WALRUS™
BALLOON GUIDE CATHETER

Rx only

Walrus US 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 cm proximal 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.
- 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

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- 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™
SELECTFLEX™ NEUROVASCULAR ACCESS

SELECTFLEX™
TECHNOLOGY

Rx only

Armadillo US 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 ineFective 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 deficits including stroke
- Sterile inflammation or granulomas at the access site
- Tissue necrosis
- Vessel spasm, thrombosis, dissection, or 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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ZEBRA™ NEUROVASCULAR ACCESS CATHETER

Rx only

Zebra US Important Safety Information

INDICATION FOR USE

The Zebra Neurovascular Access Catheter is indicated for the introduction of interventional devices into the peripheral and neurovascular. It is not intended for use in coronary arteries.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

- The Zebra Neurovascular Access Catheter should only be used by physicians who have received appropriate training in interventional techniques. Use by unqualified personnel could result in patient injury.
- The Zebra Neurovascular Access Catheter 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 6 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 Zebra Neurovascular Access Catheter because it may damage the device and injure the patient.

PRECAUTIONS

- The Zebra Neurovascular Access Catheter 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 Zebra 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:

- 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.

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LYNX™ ASPIRATION CATHETER SYSTEM

Rx only

Lynx US Important Safety Information

INDICATION FOR USE

The Lynx Aspiration Catheter with the Aspiration Tubing and a compatible suction pump is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for thrombolytic drug therapy or who fail thrombolytic drug therapy are candidates for treatment. The Aspiration Tubing is indicated to connect the Lynx Aspiration Catheter to the compatible suction pump.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

- The Aspiration Catheter should only be used by physicians who have received appropriate training in interventional techniques. Use by unqualified personnel could result in patient injury.
- Resterilization and/or Reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target neuro vasculature location.
- Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor.
- Do not use automated high-pressure contrast injection equipment with the Lynx Aspiration Catheter because it may damage the device.
- Confirm vessel diameter and select appropriate size Lynx Aspiration Catheter. Do not use in arteries with diameters smaller or equal to the distal outer diameter of the Lynx Aspiration Catheter. Refer to the Lynx Aspiration Catheter labeling for dimensional information.
- Do not advance, retract or use any component of the Lynx Aspiration Catheter against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device or system as a unit. Unrestrained torquing or forced insertion of the catheter against resistance may result in damage to the device or vessel.
- Aspiration is solely applied through the inner catheter when using coaxially.
- 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.
- A maximum of three passes should be made with the same Lynx Aspiration Catheter. For vessel safety, do not perform more than three recovery attempts in the same vessel using the Lynx Aspiration Catheter.
- The Lynx Aspiration Catheters should be introduced via femoral access only. The safety of introducing the Lynx Aspiration Catheters through other vascular access routes has not been established. The safety and effectiveness of mechanical neurothrombectomy devices has only been evaluated via transfemoral access.

PRECAUTIONS

- Use prior to the “Use By” date.
- Use the Lynx Aspiration Catheter in conjunction with fluoroscopic visualization.
- As in all fluoroscopy procedures, consider all necessary precautions to limit patient radiation exposure by using sufficient shielding, reducing fluoroscopy times and modifying radiation technical factors whenever possible.
- Maintain a constant infusion of appropriate flush solution.
- When performing aspiration, ensure that the Flow Switch is open for only the minimum time needed to remove thrombus. Excessive aspiration or failure to close the Flow Switch when aspiration is complete is not recommended.
- If repositioning of the Lynx Aspiration Catheter is necessary during the revascularization procedure, such repositioning should be performed over an appropriate neurovascular guidewire/microcatheter using standard techniques.
- Administration of anticoagulants and antiplatelets should be suspended until 24 hours post-treatment. Medical management and acute post stroke care should follow the American Stroke Association (ASA) guidelines. Any neurological deterioration should be evaluated by urgent CT scan and other evaluations as indicated according to investigator/hospital best practice.

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LYNX™
ASPIRATION
CATHETER SYSTEM

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- As in all surgical interventions, monitoring of intra-procedural blood loss is recommended so that appropriate management may be instituted.
- 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 the device safety and performance.

POTENTIAL ADVERSE EVENTS

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

- Acute occlusion
- Air embolism
- Allergic reaction and anaphylaxis from contrast media
- Arteriovenous fistula
- Death
- Device malfunction
- Distal embolization
- Emboli
- False aneurysm formation
- Hematoma or hemorrhage at access site
- Inability to completely remove thrombus
- Infection
- Intracranial hemorrhage
- Ischemia
- Kidney damage from contrast media
- Neurological deficits including stroke
- Vessel spasm, thrombosis, dissection, or perforation
- Radiation exposure that may lead to cataracts, skin reddening, burns, alopecia or neoplasia from x-ray exposure

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

Q'Apel Medical

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We're Q'Apel, a medical technology company that creates solutions. More specifically, we design novel access device technology for vascular interventions and unmet clinical needs. Because in the precious seconds that surround a stroke emergency, clinicians need technology that delivers. That's where we come in.

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