

ThromCat[®]

Thrombectomy Catheter System

THROMBECTOMY CATHETER SYSTEM

INSTRUCTIONS FOR USE (U.S.)

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

Spectranetics[®]

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to observe warnings and precautions may result in complications. Any recommendations within these instructions are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

DEVICE DESCRIPTION

The ThromCat® Thrombectomy Catheter System is a single-use, disposable medical device designed for removing thrombus from synthetic dialysis access grafts and native vessel dialysis fistulae. The device consists of a flexible catheter containing a helix with a distal end designed to track over a 0.014" guidewire. The catheter provides infusion flow at approximately 15 ml/min to "wash" the vessel, while simultaneously providing extraction flow at approximately 45 ml/min to remove thrombus, yielding an approximate net extraction rate of 30 ml/min. The catheter is advanced and retracted within the vessel to disrupt and remove thrombus. The entire system is supplied sterile and nonpyrogenic.

DEVICE COMPONENTS

The ThromCat® System consists of the following components (Figure 1):

- Catheter:** Constructed from a nylon blend with working length of 150cm. The catheter operates on a 0.014" guidewire via 6F or larger sheath or 7F or larger (0.078" minimum ID) guide catheter. The distal end of catheter contains an atraumatic flexible tip that encases a stainless steel helix designed to macerate thrombus. The flexible non-latex rubber and stainless steel tip prevents direct contact between helix and vessel wall.
- Control Unit:** Contains a motor which powers both infusion and extraction helical pumps; an Infusate Line with bag spike; an Extraction Line with a 500 ml extraction bag and a power cord that connects the Control Unit to the power supply.
- Power Supply:** A non-sterile power adaptor that connects the Control Unit power cord to an electrical outlet.

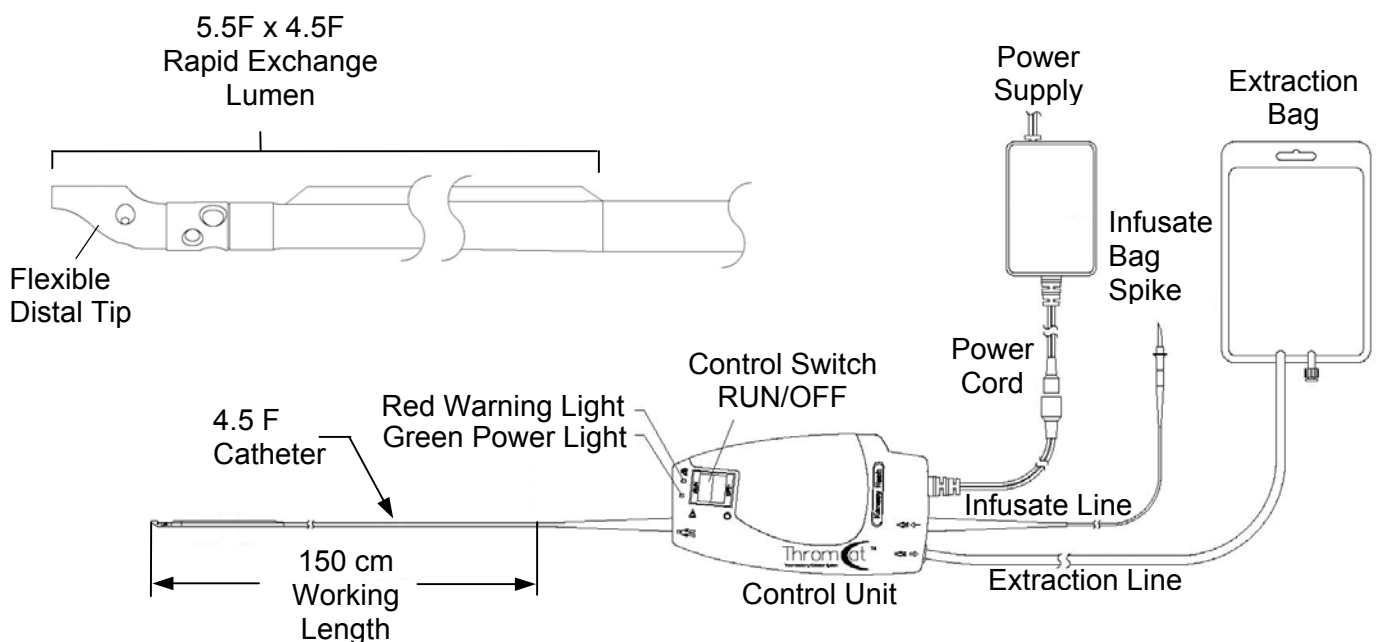


Figure1

INDICATIONS / INTENDED USE

The ThromCat® System is indicated for mechanical removal of thrombus in synthetic hemodialysis access grafts and native vessel dialysis fistulae.

The device is intended for single-use by physicians trained and experienced in diagnostic and interventional techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters and guidewires may be employed.

CONTRAINDICATIONS

- Graft or lesion that cannot be crossed with a 0.014" diameter guidewire
- Graft or vessel with reference diameter by visual estimation less than (<) 2.5 mm or greater than (>) 7mm
- Severe vessel tortuosity
- Patients with uncontrolled coagulation disorders.
- Infection
- Significant cardiopulmonary vascular compromise

WARNINGS

- Do not operate device without a guidewire, as vessel injury may result.
- Do not attempt to advance catheter against resistance until cause of resistance has been determined by fluoroscopy or other means.
- Do not use device if catheter or infusate line has been kinked, as catheter damage and/or vessel injury may result.
- If excessive slack or a loop in the guidewire is observed between the guide catheter and the monorail segment of the catheter during the procedure, the guidewire may become kinked within the vessel during catheter advancement or retraction. Remove the slack or loop in the guidewire before advancing or retracting the catheter to avoid catheter and/or vessel damage.
- Do not use device in access catheters or vessel tortuosity with excessive curvatures (<2.5 cm diameter).
- Do not allow catheter to remain in a stationary position while operating, as catheter damage and/or vessel injury may result.
- Confirm access catheter placement to insure firm seating and alignment with target vessel, as catheter damage and/or vessel injury may result.
- The safety and effectiveness of the ThromCat® System in veins outside of arteriovenous access grafts has not been determined.
- The safety and effectiveness of the ThromCat® System in vessels with an existing dissection has not been determined.

PRECAUTIONS

- Manipulation of catheter, while in vivo, should be performed under fluoroscopic guidance.
- Do not operate catheter over guidewire floppy tip as kinking of floppy tip may result.
- Do not force, rapidly advance, or excessively torque catheter as catheter damage may result.
- Do not use the device in calcified lesions as catheter damage may result.
- Do not over tighten Tuohy Borst valve as catheter may become damaged or inoperable.
- Do not use the ThromCat® catheter in access catheters smaller than 0.078" inner diameter as catheter damage may result.
- Do not allow saline infusate bag to empty during usage as catheter damage may result.
- Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
- Do not re-sterilize, re-process, or re-use device.

POTENTIAL ADVERSE EVENTS

Potential adverse events associated with use of the thrombectomy device may include, but are not limited to, the following:

- Access site bleeding/hematoma
- Anastomotic disruption
- Abrupt closure or total occlusion of treated graft or vessel
- Distal embolization of debris resulting in pulmonary compromise and/or limb ischemia
- Infection
- Vasospasm
- Vessel perforation
- Adverse reaction to contrast medium
- Emergent surgery
- Death

VISUAL ALARMS / OPERATING MODES

ThromCat® incorporates controls to maintain safe and effective performance. A green light illuminates when power is supplied to device. A red warning light illuminates when device is inactive. During the device priming procedure, the red light will illuminate until the catheter is fully primed. Additionally, during device operation, the red light will illuminate if catheter becomes kinked or clogged.

INSTRUCTIONS FOR USE

DEVICE PREPARATION:

1. Using sterile technique, carefully remove the ThromCat® System from packaging. Removable banding around catheters and extraction bag facilitates removal from packaging.
CAUTION: Do not use device if catheter or infusate line has been kinked.
NOTE: A slight curvature in the catheter is normal due to packaging and will not impact device performance or safety.
2. Orient device on procedure table so that catheter is toward patient.
3. Remove and discard paper bands from catheter and extraction bag.
4. Hand off attached infusate line and spike, extraction bag, and power cord outside sterile field.
5. Connect infusate line spike to a 500 cc bag of sterile saline and hang on IV pole at least 2 feet (60 cm) above procedure table.
6. Hang extraction bag from IV pole.
7. Connect device power cord to provided power supply.
8. Connect power supply cord to nearby electrical outlet. The green light will illuminate indicating electrical power is being delivered to the device. The red light will illuminate indicating the catheter is inactive.

PRIME PROCEDURE:

1. Ensure that infusion bag is properly spiked and verify infusion flow. Saline must reach infusion helix before proceeding.
2. Submerge flexible distal tip of catheter approximately 5 cm into a container of sterile saline.
NOTE: To successfully prime device, distal tip must be completely submerged during prime sequence.
3. Depress and hold control switch in the “RUN” position, designated by “▷”, until air bubbles stop exiting distal tip and red warning light turns off (approximately 20 seconds) indicating device is primed.
NOTE: An audible change in speed will occur as the red warning light turns off.
4. Release control switch. The switch will automatically return to its center position and device will continue to run.
5. Depress control switch to “OFF” position, designated by “O”. The red warning light will reilluminate indicating the catheter is inactive. **Device is now fully primed and ready for use.**

CATHETER DELIVERY:

1. Place an appropriately sized guide catheter or sheath into graft or vessel using standard percutaneous techniques.
2. Place a 0.014” diameter guidewire through guide catheter or sheath and advance guidewire distally to the lesion.
3. Secure guidewire position; insert guidewire through flexible distal tip and rapid exchange lumen of ThromCat™ catheter (Figure 2).

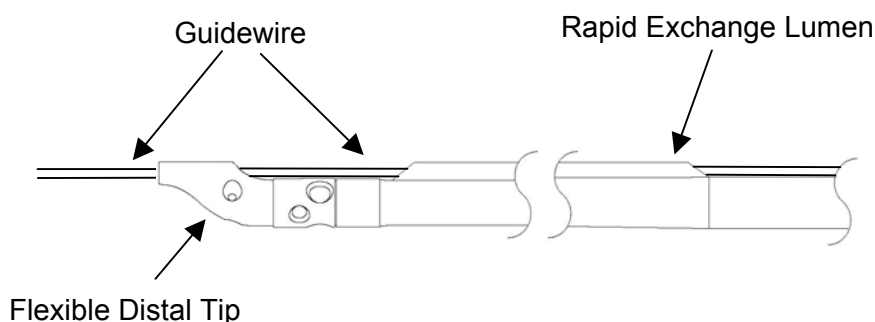


Figure 2

WARNING: Incorrect catheter loading may cause excessive catheter damage.

4. Advance catheter just proximal to thrombotic lesion.

WARNING: Do not attempt to advance catheter against resistance until cause of resistance has been determined by fluoroscopy or other means.

CAUTION: Do not force or excessively torque catheter as this may result in deformation of distal tip, or kinking of catheter.

CAUTION: Do not over tighten Tuohy Borst valve as catheter may become damaged or inoperable.

NOTE: Please refer to “TROUBLESHOOTING” section.

DEVICE OPERATION:

1. With the catheter positioned proximal to lesion site, depress and hold control switch to the “RUN”, “▷”, position to activate device.
2. Release control switch when red warning light turns off.

CAUTION: Do not operate device while catheter distal tip is inside guide catheter or sheath as this may result in catheter damage or helix failure.

CAUTION: If red warning light does not turn off, remove catheter from patient before attempting to restart. Attempt to restart device following “PRIME PROCEDURE”. If device fails to restart, discard device.

3. Advance catheter approximately 2 mm/sec through lesion beginning proximally and continuing distally. For optimal results, use short back and forth strokes. Repeat as necessary.

CAUTION: Under normal running conditions, the helix will not be visible under fluoroscopy due to its high rotational speed. If helix appears stationary (not rotating) while device is running, turn off device and remove catheter from patient. Discard device.

CAUTION: If device shuts down during use, remove catheter from patient. Attempt to restart device following “PRIME PROCEDURE”. If device fails to restart or helix does not rotate, discard device.

CAUTION: Do not allow saline infusion bag to empty during device operation. If fluid levels within saline bag are low, replace with a new 500 cc sterile bag and repeat “DEVICE PREPARATION” and “PRIME PROCEDURE”.

4. Retract catheter back until just outside of guide catheter or sheath and depress control switch to “OFF” position, “O”.

CAUTION: Do not retract catheter distal tip inside guide catheter or sheath while operating device as this may result in catheter damage or helix failure.

5. Repeat steps 1 through 4 of “DEVICE OPERATION” as necessary to achieve desired results.

CAUTION: If necessary to perform multiple procedures, and catheter is removed from patient, catheter should be flushed with saline according to “PRIME PROCEDURE” immediately following removal from patient. Continue to run device during priming sequence until effluent entering extraction line becomes clear.

6. When thrombectomy procedure is complete, remove catheter from patient.
7. Discard entire device, including power supply and cords, according to hospital procedures.

NOTE: Please refer to “TROUBLESHOOTING” section.

POST-THROMBECTOMY CARE

After thrombectomy procedure, hospital standard of care should be followed for removing sheath and providing hemostasis to prevent bleeding at vascular access site.

HOW SUPPLIED

Supplied sterilized by gamma radiation in peel-open package. Intended for one-time use; do not resterilize, reprocess or reuse. Sterile if package is unopened or undamaged. Do not use the device if there is doubt as to whether product is sterile. Upon removal from package, inspect device to ensure no damage has occurred.





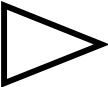


STORAGE CONDITIONS

Store in a cool, dry location.

TROUBLESHOOTING

Problem	Possible Cause(s)	Recommended Action(s)
Device Preparation		
Noticeable damage while still in packaging	Packaging/shipping	DO NOT USE; replace with new device
Device damaged anytime before use	Packaging/shipping	DO NOT USE; replace with new device
	Inappropriate handling	DO NOT USE; replace with new device
Priming Procedure		
Infusion line not primed	Saline bag empty	Replace saline bag
	Saline bag not properly spiked	Properly spike saline bag; visually confirm infusion line is primed
	Infusate tube or helix kinked	DO NOT USE; replace with new device
	Catheter tip prematurely placed in saline bowl	Remove catheter tip from saline bowl and squeeze saline bag.
Device will not prime; Red LED light will not go out; device will not reach RUN speed	Switch not held long enough	Hold switch until Red LED light turns off or hold for up to 30-40 seconds
	Catheter tip not submerged in saline	Submerge catheter tip in bowl of saline and repeat priming sequence
	Device damaged	DO NOT USE; replace with new device
Catheter Delivery or Removal		
Catheter meets resistance during advancement through guide catheter or sheath	Catheter damaged or kinked	DO NOT USE; replace with new device
	Guide catheter or sheath damaged or kinked	Replace guide catheter or sheath; repeat PRIME PROCEDURE to verify helix rotation
	Device improperly loaded on guidewire	Verify device is properly loaded on guidewire
Catheter meets resistance during advancement in vessel	Vessel size too small	Verify vessel size is ≥ 2.5 mm
	Device improperly loaded on guidewire	Verify device is properly loaded on guidewire. Remove any slack in guidewire
	Distal tip advanced beyond guidewire	Remove device and guide wire together; Re-deliver guidewire and catheter
Catheter meets resistance during retraction	Device not properly loaded on guidewire	Verify device is properly loaded on guidewire. Remove any slack in guidewire.
	Distal tip advanced beyond guidewire	Remove device and guidewire together
Device Operation		
Device will not run	No power to device	Check power connection; verify LED lights are on
	Switch not fully depressed into RUN position	Depress switch fully to RUN position
	Switch not held in RUN position long enough	Hold switch in RUN position until Red LED light turns off
	Attempting to restart device too quickly after turning off	Wait for Red LED light to illuminate before attempting to restart
Catheter helix not rotating when device is operational	Extraction helix damaged	DO NOT USE; replace with new device
Infusion helix not rotating when device is operational	Infusion helix damaged	DO NOT USE; replace with new device
Effluent not flowing into collection bag	Extraction pathway clogged	Remove device from patient; repeat PRIME PROCEDURE. If device does not successfully prime, replace with new device
	Extraction helix fractured	DO NOT USE; replace with new device
Device shuts off during use	Extraction pathway clogged	Remove device from patient; repeat PRIME PROCEDURE. If device does not successfully prime, DO NOT USE; replace with new device
	Extraction helix fractured	DO NOT USE; replace with new device
	Device inadvertently deactivated	Verify switch position and operation. If switch does not operate properly, DO NOT USE; replace with new device

NON-STANDARD GRAPHICAL SYMBOLS

 <p>PATIENT</p>	 <p>FLUID FLOW DIRECTION INTO PATIENT</p>	 <p>FLUID FLOW DIRECTION OUT OF PATIENT</p>
 <p>WARNING</p>	 <p>RUN</p>	 <p>OFF</p>
		 <p>CARDIAC PROTECTED TYPE CF EQUIPMENT</p>

Distributed By:
Spectranetics Corporation
96 Talamine Court
Colorado Springs, CO 80907 USA
1-800-231-0978
Fax: 719-633-2248
www.spectranetics.com
US Post-Market Support Line:
1-888-341-0035
complaints@spectranetics.com

Manufactured by:
Kensley Nash Corporation
Exton, PA 19341 USA

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