	Coil surface hydrophilic
SI	Coil surface silicone
EF	Tip stiffness extra floppy
F	Tip stiffness floppy
I	Tip stiffness intermediate
ST	Tip stiffness standard
D	Stent zone stiffness standard
H	Stent zone stiffness stiff
014:	Diameter of the guide wire 0.014" (0,36 mm)
L:	Length of the guide wire Available in 175, 195, 300 cm

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



Dimension

Ø 0.014" / 0,36 mm

Length

195 cm
300 cm

Distal tip form

Straight
J-tip

Stent zone stiffness

Standard

Tip stiffness (Gram Force)

3,0gf
4,5gf
6,0gf
9,0gf
12,0gf

Radiopaque length

3 cm

Coil surface

Uncoated – Stainless Steel
Hydrophilic coated

Shaft surface

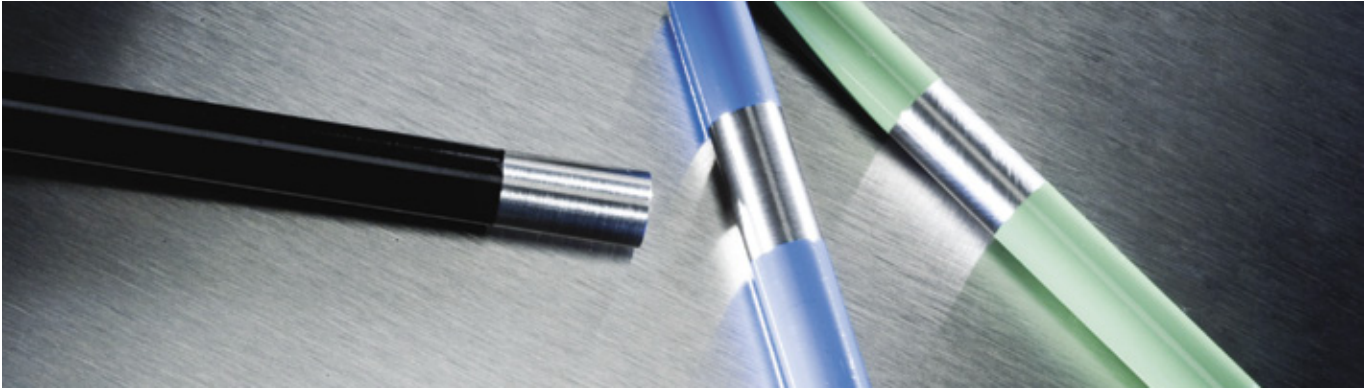
PTFE coated

**Description of item code for
PTCA guide wires (CTO)**

PTCA-CTO-S/J-M/HY-3/4,5/6/9/12-D-014-L
(example: PTCA-CTO-S-HY-3-D-014-175)

CTO	For highly stenosed lesions
S	Straight tip
J	J-tip
M	Coil surface uncoated – stainless steel
HY	Coil surface hydrophilic
3	Tip stiffness 3 Gram Force
4,5	Tip stiffness 4,5 Gram Force
6	Tip stiffness 6 Gram Force
9	Tip stiffness 9 Gram Force
12	Tip stiffness 12 Gram Force
D	Stent zone stiffness standard
014:	Diameter of the guide wire 0.014" (0,36 mm)
L:	Length of the guide wire Available in 195, 300 cm

Coating of Medical Devices and Components



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

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

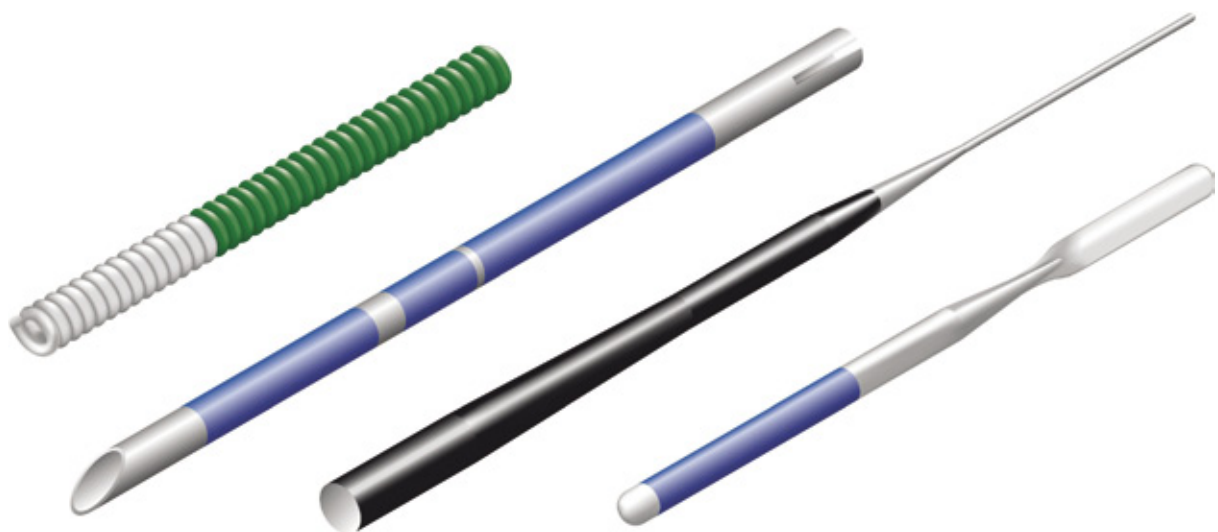
The coatings are specially designed for devices and components as: Guide wires, needles, electrodes, tubes, coils, cores, displays etc.

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

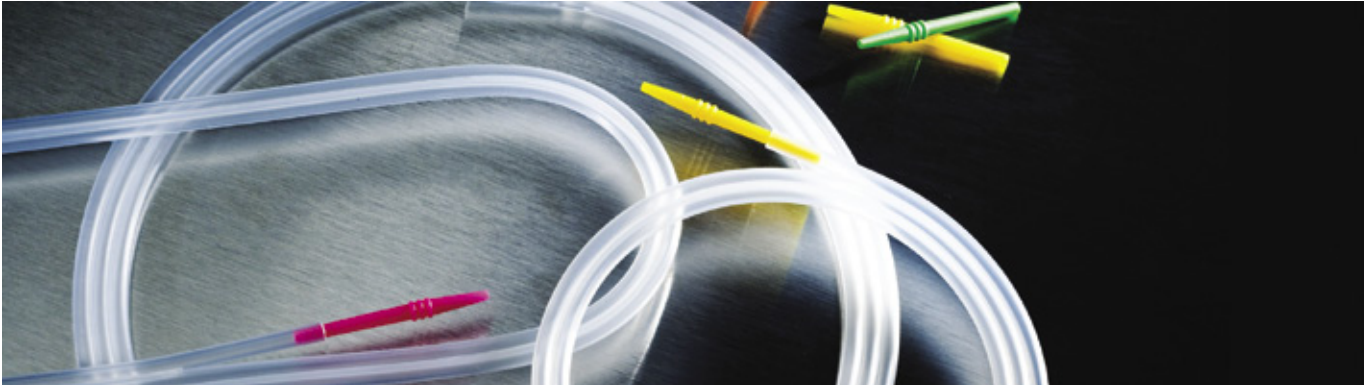
- Blue
- Black
- Green
- Grey
- Transparent

A special feature as Masking or partial coating is available.

Customised products on request



Accessories and packing material



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

Customised products on request

- Variable Dispenser shape
- Variable Dispenser diameter
- Variable tubing dimensions
- Variable tubing material and colour

Available packing components

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

Quality and Regulatory Affairs

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 an FDA-registered contract manufacturer.
- We comply with FDA Part 820 (QSR).
- We comply with the Global Harmonization Task Force Guidelines.
- We have MSA accreditation.
- We build and maintain our cleanroom environments in accordance with ISO 14644 and ISO 14698.

Quality Activity Plan

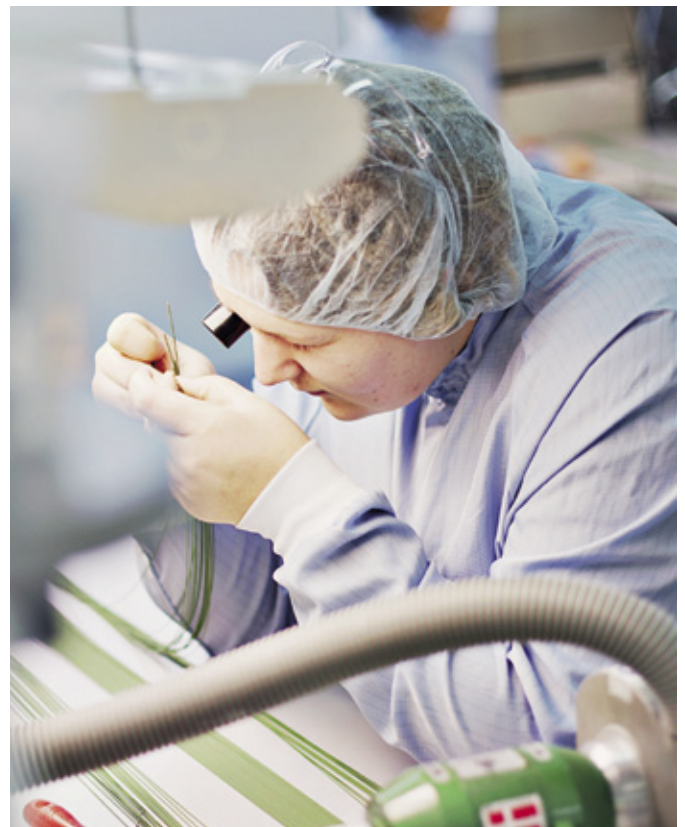
Our project management model includes a Quality Activity Plan (QAP) that defines requirements for the relevant product.

Our QAP complies with the requirements set out in EU-GMP/ GDP/GTP, 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).

Other Capabilities

For information about our other capabilities and 50 years of experience within injection moulding and plastics please check our website www.sp-medical.dk.



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