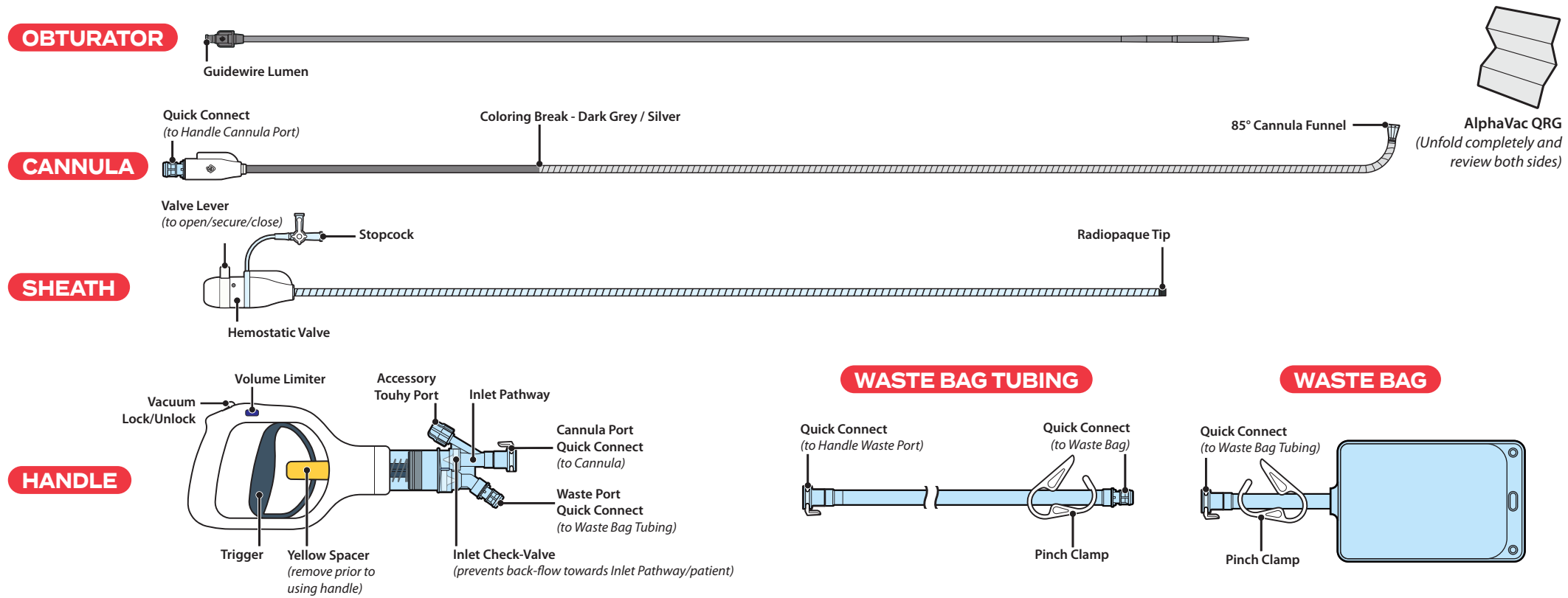


DESCRIPTION OF PARTS



PREPARING OBTURATOR & SHEATH ASSEMBLY

Setup / Preparer

Insert Obturator into Sheath

- Fully insert the obturator into the sheath.

Secure Valve Lever

- Rotate the valve lever to the Secure position to secure the obturator.

Flush Guidewire Lumen and Stopcock

- Flush guidewire lumen.
- Flush and close the stopcock on the sheath.

Check before hand off →

Sheath and obturator assembly is ready to place in patient when:

CHECK & ENSURE

- Obturator is inserted into the sheath.
- Valve lever is secured.
- Both the guidewire lumen and stopcock are flushed.
- The stopcock is closed.

Ready for physician to place in patient



PREPARING PLACING SHEATH IN PATIENT

Physician / Practitioner

Introduce and Position Sheath in Patient

- Introduce the sheath/obturator.
- Position the tip of the sheath in an area free of thromboemboli for extraction (this position allows for funnel expansion prior to aspiration).

Open Valve Lever

- Open the valve lever.

Remove both Obturator and Guidewire or just Obturator

- While keeping sheath in position, remove both the obturator and guidewire or just the obturator. Sheath should remain in patient.
- If the guidewire remains in the patient, rotate the valve lever to the Closed position. If the guidewire is removed with the obturator, the hemostatic valve will maintain blood stasis.

Sheath is ready for receiving cannula and handle when:

CHECK & ENSURE

- Sheath is positioned away from thromboemboli.
- Both Obturator and guidewire or just obturator are removed from the sheath.

Sheath is ready to receive cannula and handle



PREPARING PREPARING HANDLE ASSEMBLY

Setup / Preparer

Close Touhy and Remove Yellow Spacer

- Close the accessory touhy port.
- Lift and remove yellow spacer.

Connect Cannula, Waste Tubing and Bag

- Connect cannula to handle.
- Connect waste tubing to handle.
- Connect waste bag to tubing.

Prime the Handle Assembly

- Place the funnel end of the cannula into a bowl of sterile saline.
- Fully actuate the handle trigger three times in the 30 cc setting to prime the system.
- Disconnect and empty the waste bag of priming solution and air, and then reconnect the waste bag.

Check before hand off →

AlphaVac handle assembly is ready for physician when:

CHECK & ENSURE

- Accessory touhy port is closed.
- Yellow spacer is removed.
- Handle Assembly is primed.
- Cannula, waste bag tubing and waste bag are connected to handle.

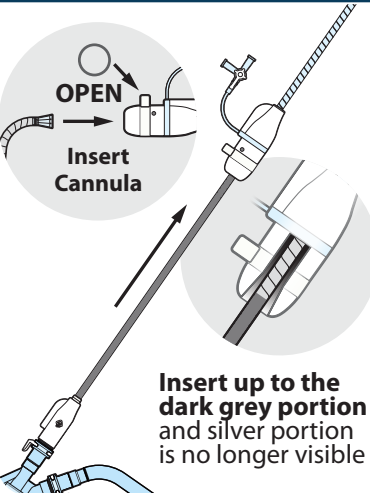
Handle assembly is ready for physician



Unfold completely and review both sides

PREPARING 4
INSERT CANNULA & PRIME SYSTEM

Physician / Practitioner

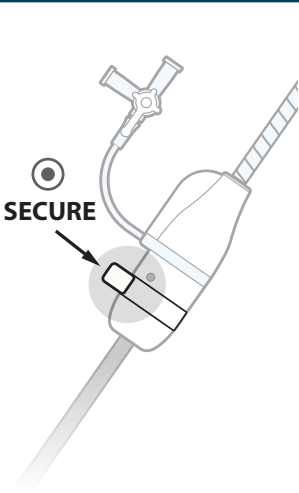


Insert Cannula into Sheath

- Check or Open the valve lever.
- Keep sheath in an area free of thromboemboli for extraction.
- Insert cannula into sheath up to the dark grey portion and until the silver portion is no longer visible.
- Pull handle trigger once at 10cc setting to evacuate any potential air introduced during cannula insertion.

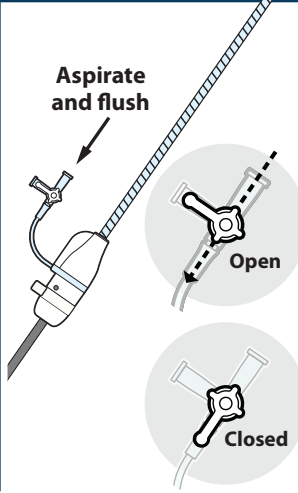
DO NOT extend the funnel out of the sheath until priming is completed.

CAUTION: Extending the funnel out of the sheath prior to priming can introduce air and endanger the patient. Keep the funnel inside the sheath until priming is completed.



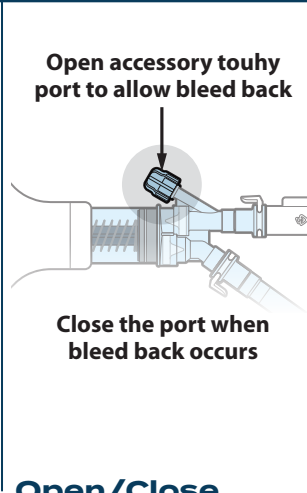
Secure Cannula

- Rotate the valve lever to the Secure position to secure the cannula.



Aspirate and Flush Sheath Stopcock

- Aspirate air from the stopcock, then flush and close stopcock.



Open/Close Touhy Port for Bleed Back

- Open accessory touhy port.
- Allow bleed back via port.
- Close the port.

AlphaVac system is primed and ready to operate when:

CHECK & ENSURE

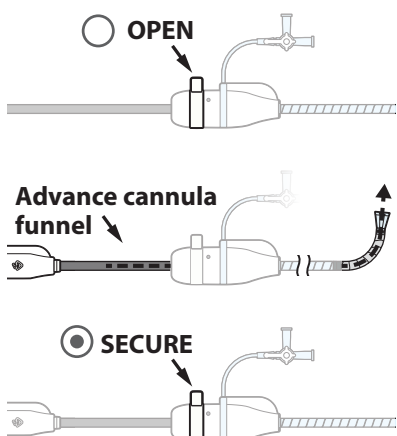
- Cannula is inserted into the sheath up to the dark grey portion.
- Valve lever is secured.
- Stopcock has been aspirated, flushed and closed.
- Bleed back via the accessory touhy port was performed.
- The accessory touhy port is closed.

AlphaVac system is ready to operate



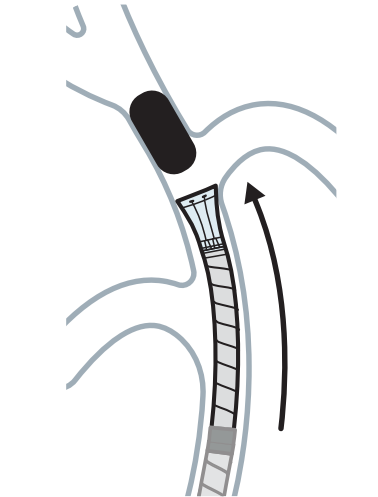
OPERATING 5
REMOVING THROMBOEMBOLI

Physician / Practitioner



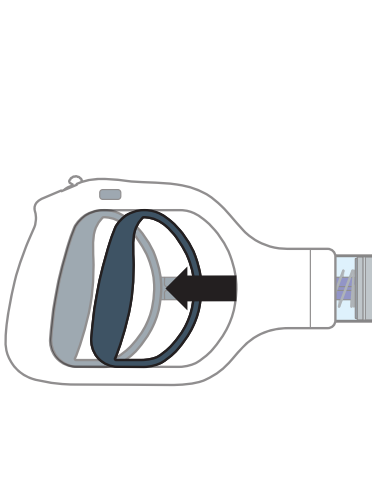
Advance Funnel

- Open the valve lever.
- Advance cannula funnel.
- Rotate the valve lever to the Secure position to secure the cannula.



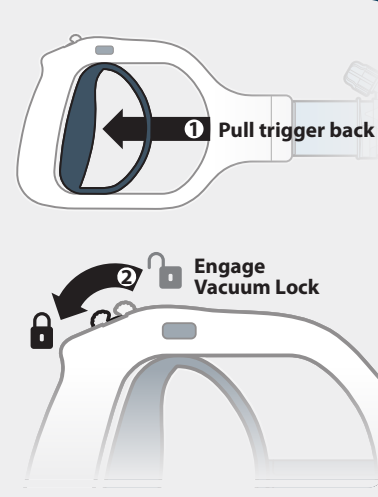
Navigate to and Engage Thromboemboli

- Navigate to thromboemboli.
- Manually pull the handle trigger as needed, using a controlled movement, to gradually engage thromboemboli.



When Thromboemboli is Engaged

- Continue to manually pump using either setting at 10 cc (mL) or 30 cc (mL).
- or use Vacuum Lock (see next image).



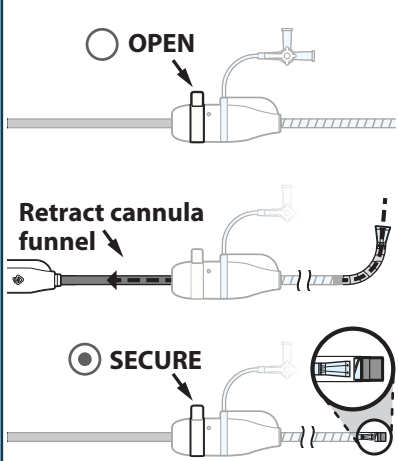
Using Vacuum Lock (Use only when cannula is occluded)

- Thromboemboli must be engaged.
- Use the 30 cc (mL) setting and engage Vacuum Lock.
- Continue to monitor procedure.

- **CAUTION:** Opening the accessory touhy port during vacuum can introduce air into the system and endanger the patient. Use caution when opening the accessory touhy port to avoid introducing air into the system.

OPERATING 6
REMOVING SYSTEM FROM PATIENT

Physician / Practitioner



Retract Funnel

- Open the valve lever.
- Pull cannula back so funnel is fully retracted inside the sheath.
- Rotate the valve lever to the Secure position to secure the cannula.



Remove System

- Keep the handle attached to the cannula when removing system from patient.

CAUTION: When removing, **DO NOT** disconnect handle from cannula. If there is thromboemboli in the cannula, it could lead to back flow of blood through the cannula and reintroduction of the thromboemboli.

ALPHAVAC
MULTIPURPOSE MECHANICAL ASPIRATION
F18⁸⁵

QUICK
REFERENCE
GUIDE

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19903659-21 Rev A 03/2025

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ALPHAVAC
MULTIPURPOSE MECHANICAL ASPIRATION
F18⁸⁵

QUICK REFERENCE GUIDE

- 1 PREPARING
OBTURATOR & SHEATH ASSEMBLY
- 2 PREPARING
PLACING SHEATH IN PATIENT
- 3 PREPARING
PREPARING HANDLE ASSEMBLY
- 4 PREPARING
INSERT CANNULA & PRIME SYSTEM
- 5 OPERATING
REMOVING THROMBOEMBOLI
- 6 OPERATING
REMOVING SYSTEM FROM PATIENT

IMPORTANT: Refer to Directions for Use provided with the product for complete Indications, Instructions, Warnings, Precautions, Possible Adverse Effects and Contraindications prior to use of the product.