CLEANER

Rotational Thrombectomy System

# Directions For Use

All directions should be read before use

**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.

**DEVICE DESCRIPTION:**

The Cleaner 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.

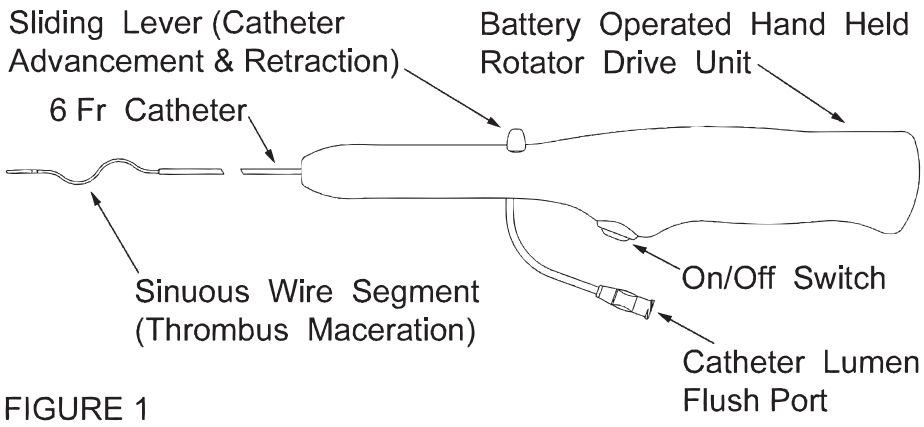


FIGURE 1

**INDICATIONS FOR USE:**

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

**CONTRAINDICATIONS:**

The Cleaner Rotational Thrombectomy System is contraindicated 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 Rotational Thrombectomy System to verify that it has not been damaged during shipment. If 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 sinuous wire may occur with prolonged activation of the Cleaner device. A withdrawal rate of 1-2 cm/second is recommended when sharp radii are encountered (i.e. radius of 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 Cleaner Rotational Thrombectomy System from package. Depress ON/OFF switch to ensure sinuous wire spins freely (refer to Figure 2). Release switch to stop rotator. **Precaution: Do not use device if rotator does not activate immediately when switch is depressed, and deactivate immediately when switch is released.**

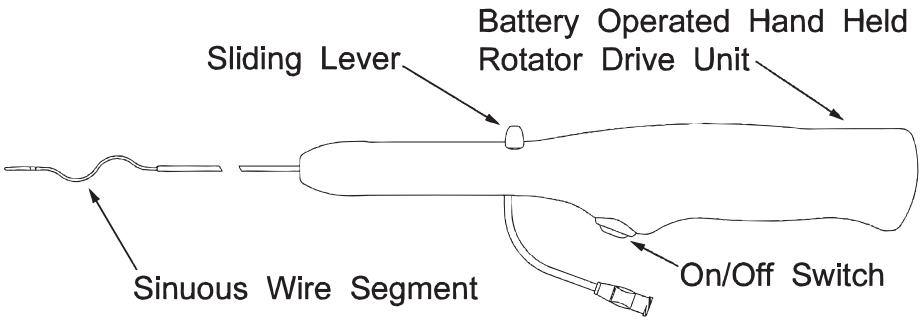


FIGURE 2

3. Flush Cleaner catheter with heparinized saline through the catheter lumen flush port. If stopcock is attached to device, return stopcock to off position prior to operation.

**Thrombolysis Procedure:**

4. Complete the Cleaner Rotational Thrombectomy System 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 puncture site for venous sheath insertion.

7. Select an appropriately sized sheath to accommodate the Cleaner catheter and other devices/catheters that may be used during the procedure. Maximum guidewire size will be dependent upon 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 graft, and directed toward the venous anastomosis. In fistulae, the venous sheath placement can be optional depending on the clot burden in vessel. If a venous sheath is used, it should be placed in the venous limb of fistula and directed toward central venous outflow. Note: If no venous sheath is used in 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 sliding lever to lock in 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 flexible tip between thumb and index finger during insertion through sheath valve. Insert covered device through venous sheath into venous limb of fistula or graft.

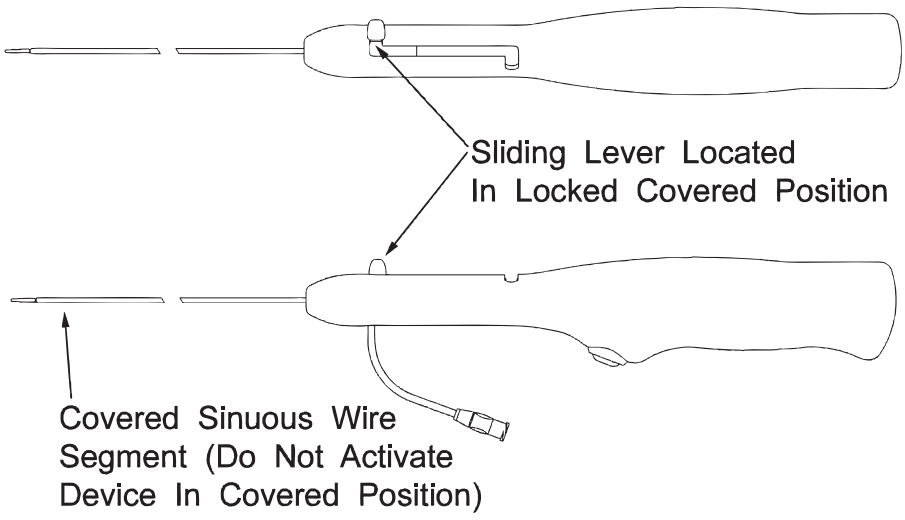


Figure 3

11. In a graft, advance flexible tip up to venous anastomosis. **Warning: Do not advance beyond anastomosis.** In a fistula, advance flexible tip up to the central most extent of the clot. Uncover sinuous wire by unlocking, fully retracting sliding lever and rotating sliding lever until an audible "click" is heard (refer to Figure 4). Confirm device positioning within fistula or graft via fluoroscopy. Press ON/OFF switch to activate rotation.

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

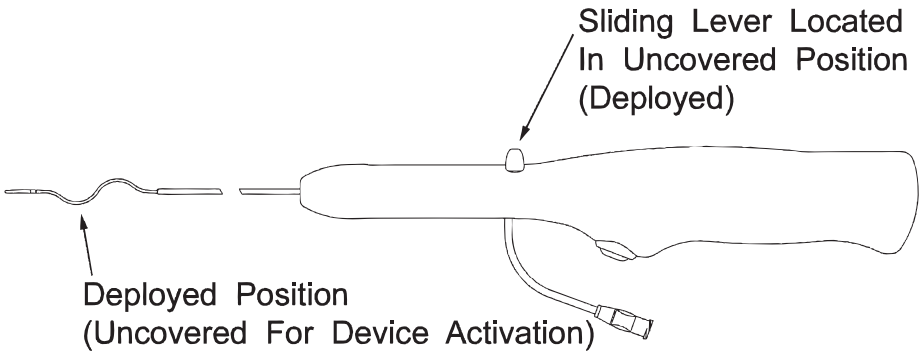


FIGURE 4

12. With device activated, slowly withdraw rotating sinuous wire along graft or fistula to break up clot. Warning: A withdrawal rate of 1-2 cm/second is recommended when sharp radii are encountered. When sinuous wire reaches tip of venous sheath, release switch to turn off rotator.

13. Cover device and remove from graft or fistula. Flush catheter lumen with heparinized saline and manually remove any accumulated fibrin from sinuous wire.

14. Aspirate macerated clot via sheath and discard aspirate. **Precaution: Continued unsuccessful aspiration may collapse sheath and graft/fistula.**

15. Inject small amount of contrast via venous sheath to assess degree of thrombus removal accomplished. **Warning: Avoid over-injection of contrast to minimize risk of arterial embolization.** Treat residual thrombus by repeating steps 11-14 until acceptable thrombus removal is achieved.

16. Administer local anesthetic at 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: Arterial and venous sheath tips must not overlap.**

17. Support flexible tip between thumb and index finger during insertion through sheath valve. Insert covered device through arterial sheath into arterial limb of fistula or graft.

18. In a graft, advance flexible tip up to arterial anastomosis. **Warning: Do not advance beyond anastomosis.** In a fistula, advance flexible tip up to the central most extent of the clot. Uncover sinuous wire by unlocking, fully retracting sliding lever and rotating sliding lever until an audible "click" is heard. Confirm device positioning within fistula or graft via fluoroscopy. Press ON/OFF switch to activate rotation.

19. With device activated, slowly withdraw rotating sinuous wire, in uncovered position, along graft or fistula to break up clot. **Warning: A withdrawal rate of 1-2 cm/second is recommended when sharp radii are encountered.** When sinuous wire reaches tip of arterial sheath, release switch to turn off rotator.

20. Cover device and remove from graft or fistula. Flush catheter lumen with heparinized saline and manually remove any accumulated fibrin from sinuous wire.

21. Aspirate macerated clot using either sheath and discard aspirate. **Precaution: Continued unsuccessful aspiration may collapse sheath and graft/fistula.**

22. Pass an appropriate catheter through arterial sheath, and carefully feed past arterial anastomosis of graft or fistula. Inflate balloon, if balloon catheter. Pull arterial plug into middle of arterial limb . Deflate balloon and remove balloon catheter.

23. Reinsert covered Cleaner device through arterial sheath into arterial limb of graft or fistula.

24. Uncover sinuous wire and active device to break up arterial plug, using contrast to guide maceration.

25. Cover device and remove from graft or fistula. Flush catheter lumen with heparinized saline and manually remove any accumulated fibrin from sinuous wire.

26. Aspirate macerated clot via sheath and discard aspirate.

27. Inject contrast to assess degree of thrombus removal. Treat any residual thrombus using Cleaner via either sheath, as needed.

28. When thrombus removal is complete, treat any underlying disease or stenosis per hospital protocol.

29. Perform the final fistulogram.

30. Remove sheaths from the fistula or graft.

31. Achieve hemostasis at 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 standard institutional procedures for medical waste including single-use, blood contacting devices.

## DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY:

There is no express or implied warranty, including without limitation and implied warranty of merchantability or fitness for a particular purpose, on the Rex Medical product(s) decribed in this publication. Under no circumstances shall Rex Medical be liable for any direct, incidental or consequential damages other than as expressly provided by specific law. No person has the authority to bind Rex Medical to any representation or warranty except as specifically set forth herein.

Descriptions or specifications in Rex Medical printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties.

Rex Medical will not be responsible for any direct, incidental or consequential damages from reuse of the product.

Distributed by: Argon Medical Devices

Argon Medical Devices, Inc.
1445 Flat Creek Rd.
Athens, TX 75751
Tel (800) 927-4669
www.argonmedical.com

Manufactured by: REX MEDICAL

1100 East Hector St., Suite 245
Conshohocken, PA 19428
Tel (610) 940-0665
Fax (610) 940-1590
www.rexmedical.com

P/N: P-1009-0136-00 Rev C

EC REP
mdi Europa GmbH
Langenhagener Str. 71
30855 Hannover-Langenhagen
Germany
+49-511-39 08 95 30

CE 0482

CLASSIFIED C UL US

MEDICAL EQUIPMENT
WITH RESPECT TO ELECTRICAL SHOCK, FIRE, AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1 AND CAN/CSA-C22.2 No. 601.1-M90
4CR3