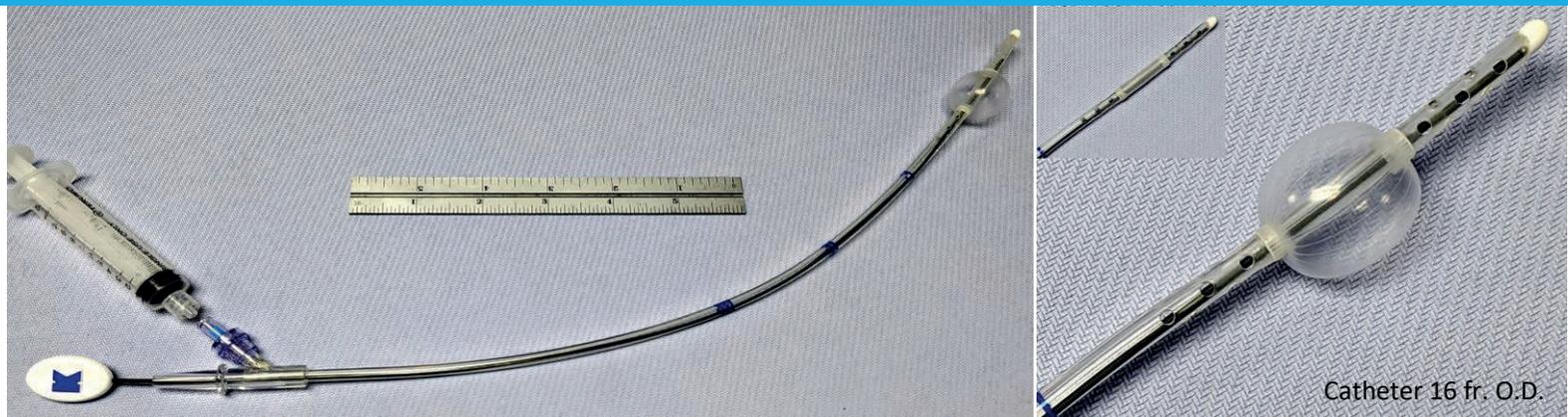


MICHLER® Heart Vent Catheter

Catalog Number: KSC-1000

FDA Cleared K200289



Application:

The MICHLER® Heart Vent Catheter is a soft balloon-tipped catheter. It can be inserted through the open left atrium during mitral valve surgery or through the right superior pulmonary vein on the beating heart and across the mitral valve into the left ventricle. Uniquely, the device is securely positioned and maintained in the LV by inflating a soft positioning balloon against the mitral annulus/valve. The soft balloon will inflate in the left ventricle, keeping the catheter tip below the mitral valve to ensure drainage of air, blood and debris from the left atrium and left ventricle. The design of the MICHLER® Heart Vent Catheter focuses on ease of passage, position and safety.

Advantages to venting the left heart:

- Prevent LV distention
- Prevent air ejection from left heart
- Aspiration of air, blood and debris
- Improved visualization of anatomy
- Prevent unintended LV Perforation
- Optimize LV positioning
- Aspiration from both LA and LV
- Diminished RBC shearing resulting in higher hemoglobin and hematocrit
- Lattice formation diminished turbulent flow resulting in decreased emboli formation

Benefits:

LV venting offers the advantage of left ventricular decompression in both the beating heart and the arrested heart. By reducing left ventricular workload, this creates a favorable myocardial oxygen supply/demand. LV venting during reperfusion is warranted in hearts with LV dysfunction or hearts that have sustained a period of severe ischemia. Multiple studies have shown that using an LV vent improves cardiac performance.

Product Description:

The MICHLER® Heart Vent Catheter consists of a flexible tube with a soft compliant balloon located on the distal portion of the flexible tube within a 2.5 cm perforated zone with holes both proximal and distal to the balloon. A small tapered radio opaque tip is formed to the distal end to aid in the insertion of the catheter within the heart. A malleable stylet is provided with the catheter. Depth markings on the catheter indicate insertion depth. Overall length of the catheter is approximately 43.8 cm (17.25 in). The inflatable balloon is filled with sterile saline solution at the proximal end of the catheter through a Y-connector and holds the catheter in place at the desired location. When a change in location for this catheter is desired, the saline solution from the balloon is removed with the aid of a syringe and refilled after the catheter is moved into the new location. The balloon is used to maintain the position of the suction tip at the required location. Catheter 16 fr. O.D. (5.5 mm dia.)

Indication for use:

The MICHLER® Heart Vent Catheter is intended for use in venting the left heart during cardiopulmonary bypass surgery up to 6 hours or less.

The MICHLER® Heart Vent Catheter is a Sterile, non-pyrogenic, single use device.

Patent Pending