



US005662609A

United States Patent [19] Slepian

[11] Patent Number: **5,662,609**
[45] Date of Patent: ***Sep. 2, 1997**

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

[75] Inventor: **Marvin J. Slepian**, Cleveland Heights, Ohio

[73] Assignee: **Endoluminal Therapeutics, Inc.**, Tucson, Ariz.

[*] Notice: The term of this patent shall not extend beyond the expiration date of Pat. No. 5,328,471.

[21] Appl. No.: **226,945**

[22] Filed: **Apr. 13, 1994**

Related U.S. Application Data

[63] Continuation of Ser. No. 101,966, Aug. 4, 1993, Pat. No. 5,328,471, which is a 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.⁶ **A61M 25/00; A61M 29/00**

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

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

[56] References Cited

U.S. PATENT DOCUMENTS

2,642,874	6/1953	Keeling .	
2,854,982	10/1958	Pagano .	
3,868,956	3/1975	Alfidi et al. .	
3,880,158	4/1975	Gurney .	
3,987,000	10/1976	Gleichenhagen et al. .	
4,140,126	2/1979	Choudhury .	
4,156,067	5/1979	Gould .	
4,272,518	6/1981	Moro et al. .	
4,377,010	3/1983	Fydeler et al. .	
4,423,725	1/1984	Baran et al.	604/101

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

0183372	6/1986	European Pat. Off. .	
8912478	12/1985	WIPO	606/198
WO88/03389	5/1988	WIPO .	
WO89/10155	11/1989	WIPO .	
WO89/12478	12/1989	WIPO .	
WO90/01969	3/1990	WIPO .	
WO91/07154	5/1991	WIPO .	
WO91/12846	9/1991	WIPO .	

OTHER PUBLICATIONS

Boretos, "Improved Intravascular Delivery of Drug Via A Polyethylene Jet Catheter," *The 13th Annual Meeting of the Society of Biomaterials*, p. 128.

Kerenyi, et al., "Local Enzymatic Treatment of Atherosclerotic Plaques" *Experimental and Molecular Pathology*, vol. 49, pp. 330-338 (1988).

McBride, et al., "Restenosis After Successful Coronary Angioplasty," *N. Eng. J. Med.*, pp. 1734-1737 (1988).

Primary Examiner—Michael Buiz

Assistant Examiner—William Lewis

Attorney, Agent, or Firm—Wolf, Greenfield & Sacks, P.C.

[57]

ABSTRACT

The present invention provides a technique for treating diseased portions of tissue lumens by the focal introduction of at least one therapeutic agent at the diseased region. A catheter is positioned in a lumen such that first and second expansile members surround the diseased portion of tissue. The expansile members are expanded to occlude the diseased region and a therapeutic agent is introduced to the occluded diseased region via the catheter. The catheter is allowed to remain in place for a therapeutically effective period of time to allow the therapeutic agent to contact the diseased portion for such a period of time. The catheter arrangement also can be used to occlude a diseased region, remove physiological fluid from the occluded region and subsequently to disrupt the diseased region and/or apply the therapeutic agent. The therapeutic agent can be selected to suppress cell proliferation in the diseased region, and the occluded region can be treated with a medicament to promote vessel healing. The occluded region also can be paved with polymeric material. Finally, the expansile members are contracted and the catheter is removed.

22 Claims, 3 Drawing Sheets

