

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:

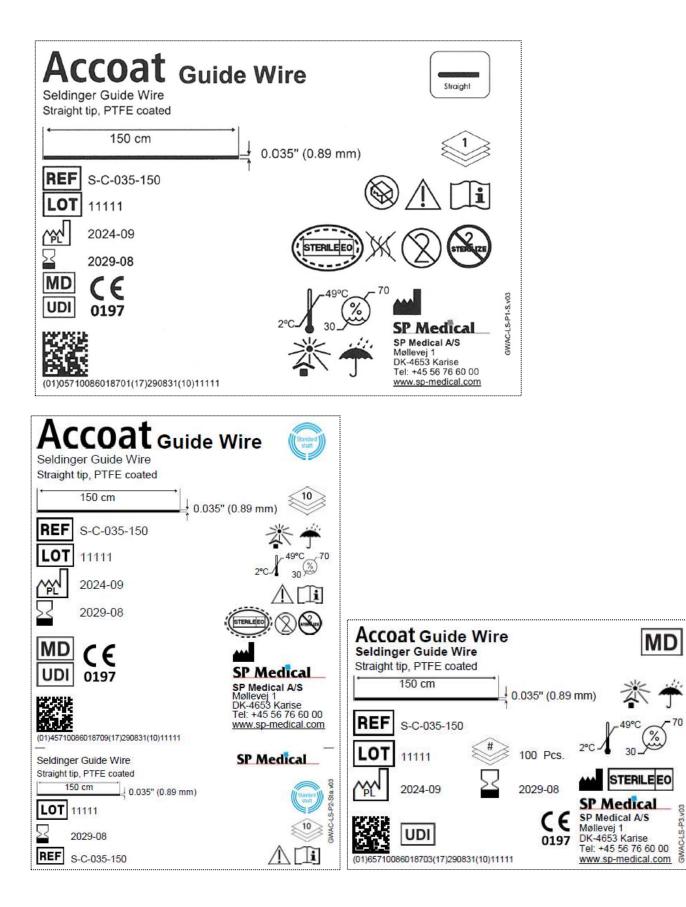
- All label layouts: Adjustment of font sizes and positions.
- Product box label layouts:
 - The symbol 5.2.13* (Single sterile barrier system with protective packaging inside) is replaced with 5.2.14* (Single sterile barrier system with protective packaging outside) to better illustrate the relationship 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

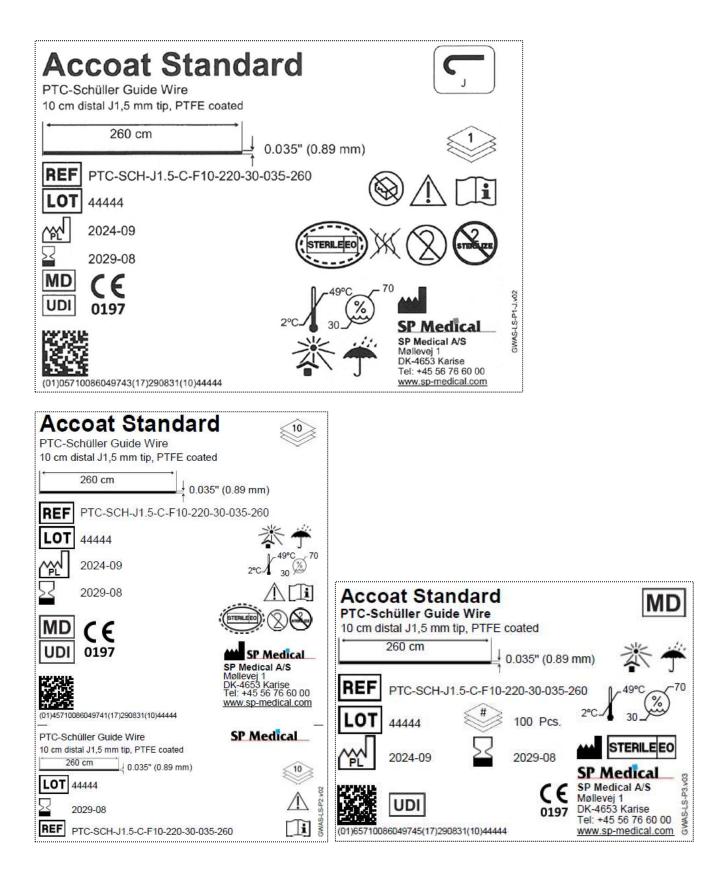
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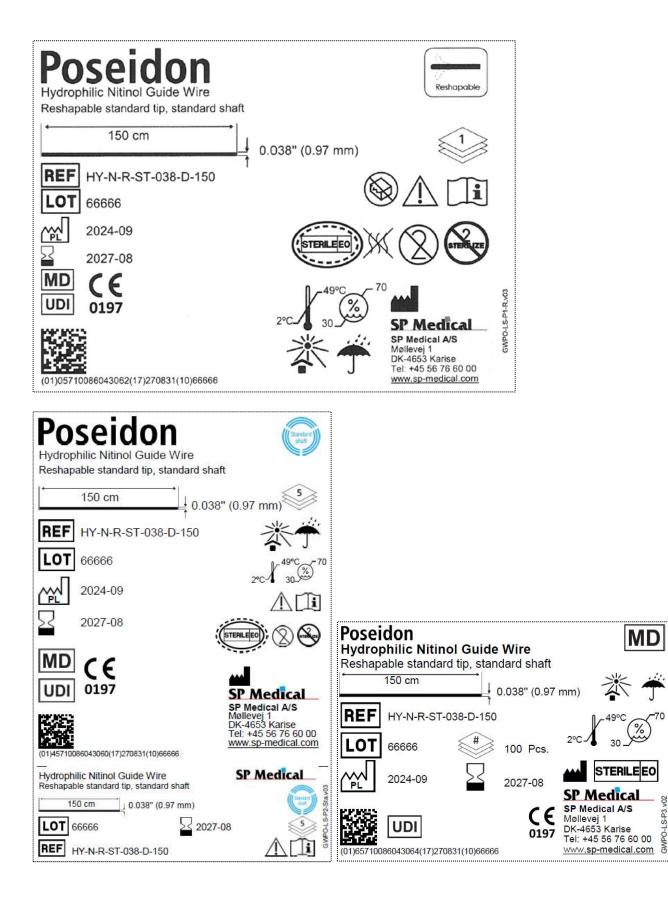
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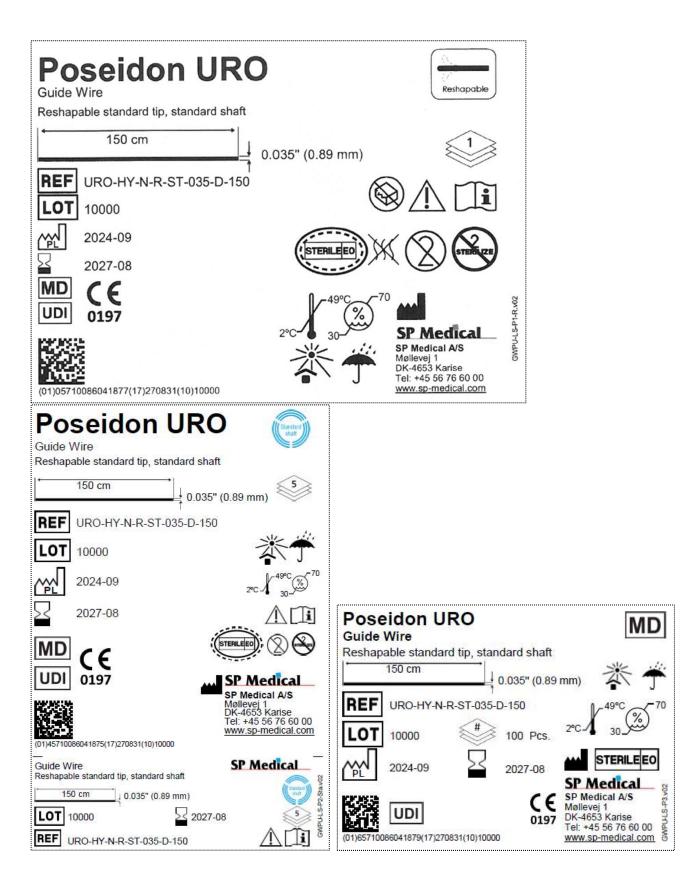
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