

Synchro²® Guidewires

Revolutionizing Access

Synchro[®] Guidewires employ microfabricated nitinol hypotube technology designed for greater torque control. The responsiveness and maneuverability offered by this advanced guidewire design could revolutionize neurovascular access.

Nitinol Hypotube Construction

Unlike conventional guidewire designs, Synchro Guidewires feature a nitinol hypotube distal segment designed to provide turn-for-turn torque control without compromising flexibility.

Soft, Atraumatic Ribbon Tip

With a soft ribbon tip engineered to mimic the softness characteristics of the Transend[®] EX Platinum Guidewire, Synchro² Guidewires are designed for atraumatic access within delicate neurovascular morphology.

Soft and Standard Distal Support Profiles

Available in two distal flexibility profiles, Synchro² Soft Guidewires are designed for extra flexibility and Synchro² Standard Guidewires are designed for extra support in the distal segment.

Durable Hydrophilic Coating

Synchro² Guidewires feature an improved hydrophilic coating that is designed to offer the coating durability characteristics of Transend EX guidewires.

Convenient Pre-shaped Tip

Synchro² Guidewires are available with a pre-shaped tip that provides ready-to-use convenience. The pre-shaped tip offers superior tip shape retention, and may also be re-shaped to address case-specific requirements.

Synchro² Guidewires

Hydrophilic

Product Number	Description	Total Length	Distal Segment	Proximal / Distal OD
2601	Access Length, Soft	200 cm	35 cm	.014 in
2611	Access Length, Soft, Pre-shaped	200 cm	35 cm	.014 in
2641	Access Length, Standard	200 cm	35 cm	.014 in
2642	Access Length, Standard, Pre-shaped	200 cm	35 cm	.014 in
2631	Exchange Length, Soft	300 cm	35 cm	.014 in
2632	Exchange Length, Soft, Pre-shaped	300 cm	35 cm	.014 in
2651	Exchange Length, Standard	300 cm	35 cm	.014 in
2652	Exchange Length, Standard, Pre-shaped	300 cm	35 cm	.014 in

Synchro-10 Guidewires

Hydrophilic

Product Number	Description	Total Length	Distal Segment	Proximal / Distal OD
1631	Access Length	200 cm	55 cm	.012 in / .0095 in
1633	Exchange Length	300 cm	55 cm	.012 in / .0095 in

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Additional Information

Torque Control

In conventional guidewire designs, torque is transmitted by the core wire. In Synchro²® Guidewires, torque is transmitted by the microfabricated distal segment to enhance control.

Microfabrication Technology

The hypotube distal segment features a pattern of micro-machined slots. Variations in the slot profiles determine the support and flexibility characteristics of the distal segment.

Flat-Ribbon Core Wire Tip

In Synchro² Guidewires, the stainless-steel core wire tip is flattened into a ribbon design for improved shape retention.

Shapeable Tip

Synchro² Guidewires feature a 10 mm ribbon tip design that is highly shapeable.

Platinum-Tungsten Alloy Coil Tip

The 10 cm platinum-tungsten alloy coil allows for fluoroscopic visualization.

Stainless-Steel Core Wire

A stainless-steel core wire is designed to offer stability where it's needed and flexibility where it counts.

Hydrophilic Distal Segment

The hydrophilic distal segment facilitates navigation and positioning of the guidewire within the neurovasculature.

PTFE-Coated Proximal Shaft

The proximal shaft features a PTFE coating engineered to enhance tracking and manipulation of the guidewire within the microcatheter.

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See package insert for complete indication, contradictions, warnings, precautions, and instructions for use.

Synchro² Guidewires Intended Use

Synchro² Guidewires are intended for general intravascular use, including neurovascular and peripheral vasculatures. The guidewire can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neurovasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.

Contraindications

This device is not intended for use within the coronary vasculature. If another interventional device is used with the Synchro² Guidewire, then refer to that product labeling for intended use, contraindications and potential complications associated with the use of that interventional device.

Warnings

As with all guidewires used in interventional procedures, the following complications can occur: emboli, hemorrhage, ischemia, vasospasm, and neurological deficits including stroke and death.

- Caution: for single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of device may lead to injury, illness or death of the patient.
- Before a guidewire is advanced or withdrawn, verify tip movement under fluoroscopy to prevent the possibility of vessel perforation or guidewire damage. Do not torque a guidewire without observing corresponding movement of the distal guidewire tip; otherwise, guidewire damage, such as tip separation, and/or vessel trauma may occur.
- Always advance or withdraw the guidewire slowly and carefully. Never advance, auger, withdraw, or torque a guidewire which meets resistance. Resistance may be felt and/or observed under fluoroscopy by noting any buckling or prolapse of the guidewire tip. Excessive force against resistance may result in damage to the guidewire, such as separation of the guidewire tip, damage to the interventional device, and/or vessel perforation. Determine the cause of the resistance under fluoroscopy and take any necessary remedial action.
- The torque device and the introducer are included to aid in the use of the guidewire and are not intended to enter the patient's body at any time.

Cautions/Precautions

- Federal law restricts this device to sale by or on the order of physician
- Confirm the compatibility of the guidewire with the microcatheter before use. The wire should move freely within the catheter.
- Securely fasten the torque device onto the wire to prevent slippage of the torque device and to avoid product damage (i.e., core wire abrasion/peeling of PTFE, etc.)
- Maintain a continuous saline flush between the guiding catheter and the interventional device and between the interventional device and the guidewire during the procedure.
- Flushing prevents contrast crystal formation and/or clotting on the guidewire and in the catheter lumen.
- Verify that package integrity has not been compromised prior to use. Do not use a product after the expiration date.
- Inspect the guidewire for any visible damage prior to use, and do not use a wire that is damaged.
- Carefully examine all equipment for defects prior to the interventional procedure. Do not use any defective equipment.

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Synchro[®] Guidewires Intended Use

Synchro Guidewires are intended for peripheral and neurovascular use. The guidewire can be torqued to facilitate the selective placement of diagnostic or therapeutic catheters. A torque device (pin vise) is included with the guidewire to facilitate directional manipulation of the guidewire.

Contraindications

This device is not intended for use in coronary arteries. If other interventional devices are used with the Synchro Guidewire, then refer to that product labeling for intended use, contraindications and potential complications associated with the use of that interventional device.

Warnings

Potential complications include, but are not limited to: hematoma at the site of entry, vessel perforation, emboli, hemorrhage, ischemia, vasospasm, and neurological deficits including stroke and death. Please be aware that potential adverse Effects may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is indicated.

- Caution: for single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- When the guidewire is in the body, it should be manipulated only under fluoroscopy.
- Do not attempt to move the wire without observing the resultant tip response.
- Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Excessive force against resistance may result in separation of the guidewire tip, damage to the catheter, or vessel perforation.

Cautions/Precautions

- Federal law restricts this device to sale by or on the order of a physician.
- Contents supplied STERILE using gamma radiation. Non-pyrogenic. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.
- This device should be used by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.
- Use the device prior to the "Use Before" date noted on the package.
- Prior to a procedure, all equipment to be used for the procedure should be carefully examined to verify proper function and integrity.
- Confirm the compatibility of the guidewire with the microcatheter before use. The wire should move freely within the catheter.
- Inspect guidewire prior to use for any surface irregularities and bends or kinks. Any guidewire damage may decrease the desired performance characteristics.
- Exercise care in handling a guidewire during a procedure to reduce the possibility of accidental breakage, bending or kinking.
- Due to the variations in the inner diameter of some catheters, abrasion of the hydrophilic coating may be caused by a tight catheter. It is advisable to stop using such catheters.
- A compatible guidewire introducer may be used during the insertion process or as a tip-shaping mandrel, according to provided instructions. Neither the guidewire introducer, nor the torque device is intended to enter the body.
- Excessive tightening of the torque device onto the wire may result in abrasion of the coating of the wire.
- Maintain a continuous saline flush between the guiding catheter and the interventional device and between the interventional device and the guidewire

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