

K9G171C

**SAFETY and EFFECTIVENESS SUMMARY**

**PROPRIETARY NAME:**

**SEP 19 1996**

Vaso-Safe Arterial Embolectomy Catheter

**COMMON USUAL NAME:**

Embolectomy Catheter

**CLASSIFICATION:**

Class II

**CLASSIFICATION NUMBER:**

74 DXE

**DEVICE DESCRIPTION:**

The Vaso-Safe Arterial Embolectomy Catheter is a single lumen nylon tube with a natural latex balloon attached to a distal end and a stopcock affixed to the proximal end. It will be packaged with a syringe. The catheter will be available in 5 french sizes and 3 lengths.

The catheters are intended for use in the removal of arterial emboli and thrombi during embolectomy and thrombectomy.

The catheter, with the balloon deflated, is advanced into the vessel beyond the clot. The balloon is inflated with sterile solution. The catheter is withdrawn pulling the embolism with it, thus removing it from the artery.

The materials used on the Vaso-Safe Arterial Embolectomy Catheters have been used for years on other models of Ideas for Medicine, Inc. catheters except the suture, which has been certified to USP grade. Other catheter materials have been certified to meet the requirements of USP Class VI tests. Every lot is supplied sterile and non-pyrogenic.

**SUBSTANTIAL EQUIVALENCE:**

The intended use of these devices is to remove arterial emboli and thrombi. This use is identical to the Fogarty Embolectomy Catheter. The Robicsek Angiography Embolectomy Catheters are for arterial emboli and thrombi removal but provide the ability to irrigate concurrent with removal.