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(54) Title: A MULTI PORT HAPTIC INTERFACE SIMULATOR

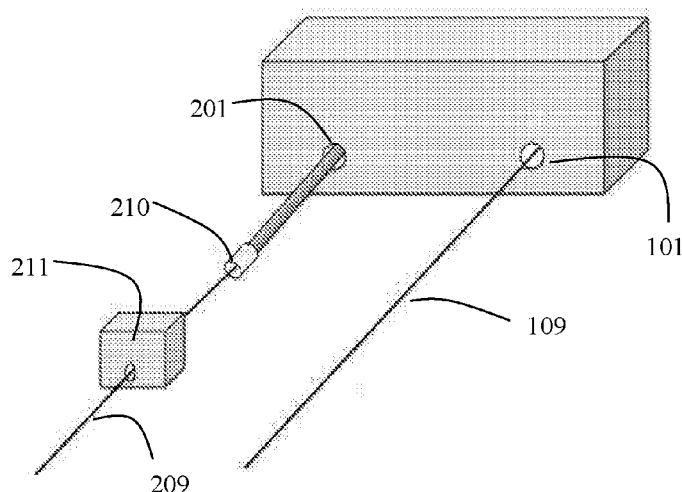


Figure 2

(57) Abstract: The present invention relates to a multi port haptic interface simulator comprising: first port (100) including: a conduit (101); at least a sensor (103) placed along and over the conduit (101); at least an actuator (105) placed along and over the conduit (101); a catheter (107); and guide wire (109); second port (200) including: a conduit (201); at least a sensor (203) placed along and over the conduit (201); at least an actuator (205) placed along and over the conduit (201); a catheter (207); and guide wire (209); a separate sensor unit (211); and a catheter hub (210); a microcontroller (300); and a power supply (400); characterized in that a micro actuator (500) is placed within the catheter hub (210). The micro actuator (500) solution to the concentric occlusion problem as it enables the generation of haptic feedback, even when the inner concentric instrument is within the outer concentric instrument.

**Declarations under Rule 4.17:**

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *of inventorship (Rule 4.17(iv))*

Published:

- *with international search report (Art. 21(3))*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

A MULTI PORT HAPTIC INTERFACE SIMULATOR

FIELD OF INVENTION

- 5 The present invention relates to a haptic interface device that is used to control virtual models of cylindrical instruments in an image guided endovascular surgery simulator.

BACKGROUND OF INVENTION

- 10 In an interface with a virtual simulator, both guide wire and catheter act as controllers for the modelled tools in the simulation software. As such, the position and orientation of the tools must be trackable at all times to ensure the realism of the simulation. Also, haptic feedback must continuously be present for the same reason. These requirements mean that the interface should be able to track and
15 apply haptic feedback to the tools when prompted by the simulation program. However, during the procedure, the guidewire is largely covered by the catheter, thereby reducing the number of contact points and line of sight to the guide wire. This represents a design challenge which we refer to as the 'concentric occlusion' problem.

- 20 The device presented in patent US 6538634 offers a partial solution to the concentric occlusion problem. A sensor-actuator pair for the catheter is placed at the entrance slot of the device whereas a second sensor-actuator pair for the guide wire is placed at the distal end of the catheter. While this design solves part of the
25 main problem, it also has a few shortcomings. There is a significant delay in the amount of time taken for the guide wire to be sensed and tracked as it has to travel the entire length of the catheter before it can be detected by the sensor. This can severely affect the realism of the simulation procedures and, more importantly, should the catheter reach the guide wire sensor, it would no longer be possible to
30 track the guide wire, potentially disrupting the simulation.

- In terms of haptic feedback, the mechanism used in the said patent involves the movement of a stepper motor arm to push clamps or cushions onto the tools to provide resistance in both translational and rotational movements. However,
35 discussions with Subject Matter Experts (SMEs) and findings from a study we

conducted (available upon request and due for publication before the end of the year) have suggested that there are potentially more varied haptic effects that are felt during endovascular procedures than just simple resistance. This includes subtle resistance and tool bump or collision haptic effects that cannot be reproduced by the clamping mechanism shown in the patent as the response time and actuator size is too large.

Patent US 7520749 describes another device for an interventional simulator. The design used here is that of a carriage system. There are multiple carriages that are mounted onto a pulley system. Each carriage is dedicated to a specific instrument where the carriage closest to the entrance port is meant for the most external instrument (ie. catheter), the second closest for the second most external and so on. Also, each carriage is equipped with sensors and actuators to track and give haptic feedback to the selected instrument. Once an instrument is inserted into the carriage, an optical sensor is used to check the instrument diameter. If the correct instrument is identified, a clip will be activated to lock the instrument within the carriage. After that, the carriage will move along the pulley when the wire is pushed and pulled. Sensors on the carriage will detect the carriage movement as insertion depth. Optical sensors would also detect rotational motion of the instrument. When haptic feedback is required, a special mechanism onboard the carriage is activated to produce resistance to instrument movement in both directions. The carriage system used here has the same flaws as that of the design shown in previous patents. The internal instruments have to travel a significant distance before being detected by the sensors. There is also a limit to each the range of movement for each instrument as each carriage can only travel as far as the telescopic connections can extend. Due to the weight of the carriage, the design may also introduce additional friction or resistance to instrument advancement and withdrawal, which could negatively affect the realism of the simulation.

While the designs in Patent US 6538634 and US 7520749 describe almost complete systems for an interface device, the design in Patent US2007/0063971 only illustrates the actuation mechanism used to achieve the same effect in terms of haptic feedback. Nonetheless, the mechanism described should be working in tandem with a non contact motion sensing component that would record any movement of the catheter. Although it is implied, there is no direct mention that the

design can also be used to apply haptic feedback to the guide wire, especially not in the concentric configuration of the wire within the catheter. Therefore, there is much less focus on solving the concentric occlusion problem in this patent. This is made more obvious by the fact that most of the designs presented feature many moving parts which include rollers and springs that are subject to wear and tear. These parts also make the design very difficult to miniaturise in order for it to be used to apply subtle forces to the guide wire as haptic feedback. The design seems optimized for applying force to the catheter to provide strong resistance effects, and is less suitable for applying subtle forces, particularly to the guide wire.

With regards to all those problems, there is a need for an invention which could address all of the problems or drawbacks mentioned.

SUMMARY OF THE INVENTION

According to an aspect of the present invention, the present invention provides a multi port haptic interface simulator comprising: first port (100) including: a conduit (101); at least a sensor (103) placed along and over the conduit (101); at least an actuator (105) placed along and over the conduit (101); a catheter (107); and guide wire (109); second port (200) including: a conduit (201); at least a sensor (203) placed along and over the conduit (201); at least an actuator (205) placed along and over the conduit (201); a catheter (207); and guide wire (209); a separate sensor unit (211); and a catheter hub (210); a microcontroller (300); and a power supply (400); characterized in that a micro actuator (500) is placed within the catheter (210).

The above provision is advantageous as the present invention is designed to overcome the limitations in current interfaces for the same application, whilst adding new features not featured in the prior art. The micro actuator (500) is able to solve the concentric occlusion problem as it enables the generation of haptic feedback, even when the inner concentric instrument is within the outer concentric instrument.

At the second port (200), the inner concentric instrument (typically a guide wire) is tracked at its proximal end by separate sensor unit (211) rather than at the distal end as in prior art. This approach removes the possibility of the outer concentric

instrument (catheter) overextending and reaching the inner concentric instrument sensor, at which point it would no longer be possible to track such instrument, potentially disrupting the simulation. The inner concentric instrument actuator (500) in the second port (200) is placed within the outer concentric instrument hub (210),
5 thus allowing haptic feedback to be applied immediately upon insertion, which was not possible in previous designs as the inner concentric instrument would need to travel some distance to reach the first actuator.

According to aforementioned survey study, there could potentially be other haptic
10 effects felt during endovascular procedures apart from resistance effects. The main other effect being a "bump effect", which is a subtle effect resulting from the collision of the instrument with vessel bifurcations. For this reason, the micro actuator (500) is designed to deliver a more subtle range of haptic feedback, with the type of haptic effect varied and controlled by the design of the actuator brake.

15

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be fully understood from the detailed description given herein below and the accompanying drawings as follows:

20

Figure 1 illustrates a schematic diagram of a multi port haptic interface simulator of the present invention.

Figure 2 illustrates a complete assembly of a multi port haptic interface simulator of
25 the present invention.

Figure 3 illustrates a micro actuator unit (500) of a multi port haptic interface simulator of the present invention.

30 Figure 4 illustrates: (a) an actuator brake (505) of a micro actuator unit (500) in sphere shape; (b) an actuator brake (505) of a micro actuator unit (500) having a shape like pin with a round head; and (c) an actuator brake (505) of a micro actuator unit (500) in roller shape.

Figure 5 illustrates channel and components used in a single port of the present invention.

Figure 6 illustrates concentric tracking sensor configuration at the first port (100).

5 Figure 7 illustrates sensor and actuator configuration at the second port (200).

Figure 8 illustrates guide wire (109) insertion at the first port (100).

10 Figure 9 illustrates sheathing of catheter (107) over guide wire (109) at the first port (100).

Figure 10 illustrates simultaneous catheter (207) and guide wire (209) manipulation at the second port (200).

15 Figure 11 illustrates: (a) extraction of guide wire (109); and (b) simulated injection of dye at the first port (100).

DETAILED DESCRIPTION OF THE PRESENT INVENTION

20 Generally, the present invention relates to a multi port haptic interface simulator comprising: first port (100) including: a conduit (101); at least a sensor (103) placed along and over the conduit (101); at least an actuator (105) placed along and over the conduit (101); a catheter (107); and guide wire (109); second port (200) including: a conduit (201); at least a sensor (203) placed along and over the conduit (201); at least an actuator (205) placed along and over the conduit (201); a catheter (207); and guide wire (209); a separate sensor unit (211); and a catheter hub (213); a microcontroller (300); and a power supply (400); characterized in that a micro actuator (500) is placed within the catheter hub (210). This is as shown in Figure 1 and Figure 2. The device features two separate ports for the insertion of instruments, with each port designed to facilitate the simulation of certain set procedures. One of the ports (first port (100)) facilitates steps such as needle puncture, initial insertion of guide wire and catheter, instrument exchanging and fluoroscopic dye injection with a mock syringe. The other port (second port (200)) is specifically designed for multiple instruments, supporting the simulated advancement of the guide wire and catheter, 35 with the guide wire concentric within the catheter.

As illustrated in Figure 3, wherein the micro actuator (500) further comprising: a ferromagnetic custom frame (501); four permanent magnets (503); a pair of brakes (505); a solenoid (507); and a solenoid casing (509). When current is supplied to the solenoid, an electromagnetic field is produced. This electromagnetic field interacts with the magnetic field produced by the permanent magnets and the generated electromagnetic force pushes the solenoid casing over the brakes. This clamping force on the instrument creates a resistance effect to instrument movement that is perceived as haptic feedback.

According to survey, there are potentially other haptic effects felt during endovascular procedures apart from resistance effects. The main other effect being a “bump effect”, which is a subtle effect resulting from the collision of the instrument with vessel bifurcations. For this reason, the micro actuator (500) is designed to deliver a more subtle range of haptic feedback, with the type of haptic effect varied and controlled by the design of the actuator brake. If a rotational resistance is required, the brake (505) can instead be a sphere as in Figure 4(a). The sliding solenoid (507) pushes against the inner concentric instrument offering resistance to movement in any direction. If a strong pinching force is required, the brake (505) can be modified to be a pin with a round head as in Figure 4(b). The sliding solenoid (507) of the actuator would push the pin down, which in turn would apply high pressure to the object resulting in high resistance to translational movement of the inner concentric instrument. If a subtle force is needed, the brake (505) can be a roller as in Figure 4(c). The sliding solenoid (507) of the actuator would then slide against the roller to produce friction opposing translational movement of the inner concentric instrument. Several actuators may also be used in tandem at different contact points to produce more detailed haptic feedback effects.

In one embodiment (Figure 5), first port (100) comprises of a single conduit (101) or channel through which a tool might be inserted. There are sensors (103), for example optical sensors and actuators (105), for example servo motor placed along and over the conduit (101). The sensors (103) track the movement of instruments within the conduit (101), whilst the actuators (105) apply haptic feedback to the instrument. The first port (100) may be used in procedures such as the initial insertion of introducer wires, the placement of a catheter (107) over a static guide wire (109) (held in place by

the user) and the exchange of tools such as switching to different guide wires. The first port (100) would also be able to facilitate needle puncture training by attaching a separate modular interface.

5 In one embodiment (Figure 6), upon inserting the guidewire into the first port (100), the guidewire's (109) movements would be tracked by a sensor (103), preferably an optical sensor, which is mounted over the port channel (101). When a catheter is introduced into the first port (100), as it is passed over the guidewire, its movements would be detected by a second sensor (103), preferably a trackball sensor (104),
10 which is also mounted over the port channel (101). With both the guidewire (109) and catheter (107) inserted into the first port (100), the guide wire (109) would be concentrically within the catheter (107). A transparent catheter (107) preferably is used, so that the movements of the guide wire (109) may be tracked through the catheter (107) by the optical sensor (103). The movements of the catheter (107) may
15 continue to be tracked by the trackball sensor (104). In a simulated procedure for tool exchange, the optical sensors (103) would detect when the guide wire (109) has been pulled out before the next step of the procedure can be continued. If the catheter (107) needs to be exchanged, the insertion depth of the catheter (107) may be tracked by the trackball sensor (104).

20 In addition to the conduit (201) fixed with the sensors (203) and the actuators (205), the second port (200) has a separate sensor unit (211), for example optical sensor as illustrated in Figure 7. This sensor unit (211) tracks the movement of the guide wire (209) at all times, whilst the sensor (203) inside the second port (200) tracks the
25 catheter (207). Haptic feedback is applied to the guide wire (209) through the micro actuator unit (500) placed within the catheter hub (210), and to the catheter (207) through the actuator (205) inside the second port (200). Both the catheter (207) and the guide wire (209) are pre-inserted into the second port (200), with the guide wire (209) is pre-inserted inside the separate sensor unit (211) as well.

30 The second port (200) allows for the simulation of procedures, where both the catheter (207) and the guide wire (209) are concentrically manipulated, either simultaneously or individually, ensuring continuous tracking and haptic feedback to both instruments. This concentric manipulation is crucial as it teaches the core skill of navigating a guide
35 wire and catheter to a target.

The following is a description of how the present invention may be used for the simulation of angiographic interventions:

5 i. Initial guide wire insertion

The user is prompted to insert the guide wire through the needle into the first port (100) to a certain pre-determined insertion depth (Figure 8). Upon insertion, guide wire movement is tracked by a sensor (103) (e.g. optical sensor) on the first port (100). Once the guide wire (109) reaches the
10 desired insertion depth, the simulation program prompts the user to pull out the needle while leaving the guide wire (109) inside the patient.

 ii. Catheter sheath over guide wire and catheter insertion

The user would then be prompted to sheath a catheter (107) over the guide wire in the first port (100). The catheter (107) is then inserted into the first
15 port (100), while the guide wire (109) is held firmly in place by the user (Figure 9). The catheter's insertion depth is measured by a sensor (104) (e.g. trackball sensor). Once the desired insertion depth is reached, the user would be directed to the next step.

20

 iii. Guide wire and catheter navigation to target vessel

The user would be instructed to switch to the second port (200) and all sensors (103) and actuators (105) on the first port (100) would be deactivated. As shown in Figure 10, the pre-inserted catheter (207) and
25 guide wire (209) on the second port (200) would already be in the initial position following the previous step in the procedure (i.e. both instruments inserted at a certain depth). The user would then be prompted to move the guide wire and catheter to the target vessel. When advancing the instruments, the actuators (500) and (205) would apply force or haptic
30 feedback to the guidewire and catheter respectively, when triggered by the simulation software. Once the branch of the target vessel is reached, the next step would be prompted.

35

iv. Guide wire extraction and dye injection

The second port (200) would be deactivated at this point and the first port (100) would be reactivated. The user would be instructed to pull out the guide wire (109) inserted in the first port (100) (Figure 11 (a)) and attach a syringe to the catheter (107) to inject contrast agent as necessary (Figure 11 (b)). Immediately when injecting contrast, a button or pedal is pressed to simulate the capture and display of radiographic images on a screen. Once this task is completed, the user would be instructed to remove the syringe and reinsert the guide wire (109) into the first port (100). Steps iii- and iv- will be repeated as necessary.

In a different embodiment of the invention, the same first port (100) or another separate port may be used to simulate corrective procedures such as angioplasty, stenting and abdominal aneurysm repair.

The present invention has been described in a preferred form only and many variations may be made in the invention which will still be comprised within its spirit, such as, in the present invention, it could comprise more than two ports with different configurations of sensors and actuators. The invention is not limited to the details cited above. The components herein described may be replaced by its technical equivalence and yet the invention can be performed. The structure thus conceived is susceptible of numerous modifications and variations, all the details may furthermore be replaced with elements having technical equivalence. In practice the materials and dimensions may be any according to the requirements, which will still be comprised within its true spirit.

30

35

CLAIMS

1. A multi port haptic interface simulator comprising:
first port (100) including: a conduit (101); at least a sensor (103) placed
5 along and over the conduit (101); at least an actuator (105) placed along and
over the conduit (101); a catheter (107); and guide wire (109);
second port (200) including: a conduit (201); at least a sensor (203) placed
along and over the conduit (201); at least an actuator (205) placed along and
over the conduit (201); a catheter (207); and guide wire (209); a separate
10 sensor unit (211); and a catheter hub (210);
a microcontroller (300); and
a power supply (400);
characterized in that,
a micro actuator (500) is placed within the catheter hub (210).
15
2. A multi port haptic interface simulator as claimed in Claim 1, wherein the micro
actuator (500) further comprising: a ferromagnetic custom frame (501); at least
four permanent magnets (503); at least a pair of brakes (505); at least one
solenoid (507); and at least one solenoid casing (509).
20
3. A multi port haptic interface simulator as claimed in Claim 2, wherein the pair of
brakes (505) further comprising spherical brakes.
4. A multi port haptic interface simulator as claimed in Claim 2, wherein the pair of
25 brakes (505) further comprising pin with a round head brakes.
5. A multi port haptic interface simulator as claimed in Claim 2, wherein the pair of
brakes (505) further comprising roller brakes.
- 30 6. A multi port haptic interface simulator as claimed in Claim 1, wherein the
catheter (107) is transparent.

1/7

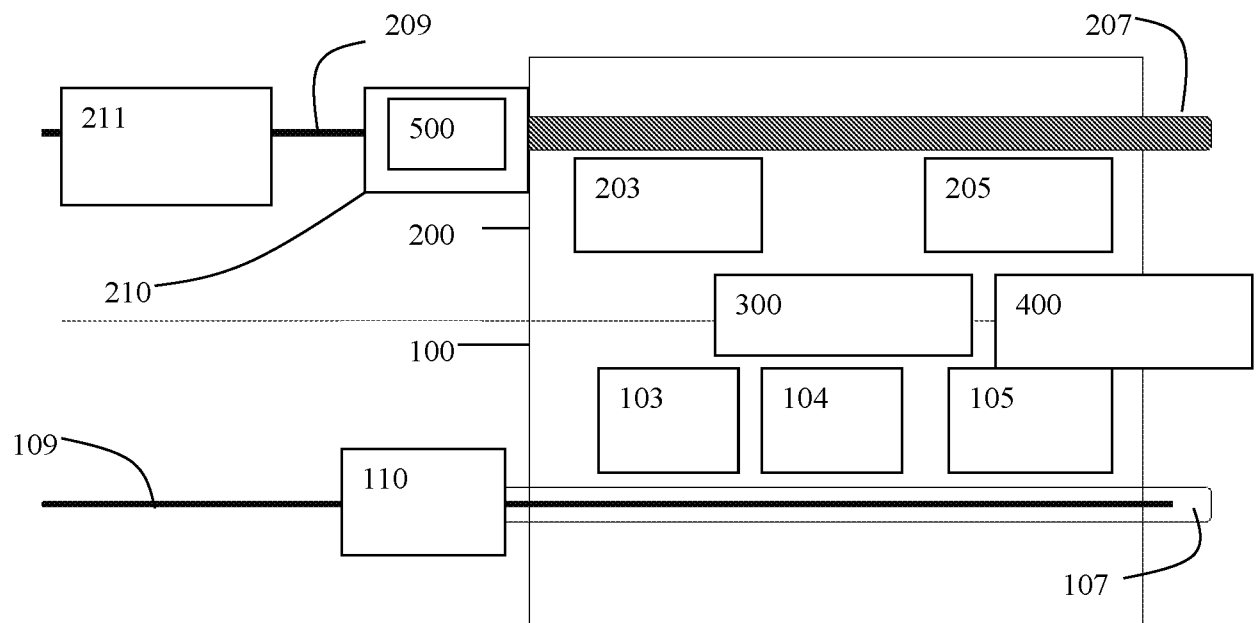


Figure 1

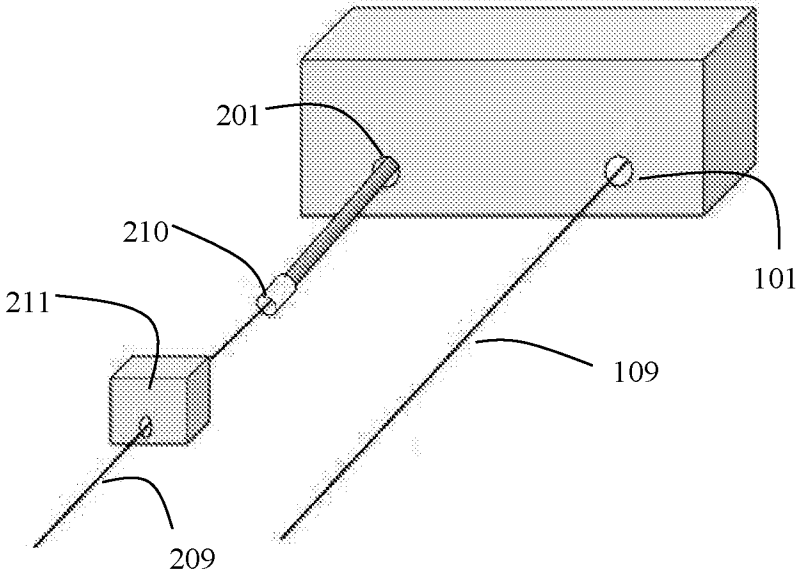


Figure 2

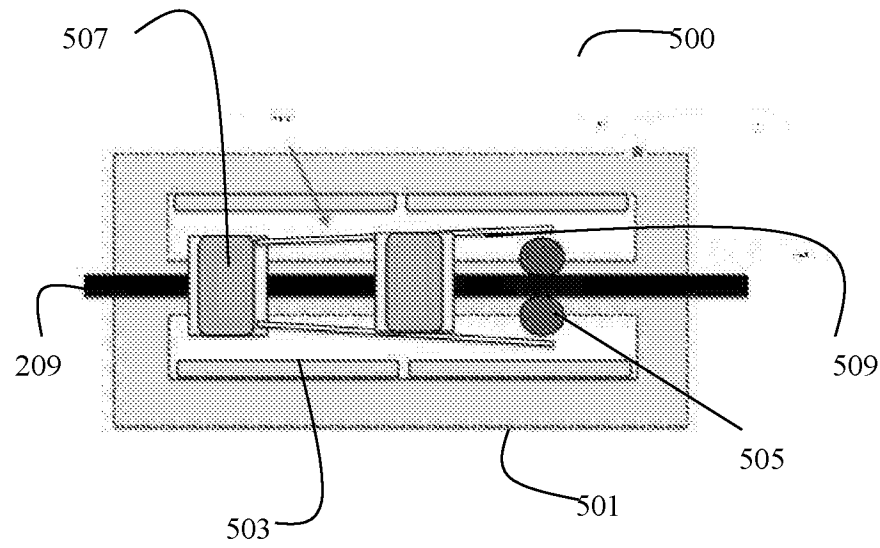


Figure 3

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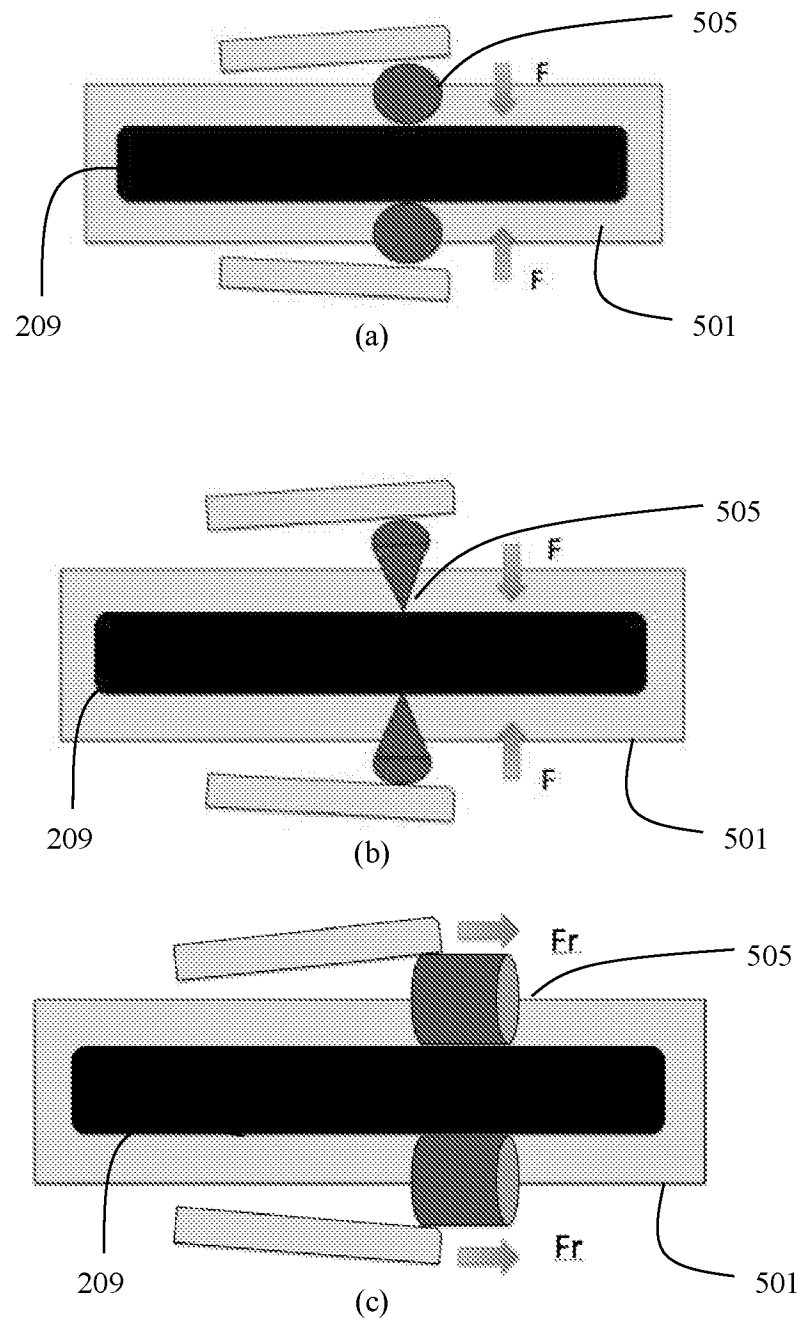


Figure 4

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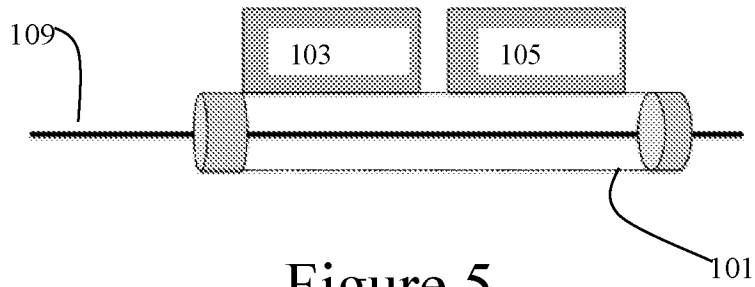


Figure 5

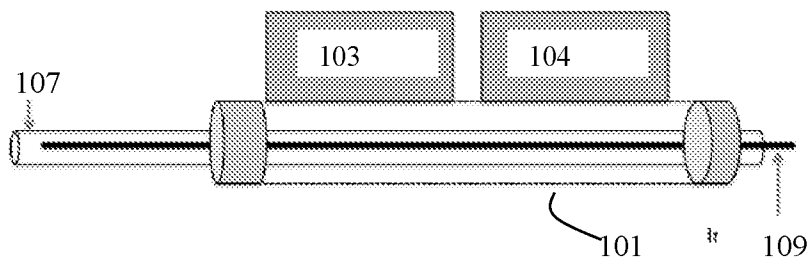


Figure 6

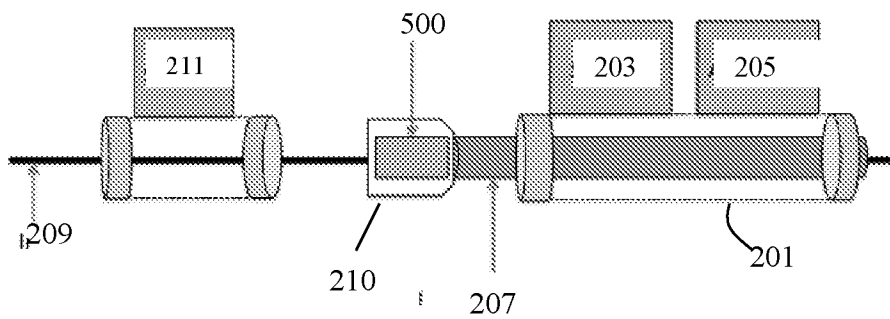


Figure 7

6/7

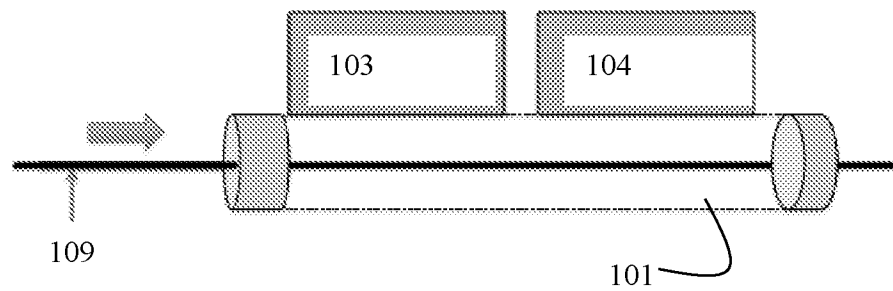


Figure 8

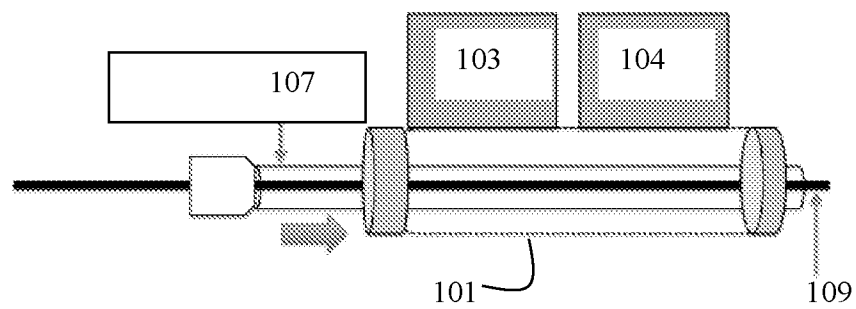


Figure 9

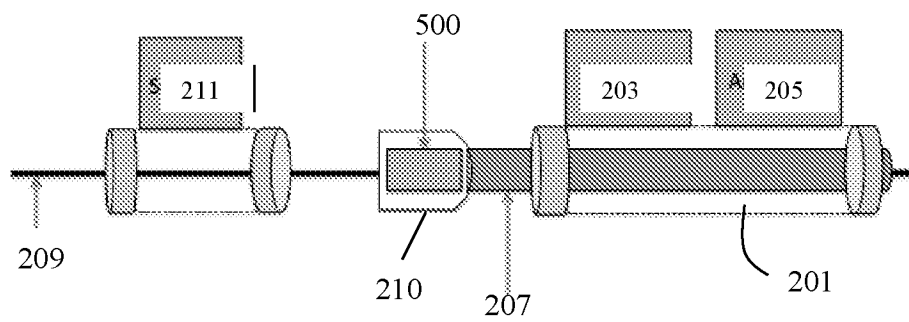


Figure 10

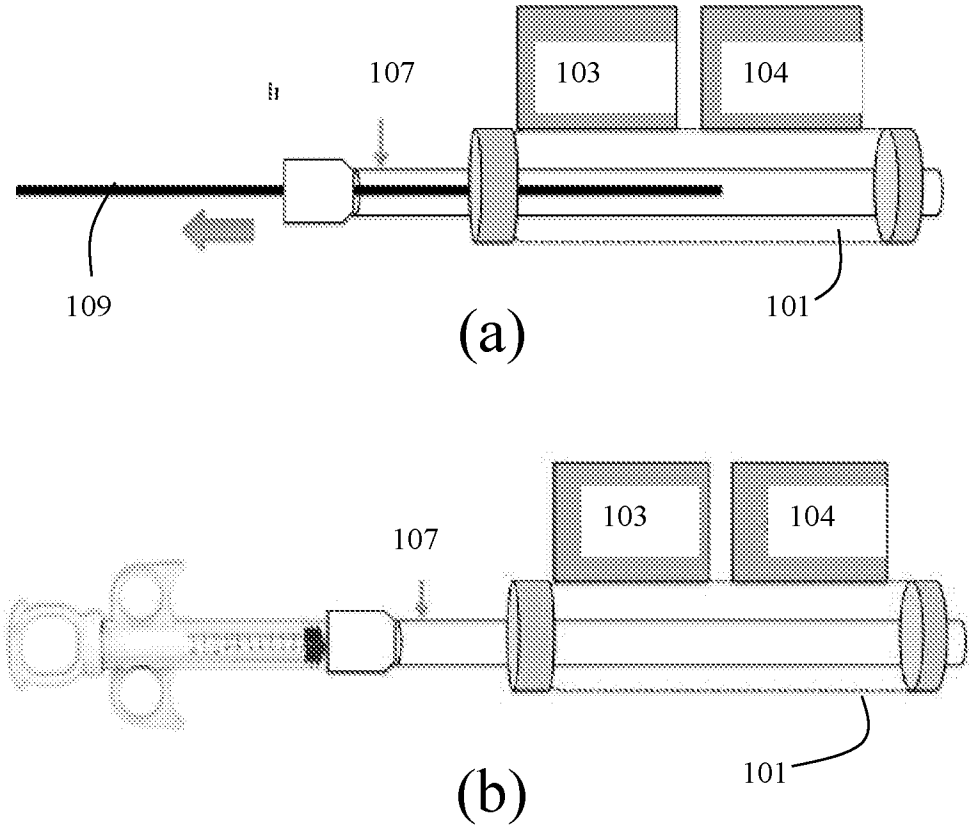


Figure 11

INTERNATIONAL SEARCH REPORT

International application No
PCT/MY2016/050048

A. CLASSIFICATION OF SUBJECT MATTER
INV. G09B23/28
ADD.

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)
G09B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2014/349263 A1 (SHABAT MATAN [IL] ET AL) 27 November 2014 (2014-11-27) paragraphs [0027], [0028], [0030], [0033], [0035], [0036], [0041] figures 1,2A,2B,3A -----	1-6
A	US 6 538 634 B1 (CHUI CHEE-KONG [SG] ET AL) 25 March 2003 (2003-03-25) cited in the application the whole document -----	1-6
A	WO 2011/028627 A2 (UNIV NEW YORK STATE RES FOUND [US]; KESAVADAS THENKURUSSI [US]; SRIMAT) 10 March 2011 (2011-03-10) the whole document ----- -/-	1-6



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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"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

10 January 2017

Date of mailing of the international search report

25/01/2017

Name and mailing address of the ISA/

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Fax: (+31-70) 340-3016

Authorized officer

Kirchler, Dominik

INTERNATIONAL SEARCH REPORT

International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 970 714 A2 (MITSUBISHI ELECTRIC CORP [JP]) 12 January 2000 (2000-01-12) the whole document -----	1-6
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A	US 8 062 038 B2 (HENDRICKSON DANIEL LEE [US] ET AL) 22 November 2011 (2011-11-22) the whole document -----	1-6

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/MY2016/050048

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