ABBOTT EDUCATION NETWORK

PERIPHERAL PORTFOLIO

CAROTID

STENT SYSTEMS

RX Acculink™
Carotid Stent System

Xact™
Carotid Stent System

EMBOLIC PROTECTION DEVICES

Emboshield NAV6™
Embolic Protection System

BALLOON DILATATION CATHETERS

Viatrac™ 14 Plus
Peripheral Dilatation Catheter

SUPERFICIAL FEMORAL ARTERY (SFA)

STENT SYSTEMS

Supera™
Peripheral Stent System

EMBOLIC PROTECTION DEVICES

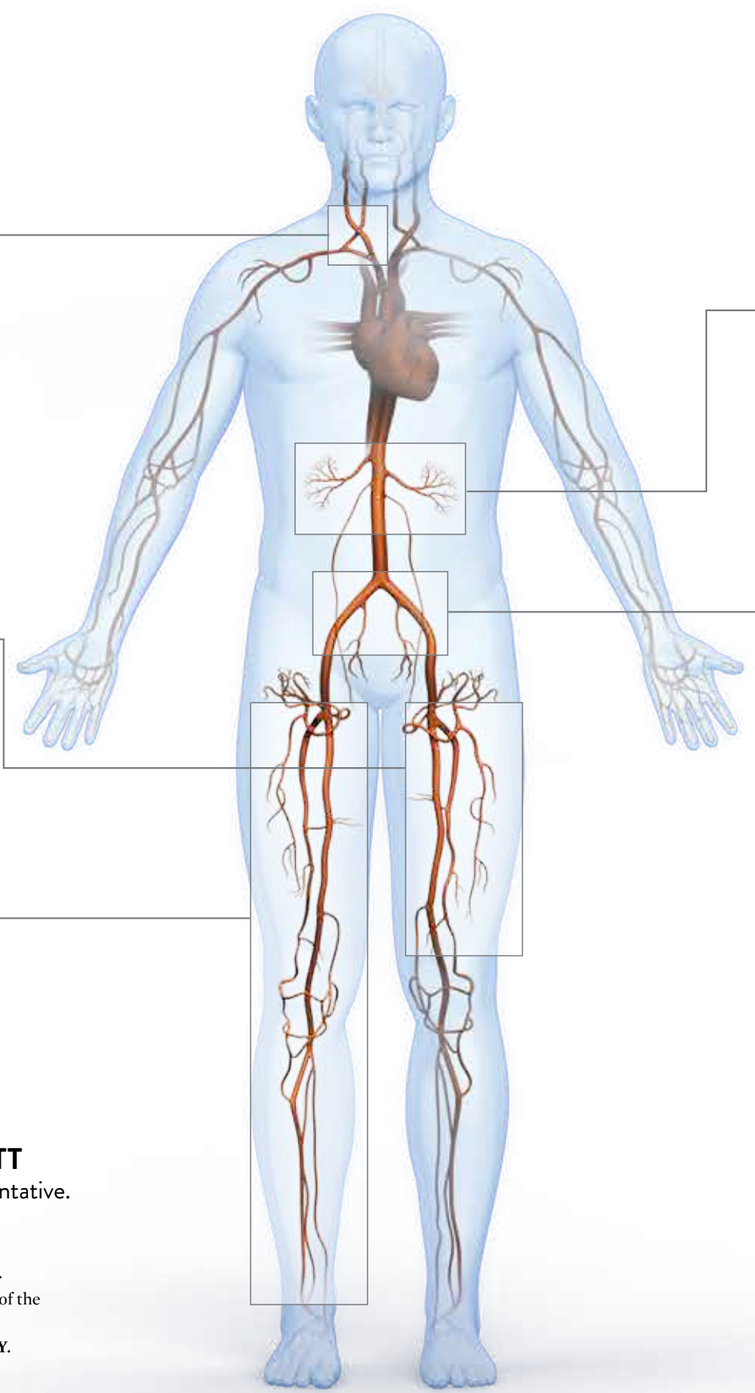
Emboshield NAV6™
Embolic Protection System

BALLOON DILATATION CATHETERS

Armada™ 14 / 14 XT
PTA Catheter

Armada™ 18
PTA Catheter

Armada™ 35 / 35 LL
PTA Catheter



THROMBUS MANAGEMENT

JETi™
Hydrodynamic Thrombectomy System

RENAL

STENT SYSTEMS

RX Herculink Elite™
Renal Stent System

BALLOON DILATATION CATHETERS

Viatrac™ 14 Plus
Peripheral Dilatation Catheter

ILIAC

STENT SYSTEMS

Absolute Pro™
Vascular Self-Expanding Stent System

Omnilink Elite™
Vascular Balloon-Expandable Stent System

BALLOON DILATATION CATHETERS

Armada™ 35
PTA Catheter

HEMOSTASIS MANAGEMENT

CLOSURE DEVICES

Perclose™ ProStyle™
Suture-Mediated Closure and Repair System

Perclose ProGlide™
Suture-Mediated Closure System

Prostar™ XL
Percutaneous Vascular Surgical System

StarClose SE™
Vascular Closure System

ASSISTED COMPRESSION

FemoStop™ Gold
Compression Assist Device

RadiStop™
Compression Assist Device

EMBOLIZATION SYSTEMS

Amplatzer™
Vascular Plug

Amplatzer™
Vascular Plug II

Amplatzer™
Vascular Plug 4

GUIDE WIRES

WORKHORSE & ACCESS

Hi-Torque Command™ 18
Guide Wire

HydroSteer™
Guide Wire

GuideRight™
Guide Wire

TigerWire™
Guide Wire

SPECIALTY

Hi-Torque Proceed™
Guide Wire

Explore the full portfolio of Guide Wires

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See Indications and Important Safety Information included within.

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PERIPHERAL PORTFOLIO

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.

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Abbott
3200 Lakeside Dr., Santa Clara, CA. 95054 USA, Tel: 1.800.227.9902

Manufactured by Walk Vascular LLC, 17171 Daimler Street, Irvine, CA 92614 USA.

www.cardiovascular.abbott

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℞ ONLY Absolute Pro™
Vascular Self-Expanding Stent System

INDICATIONS

The **Absolute Pro™ Vascular Self-Expanding Stent System** is indicated for improving luminal diameter in patients with *de novo* or restenotic atherosclerotic lesions in the native common iliac artery and native external iliac artery with reference vessel diameters between 4.3 mm to 9.1 mm and lesion lengths up to 90 mm.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

DO NOT USE IF THE TEMPERATURE INDICATOR IS BLACK.

This device is intended for single-use only; do not reuse. Do not resterilize. Do not use if the package is open or damaged.

Use prior to the "Use By" date specified on the package.

Persons with known hypersensitivities to nitinol and / or its components (e.g. nickel, titanium) may suffer an allergic reaction to this implant.

The safety and effectiveness of multiple overlapping stents have not been established. However, when multiple stents are required, stent materials should be of similar composition.

Stenting across a major bifurcation may hinder or prevent future diagnostic or therapeutic procedures.

Use of an undersized guide wire, with insufficient support, may cause kinking in the Stent Delivery System.

Use of appropriate anticoagulant and/or antiplatelet therapy per standard of care is recommended for use with this stent system.

PRECAUTIONS

Inspect the product prior to use. Do not use if the package is open or damaged. Avoid unnecessary handling, which may kink or damage the Delivery System.

Only physicians familiar with the complications, side effects and hazards commonly associated with iliac stent placement should use this device.

The stent is not designed for resheathing or recapturing. The stent is not designed for repositioning once the stent has apposed the vessel wall.

Once the stent is apposed to the vessel, it is not recommended to remove the stent with the delivery system.

The **Absolute Pro™** is intended to perform as a system. Do not remove the stent for use in conjunction with other dilatation catheters; do not use the Absolute Pro™ in conjunction with other stents.

Refer to the instructions for use supplied with any interventional devices to be used in conjunction with the Absolute Pro™ for their intended uses, contraindications, and potential complications.

Stent retrieval methods (use of additional wires, snares and / or forceps) may result in additional trauma to the vasculature.

Stent Delivery System Handling – Precautions

- **Do not remove the stent from its Delivery System,** as removal may damage the stent and / or lead to stent embolization. Stent system is intended to perform as a system.
- Special care must be taken not to handle or in any way disrupt the stent on the Delivery System. This is most important during Delivery System removal from packaging, mandrel removal, placement over guide wire, and advancement through rotating hemostatic valve (RHV) adapter and guiding catheter hub.
- Inspect to determine the outer jacket is attached to the handle. Reattach by pushing the outer jacket back into the handle.
- If the thumbwheel moves prior to unlocking, do not use unit; unintentional partial or full deployment may occur.
- Do not unlock the handle prior to positioning the stent at the intended location. Failure to follow this instruction could lead to deployment of the stent at an unintended location.
- Once unlocked, the handle locking mechanism cannot be re-locked.
- Once unlocked, the retraction sheath may unintentionally release the stent during device manipulation.

Stent Placement - Precautions

- Advance the Delivery System past the lesion and pull back to help remove slack from the system. Removing all slack from the delivery system prior to stent deployment will help ensure accurate stent delivery.
- If detachable outer jacket is not engaged in the introducer sheath, manually stabilize prior to deployment to help ensure accurate stent delivery. Do not restrict retracting sheath during stent deployment.
- If the thumbwheel moves freely in both directions after unlocking, remove the device together with the introducer sheath or guiding catheter as single unit; do not use the unit as unintentional partial or full deployment may occur.
- **Do not attempt to pull a partially expanded stent back through the sheath or guiding catheter; dislodgment of the stent from the Delivery System may occur.**
- Should **unusual resistance** be felt **at any time, including resistance unlocking the handle or rotating the thumbwheel,** during stent deployment, the entire system should be **removed together with the introducer sheath or guiding catheter as a single unit.** Failure to follow these instructions could result in failure to deploy, difficulties with deployment, partial stent deployment or deployment in an unintended location. • Do not expand the stent if it is not properly positioned in the vessel. *(See Stent / System Removal – Precautions.)*

Stent / System Removal – Precautions

Do not attempt to pull a partially-expanded stent back through the introducer sheath or guiding catheter. The stent is not designed for recapturing. The stent is not designed for repositioning once the stent has apposed the vessel. Once the stent is apposed to the vessel, it is not recommended to remove the stent with the Delivery System.

Should **unusual resistance** be felt **at any time** during lesion access or removal of the Delivery System post stent implantation, the entire system should be **removed together with the introducer sheath or guiding catheter as a single unit**. Failure to follow these instructions could result in failure to deploy, difficulties with deployment, partial stent deployment or deployment in an unintended location.

When removing the Delivery System as a single unit:

- Do not retract the Delivery System into the guiding catheter or sheath.
- Tighten the RHV (if applicable) to secure the Delivery System to the guiding catheter, and then remove the guiding catheter or sheath and Delivery System as a single unit.
- If possible, retain the guide wire position for subsequent vessel access.

Failure to follow these steps and / or applying excessive force to the Delivery System can potentially result in loss or damage to the stent and / or Delivery System components.

Post Implant – Precautions

- Exercise great care when **crossing a newly deployed stent** with a guide wire, balloon or Delivery System to avoid disrupting the stent geometry.
- This stent is an open cell design. Open cell designs allow each ring to expand independently of the adjacent ring. Under fluoroscopy the independent ring expansion may appear as a step in the contour of the stent, and be erroneously interpreted as a stent fracture. This should be considered when deciding whether additional diagnostics (x-ray and / or angiography with contrast material) is necessary.

Magnetic Resonance Imaging (MRI) Non-clinical testing has demonstrated that the Absolute Pro™ Stent in single and in overlapped configurations up to 190 mm in length is MR Conditional as defined in AS™F2503. For placement in the iliac artery, patients with this implant may be scanned safely anytime after implantation under the following conditions: • Static magnetic field of 1.5 Tesla or 3.0 Tesla. • Spatial gradient field of 2500 Gauss/cm or less. • Maximum whole body average specific absorption rate (WB-SAR) of 2 W/kg for 15 minutes of scanning per sequence for patient landmarks above umbilicus. (Total duration of all scans may exceed 15 minutes.)

- Maximum WB-SAR of 1W/kg for 15 minutes of scanning for patient landmarks below umbilicus.
- Transmit RF body coil should be used in normal operating mode, as defined in IEC 60601-2-33.

The Absolute Pro™ stent should not migrate in this MRI environment. Magnetic force on the Absolute Pro™ stent was tested according to AS™F2052-06e. Non-clinical testing at field strengths greater than 3 Tesla has not been performed to evaluate stent migration or heating.

Stent heating during MRI was derived by using the measured non-clinical, *in vitro* temperature rise according to AS™F2182-09 in a GE Signa HDx 3 Tesla scanner and in a GE 1.5 Tesla coil in combination with the calculated local specific absorption rates (SARs) in a digitized human model. For the SAR conditions above, the greatest *in-vivo* temperature rise was calculated to be 5.3°C at 128 MHz for a stent length of 60 mm. The calculations do not take into consideration the cooling effects of blood flow, and therefore, actual *in-vivo* rises are expected to be lower.

The effects of MRI on overlapped stents greater than 190 mm in length or stents with fractured struts are unknown. Image artifact may be present when scanning the Absolute Pro™ stent as demonstrated in non-clinical testing performed according to AS™F2119-07 in a GE Signa HDx 3 Tesla scanner. The image artifact (both inside and outside the device lumen) extends approximately 5 mm from the device using the spin echo sequence and 10 mm from the device using the gradient echo sequence. MR image quality may be compromised if the area of interest is in the exact same area, or relatively close to, the position of the Absolute Pro™ stent. Therefore, it may be necessary to optimize the MR imaging parameters in the presence of Absolute Pro™ stents.

Abbott Vascular recommends that patients register the MR conditions in this IFU with the MedicAlert Foundation or equivalent organization. The MedicAlert Foundation can be contacted by phone at: (888) 633-4298, (209) 668-3333 or on the internet at www.medicalert.org.

POTENTIAL ADVERSE EVENTS

Below is a list of the potential adverse effects (e.g., complications) that may be associated with the use of the device:
• Acute myocardial infarction • Allergic reaction (contrast medium, drug or stent material) • Aneurysm, pseudoaneurysm, or arteriovenous fistula • Angina or coronary ischemia • Arrhythmias, with or without the need for a temporary pacemaker • Bleeding complications from anticoagulant or antiplatelet medication requiring transfusion or surgical intervention • Death
• Detachment and/or implantation of a component of the system
• Embolization, arterial or other (air, tissue, plaque, thrombotic material, stent) • Emergent or urgent surgery to perfuse limb or remove stent • Fever • Hematoma or hemorrhagic event
• Hypotension or hypertension • Infection, local or systematic, including bacteremia or septicemia •Ischemia or infarction of tissue or organ • Pain (limb or catheter insertion site) • Pulmonary embolism • Renal failure or insufficiency secondary to contrast medium • Restenosis of vessel in stented segment • Stent malapposition or migration • Stent strut fracture • Stent thrombosis or occlusion • Stroke, cerebrovascular accident (CVA), or transient ischemic attack (TIA) • Target limb loss (amputation of toe, foot, and/or leg) • Vascular thrombosis or occlusion at puncture site, treatment site, or remote site • Vessel dissection, perforation, or rupture • Vessel spasm or recoil • Worsening claudication or rest pain

℞ ONLY Armada™14
PTA Catheter

INDICATIONS

The device is indicated to dilate stenoses in femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The 2.0 to 4.0 mm balloon diameters are also indicated for post-dilatation of balloon-expandable stents up to 40 mm and self-expanding stents up to 80 mm in the vessels listed above.

CONTRAINDICATIONS

- Inability to cross lesion with a guide wire
- Use in the coronary arteries.

WARNINGS/PRECAUTIONS

- This device should only be used by physicians who are experienced and have a thorough understanding of the clinical and technical aspects of PTA.
- One-time use only – do not resterilize! This single use device cannot be reused on another patient, 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 materials, leading to contamination due to narrow gaps and/or spaces and diminished safety and/or performance of the device. Absence of original labeling may lead to misuse and eliminate traceability. Absence of original packaging may lead to device damage, loss of sterility, and risk of injury to patient and/or user.
- Do not use if inner package is damaged or opened.
- Employ aseptic techniques during removal from the package and during use.
- Any use for procedures other than those indicated in these instructions is not recommended.
- Use prior to the use by date.
- Carefully inspect the catheter prior to use to verify that it has not been damaged during shipment and that its size, shape and condition are suitable for the procedure for which it is to be used.
- Precautions to prevent or reduce blood clotting should be taken when any catheter is used.
- Flush or rinse all products entering the vascular system with sterile isotonic saline or a similar solution via the guide wire access port prior to use. Consider the use of systemic heparinization.
- When the system is introduced into the vascular system, it should be manipulated only under high quality fluoroscopy.
- The Armada™14 PTA Catheter must always be introduced, moved and or withdrawn over a guide wire (max. 0.014″).
- Never attempt to move the guide wire when the balloon is inflated.
- Never use air or any gaseous medium to inflate the balloon.
- Do not advance the Armada™14 PTA Catheter against significant resistance. The cause of resistance should be determined via fluoroscopy and remedial action taken.
- The minimal acceptable sheath French size is printed on the package label. Do not attempt to pass the Armada™14 PTA Catheter through a smaller sized sheath introducer than indicated on the label.
- The size of the inflated balloon should be selected not to exceed the diameter of the artery immediately distal, or proximal, to the stenosis.
- Inflation in excess of the rated burst pressure may cause the balloon to rupture. Use of a pressure monitoring device is recommended.
- If a distal protection device is used, follow the manufacturer's instruction for use. Allow and maintain adequate distance between the Armada™14 PTA Catheter and the distal protection device to avoid engagement.
- Rated burst pressure and balloon fatigue testing of the Armada™14 PTA balloons within deployed stents has demonstrated the following:
- The 2.0 to 4.0 mm balloon diameters can safely post-dilate balloon expandable stents up to 40 mm in length.
- The 2.0 to 4.0 mm balloon diameters can safely post-dilate self-expanding stents up to 80 mm in length.

The safety of using additional balloon diameters and/or lengths to post dilate stents has not been established.

- When post-dilating stents, use a balloon length that is appropriate for the deployed stent length.

POTENTIAL COMPLICATIONS

The following complications may occur as a result of PTA, but may not be limited to:

• Abrupt closure • Access site hematoma • Aneurysm • Angina • Arrhythmias • Arteriovenous fistula • Bleeding complications which may require transfusion • Cerebral ischemia/transient ischemic attack (TIA) • Death • Embolism (air, tissue, thrombotic, systemic or device component) • Fever/ pyrogenic reaction • Hypersensitivity or allergic reaction to contrast agents and drug reactions • Hypertension/ hypotension • Infection • Ischemia, including tissue ischemia, steal syndrome and necrosis • Leg edema • Myocardial ischemia or infarction • Nausea and vomiting • Neuropathies or nerve injury • Occlusion • Organ failure (single, multiple) • Pain • Palpitations • Pseudoaneurysm • Renal failure/ insufficiency • Restenosis • Stroke/cerebrovascular accident (CVA) • Vascular complications, including entry site, which may require vessel repair • Vascular thrombosis • Vessel injury, e.g. dissection, perforation • Vessel spasm

Rx ONLY

Armada™ 14XT
Percutaneous Transluminal Angioplasty (PTA) Catheter

INDICATIONS
The Armada™ 14 XT PTA Catheter is indicated to dilate stenosis in femoral, popliteal, infrapopliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The 2.0 mm to 5.0 mm balloon diameters are also indicated for post-dilatation of stents in the peripheral vasculature.

CONTRAINDICATIONS
- The Armada™ 14 XT PTA Catheter is contraindicated for:
- Inability to cross lesion with a guide wire

WARNINGS
This device is intended for one time use only. DO NOT resterilize and / or reuse it, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.

Any use for procedures other than those indicated in these instructions is not recommended.

Precautions to prevent or reduce clotting should be taken when any catheter is used.

The size of the inflated balloon should be selected not to exceed the diameter of the artery immediately distal, or proximal, to the stenosis.

Balloon pressure should not exceed the rated burst pressure (RBP). The RBP is based on results of in vitro testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their RBP. Use of a pressure-monitoring device is recommended to prevent over- pressurization.

To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

Do not use, or attempt to straighten, a catheter if the shaft has become bent or kinked; this may result in the shaft breaking. Instead, prepare a new catheter.

Do not torque the catheter more than one (1) full turn.

If a distal protection device is used, follow the manufacturer's instruction for use. Allow and maintain adequate distance between the Armada™ 14 XT PTA Catheter and the distal protection device to avoid engagement. Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

When the catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of resistance before proceeding.

Treatment of moderately or heavily calcified lesions increases the risk of acute closure, vessel trauma, balloon burst, balloon entrapment, and associated complications. If resistance is felt, determine the cause before proceeding.

Continuing to advance or retract the catheter while under resistance may result in damage to the vessels and / or damage / separation of the catheter.

In the event of catheter damage / separation, recovery of any portion should be performed based on physician determination of individual patient condition and appropriate retrieval protocol.

In cases of extreme vessel tortuosity, it may be necessary to reposition the catheter in a straight segment of the vessel in order to allow guide wire exchange. Do not continue to use a catheter if excessive resistance is felt during guide wire exchanges. Instead, prepare a new catheter.

PRECAUTIONS
This device should only be used by physicians who are experienced and have a thorough understanding of the clinical and technical aspects of PTA.

Note the "Use by" date specified on the package.

Inspect all product prior to use. Do not use if the package is open or damaged.

Prior to angioplasty, the PTA catheter should be examined to verify functionality and ensure that its size is suitable for the specific procedure for which is to be used.

Precautions to prevent or reduce clotting should be taken when any catheter is used.

Flush or rinse all products entering the vascular system with sterile heparinized normal saline or a similar solution via the guide wire access port prior to use. Consider the use of systemic heparinization.

Never attempt to move the guide wire when the balloon is inflated.

The minimal acceptable sheath / guiding catheter French size is printed on the package label. Do not attempt to pass the Armada™ 14 XT PTA Catheter through a smaller sized sheath / guiding catheter than indicated on the label. If the surface of the Armada™ 14 XT PTA Catheter becomes dry, wetting with heparinized normal saline will reactivate the coating.

Do not reinsert the Armada™ 14 XT PTA Catheter into the coil dispenser after procedural use.

Bench testing was conducted with 0.014" (0.36 mm) constant diameter guide wires to establish guide wire compatibility. If another type of guide wire is selected with a different dimensional profile, the compatibility (e.g., wire resistance) should be considered prior to use.

The safety and effectiveness of this PTA balloon catheter for the treatment of in-stent restenosis (ISR) have not been established.

ADVERSE EVENTS
Possible adverse effects include, but are not limited to, the following:
• Abrupt closure • Access site hematoma • Aneurysm • Angina • Arrhythmias • Arteriovenous fistula • Bleeding complications, which may require transfusion • Cerebral ischemia / transient ischemic attack (TIA) • Death •Embolism (air, tissue, thrombotic, systemic or device component) •Fever / pyrogenic reaction • Hypersensitivity or allergic reaction to contrast agents and drug reactions •Hypertension /hypotension •Infection •Ischemia, including tissue ischemia, steal syndrome, and necrosis • Leg edema • Myocardial ischemia or infarction • Nausea and vomiting • Neuropathies or nerve injury • Occlusion • Organ failure (single, multiple) • Pain • Palpitations • Pseudoaneurysm • Renal failure / insufficiency • Restenosis • Stroke / cerebrovascular accident (CVA) • Vascular complications, including entry site, which may require vessel repair • Vascular thrombosis • Vessel injury, e.g., dissection, perforation • Vessel spasm

Rx ONLY

Armada™ 18
Percutaneous Transluminal Angioplasty Catheter

INDICATIONS
The Armada™18 is indicated to dilate stenosis in femoral, popliteal, infra-popliteal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. In addition, the device is also indicated for post-dilatation of balloon expandable and self-expanding stents.

CONTRAINDICATIONS
- Inability to cross lesion with a guide wire
- Use in the coronary arteries.

WARNINGS / PRECAUTIONS
- This device should only be used by physicians who are experienced and have a thorough understanding of the clinical and technical aspects of PTA.
- One-time use only – do not resterilize! This single use device cannot be reused on another patient, 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 materials, leading to contamination due to narrow gaps and / or spaces and diminished safety and / or performance of the device. Absence of original labeling may lead to misuse and eliminate traceability. Absence of original packaging may lead to device damage, loss of sterility, and risk of injury to patient and / or user.
- Do not use if inner package is damaged or opened.
- Employ aseptic techniques during removal from the package and during use.
- Any use for procedures other than those indicated in these instructions is not recommended.
- Use prior to the use by date.
- Carefully inspect the catheter prior to use to verify that it has not been damaged during shipment and that its size, shape and condition are suitable for the procedure for which it is to be used.
- Precautions to prevent or reduce blood clotting should be taken when any catheter is used.
- Flush or rinse all products entering the vascular system with sterile isotonic saline or a similar solution via the guide wire access port prior to use. Consider the use of systemic heparinization.
- When the system is introduced into the vascular system, it should be manipulated only under high quality fluoroscopy.
- The Armada™18 PTA Catheter must always be introduced, moved and or withdrawn over a guide wire (max. 0.018").
- Never attempt to move the guide wire when the balloon is inflated.
- Never use air or any gaseous medium to inflate the balloon.
- Do not advance the Armada™18 PTA Catheter against significant resistance. The cause of resistance should be determined via fluoroscopy and remedial action taken.
- The minimal acceptable sheath French size is printed on the package label. Do not attempt to pass the Armada™18 PTA Catheter through a smaller sized sheath introducer than indicated on the label.
- The size of the inflated balloon should be selected not to exceed the diameter of the artery immediately distal, or proximal, to the stenosis.
- Inflation in excess of the rated burst pressure may cause the balloon to rupture. Use of a pressure monitoring device is recommended.
- If a distal protection device is used, follow the manufacturer's instruction for use. Allow and maintain adequate distance between the Armada™18 PTA Catheter and the distal protection device to avoid engagement.
- Rated burst pressure and balloon fatigue testing of the Armada™18 PTA balloons within deployed stents has demonstrated that the Armada™18 can safely post-dilate balloon expandable and self-expanding stents.
- When post-dilating stents, use a balloon length that is appropriate for the deployed stent length.

POTENTIAL COMPLICATIONS
The following complications may occur as a result of PTA, but may not be limited to:

• Abrupt closure • Allergic reaction (contrast medium, drug, or stent material) • Aneurysm, pseudoaneurysm or arteriovenous fistula • Angina or coronary ischemia • Arrhythmias (including premature beats, bradycardia, atrial or ventricular tachycardia, atrial or ventricular fibrillation) • Bleeding complications requiring transfusion or surgical intervention • Death • Detachment and/ or implantation of a component of the system • Embolization, arterial or other (air, tissue, plaque, thrombotic material, device) • Emergent or urgent surgery • Fever • Hematoma or hemorrhagic event with or without surgical repair • Hyperperfusion syndrome • Hypotension or hypertension • Infection • Ischemia or infarction of tissue or organ not covered under other adverse events • Myocardial infarction • Pain (limb or catheter site) • Peripheral nerve injury • Pulmonary embolism • Renal failure or insufficiency • Restenosis of vessel • Shock • Stroke, cerebrovascular accident (CVA), or transient ischemic attack (TIA) • Target limb loss (amputation of toe, foot, and / or leg) • Vascular thrombosis or occlusion at puncture site, treatment site, or remote site • Venous thromboembolism • Vessel dissection, perforation, or rupture • Vessel spasm or recoil • Worsening claudication or rest pain

Rx ONLY

Armada™ 35 / Armada™ 35 LL
Percutaneous Transluminal Angioplasty Catheter

INDICATIONS
The device is intended for dilatation of lesions in the renal, iliac, femoral, popliteal, tibial, and peroneal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.

CONTRAINDICATIONS
- Inability to cross lesion with a guide wire
- Use in the coronary arteries.

WARNINGS/PRECAUTIONS
- This device should only be used by physicians who are experienced and have a thorough understanding of the clinical and technical aspects of PTA.
- One-time use only – do not resterilize! This single use device cannot be reused on another patient, 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 materials, leading to contamination due to narrow gaps and/or spaces and diminished safety and/or performance of the device. Absence of original labeling may lead to misuse and eliminate traceability. Absence of original packaging may lead to device damage, loss of sterility, and risk of injury to patient and/or user.
- Do not use if inner package is damaged or opened.
- Employ aseptic techniques during removal from the package and during use.
- Any use for procedures other than those indicated in these instructions is not recommended.
- Use prior to the use by date.
- Carefully inspect the catheter prior to use to verify that it has not been damaged during shipment and that its size, shape and condition are suitable for the procedure for which it is to be used.
- Precautions to prevent or reduce blood clotting should be taken when any catheter is used.
- Flush or rinse all products entering the vascular system with sterile isotonic saline or a similar solution via the guide wire access port prior to use.
- Consider the use of systemic heparinization.
- When the system is introduced into the vascular system, it should be manipulated only under high quality fluoroscopy.
- The Armada™35 / Armada™35 LL PTA Catheter must always be introduced, moved and or withdrawn over a guide wire (max. 0.035").
- Never attempt to move the guide wire when the balloon is inflated.
- Never use air or any gaseous medium to inflate the balloon.
- Do not advance the Armada™35 / Armada™35 LL PTA Catheter against significant resistance. The cause of resistance should be determined via fluoroscopy and remedial action taken.
- The minimal acceptable sheath French size is printed on the package label. Do not attempt to pass the Armada™35 / Armada™35 LL PTA Catheter through a smaller sized sheath introducer than indicated on the label.
- The size of the inflated balloon should be selected not to exceed the diameter of the artery immediately distal, or proximal, to the stenosis.
- Inflation in excess of the rated burst pressure may cause the balloon to rupture. Use of a pressure monitoring device is recommended.
- When post-dilating stents, use a balloon length that is appropriate for the deployed stent length.

POTENTIAL COMPLICATIONS
The following complications may occur as a result of PTA, but may not be limited to:
• Abrupt closure • Allergic reaction (contrast medium, drug, or device material) • Aneurysm or pseudoaneurysm in vessel, or at vascular access site • Angina or coronary ischemia • Arrhythmias (including premature beats, bradycardia, atrial or ventricular tachycardia, arterial or ventricular fibrillation) • Arteriovenous fistula • Bleeding complications requiring transfusion or surgical intervention • Death • Detachment of a system component or implantation in an unintended site • Embolization (air, tissue, plaque, thrombotic material, device) • Emergent surgery • Fever • Hematoma or hemorrhagic event, with or without surgical repair • Hyperperfusion syndrome • Hypotension or hypertension • Infection • Ischemia or infarction not covered under other adverse events • Myocardial infarction • Pain (leg, foot, and / or insertion site) • Peripheral nerve injury • Pulmonary embolism • Renal failure or insufficiency • Restenosis • Shock • Stroke • Target limb loss (amputation of toe, foot, and / or leg) • Thrombosis or occlusion • Transient ischemic attack • Venous thrombosis • Vessel dissection, perforation, or rupture • Vessel spasm or recoil • Worsening claudication or rest pain

Rx ONLY

Omnilink Elite™
Vascular Balloon-Expandable Stent System

INDICATIONS
The Omnilink Elite™Stent System is indicated for the treatment of atherosclerotic iliac artery lesions with reference vessel diameters of ≥ 5.0 mm and ≤ 11.0 mm, and lesion lengths up to 50 mm.

CONTRAINDICATIONS
There are no known contraindications.

WARNINGS
- This device is intended for single-use only; do not reuse. Do not resterilize. Do not use if package is open or damaged.
- Since the use of this device carries the associated risk of subacute thrombosis, vascular complications, and / or bleeding events, judicious selection of patients is necessary.
- Persons allergic to L605 cobalt chromium alloy may suffer an allergic reaction to this implant.
- This device should be used only by physicians trained in

angiography and percutaneous transluminal angioplasty and stent placement.

- The safety and effectiveness of multiple overlapping stents have not been established. However, when multiple stents are required, stent materials should be of similar composition to avoid the potential for dissimilar metal corrosion.
- Use of appropriate anticoagulant and/or antiplatelet therapy per standard of care is recommended for use with this stent system.

PRECAUTIONS
The device should be used only by physicians trained in angiography and percutaneous transluminal angioplasty and stent placement.

Stent Delivery System Handling – Precautions
- For single use only. Do not resterilize or reuse.
- Use the stent system prior to the "Use by" date specified on the package.
- Do not remove stent from its delivery balloon, as removal may damage the stent and / or lead to stent embolization.
- Carefully inspect the Omnilink Elite® Stent System prior to use to verify that the stent has not been damaged in shipment and that the device dimensions are suitable for the specific procedure. Take care to avoid unnecessary handling.
- The Omnilink Elite® Stent System is intended to perform as a system. The stent should not be removed for use in conjunction with other dilatation catheters, nor should the delivery system be used in conjunction with other stents.
- Refer to the instructions for use supplied with any interventional devices to be used in conjunction with the Omnilink Elite® Stent System, for their intended uses, contraindications, and potential complications.
- Special care must be taken not to handle or in any way disrupt the stent on the balloon. This is most important during stent system removal from the packaging, placement over a guide wire and advancement through a guiding catheter or introducer sheath.
- Do not "roll" the mounted stent with your fingers, as this action may loosen the stent from the delivery balloon.
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon, as this may cause uneven expansion and difficulty in deployment of the stent.
- Do not advance the stent delivery system without the guide wire extending from the tip

Stent Placement – Precautions
- Do not prepare or pre-inflate balloon prior to stent deployment other than as directed. Use balloon purging technique described in the *Clinician Use Information* section.
- The inflated balloon diameter of the system used to deploy the stent should approximate the diameter of the vessel. Oversizing of the stent can result in a ruptured vessel. To ensure full expansion of the stent, the balloon should be inflated to a minimum of nominal pressure.
- Implanting a stent may lead to dissection of the vessel distal and / or proximal to the stent and may cause acute closure of the vessel, requiring additional intervention (surgical intervention, further dilatation, placement of additional stents, or other).
- When treating multiple lesions, the distal lesion should be initially stented, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent in placement of the distal stent and reduces the chances for dislodging the proximal stent.
- Do not expand the stent if it is not properly positioned in the vessel (*See Stent / System Removal – Precautions*).
- Stenting across a major bifurcation may hinder or prevent future side branch access.
- Balloon pressures should be monitored during inflation. Do not exceed Rated Burst Pressure (RBP) as indicated on product label. Use of pressures higher than specified on product label may result in a ruptured balloon with possible vessel damage or perforation.
- Stent retrieval methods (use of additional wires, snares, and / or forceps) may result in additional trauma to the vasculature and / or the vascular access site. Complications may include bleeding, hematoma, or pseudoaneurysm.
- The Omnilink Elite® Stent System is intended for deployment and post-deployment dilatation of the stent only and should not be used to dilate other locations.
- Do not attempt to pull an unexpanded stent back through the introducer sheath / guiding catheter; dislodgment of the stent from the balloon may occur.
- Once fully deployed, the stent cannot be repositioned

Stent/System Removal – Precautions
Should unusual resistance be felt at any time during either lesion access or removal of the delivery system post-stent implantation, the entire system should be removed as a single unit.

When removing the delivery system as a single unit:
- DO NOT retract the delivery system into the introducer sheath / guiding catheter.
- Position the proximal balloon marker just distal to the tip of the introducer sheath / guiding catheter.
- Advance the guide wire in the anatomy as far distally as safely possible.
- Secure the delivery system to the introducer sheath / guiding catheter; then remove the introducer sheath / guiding catheter, guide wire and delivery system as a single unit.

Failure to follow these steps and / or applying excessive force to the delivery system can potentially result in loss or damage to the stent and / or delivery system components.

If it is necessary to retain guide wire position for subsequent vessel access, leave the guide wire in place and remove all other system components.

Post Implant – Precautions
Exercise great care when crossing a newly deployed stent with a guide wire or balloon catheter to avoid disrupting the stent geometry.

MRI Information
Non-clinical testing has demonstrated that the Omnilink Elite® stent, in single and in overlapped configurations up to 100 mm in length, is MR Conditional as defined in AS™F2503. It can be scanned safely under the conditions listed in the *Instructions for Use*.

POTENTIAL ADVERSE EVENTS
Potential complications associated with percutaneous iliac artery treatment, including the use of an iliac stent, may include, but are not limited to, the following:

• Acute myocardial infarction • Allergic reaction (contrast medium, drug, or stent material) • Aneurysm, pseudoaneurysm, or arteriovenous fistula • Angina or coronary ischemia • Arrhythmias, with or without the need for a temporary pacemaker • Bleeding complications from anticoagulant or antiplatelet medication requiring transfusion or surgical intervention • Death • Detachment and/or implantation of a component of the system • Embolization, arterial or other (air, tissue, plaque, thrombotic material, stent) • Emergent or urgent surgery to perfuse limb or remove stent • Fever • Hematoma or hemorrhagic event • Hypotension or hypertension • Infection, local or systemic, including bacteremia or septicemia • Ischemia or infarction of tissue or organ • Pain (limb or catheter site) • Pulmonary embolism • Renal failure or insufficiency secondary to contrast medium • Restenosis of vessel in stented segment • Stent malapposition or migration • Stent strut fracture • Stent thrombosis or occlusion • Stroke, cerebrovascular accident (CVA), or transient ischemic attack (TIA) • Target limb loss (amputation of toe, foot, and/or leg) • Vascular thrombosis or occlusion at puncture site, treatment site, or remote site • Vessel dissection, perforation, or rupture • Vessel spasm or recoil • Worsening claudication or rest pain

Rx ONLY Prostar™ XL Percutaneous Vascular Surgical (PVS) System

INDICATIONS FOR USE
The Prostar™ XL PVS System is indicated for the percutaneous delivery of sutures for closing the common femoral artery access site and reducing the time to hemostasis and time to ambulation (patient walks ten feet) of patients who have undergone catheterization procedures using 8.5F to 10F sheaths. (Refer to **PRECAUTIONS, SPECIAL PATIENT POPULATIONS** sections).

CONTRAINDICATIONS
None known.

WARNINGS

The outer pouch of the Prostar™ XL PVS System and the individual accessories provides the sterile barrier. Do not use the Prostar™ PVS System or accessories if the packaging or sterile barrier have been previously opened or damaged, or if the components appear to be damaged or defective.

DO NOT RESTERILIZE OR REUSE. The Prostar™ XL PVS System and accessories are intended for single use only.

Do not use the Prostar™ XL PVS System if the puncture site is proximal to the inguinal ligament as this may result in a retroperitoneal hematoma.

PRECAUTIONS
1. The Prostar™ XL PVS device and accessories should only be used by physicians (or other healthcare professionals authorized by or under the direction of such physicians) after they have been trained in the use of the Prostar™ XL PVS System and accessories, e.g., participation in a Prostar™ XL PVS System training program or equivalent.
2. Observe sterile technique at all times when using the Prostar™ XL PVS System. Employ appropriate groin management, as per hospital protocol, post procedure and post hospital discharge to prevent infection.
3. Use a single wall puncture technique. Do not puncture the posterior wall of the artery.
4. Adequate knot security requires accepted surgical technique as warranted by surgical circumstances and the experience of the operator.
5. There are no reaccess restrictions if previous arteriotomy repairs were achieved with an Abbott Vascular Suture Mediated Device.
6. Do not insert the Prostar™ XL device into the femoral artery at an angle greater than 45 degrees to the longitudinal plane of the artery.
7. **Do not advance or withdraw the Prostar™ XL device against resistance until the cause of that resistance has been determined** (see **CLINICAL PROCEDURE-Device Placement** section)**. Excessive force used to advance or torque the Prostar™ XL device should be avoided as it may lead to significant arterial damage and / or breakage of the device, which may necessitate intervention and / or surgical removal of the device and arterial repair.**
8. If excessive resistance in advancing the Prostar™ XL device is encountered, withdraw the Prostar™ XL device over a 0.038" (or smaller) guide wire and reinsert the introducer sheath or use conventional compression therapy.
9. In the event suture breakage occurs after an initial knot has been tied, care should be taken to avoid excessive force if the reintroduction of the Prostar™ XL device or introducer sheath is required. Any resistance to introduction should result in advancement of an introducer sheath small enough to be introduced without undue force.
10. If significant blood flow is evident through or around the barrel of the Prostar™ XL device, do not deploy needles. Remove the Prostar™ XL device over a 0.038" (or smaller) guide wire and insert an appropriately sized introducer sheath.
11. Remove the Prostar™ XL sheath before tightening the suture. Failure to remove the sheath prior to tightening the suture may result in detachment of the tip of the sheath.
12. Do not attempt to re-deploy Prostar™ XL needles after the needles have been "backed-down" into the sheath (refer to the TECHNIQUE FOR NEEDLE BACK-DOWN section).
13. In the event bleeding from the femoral access site persists after the use of the Prostar™ XL device and accessories, use conventional compression therapy.

ADVERSE EVENTS
The following adverse events have been reported and may occur include

• Device Malfunction • Device Complication • Vascular Repair • Ultrasound Guided Compression • Transfusion • Infection Requiring IV Antibiotics • Hematoma > 6 cm • AV Fistula • Nerve Injury • Pseudoaneurysm • Deep Vein Thrombosis • Late Bleeding • Wound Dehiscence • Vessel Laceration • Local Pulse Deficits or Ischemia • Embolization • Transitory Local Irritation • Nerve Injury • Vascular Spasm

Rx ONLY RX Acculink™ Carotid Stent System

INDICATIONS
The RX Acculink™ Carotid Stent System, used in conjunction with the Abbott Vascular embolic protection system specified below, is indicated for the treatment of patients at high and standard risk for adverse events from carotid endarterectomy who require carotid revascularization and meet the criteria outlined below:

	HIGH RISK	STANDARD RISK
Embolic Protection System	Abbott Vascular's Accunet™ or Emboshield® Family	
With neurological symptoms	≥ 50% stenosis of the common or internal carotid artery by ultrasound or angiogram	≥ 70% stenosis of the common or internal carotid artery by angiogram
Without neurological symptoms	≥ 80% stenosis of the common or internal carotid artery by ultrasound or angiogram	≥ 70% stenosis of the common or internal carotid artery by ultrasound or ≥ 60% stenosis of the common or internal carotid artery by angiogram
Reference vessel diameter	Must be within 4.0 mm – 9.0 mm at the target lesion	

CONTRAINDICATIONS
The RX Acculink™ Carotid Stent System is contraindicated for use in:
- Patients in whom anti-coagulant and / or anti-platelet therapy is contraindicated.
- Patients with severe vascular tortuosity or anatomy that would preclude the safe introduction of a guide catheter, sheath, embolic protection system, or stent system.
- Patients with known hypersensitivity to nickel-titanium.
- Patients with uncorrected bleeding disorders.
- Lesions in the ostium of the common carotid artery.

WARNINGS

Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid stent placement should use this device

GENERAL

Refer to the Instructions for Use supplied with any interventional devices to be used in conjunction with the RX Acculink™ Carotid Stent System for their intended uses, contraindications, and potential complications.

The safety and efficacy of the Acculink™ Carotid Stent System have not been demonstrated with embolic protection systems other than Abbott Vascular's Accunet™ or Emboshield™ family of Embolic Protection Systems (EPS). Refer to the Instructions for Use document for the Embolic Protection System that will be used for specific device instructions.

Clinical study results suggest lower event rates when the RX Acculink™ Carotid Stent System is used in conjunction with an embolic protection device.

The long-term performance (> 3 years) of the Acculink™ Carotid Stent System has not been established.

As with any type of vascular implant, infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm, or rupture.

Stenting across a major bifurcation may hinder or prevent future diagnostic or therapeutic procedures.

In patients requiring the use of antacids and / or H2-antagonists before or immediately after stent placement, oral absorption of antiplatelet agents (e.g. aspirin) may be adversely affected. The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure as suggested in these instructions. Special consideration should be given to those patients with recently active gastritis or peptic ulcer disease.

When multiple stents are required, stent materials should be of similar composition.

Patient Selection
The safety and effectiveness of the RX Acculink™ Carotid Stent System have NOT yet been established in patients with the characteristics noted below.

Patient Characteristics:
Patients experiencing acute ischemic neurologic stroke or who experience a stroke within 7 days prior to the procedure.
• Patients with an intracranial mass lesion (i.e., abscess, tumor, or infection) or aneurysm > 5 mm. • Patients with arteriovenous malformations of the territory of the target carotid artery.
• Patients with coagulopathies. • Patients with poor renal function who, in the physician's opinion, may be at high risk for a reaction to contrast medium. • Patients with perforated vessels evidenced by extravasation of contrast media. • Patients with aneurysmal dilation immediately proximal or distal to the lesion. • Pregnant patients or patients under the age of 18.

Lesion Characteristics:
Patients with evidence of intraluminal thrombus thought to increase the risk of plaque fragmentation and distal embolization.
- Patients whose lesion(s) may require more than two stents.
- Patients with total occlusion of the target vessel.
- Patients with highly calcified lesions resistant to PTA.

Access Characteristics:

• Patients with known peripheral vascular, supra-aortic or internal carotid artery tortuosity that would preclude the use of catheter-based techniques. • Patients in whom femoral access is not possible. • Risk of distal embolization may be higher if the RX Acculink™ Carotid System cannot be used in conjunction with an embolic protection system during the carotid stenting procedure.

The safety and effectiveness of concurrent treatment of lesions in patients with bilateral carotid artery disease have not been established.

DEVICE USE

This device is intended for single-use only. Do not reuse. Do not resterilize, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.

Do not use the product after the "Use by" date specified on the package.

Do not use the product if the temperature indicator on inner pouch is black.

Maintain the patient's Activated Clotting Time (ACT) at > 250 seconds throughout RX Acculink™ Carotid Stent System usage to prevent thrombus formation on the device.

Maintain continuous flush while removing and reinserting devices on the guide wire. Perform all exchanges slowly to prevent air embolism or trauma to the artery.

Caution should be used if pre-dilating the lesion without embolic protection as this may increase the risk of an adverse outcome.

Implanting a stent may lead to dissection of the vessel distal and / or proximal to the stent and may cause acute closure of the vessel, requiring additional intervention (carotid endarterectomy, further dilatation, or placement of additional stents).

The stent may cause a thrombus, distal embolization or may migrate from the site of implant down the arterial lumen. Appropriate sizing of the stent to the vessel is required to reduce the possibility of stent migration. In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.

In the event of complications such as infection, pseudoaneurysm or fistulization, surgical removal of the stent may be required.

Overstretching of the artery may result in rupture and life-threatening bleeding.

If a filter-based embolic protection system (EPS) is used, allow for and maintain adequate distance between the RX Acculink™ Carotid Stent System and the EPS to avoid potential filter engagement with the RX Acculink™ Carotid Stent System tip and / or filter entanglement with the deployed stent. If filter engagement and / or entanglement or filter detachment occurs, surgical conversion or additional catheter-based intervention may be required.

Ensure optimal positioning of the stent prior to deployment. Once deployment is initiated, the stent cannot be repositioned or recaptured. Stent retrieval methods (use of additional wires, snares and / or forceps) may result in additional trauma to the carotid vasculature and / or the vascular access site. Complications may include death, stroke, bleeding, hematoma or pseudoaneurysm.

PRECAUTIONS

Stent Handling – Precautions

Carefully inspect the RX Acculink™ Carotid Stent System to verify that the device has not been damaged in shipment. Do not use damaged equipment.

The delivery system has an internal hypotube. Take care to avoid unnecessary handling, which may kink or damage the delivery system. Do not use if device is kinked.

Do not expose the delivery system to organic solvents (e.g. alcohol) as structural integrity and / or function of the device may be impaired.

Do not remove the stent from its delivery system as removal may damage the stent. The stent on the delivery system is intended to perform as a system. If removed, the stent cannot be put back on the delivery system.

The delivery system should not be used in conjunction with other stents.

Special care must be taken not to handle or in any way disrupt the stent on the delivery system. This is most important during catheter removal from packaging, mandrel removal, placement over the guide wire, and advancement through a Rotating Hemostatic Valve (RHV) adapter and guiding catheter hub.

Do not hold the sheath or stent during mandrel removal.

Stent Placement – Precautions

Use with bleedback control hemostatic valves is not recommended.

The RX Acculink™ Carotid Stent System is not compatible with any guide wire larger than 0.014" (0.36 mm).

Leave the safety lock closed until the stent is ready to deploy.

The RX Acculink™ Carotid Stent System must be used with a guiding catheter or introducer sheath to maintain adequate support of the 0.014" (0.36 mm)guide wire throughout the procedure.

For best device performance, the guide wire exit notch should remain within the guiding catheter or sheath.

Ensure the stent system is fully flushed with heparinized saline prior to use. Do not use the delivery system if flush is not observed exiting at the distal end of the sheath.

Do not attempt to pull a partially expanded stent back through the guiding catheter or sheath; dislodgment of the stent from the delivery system may occur.

Venous access should be available during carotid stenting to manage bradycardia and / or hypotension by either pharmaceutical intervention or placement of a temporary pacemaker, if needed.

When catheters are in the body, they should be manipulated only under fluoroscopy. Radiographic equipment that provides high quality images is needed.

The delivery system is not designed for use with power injection. Use of power injection may adversely affect device performance.

If resistance is met during delivery system introduction, the system should be withdrawn and another system used.

Prior to stent deployment, remove all slack from the delivery system.

When more than one stent is required to cover the lesion, or if there are multiple lesions, the distal lesion should be stented first, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent for placement of the distal stent and reduces the chance of dislodging stents that have already been placed.

If overlap of sequential stents is necessary, the amount of overlap should be kept to a minimum (approximately 5 mm). In no instance should more than 2 stents overlap.

Post-Implant – Precautions

Care must be exercised when crossing a newly deployed stent with other interventional devices to avoid disrupting the stent geometry and placement of the stent.

In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.

MRI Compatibility

Non-clinical testing has demonstrated that the Acculink™ Carotid Stent System, in single and overlapped configurations up to 75 mm in length, is MR Conditional. Patients with this implant can be scanned safely under the following conditions:

• Static magnetic field of 1.5 or 3.0 Tesla,

• Spatial gradient of 2500 Gauss/cm (25 T/m),

• Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode).

Under the scan conditions defined above, the Acculink™ Carotid Stent System is expected to product a maximum temperature rise of less than 3.4°C after 16 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extents approximately 5 mm from the Acculink™ Carotid Stent System when imaged with a spin echo pulse sequence and a 3.0 Tesla MRI system.

POTENTIAL ADVERSE EVENTS

Based on the literature, and on clinical and commercial experience with carotid stents and embolic protection systems, the following alphabetical list includes possible adverse events associated with use of these devices:

• Allergic reactions to anti-platelet agents / contrast medium • Aneurysm • Angina / coronary ischemia • Arrhythmia • Arterial occlusion / thrombosis at puncture site or remote site • Arteriovenous fistula • Bacteremia or septicemia • Bleeding from anticoagulant or antiplatelet medications • Cerebral edema • Cerebral hemorrhage • Cerebral ischemia / transient ischemic attack (TIA)m • Congestive heart failure (CHF) • Death • Detachment and / or implantation of a component of the system • Emboli, distal (air, tissue or thrombotic emboli) • Emergent or urgent endarterectomy surgery (CEA) • Fever • Filter thrombosis / occlusion • Groin hematoma, with or without surgical repair

• Hemorrhage, with or without transfusion • Hyperperfusion syndrome • Hypotension / hypertension • Infection and pain at insertion site • Ischemia / infarction of tissue / organ • Myocardial infarction (MI) • Pain (head, neck) • Pseudoaneurysm, femoral • Renal failure / insufficiency • Restenosis of stented segment • Seizure • Severe unilateral headache • Stent / filter entanglement / damage • Stent embolization • Stent malposition • Stent migration • Stent thrombosis / occlusion • Stroke / cerebrovascular accident (CVA) • Total occlusion of carotid artery • Vessel dissection, perforation, or rupture • Vessel spasm or recoil

℞ ONLY RX Herculink Elite™ Renal Stent System

INDICATIONS

The **RX Herculink Elite™ Renal Stent System** is indicated for use in patients with atherosclerotic disease of the renal arteries following sub-optimal percutaneous transluminal renal angioplasty (PTRA) of a *de novo* or restenotic atherosclerotic lesion (≤ 15 mm in length) located within 10 mm of the renal ostium and with a reference vessel diameter of 4.0 - 7.0 mm. Suboptimal PTRA is defined as ≥ 50% residual stenosis, ≥ 20 mmHg peak systolic or ≥ 10 mmHg mean translesional pressure gradient, flow-limiting dissection, or TIMI [Thrombolysis In Myocardial Infarction] flow < 3.

CONTRAINDICATIONS

The RX Herculink Elite™ Renal Stent System is contraindicated for use in:

- Patients with a contraindication for antiplatelet/ anticoagulant therapy
- Patients who have a lesion that cannot be crossed with a wire or a balloon angioplasty catheter
- Patients with bleeding disorders
- Patients with a known hypersensitivity to cobalt or chrome
- Target lesions that are resistant to complete balloon inflation
- Stenting of an arterial vessel where leakage from the artery could be exacerbated by placement of a stent
- Patients with a target lesion with a large amount of adjacent acute or subacute thrombus.

WARNINGS

The long term safety and effectiveness of this device for use in the renal arterial system have not been established.

Should **unusual resistance** be felt **at any time** during lesion access or Delivery System removal, the introducer sheath/guiding catheter and stent system should be removed **as a single unit**. Applying excessive force to the Stent Delivery System can potentially result in loss or damage to the Stent and Delivery System components. (See *Stent/System Removal – Precautions*.)

Since the use of this device carries the associated risk of subacute thrombosis, vascular complications and/or bleeding events, judicious selection of patients is necessary.

Stenting across a major bifurcation may hinder or prevent future diagnostic or therapeutic procedures.

Once fully deployed, the stent cannot be repositioned.

Persons allergic to L605 cobalt chromium alloy may suffer an allergic reaction to this implant.

Only physicians familiar with the complications, side effects and hazards commonly associated with renal stent placement should use this device.

The RX Herculink Elite™ Renal Stent System is intended to perform as a system. The stent should not be removed for use in conjunction with other dilatation catheters, nor should the RX Herculink Elite™ Renal Stent System be used in conjunction with other stents.

The safety and effectiveness of multiple overlapping stents have not been established. However, when multiple stents are required, stent materials should be of similar composition.

PRECAUTIONS

Stent Delivery System Handling - Precautions

- **For single use only.** Do not resterilize or reuse. Note product "Use By" date.
- **Do not remove stent from its delivery balloon as removal may damage the stent and/or lead to stent embolization.**
- Carefully inspect the RX Herculink Elite™ Renal Stent System prior to use to verify that the stent has not been damaged in shipment and that the device dimensions are suitable for the specific procedure. Take care to avoid unnecessary handling.
- Refer to the instructions for use supplied with any interventional devices to be used in conjunction with the RX Herculink Elite™ Renal Stent System, for their intended uses, contraindications, and potential complications.
- Special care must be taken not to handle or in any way disrupt the stent on the balloon. This is most important during stent system removal from the packaging, placement over a guide wire and advancement through a guiding catheter or introducer sheath.
- Do not "roll" the mounted stent with your fingers as this action may loosen the stent from the delivery balloon.
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the stent.

Stent Placement - Precautions

- **Do not prepare or pre-inflate balloon prior to stent deployment** other than as directed.
- Use balloon purging technique described in the 'Clinician Use Information' section.
- The inflated balloon diameter of the system used to deploy the stent should approximate the diameter of the vessel. Oversizing of the stent can result in a ruptured vessel. To ensure full expansion of the stent, the balloon should be inflated to a minimum of nominal pressure.
- Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stent and may cause acute closure of the vessel requiring additional intervention (surgical intervention, further dilatation, placement of additional stents, or other).
- Do not expand the stent if it is not properly positioned in the vessel. (See *Stent/System Removal - Precautions*.)
- Stenting across a major bifurcation may hinder or prevent future side branch access.
- Balloon pressures should be monitored during inflation. **Do not exceed Rated Burst Pressure (RBP) as indicated on product label.** Use of pressures higher than specified on product label may result in a ruptured balloon with possible vessel damage or perforation.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the vasculature and/or the vascular access site. Complications may include bleeding, hematoma or pseudoaneurysm.
- The RX Herculink Elite™ Renal Stent System is intended for deployment and post-deployment dilatation of the stent only and should not be used to dilate other lesions.
- **Do not attempt to pull an unexpanded stent back through the introducer sheath/guiding catheter; dislodgment of the stent from the balloon may occur.**

Stent/System Removal - Precautions

Should **unusual resistance** be felt **at any time** during either lesion access or removal of the Delivery System post-stent implantation, the entire system should be removed **as a single unit**.

When removing the Delivery System as a single unit:

- DO NOT retract the Delivery System into the introducer sheath/guiding catheter.
- Position the proximal balloon marker just distal to the tip of the introducer sheath/guiding catheter.
- Advance the guide wire in the anatomy as far distally as safely possible.
- Secure the Delivery System to the introducer sheath/guiding catheter; then remove the introducer sheath/guiding catheter, guide wire and Delivery System as a **single unit**.

Failure to follow these steps and/or applying excessive force to the Delivery System can potentially result in loss or damage to the stent and/or Delivery System components.

If it is necessary to retain guide wire position for subsequent vessel access, leave the guide wire in place and remove all other system components.

Post Implant - Precautions

Great care must be exercised when **crossing a newly deployed stent** with a guide wire or balloon catheter to avoid disrupting the stent geometry.

Magnetic Resonance Imaging (MRI)

Non-clinical testing has demonstrated that the Herculink Elite™ stent, in single and in overlapped configurations up to 33 mm in length, is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 or 3 Tesla
- Spatial gradient field of 2500 Gauss/cm or less

- Maximum whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode) for any duration of MRI scan that would otherwise be safe for the patient without implant.

MRI at 1.5 or 3 Tesla may be performed immediately following the implantation of the Herculink Elite™ stent.

The Herculink Elite™ stent should not migrate in this MRI environment. Magnetic force on the Herculink Elite™ stent was tested according to AS™F2052-06e. Non-clinical testing at field strengths greater than 3 Tesla has not been performed to evaluate stent migration or heating.

Stent heating was derived by using the measured non-clinical, *in vitro* temperature rise according to AS™F2182-09 in a GE Signa HDx 3 Tesla scanner and in a GE 1.5 Tesla coil in combination with the local specific absorption rates (SARs) in a digitized human heart model. The temperature rise was derived by a validated calculation. At overlapped lengths up to 33 mm, the Herculink Elite™ stent produced a non-clinical maximum local temperature rise of less than 3ºC at a maximum whole body averaged SAR of 2.0 W/kg (normal operating mode) for an MRI sequence of 15 minutes. These calculations do not take into consideration the cooling effects of blood flow.

The effects of MRI on overlapped stents greater than 33 mm in length or stents with fractured struts are unknown.

Image artifact may be present when scanning the Herculink Elite™ stent as demonstrated in non-clinical testing performed according to AS™F2119-07 in a GE Signa HDx 3 Tesla scanner. The image artifact (both inside and outside the device lumen) extends approximately 7 mm from the device using the spin echo sequence (TR = 500 ms; TE = 20 ms; flip angle = 90º) and 13 mm from the device using the gradient echo sequence (TR = 100 ms; TE = 15 ms; flip angle = 30º). MR image quality may be compromised if the area of interest is in the exact same area, or relatively close to, the position of the Herculink Elite™ stent. Therefore, it may be necessary to optimize the MR imaging parameters in the presence of Herculink Elite™ stents.

POTENTIAL ADVERSE EVENTS

Potential complications associated with percutaneous renal artery treatment including the use of a renal stent may include, but are not limited to, the following:

• Abscess • Allergic reaction to Cobalt Chromium or contrast agents • Arrhythmias (ventricular fibrillation, ventricular tachycardia, other) • Arteriovenous fistula • Bowel infarct • Death • Dialysis • Dissection • Drug reaction to antiplatelet agents • Drug reaction, allergic reaction to contrast media • Emboli (air, tissue, or thrombotic emboli) resulting in tissue ischemia/infarction • Emergency surgery to correct vascular complications • Emergent renal artery bypass surgery • Extremity ischemia/amputation • Fever • Gastrointestinal symptoms from anticoagulation/antiplatelet medication • Hematoma at vascular access site • Hemorrhage requiring transfusion • Hypersensitivity reactions • Hypertension / hypotension • Infection and pain at vascular access site • Intimal tear • Kidney infarct • Myocardial infarction • Myocardial ischemia • Nephrectomy • Peripheral neuropathy • Pseudoaneurysm at vascular access site • Pseudoaneurysm formation • Renal artery thrombosis, aneurysm, rupture, perforation, occlusion, spasm, or restenosis • Renal insufficiency or failure • Stent migration or embolization • Stent misplacement • Stroke/cerebral vascular accident • Tissue necrosis or ulceration

Rx ONLY Viatrac™ 14 Plus Peripheral Dilatation Catheters

INDICATIONS

The Viatrac™ 14 Plus Peripheral Dilatation Catheter is intended:

- To dilate stenosis in the peripheral arteries (iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal arteries).
- For the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

CONTRAINDICATIONS

None known for percutaneous transluminal angioplasty (PTA).

WARNINGS

The Viatrac™ 14 Plus Peripheral Dilatation Catheter is not intended for use in the coronary arteries.

This device is intended for one-time use only. DO NOT resterilize and / or reuse it, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.

To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

Balloon pressure should not exceed the rated burst pressure (RBP). Refer to the product label for device specific information. The RBP is based on results of in vitro testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their RBP. Use of a pressure-monitoring device is recommended to prevent over-pressurization.

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Use the catheter prior to the "Use by" date specified on the package.

Do not use, or attempt to straighten, a catheter if the shaft has become bent or kinked, as this may result in the shaft breaking. Instead, prepare a new catheter.

PRECAUTIONS

A thorough understanding of the principles, clinical applications, and risks associated with percutaneous transluminal angioplasty (PTA) is necessary before using this product.

Any use for procedures other than those indicated in these instructions is not recommended.

This device is not recommended for use in lesions that may require inflation higher than those recommended for this catheter.

Do not use if package is open or damaged.

Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.

During the procedure, appropriate anticoagulant therapy must be provided to the patient as needed. Anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure.

Shaft diameter differences should be taken into consideration when opening and tightening the hemostatic valve and upon withdrawal of the catheter.

It is important that the hemostatic valve (if used) is closed tightly enough to prevent blood leakage around the catheter shaft, yet not so tightly that it restricts the flow of contrast into and out of the balloon or restricts guide wire movement.

ADVERSE EFFECTS

Potential adverse events include but are not limited to:

• Abrupt closure • Allergic reaction (contrast medium; drug; device 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 • Death • Detachment of a system component or implantation in an unintended site • Dialysis • Embolization (air, tissue, plaque, thrombotic material, device) • Emergent / urgent surgery • Fever • Heart failure • Hematoma or hemorrhagic event, with or without surgical repair • Hyperperfusion syndrome • Hypotension / hypertension • Infection • Ischemia or infarction not covered under other AEs • Myocardial infarction • Pain (leg, foot, and / or insertion site) • Peripheral nerve injury • Pulmonary embolism • Renal failure or insufficiency • Restenosis • Shock • Stent malapposition or migration, which may require emergency surgery to remove stent • Stent strut fracture • Stroke • Thrombosis or occlusion • Tissue necrosis or ulceration • Transient ischemic attack • Venous thromboembolism • Vessel dissection, perforation or rupture • Vessel spasm or recoil • Worsening claudication or rest pain

Rx ONLY Xact™ Carotid Stent System

INDICATIONS

The XACT™ Carotid Stent System (XACT™), used in conjunction with the Emboshield™ family of Embolic Protection System is indicated for the improvement of the lumen diameter of carotid arteries in patients considered at high risk for adverse events from carotid endarterectomy who require percutaneous carotid angioplasty and stenting for occlusive artery disease and meet the criteria outlined below:

Patients with carotid artery stenosis (≥ 50% for symptomatic patients by ultrasound or angiography or ≥ 80% for asymptomatic patients by ultrasound or angiography), located between the origin of the common carotid artery and the intra-cranial segment of the internal carotid artery AND

Patients must have a reference vessel diameter ranging between 4.8 mm and 9.1 mm at the target lesion.

CONTRAINDICATIONS

Contraindications associated with angioplasty must be considered when using the XACT™ Carotid Stent System. These include, but are not limited to:

- Patients in whom anticoagulant and / or antiplatelet therapy is contraindicated.
- Patients with severe vascular tortuosity or anatomy that would preclude the safe introduction of the Guiding Catheter / Introducer Sheath, BareWire™ guide wire, Emboshield™ Delivery Catheter, Filtration Element, and / or Retrieval Catheter.
- Patients with a known hypersensitivity to nickel-titanium.
- Patients with uncorrected bleeding disorders.
- Lesions in the ostium of the common carotid artery.

WARNINGS

Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device.

GENERAL

interventional devices to be used with the XACT™ Carotid Stent System for their intended uses, contraindications, and potential complications.

The safety and efficacy of the XACT™ Carotid Stent System has not been demonstrated with embolic protection systems other than the Emboshield™ Embolic Protection System.

The long-term performance (> 1 year) of the XACT™ Carotid Stent System has not been established.

As with any type of vascular implant, infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm, or rupture.

Stenting across a major bifurcation may hinder or prevent future diagnostic or therapeutic procedures.

In patients requiring the use of antacids and / or H2-antagonists before or immediately after stent placement, oral absorption of antiplatelet agents (e.g. aspirin) may be adversely affected.

The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure as suggested in these instructions. Special consideration should be given to those patients with recently active gastritis or peptic ulcer disease.

When multiple stents are required, stent materials should be of similar composition.

The safety and effectiveness of the XACT™ Carotid Stent System has NOT yet been established in patients with the characteristics noted below.

- Low to moderate risk for adverse events from carotid endarterectomy.
- Previously placed stent in target artery.
- Total occlusion of target lesion.
- Angiographically visible thrombus.
- Carotid string sign (a tiny, long segment of contrast in the true lumen of the artery).
- Vessel anatomy precluding the use of the stent system or appropriate positioning of the embolic protection system.
- Presence of carotid artery dissection prior to initiation of the procedure.
- Evidence of a stroke within the previous 30 days.
- History of ipsilateral stroke with fluctuating neurologic symptoms within 1 year.
- History of intracranial hemorrhage within the past 3 months.
- Any condition that precluded proper angiographic assessment or made percutaneous arterial access unsafe, (e.g. morbid obesity, sustained systolic blood pressure > 180 mmHg).
- Contraindication to aspirin, or to clopidogrel AND ticlopidine, or stent material.
- History or current indication of bleeding diathesis or coagulopathy including thrombocytopenia or an inability to receive heparin in amounts sufficient to maintain an activated clot time at > 250 seconds.
- Hemoglobin (Hgb) < 8 gm / dl (unless on dialysis), platelet count < 50,000, INR > 1.5 (irreversible), or heparin-associated thrombocytopenia.
- Known cardiac sources of emboli.
- Atherosclerotic disease involving adjoining vessels precluding safe placement of the guiding catheter or sheath.
- Other abnormal angiographic findings that indicated the patient was at risk of a stroke due to a problem other than that of the target lesion, such as: ipsilateral arterial stenosis greater in severity than the target lesion, cerebral aneurysm, or arteriovenous malformation of the cerebral vasculature.
- Severe dementia.
- Life threatening allergy to contrast media that could not be treated.
- Pregnant patients or patients under the age of 18.
- Patients in whom femoral access is not possible.
- Patients with aneurysmal dilation immediately proximal or distal to the lesion.

The safety and effectiveness of concurrent treatment of lesions in patients with bilateral carotid artery disease have not been established.

PRECAUTIONS

Carefully inspect device components prior to use to verify that they have not been damaged and that the size, shape and condition are suitable for the procedure for which they are to be used. A device or access device which is kinked or damaged in any way should not be used. If pouch is damaged do not use.

Confirm the compatibility of the XACT™ Stent Delivery System with the interventional devices before actual use.

Precautions to prevent or reduce clotting should be taken when any interventional device is used. Flush or rinse all devices entering the vascular system with sterile isotonic heparinized saline prior to use.

Do not remove the stent from its delivery system as removal may damage the stent. The stent and delivery system are intended to be used in tandem. If removed, the stent cannot be put back on the delivery system.

The delivery system should not be used in conjunction with other stents.

To reduce the potential for the liberation of emboli during lesion crossing, the device should be carefully manipulated and not advanced against resistance.

During stent placement, 1.5 cm of vessel should be left between the distal margin of the stent and the Filtration Element. The stent delivery system should not contact the Filtration Element.

Venous access should be available during carotid stenting in order to manage bradycardia and / or hypotension by either pharmaceutical intervention or placement of a temporary pacemaker, if needed.

The device must only be flushed using the 3-ml syringe and flushing tip provided.

The outside diameter of the Outer Sheath is 5.7 Fr. An appropriate sized sheath / guiding catheter should be selected based on this diameter.

Do not use a prepared XACT™ Carotid Stent System if the stent is not fully constrained within the Delivery System.

Do not use if the stent is partially deployed.

If, after preparation, a gap between the catheter tip and the outer sheath exists, rotate the Deployment Actuator in an anti-clockwise direction until the gap is closed.

Advancement and deployment of the XACT™ Carotid Stent System should only be performed under fluoroscopic observation.

Do not advance any component, or section thereof, of the XACT™ Carotid Stent System against significant resistance. The cause of any resistance should be determined via fluoroscopy and remedial action taken.

Do not attempt to reposition the Delivery System once the stent has made contact with the vessel wall.

Do not torque the XACT™ Carotid Stent System.

If more than one stent is required to cover the lesion, or if there are multiple lesions, the distal lesion should be stented first, followed by stenting of the proximal lesion.

If overlap of sequential stents is necessary, the amount of overlap should be kept to a minimum.

MRI INFORMATION

Non-clinical testing has demonstrated that the XACT™ Carotid Stent is MR Conditional. It can be scanned safely under the conditions listed in the *Instructions for Use*.

POTENTIAL ADVERSE EFFECTS

As reported in the literature, the following adverse events are

potentially associated with carotid stents and embolic protection systems:

• Abrupt closure • Allergic reactions • Aneurysm • Angina Coronary ischemia • Arteriovenous Fistula • Bacteremia or septicemia • Bleeding from anticoagulant or antiplatelet medications • Bradycardia/arrhythmia • Cerebral edema • Cerebral hemorrhage • Congestive Heart Failure • Death • Drug reactions • Embolism (including air and device) • Emergent or urgent Endarterectomy • Fever • Filter thrombosis / occlusion • Fluid overload • Groin hematoma, with or without surgical repair • Hemorrhage or hematoma • Hemorrhagic stroke • Headache • Hypotension • Hyperperfusion syndrome • Hypertension • Infection / sepsis • Ischemia / infarction of tissue / organ • Myocardial Infarction • Other conduction disturbances • Pain and tenderness • Pain, infection, or discomfort at the access site • Pseudoaneurysm • Renal failure / insufficiency • Restenosis of the stented artery • Seizure • Stent deformation, collapse, fracture, movement of stent, possibly requiring emergency surgery • Stent / filter entanglement / damage • Stroke or other neurological complications • Thromboembolic episodes • Thrombophlebitis • Total occlusion of the artery • Transient ischemic attacks (TIAs) • Vascular access complications (e.g. loss of pulse, femoral artery pseudoaneurysm and infection) • Ventricular fibrillation • Vessel dissection, rupture, or perforation • Vessel thrombosis (partial blockage) • Unstable angina pectoris

Rx ONLY HydroSteer™ GUIDEWIRES

INDICATIONS

Abbott 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. Abbott 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 RadiStop™ Compression Assist Device

INDICATIONS

RadiStop™ Compression Assist Device is indicated in the compression of the radial artery after catheterization.

CONTRAINDICATIONS

RadiStop™ Compression Assist Device is contraindicated in patients who do not have two functional arteries (ulnar and radial). RadiStop™ Compression Assist Device should not be used on patient having an abnormal Allen's test.

WARNINGS

- For one time use only. Do not resterilize or reuse. Inspect the sealed sterile packaging prior to use. Do not use if the original sterile package is not intact. Reuse after cleaning attempts, resterilization and repackaging may result in patient/user infections.
- Do not leave the system on for inappropriately long compressions, as tissue damage may be produced. A brief interruption every three (3) hours of pressure is recommended during long compression periods.
- Do not use RadiStop™ Compression Assist Device without the support plate. The support plate ensures that the venous flow is not obstructed.

PRECAUTIONS

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Use of RadiStop™ Compression Assist Device is not intended to replace careful monitoring of the patient's puncture site.
- The patient should not be left completely unattended during the time of compression.

ADVERSE EVENTS

Potential complications which may be encountered during catheterization via the radial route include but are not limited to puncture of the posterior wall of the artery, artery occlusion, hematoma, paresthesia and ischemia.

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 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

Rx ONLY HI-TORQUE Guide Wires 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.

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 AMPLATZER™ Vascular Plug

INTENDED USE

The AMPLATZER ™ Vascular Plug is indicated for arterial and venous embolizations in the peripheral vasculature.

CONTRAINDICATIONS

None known.

WARNINGS

The safety and effectiveness of this device for cardiac uses (for example, patent ductus arteriosus or paravalvular leak closures) and neurological uses have not been established.

PRECAUTIONS

Handling

The safety and effectiveness of this device for cardiac uses (for example, patent ductus arteriosus or paravalvular leak closures) and neurological uses have not been established.

MRI SAFETY INFORMATION

MR	A patient with the Amplatzer™ Vascular Plugs may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.
Device Name	Amplatzer™ Vascular Plugs
Static Magnetic Field Strength (B_0)	1.5 T or 3.0 T
Maximum Field Spatial Gradient	19T/m (1900 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Body Coil
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR	2.0W/kg (Normal Operating Mode)
Maximum Head SAR	N/A
Scan Duration	2.0W/kg whole-body-averaged SAR for 15 minutes of continuous scanning
MR Image Artifact	MR Image Artifact

POTENTIAL ADVERSE EVENTS

Potential complications include, but are not limited to: death, embolization of the device, hematoma at the site of entry, stroke, or vessel perforation, or embolization of the device.

⚠ State of California (USA) Only:

WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

Rx ONLY AMPLATZER™ Vascular Plug II

INTENDED USE
The Amplatzer ™ Vascular Plug II is indicated for arterial and venous embolizations in the peripheral vasculature.

CONTRAINDICATIONS
None known.

WARNINGS
The safety and effectiveness of this device for cardiac uses (for example, patent ductus arteriosus or paravalvular leak closures) and neurological uses have not been established.

PRECAUTIONS
- This device was sterilized with ethylene oxide and is for single use only. Do not reuse or resterilize this device. Attempts to resterilize this device can cause a malfunction, insufficient sterilization, or harm to the patient.
- Use on or before the last day of the expiration month that is printed on the product packaging label.
- Patients with nickel allergy can experience an allergic reaction to this device.
- Do not use this device if the sterile package is open or damaged.
- This device should be used only by physicians who are trained in standard endovascular techniques. The physician should determine which patients are candidates for procedures that use this device.
- The physician should exercise clinical judgment in situations that involve the use of anticoagulants or antiplatelet drugs before, during, and/or after the use of this device.
- Store in a dry place.

MRI SAFETY INFORMATION

MR	A patient with the Amplatzer™ Vascular Plug II may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.
Device Name	Amplatzer™ Vascular Plug II
Static Magnetic Field Strength (B_0)	1.5 T or 3.0 T
Maximum Field Spatial Gradient	19T/m (1900 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Body Coil
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR	2.0W/kg (Normal Operating Mode)
Maximum Head SAR	N/A
Scan Duration	2.0W/kg whole-body-averaged SAR for 15 minutes of continuous scanning
MR Image Artifact	MR Image Artifact

POTENTIAL ADVERSE EVENTS
Potential complications include, but are not limited to: death, migration of the device, stroke, or vessel perforation.

⚠ State of California (USA) Only:

WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

Rx ONLY AMPLATZER™ Vascular Plug 4

INTENDED USE
The Amplatzer™ Vascular Plug 4 is indicated for arterial and venous embolizations in the peripheral vasculature.

CONTRAINDICATIONS
None known.

WARNINGS
- The safety and effectiveness of this device for cardiac uses (eg, cardiac septal occlusion, patent ductus arteriosus, paravalvular leak closures) and neurologic uses have not been established.
- Do not use this device if the sterile package is open or damaged.
- Use on or before the last day of the expiration month that is printed on the product packaging label.
- The device was sterilized with ethylene oxide and is for single use only. Do not reuse or resterilize this device. Attempts to resterilize this device can cause a malfunction, insufficient sterilization, or harm to the patient.
- Do not use a power injection syringe to inject contrast solution through this device.
- Physicians must be prepared to deal with urgent situations, such as device embolization, which require removal of the device. This includes the availability of an on-site surgeon.

PRECAUTIONS
- The AMPLATZER™ Vascular Plug 4 device consists of a nickel-titanium alloy, which is generally considered safe. However, in vitro testing has demonstrated that nickel is released from this device for a minimum of 60 days. Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. Certain allergic reactions can be serious; patients should be instructed to notify their physicians immediately if they suspect they are experiencing an allergic reaction such as difficulty breathing or inflammation of the face or throat. Some patients may also develop an allergy to nickel if this device is implanted.
- The physician should exercise clinical judgment in situations that involve the use of anticoagulants or antiplatelet drugs before, during, and/or after use of the device.
- Store in a dry place.
- This device should be used only by physicians who are trained in standard endovascular techniques. The physician should determine which patients are candidates for procedures that use this device.
- Use in specific populations
  - Pregnancy - care should be taken to minimize the radiation exposure to the fetus and the mother.
  - Nursing mothers - there has been no quantitative assessment of the presence of leachables in breast milk.

MRI SAFETY INFORMATION

MR	A patient with the Amplatzer™ Vascular Plug 4 may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.
Device Name	Amplatzer™ Vascular Plug 4
Static Magnetic Field Strength (B_0)	1.5 T or 3.0 T
Maximum Field Spatial Gradient	19T/m (1900 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Body Coil
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR	2.0W/kg (Normal Operating Mode)
Maximum Head SAR	N/A
Scan Duration	2.0W/kg whole-body-averaged SAR for 15 minutes of continuous scanning
MR Image Artifact	MR Image Artifact

POTENTIAL ADVERSE EVENTS
Potential adverse events that may occur during or after a procedure placing this device include, but are not limited to:

• Air embolus • Allergic reaction/toxic effects • Bleeding • Death • Device migration • Fever • Foreign material embolic event • Hemolysis • Infection • Occlusion of unintended vessel • Peripheral embolism • Recanalization • Residual flow • Stroke/TIA • Surgical intervention • Vascular access site complication • Vessel trauma/perforation

⚠ **State of California (USA) Only:**

WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

Rx ONLY FemoStop™ Gold Femoral Compression System

INDICATIONS FOR USE
The FemoStop™ Femoral Compression System is indicated for use in the compression of the femoral artery or vein after vessel cannulation and in ultrasound-guided compression repair of a femoral artery pseudoaneurysm.

CONTRAINDICATIONS
- Severe peripheral vascular disease due to the risk of arterial thrombosis.
- Critical limb ischemia.
- Overlying skin necrosis and/or infection.
- Arterial injuries above or near the inguinal ligament.
- The inability to adequately compress due to e.g. coexisting very large hematomas, excessive pain or discomfort (despite anesthetics/analgesics).
- Patients not suitable for compression of their femoral artery due to leg edema, femoral nerve compression, or arterial obstruction.
- Femoral artery graft or vein graft due to the risk of damage.
- Ultrasound-guided compression repair of infected femoral pseudoaneurysms.

WARNINGS
- For one time use only. Do not reuse or resterilize. Do not use if the original sterile package is not intact. Inspect the system carefully prior to use to verify that all parts are present and undamaged.
- Reuse after cleaning attempts, resterilization and repackaging may result in patient/user infections, product deterioration leading to, e.g. reduced concentration of dome pressure, causing bleeding. Do not disassemble or attempt to repair the system.
- Adequate compression may not be obtained in markedly obese patients.
- Avoid releasing pressure suddenly to reduce any risk of flushing thrombotic material into the artery. Release of thrombotic material may result in embolization which could lead to patient injury.
- Do not leave the system on the patient for inappropriately long compressions, as tissue damage may occur. A brief interruption at least every three hours of pressure is recommended during long compression periods. Inappropriately long compression and/or immobilization may increase the risk for thrombosis or embolization which could lead to patient injury or death.
- If arterial/venous hemostasis is not achieved, significant bleeding may occur which could result in patient injury or death.
- While removing the sheath, ensure that the pressure applied is kept low, to avoid damage to the vessel or a "milking" effect. Allowance for slight bleeding at the site is preferred to preclude introduction of thrombus to the vessel.
- To prevent limb ischemia, do not leave artery completely blocked for more than 3 minutes. Check pedal pulse periodically to confirm whether or not flow remains in the vessels.
- To minimize the risk for arterial/venous fistula formation, venous hemostasis should be achieved prior to removal of the arterial sheath.
- Do not apply pressure to a femoral artery stent due to risk of damage.

PRECAUTIONS
- The FemoStop™ Femoral Compression System should only be used for compression of the femoral artery or vein after vessel cannulation by or on the order of physicians trained in femoral artery or vein compression procedures.
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- When removing the sheath for an Intra-Aortic Balloon Pump (IABP), the Instruction for Use for the IABP should be followed as appropriate.
- For successful compression, the system must be snug and secure around the patient's hips before pressure is applied. Do not over-tighten the belt.
- For successful compression, the system must be correctly positioned throughout the procedure so that pressure is applied to the point intended.
- On very obese patients, it may be necessary to tighten the belt slightly more to enhance downward compression.
- When using the system on obese patients, fatty tissue may be displaced giving a false impression of a developing hematoma.
- Placement of the system may not be suitable on large patients, or patients with very wide hips as the belt may be too short. An abdominal strap/tape may be used to pull excessive adipose tissue away from dome.
- The target inflation pressure should be 10-20mmHg above the systolic pressure, or higher if necessary to control the bleeding. Exceeding pressures of 200mmHg may indicate the need to tighten the belt or reposition the dome.
- Careful monitoring of the dome pressure during the initial period of use is recommended, as the elastic material of the dome may stretch slightly during the first few minutes. You may notice a slight drop in pressure on the manometer. If this occurs, reinflate to initial pressure.
- Ensure that the control knob on the pump is closed when increasing the pressure and open when decreasing the pressure.
- Ensure that the pinch clamp is open when increasing or decreasing the pressure.
- Use of the FemoStop™ Femoral Compression System is not intended to replace careful monitoring of the patient's puncture site. The patient should not be left completely unattended during the time of compression.
- The compression system is for single use only.
- Avoid exposing the pump to any liquid.
- After use, this product may be a potential biohazard. Handle and dispose of all such devices in accordance with accepted medical practice and applicable local, state and federal laws and regulations.
- The temperature range on the label represents the temperature for long-term storage.

ADVERSE EVENTS
Possible adverse effects that may result from the use of this device include but are not limited to:
- tissue necrosis
- blistering of the skin/skin abrasion
- compression injuries to nerves with subsequent sensory and motor deficits
- femoral artery and/or vein thrombosis
- embolization
- bleeding or hematoma
- arterio-venous fistula or pseudoaneurysm
- acute distension or rupture of a pseudoaneurysm during compression repair

Additional warnings and precautions for ultrasound-guided compression repair of a pseudoaneurysm in the femoral artery

WARNINGS
- To prevent limb ischemia, do not leave artery completely blocked for more than 3 minutes.
- Use color Doppler to periodically confirm whether or not flow remains in the vessels.
- Do not leave the system on the patient for inappropriately long compressions, as tissue damage may occur.
- During long compression periods, pressure should be briefly interrupted at least every three hours. Use manual compression

during this break to limit new flow into the pseudoaneurysm.

- Inappropriately long compression and/or immobilization may increase the risk for thrombosis or embolization which could lead to patient injury or death.

PRECAUTIONS

- The FemoStop™ Femoral Compression System should only be used for ultrasound-guided compression repair of a pseudoaneurysm in the femoral artery, by physicians trained in the treatment of pseudoaneurysm.
- Remove any residual ultrasound gel from the skin overlying the point to be compressed as it may cause the system to slip out of position during the application of pressure.
- Exceeding pressures of 200mmHg may indicate the need to tightly secure the belt or reposition the arch.

Rx ONLY Supera™ Peripheral Stent System

INDICATIONS

The Supera™ Peripheral Stent System is indicated to improve luminal diameter in the treatment of patients with symptomatic de novo or restenotic native lesions or occlusions of the superficial femoral artery (SFA) and / or proximal popliteal artery with reference vessel diameters of 4.0 to 7.5 mm, and lesion lengths up to 140 mm.

CONTRAINDICATIONS

The Supera™ Peripheral Stent System is contraindicated in:

- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system.
- Patients who cannot receive antiplatelet or anticoagulation therapy. Based on in vivo thrombogenicity testing, the device should not be used in patients who cannot be anticoagulated as there may be some thrombus formation in the absence of anticoagulation.

WARNINGS

- This device is intended for single-use only. Do not reuse. Do not resterilize. Do not use if the package is opened or damaged.
- Use this device prior to the "Use by" date as specified on the device package label.

Store in a dry, dark, cool place.

- DO NOT use if it is suspected that the sterility of the device has been compromised.
- Persons with known hypersensitivities to Nitinol and / or its components

(e.g., nickel-titanium) may suffer an allergic reaction to this implant.

- Administer appropriate antiplatelet therapy pre- and post-procedure.
- Careful attention should be paid when sizing and deploying the stent to prevent stent elongation. In the SUPERB clinical study, stent elongation was associated with a decrease in patency at 12 months.

PRECAUTIONS

The Supera™ Peripheral Stent System should only be used by physicians and medical personnel trained in vascular interventional techniques and trained on the use of this device.

- The long-term safety and effectiveness of the Supera Peripheral Stent System has not been established beyond three years.
- The safety and effectiveness of the Supera Peripheral Stent System has not been established in patients who:
  - o are less than 18 years old
  - o are pregnant or lactating
  - o have in-stent restenosis of the target lesion
  - o have known hypersensitivity to any component of the stent system (e.g., nickel)
  - o cannot tolerate contrast media and cannot be pre-treated
  - o have uncontrolled hypercoagulability and / or another coagulopathy
- This device is not designed for use with contrast media injection systems or power injection systems.
- The flexible design of the Supera stent may result in variation in the deployed stent length.

Magnetic Resonance Imaging (MRI) Safety Information

Nonclinical testing has demonstrated that the Supera stent, in single and in overlapped configurations up to 250 mm in length, is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Maximum spatial gradient magnetic field of 2,500 Gauss/cm (25 T/m)
- Maximum MR whole-body-averaged specific absorption rate (SAR) of
  - o 2 W/kg for landmarks (i.e., center of RF coil) above the umbilicus
  - o 1 W/kg for landmarks below the umbilicus and above the mid-thigh
  - o 0.5 W/kg for landmarks below the mid-thigh

Under the scan conditions defined above, the Supera stent is expected to produce a maximum temperature rise of 7.6 C after 15 minutes of continuous scanning.

In nonclinical testing, the image artifact caused by the device extends approximately 2 cm from the Supera stent when imaged with a gradient echo or spin echo sequence and a 3T MRI system.

POTENTIAL ADVERSE EVENTS

Potential adverse events include, but are not limited to:

• Abrupt closure • Allergic reaction (contrast medium; drug; stent 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 • Death • Detachment of a system component or implantation in an unintended site • Embolization, arterial or other (e.g., air, tissue, plaque, thrombotic material, or stent) • Emergent surgery • Fever • Hematoma or hemorrhagic event, with or without surgical repair • Hyperperfusion syndrome • Hypertension / hypotension • Infection • Myocardial infarction • Pain (leg, foot, and / or insertion site) • Partial stent deployment • Peripheral nerve injury • Pulmonary embolism • Renal failure or insufficiency

Rx ONLY Emboshield NAV6™ Embolic Protection System

INDICATIONS

The Emboshield NAV6™ Embolic Protection System is indicated for use as a guide wire and embolic protection system to contain and remove embolic material (thrombus / debris) while performing angioplasty and stenting procedures in carotid arteries and while performing atherectomy, during standalone procedures or together with PTA and / or stenting, in lower extremity arteries. The diameter of the artery at the site of the Filtration Element placement should be between 2.5 and 7.0 mm.

CONTRAINDICATIONS

The **Emboshield NAV6™ Embolic Protection System** is contraindicated for use in:

- Patients in whom anticoagulant and / or antiplatelet therapy is contraindicated.
- Patients with severe vascular tortuosity or anatomy that would preclude the safe introduction of the Guiding Catheter / Introducer Sheath, Embolic Protection System.
- Patients with a known allergy or hypersensitivity to device materials (Nitinol, Nickel, Titanium) or contrast medium, who cannot be adequately premedicated.
- Patients with uncorrected bleeding disorders.
- Lesions in the ostium of the common carotid artery.
- Inability to cross the lesion with the BareWire™ Filter Delivery Wire.
- Diffusely diseased vessels where there is no disease-free section in which to deploy the Filtration Element.
- Insufficient straight section of vessel distal to the lesion to permit Filtration Element deployment.

WARNINGS

Use of the device should be restricted to physicians trained to the specifics of the device and to the Instructions for Use. Operators must be knowledgeable of the current medical literature and familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid and lower extremity interventional procedures.

Refer to instructions supplied with all interventional devices to be used with the Emboshield NAV6™ Embolic Protection System for their intended uses, contraindications, and potential complications.

The Emboshield NAV6™ System is supplied sterile. Do not use if the package has been opened or is damaged. Carefully inspect the system components prior to use to verify that they have not been damaged and that the size, shape and condition are suitable for the procedure for which they are to be used. A device or access device that is kinked or damaged in any way should not be used.

Safety and effectiveness of this device as an embolic protection system has not been established in the coronary or cerebral vasculature.

The safety and efficacy of the Emboshield NAV6™ Embolic Protection System has not been demonstrated with carotid stent systems other than the Xact™ or Acculink™ Carotid Stent Systems.

The safety and efficacy of the Emboshield NAV6™ Embolic Protection System has not been demonstrated with atherectomy devices other than Turbo-Elite™ Laser Atherectomy Catheter, Jetstream™ Single Cutter (SC) Atherectomy Catheter, Jetstream™ eXpandable Cutter (XC) Atherectomy Catheter and TurboHawk™ Peripheral Plaque Excision System.

The Emboshield NAV6™ device can only be used with the BareWire™ Filter Delivery Wire. Use of the device with any guide wire other than the BareWire™ Filter Delivery Wire will lead to loss of the Filtration Element during the procedure or an inability to retrieve the Filtration Element.

To reduce the potential for the liberation of emboli during lesion crossing, the device should be carefully manipulated and not advanced against resistance.

If the Filtration Element moves into the stented vessel segment prior to retrieval, DO NOT RETRIEVE. Use the Retrieval Catheter to gently maneuver the Filtration Element distally until it is situated in an unstented portion of vessel. Retrieval should then proceed.

Maintain proper guiding catheter / sheath support throughout the procedure. Ensure that there is enough distance between the proximal tip of the Filtration Element and the most distal tip of any interventional device to be introduced over the Filter Delivery Wire to avoid engagement. The tip of a balloon catheter or a stent delivery system or an atherectomy device should not contact the Filtration Element. Failure to maintain adequate distance could result in inadvertent Filtration Element movement and Stent Delivery System tip / Filtration Element entanglement and / or Filtration Element / Stent entanglement if guide catheter or sheath prolapse occurs.

PRECAUTIONS

Precautions to prevent or reduce clotting should be taken when any interventional device is used. Flush or rinse all devices entering the vascular system with heparinized normal saline or alternative anticoagulant, prior to use.

The Emboshield NAV6™ Embolic Protection System must be used with a guiding catheter or introducer sheath to maintain adequate support for the BareWire™ Filter Delivery Wire throughout the procedure.

Venous access should be available during carotid stenting in order to manage bradycardia and / or hypotension by either pharmaceutical intervention or place of a temporary pacemaker, if needed.

Removal of the BareWire™ Filter Delivery Wire with the Emboshield NAV6™ Filtration Element through any interventional devices other than the Emboshield NAV6™ RX Retrieval Catheter has not been tested.

The minimum expanded stent internal diameter required for retrieval of a large embolic load is 2.5 mm.

ADVERSE EVENTS

As reported in the literature, the following adverse events are potentially associated with carotid stents and embolic protection systems:

- Allergic reaction or hypersensitivity to latex, contrast agent, anesthesia, stent material (Nitinol, Nickel, Titanium) and drug reactions to anticoagulation, or antiplatelet drugs
- Vascular access complications which may require transfusion or 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)
  - Thrombophlebitis
- 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)
  - Stenosis or restenosis
  - Artery, stent, or filter thrombosis / occlusion thrombosis
  - Vessel spasm
- Cardiac arrhythmias (including conduction disorders, atrial and ventricular arrhythmias)
- Cardiac ischemic conditions (including myocardial ischemia, myocardial infarction, and unstable or stable angina pectoris)
- Stroke / Cerebrovascular accident (CVA) and Transient Ischemic Attack (TIA)
- System organ failures:
  - Cardio Pulmonary failure
  - Renal failure / insufficiency
- Blood cell disorders including heparin induce thrombocytopenia and other coagulopathy
- Hypotension / hypertension
- Peripheral nerve injury
- Other ischemic conditions / infarct
- Infection - local and systemic (including postprocedural)
- Nausea and vomiting
- Chest pain
- Edema / Cerebral edema and fluid overload
- Fever
- Pain, including headache
- Hyperperfusion syndrome
- Other neurologic and systemic complications
- Cerebral hemorrhage
- Death

Any adverse event occurring involving the Emboshield NAV6™ Embolic Protection System should be reported immediately to Abbott Vascular, Customer Service: 1-800 227-9902.

Rx ONLY Perclose ProGlide™ Suture-Mediated Closure (SMC) System

INDICATIONS

The Perclose ProGlide™ Suture-Mediated Closure System is indicated for the percutaneous delivery of suture for closing the common femoral artery and vein access site of patients who have undergone diagnostic or interventional catheterization procedures.

The Perclose ProGlide™ SMC System is indicated for closing the common femoral vein in single or multiple access sites per limb.

The Perclose ProGlide™ SMC System is used without or, if required, with adjunctive manual compression.

For access sites in the common femoral artery using 5F to 21F sheaths. For arterial sheath sizes greater than 8F, at least two devices and the pre-close technique are required.

For access sites in the common femoral vein using 5F to 24F sheaths. For venous sheath sizes greater than 14F, at least two devices and the pre-close technique are required.

CAUTION

Federal law restricts this medical device to sale by or on the order of a physician (or allied healthcare professionals, authorized by, or under the direction of, such physicians) who is trained in diagnostic and / or interventional catheterization procedures and who has been trained by an authorized representative of Abbott.

Prior to use, the operator must review the Instructions for Use and be familiar with the deployment techniques associated with the use of this device.

During closure of access sites using a procedural sheath greater than 8F, it is recommended that a vascular surgeon or a surgeon with vascular training be available in case surgical conversion to control bleeding and to repair the vessel is needed.

CONTRAINDICATIONS

There are no known contraindications to the use of this device.

WARNINGS

Do not use the Perclose ProGlide™ SMC System if the packaging or sterile barrier has been previously opened or damaged or if the components appear to be damaged or defective.

DO NOT RESTERILIZE OR REUSE. The Perclose ProGlide™ SMC System is intended for single use only.

Do not use the Perclose ProGlide™ SMC System if the sterile field has been broken where bacterial contamination of the sheath or

surrounding tissues may have occurred, since such a broken sterile field may result in infection.

Do not use the Perclose ProGlide™ SMC System if the puncture site is located above the most inferior border of the inferior epigastric artery (IEA) and / or above the inguinal ligament based upon bony landmarks, since such a puncture site may result in a retroperitoneal hematoma. Perform a femoral angiogram to verify the location of the puncture site. Note: This may require both a right anterior oblique (RAO) and left anterior oblique (LAO) angiogram to adequately visualize where the sheath enters the femoral vessel.

Do not use the Perclose ProGlide™ SMC System in arterial or venous access if the puncture is through the posterior wall or if there are multiple punctures in the same access site, since such punctures may result in a hematoma or retroperitoneal bleed.

Do not use the Perclose ProGlide™ SMC System if the puncture site is located in the superficial femoral artery or the profunda femoris artery, or the bifurcation of these vessels, since such puncture sites may result in a pseudoaneurysm, intimal dissection, or an acute vessel closure (thrombosis of small artery lumen). Perform a femoral angiogram to verify the location of the puncture site. Note: This may require both a right anterior oblique (RAO) and left anterior oblique (LAO) angiogram to adequately visualize where the sheath enters the vessel.

PRECAUTIONS

1. Prior to use, inspect the Perclose ProGlide™ SMC System to ensure that the sterile packaging has not been damaged during shipment. Examine all components prior to use to verify proper function. Exercise care during device handling to reduce the possibility of accidental device breakage.
2. As with all catheter-based procedures, infection is a possibility. Observe sterile technique at all times when using the Perclose ProGlide™ SMC System. Employ appropriate groin management, as per hospital protocol, post procedure and post hospital discharge to prevent infection.
3. Use a single wall puncture technique. Do not puncture the posterior wall of the vessel in arterial and venous access.
4. Do not deploy the Perclose ProGlide™ Device at an elevated angle against resistance as this may cause a cuff miss or device breakage.
5. There are no reaccess restrictions if previous arteriotomy / venotomy repairs were achieved with Abbott Medical SMC or SMCR systems.
6. If significant blood flow is present around the Perclose ProGlide™ Device, do not deploy needles. Remove the device over a 0.038" (0.97 mm) (or smaller) guide wire and insert an appropriately sized sheath.
7. Prior to depressing the plunger to advance the needles, stabilize the device by the body to ensure the foot is apposed to the vessel wall and the device does not twist during deployment. Twisting (torquing) the device could lead to needle deflection resulting in a cuff miss. Do not use excessive force or repeatedly depress the plunger. Excessive force on the plunger during deployment could potentially cause breakage of the device, which may necessitate intervention and / or surgical removal of the device and vessel repair.
8. Do not apply excessive force to the lever when opening the foot and returning the foot to its original position down to the body of the device. Do not attempt to remove the device without closing the lever. Excessive force on the lever or attempting to remove the device without closing the lever could cause breakage of the device and / or lead to vessel trauma, which may necessitate intervention and / or surgical removal of the device and vessel repair.
9. **Do not advance or withdraw the Perclose ProGlide™ Device against resistance until the cause of that resistance has been determined. Excessive force used to advance or torque the Perclose ProGlide™ Device should be avoided, as this may lead to significant vessel damage and / or breakage of the device, which may necessitate intervention and / or surgical removal of the device and vessel repair.**
10. If excessive resistance in advancing the Perclose ProGlide™ Device is encountered, withdraw the device over a 0.038" (0.97 mm) (or smaller) guide wire and reinsert the introducer sheath or use manual compression.
11. Remove the Perclose ProGlide™ sheath before tightening the suture. Failure to remove the sheath prior to tightening the suture may result in detachment of the tip of the sheath.
12. Care should be taken to avoid damage to the suture from handling. Avoid crushing damage due to application of surgical instruments such as clamps, forceps or needle holders.
13. For catheterization procedures using a 5 – 8F procedural sheath, use manual compression in the event that bleeding from the femoral access site persists after the use of the Perclose ProGlide™ SMC System to obtain hemostasis.
14. For catheterization procedures using a procedural sheath > 8F, use manual compression, compression assisted devices, surgical repair, and / or other appropriate treatment methods in the event that bleeding from the femoral access site persists after the use of the Perclose ProGlide™ SMC System to obtain hemostasis.
15. For catheterization procedures using a procedural sheath > 8F, where the operating physician is not a vascular surgeon, it is recommended that a vascular surgeon or a surgeon with vascular training be available during the procedure to perform any necessary surgical intervention.
16. If the Perclose ProGlide™ Device is used to close and repair multiple access sites in the same vessel, space the access sites apart adequately to minimize sheath-device interference.

POTENTIAL ADVERSE EVENTS

Potential adverse events associated with use of vessel closure devices may include, but are not limited to, the following:

- Allergic reaction or hypersensitivity to device components
- Vascular access complications which may require transfusion or vessel repair, including:
  - o Anemia
  - o Aneurysm
  - o Arteriovenous fistula
  - o Bleeding / hemorrhage / re-bleeding
  - o Bruising / hematoma
  - o Embolism
  - o Inflammation
  - o Intimal tear / dissection
  - o Perforation
  - o Pseudoaneurysm
  - o Retroperitoneal hematoma / bleeding
  - o Scar formation
  - o Wound dehiscence
- Cardiac arrhythmias (including conduction disorders, atrial and ventricular arrhythmias)
  - o Atrial arrhythmias
  - o Ventricular arrhythmias
- Femoral artery / venous complications which may require additional intervention, including:
  - o Arterial / venous stenosis
  - o Arterial / venous occlusion
  - o Arteriovenous fistula
  - o Intimal tear / dissection
  - o Ischemia distal to closure site
  - o Nerve injury
  - o Numbness
  - o Thrombus formation
  - o Vascular injury
- Venous thromboembolism (including deep vein thrombosis, pulmonary embolism, post-procedure pulmonary embolism)
- Infection – local or systemic
- Pain
- Hemodynamic instability:
  - o Hypotension / hypertension
  - o Vasovagal episode
- Death
- Device complications
- Device failure
- Device malfunction

℞ ONLY TigerWire™ STEERABLE GUIDEWIRE

INTENDED USE

The Abbott Medical 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-Abbott 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.

℞ ONLY GuideRight™ STEERABLE GUIDEWIRE

INDICATIONS

Abbott Medical 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-Abbott 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.

℞ ONLY StarClose SE™ Vascular Closure System

INDICATIONS FOR USE

The StarClose SE™ Vascular Closure System is indicated for the percutaneous closure of common femoral artery access sites while reducing times to hemostasis, ambulation, and dischargeability in patients who have undergone diagnostic endovascular catheterization procedures utilizing a 5F or 6F procedural sheath.

The StarClose SE™ Vascular Closure System is indicated for use to allow patients who have undergone diagnostic endovascular catheterization procedures to ambulate and be eligible for discharge as soon as possible after device placement.

The StarClose SE™ Vascular Closure System is indicated for the percutaneous closure of common femoral artery access sites while reducing times to hemostasis and ambulation in patients who have undergone interventional endovascular catheterization procedures utilizing a 5F or 6F procedural sheath.

CAUTION

Federal law restricts this device to sale by or on the order of a physician (or allied healthcare professionals, authorized by, or under the direction of, such physicians) who is trained in diagnostic and therapeutic catheterization procedures and who has been trained by an authorized representative of Abbott Vascular.

Prior to use, the operators must review the Instructions for Use and be familiar with the deployment techniques associated with the use of this device.

CONTRAINDICATIONS

The StarClose SE™ Vascular Closure System is contraindicated for use in patients with known hypersensitivity to nickel-titanium.

WARNINGS

Do not use the StarClose SE™ Vascular Closure System if the packaging or sterile barrier has been previously opened or damaged or if the components appear to be damaged or defective.

DO NOT RESTERILIZE OR REUSE. The StarClose SE™ Vascular Closure System and accessories are intended for single use only.

Do not use the StarClose SE™ Vascular Closure System if the sterile field has been broken where bacterial contamination of the sheath or surrounding tissues may have occurred, since such a broken sterile field may result in infection.

Do not use the StarClose SE™ Vascular Closure System if the puncture site is located above the most inferior border of the inferior epigastric artery (IEA) and / or above the inguinal ligament based upon bony landmarks, since such a puncture site may result in a retroperitoneal hematoma. Perform a femoral angiogram to verify the location of the puncture site.

Do not use the StarClose SE™ Vascular Closure System if the puncture is through the posterior wall or if there are multiple punctures, since such punctures may result in a retroperitoneal hematoma.

Do not use the StarClose SE™ Vascular Closure System if the puncture site is located in the superficial femoral artery or the profunda femoris artery, since such puncture sites may result in a pseudoaneurysm, intimal dissection, or an acute vessel closure (thrombosis of small artery lumen). Perform a femoral angiogram to verify the location of the puncture site.

PRECAUTIONS

1. The StarClose SE™ Vascular Closure System should be used only by operators trained in diagnostic and interventional catheterization procedures who have been certified by an authorized representative of Abbott Vascular Inc.
2. The StarClose SE™ Vascular Closure System is provided sterile and non-pyrogenic in unopened, undamaged packaging. Products are sterilized with ethylene oxide and intended for single use only. Do not resterilize. Store in a cool, dry place.
3. Prior to use, inspect the StarClose SE™ Vascular Closure System to ensure that the sterile packaging has not been damaged during shipment. Examine all components prior to use to verify proper function. Exercise care during device handling to reduce the possibility of accidental device breakage.
4. As with all catheter-based procedures, infection is a possibility. Observe sterile technique at all times when using the StarClose SE™ Vascular Closure System. Employ appropriate groin management, as per hospital protocol, post-procedure and post-hospital discharge to prevent infection.
5. Use a single wall puncture technique. Do not puncture the posterior wall of the artery.
6. Do not use the StarClose SE™ Vascular Closure System to close vessels with diameters less than 5 mm.
7. Do not deploy the Clip in areas of calcified plaque.
8. The StarClose SE™ Vascular Closure System can **ONLY** be used with the StarClose Exchange System (included in the StarClose SE™ Vascular Closure System packaging).
9. **Do not advance or withdraw the StarClose SE™ Vascular Closure Device against resistance until the cause of that resistance has been determined.** Excessive force used to advance or torque the StarClose SE™ device should be avoided, as this may lead to significant vessel damage and / or breakage of the device, which may necessitate interventional and / or surgical removal of the device and vessel repair.

MRI SAFETY INFORMATION

The StarClose Clip has been shown to be MR Conditional immediately following implantation. A patient with this implant can be scanned safely immediately after clip placement under the following conditions:

- Static magnetic field of 3 Tesla or less
- Spatial gradient magnetic field of 720 Gauss/cm or less
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning.

In non-clinical testing, the StarClose Clip produced a temperature rise of 0.5ºC at maximum MR system-reported whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of MR scanning in a 3 Tesla MR system using a transmit/receive body coil.

The MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the StarClose Clip. Therefore, optimization of MR imaging parameters

to compensate for the presence of this implant may be necessary.

ADVERSE EVENTS

Potential adverse events that could be associated with the use of this device include:

• Major Vascular Complications (Composite) • Vascular Injury Requiring Repair • Surgery • Angioplasty • Ultrasound Guided Compression • Thrombin Injection or Other Percutaneous Procedure • New Ipsilateral Lower Extremity Ischemia • Access Site-related Bleeding Requiring Transfusion • Access Site-related Infection Requiring Intravenous Antibiotics or Prolonged Hospitalization • Access Site-related Nerve Injury Requiring Intervention • Death • Minor Vascular Complications (Composite) • Pseudoaneurysm • Arteriovenous Fistula • Hematoma (≥ 6 cm) • Late Access Site-related Bleeding • Transient Lower Extremity Ischemia • Ipsilateral Deep Vein Thrombosis • Transient Access Site-related Nerve Injury • Access Site-related Vessel Injury • Access Site Wound-related Dehiscence • Access Site-related Bleeding Requiring ≥ 30 minutes to Re-achieve Hemostasis • Localized Access Site Infection Treated with IM or Oral Antibiotics • UADE

℞ ONLY HI-TORQUE Proceed™ Guide Wire

INDICATIONS

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 hypersen sitivity 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.

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.

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

℞ ONLY Perclose™ ProStyle™ Suture-Mediated Closure and Repair System

INDICATIONS

The Perclose™ ProStyle™ Suture-Mediated Closure and Repair System is indicated for the percutaneous delivery of suture for closing the common femoral artery and vein access sites of patients who have undergone diagnostic or interventional catheterization procedures.

The Perclose™ ProStyle™ SMCR System is indicated for closing the common femoral vein in single or multiple access sites per limb.

The Perclose™ ProStyle™ SMCR System is used without or, if required, with adjunctive manual compression.

For access sites in the common femoral artery using 5F to 21F sheaths. For arterial sheath sizes greater than 8F, at least two devices and the pre-close technique are required.

For access sites in the common femoral vein using 5F to 24F sheaths. For venous sheath sizes greater than 14F, at least two devices and the pre-close technique are required.

CAUTION

Federal law restricts this medical device to sale by or on the order of a physician (or allied healthcare professionals, authorized by, or under the direction of, such physicians) who is trained in diagnostic and / or interventional catheterization procedures and who has been trained by an authorized representative of Abbott.

Prior to use, the operator must review the Instructions for Use and be familiar with the deployment techniques associated with the use of this device.

During closure of access sites using a procedural sheath greater than 8F, it is recommended that a vascular surgeon or a surgeon with vascular training be available in case surgical conversion to control bleeding and to repair the vessel is needed.

CONTRAINDICATIONS

There are no known contraindications to the use of this device.

WARNINGS

Do not use the Perclose™ ProStyle™ SMCR System if the packaging or sterile barrier has been previously opened or damaged or if the components appear to be damaged or defective.

DO NOT RESTERILIZE OR REUSE. The Perclose™ ProStyle™ SMCR System is intended for single use only.

Do not use the Perclose™ ProStyle™ SMCR System if the sterile field has been broken where bacterial contamination of the sheath or surrounding tissues may have occurred, since such a broken sterile field may result in infection.

Do not use the Perclose™ ProStyle™ SMCR System if the puncture site is located above the most inferior border of the inferior epigastric artery (IEA) and / or above the inguinal ligament based upon bony landmarks, since such a puncture site may result in a retroperitoneal hematoma. Perform a femoral angiogram to verify the location of the puncture site. **Note:** This may require both a right anterior oblique (RAO) and left anterior oblique (LAO) angiogram to adequately visualize where the sheath enters the femoral vessel.

Do not use the Perclose™ ProStyle™ SMCR System in arterial or venous access if the puncture is through the posterior wall or if there are multiple punctures in the same access site, since such punctures may result in a hematoma or retroperitoneal bleed.

Do not use the Perclose™ ProStyle™ SMCR System if the puncture site is located in the superficial femoral artery or the profunda femoris artery, or the bifurcation of these vessels, since such puncture sites may result in a pseudoaneurysm, intimal dissection, or an acute vessel closure (thrombosis of small artery lumen). Perform a femoral angiogram to verify the location of the puncture site. **Note:** This may require both a right anterior oblique (RAO) and left anterior oblique (LAO) angiogram to adequately visualize where the sheath enters the vessel.

PRECAUTIONS

1. Prior to use, inspect the Perclose™ ProStyle™ SMCR System to ensure that the sterile packaging has not been damaged during shipment. Examine all components prior to use to verify proper function. Exercise care during device handling to reduce the possibility of accidental device breakage.
2. As with all catheter-based procedures, infection is a possibility.

Observe sterile technique at all times when using the Perclose™ ProStyle™ SMCR System. Employ appropriate groin management, as per hospital protocol, post-procedure, and post-hospital discharge to prevent infection.

3. Use a single wall puncture technique. Do not puncture the posterior wall of the vessel in arterial and venous access.
4. Do not deploy the Perclose™ ProStyle™ Device at an elevated angle against resistance as this may cause a cuff miss or device breakage.
5. There are no reaccess restrictions if previous arteriotomy / venotomy repairs were achieved with Abbott Medical SMC or SMCR systems.
6. If significant blood flow is present around the Perclose™ ProStyle™ Device, do not deploy needles. Remove the device over a 0.038" (0.97 mm) (or smaller) guide wire and insert an appropriately sized sheath.
7. Prior to depressing the plunger to advance the needles, stabilize the device by the body to ensure the foot is apposed to the vessel wall and the device does not twist during deployment. Twisting (torquing) the device could lead to needle deflection resulting in a cuff miss. Do not use excessive force or repeatedly depress the plunger. Excessive force on the plunger during deployment could potentially cause breakage of the device, which may necessitate intervention and / or surgical removal of the device and vessel repair.
8. Do not apply excessive force to the lever when opening the foot and returning the foot to its original position down to the body of the device. Do not attempt to remove the device without closing the lever. Excessive force on the lever or attempting to remove the device without closing the lever could cause breakage of the device and / or lead to vessel trauma, which may necessitate intervention and / or surgical removal of the device and vessel repair.
9. Do not advance or withdraw the Perclose™ ProStyle™ Device against resistance until the cause of that resistance has been determined. Excessive force used to advance or torque the Perclose™ ProStyle™ Device should be avoided, as this may lead to significant vessel damage and / or breakage of the device, which may necessitate intervention and / or surgical removal of the device and vessel repair.
10. If excessive resistance in advancing the Perclose™ ProStyle™ Device is encountered, withdraw the device over a 0.038" (0.97 mm) (or smaller) guide wire and reinsert the introducer sheath or use manual compression.
11. Remove the Perclose™ ProStyle™ sheath before tightening the suture. Failure to remove the sheath prior to tightening the suture may result in detachment of the tip of the sheath.
12. Care should be taken to avoid damage to the suture from handling. Avoid crushing damage due to application of surgical instruments such as clamps, forceps or needle holders.
13. For catheterization procedures using a 5F – 8F procedural sheath, use manual compression in the event that bleeding from the femoral access site persists after the use of the Perclose™ ProStyle™ SMCR System to obtain hemostasis.
14. For catheterization procedures using a procedural sheath > 8F, use manual compression, compression assisted devices, surgical repair, and / or other appropriate treatment methods in the event that bleeding from the femoral access site persists after the use of the Perclose™ ProStyle™ SMCR System to obtain hemostasis.
15. For catheterization procedures using a procedural sheath > 8F, where the operating physician is not a vascular surgeon, it is recommended that a vascular surgeon or a surgeon with vascular training be available during the procedure to perform any necessary vascular surgical intervention.
16. If the Perclose™ ProStyle™ Device is used to close and repair multiple access sites in the same vessel, space the access sites apart adequately to minimize sheath-device interference.

POTENTIAL ADVERSE EVENTS

Potential adverse events associated with use of vessel closure devices may include, but are not limited to, the following:

- Allergic reaction or hypersensitivity to device components
- Vascular access complications which may require transfusion or vessel repair, including:
  - o Anemia
  - o Aneurysm
  - o Arteriovenous fistula
  - o Bleeding / hemorrhage / re-bleeding
  - o Bruising / hematoma
  - o Embolism
  - o Inflammation
  - o Intimal tear / dissection
  - o Perforation
  - o Pseudoaneurysm
  - o Retroperitoneal hematoma / bleeding
  - o Scar formation
  - o Wound dehiscence
- Cardiac arrhythmias (including conduction disorders, atrial and ventricular arrhythmias)
  - o Atrial arrhythmias
  - o Ventricular arrhythmias
- Femoral artery / venous complications which may require additional intervention, including:
  - o Arterial / venous stenosis
  - o Arterial / venous occlusion
  - o Arteriovenous fistula
  - o Intimal tear / dissection
  - o Ischemia distal to closure site
  - o Nerve injury
  - o Numbness
  - o Thrombus formation
  - o Vascular injury
- Venous thromboembolism (including deep vein thrombosis, pu lmonary embolism, post-procedure pulmonary embolism)
- Infection – local or systemic
- Pain
- Hemodynamic instability:
  - o Hypotension / hypertension
  - o Vasovagal episode
- Death
- Device complications
- Device failure
- Device malfunction

℞ ONLY JETi™ Hydrodynamic Thrombectomy System

INDICATIONS

The JETi™ Hydrodynamic Thrombectomy System is intended to remove/aspirate fluid and break-up soft emboli and thrombus from the peripheral vasculature and to sub selectively infuse/deliver diagnostics or therapeutics with or without vessel occlusion.

CONTRAINDICATIONS

The JETi™ Hydrodynamic Thrombectomy System is contraindicated for use in:

- Vessels smaller than 4 mm (0.16")
- Coronary, pulmonary, and neurovasculature

WARNINGS

- The catheter, suction tubing, and pump set contents are supplied sterile using ethylene oxidi (EO). Do not use if the expiration date has passed or the sterile barrier is damaged.
- The catheter, suction tubing and pump set contents are for single patient use only. Dispose after use. Do not reuse, reprocess, modify, or resterilize. Reuse, reprocessing, modification, or resterilization may compromise the structural integrity of the device and/or lead to device failure which, may result in patient injury, illness or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.
- The JETi™ Hydrodynamic Thrombectomy System is not approved for use with defibrillation. In the event shock must be delivered to the patient, remove the catheter and clear all connected system components from the patient before delivering shock.
- Do not use a catheter that has been kinked or damaged.
- Do not use a pump set if it does not prime.
- Only use the JETi™ Catheter, JETi™ Pump Set, JETi™ Suction Tubing, and JETi™ Non-Sterile Canister Set with the JETi AIO Saline Drive Unit or the JETi™ Saline Drive Unit.
- Do not mix contrast media in the saline bag.
- When the catheter is exposed to the arterial system, it should be manipulated while under high-quality fluoroscopic observation.
- In the event that the catheter becomes blocked or clogged with thrombus, remove and replace the device with a new device.
- Do not use if package is opened or damaged.
- To avoid risk of electric shock, the SDU must only be connected to mains power with a protective earth.
- The power socket-outlet must be located near the device and must be easily accessible.
- Do not modify or alter the device.
- Do not step or stand on the base of the device.
- Do not push or lean against the IV pole.

PRECAUTIONS

- Physicians must read and understand the Instructions for Use (IFU) prior to using the device. The device must be used by physicians skilled in percutaneous, intravascular techniques in a fully equipped catheterization laboratory.
- When delivering fluid through the catheter aspiration lumen, do not exceed the maximum recommended flow rate, per Table 1 below.

Table 1. Catheter Fluid Delivery Flow Rate

Fluid	Maximum Recommended Fluid Delivery Flow Rate
Saline	4.0 mL/s
60% Ionic Contrast Media	1.8 mL/s

POTENTIAL ADVERSE EVENTS

Potential adverse events include, but are not limited to:

• Acute closure • Aneurysm or pseudo aneurysm • Allergic reaction to contrast • Arrhythmia • Death • Embolism (air or device) • Embolization (thrombotic) • Emergency surgery • Access site pain, hemorrhage, or hematoma • Infection (systemic/sepsis) • Local infection (puncture site) • Minimal blood loss • Vessel dissection, perforation, or other injury • Vessel spasm • Thrombosis