US005824048A

United States Patent [19]

Tuch

[11] **Patent Number: 5,824,048**

[45] **Date of Patent: Oct. 20, 1998**

[54] **METHOD FOR DELIVERING A THERAPEUTIC SUBSTANCE TO A BODY LUMEN**

[75] Inventor: **Ronald J. Tuch**, Plymouth, Minn.

[73] Assignee: **Medtronic, Inc.**, Minneapolis, Minn.

[21] Appl. No.: **731,106**

[22] Filed: **Oct. 9, 1996**

Related U.S. Application Data

[60] Division of Ser. No. 482,246, Jun. 7, 1995, Pat. No. 5,679,400, which is a continuation-in-part of Ser. No. 52,878, Apr. 4, 1993, Pat. No. 5,464,650.

[51] **Int. Cl.**[6] **A61F 2/06**

[52] **U.S. Cl.** **623/1**; 623/12; 427/2.25; 427/2.3; 606/191

[58] **Field of Search** 623/1, 12; 427/2.25, 427/2.3; 606/191

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,292,965	10/1981	Nash et al. .
4,529,614	7/1985	Burns .
4,532,929	8/1985	Matei et al. .
4,733,665	3/1988	Palmaz .
4,753,652	6/1988	Langer et al. .
4,776,337	10/1988	Palmaz .
4,800,882	1/1989	Gianturco .
4,869,909	9/1989	Takahashi et al. .
4,886,062	12/1989	Wiktor .
4,888,009	12/1989	Lederman et al. .
4,894,231	1/1990	Moreau et al. .
5,019,090	5/1991	Pinchuk .
5,092,841	3/1992	Spears .
5,102,402	4/1992	Dror et al. .
5,102,417	4/1992	Palmaz .
5,176,907	1/1993	Leong .
5,192,308	3/1993	Ostapchenko .
5,213,580	5/1993	Slepian et al. .
5,221,698	6/1993	Amidon et al. .
5,234,456	8/1993	Silvestrini .
5,242,391	9/1993	Place et al. .
5,290,266	3/1994	Rohling et al. .
5,295,978	3/1994	Fan et al. .

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

0566245	10/1993	European Pat. Off. .
9013332	11/1990	WIPO .
9112779	9/1991	WIPO .
9116102	10/1991	WIPO .
9117789	11/1991	WIPO .
9118940	12/1991	WIPO .
9215286	9/1992	WIPO .
9306792	4/1993	WIPO .

OTHER PUBLICATIONS

"Seeding of Intravascular Stents with Genetically Engineered Endothelial Cells" by Dicket et al, in Circulation, vol. 80, No. 5 Nov. 1989.

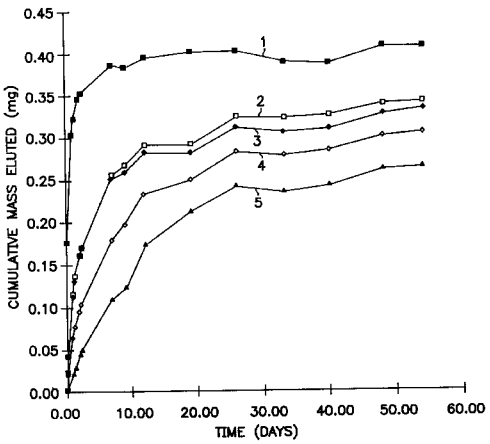
"Restenosis and the Proportional Neointimal Response to Coronary Artery Injury: Results in a Porcine Model" by Schwartz et al., in JACC, vol. 19, No. 2, Feb. 1992 pp. 267–274.

"Restenosis After Balloon Angioplasty" by Schwartz, et al., in Circulation, vol. 82, No. 6, Dec. 1990.

Primary Examiner—Paul B. Prebilic

Attorney, Agent, or Firm—Daniel W. Latham; Harold R. Patton

[57] **ABSTRACT**

A method for delivering a therapeutic substance to a body lumen utilizing an intravascular stent having a coating comprising a polymer and a therapeutic substance in a solid/solid solution with the polymer. The coating comprises a first coating layer nearer the stent body having a first concentration of therapeutic substance overlaid by a second porous coating layer having a second lesser concentration of therapeutic substance. The inclusion of a porous polymer coating layer on the stent helps retain the therapeutic substance on the stent during expansion of the stent and also controls the administration of the therapeutic substance following implantation. By this method, drugs such as dexamethasone can be applied to a stent, retained on a stent during expansion of the stent and elute at a controlled rate.

9 Claims, 5 Drawing Sheets