DESCRIPTION

The ANGIOPULSE device is an electromechanical system used for the inflation and deflation of an intra-aortic balloon for weaning from conventional pumping. It provides temporary support to the left ventricle based on the principle of pumping. The intra-aortic balloon pump is placed in the descending aorta, distal to the left subclavian artery. Once the balloon is put in place, the device is set to improve the patient's cardiac output through pulsatile activity of the balloon. Balloon inflation values along with others related to the process can be changed based on the operator's specific criteria to achieve optimal relative support for each patient.

ANGIOPULSE LIFETIME:

- 10 years

PRINCIPAL FEATURES

- Passive counterpulsation
- Cardiac functions recovery but no additional heart work
- Suitable for patients with arrhythmias or with atrial fibrillations
- Unique patented technology
- No synchronization constraint
- Effective weaning
- Compatibility and user-friendliness
- No pumping rumors

Rev. 00 – 10/11/2023

Angiodroid SpA
Via Speranza 35 - 40068 San Lazzaro di Savena (BO) Italy
Tel/fax+39 051 0261383

INTENDED USE: The Angiopulse device is an aortic counterpulsator console that allows the inflation of an intra-aortic balloon for assisting ventricular pulsatility. Its use is intended for the weaning phase from conventional counterpulsator consoles.

- Intended Users→ The device must only be used by medical personnel, with specialisation in the field of interventional cardiology and intensive care, authorised and prepared for its use.
- Intended Population→ The device is indicated for patients who have already undergone pumping via conventional consoles and is not intended for Paediatric patients.
- Intended Use Environment→ Angiopulse is intended for use in hospitals, clinics and other medical facilities where power is supplied via a MV/LV cubicle. The device is intended for use in a covered and protected place with medical care near the patient. Ambient temperature between + 5ºC and + 35ºC. Relative humidity between 30% and 75%. Pressure range: 700 hPa – 1060 hPa

CONNECTING DEVICE:

ANGIOPULSE is designed to be connected to an aortic catheter by means of a specific extension tube. The extension tube allows the passage of helium for inflating the balloon installed at the end of the aortic catheter.

The counterpulsation catheter with its extension tube is not supplied by Angiodroid SpA and is issued by external medical companies in accordance with the applicable certification standards.

CONTRAINDICATIONS TO USE OF ANGIOPULSE:

Care using the ANGIOPULSE device is not indicated for patients who have not already undergone pumping via conventional consoles and is not intended for patients with:

- Severe aortic regurgitation
- Aortic dissection
- Aortic aneurysm
- Severe aortic calcification or peripheral vascular disease
- Paediatric patients.

PRECAUTIONS TO BE TAKEN IN THE CONTEXT OF USING AN INTRA-AORTIC BALLOON PUMP:

• Follow the intra-aortic balloon pump catheter documentation during the percutaneous access balloon insertion procedures.

• Only connect intra-aortic balloon pump catheters to the ANGIOPULSE device.

• Only connect the outlet of the intra-aortic balloon pump connected to the relative extension to the ANGIOPULSE device, without interposing other devices unless specified in this manual or in the intra-aortic balloon pump instructions.

• After initiating the support, constantly monitor the patient's clinical status and check for blood in the catheter or the extension line if a possible balloon rupture is suspected.

• If the device warns of a possible leak in the external circuit, check the connection of the catheter extension to the device and all the connectors used up to the catheter.

• If the device emits a warning message, specifically follow the instructions in order to solve the problem detected.

• If blood is detected within the intra-aortic balloon pump catheter or the extension line, discontinue the pumping procedure and contact a doctor.

• Extended standby time and thrombus formation on the balloon membrane: if the device is inadvertently placed in a STANDBY state, the time elapsed in this state will be displayed on the right side of the main panel screen, above the graph. An informational message will be displayed after 10 minutes. Check if support is to be restored. If yes, press the START key to resume pumping.

• Power failure - if power to the ANGIOPULSE equipment is inadvertently interrupted and in particular if the catheter was already connected to the machine, the catheter must be disconnected and the parameter selection and loading phase repeated. After the power has been restored, the device automatically performs a circuit flushing phase.

Rev. 00 – 10/11/2023

WARNINGS

- Any transmission with mobile radio equipment must be avoided and cell phones must be switched off.

- Internal electrocution hazard – Angiopulse does not contain any components that can be serviced by the operator. Do not remove the device covers. Do not open the unit there are no usable parts and there are dangerous voltages inside.

- Before connecting the unit to the mains, make sure that the socket has a protective earth and that the network will maintain the correct supply voltage as indicated on the characteristics label.

- The balloon should not remain inactive (i.e., without inflating or deflating) within the patient for more than 30 minutes, due to the potential for thrombus formation. Angiopulse should only be used in accordance with the safety instructions contained in its User Manual and should not be used for any other purpose except as intended.
- Do not use the device while a Nuclear magnetic resonance (NMR) is being performed or in the vicinity of a related device.
- As any active device, Angiopulse must be used appropriately with periodic checks and maintenance. Perform routine maintenance periodically as indicated by the manufacturer.
- Periodically clean the equipment following manufacturer instruction.
- Products used for cleaning and disinfection, including those used for patients, could create gaseous and explosive mixtures. For this reason, it is recommended using only products in accordance with the rules applied.

- This equipment is not suitable for use in the presence of ANAESTHETIC MIXTURES THAT ARE FLAMMABLE IN AIR, OXYGEN OR NITROUS OXIDE.
- Connect the ANGIOPULSE device to a power outlet behind the uninterruptible power supply to prevent the equipment from locking during the circuit flushing phase.
- Do not connect the machine to multiple mains sockets, but only to a suitable ground terminal power socket that is part of an electrical system that complies with the regulations in force.
- It is advisable not to use the device in contact with other equipment. If contact with other equipment cannot be avoided, verify normal operation of the device in the location in which it will be used.
- Isolation from the mains is done by disconnecting the detachable plug. Do not position the appliance in a way that makes it difficult to disconnect the detachable plug.
- After positioning the system, apply the parking brakes.
- Do not tip the appliance upside down.
- Use only the handles provided to move the unit and avoid collisions with obstacles.
- The floor on which the device may be placed must ensure a capacity of 400Kg/m^3.

STORAGE AND TRANSPORT CONDITIONS:

- Ambient temperature between -5 °C and +50 °C

- Keep dry

- Pressure range: 700 hPa - 1060 hPa