CE 2409

PulseCath iVAC®

Instructions for Use

		Page
EN	Instructions for use	2
NL	Gebruiksaanwijzing	9
DE	Bedienungsanleitung	16
FR	Mode d'emploi	23
IT	Istruzioni per l'uso	30
ES	Instrucciones de uso	37
CZ	Návod k použití	44
GR	Οδηγίες χρήσης	50
PL	Instrukcja stosowania	58
RU	Руководство по использованию	65
SK	Pokyny pre používanie	74
SE	Bruksanvisning	80
TR	Kullanma talimatları	87

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17pirkimo dalis Širdies kairiojo skilvelio pavaduojančio prietaiso kateteris.

CE 2409

Instructions for use

PULSECATH iVAC2L®

STERILE: all contents are sterile. **For single use only**. Do not re-sterilize!

Contents:
- LV17 catheter with insertion set
- Membrane pump
- Catheter protector
- Extra PTFE Catheter inner tube
- Introducer Sheath

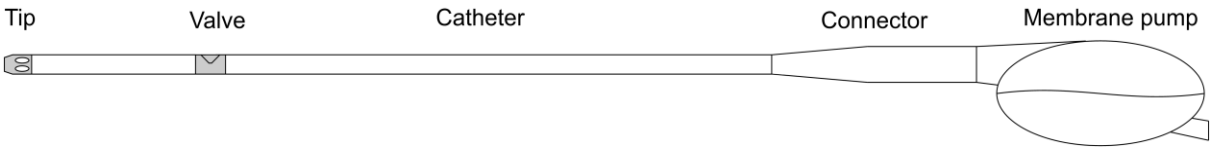

Figure 1: the iVAC2L®, sizes and diameters are indicated on the product labels.

Device description

Kateteris ; esant širdies susitraukimų dažniui nuo 60 iki 120 k./min., veikiantis kateteris padidina širdies minutinį tūrį 1,0 - 1,5 l/min.

The iVAC is designed to provide circulatory support to patients with impaired left ventricular function.

At heart rates from 60 to 120 beats per minute, the circulatory support provided by the iVAC2L is 1.0 – 1.5 L/min. The iVAC functions in combination with an Intra Aortic Balloon Pump (IABP) driver.

Indication

Kateteris skirtas mechaniškai iki 24 valandų palaikyti ir pagerinti kairiojo širdies silvelio cirkuliacinę funkciją, esant jos sutrikimui; skirtas įvedimui į kairįjį skilvelį per šlaunies arteriją

The iVAC is intended for use in patients with impaired left ventricular function which require left ventricular mechanical circulatory support for up to 24 hr.

The iVAC2L Tip should be positioned in the left ventricular cavity through the femoral artery.

Contra indications

- Aortic disease: ascending aortic aneurism, severe aortic wall calcifications
- Aortic valve disease: aortic valve stenosis, aortic valve insufficiency
- Aortic valve prosthesis
- Femoral artery stenosis
- Aneurism of the aorta
- Thrombus in left ventricle
- No residual function of left ventricle
- “Right ventricular failure”

Warnings

- Read these instructions carefully before use.
- These instructions describe the use of the iVAC in combination with IABP drivers (Datascope 98XT, CS100 and CS300 IABP driver, Arrow Acat 1 and AutoCat2wave). This manual does not replace the IABP driver’s manual.
- Be sure that all relevant personnel is adequately trained in using the iVAC and the IABP driver.
- Do not reintroduce the insertion set once removed from the catheter.
- Do not leave the device dormant for extended periods of time in order to prevent formation of thrombi.
- In case of problems please contact the manufacturer.
- The iVAC is for single use only. Do not Reuse or re-sterilize! Reuse or re-sterilization will compromise the mechanical properties of the device which may lead to device failure. As a result, the patient might be injured or die. Reuse or re-sterilization will also create a risk of contamination of the device. Contamination may cause patient infection, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

- The iVAC is permitted for use up to 24 hours. There is lack of clinical data to support the application of the iVAC beyond this time point.
- The iVAC functions are sub-optimal at heart rates lower than 60 bpm or higher than 120 bpm.
- Use of the internal triggering mode will decrease the functioning of the iVAC.
- The iVAC is not suitable for mobile use.
- Patients should be kept sedated during use.
- Make sure the femoral artery diameter is sufficiently large prior to insertion.
- Do not use alcohol containing detergents to clean or disinfect the device prior to removal, as these might damage the device which could lead to leakage of parts of the device.
- Do not use tie-wraps to fasten the connection between the catheter and the membrane pump, as tie-wraps can cause leakage of the connection.
- Beware of needle sticks into the catheter: a puncture of the catheter will immediately cause aspiration of air into the device, resulting in the air being ejected in the aorta of the patient. The IABP driver should be switched off immediately when a problem is suspected.
- For Datascope IABP driver, “IAB” in help screens should be read as “iVAC”.
- Make sure the IAB catheter extender (driveline) remains connected to the IABP driver and the membrane pump. Also make sure the IAB catheter extender is not kinked or compressed. A loose connection or kink will stop the pumping action of the iVAC.
- It is recommended to flush both ports of the LV17 catheter with insertion set every 5 minutes with heparinized saline after insertion, as long as the insertion set has not been taken out. Make sure the insertion set is fully de-aired before flushing.

Accordingly, PulseCath will not be responsible for any direct, incidental or consequential damages or expenses resulting from use by untrained personnel or reuse of the product.

Precautions

- Store in a dry, dark and cool place.
- Do not use open or damaged packages.
- Use prior to the ‘Use by’ date.
- Use a pigtail catheter and corresponding guide wire to introduce the iVAC.
- The product has been tested and qualified with accessories (see necessary equipment and disposables). The use of any other accessory could result in complications and/or malfunction of the iVAC.
- Do not leave the patient unattended during use of the iVAC.
- To prevent thrombosis and product malfunction the patient coagulation has to be suppressed continuously. An ACT of 200 seconds minimum is recommended. Anticoagulation should be monitored regularly.
- Arterial pressure and ECG activity should be monitored continuously during iVAC use.
- Oxygen saturation of the leg should be monitored.
- The iVAC performance is optimal at 1:1 frequency. At 1:2 frequency the performance decreases with 50% and at 1:4 frequency with 75%.
- Keep the mean blood pressure above 60 mmHg in order to obtain optimal circulatory support.
- At any sign of improper positioning of the iVAC (i.e. bad filling, sharp peaks in pressure graph) verify correct position of the catheter by transesophageal echo (TEE) or X-ray.
- If severe difficulty or strong resistance is met during any stage of the procedure, discontinue the procedure and determine the cause before proceeding.
- When using an Arrow ACAT1 or AutoCat2Wave IABP driver the option to permanently disable the Gas Alarms needs to be enabled by the Distributor of these devices.

Complications

Invasive procedures should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during the procedure. Possible complications include, but are not limited to the following:

- Ischemia of the leg due to obstruction of the femoral artery.
- Vascular damage to the femoral artery or aorta.
- Perforation.
- Thrombosis at the insertion site.
- Thrombosis when the iVAC is stopped for a longer period of time.
- CVA.

- Thrombus formation.
- Injury of the aortic valve.
- Potential induction of mitral valve incompetence.
- Infection.
- Damage of blood cells.

Kateteris įvedamas į šlaunies arteriją per 18F ar didesnio storio introdiuserį; komplektuojamas kartu su reikiamo dydžio introdiuseriu.

Necessary equipment and disposables

- IABP driver.
- Introducer Sheath, with inside diameter 18 Fr minimum.
- Guide wire: 0.035" or 0.038", length 260 cm (Super Stiff) and corresponding needle.
- Heparinized saline (2500 IU heparin in 500 mL saline).
- "IAB catheter extender" (Datascope, ref. 0684-00-0186).
- When using an Arrow ACAT1 or AutoCat2Wave IABP driver: Arrow 50 cc IAB connector. This connector replaces the male lure lock of the "IAB catheter extender".

Kteteris veikia, pajungtas prie intraaortinės balioninės kontrapulsacijos aparato AutoCat2wave

Preparation of the patient

Additionally to normal clinical proceedings it should be assured that:

- The patient is sufficiently heparinized, an ACT of 200 seconds minimum is recommended during use of the iVAC.
- Arterial pressure and ECG are monitored continuously.
- Arterial pressure and ECG signals are connected to the IABP driver.
- The diameter of the entry artery is measured to determine whether it is sufficiently larger than the iVAC catheter diameter.
- Oxygen saturation of the leg is monitored as a control on peripheral perfusion.

Preparation of the iVAC

- Open the pouches in such a way that the devices remain sterile.
- Exchange the Catheter inner tube with the extra inner tube available in the box by pulling out the existing inner tube and inserting the new PTFE inner tube carefully up to Catheter tip.
- Flush the inner lumen of the catheter and the inner lumen of the insertion set with heparinized saline through the sideline extending from the plug at the proximal end of the catheter and the sideline of the hemostasis valve at the proximal end of the insertion set.
- Make sure that all stopcocks are in the open position to let escape the air during insertion.
- De-air the membrane pump by filling it with heparinized saline and remove all air-bubbles by shaking and by ticking against its housing.

Preparation of the IABP driver

- Switch on the IABP driver and open the helium gas bottle.
- For Datascope IABP drivers: make sure an Adult safety disc is used.
- For Arrow IABP drivers: make sure an Arrow 50 cc connector is present.

As the iVAC has a different resistance than an IAB, additional actions, depending on the type of IABP driver should be taken:

Datascope 98XT IABP driver:

1. Set Trigger Select on ECG or AP.
2. Disable the Augmentation Alarm.
3. When the iVAC is connected: press IAB Fill button (press 2 seconds).
4. Let IABP driver fill the membrane pump.
5. Set IAB Fill mode at Manual Fill. The Slow Gas Loss Alarm is now disabled.
6. Disable the R-trac option.
7. Start the IABP driver at 1:2 frequency with maximum augmentation and observe the movements of the membrane of the Membrane pump.
8. When the membrane is moving smoothly and the timing is correct, set the frequency at 1:1 for maximum performance.
9. In case it is necessary to use internal triggering: remove the ECG cable from the IABP driver. Replace the ECG cable when returning to the ECG or AP triggering mode.

Datascope CS100 and CS300 IABP driver:

1. Set Operation mode on Semi-Automatic.
2. Set Trigger Source at ECG or AP.
3. Disable the Augmentation Alarm.
4. Disable the R-trac option.
5. When the iVAC is connected: press the Start button.
6. Let the IABP driver fill the membrane pump.
7. Start the IABP driver at 1:2 frequency with maximum augmentation and observe the movements of the membrane of the membrane pump.
8. When the membrane is moving smoothly and the timing is correct, set the frequency at 1:1 for maximum performance.
9. In case it is necessary to use internal triggering: remove the ECG cable from the IABP driver. Replace the ECG cable when returning to the ECG or AP triggering mode.
10. In case of repeating alarms: set Operation mode on Semi-Automatic; Press IAB Fill button (press 2 seconds); Let the IABP driver fill the Membrane pump.
11. Then Set the IABP Fill mode at Manual Fill: Press the Pump options button, scroll through menu and set the Fill mode to manual. The Slow Gas Loss Alarm is now disabled; Press the Start button.

Kteteris veikia, pajungtas prie intraaortinės balioninės kontrapulsacijos aparato AutoCat2wave

Arrow ACAT1 / AutoCat2Wave IABP driver:

1. Set the driver in Operator Mode (for AutoCat2Wave driver only).
2. Set the Trigger mode at Pattern, Peak or AP.
3. Set Alarms Permanent Off: press the Alarms button, press Permanent Off and confirm. The Gas Loss alarms are now disabled. The option of permanent disabling the Alarms needs to be enabled by the Arrow distributor.
4. Cut the male luer lock of the “IAB catheter extender” and replace it by an Arrow 50 cc connector. See the Arrow manual for further information on changing the connector.
5. When the iVAC is connected: start the IABP driver at an 1:2 frequency and observe the movements of the membrane of the Membrane pump.
6. When the membrane is moving smoothly and the timing is correct, set the frequency at 1:1.
7. To restart pumping after a stop: press the Reset button twice and then press the Start button.

Introduction procedure

Introduction of the iVAC into the femoral artery can be performed via an 18 Fr introducer sheath, and using a guide wire to guide the catheter through the aortic valve into the left ventricle. To determine the correct position of the iVAC (tip in left ventricle and valve in aorta) it is strongly recommended to use X-ray or TEE imaging.

The arrow on the Connector of the iVAC catheter indicates the position of the opening of the valve of the iVAC.

1. Prepare the entrance site in the femoral artery according to the hospital standard procedure.
2. Introduce the introducer sheath in the entrance site according to the instruction for use of the sheath.
3. Forward the guide wire into the femoral artery until the tip is in the left ventricle (TEE or X-ray control).
4. Insert the proximal end of the guide wire into the tip of the iVAC catheter, so that the proximal end of the guide wire extends out of the proximal end of the iVAC catheter.
5. Close the haemostasis valve of the iVAC catheter by rotating the cap until there is no bleeding. Leave freedom to move the iVAC catheter over the guide wire.
6. Guide the iVAC catheter over the guide wire into the insertion sheath in the femoral artery.
7. Forward the catheter and de-air the catheter using the sideline extending from the plug at the proximal end.
8. Carefully guide the tip of the iVAC catheter into the ventricle.
9. Inspect the position of the iVAC catheter tip by TEE or X-ray.
10. Fixate the iVAC catheter by fixating the purse string sutures firmly around the catheter protector.
11. When the position is correct, remove the guide wire.
12. Pull back the iVAC Catheter inner tube until the tip of the tube is in the plug at the proximal end of the iVAC catheter.

13. Place a Tube Clamp in the middle of the Connector of the iVAC catheter.
14. Remove the plug with the iVAC Catheter inner tube.
15. Fill the iVAC catheter Connector, and the membrane pump, completely with heparinized saline and connect them while continuously adding heparinized saline to prevent air-entrapment.
16. Remove the Tube Clamp and make sure (visually) that there are no air bubbles in the membrane pump.
17. In case of air bubbles in the membrane pump, go back to step 13 and disconnect the membrane pump. De-air the membrane as mentioned at “preparation of the iVAC” chapter and return to step 15.
18. Connect the “IAB catheter extender” with the driveline of the membrane pump.
19. Connect the “IAB catheter extender” with the IABP driver.
20. Start pumping at 1:2 frequency with maximal augmentation, see “Preparation of the IABP driver”.
21. Adjust timing, see “Operating the IABP driver”.
22. When the membrane of the Membrane pump is moving smoothly and the timing is correct: set the frequency at 1:1.

Operating the IABP driver

The control of the IABP driver with the iVAC is similar to the control of the IAB. ECG signal and Aortic Pressure (AP) signal should be connected to the IABP driver. See IABP driver manual for further instructions on handling the driver.

The IABP driver should be set at ECG triggering or at AP triggering. The Internal triggering mode should only be used in case of a very irregular heart rate or at very high heart beat rates.

The iVAC should eject during diastole and aspire during systole. The timing should be set in such a way that the inflation may come as soon as the slope of AP curve is decreasing, just prior to the diacritic notch. The deflation should be set prior to the systole of the heart. Correct timing should be determined by the shape of the AP curvature.

Smooth movement of the membrane pump indicates unrestricted blood inflow. Disturbed membrane movement or membrane pump vibration during aspiration shows restricted blood inflow. This can be solved by gently pulling the iVAC catheter backwards. Always check if the tip of the catheter is still in the ventricle.

The “ticking” of the iVAC valve is audible. One “tick” per beat indicates unrestricted functioning of the iVAC. A series of ticks per beat indicates restricted movements. This can be solved by rotating the iVAC catheter.

The shape of the “Balloon Pressure Waveform” gives an indication of correct functioning (Fig 2). A round shape of the pressure peaks indicate correct functioning. Sharp peaks indicate an inflow obstruction, an incorrect position, or bad timing.

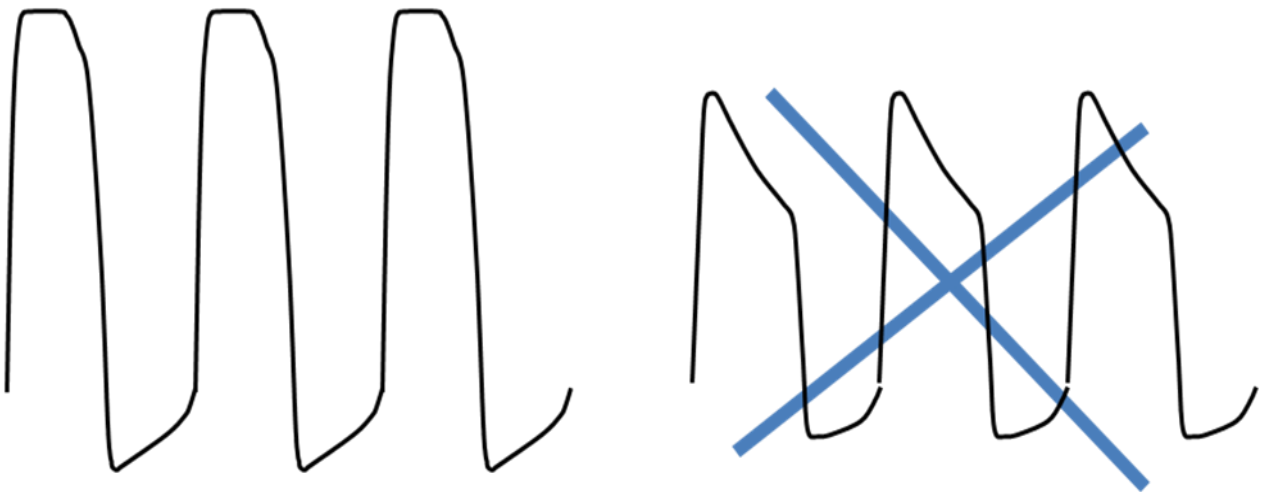

Figure 2: Balloon pressure waveform. Left: correct (round) peaks; Right: incorrect (sharp) peaks.

Explanation procedure

During explanation of the iVAC the patient should be sedated. All necessary steps should be undertaken to prevent infection.

When using disinfectants, do not use alcohol based disinfectants as these can damage the device.

1. Wean the patient by setting the frequency to 1:2 and to 1:4 for a period of time depending on the condition of the patient.
2. Stop the IABP driver.
3. Place a Tube Clamp on the Connector and disconnect the membrane pump.
4. Pull the iVAC backwards. Pull gently, do not put any force on the catheter. Make sure the catheter was removed completely.
5. Close the artery and close the wound.

NOTE: Dispose contaminated products and packaging materials utilizing standard hospital procedures and universal precautions for bio-hazardous waste.

	=	Refer to accompanying instructions for use.
	=	Use by
REF	=	Catalogue number
	=	For single use only
	=	Lot number
	=	Do not re sterilize
	=	Sterile product
	=	Sterilized by ethylene oxide
	=	Sterilized by gamma radiation
	=	Do not use if package is opened or damaged
	=	Keep away from sunlight
	=	Keep dry
	=	25°C upper limit storage temperature, 0°C lower limit storage temperature. Transient distribution temperatures may exceed these limits.

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