

## INTRAVASCULAR FLOW MODIFIER AND REINFORCEMENT DEVICE

### RELATED APPLICATIONS

This is a divisional of Ser. No. 09/590,793, filed Jun. 8, 2000, now U.S. Pat. No. 6,656,218 which is a continuation-in-part of Ser. No. 09/122,243 filed Jul. 24, 1998, now U.S. Pat. No. 6,165,194.

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

The present invention relates to an intravascular flow modifier and reinforcement device for use within a body vessel, and more particularly, for a device to be used in combination with vasoocclusive devices placed in an aneurysm for the purpose of occluding an aneurysm, whereby the invention provides reinforcement for the area of the blood vessel in the vicinity of the aneurysm.

#### 2. Description of the Related Art

The progress of the medical arts related to treatment of vascular malformations has dramatically improved with the availability of intravascular devices capable of operating entirely within the vasculature. Thus, many highly invasive surgical procedures and inoperable conditions have been treated by the use of an expanding number of devices and procedures designed for those purposes. One particularly useful development in the medical arts has been the ability to treat defects in relatively small arteries and veins, such as those in the neurovascular system, by use of a micro-catheter and the placement of embolic coils and the like in areas where the malformation is likely to cause or has already caused a rupture in the blood vessel. More specifically, it has been found that the treatment of aneurysms by such devices and procedures allows the medical practitioner to avoid otherwise risky medical procedures. For example, when the placement of the defect is in the brain, a great deal of difficulty is presented to treatment of small defects in the blood vessels with conventional surgical techniques. For these reasons, the progress in development of devices to treat such defects has been encouraged and has produced useful results in a wide variety of patients.

One aspect of these surgical treatments is that an aneurysm or other malformation is symptomatic of a general weakening of the vasculature in the area containing the aneurysm, and mere treatment of the aneurysm does not necessarily prevent a subsequent rupture in the surrounding area of the vessel. Moreover, it is often desirable to provide a means to prevent the migration of the vasoocclusive devices, such as coils and the like, out of the aneurysm in the event that the aneurysm has a relatively large neck to dome ratio.

Stents, which are tubular reinforcements inserted into a blood vessel to provide an open path within the blood vessel, have been widely used in intravascular angioplasty treatment of occluded cardiac arteries. In such a case, the stent is inserted after an angioplasty procedure or the like in order to prevent restenosis of the artery. In these applications, the stents are often deployed by use of inflatable balloons, or are self-expanding, forcing the stent open, thereby reinforcing the artery wall in the clear through-path in the center of the artery after the angioplasty procedure to prevent restenosis. While such procedures may be useful in certain aspects of vascular surgery in which vasoocclusive devices are used, the weakness of the vasculature and the inaccessibility of the interior of the aneurysm from the vessel after the placement

of such a stent, places limits on the applicability of such stents in procedures to repair aneurysms, particularly neurovascular aneurysms. Furthermore; the use of placement techniques, such as balloons or self-expanding mechanical devices of the type often found to be useful in cardiac surgery are relatively less useful in vasoocclusive surgery, particularly when tiny vessels, such as those found in the brain, are to be treated. For these reasons, it would be helpful if a device were available which was compatible with new techniques in vasoocclusive treatment of aneurysms and provides selective reinforcement in the vicinity of the artery, while avoiding any unnecessary trauma or risk of rupture to the blood vessel. The present invention provides these and other advantages.

### SUMMARY OF THE INVENTION

Briefly, and in general terms, the invention relates to a three-dimensional wire intravascular flow modifier which is formed of superelastic or shape memory material, which, in its deployed configuration comprises a series of circumferential loops connected by longitudinal portions proceeding in a multiple loop fashion from two free ends of the wire to a closed end loop of the wire. Upon deployment, the device is placed within the vasculature so that it extends from a position proximal to a position distal of the aneurysm to be treated. The device may be arranged so that an open portion of the loop straddles the neck of the aneurysm to allow placement of embolic coils and the like through the opening into the aneurysm. Prior to placement, the device is deformed into a linear form and placed within a micro-catheter, which is used to position the distal end of the device so that the device is pushed out of the micro-catheter by means of a pusher and detached from the pusher by a variety of means to complete placement of the device. After placement of the device, the pusher and catheter are withdrawn.

In a presently preferred method of manufacture of the invention, a single piece of shape memory or superelastic alloys such as nickel titanium alloy, is wound over an essentially cylindrical mandrel into which are formed channels representing the progressive loop configuration of the invention. Alternatively, the mandrel may be cylindrical with pegs inserted in positions representing transitions between the circumferential loops and the longitudinal portions of the wire. A single wire is best wound progressively down the mandrel forming loops and longitudinal transitions until a desired length of the device is reached, at which point the path is retraced similarly to the position at which the device was begun on the mandrel. The wire can then be heat treated on the mandrel to create a shape memory or treated to reach a superelastic state. Thereafter, the device can be taken off of the mandrel and stretched to be inserted into a micro-catheter prior to insertion into the vasculature. The configuration of the present invention provides important advantages over prior art devices in that it eliminates the necessity for balloon or mechanical placement devices which can cause unnecessary trauma to the delicate vasculature which has already been damaged by the presence of the aneurysm. For this reason, the invention is particularly useful to cover and reinforce large neck aneurysms. The presence of the longitudinal portion of the coil dramatically improves the pushability of the device, thereby enhancing the ability to deploy and place the device within the vasculature, an issue of considerable importance if neither balloon nor mechanical placement methods are to be used. Furthermore, the invention can be arranged in a variety of configurations which allow overlapping of the circumferen-