BIOMODEX® LAACS™

Left Atrial Appendage Closure 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® LAACS™ has been designed for training and its safety and effectiveness as a medical device has not been demonstrated.

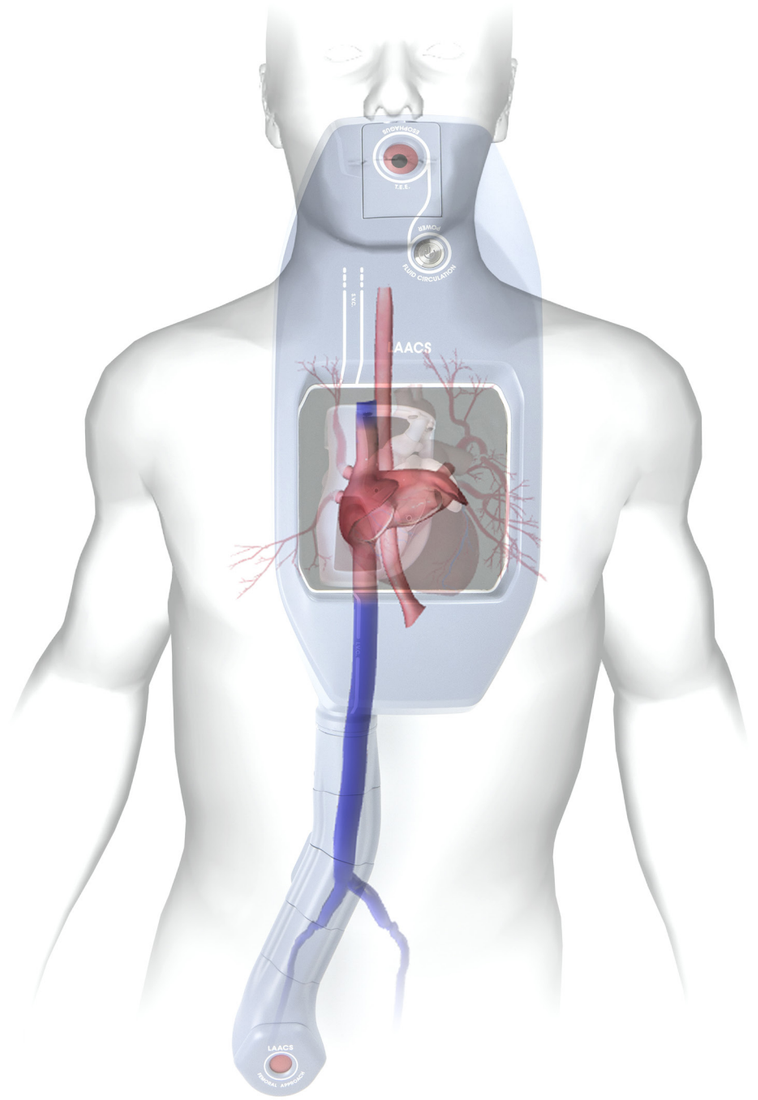

Fig.1: BIOMODEX® LAACS™ Station overayed on patient anatomy

I. INTENDED USE

BIOMODEX® LAACS™ (Left Atrial Appendage Closure System) is a laboratory instrument used for physician education, training, and rehearsal.

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II. PRODUCT DESCRIPTION

BIOMODEX® LAACS™ (Station, accessories and Cartridge) has been designed to simulate specific cardiac anatomies for LAA closure procedures. It is intended to be used in non-sterile laboratory environment.

Fig.2: BIOMODEX® LAACS™ Station set-up

Station

Fig.3: BIOMODEX® LAACS™ Station

Accessories

Fig.4: BIOMODEX® LAACS™ accessories

A FEMORAL APPROACH **B POWER SUPPLY** **C TANK FILLING BAG** **D FLUSH BOX**

E TANK FLUSH BAG **F FEMORAL MEMBRANES** **G CLEANING POWDER**

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A FEMORAL APPROACH: simulates the vena cava pathway from the femoral puncture to the entrance of the right atrium.

B POWER SUPPLY: 12V dc, 3.34A, Mean Well GSM40A12-P1J. Several power chords available for different countries.

C TANK FILLING BAG: aids in pouring tap water into the tank. Volume: 4 liters.

D FLUSH BOX: flushes the liquid out of the tank.

E TANK FLUSH BAG: aids in collecting the liquid from the tank during flushing, when used with Flush Box. Volume: 4 liters.

F FEMORAL MEMBRANES: simulates femoral puncture. Includes three (3) spare membranes.

G CLEANING POWDER: used to clean the Station. Includes two (2) containers of cleaning powder.

All the accessories listed above are provided with the System. Cleaning powder and the puncture membranes are reordered as needed.

Cartridge

Single use 3D printed anatomical twin extracted from images depicting specific cardiac anatomies for LAA closure. The Cartridges are ordered separately.

Fig.5: BIOMODEX® LAACS™ Cartridge

III. WARNINGS & PRECAUTIONS

- Read, follow, and retain User Guide.
- Use the product only in accordance with its intended use (p.4).
- 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, contact BIOMODEX® for further instructions.
- Do not use any parts other than BIOMODEX® LAACS™ components as damage to the Station, Cartridge, or substandard performance could occur.
- Do not operate BIOMODEX® LAACS™ without the use of protective gloves.

Station & Accessories

- To avoid the risk of electrical shock, 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 water and contrast may lead to damage of the System.
- Do not attempt to change the Femoral Membrane when the System is filled.
- Do not attempt to unscrew the Femoral Approach when the System is filled.
- Be careful when connecting the Tank Flush Bag at the tip of the flush tube when flushing. Make sure the Tank Flush Bag ziplock is closed.
- Repair and/or modification to the BIOMODEX® LAACS™ 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 System in the storage case, when not in use.

Cartridge

- The Cartridge is for single use only.
- Ensure that the Cartridge is properly positioned in Station's tank.
- System is to be used by trained personnel only.
- Insertion of other devices not intended for the treatment of the treatment of LAA closure may lead to the damaging of the Cartridge.
- Ensure air bubbles are purged from the Cartridge prior to use.
- Do not attempt to change a Cartridge when the catheters are inside the System.
- Remove and discard Cartridges and accessories in accordance with local regulations for proper disposal.
- Store the cartridges in a dry, clean and safe place.

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IV. EQUIPMENT INSTALLATION & USE

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

Fig.6: Top view of the final set-up of BIOMODEX® LAACS™

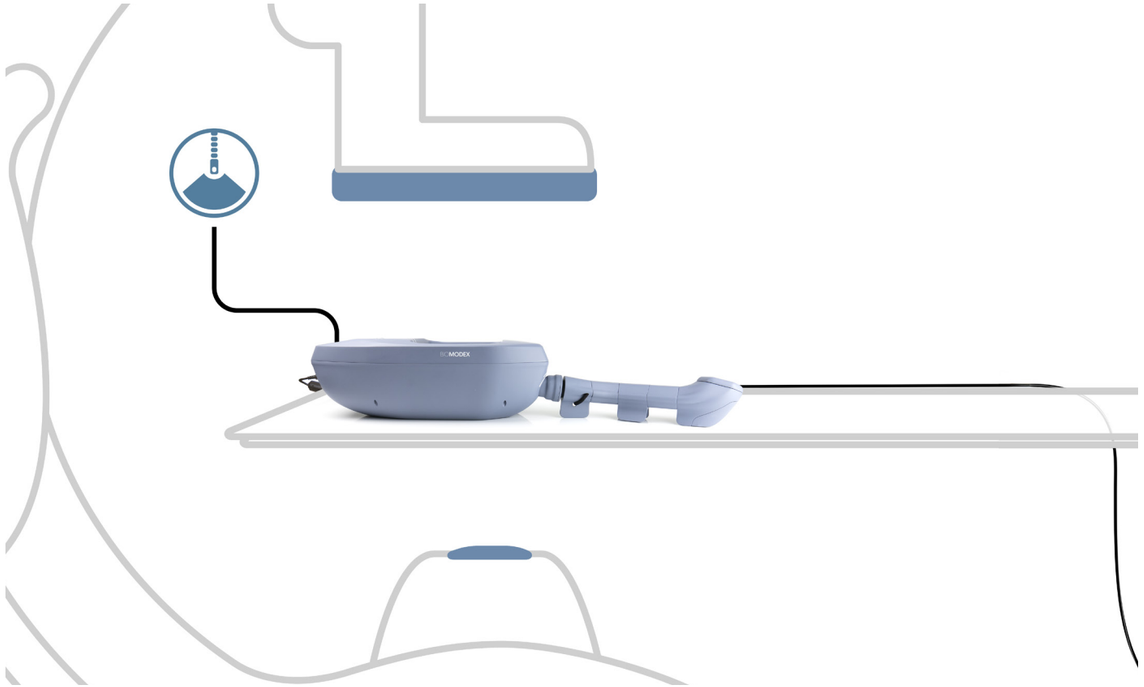


Fig.7: Side view of the final set-up of BIOMODEX® LAACS™

SET-UP

1 / Connect the femoral approach to the Station: rotate clock-wise and screw it tight to avoid leakage.

2 / Pour the water with the Tank Filling Bag into the Station until the water level reaches the white line.

3 / Plug the power supply into the Station.

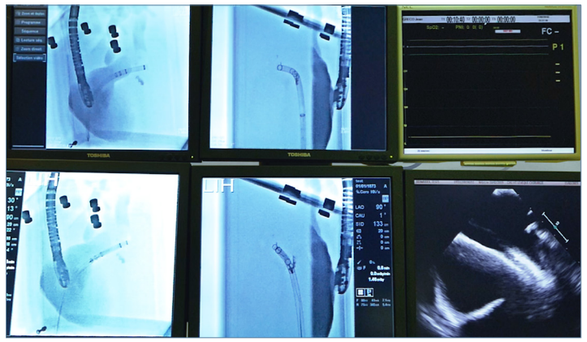
4 / Clear out all bubbles from the System by launching the Station.

5 / Position the Cartridge inside the Station's tank. Verify no air bubbles exist.

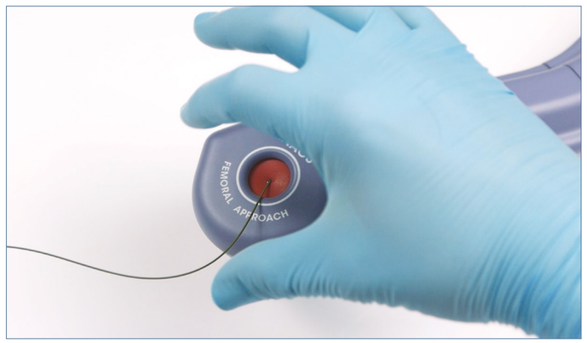
6 / Clear out bubbles from the LAA by squeezing it gently. Relaunch the Station to clear out bubbles if needed.

PROCEDURE

7 / Insert the TEE probe into the simulated esophagus. See TEE instructions p.12.

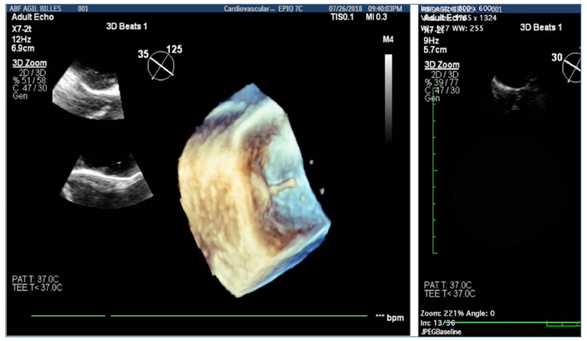


8 / Follow the intervention through the use of the monitors.

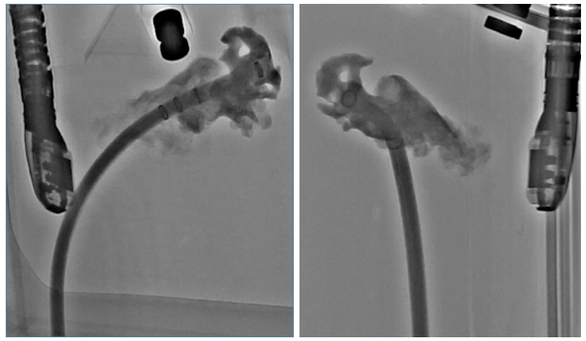


9 / Insert guidewires through the pre-punctured Femoral Membrane using the black spot as a positioning target.

10 / Insert all catheters through the simulated vena cava. If needed, use an introducer to reduce friction (recommend using 18F - 30cm/11.8").



11 / Procedure steps (tenting, transseptal puncture and device deployment) are visible in 2D & 3D imaging.



12 / BIOMODEX® LAACS™ System is contrast agent compatible.

TEE PROBE INSTRUCTIONS

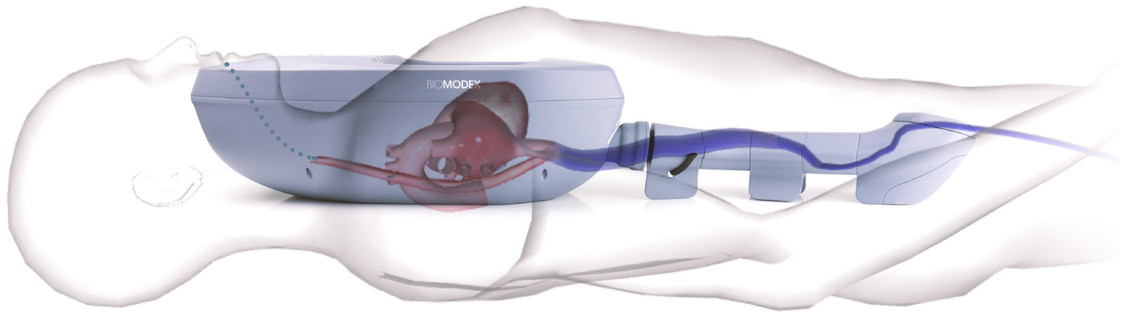
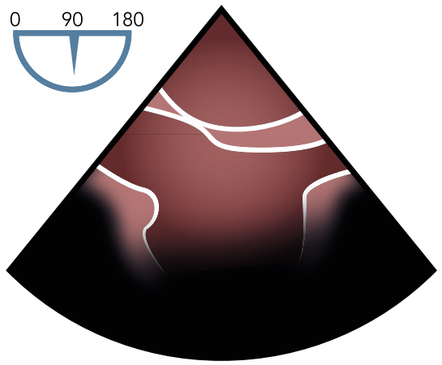


Fig.8: BIOMODEX® LAACS™ Station overayed on patient esophagus & vena cava

a / Set the TEE angle around 45°. Insert the TEE in the Station and stop when the aortic root is visible: around the scale 3 (+/-1).



b / Set the TEE angle around 90°.
Turn the probe counter-clockwise to visualize the septum in the bicaval view. Check the position of the catheter in the right atrium. This view helps the cardiologist to position the catheter in the fossa ovalis when retrieving or positioning along the septum.

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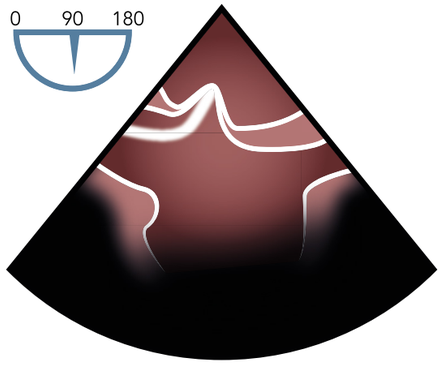
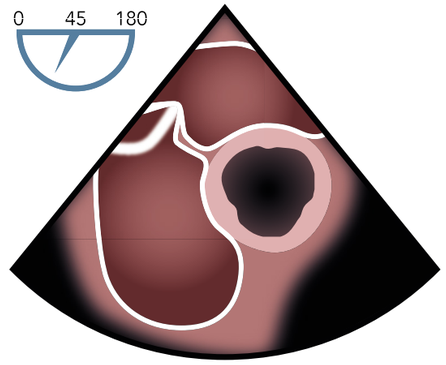
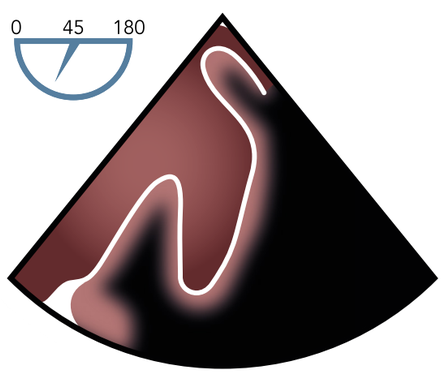


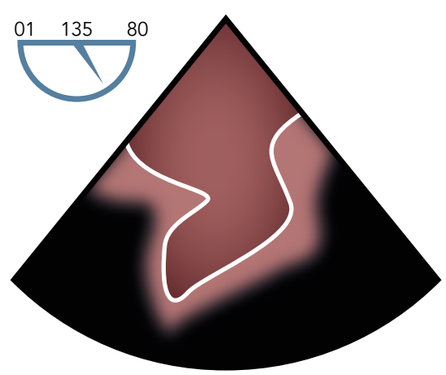
c / Stay in the bicaval view, around 90°.
Once in the fossa ovalis, the cardiologist depicts the catheter position by performing a tenting. Check the position of the catheter in the fossa ovalis. The bicaval view helps to evaluate the height of the puncture area.



d / Set the TEE at an angle around 45°.
Turn the probe clockwise to visualize the aortic root and the septum in the short axis view. Verify the tenting is not too close to the aorta. If the tenting is too close to the aorta, the cardiologist will have to turn the catheter clockwise to create additional distance from the aorta.



e / Stay at an angle around 45°.
Turn the probe clockwise to visualize the LAA. Once you can see it properly, switch to a biplane view (if a 3D probe is used), set the second view to an angle around 135° in order to see the entire LAA. Check the position of the catheter in the LAA.



TEAR DOWN & FLUSH

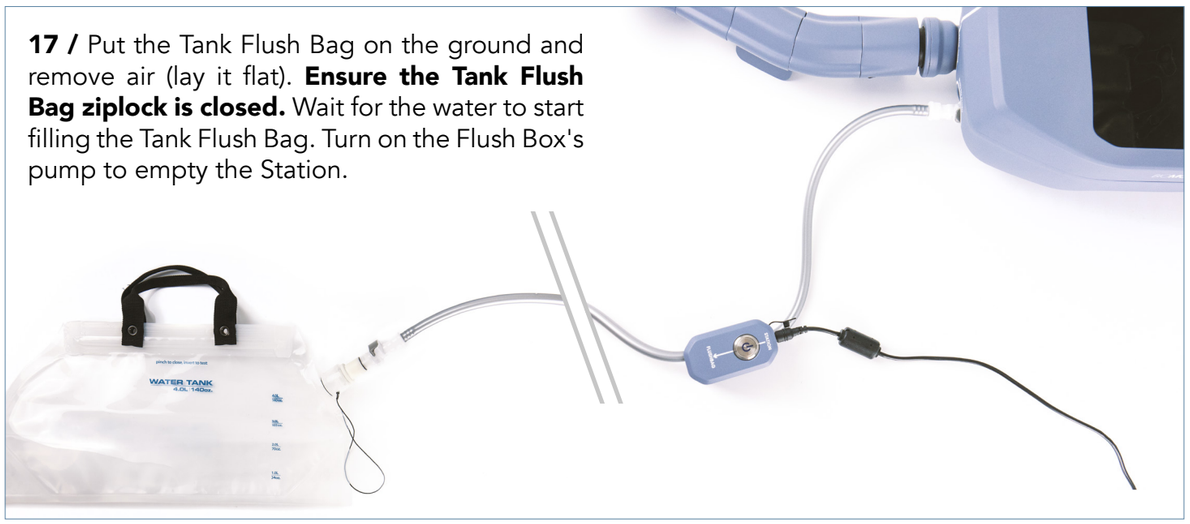
13 / Plug the Flush Box on the Tank Flush Bag.

14 / Plug the Tank Flush Box on the Station.

15 / Unplug the Power Supply...

16 / ...And plug it into the Flush Box.

17 / Put the Tank Flush Bag on the ground and remove air (lay it flat). **Ensure the Tank Flush Bag ziplock is closed.** Wait for the water to start filling the Tank Flush Bag. Turn on the Flush Box's pump to empty the Station.



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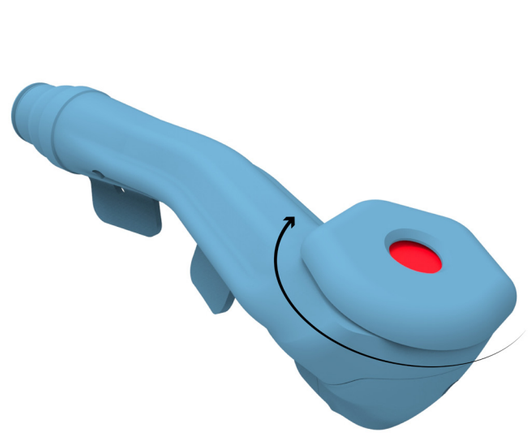
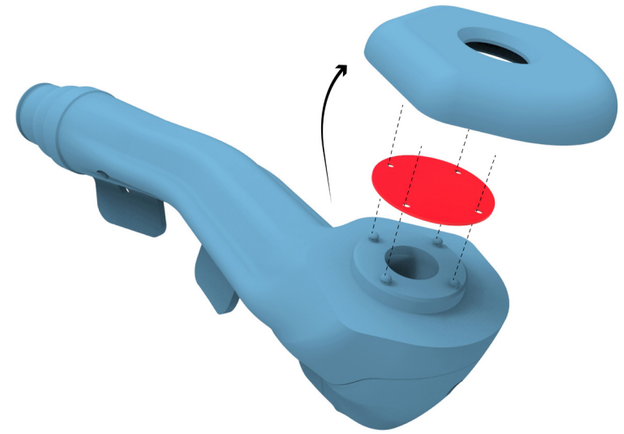
REPLACEMENT OF THE FEMORAL MEMBRANE



When the Station is empty, turn the top of the femoral approach and lift it.



Replace the femoral membrane. Ensure the holes are aligned with the femoral approach.

Be careful when opening / closing: magnetic contacts could result in fingers being pinched by the rapid closure of the cover.

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 7 days, perform the cleaning process before the use of the Station.

1. Make sure all the accessories are connected
2. Fill the tank of the Station with tap water until it reaches the white line
3. Launch the System by pressing the on button
4. Pour the two containers of cleaning powder directly into the tank
5. Wait for 10 minutes (the fluid circulation will mix the solution)
6. Turn off and flush the System
7. For rinsing the System, pour tap water into the tank until it reaches the white line
8. Launch the System and wait for 5 minutes
9. Turn off and flush the System
10. Dry the System of residual water

Once the cleaning and drying is completed, place all the items back into the Station's storage case (see *Fig.9*).

Fig.9: Packaging of the BIOMODEX® LAACS™ Station and accessories

A FEMORAL APPROACH
B POWER SUPPLY
C TANK FILLING BAG
D FLUSH BOX
E TANK FLUSH BAG
F FEMORAL MEMBRANES
G CLEANING POWDER
G 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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