



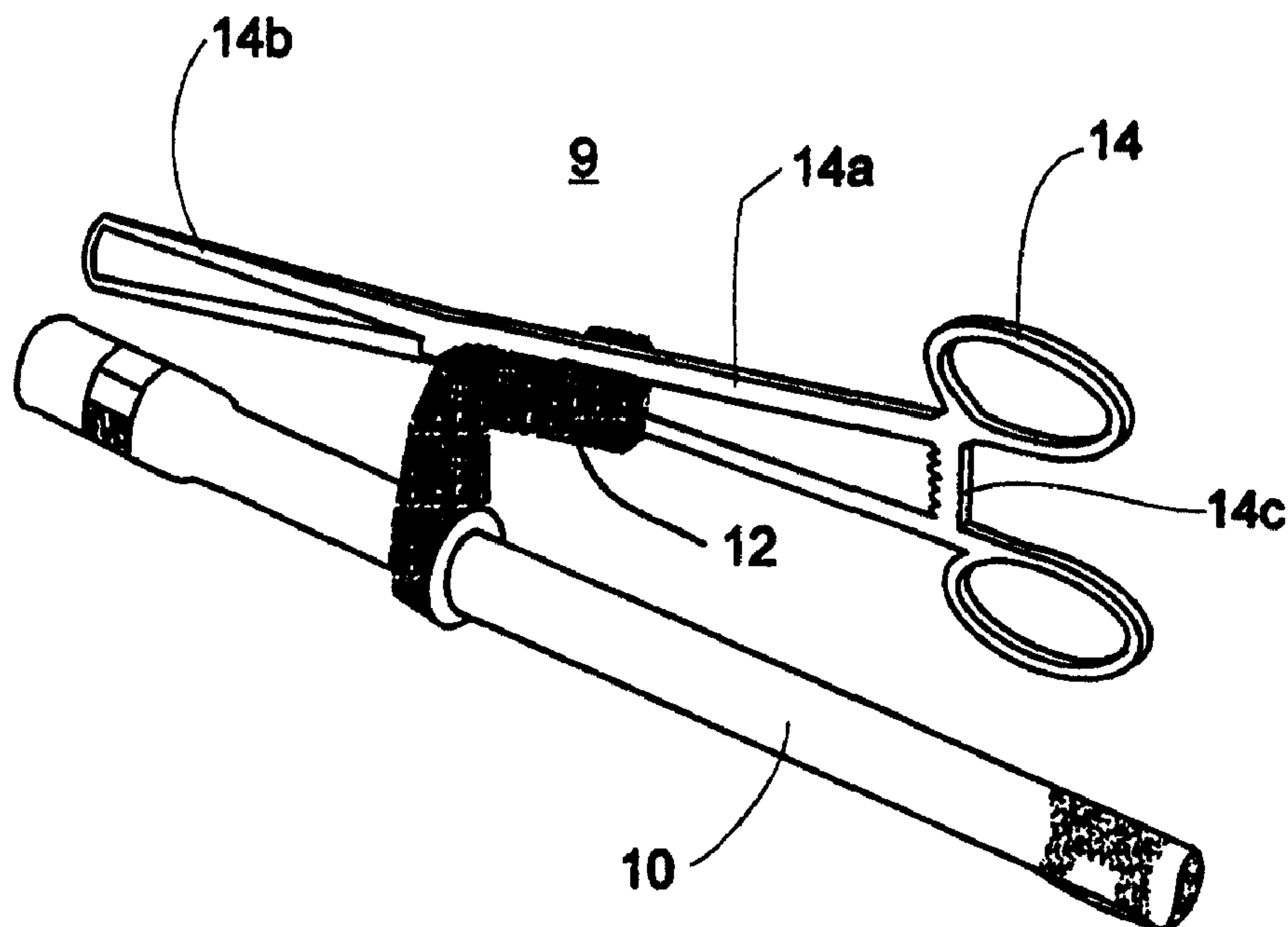
(72) TEPPER, RON, IL
(72) HADANI, RON, US
(71) RON-TECH MEDICAL LTD., IL

(51) Int.Cl.⁷ A61B 8/00

(30) 1997/07/17 (08/896,052) US

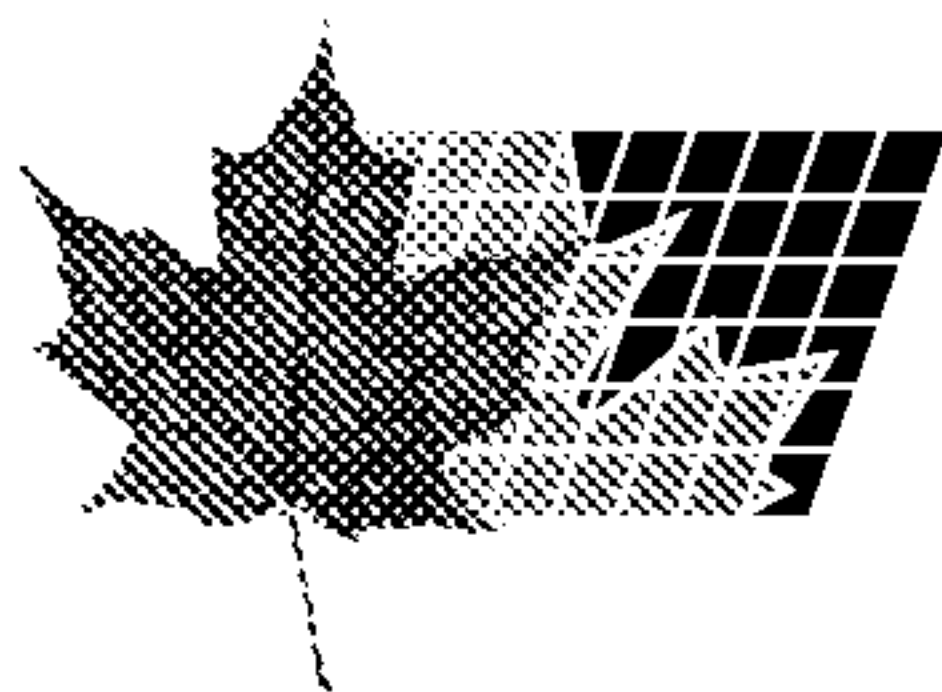
(54) **GUIDAGE D'ECHOGRAPHIE ENDOVAGINALE LORS
D'INTERVENTIONS INTRA-UTERINES, CERVICALES ET
TUBAIRES**

(54) **ENDOVAGINAL SONOGRAPHY GUIDANCE OF INTRA-
UTERINE PROCEDURES**



(57) L'invention concerne un système de guidage et de surveillance destiné à des interventions intra-utérines, cervicales et tubaires. Ce système comprend (a) un ensemble pouvant être commandé par la main non-dominante d'un chirurgien. L'ensemble comprend (i) un transducteur à ultrasons endovaginal conçu pour être introduit dans une partie du vagin de la patiente, le transducteur à ultrasons endovaginal étant destiné à générer un faisceau d'ultrasons; (ii) un support cervical destiné à supporter le col de l'utérus de la patiente; et (iii) un connecteur destiné à l'interconnexion du transducteur à ultrasons et du support du col de l'utérus; (b) un

(57) A system for guidance and monitoring of intra-uterine, cervical and tubal procedures. The system includes (a) an assembly being operable by a weak hand of a surgeon. The assembly includes: (i) an endovaginal ultrasound transducer (10) being adapted for insertion into a portion of a patient's vagina, the endovaginal ultrasound transducer being for generating an ultrasound beam; (ii) a cervical hold (14) for holding a patient's cervix; and (iii) a connector (12) for interconnecting the ultrasound transducer and the cervical holder (14); (b) a medical instrument (60) for performing the procedure, the medical instrument being operable by a strong hand



(21) (A1) **2,294,497**
(86) 1998/07/02
(87) 1999/01/28

instrument médical permettant de mettre en oeuvre la procédure, l'instrument médical pouvant être commandé par la main dominante du chirurgien; et (c) un dispositif permettant de surveiller un alignement de l'instrument médical en ce qui concerne le transducteur à ultrasons endovaginal et donc en ce qui concerne également le faisceau d'ultrasons.

of the surgeon; and (c) a device for monitoring an alignment of the medical instrument with respect to the endovaginal ultrasound transducer and therefore also with respect to the ultrasound beam.

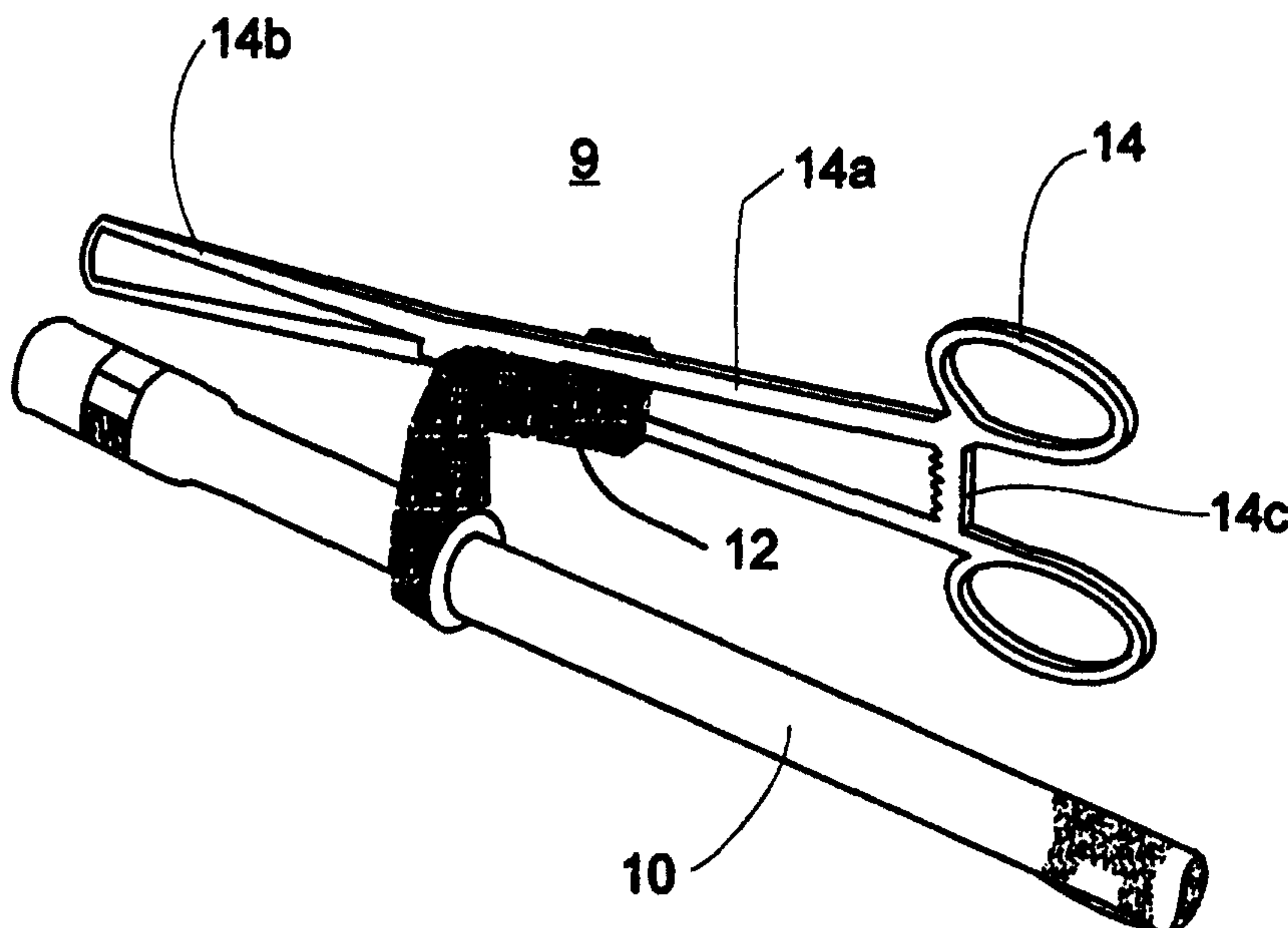
PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 8/00	A1	(11) International Publication Number: WO 99/03399 (43) International Publication Date: 28 January 1999 (28.01.99)
(21) International Application Number: PCT/US98/14012 (22) International Filing Date: 2 July 1998 (02.07.98) (30) Priority Data: 08/896,052 17 July 1997 (17.07.97) US (71) Applicant (for TJ only): FRIEDMAN, Mark, M. [US/IL]; Alharizi 1, 43406 Raanana (IL). (71)(72) Applicants and Inventors: TEPPER, Ron [IL/IL]; Hamat- mid 3, 46407 Herzlia (IL). HADANI, Ron [IL/US]; 417 Rutland Avenue, Teaneck, NJ 07666 (US). (74) Common Representative: FRIEDMAN, Mark, M.; c/o Casto- rina, Anthony, Suite 207, 2001 Jefferson Davis Highway, Arlington, VA 22202 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>

(54) Title: ENDOVAGINAL SONOGRAPHY GUIDANCE OF INTRA-UTERINE PROCEDURES**(57) Abstract**

A system for guidance and monitoring of intra-uterine, cervical and tubal procedures. The system includes (a) an assembly being operable by a weak hand of a surgeon. The assembly includes: (i) an endovaginal ultrasound transducer (10) being adapted for insertion into a portion of a patient's vagina, the endovaginal ultrasound transducer being for generating an ultrasound beam; (ii) a cervical hold (14) for holding a patient's cervix; and (iii) a connector (12) for interconnecting the ultrasound transducer and the cervical holder (14); (b) a medical instrument (60) for performing the procedure, the medical instrument being operable by a strong hand of the surgeon; and (c) a device for monitoring an alignment of the medical instrument with respect to the endovaginal ultrasound transducer and therefore also with respect to the ultrasound beam.



ENDOVAGINAL SONOGRAPHY GUIDANCE OF INTRA-UTERINE PROCEDURES

FIELD AND BACKGROUND OF THE INVENTION

5 The present invention relates to apparatus system and method for real-time endovaginal sonography guidance of intra-uterine, cervical and tubal procedures.

Endovaginal ultrasound transducers for diagnosis and monitoring of obstetric and gynecologic disorders are well known in the art. However, the
10 use of such endovaginal probes for real-time monitoring of surgical procedures is very limited.

Examples of endovaginal ultrasound transducers for real-time monitoring and guidance of surgical procedures are disclosed in U.S. Pat. Nos. 4,497,325, 4,671,292, 4,681,103, 4,742,829, 4,877,033, 4,883,059 and 5,280,427, which
15 are incorporated by reference as if fully set forth herein.

Most of these disclosures provide ultrasound transducers including a needle and/or catheter guide attached thereto for introducing a needle and/or catheter to a targeted tissue. However, the surgical procedures which may be carried out by such endovaginal probes are usually very limited and include
20 puncturing and drainage of abscesses, local tissue sampling and fluid collection.

The prior art fails to provide endovaginal apparatus and method for real-time monitoring and guidance of more complicated surgical procedures. In particular, the prior art fails to provide endovaginal apparatus and method for real-time monitoring and guidance of intra-uterine, cervical and tubal
25 procedures requiring manual dexterity of a surgeon, such as, but not limited to, (i) curettage or evacuation of the uterine cavity for diagnostic and/or therapeutic purposes; (ii) removal of an endometrial polyp, submucous myoma or other tissue; (iii) introduction or extraction of an intra-uterine contraceptive device (IUCD) and other foreign bodies; (iv) systematic sampling of the
30 endometrium and/or the endocervix for diagnostic purposes; (v) embryo transfer into the endometrial cavity; (vi) embryo transfer into the fallopian tube; (vii) fallopian tube cannulation; (viii) ultrasound guided fetal reduction; (ix) simultaneous insertion of an image transmitting device such as endoscopy equipment into the uterine cavity for complementary diagnostic and/or
35 therapeutic purposes; (x) chorionic villi sampling; (xi) fetoscopy; (xii) amniocentesis; and (xiii) fetal tissue sampling.

Transabdominal ultrasound is regularly not used for real-time monitoring and guidance of such surgical procedures due to its relatively limited resolution, the need to keep the patient's urinary bladder full during operation, and the need of extra-operating stuff.

5 As a consequence, such surgical procedures are in many cases carried out blindly, relying solely on the "feel" transmitted through manual manipulation of the instrument and the surgeon's experience. However, when the position or size of the uterus is incorrectly diagnosed by the surgeon, uterine perforation may occur with remarkable ease. The chances of
10 perforation are higher in the presence of cervical stenosis or uterine malignancy (endometrial or sarcoma).

The main dangers of such uterine perforation include bleeding and trauma to the abdominal viscera as well as damage to internal organs such as bowel, omentum, mesentery, ureter and fallopian tube. Thus, exploration of
15 the abdominal cavity by laparoscopy or laparotomy is often needed due to accidental uterine perforation. Other poor outcomes of blind operation include, for example, failure to completely remove uterine tissues such as placental or fetal tissues, which necessitates a second curettage under general anesthesia, or misplacement of foreign bodies or embryos therein.

20 There is thus a widely recognized need for, and it would be highly advantageous to have, an apparatus and method for real-time endovaginal sonography guidance and monitoring of intra-uterine, cervical and tubal surgical and non-surgical procedures.

Specifically, it would be advantageous to have such apparatus and
25 method for real time monitoring and guidance of procedures such as, but not limited to, (i) curettage or evacuation of the uterine cavity for diagnostic and/or therapeutic purposes; (ii) removal of an endometrial polyp, submucous myoma or other tissue; (iii) introduction or extraction of an intra-uterine contraceptive device (IUCD) and other foreign bodies; (iv) systematic sampling of the
30 endometrium and/or the endocervix for diagnostic purposes; (v) embryo transfer into the endometrial cavity; (vi) embryo transfer into the fallopian tube; (vii) fallopian tube cannulation; (viii) ultrasound guided fetal reduction; (ix) simultaneous insertion of an image transmitting device such as endoscopy equipment into the uterine cavity for complementary diagnostic and/or
35 therapeutic purposes; (x) chorionic villi sampling; (xi) fetoscopy; (xii) amniocentesis; and (xiii) fetal tissue sampling.

It would be further advantageous to have such apparatus and method which enable the surgeon to perform such intra-uterine and cervical procedures safely, conveniently and efficiently. In particular, it would be advantageous to have such apparatus and method which enable to substantially shorten the duration of surgical procedures currently carried out under general anesthesia and to reduce the rate of complications associated with such procedures.

It would be further advantageous to have apparatus and method which enable the surgeon to simultaneously monitor and guide surgical and non-surgical intra-uterine procedures by means of endovaginal sonography and/or intra-uterine endoscopy.

SUMMARY OF THE INVENTION

According to the present invention there is provided an apparatus for guidance and monitoring of intra-uterine, cervical and tubal procedures, comprising an assembly, including (a) an endovaginal ultrasound transducer being adapted for insertion into a portion of a patient's vagina; (b) a cervical holder for holding the patient's cervix; and (c) a connector for interconnecting the ultrasound transducer and the cervical holder.

According to another embodiment of the present invention there is further provided a method of guidance and monitoring of intra-uterine, cervical and tubal procedures, comprising (a) holding a patient's cervix by a cervical holder; (b) inserting an endovaginal ultrasound transducer into a portion of the patient's vagina, the ultrasound transducer and the cervical holder being interconnected by a connector; (c) performing the procedure, while holding the patient's cervix by the cervical holder; and (d) real-time monitoring the procedure by the ultrasound transducer.

According to further features in preferred embodiments of the invention described below, the procedure includes inserting an image transmitting device into the patient's uterine cavity and monitoring the procedure by the image transmitting device.

According to still further features in the described preferred embodiments the image transmitting device is an endoscope.

According to still further features in the described preferred embodiments the image transmitting device includes a CCD.

According to still further features in the described preferred embodiments the image transmitting device is an optic fiber.

According to yet another embodiment of the present invention there is further provided a system for guidance and monitoring of intra-uterine, cervical and tubal procedures, the system comprising (a) an assembly being operable by a weak hand of a surgeon, the assembly including (i) an endovaginal ultrasound transducer being adapted for insertion into a portion of a patient's vagina, the endovaginal ultrasound transducer being for generating an ultrasound beam; (ii) a cervical holder for holding a patient's cervix; and (iii) a connector for interconnecting the ultrasound transducer and the cervical holder; (b) a medical instrument for performing the procedure, the medical instrument being operable by a strong hand of the surgeon; and (c) a device for monitoring an alignment of the medical instrument with respect to the endovaginal ultrasound transducer and therefore also with respect to the ultrasound beam.

According to still another embodiment of the present invention there is further provided a method of guidance and monitoring of intra-uterine, cervical and tubal procedures, comprising (a) holding a patient's cervix by a cervical holder; (b) inserting an endovaginal ultrasound transducer into a portion of the patient's vagina, the endovaginal ultrasound transducer being for generating an ultrasound beam, the ultrasound transducer and the cervical holder being interconnected by a connector to form an assembly, the assembly further including a device for monitoring an alignment of a medical instrument with respect to the endovaginal ultrasound transducer and therefore also with respect to the ultrasound beam; (c) performing the procedure by (i) pointing the endovaginal ultrasound transducer such that a treated area is identifiable; and (ii) inserting a medical instrument through the cervix, while holding the patient's cervix by the cervical holder and via the device aligning the medical instrument with respect to the endovaginal ultrasound transducer and therefore also with respect to the ultrasound beam; and (d) real-time monitoring the procedure and the medical instrument by the ultrasound transducer.

According to still further features in the described preferred embodiments the cervical holder includes two arms having a securing member, and two holders, the holders being for holding the patient's cervix.

According to still further features in the described preferred embodiments the connector includes an aperture for accommodating the ultrasound transducer therein.

According to still further features in the described preferred embodiments the connector includes an adjustment member for adjusting the orientation of the ultrasound transducer relative to the connector.

5 According to still further features in the described preferred embodiments the connector includes a protrusion for locking the connector between the arms of the cervical holder upon securing of the cervical holder by means of the securing member.

According to still further features in the described preferred embodiments the connector and the cervical holder are integrally made.

10 According to still further features in the described preferred embodiments the connector and the ultrasound transducer are integrally made.

According to still further features in the described preferred embodiments the device includes an extension coaxially connected at a distal
15 end of the endovaginal ultrasound transducer thereby facilitating visual alignment of the medical instrument with respect to the endovaginal ultrasound transducer and therefore also with respect to the ultrasound beam.

According to still further features in the described preferred embodiments the device includes at least one light beam generator connected to
20 the assembly for generating at least one light beam substantially in a plane defined by the ultrasound beam, when impinges on the medical instrument the at least one light beam serves for facilitating visual alignment of the medical instrument with respect to the endovaginal ultrasound transducer and therefore also with respect to the ultrasound beam.

25 According to still further features in the described preferred embodiments the device includes an imaging implement connected to the assembly for generating an image of objects in a plane defined by the ultrasound beam, thereby facilitating alignment of the medical instrument with respect to the endovaginal ultrasound transducer and therefore also with respect
30 to the ultrasound beam.

According to still further features in the described preferred embodiments the image is displayed on a screen.

According to still further features in the described preferred embodiments the imaging implement is a camera.

35 According to still further features in the described preferred embodiments the camera is sensitive to light in the visible range.

According to still further features in the described preferred embodiments the camera is an infrared camera, i.e., a thermal camera.

According to still further features in the described preferred embodiments the imaging implement is an ultrasound implement.

5 According to still further features in the described preferred embodiments the medical instrument is provided with marks along at least a portion thereof, the marks are identifiable by the imaging implement and are therefore usable for image recognition analysis.

10 According to still further features in the described preferred embodiments the device includes at least two electromagnetic field generators for generating electromagnetic fields, one of the electromagnetic field generator is connected to the assembly, whereas the other electromagnetic field generator is connected to the medical instrument, the device further includes at least one
15 electromagnetic field sensor of a predetermined position, such that by analyzing magnetic fields perceived by the at least one electromagnetic sensor, spatial information of the relative locations of the electromagnetic field generators and therefore of the assembly and the medical instrument is obtainable, thereby facilitating alignment of the medical instrument with respect to the endovaginal ultrasound transducer and therefore also with respect to the ultrasound beam.

20 According to still further features in the described preferred embodiments the medical instrument is selected from the group consisting of an image transmitting device and a surgical instrument.

The present invention successfully addresses the shortcomings of the presently known configurations by providing an apparatus system and methods
25 for real-time endovaginal sonography guidance and monitoring of intra-uterine, cervical and tubal procedures, such as, but not limited to, (i) curettage or evacuation of the uterine cavity for diagnostic and/or therapeutic purposes; (ii) removal of an endometrial polyp, submucous myoma or other tissue; (iii) introduction or extraction of an intra-uterine contraceptive device (IUCD) and
30 other foreign bodies; (iv) systematic sampling of the endometrium and/or the endocervix for diagnostic purposes; (v) embryo transfer into the endometrial cavity; (vi) embryo transfer into the fallopian tube; (vii) fallopian tube cannulation; (viii) ultrasound guided fetal reduction; (ix) simultaneous insertion of an image transmitting device such as endoscopy equipment into the uterine
35 cavity for complementary diagnostic and/or therapeutic purposes; (x) chorionic

villi sampling; (xi) fetoscopy; (xii) amniocentesis; and (xiii) fetal tissue sampling.

The present invention discloses novel apparatus, system and method for real-time endovaginal sonography guidance and monitoring of intra-uterine, cervical and tubal procedures. When using an apparatus or system according to the present invention, the cervical holder and the endovaginal ultrasound transducer are preferably held by the weak of the surgeon so that the other strong hand of the surgeon is free to conduct the surgical procedure. Since in most cases the diameter of the endovaginal ultrasound transducer is substantially small, the surgeon may conveniently introduce a medical instrument such as a curette through the cervix into the uterine cavity of the patient. Thus, the surgical procedure is continuously guided and monitored by means of the endovaginal ultrasound transducer. The medical instrument (or tool) is aligned with respect to the ultrasonic beam of the transducer, such that the surgeon can, view the treated region before, during and after the procedure, and conveniently and safely direct the medical instrument of choice to that region.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

FIG. 1 is a schematic illustration of an apparatus according to the present invention;

FIG. 2 is a detailed description of a preferred embodiment of a connector according to the present invention;

FIG. 3 illustrates the use of the apparatus shown in Figure 1 for guiding and monitoring intra-uterine curettage;

FIGs. 4-7 are schematic illustrations of alternative embodiments of a system according to the present invention including the apparatus shown in Figure 1, a medical instrument and a device for monitoring the alignment of the medical instrument with respect to the ultrasound transducer and therefore also with respect to the ultrasound beam; and

FIG. 8 is a schematic illustration of a screen displaying images according to the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is of apparatus, system and method for real-time endovaginal sonography guidance of intra-uterine, cervical and tubal surgical and non-surgical procedures. Specifically, the present invention can be used to guide and monitor intra uterine, cervical and tubal procedures such as, but not
5 limited to, (i) curettage or evacuation of the uterine cavity for diagnostic and/or therapeutic purposes; (ii) removal of an endometrial polyp, submucous myoma or other tissue; (iii) introduction or extraction of an intra-uterine contraceptive device (IUCD) and other foreign bodies; (iv) systematic sampling of the endometrium and/or the endocervix for diagnostic purposes; (v) embryo
10 transfer into the endometrial cavity; (vi) embryo transfer into the fallopian tube; (vii) fallopian tube cannulation; (viii) ultrasound guided fetal reduction; and (ix) simultaneous insertion of an image transmitting device such as endoscopy equipment into the uterine cavity for complementary diagnostic and/or therapeutic purposes.

15 The principles and operation of apparatus and method according to the present invention may be better understood with reference to the drawings and the accompanying description.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details
20 of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

25 Referring now to the drawings, Figure 1 illustrates a preferred embodiment of an apparatus according to the present invention, which is referred to herein below as apparatus 9. As shown, apparatus 9 includes an endovaginal ultrasound transducer 10, a cervical holder 14 and a connector 12 for connecting endovaginal ultrasound transducer 10 to cervical holder 14.
30 Preferably, endovaginal transducer 10 features substantially small diameter so as to allow simultaneous insertion of transducer 10 and cervical holder 14 into the patient's vagina. Cervical holder 14 is preferably a conventional cervical holder, including two arms 14a each including a securing member 14c; and two holders 14b for holding a cervix of a patient, as for example shown in Figure
35 3.

As shown in Figure 2, connector 12 preferably includes a first segment 12a and a second segment 12b. Preferably, first segment 12a features a flat configuration and includes a circular aperture 16 for accommodating transducer 10 therein. Preferably, an adjustment annular member 16a is embedded within aperture 16 for adjusting the orientation of transducer 10 relative to first segment 12a. Preferably, second segment 12b features an elongated configuration and includes a protrusion 18 for locking connector 12 between arms 14a, as holders 14b grip the cervix of the patient upon securing of cervical holder 14 by means of securing member 14c. The dimensions of connector 12 may be specifically adapted for various probes. Connector 12 may be made of any appropriate material. Preferably, connector 12 is disposable.

According to an alternative configuration, connector 12 and cervical holder 14 are integrally made. Alternatively, connector 12 and endovaginal ultrasound transducer 10 are integrally made.

Figure 3 illustrates the use of apparatus 9 according to the present invention for monitoring and guiding curettage of a patient's uterus 40. When using apparatus 9, which is also shown in Figure 1, endovaginal ultrasound transducer 10 is assembled with connector 12 by inserting transducer 10 into aperture 16 of connector 12. Cervical holder 14 is then used to grip the cervix 28 of a patient by means of holders 14b, such that protrusion 18 of connector 12 is locked between arms 14a when securing the cervical holder. Preferably, endovaginal transducer 10 is then slidably inserted into the fornix of the patient, and its desired orientation is set so as to allow optimal guidance and monitoring of the intra-uterine procedure.

During a uterine procedure, cervical holder 14 and endovaginal ultrasound transducer 10 are preferably held by one hand of the surgeon so that the other hand is free to conduct the surgical procedure. Since the diameter of endovaginal ultrasound transducer 10 is substantially small, the operator may conveniently introduce a medical instrument such as curette 32 through the cervix 28 into the uterine cavity 30 of the patient. The surgical procedure is then carried out and is continuously guided and monitored by means of endovaginal ultrasound transducer 10. The orientation of transducer 10 relative to connector 12 may be continuously changed as the surgical procedure proceeds.

It will be appreciated by one ordinarily skilled in the art that guiding a curettage is used herein as a non limiting example for guiding any other medical instrument (tool) for diagnostic and/or surgical purposes into the cervix, uterine or fallopian tubes of the patient. Such instruments include, but are not limited to, uterine sound - plastic disposable or stainless steel, uterine dilators - hegar double or single end, uterine curettes, uterine dressing, hysterectomy forceps, ovum forceps, intra-uterine device remover, biopsy punches, endocervical speculum, aspirate curette, vacuum curette, aspirate tube, coagulator, embryo transfer set, insemination device, embryo gamete intra-fallopian transfer (GIFT) catheter, embryo intra uterine insemination (IUI) catheter, Karman catheter for uterine aspiration, minimally invasive surgery equipment, such as, grasping forceps, scissors, light dissecting/grasping forceps, diathermy balloon intra cavitary, IUCD, hysterosalpingography catheter, uterine catheter, tubal catheter, brush cytology, cervical adapter for hydrotubation, uterine controlling instruments, vacuum intrauterine sound, uterine elevator, Spackmann cannula, Scott uterine manipulator, Hulka controlling tenaculum or forceps, rocket vacuum aspirator curette, uterine depth probe, sampling devices, NOVAK, KEVORKIAN, EXPORA and Pipelle.

A common feature to the above listed medical instruments is that they are typically operated by the strong hand (e.g., the right hand of a right handed surgeon) of the surgeon, while apparatus 9 is held and operated by the weak hand (e.g., the left hand of a right handed surgeon) thereof.

According to another embodiment (not shown), connector 12 is used to connect endovaginal ultrasound transducer 10 to an image transmitting device for diagnostic and/or therapeutic purposes such that ultrasound transducer 10 is preferably inserted into the patient's fornix and the image transmitting device is preferably inserted through the cervical canal into the uterine cavity. The image transmitting device may be, for example, an optic fiber, or endoscopy equipment. The image transmitting device may include an image transmitting element such as a CCD or a video camera.

Thus, for example, transducer 10 may be connected by means of connector 12 to an endoscopy equipment so as to allow simultaneous monitoring of the surgical procedure by means of two complementary methods, thereby enabling to accurately determine the position of a medical instrument with relation to the uterine wall.

Apparatus 9 described hereinabove not only allows for ultrasonic view of the treated area in the cervix, uterine or fallopian tube, it further allows for ultrasonic view of the operating medical instrument. This is the case, provided that the medical instrument is brought "inside" or "into" the beam generated by the ultrasound transducer, which beam is shaped as a triangle located within the ultrasound plane of view.

Since apparatus 9 is inserted into a portion of the vagina of the patient prior to the insertion of a medical instrument through the cervix, and further since the medical instrument and apparatus 9 are each held by a different hand of the surgeon, a non-practiced surgeon may find it difficult to bring the medical instrument "inside" or "into" the sonography beam.

As further detailed hereinunder, the following embodiments of the present invention specifically address this problem.

With reference now to Figures 4-7, presented is a system for guidance and monitoring of intra-uterine, cervical and tubal procedures, which is referred to hereinbelow as system 50.

System 50 includes an assembly 52 typically operable by a weak hand of a surgeon. Assembly 52 includes an endovaginal ultrasound transducer 54 adapted for insertion into a portion of a patient's vagina. Endovaginal ultrasound transducer 54 serves for generating an ultrasound beam. Assembly 50 further includes a cervical holder 56 for holding a patient's cervix. A connector 58 is used for interconnecting ultrasound transducer 54 and cervical holder 56. Assembly 52, as so far described, is, in fact, structurally and functionally identical to apparatus 9 (Figure 1) described hereinabove and serves identical purposes. Thus, all the features described hereinabove with respect to apparatus 9 apply also to assembly 52.

System 50 further includes a medical instrument 60. Instrument 60 serves to perform the intra-uterine, cervical or tubal procedure and is typically operable by a strong hand of the surgeon. Medical instrument 60 may be a diagnostic instrument, such as, but not limited to, hysterosalpingography catheter, uterine catheter, tubal catheter, brush cytology, cervical adapter for hydrotubation, uterine controlling instruments, vacuum intrauterine sound, uterine elevator, Spackmann cannula, Scott uterine manipulator, Hulka controlling tenaculum or forceps, rocket vacuum aspirator curette, uterine depth probe, sampling devices, NOVAK, KEVORKIAN, EXPORA and Pipelle, or a surgical instrument, such as, but not limited to, uterine sound -

plastic disposable or stainless steel, uterine dilators - hegar double or single end, uterine curettes, uterine dressing, hysterectomy forceps, ovum forceps, intra-uterine device remover, biopsy punches, endocervical speculum, aspirate curette, vacuum curette, aspirate tube, coagulator, embryo transfer set, insemination device, embryo gamete intra-fallopian transfer (GIFT) catheter, embryo intra uterine insemination (IUI) catheter, Karman catheter for uterine aspiration, minimally invasive surgery equipment, such as, grasping forceps, scissors, light dissecting/grasping forceps, diathermy balloon intra cavitary and IUCD.

10 A common feature to the above listed medical instruments is that they are all typically operated by the strong hand (e.g., the right hand of a right handed surgeon) of the surgeon, while assembly 52 is held and operated by the weak hand (e.g., the left hand of a right handed surgeon) thereof.

System 50 further includes a device 62 which serves for monitoring the alignment of medical instrument 60 with respect to endovaginal ultrasound transducer 54 and therefore also with respect to the ultrasound beam generated thereby.

Several exemplary embodiments of device 62 are described hereinbelow. Each of which readily enables the surgeon to align the medical instrument employed with the ultrasound transducer and therefore also with the beam generated thereby. By inserting the medical instrument coaxially with its alignment, the surgeon ensures that the medical instrument is moved on the plane in which the ultrasound beam resides and therefore, eventually the instrument will be visualized in the ultrasound image obtained. This procedure assists the surgeon in bringing the medical instrument "inside" or "into" the ultrasound beam. Device 62 is typically connected to the distal end of transducer 54 via a suitable connector, generally marked as 64. However, direct connection, and other locations are also envisaged.

Connector 64, is preferably equipped with wings 65, being aligned within the plane of the ultrasound beam. To this end, distal end 68 of transducer 54, is asymmetrically formed, such that when connector 64 is applied thereon, wings 65 acquire their respective positions.

As specifically shown in Figure 4, according to one embodiment, device 62 includes an extension 66 coaxially connected at a distal end 68 of endovaginal ultrasound transducer 54, thereby facilitating visual alignment of

medical instrument 60 with respect to endovaginal ultrasound transducer 54 and therefore also with respect to the ultrasound beam generated thereby.

According to this embodiment, while inserting medical instrument 60 through the cervix of the patient, the surgeon ensures that instrument 60
5 parallels extension 66, to thereby direct instrument 60 "inside" or "into" the ultrasound beam.

As specifically shown in Figure 5, according to yet another embodiment of the present invention, device 62 includes at least one light beam generator 68 (say, e.g., two, four are shown) connected to assembly 52, preferably to
10 transducer 54 thereof, preferably via connector 64. Light beam generators 68 serve for generating at least one focused light beam 70. Light beams 70 reside substantially in the plane defined by the ultrasound beam of transducer 54.

When impinge on medical instrument 60, light beams 70 serve for facilitating visual alignment of medical instrument with respect to endovaginal
15 ultrasound transducer 54 and therefore also with respect to the ultrasound beam.

Each of light beam generators 68 may be, for example, a laser source, generating, for example, a green laser beam, which is known not to be absorbed by living tissues. However, non-coherent light sources are also
20 applicable.

According to this embodiment of the invention, while inserting medical instrument 60 through the cervix of the patient, the surgeon ensures that light beams 70 impinge on instrument 60, to thereby direct instrument 60 "inside" or "into" the ultrasound beam of transducer 54. Light beam generators 68
25 preferably receive energy from a power source, e.g., a battery, implemented in a battery housing located within connector 64.

Each of generators 68 may be, for example, a pointer type laser diode, having, for example, a maximum output below 5 mW, wavelength of 650 nm, with beam dimensions of about 3.0 nm x 2.5 nm. A suitable diode is the "ES
30 smallest laser pointer" Cat. No. D53,050 which is available from Edmund Scientific, Industrial Optics Division, Barrington, NJ 08007-1380 U.S.A. Generators 68 may alternatively be selected to generate a stripe of light. Edmund Scientific Cat. No. D52,562 "Gamma-x laser light show".

Each of generators 68 preferably further includes a beam splitter, e.g.,
35 a TECH SPEC pellicle beam splitter. The pellicles are very thin nitrocellulose membranes bonded to lapped aluminum frames. Ghost images

are eliminated by the thinness of the membrane as the second surface reflection superimposed on the first surface reflection. The uncoated pellicle reflects 8 % and transmits 92 % through the visible and near infrared regions. The pellicles' thickness is in the range of 2 μm , their index of reflection is (Nd):1.5. Suitable pellicles are available from Edmund Scientific, Industrial Optics Division, Barrington, NJ 08007-1380 U.S.A., Cat. No. D39,478).

As specifically shown in Figure 6, according to still another embodiment of the present invention, device 62 includes an imaging implement 72 connected to assembly 52, preferably to transducer 54 thereof, preferably via connector 64. Imaging implement 72 serves for generating an image of objects in the plane defined by the ultrasound beam. Implement 72 thereby serves for facilitating alignment of medical instrument 60 with respect to endovaginal ultrasound transducer 54 and therefore also with respect to the ultrasound beam generated thereby. According to this embodiment, while inserting medical instrument 60 through the cervix of the patient, the surgeon ensures that imaging implement 72 "sees" or "captures" instrument 60, to thereby direct instrument 60 "inside" or "into" the ultrasound beam. The image generated by implement 72 is preferably displayed on a screen. A single screen may serve for presenting, in real time, the ultrasound image perceived through transducer 54 and the image perceived through imaging implement 72.

An example is shown in Figure 8, showing a screen 74 displaying an ultrasound image 76 and an image 78, perceived through implement 72. Implement 72 is positioned such that when image 78 shows instrument 60 in, for example, a vertical alignment with respect to screen 74, as indicated in Figure 8 by 60a, then the surgeon knows that medical instrument 60 is aligned with respect to endovaginal ultrasound transducer 54 and therefore also with respect to the ultrasound beam generated thereby. To this end, screen 74 may further provide a displayed grid or coordinates, such that assessing the verticality of the image 60a of instrument 60 is facilitated. Implement 72 preferably receive energy from a power source, e.g., a battery, implemented in a battery housing located within connector 64.

According to a preferred embodiment of the present invention imaging implement 72 is a camera 82, e.g., a charge coupled device (CCD) camera equipped with a lens or optic fibers arrangement, which is adapted to perceive light in the visible range. According to an alternative embodiment of the

present invention implement 72 is a camera sensitive to light in the infrared range, i.e., an infrared (thermal) camera 84, which may similarly include a lens or an optic fibers arrangement. According to yet another preferred embodiment of the invention imaging implement 72 is an ultrasound implement 5 86. According to yet another preferred embodiment of the present invention imaging implement 72 is an X ray implement 86. In the latter case, an X rays sensitive plate is provided to perceive the image of instrument 60 thereby. Such plates are well known in the art.

According to each of the imaging embodiments described herein an 10 image of instrument 60 is generated, which image enables the surgeon to direct instrument 60 "inside" or "into" the beam generated by ultrasound transducer 54.

As further shown in Figure 6, according to a preferred embodiment of the present invention medical instrument 60 is provided with marks 88 along at 15 least a portion thereof. Marks 88 are selected identifiable by imaging implement 72 of choice and are therefore usable for image recognition analysis, which may be used to estimate the depth to which instrument 60 has been inserted at any given time. Image recognition is well known art and therefore will not be further elaborated herein.

20 The nature of marks 88 must depend on the nature of imaging implement 72 of choice. Thus, if a CCD camera is selected, marks 88 may acquire a color distinguishable from the background color of instrument 60. If an infrared (thermal) camera is selected, marks 88 may be applied, for example, as substances of increased or decreased heat conductivity as compared with the 25 substance from which instrument 60 is made. If ultrasound or X ray implements are selected, marks 88 may be applied, for example, as holes, recessions, protrusions, etc., to render them distinguishable from the background of instrument 60. In each of these cases, marks 88 may be further selected distinguishable from one another in a fashion, e.g., similar to a bar- 30 code, such that image recognition analysis may be applied.

A suitable CCD is a CCD sensitive to light at 0.2 lux, having a S/N ratio greater than 46 Db. The CCD is preferably monochromatic and is capable of sensing an area of 6.4 X 4.8 mm. The CCD preferably features miniature size e.g., 30 x 30 x 60 mm, and low weight, e.g., 120 grams. A 35 CCD obeying all of the above criteria is distributed by Edmund Scientific, Cat No. D39,244.

As specifically shown in Figure 7, according to still another embodiment of the present invention device 62 includes at least two electromagnetic field generators 90 which serve for generating electromagnetic fields. One of electromagnetic field generators 90 is connected to assembly 52, preferably to transducer 54 thereof, preferably via connector 64. The other electromagnetic field generator 90 is connected to medical instrument 60. According to this embodiment of the present invention, device 62 further includes at least one electromagnetic field sensor, generally indicated by 92. Sensor 92 is positioned in a predetermined position in space, such that by analyzing the magnetic fields perceived by electromagnetic sensor 92, spatial information of the relative locations of electromagnetic field generators 90 and therefore of transducer 54 and medical instrument 60 is obtainable, thereby facilitating alignment of medical instrument 60 with respect to endovaginal ultrasound transducer 54 and therefore also with respect to the ultrasound beam generated thereby. Further description concerning the operation of electromagnetic field generators and electromagnetic field sensors and the use of the latter to retrieve spatial information of the formers is disclosed in, for example, PCT/IL96/00050 (WO 97/03609) and further in U.S. Pat. No. 4,945,305, both are incorporated by reference as if fully set forth herein. Generators 90 are preferably powered by a mutual power source implemented in a dedicated housing in connector 64 or by independent power sources. Suitable power wiring is envisaged.

Further according to the present invention there is provided a method of guidance and monitoring of intra-uterine, cervical and tubal procedures. The method is effected by executing the following method steps, in which is a first step a cervical holder is employed for holding a patient's cervix. In a second step an endovaginal ultrasound transducer is inserted into a portion of the patient's vagina. The endovaginal ultrasound transducer serves for generating an ultrasound beam. The ultrasound transducer and the cervical holder are inter-connected there between by a connector to form an assembly which further includes a device for monitoring an alignment of a medical instrument with respect to the endovaginal ultrasound transducer and therefore also with respect to the ultrasound beam generated thereby.

In a third step of the method the procedure is performed by (i) pointing the endovaginal ultrasound transducer such that a treated area is identifiable; and (ii) inserting the medical instrument through the cervix, while holding the patient's cervix by the cervical holder and via the device, aligning

the medical instrument with respect to endovaginal ultrasound transducer and therefore also with respect to the ultrasound beam.

In a fourth step the procedure and medical instrument are both monitored in real-time by the ultrasound transducer.

5

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the
10 spirit and broad scope of the appended claims.

WHAT IS CLAIMED IS:

1. An apparatus for guidance and monitoring of intra-uterine, cervical and tubal procedures, comprising an assembly, including:
 - (a) an endovaginal ultrasound transducer being adapted for insertion into a portion of a patient's vagina;
 - (b) a cervical holder for holding the patient's cervix; and
 - (c) a connector for interconnecting said ultrasound transducer and said cervical holder.
2. The apparatus of claim 1, wherein said cervical holder includes two arms having a securing member and two holders, said holders being for holding the patient's cervix.
3. The apparatus of claim 1, wherein said connector includes an aperture for accommodating said ultrasound transducer therein.
4. The apparatus of claim 1, wherein said connector includes an adjustment member for adjusting the orientation of said ultrasound transducer relative to said connector.
5. The apparatus of claim 1, wherein said connector includes a protrusion for locking said connector between said arms of said cervical holder upon securing of said cervical holder by means of said securing member.
6. The apparatus of claim 1, wherein said connector and said cervical holder are integrally made.
7. The apparatus of claim 1, wherein said connector and said ultrasound transducer are integrally made.
8. A method of guidance and monitoring of intra-uterine, cervical and tubal procedures, comprising:
 - (a) holding a patient's cervix by a cervical holder;

- (b) inserting an endovaginal ultrasound transducer into a portion of the patient's vagina, said ultrasound transducer and said cervical holder being inter-connected by a connector;
- (c) performing the procedure, while holding the patient's cervix by said cervical holder; and
- (d) real-time monitoring the procedure by said ultrasound transducer.

9. The method of claim 8, wherein said procedure includes inserting an image transmitting device into the patient's uterine cavity and monitoring the procedure by said image transmitting device.

10. The method of claim 9, wherein said image transmitting device is an endoscope.

11. The method of claim 9, wherein said image transmitting device includes a CCD.

12. The method of claim 9, wherein said image transmitting device is an optic fiber.

13. A system for guidance and monitoring of intra-uterine, cervical and tubal procedures, the system comprising:

- (a) an assembly being operable by a weak hand of a surgeon, said assembly including:
 - (i) an endovaginal ultrasound transducer being adapted for insertion into a portion of a patient's vagina, said endovaginal ultrasound transducer being for generating an ultrasound beam;
 - (ii) a cervical holder for holding a patient's cervix; and
 - (iii) a connector for interconnecting said ultrasound transducer and said cervical holder;
- (b) a medical instrument for performing the procedure, said medical instrument being operable by a strong hand of the surgeon; and
- (c) a device for monitoring an alignment of said medical instrument with respect to said endovaginal ultrasound transducer and therefore also with respect to said ultrasound beam.

14. The system of claim 13, wherein said cervical holder includes two arms having a securing member, and two holders, said holders being for holding the patient's cervix.

15. The system of claim 13, wherein said connector includes an aperture for accommodating said ultrasound transducer therein.

16. The system of claim 13, wherein said connector includes an adjustment member for adjusting the orientation of said ultrasound transducer relative to said connector.

17. The system of claim 13, wherein said connector includes a protrusion for locking said connector between said arms of said cervical holder upon securing of said cervical holder by means of said securing member.

18. The system of claim 13, wherein said connector and said cervical holder are integrally made.

19. The system of claim 13, wherein said connector and said ultrasound transducer are integrally made.

20. The system of claim 13, wherein said device includes an extension coaxially connected at a distal end of said endovaginal ultrasound transducer thereby facilitating visual alignment of said medical instrument with respect to said endovaginal ultrasound transducer and therefore also with respect to said ultrasound beam.

21. The system of claim 13, wherein said device includes at least one light beam generator connected to said assembly for generating at least one light beam substantially in a plane defined by said ultrasound beam, when impinges on said medical instrument said at least one light beam serves for facilitating visual alignment of said medical instrument with respect to said endovaginal ultrasound transducer and therefore also with respect to said ultrasound beam.

22. The system of claim 13, wherein said device includes an imaging implement connected to said assembly for generating an image of objects in a plane defined by said ultrasound beam, thereby facilitating alignment of said medical instrument with respect to said endovaginal ultrasound transducer and therefore also with respect to said ultrasound beam.

23. The system of claim 22, wherein said image is displayed on a screen.

24. The system of claim 22, wherein said imaging implement is a camera.

25. The system of claim 24, wherein said camera is sensitive to light in the visible range.

26. The system of claim 24, wherein said camera is an infrared camera.

27. The system of claim 22, wherein said imaging implement is an ultrasound implement.

28. The system of claim 22, wherein said medical instrument is provided with marks along at least a portion thereof, said marks are identifiable by said imaging implement and are therefore usable for image recognition analysis.

29. The system of claim 13, wherein said device includes at least two electromagnetic field generators for generating electromagnetic fields, one of said electromagnetic field generator is connected to said assembly, whereas the other electromagnetic field generator is connected to said medical instrument, the device further includes at least one electromagnetic field sensor of a predetermined position, such that by analyzing magnetic fields perceived by said at least one electromagnetic sensor, spatial information of the relative locations of said electromagnetic field generators and therefore of said assembly and said medical instrument is obtainable, thereby facilitating alignment of said

medical instrument with respect to said endovaginal ultrasound transducer and therefore also with respect to said ultrasound beam.

30. The system of claim 13, wherein said medical instrument is selected from the group consisting of an image transmitting device and a surgical instrument.

31. A method of guidance and monitoring of intra-uterine, cervical and tubal procedures, comprising:

- (a) holding a patient's cervix by a cervical holder;
- (b) inserting an endovaginal ultrasound transducer into a portion of the patient's vagina, said endovaginal ultrasound transducer being for generating an ultrasound beam, said ultrasound transducer and said cervical holder being inter-connected by a connector to form an assembly, said assembly further including a device for monitoring an alignment of a medical instrument with respect to said endovaginal ultrasound transducer and therefore also with respect to said ultrasound beam;
- (c) performing the procedure by:
 - (i) pointing said endovaginal ultrasound transducer such that a treated area is identifiable; and
 - (ii) inserting a medical instrument through the cervix, while holding the patient's cervix by said cervical holder and via said device aligning said medical instrument with respect to said endovaginal ultrasound transducer and therefore also with respect to said ultrasound beam; and
- (d) real-time monitoring the procedure and said medical instrument by said ultrasound transducer.

32. The method of claim 31, wherein said cervical holder includes two arms having a securing member, and two holders, said holders being for holding the patient's cervix;

33. The method of claim 31, wherein said connector includes an aperture for accommodating said ultrasound transducer therein.

34. The method of claim 31, wherein said connector includes an adjustment member for adjusting the orientation of said ultrasound transducer relative to said connector.

35. The method of claim 31, wherein said connector includes a protrusion for locking said connector between said arms of said cervical holder upon securing of said cervical holder by means of said securing member.

36. The method of claim 31, wherein said connector and said cervical holder are integrally made.

37. The method of claim 31, wherein said connector and said ultrasound transducer are integrally made.

38. The method of claim 31, wherein said device includes an extension coaxially connected at a distal end of said endovaginal ultrasound transducer thereby facilitating visual alignment of said medical instrument with respect to said endovaginal ultrasound transducer and therefore also with respect to said ultrasound beam.

39. The method of claim 31, wherein said device includes at least one light beam generator connected to said assembly for generating at least one light beam substantially in a plane defined by said ultrasound beam, when impinges on said medical instrument said at least one light beam serves for facilitating visual alignment of said medical instrument with respect to said endovaginal ultrasound transducer and therefore also with respect to said ultrasound beam.

40. The method of claim 31, wherein said device includes an imaging implement connected to said assembly for generating an image of objects in a plane defined by said ultrasound beam, thereby facilitating alignment of said medical instrument with respect to said endovaginal ultrasound transducer and therefore also with respect to said ultrasound beam.

41. The method of claim 40, wherein said image is displayed on a screen.

42. The method of claim 40, wherein said imaging implement is a camera.

43. The method of claim 42, wherein said camera is sensitive to light in the visible range.

44. The method of claim 42, wherein said camera is an infrared camera.

45. The method of claim 40, wherein said imaging implement is an ultrasound implement.

46. The method of claim 40, wherein said medical instrument is provided with marks along at least a portion thereof, said marks are identifiable by said imaging implement and are therefore usable for image recognition analysis.

47. The method of claim 31, wherein said device includes at least two electromagnetic field generators for generating electromagnetic fields, one of said electromagnetic field generator is connected to said assembly, whereas the other electromagnetic field generator is connected to said medical instrument, the device further includes at least one electromagnetic field sensor of a predetermined position, such that by analyzing magnetic fields perceived by said at least one electromagnetic sensor, spatial information of the relative locations of said electromagnetic field generators and therefore of said assembly and said medical instrument is obtainable, thereby facilitating alignment of said medical instrument with respect to said endovaginal ultrasound transducer and therefore also with respect to said ultrasound beam.

48. The method of claim 31, wherein said medical instrument is selected from the group consisting of an image transmitting device and a surgical instrument.

1/7

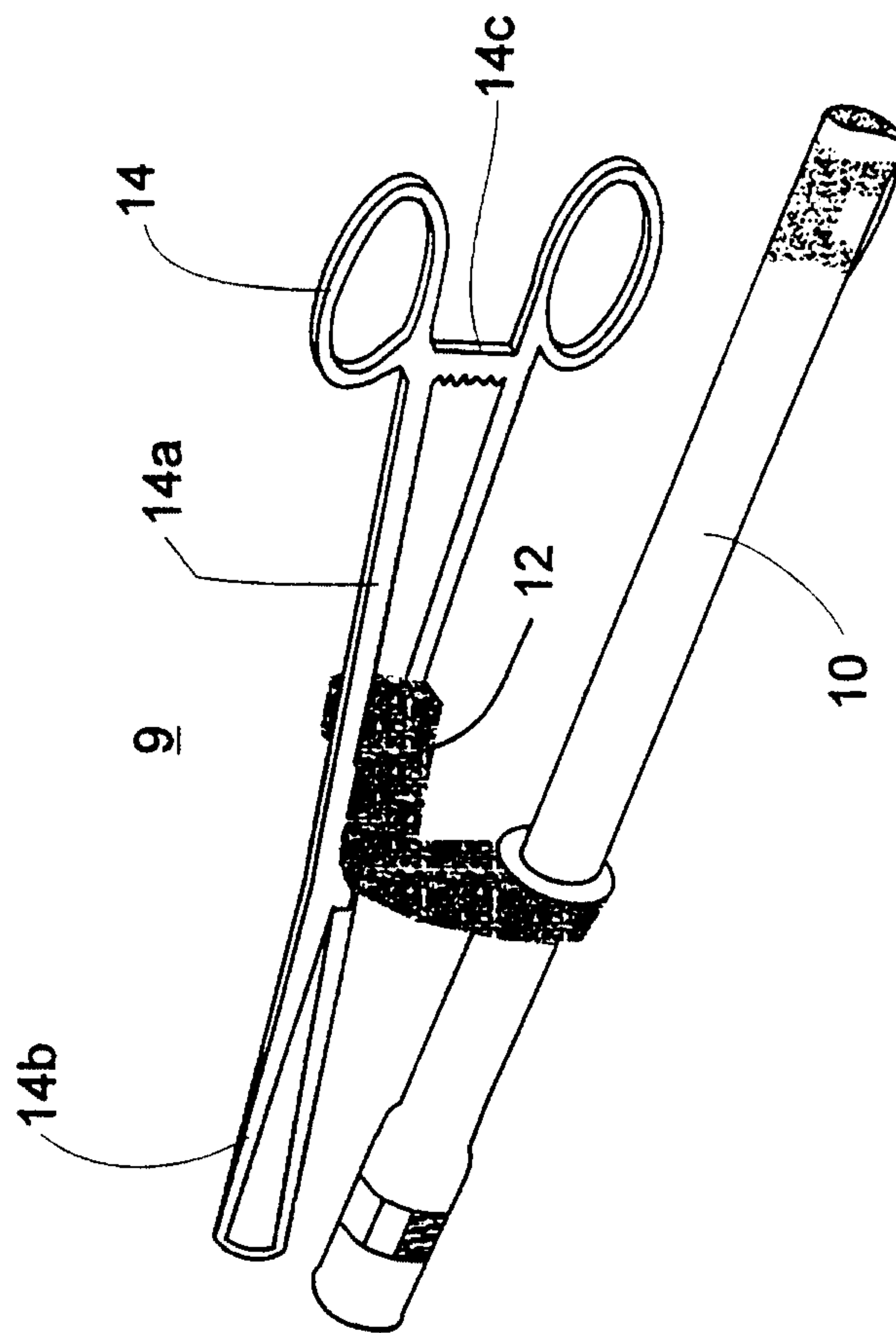


Fig. 1

2/7

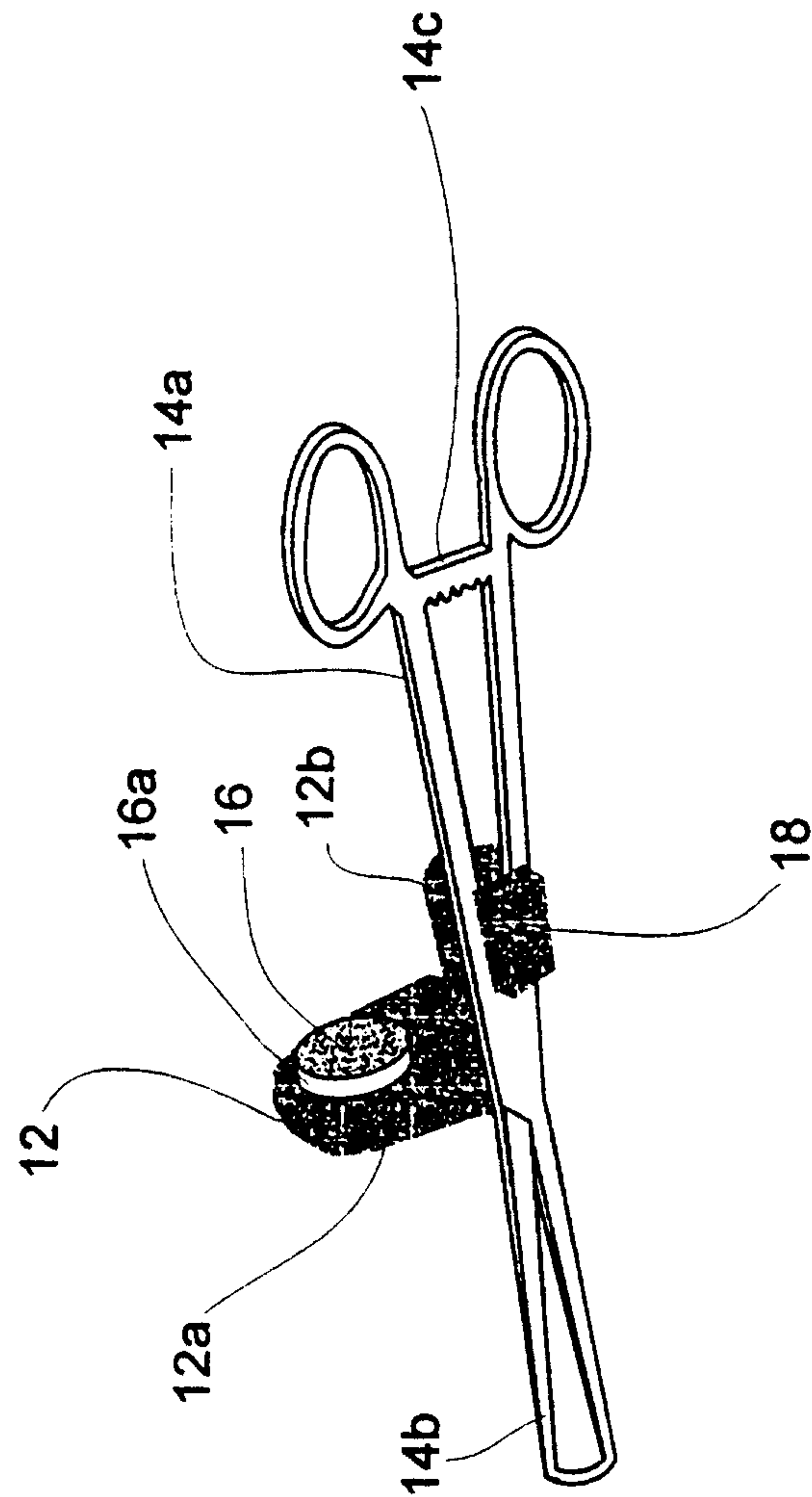


Fig. 2

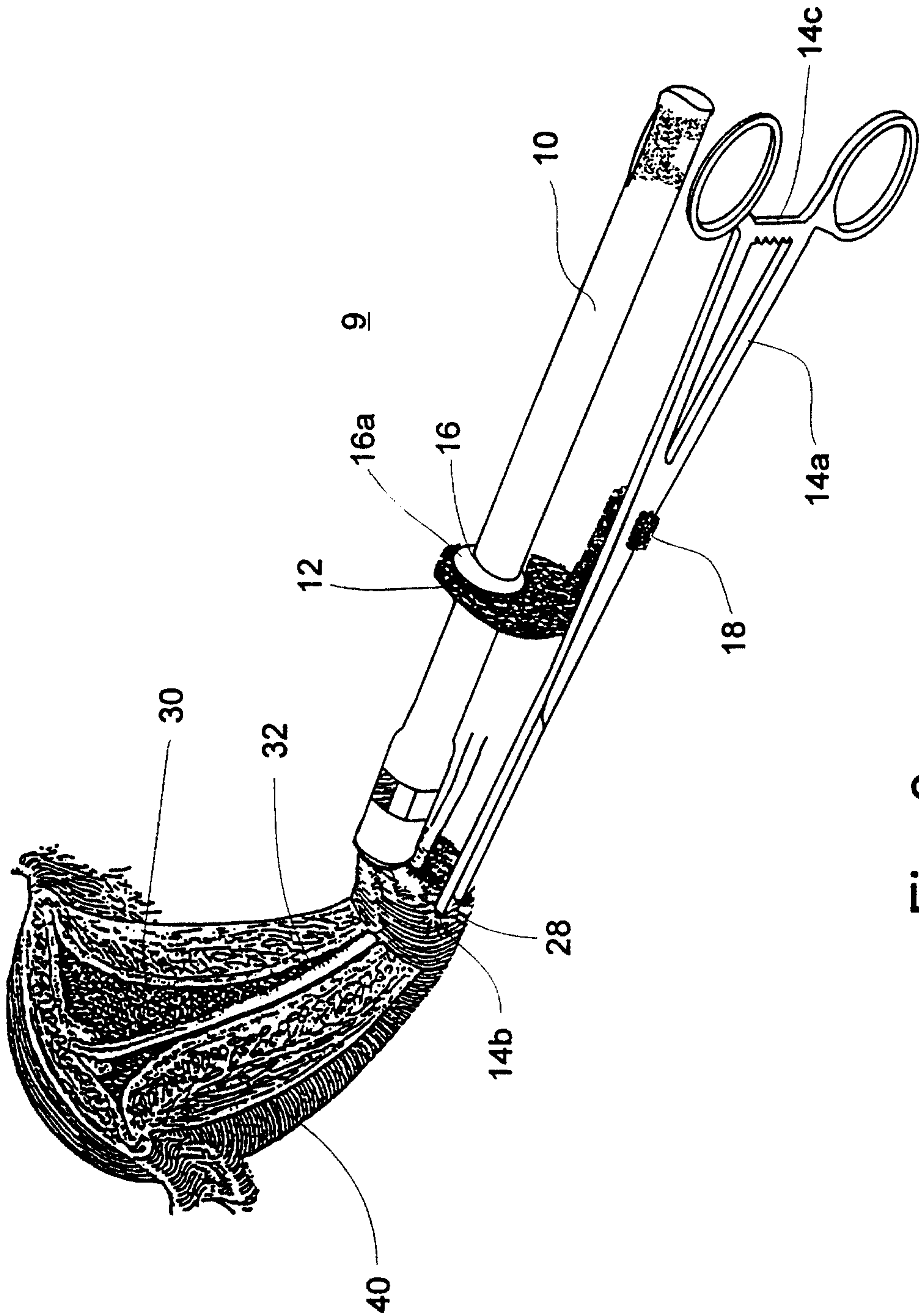


Fig. 3

4/7

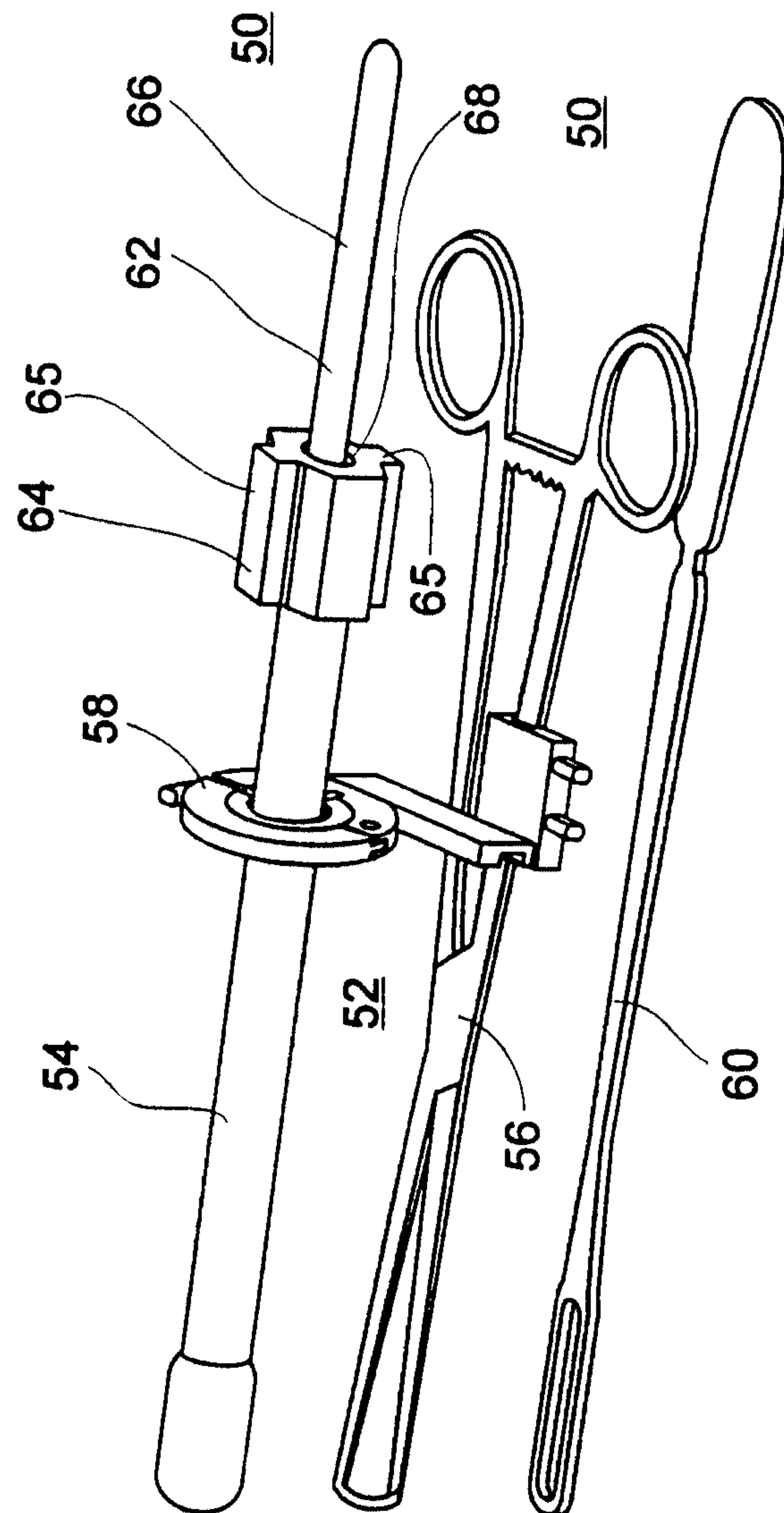


Fig. 4

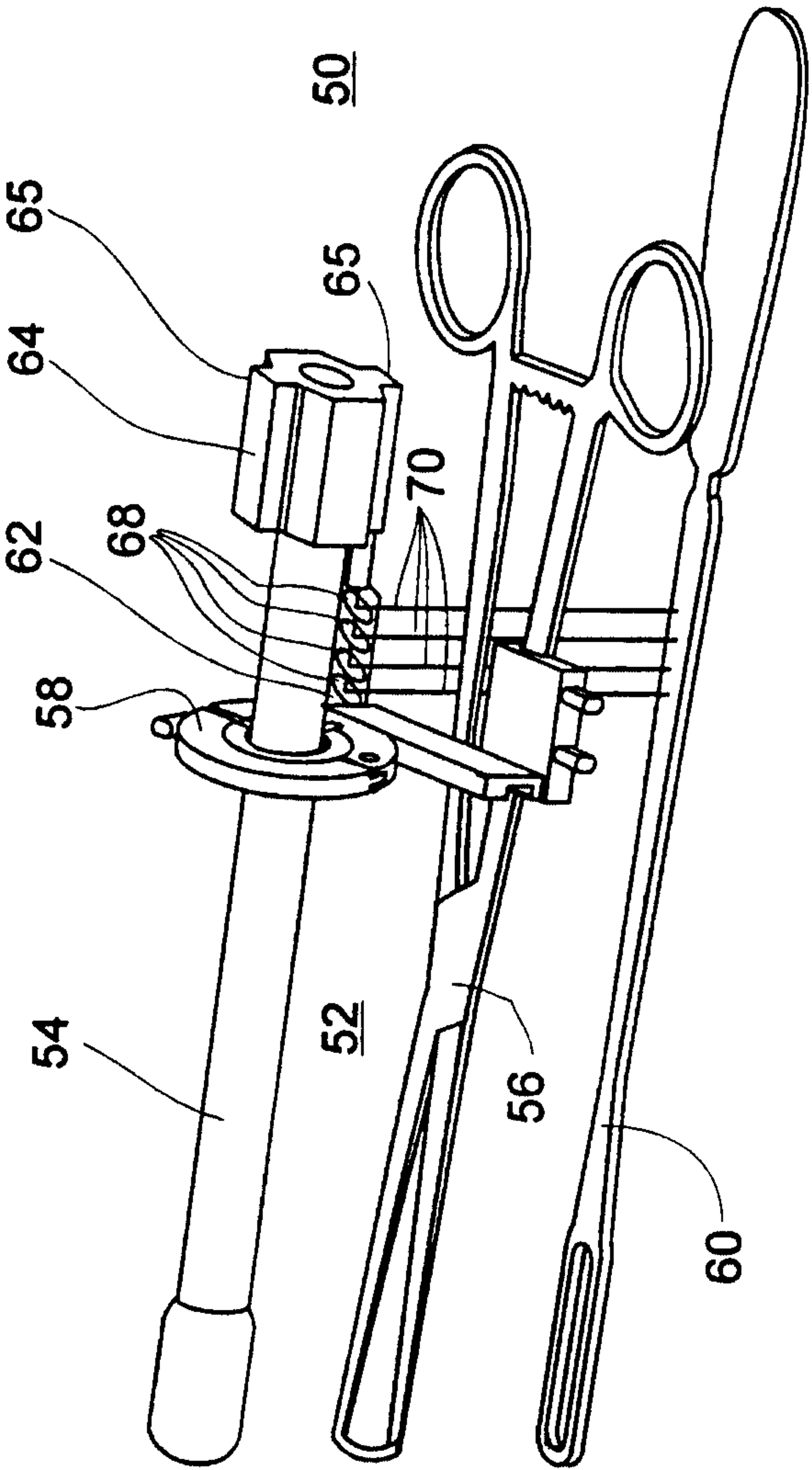


Fig. 5

6/7

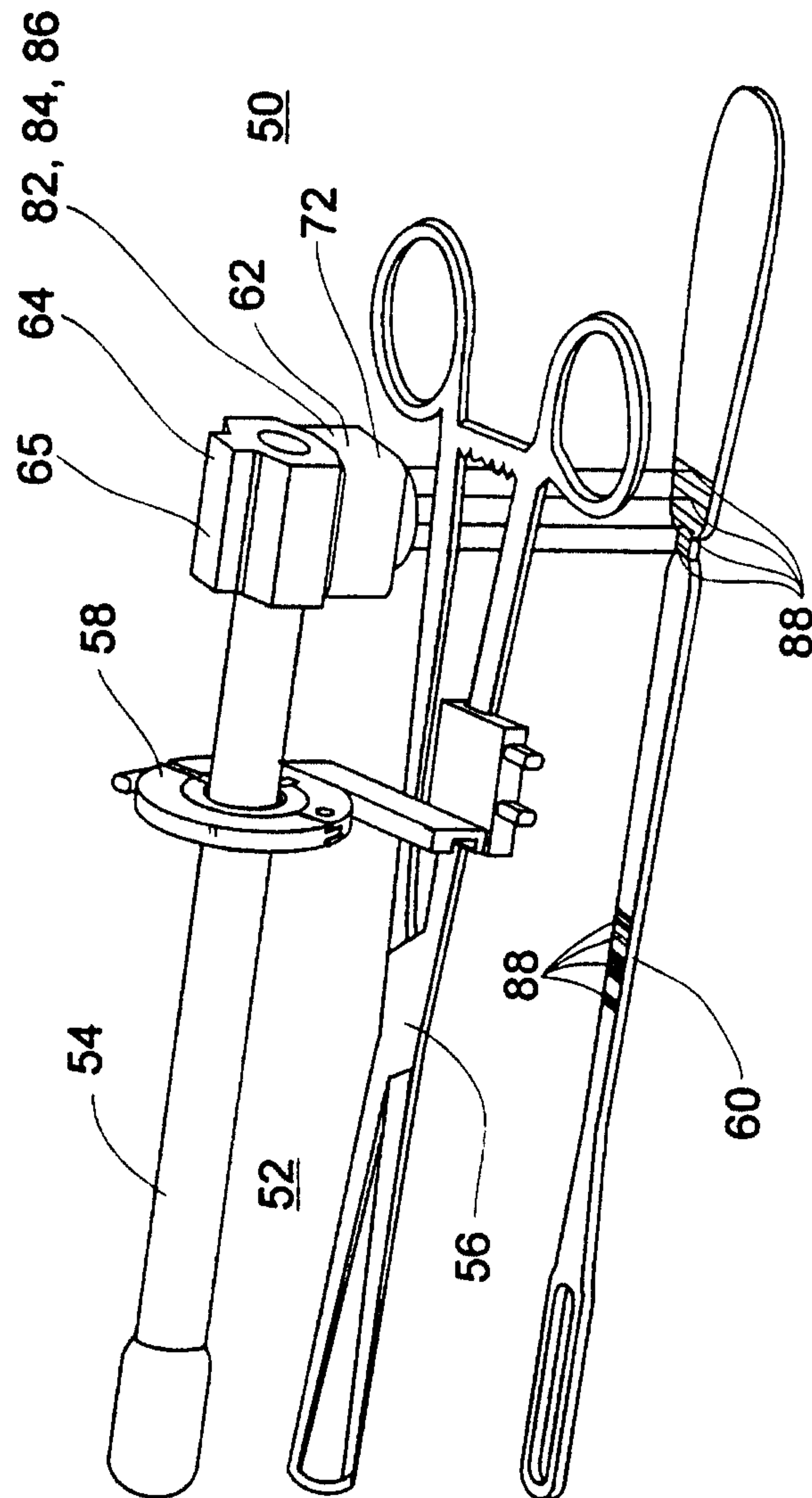


Fig. 6

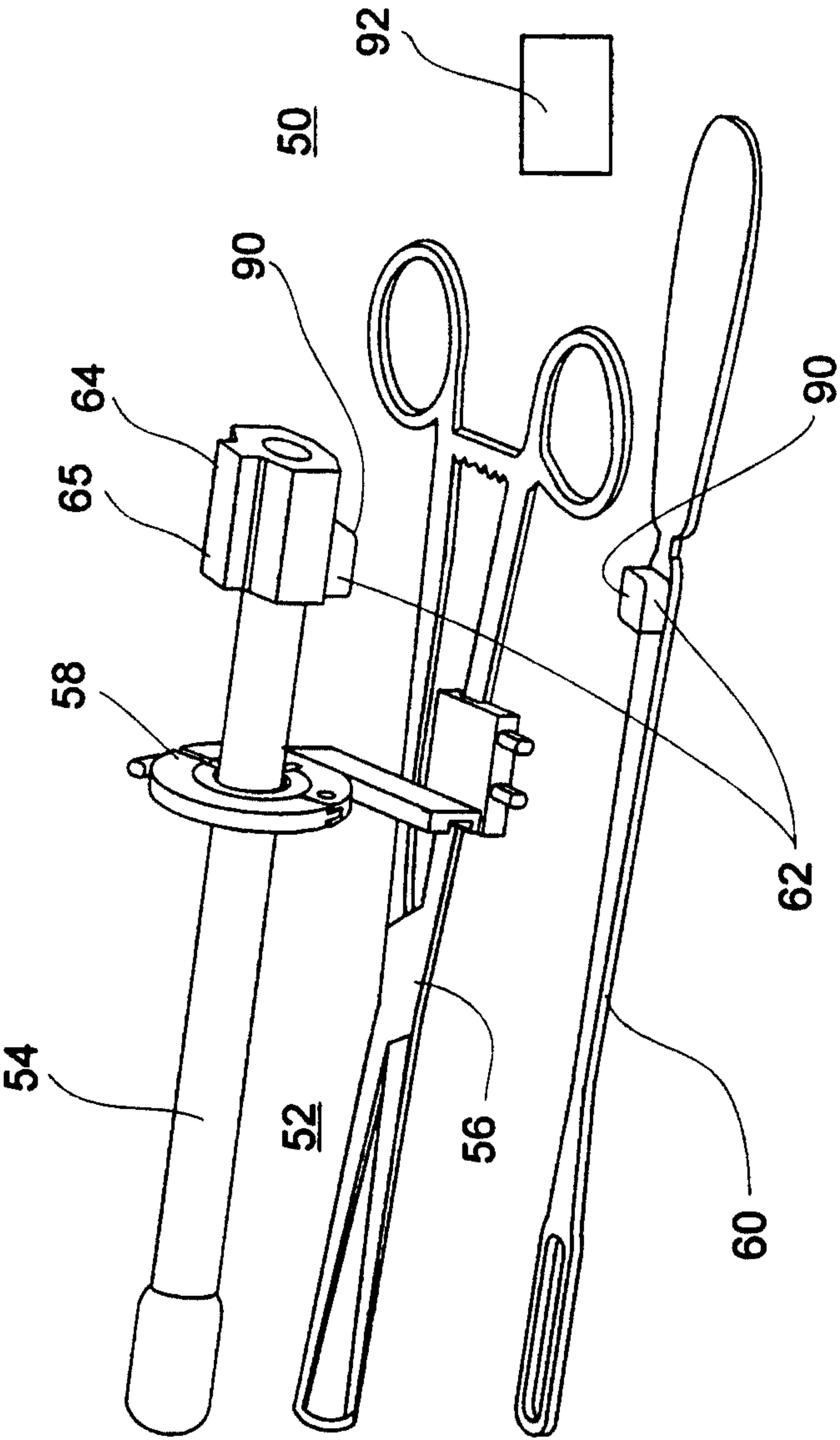


Fig. 7

7/7

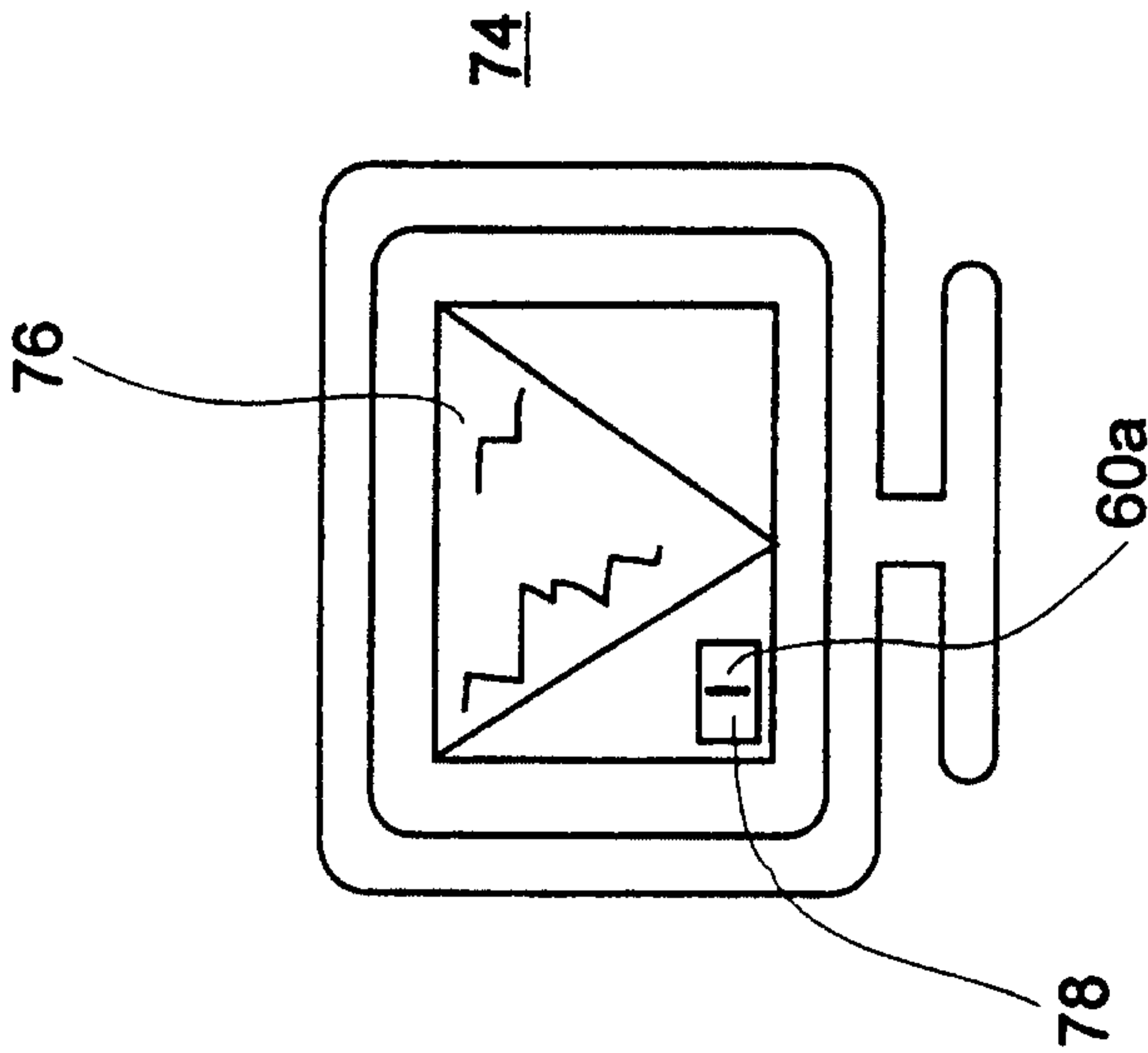


Fig. 8