ABBOTT PERIPHERAL GUIDE WIRES

LEADING
THE WAY IN
GUIDE WIRE
DEVELOPMENT

HI-TORQUE
Confidence in your hands.

30+ YEARS

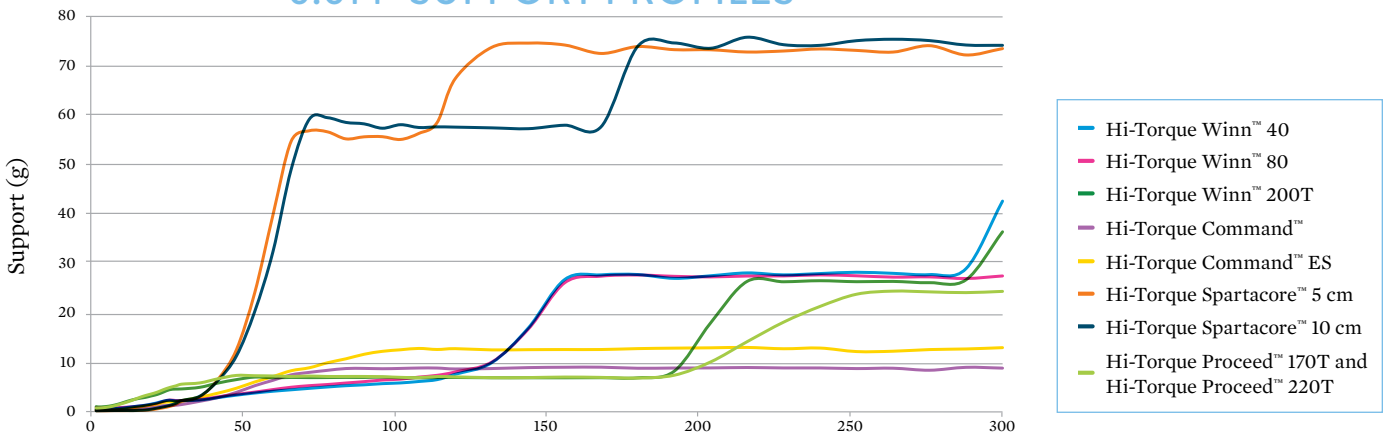
See Important Safety Information referenced within.
Information contained herein for DISTRIBUTION in the U.S. ONLY.

MAT-2100352 v2.0

.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 40% more supportive than Hi-Torque Command™		Nitinol/ Durasteel	Full Polymer	Core-To-Tip	Hydrophilic	3.5
Specialty	**Hi-Torque Proceed™ 170T** • Unique microtextured tip, 0.009″ tapered, pre-shaped tip, 167 kg/in² penetration power*		Durasteel	Coils and Uncoated Tip	Core-To-Tip	Hydrophilic	11
	Hi-Torque Proceed™ 220T • Unique microtextured tip, 0.009″ tapered, pre-shaped tip, 224 kg/in² penetration power*		Durasteel	Coils and Uncoated Tip	Core-To-Tip	Hydrophilic	14
	Hi-Torque Winn™ 40 • 0.012″ tip and 45 kg/in² penetration power*		Durasteel	Intermediate Polymer Sleeve	Core-To-Tip	Hydrophilic	5.1
	Hi-Torque Winn™ 80 • 0.012″ tip and 100 kg/in² penetration power*		Durasteel	Intermediate Polymer Sleeve	Core-To-Tip	Hydrophilic	11.3
	Hi-Torque Winn™ 200T • 0.009″ tip and 224 kg/in² penetration power*		Durasteel	Intermediate Polymer Sleeve	Core-To-Tip	Hydrophilic	14.3
Supportive Delivery	**Hi-Torque Spartacore™ 5 cm** • 0.014″ supportive wire with soft tip ideal for device delivery		Stainless Steel	Bare Coils	Core-To-Tip	MICROGLIDE™ Hydrophobic	1.1
	Hi-Torque Spartacore™ 10 cm • 0.014″ supportive wire with soft tip ideal for device delivery		Stainless Steel	Bare Coils	Core-To-Tip	MICROGLIDE™ Hydrophobic	1.0

0.014" SUPPORT PROFILES*



*Test(s) performed by and data on file at Abbott.

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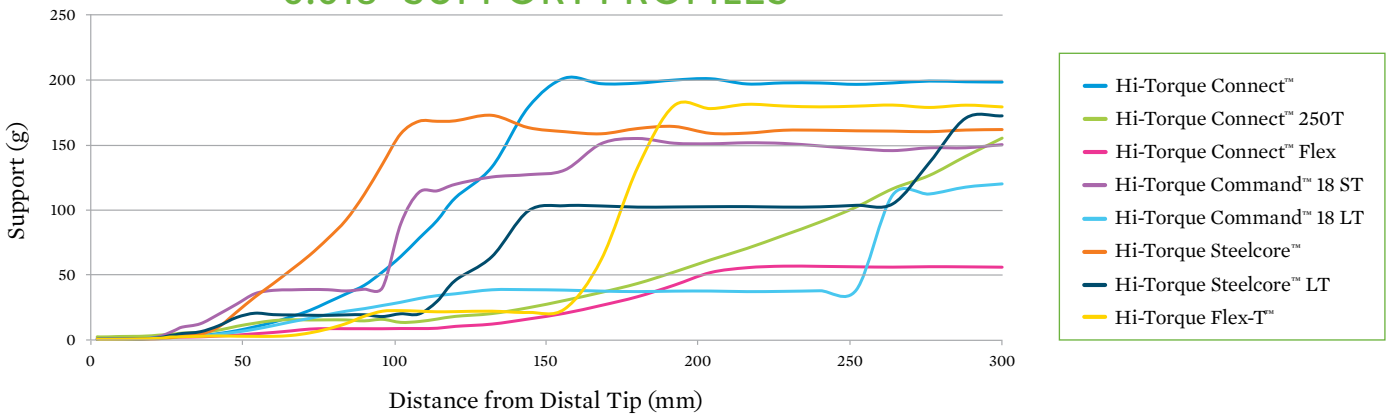
.018 GUIDE WIRES

			CORE MATERIAL	COVER TYPE OR COILS	TIP STYLE	COATINGS	TIP LOAD* (g)
Navigation Workhorse	**Hi-Torque Connect™ Flex** • For moderately calcified lesions		Stainless Steel	Full Polymer	Core-To-Tip	Hydrophilic	14.9
	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
Supportive Workhorse	**Hi-Torque Connect™** • For soft to moderately calcified lesions		Stainless Steel	Full Polymer	Core-To-Tip	Hydrophilic	4.4
	Hi-Torque Command™ 18 ST • 10 cm Nitinol segment at distal end for durability, crossing lesions, and tip prolapse		Nitinol / Durasteel	Full Polymer	Core-To-Tip	Hydrophilic	4
Specialty	**Hi-Torque Connect™ 250T** • 0.013″ tapered tip and 310 kg/in² penetration power* designed for challenging occlusions		Stainless Steel	Bare Coils	Core-To-Tip	Hydrophilic	38.1
Supportive Delivery	**Hi-Torque Steelcore™** • 0.018″ short-taper supportive wire with soft tip ideal for device delivery		Stainless Steel	Bare Coils	Core-To-Tip	MICROGLIDE™ Hydrophobic	4.6
	Hi-Torque Steelcore™ LT • 0.018″ long-taper supportive wire with soft tip ideal for device delivery		Stainless Steel	Bare Coils	Core-To-Tip	MICROGLIDE™ Hydrophobic	5.8
	Hi-Torque Flex-T™ • Added shaft support and long flexible tip for navigating tortuous anatomy		Stainless Steel	Bare Coils	Core-To-Tip	MICROGLIDE™ Hydrophobic	2.4

0.018" SUPPORT PROFILES*



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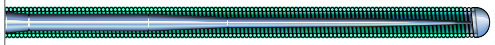
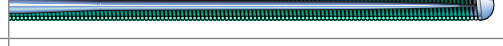
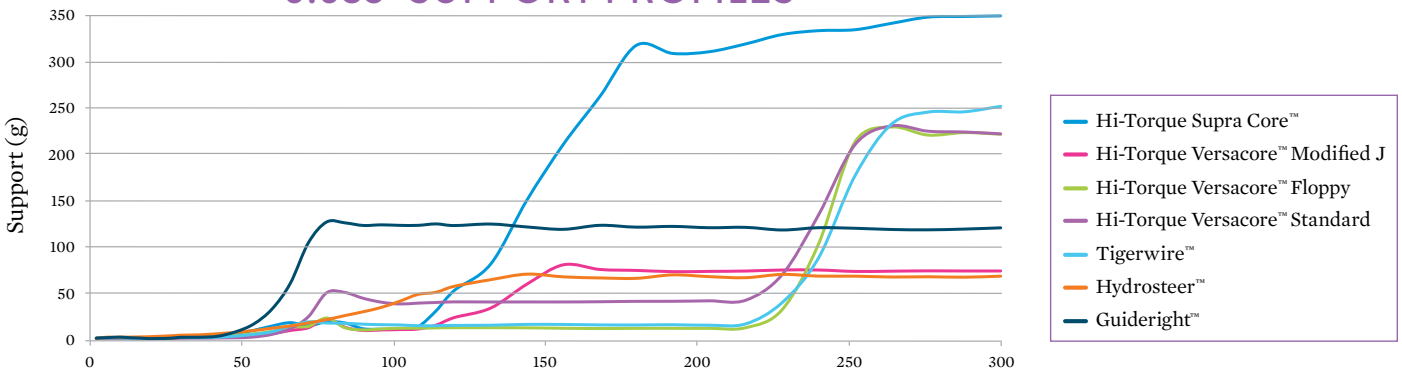
.035 GUIDE WIRES

			CORE MATERIAL	COVER TYPE OR COILS	TIP STYLE	COATINGS	TIP LOAD* (g)
Access	**GuideRight™** • Access wire designed to overcome standard clinical challenges		Stainless Steel	PTFE Coated Coils	Core-To-Tip	PTFE	n/a
Navigation Workhorse	**HydroSteer™** • Nitinol wire for excellent durability and flexibility in navigating tortuous vasculature		Nitinol	Polymer Jacket	Core-To-Tip	Hydrophilic	n/a
Supportive Workhorse	**Hi-Torque Versacore™ Standard** • Increased support and trackability for transversing acute angles		Stainless Steel	PTFE Coated Coils	Core-To-Tip	PTFE	n/a
	Hi-Torque Versacore™ Floppy • Highly flexible wire for negotiating high-grade stenoses and multiple lesions		Stainless Steel	PTFE Coated Coils	Core-To-Tip	PTFE	n/a
	Hi-Torque Versacore™ Modified J • Highly versatile wire with combination of support and flexibility for success with a range of vascular anatomy		Stainless Steel	PTFE Coated Coils	Core-To-Tip	PTFE	n/a
	TAD™ Tapered • Tapered (0.035″ - 0.018″) wire with supportive body and soft tip with shaping ribbon for tight lesions and vessels sensitive to spasm		Stainless Steel	Bare Coils	Shaping Ribbon	MICROGLIDE™ Hydrophobic	n/a
	TAD™ II Tapered • Tapered (0.035″ - 0.018″) wire with supportive body and soft tip with shaping ribbon for tight lesions and vessels sensitive to spasm		Stainless Steel	Bare Coils	Shaping Ribbon	MICROGLIDE™ Hydrophobic	n/a
	TigerWire™ • Stainless steel wire designed for exceptional steering		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*



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GUIDE WIRE CATEGORIES & SUPPORT/OUTPUT GRAPHS

Higher

\+

Tip Load (g)

\-

Lower

Specialty

Provides increasing tip stiffness for superb crossing performance especially in lesions with increasing complexity and calcification.

Navigation Workhorse

Flexible with a trackable body and varying tip stiffnesses for outstanding deliverability especially in tortuous or delicate anatomy.

Supportive Workhorse

Pushable body and soft tip for outstanding deliverability especially in focal stenosis.

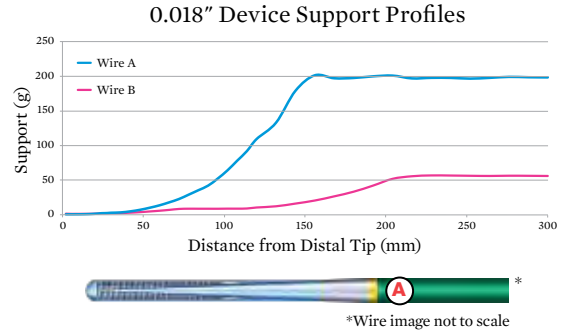
Supportive Delivery

Designed to provide additional support for delivery of devices.

\- More Flexible — Support (g) — More Supportive +

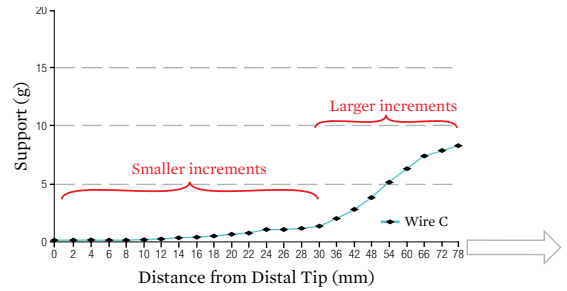
How to Read Device Support Profile Graphs

1. Visualize a guide wire on the X-axis of the graph (A).
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.



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IMPORTANT SAFETY INFORMATION

Rx ONLY 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 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.

Rx ONLY 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 RESTERILIZE 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 extendable 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.

Rx ONLY 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.

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IMPORTANT SAFETY INFORMATION (Cont.)

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 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.

Rx ONLY 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.

Rx ONLY 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 RESTERILIZE 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.

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.

Rx ONLY Hi-Torque Steerable Guide Wires

WARNINGS
This device is designed and intended for ONE TIME USE ONLY. DO NOT RESTERILIZE 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.

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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.

Rx ONLY 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 RESTERILIZE 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.

Rx ONLY 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 pseudo-aneurysm in vessel or at vascular access site • Angina or coronary ischemia, arrhythmia (including premature beats, bradycardia, atrial or ventricular tachycardia, atrial or ventricular fibrillation) • Arterio-venous 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 • Hypo-tension / 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 thrombo-embolism • Vessel dissection • Vessel spasm or recoil • Worsening claudication

Rx ONLY HydroSteer™ GUIDEWIRES

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

Information contained herein for DISTRIBUTION in the U.S. ONLY.

IMPORTANT SAFETY INFORMATION (Cont.)

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.

Rx ONLY GuideRight™ STEERABLE GUIDEWIRE

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.

Rx ONLY 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.

Rx ONLY Hi-Torque Proceed™ Guide Wire

INDICATIONS FOR USE
Intended to facilitate the delivery of catheter-based interventional devices during percutaneous transluminal angioplasty (PTA), in arteries such as the femoral, popliteal, and infrapopliteal arteries. This guide wire may be used with compatible stent devices during therapeutic procedures. The guide wire may 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 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 are unestablished.

The lifetime of this device is the labeled 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 uses.

This device has a hydrophilic coating at the distal end of the device for a length of 25.6 cm, and a silicone based hydrophobic coating at the proximal end for a length of 133 cm (on 190 cm wires) and 250 cm (on 300 cm wires), and a polytetrafluoroethylene (PTFE) hydrophobic coating at the proximal end for a length of 156.5 cm (on 190 cm wires) and 266.5 cm (on 300 cm wires).

Please refer to section PREPARATION FOR USE for further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

Use extreme caution and careful judgement in patients for whom anticoagulation is not indicated.

If contrast agents are used, use extreme caution in patients who have had a severe reaction to contrast agents and who cannot be adequately premedicated.

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

This device contains stainless steel, platinum-nickel alloy, tin-silver alloy, gold-tin alloy, Microglide™ silicone coating, PTFE coating, polyvinylpyrrolidone (PVP) coating that may cause allergic or hypersensitivity reactions. Persons allergic to these may suffer an allergic reaction to this guide wire. Prior to its use on the patient, the patient should be counseled on the materials contained in the device, and a thorough history of allergies must be discussed.

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 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.
- 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.

Information contained herein for DISTRIBUTION in the U.S. ONLY.

IMPORTANT SAFETY INFORMATION (Cont.)

For the Hi-Torque guide wire family only: The Hi-Torque family of guide wires have 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.

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.

Please refer to the indication on the label and the Instructions for Use to confirm the appropriate vasculature that this guide wire may be used in. Failure to abide by the above recommendation may result in size mismatch of blood vessel and guide wire, which can result in vessel injury, such as, but not limited to, perforation, dissection, rupture, and avulsion.

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. It is recommended that the user determine the source of resistance, exercise caution when removing the device and / or other components as a unit, and exchange the device for a new one to complete the procedure.

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.

Avoid abrasion of the hydrophilic coating. Do not withdraw or manipulate the hydrophilic-coated wire through a metal cannula or sharp-edged object. Manipulation, advancement, and / or withdrawal through a metal device may result in destruction and / or separation of the outer coating, which may cause coating material to remain in the vasculature. This in turn may lead to unintended adverse events requiring additional intervention.

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

CAUTION: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

When wet, a hydrophilic coating increases the lubricity of the guide wire surface.

Do not soak the device for longer than 4 hours when the device is not in use. Avoid pre-soaking devices for longer than instructed, as this may impact the coating performance.

Percutaneous transluminal angioplasty (PTA) should only be performed at centers where emergency peripheral artery bypass surgery is available.

This guide wire family has distal ends of varying stiffness. Operate these guide wires carefully so as to not injure the blood vessels, 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.

The coating swells when exposed to aqueous media, but does not have any impact on device use.

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

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

- Avoid wiping 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 rotoflush) 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 instructed methods may compromise the coating integrity, and that damage to the coating may not always be noticeable to the naked eye.

ADVERSE EVENTS

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

- Allergic reaction or hypersensitivity to latex, contrast agent, anesthesia, device materials, and drug reactions to anticoagulation, or antiplatelet drugs
- Vascular access complications which may require transfusion of vessel repair, including:
  - Bleeding (ecchymosis, oozing, hematoma, hemorrhage, retroperitoneal hemorrhage)
  - Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation / rupture, and laceration
  - Embolism (air, tissue, plaque, thrombotic material or device)
- Target artery complications which may require additional intervention, including:
  - Total occlusion or abrupt closure
  - Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation / rupture
  - Embolism (air, tissue, plaque, thrombotic material or device)
  - Artery or stent thrombosis
  - Stenosis or restenosis
  - Vessel spasm
  - Claudication
- Venous thromboembolism (including pulmonary embolism)
- Hypotension / hypertension
- Peripheral nerve injury, neuropathy
- Other ischemic conditions / infarction
  - Tissue / organ ischemia
  - Tissue necrosis
  - Ulcer
  - Acute limb ischemia
- Infection – local and systemic (including post-procedural)
  - Abscess
  - Sepsis / infection including bacteremia / cellulitis / septicemia
- Contrast-induced renal insufficiency or renal failure

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at *vascular.eifu.abbott* or at *medical.abbott/manuals* for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. This material is intended for use with healthcare professionals only.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs.

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