CATHETER TIP DESIGNS AND METHODS FOR IMPROVED STENT CROSSING

Abstract: A balloon catheter having a first balloon member and a second distal expandable member. The increased distal profile of the catheter with inflation of the second distal expandable member can deflect the distal-most end away from stent walls and edges. Another catheter has a distal region including longitudinal slits and a pre-stressed body configured to expand upon exposure to warm body fluids. Another catheter has a distal region including a first, inner tube disposed about a second, innermost tube. The inner and innermost tubes are secured at the distal-most end. The distal region includes longitudinal slits through the inner tube, thereby defining flaps between the slits. The innermost tube can be retracted relative to the inner tube disposed about the innermost tube, thereby causing the longitudinal flaps to expand outward, thereby increasing the maximum radial extent of the distal region. In yet another embodiment, a balloon catheter having a first guide wire tube is provided. A second guide wire tube is also provided, adapted to be received within the larger, first guide wire tube.
# INTERNATIONAL SEARCH REPORT

**A. CLASSIFICATION OF SUBJECT MATTER**

| IPC 6 | A61M25/00 | A61M25/10 |

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 | A61M | A61F |

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**

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
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</table>
| X        | WO 96 39219 A (UROLOGIX, INC.)
12 December 1996 (1996-12-12)
page 6, line 20 - line 22
page 12, line 16 - line 25
figures 2,7
--- | 1-3,13, 14 |
| X        | US 3 631 848 A (MULLER)
4 January 1972 (1972-01-04)
column 2, line 22 - column 3, line 4
figures 1-3
--- | 1,11,12 |
| X        | US 5 591 129 A (SHOUP ET AL.)
7 January 1997 (1997-01-07)
column 4, line 42 - line 63
column 7, line 17 - line 47
column 8, line 65 - column 9, line 55
figures 1,12-14,20-25
--- | 1,15,16 |
| A        |                                                                                   | 36,39 |

Further documents are listed in the continuation of box C.

**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 doubt 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.

**Date of the actual completion of the international search**

7 June 1999

**Date of mailing of the international search report**

14.09.1999

**Name and mailing address of the ISA**

European Patent Office, P.B. 5818 Patentlaan 2
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**Authorized officer**

SCHOENLEBEN J.
<table>
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<th>Category</th>
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<tr>
<td>A</td>
<td>US 4 725 264 A (GLASSMAN) 16 February 1988 (1988-02-16) column 3, line 10 - line 24 figures 4,6</td>
<td>4</td>
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<tr>
<td>A</td>
<td>US 4 122 591 A (KRAMANN ET AL.) 31 October 1978 (1978-10-31) column 4, line 6 - line 63 figures 1-3</td>
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<td>A</td>
<td>US 5 114 403 A (CLARKE ET AL.) 19 May 1992 (1992-05-19) column 1, line 19 - column 2, line 15 column 9, line 22 - line 45 figures 1,14</td>
<td>24</td>
</tr>
<tr>
<td>A</td>
<td>CH 671 883 A (SARCEM S.A.) 13 October 1989 (1989-10-13) abstract figure 1</td>
<td>28</td>
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</tbody>
</table>
**INTERNATIONAL SEARCH REPORT**

**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.: 43-47
   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:

1. □ 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. **X** 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.:
   - 1-16, 24-40

**Remark on Protest**

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

□ No protest accompanied the payment of additional search fees.
1. Claims: 1-16,24-40
   A catheter tip assembly having means for reconfiguration of
   the catheter tip from a first configuration for crossing a
   vessel lumen obstruction to a second configuration for
   crossing a placed stent.

2. Claims: 17-23
   A catheter tip and guide wire assembly for crossing a placed
   stent, said guide wire having means for deflecting the
   catheter tip away from the interior wall of the stent.

3. Claims: 41,42
   A therapeutic catheter system having first and second
   elongate tubular members providing a better support for a
   small guide wire.
<table>
<thead>
<tr>
<th>Patent document cited in search report</th>
<th>Publication date</th>
<th>Patent family member(s)</th>
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<tbody>
<tr>
<td>US 3631848</td>
<td>04-01-1972</td>
<td>NONE</td>
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<td>US 5591129</td>
<td>07-01-1997</td>
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<td>US 5395341</td>
<td>07-03-1995</td>
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