PHILIPS

Attention - Before using this device, Consult Instructions for Use

QuickClear™ Mechanical Thrombectomy System

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

QuickClear Mechanical Thrombectomy System comprising of:

- QuickClear Aspiration Pump
- QuickClear Aspiration Catheter

CAUTION: FEDERAL (US) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON ORDER OF A PHYSICIAN.

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE, NOTING ALL WARNINGS AND PRECAUTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

INDICATIONS

The QuickClear Mechanical Thrombectomy System is intended for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems.

CONTRAINDICATIONS

The use of the QuickClear Mechanical Thrombectomy System is contraindicated where introduction of any catheter would constitute an unacceptable risk to the patient. Contraindications include:

- Not for use in the coronary or neuro vasculature.

SYSTEM DESCRIPTION

The QuickClear Mechanical Thrombectomy System has two main components: the QuickClear Aspiration Catheter and the QuickClear Aspiration Pump. All system components are sterile, single-use devices designed for aspiration in the peripheral arterial and/or venous vasculature.

The aspiration catheter is a sterile, single use, single lumen sheath that is 0.035” guidewire (GW) compatible. The aspiration catheter is available in 6F, 8F and 10F sizes with various tip configurations (See Table 1). The aspiration catheters are used for direct aspiration of thrombus when connected to the aspiration pump.

The distal 30 cm of the aspiration catheter has a lubricious hydrophilic-coating to allow ease of delivery to the target site. A radiopaque (RO) distal marker band is located at the distal tip to allow for visibility under fluoroscopic guidance.

An obturator is provided with the 8F and 10F aspiration catheter sizes to provide support for insertion into the introducer sheath and aid the catheter to track over a 0.035” guidewire while accessing the target peripheral vessel(s). Additionally, the 8F and 10F are provided with a shaped tip configuration to enable thrombus removal within larger vessels.

A rotating Hemostasis Valve Y-connector is attached to the proximal catheter luer lock hub facilitating connection to the aspiration pump tubing. An inline flow control switch connects the pump tubing to the Y-connector and can be used to start/stop the removal of thrombus.

A Waste Collection Bag is provided with system and connects to the proximal pump tubing. The bag collects the thrombus, emboli, fluids, and blood that are aspirated from the vasculature.

The aspiration pump is a sterile, single-use, battery-operated vacuum aspiration pump device that connects to the Aspiration Catheter via the pump’s aspiration tubing. The exit end of the aspiration pump is connected to a Waste Collection Bag to collect aspirated material. A 60cc syringe is provided with the pump to assist in priming the pump

tubing and purging the aspiration system of air. The syringe can also be used to provide additional vacuum boost by pulling the plunger during active aspiration.

See Figure 1 for the assembled QuickClear Mechanical Thrombectomy System with the Aspiration Catheter and Aspiration Pump.

Table 1. QuickClear Aspiration Catheter Key Specifications

Catheter Tip Diameter & Shape	Minimum Introducer Size	Maximum Guidewire Diameter (inch)	Maximum Outer Diameter	Lumen Inner Diameter	Working Length (cm)	Minimum Vessel Diameter[1] (mm)
6F Straight	6F	0.035	2.06 mm 0.081 inch	1.80 mm 0.071 inch	130	>3.0
8F Straight	8F	0.035 (with Obturator)	2.72 mm 0.107 inch	2.31 mm 0.091 inch	85	>4.0
8F Shaped	8F	0.035 (with Obturator)	2.72 mm 0.107 inch	2.31 mm 0.091 inch	85	>4.0
10F Shaped	10F	0.035 (with Obturator)	3.30 mm 0.130 inch	2.82 mm 0.111 inch	85	>5.0

[1]**Warning**: Do not use the QuickClear Aspiration Catheter in vessels smaller than the indicated size or harm to patient (vessel perforation, dissection or injury) could occur.

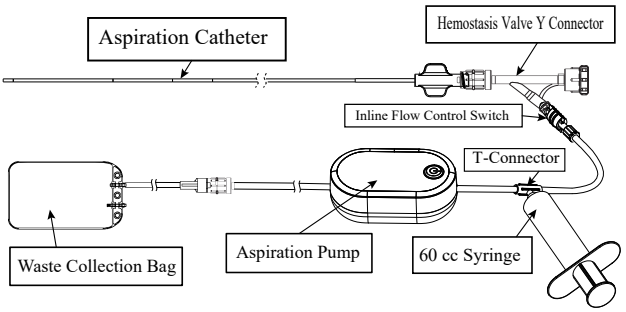

Figure 1: QuickClear Mechanical Thrombectomy System

ACCESSORIES / REMOVEABLE PARTS

Table 2. QuickClear Mechanical Thrombectomy System Accessories

Device	Accessory
Aspiration Catheter	1. Hemostatis Valve 2. Obturator (8F & 10F Catheter)
Aspiration Pump	1. 60cc Syringe 2. Waste Collection Bag 3. Inline Flow Control Switch

WARNINGS

- Failure to abide by the warnings listed in this Instructions for Use could result in damage to the device, which may necessitate intervention or result in serious adverse events.
- For use only by physicians trained in the use of the QuickClear Mechanical Thrombectomy System and percutaneous peripheral interventional procedures.
- The QuickClear Mechanical Thrombectomy System is intended for one-time use only. Do NOT resterilize and/or reuse. Resterilization or reuse may potentially compromise device performance and safety and may increase the risk of infection.
- Do not operate the QuickClear Mechanical Thrombectomy System in vessels smaller than the indicated size as perforation, dissection or injury may occur.
- Do not advance or retract any components against resistance without careful assessment of the cause of resistance by using fluoroscopy; determine the cause of the resistance before continuing.
- All air must be removed from all catheter lumens by priming the Aspiration Catheter as described in the Instructions for Procedure section prior to inserting the catheter into the patient.
- Do not activate aspiration across venous valves if known. Turn the Pump OFF before crossing a valve with the Aspiration Catheter.
- The operator shall observe care when using the Aspiration Pump in areas in which flammable anesthetics or flammable agents for disinfection or cleaning are applied.

- Do not use the Aspiration Catheters with a pump other than the QuickClear Aspiration Pump.
- Do not use the Aspiration Pump with catheters other than the QuickClear Aspiration Catheters.
- Do not place objects on the Aspiration Pump.

PRECAUTIONS

- Prior to use, all QuickClear Mechanical Thrombectomy System components should be examined to verify functionality. Do not use any component found to be damaged or non-functional
- Do NOT use, or attempt to correct, the Aspiration Catheter if it is bent or kinked or has any evidence of damage as this may result in breakage or compromised performance.
- Use the QuickClear Mechanical Thrombectomy System products prior to the “Use Before Date” specified on each individual package label.
- Prime and flush the catheter prior to insertion into the patient as described in the “Instructions for Procedure” section below.
- Take care not to immerse the QuickClear Aspiration Pump in fluids because damage to the electrical components of the Pump could occur.
- As in all thrombectomy procedures, the duration of the procedure should be determined by the physician based on patient condition.
- The maximum recommended length of run time for the QuickClear Mechanical Thrombectomy System during a procedure is 20 minutes.
- Ensure the aspiration catheter tracks smoothly and easily over guidewire prior to aspiration pump operation. If the catheter does not track easily over the guidewire, replace the catheter.
- Carefully monitor the Aspiration Catheter tip under fluoroscopy during Aspiration Pump operation.
- Monitor flow of aspirated material into the Waste Collection Bag during operation of the Aspiration Catheter. Excessive aspiration or failure to close the inline flow control switch when aspiration is complete is not recommended.
- When performing aspiration, ensure the inline flow control switch is open for only the minimum time needed to remove thrombus.

ADVERSE EVENTS

- Potential adverse events associated with the use of this device and other interventional catheters include but are not limited to the following:
- Access site injury, including pain
- Vessel dissection
- Vessel occlusion
- Vessel perforation or pseudoaneurysm
- Vessel restenosis
- Vessel rupture
- Vasospasm, pseudo aneurysm, or abrupt or sub-acute closure
- Venous valve or vessel damage
- Vascular injury which may require surgical repair
- Bleeding complications which may require transfusion
- Death
- Embolism, including thrombus, plaque, air, device, etc.
- Emergency or non-emergency arterial bypass surgery
- Fracture malfunction of any component of the device that may or may not lead to serious injury or surgical intervention
- Hematoma and/or bleeding hemorrhage at access site
- Hemorrhage
- Hypotension
- Infection or fever
- Ischemia
- Myocardial infarction
- Emergent surgery
- Fibrillation
- Respiratory failure
- Inability to completely remove thrombus
- Kidney damage from contrast media
- Neurological deficits including stroke
- Reaction to contrast media, procedure medications or catheter materials, including allergic reaction.
- Intimal damage/disruption

The occurrence of these adverse events may lead to the need for repeat catheterization/angioplasty, emergency bypass surgery, or death.

HOW SUPPLIED, STERILIZATION, AND EXPIRATION

The QuickClear Mechanical Thrombectomy System is supplied with the Aspiration Catheter and QuickClear Aspiration Pump, which are packaged and sterilized individually. Both packages are sterilized using ethylene oxide gas. Each device is sterile if the sealed pouch is unopened and undamaged. All are intended for single use only and should not be reused or re-sterilized. Use products prior to the "Use Before Date" dated printed on the package labels. Store products indoors at room temperature in their original packaging away from sunlight and keep dry.

All system components are intended to be used in typical operating room/catheterization laboratory environments.

SUPPLIES REQUIRED FOR THE QUICKCLEAR MECHANICAL THROMBECTOMY SYSTEM PROCEDURE:

NOTE: The QuickClear Mechanical Thrombectomy System is protected against electrical shock (Type CF applied part)

Item description (Single use items only - Do not re-sterilize or reuse):

1. The appropriately sized QuickClear Aspiration Catheter; Obturator with 8F and 10F Catheters (Optional)
2. QuickClear Aspiration Pump
3. Appropriately sized introducer sheath with cross-cut valve
4. Sterile heparinized (10,000 IU/L) 0.9% normal saline for priming the Aspiration Catheter and Aspiration Pump prior to use
5. 10cc or larger slip-tip syringe for priming the catheter prior to use
6. Compatible 0.035" sized, exchange length guidewire (260 cm length minimum for 6F; 180 cm length for 8F & 10F)

INSTRUCTIONS FOR PROCEDURE:

INSPECTION OF QUICKCLEAR MECHANICAL THROMBECTOMY SYSTEM COMPONENTS

Prior to use, all equipment to be used for the procedure should be examined carefully for defects. Examine the packaging for cuts, tears, or other breach of the sterile barrier. Do not use open or damaged package. Examine the QuickClear Aspiration Catheter, in particular the catheter tip for bends, kinks or other damage. Turn ON the Aspiration Pump and ensure that it can be activated. Do not use any defective equipment. Return all damaged devices with packaging to the manufacturer/distributor.

PREPARATION OF THE QUICKCLEAR ASPIRATION SYTEM

Use aseptic technique to prepare the aspiration system for use.

PREPARATION OF THE ASPIRATION CATHETER

1. Withdraw the Aspiration Catheter from the sterile protective packaging by carefully removing the tip and any tip holder from the backing card, and set the Catheter on the sterile table. Ensure not to damage the catheter tip.
2. Priming the Aspiration Catheter: Attach the supplied Hemostatis Valve Y Connector to the hub of the catheter. Attach a 10cc syringe filled with sterile heparinized normal saline onto the side port of the Hemostasis Valve Y Connector and flush slowly with gentle pressure until saline drips out of the hemostasis valve.
3. Close the hemostasis valve and continue to flush until saline drips out of the catheter tip.
4. For the 8F and 10F aspiration catheter
    a. Flush the obturator with sterile saline.
    b. Open the hemostasis valve. Insert the obturator through the hemostasis valve until the hub of the obturator engages with the valve. The obturator should extend out of the aspiration catheter tip.
    c. Close the hemostasis valve around the obturator to minimize blood loss.
5. Prior to insertion, immerse the distal 30 cm of the catheter in sterile heparinized normal saline container. Alternatively, use gauze dampened with sterile heparinized normal saline to wet the lubricious coating.

PRIMING THE ASPIRATION PUMP

1. Remove the pump, waste collection bag, and syringe from the sterile packaging, and set on the sterile table.
2. Ensure that the inline flow control switch is in the open position.
3. Attach the waste collection bag to the proximal end of the pump tubing.
4. Attach the 60cc syringe partially filled (approximately 20-30cc) with sterile heparinized normal saline into the t-connector on the aspiration pump tubing, and flush slowly with gentle pressure until saline drips out of the valve at the end of the tubing. Close the flow control switch and flush slowly with gentle pressure until the syringe is fully depressed. Some fluid will enter the waste collection bag. Keep the 60cc syringe attached to the aspiration tubing set after priming.

THERAPEUTIC PROCEDURE

A. Insertion

1. Insert an appropriately sized introducer sheath (see Table 1) with a hemostasis valve using standard techniques.
2. Advance the catheter and obturator, if used, into the target vessel over a guidewire taking care not to damage the catheter tip during insertion into the introducer sheath. Close the hemostasis valve over the guidewire and obturator (if used).
3. If applicable, close the introducer hemostasis valve tight enough to prevent blood leakage around the catheter shaft, but still allow axial movement of the catheter through the valve.
4. Connect the Aspiration Pump to the Aspiration Catheter via the aspiration tubing to the side port of the hemostasis valve.
5. Close the inline flow control switch prior to intervention.

B. Aspirating/removing clot

1. Verify the position of the aspiration catheter relative to the lesion site through fluoroscopic visualization of the radiopaque tip.
2. Remove the guidewire and obturator from the catheter once catheter is placed in the target area and adjacent to the blockage intended for removal. Close the hemostasis valve.
3. Under fluoroscopic guidance, turn ON the Aspiration Pump and open the inline flow control switch connected to the Y-connector to initiate removal of thrombus.
    a. Verify that thrombus is being removed by monitoring blood being collected in the Waste Collection Bag.

    WARNING: Do not operate the Aspiration System across venous valves; CLOSE the Inline Flow Control Switch before crossing the valve.
4. Advance the catheter carefully through the occluded region. In highly thrombotic regions of vessels > 10 cm in length, periodically pause and withdraw the catheter slightly to allow improved blood flow and clot removal during aspiration. Additionally, cycle the inline flow control switch (open/close) to enhance thrombus removal and/or assess clot aspiration. Continue to advance until the distal tip of catheter has crossed occluded region.
    a. Additional vacuum may be generated by pulling the plunger on the 60cc syringe connected to the tubing.
5. The 8F and 10F shaped tip catheters may be rotated and advanced to aspirate thrombus from a larger diameter. Advance the catheter slowly and carefully while aspirating. Always monitor the catheter tip position during aspiration as material is removed. Reposition the catheter tip as desired during or between aspiration passes. If there is resistance to rotating the tip, stop rotating the tip.

    PRECAUTION: Periodically monitor the Waste Collection Bag for air and vent bag as required.
6. The QuickClear Aspiration Pump must remain ON in order to effectively remove clot/thrombus.

7. If flow of aspirated material ceases during the procedure, this is a sign that the catheter may be clogged either within the shaft or at the tip.
    a. Turn OFF the aspiration pump. Pull the aspiration catheter back gently under fluoroscopy to verify the tip is not caught in the vessel wall.
    b. If the tip appears to be caught, disconnect the aspiration line/ aspiration pump from the catheter to allow catheter pressure to open and gently retract the catheter proximal to the lesion to re-establish blood flow. Reconnect aspiration pump and turn Pump ON to aspirate/clear blood through the catheter and resume aspiration.
    c. If the source of the ceased flow is due to a clogged shaft or if flow of aspirated material is not re-established, disconnect the aspiration pump from the catheter. Remove the catheter from the patient. Flush the catheter into a sterile bowl to clear blood and/or aspirated material within the catheter lumen.
    d. Once catheter is clear, reconnect pump tubing to the catheter. Resume procedure per Step A-2.
8. To stop aspiration, close the flow control switch on the aspiration tubing and/or turn OFF the Aspiration Pump with the power switch on the pump when aspiration is completed.
9. Obtain a post procedure angiogram/venogram by injecting contrast media through the guide catheter or introducer.
10. Continue aspiration if desired and reassess the lumen with an angiogram/venogram.

C. Aspiration Catheter Removal

1. To remove the Aspiration Catheter, carefully pull the aspiration catheter out of the sheath under fluoroscopic guidance. Ensure the flow control switch is closed and that the Aspiration pump is OFF.

Note: If the QuickClear Aspiration Catheter is used to treat multiple thrombotic occlusions where the catheter is removed and re-inserted through the introducer sheath, the catheter must be flushed between re-insertions.

D. Removing the Sheath

1. Leave the sheath in situ until the hemodynamic profile becomes normal. Close the puncture site per routine practice.

DEVICE DISPOSAL:

1. The Aspiration Catheter is disposable per hospital biohazard procedures.
2. The Aspiration Pump contains Lithium batteries and is NOT disposable per standard biohazard procedures but should be disposed per standard hospital hazardous waste procedures.

CAUTION: Do not incinerate the Aspiration Pump. The pump contains Lithium batteries and should be disposed per standard hospital hazardous waste procedures.

The **QuickClear Aspiration Pump** has been tested and found to comply with the EMC limits for the (IEC/EN 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses and can radiate radiofrequency energy and, if not used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular setting. Compliance with electrical standards is provided in Table 3.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Portable RF communications and electrical equipment, such as those for diathermy, lithotripsy, electrocautery, RFID, and electromagnetic anti-theft systems, can affect any medical electrical equipment including the Aspiration Pump. Care should be taken to

Keep dry	Keep away from sunlight	Not made with natural rubber latex
STERILE EO Sterilized using Ethylene Oxide		Rx ONLY Prescription Only
Do not use if package is damaged		"ON"/"OFF" (push-push)
Contents: One (1)	Nonpyrogenic	Do not re-sterilize
Type CF Applied Part	For Single Use Only	Date of Manufacture
REF Catalogue Number	LOT Batch Code	Use Before Date
SYSTEM Mechanical Thrombectomy System Catalogue Number		

ensure that such devices are not adjacent and/or powered off when the Aspiration Pump are in use.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A) and not intended for residential use.

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The QUICKCLEAR MECHANICAL THROMBECTOMY SYSTEM (including components and/or methods thereof) may be protected under one or more pending United States Patent Applications, as well as corresponding international patent applications.

REPORTING OF A SERIOUS INCIDENT

If a serious incident has occurred in relation to the device, it should be reported to the manufacturer and the regulatory/competent authority of the country in which the user and/or patient is established. A serious incident means any incident that directly or indirectly led, might have led or, in case of recurrence, could lead to any of the following: the death of a patient, user or other person, the temporary or permanent serious deterioration of a patient's, user's, fetus or other person's state of health, or a serious public health threat.

REACH DECLARATION:

REACH requires Philips Healthcare (PH) to provide chemical content information for "Substances of Very High Concern (SVHC) if they are present above 0.1% of the product weight. The SVHC list is updated on a regular basis. Therefore, refer to the following Philips REACH website for the most up-to-date list of products containing SVHC above the threshold: www.philips.com/REACH.

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Table 3: Guidance and manfuacturers's declaration of compliance with electrical safety standards.

Electromagnetic Emissions Test Summary

Test Type	IEC Test Level	Compliance Level	Guidance and Manufacturer's Declaration- Electromagnetic Emmisions
Radiated Emissions EN 55011:2009+A1:2010, CISPR 11:2009+A1:2010	Class A Group 1 30 MHz to 1 GHz	Class A Group 1 30 MHz to 1 GHz	

Electrogmagnetic Immunity Test Summary

Test Type	IEC Test Level	Compliance Level	Guidance and Manufacturer's Declaration- Electromagnetic Emmisions
Electrostatic Discharge IEC/EN 61000-4-2	±8 kV contact discharge ± 2, 4, 8 &15kV air discharge	±8 kV contact discharge ± 2, 4, 8 &15kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Radiated Immunity IEC/EN 61000-4-3 .	80 MHz - 2.7 GHz 3 V/m 80% @ 1 kHz Spot frequencies 385MHz – 5.750 GHz Pulse Modulation	80 MHz - 2.7 GHz 3 V/m 80% @ 1 kHz Spot frequencies 385MHz – 5.750 GHz Pulse Modulation	Portable and mobile RF communications equipment should be used no closer to any part of the Electrical Stimulator including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. Recommend separation distance d = 1.2 √P d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to he transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range. (b) Interference may occur in the vicinity of equipment marked with the following symbol: 
Proximity field from RF wireless communications equipment IEC 61000-4-3	See Section 6.17.3.1 Or Table 9 of standard	See Section 6.17.3.1 Or Table 9 of standard	
Magnetic Immunity IEC/EN-61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

ENVIRONMENTAL SPECIFICATIONS:

	Temperature	Humidity	Altitude
Transport & Storage	0-60˚C	15-90% RH non-condensing	<3000 Meters
Operation	15-29˚C	<50% RH	<3000 Meters