

# BIOMODEX® EVIAS Plus™

EndoVascular Aneurysm and  
Ischemic Stroke System



## USER GUIDE



**WARNING:** This product is not a medical device and is not intended to diagnose, treat, cure, or prevent any health condition. BIOMODEX® EVIAS Plus™ has been designed for training and its safety and effectiveness as a medical device has not been demonstrated.

# BIOMODEX® EVIAS Plus™

EndoVascular Aneurysm and Ischemic Stroke System

## I. INTENDED USE

BIOMODEX® EVIAS Plus™ is a laboratory instrument used for physician education, training, and rehearsal.

DISCLAIMER: BIOMODEX® products are not medical devices and are not intended to diagnose, treat, cure, or prevent any health condition. These products have been designed for training and their safety and effectiveness as medical devices have not been demonstrated.

## II. PRODUCT DESCRIPTION

BIOMODEX® EVIAS Plus™ (station, accessories and cartridge) has been designed to simulate the characteristics of intracranial anatomies (geometry and physiological temperature) for simulation of unruptured aneurysm and ischemic stroke procedures. It is intended to be used in a non-sterile laboratory environment.

### Station



Fig.1: BIOMODEX® EVIAS Plus™ Station

# BIOMODEX® EVIAS Plus™

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## Accessories



**A** FEMORAL ACCESS TUBE & FLOW CONECTOR

**B** AORTIC ARCH

**C** INTRODUCTION PAD

**D** POWER SUPPLY

**E** INTRODUCER

**F** CLOT INSERTER

**G** SPARE VALVES

**H** DISTAL CLOT FILTER

**I** STOPPER

**J** BIOMODEX® BLOODSIM

**K** SHAKER

**L** CLEANING POWDER

**M** FLUSH TUBE

# BIOMODEX® EVIAS Plus™

## EndoVascular Aneurysm and Ischemic Stroke System

- (A) **FEMORAL ACCESS TUBE & FLOW CONNECTOR:** simulates the artery pathway from the femoral artery to the entrance of the right/left internal carotid artery (ICA) or end of vertebral artery and allows the continuity of the flow circulation.
- (B) **AORTIC ARCH:** simulates the aortic arch pathway with several levels of tortuosity – type I-II-III are represented.
- (C) **INTRODUCTION PAD:** gives the appropriate angle that you would have at the insertion site at the level of the femoral artery.
- (D) **POWER SUPPLY:** medical, 24V dc, 2.5A, mean well, ref GSM60A24P1J. Several power chords available for different countries.
- (E) **INTRODUCER:** simulates the introducer at the femoral artery. Two 9F introducers are available.
- (F) **CLOT INSERTER:** Clot Inserter gives the ability to inject the clot at the entry level of the cartridge to perform ischemic procedures.
- (G) **SPARE VALVES:** Three (3) spare valves are included for the Clot Inserter.
- (H) **DISTAL CLOT FILTER:** filter positioned at the distal end of the cartridge to collect dislodged clots during ischemic procedures.
- (I) **STOPPER:** cap allowing to close the clot insertion lumen to avoid leakage when performing aneurysm treatment procedures.
- (J) **BIOMODEX® BLOODSIM:** powder that, mixed with saline water, gives the same viscosity and density as the one of human blood. Three (3) containers of BIOMODEX® BLOODSIM are available with each station purchased.
- (K) **SHAKER:** container to prepare the BIOMODEX® BLOODSIM and the cleansing mixture.
- (L) **CLEANING POWDER:** powder that, mixed with water, allow to decontaminate the station. One (1) shot of cleaning powder is available.
- (M) **FLUSH TUBE:** enables to flush the liquid out of the station at the end of a procedure.

All the accessories listed above are provided with the station. BIOMODEX® BLOODSIM, cleaning powder, introducer, cartridges and replacement parts can be reordered at [orders.biomodex.com](https://orders.biomodex.com).

### Cartridge

3D printed anatomical twin created from medical images are available for aneurysm and ischemic stroke procedures. The cartridges have to be ordered separately.



Fig.2: Ischemic stroke and aneurysm Cartridges



### III. WARNINGS & PRECAUTIONS

- Read, follow, and keep the instructions for use handy.
- Use the product only in accordance with its intended use (see Intended use).
- Prior to each use, inspect the product for loose, bent, broken, cracked, worn, or fractured components. Do not use the product if damaged or defective. If damaged, pack the product back and contact immediately the person of contact indicated on the suitcase.
- Do not use any parts other than BIOMODEX® EVIAS Plus™ components as damage to the station or cartridge or substandard performance could occur.
- Do not operate BIOMODEX® EVIAS Plus™ without the use of surgical gloves.

#### Station & accessories

- To avoid the risk of electrical shock, achieve electrical grounding reliability with proper connections. Connect the station to hospital grade receptacles only.
- Place the power supply under the table and make sure the power cord is out of the way.
- Make sure that the power supply is always accessible.
- Verify that electrical contacts are dry prior to use.
- Before using contrast agent, refer to the package leaflet and follow the instructions and warnings.
- Use adequate fluid in the system. The use of a liquid other than the BIOMODEX® BLOODSIM or water may lead to the malfunctioning of the station.
- Be careful to place a container at the end of the tube when flushing.
- Repair and/or modification to the BIOMODEX® EVIAS Plus™ by anyone other than qualified service personnel may significantly compromise the system's ability to perform effectively and will void the equipment warranty.
- Store the product in a dry, clean and safe place.

#### Cartridge

- The aneurysm cartridges are intended for single use only.
- The ischemic stroke cartridges are intended for multiple use, however we cannot guarantee against operator improper use.
- Ensure that the cartridge is used by personnel with the appropriate medical training, knowledge, and experience.
- Ensure the cartridge is placed at the caudal socket when starting a procedure. Bad cartridge placement could lead to a station malfunction.
- Insertion of devices that are not intended for treating the simulated pathologies may lead to the irreversible damaging of the cartridge.
- Do not attempt to change a cartridge when the station is in operation.
- Remove and discard cartridges and accessories in accordance with local regulations for proper disposal.

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## IV. EQUIPMENT INSTALLATION & USE

Before setting up the system, place a drape onto the operating table and install BIOMODEX® EVIAS Plus™ according to the diagram below:

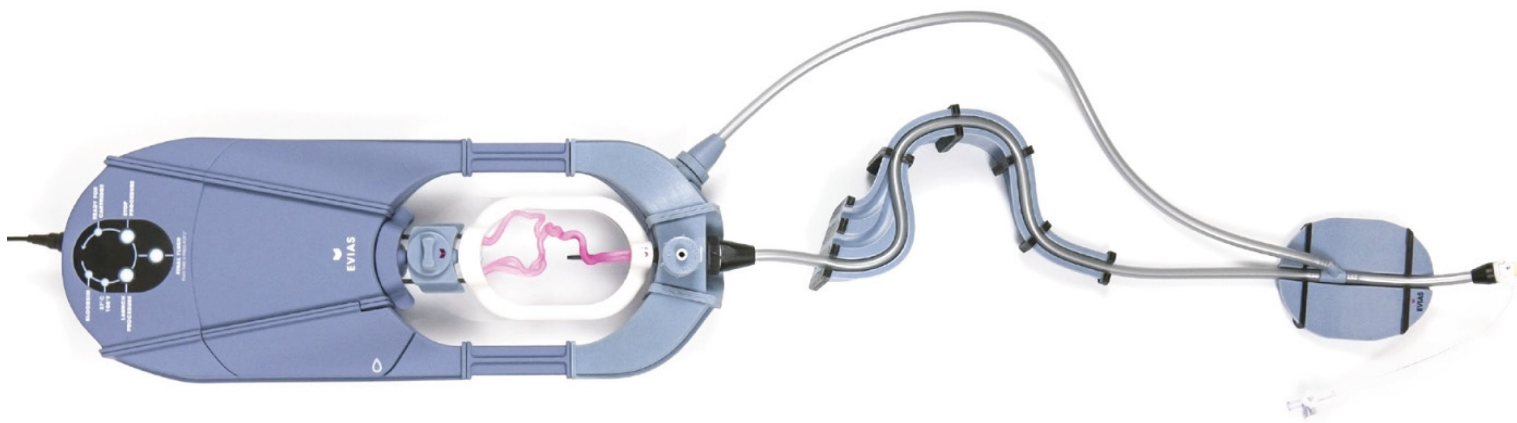


Fig.3: Top view of the ischemic set-up of BIOMODEX® EVIAS Plus™

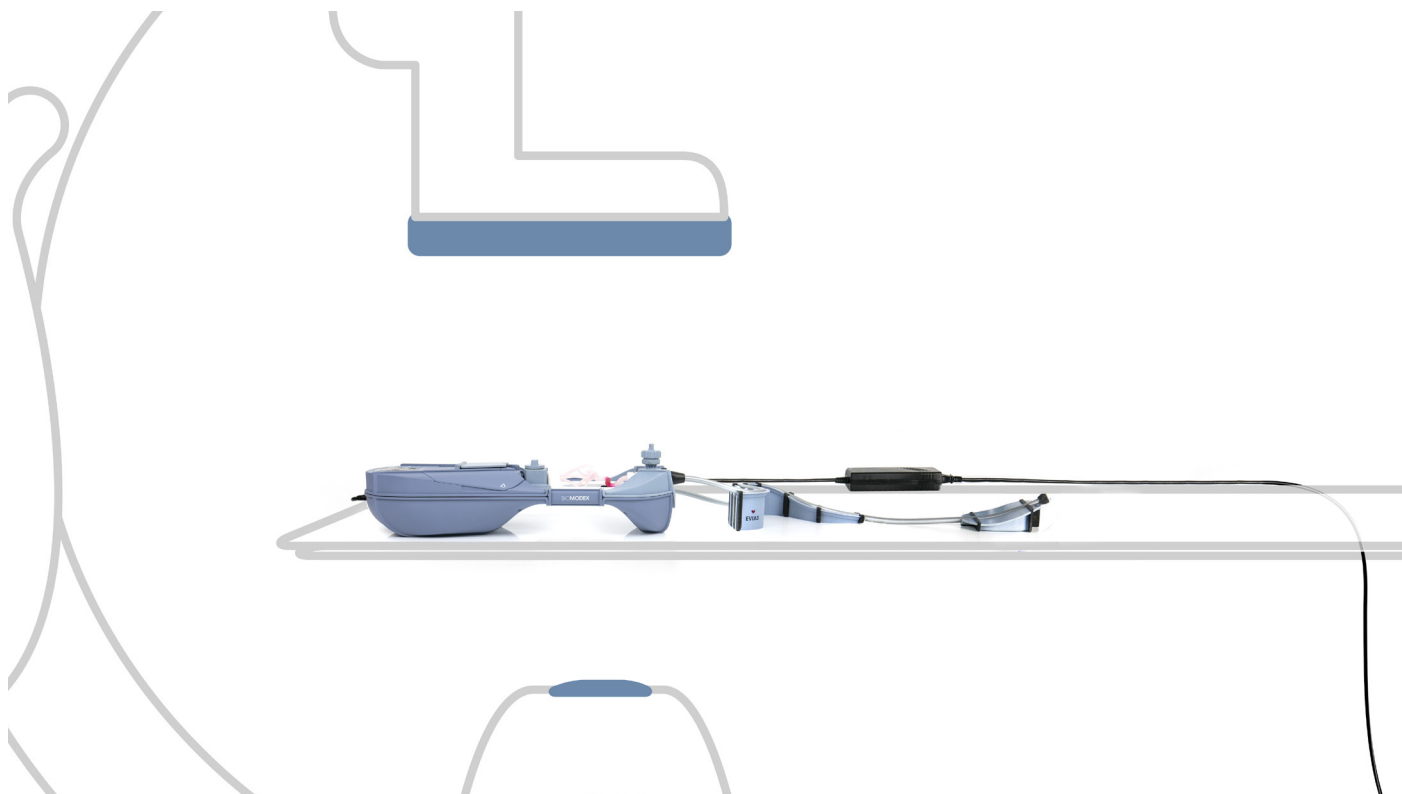
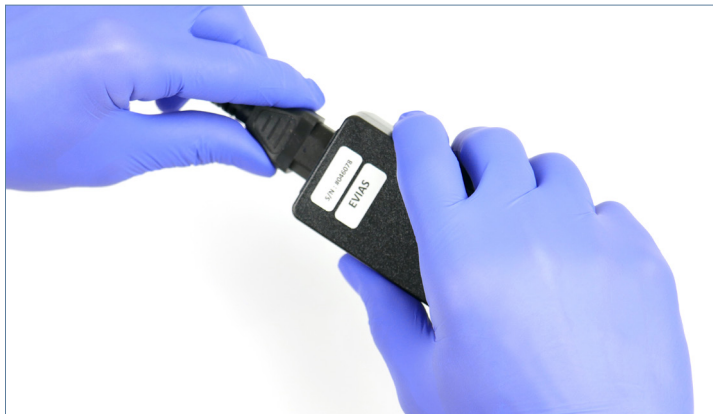


Fig.4: Side view of the final set-up of BIOMODEX® EVIAS Plus™

# BIOMODEX® EVIAS Plus™

EndoVascular Aneurysm and Ischemic Stroke System

## SET-UP



1 / Plug the power cord into the power supply.



2 / Plug the power supply into the Station.



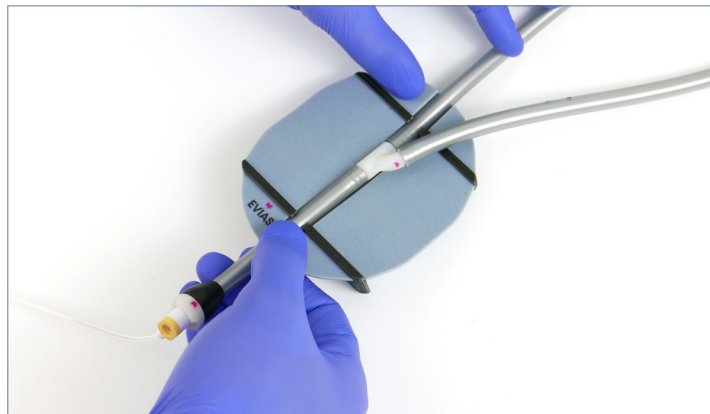
3 / Connect the Femoral Access Tube to the Station approach plug



4 / Connect the Flow Connector Tube to the station flow outlet.



5 / Place the Femoral Access Tube into the Aortic Arch.



6 / Place the Femoral Access Tube into the introduction pad.

# BIOMODEX® EVIAS Plus™

EndoVascular Aneurysm and Ischemic Stroke System



**7 /** Connect the Flush Tube at the back of the Station.



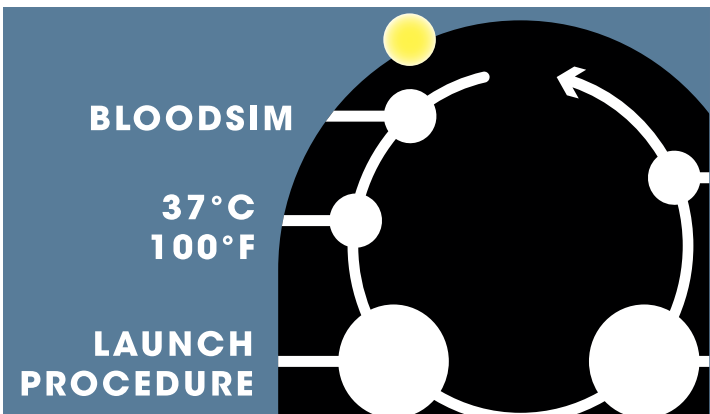
**8 /** For aneurysm treatment procedures, ensure the clot insertion lumen is sealed with the Stopper.



**9 /** For ischemic stroke procedures, ensure the clot insertion lumen is connected to the Clot Inserter.



**10 /** Switch the Station on.



**11 /** The blinking led indicates the station is waiting for BIOMODEX® BLOODSIM.



# BIOMODEX® EVIAS Plus™

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## BIOMODEX® BLOODSIM™ PREPARATION



**12 /** Pour the BIOMODEX® BLOODSIM powder in the Shaker and top it off with water until the 20cl mark is reached.



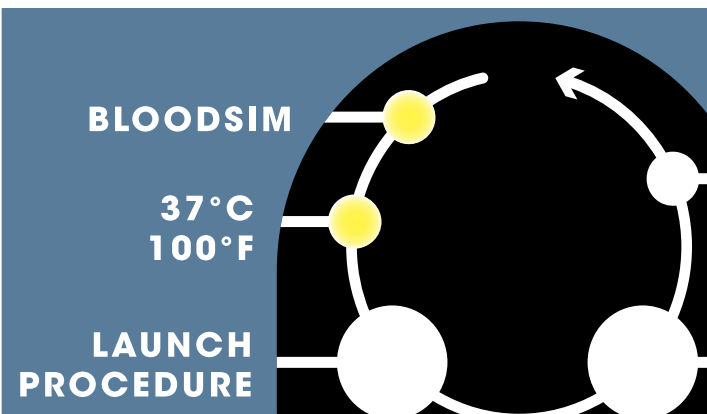
**13 /** Mix by agitating the Shaker up and down until a homogeneous liquid is obtained.



**14 /** Open the cap by turning it counterclockwise.



**15 /** Pour the BIOMODEX® BLOODSIM into the tank.



**16 /** The blinking LED indicates the BIOMODEX® BLOODSIM is heating. A solid LED means the heating is completed.

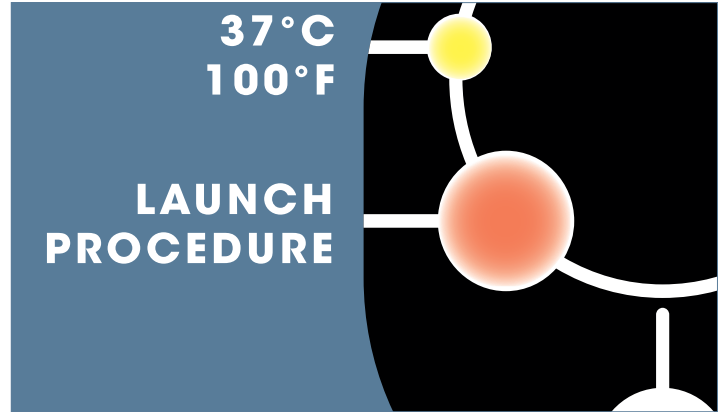
# BIOMODEX® EVIAS Plus™

EndoVascular Aneurysm and Ischemic Stroke System

## ANEURYSM TREATMENT PROCEDURE



**17 /** Place the cartridge at the caudal connection. Be sure the cartridge is secured in the rail.



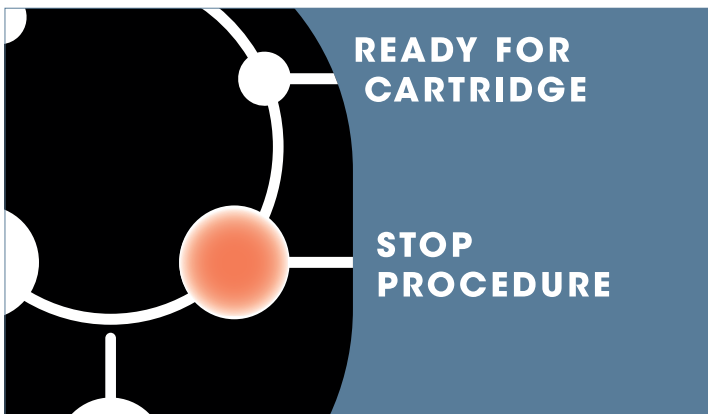
**18 /** Launch the procedure by clicking on the "LAUNCH PROCEDURE" button.



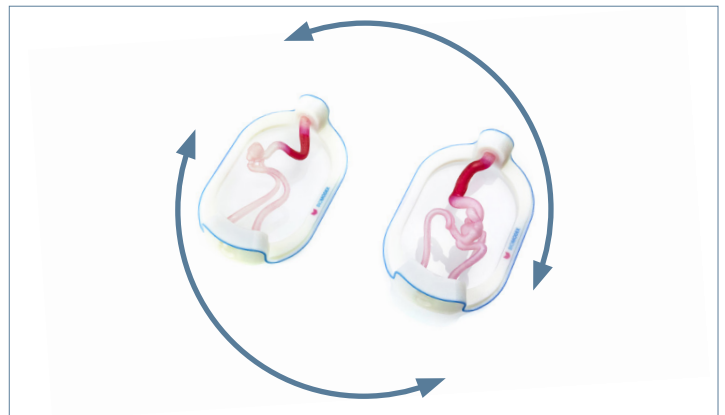
**19 /** Purge the air from the circuit by opening the introducer valve located at the tip of the femoral access tube.



**20 /** You are ready to perform the procedure. You may inject contrast (70/30) in the system to improve the visualization under fluoroscopy.



**21 /** Once you're done with the procedure, stop the procedure by clicking on the "STOP PROCEDURE" button.

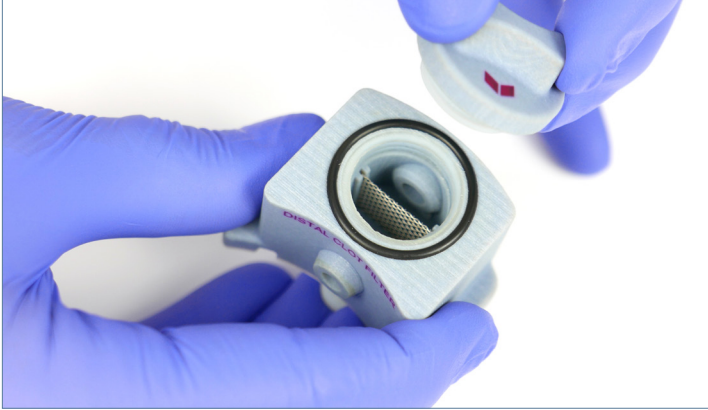


**22 /** Once the procedure is complete remove the cartridge or swap it as needed.

# BIOMODEX® EVIAS Plus™

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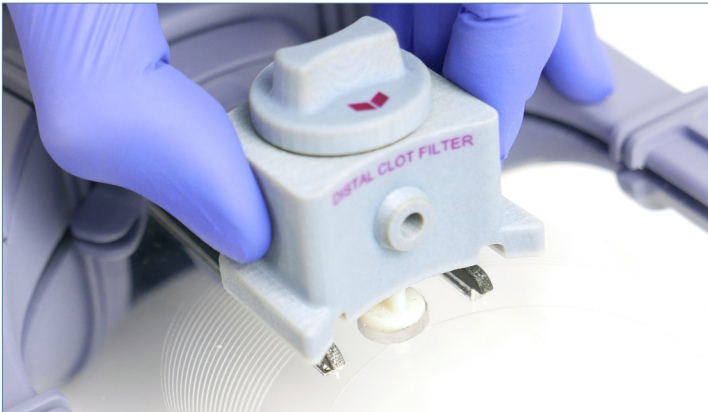
## ISCHEMIC STROKE PROCEDURE



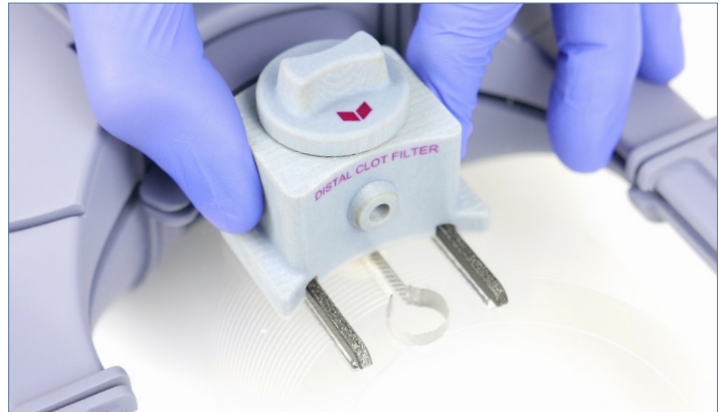
**23 /** Ensure the mesh in the Distal Clot Filter is well placed in the tank of the filter.



**24 /** Attach and tighten the cap to the filter.



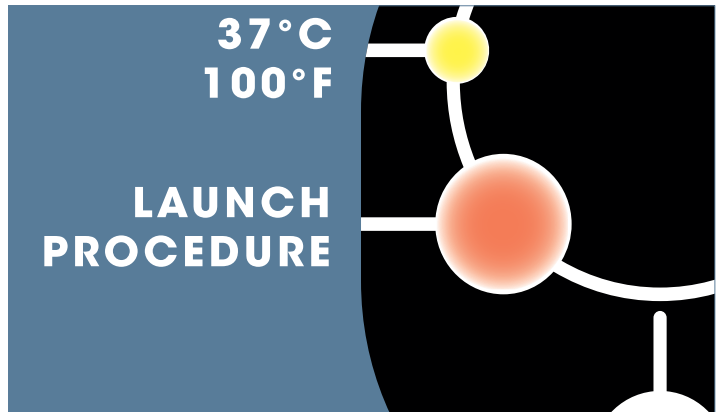
**25 /** Place the Distal Clot Filter in the opening of the plexiglas.



**26 /** Slide the Distal Clot Filter against the plunger. Be sure it is secured on the rails.



**27 /** Place the cartridge at the caudal connection. Be sure the cartridge is secured on the rails.



**28 /** Launch the procedure by clicking on the "LAUNCH PROCEDURE" button.



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**29 /** Purge the air from the circuit by opening the introducer valve located at the tip of the Femoral Access Tube.



**30 /** Unscrew the Clot Inserter top.



**31 /** Place the clot in the Clot Inserter.



**32 /** Screw the Clot Inserter cap and flush 10mL of BIOMODEX® BLOODSIM to inject the clot.



**33 /** You are ready to perform the procedure. You may inject contrast (70/30) in the system to improve the visualization under fluoroscopy.

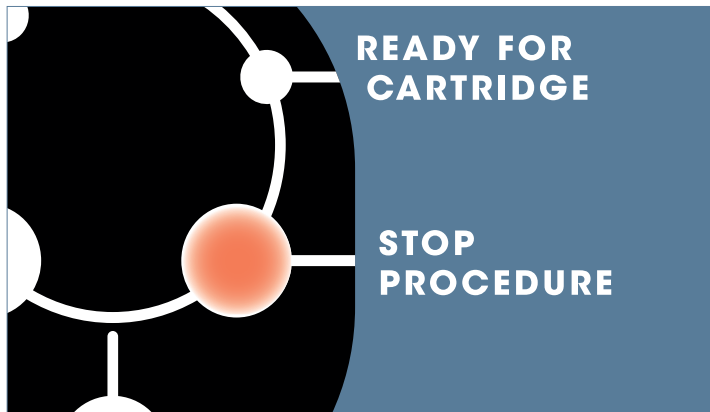


**34 /** Repeat steps 30 to 32 to inject additional clots.

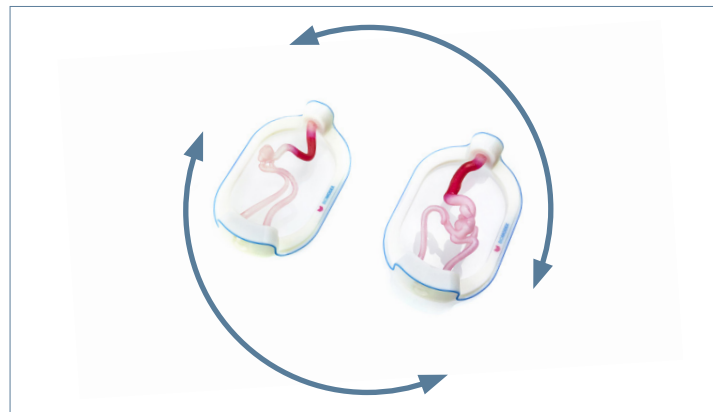


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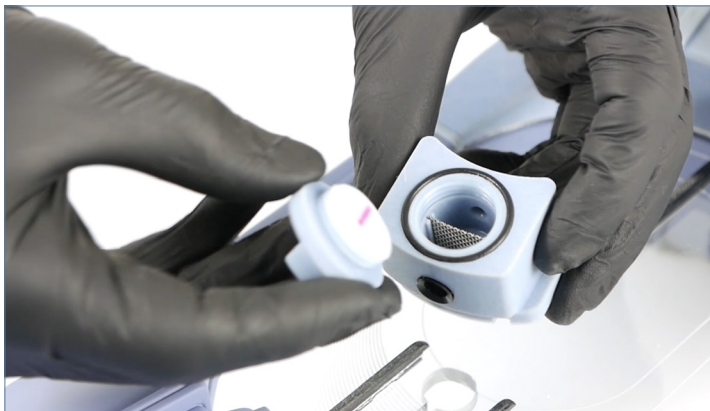


**35 /** Stop the procedure by clicking on the "STOP PROCEDURE" button.

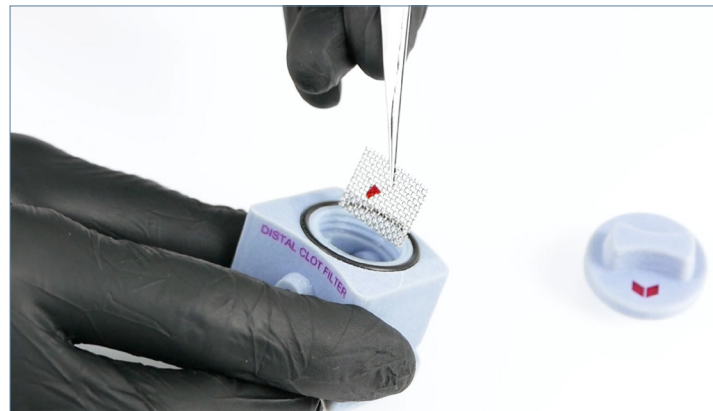


**36 /** Once the procedure is complete remove the cartridge or swap it as needed.

## CLOT RESIDUAL CLEANING



**37 /** Open the Distal Clot Filter.



**38 /** Check for clot residuals and clean the Distal Clot Filter as needed by rinsing the mesh under water.

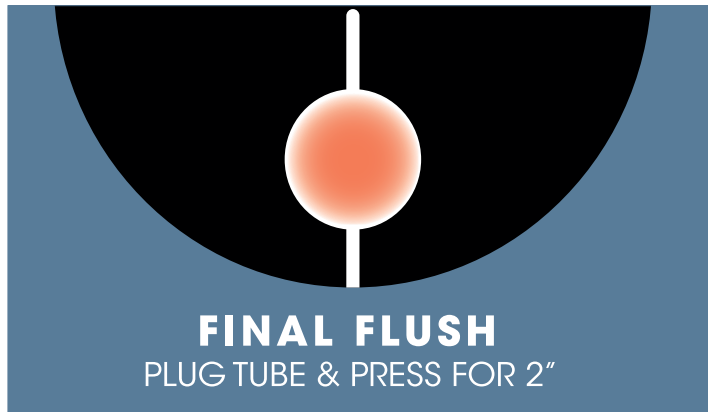
# BIOMODEX® EVIAS Plus™

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## SHUT DOWN



**40 /** Place the Flush Tube in a container big enough to hold all the fluid.



**41 /** Press the "FINAL FLUSH" button to flush the system. The process is complete when all the LEDs are blinking. It will take approximately 1 minute.



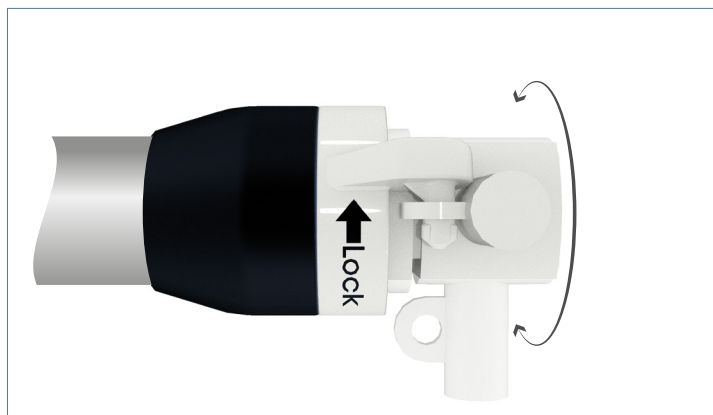
**42 /** Turn the Station off.



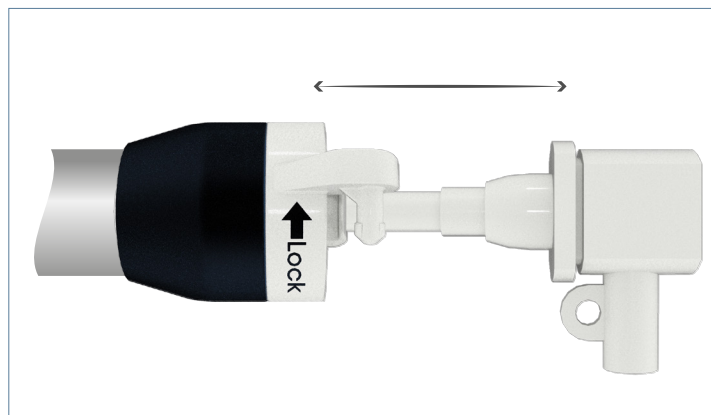
**43 /** Remove the Clot Inserter from the station and place the Stopper to store the system.

### REPLACEMENT OF THE INTRODUCER

To be performed once the station has been flushed and turned off.



Turn counterclockwise.

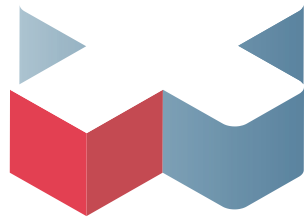


Pull on the introducer.

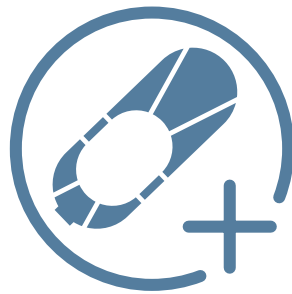
### V. STATION CLEANING

The cleaning of the station must be performed by the customer after daily sessions. If the station has not been used for 15 days, perform the cleaning process before the use of the station.

1. Open the station clot collector and remove potential residues.
2. Turn the system back on
3. Pour one shot of cleaning powder in the shaker
4. Top it off with 200mL of saline water
5. Mix by agitating the shaker until a homogeneous solution is achieved
6. If the Clot Inserter was used, take 100mL from the cleaning solution in a syringe and flush the Clot Inserter.
7. Pour the rest of the cleaning solution into the tank
8. Wait for the solution to warm up
9. Launch the procedure with a cartridge already used. If the Clot Inserter was used leave the Distal Clot Filter for cleaning step
10. Wait for 10 minutes
11. Flush the system
12. Turn the system off
13. Turn the system back on again
14. Fill the tank with 200mL of saline water
15. Wait for the solution to warm up
16. Launch a procedure with the same cartridge, leave the Distal Clot Filter for rinsing step if used
17. If the Clot Inserter was used, take 100mL of saline water in a syringe and flush the Clot Inserter.
18. Wait for 5 minutes
19. Flush the system



BIOMODEX®



**WARRANTY:** BIOMODEX® warrants that all Cartridges are free from defects in manufacturing, materials and workmanship for a period of six months from the date of purchase. BIOMODEX® warrants that all Stations are free from defects in manufacturing, materials and workmanship for a period of two years from the date of purchase.

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