

Regulatory Information October 2024-GW

Accoat Guide Wire Accoat Standard Guide Wire Poseidon Hydrophilic Nitinol Guide Wire Poseidon URO Guide Wire Champion PTCA Guide Wire

Instructions for Use and label revision

The Instructions for Use (IFU) and label layouts for SP Medical's five guide wire brands have been revised.

The Instructions for Use are implemented successively. Both the new version of Instructions for Use and the earlier versions are available for download from SP Medical's website from Q4 2024. The label layouts are implemented in Q4 2024.

Main changes to Instructions for Use:

- Chinese and Russian languages removed.
- Linguistic adjustments.
- Content revised to achieve a more uniform expression of SP Medical's guide wire IFUs without compromising the differences between the product families.

Main changes to label layouts:

- All label layouts: Adjustment of font sizes and positions.
- Product box label layouts:
 - The symbol 5.2.13* (Single sterile barrier system with protective packaging inside) is replaced with 5.2.14* (Single sterile barrier system with protective packaging outside) to better illustrate the relationship between package and sterile entity.
 - Symbol 5.6.3* (Non-pyrogenic) is removed from the product box label because it is not relevant here.
- Shipping box label layout:
 - the symbol 5.2.13* (Single sterile barrier system with protective packaging inside) is replaced with symbol 5.2.3 (Sterilized using ethylene oxide).
 - Symbol 5.7.10* (Unique Device Identifier) and data matrix is added.

*) Symbols from ISO 15223-1, Fourth edition 2021-07

Label layout examples:

Page 2: Accoat Guide Wire
Page 3: Accoat Standard Guide Wire
Page 4: Poseidon Hydrophilic Nitinol Guide Wire
Page 5: Poseidon URO Guide Wire
Page 6: Champion PTCA Guide Wire

Acccoat Guide Wire

Seldinger Guide Wire
Straight tip, PTFE coated

150 cm
0.035" (0.89 mm)

REF S-C-035-150
LOT 11111
2024-09
2029-08
MD **CE**
UDI 0197

STERILE EO

49°C 70
2°C 30

SP Medical
SP Medical A/S
Møllevvej 1
DK-4653 Karise
Tel: +45 56 76 60 00
www.sp-medical.com

GWAC-LS-P1-S.V03

Acccoat guide Wire

Seldinger Guide Wire
Straight tip, PTFE coated

150 cm
0.035" (0.89 mm)

REF S-C-035-150
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DK-4653 Karise
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www.sp-medical.com

Standard shaft

10

GWAC-LS-P2-S1a.V03

Seldinger Guide Wire
Straight tip, PTFE coated

150 cm
0.035" (0.89 mm)

LOT 11111
2029-08
REF S-C-035-150

Acccoat Guide Wire

Seldinger Guide Wire
Straight tip, PTFE coated

150 cm
0.035" (0.89 mm)

REF S-C-035-150
LOT 11111
2024-09
2029-08
MD **CE**
UDI 0197

STERILE EO

49°C 70
2°C 30

SP Medical
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Møllevvej 1
DK-4653 Karise
Tel: +45 56 76 60 00
www.sp-medical.com

100 Pcs.

Standard shaft

10

GWAC-LS-P3.V03

Accoat Standard

PTC-Schüller Guide Wire
10 cm distal J1,5 mm tip, PTFE coated

260 cm
0.035" (0.89 mm)

REF PTC-SCH-J1.5-C-F10-220-30-035-260
LOT 44444
2024-09
2029-08
MD **CE**
UDI 0197

SP Medical
SP Medical A/S
Møllevvej 1
DK-4653 Karise
Tel: +45 56 76 60 00
www.sp-medical.com

(01)05710086049743(17)290831(10)44444

GWAS-LS-P1-J.V02

Accoat Standard

PTC-Schüller Guide Wire
10 cm distal J1,5 mm tip, PTFE coated

260 cm
0.035" (0.89 mm)

REF PTC-SCH-J1.5-C-F10-220-30-035-260
LOT 44444
2024-09
2029-08
MD **CE**
UDI 0197

SP Medical
SP Medical A/S
Møllevvej 1
DK-4653 Karise
Tel: +45 56 76 60 00
www.sp-medical.com

SP Medical

(01)45710086049741(17)290831(10)44444

PTC-Schüller Guide Wire
10 cm distal J1,5 mm tip, PTFE coated

260 cm
0.035" (0.89 mm)

LOT 44444
2029-08
REF PTC-SCH-J1.5-C-F10-220-30-035-260

SP Medical

GWAS-LS-P2.V02

Accoat Standard

PTC-Schüller Guide Wire
10 cm distal J1,5 mm tip, PTFE coated

260 cm
0.035" (0.89 mm)

REF PTC-SCH-J1.5-C-F10-220-30-035-260
LOT 44444
2024-09
2029-08
MD **CE**
UDI 0197

SP Medical
SP Medical A/S
Møllevvej 1
DK-4653 Karise
Tel: +45 56 76 60 00
www.sp-medical.com

100 Pcs.

STERILEEO

SP Medical
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(01)65710086049745(17)290831(10)44444

GWAS-LS-P3.V03

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Poseidon
Hydrophilic Nitinol Guide Wire
Reshapable standard tip, standard shaft

150 cm
0.038" (0.97 mm)

REF HY-N-R-ST-038-D-150
LOT 66666
2024-09
2027-08
MD **CE**
UDI 0197

Reshapable

STERILEEO

49°C 70
2°C 30

SP Medical
SP Medical A/S
Møllevvej 1
DK-4653 Karise
Tel: +45 56 76 60 00
www.sp-medical.com

GWPO-LS-P1-R.v03

(01)05710086043062(17)270831(10)66666

Poseidon
Hydrophilic Nitinol Guide Wire
Reshapable standard tip, standard shaft

150 cm
0.038" (0.97 mm)

REF HY-N-R-ST-038-D-150
LOT 66666
2024-09
2027-08
MD **CE**
UDI 0197

Standard shaft

STERILEEO

49°C 70
2°C 30

SP Medical
SP Medical A/S
Møllevvej 1
DK-4653 Karise
Tel: +45 56 76 60 00
www.sp-medical.com

Standard shaft

SP Medical

Hydrophilic Nitinol Guide Wire
Reshapable standard tip, standard shaft

150 cm 0.038" (0.97 mm)

LOT 66666
REF HY-N-R-ST-038-D-150

2027-08

GWPOL-SP2-S1a.v03

(01)45710086043060(17)270831(10)66666

Poseidon
Hydrophilic Nitinol Guide Wire
Reshapable standard tip, standard shaft

150 cm
0.038" (0.97 mm)

REF HY-N-R-ST-038-D-150
LOT 66666
2024-09
2027-08
MD **CE**
UDI 0197

MD

STERILEEO

49°C 70
2°C 30

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Møllevvej 1
DK-4653 Karise
Tel: +45 56 76 60 00
www.sp-medical.com

100 Pcs.

SP Medical

Hydrophilic Nitinol Guide Wire
Reshapable standard tip, standard shaft

150 cm 0.038" (0.97 mm)

LOT 66666
REF HY-N-R-ST-038-D-150

2027-08

GWPO-LS-P3.v02

(01)65710086043064(17)270831(10)66666

Poseidon URO

Guide Wire
Reshapable standard tip, standard shaft

150 cm
0.035" (0.89 mm)

REF URO-HY-N-R-ST-035-D-150
LOT 10000

2024-09
2027-08

MD
UDI 0197

(01)05710086041877(17)270831(10)10000

Reshapable

1

SP Medical
SP Medical A/S
Møllevvej 1
DK-4653 Karise
Tel: +45 56 76 60 00
www.sp-medical.com

GMPULS-P1-R.V02

Poseidon URO

Guide Wire
Reshapable standard tip, standard shaft

150 cm
0.035" (0.89 mm)

REF URO-HY-N-R-ST-035-D-150
LOT 10000

2024-09
2027-08

MD
UDI 0197

(01)45710086041875(17)270831(10)10000

Standard shaft

5

SP Medical
SP Medical A/S
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DK-4653 Karise
Tel: +45 56 76 60 00
www.sp-medical.com

SP Medical

GMPULS-P2-Statv02

Guide Wire
Reshapable standard tip, standard shaft

150 cm
0.035" (0.89 mm)

LOT 10000
REF URO-HY-N-R-ST-035-D-150

2027-08

5

Poseidon URO

Guide Wire

Reshapable standard tip, standard shaft

150 cm
0.035" (0.89 mm)

REF URO-HY-N-R-ST-035-D-150
LOT 10000

2024-09
2027-08

MD
UDI 0197

(01)65710086041879(17)270831(10)10000

Standard shaft

100 Pcs.

STERILEEO

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GMPULS-F3-V02

Champion

PTCA Guide Wire
CAR, J tip, floppy

195 cm

Hydrophilic PTFE

3 cm radiopaque 0.014" (0.36mm)

REF PTCA-CAR-J-HY-F-D-014-195

LOT 14000

2024-09

2028-08

MD

UDI 0197

(01)05710086046780(17)280831(10)14000

SP Medical
Champion
(01)05710086046780(17)280831(10)14000

SP Medical
Champion
(01)05710086046780(17)280831(10)14000

SP Medical
Champion
(01)05710086046780(17)280831(10)14000

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DK-4653 Karise
Tel: +45 56 76 60 00
www.sp-medical.com

GWC2, LB, PT, J, V2

Champion

PTCA Guide Wire
CAR, J tip, floppy

195 cm

Hydrophilic PTFE

3 cm radiopaque 0.014" (0.36mm)

REF PTCA-CAR-J-HY-F-D-014-195

LOT 14000

2024-09

2028-08

MD

UDI 0197

(01)45710086046788(17)280831(10)14000

SP Medical
Champion
(01)45710086046788(17)280831(10)14000

SP Medical
Champion
(01)45710086046788(17)280831(10)14000

SP Medical
Champion
(01)45710086046788(17)280831(10)14000

SP Medical
SP Medical A/S, Møllevvej 1, DK-4653 Karise
Tel: +45 56 76 60 00, www.sp-medical.com

SP Medical

LOT 14000

2024-09

2028-08

REF PTCA-CAR-J-HY-F-D-014-195

PTCA Guide Wire
CAR, J tip, floppy

195 cm

Hydrophilic PTFE

3 cm radiopaque 0.014" (0.36mm)

MD

STERILEEO

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GWC2, LB, PT, J, V2

Champion

PTCA Guide Wire
CAR, J tip, floppy

195 cm

Hydrophilic PTFE

3 cm radiopaque 0.014" (0.36mm)

REF PTCA-CAR-J-HY-F-D-014-195

LOT 14000

2024-09

2028-08

MD

UDI 0197

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100 Pcs.

STERILEEO

GWC2, LB, PT, J, V2