CLEANER XT™

Rotational Thrombectomy System

Directions For Use

All directions should be read before use

DEVICE DESCRIPTION:

The CLEANER XT™ Rotational Thrombectomy System is a percutaneous, 6Fr catheter based system (single piece construction) that is compatible with a 6Fr introducer sheath. A disposable, hand-held battery operated rotator drive unit is attached to a wire which rotates at approximately 4000 RPM. The distal, sinuous shaped tip of the wire facilitates gentle mechanical declotting of occluded native vessel dialysis fistulae and synthetic dialysis access grafts. The wire is radiopaque for fluoroscopic visualization.

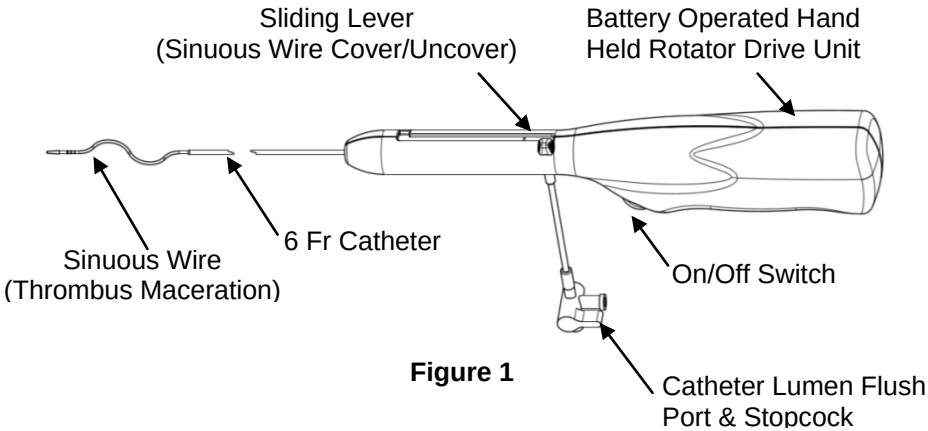

Figure 1

INDICATIONS FOR USE:

The CLEANER XT™ Rotational Thrombectomy System is indicated for mechanical declotting of native vessel dialysis fistulae and synthetic dialysis access grafts.

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:

- When in the medical judgment of the physician, such a procedure may compromise the patient's condition.
- Existing hemodialysis access site infection.
- Immature native vessel dialysis fistulae (fistulae that have not been used for at least one hemodialysis treatment).

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.
- Practitioners must be aware of potential complications associated with dialysis fistula and graft thrombolysis including:
  - Hemorrhage
  - Symptomatic pulmonary embolism
  - Arterial embolization
  - Allergic reaction to contrast media
  - Pseudoaneurysm
  - Pain and/or tenderness
  - Vessel tear or disruption
  - Infection
  - Perforation of the artery or vein
  - Hematoma
  - Death

- Caution should be used when dislodging the plug at the arterial anastomosis to minimize the risk of arterial embolization.
- Due to the lack of excretion associated with hemodialysis patients, use of contrast should be kept to a minimum throughout this procedure.
- 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 rotator does not activate immediately when the switch is depressed, and deactivate immediately when the switch is released.**

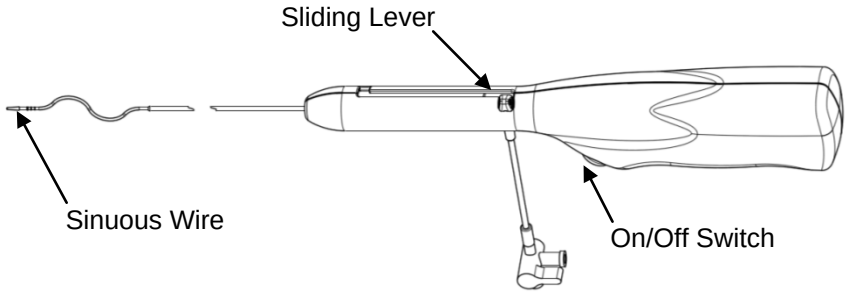

Figure 2

3. Flush the CLEANER XT™ catheter with heparinized saline through the catheter lumen flush port. Return the stopcock to the off position prior to operation.

Thrombolysis Procedure:

4. Complete the CLEANER XT™ thrombolysis procedure under continuous fluoroscopy. Do not initiate sinuous wire rotation (device activation) unless proper device positioning is confirmed within the fistula or graft.
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.
8. Prepare and place the venous introducer sheath per hospital protocol. The venous sheath should be placed in the venous limb of the graft, and directed toward the venous anastomosis. In fistulae, the venous sheath placement can be optional depending on the clot burden in the vessel. If a venous sheath is used, it should be placed in the venous limb of the fistula and directed toward the central venous outflow. Note: If no venous sheath is used in the AV fistula, then go to step 16.
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. 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 fistula or graft.

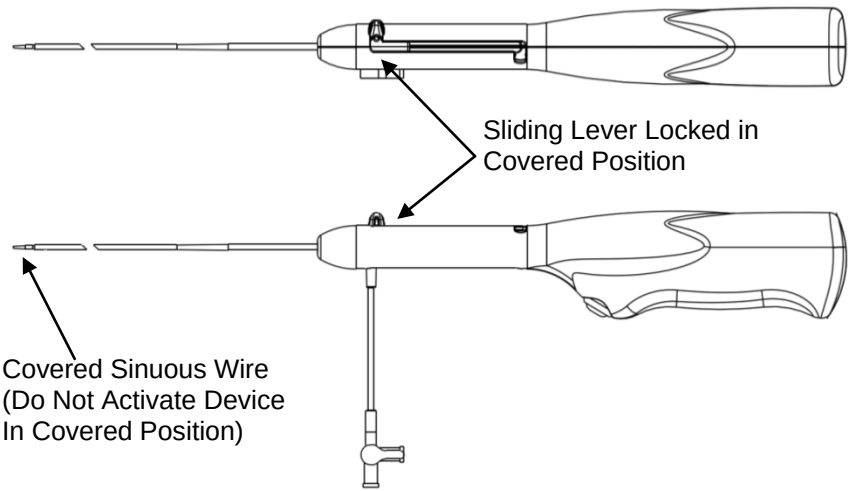

Figure 3

11. In a graft, advance the flexible tip up to the venous anastomosis. **Warning: Do not advance it beyond the anastomosis.** In a fistula, advance the flexible tip up to the central 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 fistula or graft via fluoroscopy. Press the ON/OFF switch to activate rotation.

Note: Caution should be taken while uncovering the wire to avoid advancing the wire into the clot and past the anastomosis.

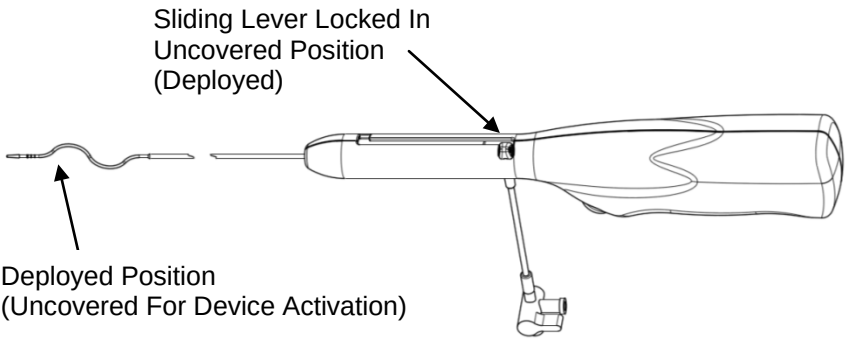

Figure 4

12. With the device activated, slowly withdraw the rotating sinuous wire along the graft or fistula 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 rotator.
13. Cover the device and remove it from the graft or fistula. Flush the catheter lumen with heparinized saline and manually remove any accumulated fibrin from the sinuous wire.
14. Aspirate the macerated clot via the sheath and discard the aspirate. **Precaution: Continued unsuccessful aspiration may collapse the sheath and graft/fistula.**
15. 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 arterial embolization.** Treat the residual thrombus by repeating steps 11-14 until acceptable thrombus removal is achieved.
16. Administer local anesthetic at the puncture site for arterial sheath insertion. Prepare and place the arterial introducer sheath per hospital protocol. The arterial sheath should be directed toward the arterial anastomosis. **Precaution: The arterial and venous sheath tips must not overlap.**
17. Support the flexible tip between the thumb and index finger during insertion through the sheath valve. Insert the covered device through the arterial sheath into the arterial limb of the fistula or graft.
18. In a graft, advance the flexible tip up to the arterial anastomosis. **Warning: Do not advance it beyond the anastomosis.** In a fistula, advance the flexible tip up to the central 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. Confirm device positioning within the fistula or graft via fluoroscopy. Press the ON/OFF switch to activate rotation.

19. With the device activated, slowly withdraw the rotating sinuous wire, in the uncovered position, along the graft or fistula to break up the clot. **Warning: A withdraw rate of 1-2 cm/second is recommended when sharp radii are encountered.** When the sinuous wire reaches the tip of the arterial sheath, release the switch to turn off the rotator.
20. Cover the device and remove it from the graft or fistula. Flush the catheter lumen with heparinized saline and manually remove any accumulated fibrin from the sinuous wire.
21. Aspirate the macerated clot using either sheath and discard the aspirate. **Precaution: Continued unsuccessful aspiration may collapse the sheath and graft/fistula.**
22. Pass an appropriate catheter through the arterial sheath, and carefully feed it past the arterial anastomosis of the graft or fistula. Inflate the balloon, if it is a balloon catheter. Pull the arterial plug into the middle of the arterial limb. Deflate the balloon and remove the balloon catheter.
23. Reinsert the covered CLEANER XT™ device through the arterial sheath into the arterial limb of the graft or fistula.
24. Uncover the sinuous wire and activate the device to break up the arterial plug, using contrast to guide maceration.
25. Cover the device and remove it from the graft or fistula. Flush the catheter lumen with heparinized saline and manually remove any accumulated fibrin from the sinuous wire.
26. Aspirate the macerated clot via the sheath and discard the aspirate.
27. Inject contrast to assess the degree of thrombus removal. Treat any residual thrombus using the CLEANER XT™ via either sheath, as needed.
28. When the thrombus removal is complete, treat any underlying disease or stenosis per hospital protocol.
29. Perform the final fistulogram.
30. Remove the sheaths from the fistula or graft.
31. 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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The device can have no direct cardiac contact with the patient.


Sterile, Unless Package is Damaged or Opened


Do Not Resterilize


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

MEDICAL — GENERAL MEDICAL EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH IEC60601-1 3rd Ed. & CAN/CSA-C22.2
NO. 60601.1 (2008), AAMI ES 60601-1:2008
4CR3

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P/N: X-1009-0204-00 Rev A