

# Guide Wires



- 3 A Brief Guide Wire Introduction
- 4 Accoat™ Guide Wire Seldinger
- 5 Accoat™ Guide Wire Double ended Seldinger
- 6 Accoat™ Guide Wire Movable
- 7 Accoat™ Standard Guide Wire Lunderquist PTC
- 8 Accoat™ Standard Guide Wire Schüller PTC
- 9 Poseidon™ Hydrophilic Nitinol Guide Wire
- 10 CHAMPION™ PTCA Guide Wire For Cardiology use (CAR)
- 11 CHAMPION™ PTCA Guide Wire Stiff tip for highly stenosed lesions (CTO)
- 12 Coating of Medical Devices and Components
- 13 Accessories and packing material
- 14 Quality and Regulatory Affairs

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 functionenhancing 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 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:

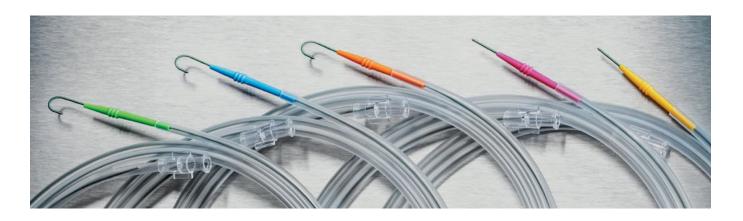
- Complete and functional coating from distal to proximal end.
- Polished and 100% inspected in both ends.
- No possibility for drainage of blood due to special coating method.
- Smooth surface due to homogeneous coating.

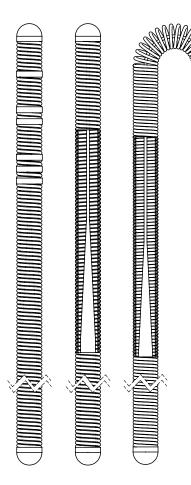
#### Poseidon™ Hydrophilic Nitinol Guide Wire:

- 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 with or without markers 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

Extra stiff

Super stiff

(Exstra stiff & Super stiff not available in dim: 0.018"; 0.021"; 0.025")

#### Markers

Uncoated stainless steel Length 30-150 cm 1 mm wide surface markers 10 cm step

#### **Customised products on request**

### Description of item code

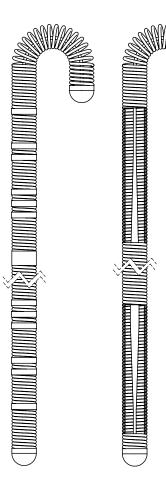
(H/X/X)-S/Jx-(C)-0xx-L(example: J3-C-035-150)

Н	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
M	Surface marker
0xx:	Diameter of the guide wire
	<b>018:</b> 0.018" (0,46 mm)
	<b>021:</b> 0.021" (0,53 mm)
	<b>025:</b> 0.025" (0,63 mm)
	<b>028:</b> 0.028" (0,71 mm)
	<b>032:</b> 0.032" (0,81 mm)
	<b>035:</b> 0.035" (0,89 mm)
	<b>038:</b> 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 with or without markers 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

#### Markers

Uncoated stainless steel Length 30-150 cm 1 mm wide surface markers 10 cm step

#### **Customised products on request**

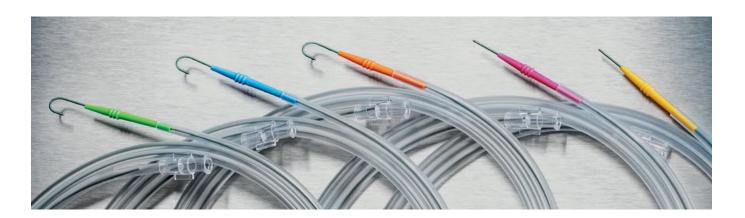
#### Description of item code

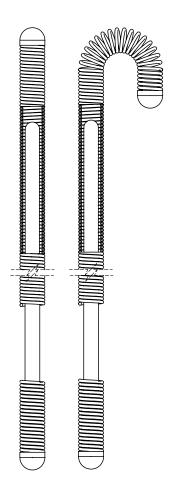
(H)-D-S-Jx-(C)-0xx-L(example: D-S-J3-C-035-150)

Н	Stiff Guide Wire
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
С	PTFE coated
Without C	stainless steel
M	Surface marker
0xx:	Diameter of the guide wire <b>025:</b> 0.025" (0,63 mm) <b>032:</b> 0.032" (0,81 mm) <b>035:</b> 0.035" (0,89 mm) <b>038:</b> 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

50 - 260 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 products on request** 

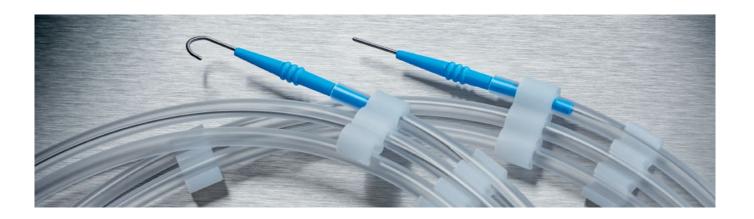
# Description of item code

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

M	Movable Guide Wire
H-M	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 032: 0.032" (0,81 mm) 035: 0.035" (0,89 mm) 038: 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

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
С	PTFE coated
Without C	stainless steel
Fx	Distal Flexible ler
	F5 - 5 cm flexible

0xx:

Ŀ

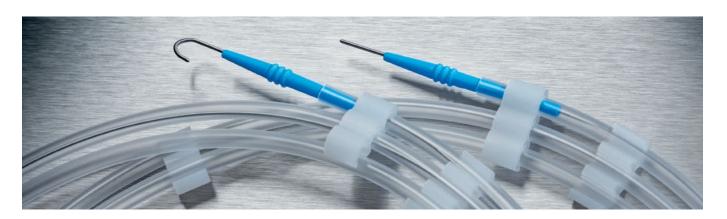
e tip F7 - 7 cm flexible tip F10 - 10 cm flexible tip F12 - 12 cm flexible tip F15 - 15 cm flexible tip F17 - 17 cm flexible tip

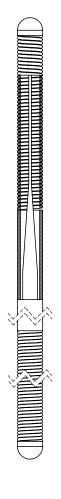
> Diameter of the guide wire **025:** 0.025" (0,63 mm) **035:** 0.035" (0,89 mm)

Length of the guide wire 50, 60, 70, 80, 90, 100, 120, 150 and 260 cm



# Accoat™ Standard Guide Wire – Schüller PTC





Dimensions	Distal flexible length
Ø 0.025" / 0,63 mm	5 cm
Ø 0.035" / 0,89 mm	7 cm
	10 cm
Length	12 cm
50 cm	15 cm
60 cm	17 cm
70 cm	
80 cm	Proximal flexible
90 cm	length
100 cm	30 cm
110 cm	33 cm
120 cm	35 cm
150 cm	38 cm
260 cm	40 cm
	43 cm
Surface	45 cm
Stainless steel	50 cm
PTFE coated	53 cm
	55 cm
Distal tip form	60 cm
Straight tip	63 cm
J-tip radius:	65 cm
1,5 – 3 – 6 mm	

**Customised products on request** 

S	Straight tip
Jx	J-tip radius J1,5 mm tip J3 mm tip J6 mm tip
С	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
уу	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 <b>025:</b> 0.025" (0,63 mm) <b>035:</b> 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 (Stiff not available in dim: 0.018")

#### **Tip stiffness**

Standard Soft Floppy

#### Speciality Guide Wire:

#### Double Ended Flexible Tip

One end angled standard tip, other end straight soft tip. Stiff shaft stiffness. Available in 150 & 180 cm.

#### **Customised products on request**

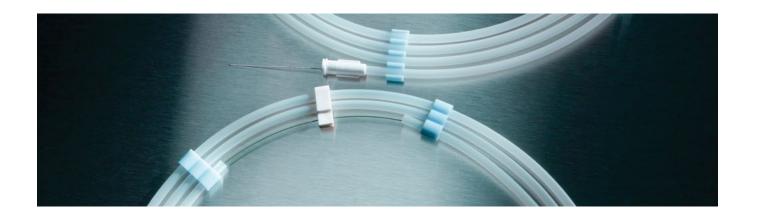
#### Description of item code

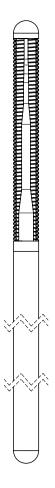
Hy - N - S/R/A - ST/SO/F - 0xx - D/H - L(example: Hy-N-A-ST-035-D-150)

DE	Double ended
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
0хх	Diameter of the guide wire 018: 0.018" (0,46 mm) 025: 0.025" (0,63 mm) 032: 0.032" (0,81 mm) 035: 0.035" (0,89 mm) 038: 0.038" (0,96 mm)
Н	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

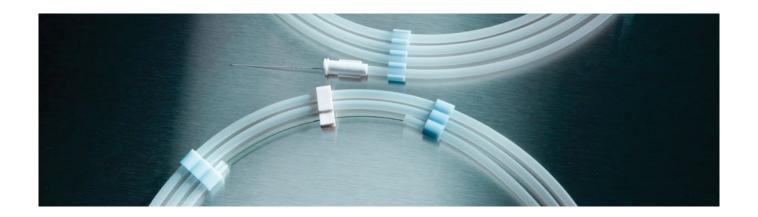
#### **Description of item code**

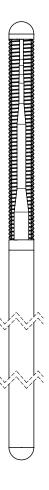
PTCA-CAR-S/J-M/HY/SI-EF/F/I/ST-D/H-014-L (example: PTCA-CAR-S-HY-F-D-014-175)

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
ı	Tip stiffness intermediate
ST	Tip stiffness standard
D	Stent zone stiffness standard
Н	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**

Hydrophilic coated Silicone coated

#### **Shaft surface**

PTFE coated

#### Description of item code

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

СТО	For highly stenosed lesions
S	Straight tip
J	J-tip
HY	Coil surface hydrophilic
SI	Coil surface silicone
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 and hydrophilic coatings for optimizing of different product features.

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

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



#### 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 with protection grid
- 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 device industry:

- 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 the Global Harmonization Task Force Guidelines.
- We build and maintain our cleanroom environments in accordance with ISO 14644 and ISO 14698.







Møllevej 1 DK-4653 Karise Denmark

Tel.: (+45) 5676-6000 Fax: (+45) 5676-6001 E-mail: gw@sp-medical.com www.sp-medical.com