IMPORTANT SAFETY INFORMATION

℞ Only

WALRUS IMPORTANT SAFETY INFORMATION

INDICATION FOR USE

The 087 Balloon Guide Catheter System is indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neurovasculature. The balloon provides temporary vascular occlusion during such procedures. The 087 Balloon Guide Catheter system is also indicated for use as a conduit for Retrieval devices.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

• The 087 Balloon Guide Catheter is intended for single use only. Discard after one procedure. Do not resterilize or reuse. Resterilization and/or reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target vasculature location and/or may compromise the structural integrity of the device.

• Do not use kinked or damaged devices. Do not use open or damaged packages. Use of compromised devices may result in performance and safety issues.

• Do not advance or withdraw the 087 Balloon Guide Catheter against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device. Unrestrained moving or torquing the device against resistance may result in damage to the vessel or device.

• Torquing guide catheter while kinked may cause damage that could result in separation of catheter shaft.

• The 087 Balloon Guide Catheter is coated with a hydrophilic coating at the distal end of the device for a length of 15 cmproximal to the balloon. Please refer to the recommended procedure 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.

• The 087 Balloon Guide Catheter System should only be used by physicians who have received appropriate training in interventional techniques. Use by unqualified personnel could result in patient injury.

• To reduce risk of complications due to slow balloon deflation, adhere to the following recommendations:– Wet distal shaft with saline before advancing peel-away introducer over balloon.– Use peel-away introducer to advance catheter into introducer sheath.– Minimize pushing forces on shaft during advancement. These forces can cause wrinkles in shaft that can slow balloon deflation.– Do not use device if shaft is damaged during use.– Prepare balloon according to Recommended Procedure.

• To reduce risk of complications due to air emboli, remove air sufficiently from balloon according to Recommended Procedure.

PRECAUTIONS

• Limit the exposure to X-ray radiation doses by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors when possible.

• Use prior to the “Use By” date. Use of the product after this date could result in compromised device performance.

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• Use the 087 Balloon Guide Catheter in conjunction with fluoroscopic visualization to ensure that desired position is achieved.

• To prevent thrombus formation and contrast media crystal formation maintain a constant infusion of appropriate flush solution through catheter lumen. Failure to do so could result in damage to the vessel or device.

POTENTIAL ADVERSE EVENTS

Possible complications include, but are not limited to, the following: • Acute occlusion • Clot formation • Air embolism • Arterial rupture • Death • Distal embolization • Emboli • False aneurysm formation • Hematoma or hemorrhage at puncture site • Infection • Intracranial hemorrhage • Ischemia • Neurological deficits including stroke vessel spasm, thrombosis, dissection, or perforation • Sterile inflammation or granulomas at access site • Pulmonary embolism • Pulmonary infarct • Myocardial embolism • Myocardial infarct • Embolic stroke • Cerebral infarct • Tissue necrosis • Exposure X-radiation include, but not limited to cataracts, delayed neoplasia (cancers)

For additional safety information, please refer to the full Instructions for Use.

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ARMADILLO IMPORTANT SAFETY INFORMATION

INDICATION FOR USE

The SelectFlex Neurovascular Access System Family is indicated for the introduction of interventional devices into the peripheral and neurovasculature.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

• The SelectFlex Neurovascular Access System should only be used by physicians who have received appropriate training in interventional techniques. Use by unqualified personnel could result in patient injury.

• This device is coated with a hydrophilic coating at the distal end of the device for a length of either a) 11.5cm or b) 30.0cm. Please refer to step 12 of the Device Preparation for Use Section for further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

• The safety and effectiveness of this device for radial neurovasculature access in direct comparison to a transfemoral approach has not been demonstrated. The risks and benefits for radial access against a transfemoral approach should be carefully weighed and considered for each patient.

PRECAUTIONS

• The SelectFlex Neurovascular Access System is intended for single use only. Do not resterilize or reuse. Resterilization and/or reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target vasculature location, and/or may compromise the structural integrity of the device.

• Do not use kinked or damaged devices. Do not use open or damaged packages. Use of compromised devices may result in performance and safety issues.

• Use prior to the “Use By” date. Use of the product after this date could result in compromised device performance.

• Avoid using alcohol, antiseptic solutions or other solvents to pre-treat the device because this may cause unpredictable changes in the coating, which could affect safety and performance of the device.

• Do not advance or withdraw the SelectFlex Catheter against resistance, without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device. Unrestrained moving or torquing of the device against resistance may result in damage to the vessel or device.

• If using radial artery access, perform a screening examination of the radial artery per institutional practices to ensure that radial access is appropriate for the patient.

POTENTIAL ADVERSE EVENTS

Possible complications include, but are not limited to, the following:

• acute occlusion • air embolism • death • distal embolization • emboli • false aneurysm formation • hematoma or hemorrhage at puncture site • infection • intracranial hemorrhage • ischemia • neurological de cits including stroke • sterile in ammation or granulomas at the access site • tissue necrosis • vessel spasm, thrombosis, dissection, or

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perforation • access site complications like hematoma, in ammation, infection, necrosis, pain and tenderness, granuloma • hand dysfunction • pathological hand cold intolerance • risks associated with x-radiation exposure from the use of uoroscopic imaging (e.g., alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia

For additional safety information, please refer to the full Instructions for Use.

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℞ Only

ZEBRA IMPORTANT SAFETY INFORMATION

INDICATION FOR USE

The Neurovascular Access System Family is indicated for the introduction of interventional devices into the peripheral and neuro vasculature. It is not intended for use in coronary arteries.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

• The Neurovascular Access System Family should only be used by physicians who have received appropriate training in interventional techniques. Use by unqualified personnel could result in patient injury.

• The Neurovascular Access System Family is coated with a hydrophilic coating at the distal end of the device for a length of either a) 11.5cm or b) 30.0cm for the 6F configurations or 25cm for the 7F configurations. Please refer to step 12 of the Device Preparation for Use Section for further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

- The safety and effectiveness of this device for radial neurovasculature access in direct comparison to a transfemoral approach has not been demonstrated. The risks and benefits for radial access against a transfemoral approach should be carefully weighed and considered for each patient.
- Radial artery access should be used only when femoral artery access is not feasible.
- Do not use automated high-pressure contrast injection equipment with the Neurovascular Access Catheters or Access Tools because it may damage the device and injure the patient.

PRECAUTIONS

- The Neurovascular Access System Family is intended for single use only. Do not resterilize or reuse. Resterilization and/or reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target vasculature location, and/or may compromise the structural integrity of the device.
- Avoid using alcohol, antiseptic solutions, or other solvents to pretreat the device because this may cause unpredictable changes in the coating, which could affect safety and performance of the device.
- If using radial artery access, perform a screening examination of the radial artery per institutional practices to ensure that radial access is appropriate for the patient. At a minimum, the radial artery lumen diameter should be larger than the outer diameter of the Neurovascular Access Catheter.
- Vasospasm may occur from accessing the radial artery, thus reducing vessel lumen diameter below that which was anticipated prior to the procedure and that which was measured by ultrasound examination of the artery prior to access.
- Vasospasm may occur while the device is within the artery. Manipulations of the device increase the risk of vasospasm.

POTENTIAL ADVERSE EVENTS

Possible complications include, but are not limited to, the following:

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- Acute occlusion
- Death
- Distal embolization
- Emboli
- False aneurysm formation
- Hematoma or hemorrhage at puncture site
- Vessel spasm, thrombosis, dissection, or perforation
- Air embolism
- Radial artery occlusion
- Compartment syndrome
- Infection
- Intracranial hemorrhage
- Ischemia
- Neurological deficits including stroke
- Tissue necrosis
- Sterile inflammation or granulomas at the access site
- Pathological hand cold intolerance
- Hand dysfunction
- Access site complications (e.g., hematoma, inflammation, infection, necrosis, pain, tenderness, granuloma, hemorrhage)
- Risks associated with x-radiation exposure from fluoroscopic imaging (e.g., alopecia, burns ranging from skin reddening to ulcers, cataracts, delayed neoplasia)

For additional safety information, please refer to the full Instructions for Use.