# Symphony® Thrombectomy System

**16F, 82CM**

ImperativeCare®

## INSTRUCTIONS FOR USE

### DEVICE DESCRIPTION

The Symphony® 16F 82cm Thrombectomy System is comprised of several devices:

- 16F 82cm Symphony Catheter
- 16F 82cm Symphony Length Matched Dilator
- Symphony Clot Container
- Imperative Care® Pump
- Vascular Canister
- Vascular Tubeset

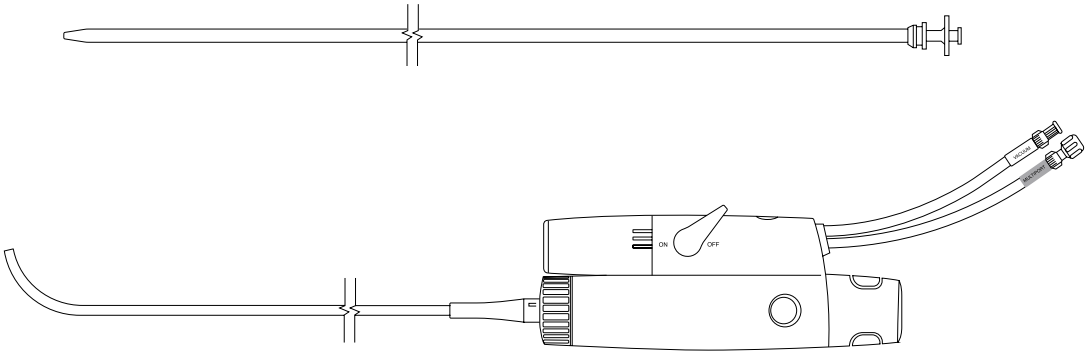



FIGURE 1: SYMPHONY 16F 82CM THROMBECTOMY CATHETER AND LENGTH MATCHED DILATOR

The Symphony 16F 82cm Thrombectomy System is designed to remove thrombus/embolus (hereupon referred to as 'thrombus' or 'clot') from the vasculature using controlled aspiration. The Symphony 16F 82cm Catheter targets aspiration from the Imperative Care Pump* directly to the thrombus.

The Symphony 16F 82cm Catheter has a lubricious hydrophilic coating on the distal 20 cm of the catheter shaft. The Symphony 16F 82cm Catheter and Symphony length matched Dilator are introduced through a vascular access (introducer) sheath into the peripheral vasculature and guided over a guidewire to the site of the thrombus. The Symphony 16F 82cm Catheter is used with the Imperative Care Pump connected using the Vascular Tubeset and the Vascular Canister, to aspirate thrombus.

### INDICATION 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.

### 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.

The Symphony 16F 82cm Thrombectomy Catheter has been verified for use with the Vascular Tubeset and Imperative Care Pump. The Imperative Care Pump is capable of delivering vacuum pressures between -20 inHg and -29.9 inHg during use and is characterized by the pressure-flow performance curve presented in Figure 2. If using a vacuum pump other than the Imperative Care Pump, carefully review the vacuum pump performance parameters to ensure it can achieve the same operating vacuum pressures between -20 inHg and -29.9 inHg and corresponds to the same flow rate ranges (Figure 2).

*The TRUVIC Generator can be used as the vacuum source as it can achieve the required pump pressure-flow performance curve.

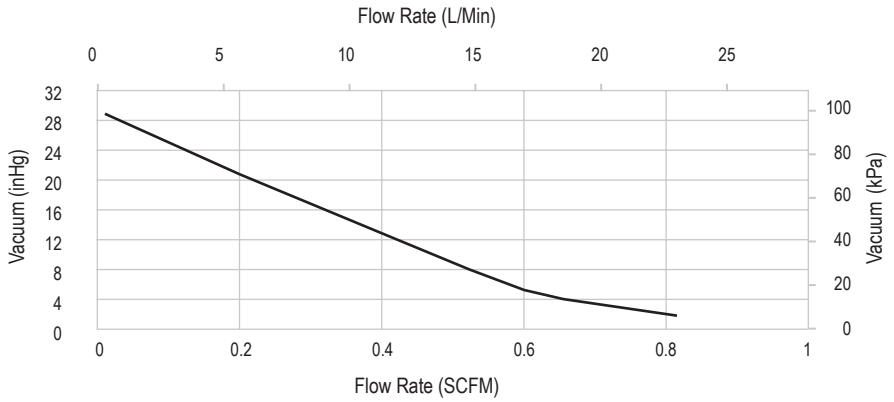



FIGURE 2: PUMP PRESSURE-FLOW PERFORMANCE CURVE FOR THE IMPERATIVE CARE PUMP

## 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 with the 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
- Ischemia
- Fever
- Acute myocardial infarction
- Infarction/Necrosis
- Amputation of an extremity
- Arterial injury
- Thrombosis
- Suboptimal revascularization
- Local reaction
- Neurological deficits, including stroke

## PROCEDURE AND PREPARATION

1. Refer to **Warnings, Precautions, and Potential Adverse Events** prior to use.
2. Prepare and place an introducer sheath according to the manufacturer’s Instructions for Use.
3. Prior to introducing the Symphony 16F 82cm System, ensure an appropriate 0.035” guidewire is placed into the target vessel. When using the 16F 82cm Catheter, a guidewire of at least 260 cm length should be used.

## 16F 82CM SYMPHONY SYSTEM PREPARATION AND USE

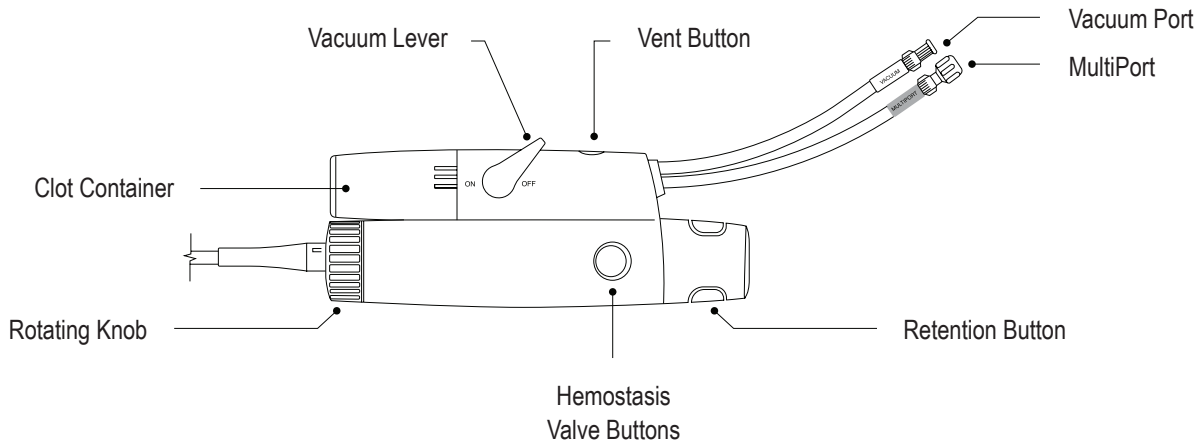



FIGURE 3: SYMPHONY 16F 82CM CATHETER HANDLE, LABELED

1. As each device of the Symphony 16F 82cm Thrombectomy System is used, remove the device from the packaging, and inspect for damage or for kinks.
2. Remove the Hemostasis Valve clip.
3. Flush the lumens of the Symphony 16F 82cm Catheter and length matched Dilator with heparinized saline and prepare the Vascular Tubeset and Canister according to their respective IFUs. To flush the Symphony 16F 82cm Catheter, confirm that the Vacuum Lever is in the “OFF” position, add a stopcock to the Handle injection port labelled “MultiPort”, and flush saline through the Handle injection port until saline flows from the tip of the Symphony 16F 82cm Catheter.
4. Hydrate the outer surfaces of the Symphony 16F 82cm Catheter and length matched Dilator shafts.

   Note: The length matched Dilator has a gray hub that matches the gray vacuum lever on the Symphony 16F 82cm Catheter Handle.
5. Press the Hemostasis buttons to open the hemostasis valve and insert the Dilator through the open Hemostasis Valve of the Handle. Advance the Dilator through the 16F 82cm Catheter until Dilator hub snaps into the Retention Clip of the Handle.
6. If desired, attach a manifold or syringe to the stopcock on the end of the Handle tubing labelled “MULTIPORT”.
7. Insert the Dilator and 16F 82cm Catheter over the previously placed 0.035” guidewire into the introducer sheath.
8. Advance the Symphony 16F 82cm System until the tip of the Dilator is in the desired position in the selected vessel.
9. Connect the Primary Tubing to the Handle tubing labelled “VACUUM”.
10. Attach the other end of the Primary Tubing to the Vascular Canister and ensure the stopcock on the Tubing is closed to the Pump.
11. Release the Dilator by pressing the Retention Clip buttons on the Handle.
    a. Withdraw the Dilator approximately 1 cm then press the Hemostasis Valve buttons on the Handle to reduce friction and completely withdraw the Dilator while maintaining the 16F 82cm Catheter and guidewire position.
    b. Guidewire may also be removed if desired.
12. Confirm the Handle vacuum lever is in the “OFF” position and open the stopcock on the Tubing.
13. Ensure the Pump is on and the Pump gauge reads -20 inHg or greater vacuum (refer to Imperative Care Pump IFU).
14. Confirm tip of the Symphony 16F 82cm Catheter is in the desired location.
15. To begin aspiration, move the vacuum lever on the Handle to the “ON” position.
16. When unrestricted blood flow through the clot container and into the canister is observed, move the lever on the Handle to the “OFF” position.
17. If desired, thrombus in the Symphony clot container can be removed by pressing and holding the vent button, rotating the clot container to unlocked position, pulling away from the Handle, and emptying the thrombus from the container. Alternatively, a replacement clot container can be used. Verify integrity before replacing the clot container on the Handle, then reconnect the container and rotate to the locked position.
18. If aspiration in another location is desired, reposition the tip of the 16F 82cm Catheter using the Dilator, as necessary.

19. Confirm clot removal by briefly pressing the Vent Button to evacuate blood and visualize the clot in the container of the Handle.
20. To remove any thrombus that may remain in 16F 82cm catheter, momentarily turn on aspiration by switching the vacuum lever to the “ON” position and ensure there is unrestricted blood flow into the clot container of the Handle.
21. If clot removal is complete, turn off the Pump. To obtain a post-treatment angiogram, inject contrast media and saline through the tubing labeled “MultiPort” on the Handle.
22. If repositioning the device for removal of additional thrombus in a different location is desired, flush and insert the Dilator over the previously placed guidewire, re-position, and return to step 11.
23. Remove the Symphony 16F 82cm Thrombectomy System and flush all Symphony components prior to reintroducing the System during the procedure.

## STORAGE

Store in a cool, dry place.

## DISPOSAL

Dispose of all devices in accordance with applicable hospital administrative and/or local government policy.

## SYMBOL GLOSSARY

| Symbol | Definition |
|---|---|
|  | Manufacturer |
|  | Lot number |
|  | Use by date |
|  | Attention, see instructions for use |
|  | Model number |
|  | Sterilized using ethylene oxide |
|  | Non pyrogenic |
|  | Prescription Only: Federal law restricts this device to sale by or on the order of a physician |
|  | Do not use if package is damaged |
|  | Do not resterilize |
|  | Do not reuse |

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