

## Instructions for Use

### PRIME™

### Venous Cannula

#### Description:

PRIME™ venous cannula is single stage cannula and is composed of a tip and a wire wound cannula body. The cannulas are available in 3 forms either with a straight plastic tip, an angled plastic tip or an angled metal tip. The tips of the three types of the venous cannulas have of multiple side ports for steady fluid flow. The cannula body is flexible wire wound body.

The plastic tip cannulas are formed as one single unit (body and tip), while for the metal tip cannulas, the tip is bonded to the cannula body. Overall length of the venous cannulas is 380mm to 400 mm. The venous cannulas include a connector in the package. The connector is to connect the proximal end of the venous return cannula to the tubing of extracorporeal circuit and is supplied with all three types of cannulas. The plastic tip cannulas also come with a locating ring, which is used to locate the depth of the tip into the body.

#### Indications for Use:

The cannula is intended for collection of venous blood from the right side of the heart via the superior or inferior vena cava during cardiopulmonary bypass surgery for up to six hours.

#### Contraindications:

1. The device is to be used only as indicated
2. This device is contraindicated for long-term use ( $\geq 6$  hours). Do not use for extended terms such as Ventricular Assist procedures.

#### Warnings:

1. Cannula sizes must be selected to provide adequate venous return rates for a given size patient.
2. Do not clamp the cannula over the reinforcing spring.
3. Cannula should be operated by medical professional.

#### Precautions:

1. Aseptic techniques must be used wherever possible, especially during removal from packaging.
2. This device is designed for one time use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
3. Rx Only. The device must be used by trained physicians only.

#### Instructions for Use:

1. Inspect the package and product for damage and expiration date then Open the package carefully using the aseptic technique.
2. After ensuring adequate systemic heparinization has been obtained, place a purse string suture at the desired cannulation site. Draw the purse string suture through a ligature tube/tourniquet.
3. Make an appropriately sized incision to receive the cannula tip within the purse string suture.
4. Dilate the incision to proper size for the cannula. Place a finger over the incision after dilation.
5. Insert the cannula tip into the incision. Guide the cannula gently into the vena cava.
6. Palpate the vena cava to ensure proper cannula location during insertion. For cannula with straight tip, a location ring is provided to be put around the tip to tie the purse string suture as well as locate the depth of the straight cannula tip into the VC.
7. Tighten the purse string suture and tie or clamp the tourniquet at a convenient site. Secure the cannula or venous return line to the surgical field to maintain proper tip orientation and prevent cannula dislodgment or excessive tension on the cannula.

8. Once the cannula and venous lines are primed and de-aired, clamp the cannula at the clamping site. The connector supplied with the venous return cannula can be used for connecting the cannula with the venous line. The two ends of the connector should be connected to the right device according to the hereunder table. The number expressed on the connector shows that end should be connected to which device.
9. Remove the clamp prior to initiating cardiopulmonary bypass.
10. After initiating total cardiopulmonary bypass, secure a caval tape around both vena cava and cannulas tips to prevent entrainment of air into the venous drainage system.
11. After cessation of bypass, remove the cannula from the vena cava and close the suture line.

**Disposal:**

12. 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**



Venous 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**

Venous 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

 Manufactured By:  
Advanced LifeSciences Pvt. Ltd.  
D-22 Okhla Industrial Area Phase – 1,  
New Delhi – 110020,  
India  
E-mail: [customerservice@alspl.com](mailto:customerservice@alspl.com)  
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