

BIOMODEX® AORTIC ARCH

USING
BIOMODEX® EVIAS Plus™



USER GUIDE



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

The following IFU is intended for any BIOMODEX[®] Aortic Arch.

I. INTENDED USE

BIOMODEX[®] Aortic Arch 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[®] Aortic Arch has been designed to simulate the characteristics of aortic arch anatomies and enhance the experience of neurovascular interventions performed with the BIOMODEX[®] EVIAS Plus[™] system. It is intended to be used in non-sterile laboratory environment.

BIOMODEX® AORTIC ARCH

Aortic Arch & Accessories



Fig.1: BIOMODEX® Aortic Arch Type I

- | | | |
|--------------------------------|-------------------------------------|--------------------------------|
| A AORTIC ARCH | B STATION APPROACH CONNECTOR | C CAPS (X5) |
| D FLOW OUTLET CONNECTOR | E AIR PURGE CAP | F FEMORAL APPROACH TUBE |
| G RADIAL APPROACH TUBE | | |



BIOMODEX® AORTIC ARCH

- Ⓐ **AORTIC ARCH:** customizable patient-specific aortic arch utilizing FDA cleared and CE marked software for segmentation of 3D RA or CTA. BIOMODEX® standard type I/II/III Aortic Arch models available.
- Ⓑ **STATION APPROACH CONNECTOR:** connects the Aortic Arch to the EVIAS Plus™ Station.
- Ⓒ **CAPS:** Five (5) caps are provided with the Aortic Arch to seal the arteries that are not in use.
- Ⓓ **FLOW OUTLET CONNECTOR:** allows for continuous flow circulation throughout the system.
- Ⓔ **AIR PURGE CAP:** seals the outlet used to purge the air from the Aortic Arch.
- Ⓕ **FEMORAL APPROACH TUBE:** simulates the artery pathway from the femoral artery to the descending aorta.
- Ⓖ **RADIAL APPROACH TUBE:** simulates the artery pathway from the radial access entrance to the right or left subclavian artery.

The above accessories are provided when purchasing a BIOMODEX® Aortic Arch. Replacement parts can be reordered at orders.biomodex.com.

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® Aortic Arch components as damage to the station or cartridge or substandard performance could occur.
- BIOMODEX® Aortic Arch is intended to be used with the BIOMODEX® EVIAS Plus™ system. Do not use the product with another system.
- Do not operate BIOMODEX® Aortic Arch without the use of surgical gloves.

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- 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.
- Repair and/or modification to the BIOMODEX® Aortic Arch by anyone other than qualified service personnel may significantly compromise its ability to perform effectively.
- Make sure to flush and clean the BIOMODEX® Aortic Arch properly, according to the section V.
- Store the product in a dry, clean and safe place.
- The BIOMODEX® Aortic Arch is intended for multiple use, however we cannot guarantee against operator improper use.
- Ensure the BIOMODEX® Aortic Arch is used by personnel with the appropriate medical training, knowledge, and experience.
- Ensure all tubes of the BIOMODEX® Aortic Arch are connected to the station and non-used arteries are capped before starting the procedure. Improper capping or connection could lead to significant leakage.
- Insertion of devices that are not intended for treating the simulated pathologies may lead to the irreversible damaging of the BIOMODEX® Aortic Arch.
- Do not attempt to change a BIOMODEX® Aortic Arch when the station is in operation.

IV. EQUIPMENT INSTALLATION & USE

Before setting up the system, place a drape onto the operating table and place the BIOMODEX® Aortic Arch in front of the BIOMODEX® EVIAS Plus™ Station according to the diagram below:

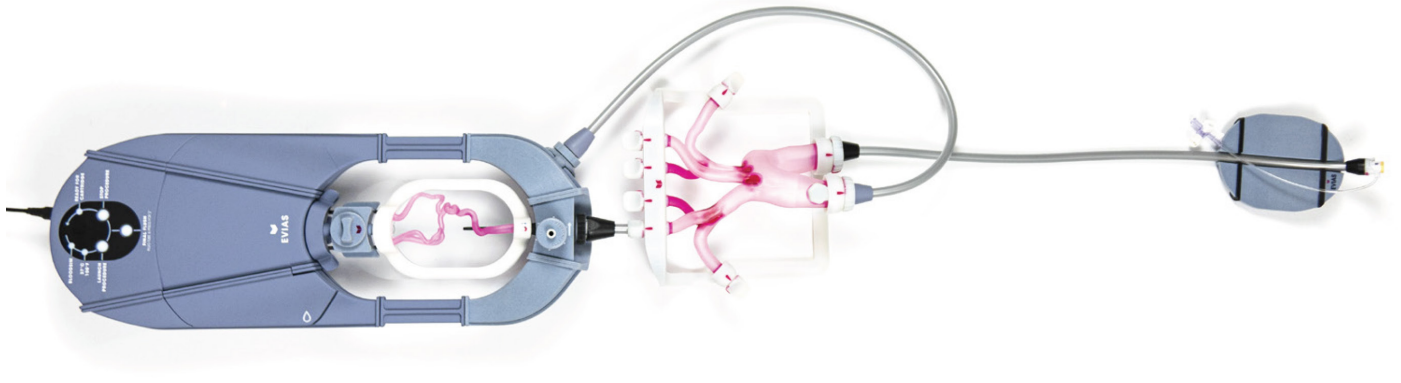


Fig.3: Top view of the final set-up of BIOMODEX® EVIAS Plus™ with the Aortic Arch



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

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SYSTEM CONNECTORS

All connectors and caps must be attached by aligning their red indicator with the aortic arch's and turning $\frac{3}{4}$ of a turn clockwise as shown below.



SET-UP



1 / Attach Caps to the 3 non-connected upper arteries.



2 / Attach the Station Approach Connector to the selected upper artery pathway (L/R CCA or L/R vertebral).



3 / If a radial approach was chosen, connect the Radial Approach Tube to the radial artery.



4 / Cap the non used radial arteri(es).

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5 / Attach the Flow Outlet Connector to the ascending aorta



6 / Attach the Femoral Approach Tube to the descending aorta



7 / Connect the black Quick Connect of the Station Approach Connector to the black approach plug of the Station.



8 / Connect the grey Quick Connect of the Flow Outlet Connector to the grey Flow Outlet of the station

IMPORTANT: all arteries of the BIOMODEX® Aortic Arch must be connected to a cap or an approach tube prior to launching the procedure.



9 / Ensure that the Aortic Arch Air Purge Cap is connected.

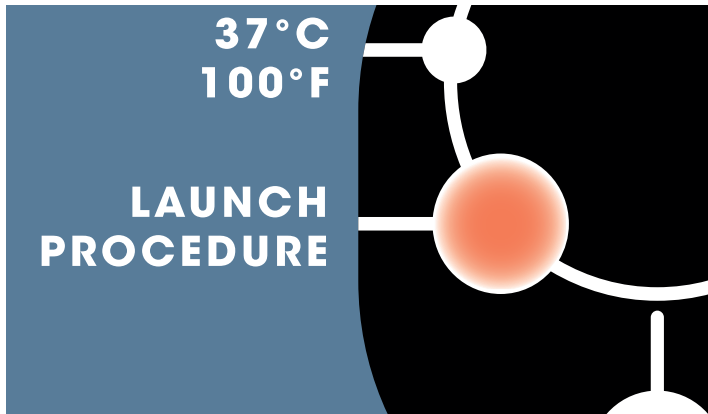


10 / Place the Femoral or Radial Access Tube into the Introduction Pad

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PROCEDURE

Launch procedure as per explained in the BIOMODEX® EVIAS Plus™ system instruction for use.



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



12 / Refill the tank of the BIOMODEX® EVIAS Plus™ Station while the Aortic Arch is being filled.



13 / Purge the air from the circuit by opening the introducer valve and the Air Purge Cap on the ascending aorta of the Aortic Arch.



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

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V. AORTIC ARCH FLUSH

FLUSH

The flush of the aortic arch must be performed when flushing the BIOMODEX® EVIAS Plus™ system.



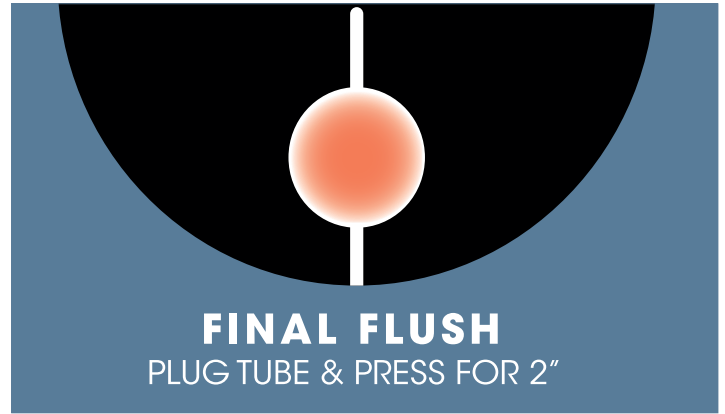
15 / Place the station Flush Tube in a container large enough to hold all the fluid.



17 / Remove the 9FR introducer and place the proximal end of the Femoral Approach Tube in a container large enough to hold all the fluid.



19 / Lift the Aortic Arch and drain the water in the container through the Femoral Approach Tube.



16 / 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.



18 / Disconnect the Station Approach Connector and the Flow Connector.

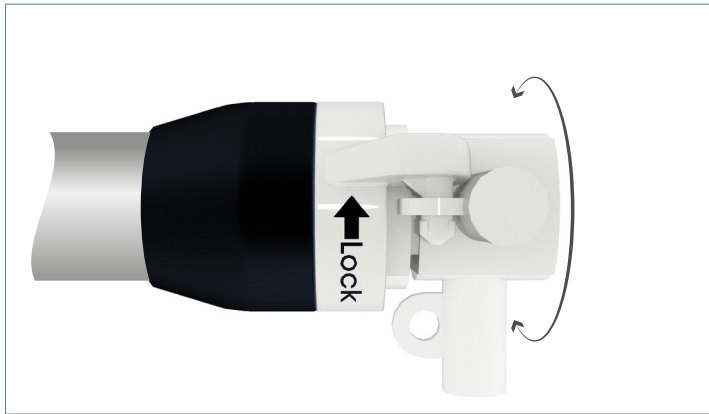


20 / Turn the station off.

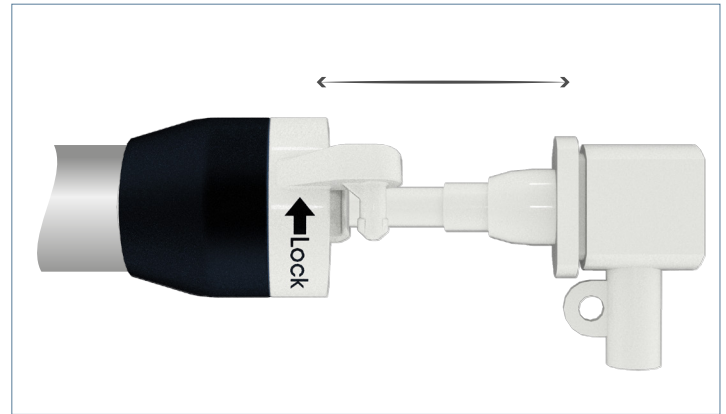
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REPLACEMENT OF THE INTRODUCER

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



Turn counterclockwise.

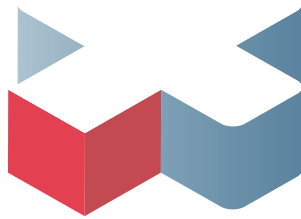


Pull on the introducer.

V. AORTIC ARCH CLEANING

The cleaning of the aortic arch must be performed by the customer after daily sessions. For more details about the BIOMODEX® EVIAS Plus™ system cleaning, please refer to its IFU.

1. Turn the system back on with the aortic arch connected
2. Pour one shot of cleaning powder in the shaker
3. Top it off with 20cl (200ml) of saline water
4. Mix by agitating the shaker until a homogeneous solution is achieved
5. Pour the content in the tank
6. Wait for the solution to warm up
7. Launch the procedure with a cartridge already used
8. Repeat the steps 2 through 5 to ensure the arch is filled
9. Wait for 10 minutes
10. Flush the system and the aortic arch
11. Turn the system off
12. Turn the system back on again
13. Fill the tank with 20cl (200ml) of saline water
14. Wait for the solution to warm up
15. Launch a procedure with the same cartridge
16. Repeat the steps 13 to ensure the arch is filled
17. Wait for 5 minutes
18. Flush the system and the aortic arch
19. Dry out the aortic arch before storing



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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.

US Office:
300 Crown Colony Drive, Suite 504
Quincy, MA 02169 - USA

EMEA Office:
2 rue de la Roquette
75011 Paris - FRANCE