ev3™ TurboHawk™
Peripheral Plaque Excision System

English

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The TurboHawk™ Peripheral Plaque Excision System (TurboHawk Catheter and SilverHawk™ Cutter Driver) is designed for the treatment of de novo and restenotic atherosclerotic calcified and non-calcified lesions located in native peripheral arteries. The TurboHawk Catheter consists of a flexible shaft designed to track over a 0.014" guidewire. At the distal end of the TurboHawk Catheter is a small cutting assembly comprised of a rotating inner cutter contained within a tubular housing. The proximal end of the TurboHawk Catheter contains a connector and cutter positioning lever (thumb switch) designed to fit into the SilverHawk Cutter Driver. The SilverHawk Cutter Driver is a handheld, disposable, battery-driven unit (Catalog No: 025501) which powers the system.

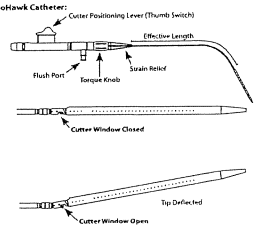
The TurboHawk Peripheral Plaque Excision System has two switches: 1) the SilverHawk Cutter Driver main power switch and 2) the TurboHawk Catheter thumb switch. The SilverHawk Cutter Driver main power switch supplies power to the device when turned ON. The TurboHawk Catheter thumb switch activates the drive shaft and engages the cutter when pulled proximally to the ON position. With the cutter engaged, the TurboHawk Catheter is slowly advanced across the lesion, shaving occlusive material from the artery. The excised tissue is captured and stored in the tip of the device. The cutting process is completed by advancing the TurboHawk Catheter thumb switch distally deactivating the drive shaft and disengaging the cutter. The TurboHawk Catheter thumb switch is fully advanced distally to the OFF position in order to pack the excised plaque into the tip. This cutting sequence is repeated as necessary to achieve the desired degree of plaque excision.

Key TurboHawk Catheter Specifications

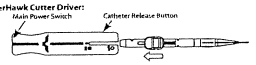
Catalog Number	THS-LS-C	THS-LX-C
Model	LS-C	LX-C
Vessel Diameter Range	3.5 mm - 7.0 mm	3.5 mm - 7.0 mm
Tip Length	6.0 cm	9.0 cm
Recommended Sheath Size	8F	8F
Maximum Profile	0.105" (2.7 mm)	0.105" (2.7 mm)
Effective Length	104 cm	104 cm
Maximum Guidewire Diameter	0.014" (0.36 mm)	0.014" (0.36 mm)

Illustration and Nomenclature

TurboHawk Catheter:



SilverHawk Cutter Driver:



NOTE: The SilverHawk Cutter Driver is protected against electrical shock (defibrillation proof - type CF) and against water (ordinary - type IPX0). Not suitable for use in the presence of a flammable anesthetic mixture. The SilverHawk Cutter Driver operates in a continuous mode and is internally powered by batteries.

INDICATIONS FOR USE

The TurboHawk Peripheral Plaque Excision System is intended for use in atherosclerosis of the peripheral vasculature. The TurboHawk Catheter is NOT intended for use in the coronary, carotid, iliac, or renal vasculature.

CONTRAINDICATIONS

- Do not use in the coronary arteries
- Do not use in the carotid artery
- Do not use in the iliac or renal vasculature
- Do not use for in-stent restenosis in the peripheral vascular site
- Any evidence or history of intracranial bleeding or aneurysm
- Any history of thrombotic or hemorrhagic stroke
- Known hypercoagulable state or coagulopathy or abnormal bleeding tendency
- Evidence of intraocular hemorrhage by opthalmoscopic exam
- History of thrombocytopenia or thrombocytinosis
- Severe trauma, fracture, major surgery or biopsy of a parenchymal organ within the past 3 months
- Prolonged cardiopulmonary resuscitation
- Endoscopic peptic ulcer disease in the past 3 years or gastrointestinal bleeding within the past 3 months
- Genitourinary bleeding within the past 3 months
- Severe persistent hypertension (systolic pressure >180 mmHg)
- Allergy or intolerance to aspirin

WARNINGS

- The TurboHawk Peripheral Plaque Excision System should only be used by physicians trained in percutaneous peripheral interventional procedures.
- Use of this device should be limited to hospitals where surgical support is readily available in the event of a serious complication.
- The TurboHawk Catheter may only be used with the SilverHawk Cutter Driver.
- This device is supplied STERILE for single use only. Do not reprocess or re-sterilize. Reprocessing and re-sterilizing could increase the risk of patient infection and risk of compromised device performance.
- Do not use the device after the labeled "Use By" expiration date.
- This device is not to be used in the presence of combustible or flammable gases, anesthetics, or cleaners/disinfectants.
- Do not use in hard, complex calcified lesions due to the risk of distal embolization that may result from excising this type of lesion.
- Always use direct fluoroscopic observation when manipulating the TurboHawk Catheter in the peripheral vessels. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Never advance the distal tip of the TurboHawk Catheter near the floppy end of the guidewire. A catheter advanced to this position may not follow the guidewire when it is retracted and cause the guidewire to buckle into a loop. If this occurs, the TurboHawk Catheter and guidewire should be removed together to prevent potential damage to vessel walls. If resistance is still felt, the sheath should also be removed as part of the unit.
- Avoid excessive movement of the TurboHawk Catheter within the vessel at all times as doing so could result in embolization or vessel damage.
- The cutter section of the TurboHawk Catheter is a rigid component. Do not use excessive force or torque to advance the TurboHawk Catheter as vessel trauma and/or device failure may result.
- Do not use the TurboHawk Catheter in bends in excess of 90°.
- Operation of the device with the cutter partially opened or closed could result in vessel trauma or possible embolization of previously excised tissue.
- Exceeding the recommended maximum length of cut and/or number of cut passes prior to removing and emptying the device will increase the risk of embolization of excised tissue fragments.
- If the TurboHawk Catheter does not advance easily, close the cutter by advancing the cutter positioning lever (thumb switch). Excessive force should not be used to advance the cutter positioning lever (thumb switch). Device repositioning or predilatation may be required.
- The storage capacity of the TurboHawk Catheter tip must not be exceeded or embolization of excised tissue may result.

PRECAUTIONS

- Federal (U.S.A) Law restricts this device to sale by or on the order of a physician.
- Do not sharply bend or kink the TurboHawk Catheter shaft during handling as this could damage the device and impair its function.
- Refer to the Key TurboHawk Catheter Specifications table for appropriate sheath size requirements. Use of sheaths smaller than those recommended may compromise device performance.
- The Guidewire MUST go through BOTH Lumens; otherwise, the tip may be open. Operation of the device with the tip open could result in embolization of excised tissue.
- Do not over tighten the hemostasis valve as this may inhibit smooth advancement and rotation of the TurboHawk Catheter or possibly damage the shaft.
- If device is not rotating easily, do not torque the TurboHawk Catheter shaft more than 360° in one direction. Doing so could result in device failure such as shaft kinking or tip fracture. Device repositioning or lesion predilatation may be required.

POTENTIAL COMPLICATIONS / ADVERSE EFFECTS

Potential adverse events associated with use of this device and other interventional catheters include, but are not limited to the following:

- Amputation
- Arterial dissection
- Arterial perforation
- Arterial rupture
- Arterial spasm
- Arterio-venous fistula
- Bleeding complications
- Death
- Embolism and/or arterial thrombosis
- Emergency or non-emergency arterial bypass surgery
- Entry site complications
- Hypotension
- Infection
- Ischemia
- Restenosis of the treated segment
- Total occlusion of the peripheral artery
- Vascular complications which may require surgical repair

HOW SUPPLIED

The TurboHawk Catheter and SilverHawk Cutter Driver are packaged and sterilized individually. Both are intended for single patient use only.

STORAGE

Store sterile packaged TurboHawk Catheters and SilverHawk Cutter Drivers in a cool dry place until ready to use. Do not expose to organic solvents, ionizing radiation, ultraviolet light or alcohol-based fluids.

DIRECTIONS FOR USE

INSPECTION

1. Prior to use, carefully inspect the TurboHawk Catheter and SilverHawk Cutter Driver to verify that neither the sterile packaging nor the devices themselves have been damaged.
2. Connect the TurboHawk Catheter and SilverHawk Cutter Driver by inserting the proximal end of the TurboHawk Catheter into the motor. Ensure the cutter positioning lever (thumb switch) aligns with the slot in the SilverHawk Cutter Driver. When fully inserted, the TurboHawk Catheter connector will lock into the SilverHawk Cutter Driver. To remove the TurboHawk Catheter from the SilverHawk Cutter Driver, depress the Catheter Release button and pull the TurboHawk Catheter from the motor.

NOTE: To avoid accidental activation of the SilverHawk Cutter Driver, be sure the cutter positioning lever (thumb switch) is in the fully forward position prior to insertion into the SilverHawk Cutter Driver.

3. To confirm functionality of the TurboHawk Catheter, retract and advance the cutter positioning lever (thumb switch). Ensure that the motor turns on and off automatically and that the inner cutter moves freely. The TurboHawk Catheter tip should deflect and return to its original configuration as the cutter position is cycled. Advance the cutter positioning lever (thumb switch) to close the cutter and turn off the motor.

NOTE: The automatic motor control feature of the SilverHawk Cutter Driver can be disabled by using the main power switch. When the main power switch is ON, the automatic motor control is enabled. When the main power switch is OFF, the cutter positioning lever (thumb switch) can be advanced and retracted without activating the motor.

4. Inspect the shaft, cutter housing and distal tip for smooth transitions. Do not use the TurboHawk Catheter if a sharp edge or protrusion is detected.

CAUTION: Do not sharply bend or kink the TurboHawk Catheter shaft during handling as this could damage the device and impair its function.

5. Check the TurboHawk Catheter shaft for functionality of the hydrophilic coating. When wetted with sterile saline, the TurboHawk Catheter shaft should feel slippery.

NOTE: To facilitate TurboHawk Catheter handling, the proximal most portion of shaft is not coated.

6. Should the TurboHawk Catheter become kinked or damaged during use, replace the damaged TurboHawk Catheter with a new TurboHawk Catheter and return used device to ev3 Inc. for evaluation.

PREPARATION OF DEVICE

1. Purge Air From the TurboHawk Catheter.
   a) Fill a syringe (3 cc or larger) with heparinized saline
   b) Flush the TurboHawk Catheter shaft by attaching the heparinized saline filled syringe to the TurboHawk Catheter flush port. Gently apply pressure to the syringe until all air has been flushed from the TurboHawk Catheter and saline is seen exiting the cutter window.
   c) Submerge the Tissue Flush Tool (TFT) in saline to lubricate the inner diameter.
   d) Submerge the catheter tip in saline to activate the hydrophilic coating.
   e) Fully advance the cutter positioning lever (thumb switch) to the closed and off position. Turn the main power switch on the Cutter Driver to OFF and detach the catheter from the Cutter Driver.
   f) Slide TFT onto the distal end of the catheter tip and position the TFT luer over the cutter window. Tighten the TFT down onto the catheter.
   g) Attach the filled syringe to the luer on the TFT.
   h) Rotate the distal end of the tip to open.
   i) Retract the cutter positioning lever (thumb switch) to expose the cutter within the cutter window.
   j) Flush the tip until fluid exits the distal end of the tip.
   k) Fully advance the cutter positioning lever (thumb switch) to the closed and off position.
   l) Loosen the TFT, slide it distally and remove from the tip of the catheter.
   m) Rotate the distal end of the tip to close.

INSERTION AND USE

Once prepared, the TurboHawk Catheter is ready for insertion into the patient.

1. Insertion
   a) Prepare the patient and administer the appropriate anticoagulant and vasodilator therapy for standard percutaneous intervention.
   b) Insert the appropriate sized sheath and hemostasis valve using standard techniques.

CAUTION: Refer to the Key TurboHawk Catheter Specifications table for appropriate sheath size requirements. Use of sheaths smaller than those recommended may compromise device performance.

   c) Angiographic assessment of the vessel should be performed to locate the target lesion.

WARNING: Do not use in hard, complex calcified lesions due to the risk of distal embolization that may result from excising this type of lesion.

   d) Using standard technique, place a guidewire across the target lesion.
   e) Ensure that the cutter positioning lever (thumb switch) is in its fully advanced, i.e. closed and off, position. Carefully backload the end of the guidewire through the tip of the TurboHawk Catheter.

CAUTION: The Guidewire MUST go through BOTH Lumens; otherwise, the tip may be open. Operation of the device with the tip open could result in embolization of excised tissue.

   f) Loosen the hemostasis valve and carefully insert the TurboHawk Catheter into the sheath. Retighten the hemostasis valve to prevent blood loss.

CAUTION: Do not over tighten the hemostasis valve as this may inhibit smooth advancement and rotation of the TurboHawk Catheter or possibly damage the shaft.

2. Lesion Treatment
   a) Using fluoroscopic guidance, carefully advance the TurboHawk Catheter to the edge of the target lesion.

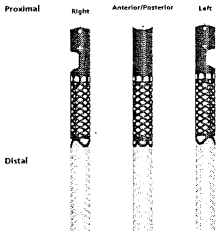
WARNING: The cutter section of the TurboHawk Catheter is a rigid component. Do not use excessive force or torque to advance the TurboHawk Catheter as vessel trauma and/or device failure may result.

WARNING: Do not use the TurboHawk Catheter in bends in excess of 90°.

Note: If the TurboHawk Catheter cannot be advanced across the lesion, it may be necessary to carefully remove the TurboHawk Catheter and pre-dilate the lesion with a small diameter balloon angioplasty catheter.

   b) Carefully rotate the TurboHawk Catheter cutter window toward the treatment site. Additional angiographic assessment should be performed to confirm TurboHawk Catheter position in relation to the lesion.

NOTE: The cutter housing is radiopaque to facilitate angiographic visualization of the device orientation.



In addition, a radiopaque ring is located just proximal to the distal most edge of the tip.

CAUTION: If device is not rotating easily, do not torque the TurboHawk Catheter shaft more than 360° in one direction. Doing so could result in device failure such as shaft kinking or tip fracture. Device repositioning or lesion predilatation may be required.

   c) To begin plaque excision, retract the cutter positioning lever (thumb switch) which will expose the rotating cutter and deflect the TurboHawk Catheter tip.

NOTE: When advancing or retracting the cutter positioning lever (thumb switch), the cutter positioning lever (thumb switch) must be moved until a "click" is felt at the end of the cutter positioning lever (thumb switch) travel. This indicates that the TurboHawk Catheter has achieved its FULLY retracted or FULLY advanced position.

WARNING: Operation of the device with the cutter partially opened or closed could result in vessel trauma or possible embolization of previously excised tissue.

   d) With the motor running, slowly advance the TurboHawk Catheter through the treatment site under fluoroscopic guidance.

Reference the following matrix for the maximum length of cut that may be completed for each Catalog Number:

Catalog #	Maximum Length of Cut	Cutting Passes per Insertion
THS-LS-C	50 mm	1
THS-LX-C	75 mm	1

WARNING: Exceeding the recommended maximum length of cut and/or number of cut passes prior to removing and emptying the device will increase the risk of embolization of excised tissue fragments.

WARNING: If the TurboHawk Catheter does not advance easily, close the cutter by advancing the cutter positioning lever (thumb switch). Excessive force should not be used to advance the cutter positioning lever (thumb switch). Device repositioning or predilatation may be required.

   e) Once the end of the target segment is reached, stop advancing the TurboHawk Catheter. Carefully advance the cutter positioning lever (thumb switch) to close the cutter and turn off the SilverHawk Cutter Driver, this will be indicated by a tactile "click".
   f) At this point, a combination of angiographic and/or intravascular ultrasound imaging should be used to assess the extent of plaque excision.

WARNING: The storage capacity of the TurboHawk Catheter tip must not be exceeded or embolization of excised tissue may result.

3. TurboHawk Catheter Removal
   a) The TurboHawk Catheter should be carefully removed from the patient under fluoroscopic guidance.
   b) If lesion treatment is complete, final angiographic and/or intravascular ultrasound evaluation should be performed. Otherwise, proceed to step 4. Tissue Removal.