

(Version 3.1 3/21/2005)

CoAxia NeuroFlo™ Catheter

Patient Information

HUMANITARIAN USE DEVICE:

Authorized by Federal Law for use in the treatment of cerebral ischemia resulting from symptomatic vasospasm following aneurismal subarachnoid hemorrhage secured by either surgical or endovascular intervention for patients who have failed maximal medical management. The effectiveness of this device for this use has not been demonstrated.

Caution: Federal law restricts this device to sale by or on the order of a physician.

INTENDED USE

The CoAxia NeuroFlo™ Catheter is intended for the treatment of cerebral ischemia resulting from symptomatic vasospasm following aneurismal subarachnoid hemorrhage, secured by either surgical or endovascular intervention for patients who have failed maximal medical management.

PROCEDURE

Your doctor has determined that you have suffered a bleed in your brain and that you are having symptoms from spasm of arteries in your brain (symptomatic vasospasm*). Your doctor feels that you might benefit from the use of the NeuroFlo Catheter. The NeuroFlo Catheter* is a device with two balloons attached near the end of the catheter or tube. The catheter is placed in the large blood vessel (Aorta) that leads from your heart to the lower part of your body, through a small hole in the upper part of your leg. The balloons on the catheter are inflated for approximately 45 minutes. The assumption is that during this time, blood flow to the lower part of your body will be reduced while that to your upper part, including your brain, will be increased. When the procedure is completed, the catheter is removed.

RISKS AND PROBABLE BENEFITS OF USING THE NEUROFLO CATHETER

There is the risk that use of the NeuroFlo catheter can make your vasospasm and/or neurological condition worse or cause other complications like brain swelling, irregular heart rhythm, kidney failure, fluid in your lungs or death. There is a risk that the NeuroFlo device could fail causing damage to the large blood vessel. If the damage to the aorta is severe, an emergent procedure or surgery may be required to repair the damage. You could also have bleeding problems from the small hole in your upper leg; these bleeding problems can range from mild to serious. During the procedure you will receive a blood thinner called heparin. This may increase the risk of bleeding at the insertion site or elsewhere. Because the NeuroFlo is used only by your doctor, and you will be in the

hospital before and after its use, there are no special instructions for you to follow with regard to the NeuroFlo device.

There is the chance that the NeuroFlo could improve your vasospasm and/or neurological condition. In a study of the NeuroFlo conducted at three institutions in Mexico, Argentina, and Brazil between May 2002 and April 2003, 8/16 (50%) patients with symptomatic vasospasm had improvement in their neurological status within 24 hours. However, due to the small sample size, the reliability of this number is unknown. Also unknown is the long term benefit of this device.

ALTERNATIVE PRACTICES AND PROCEDURES

Currently there are not any approved device *treatments* for symptomatic vasospasm. The only FDA approved therapy is oral Nimodipine, a drug which is used as a preventive measure for vasospasm following subarachnoid hemorrhage. Your doctor can tell you what he/she currently uses as a treatment for vasospasm. Some common therapies being used are percutaneous transluminal angioplasty*, intra-arterial vasodilators* and Triple-H therapy* (i.e., hypertension, hypervolemia, and hemodilution). The safety and efficacy of these therapies for the treatment of vasospasm has not been evaluated by the FDA.

GLOSSARY OF TERMS

Words with an (*) next to them are defined below:

- Symptomatic vasospasm – squeezing down of a blood vessel [in the brain] that results in symptoms of a stroke such as difficulty in talking, weak arms or legs or the inability to move your eyes from side to side
- NeuroFlo catheter – a long, stiff tube with two small balloons on one end that is used to partially block blood flow in large blood vessels
- Percutaneous transluminal angioplasty – a minimally invasive procedure where spastic vessels are dilated mechanically using a balloon catheter
- Intra-arterial vasodilators – drug or chemical agents that causes dilation of the blood vessels
- Triple-H therapy – a procedure for increasing blood flow through narrowed vessels in the brain through increased pressure and volume of fluid to the patient who had symptomatic vasospasm