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Tavigny B.V. i.o. te Den Haag.

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74 Gemachtigde:
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54 **Uterine manipulator and cutting unit.**

57 The invention relates to a uterine manipulator comprising:
- a mobilisation rod comprising a central tubular body connected in an articulated manner at one end to a first control grip and at the other end to a screw and means for transmitting commands from said first control grip to said screw;
- a complementary unit comprising a sleeve suitable for being associated coaxially and slidingly with said central tubular body of said mobilisation rod, for guiding its movement, wherein the complementary unit has a sectioning device positioned at a distal end of the sleeve, which sectioning device is selected from the group comprising a knife-blade and an ultrasonic cutter.

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Dit octrooi is verleend ongeacht het bijgevoegde resultaat van het onderzoek naar de stand van de techniek en schriftelijke opinie. Het octrooischrift komt overeen met de oorspronkelijk ingediende stukken.

Uterine manipulator and cutting unit

The invention relates to a uterine manipulator comprising:

- a mobilisation rod comprising a central tubular body connected in an articulated manner at one end to a first control grip and at the other end to a positioning organ and means for transmitting commands from said first control grip to said positioning organ;

- a complementary unit comprising a sleeve suitable for being associated coaxially and slidingly with said central tubular body of said mobilisation rod, for guiding its movement.

Such a uterine manipulator is known from WO 2008/136024 and may be used when executing a laparoscopic hysterectomy.

As is well known in the art the function of uterine manipulators is to help surgeons to visualize the peritoneal cavity and the uterus by laparoscopy during a check-up or diagnostic examination or during a surgical operation, such as hysterectomy.

It is known from US 2001/0021854 to provide a uterine manipulator with a monopolar or bipolar electrode, which is rotationally provided on a cupula forming part of the manipulator. Said electrode is used for making an incision in and cut the vaginal wall directly via the vagina, in order to increase safety and speed of this operation whereby the dissected uterus can be removed through the vagina.

A first problem of the device known from US 2001/0021854 is that the use of a monopolar or bipolar electrode for making an incision and cut the vaginal wall is that surrounding tissue is damaged. In case of using a bipolar electrode the damage concerns at least approximately five millimetre tissue at both sides of the cut whereas when using a monopolar electrode the damage at both sides of the cut concerns at least approximately 10 mm of tissue. The increase in vaginal cuff dehiscence is believed to be mainly caused by an excessive cauterization of the tissue during the amputation of the uterus from the vagina when using a monopolar or bipolar electrode.

A further problem of the device known from US 2001/0021854 is that its construction is quite complicated due to the necessity to have the electrode be construed in a manner

that it can rotate around the stationary cupula.

It is an object of the invention to alleviate said problems and to provide a uterine manipulator with which the making of an incision and a cut in the vaginal wall can be performed with increased accuracy and with very limited damage to surrounding tissue.

The uterine manipulator of the invention is to that end characterized by the features of one or more of the appended claims.

10 In a first aspect of the invention the uterine manipulator is characterized in that the complementary unit has a sectioning device positioned at a distal end of the sleeve, which sectioning device is selected from the group comprising a knife-blade and an ultrasonic cutter. Making use of a knife or an ultrasonic cutter, largely avoids the tissue damage that occurs with the device known from US 2001/0021854.

When the sectioning device is an ultrasonic cutter this cutter can simply be switched on or off depending on the needs during the surgical operation.

20 When the sectioning device is a knife blade, this knife blade is preferably arranged such that it is retractable or rotatable between an operational and an inoperational position. In this manner also unintended damage to the vaginal wall or other tissue can be effectively avoided when moving the manipulator into or out of the vagina.

It is further preferred that the distal end of the sleeve is provided with at least one light source. This has the advantage that during the execution of the surgical operation, which takes place while simultaneously the external wall of the uterus is viewed in the abdominal cavity by using a laparoscopic viewing instrument, the position of the sectioning device inside the vagina can be simply detected by looking at the light from the light source shining through the vaginal wall. This is a very effective way to easily determine where to start with the incision and how the cut through the vaginal wall should be further executed and damage to other bodily parts such as the bladder, ureter and the intestines be avoided.

The applicant points out that the invention is also embodied in a separate cutting unit comprising an elongated body having a sectioning device positioned at a distal end of the body, which sectioning device is selected from the group com-

prising a knifeblade, an ultrasonic cutter.

A preferable embodiment of this cutting unit has the feature that the sectioning device is a knifeblade and that said knifeblade is retractable or rotatable between an operational
5 and an inoperational position.

It is further preferred that the cutting unit of the invention has at the distal end of the body at least one light source.

The invention will hereinafter be further elucidated
10 with reference to some exemplary embodiments of the uterine manipulator of the invention and with reference to the drawing. Although the disclosure and discussion offered hereinafter concern embodiments of the uterine manipulator of the invention, it is expressly pointed out that the invention is also embodied in
15 a separate cutting unit which is essentially embodied similarly as the complementary unit forming part of the disclosed uterine manipulator as discussed in the following.

In the drawing:

- Fig. 1 and Fig. 2 show a mobilisation rod and a complementary
20 together forming the uterine manipulator of the invention;

- Fig. 3 shows a detail of the combined mobilisation rod and complementary unit;

- Fig. 4 shows a first preferred embodiment pertaining
25 to the uterine manipulator of the invention, and

- Fig. 5 shows a detail of the second preferred embodiment of the uterine manipulator of the invention.

Wherever in the figures the same reference numerals are applied these numerals refer to the same parts.

30 With reference first to Fig. 1 and Fig. 2 a mobilisation rod 1 is shown comprising a central tubular body 3, which is connected in an articulated manner at one end to a first control grip 4 and at the other end to a positioning organ in the form of a screw 5. The first control grip 4 and the screw 5 are
35 connected in a manner known per se by means for transmitting commands from the first control grip 4 to the screw 5. This is used in practice to manipulate the uterus in a desired position which is beneficial for carrying out a surgical operation.

The mobilisation rod 1 as shown in Fig. 1 cooperates
40 for that purpose with a complementary unit 2 as shown in Fig. 2 which comprises a sleeve 6, which is suitable for being associ-

ated coaxially and slidingly with the said central tubular body 3 of the mobilisation rod 1 shown in Fig. 1. In this assembled position of the mobilisation rod 1 and the complementary unit 2, the uterine manipulator may be inserted into the vagina up to the point where the screw 5 reaches a suitable position in the uterus for manipulating the uterus' position.

Fig. 2 shows further that the complementary unit 2 is provided with a second control grip 12, which can be used to rotate the sleeve 6 for bringing the distal end 7 of said sleeve 6 into a desired position with respect to the screw 5. Further, the complementary unit 2 is provided with a sealing means 8, for instance an inflatable balloon which can be inflated through a hose 13 for sealing off the vagina when carrying out the surgical operation in order to prevent the escape of gas, mostly CO₂, which is brought into the abdominal cavity for assisting the simultaneous laparoscopic viewing taking place through the abdominal wall.

For clarity purposes the assembled position of the mobilisation rod 1 and the complementary unit 2 of the uterine manipulator is shown, in the detailed view of Fig. 3.

With reference further to Fig. 4 a first preferred embodiment of the complementary unit 2 of the uterine manipulator is shown, wherein at the distal end 7 of the sleeve 6 a knife blade 10 is provided which is retractable or - in the shown embodiment - rotatable according to the arrow A between an operational and an inoperational position. The knife blade 10 is shown in Fig. 4 in the operational position such that it can be used to make an incision and cut the vaginal wall in order to separate the uterus from the vagina.

Fig. 5 shows a detail of a second embodiment of the complementary unit 2 of the uterine manipulator of the invention, wherein the sectioning device positioned at the distal end 7 of the sleeve 6 is an ultrasonic cutter 9. The operation of this cutter 9 can be easily switched on and off from the proximal side of the uterine manipulator by a suitable controllable source of ultrasonic energy.

Fig. 5 also shows that the distal end 7 of the sleeve 6 is provided with at least one light source 11. In the shown embodiment there are two such light sources 11 which are located in the immediate vicinity or adjacent to the cutter 9 in order to assist the surgeon to decide where to initiate and make the

cut in the tissue connecting the uterus to the vagina, by looking laparoscopically at the light shining through the vaginal wall into the abdominal cavity.

5 These light sources 11 provide a reliable indication where the sectioning device resides in the vagina. This makes it easy to avoid damage to neighbouring intestines and other bodily parts, when making an incision into the vaginal wall in order to cut loose the uterus.

10 As mentioned above the invention is also embodied in a separate cutting unit having essentially the features of the complementary unit 2 that has been discussed here above. It is remarked though that such a separate cutting unit may be embodied with an elongated body that may be entirely or partly solid rather than be shaped as a sleeve, as is the case with the complementary unit forming part of the uterine manipulator of the
15 invention.

CONCLUSIES

1. Baarmoedermanipulator omvattende:

- een bewegingsstang (1) omvattende een centraal buisvormig lichaam (3) welke op een gelede wijze aan één uiteinde verbonden is met een eerste bedieningshandvat (4) en aan het andere uiteinde met een positioneerorgaan (5) en middelen voor het overbrengen van een bediening van het eerste bedieningshandvat (4) naar genoemd positioneerorgaan (5);

- een aanvullende eenheid (2) omvattende een huls (6) die geschikt is om coaxiaal en verschuifbaar samen te werken met genoemd centraal buisvormig lichaam (3) van de bewegingsstang (1) voor het geleiden van haar beweging, **met het kenmerk**, dat de aanvullende eenheid (2) een deelinrichting (9, 10) heeft die gepositioneerd is aan een distaal uiteinde (7) van de huls (6), welke deelinrichting (9, 10) geselecteerd is uit de groep omvattende een mesblad (10), een ultrasonische snijder (9).

2. Baarmoedermanipulator volgens conclusie 1, **met het kenmerk**, dat de deelinrichting een mesblad (10) is en dat genoemd mesblad intrekbaar of roteerbaar is tussen een operationele en een inoperationele positie.

3. Baarmoedermanipulator volgens conclusie 1 of 2, **met het kenmerk**, dat het distale uiteinde (7) van de huls (6) voorzien is van ten minste één lichtbron (11).

4. Snijinrichting (2) omvattende een langwerpige lichaam (6), **met het kenmerk**, dat deze een deelinrichting (9, 10) heeft gepositioneerd op een distaal uiteinde (7) van het lichaam (6), welke deelinrichting (9, 10) geselecteerd is uit de groep omvattende een mesblad (10), een ultrasonische snijder (9).

5. Snijinrichting volgens conclusie 4, **met het kenmerk**, dat de deelinrichting een mesblad (10) is en dat genoemd mesblad intrekbaar of roteerbaar is tussen een operationele en een inoperationele positie.

6. Snijinrichting volgens conclusie 4 of 5, **met het kenmerk**, dat het distale uiteinde (7) van het lichaam (6) voorzien is van ten minste één lichtbron (11).

1/2

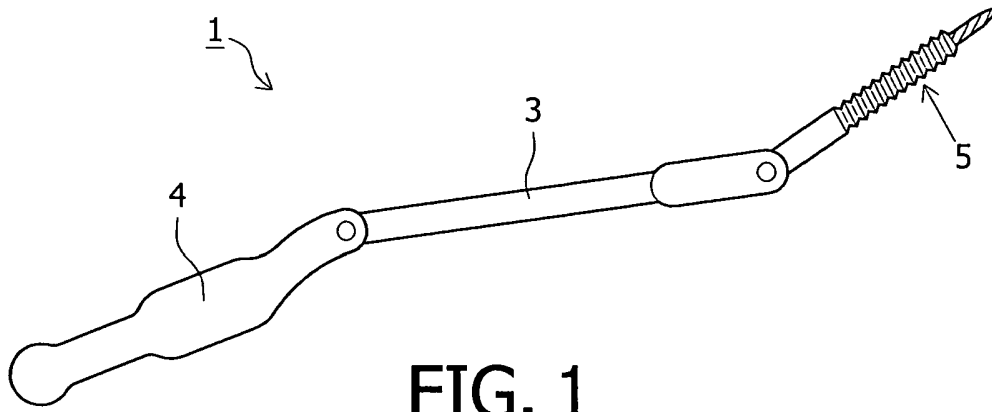


FIG. 1

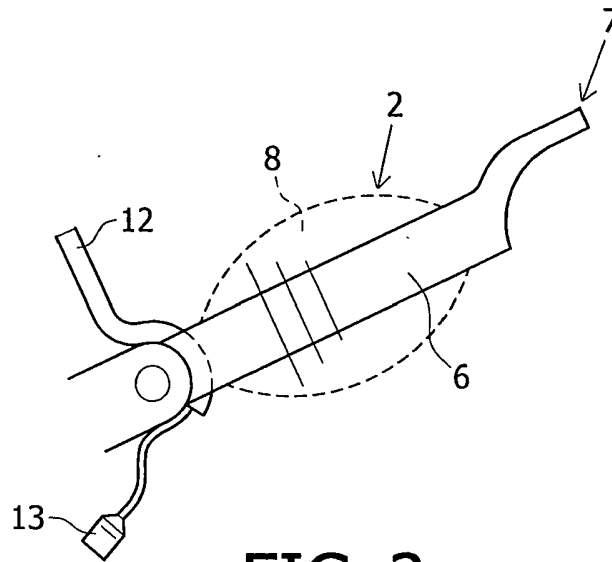


FIG. 2

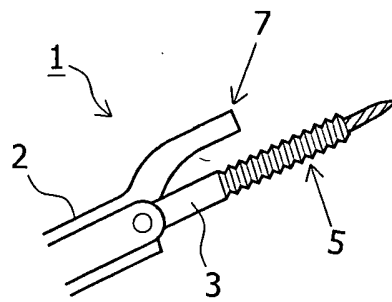


FIG. 3

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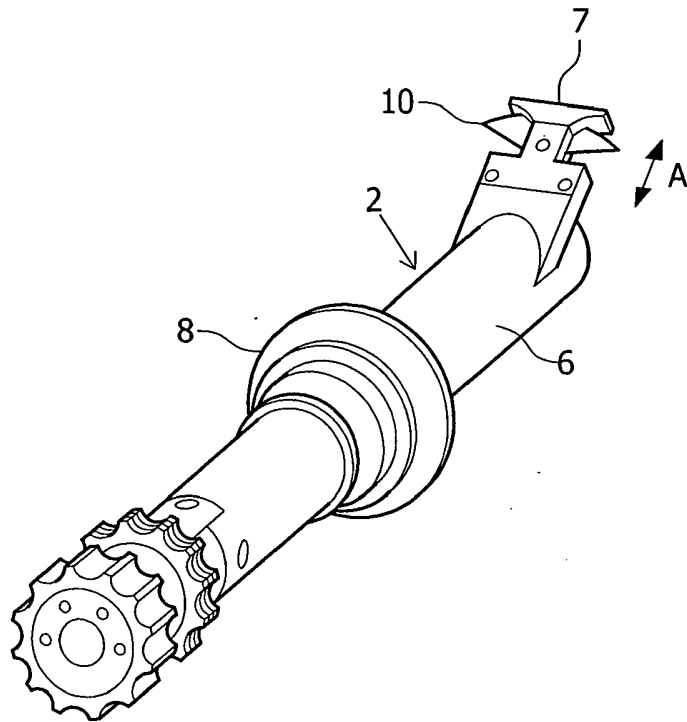


FIG. 4

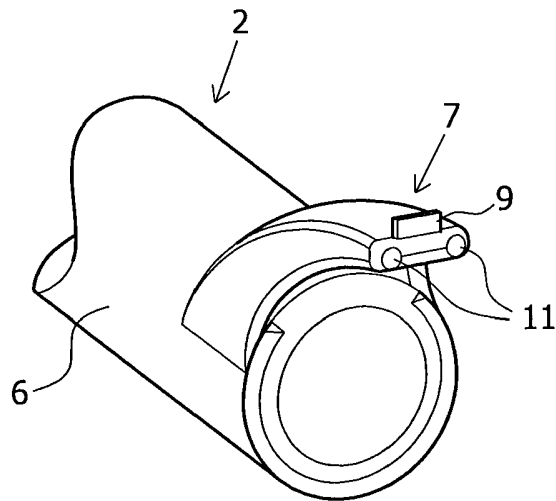


FIG. 5

SAMENWERKINGSVERDRAG (PCT)

RAPPORT BETREFFENDE NIEUWHEIDSONDERZOEK VAN INTERNATIONAAL TYPE

IDENTIFICATIE VAN DE NATIONALE AANVRAGE	KENMERK VAN DE AANVRAGER OF VAN DE GEMACHTIGDE NL47985-VB
Nederlands aanvraag nr. 2002922	Indieningsdatum 25-05-2009
	Ingeroepen voorrangsdatum
Aanvrager (Naam) Tavigny B.V.	
Datum van het verzoek voor een onderzoek van internationaal type 31-07-2009	Door de Instantie voor Internationaal Onderzoek aan het verzoek voor een onderzoek van internationaal type toegekend nr. SN 52663
I. CLASSIFICATIE VAN HET ONDERWERP (bij toepassing van verschillende classificaties, alle classificatiesymbolen opgeven)	
Volgens de internationale classificatie (IPC) A61B17/42 A61B19/00	
II. ONDERZOCHETE GEBIEDEN VAN DE TECHNIEK	
Onderzochte minimumdocumentatie	
Classificatiesysteem	Classificatiesymbolen
IPC8	A61B
Onderzochte andere documentatie dan de minimum documentatie, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen	
III. <input type="checkbox"/>	GEEN ONDERZOEK MOGELIJK VOOR BEPAALDE CONCLUSIES (opmerkingen op aanvullingsblad)
IV. <input type="checkbox"/>	GEBREK AAN EENHEID VAN UITVINDING (opmerkingen op aanvullingsblad)

**ONDERZOEKSRAPPORT BETREFFENDE HET
RESULTAAT VAN HET ONDERZOEK NAAR DE STAND
VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE**

Nummer van het verzoek om een onderzoek naar
de stand van de techniek
NL 2002922

A. CLASSIFICATIE VAN HET ONDERWERP
INV. A61B17/42 A61B19/00

Volgens de Internationale Classificatie van octrooien (IPC) of zowel volgens de nationale classificatie als volgens de IPC.

B. ONDERZOCHE GEBIEDEN VAN DE TECHNIEK

Onderzochte minimum documentatie (classificatie gevolgd door classificatiesymbolen):
A61B

Onderzochte andere documentatie dan de minimum documentatie, voor dergelijke documenten, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

Tijdens het onderzoek geraadpleegde elektronische gegevensbestanden (naam van de gegevensbestanden en, waar uitvoerbaar, gebruikte trefwoorden)
EPO-Internal

C. VAN BELANG GEACHTE DOCUMENTEN

Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
A	WO 2008/136024 A (SOFAR SPA [IT]; DAMIANI ALFREDO MARIA [IT]; MELGRATI LUIGI [IT]; FRANZ) 13 november 2008 (2008-11-13) in de aanvraag genoemd het gehele document -----	1-6
A	WO 03/043510 A (ENDOLINK AB [SE]; ENGMAN MIKAEL [SE]) 30 mei 2003 (2003-05-30) het gehele document -----	1-6
A	US 2001/021854 A1 (DONNEZ JACQUES [BE] ET AL) 13 september 2001 (2001-09-13) het gehele document -----	1-6
A	DE 195 43 576 A1 (STORZ KARL GMBH & CO [DE]) 5 juni 1997 (1997-06-05) kolom 2, regel 9 - regel 16; figuur 1 ----- -/--	1,3,6

Verdere documenten worden vermeld in het vervolg van vak C.

Leden van dezelfde octroofamilie zijn vermeld in een bijlage

° Speciale categorieën van aangehaalde documenten

A niet tot de categorie X of Y behorende literatuur die de stand van de techniek beschrijft

D in de octrooiaanvraag vermeld

E eerdere octrooi(aanvraag), gepubliceerd op of na de indieningsdatum, waarin dezelfde uitvinding wordt beschreven

L om andere redenen vermelde literatuur

O niet-schriftelijke stand van de techniek

P tussen de voorrangsdatum en de indieningsdatum gepubliceerde literatuur

T na de indieningsdatum of de voorrangsdatum gepubliceerde literatuur die niet bezwaard is voor de octrooiaanvraag, maar wordt vermeld ter verheldering van de theorie of het principe dat ten grondslag ligt aan de uitvinding

X de conclusie wordt als niet nieuw of niet inventief beschouwd ten opzichte van deze literatuur

Y de conclusie wordt als niet inventief beschouwd ten opzichte van de combinatie van deze literatuur met andere geciteerde literatuur van dezelfde categorie, waarbij de combinatie voor de vakman voor de hand liggend wordt geacht

& lid van dezelfde octroofamilie of overeenkomstige octrooipublicatie

Datum waarop het onderzoek naar de stand van de techniek van internationaal type werd voltooid

13 November 2009

Verzenddatum van het rapport van het onderzoek naar de stand van de techniek van internationaal type

Naam en adres van de instantie

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
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De bevoegde ambtenaar

Strazdauskas, Gedas

**ONDERZOEKSRAPPORT BETREFFENDE HET
RESULTAAT VAN HET ONDERZOEK NAAR DE STAND
VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE**

Nummer van het verzoek om een onderzoek naar
de stand van de techniek
NL 2002922

C. (Vervolg) VAN BELANG GEACHTE DOCUMENTEN		
Categorie	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
A	US 6 516 216 B1 (FONTENOT MARK G [US] ET AL) 4 februari 2003 (2003-02-04) het gehele document -----	3,6
A	US 5 394 863 A (SANFORD THEODORE H [US] ET AL) 7 maart 1995 (1995-03-07) het gehele document -----	3,6
A	DE 201 10 921 U1 (TROKAMED HENGSTLER GMBH [DE]) 6 december 2001 (2001-12-06) het gehele document -----	1
E	WO 2009/078953 A (VONYOON ENTPR LLC [US]; PECHMANN WALTER VON [US]; YOON SAMUEL C [US];) 25 juni 2009 (2009-06-25) bladzijde 21, regel 19 - bladzijde 22, regel 10; figuur 3 bladzijde 9, regel 5 - regel 13 -----	1,2,4-6
X	US 2008/045989 A1 (WELBORN KENNETH W [US]) 21 februari 2008 (2008-02-21) het gehele document -----	4-6
X	WO 2008/097119 A (BRUTO DA COSTA FERNANDO ANTONI [PT]) 14 augustus 2008 (2008-08-14) samenvatting; figuur 6 -----	4-6
X	US 3 628 522 A (KATO MIKIO) 21 december 1971 (1971-12-21) het gehele document -----	4,5
X	US 3 147 749 A (MARSH CHARLES W) 8 september 1964 (1964-09-08) het gehele document -----	4,5
X	US 3 357 422 A (CREELMAN RAYMOND C) 12 december 1967 (1967-12-12) het gehele document -----	4,5

**ONDERZOEKSRAPPORT BETREFFENDE HET
RESULTAAT VAN HET ONDERZOEK NAAR DE STAND
VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE**

Informatie over leden van dezelfde octroofamilie

Nummer van het verzoek om een onderzoek naar
de stand van de techniek

NL 2002922

In het rapport genoemd octrooigeschrift	Datum van publicatie	Overeenkomend(e) geschrift(en)	Datum van publicatie
WO 2008136024	A	13-11-2008	GEEN
WO 03043510	A	30-05-2003	AU 2002347724 A1 10-06-2003 SE 518937 C2 10-12-2002 SE 0103834 A 10-12-2002
US 2001021854	A1	13-09-2001	EP 1125556 A1 22-08-2001
DE 19543576	A1	05-06-1997	WO 9718757 A1 29-05-1997 EP 0871403 A1 21-10-1998 US 5951465 A 14-09-1999
US 6516216	B1	04-02-2003	GEEN
US 5394863	A	07-03-1995	WO 9621392 A1 18-07-1996
DE 20110921	U1	06-12-2001	GEEN
WO 2009078953	A	25-06-2009	GEEN
US 2008045989	A1	21-02-2008	GEEN
WO 2008097119	A	14-08-2008	AU 2008213175 A1 14-08-2008 CA 2677321 A1 14-08-2008 PT 103654 A 29-08-2008
US 3628522	A	21-12-1971	GEEN
US 3147749	A	08-09-1964	GEEN
US 3357422	A	12-12-1967	GEEN



OCTROOICENTRUM NEDERLAND

WRITTEN OPINION

File No. SN52663 Filing date (*day.month.year*) 25.05.2009 Priority date (*day.month.year*) Application No. NL2002922

International Patent Classification (IPC)
INV. A61B17/42 A61B19/00

Applicant
Tavigny B.V. i.o. te Den Haag

This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the application
- Box No. VIII Certain observations on the application

Examiner

Strazdauskas, Gedas

WRITTEN OPINION

Application number
NL2002922

Box No. I Basis of this opinion

1. This opinion has been established on the basis of the latest set of claims filed before the start of the search.
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - a sequence listing
 - table(s) related to the sequence listing
 - b. format of material:
 - on paper
 - in electronic form
 - c. time of filing/furnishing:
 - contained in the application as filed.
 - filed together with the application in electronic form.
 - furnished subsequently for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty	Yes: Claims	1-3
	No: Claims	4-6
Inventive step	Yes: Claims	1-3
	No: Claims	4-6
Industrial applicability	Yes: Claims	1-6
	No: Claims	

2. Citations and explanations

see separate sheet

WRITTEN OPINION

Application number
NL2002922

Box No. VI Certain documents cited

- Certain published documents
see the Search Report
- Non-written disclosures

Re Item V.

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

Reference is made to the following documents:

- D1: WO 2008/136024 A (SOFAR SPA [IT]; DAMIANI ALFREDO MARIA [IT]; MELGRATI LUIGI [IT]; FRANZ) 13 november 2008 (2008-11-13) in de aanvraag genoemd
- D2: WO 03/043510 A (ENDOLINK AB [SE]; ENGMAN MIKAEL [SE]) 30 mei 2003 (2003-05-30)
- D3: US 2001/021854 A1 (DONNEZ JACQUES [BE] ET AL) 13 september 2001 (2001-09-13)
- D4: DE 195 43 576 A1 (STORZ KARL GMBH & CO [DE]) 5 juni 1997 (1997-06-05)
- D5: US-B1-6 516 216 (FONTENOT MARK G [US] ET AL) 4 februari 2003 (2003-02-04)
- D6: US-A-5 394 863 (SANFORD THEODORE H [US] ET AL) 7 maart 1995 (1995-03-07)
- D7: DE 201 10 921 U1 (TROKAMED HENGSTLER GMBH [DE]) 6 december 2001 (2001-12-06)
- D8: WO 2009/078953 A (VONYOON ENTPR LLC [US]; PECHMANN WALTER VON [US]; YOON SAMUEL C [US];) 25 juni 2009 (2009-06-25)
- D9: US 2008/045989 A1 (WELBORN KENNETH W [US]) 21 februari 2008 (2008-02-21)
- D10: WO 2008/097119 A (BRUTO DA COSTA FERNANDO ANTONI [PT]) 14 augustus 2008 (2008-08-14)
- D11: US-A-3 628 522 (KATO MIKIO) 21 december 1971 (1971-12-21)
- D12: US-A-3 147 749 (MARSH CHARLES W) 8 september 1964 (1964-09-08)
- D13: US-A-3 357 422 (CREELMAN RAYMOND C) 12 december 1967 (1967-12-12)

1 Independent claim 1 and 4

1.1 Although claims 1 and 4 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness.

1.2 The present application does not meet the criteria of patentability, because the subject-matter of the independent claim 4 is not new. The document D1 discloses (the references in parentheses applying to this document):

a cutting unit (see figs. 1a - 3b, pos. 10; and §26-§29) comprising an elongated body having a sectioning device (12) positioned at a distal end of the body, wherein the sectioning device is a knife-blade (12) or an ultrasonic cutter.

1.3 The two-part-form of claim 1 is applied incorrectly. The feature defining that: "the complementary unit (fig. 1A; pos. 2) has a sectioning device (pos. 21; and pg. 15, lines 9-16) positioned at a distal end of the sleeve" is disclosed in D1 (see the references in parentheses applying to this document, above).

1.4 The subject-matter of claim 1 is not clear, because it defines the device via method steps i.e. "the sectioning device is selected from the group...". The scope to which protection is sought is unclear as one cannot know what exactly is to be protected i.e. the device as defined in claim 1 during one selects a knife-blade for a sectioning device or the device wherein the sectioning device has already been selected or perhaps before selection. For further opinion this feature was interpreted as follows: "the sectioning device is a knife-blade or an ultrasonic cutter". The same applies mutatis mutandis to claim 4.

1.5 The differentiating feature of claim 1 is formulated so that they split into two independent claims i.e. the first one: a uterine manipulator as defined in claim 1, wherein a sectioning device is a knife and the second one: an uterine manipulator as defined in claim 1, wherein a sectioning device is an ultrasonic cutter". However, both differentiating features relate to the same technical problem i.e. finding an alternative cutting means for complementary unit of a uterine manipulator, thus the subject-matter of said split independent claims is unitary. The same applies mutatis mutandis to claim 4.

1.6 The closes prior art document D1 does not disclose that "the sectioning device is a knife-blade or an ultrasonic cutter" thus the subject-matter of claim 1 is new.

1.7 Other known uterine manipulators comprising the complementary unit having a sectioning device (see D1-D3) use monopolar or bipolar electrodes for cutting by applying electrical current. None of known manipulators suggest cutting by any other means than electrical

current. Furthermore when using the cutting technics suggested by the differentiating features of claim 1 the cauterisation of surrounding tissues are avoided or reduced. The subject-matter of claim 1 is therefore not obvious.

2 Dependent claims

2.1 The subject-matter of dependent claim 5 is also not new over one of documents D9-D12 or D13 (see e.g. D12: figs 3 and 5).

2.2 The subject-matter of dependent claim 6 is also not over D9 or D10 (see e.g. D9: figs 2a-4b, pos. 18 and 22; and §27; OR D10: fig. 6, pos. 1 and abstract).

Re Item VI

Certain documents cited

Certain published documents:

D8: WO 2009/078953 A (VONYOON ENTPR LLC [US]; PECHMANN WALTER VON [US]; YOON SAMUEL C [US];) 25 juni 2009 (2009-06-25)