CLEANER XT™

Rotational Thrombectomy System

Directions For Use in Peripheral Vasculature

All directions should be read before use

DEVICE DESCRIPTION:

The CLEANER XT™ Rotational Thrombectomy System is a percutaneous catheter based system (single piece construction). A disposable, hand-held battery operated rotator drive unit is attached to a dispersion wire which rotates at approximately 4000 RPM. The distal, sinuous shaped tip of the wire facilitates the delivery of therapeutic agents in the peripheral vasculature. The wire and atruamatic soft tip are radiopaque for fluoroscopic visualization.

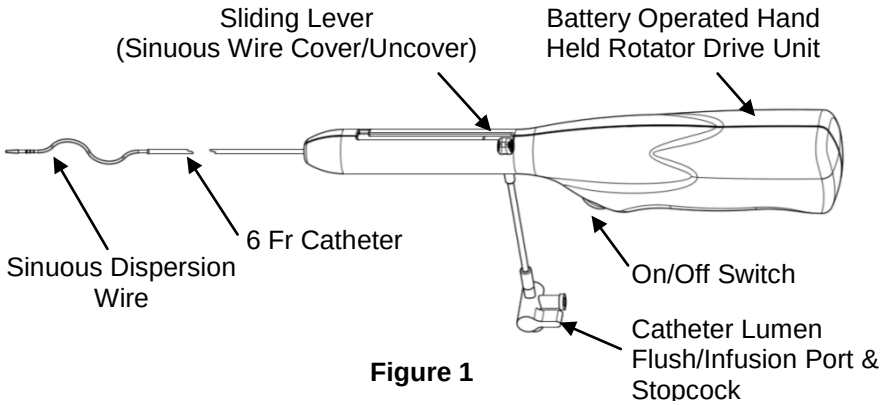

Figure 1

INDICATIONS FOR USE:

The CLEANER XT™ Rotational Thrombectomy System is indicated for mechanical declotting and controlled and selective infusion of physician-specified fluids, including thrombolytics, in the peripheral vasculature.

WARNING:

For single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

CONTRAINDICATIONS:

The CLEANER XT™ Rotational Thrombectomy System is contraindicated in the following:

- This system is contraindicated when, in the medical judgment of the physician, such a procedure may compromise the patient's condition.
- Not designed for peripheral vasculature dilation purposes.
- This system is not intended for the infusion of blood or blood products.
- Refer to the product insert of the therapeutic solution of choice for indications, contraindications, side effects, and precautions.
- In patients without a vascular filter such as an inferior vena cava filter.

WARNINGS AND PRECAUTIONS:

- Prior to use, read all package insert warnings, precautions, and instructions. Failure to do so may result in severe patient injury and death.
- These procedures should only be performed by physicians and staff familiar with the equipment and techniques involved. The device has been sterilized by EtO and is sterile unless the package is opened or damaged. The package should be examined before use; if damaged, DO NOT USE. The device is intended for single patient use only; DO NOT REUSE OR RE-STERILIZE.
- Prior to use, carefully examine the CLEANER XT™ Rotational Thrombectomy System to verify that it has not been damaged during shipment. If the product components show any sign of damage, DO NOT USE.
- Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care workers should routinely use universal blood and body fluid precautions in the care of all patients. Sterile technique must be strictly adhered to during any handling of the device.
- Do not advance if resistance is met without first determining the cause of resistance under fluoroscopy and taking any necessary remedial action. Excessive force against resistance may result in damage to the device or vasculature.
- Prior to introduction, and anytime the CLEANER XT™ is removed from the vascular system, the catheter should be flushed.
- If the catheter or guidewire becomes kinked or otherwise damaged during use, discontinue use and replace.

- Practitioners must be aware of potential complications associated with peripheral vasculature thrombolysis including:

- Vessel perforation or rupture
- Vessel spasm
- Hematoma
- Sepsis/Infection
- Intimal disruption
- Vascular thrombosis
- Allergic reaction to contrast medium
- Thromboembolic episodes
- Distal embolization of blood clots
- Hemorrhage
- Pain and tenderness
- Thrombophlebitis
- Arterial dissection
- Drug reactions
- Arteriovenous fistula
- Amputation

- Potential fatigue failure of the CLEANER XT™ sinuous wire may occur with prolonged activation of the CLEANER XT™ device. A withdrawal rate of 1-2 cm/second is recommended when sharp radii are encountered (i.e. radius of a loop graft or fistula, radii < 3 cm).

A SUGGESTED PROCEDURE:

Use sterile technique.

Patient Preparation:

1. Premedicate with appropriate anxiolytic, analgesic and/or antibiotic per hospital protocol.

Device Performance Testing:

2. Remove the CLEANER XT™ Rotational Thrombectomy System from the package. Depress the ON/OFF switch to ensure that the sinuous wire spins freely (refer to Figure 2). Release the switch to stop the rotator. **Precaution: Do not use the device if the sinus wire does not activate immediately when the switch is depressed, and deactivate immediately when the switch is released.**

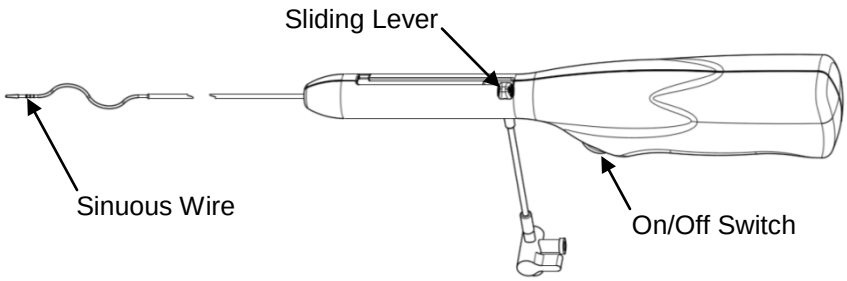

Figure 2

3. Attach a syringe of therapeutic agent or heparinized saline to the catheter flush port and flush the CLEANER XT™ catheter. Be sure that fluid exits from the most distal catheter hole which is located near the end of the catheter. Close the stopcock to "lock" the therapeutic agent or heparin in the catheter and remove the syringe.

Treatment:

The exact treatment procedure is to be determined by the physician. The following option describes how the procedure may be performed.

4. Complete the procedure under continuous fluoroscopy. Do not initiate sinuous wire rotation (device activation) unless proper device positioning is confirmed within the peripheral vasculature.
5. Prepare and drape the puncture site as required.
6. Administer local anesthetic at the puncture site for venous sheath insertion.
7. Select an appropriately sized sheath to accommodate the CLEANER XT™ catheter and other devices/ catheters that may be used during the procedure. Maximum guidewire size will be dependent upon the introducer sheath/dilator assembly chosen. If crossing the iliac bifurcation, a long reinforced sheath should be used.
8. Prepare and place the venous introducer sheath per hospital protocol. The venous sheath should be placed in the venous limb of the peripheral vasculature, and directed toward the treatment site. The venous sheath placement can be optional depending on the clot burden in the vessel.
9. Place the device in the covered position by pushing the sliding lever to the distal position and rotating the sliding lever to lock in the covered position (refer to Figure 3). When in the covered position, only the flexible tip of the sinuous wire should extend from the catheter. **Warning: The device should not be activated in the covered position.**
10. Support the flexible tip between the thumb and index finger during insertion through the sheath valve. Insert the covered device through the venous sheath and into the venous limb of the peripheral vasculature.
11. Attach a 10cc syringe containing the therapeutic agent intended for infusion to the stopcock. Open the stopcock to enable flow. **Warning: Do not draw blood back into the catheter.**

    Note: Follow the manufacturer's instructions regarding reconstitution and dilution of specified fluids.

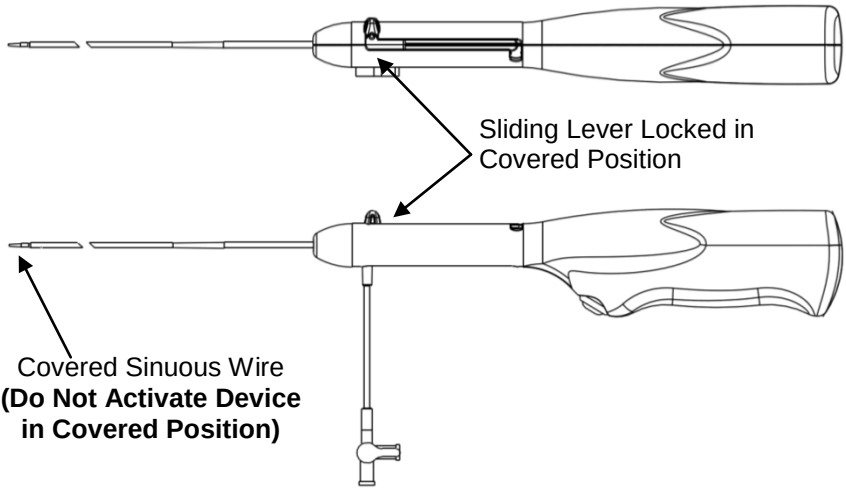

Figure 3

12. Advance the flexible tip up to the distal most extent of the clot. Uncover the sinuous wire by unlocking, fully retracting the sliding lever and rotating the sliding lever until an audible “click” is heard (refer to Figure 4). Confirm device positioning within the treatment site via fluoroscopy. Press the ON/OFF switch to activate rotation.

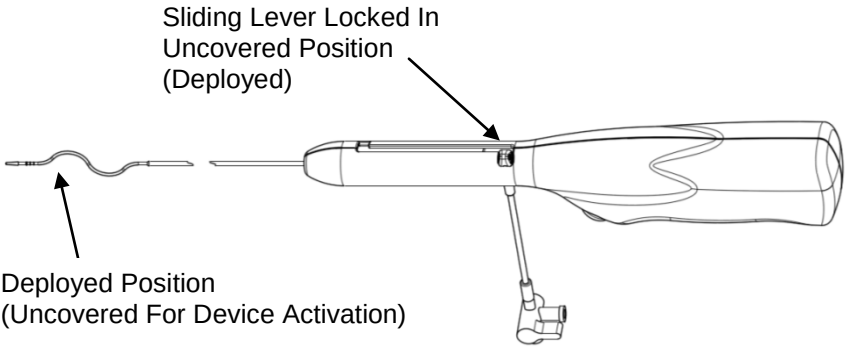

Figure 4

13. With the device activated, slowly withdraw the rotating sinuous wire along the treatment site while infusing therapeutic agent through the infusion port to break up the clot. **Warning: A withdrawal rate of 1-2 cm/second is recommended when sharp radii are encountered.** When the sinuous wire reaches the tip of the venous sheath, release the switch to turn off the rotating dispersion wire.

14. Cover the device and remove it from the peripheral vasculature. Flush the catheter lumen with heparinized saline and manually remove any accumulated fibrin from the sinuous wire.
15. Aspirate the macerated clot via the sheath and discard the aspirate. **Precaution: Continued unsuccessful aspiration may collapse the sheath and vessel.**
16. Inject a small amount of contrast via the venous sheath to assess the degree of thrombus removal accomplished. **Warning: Avoid over-injection of contrast to minimize the risk of embolization.** Treat the residual thrombus by repeating steps 11-15 until acceptable thrombus removal is achieved.
17. When the thrombus removal is complete, treat any underlying disease or stenosis per hospital protocol.
18. Perform the final angiogram.
19. Remove the sheaths from the peripheral vasculature.
20. Achieve hemostasis at the puncture site(s) per hospital protocol.

STORAGE:

Store at controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light.

DISPOSAL:

Dispose of the catheter system in accordance with the Waste Electrical and Electronic Equipment Directive (WEEED) and according to the standard institutional procedures for medical waste including single-use, blood contacting devices.

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Sterile, Unless Package is Damaged or Opened

Do Not Resterilize

STERILE EO

Single Use

Store in a cool, dark, dry place.

Follow Instructions For Use

Attention, See Instructions For Use.

Fluid pathway components are **NON-PYROGENIC**

Warning: After use, the CLEANERXT™ may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.

Type B Applied Part

CLASSIFIED C UL US
E353911

MEDICAL — GENERAL MEDICAL EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH IEC60601-1 3rd Ed. & CAN/CSA-C22.2
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