Instructions for Use

PRIME™

Aortic Root Cannula

Description:

PRIME™ Aortic Root Cannulas are composed of the tip, introducer needle, PVC body, female luer adapter, and needle handle. They are available in 2 forms, with or without a Vent line. The model with vent line has an additional tube for venting and the model without vent line has an additional three-way valve. The cannula inlet fitting is a female luer and the vent port fitting is a slip-on connector for 6.0mm (1/4in) ID tubing. The introducer needle is packaged within the cannula body

Indications for Use:

Aortic Root Cannulas are intended for use during cardiopulmonary bypass surgery for delivering cardioplegia solutions and venting of the left heart for up to 6 hours. The cannula may be used to aspirate air from the aorta at the conclusion of the bypass procedure.

Contraindications:

- The device is to be used only as indicated

Warnings and Precautions:

1. Please read all packaging insert warnings, precautions, and instructions before use. Failure to do so may result in severe patient injury or death.
2. Warning: Sterile by EO, Single Use: Do not reuse, reprocess or re-sterilize under any circumstance.
3. Warning: Do not use if the packaging is damaged or opened unintentionally before use. This will lead to loss of sterility.
4. Warning: Rx Only. The device must be used by trained physicians only
5. Precaution: Aseptic techniques must be used wherever possible, especially during removal from packaging.
6. Warning: If the introducer needle is removed from the cannula BEFORE placement into the aorta, use caution when reinserting the introducer to prevent cutting or gouging the inner surface of the cannula or tip.
7. Warning: DO NOT reinsert the introducer needle into the cannula once removed after placement into the aorta.
8. Warning: Utilization of this cannula in conjunction with aortic cross-clamping for perfusion of the coronary arteries may not result in adequate perfusion of the heart if the aortic valve is incompetent or the coronary arteries have extensive disease and/or occlusions.
9. Precaution: When infusing cardioplegia solution use the lowest possible pressures consistent with the surgical techniques to minimize haemolysis, or damage to the vessels.

Instructions for Use:

<u>Aortic Root Cannula without Vent Line</u>

1. Remove the tubing that has been placed over the flexible tip as a protector and discard it.
2. Check the luer fitting connection by first holding the female luer adapter of the cannula and twisting the male luer of the needle assembly counterclockwise.
3. Withdraw the introducer from the cannula completely to ensure that the introducer can be withdrawn smoothly. Inspect the point on the introducer to ensure that the point has not been inadvertently bent or damaged. Carefully replace the introducer in the cannula, then twist the needle handle to insure the introducer in place. Do not overtighten.

Note: Use caution when reinserting introducer.

4. Place two purse string sutures using pledgets at the desired cannulation site. Draw the sutures through tourniquets.
5. Insert the cannula into the aorta in the centre of the area enclosed by the purse string suture with a rotating motion.

Caution: Cannula must be fully inserted with side holes or slots inside the aorta to avoid risk of false lumen within the aortic wall. During infusion of the cardioplegia solution, care should be taken to avoid manipulations of the heart and aorta that could displace the cannula.

6. Draw the suture ends through one of the slots in the flange. Place the pledget on top of the flange. Draw the tourniquets tight and clamp. Repeat with the other suture.
7. Tie the tourniquets to the cannula at a convenient site.
8. Remove the introducer by rotating the locking fitting and drawing the introducer smoothly out of the cannula. Clamp the cannula at a convenient point on the flexible tubing below the inlet fitting. Once retracted, DO NOT push the needle back into the cannula body. After the cannula fills with blood, clamp the cannula at a convenient point below the female luer adapter.
9. Connect the inlet fitting to the cardioplegia delivery circuit, taking the necessary precautions to adequately remove any entrapped air by back bleeding from the aortic root.
10. After the cardiopulmonary bypass procedure has been completed, withdraw the cannula completely and then tie the purse string suture(s)

<u>Aortic Root Cannula with Vent Line</u>

11. Remove the tubing that has been placed over the flexible tip as a protector and discard it.
12. Check the luer fitting connection by first holding the female luer adapter of the cannula and twisting the male luer of the needle assembly counterclockwise.
13. Withdraw the introducer from the cannula completely to ensure that the introducer can be withdrawn smoothly. Inspect the point on the introducer to ensure that the point has not been inadvertently bent or damaged. Carefully replace the introducer in the cannula, then re-engage the male luer and lock it into place by holding the female luer of the cannula and twisting the male luer of the needle assembly clockwise. Do not overtighten.

Note: Use caution when reinserting introducer.

14. Close the clamp on the vent line.
15. Place two purse string sutures using pledgets at the desired cannulation site. Draw the sutures through tourniquets.
16. Insert the cannula into the aorta in the centre of the area enclosed by the purse string suture with a rotating motion.

Caution: Cannula must be fully inserted with side holes or slots inside the aorta to avoid risk of false lumen within the aortic wall. During infusion of the cardioplegia solution, care should be taken to avoid manipulations of the heart and aorta that could displace the cannula.

17. Draw the suture ends through one of the slots in the flange. Place the pledget on top of the flange. Draw the tourniquets tight and clamp. Repeat with the other suture.
18. Tie the tourniquets to the cannula at a convenient site.
19. Open the clamp on the vent line and purge any air which may be entrapped between the tip and the clamp by back bleeding from the aorta. Close the clamp.
20. Remove the introducer by rotating the locking fitting and drawing the introducer smoothly out of the cannula. Clamp the cannula at a convenient point on the flexible tubing below the inlet fitting. Once retracted, DO NOT push the needle back into the cannula body. After the cannula fills with blood, clamp the cannula at a convenient point below the female luer adapter. Disconnect the needle assembly from the cannula.
21. Connect the inlet fitting to the cardioplegia delivery circuit, taking the necessary precautions to adequately remove any entrapped air by back bleeding from the aortic root.
22. Connect the outlet fitting on the vent line to the suction line from the heart-lung machine.

23. Cardioplegia solution should be administered only when the cannula (including the vent line up to the clamp) is completely free of air. Open the clamp on the inlet line with the vent line clamped to administer cardioplegia. If air remains in the cannula, the vent line should be opened and suction applied. The cardioplegia solution should be administered at a very slow rate causing any entrapped air to move down the cannula and then to be pulled into the vent.
24. After the aorta has been cross-clamped, venting can be initiated by opening the clamp on the vent line and closing the clamp on the inlet line.
25. After the cardiopulmonary bypass procedure has been completed, withdraw the cannula completely and then tie the purse string suture(s).

Disposal:

26. The device can be a biological hazard if disposed incorrectly. They should be disposed using recognised medical procedures and industry best practices. Local laws and regulations should be taken into account during disposal

Potential Complications / Adverse Effects

Aortic Root Cannulas are accessories used in extracorporeal circuits. This device, as with all extracorporeal blood system devices, has possible side effects which include, but are not limited to, infections, blood loss, thrombus formation, embolic events and dislocation. Vessel damage and complications at the puncture site may occur if the instructions for use are not followed.

Warranty and Limitations

Aortic Root Cannulas are sold in 'as is' condition. The entire risk as to the quality and performance of the product is with the buyer. ALSPL disclaims all warranties, expressed or implied, with respect to its products, including but not limited to, any implied warranty of merchantability or fitness for a particular purpose. ALSPL shall not be liable to any person for any medical expenses or any direct or consequential damages resulting from the use of any product or caused by any defect, failure, or malfunction of any product, whether a claim for such damages is based upon warranty, contract, tort, or otherwise. No person has any authority to bind ALSPL to any representation or warranty with respect to its products.

Symbols Glossary

	Caution, Consult Indications for Use
	Date of Manufacture
	Do not re-use
	Do not use if package is damaged
	Sterilized using ethylene oxide
	Keep away from sunlight
	Batch code
	Catalogue Number
	Manufacturer

	Use-by date
	Keep dry
	Temperature Limit

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