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- (81) **Designated States (unless otherwise indicated, for every
kind of national protection available):** AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ,

CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO,
DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN,
HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR,
KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME,
MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ,
OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG,
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- (84) **Designated States (unless otherwise indicated, for every
kind of regional protection available):** ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG,
ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ,
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,
EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— as to the identity of the inventor (Rule 4.17(i))

Published:

— with international search report (Art. 21(3))

- (88) **Date of publication of the international search report:**
27 December 2012

(54) **Title:** MEDICAL DEVICE FOR TREATMENT OF URINARY INCONTINENCE IN FEMALES

(57) **Abstract:** An intra-vaginal device for controlling urinary incontinence, designed to be placed longitudinally in the vagina, comprises: a. a deformable distal portion, placed in the subvesical region of the vagina, characterized by a deformable state and an un-deformable state; b. a deformable proximal portion placed in the suburethral portion of the vagina, characterized by a deformable state and an un-deformable state; c. a deformation controlling mechanism interconnecting said distal portion and said proximal portion, adapted to at reversibly transform said distal portion and said proximal portion from said deformable state to said un-deformable state; and from said un-deformable state to said deformable state; wherein upon predetermined amount of intra-vaginal pressure applied on said proximal pressure, said deformation controlling mechanism is adapted to transform proximal portion from said un-deformable state to said deformable state such that pressure is applied on said urethra.



INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL 11/00288

A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61F 2/04 (2011.01) USPC - 600/30 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) USPC: 600/30 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched USPC: 600/29, 30, 31, 37; 623/11.11, 23.65, 23.66, 23.67, 23.68 (keyword limited; terms below) Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) PubWEST(PGPB, USPT, EPAB, JPAB); Google Search Terms Used: stress, incontinen\$2, sens\$3, pressure, proximal, distal, deform\$4, inflat\$4, intra, vagin\$2, expand\$4, insert\$3, balloon, valve, control, remote, open\$3, clos\$3, magnet, underwear, nitinol, shape memory, electroactive polymer, diaphragm, urethr\$2.																						
C. DOCUMENTS CONSIDERED TO BE RELEVANT																						
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:10%; padding: 5px;">Category*</th> <th style="width:60%; padding: 5px;">Citation of document, with indication, where appropriate, of the relevant passages</th> <th style="width:30%; padding: 5px;">Relevant to claim No.</th> </tr> </thead> <tbody> <tr> <td style="text-align:center; padding: 5px;">Y</td> <td style="padding: 5px;">US 2004/0158122 A1 (GUERQUIN) 12 August 2004 (12.08.2004) fig 7, abstract, para [0034], [0038], [0043], [0045], [0062]-[0063]</td> <td style="padding: 5px;">1-28, 32-39, 66/(1)-70/(1), 87, 89/(87)-95/(87), 97, 98/(87)-117/(87), 118, 119, 123-130, 152/(1), 153/(87)</td> </tr> <tr> <td style="text-align:center; padding: 5px;">Y</td> <td style="padding: 5px;">US 6,110,099 A (BENDEREV) 29 August 2000 (29.08.2000) fig 1, 8, 10, 20, col 5, ln 66-67, col 6, ln 1-2, col 6, ln 10-17, col 8, ln 4-13, col 9, ln 16-38, col 11, ln 6-18, col 13, ln 28-42</td> <td style="padding: 5px;">1-28, 32-39, 66/(1)-70/(1), 87, 89/(87)-95/(87), 97, 98/(87)-117/(87), 118, 119, 123-130, 152/(1), 153/(87)</td> </tr> <tr> <td style="text-align:center; padding: 5px;">Y</td> <td style="padding: 5px;">US 6,135,945 A (SULTAN) 24 October 2000 (24.10.2000) abstract, col 4, ln 19-20, col 5, ln 34-41</td> <td style="padding: 5px;">1-28, 32-39, 66/(1)-70/(1), 87, 89/(87)-95/(87), 97, 98/(87)-117/(87), 118, 119, 123-130, 152/(1), 153/(87)</td> </tr> <tr> <td style="text-align:center; padding: 5px;">Y</td> <td style="padding: 5px;">US 5,795,288 A (COHEN et al) 18 August 1998 (18.08.1998) col 3, ln 48-66</td> <td style="padding: 5px;">5-6, 95/(87), 97</td> </tr> <tr> <td style="text-align:center; padding: 5px;">Y</td> <td style="padding: 5px;">US 2009/0105527 A1 (CONNORS et al) 23 April 2009 (23.04.2009) para [0120]</td> <td style="padding: 5px;">9, 24, 100/(87), 115/(87), 152/(1), 153/(87)</td> </tr> <tr> <td style="text-align:center; padding: 5px;">Y</td> <td style="padding: 5px;">US 2009/0247817 A1 (FORSELL) 01 October 2009 (01.10.2009) para [0037]</td> <td style="padding: 5px;">15, 106/(87)</td> </tr> </tbody> </table>	Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	Y	US 2004/0158122 A1 (GUERQUIN) 12 August 2004 (12.08.2004) fig 7, abstract, para [0034], [0038], [0043], [0045], [0062]-[0063]	1-28, 32-39, 66/(1)-70/(1), 87, 89/(87)-95/(87), 97, 98/(87)-117/(87), 118, 119, 123-130, 152/(1), 153/(87)	Y	US 6,110,099 A (BENDEREV) 29 August 2000 (29.08.2000) fig 1, 8, 10, 20, col 5, ln 66-67, col 6, ln 1-2, col 6, ln 10-17, col 8, ln 4-13, col 9, ln 16-38, col 11, ln 6-18, col 13, ln 28-42	1-28, 32-39, 66/(1)-70/(1), 87, 89/(87)-95/(87), 97, 98/(87)-117/(87), 118, 119, 123-130, 152/(1), 153/(87)	Y	US 6,135,945 A (SULTAN) 24 October 2000 (24.10.2000) abstract, col 4, ln 19-20, col 5, ln 34-41	1-28, 32-39, 66/(1)-70/(1), 87, 89/(87)-95/(87), 97, 98/(87)-117/(87), 118, 119, 123-130, 152/(1), 153/(87)	Y	US 5,795,288 A (COHEN et al) 18 August 1998 (18.08.1998) col 3, ln 48-66	5-6, 95/(87), 97	Y	US 2009/0105527 A1 (CONNORS et al) 23 April 2009 (23.04.2009) para [0120]	9, 24, 100/(87), 115/(87), 152/(1), 153/(87)	Y	US 2009/0247817 A1 (FORSELL) 01 October 2009 (01.10.2009) para [0037]	15, 106/(87)	<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/>
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.																				
Y	US 2004/0158122 A1 (GUERQUIN) 12 August 2004 (12.08.2004) fig 7, abstract, para [0034], [0038], [0043], [0045], [0062]-[0063]	1-28, 32-39, 66/(1)-70/(1), 87, 89/(87)-95/(87), 97, 98/(87)-117/(87), 118, 119, 123-130, 152/(1), 153/(87)																				
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* 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 04 December 2011 (04.12.2011)	Date of mailing of the international search report <div style="font-size: 24pt; font-weight: bold; text-align: center;">16 DEC 2011</div>																					
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. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774																					

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL 11/00288

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,056,699 A (SOHN et al) 02 May 2000 (02.05.2000) col 4, ln 49-51	25-26, 116/(87)-117/(87)
Y	US 2010/0016652 A1 (BONNI) 21 January 2010 (21.01.2010) para [0009], [0036], [0049]	32-39, 93/(87)-94/(87), 123-130
Y	US 2010/0049192 A1 (HOLTZ et al) 25 February 2010 (25.02.2010) fig 4C, para [0160]	5, 95/(87)
Y	US 2006/0264699 A1 (GERTNER) 23 November 2006 (23.11.2006) para [0151], [0164]	26, 117/(87)
Y	US 2009/0131959 A1 (ROLLAND) 21 May 2009 (21.05.2009) para [0045]	37, 38, 128, 129
Y	US 2007/0043254 A1 (DEMARCO) 22 February 2007 (22.02.2007) abstract	38, 129

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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 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.:
because they relate to subject matter not required to be searched by this Authority, namely:

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.: 29-31, 76, 77, 120-122, 133, and 134
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
See extra 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 additional fees, this Authority did not invite payment of additional fees.
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.:
1-28, 32-39, 66/(1)-70/(1), 87, 89/(87)-95/(87), 97, 98/(87)-117/(87), 118, 119, 123-130, 152/(1), 153/(87)

- Remark on Protest**
- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
 - The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
 - No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

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This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-28, 32-39, 66/(1)-70/(1), 87, 89/(87)-95/(87), 97, 98/(87)-117/(87), 118, 119, 123-130, 152/(1), 153/(87); directed to a device and method for treating urinary incontinence, comprising a deformation controlling mechanism adapted to reversibly transform a distal portion and a proximal portion from a deformable state to an un-deformable state.

Group II: Claims 40-65, 66/(40)-70/(40), 71-75, 78-86, 88, 89/(88)-95/(88), 96, 98/(88)-117/(88), 131, 132, 135-143, 152/(40), 153/(88); directed to a device and method for treating urinary incontinence, comprising a reservoir.

Group III: Claims 144-151; directed to a method for treating urinary incontinence, comprising contracting at least a portion of the pelvic muscles.

The inventions listed as Groups I - III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is a deformation controlling mechanism adapted to reversibly transform a distal portion and a proximal portion from a deformable state to an un-deformable state, which is not present in Groups II or III. The special technical feature of Group II is a reservoir, which is not present in Groups I or III. The special technical feature of Group III is contracting at least a portion of the pelvic muscles, which is not present in Groups I or II.

The sole element of commonality between groups I-III is that of obtaining an intra-vaginal device for controlling urinary incontinence and inserting said device into the vagina such that said distal portion is located in the subvesical region and said proximal portion is located in the suburethral region, which is known in the prior art (ref. US 2004/0158122 A1 to Guerquin; Abstract--"a device (10) for preventing female stress incontinence"; para [0062]--"after the treatment element 20 has been positioned in the vagina 120, the proximal portion 22 extends into the front or sub-urethral portion 122 of the vagina 120 [...] and the distal portion 24 extends into the rear or sub-vesical portion 124 of the vagina 120").

The only elements of commonality between groups I and II are those of a deformable distal portion designed to be placed in the subvesical region of the vagina and a deformable proximal portion designed to be placed in the suburethral portion of the vagina, which is known in the prior art or would have been obvious to one of ordinary skill in the art (ref. US 2004/0158122 A1 to Guerquin; Abstract--"distal part (24) extending the second end (22b) of the proximal part (22), made of a material reversibly deformable under pressure"; para [0062]--"after the treatment element 20 has been positioned in the vagina 120, the proximal portion 22 extends into the front or sub-urethral portion 122 of the vagina 120 [...] and the distal portion 24 extends into the rear or sub-vesical portion 124 of the vagina 120"; it would have been obvious to one of ordinary skill in the art that the proximal portion might also be deformable in order to permit variable pressure to be exerted on the urethra), sensing intra-vaginal pressure, which is known in the prior art (ref. US 6,086,549 A to Neese et al.; col 8, ln 55-67--"the system represented in FIG. 2 can be used to determine the intravaginal pressure"), and if pressure is above predetermined threshold, said device is activated, thereby applying pressure on the urethra such that urinary incontinence is treated, which is known in the prior art (ref. US 6,135,945 A; Abstract--"a pressure sensor operable for sensing intra-abdominal pressure when implanted in a patient and operable for generating a pressure signal in response to said sensed pressure. An actuating device is operably coupled to the pressure sensor and is responsive for generating an electrical signal in response to the pressure signal. A controller is operably coupled to the actuating device and configured for engaging a urethra to selectively compress the urethra and prevent incontinence"; col 2, ln 22-26--"The current invention is an implantable device which enhances urethral sphincter closure only when intra-abdominal pressure rises above a certain value").

The sole element of commonality between groups I and III is that of said proximal portion applying pressure on the urethra, which is known in the prior art (ref. US 5,163,897 to Persky; col 2, ln 56-59--"prosthesis 14 includes a central compressing portion 20 which is an elongated, inflatable, proximal portion. This proximal portion when in use is positioned adjacent the urethra"; col 2, ln 65 to col 3, ln 1--"central portion 20 includes a raised central compressor part 25 best seen in FIGS. 5 and 8. The compressor part 25 extends longitudinally of the urethra and is positioned centrally, transversely speaking, of the urethra to provide effective compression of the urethra"; Fig. 2).

Accordingly, unity of invention is lacking under PCT Rule 13.1.

Certain claims have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention. Claims 29-31, 76, 77, 120-122, 133, and 134 are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).