We claim:

1. 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.

2. The apparatus of claim 1, further comprising a tensioning element coupled between the inner member and the outer member for biasing the inner member towards the proximal position.

3. The apparatus of claim 1 or 2, further comprising a handle on the outer member proximal end, and an actuator on the handle for directing the inner member from the second position to the first position to open the balloon outlet.

4. The apparatus of claim 1, wherein the inner member comprises a second lumen extending between the inner member proximal and distal ends for receiving an elongate member therethrough.

5. The apparatus of claim 1, wherein the sealing member comprises a tapered proximal end for enhancing seating the sealing member in the outlet of the outer member in the second position.

~~6. The apparatus of claim 1, 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.~~

~~7~~6. The apparatus of claim 1, further comprising 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 distally to a third position to cause the helical member to expand radially outwardly, the balloon overlying the helical member to define an expanded helical shape.

~~8~~7. 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..

98. The apparatus of claim 87, 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.

109. The apparatus of claim 98, wherein the treatment element further comprises a prosthesis on the balloon that is expandable when the balloon is expanded.

1110. The apparatus of claim 98, wherein the treatment element further comprises one or more elements on the balloon for delivering energy to tissue adjacent a body lumen.

1211. The apparatus of claim 110, further comprising a generator coupled to the handle for delivering electrical energy to the one or more elements on the balloon.

132. The apparatus of claim 98, wherein the treatment element further comprises a cooling apparatus within the balloon for cooling tissue adjacent the body lumen.

~~14. The apparatus of claim 8, 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.~~

153. The apparatus of claim 147, 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.

164. 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.

~~17. The apparatus of claim 16,~~ wherein the treatment element comprises a balloon, the inner member comprising an inflation lumen communicating with an interior of the balloon.

1~~8~~5. The apparatus of claim 1~~6~~4, further comprising a distal tip on the distal end of the inner member distally beyond the treatment element, the distal tip comprising a guidewire lumen communicating between a distal port and a side port proximal to the distal port and distal to the treatment element.

1~~9~~6. The apparatus of claim 1~~6~~4, further comprising a distal tip on the distal end of the inner member distally beyond the treatment element, the distal tip comprising a flexible curved shape, and wherein the inner member is rotatable relative to the outer member for changing an orientation of the distal tip.

~~21~~70. The apparatus of claim 1~~6~~4, further comprising a distal tip on the distal end of the inner member distally beyond the treatment element, the distal tip being biased to a flexible curved shape, the inner member comprising a guidewire lumen extending between the proximal and distal ends and through the distal tip, the distal tip sufficiently flexible

such that the distal tip is at least partially straightened when a guidewire is introduced through the guidewire lumen, the distal tip biased to the curved shape.

~~21~~18. 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.

~~22~~19. The apparatus of claim ~~21~~18, further comprising a handle on the outer member proximal end, and an actuator on the handle for directing the inner member between the first and second positions.

~~23~~20. The apparatus of claim ~~22~~19, wherein the tensioning element is biased to automatically direct the inner member from the first position to the second position when the actuator is released.

~~24~~21. The apparatus of claim ~~21~~92, wherein the actuator is configured to overcome the bias of the tensioning element to direct the inner member from the second position to the first position.

~~25~~22. The apparatus of claim ~~21~~18, wherein the inner member extends through the balloon outlet such that the sealing member is disposed distal to the outlet, and wherein the inner member distal end has a cross-section smaller than the balloon outlet such that an annular lumen is defined between the inner member and the balloon outlet for delivering fluid from the balloon interior through the balloon outlet when the inner member is in the first position.

~~26~~3. The apparatus of claim ~~24~~18, wherein the sealing member is disposed within the balloon interior in the first position, and wherein the sealing member is disposed at least partially within the balloon distal end in the second position.

~~27~~24. The apparatus of claim ~~26~~3, wherein the balloon distal end and the sealing member comprise stops that engage one another to limit distal advancement of the inner member in the second position.

~~28. The apparatus of claim 26, 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.~~

~~29~~5. The apparatus of claim ~~21~~84, wherein the inner member has a cross-section smaller than the first lumen such that an annular lumen is defined between the inner member and the outer member for delivering fluid from the outer member proximal end into the balloon interior.

~~30~~26. 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 within the balloon interior adjacent the balloon outlet;

a sealing member on the inner member distal end;

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 proximal 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 distal position wherein the sealing member is received at least partially within the balloon distal end to substantially seal 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.

~~31~~27. The apparatus of claim ~~30~~26, further comprising a tensioning element coupled between a stop in the balloon distal end and the sealing member for biasing the sealing member towards the proximal position.

~~32~~28. The apparatus of claim ~~30~~26, further comprising a tensioning element coupled between the proximal and distal ends of the balloon for biasing the balloon distal end distally.