SUMMARY

Embodiments of ~~T~~the present invention ~~is directed~~ seek to provide an apparatus for treating a body lumen of a patient, e.g., a tubular graft, aorto-venous fistula, blood vessel, and the like. More particularly, embodiments of the present invention ~~is directed~~ seek to provide an apparatus for infusing fluids into a body lumen, for removing or otherwise capturing thrombus or other obstructive material within a body lumen, and/or for dilating a body lumen, and to methods for making and using such apparatus.

According to an aspect, an apparatus is provided for treating a body lumen that includes an elongate tubular member including a proximal end, a distal end sized for introduction into a body lumen, and a first lumen extending between the proximal and distal ends; an expandable balloon including a proximal end secured to the tubular member distal end, and a distal end including an outlet, the balloon including an interior communicating with the first lumen and the balloon outlet; and an elongate member slidably disposed within the first lumen. The elongate member may include a proximal end adjacent the tubular member proximal end, and a distal end extending from the balloon outlet. The balloon and elongate member may include cooperating features providing a valve for selectively opening and closing the balloon outlet. For example, a sealing member on the distal end of the elongate member sized to be engaged with the balloon distal end to substantially seal the outlet from fluid flow.

The elongate member may be movable between a first position wherein the sealing member is spaced apart from the balloon outlet such that fluid introduced through the first lumen passes through the balloon interior and out the balloon outlet, and a second position wherein the sealing member substantially seals the balloon outlet such that fluid introduced through the first lumen enters the balloon interior to expand the balloon.

Optionally, the apparatus may include a helical member including a first end coupled to the tubular member distal end and a second end coupled to the elongate member distal

end, the helical member extending helically around the elongate member within the balloon interior. The elongate member may be movable to a third position in which the elongate member distal end is directed towards the tubular member distal end to cause the helical member to compress axially and expand radially outwardly, thereby expanding the balloon to an expanded helical shape.

In accordance with an ~~first~~ embodiment, an apparatus is provided for treating a body lumen that is operable in different modes to perform various functions, e.g., possibly reducing the number of device exchanges during a procedure. For example, the apparatus may include a shaft including a proximal end, a distal end sized for introduction into a body lumen, a lumen extending therebetween, and a balloon on the distal end having an interior communicating with the lumen. The apparatus may also include a valve on the distal end of the shaft that selectively opens or closes an outlet communicating with the lumen. With the valve open, fluid introduced into the lumen may exit the outlet into a body lumen beyond the distal end. With the valve closed, fluid introduced into the lumen may expand the balloon from a contracted condition to an expanded condition, e.g., a cylindrical shape for dilating an obstruction within a body lumen or a bulbous shape for removing material within the body lumen. Optionally, the valve may include a stop that may be extended to push a distal end of the balloon, e.g., to stretch or otherwise reduce a profile of the balloon and/or otherwise facilitate introduction into a patient's body.

In addition or alternatively, the apparatus may include an actuator for axially compressing the balloon, and the balloon may be configured to expand from the contracted condition to an expanded helical shape when axially compressed. For example, the actuator may include an inner member within the shaft that is coupled to a distal end of the balloon, and a helical member may extend around the inner member within the balloon. When the inner member is directed proximally or otherwise actuated, the helical member may be

compressed and consequently expand radially outwardly, thereby expanding the balloon *to* the expanded helical shape. The inner member may be extended distally to extend and return the balloon back towards the contracted condition, e.g., after using the balloon in the expanded helical shape to remove material within a body lumen.

~~In accordance with another embodiment, an apparatus is provided for treating a body lumen that includes an elongate tubular member including a proximal end, a distal end, and a first lumen extending between the proximal and distal ends; an expandable balloon including a proximal end secured to the tubular member distal end, and a distal end including an outlet, the balloon including an interior communicating with the first lumen and the balloon outlet; and an elongate member slidably disposed within the first lumen. The elongate member may include a proximal end adjacent the tubular member proximal end, and a distal end extending from the balloon outlet. The balloon and elongate member may include cooperating features providing a valve for selectively opening and closing the balloon outlet. For example, a sealing member on the distal end of the elongate member sized to be engaged with the balloon distal end to substantially seal the outlet from fluid flow.~~

~~The elongate member may be movable between a first position wherein the sealing member is spaced apart from the balloon outlet such that fluid introduced through the first lumen passes through the balloon interior and out the balloon outlet, and a second position wherein the sealing member substantially seals the balloon outlet such that fluid introduced through the first lumen enters the balloon interior to expand the balloon.~~

~~Optionally, the apparatus may include a helical member including a first end coupled to the tubular member distal end and a second end coupled to the elongate member distal end, the helical member extending helically around the elongate member within the balloon interior. The elongate member may be movable to a third position in which the elongate member distal end is directed towards the tubular member distal end to cause the helical~~

~~member to compress axially and expand radially outwardly, thereby expanding the balloon to an expanded helical shape.~~

In accordance with yet another embodiment, an apparatus is provided for treating a body lumen that includes an outer tubular member including a proximal end, a distal end, and a first lumen extending between the proximal and distal ends; an inner member slidably disposed within the first lumen; and an expandable balloon including a proximal end secured to the outer member distal end, an interior communicating with the first lumen and a balloon outlet. The inner member includes a distal end extending from the balloon outlet, and carrying one or more sealing members. A helical member includes a first end coupled to the outer member distal end and a second end coupled *to* the inner member distal end, the helical member extending helically around the inner member within the balloon interior.

The inner member may be movable relative *to* the outer member for deploying the balloon in multiple modes. For example, the inner member may be movable from a first position wherein the sealing member is spaced from the balloon outlet such that fluid introduced through the first lumen passes through the balloon interior and out the balloon outlet, and a second position wherein the sealing member substantially seals the balloon outlet such that fluid introduced through the first lumen enters the balloon interior *to* expand the balloon. In addition or alternatively, the inner member may be movable from the first position *to* a third position in which the inner member distal end is directed proximally towards the outer member distal end *to* cause the helical member *to* expand radially outwardly, thereby expanding the balloon *to* an expanded helical shape.

In accordance with still another embodiment, an apparatus is provided for treating a body lumen that includes an outer tubular member including a first lumen extending between proximal and distal ends thereof, an inner member slidably disposed within the first lumen, and an expandable balloon comprising a proximal end secured to the outer

directed between the second and third positions.

11. The apparatus of claim 9, further comprising a source of vacuum communicating with the first lumen for collapsing the balloon before the elongate member is directed to the third position such that the balloon conforms substantially to the expanded helical shape of the helical member.

12. The apparatus of claim 9, wherein the balloon distal end is directed towards the balloon proximal end when the elongate member is moved to the third position, thereby axially compressing the balloon.

13. The apparatus of claim 12, further comprising a stop on the elongate member distal end proximal to the balloon distal end, the elongate member movable from the third position back towards the second position, thereby extending and collapsing the helical member, the stop engaging the balloon distal end and directing the balloon distal end distally as the elongate member is moved from the third position back towards the second position, thereby axially extending and collapsing the balloon.

~~14. An apparatus for treating a body lumen, comprising:~~

~~an outer tubular member including a proximal end, a distal end sized for introduction into a body lumen, and a first lumen extending between the proximal and distal ends;~~

~~an expandable balloon comprising a proximal end secured to the outer member distal end, and a distal end comprising an outlet, the balloon comprising an interior communicating with the first lumen and the balloon outlet;~~

an inner member slidably disposed within the first lumen and having a cross-section smaller than the first lumen such that an annular lumen is defined between the outer and inner members between the proximal and distal ends of the outer member, the inner member comprising a proximal end adjacent the outer member proximal end, and a distal end extending from the balloon outlet;

a sealing member on the inner member distal end, the inner member movable between a first position wherein the sealing member is spaced from the balloon outlet such that fluid introduced through the first lumen passes through the balloon interior and out the balloon outlet, and a second position wherein the sealing member substantially seals the balloon outlet such that fluid introduced through the first lumen enters the balloon interior to expand the balloon; and a helical member comprising a first end coupled to the outer member distal end and a second end coupled to the inner member distal end, the helical member extending helically around the inner member within the balloon interior, the inner member movable to a third position in which the inner member distal end is directed towards the outer member distal end to cause the helical member *to* expand radially outwardly, thereby expanding the balloon to an expanded helical shape.

15. The apparatus of claim 14, wherein the balloon comprises substantially inelastic material.

16. The apparatus of claim 14, wherein the helical member second end is coupled to a stop secured to the inner member distal end, the stop having a cross-section larger than the balloon outlet such that the stop limits relative movement of the balloon distal end relative to the inner member distal end as the elongate member is directed between the second and third positions.

17. The apparatus of claim 14, further comprising a source of vacuum communicating with the first lumen for collapsing the balloon before the inner member is directed to the third position such that the balloon conforms substantially to the shape of the helical member as the balloon is expanded to the expanded helical shape.

18. An apparatus for treating a body lumen, comprising:

an outer tubular member including a proximal end, a distal end sized for introduction into a body lumen, and a first lumen extending between the proximal and distal ends;

an inner member slidably disposed within the first lumen and having a cross-section smaller than the first lumen such that an annular lumen is defined between the outer and inner members between the proximal and distal ends of the outer member, the inner member comprising a proximal end adjacent the outer member proximal end, and a distal end extending beyond the outer member distal end;

an expandable balloon comprising a proximal end secured to the outer member distal end, and a distal end coupled to the inner member distal end, the balloon comprising an interior communicating with the first lumen and the balloon outlet;

a source of inflation media communicating with the first lumen for delivering inflation media through the first lumen into the balloon interior for expanding the balloon radially outwardly from a contracted condition to a cylindrical expanded condition; and

a helical member comprising a first end coupled to the outer member distal end and a second end coupled to the inner member distal end, the helical member extending helically around the inner member within the balloon interior, the inner member

~~movable from a first distal position in which the helical member is disposed adjacent the inner member and the balloon is in the contracted condition to a second proximal position that causes the helical member to compress axially and expand radially outwardly, thereby compressing axially and expanding radially the balloon to an expanded helical shape.~~

~~19~~14. The apparatus of claim ~~18~~9, wherein the helical member comprises first and second regions between the first and second ends, the first region expandable to a diameter greater than the second region such that the balloon defines first and second helical regions in the expanded helical shape, the first helical region having a diameter greater than the second helical region.

~~20. The apparatus of claim 18, further comprising a source of vacuum communicating with the first lumen for collapsing the balloon towards the contracted condition before the inner member is directed to the second position such that the balloon conforms substantially to the shape of the helical member in the expanded helical shape.~~

~~21. An apparatus for treating a body lumen, comprising:~~

~~an outer tubular member including a proximal end, a distal end sized for introduction into a body lumen, and a first lumen extending between the proximal and distal ends;~~

~~an inner member slidably disposed within the first lumen and comprising a proximal end adjacent the outer member proximal end, and a distal end extending beyond the outer member distal end;~~

~~an expandable balloon comprising a proximal end secured to the outer member distal end, and a distal end coupled to the inner member distal end, the balloon comprising an interior communicating with the first lumen and the balloon outlet; and~~

~~a helical member comprising a first end coupled to the outer member distal end and a second end coupled to the inner member distal end, the helical member extending helically around the inner member within the balloon interior, the inner member movable from a first distal position in which the helical member is disposed adjacent the inner member and the balloon is in the contracted condition to a second proximal position that causes the helical member to compress axially and expand radially outwardly, thereby compressing axially and expanding radially the balloon to an expanded helical shape, the helical member comprising first and second regions between the first and second ends, the first region expandable to a diameter greater than the second region such that the balloon defines first and second helical regions in the expanded helical shape, the first helical region having a diameter greater than the second helical region.~~