

The AngioVac System Generation 3: Frequently Asked Questions

1. Has the AngioVac System indication for Generation 3 changed?

No. The AngioVac* Cannula is indicated for use as a venous drainage cannula and for removal of fresh, soft thrombi or emboli during extracorporeal bypass for up to six hours. The AngioVac Circuit is indicated for use in procedures requiring extracorporeal circulatory support for periods of up to six hours.

2. What is AngioVac System commonly used for?

The AngioVac System can be used for the removal of commonly encountered undesirable intravascular material, such as fresh, soft thrombi, emboli or vegetation in the Right Atrium, Right Ventricle, superior vena cava, inferior vena cava, and the iliofemoral veins.

3. How do the Generation 2 and Generation 3 cannula differ?

The AngioVac Cannula is now available in a 20 degree and 180-degree angled tip. These options facilitate potentially easier navigation through the patient's vasculature. The balloon tip has been replaced with a new self-expanding nitinol funnel shaped tip. The funnel tip enhances drainage flow when actuated using a sliding over sheath. The sliding over sheath aids in funnel capture, deployment, and curve manipulation. The nitinol funnel tip aids in consistent deployment and prevents clogging of the cannula with commonly encountered undesirable intravascular material, such as fresh, soft thrombi, emboli, or vegetation.

The inner diameter of the cannula has been increased from 19F (6.33mm) to 20.2F (6.73mm), the outer diameter has been decreased from 26F (8.67mm) to 23F (7.56mm). This allows for more steerability and easier use in specific anatomies.

The new iteration features a flat wire coil extruded in the cannula body, rather than a round wire coil, resulting in a reduced wall thickness.

4. What is the purpose of the 180-degree design?

The 180-degree design allows for the AngioVac Cannula to shift its angled tip from anywhere between 0 degrees and 180 degrees when actuated using the sliding over sheath. This angled design aids in potentially easier navigation and ease of placement throughout the vasculature, such as the right heart.

5. What changes have been made to the bypass circuit?

None; the AngioVac Circuit is the same product, UPN, and price.

6. Can I still use Generation 2?

Yes, throughout the limited market release, and subsequently following full market release, until inventory is depleted.

7. What are the new part numbers?

AngioVac Gen 2 (Existing)	UPN		AngioVac Gen 3 (New)	UPN
Cannula with Dilator (Straight)	H965251850		Cannula with Dilator (C180)	H965251940
Cannula with Dilator (20° Angle)	H965251860	<u>TO</u>	Cannula with Dilator (C20)	H965251930
Circuit with Bubble Traps (x2)	H965251880		Circuit with Bubble Traps (x2)	H965251880
Cannula with Dilator (Straight), Circuit and Bubble Traps	H965251900		Cannula with Dilator (C180), Circuit and Bubble Traps	H965251960
Cannula with Dilator (20° Angle), Circuit and Bubble Traps	H965251920		Cannula with Dilator (C20), Circuit and Bubble Traps	H965251950

8. Will our current price be automatically loaded with AngioDynamics?

No, you will need to work with your local AngioDynamics Sales Representative to load pricing, as previous pricing will not automatically be loaded.

AngioVac Cannula

Indication for Use: The AngioVac Cannula is indicated for use as a venous drainage cannula and for removal of fresh, soft thrombi or emboli during extracorporeal bypass for up to 6 hours.

Contraindications: Contraindicated for patients with severe arterial or venous vascular disease, contraindicated for removal of chronic firmly adherent intravascular material (e.g., atherosclerotic plaque, chronic pulmonary embolism) and for use in the right heart or pulmonary arteries during active cardiopulmonary resuscitation.

Refer to Directions for Use and/or User Manual provided with the product for complete Instructions, Warnings, Precautions, Possible Adverse Effects and Contraindications prior to use of the product.

AngioVac Circuit

Indications for Use: The AngioVac Circuit is indicated for use in procedures requiring extracorporeal circulatory support for periods of up to six hours.

Contraindications: Refer to the AngioVac Cannula Directions for Use (DFU) for procedure-specific contraindications.

Refer to Directions for Use and/or User Manual provided with the product for complete Instructions, Warnings, Precautions, Possible Adverse Effects and Contraindications prior to use of the product.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

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