# QuickClear Certification Guide for Reps

The trainee should be able to verbalize the following:

Indications and contraindications for using QuickClear.

* **Indication:** Removal of fresh, soft emboli and thrombi from vessels of the arterial and venous systems
* **Contraindication:** Use in the coronary or neuro vasculature

Which sizes are indicated for both arterial and venous vasculature?

* Both 6fr and 8fr indicated for arterial and venous vasculature
* Only 10fr indicated for venous vasculature.

Provie a quick overview of the QuickClear Mechanical Thrombectomy System.

* Two main components:
	1. QuickClear Aspiration Catheter Kit
	2. QuickClear Aspiration Pump Kit
* **Aspiration catheter:**
	+ Sterile, single use, single lumen sheath that is 0.035” guidewire (GW) compatible with various tip configurations including straight tip for 6F & shaped tip for 8F&10F catheters
	+ 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
* **Obturator:** Provided with the 8F and 10F aspiration catheter sizes to provide support for insertion into the introducer sheath and aide the catheter to track over a 0.035” guidewire while accessing the target peripheral vessel(s)

What do you need to validate when opening the QuickClear Mechanical Thrombectomy System?

* Packaged and **sterilized** individually—each device/kit is sterile if the sealed pouch is unopened and undamaged
* 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**
* Intended for single use only and should not be reused or re-sterilized
* Verify the “Use Before Date” dated printed on the package labels

List the equipment required per the IFU.

* The appropriately sized QuickClear Aspiration Catheter Kit
* QuickClear Aspiration Pump Kit
* Appropriately Sized introducer sheath with cross-cut valve
* Sterile heparinized (10,000 IU/L) 0.9% normal saline and 10cc or larger slip-tip syringe for priming device
* Compatible 0.035” sized, exchange length guidewire (260 cm length minimum for 6F; 180 cm length for 8F & 10F)

List the steps to prepare the catheter for insertion.

* 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.
* Prime the Aspiration Catheter
* For the 8F and 10F aspiration catheter, flush the obturator with sterile saline and insert the obturator through the Hemostasis Valve Y Connector through to the tip of the aspiration catheter.

Describe the pump priming process.

* 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. Ensure that the inline flow control switch is in the open position.
* Attach the 60cc syringe partially filled (approximately 20-30cc) with sterile heparinized normal saline into the t-connector on the aspiration pump tubing.
* 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 fluid exits out the proximal end of the pump tubing.
* Keep the 60cc syringe attached to the aspiration tubing set after priming.
* Attach the waste collection bag to the proximal end of the pump tubing.

Describe the steps for insertion.

* Insert an appropriately sized introducer sheath with a cross-cut hemostasis valve using standard techniques.
* 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 introducer hemostasis valve tight enough to prevent blood leakage around the catheter shaft, but still allow axial movement of the catheter through the valve.
* Connect the Aspiration Pump to the Aspiration Catheter via the aspiration tubing to the side port of the hemostasis valve.
* Close the inline flow control switch prior to intervention

List the steps for aspirating/removing a thrombus.

* Verify the position of the aspiration catheter relative to the lesion site through fluoroscopic visualization of the radiopaque tip.
* Remove the guidewire from the catheter once catheter is placed in the target area and adjacent to the blockage intended for removal.
* 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.
	+ 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.

* 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.
	+ Additional vacuum may be generated by pulling the plunger on the 60cc syringe connected to the
	T-connector.
* The 8F and 10F shaped tip catheters may be rotated and advanced slowly to aspirate thrombus from a larger diameter vessel. Reposition the catheter tip as desired during or between aspiration passes. If there is resistance to rotating the tip, stop rotating the tip.

List the steps you should perform if the flow of aspirated material ceases during the procedure.

* Turn OFF the aspiration pump.
* Pull the aspiration catheter back gently under fluoroscopy to verify the catheter tip is not caught in the vessel wall.
* **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. Turn Pump ON to aspirate/clear blood through the catheter and resume aspiration.
* **If 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 within a sterile heparinized normal saline bowl with the catheter tip completely submerged in the saline to actively clear blood and/or aspirated material that may be within the catheter lumen.
* Obtain a post procedure angiogram/venogram by injecting contrast media through the guide catheter or introducer.
* Periodically monitor the Waste Collection Bag for air and vent bag as required.

List the steps you should take 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 by flushing the catheter within a sterile heparinized normal saline bowl with the catheter tip completely submerged in the saline to actively clear blood and/or aspirated material that may be within the catheter lumen.

Describe how to dispose of the used device.

* **Aspiration Catheter:** Disposable per hospital biohazard procedures
* Aspiration Pump:
	+ Contains Lithium batteries
	+ Is NOT disposable per standard biohazard procedures
	+ Should be disposed per standard hospital hazardous waste procedures

**Caution:** Do not incinerate the Aspiration Pump.

**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.

Practice Grade: \_\_\_\_ Pass: \_\_\_\_\_\_ Fail: \_\_\_\_\_\_