

SAFETY and EFFECTIVENESS SUMMARY

K960715

PROPRIETARY NAME:

Pruitt-Inahara Carotid Shunt and
Inahara-Pruitt Carotid Shunt

SEP - 9 1996

COMMON USUAL NAME:

Vascular Balloon Catheter

CLASSIFICATION:

Class II

CLASSIFICATION NUMBER:

Unknown

DEVICE DESCRIPTION:

The Pruitt-Inahara Carotid Shunt (Model 400-40-8F) and the Inahara-Pruitt Carotid Shunt (Model 500-50-8F) are dual lumen balloon shunts which channel and divert blood in the carotid artery during endarterectomy. The 8 French shunts are for use in arteries too small to accommodate a 9 French shunt. Both the 400-40-8F and 500-50-8F have a T Port to confirm patency and allow back-bleeding after insertion. There is an external safety balloon on the inflation port for the balloon which lies in the internal carotid artery. The safety balloon is designed to inflate when the internal carotid balloon reaches 17 psi; this reduces the possibility of balloon overinflation and resultant vessel damage. All the materials are identical to those used in other models of Ideas for Medicine's shunts. These materials have been used for years and were certified to meet the requirements of the USP Class VI testing for biocompatibility. Every lot is supplied sterile and non-pyrogenic.

SUBSTANTIAL EQUIVALENT:

The intended use of these devices is to provide a temporary bypass during carotid endarterectomy. The 8 French Pruitt Shunts are identical in both materials and intended use to the 9 French Pruitt-Inahara Shunts. The smaller OD of the shaft will allow it to be used in smaller arteries.