



Abbott International BVBA
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October 1, 2022

Dear Valued Customer,

Abbott is making changes for the Hi-Torque Supra Core™ 35, Hi-Torque Steelcore™ 18/18 LT, and Hi-Torque Spartacore™ 14 Peripheral Guide Wires as part of recent activities to comply with the new European Union Medical Device Regulation (EU MDR). There will be new product numbers and revision to the intended use / indications for use presented in the product Instructions for Use (IFUs), **effective November 1, 2022**. The revised indications for use will present a uniform intended use / indication for use across these products, as well as better align with how these products are generally used in the clinical setting.

The Hi-Torque Supra Core™ 35, Hi-Torque Steelcore™ 18/18 LT, and Hi-Torque Spartacore™ 14 Guide Wires will continue to be the same, high quality product that is currently available.

Timeline

Please note that the new part numbers will be implemented starting **November 1, 2022** and the current part numbers will no longer be available. This transition may take several months to replace with the new part numbers.

Required Action

These changes do not impact your current inventory. There will be no need to return your current product inventory. Current product part numbers will continue to be available until **November 1, 2022** and therefore, you may continue to order products in the same way. Also, if your local distribution center continues to have products in their inventory, you may order with the current part number until the stocks run out. When all the stocks of the current part numbers are no longer in the distribution center, you will need to place an order with the new part numbers identified in the table below. Please note we can not at this time predict how much inventory of the current part numbers will be available after November 1, 2022 so we encourage you to please change the part numbers in your system prior to November 1st.

Please note that we are not retiring the products. The same products are still available for order under new part numbers.

A comparison between current and new part numbers for the Hi-Torque Supra Core™ 35, Hi-Torque Steelcore™ 18/18 LT, and Hi-Torque Spartacore™ 14 Peripheral Guide Wires are provided in the tables below.

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Below is a list of all Hi-Torque Supra Core™ 35, Hi-Torque Steelcore™ 18/18 LT, and Hi-Torque Spartacore™ 14, Peripheral Guide Wires part numbers to be replaced.

Global Part Numbers Being Replaced		
Product	Current Global Part Numbers/To Be Discontinued Part Numbers for CE Marked Countries	New CE Part Numbers
HT Steelcore™ 18, 190 cm Guide Wire	1003281	1903281
HT Steelcore™ 18, 300 cm Guide wire	1003282	1903282
HT Steelcore™ LT 18, 190 cm Guide Wire	1007709	1907709
HT Steelcore™ LT 18, 300 cm Guide Wire	1007710	1907710
HT Steelcore™ LT 18 J Tip, 190 cm Guide Wire	1007709-J	1907709-J
HT Steelcore™ LT 18 J Tip, 300 cm Guide Wire	1007710-J	1907710-J
HT Supracore™ 35 ,145 cm Guide Wire	1002703	1902703
HT Supracore™ 35, 190 cm Guide Wire	1002703-01	1902703-01
HT Supracore™ 35 ,300 cm Guide Wire	1002703-02	1902703-02
HT Spartacore™ 14,130, 5cm Guide wire	1005201	1905201
HT Spartacore™ 14,190, 5cm Guide wire	1005202	1905202
HT Spartacore™ 14,300, 5cm Guide wire	1005203	1905203
HT Spartacore™ 14,130, 10cm Guide wire	1005204	1905204
HT Spartacore™ 14,190, 10cm Guide wire	1005205	1905205
HT Spartacore™ 14,300, 10cm Guide wire	1005206	1905206

Please note that the indication for use with Percutaneous Transluminal Coronary Angioplasty (PTCA) has been removed.

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Product	Current	New
HT Supra Core™ 35	<p>Intended Use: The Hi-Torque™ Peripheral Guide Wires are intended to facilitate the placement and exchange of interventional devices during diagnostic or therapeutic interventional procedures.</p>	<p>Intended Use: The Hi-Torque™ Peripheral Guide Wires are intended to facilitate navigation across vascular anatomies and structures in order to deliver diagnostic and therapeutic devices.</p>
HT Steelcore™ 18 HT Steelcore™ 18 LT HT Spartacore™14	<p>Intended Use: The Hi-Torque™ Peripheral Guide Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). They are not intended for use in the cerebral vasculature.</p>	<p>Indications for Use: The Guide Wires are indicated to facilitate the placement and exchange of interventional devices during peripheral diagnostic or peripheral therapeutic interventional procedures. It is not intended for use in the cerebral vasculature.</p>

We appreciate your commitment to Abbott as we make this transition. If you have any questions about the additional information, please contact your local Abbott representative.

Sincerely,



Jose Goldschmied
Endovascular Global Marketing Director

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S-core Wires Part Numbers Change Letter

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