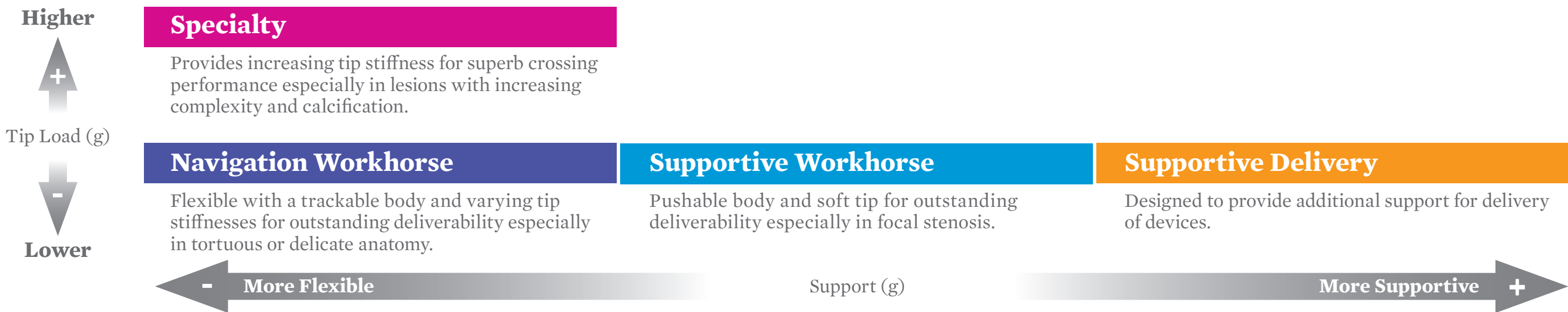


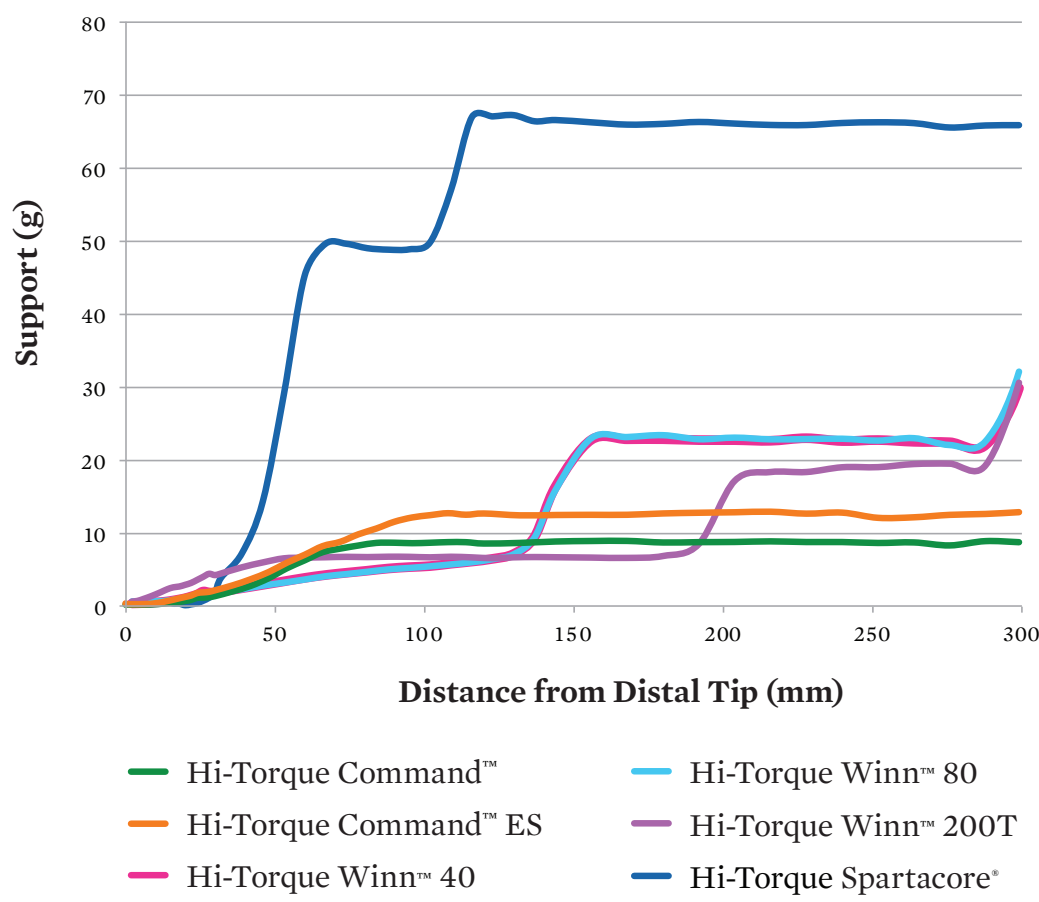
Abbott Vascular Peripheral Guide Wires

HI-TORQUE
Confidence in your hands.



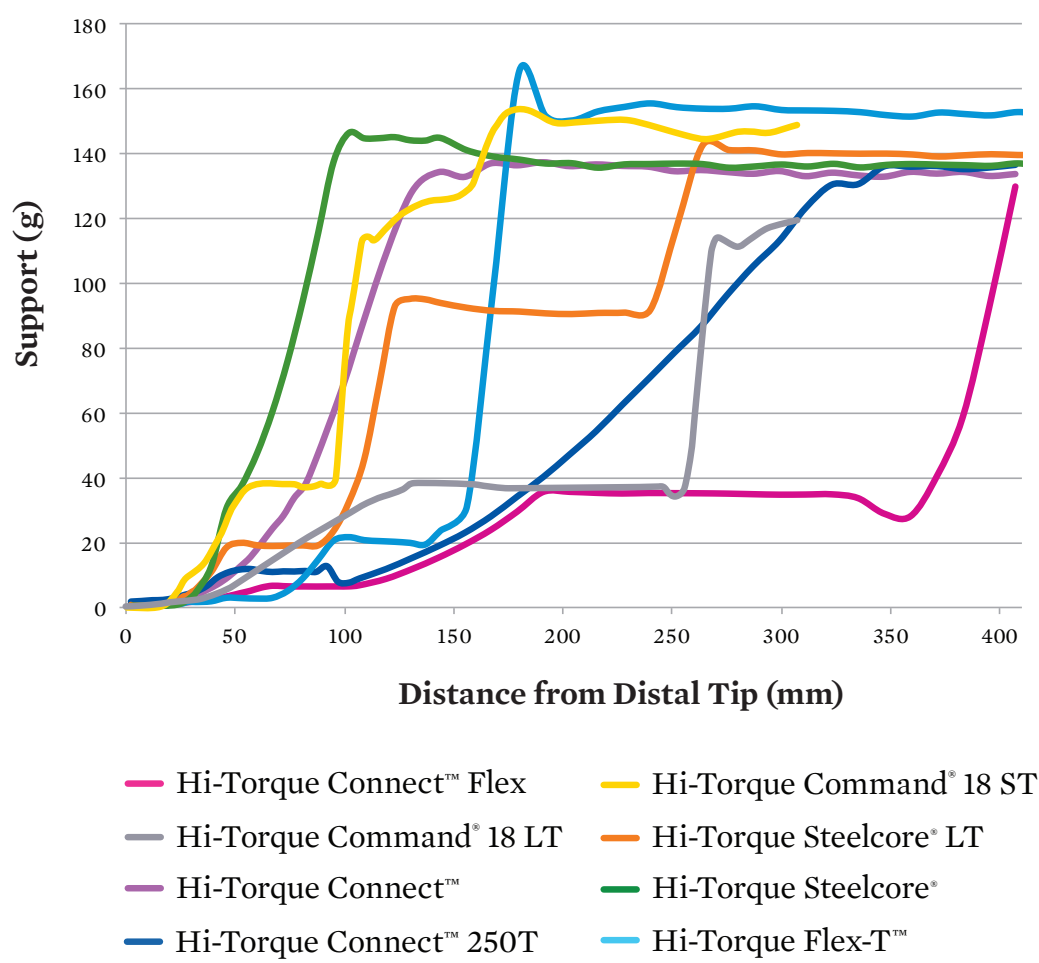
.014 Guide Wires			Core Material	Cover Type or Coils	Tip Style	Coatings	Tip Load (g)
Navigation Workhorse	Hi-Torque Command™ • For navigation and lesion access		Nitinol/DURASTEEL	Full Polymer	Core-To-Tip	Hydrophilic	2.8
Supportive Workhorse	Hi-Torque Command™ ES • For navigation and lesion access and 35% more supportive than Hi-Torque Command™		Nitinol/DURASTEEL	Full Polymer	Core-To-Tip	Hydrophilic	3.5
Specialty	Hi-Torque Winn™ 40 • 40 kg/in ² penetration power		DURASTEEL	Intermediate Polymer Sleeve	Core-To-Tip	Hydrophilic	4.8
	Hi-Torque Winn™ 80 • 80 kg/in ² penetration power		DURASTEEL	Intermediate Polymer Sleeve	Core-To-Tip	Hydrophilic	9.7
	Hi-Torque Winn™ 200T • 0.009" tapered tip and 200 kg/in ² penetration power		DURASTEEL	Intermediate Polymer Sleeve	Core-To-Tip	Hydrophilic	13.0
Supportive Delivery	Hi-Torque Spartacore®		Stainless Steel	Bare Coils	Core-To-Tip	MICROGLIDE® Hydrophobic	n/a

0.014" Support Profiles



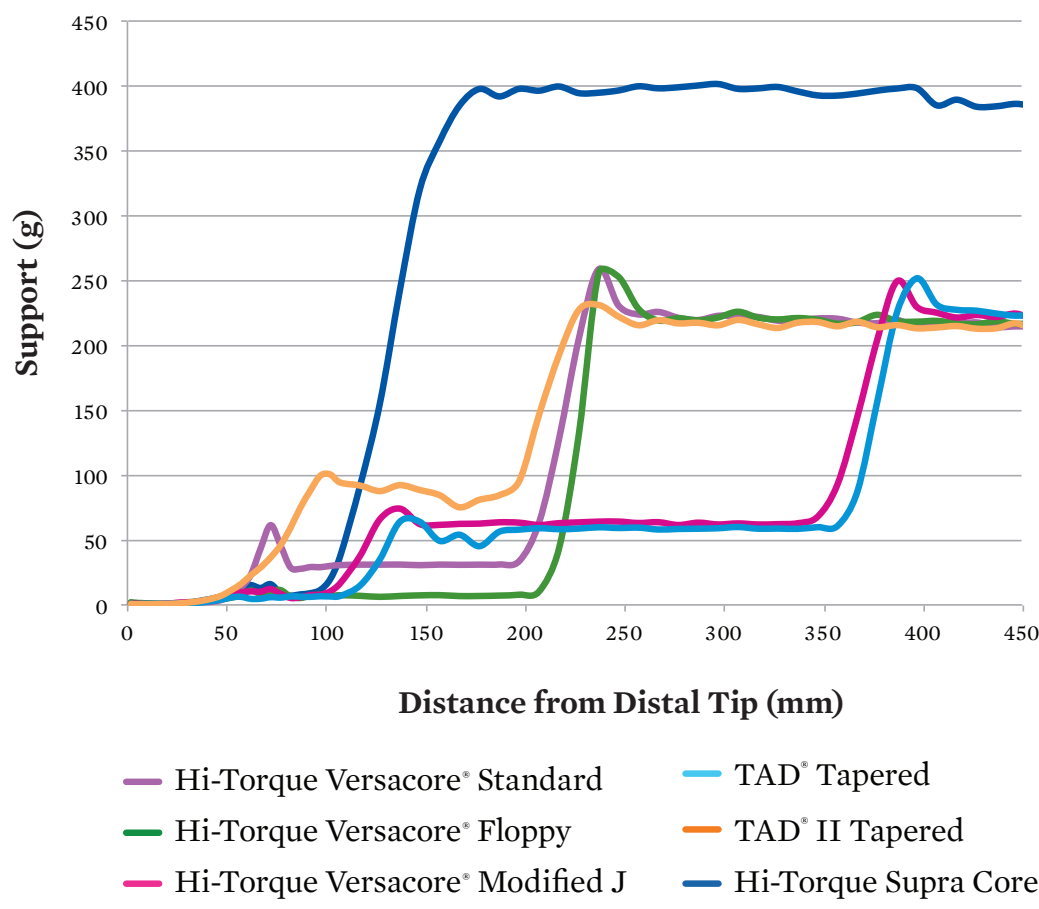
.018 Guide Wires			Core Material	Cover Type or Coils	Tip Style	Coatings	Tip Load (g)
Navigation Workhorse	Hi-Torque Connect™ Flex • Increased flexibility for navigating distal and tortuous anatomies		Stainless Steel	Full Polymer	Core-To-Tip	Hydrophilic	12.0
	Hi-Torque Command® 18 LT • 25 cm Nitinol segment at distal end for durability, navigation and flexible support		NITINOL / Durasteel	Full Polymer	Core-To-Tip	Hydrophilic	4.0
Supportive Workhorse	Hi-Torque Connect™ • Ideal for straight anatomy (SFA)		Stainless Steel	Full Polymer	Core-To-Tip	Hydrophilic	4.0
	Hi-Torque Command® 18 ST • 10cm Nitinol segment at distal end for durability, crossing lesions, and tip prolapse		NITINOL / Durasteel	Full Polymer	Core-To-Tip	Hydrophilic	4.0
Specialty	Hi-Torque Connect™ 250T • 0.0125" tapered tip and 250 kg/in ² penetration power		Stainless Steel	Bare Coils	Core-To-Tip	Hydrophilic	30.0
Supportive Delivery	Hi-Torque Steelcore® • Short taper		Stainless Steel	Bare Coils	Core-To-Tip	MICROGLIDE® Hydrophobic	n/a
	Hi-Torque Steelcore® LT • Long taper		Stainless Steel	Bare Coils	Core-To-Tip	MICROGLIDE® Hydrophobic	n/a
	Hi-Torque Flex-T™		Stainless Steel	Bare Coils	Core-To-Tip	MICROGLIDE® Hydrophobic	n/a

0.018" Support Profiles



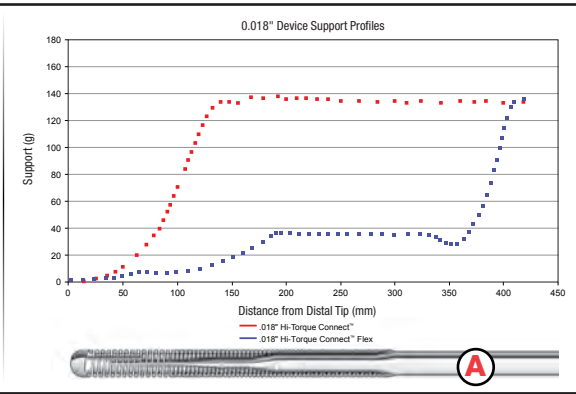
.035 Guide Wires			Core Material	Cover Type or Coils	Tip Style	Coatings	Tip Load (g)
Access	GuideRight™		Stainless Steel	PTFE Coated Coils	Core-To-Tip	PTFE Hydrophilic	n/a
Navigation Workhorse	HydroSteer™		Nitinol	Polymer Jacket	Core-To-Tip	Hydrophilic	n/a
Supportive Workhorse	Hi-Torque Versacore® Standard • For access with a shorter, flexible tip		Stainless Steel	Bare Coils	Core-To-Tip	None	n/a
	Hi-Torque Versacore® Floppy • For navigation and access with a longer, flexible tip		Stainless Steel	Bare Coils	Core-To-Tip	None	n/a
	Hi-Torque Versacore® Modified J • For navigation and access with more flexible body		Stainless Steel	Bare Coils	Core-To-Tip	None	n/a
	TAD® Tapered • 0.018" tapered tip		Stainless Steel	Bare Coils	Shaping Ribbon	MICROGLIDE® Hydrophobic	n/a
	TAD® II Tapered • 0.018" tapered tip • More supportive body than TAD® Tapered		Stainless Steel	Bare Coils	Shaping Ribbon	MICROGLIDE® Hydrophobic	n/a
	TigerWire™		Stainless Steel	PTFE Coated Coils	Core-To-Tip	PTFE	n/a
Supportive Delivery	Hi-Torque Supra Core® • Extra supportive body with a soft, shapeable tip		Stainless Steel	Bare Coils	Core-To-Tip	MICROGLIDE® Hydrophobic	n/a

0.035" Support Profiles



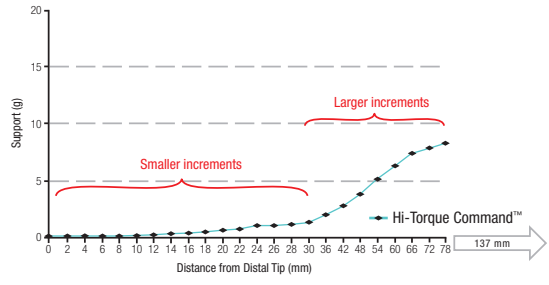
For Important Safety Information see reverse.
Read the Instructions for Use for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.
Abbott
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www.Vascular.Abbott
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How to Read Device Support Profile Graphs
1. Visualize a guide wire on the X-axis of the graph.
2. Each point measures the stiffness of the wire.
3. The Support Profile graph is best utilized when comparing two or more guide wires.



Device Support Level Test Output

- The test cycle begins near the tip and is repeated at several intervals across the wire. The intervals are smaller near the tip, then become larger as the test progresses down the wires.
- The final data is recorded and a chart is produced showing the support along the length of the guide wire.



Hi-TORQUE Guide Wires for PTCA, PTA, and Stents

INDICATIONS FOR USE

This Hi-Torque guide wire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). This guide wire may also be used with compatible stent devices during therapeutic procedures.

CONTRAINDICATIONS

Not intended for use in the cerebral vasculature or with atherectomy devices.

WARNINGS

This device is designed and intended for ONE-TIME USE ONLY. Do not resterilize and / or reuse.

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 stent 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 excessive resistance.
- Torque a guide wire if the tip becomes entrapped within the vasculature.
- Allow the guide wire tip to remain in a prolapsed condition.

Do:

- Advance or withdraw the guide wire slowly.
- Use the radiopaque marker of the interventional device to confirm position.
- Examine the tip movement under fluoroscopy before manipulating, moving, or torquing the guide wire.
- Observe the wire under fluoroscopy for tip buckling, which is a sign of resistance.
- Maintain 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.
- When reintroducing the guide wire, confirm that the interventional device tip is free within the vessel lumen and that the tip is parallel to the vessel wall.
- Use extreme caution when moving a guide wire through a non-endothelialized 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 caught on the stent strut.
- Consider that if a secondary wire is placed in a bifurcation branch, this wire may need to be retracted prior to stent deployment, because there is additional risk that the secondary wire may become entrapped between the vessel wall and the stent.

For Winn family only: The Winn family of guide wires have distal ends of varying stiffness. Operate these guide wires carefully so as not to injure the blood vessel, observing the information in these instructions. The higher torque performance, stiffer distal ends, 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, use the guide wire with the least stiff distal end that will treat the lesion, and use extreme care to minimize the risk of perforation or other damage to blood vessels.

PRECAUTIONS

Guide wires are delicate instruments and should be handled carefully. Prior to use and when possible during the procedure, 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 inaccurate torque response.

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

Free movement of the 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 system for any resistance prior to use. Adjust or replace the hemostatic valve with an adjustable valve if it is found to inhibit guide wire movement.

Never attach the torque device to the modified portion of the proximal end of the extendible guide wire; otherwise, guide wire damage may occur, preventing the ability to attach the DOC Guide Wire Extension.

Hi-Torque Guide Wires with Hydrophilic Coating: Avoid abrasion of the hydrophilic coating. Do not withdraw or manipulate the hydrophilic-coated wire through a metal cannula or sharp-edged object.

ADVERSE EVENTS

Potential Adverse Events associated with use of this device may include the following but not limited to perforation, dissection, occlusion, myocardial infarction, embolism and infection.

Hi-Torque Guide Wires

INTENDED USE

All Hi-Torque Guide Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).

CONTRAINDICATIONS

Hi-Torque Guide Wires are not intended for use in the cerebral vasculature.

WARNINGS

This device is designed and intended for ONE TIME USE ONLY. DO NOT RSTERILIZE AND / OR REUSE.

Observe guide wire movement in the vessels. Before a guide wire is moved or torqued, the tip movement should be examined under fluoroscopy. Do not torque a guide wire without observing corresponding movement of the tip; otherwise, vessel trauma may occur. In addition, during catheter manipulations, ensure that the distal guide wire tip is visible.

Torquing a guide wire against resistance may cause guide wire damage and / or guide wire tip separation. Always advance or withdraw the guide wire slowly. Never push, auger, withdraw or torque a guide wire, which meets resistance. Resistance may be felt and / or observed under fluoroscopy by noting any buckling of the guide wire tip. If guide wire tip prolapse is observed or used for positioning, do not allow the tip to remain in a prolapsed condition; otherwise, damage to the guide wire may occur. Determine the cause of resistance under fluoroscopy and take any necessary remedial action.

If the guide wire tip becomes entrapped within the vasculature, DO NOT TORQUE THE GUIDE WIRE.

Maintain 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.

When reintroducing the guide wire, confirm that the interventional device tip is free within the vessel lumen and not against the vessel wall. Failure to do so may result in vessel trauma upon guide wire exit of the device. Use the radiopaque marker of the interventional device to confirm position.

PRECAUTIONS

Guide wires are delicate instruments and should be handled carefully. Prior to use and when possible during the procedure, 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 inaccurate torque response.

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

Free movement of the 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 system for any resistance prior to use. Adjust or replace the hemostatic valve with an adjustable valve if it is found to inhibit guide wire movement.

Never attach the torque device to the modified portion of the proximal end of the extendible guide wire; otherwise, guide wire damage may occur, preventing the ability to attach the DOC Guide Wire Extension.

Hi-Torque Guide Wires with Hydrophilic Coating: Avoid abrasion of the hydrophilic coating. Do not withdraw or manipulate the hydrophilic-coated wire in a metal cannula or sharp-edged object.

ADVERSE EVENTS

Potential Adverse Events associated with use of this device may include the following but not limited to perforation, dissection, occlusion, myocardial infarction, embolism and infection.

Hi-Torque Guide Wires for PTA

INDICATIONS FOR USE

This HI-TORQUE guide wire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal angioplasty (PTA), in arteries such as the femoral, popliteal and infra-popliteal arteries. This guide wire may also be used with compatible stent devices during therapeutic procedures.

The guide wire may also be used 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 the vasculature.

CONTRAINDICATIONS

Not intended for use in the coronary or cerebral vasculature.

WARNINGS

This device is not designed for use with atherectomy devices.

This device is designed and intended for ONE-TIME USE ONLY. Do not resterilize and / or reuse.

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 stent 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 excessive resistance.
- Torque a guide wire if the tip becomes entrapped within the vasculature.
- Allow the guide wire tip to remain in a prolapsed condition.
- 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 radiopaque marker of the interventional device to confirm position.
- Examine the tip movement under fluoroscopy before manipulating, moving, or torquing the guide wire.
- Observe the wire under fluoroscopy for tip buckling, which is a sign of resistance.
- Maintain 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.
- When reintroducing the guide wire, confirm that the interventional device tip is free within the vessel lumen and that the tip is parallel to the vessel wall.
- Use extreme caution when moving a guide wire through a non-endothelialized 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 caught on the stent strut.

PRECAUTIONS

Guide wires are delicate instruments and should be handled carefully. Prior to use and when possible during the procedure, 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 inaccurate torque response.

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

Free movement of the 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 system for any resistance prior to use. Adjust or replace the hemostatic valve with an adjustable valve if it is found to inhibit guide wire movement.

Never attach the torque device to the modified portion of the proximal end of the extendible guide wire; otherwise, guide wire damage may occur, preventing the ability to attach the DOC Guide Wire Extension.

HI-TORQUE Guide Wires with Hydrophilic Coating: Avoid abrasion of the hydrophilic coating. Do not withdraw or manipulate the hydrophilic-coated wire through a metal cannula or sharp-edged object.

ADVERSE EVENTS

Potential Adverse Events associated with use of this device may include the following but not limited to perforation, dissection, occlusion, myocardial infarction, embolism and infection.

Hi-Torque Connect Guide Wire

INDICATIONS

Hi-Torque guide wires are indicated to facilitate the placement of percutaneous devices during Percutaneous Transluminal Angioplasty (PTA) in peripheral arteries such as femoral, popliteal and infra-popliteal arteries. This guide wire may also be used with compatible stent devices during therapeutic procedures.

CONTRAINDICATIONS

Hi-Torque wires are not intended for use in the coronary and cerebral vasculature or in patients judged not acceptable for percutaneous intervention.

WARNINGS

• A guide wire is a delicate instrument and must not be advanced, withdrawn, or torqued if resistance is met. Guide wire manipulations must always be observed under fluoroscopy • The Hi-Torque family of guide wires has distal ends of varying stiffness. Operate these guide wires carefully so as to not injure the blood vessel, observing the information in these instructions. The higher torque performance, stiffer distal ends, 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, use the guide wire with the least stiff distal end that will treat the lesion, and use extreme care to minimize the risk of perforation or other damage to blood vessels • If the guide wire is removed and is to be re-inserted, it must be inspected for signs of damage (weakened or kinked segments) prior to re-introduction. Do not re-introduce if guide wire is weakened or kinked.

Do Not:

- Push, auger, withdraw, or torque a guide wire that meets excessive resistance
- Torque a guide wire if the tip becomes entrapped within the vasculature
- Allow the guide wire tip to remain in a prolapsed condition.

Do:

- Advance or withdraw the guide wire slowly
- Use the radiopaque marker of the interventional device to confirm position
- Examine the tip movement under fluoroscopy before manipulating, moving, or torquing the guide wire
- Observe the wire under fluoroscopy for tip buckling, which is a sign of resistance
- Maintain 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
- When reintroducing the guide wire, confirm that the interventional device tip is free within the vessel lumen and that the tip is parallel to the vessel wall
- Use extreme caution when moving a guide wire through a non-endothelialized 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 caught on the stent strut.

PRECAUTIONS

• Failure to follow the instructions may compromise guide wire performance and result in complications • Prior to use, confirm compatibility of guide wire outer diameter with the balloon catheter • Guide wire advancement, withdrawal, and torquing should be monitored by fluoroscopy.

Hi-Torque Steerable Guide Wires

INDICATIONS

The Hi-Torque Steerable Guide Wire is intended for use in angiographic procedures to introduce and position diagnostic and interventional devices within the peripheral vasculature during percutaneous procedures. The wire can be torqued to facilitate navigation through tortuous vessels.

The Hi-Torque Steerable Guide Wire is not intended for use in the coronary or neurovasculature.

CONTRAINDICATIONS

The Hi-Torque Steerable Guide Wire is not intended for use in the coronary or neurovasculature.

WARNINGS

This device is designed and intended for ONE TIME USE ONLY. DO NOT RSTERILIZE AND / OR REUSE.

Observe all guide wire movement in the vessels. Before a guide wire is moved or torqued, the tip movement should be examined under fluoroscopy. Do not torque a guide wire without observing corresponding movement of the tip; otherwise, vessel trauma may occur.

Torquing a guide wire against resistance may cause guide wire damage and / or guide wire tip separation. Always advance or withdraw the guide wire slowly. Never push, auger, withdraw, or torque a guide wire which meets resistance. Resistance may be felt and / or observed under fluoroscopy by noting any buckling of the guide wire tip. Determine the cause of resistance under fluoroscopy and take any necessary remedial action.

If the wire tip becomes entrapped within the vasculature, DO NOT TORQUE THE GUIDE WIRE.

Maintain continuous flush while removing and reinserting the guide wire to prevent air from entering the catheter system. Perform all exchanges slowly to prevent air entry and / or trauma. Wipe the wire before all exchanges.

When reintroducing the guide wire, confirm that the interventional device tip is free within the vessel lumen and not against the vessel wall. Failure to do so may result in vessel trauma upon guide wire exit from the device. Use the radiopaque marker of the interventional device to confirm position.

PRECAUTIONS

Guide wires are delicate instruments and should be handled carefully. Prior to use and when possible during the procedure, inspect the guide wire carefully for bends, kinks, or other damage. Do not use damaged wires. Using a damaged wire may result in vessel damage and / or inaccurate torque response.

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

Free movement of the 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 system for any resistance prior to use. Adjust or replace the hemostatic valve with an adjustable valve if it is found to inhibit guide wire movement.

PRECAUTIONS

Potential Adverse Events associated with use of this device may include the following but not limited to perforation, dissection, occlusion, myocardial infarction, embolism and infection.

Hi-Torque Supra Core 35 Guide Wire

INTENDED USE

Hi-Torque Supra Core 35 Guide Wires are intended to facilitate the placement and exchange of interventional devices during diagnostic or therapeutic interventional procedures.

INDICATIONS

Refer to the device label for any additional product specific indications which may apply.

CONTRAINDICATIONS

The Hi-Torque Supra Core 35 Guide Wire is not intended for use in the cerebral vasculature. Refer to the device label for any additional product specific contraindications which may apply.

WARNINGS

This device is designed and intended for ONE TIME USE ONLY. DO NOT RSTERILIZE AND / OR REUSE. Observe all guide wire movement in the vessels. Before a guide wire is moved or torqued, the tip movement should be examined under fluoroscopy. Do not torque a guide wire without observing corresponding movement of the tip; otherwise, vessel trauma may occur.

Torquing a guide wire against resistance may cause guide wire damage and/or guide wire tip separation. Always advance or withdraw the guide wire slowly. Never push, auger, withdraw or torque a guide wire which meets resistance. Resistance may be felt and / or observed under fluoroscopy by noting any buckling of the guide wire tip. Determine the cause of resistance under fluoroscopy and take any necessary remedial action.

If the wire tip becomes entrapped within the vasculature, DO NOT TORQUE THE GUIDE WIRE.

Maintain continuous flush while removing and reinserting the guide wire to prevent air from entering the catheter system. Perform all exchanges slowly to prevent air entry and / or trauma. Wipe the wire before all exchanges.

When reintroducing the guide wire, confirm that the interventional device tip is free within the vessel lumen and not against the vessel wall. Failure to do so may result in vessel trauma upon guide wire exit of the device. Use the radiopaque marker of the interventional device to confirm position.

PRECAUTIONS

Guide wires are delicate instruments and should be handled carefully. Prior to use and when possible during the procedure, inspect the guide wire carefully for bends, kinks, or other damage. Do not use damaged wires. Using a damaged wire may result in vessel damage and / or inaccurate torque response.

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

Free movement of the 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 system for any resistance prior to use. Adjust or replace the hemostatic valve with an adjustable valve if it is found to inhibit guide wire movement.

ADVERSE EVENTS

Potential Adverse Events associated with use of this device may include the following but not limited to perforation, dissection, occlusion, myocardial infarction, embolism and infection.

Hi-Torque Command 18 Guide Wire for PTA

INDICATIONS

This Hi-Torque Guide Wire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal angioplasty (PTA), in arteries such as the femoral, popliteal and infra-popliteal arteries. This guide wire may also be used with compatible stent devices during therapeutic procedures.

The guide wire may also be used 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 the vasculature.

CONTRAINDICATIONS

Not intended for use in the coronary or cerebral vasculature.

WARNINGS

This device is not designed for use with atherectomy devices.

This device is designed and intended for ONE-TIME USE ONLY. Do not resterilize and / or reuse.

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 stent 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 excessive resistance.
- Torque a guide wire if the tip becomes entrapped within the vasculature.
- Allow the guide wire tip to remain in a prolapsed condition.
- 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 radiopaque marker of the interventional device to confirm position.
- Examine the tip movement under fluoroscopy before manipulating, moving, or torquing the guide wire.
- Observe the wire under fluoroscopy for tip buckling, which is a sign of resistance.
- Maintain 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.
- When reintroducing the guide wire, confirm that the interventional device tip is free within the vessel lumen and that the tip is parallel to the vessel wall.
- Use extreme caution when moving a guide wire through a

non-endothelialized 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 caught on the stent strut.

PRECAUTIONS

Guide wires are delicate instruments and should be handled carefully. Prior to use and when possible during the procedure, 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 inaccurate torque response.

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

Free movement of the 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 system for any resistance prior to use. Adjust or replace the hemostatic valve with an adjustable valve if it is found to inhibit guide wire movement.

Avoid abrasion of the hydrophilic coating.

Do not withdraw or manipulate the hydrophilic-coated wire through a metal cannula or sharp-edged object.

ADVERSE EVENTS (AEs)

Potential Adverse Events associated with use of this device may include the following but are not limited to:

- Abrupt closure
- Allergic reaction (contrast medium, drug, guide wire material)
- Amputation or limb loss
- Aneurysm or pseudoaneurysm in vessel or at vascular access site
- Angina or coronary ischemia, arrhythmia (including premature beats, bradycardia, atrial or ventricular tachycardia, atrial or ventricular fibrillation)
- Arteriovenous fistula
- Bleeding complications requiring • transfusion or surgical intervention
- Critical limb ischemia
- Death
- Detachment of a system component
- Embolization (air, tissue, plaque, thrombotic material, device)
- Emergent surgery
- Fever
- Hematoma or hemorrhagic event, with or without surgical repair
- Hypotension / hypertension
- Infection
- Ischemia or infarction not covered under other AEs
- Myocardial infarction
- Occlusion
- Pain (leg, foot, back and / or insertion site)
- Perforation or rupture
- Peripheral nerve injury
- Pulmonary embolism
- Renal failure or insufficiency secondary to contrast medium (with or without treatment including dialysis)
- Restenosis
- Shock
- Stroke
- Thrombosis
- Tissue injury
- Transient ischemic attack
- Venous thromboembolism
- Vessel dissection
- Vessel spasm or recoil
- Worsening claudication

HydroSteer™ Guidewires

INDICATIONS

St. Jude Medical™ guidewires are intended for use in the percutaneous introduction of catheters.

CONTRAINDICATIONS

There are no known contraindications for this device.

WARNINGS

Do not reuse this device. Discard after one procedure. Thorough cleaning of biological and foreign material is not possible. Adverse patient reactions may result from reuse of this device.

1. The hydrophilic guidewire may slide entirely into the catheter, sheath introducer, vessel dilator or other device because of its low sliding friction. To prevent this, keep at least 5 cm of the wire protruding from the device fitting at all times.

2. To prevent possible tissue damage, care should be taken when manipulating a device over a guidewire during the device's placement and withdrawal. If resistance is felt during device placement, discontinue the procedure and determine the cause of resistance before proceeding. If the cause of resistance cannot be determined, remove the guidewire and device as a unit to prevent possible damage and/or complications.

3. When using a guidewire, potential exists for thrombus formation or emboli, arterial or venous wall damage and/or plaque dislodgment. The physician should be familiar with the literature concerning the complications of angiography.

4. St. Jude Medical does not recommend a particular technique for the use of this guidewire. The steps contained in the directions are for information purposes only. Each physician should evaluate their appropriateness according to individual patient condition and his or her medical training and experience.

COMPLICATIONS

Procedures requiring percutaneous catheter/guidewire introduction should not be attempted by physicians unfamiliar with the possible complications. Complications may occur during certain procedures but may not be limited to air embolism, hematoma formation, sepsis/infection, excessive bleeding, vessel damage.

GuideRight™ Guidewires

INDICATIONS

SJM™ Guidewires are intended for use in the percutaneous introduction of catheters.

CONTRAINDICATIONS

There are no known contraindications for this device.

WARNINGS

For Single Use Only! Single-use devices are designed and tested for only one patient application. These are disposable devices and are not designed for reprocessing and reuse. Reuse of designated “single-use” devices creates a risk of patient or user infections due to prior patient use and the difficulty in cleaning the narrow structures at material interfaces following direct blood contact. Contamination or reprocessing cleaning agent residues may lead to adverse patient reactions and may damage the device. Use of non-St. Jude Medical packaging may compromise device functionality and sterility due to compromised protection from shipping and handling damage. The absence of labeling after reprocessing, may lead to misuse of the device and impaired traceability. Reprocessing and reuse may result in patient or user injury, permanent impairment or death.

COMPLICATIONS

Procedures requiring percutaneous catheter/guidewire introduction should not be attempted by physicians unfamiliar with the possible complications. Complications may occur during certain procedures but may not be limited to air embolism, hematoma formation, sepsis/infection, excessive bleeding, vessel damage.

TigerWire™ Steerable Guidewire

INTENDED USE

The SJM™ Steerable Guidewires facilitate placement of a catheter during diagnostic angiography and interventional procedures. The Steerable Guidewire can be accurately controlled to facilitate navigation through tortuous vessels and/or adjoining side branches.

WARNINGS

For Single Use Only! Single-use devices are designed and tested for only one patient application. These are disposable devices and are not designed for reprocessing and reuse. Reuse of designated “single-use” devices creates a risk of patient or user infections due to prior patient use and the difficulty in cleaning the narrow structures at material interfaces following direct blood contact. Contamination or reprocessing cleaning agent residues may lead to adverse patient reactions and may damage the device. Use of non-St. Jude Medical packaging may compromise device functionality and sterility due to compromised protection from shipping and handling damage. The absence of labeling after reprocessing, may lead to misuse of the device and impaired traceability. Reprocessing and reuse may result in patient or user injury, permanent impairment or death.

Caution: These products are intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use provided inside the product carton (when available), at eftu.abbottvascular.com or at Manuals.sjm.com for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events

Tests performed by and data on file at Abbott. All tip load values are averages, based on a sample of 5 guide wires, tested with an automated machine in a controlled environment. All tip stiffness values are averages, based on a sample of 5 guide wires, tested with an automated machine in a controlled environment. All Device Support Level values are test results on a single guide wire under the same ambient conditions. Illustrations are artist's representations only and should not be considered as engineering drawings or photographs.

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Hi-Torque Command, Hi-Torque Connect, Hi-Torque Flex-T, Hi-Torque Spartacore, Hi-Torque Steelcore, Hi-Torque Supra