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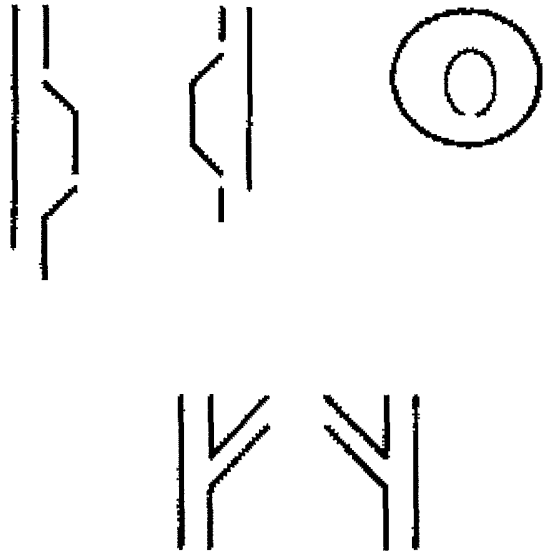
Declarations under Rule 4.17:
— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*
— *of inventorship (Rule 4.17(iv)) for US only*

Published:
— *with international search report*
— *with amended claims*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: LINED BALLOON MOUNTED STENT



(57) Abstract: This invention is concerned with a lined inflatable and dilatable stent (the stent is dilatable and its lining is either inflatable or dilatable) that will be introduced inside vessels to control the blood (or other fluids) flow.

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Lined Balloon Mounted Stent (detailed description):

This invention is about to mount a non reactive inflatable tissue on an appropriate size intravascular stent to control the flow distally. This created stent is then placed on the intended vessel per catheter. This tissue can be put in different designs:

1. A tire in a wheel with a central opening.
2. In the form of successive openings of different sizes to allow for future change in the size of the stenosis imposed to the circulation by interventions e.g. balloon catheters to remove one of the narrowings for example.
3. Crescentic or boggy masses of enclosed tissue that can be compressed later on e.g. by a balloon to modify the gradient across the stenosis produced e.g. pulmonary artery.
4. A design similar to naturally occurring stenotic valves.
5. A stenotic absorbable material to allow for natural progressive dilatation.
6. A stenotic material that swells with time to allow for progressive narrowing.

Figure 1 and 2 demonstrate a sketch of one version of items 1 and 4.

All these designs can be inflated or deflated to control their size during the procedure and sometimes later as well. The inflation can be done by carbon dioxide, air or even different fluids e.g. normal saline. The addition of the ability to compress the narrowed segment later on by dilating balloons is again feasible as well.

This could replace state of the art procedures e.g. the pulmonary artery band that we know and are using now.

For this purpose the metallic dilatable stents in common use in cardiology practice can be prepared to hold the balloon inside it. The balloon material that can be used is similar to the one used in valvotomy balloons in our current practice, however the essential requirement is only inflatability and non reactivity.

As this procedure is expected to be done in the catheterization laboratory, I believe it would be executed with much less mortality, morbidity and expense as compared to its surgical counterpart. I expect it thus to revolutionize the practice. Because the ability to perform a per catheter band without mortality will definitely make surgical corrections of some simple as well complicated cardiac lesions not needed or at least deferrable to the time where they could be done with less mortality. If we combine this by the ability to control the pressure gradient during insertion (e.g. doing echo or direct measurement in the cath and ascertaining the hemodynamic consequences directly). Again,

the ability to reduce or increase the pressure gradient at the same setting or at later settings. For more complex lesion, it can be done as a permanent palliation or in preparation for future palliation.
I suggest the name of Lotfy's stent for the stent that will be designed for this purpose.

The previous state of the art:

To achieve control over the blood flow inside the vessels a surgical procedure is undertaken (with its inherent costs, risks) to band the vessel from outside. Different systems had been devised for this but they were all applied from outside the vessel.

Problems in the previous state of the art:

1. High cost of the surgery, with inherent risks and problems associated with the throracic surgeries.
2. Sometimes the condition of the patient (e.g. a sick baby) is not suitable for the operation despite its urgency.
3. The inability to change the degree of the band once the operation is over except with another operation with again higher risks.
4. Fibrosis and distortion produced during and after the surgery would make future operations in the area involved more difficult.

What is new about the invention ?

1. Achieve the same result as the surgical intervention.
2. Avoid the risk and complications of surgery and reoperation.
3. The ability to change the degree of narrowing produced during and after the catheter procedure.

The procedure of pulmonary artery banding and related procedures was never reported in the literature to be done intravascularly.

How can it be used ?

A selected company producing the common use intravascular stent will be chosen after agreement with the inventor to upgrade some of its stents with the new designs and linings I suggested.

Claims:

1. The addition of inflatable and /or compressible and/or controllable lining to stents (medical or non medical) to control or limit the flow of fluids or gases through.
    a. This includes any form of stents including but not limited to metallic, plastic, totally inflatable stents or otherwise of medical or non medical use.
    b. This includes all shapes of stent designs including but not limited to ring, tubular, cylindrical, cone, pentagonal …etc.
    c. This includes all shapes and materials of linings used for the same purpose including but not limited to Gortex, Teflon, PTFE.
2. The addition of fixed lining narrowing to stents (medical or non medical) to control or limit the flow of fluids or gases through.
    a. This includes any form of stents including but not limited to metallic, plastic, totally inflatable stents or otherwise of medical or non medical use.
    b. This includes all shapes of stent designs including but not limited to ring, tubular, cylindrical, cone, pentagonal …etc.
    c. This includes all shapes and materials of linings used for the same purpose including but not limited to Gortex, Teflon, PTFE.
3. Stentless designs used for the same purpose (to control or limit the flow of fluids or gases through a vessel). The implantation techniques includes but is not limited to interventional, surgical or endoscopic).
4. The use of this technique includes but is not limited to inside the blood vessels, airways, urinary, gastrointestinal passages or industrial pipes.
5. This includes but is not limited to the different designs suggested above for this purpose.
6. The designs that will achieve the limitation or control of the flow inside the vessel in one or more than one direction are included as well.

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AMENDED CLAIMS

received by the International Bureau on 08 December 2004 (08.12.04): original claims 1 and 2 are unchanged ; original claims 3,4,5,6 are cancelled ; new claims 7 to 22 are added.

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Fax : 41 22 740 14 35.

Subject :
International application number PCT/EG 2003/000009

In correspondance to your last written report,

As regards section C documents given under category X, I only have a short comment:
All these inventions had the aim of dilating a narrow segment of a vessel while my invention aims at the reverse i.e. narrowing a normal or a dilated or even an originally narrow tube.
These authors used the inflatable part of their stents to dilate their stents into their proper size, I use mine with a clearly different design essentially to produce a modifiable narrowing inside the stent.

Claims:

The claims 1 and 2 are unchanged, claims 3, 4, 5, 6 are cancelled; claims 7 to 22 are added.

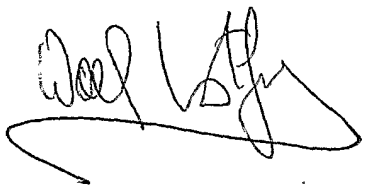
7. Means for injecting an inflation material into the lining when needed.
8. The lining of claim 1 where the lining is connected to a check valve for inflating and deflating the lining.
9. The lining of claim 1 where the proximal lining end is adapted to accept an inflating fluid or gas comprising a one or two way valve.
10. The lining of claim 1 where the valve comprises a plug of an elastomer having a slit breakthrough which closes upon application with pressure within the tubing.
11. The lining of claim 1 where the material is selected from polyethylene, polypropylene, their interpolymers and block copolymers, polyacrylonitrile, polyethylene terephalate and polybutylene terephalate, polytetrafluoroethylene, Teflon,

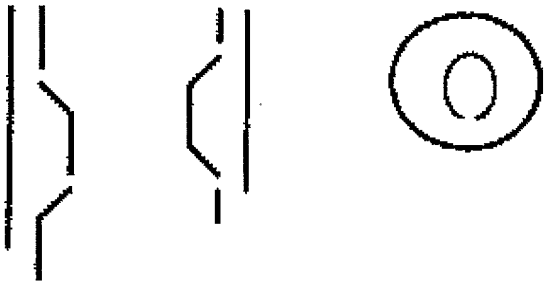
silicones, polymeric plastic, natural and synthetic rubber and mixtures thereof.

12. The lining of claim 1 which has been collapsed or ballooned to an enlarged diameter.
13. The lining of claim 1 comprising a radioopaque marker.
14. The lining of claim 1 that is inflatable by CO2, air, fluid, flowable gelatinous material, metallic powder or a hardening agent.
15. The lining of claim 1 wherein the check valve for inflation is of a breakaway design to permit separation from the means for injecting.
16. The lining of claim 1 that is fabricated solely or at least partly from a semipermeable membrane, and wherein the hollow wall has disposed hydrophilic material capable of absorbing a liquid to thereby increase the volume of said material. The final shape may be appropriate or modifiable by ballooning from the lumen or by inflation.
17. The lining of claim 11 that is fabricated from a semipermeable membrane, and wherein the hollow wall has disposed hydrophilic material that is a gel.
18. A lining for the stent as in claim 1 where the configuration is cylindrical, conal, pentagonal, trapezoidal, similar to naturally stenotic valves.. etc to achieve lumen narrowing.
19. The use of ultrashort stents (whether fixed, balloonable or inflatable) i.e. rings to support the narrowing lumen in claim 1.
20. Shaping the narrowing lining of claim 1 to direct the flow inside towards or away from a particular direction e.g. in a branched tube. Whether from the start or later on by either inflation of the lining or ballooning from the lumen.
21. The lining of claim 1 that is inflatable together with the stent with the same inflation procedure.
22. The lining of claim 1 that is inflatable to the point of totally occluding the lumen of the tube destined.

Yours sincerely,

Wael Lotfy, MD, MRCP
Associate Professor of Pediatrics
Cairo University





INTERNATIONAL SEARCH REPORT

International application No.
PCT/EG 2003/000009

CLASSIFICATION OF SUBJECT MATTER

IPC[7]: A61F2/06

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[7]: A61F2/06, 2/04 // A61M29/02

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 practicable, search terms used)

WPI, EPODOC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 293 968 B1 (S. TAHERI) 25 September 2001 (25.09.2001) *the whole document; especially figure 5; column 6, lines 39-46.*	1, 2
X	US 5 370 691 A (G. SAMSON) 6 December 1994 (06.12.1994) *the whole document; especially figures 1-3B; column 3, lines 1-57; column 4, lines 7-16, 39-56.*	1
X	US 5 234 456 A (T. SILVESTRINI) 10 August 1993 (10.08.1993) *the whole document; especially figures 1-4; column 2, lines 26- column 4, line 60.*	1
X	US 6 007 575 A (S. SAMUELS) 28 December 1999 (28.12.1999) *the whole document; especially figures 1, 2, 5a-6d; column 3, lines 24-53; column 4, line 7; column 4, line 45 - column 5, lines 16.*	1

☐ Further documents are listed in the continuation of Box C. ☒ See patent family 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 application or patent 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
14 October 2004 (14.10.2004)	25 October 2004 (25.10.2004)
Name and mailing adress of the ISA/AT Austrian Patent Office Dresdner Straße 87, A-1200 Vienna Facsimile No. 1/53424/535	Authorized officer LUDWIG H. Telephone No. 1/53424/340

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EG 2003/000009

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. ☒ Claims Nos.: 4
because they relate to subject matter not required to be searched by this Authority, namely:

claim 4 relates to the use of the stent and thus to a method for therapeutical treatment of the human or animal body according to PCT Rule 39.1 (iv) under Article 17(2)(a)(i)

2. ☒ Claims Nos.: 3,5,6
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:

claims 3,5,6 do not refer to exactly defined technical features of a stent (".. stentless design used for .."; ".. this includes but is not limited to the different designs .."; ".. the designs that will achieve .."); according to PCT Rule 6.3 (a)(b) claims should contain technical features of the invention which are necessary for the definition of the claimed subject matter

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. ☐ 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.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Int[redacted]nal application No.
PCT/EG 2003/000009

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US A 5234456	1993-08-10	IE A 910398	1991-08-14
		DK T 441516T	1995-06-12
		IE B 65798	1995-11-15
		ES T 2071207T	1995-06-16
		EP A 0441516	1991-08-14
US A 5370691	1994-12-06	none	
US A 6007575	1999-12-28	none	
US B 6293968	2001-09-25	none	