

Regulatory Information September 2026

Champion PTCA Guide Wire

Instructions for Use and label update

SP Medical has revised the Instructions for Use (IFU) and product labels for the Champion PTCA Guide Wire product range.

Instructions for Use (IFU) updates

- **Preparation Before Use**

The instructions have been updated to clarify that the guide wire must be fully advanced beyond the retention clip before it is removed from the dispenser. This reduces the risk of damaging the guide wire during removal.

- **Directions for Use**

The instructions have been updated to emphasize that the guide wire must be moistened with sterile saline before any shaping of the tip is performed.

The change is not significant and does not change the safety profile of the product. It is merely an improvement of the IFU, intended to reduce the risk of the user damaging the guide wire before use and to enhance clarity and user understanding.

The description in the current IFU is correct, and therefore, existing inventory and products already placed on the market remain unchanged and fully compliant.

Label Updates

The following changes have been made to the product labels:

- The date format has been changed from **YYYY.MM** to **YYYY.MM.DD**.
- The Data Matrix code has been updated to include the manufacturing date.
- Due to limited space in the peel-off section of the pouch label, the Human Readable Interpretation (HRI) of the Data Matrix code is now displayed adjacent to the Data Matrix symbol.
- To align the visual appearance of the Champion product family with other SP Medical product families, the box label design has been updated to match the format used across the portfolio (see the photo).



Implementation

The revised IFU will be implemented gradually. Both the updated and previous versions will be available for download on the SP Medical website **from Q4 2026**.

<https://www.sp-medical.com/guide-wires>

The updated labels will be applied to products ordered on or after **20 July 2026**.

Products already in stock or currently in the production pipeline will not be affected.