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[54] **METHOD AND APPARATUS FOR TREATMENT OF FOCAL DISEASE IN HOLLOW TUBULAR ORGANS AND OTHER TISSUE LUMENS**

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Related U.S. Application Data

[63] Continuation of Ser. No. 14,043, Feb. 5, 1993, abandoned, which is a continuation of Ser. No. 869,907, Apr. 15, 1992, abandoned, which is a continuation of Ser. No. 759,048, Sep. 5, 1991, abandoned, which is a continuation of Ser. No. 485,287, Feb. 26, 1990, abandoned.

[51] Int. Cl.⁵ **A61M 25/00; A61M 29/00**

[52] U.S. Cl. **604/101; 606/194; 128/898**

[58] Field of Search **604/95-103; 606/191, 194, 195; 128/898**

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[57] ABSTRACT

Diseased portions of tissue lumens can be advantageously treated by the focal introduction of at least one therapeutic agent to the lumen at the diseased point. This can be accomplished by

- (a) introducing a catheter into the tissue lumen, said catheter comprising first and second expansile members and means for supplying therapeutic agent into a space between said first and second expansile members, and said catheter being positioned such that said first and second expansile members are disposed on opposite sides of the diseased region;
- (b) expanding the expansile members to occlude the diseased region of the tissue lumen;
- (c) introducing therapeutic agent to the occluded diseased region via said means for supplying therapeutic agent;
- (d) allowing the catheter to remain in place for a therapeutically effective period of time;
- (e) contracting the expansile members; and
- (f) removing the catheter. A particularly preferred application of the method of the invention is "bloodless angioplasty," in which the occluded diseased region is washed to remove blood prior to the introduction of the therapeutic agent. Then, the diseased region is treated with a therapeutic agent to suppress cell proliferation in the diseased region. The plaque is then disrupted. Finally, the occluded region may be treated with a medicament to promote vessel healing and sealed with a polymeric coating.

13 Claims, 3 Drawing Sheets

