℞ Only

The Prodigy™ Thrombectomy System

Indications for Use: The Prodigy™ Thrombectomy System is intended for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems. Not for use in the coronaries, pulmonary vasculature, or the neurovasculature.

Contraindications: There are no known contraindications.

Warnings:

The Prodigy Thrombectomy System should only be used by physicians who have received appropriate training in interventional techniques.

Do not advance, retract, or use any component of the Prodigy Thrombectomy System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device or system as a unit. Torquing, forced insertion or withdrawal of the Prodigy Catheter or Prodigy Twist against resistance may result in damage to the device or vessel; do not rotate the devices against resistance more than 1 revolution.

Do not retract the Prodigy Twist through the RHV unless the RHV is opened sufficiently to allow passage.

Verify aspiration pump is appropriate before use.

Precautions:

- The device 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
- Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/ distributor
- Use prior to the “Use By” date
- Use the Prodigy Thrombectomy System in conjunction with fluoroscopic visualization
- In order to minimize blood loss, ensure that the Prodigy Hotshot Controller vacuum switch is in the “ON” position for the minimum time needed to remove thrombus
- The Prodigy Twist is not intended for use as a guidewire. If repositioning of the Prodigy Catheter is necessary during the revascularization procedure, such repositioning should be performed over an appropriate guidewire using standard techniques
- Do not use automated high-pressure contrast injection equipment with the Prodigy Catheter

Potential Adverse Events:

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

- acute occlusion
- occlusion of target artery
- arrhythmia
- death
- distal embolization
- air embolism
- hematoma or hemorrhage at puncture site
- peripheral vascular hemorrhage
- hypotension
- hypertension
- infection, sepsis
- fever
- ischemia
- acute myocardial infarction
- infarction/necrosis
- amputation of an extremity
- vessel spasm
- arterial injury
- thrombosis
- renal insufficiency/failure
- suboptimal revascularization
- device malfunction
- local reaction

See IFU packaged with product for complete instructions on device usage

℞ Only

The Symphony™ Thrombectomy System

Indications for Use:

The Symphony Thrombectomy System is intended for:

- The non-surgical removal of fresh, soft emboli and thrombi from blood vessels.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

The Symphony Thrombectomy System is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism.

Contraindications: There are no known contraindications.

Warnings:

The Symphony Thrombectomy System should only be used by physicians who have received appropriate training in interventional techniques.

Do not advance, retract, or use any component of the Symphony Thrombectomy System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device or system as a unit. Torquing, forced insertion or withdrawal of the Symphony Catheter or Symphony ProHelix against resistance may result in damage to the device or vessel; do not rotate the devices against resistance more than 1 revolution.

Do not retract the Symphony ProHelix through the hemostasis valve on the Symphony Catheter unless the hemostasis valve is opened sufficiently to allow passage. Failing to actuate the Hemostasis Valve buttons while inserting or withdrawing a device through the Hemostasis Valve may damage the valve or the device.

Verify aspiration pump is appropriate before use.

Precautions:

- This device 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.
- Do not use kinked or damaged devices. Do not use open or damaged packages.
- Use prior to the “Use By” date.
- Use the Symphony Thrombectomy System in conjunction with fluoroscopic visualization.
- Do not use automated high-pressure contrast injection equipment with the Symphony Catheter.
- In order to minimize blood loss, ensure that the Symphony Catheter handle vacuum lever is in the “ON” position for the minimum time needed to remove thrombus.

- If repositioning of the Symphony Catheter is necessary during the revascularization procedure, such repositioning should be performed over an appropriate guidewire and the Symphony Dilator as needed, using standard catheter and guidewire techniques.

Potential Adverse Events:

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

- Acute occlusion
- Amputation of an extremity
- Anemia
- Angina
- Arrhythmia, including ventricular fibrillation
- Bradycardia
- Cardiac injury
- Cardiac tamponade
- Cardiogenic shock
- Cardio-respiratory arrest
- Compartment syndrome
- Death
- Embolism (air, thrombus, foreign body)
- Fever
- Fistula
- Hematoma
- Hemolysis
- Hemoptysis
- Hemorrhage or excessive blood loss (including retroperitoneal hemorrhage)
- Hypertension
- Hypotension
- Hypoxemia
- Infarction/Necrosis
- Infection (access site, respiratory tract, etc.)
- Inflammatory or allergic reactions and anaphylaxis from contrast media or device
- Ischemia
- Myocardial infarction
- Nerve damage
- Neurological deficits, including stroke
- Occlusion of target vasculature
- Perforation of the pulmonary arteries
- Pericardial effusion
- Pleural effusion
- Pneumonia
- Pneumothorax
- Pseudoaneurysm
- Pulmonary edema
- Pulmonary infarction

- Pulmonary injury
- Renal insufficiency/ failure
- Respiratory failure
- Right bundle branch block
- Sepsis
- Suboptimal revascularization
- Tachycardia
- Thrombocytopenia
- Thrombosis
- Valvular disruption/injury
- Vasovagal reaction
- Ventricular rupture
- Vessel injury
- Vessel spasm

See IFU for complete instructions on device usage

℞ Only

The Symphony™ 16F 82cm Thrombectomy System

Indications for Use:

The Symphony 16F 82cm Thrombectomy System is intended for:

- The non-surgical removal of fresh, soft emboli and thrombi from blood vessels.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

The Symphony 16F 82cm Thrombectomy System is intended for use in the peripheral vasculature. It is not for use in the pulmonary vasculature.

Contraindications: There are no known contraindications.

Warnings:

The Symphony 16F 82cm Thrombectomy System should only be used by physicians who have received appropriate training in interventional techniques.

Do not advance, retract, or use any component of the Symphony 16F 82cm Thrombectomy System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device or system as a unit. Torquing, forced insertion, or withdrawal of the Symphony 16F 82cm Catheter against resistance may result in damage to the device or vessel; do not rotate the devices against resistance more than 1 revolution.

Verify aspiration pump is appropriate before use.

Precautions:

- This device 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.
- Do not use kinked or damaged devices. Do not use open or damaged packages.
- Use prior to the “Use By” date.
- Use the Symphony 16F 82cm Thrombectomy System in conjunction with fluoroscopic visualization.
- Do not use automated high-pressure contrast injection equipment with the Symphony 16F 82cm Catheter.
- In order to minimize blood loss, ensure that the Symphony 16F 82cm Catheter handle vacuum lever is in the “ON” position for the minimum time needed to remove thrombus.
- If repositioning of the Symphony 16F 82cm Catheter is necessary during the revascularization procedure, such repositioning should be performed over an appropriate guidewire and the Symphony length matched Dilator as needed, using standard catheter and guidewire techniques.

Potential Adverse Events:

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

- acute occlusion
- occlusion of target artery
- death
- thrombus embolization
- air embolism
- hematoma or hemorrhage at puncture site
- peripheral vascular hemorrhage
- hypotension
- infection, sepsis
- fever
- ischemia
- acute myocardial infarction
- infarction/necrosis
- amputation of an extremity
- arterial injury
- thrombosis
- suboptimal revascularization
- local reaction
- neurological deficits, including stroke

See eIFU at imperativecare.com/files/ifu for complete instructions on device usage.