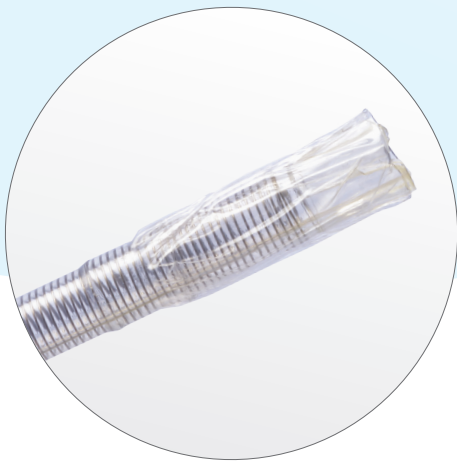


AngioVac

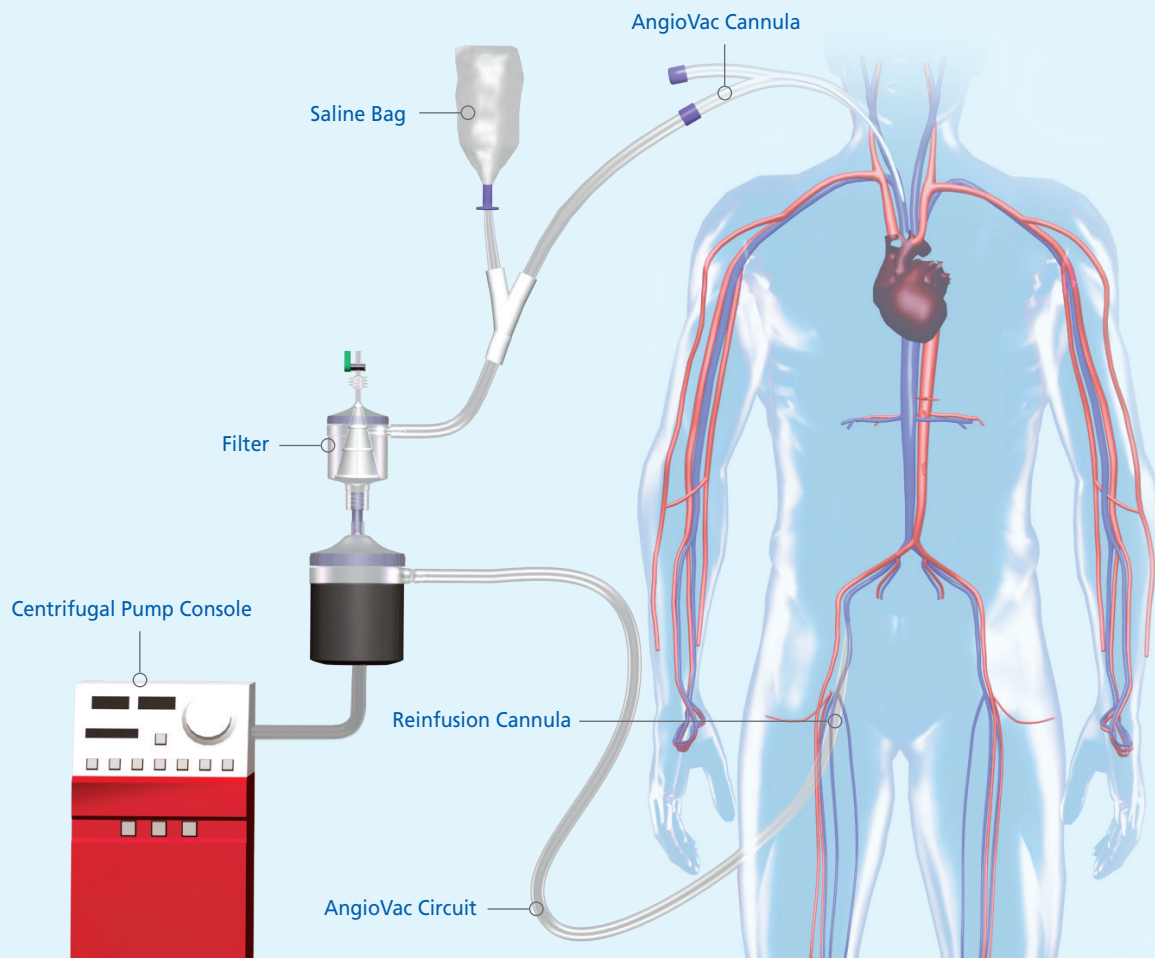
Cannula and Circuit



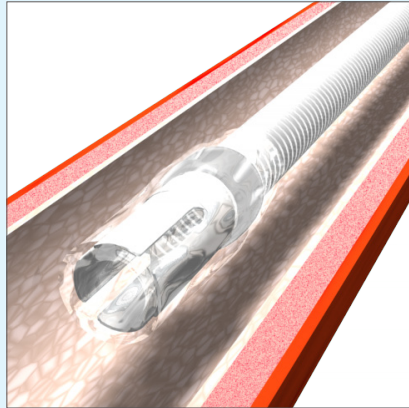
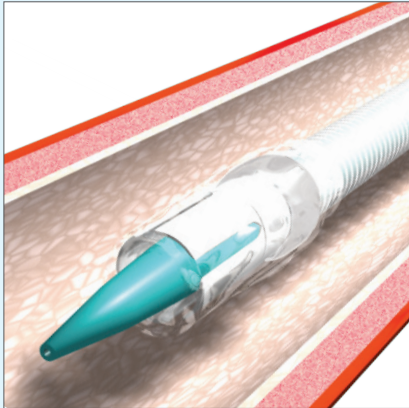


AngioVac Cannula and Circuit

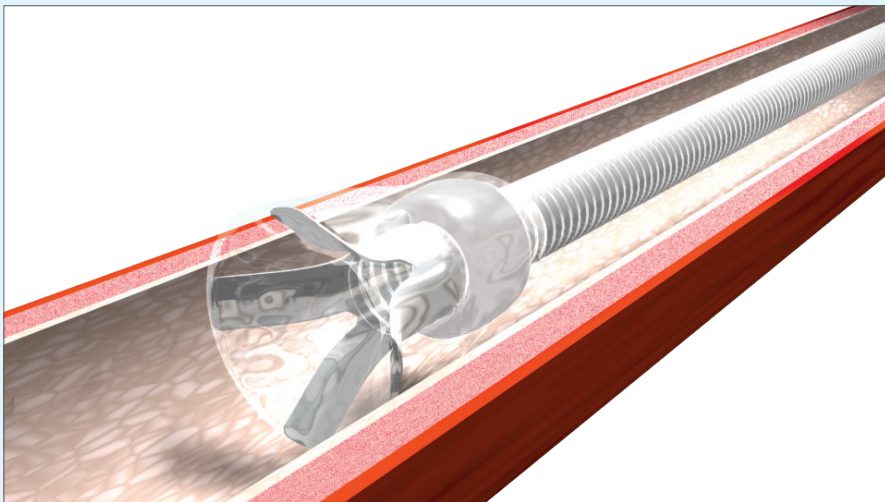
The AngioVac[®] venous drainage system includes the Venous Drainage Cannula and the Cardiopulmonary Bypass Circuit. The cannula is intended for use as a venous drainage cannula during extracorporeal bypass for up to six hours. The cardiopulmonary bypass circuit is intended for use in procedures requiring extracorporeal circulatory support for periods of up to six hours.



The AngioVac devices are for use with other manufacturer's off-the-shelf pump, filter, and reinfusion cannula, to facilitate venous drainage as part of an extracorporeal bypass procedure for up to six hours.



The AngioVac venous drainage cannula is a 22F coil-reinforced cannula.



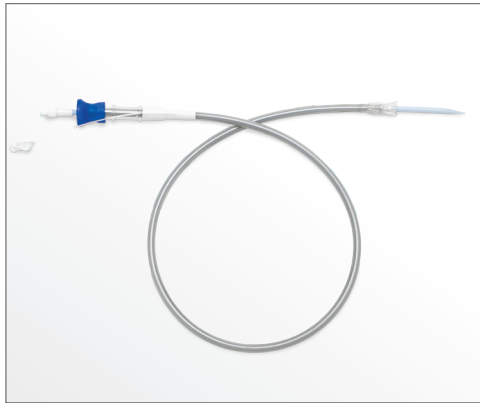
The AngioVac Cannula is designed with a balloon-actuated, expandable funnel shaped distal tip. The proprietary funnel shaped tip enhances venous drainage flow when the balloon is inflated, prevents clogging of the cannula with commonly encountered undesirable intravascular material, and facilitates en bloc removal of such extraneous material.

Actual Procedure Results

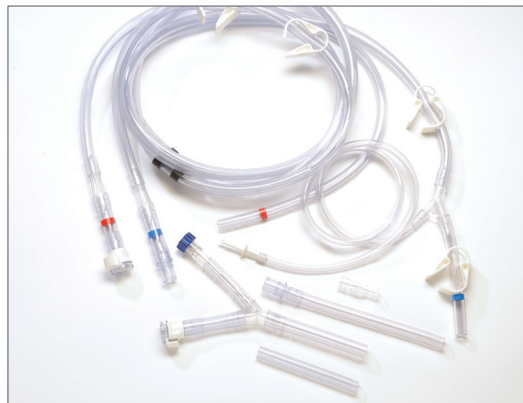


AngioVac Cannula and Circuit

Description	Part #
AngioVac Full Unit	VTX-4000
AngioVac Cannula	VTX-3022
AngioVac Circuit	VTX-3100



AngioVac Cannula



AngioVac Circuit

CANNULA INDICATIONS FOR USE: The Vortex Medical AngioVac Cannula is intended for use as a venous drainage cannula during extracorporeal bypass for up to six hours. The AngioVac Cardiopulmonary bypass circuit is intended for use in procedures requiring extracorporeal circulatory support for periods up to six hours.

WARNING: Do not use if product or sterile packaging is damaged. For single use only, do not resterilize or reuse. Do not autoclave. Do not use in conjunction with a power injector. There are user serviceable parts. Do not alter the AngioVac products in any way. Instructions for use and manuals for all related extracorporeal circulatory devices should be read prior to use and used as indicated. DO NOT reuse or resterilize and discard after use. DO NOT use alcohol or alcohol-based fluids for lubrication.

CIRCUIT INDICATIONS FOR USE: The AngioVac Cardiopulmonary bypass circuit is intended for use in procedures requiring

extracorporeal circulatory support for periods up to six hours.

WARNING: Instructions for use and manuals for all related extracorporeal circulatory devices should be read prior to use, including but not limited to the centrifugal pump head, control console and circuit filter. It is recommended that one pack be set up and evaluated in a laboratory or bench test prior to first clinical use. Carefully examine the circuit for leaks before and during use. Leakage may result in loss of sterility, blood loss or air embolism. If leakage is observed replace the circuit, the leaking component or tighten the leaking connection. Check all pumps and components to ensure that they are set up for proper flow direction prior to initiating extracorporeal circulation. Do not allow organic solvents, anesthetic agents or alcohol or alcohol-based fluids to come in contact with the circuit components as they may compromise structural integrity. Always ensure adequate priming and complete de-airing of the circuit prior to use. All luer connections should be

finger-tight only. Over-tightening connections may result in cracks of the components and leaks in the circuit. When infusing solutions from bags, remove all air from the bag during setup to prevent air from entering the circuit. Carefully monitor for both inflow and outflow obstruction/occlusion of the circuit during use. Thoroughly inspect all circuit components prior to use to verify that all lumen are patent and that the circuit has not been damaged or kinked prior to use. Initiate adequate systemic anticoagulation therapy prior to patient cannulation and utilization of this product for the conduct of extracorporeal circulation. A strict anticoagulation protocol should be followed and anticoagulation should be carefully monitored during all procedures. During the performance of extracorporeal circulation, do not exceed appropriate pressure ratings of the circuit (520mmHg/10psi).

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



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