

BIOMODEX® EVIAS™

Endovascular Intracranial Aneurysm System



USER GUIDE



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

I. INTENDED USE

BIOMODEX® EVIAS™ (EndoVascular Intracranial Aneurysm System) is a laboratory instrument used for physician education, training, and rehearsal.

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II. PRODUCT DESCRIPTION

BIOMODEX® EVIAS™ (station, accessories and cartridge) has been designed to simulate the characteristics of intracranial aneurysms (geometry and physiological temperature). It is intended to be used in non-sterile laboratory environment.

Station



Fig.1: BIOMODEX® EVIAS™ Station

Accessories



- | | | |
|------------------------------|----------------------|---------------------------|
| A FEMORAL ACCESS TUBE | B AORTIC ARCH | C INTRODUCTION PAD |
| D POWER SUPPLY | E INTRODUCER | F CONNECTOR |
| G BLOODSIM™ | H SHAKER | I CLEANING POWDER |
| J FLUSH TUBE | | |

- A FEMORAL ACCESS TUBE:** simulates the artery pathway from the femoral artery to the entrance of the right/left internal carotid artery (ICA) or end of vertebral artery.
- 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:** imulates the introducer at the femoral artery. Two (2) 9F introducers are available.
- F CONNECTOR:** gives the ability to place several devices in the system. One (1) connector is available.
- G BLOODSIM™:** powder that mixed with saline water gives the same viscosity and density of the blood. 3 shots are available. Three (3) shots of BLOODSIM™ are available.
- H SHAKER:** container to prepare the BLOODSIM™ and the cleansing mixture.
- I CLEANING POWDER:** powder that mixed with water allow to decontaminate the station. One (1) shot of cleaning powder is available.
- J FLUSH TUBE:** aims to flush the liquid out of the station at the end of a procedure.

All the accessories listed above are provided with the station. Consumables are the BLOODSIM™, the cleaning powder, the introducer, the connector and the cartridges. They might be reordered.

Cartridge

Single use 3D printed anatomical twin extracted from images showing unruptured aneurysm. The cartridges have to be ordered separately.

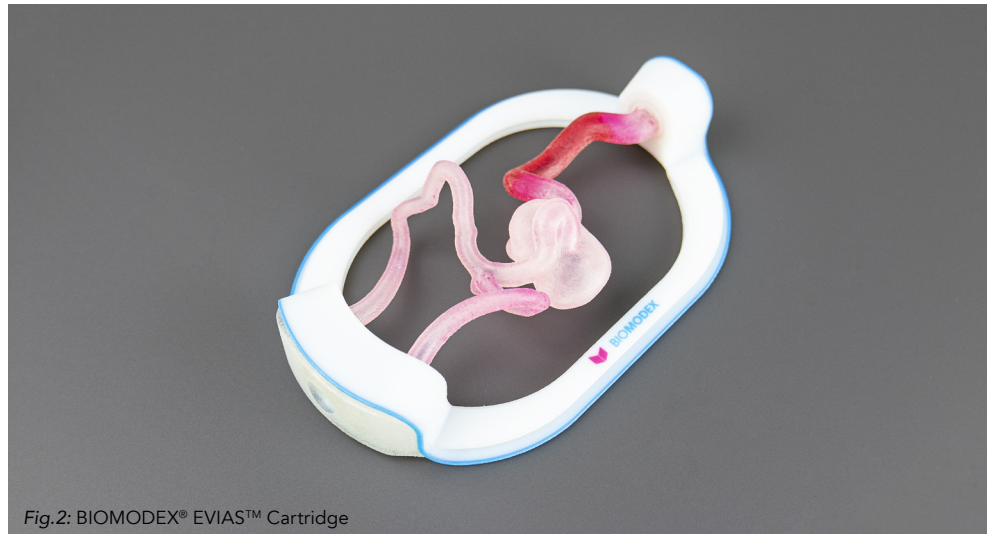


Fig.2: BIOMODEX® EVIAS™ Cartridge

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™ components as damage to the station or cartridge or substandard performance could occur.
- Do not operate BIOMODEX® EVIAS™ 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 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™ 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 cartridge is for single use only.
- Ensure that the cartridge is operated and used by the persons with the requisite 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 other devices not intended for the treatment of intracranial aneurysms may lead to the 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.

IV. EQUIPMENT INSTALLATION & USE

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

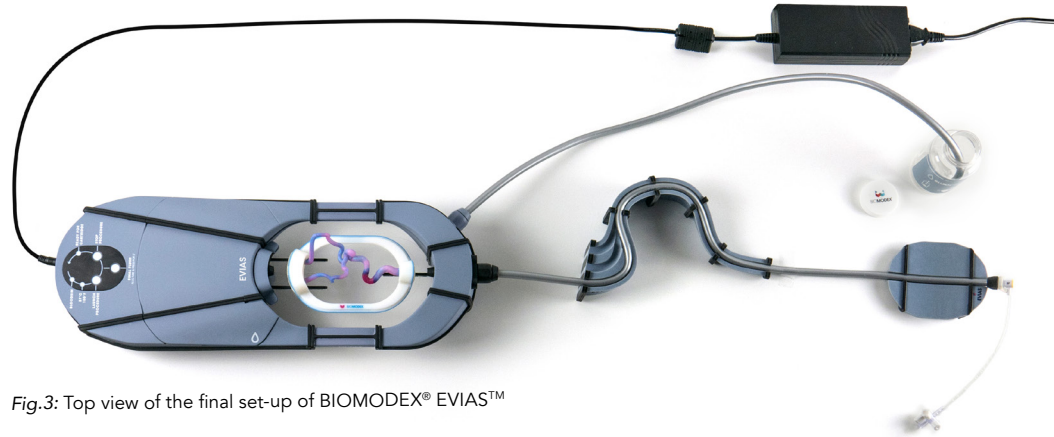


Fig.3: Top view of the final set-up of BIOMODEX® EVIAS™

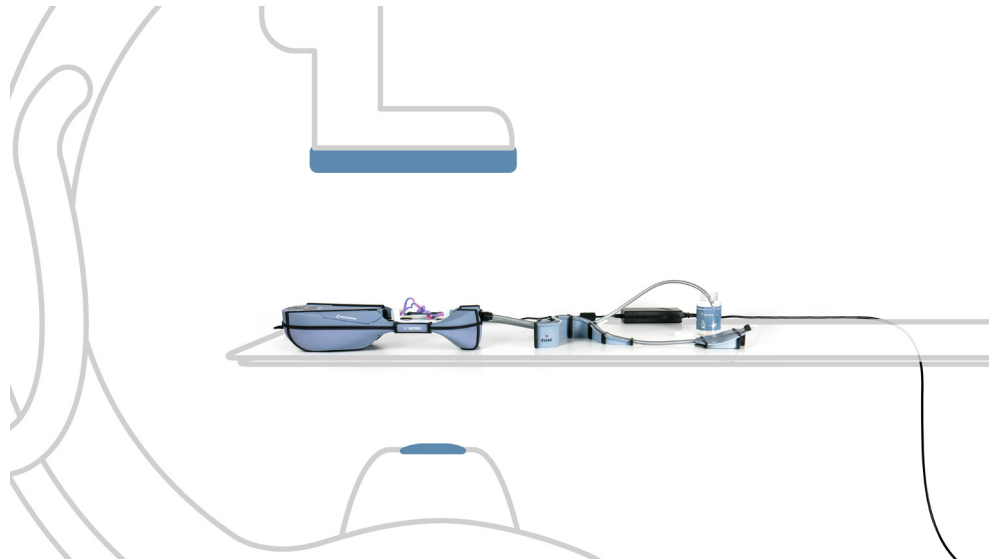


Fig.4: Side view of the final set-up of BIOMODEX® EVIAS™

SET-UP



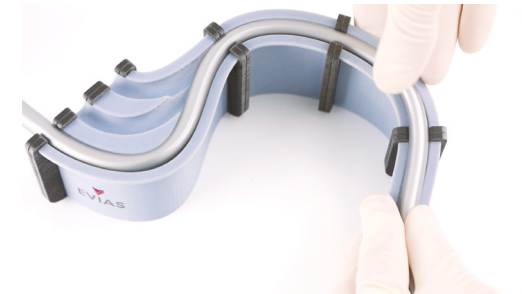
1 / Plug the power cord into the power supply.



2 / Plug the power supply into the station.



3 / Connect the femoral access tube to the station.



4 / Place the femoral access tube into the aortic arch.



5 / Place the femoral access tube into the introduction pad.



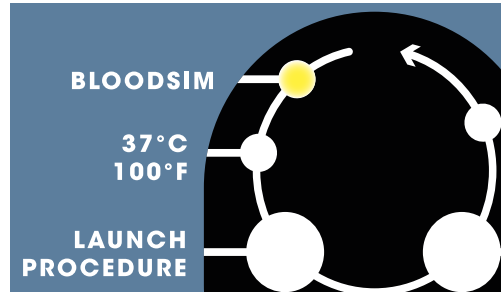
6 / Connect the flush tube.

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7 / Switch the station on.



8 / The blinking led indicates the station is waiting for BLOODSIM™.

BLOODSIM™ PREPARATION



9 / Pour the BLOODSIM™ powder in the shaker and top it off with water until the 20cL mark is reached.



10 / Mix by agitating the shaker up and down until a homogeneous liquid is obtained.



11 / Open the door of the tank.



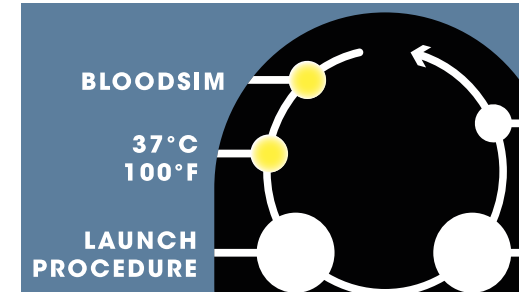
12 / Open the cap by turning it counterclockwise.

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13 / Pour the BLOODSIM™ into the tank.

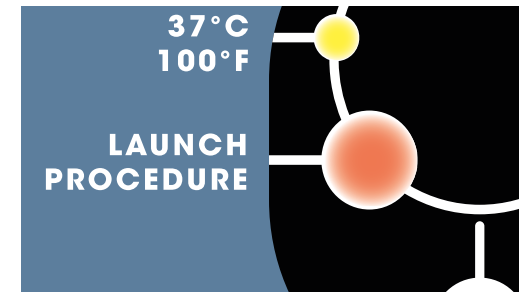


14 / The blinking LED indicates the BLOODSIM™ is heating. A solid LED means the heating is completed.

PROCEDURE



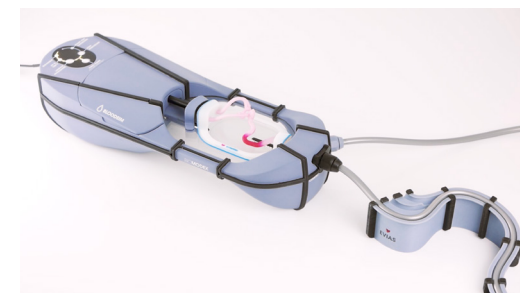
15 / Place the cartridge at the caudal connection. Be sure the cartridge is secured in the rail.



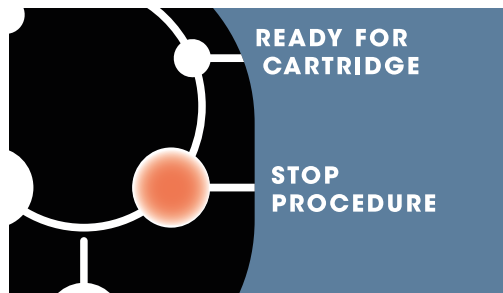
16 / Launch the procedure by clicking on the "LAUNCH PROCEDURE" button.



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



18 / You are ready to perform the procedure. Inject contrast (50/50) in the system to improve the visualization under fluoroscopy.



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

SHUT DOWN



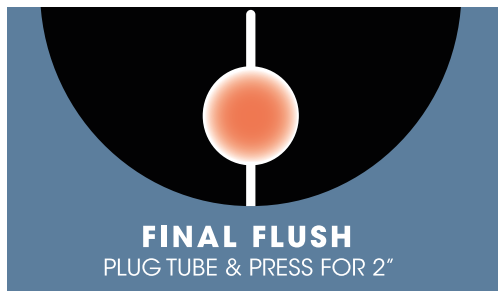
21 / Place the flush tube in a container big enough to hold all the fluid (max. 350mL).



23 / Turn the station off.



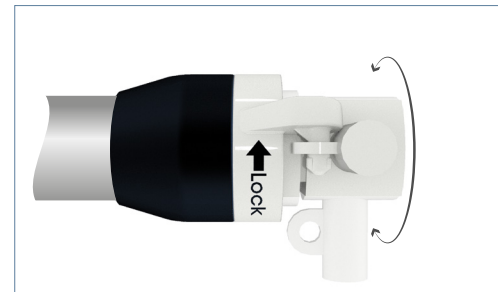
20 / Once the procedure is complete remove the cartridge or swap it as needed.



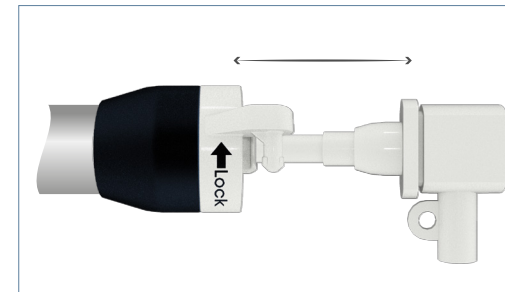
22 / Press the "FINAL FLUSH" button to flush the system. The process is complete when all the LEDs are blinking. It will take approximately 1 minute.

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. Turn the system back on
2. Pour one shot of cleaning powder in the shaker
3. Top it off with 20cL 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. Wait for 10 minutes
9. Flush the system
10. Turn the system off
11. Turn the system back on again
12. Fill the tank with 20cL of saline water
13. Wait for the solution to warm up
14. Launch a procedure with the same cartridge
15. Wait for 5 minutes
16. Flush the system

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Once the cleaning is completed, place all the items back in the station's storage case (see Fig.5).



Fig.5: Packaging of the BIOMODEX® EVIAS™ station and accessories

- | | | |
|------------------------------|----------------------|---------------------------|
| A FEMORAL ACCESS TUBE | B AORTIC ARCH | C INTRODUCTION PAD |
| D POWER SUPPLY | E INTRODUCER | F CONNECTOR |
| G BLOODSIM™ | H SHAKER | I CLEANING POWDER |
| J FLUSH TUBE | K USER GUIDE | L STATION |

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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