FRONT SIDE OF PRINTER

TOTAL LENGTH of piece is 37.5/16"

5-7/16" | 5-13/32" | 5-13/32" | 5-15/32" | 5-7/16" | 5-3/8"

5-3/4" | 5-11/16" | 5-11/16" | 5-3/4"

TOTAL HEIGHT of piece is 20.7/8"

English

HI-TORQUE™ Guide Wire

CAUTIONS

This medical device should be used only by physicians trained in angiography and percutaneous transluminal coronary angioplasty (PTCA), and / or percutaneous transluminal angioplasty (PTA).

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

Refer to the instructions supplied with any interventional devices to be used in conjunction with the HI-TORQUE™ Guide Wire, for their intended uses, contraindications, and potential complications.

A summary of the safety and clinical performance (SSCP) for this device is available at http://ec.europa.eu/tools/eudamed. Search for the device using the Basic UDI-DI provided in Table 1. This is the SSCP location after the launch of the European Medical Device Information System (EUDAMED).

This Instructions for Use as per European Regulation (EU) 2017/745 can be found on the Abbott eLabeling website at vascular.eifu.abbott.

DESCRIPTION

This Instructions for Use pertains to the HI-TORQUE PROGRESS™ 40, HI-TORQUE PROGRESS 30, HI-TORQUE PROGRESS 14ST, HI-TORQUE PROGRESS 14ST, and HI-TORQUE PROGRESS 200T Guide Wires.

Table 1

Product Name	Basic UDI-DI	Method de stérilisation
HI-TORQUE PROGRESS 40 Guide Wire	07116456029035	Electron-beam Radiation (R)
HI-TORQUE PROGRESS 30 Guide Wire		
HI-TORQUE PROGRESS 14ST Guide Wire		
HI-TORQUE PROGRESS 200T Guide Wire		

The HI-TORQUE™ Family of Guide Wires are medical devices that are intended for use in PTCA and PTA to treat patients with coronary or peripheral artery disease as specified in the indications for use section of this document. The Guide Wires are intended to be available in several lengths and diameters and have a disposable distal tip. Refer to the product label for product specifications (e.g., wire length, diameter, and length of tip configuration).

Coronary guide wires facilitate PTCA and PTA, which other clinical benefits for treatment of coronary or peripheral artery disease, as compared to non-guidewire assisted angioplasty. HI-TORQUE PROGRESS Guide Wires have been found safe and effective in preclinical and clinical trials, and are intended for use in conjunction with the DEC™ Guide Wire Extension. Refer to the product label for Guide Wire Extension compatibility information. Joining the Guide Wire Extension to the guide wire facilitates the exchange of one interventional device for another while maintaining intravascular access to the treatment site. Although the guidewire and device exchange has been completed, the extension can be detached and the guide wire can be used in its original capacity.

Guide Wire Coating and Lubricity Potential Markers: Brachial and femoral markers assist on the proximal segment of the 0.014" (0.36 mm) guide wire; all guide wires provide wire position relative to the guiding catheter tip when using basic wire technique. These guide wires are compatible with guiding catheters of the size and shape specified in (brachial) or 100 cm (femoral) tip.

Guide Wire Coating and Lubricity Hydrophilic Markers: Some HI-TORQUE Guide Wires have distal radiopaque markers. Refer to the product drawing on the label to determine the presence and location of the markers. Markers are represented by the following designation: **M**. A series of square markers on a single wire are represented by the **M** designation.

Refer to the product label for **Hydrophilic Coating**. Refer to the product label for presence of a hydrophilic coating.

HOW SUPPLIED

Sterile – Sterilized with electron-beam radiation. Refer to the product label for the sterilization method. Discard if package is damaged or if the seal is compromised. This single-use device cannot be reused or resterilized safely, as it is not designed to perform as intended after the first usage. Changes in mechanical, physical, and / or chemical characteristics introduced under conditions of repeated use, cleaning, and / or resterilization may compromise the integrity of the design and, or material, resulting in unpredictable performance. Do not use if package is damaged or if signs of performance of the device. Absence of original labeling may lead to misuse and stimmata traceability. Absence of original packaging may lead to device damage, loss of sterility, loss of ease of use, or loss of the patient data1 or user.

Contents – One (1) guide wire per pouch.

Storage – Store in a cool, dry place.

INTENDED PURPOSE

Guide Wires are intended to facilitate navigation across vascular anatomies and stenoses in order to deliver diagnostic and therapeutic devices.

INDICATIONS FOR USE

HI-TORQUE™ Guide Wires are indicated to facilitate the delivery of catheter-based interventional devices during PTCA and PTA. This guide wire may be used with angiographic and fluoroscopic imaging systems. Refer to the product label for guide wire length, and choose a guide wire of a length, diameter, and shape suitable for the intended use. Refer to the product label, provide a guidewire which exceeds the distal end of the intended device for another, and to distinguish the vasculature. This guide wire may be used to cross or assist in crossing or revise chronic total coronary occlusions (CTO).

CONTRAINDICATIONS

Not indicated for use in the cerebral vasculature.

WARNINGS

This device is not designed for use with atherectomy devices. The safety and effectiveness of the HI-TORQUE™ Guide Wire with atherectomy devices are unknown.

The lifetime of the device is the labeled shelf life. This device is designed and intended for ONE TIME USE ONLY. Do not resterilize. The safety and effectiveness of this device have not been established after being reprocessed and reused.

Use the guide wire only as exposed in the vascular system. Do not use it should be manipulated while under high quality fluoroscopic observation.

This device is hydrophilic coated. Do not use if the device for a length of 25 cm. The proximal section of the wire is coated with polytetrafluoroethylene (PTFE) and is lubricious. Exercise caution when using this device with other PTFE-coated devices. Hydrophilic Coating is coated on the distal end of the guide wire for a length of 140 cm for 12M guide wires, and 25 cm for 300 cm guide wires, and the PTFE coating is coated on the proximal end for a length of 300 cm for 12M guide wires, and 25 cm for 300 cm guide wires.

Refer to PREPARATION FOR USE section for further information on how to prepare and use this device to ensure it performs as intended. Failure to follow the warnings in this labeling might result in damage to the device coating, which may increase friction and reduce lubricity of the device.

The safety and effectiveness of this device in the treatment of lesions in vessels or vascular regions other than those specifically indicated.

Do not use the device if any of the following or other components of this device listed below may suffer an allergic reaction to this guide wire. Prior to its use on the patient, carefully review the patient's medical history to ensure that the device is not a **foreign body if allergies must be discussed. This device contains a polymer made nickel alloy, stainless steel, gold-tin alloy, tin-polymer-silver, tungsten-silver, **platinum, **epoxy adhesive, **MEDRONIC SILTHERM Coating, **polytetrafluoroethylene (PTFE) coating, and PTFE coating.

Carefully observe the instructions under "Do Not" and "Do" below. Failure to do so may result in vessel trauma, guide wire damage, guide wire tip separation, or damage to other components of the system. Do not use the device if any of the following are present: Thrombus, Dissection, Calcium, Tortuosity, Stenosis, Thrombus and other emboli. Use the most suitable guide wire for the lesion being treated.

Do Not:

- Push, anger, withdraw, or torque a guide wire that meets resistance.
- Use force when the guide wire is in the vascular system.
- Allow the guide wire tip to remain in a vessel for prolonged periods.
- Deploy a stent such that it will entrap the wire between the vessel wall and the stent.

Do:

- Advance or withdraw the guide wire slowly.
- Use the guidewire with the proper hydrophilic device to confirm position.
- Examine the tip movement under fluoroscopy before manipulating, moving, or advancing the guide wire.
- Observe the wire under fluoroscopy for buckling, which is a sign of resistance.
- Maintain a continuous flush while removing and reinserting the guide wire to prevent air from entering the catheter system.
- Perform exchanges slowly to prevent air entry and / or trauma.
- Ensure that the guide wire tip is in the distal vessel before attempted device tip is free within the vessel lumen and that the tip is parallel to the vessel wall.
- Use extreme caution when inserting a guide wire through a non-endobilliary stent, or through stent struts, into a bifurcated vessel. Use of this technique involves additional patient risks, including the risk that the wire may become entrapped in the stent struts.
- Consider that if a vessel ruptures while a guidewire is in place, the guidewire may need to be retracted prior to stent deployment, because there is additional risk of vessel rupture if the guidewire is in place when the stent is being deployed and the stent.

For the HI-TORQUE PROGRESS™ Family of Guide Wires only:

In HI-TORQUE PROGRESS Family of Guide Wires, there are three mode of varying stiffness. Operate these guide wires carefully so as to not injure the vessel. Operate the guide wire in the stiffer mode only when it is necessary to cross a lesion. Use stiffer distal, and / or shaper adjustments force may cause a higher risk of perforation or injury than a guide wire with a more pliable distal end. Therefore, use the guide wire with the least stiff distal end that will meet the needs. Do not use extreme care to minimize the risk of perforation or other damage to blood vessels.

CAUTIONS

These HI-TORQUE™ Guide Wires do not have a specific limitation in diameter of use but are designed to be used in conjunction with a guiding catheter designed for use in coronary, Percutaneous transluminal coronary angioplasty (PTCA) should only be performed at centers where emergency coronary bypass surgery (CABG) surgery is available.

PREPARATION

Use only sterile devices and instruments and should be handled carefully. Prior to use and after possible damaging events, inspect the guide wire carefully for bends, kinks, or other damage. Do not use damaged guide wires. Using a damaged guide wire may result in vessel damage and / or microvascular blockage.

Confirm the compatibility of the guide wire diameter with the interventional device before use.

Refer to the instructions of other devices to be used in the procedure to confirm the appropriate vasculature that this guide wire may be used in. Failure to abide by the above recommendations may result in non-insertion of the proposed vessel guide wire, which can result in vessel injury such, but not limited to, perforation, dissection, rupture, and / or thrombosis.

The safety and effectiveness of this HI-TORQUE™ Guide Wire has not been established in the pediatric population.

Prep movement of guide wire within the interventional device is an important feature of a steerable guide wire system, because it gives the user valuable tactile information. Test the movement of the guide wire within the interventional device before introduction into the vasculature. Hold it in located to orient guide wire movement. It is recommended that the user determine the source of resistance, exercise caution when removing the device and / or other components are by the proximal end of the guide wire, and not by the tip of the guide wire.

Never attach the hinge device to the modified portion of the proximal end of the adjustable guide wire, otherwise, guide wire manipulation may occur, preventing the ability to adjust the guide wire shape.

HI-TORQUE GUIDE WIRES ARE NOT DESIGNED FOR USE WITH ATHERECTOMY DEVICES. Do not withdraw or manipulate the hydrophilic-coated wire through a metal cannula or sharp-edged object. Damage to the hydrophilic coating may occur, which may result in a metal device may result in detachment and / or separation of the outer coating, which may increase friction and reduce lubricity of the device. Do not use the device if signs of damage are present. Damage to the hydrophilic coating may result in a metal device may result in detachment and / or separation of the outer coating, which may increase friction and reduce lubricity of the device. Do not use the device if signs of damage are present.

When wet, a hydrophilic coating increases the lubricity of the guide wire surface. Do not soak the device for longer than 60 minutes. Do not soak the device if the pre-soaking devices for longer than instructed, as this may impact the coating performance. The coating swells when exposed to aqueous media, but does not have any impact on device use.

The integrity and performance of the device coating can be negatively impacted by preparation with incompatible media or substances. Take note of the following important preparation information:

- Avoid exposing the device with dry gauze as this may damage the device coating.
- Avoid excessive wiping of the coated device.
- Avoid using alcohol, antiseptic solutions, or other solvents (e.g., use of medications and iodine/povi) to pre-treat the device because this may cause unpredictable changes in the coating which could negatively affect the safety and performance of the guide wire.

Attempting to alter the shape of devices by bending, twisting, or similar methods beyond recommended manipulations may damage the device integrity, and that damage to the coating may not always be noticeable to the naked eye.

One or more components of this device may contain the following substances defined as CMR (this is a concentration above 0.1% weight by weight): Cobalt, Chromium Nickel. Service (CAS) No. 7440-47-0 No. 231-158-0

Medical devices containing CMR substances or devices manufactured from materials containing CMR substances could do not cause an occurrence of cancer or adverse reproductive effects.

After use, this product can be a potential biohazard. Handle and dispose of it in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

ADVERSE EVENTS

Potential adverse events associated with use of this device may include the following, but are not limited to:

- Allergic reaction or hypersensitivity
- Arrhythmia
- Arteriovenous fistula
- Bleeding
- Blood clot (thrombus) / pseudoaneurysm
- Embolus
- Fever
- Fistula
- Hematoma
- Hemorrhage
- Hypotension
- Infection
- Inflammation
- Pain
- Pseudoaneurysm
- Stenosis / restenosis
- Thrombosis
- Vasospasm
- Vessel perforation
- Vessel rupture
- Vessel trauma
- Vessel wall damage
- Vessel wall dissection
- Vessel wall puncture
- Vessel wall tear
- Vessel wall thrombosis
- Vessel wall trauma
- Vessel wall injury
- Vessel wall spasm
- Vessel wall stenosis
- Vessel wall occlusion
- Vessel wall rupture
- Vessel wall perforation
- Vessel wall hemorrhage
- Vessel wall hematoma
- Vessel wall embolism
- Vessel wall dissection
- Vessel wall aneurysm
- Vessel wall fistula
- Vessel wall fistula formation
- Vessel wall fistula formation
- Vessel wall fistula formation

(37/138) i calificacje acetabularne em 13,8% (19/138) dla kodów. Dla kodów dwu avulsiów, 12,5% (17/136) ewn. eochirotica s. 0,7% (1/138) spierzchnienie tronu. Dr ukazała kontrolę i detektyw z angielską, a między kodem do wysa de referencji (PRO) artes do przeciętnie (z 9% em do 2,66 c. 0,44) ewn. o dziennie miało do uzyskać ewn. Dla ewn. Dla ewn. Dla

TOTAL LENGTH of piece is 37-15/16"

5-1/2"

5-7/16"

5-3/8"

5-7/16"

5-3/8"

5-3/8"

5-7/16"

5-3/8"

5-3/8"

6-13/16"

6-5/8"

6-13/16"

6-5/8"

TOTAL HEIGHT of piece is 13- 7/16"

INSIDE OF PIECE

FRONT SIDE OF PIECE

Fold template along this center line to view the piece backed-up.

Fold template along this center line to view the piece backed-up.

Fold template along this center line to view the piece backed-up.

Fold template along this center line to view the piece backed-up.

English

HI-TORQUE™ Guide Wire

CAUTIONS

This medical device should be used only by physicians trained in angiography and percutaneous transluminal coronary angioplasty (PTCA), and/or percutaneous transluminal angioplasty (PTA).

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY CAUSE COMPLICATIONS.

Refer to the instructions supplied with any interventional devices to be used in conjunction with the HI-TORQUE™ Guide Wire, for their intended uses, contraindications, and potential complications.

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EC REP
Abbott Vascular International BVBA
Park Lane, Culliganlaan 2B
1831 Diegem, BELGIUM
TEL: +32 2 714 51 11
FAX: +32 2 714 54 12

Intended Use

This medical device should be used only by physicians trained in angiography and percutaneous transluminal coronary angioplasty (PTCA), and/or percutaneous transluminal angioplasty (PTA).

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY CAUSE COMPLICATIONS.

Refer to the instructions supplied with any interventional devices to be used in conjunction with the HI-TORQUE™ Guide Wire, for their intended uses, contraindications, and potential complications.

Device Description

Guide Wires are intended to facilitate navigation across vascular anatomies and structures in order to deliver diagnostic and therapeutic devices.

INDICATIONS FOR USE

HI-TORQUE™ Guide Wires are indicated to facilitate the delivery of catheter-based interventional devices during PTCA and PTA. This guide wire may be used with balloon dilatation catheters, stent delivery systems, and other devices that are designed to reach and cross a target lesion, provide a pathway within the vessel structure, facilitate the substitution of one diagnostic or interventional device for another, and to distinguish between vessel branches. This guide wire is not intended to cross or assist in crossing dense chronic total coronary occlusions (CTO).

CONTRAINDICATIONS

Not indicated for use in the cerebral vasculature.

WARNINGS

This device is not designed for use with atherectomy devices. The safety and effectiveness of the use of this HI-TORQUE™ Guide Wire with atherectomy devices has not been established.

The lifetime of the guide wire is the intended shelf life. This device is designed and intended to ONE-TIME USE ONLY. Do not resterilize and / or reuse. The safety and effectiveness of the devices have not been established after being reprocessed for multiple use.

If a guide wire is exposed to the vascular system, it should be manipulated while under fluoro with extreme care.

This device has a hydrophilic coating at the distal end of the device for a length of 25 cm. The proximal section of the wire is coated with polytetrafluoroethylene (PTFE) and a single coat of SILICONE-LIKE™ also called MICROGLIDE™ hydrophilic coating. The distal section of the wire is coated with a single coat of SILICONE-LIKE™ and a 100 cm polymer, and 25 cm for 300 cm guide wires, and the PTFE is coated at the proximal end for a length of 142 cm for 190 cm guide wires, and 242 cm for 300 cm guide wires.

Prior to PROTHROMBIN COD coagulation for further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the instructions may result in a failure to perform as intended, or in a device malfunction or accidentally introduce or result in serious adverse events.

The safety and effectiveness of the devices have not been established, or is unknown, in certain populations or anatomic locations/structures.

Pacemaker and implantable cardioverter defibrillator (ICD) patients:

Pacers with bosses intelligency or any of the components of this device may affect the function of implanted pacemakers and ICDs. Prior to use of this device, the patient should be counseled on the cautions contained in the device and a thorough history of allergies must be discussed. This device contains platinum and nickel. Patients with allergies to these or other metals should be treated with antibiotics, steroids, antihistamines, NEUROLEPTIC STATE (Leroy Cushing, perphenazine/Prolixin [PMP]) coating, and PTFE coating.

Carefully advance the introducer sheath "Tie Rod" and "Zip" Valve Tubes to the ostium. Do not advance or manipulate the hydrophilic-coated wire through a metal introducer needle. Damage to the hydrophilic coating may occur. Do not advance or retract device may result in damage to the device and/or injury to the patient. Use caution when fluoroscopy and take remedial action to avoid. Use the most suitable guide wire for the procedure being performed.

When well, a hydrophilic coating increases the lubricity of the guide wire surface. Although the coating is designed to minimize blood loss, it does not prevent blood loss. Blood loss may occur if the coating is damaged or lost, as this may impact the coating. The coating swells when exposed to aqueous media, but does not have any impact on device size.

The integrity and performance of the device coating can be negatively impacted by preparation with incompatible media or solvents. Take note of the following important recommendations:

- Avoid wiping the device with dry gauze as this may damage the device coating. Instead, remove excess fluid with wet gauze.
- Avoid using alcohol, antiseptic solutions, or other cleaners (e.g., use of medicated and citrofloxin) to pre-treat the device because this may cause unpredictable changes in the coating which could negatively affect the safety and performance of the guide wire.

Attempting to alter the shape of devices by bending, twisting, or similar methods beyond instructor methods may compromise the coating's integrity and that damage to the coating may not always be noticeable to the naked eye.

Before using the device, carefully inspect the coating through the following substitute defined as follows: Fill in a concentration of 1% weight by weight Cetrali, Cetrali Chloride Monohydrate Serve (CCM): No. 1440-48-4; EC No. 215-158-9.

Current scientific evidence suggests that medical devices manufactured from stainless steel alloys containing chloride do not cause an increased risk of cancer or adverse reactions in patients.

After use, the physician may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

ADVERSE EVENTS

Potential adverse events associated with use of this device may include the following, but not limited to:

- Allergic reactions or hypersensitivity
- In stent, contrast agent, antibiotics, device materials, and drug reactions to medications or antiplatelet drugs
- Perforation
- Dissection
- Bleeding
- Stenosis / restenosis
- Thrombosis
- Arrhythmia
- Myocardial infarction
- Embolism
- Air fistula
- Coronary / pseudoaneurysm
- Infection
- Vasoconstriction
- Vasospasm
- Hypotension
- Hypertension
- Hematoma

REPORTING OF ADVERSE EVENTS

The wire and / or patient should report any serious incident that has occurred in relation to this HI-TORQUE™ Guide Wire to the manufacturer and the competent authority of the European Member State in which the user and / or patient is established.

EVALUATION OF HI-TORQUE™ PROCEDURE WIRES / HI-TORQUE PLUS™ PROCEDURE WIRES / HI-TORQUE™ ADVANCE

Twenty (20) sets of wires were selected randomly from a production lot. Each set was tested for ease of use, and therefore, the HI-TORQUE™ PROCEDURE WIRE / HI-TORQUE PLUS™ PROCEDURE WIRE / HI-TORQUE™ ADVANCE PROCEDURE WIRE was specifically evaluated for ease of use. EXPERTS CITED clinical trial.

Clinical Evaluation Results

Data for EXPERTS CITED that the guide wire-related effectiveness of the study, in-hospital PTCA procedure, HI-TORQUE™ PROCEDURE WIRE / HI-TORQUE PLUS™ PROCEDURE WIRE / HI-TORQUE™ ADVANCE PROCEDURE WIRE, and HI-TORQUE™ ADVANCE PROCEDURE WIRE, and HI-TORQUE™ ADVANCE PROCEDURE WIRE, and

TOTAL LENGTH of piece is 37-15/16"

5-1/2" | 5-7/16" | 5-3/8" | 5-7/16" | 5-3/8" | 5-3/8"

TOTAL HEIGHT of piece is 13-7/16"

6-5/8" | 6-13/16" | 6-5/8" | 6-13/16"

HI-TORQUE™ Guide Wire

Abbott

℞ ONLY

2797

PL212246035-02 (2021-11-01)

CAUTIONS

This medical device should be used only by physicians trained in angiography and percutaneous transluminal coronary angioplasty (PTCA), and / or percutaneous transluminal angioplasty (PTA).

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO COULD RESULT IN COMPLICATIONS.

Refer to the instructions supplied with any interventional devices to be used in conjunction with the HI-TORQUE™ Guide Wire, for their intended uses, contraindications, and potential complications.

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English

HI-TORQUE™ Guide Wire

CAUTIONS

This medical device should be used only by physicians trained in angiography and percutaneous transluminal coronary angioplasty (PTCA), and / or percutaneous transluminal angioplasty (PTA).

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO COULD RESULT IN COMPLICATIONS.

Refer to the instructions supplied with any interventional devices to be used in conjunction with the HI-TORQUE™ Guide Wire, for their intended uses, contraindications, and potential complications.

A summary of the safety and clinical performance (SSCP) for this device is available at https://ec.europa.eu/tools/eudamed. Search for device using the Basic UDI-DI provided in Table 1. This is the SSCP location after the launch of the European Medical Device Information System (EUDAMED).

This instructions for Use are for European Medical Devices (EU) 2017/745 can be found on the HI-TORQUE PROGRESS 200T Guide Wire.

DESCRIPTION

This Instructions for Use pertains to the HI-TORQUE PROGRESS™ 40, HI-TORQUE PROGRESS 60, HI-TORQUE PROGRESS 120, HI-TORQUE PROGRESS 140T, and HI-TORQUE PROGRESS 200T Guide Wires.

CONTRAINDICATIONS

Not indicated for use in the coronal vasculature.

WARNINGS

This device is not designed for use with atherectomy devices. The safety and effectiveness of the use of this HI-TORQUE™ Guide Wire with atherectomy devices has not been established.

The lifetime of the device is the indicated shelf life. This device is designed and intended for ONE-TIME USE ONLY. Do not resterilize and / or reuse. The safety and effectiveness of this device have not been established after being reprocessed for multiple use.

If a guide wire is exposed to the vascular system, it should be manipulated while under high angiographic visualization.

This device has a hydrophilic coating at the distal end of the device for a length of 25 cm. The proximal section of the device is coated with polytetrafluoroethylene (PTFE) and a single coat of SERVOSYL™ (also called MEDIGLIDE™). Hydrophilic coatings have inherent slippery characteristics when wet. The HI-TORQUE™ Guide Wire Size 0.36 mm (0.014 in) and 200 cm for HI-TORQUE 200 guide wires, and the PTFE coated at the proximal end for a length of 142 cm for 190 cm guide wires, and the PTFE coated for a length of 150 cm for 200 cm guide wires.

Prior to PROTECTION and / or further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the instructions for use, contraindications, warnings, cautions, may lead to adverse events/side effects and result in serious adverse events.

The safety and effectiveness of the devices have not been established, or is unknown, for patients with the following medical conditions:

Patients with known history of allergies to any of the components of this device

Patients who are allergic to medical grade stainless steel, PTFE, or silicone

Patients who are allergic to any of the medications contained in the device and / or a thorough history of allergies must be discussed. This device contains platinum, nickel, and cobalt-chromium-alloy. Patients who are allergic to platinum, nickel, cobalt, or chromium, may experience, HEADACHE, DIZZINESS, FEVER, pericardial effusion, cardiac tamponade, and / or cardiac arrest.

Patients with Coronary Artery Disease (CAD) with Myocardial Infarction (MI) and / or Cardiac Tamponade, and PTA coating.

Carefully follow the instructions under "On Not" and "Do" below. Failure to follow these instructions may result in vessel trauma, guide wire damage, guide wire tip separation, or vessel damage. If resistance is observed at any time, determine the cause under fluoroscopy and take remedial action as needed. Use the most suitable guide wire for the intended procedure.

Do Not

- Push, auger, withdraw or torque a guide wire that meets resistance.
- Torque a guide wire if the tip becomes entangled in the vasculature.
- Allow the guide wire tip to remain in a polyimide coated introducer, because it will scrape the polyimide coat and it will embed the wire between the vessel wall and the sheath.

HOW SUPPLIED

Sterile – Sterilized with electron-beam radiation. Refer to the product label for the sterilization method. Non-pyrogenic. Do not reuse. Do not resterilize. Single use only. This single-use device cannot be reused on another patient, as it is not designed to withstand decontamination or reprocessing. Reprocessing may lead to changes in chemical characteristics (introduction of new conditions of repeated use, cleaning, and / or resterilization may compromise the integrity of the design and / or materials, leading to deterioration of performance, or failure of the device, which may compromise the performance of the device. Absence of performance or deterioration of performance and elevated attributable hazards. Absence of original packaging may lead to device damage, loss of sterility, and risk of injury to the patient and / or user.

Contents – One (1) guide wire per pouch.

Storage – Store in a cool, dry, dark, room place.

Shelf Life – Refer to product label.

Guide Wires are intended to facilitate navigation across vascular anatomies and structures in order to deliver diagnostic and therapeutic devices.

INDICATIONS FOR USE

HI-TORQUE™ Guide Wires are indicated to facilitate the delivery of catheter-based interventional devices during PTCA and PTA. This guide wire may be used with compatible devices such as balloon catheters, stents, and other devices. The guide wire is designed to reach and cross a target lesion, provide a pathway within the vessel structure, facilitate the substitution of one diagnostic or interventional device for another, and to distinguish between different vessel branches. The guide wire is used to cross or assist in crossing an obstructive chronic total coronary occlusion (CTO).

CONTRAINDICATIONS

Not indicated for use in the coronal vasculature.

WARNINGS

This device is not designed for use with atherectomy devices. The safety and effectiveness of the use of this HI-TORQUE™ Guide Wire with atherectomy devices has not been established.

The lifetime of the device is the indicated shelf life. This device is designed and intended for ONE-TIME USE ONLY. Do not resterilize and / or reuse. The safety and effectiveness of this device have not been established after being reprocessed for multiple use.

If a guide wire is exposed to the vascular system, it should be manipulated while under high angiographic visualization.

This device has a hydrophilic coating at the distal end of the device for a length of 25 cm. The proximal section of the device is coated with polytetrafluoroethylene (PTFE) and a single coat of SERVOSYL™ (also called MEDIGLIDE™). Hydrophilic coatings have inherent slippery characteristics when wet. The HI-TORQUE™ Guide Wire Size 0.36 mm (0.014 in) and 200 cm for HI-TORQUE 200 guide wires, and the PTFE coated at the proximal end for a length of 142 cm for 190 cm guide wires, and the PTFE coated for a length of 150 cm for 200 cm guide wires.

Prior to PROTECTION and / or further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the instructions for use, contraindications, warnings, cautions, may lead to adverse events/side effects and result in serious adverse events.

The safety and effectiveness of the devices have not been established, or is unknown, for patients with the following medical conditions:

Patients with known history of allergies to any of the components of this device

Patients who are allergic to medical grade stainless steel, PTFE, or silicone

Patients who are allergic to any of the medications contained in the device and / or a thorough history of allergies must be discussed. This device contains platinum, nickel, and cobalt-chromium-alloy. Patients who are allergic to platinum, nickel, cobalt, or chromium, may experience, HEADACHE, DIZZINESS, FEVER, pericardial effusion, cardiac tamponade, and / or cardiac arrest.

Patients with Coronary Artery Disease (CAD) with Myocardial Infarction (MI) and / or Cardiac Tamponade, and PTA coating.

Carefully follow the instructions under "On Not" and "Do" below. Failure to follow these instructions may result in vessel trauma, guide wire damage, guide wire tip separation, or vessel damage. If resistance is observed at any time, determine the cause under fluoroscopy and take remedial action as needed. Use the most suitable guide wire for the intended procedure.

Do Not

- Push, auger, withdraw or torque a guide wire that meets resistance.
- Torque a guide wire if the tip becomes entangled in the vasculature.
- Allow the guide wire tip to remain in a polyimide coated introducer, because it will scrape the polyimide coat and it will embed the wire between the vessel wall and the sheath.

Do

- Advance or withdraw the guide wire slowly.
- Use the optimum guide wire for the interventional device to confirm position.
- Examine the by movement under fluoroscopy before manipulating, moving, or advancing the device.
- Observe the wire under fluoroscopy for tip buckling, which is a sign of resistance.
- Remove the interventional device while removing and remoistening the guide wire to prevent an drier entering the catheter system.
- Perform exchanges slowly to prevent an entry and / or trauma.
- When reintroducing the guide wire, confirm that the intervention device tip is free within the vessel lumen and that the tip is parallel to the vessel wall.
- Use caution when using the guide wire in the presence of calcified lesions, stenosis, or through stent struts, which may cause a fenestrated vessel. Use of the fenestrated vessels additional patient risks, including the risk that the wire may become entangled in the stent struts.
- Consider that if a secondary guide wire is placed in a bifurcated branch, the wire may need to be retracted prior to stent deployment, because there is additional risk of the secondary wire being trapped in the space between the vessel wall and the stent.

For the HI-TORQUE PROGRESS™ Family of Guide Wires only:

**For the HI-TORQUE PROGRESS™ Family of Guide Wires have distal ends of varying stiffness. Operate these guide wires carefully so as to not injure the blood vessel. Operate the guide wire with the distal end in the straight position. Do not operate the guide wire distal end, and / or the proximal end, in a bent position. Do not use force if you encounter any resistance. Do not use force if you encounter any resistance. Do not use force if you encounter any resistance

TOTAL LENGTH of piece is 37-15/16"

5-1/2" | 5-7/16" | 5-3/8" | 5-7/16" | 5-3/8" | 5-3/8"

5-5/8"

6-13/16"

6-13/16"

6-5/8"

TOTAL HEIGHT of piece is 13- 7/16"

FRONT SIDE OF PIECE

INSIDE OF PIECE

Abbott

English

HI-TORQUE™ Guide Wire

CAUTIONS

This medical device should be used only by physicians trained in angiography and percutaneous transluminal coronary angioplasty (PTCA), and/or percutaneous transluminal angioplasty (PTA).

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY CAUSE COMPLICATIONS.

Refer to the instructions supplied with any interventional devices to be used in conjunction with the HI-TORQUE™ Guide Wire, for their intended uses, contraindications, and potential complications.

HOW SUPPLIED

Sterile – Sterilized with electron-beam radiation. Refer to the product label for the sterilization method/dose/expiration. Do not use if the package is damaged or past expiration. This single-use device cannot be reused on another patient, as it is not designed to withstand cleaning/sterilization. Reuse may cause injury or illness due to loss of chemical characteristics introduced under conditions of repeated use, cleaning, and / or resterilization may compromise the integrity of the design and / or materials, leading to device malfunction and failure. Reuse may also pose a contamination risk to the performance of the device. Absence of original labeling may lead to misuse and attendant traceability. Absence of original packaging may lead to device damage, loss of sterility, and risk of injury to the patient and / or user.

Contents – One (1) guide wire per pouch.

Size – 0.014 inch (0.36 mm) diameter.

Coating – Hydrophilic coating.

Guidewire – Intended to facilitate navigation across vascular anatomies and structures in order to deliver diagnostic and therapeutic devices.

INDICATIONS FOR USE

HI-TORQUE™ Guide Wires are indicated to facilitate the delivery of catheter-based interventional devices during PTCA and PTA. This guide wire may be used with percutaneous transluminal angioplasty catheters, stents, and other devices that are designed to reach and cross a stenged lesion, provide a pathway within the vessel structure, facilitate the substitution of one diagnostic or interventional device for another, and to distinguish between vessel branches. This guide wire is not to be used to cross or assist in crossing an intact chronic total coronary occlusion (CTO).

CONTRAINDICATIONS

Not indicated for use in the cerebral vasculature.

WARNINGS

This device is not designed for use with atherectomy devices. The safety and effectiveness of the use of this HI-TORQUE™ Guide Wire with atherectomy devices has not been established.

The lifetime of this device is the indicated shelf life. This device is designed and intended to ONE-TIME USE ONLY. Do not resterilize and / or reuse. The safety and effectiveness of this device have not been established after being reprocessed for multiple uses.

If a guide wire is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation.

This device has a hydrophilic coating at the distal end of the device for a length of 25 cm. The proximal section of the wire is coated with polytetrafluoroethylene (PTFE) and a single coil of 304L/316L SS **"also called MERIFLEX®"** **Hydrophilic coating is not applied to the proximal section of the wire. Use caution when the HI-TORQUE™ Guide Wire is used with the HI-TORQUE™ Introducer, because the PTFE coated proximal section of the wire may be slippery. Hydrophilic coating may cause a loss of 0.5 to 1 inch of the distal end of the guide wire, and this portion of the guide wire may be left in the patient's vasculature. Use caution when the HI-TORQUE™ Guide Wire is used with a Rotating Hemostasis Valve (RHV), because the RHV may cause a loss of hydrophilic coating. Do not withdraw or manipulate the hydrophilic-coated wire through a metal introducer, because the hydrophilic coating may be damaged. Do not use if the hydrophilic coating is damaged and / or is not hydrophilic. Do not resterilize or reuse. Do not use if the hydrophilic coating may cause coating material to remain in the vasculature. This is turn may lead to embolized material causing vascular occlusion and injury.**

When well, a hydrophilic coating increases the lubricity of the guide wire surface. Hydrophilic coating may be damaged if the device is touched with bare hands or other material. Use care when handling the device. Do not touch the coated surface with bare hands. The coating swells when exposed to aqueous media, but does not have any impact on device size.

The integrity and performance of the device coating can be negatively impacted by preparation with incompatible media or solvents. Take note of the following incompatibilities:

- Avoid wiping the device with dry gauze as this may damage the device coating. Remove excess fluid with a moist gauze or sponge.
- Avoid using alcohol, antiseptic solutions, or other cleaners (e.g., use of medicated and citrisfoam) to pre-treat the device because this may cause unpredictable changes in the coating which could negatively affect the safety and performance of the guide wire.

Attempting to alter the shape of devices by bending, twisting, or similar methods beyond instructor methods may compromise the coating's integrity, and that damage to the coating may not always be noticeable to the naked eye.

Use care when manipulating the device through the following substances defined as "Not to be Used" in a comparative study of Hydrophilic Coated Guide Wire Interaction Devices (ATCC No. 7468-48-4): Ext. Tec 2010-1.

Current scientific evidence suggests that medical devices manufactured from stainless steel alloys containing chromium do not cause an increased risk of cancer or adverse reproductive effects.

After use, this product has the potential to contain biological hazards and disposal of it in accordance with its intended medical practice and applicable local, state, and federal laws and regulations.

ADVERSE EVENTS

Potential adverse events associated with use of this device may include the following, but not limited to:

- Allergic reaction or hypersensitivity to latex, contrast agent, drugs, device materials, and drug reactions to medications or antiplatelet drugs
- Perforation
- Dissection
- Bleeding
- Stenosis / restenosis
- Thrombosis
- Arrhythmia
- Myocardial infarction
- Embolism
- Air fistula
- Coronary / pseudoaneurysm
- Infection
- Vasoconstriction
- Vasospasm
- Hypotension
- Hypertension
- Hematoma
- Pain

REPORTING OF ADVERSE EVENTS

The year and / or patient should report any serious incident that has occurred in relation to this HI-TORQUE™ Guide Wire to the manufacturer and the competent authority of the European Member State in which the user and / or patient is established.

EVALUATION OF HI-TORQUE™ FOR VASCULAR WORK: / HI-TORQUE PILOT™ ANGIOGRAPHIC EVALUATION PROCEDURE

Twenty (20) patients with coronary or peripheral artery disease as specified in the indications section of these instructions. These devices are clinicalle guide wires available in several lengths and diameters and have a shapable distal tip. Refer to the product label for product specifications (e.g., wire length, diameter, and weight (g) of the distal tip).

Coronary guide wires (including PCA and PTA, which offer clinical benefits for the treatment of coronary artery disease (CAD) and multiple types of diseases in peripheral vessels).

HI-TORQUE Extensions Guide Wires: HI-TORQUE Guide Wires have a hydrophilic polymer and that permits the attachment of the HI-TORQUE™ Guide Wire Extension. Refer to the product label for product specifications (e.g., wire length, diameter, and weight (g) of the Extension). The Extension is the guide wire extension that is intended to be connected to another, while maintaining guide wire position in the anatomy. After the interventional device has been exchanged for the HI-TORQUE™ Guide Wire, the extension can be detached and the guide wire can be used in its original capacity.

2014-16 PCR Guide Wires with Polymer Materials: Brachial and femoral markers located on the proximal segment of the 0.014" (0.36 mm) guide wire set to gauge guide wire position relative to the guiding catheter by when using bare wire technique. Distal markers located on the distal segment of the guide wire set at least 30 cm (brachial) or 100 cm (femoral) long.

HI-TORQUE Guide Wires with Distal Radiopaque Markers: Some HI-TORQUE Guide Wires have distal radiopaque markers. The distal radiopaque markers are used to determine the proximal and distal location of the markers. Markers are represented by the following designation: ■ X series of spaced markers are provided proximal to the coil as reference to distinguish lesion length.

HI-TORQUE Guide Wires with Hydrophilic Coating: Refer to the product label for presence of a hydrophilic coating.

HOW TO USE

Sterile – Sterilized with electron-beam radiation. Refer to the product label for the sterilization method/dose/expiration. Do not use if the package is damaged or past expiration.

This single-use device cannot be reused on another patient, as it is not designed to withstand cleaning/sterilization. Reuse may cause injury or illness due to loss of chemical characteristics introduced under conditions of repeated use, cleaning, and / or resterilization may compromise the integrity of the design and / or materials, leading to device malfunction and failure. Reuse may also pose a contamination risk to the performance of the device. Absence of original labeling may lead to misuse and attendant traceability. Absence of original packaging may lead to device damage, loss of sterility, and risk of injury to the patient and / or user.

Contents – One (1) guide wire per pouch.

Size – 0.014 inch (0.36 mm) diameter.

Coating – Hydrophilic coating.

Guidewire – Intended to facilitate navigation across vascular anatomies and structures in order to deliver diagnostic and therapeutic devices.

INDICATIONS FOR USE

HI-TORQUE™ Guide Wires are indicated to facilitate the delivery of catheter-based interventional devices during PTCA and PTA. This guide wire may be used with percutaneous transluminal angioplasty catheters, stents, and other devices that are designed to reach and cross a stenged lesion, provide a pathway within the vessel structure, facilitate the substitution of one diagnostic or interventional device for another, and to distinguish between vessel branches. This guide wire is not to be used to cross or assist in crossing an intact chronic total coronary occlusion (CTO).

CONTRAINDICATIONS

Not indicated for use in the cerebral vasculature.

WARNINGS

This device is not designed for use with atherectomy devices. The safety and effectiveness of the use of this HI-TORQUE™ Guide Wire with atherectomy devices has not been established.

The lifetime of this device is the indicated shelf life. This device is designed and intended to ONE-TIME USE ONLY. Do not resterilize and / or reuse. The safety and effectiveness of this device have not been established after being reprocessed for multiple uses.

If a guide wire is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation.

This device has a hydrophilic coating at the distal end of the device for a length of 25 cm. The proximal section of the wire is coated with polytetrafluoroethylene (PTFE) and a single coil of 304L/316L SS **"also called MERIFLEX®"** **Hydrophilic coating is not applied to the proximal section of the wire. Use caution when the HI-TORQUE™ Guide Wire is used with the HI-TORQUE™ Introducer, because the PTFE coated proximal section of the wire may be slippery. Hydrophilic coating may cause a loss of 0.5 to 1 inch of the distal end of the guide wire, and this portion of the guide wire may be left in the patient's vasculature. Use caution when the HI-TORQUE™ Guide Wire is used with a Rotating Hemostasis Valve (RHV), because the RHV may cause a loss of hydrophilic coating. Do not withdraw or manipulate the hydrophilic-coated wire through a metal introducer, because the hydrophilic coating may be damaged. Do not use if the hydrophilic coating is damaged and / or is not hydrophilic. Do not resterilize or reuse. Do not use if the hydrophilic coating may cause coating material to remain in the vasculature. This is turn may lead to embolized material causing vascular occlusion and injury.**

When well, a hydrophilic coating increases the lubricity of the guide wire surface. Hydrophilic coating may be damaged if the device is touched with bare hands or other material. Use care when handling the device. Do not touch the coated surface with bare hands. The coating swells when exposed to aqueous media, but does not have any impact on device size.

Do:

- Advance or withdraw the guide wire slowly.
- Use care when introducing the of the interventional device to confirm position.
- Examine the by movement under fluoroscopy before manipulating, moving, or advancing the device.
- Observe the wire under fluoroscopy for its buckling, which is a sign of resistance.
- Use a continuous flush while removing and reinserting the guide wire to prevent air from entering the catheter/sheath.
- Perform exchanges slowly to prevent an entry and / or trauma.
- When reintroducing the guide wire, confirm that the intervention device tip is free within the vessel lumen and that the tip is parallel to the vessel wall.
- Use care when introducing the guide wire into the hemostasis valve to prevent damage to the tip, which could result in a loss of hydrophilic coating. Use of this technique involves additional patient risks, including the risk that the wire may become embolized and cause injury.
- Consider that if a guide wire is placed in a bifurcated branch, the wire may need to be retracted prior to stent deployment, because there is additional risk of the guide wire being trapped between the stent and the stent.

For the HI-TORQUE PROGRESS™ / Family of Guide Wires only:

Use the HI-TORQUE PROGRESS™ Guide Wire with the 2 distal ends of varying stiffness. Operate these guide wires carefully so as to not injure the blood vessel. Improper use of the HI-TORQUE PROGRESS™ Guide Wire may result in damage to either distal end, and / or higher advancement force may present a higher risk of perforation or injury than a guide wire with a more pliable distal end. Therefore, the HI-TORQUE PROGRESS™ Guide Wire should be used only by physicians who are extreme care to minimize the risk of perforation or other injury to blood vessel.

LIMITATIONS

Since HI-TORQUE™ Guide Wires do not have a specific limitation in duration of use but are designed for vascular procedures that vary in duration depending on lesion complexity, Percutaneous transluminal coronary angioplasty (PTCA) should only be performed at centers where emergency coronary artery bypass graft (CABG) surgery is available.

PRECAUTIONS

Guide wires are delicate instruments and should be handled carefully. Prior to use and during use, inspect the guide wire for any damage, such as kinks or bends in the distal tip or shaft. Do not use if damaged. Do not bend the distal tip of the guide wire may result in vessel damage and / or inadvertent torque response.

Know about the torque device to the modified portion of the proximal end of the guidewire guide wire, otherwise, guide wire damage may occur, preventing the ability to remove the torque device.

HI-TORQUE™ Guide Wires are intended to be used with fluoroscopic observation. Use care when introducing the hydrophilic-coated wire through a metal introducer, because the hydrophilic coating may be damaged. Do not use if the hydrophilic coating is damaged and / or is not hydrophilic. Do not resterilize or reuse. Do not use if the hydrophilic coating may cause coating material to remain in the vasculature. This is turn may lead to embolized material causing vascular occlusion and injury.

Hydrophilic coated guide wires may be slippery when wet. Use care when handling the device. Do not touch the coated surface with bare hands.

Hydrophilic coated guide wires may cause a loss of the distal tip of the guide wire, and this portion of the guide wire may be left in the patient's vasculature. Use care when introducing the device into the hemostasis valve, because this may damage the distal tip of the guide wire. Use care when using a Rotating Hemostasis Valve (RHV), because the RHV may cause a loss of hydrophilic coating. Use care when using a Rotating Hemostasis Valve (RHV), because the RHV may cause a loss of hydrophilic coating.

Hydrophilic coated guide wires may cause a loss of the distal tip of the guide wire, and this portion of the guide wire may be left in the patient's vasculature

TOTAL LENGTH of piece is 37-15/16"

5-1/2" | 5-7/16" | 5-3/8" | 5-7/16" | 5-7/16" | 5-3/8" | 5-3/8"

6-5/8"

6-13/16"

TOTAL HEIGHT of piece is 13-7/16"

HI-TORQUE™ Guide Wire

PPL2124035-04 (2021-11-01)

Rx ONLY

2797

CAUTIONS

This medical device should be used only by physicians trained in angiography and percutaneous transluminal coronary angioplasty (PTCA), and / or percutaneous transluminal angioplasty (PTA).

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

Refer to the instructions supplied with any interventional devices to be used in conjunction with the HI-TORQUE™ Guide Wire, for their intended uses, contraindications, and potential complications.

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English

HI-TORQUE™ Guide Wire

CAUTIONS

This medical device should be used only by physicians trained in angiography and percutaneous transluminal coronary angioplasty (PTCA), and / or percutaneous transluminal angioplasty (PTA).

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

A summary of the safety and clinical performance (SSCP) for this device is available at https://ec.europa.eu/tools/eudamed. Search for the device using the Basic UDI-DI provided in Table 1. This is the SSCP location after the launch of the European Medical Device Information System (EUDAMED).

This instructions for use are for European Regulation (EU) 2017/745 can be found on the Abbott Vascular website, at www.abbottvascular.com.

DESCRIPTION

This Instructions for Use pertains to the HI-TORQUE PROGRESS™ 40, HI-TORQUE PROGRESS 60, HI-TORQUE PROGRESS 120, HI-TORQUE PROGRESS 140T, and HI-TORQUE PROGRESS 200T Guide Wires.

CONTRAINDICATIONS

Not indicated for use in the cerebral vasculature.

WARNINGS

This device is not designed for use with atherectomy devices. The safety and effectiveness of the use of this HI-TORQUE™ Guide Wire with atherectomy devices has not been established.

The lifetime of the device is the intended shelf life. This device is designed and intended for ONE-TIME USE ONLY. Do not resterilize and / or reuse. The safety and effectiveness of this device have not been established after being reprocessed for multiple use.

Use of a guide wire is exposed to the vascular system, it should be manipulated while under high vision (fluoroscopy).

This device has a hydrophilic coating at the distal end of the device for a length of 25 cm. The proximal section of the 25 cm is coated with polytetrafluoroethylene (PTFE) and a single coat of SERVOSYL™ silicon (after MICROGLIDE™ hydrophilic coating). The remaining proximal section is coated with PTFE and SERVOSYL™. The 40 cm for 140 cm guide wires, and 20.5 cm for 200 cm guide wires, and the PTFE is coated at the proximal end for a length of 14.5 cm for 140 cm guide wires, and 12 cm for 200 cm guide wires.

Use the PROTECTOR® 150 guidewire for further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the instructions for use provided with the PROTECTOR® 150 guidewire, which may necessitate intervention or result in serious adverse events.

The safety and effectiveness of the device have not been established, or is unknown, in certain regions other than those specifically indicated.

Pieces with lesions totally or adjacent to any of the components of this device should not be implanted. If a lesion is found on any part of the device after it is pulled, the patient should be consulted on the medical consideration of the device and a thorough history of allergies must be discussed. This device contains platinum-iridium, 316L stainless steel, nickel-titanium, and a polymer-based hydrophilic coating. Use caution when using adhesive, MICROGLIDE™ Green Lubricating Coating, proprietary solvent, PTFE coating, and PTFE coating.

Carefully inspect the instructions under "Do Not" and "Do" below. **Failure to do so may result in vessel trauma, guide wire damage, guide wire tip separation, or short detached fragments in vessel or any item. Determine the cause under fluoroscopy and take remedial action as needed. Use the most suitable guide wire for the procedure.**

Do Not

- Push, auger, withdraw or torque a guide wire that meets resistance.
- Torque a guide wire if the tip is not pointed in the desired direction.
- Allow the guide wire tip to remain in a polypropylene container.
- Use a guide wire that is self-entering into any lesion between the vessel and the stent.

Do

- Advance or withdraw the guide wire slowly.
- Use the subtracter mode of the interventional device to confirm position.
- Examine the by movement under fluoroscopy before manipulating, moving, or advancing the device.
- Observe the wire under fluoroscopy for tip buckling, which is a sign of resistance.
- Use continuous flush while removing and remoulding the guide wire to prevent air from entering the catheter/sheath.
- Perform exchanges slowly to prevent air entry and / or trauma.
- When remoulding the guide wire, confirm that the intervention device tip is free within the vessel lumen and that the tip is parallel to the vessel wall.
- Remove the guide wire from the patient before using other accessories, such as stent, or through stent struts, to avoid damage to the device. Use of the fluoroscopic involves additional patient risks, including the risk that the wire may become damaged and / or fragments.
- Consider that if a guidewire is used in a patient with a bioprosthetic heart valve, there may need to be retrieved prior to stent deployment, because there is additional risk of the guidewire being entrapped between the bioprosthetic leaflets and the stent.

For the HI-TORQUE PROGRESS™ Family of Guide Wires only:

**For the HI-TORQUE PROGRESS™ Family of Guide Wires have distal ends of varying stiffness. Operate these guide wires carefully so as to not injure the blood vessel. Operate the guide wire with the distal end pointed in the direction of the desired coronary artery. Use caution when using the HI-TORQUE PROGRESS™ Guide Wire with a guide wire that has a more pliable distal end. Therefore, it may be necessary to use a guide wire with a more pliable distal end. Therefore, it may be necessary to use a guide wire with a more pliable distal end. Therefore, it may be necessary to use a guide wire with

TOTAL LENGTH of piece is 37-15/16"

5-1/2" | 5-7/16" | 5-3/8" | 5-7/16" | 5-3/8" | 5-3/8"

6-5/8" | 6-13/16" | 6-5/8"

TOTAL HEIGHT of piece is 13- 7/16"

FRONT SIDE OF PIECE

INSIDE OF PIECE

Fold template along this center line to view the piece backed-up.

Abbott

HI-TORQUE™ Guide Wire

PPL2124035-05 (2021-11-01)

Rx ONLY

CE 2797

CAUTIONS

This medical device should be used only by physicians trained in angiography and percutaneous transluminal coronary angioplasty (PTCA), and / or percutaneous transluminal angioplasty (PTA).

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

Refer to the instructions supplied with any interventional devices to be used in conjunction with the HI-TORQUE™ Guide Wire, for their intended uses, contraindications, and potential complications.

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English

HI-TORQUE™ Guide Wire

CAUTIONS

This medical device should be used only by physicians trained in angiography and percutaneous transluminal coronary angioplasty (PTCA), and / or percutaneous transluminal angioplasty (PTA).

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

Refer to the instructions supplied with any interventional devices to be used in conjunction with the HI-TORQUE™ Guide Wire, for their intended uses, contraindications, and potential complications.

HOW SUPPLIED:

Sterile – Sterilized with electron-beam radiation. Refer to the product label for the sterilization method (ethylene oxide, steam, or electron-beam). Do not resterilize.

This single-use device cannot be reused on another patient, as it is not designed to withstand cleaning or sterilization. Reprocessing may cause the device to fail due to chemical characteristics introduced under conditions of repeated use, cleaning, and / or resterilization may compromise the integrity of the design and / or materials, leading to device malfunction and failure. Such failure may result in complications, such as performance of the device. Absence of original labeling may lead to misuse and attributable liability. Absence of original packaging may lead to device damage, loss of sterility, and risk of injury to the patient and / or user.

Contents – One (1) guide wire per pouch.

Size – Refer to the product label for guide wire diameter.

INTENDED USE:

The device is intended to facilitate navigation across vascular anatomies and structures in order to deliver diagnostic and therapeutic devices.

INDICATIONS FOR USE

HI-TORQUE™ Guide Wires are indicated to facilitate the delivery of catheter-based interventional devices during PTCA and PTA. This guide wire may be used with balloon dilatation catheters, stent delivery systems, and other devices designed to reach and cross a target lesion, provide a pathway within the vessel structure, facilitate the substitution of one diagnostic or interventional device for another, and to distinguish between vessel and other structures. It may also be used to cross or assist in crossing vessel chronic total occlusions (CTO).

CONTRAINDICATIONS

Not indicated for use in the cerebral vasculature.

WARNINGS

This device is not designed for use with atherectomy devices. The safety and effectiveness of the use of this HI-TORQUE™ Guide Wire with atherectomy devices has not been established.

The lifetime of the device is the intended shelf life. This device is designed and intended to ONE-TIME USE ONLY. Do not resterilize and / or reuse. The safety and effectiveness of this device have not been established after being reprocessed for multiple use.

If a guide wire is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation.

This device has a hydrophilic coating at the distal end of the device for a length of 25 cm. The proximal section of the wire is coated with polytetrafluoroethylene (PTFE) and a single coat of SERPERA™ 3101 coat (other MEDSLIDE™ hydrophilic coatings may be applied to the proximal section of the wire). Do not use if the coating has lost its luster or has cracked, and 25 cm for 300 cm guide wires, and 35 cm for 260 cm guide wires, and 25 cm for 200 cm guide wires, and the PTFE coated is at the proximal end for a length of 143 cm for 190 cm guide wires, and 143 cm for 300 cm guide wires, and 143 cm for 260 cm guide wires.

Refer to PRECAUTIONS (GS) section for further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the instructions may result in damage to the device, such as kinking, which may necessitate intervention or result in serious adverse events.

The safety and effectiveness of the device have not been established, or is unknown, in the following vascular beds or lesion specifically indicated:

Percus with lesions involving or adjacent to any of the components of this device (such as the radiopaque markers, the distal tip, the PTFE coated, the SERPERA™ 3101 film Extension) in the guide wire functions the exchange of one interventional device for another, while maintaining guide wire position in the anatomy. After the interventional device has been exchanged for the desired, the extension can be detached and the guide wire can be used in its original capacity.

2014-16 TORQUE Guide Wire with Polymer Markers: Brachial and femoral markers located on the proximal segment of the 0.014" (0.36 mm) guide wire set to geographic guide wire position relative to the guiding catheter by when using bare wire technique. Markers are radiopaque and are visible under fluoroscopy (markers are at least 60 cm from the tip).

HI-TORQUE Guide Wires with Distal Radiopaque Markers: Some HI-TORQUE Guide Wires have distal radiopaque markers. The distal radiopaque markers are used to determine the proximal end location of the markers. Markers are represented by the following designation: ■ X series of spaced markers are provided proximal to the coil as references in determining lesion length.

HI-TORQUE Guide Wires with Hydrophilic Coating: Refer to the product label for presence of a hydrophilic coating.

The integrity and performance of the device coating can be negatively impacted by preparation with incompatible media or solvents. Take note of the following recommendations:

- Avoid wiping the device with dry gauze as this may damage the device coating. Instead, remove excess fluid with wet gauze.
- Avoid using alcohol, antiseptic solutions, or other solvents (e.g., use of medicated and vitrifiedh to pre-treat the device because this may cause unpredictable changes to the coating which could negatively affect the safety and performance of the guide wire.

Attempting to alter the shape of devices by bending, twisting, or similar methods beyond instructor methods may compromise the coating's integrity and that damage to the coating may not always be noticeable to the eye.

Before using the device, carefully inspect the following substances defined as "Incompatible" in the Compatibility Table: Polyvinyl Chloride (PVC), Acrylonitrile Butadiene Styrene (ABS) No. 1440-48-4; CE No. 231-156-6.

Current scientific evidence suggests that medical devices manufactured from stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.

Take care, when placing the proximal end of the guide wire into the hub of the guide wire in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

ADVERSE EVENTS

Potential adverse events associated with use of this device may include the following, but are not limited to:

- Allergic reactions or hypersensitivity
- Bleeding
- Coagulation
- Dissection
- Embolism
- Fever
- Hematoma
- Hemorrhage
- Infection
- Inflammation
- Myocardial infarction
- Pain
- Pancreatitis
- Pseudoaneurysm
- Pulmonary edema
- Sepsis
- Stenosis / restenosis
- Thrombosis
- Vasoconstriction
- Vasospasm
- Vessel perforation
- Vessel rupture
- Vessel occlusion
- Hypotension
- Hypertension
- Tachycardia
- Arrhythmia
- Death

REPORTING OF ADVERSE EVENTS

The year and / or patient unique serious adverse event (SAE) that has occurred in relation to this HI-TORQUE™ Guide Wire to the manufacturer and the competent authority of the European Member State in which the user and / or patient is established.

EVALUATION OF HI-TORQUE™ GUIDE WIRES / HI-TORQUE PILOT™ HI-TORQUE PROGRESS™ GUIDE WIRES

Twenty (20) Guide Wires were evaluated to determine if they met specifications, and, therefore, the HI-TORQUE™ Guide Wire / HI-TORQUE PILOT™ Guide Wire / HI-TORQUE PROGRESS™ Guide Wire was specifically evaluated for the following: EXPERT CTO clinical trial.

Clinical Performance Evaluation

Data for EXPERT CTO: Data for the guide wire-related effectiveness of the study, is-treated CTO lesions, HI-TORQUE™ Guide Wire, HI-TORQUE PILOT™ Guide Wire, HI-TORQUE PROGRESS

TOTAL LENGTH of piece is 37-15/16"

5-1/2" | 5-7/16" | 5-3/8" | 5-7/16" | 5-7/16" | 5-3/8" | 5-3/8"

TOTAL HEIGHT of piece is 13- 7/16"

6-5/8" | 6-13/16" | 6-13/16" | 6-5/8"

INSIDE OF PIECE

FRONT SIDE OF PIECE

Fold template along this center line to view piece backed-up.

Fold template along this center line to view piece backed-up.

Fold template along this center line to view piece backed-up.

English

HI-TORQUE™ Guide Wire

CAUTIONS

This medical device should be used only by physicians trained in angiography and percutaneous transluminal coronary angioplasty (PTCA), and / or percutaneous transluminal angioplasty (PTA).

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

Refer to the instructions supplied with any interventional devices to be used in conjunction with the HI-TORQUE™ Guide Wire, for their intended uses, contraindications, and potential complications.

Abbott Medical
3200 Lakeside Drive
Santa Clara, CA 95054 USA
CUSTOMER SERVICE
TEL: (800) 227-9902
FAX: (800) 671-8674
Outside USA TEL: +1 951-914-4669
Outside USA FAX: +1 951-914-4699

EC REP
Abbott Vascular International BVBA
Park Lane, Culliganlaan 2B
1831 Diegem, BELGIUM
TEL: +32 2 714 54 11
FAX: +32 2 714 54 12

Fold template along this center line to view piece backed-up.

HI-TORQUE™
Guide Wire

PPL212403S-06 (2021-11-01)

℞ ONLY

CE 2797

Caracteristicas de las guias

	Guiaos OTT para el sistema de valoración principal de la guia (N = 108 guiaos).
Guiaos los guias del estudio (por guiaos)	108/0 (1.00/0.00)
1 guia del estudio utilizada	101/5 (1/1/38)
2 guias del estudio utilizadas	5/1/0 (1/1/38)
3 guias del estudio utilizadas	1/0/0 (1/1/38)
4 o mas guias del estudio utilizadas	1/0/0 (1/1/38)
5 o mas guias del estudio utilizadas	1/0/0 (1/1/38)
Guias de repuesto utilizadas (por guiaos)	0/0/0 (1/1/38)
1 dispositivo de recanalización utilizado	10/0/0 (1/1/38)
2 o mas dispositivos de recanalización utilizados	10/0/0 (1/1/38)
Guia introducida correctamente en la lesion (a mas de 2cm)	98/2/0 (1.00/1.00)
Guia introducida correctamente en la lesion	98/0/0 (1.00/1.00)
Guia no perforadora del estudio introducida correctamente en la lesion**	98/0/0 (1.00/1.00)
Otros dispositivos de recanalización introducidos en la lesion	50/0/0 (1.00/1.00)
Fracaso de la guia del estudio (a nivel de guia)	3/4/3 (0/0/1.00)
Perforación	0/0/0 (0/0/1.00)
Introducción	0/0/0 (0/0/1.00)
Otros motivos	1/3/0 (0/0/1.00)
Metodos de introducción de la guia*	
Solo antegrado***	81/0/0 (1.00/0.00)
Introducción antegrada (o metodo de microcanal)	70/0/0 (1.00/1.00)
SSMA	0/0/0 (1.00/1.00)
Técnica Kissoka-wire	0/0/0 (1.00/1.00)
Guia doble	0/0/0 (1.00/1.00)
Solo retrogrado	13/0/0 (0.00/1.00)
Introducción retrograda	0/0/0 (0.00/1.00)
Tecnica Kissoka-wire	1/1/0 (0.00/1.00)
Guia antegrado/retrogrado combinado	0/0/0 (0.00/1.00)
CART	0/2/0 (0.00/1.00)
CART inverso	2/1/0 (0.00/1.00)
Tecnica Kissoka-Wire	0/0/0 (0.00/1.00)
Otros	2/1/0 (0.00/1.00)
Subintimal	1/1/0 (0.00/1.00)
Disección antegrada y metodo de reentrada	0/0/0 (0.00/1.00)
Disección retrograda	0/0/0 (0.00/1.00)

* El número de guiaos incluye el número de guiaos del estudio, el número de guiaos de recanalización y el número de guiaos de valoración principal. Los porcentajes se basan en los guiaos con los que se intento observar la lesion, según la función especificada

** La lesion se atravesó correctamente con los guias en el sujeto 29-M06-0001, pero no se especificó el motivo para este caso.

Indications

Sterile – Sterilized with electron-beam radiation. Refer to the product label for the sterilization method. Non-pyrogenic. Do not reuse. Do not re-sterilize. Do not reuse if package is damaged. This single-use device cannot be reused on another patient, as it is not designed to withstand cleaning or sterilization. Reusing this device may lead to a loss of its chemical characteristics irrelevant under conditions of repeated use, cleaning, and / or resterilization may compromise the integrity of the design and / or materials, leading to device malfunction and / or failure, which may result in complications and / or delay in performance of the device. Absence of original labeling may lead to misuse and attendant traceability. Absence of original packaging may lead to device damage, loss of sterility, and risk of injury to the patient and / or user.

Contents – One (1) guide wire per pouch.

Description – The HI-TORQUE™ Guide Wire is a flexible, solid, coated, stainless steel, or through steel shaft, into a fabricated tubular. One of the HI-TORQUE™ Guide Wire offers a distinctive feature, including the risk that the wire may become entangled in the lesion.

INDICATIONS FOR USE

The HI-TORQUE™ Guide Wires are indicated to facilitate the delivery of catheter-based interventional devices during PTCA and PTA. This guide wire may be used with angiographic equipment to provide a pathway for the delivery of a dilatation catheter to reach and cross a target lesion, provide a pathway within the vessel structure, facilitate the substitution of one diagnostic or interventional device for another, and to distinguish anatomical structures. The guide wire may also be used to cross or assist in crossing an intra chronic total coronary occlusion (CTO).

CONTRAINDICATIONS

Not indicated for use in the cerebral vasculature.

WARNINGS

This device is not designed for use with atherectomy devices. The safety and effectiveness of the use of this HI-TORQUE™ Guide Wire with atherectomy devices has not been established.

The lifetime of the device is the intended shelf life. This device is designed and intended to ONLY FIRE USE ONCE. Do not resterilize and / or reuse. The safety and effectiveness of this device have not been established after being reprocessed for multiple use.

Use of a guide wire is exposed to the vascular system, it should be manipulated while under high vision, fluoroscopic visualization.

This device has a hydrophilic coating at the distal end of the device for a length of 25 cm. The proximal section of the wire is coated with polytetrafluoroethylene (PTFE) and a single coat of SERVOLUBE™ lube called MEDRALUBE™ Hydrophilic Lubricant. The distal section of the wire is coated with a single coat of SERVOLUBE™ lube for 100 cm guide wires, and 263 cm for 300 cm guide wires, and the PTFE is coated at the proximal end for a length of 143 cm for 190 cm guide wires, and 343 cm for 300 cm guide wires.

Refer to PREPARATION FOR USE section for further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the instructions may result in device failure, loss of lesion crossing, loss of lesion accessibility, intravascular or vessel or serious adverse events.

The safety and effectiveness of the device have not been established, or is unknown, in vascular regions other than those specifically indicated.

Persons with known history of allergies to any of the components of this device should not use this device. Refer to the Medical Device Report (MDR) section of this Instructions for Use (IFU) for information on the materials contained in the device and a thorough history of allergies must be discussed. This device contains platinum-iridium, 316L stainless steel, nickel-titanium, and a hydrophilic polymer coating with urethane, epoxy adhesive, MEDRALUBE™ Hydrophilic Coating, polytetrafluoroethylene (PTFE) coating, and PTFE coating.

Carefully follow the instructions for "Preparation" and "Use" listed below to do as you may result in vessel trauma, guide wire damage, guide wire tip separation, or short damage. If resistance is observed at any time, determine the cause under fluoroscopy and take remedial action as needed. Use the most suitable guide wire for the lesion being treated.

Do not

- Push, auger, withdraw or torque a guide wire that meets resistance.
- Torque a guide wire if the tip becomes entrapped within the vasculature.
- Allow the guide wire tip to remain in a prolapsed condition.
- Advance a short bent curve that is will entrap the wire between the vessel wall and the stent.

Do

- Advance or withdraw the guide wire slowly.
- Use the colliquate marker of the interventional device to confirm position.
- Examine the by movement under fluoroscopy before manipulating, moving, or advancing the device.
- Observe the wire under fluoroscopy for tip buckling, which is a sign of resistance.
- Withdraw the guide wire without fully while removing and remounting the guide wire to prevent an knee entering the catheter opening.
- Perform exchanges slowly to prevent an entry and / or trauma.
- When remoistening the guide wire, confirm that the intervention device tip is free within the vessel lumen and that the tip is parallel to the vessel wall.
- Use extreme caution when crossing a stent with a guide wire, balloon catheter, or stent, or through stent struts, into a bifurcated vessel. Use of this technique involves additional patient risks, including the risk that the wire may become entangled in the stent struts.
- Consider that if a secondary wire is placed in a bifurcated branch, the wire may need to be retracted prior to stent deployment, because there is additional risk of the secondary wire being entrapped between the vessel wall and the stent.

For the HI-TORQUE PROGRESS™ Family of Guide Wires only:
The HI-TORQUE PROGRESS™ Family of Guide Wires have distal ends of varying stiffness. Operate these guide wires carefully so as to not injure the blood vessel. Operate the HI-TORQUE PROGRESS™ Family of Guide Wires with the softer end of the stiffer distal ends, and / or higher stiffness/torque ratio may prevent a physician or a permeator or injury from a guide wire with a more pliable distal end. Therefore, the softer end of the stiffer distal ends, and / or higher stiffness/torque ratio, is a common case to sensitive to and particularly at risk damage to blood vessel.

LIMITATIONS

These HI-TORQUE™ Guide Wires do not have a specific limitation in duration of use but are designed for vascular procedures that vary in duration depending on lesion complexity.

Percutaneous transluminal coronary angioplasty (PTCA) should only be performed at centers where emergency coronary artery bypass graft (CABG) surgery is available.

PRECAUTIONS

Guide wires are delicate instruments and should be handled carefully. Prior to use and during insertion, inspect the guide wire for any damage. Do not use if damage is found or damage. In case of damage, discontinue use and replace with a new sterile product to vessel damage and / or inaccurate torque response.

Never attach the torque device to the proximal end of the guidewire and, otherwise, grasp the guide wire with gloved hands, since this may occur, preventing the ability to control the guide wire.

If Carefully Guide Wire Operation, Do not force the guide wire in Failure to abide by the above recommendation may result in sole mismatch of blood vessel and guide wire, which can lead to vessel trauma and / or damage to the guide wire. Discontinue its utilization if such occurs.

The safety and effectiveness of this HI-TORQUE™ Guide Wire have not been established in the pediatric population.

Free movement of the guide wire within the interventional device is an important feature of the system. Inadequate movement of the guide wire may indicate a problem with the system for any intelligent device interaction and / or. Adjust or replace if any interaction or adjustable value if it is found to impair adjustable wire movement. It is recommended that the guide wire be advanced and retracted in small increments to prevent damage to the distal end. Do not advance the guide wire against resistance without first determining the cause of the procedure.

Never attach the torque device to the modified portion of the proximal end of the adjustable guide wire; otherwise, guide wire damage may occur, preventing the ability to control the guide wire.

If Carefully Guide Wire Operation, Do not force the guide wire in Failure to abide by the above recommendation may result in sole mismatch of blood vessel and guide wire, which can lead to vessel trauma and / or damage to the guide wire. Discontinue its utilization if such occurs.

The safety and effectiveness of this HI-TORQUE™ Guide Wire have not been established in the pediatric population.

Do not

- Push, auger, withdraw or torque a guide wire that meets resistance.
- Torque a guide wire if the tip becomes entrapped within the vasculature.
- Allow the guide wire tip to remain in a prolapsed condition.
- Advance a short bent curve that is will entrap the wire between the vessel wall and the stent.

Do

- Advance or withdraw the guide wire slowly.
- Use the colliquate marker of the interventional device to confirm position.
- Examine the by movement under fluoroscopy before manipulating, moving, or advancing the device.
- Observe the wire under fluoroscopy for tip buckling, which is a sign of resistance.
- Withdraw the guide wire without fully while removing and remounting the guide wire to prevent an knee entering the catheter opening.
- Perform exchanges slowly to prevent an entry and / or trauma.
- When remoistening the guide wire, confirm that the intervention device tip is free within the vessel lumen and that the tip is parallel to the vessel wall.
- Use extreme caution when crossing a stent with a guide wire, balloon catheter, or stent, or through stent struts, into a bifurcated vessel. Use of this technique involves additional patient risks, including the risk that the wire may become entangled in the stent struts.
- Consider that if a secondary wire is placed in a bifurcated branch, the wire may need to be retracted prior to stent deployment, because there is additional risk of the secondary wire being entrapped between the vessel wall and the stent.

For the HI-TORQUE PROGRESS™ Family of Guide Wires only:
The HI-TORQUE PROGRESS™ Family of Guide Wires have distal ends of varying stiffness. Operate these guide wires carefully so as to not injure the blood vessel. Operate the HI-TORQUE PROGRESS™ Family of Guide Wires with the softer end of the stiffer distal ends, and / or higher stiffness/torque ratio may prevent a physician or a permeator or injury from a guide wire with a more pliable distal end. Therefore, the softer end of the stiffer distal ends, and / or higher stiffness/torque ratio, is a common case to sensitive to and particularly at risk damage to blood vessel.

LIMITATIONS

These HI-TORQUE™ Guide Wires do not have a specific limitation in duration of use but are designed for vascular procedures that vary in duration depending on lesion complexity.

Percutaneous transluminal coronary angioplasty (PTCA) should only be performed at centers where emergency coronary artery bypass graft (CABG) surgery is available.

PRECAUTIONS

The safety and effectiveness of the device have not established in the pediatric population.

Free movement of the guide wire within the interventional device is an important feature of the system. Inadequate movement of the guide wire may indicate a problem with the system for any intelligent device interaction and / or. Adjust or replace if any interaction or adjustable value if it is found to impair adjustable wire movement. It is recommended that the guide wire be advanced and retracted in small increments to prevent damage to the distal end. Do not advance the guide wire against resistance without first determining the cause of the procedure.

Never attach the torque device to the modified portion of the proximal end of the adjustable guide wire; otherwise, guide wire damage may occur, preventing the ability to control the guide wire.

If Carefully Guide Wire Operation, Do not force the guide wire in Failure to abide by the above recommendation may result in sole mismatch of blood vessel and guide wire, which can lead to vessel trauma and / or damage to the guide wire. Discontinue its utilization if such occurs.

The safety and effectiveness of this HI-TORQUE™ Guide Wire have not

TOTAL LENGTH of piece is 37-15/16"

5-1/2" | 5-7/16" | 5-3/8" | 5-7/16" | 5-7/16" | 5-3/8" | 5-3/8"

TOTAL HEIGHT of piece is 13- 7/16"

6-5/8" | 6-13/16" | 6-13/16" | 6-5/8"

INSIDE OF PIECE

English

HI-TORQUE™ Guide Wire

CAUTIONS

This medical device should be used only by physicians trained in angiography and percutaneous transluminal coronary angioplasty (PTCA), and / or percutaneous transluminal angioplasty (PTA).

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

Refer to the instructions supplied with any interventional devices to be used in conjunction with the HI-TORQUE™ Guide Wire, for their intended uses, contraindications, warnings, and precautions.

A summary of the safety and clinical performance (SSCP) for this device is available at https://ec.europa.eu/tools/eudamed. Search for the device using the Basic UDI-DI provided in Table 1. This is the SSCP location after the launch of the European Medical Device Information System (Eudamed).

This instructions for Use are as per European Regulation (EU) 2017/745 can be found on the Abbott eLabeling website at www.abbottvascular.com/eu

DESCRIPTION

This Instructions for Use pertains to the HI-TORQUE PROGRESS™ 40, HI-TORQUE PROGRESS 80, HI-TORQUE PROGRESS 125, HI-TORQUE PROGRESS 140T, and HI-TORQUE PROGRESS 200T Guide Wires.

Table 1

Product Name	Basic UDI-DI	Sterilization Method
HI-TORQUE PROGRESS 40 Guide Wire		Electron-beam Radiation (R)
HI-TORQUE PROGRESS 80 Guide Wire		
HI-TORQUE PROGRESS 125 Guide Wire	07715149G0000GVH	
HI-TORQUE PROGRESS 140T Guide Wire		
HI-TORQUE PROGRESS 200T Guide Wire		

The HI-TORQUE™ Family of Guide Wires are medical devices that are intended for use in PTCA and PTA to treat patients with coronary or peripheral vascular disease as specified in the indications section of these instructions. These devices are sterilizable guide wires, available in several lengths and diameters and have a disposable distal tip. Refer to the product label for product specifications (e.g., wire length, diameter, and length of tip segment).

Coronary guide wires facilitate PTCA and PTA, which offer clinical benefits for treatment of coronary artery disease (CAD) and multiple types of diseases in peripheral vessels.

HI-TORQUE Guidewire Wires, Some HI-TORQUE Guide Wires have a modified proximal end that permits the attachment of the DOC® Guide Wire Extension. Refer to the Instructions for Use provided with the DOC® Guide Wire Extension. Refer to the Instructions for Use provided with the guide wire Instructions for exchange of one interventional device for another, while maintaining guide wire position in the anatomy. After the interventional device has been exchanged for another, the extension can be detached and the guide wire can be used in its original capacity.

J514 HI-TORQUE Guide Wires with Proximal Markers: Brachial and femoral markers located on the proximal segment of the 0.014" (0.36 mm) guide wire aid in gauging guide wire position relative to the guiding catheter by when using bare wire technique. Refer to the instructions for use for specific guiding catheters that are at least 50 cm. (brachial) or 65 cm (femoral) long.

HI-TORQUE Guide Wires with Distal Radiopaque Markers: Some HI-TORQUE Guide Wires have distal radiopaque markers. These markers are intended to aid in determine the presence and location of the markers. Markers are represented by the following designation: ■ A series of spaced markers are provided proximal to the coil as reference to determine lesion length.

HI-TORQUE Guide Wires with Hydrophilic Coating: Refer to the product label for presence of a hydrophilic coating.

The integrity and performance of the device coating can be negatively impacted by preparation with incompatible media or solvents. Take note of the following precautions:

- Avoid wiping the device with dry gauze as this may damage the device coating.
- Do not immerse the device in any solvent.
- Avoid using alcohol, antiseptic solutions, or other contrast (e.g., use of medications and vitrofluid) to pre-treat the device because this may cause unpredictable changes in the coating which could negatively affect the safety and performance of the guide wire.

Attempting to alter the shape of devices by bending, twisting, or similar methods beyond instructor methods may compromise the coating integrity, and that damage to the coating may not always be noticeable to the naked eye.

Use the following precautions when using the hydrophilic coated guidewires:

- Prepare the hydrophilic coated guidewire according to the manufacturer's instructions.
- Do not use if coating appears damaged.
- Carefully insert the guidewire into the hemostasis valve or other hemostasis device. Do not force the guidewire through the hemostasis valve if resistance is felt. Adjust or replace the hemostasis valve if resistance is felt.
- Do not allow the guidewire to be pushed or withdrawn without lubrication. Lubricate the guidewire as needed. **Lubricant should be consistent with the materials contained in the device and a thorough history of allergies must be discussed. This device contains platinum-iridium, 304 stainless steel, nickel-titanium alloy, gold, polyurethane, polyethylene, silicone, aqueous adhesive, HEUCHERIN (Bovine Collagen), polytetrafluoroethylene (PTFE), coating, and PTFE coating.**
- **Carefully observe the instructions under "Torque" and "Dot" Markers. Failure to do so may result in vessel trauma, guide wire damage, guide wire tip separation, or chest damage. If resistance is observed at any time, determine the cause under fluoroscopy and take remedial action as needed. Use the most suitable guide wire for the lesion being treated.**

Do not

- Push, auger, withdraw or torque a guide wire that meets resistance.
- Torque a guide wire if the tip becomes entrapped within the vasculature.
- Allow the guide wire tip to remain in a prolapsed condition.
- Attempt to twist a kink (bend) in a wire between the vessel wall and the stent.

Do:

- Advance or withdraw the guide wire slowly.
- Use the subtlest torque needed of the interventional device to confirm position.
- Examine the by movement under fluoroscopy before manipulating, moving, or advancing the device.
- Observe the wire under fluoroscopy for tip buckling, which is a sign of resistance.
- Use gentle continuous fluoro while removing and remounting the guide wire to prevent an injury entering the catheter system.
- Perform exchanges slowly to prevent an entry and / or trauma.
- When remoistening the guide wire, confirm that the intervention device tip is free within the vessel lumen and that the tip is parallel to the vessel wall.
- Use caution when using the device in patients with severe calcification, spasm, or, through stent struts, which may cause a fenestrated vessel. Use of this technique involves additional patient risks, including the risk that the wire may become entrapped in the stent.
- Consider that if a guidewire wire is placed in a bifurcation branch, the wire may need to be retracted prior to stent deployment, because there is additional risk that the guidewire wire may become entrapped between the vessel wall and the stent.

For the HI-TORQUE PROGRESS™ Family of Guide Wires only:
The HI-TORQUE PROGRESS Family of Guide Wires have distal ends of varying stiffness. Operate these guide wires carefully so as to not injure the blood vessel. Operate the guide wire with the minimum force required to achieve the desired effect. Use **distal ends, and / or higher maximum torque ratings when greater force is required to overcome a lesion or to cross a lesion with a more pliable distal end. Therefore, **use caution when using the guide wire in a vessel with a lesion that is severe or if extreme care is needed in the risk of perforation or other damage to blood vessel.**

LIMITATIONS

These HI-TORQUE™ Guide Wires do not have a specific limitation in duration of use but are designed for vascular procedures that vary in duration depending on lesion complexity.

Percutaneous transluminal coronary angioplasty (PTCA) should only be performed at centers where emergency coronary artery bypass graft (CABG) surgery is available.

PRECAUTIONS

Guide wires are delicate instruments and should be handled carefully. Prior to use and during the procedure, inspect the device for damage. Do not use if damaged. Damage to the device may result in embolization of fragments. Do not reuse, reprocess, or resterilize. Reuse or resterilization may compromise the integrity of the device and / or materials, leading to device malfunction and / or failure, which may result in patient injury, illness, or death. Reuse of a device, or attempt at cleaning and resterilization may also pose a risk of infection and/or transmissible disease. Adverse effects of original packaging may lead to device damage, loss of sterility, and risk of injury to the patient and / or user.

Contents – One (1) guide wire per pouch.

Storage – Store in a cool, dry place. Protect from sunlight.

Sterile – Sterilized with electron-beam radiation. Refer to the product label for the sterilization method. Non-pyrogenic. Do not use if the package is damaged.

This single-use device cannot be reused on another patient, as it is not designed to withstand cleaning, disinfection, or sterilization. Reuse may cause a change in chemical characteristics introduced when conditions of repeated use, cleaning, and / or resterilization may compromise the integrity of the design and / or materials, leading to device malfunction and / or failure, which may result in patient injury, illness, or death. Reuse of a device, or attempt at original starting may lead to reduce and eventually unusable, disposal of original packaging may lead to device damage, loss of sterility, and risk of injury to the patient and / or user.

Contents – One (1) guide wire per pouch.

Storage – Store in a cool, dry place. Protect from sunlight.

Sterile – Sterilized with electron-beam radiation.

Guide Wires are intended to facilitate navigation across vascular anatomies and structures in order to deliver diagnostic and therapeutic devices.

INDICATIONS FOR USE

HI-TORQUE™ Guide Wires are indicated to facilitate the delivery of catheter-based interventional devices during PTCA and PTA. This guide wire may be used with interventional devices such as balloon dilatation catheters, stents, and other devices that are intended to reach and cross a target lesion, provide a pathway within the vessel structure, facilitate the substitution of one diagnostic or interventional device for another, and to distinguish between vessel and lesion anatomy. Guide Wires can be used to cross or assist in crossing an intra-chronic total coronary occlusions (CTO).

CONTRAINDICATIONS

Not indicated for use in the cerebral vasculature.

WARNINGS

This device is not designed for use with atherectomy devices. The safety and effectiveness of the use of this HI-TORQUE™ Guide Wire with atherectomy devices has not been established.

The lifetime of the device is the intended shelf life. This device is designed and intended for ONE-TIME USE ONLY. Do not resterilize and / or reuse. The safety and effectiveness of this device have not been established after being reprocessed for multiple use.

If a guide wire is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation.

This device has a hydrophilic coating at the distal end of the device for a length of 25 cm. The proximal section of the wire is coated with polytetrafluoroethylene (PTFE) and a single coat of HEUCHERIN™ (also called HEUCHERIN). **™ Hydrophilic coating, proximal section of the wire is coated with PTFE. The distal tip is at least for 100 cm guide wires, and 25 cm for 200 cm guide wires, and the PTFE is coated at the proximal end for a length of 143 cm for 190 cm guide wires, and 43 cm for 200 cm guide wires.**

Refer to PREPARATION FOR USE section for further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the instructions for preparation and use of this device may lead to device failure, which may necessitate intervention or result in serious adverse events.

The safety and effectiveness of the device have not been established, or is unknown, in vessels other than those specifically indicated.

Pieces with loosen kinkings or signs of the components of this device fracturing, breaking, or separating should not be used. If any part of the device is defined, the patient should be concerned on the materials contained in the device and a thorough history of allergies must be discussed. This device contains platinum-iridium, 304 stainless steel, nickel-titanium alloy, gold, polyurethane, polyethylene, silicone, aqueous adhesive, HEUCHERIN (Bovine Collagen), polytetrafluoroethylene (PTFE), coating, and PTFE coating.

Do not advance or withdraw the guide wire against resistance until the cause of the resistance is determined. Damage to the guide wire may occur, and fragments may be released into the circulation if the guide wire is damaged.

Do:

- Use the subtlest torque needed of the interventional device to confirm position.
- Examine the by movement under fluoroscopy before manipulating, moving, or advancing the device.
- Observe the wire under fluoroscopy for tip buckling, which is a sign of resistance.
- Use gentle continuous fluoro while removing and remounting the guide wire to prevent an injury entering the catheter system.
- Perform exchanges slowly to prevent an entry and / or trauma.
- When remoistening the guide wire, confirm that the intervention device tip is free within the vessel lumen and that the tip is parallel to the vessel wall.
- Use caution when using the device in patients with severe calcification, spasm, or, through stent struts, which may cause a fenestrated vessel. Use of this technique involves additional patient risks, including the risk that the wire may become entrapped in the stent.
- Consider that if a guidewire wire is placed in a bifurcation branch, the wire may need to be retracted prior to stent deployment, because there is additional risk that the guidewire wire may become entrapped between the vessel wall and the stent.

For the HI-TORQUE PROGRESS™ Family of Guide Wires only:
The HI-TORQUE PROGRESS Family of Guide Wires have distal ends of varying stiffness. Operate these guide wires carefully so as to not injure the blood vessel. Operate the guide wire with the minimum force required to achieve the desired effect. Use **distal ends, and / or higher maximum torque ratings when greater force is required to overcome a lesion or to cross a lesion with a more pliable distal end. Therefore, **use caution when using the guide wire in a vessel with a lesion that is severe or if extreme care is needed in the risk of perforation or other damage to blood vessel.**

LIMITATIONS

These HI-TORQUE™ Guide Wires do not have a specific limitation in duration of use but are designed for vascular procedures that vary in duration depending on lesion complexity.

Percutaneous transluminal coronary angioplasty (PTCA) should only be performed at centers where emergency coronary artery bypass graft (CABG) surgery is available.

PRECAUTIONS

Guide wires are delicate instruments and should be handled carefully. Prior to use and during the procedure, inspect the device for damage. Do not use if damaged. Damage to the device may result in embolization of fragments. Do not reuse, reprocess, or resterilize. Reuse or resterilization may compromise the integrity of the design and / or materials, leading to device malfunction and / or failure, which may result in patient injury, illness, or death. Reuse of a device, or attempt at cleaning and resterilization may also pose a risk of infection and/or transmissible disease. Adverse effects of original packaging may lead to device damage, loss of sterility, and risk of injury to the patient and / or user.

Contents – One (1) guide wire per pouch.

Storage – Store in a cool, dry place. Protect from sunlight.

Sterile – Sterilized with electron-beam radiation. Refer to the product label for the sterilization method. Non-pyrogenic. Do not use if the package is damaged.

This single-use device cannot be reused on another patient, as it is not designed to withstand cleaning, disinfection, or sterilization. Reuse may cause a change in chemical characteristics introduced when conditions of repeated use, cleaning, and / or resterilization may compromise the integrity of the design and / or materials, leading to device malfunction and / or failure, which may result in patient injury, illness, or death. Reuse of a device, or attempt at original starting may lead to reduce and eventually unusable, disposal