DEVICE DESCRIPTION

The Prodigy™ Thrombectomy System is comprised of several devices:

- Prodigy Catheter (provided accessory: Rotating Hemostasis Valve [RHV])
- Prodigy Twist™
- Prodigy Hotshot™ Controller (provided accessories: stopcock & 6" extension tubing)
- TRUVIC Generator
- TRUVIC Canister
- TRUVIC Tubeset

The Prodigy Thrombectomy System is designed to remove thrombus from the peripheral vasculature using continuous aspiration. The Prodigy Catheter targets aspiration from the TRUVIC Generator and through the Prodigy Hotshot Controller and Prodigy Catheter directly to the thrombus. The Prodigy Twist may be used to facilitate thrombus removal through the Prodigy Catheters.

The Prodigy Catheter is introduced through a guide catheter or introducer sheath and into the peripheral vasculature and guided over a guidewire to the site of the target thrombus. The Prodigy Catheter is used with the TRUVIC Generator, TRUVIC Canister, TRUVIC Tubeset and Prodigy Hotshot Controller, to aspirate thrombus. As needed, a Prodigy Twist may be introduced through the Prodigy Catheter and rotated while advancing and retracting through the Prodigy Catheter tip to assist with thrombus removal or to facilitate clearing of the thrombus from the Prodigy Catheter. The Prodigy Catheter is provided

with a rotating hemostasis valve (RHV). The Prodigy Catheters and Prodigy Twists have distal radiopaque markers which are visible under fluoroscopy. The Prodigy Catheter radiopaque marker is approximately 1 mm from the end of the atraumatic catheter tip. The Prodigy Twist has two radiopaque markers contained within the polymer tip.

INDICATION 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.

CONTRAINDICATION

There are no known contraindications.

WARNINGS

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

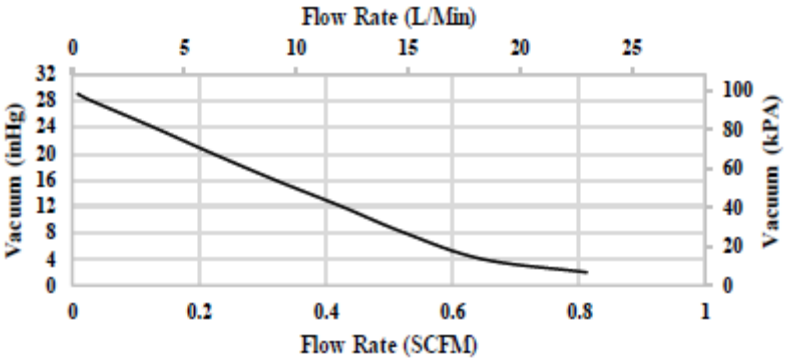
Do not advance, retract, or use any component of the Prodigy Thrombectomy System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device or system as a unit. Torquing, forced insertion or withdrawal of the Prodigy Catheter or 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.

The Prodigy Catheters have been verified for use with the TRUVIC Tubeset and TRUVIC Generator. The TRUVIC Generator 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 1. If using a vacuum pump other than the TRUVIC Generator, 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 1).

Figure 1 – Pump Pressure-Flow Performance Curve for the TRUVIC Generator



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

PRODIGY THROMBECTOMY SYSTEM
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

PROCEDURE

1. Refer to **Warnings, Precautions, and Potential Adverse Events** prior to use
2. As each device of the Prodigy Thrombectomy System is used, remove the device from the packaging, and inspect for damage or for kinks
3. Prepare Prodigy Thrombectomy System devices for use by flushing with heparinized saline
4. Prepare a guide catheter or introducer sheath according to the manufacturer's Instructions for Use
5. Using conventional catheterization techniques under fluoroscopic guidance, place the guide catheter or introducer sheath over an appropriate guidewire and into the artery or vein to approach the thrombus site

PRODIGY SYSTEM PREPARATION AND USE

1. Confirm vessel diameter and select an appropriately sized Prodigy Catheter and corresponding Prodigy Twist
2. Hydrate the outer surface of the Prodigy Catheter
3. Attach the provided RHV to the Prodigy Catheter
4. Attach the TRUVIC Tubeset to the TRUVIC Canister and the luer connector labelled “VACUUM” of the Prodigy Hotshot Controller as indicated in Figure 2
5. As shown in Figure 2:

a. Attach the stopcock provided with the Prodigy Hotshot Controller to the end of the Prodigy Hotshot Controller
b. Attach the 6” extension tubing to the stopcock
c. Connect the other end of the 6” extension tubing to the side port of the RHV

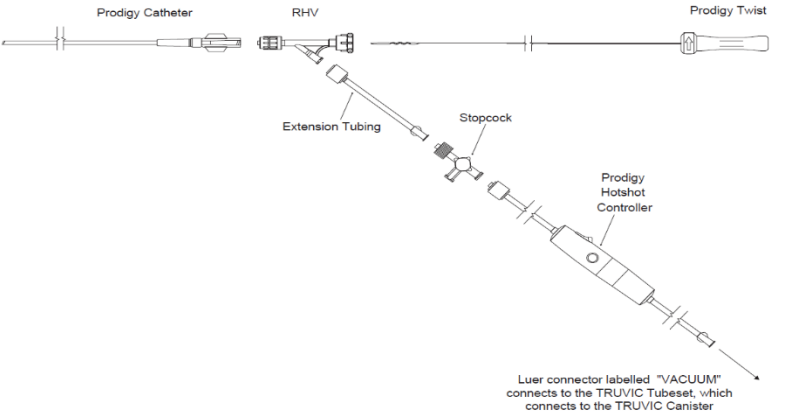


Figure 2. Assembled Prodigy Thrombectomy System

6. Switch the vacuum switch on the Prodigy Hotshot Controller to the “OFF” position
7. Insert the Prodigy Catheter over the guidewire and into the guide catheter, introducer sheath, or a primary Prodigy Catheter already in place (telescoping)
   a. Use a sterile gauze pad to help grasp the distal end of the catheter while inserting through the valve

   b. If telescoping catheters are used, do not overtighten RHV of the primary catheter onto telescoping catheter
8. Advance the Prodigy Catheter into the target vessel over the guidewire. Position the Prodigy Catheter tip at the thrombus site
9. Remove the guidewire from the Prodigy Catheter
10. Turn on the TRUVIC Generator. Confirm that the vacuum gauge reads -20 inHg or greater vacuum (Refer to the TRUVIC Generator IFU)
11. Ensure the clot container is rotated to the locked position
12. Insert the Prodigy Twist through the RHV into the Prodigy Catheter, leaving the Prodigy Twist torquing handle at least 8cm (3 inches) from the RHV
13. Advance the Prodigy Catheter distal tip to be approximately 2-3 mm from the thrombus
14. To begin aspiration thrombectomy, ensure the stopcock is open between the Prodigy Catheter and Prodigy Hotshot Controller, toggle the vacuum switch on the Prodigy Hotshot Controller to the “ON” position
15. To assist with aspiration and removal of the thrombus, continuously rotate the Prodigy Twist in the clockwise direction (as indicated by the arrow on the torquing handle) while advancing and retracting the tip of the Prodigy Twist in and out of the Prodigy Catheter tip. As the Prodigy Twist is advanced and retracted, ensure via fluoroscopy that both radiopaque markers on the Prodigy Twist extend at least 1

cm distal to the Prodigy Catheter distal tip marker and retract proximal to the Prodigy Catheter distal tip marker

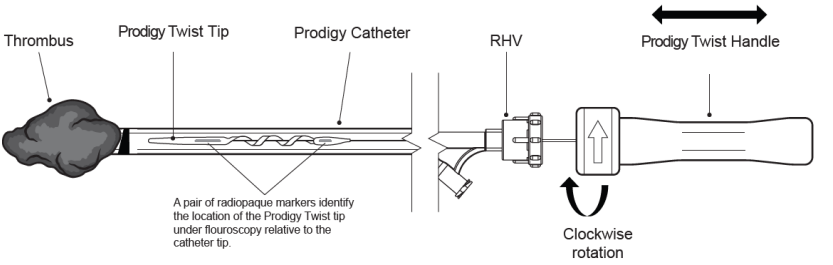


Figure 3. Thrombus Aspiration Using the Prodigy Twist

16. To stop aspiration, toggle the vacuum switch on the Prodigy Hotshot Controller to the "OFF" position
17. Remove the Prodigy Twist if appropriate
18. To remove any thrombus that may remain in the Prodigy catheter, momentarily turn on aspiration by switching the vacuum switch to the ON position and ensure there is unrestricted blood flow into the clot container of the Prodigy Hotshot Controller
19. To visualize the thrombus in the clot container of the Prodigy Hotshot Controller press the vent button to evacuate blood from the clot container
20. If desired, thrombus in the Prodigy Hotshot Controller can be removed by pressing and holding the vent button and rotating the clot container to the unlocked position

21. Remove the Prodigy Catheter
22. Turn off the TRUVIC Generator
23. If removal of additional thrombus is desired, repeat all steps above as appropriate

STORAGE

Store in a cool, dry place

SYMBOLS GLOSSARY


Do not reuse

Do not resterilize


Attention, see instructions for use


Nonpyrogenic

Sterilized by ethylene oxide


Do not use if packaging is damaged

Prescription only - U.S. Federal Law restricts this device to use by or on the order of a physician


Manufacturer

WARRANTY

Truvic Medical, Inc. (TRUVIC) warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular use. Handling, storage, cleaning, and sterilization of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond TRUVIC's control directly affect the device and the results obtained from its use. TRUVIC's obligation under this warranty is limited to the replacement of this device and TRUVIC shall not be liable for any incidental, consequential, or special loss, damage, or expense directly or indirectly arising from the use of this device. TRUVIC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. This warranty is valid only if the device is used in accordance with the manufacturer's instructions, and the warranty is limited to the original user. Any sale or other transfer or use of the device covered by this warranty to or by a user other than the original user shall cause this warranty to terminate immediately. TRUVIC assumes no liability with respect to devices reused, reprocessed, or resterilized, or serviced, repaired or modified by any party other than the original manufacturer, and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for intended use, with respect to such devices.

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