

Prodigy** THROMBECTOMY SYSTEM



The Power of Controlled Aspiration in the Palm of Your Hands

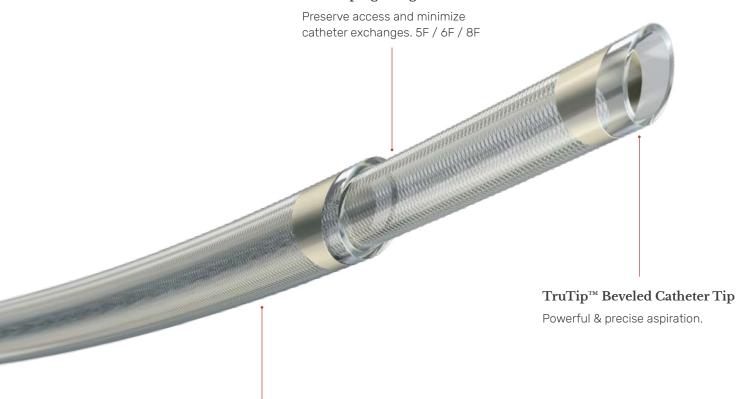
- Precise thrombus removal
- Ingenious device integration
- Designed to gain an advantage throughout the case



Advanced Catheter Design, Optimized Performance

Prodigy[™]Catheter

Telescoping Design



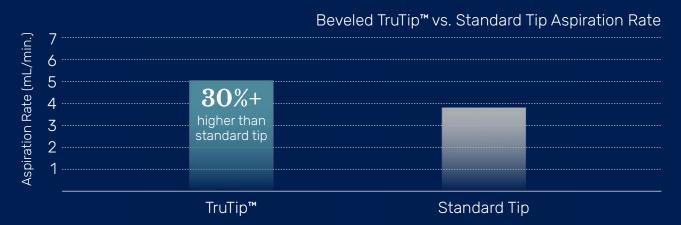
Innovative Braided Construction

Strength + torque resistance for maximum proximal pushability & distal flexibility.

Design Delivers 30% Greater Aspiration Rate

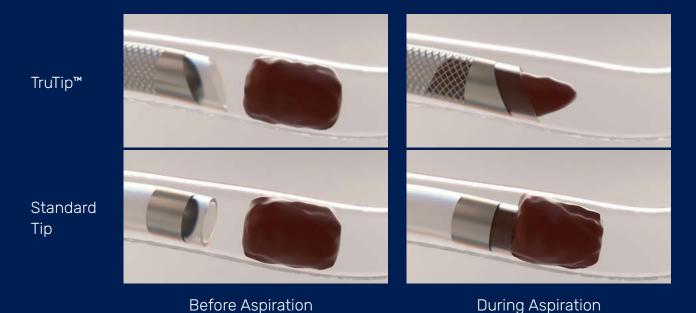
The innovative braided Prodigy™ Catheter with unique beveled TruTip™ design combines optimized strength and torque resistance for ultra-smooth navigation and maximum clot removal.

The Prodigy[™]Advantage¹



Prodigy TruTip vs. Standard Tip Clot Ingestion

Beveled tip demonstrates greater rate of clot ingestion.1



¹ Data on File

Triple-Action Thrombus Removal

HotShot[™] Controller



Triple Action Controlled Aspiration

3 on-demand modes (Full/Pulse/Assist) for maximum thrombus removal.



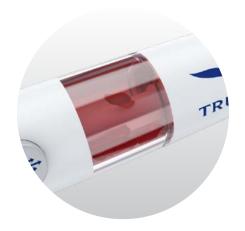
TruView[™] Assessment

Procedural progress visibility with transparent TruView clot capture.



On-Demand Vacuum

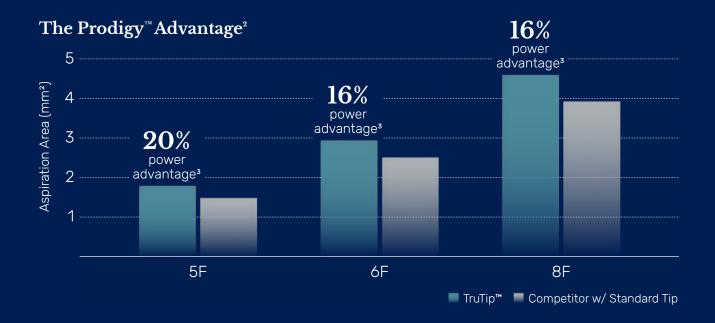
Immediate, integrated vacuum control places full power in the physician's hands.





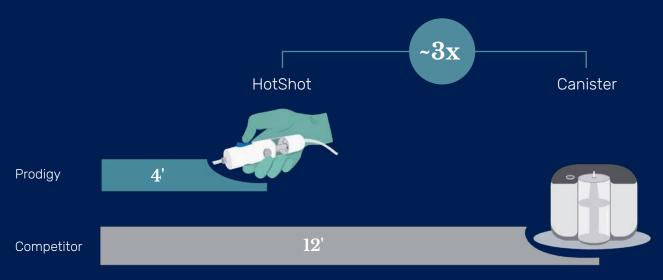
Designed for Confident, Precise Aspiration

The Prodigy™ HotShot™ Controller delivers powerful, precise and predictable aspiration for removal of all anticipated clot types.



Rapid, Real-Time Assessment

HotShot reduces distance to the clot capture zone.2



² Data on File

³ Aspiration Power: Force = Pressure x Area

On-Demand Assist Optimizes Clot Engagement

Prodigy Twist[™]



Maximum Aspiration Area

Sleek profile maximizes catheter lumen area for safe thrombus removal.



Clot Engagement

Mechanical assist disrupts thrombus.

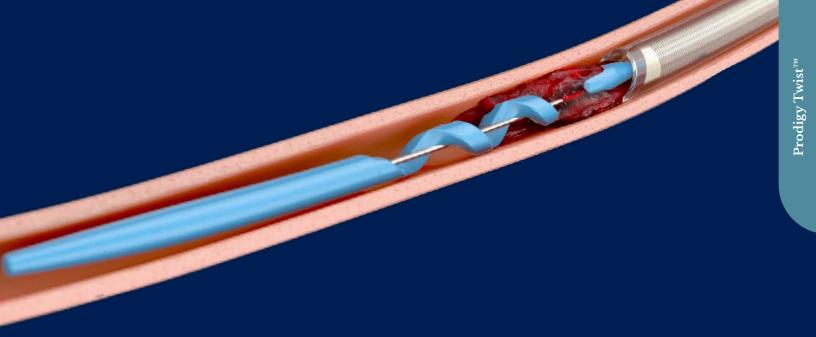


1:1 Torque Control

Transfers disruption power with intuitive positioning to facilitate quick clot removal.







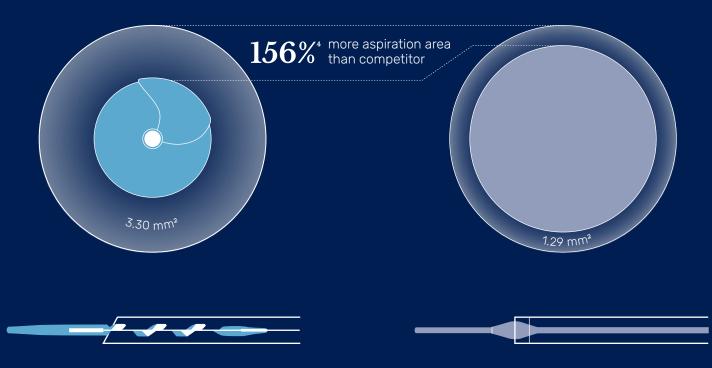
Maximum Aspiration Area Enhances Clot Engagement & Removal

The innovative Twist™ mechanical assist technology with 1:1 torque control and intuitive positioning safely maximizes clot engagement and transport.

The Prodigy[™]Advantage

Prodigy™ 8F Catheter + Twist™

Competitor 8F Catheter





Product Ordering Information

Prodigy™ Catheters	Model	Length	Inner Diameter	Outer Diameter	Outer Diameter
5F	PRODIGY5F	160 cm	0.055 in	0.067 in	1.70 mm
6F	PRODIGY6F	137 cm	0.071 in	0.084 in	2.13 mm
8F	PRODIGY8F	90 cm	0.088 in	0.110 in	2.80 mm
8F-s	PRODIGY8F-S	50 cm	0.088 in	0.110 in	2.80 mm

Prodigy Twist™	Model	Length
5F	TWIST5F	177 cm
6F	TWIST6F	154 cm
8F	TWIST8F	107 cm
8F-s	TWIST8F-S	67 cm

HotShot™Controller	Model	
Controller	HOTSHOT	

Truvic™ Generator & Accessories	Model
Generator	PTG1B
Canister	PTC001B
Tubeset	PAT10261B

Customer Service: +1-833-TRUVIC2

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Find out more about the Prodigy™ Thrombectomy System.



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Rx 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

Bench test data is not necessarily indicative of clinical performance.

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