**PCT** WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :
**A61F 2/06, A61B 17/32, 17/115**

**A3**

(11) International Publication Number: **WO 98/19636**

(43) International Publication Date: 14 May 1998 (14.05.98)

(21) International Application Number: PCT/US97/20847

(22) International Filing Date: 5 November 1997 (05.11.97)

(30) Priority Data:
08/745,618 7 November 1996 (07.11.96) US

(71) Applicant: VASCULAR SCIENCE INC. [US/US]; Suite 202, 701 Decatur Avenue North, Minneapolis, MN 55427 (US).

(72) Inventors: GOLDSTEEN, David, S.; 4885 East Lake Harriet Parkway, Minneapolis, MN 55409 (US). BACHINSKI, Thomas, J.; 19059 Orchard Trail, Lakeville, MN 55044 (US). MAZZOCCHI, Rudy; 12 Apple Orchard Court, Dellwood, MN 55110 (US). SULLIVAN, Daniel, J.; 1245 Oak View Road, Medina, MN 55356 (US).

(74) Agents: JACKSON, Robert, R. et al.; Fish & Neave, 1251 Avenue of the Americas, New York, NY 10020 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

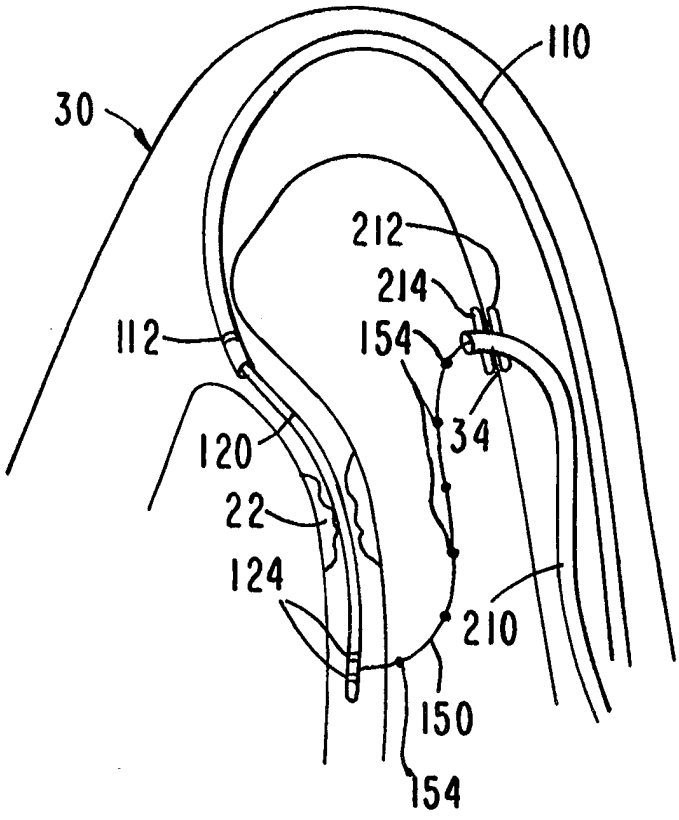
**Published**
*With international search report.*
*Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.*

(88) Date of publication of the international search report:
8 October 1998 (08.10.98)

(54) Title: MEDICAL GRAFTING METHODS AND APPARATUS

(57) Abstract

Methods and apparatus for delivering and installing a new length of tubing between two sections of a patient's existing body organ tubing and at least partly outside of that existing structure. For example, the new length of tubing may be for the purpose of providing the patient with a coronary bypass. The new tubing may be an artificial graft, a natural graft (harvested elsewhere from the patient), or both. The new tubing is delivered to and installed at the operative site primarily by working through the patient's existing tubular body organ structure. This avoids the need for any significant surgery on the patient. The artificial grafts may have shapes other than tubular. Certain procedural and apparatus aspects of the invention have uses other than in connection with grafting in general or tubular grafting in particular.



*FOR THE PURPOSES OF INFORMATION ONLY*

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **AL** | Albania | **ES** | Spain | **LS** | Lesotho | **SI** | Slovenia |
| **AM** | Armenia | **FI** | Finland | **LT** | Lithuania | **SK** | Slovakia |
| **AT** | Austria | **FR** | France | **LU** | Luxembourg | **SN** | Senegal |
| **AU** | Australia | **GA** | Gabon | **LV** | Latvia | **SZ** | Swaziland |
| **AZ** | Azerbaijan | **GB** | United Kingdom | **MC** | Monaco | **TD** | Chad |
| **BA** | Bosnia and Herzegovina | **GE** | Georgia | **MD** | Republic of Moldova | **TG** | Togo |
| **BB** | Barbados | **GH** | Ghana | **MG** | Madagascar | **TJ** | Tajikistan |
| **BE** | Belgium | **GN** | Guinea | **MK** | The former Yugoslav Republic of Macedonia | **TM** | Turkmenistan |
| **BF** | Burkina Faso | **GR** | Greece | | | **TR** | Turkey |
| **BG** | Bulgaria | **HU** | Hungary | **ML** | Mali | **TT** | Trinidad and Tobago |
| **BJ** | Benin | **IE** | Ireland | **MN** | Mongolia | **UA** | Ukraine |
| **BR** | Brazil | **IL** | Israel | **MR** | Mauritania | **UG** | Uganda |
| **BY** | Belarus | **IS** | Iceland | **MW** | Malawi | **US** | United States of America |
| **CA** | Canada | **IT** | Italy | **MX** | Mexico | **UZ** | Uzbekistan |
| **CF** | Central African Republic | **JP** | Japan | **NE** | Niger | **VN** | Viet Nam |
| **CG** | Congo | **KE** | Kenya | **NL** | Netherlands | **YU** | Yugoslavia |
| **CH** | Switzerland | **KG** | Kyrgyzstan | **NO** | Norway | **ZW** | Zimbabwe |
| **CI** | Côte d'Ivoire | **KP** | Democratic People's Republic of Korea | **NZ** | New Zealand | | |
| **CM** | Cameroon | | | **PL** | Poland | | |
| **CN** | China | **KR** | Republic of Korea | **PT** | Portugal | | |
| **CU** | Cuba | **KZ** | Kazakstan | **RO** | Romania | | |
| **CZ** | Czech Republic | **LC** | Saint Lucia | **RU** | Russian Federation | | |
| **DE** | Germany | **LI** | Liechtenstein | **SD** | Sudan | | |
| **DK** | Denmark | **LK** | Sri Lanka | **SE** | Sweden | | |
| **EE** | Estonia | **LR** | Liberia | **SG** | Singapore | | |

# INTERNATIONAL SEARCH REPORT

Interna..ial Application No
PCT/US 97/20847

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06 A61B17/32 A61B17/115

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | WO 94 01056 A (BOSTON SCIENT CORP) 20 January 1994<br><br>see page 4, line 23 - page 6, line 10; figures | 80-82, 85-88, 91,103, 138-140, 144-149, 151-157 |
| A | | 94-96, 102,104, 105,141, 143 |

---

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 29 July 1998 | 18. 08. 98 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016 | Neumann, E |

2

Form PCT/ISA/210 (second sheet) (July 1992)

# INTERNATIONAL SEARCH REPORT

Intern. .nal Application No
PCT/US 97/20847

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | WO 96 25897 A (MENLO CARE INC) 29 August 1996<br>see page 5, paragraph 2; claims; figures | 80-82, 85-89, 91,95, 96, 98-100, 103, 138-140, 143 |
| A | | 97,114, 146,147, 151-158 |
| | --- | |
| X | US 5 549 663 A (COTTONE JR ROBERT J) 27 August 1996<br>see column 6, line 15 - column 8, line 3; claim 12; figures | 80-82, 86-88, 91, 95-97, 100, 103-105, 138-140, 143-147, 151-153, 155-157 |
| A | | 85 |
| | --- | |
| X | EP 0 732 087 A (ADVANCED CARDIOVASCULAR SYSTEM) 18 September 1996<br>see column 6, line 27 - column 7, line 46; figures | 106-113, 129-134, 137 |
| A | | 135,136 |
| | --- | |
| X | EP 0 737 453 A (STACK RICHARD S ;CLARK HOWARD G III (US); WALKER WILLIAM F (US)) 16 October 1996<br>see column 5, line 12 - line 50; figures 1-6 | 106-111, 113,129, 130,137 |
| A | | 112 |
| | --- | |
| X | US 5 571 172 A (CHIN ALBERT K) 5 November 1996<br>see column 6, line 15 - column 7, line 15; figures | 106,107, 129,130, 137 |
| A | | 114 |
| | --- | |
| A | WO 96 22745 A (SCHNEIDER USA INC ;INDIANA UNIVERSITY FOUNDATION (US); UNIV JOHNS) 1 August 1996<br>see page 2, line 19 - page 4, line 33; figures | 1,5,14, 45-47, 50,51,60 |
| | --- | |
| | -/-- | |

2

# INTERNATIONAL SEARCH REPORT

Internal Application No
PCT/US 97/20847

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | US 4 418 693 A (LEVEEN ERIC G ET AL) 6 December 1983<br>see the whole document | 1,45 |
| A | WO 95 17127 A (OTICON AS ;RYGAARD JOERGEN A (DK)) 29 June 1995<br>see page 5, line 1 - page 10, line 32; figures | 1,45,114 |
| A | US 4 592 754 A (GUPTE PRADEEP M ET AL) 3 June 1986<br>see the whole document | 1,45 |
| A | US 5 542 944 A (BHATTA KRISHAN M) 6 August 1996<br>see column 4, line 16 - line 33; figures | 72,74, 75,77,78 |
| A | US 3 903 892 A (KOMIYA OSAMU) 9 September 1975<br>see column 1, line 53 - column 2, line 15; figures | 72,74, 75,77,78 |
| A | DE 44 04 806 C (WINTER & IBE OLYMPUS) 23 February 1995<br>see column 2, line 67 - column 3, line 40; figures | 72,75, 78,79 |
| A | US 5 211 683 A (MAGINOT THOMAS J) 18 May 1993<br>see the whole document | 106,107, 114,129, 130 |

2

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 97/20847

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 160-200
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest.

[X] No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

International Application No. PCT/US 97/20847

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-44,45-71

   Apparatus for making a tubular connection between two tubular body organs comprising two instruments which are inserted by remote control into the existing body organs to create apertures in their side walls and attaching the tubing to the apertures.

2. Claims: 72-79

   Instrument comprising illuminating means and a snare structure insertable into a patient and image control.

3. Claims: 80-105,138-143

   Graft having a frame structure and a covering made of elastic material.

4. Claims: 106-137

   Delivery device for a tubular graft whereby the graft is disposed coaxially around the longitudinal and inside the tubular structure of the device.

5. Claims: 144-159

   A tubular member having fasteners which are resiliently biased to project from the tubular member.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern nal Application No
PCT/US 97/20847

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| WO 9401056 A | 20-01-1994 | US 5366504 A | 22-11-1994 |
| | | EP 0651624 A | 10-05-1995 |
| | | JP 7509152 T | 12-10-1995 |
| | | US 5674276 A | 07-10-1997 |
| WO 9625897 A | 29-08-1996 | AU 4929696 A | 11-09-1996 |
| | | CA 2213403 A | 29-08-1996 |
| | | EP 0810845 A | 10-12-1997 |
| | | US 5674241 A | 07-10-1997 |
| US 5549663 A | 27-08-1996 | NONE | |
| EP 0732087 A | 18-09-1996 | US 5647857 A | 15-07-1997 |
| | | CA 2171787 A | 17-09-1996 |
| | | JP 8322943 A | 10-12-1996 |
| EP 0737453 A | 16-10-1996 | AU 653159 B | 22-09-1994 |
| | | AU 8001891 A | 10-12-1991 |
| | | EP 0528993 A | 03-03-1993 |
| | | JP 5509008 T | 16-12-1993 |
| | | WO 9117789 A | 28-11-1991 |
| | | US 5527337 A | 18-06-1996 |
| US 5571172 A | 05-11-1996 | NONE | |
| WO 9622745 A | 01-08-1996 | US 5591226 A | 07-01-1997 |
| | | US 5755775 A | 26-05-1998 |
| US 4418693 A | 06-12-1983 | NONE | |
| WO 9517127 A | 29-06-1995 | DK 145593 A | 24-06-1995 |
| | | AU 687807 B | 05-03-1998 |
| | | AU 6719894 A | 10-07-1995 |
| | | AU 691808 B | 28-05-1998 |
| | | AU 6719994 A | 10-07-1995 |
| | | CA 2179507 A | 29-06-1995 |
| | | CA 2179508 A | 29-06-1995 |
| | | WO 9517128 A | 29-06-1995 |
| | | EP 0740531 A | 06-11-1996 |
| | | EP 0774923 A | 28-05-1997 |

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern. ..al Application No
PCT/US 97/20847

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| WO 9517127 A | | JP 9503420 T | 08-04-1997 |
| | | JP 9503421 T | 08-04-1997 |
| | | NO 962632 A | 09-08-1996 |
| | | NO 962633 A | 09-08-1996 |
| | | US 5725544 A | 10-03-1998 |
| US 4592754 A | 03-06-1986 | NONE | |
| US 5542944 A | 06-08-1996 | NONE | |
| US 3903892 A | 09-09-1975 | NONE | |
| DE 4404806 C | 23-02-1995 | NONE | |
| US 5211683 A | 18-05-1993 | US 5304220 A | 19-04-1994 |
| | | US 5456712 A | 10-10-1995 |
| | | US 5571167 A | 05-11-1996 |
| | | US 5749375 A | 12-05-1998 |