

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
16 October 2003 (16.10.2003)

PCT

(10) International Publication Number  
**WO 2003/084389 A3**

(51) International Patent Classification<sup>7</sup>: **A61B 17/08**

(21) International Application Number:  
PCT/US2003/009652

(22) International Filing Date: 31 March 2003 (31.03.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
10/114,662 1 April 2002 (01.04.2002) US

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, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (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).

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**Declaration under Rule 4.17:**

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for all designations*

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**Published:**

— *with international search report*

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(88) Date of publication of the international search report:  
21 May 2004

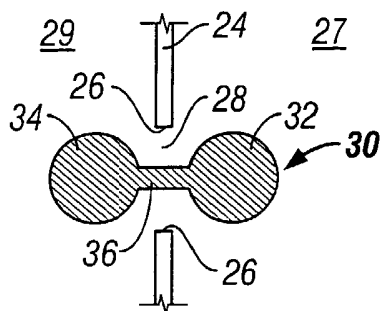
(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,

*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.*



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(54) Title: METHOD AND BARRIER FOR LIMITING FLUID MOVEMENT THROUGH A TISSUE RENT

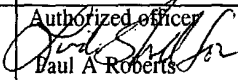


(57) Abstract: A method and device provides for limiting fluid movement through a rent in a membranous tissue by forming a biocompatible and biodegradable barrier at the site of the rent. The barrier (80) is formed by inserting into the rent (28) a plug (60) that includes connected water-swellaable parts (62, 64), so that within a short time following placement of the plug at the site the swellaable parts (62, 64) expand (82, 84) *in situ* to form the barrier (80) and occlude the rent (28). As fluids near the site are taken up by the swellaable material, the material expands rapidly to fill the rent, engaging the marginal surfaces of the membrane (24) near the edges of rent (26) and forming a secure barrier (80) at the site. All the materials of the plug are biocompatible and, over a period of time that allows for healing of the rent, all the components of the barrier are completely degraded without leaving any residual material at the site.

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/09652

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(7) : A61B 17/08 US CL : 606/214 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) U.S. : 606/213; 606/214  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)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,976,174 A (RUIZ) 02 November 1999 (02.11.1999), figure 6.	1, 2, 4, 7, 9, 10, 13, 15, 16, 27, 29, 30, 32- 35, 57-64 ----- 36, 37, 38, & 39
Y	US 5,192,301 A (KAMIYA et al) 09 March 1993 (09.03.1993), see entire document.	36, 37, 38, & 39
A	US 5,861,003 A (LATSON et al) 19 January 1999 (19.01.1999), see entire document.	1
X	US 6,096,021 A (HELM et al) 01 August 2000 (01.08.2000), figure 4.	1 and 29
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> 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	"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
"E"	earlier application or patent published on or after the international filing date	"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
"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)	"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
"O"	document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed	
Date of the actual completion of the international search 16 January 2004 (16.01.2004)		Date of mailing of the international search report <b>01 MAR 2004</b>
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230		Authorized officer  Paul A. Roberts Telephone No. (703) 308-0858

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/09652

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

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

1. ☐ Claim Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claim 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. ☐ Claim 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:  
Please See Continuation Sheet

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.: 1 2 4 5 7 9 10 13 15 16 27 29 30 32-35 36 37 38 39 44 57-64

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

PCT/US03/09652

### BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

Each invention is considered one selection from each letter. An example of one invention is A1 - B2 - C2 - D1 - E 1, 2, 3, 7, 10\* - F1, G2). Thus there are 2 + 2 + 4 + 10 + 6 + 4 inventions to choose from constituting a total 28 unique inventions.

The claims associated with the first invention, which is automatically elected are:

1, 2, 4, 5, 7, 9, 10, 13, 15, 16, 27, 29, 30, 32-35, 36, 37, 38, 39, 44, and 57-64

Method of placing the plug wherein:

A) Plug parts:

1. Plug has two portions. Claims 2, 16
2. Plug has a section that has a plurality of portions Claims, 3, 17

B) Method uses:

1. A blade. Claim 5, 19
2. A probe. Claims 6, 20

C) Method uses:

1. A lumen of a needle. Claim 7, 21
2. A catheter. Claims 8, 12

D. Method location:

1. Intraspinal. Claims 10, 13, 24, 27
2. Intracranial. Claims 11, 14, 25, 28
3. GI tract. Claims 67
4. Urinary bladder. Claims 68

E. Materials or material to make plug out of:

(\*If the selection is a subsidiary of another selection both maybe selected and counted as one invention. Example a hydrogel is usually from biological tissue, and biosynthesis, possibly from collagen, and generally swellable.)

1. Gelatin or similar material. Claim 38
2. From biological tissue. Claim 39
3. From biosynthesis. Claim 40
4. Non biological. Claims 41 and 42
5. Foamed Gel or similar material. Claim 43
6. Hydrogel. Claim 44
7. Non Swellable. Claims 45, 46, 47
8. Collagen. Claim 49
9. Synthetic polymer. Claim 50
10. Water swellable. Claim 36

F. Various shapes:

1. Dumbell. Claim 31
2. Beads. Claim 32
3. Axially elongated. Claim 53
4. Polygonal. Claim 54
5. Discoid. Claim 55
6. Ovoid. Claim 56

G. Filament Composition:

1. Monofilament. Claim 48
2. Collagen filament. Claim 49

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3. Sterile Synthetic filament Claim 50

4. Absorbant suture. Claim 51

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The base claims these species depend on which claims the method of placing a swellable plug into an corporeal space is well-known in the art. A reference such as Weinstein et al. US 5370660 discloses this method.