capturing thrombus or other obstructive material within a body lumen, e.g., procedures involving removing obstructive or other material, dilating a body lumen, delivering a prosthesis within a body lumen, and /or other procedures.

In accordance with a first embodiment, there is provided an apparatus for treating a body lumen, comprising: an outer member including a proximal end, a distal end sized for introduction into a body lumen, and a first lumen extending between the proximal end and an outlet in the distal end; an inner member slidably disposed within the first lumen, the inner member comprising a proximal end adjacent the outer member proximal end, and a distal end extending distally beyond the outer member distal end; a sealing member on the inner member distal end comprising one or more passages therethrough; and an expandable balloon comprising a distal end secured to the inner member distal end distally beyond the sealing member, and a proximal end secured to the sealing member such that an interior of the balloon communicates with the one or more passages; the inner member being movable between a distal position wherein the sealing member is spaced from the outlet such that fluid introduced through the first lumen passes through the outlet into a region around the apparatus, and a proximal position wherein the sealing member substantially seals the outlet such that fluid introduced through the first lumen passes through the one or more passages and enters the balloon interior to expand the balloon, and wherein sealing member comprising a valve body sized to be received through the outlet into the first lumen in the proximal position, and one or more valve seals on the valve body that slidably engage an inner surface of the first lumen for substantially sealing the outlet.

In accordance with a second embodiment, there is provided an apparatus for treating a body lumen, comprising: an outer member including a proximal end, a distal end sized for introduction into a body lumen, and a first lumen extending between the proximal end and an outlet in the distal end; an inner member slidably disposed within the first lumen, the inner member comprising a proximal end, and a distal portion extending distally beyond the outer member distal end; a treatment element on the distal portion; a sealing member on the distal portion proximal to the treatment element; a handle on the outer member proximal end; and an actuator on the handle coupled to the inner member for directing the inner member between a distal position wherein the sealing member is spaced from the outlet such that fluid introduced through the first lumen passes through the outlet into a region around the apparatus, and a proximal position wherein the sealing member substantially seals the outlet, wherein the treatment element comprises a prosthesis carried on the distal portion in a contracted condition and biased to expand to an enlarged condition, the treatment element further comprising a constraint that overlies the prosthesis to maintain the prosthesis in the contracted condition, the constraint being removable to expose the prosthesis, whereupon the prosthesis resiliently expands towards the enlarged condition.

In accordance with a third embodiment, there is provided an apparatus for treating a body lumen, comprising: an outer member including a proximal end, a distal end sized for introduction into a body lumen, and a first lumen extending between the proximal end and an outlet in the distal end; an inner member slidably disposed within the first lumen, the inner member comprising a proximal end adjacent the outer member proximal end, and a distal end extending distally beyond the outer member distal end; a treatment element on the distal portion; and a sealing member on the distal portion proximal to the treatment element, the distal portion member comprising one or more passages extending from one or more ports in the sealing member to a distal tip of the inner member; the inner member being movable between a distal position wherein the sealing member is spaced from the outlet such that fluid introduced through the first lumen passes through the outlet into a region around the apparatus proximal to the treatment element, and a proximal position wherein the sealing member substantially seals the outlet such that fluid introduced through the first lumen passes through the one or more passages and into a region around the apparatus distal to the treatment element, wherein the treatment element comprises a balloon, the inner member comprising an inflation lumen communicating with an interior of the balloon.

In accordance with a fourth embodiment, there is provided an apparatus for treating a body lumen, comprising: an outer 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, the inner member comprising a proximal end adjacent the outer member proximal end, and a distal end adjacent the balloon outlet; a sealing member on the inner member distal end, the inner member being 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 tensioning element between a stop in the balloon distal end and the inner member distal end for biasing the inner member towards the second position, wherein sealing member comprising a valve body sized to be received through the balloon distal end in the second position, and one or more valve seals on the valve body that slidably engage an inner surface of the balloon distal end for substantially sealing the outlet.

In accordance with once ~~a first~~ embodiment, an apparatus is provided for performing a procedure within 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 adjacent 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., to dilate an obstruction within a body lumen, to remove thrombus or other material within the body lumen, to deliver a prosthesis carried on the distal end, to deliver drugs or other agents carried on the distal end, and the like.

In accordance with another embodiment, an apparatus is provided for treating a body lumen that includes an elongate tubular outer 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. An elongate inner member is slidably disposed within the first lumen that includes a proximal end adjacent the tubular member proximal end, and a distal end extending into, through, and/or beyond the balloon. The balloon and inner member may include cooperating features providing a valve for selectively opening and closing the balloon outlet. For example, the valve may include a sealing member on the distal end of the inner member sized to be engaged with the balloon distal end to substantially seal the outlet from fluid flow.

The inner member may be movable between a first position wherein the sealing member is spaced apart from the balloon distal end 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.

expose the prosthesis, whereupon the prosthesis resiliently expands towards the enlarged condition.

8. The apparatus of claim 7, wherein the treatment element comprises a balloon including an interior communicating with one or more passages extending through the sealing member such that, with the inner member in the proximal position, fluid introduced through the first lumen passes through the one or more passages and enters the balloon interior to expand the balloon.

9. The apparatus of claim 8, wherein the treatment element further comprises a prosthesis on the balloon that is expandable when the balloon is expanded.

10. The apparatus of claim 8, wherein the treatment element further comprises one or more elements on the balloon for delivering energy to tissue adjacent a body lumen.

11. The apparatus of claim 10, further comprising a generator coupled to the handle for delivering electrical energy to the one or more elements on the balloon.

12. The apparatus of claim 8, wherein the treatment element further comprises a cooling apparatus within the balloon for cooling tissue adjacent the body lumen.

13. The apparatus of claim 17, wherein the constraint comprises a sleeve overlying the prosthesis, the handle comprising a second actuator coupled to the sleeve for directing the sleeve axially to expose the prosthesis.

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

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