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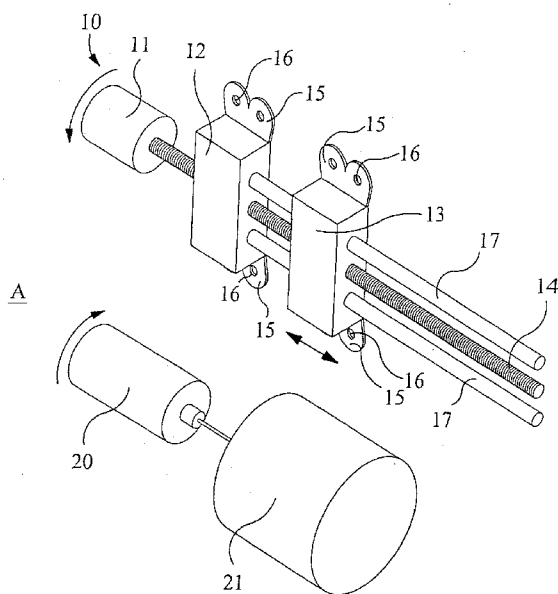
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(54) Title: DISTRACTION DEVICE



(57) Abstract: A distraction device (10) comprising first and second distraction elements (12, 13) capable of being secured, respectively, to first and second parts to be distracted, said first and second distraction elements (12, 13) being relatively moveable so as to effect distraction of the said first and second parts, in use; at least one magnetic element (11) mounted so as to be rotatable under the influence of an external magnetic field; and converting means (14) arranged to effect relative movement of said first and second distraction elements (12, 13) upon rotation of said at least one magnetic element (11); wherein said relative movement of said first and second distraction elements (12, 13) is permitted in both a direction to draw apart and a direction to draw together said first and second distraction elements (12, 13).

WO 2008/003952 A1



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- 1 -

## **DISTRACTION DEVICE**

### **Technical Field**

This invention relates to a distraction device. In particular, but not exclusively, it relates to an osteosynthetic distraction device for the lengthening of bones.

### **Background**

Traditionally, the lengthening of a bone involves breaking the bone and attaching pins to each of the bone parts. The pins usually extend through the skin and are connected via a threaded distraction bar apparatus. The distraction apparatus is manipulated to gradually move the pins apart from each other and thereby increase the separation between each bone part. Commonly, distraction is performed at a rate of 1mm per day for 10 to 20 days. As the bone parts are moved apart, new bone forms in an attempt to close the gap. Thus, gradual separation of the original bone parts leads to an extension of the bone. Although this apparatus is capable of providing adequate bone distraction, the necessary puncturing of the skin, to allow the pins to pass through, leads to scarring of the outer skin and an increased risk of infection.

Consequently, it is desirable for a distraction device to be fully implantable beneath the skin and therefore not require connecting elements to protrude through the skin. However, the problem then becomes one of how to operate the device in a controlled and effective manner.

- 2 -

Past proposals for fully implantable distraction devices have included motor driven elements, pneumatic pumps and pressurised gas chambers, all of which may be operated via a magnetic or other wireless connection to an external actuator. A common characteristic of such devices has been a certain degree of complexity that ultimately makes the device unreliable, cumbersome and expensive. Not only are these devices prone to operational failure but they may also carry an increased risk of infection due to the nature of the substances contained therein. For example, several of these devices contain batteries that may leak, releasing harmful chemicals into the body. Another drawback with these devices is that their complexity largely determines their size. This may not be a problem when dealing with large bones such as those of the arm or leg but it may prevent the device from being appropriately scaled down for use with small bones such as the jaw or skull.

In PCT/GB99/01039, of the present Applicants', there is disclosed a mechanical distraction device, particularly for use with small bones. In this device, an internal magnet was capable of linear movement, within a housing, under the influence of a linear external magnetic field. The linear movement of the internal magnet was translated through a ratchet-like connection means into linear separation of first and second distraction elements. This resulted in linear separation of the bone parts attached, respectively, to the first and second distraction elements. Although this device was capable of delivering the required force and stepwise distraction increments, it lacked a degree of mechanical strength that impacted upon its reliability. Also, the device was unidirectional by design and therefore it was

- 3 -

not possible to reduce the bone gap after extension if, for example, the patient was in pain.

It is therefore the aim of the present invention to provide a simplified but robust distraction device that addresses the above issues.

### **Statements of Invention**

In accordance with the present invention there is provided a distraction device comprising first and second distraction elements capable of being secured, respectively, to first and second parts to be distracted, said first and second distraction elements being relatively moveable so as to effect distraction of the said first and second parts, in use; at least one magnetic element mounted so as to be rotatable under the influence of an external magnetic field; and converting means arranged to effect relative movement of said first and second distraction elements upon rotation of said at least one magnetic element; wherein said relative movement of said first and second distraction elements is permitted in both a direction to draw apart and a direction to draw together said first and second distraction elements.

The above construction has the advantage that it may be operated simply upon application of an external magnetic field. This means the device may be fully implanted under a patient's skin with no parts being required to penetrate through the skin during the distraction period. Thus, the amount of scarring and the risk of infection are both reduced. In addition, the above device comprises a simple construction and therefore is less likely to be prone to operational failure, and is more easily scalable to suit different sized applications, than more complicated devices. Thus, the present device may

- 4 -

be used for the distraction of small bones such as the jaw or skull as well as long bones, for example, in the leg or arm. A further advantage is that the simplicity of the device makes it relatively cheap and easy to manufacture. It is also quick and easy to operate and so the distraction itself need not be performed by a surgeon but may be performed by, say, a nurse who is less skilled and therefore less expensive than a surgeon. Moreover, the above device is capable of bi-directional operation and this has the advantage that if a patient is in considerable pain after a distraction movement, the distraction may be reversed. Finally, in the present device the distraction is effected by rotational movement of the (internal) magnetic element, and this requires less room than if linear movement were employed, and so allows for a more compact device.

Preferably, the converting means comprises a screw-threaded rod whereby the first distraction element is held in a fixed position relative to the rod and the second distraction element is free to move longitudinally along the length of the rod, as the rod is rotated about its longitudinal axis.

Preferably, the at least one magnetic element is axially coupled to the rod and rotatable about its longitudinal axis.

In one embodiment, the at least one magnetic element is incorporated within the rod. Alternatively, the rod itself may constitute the at least one magnetic element by being formed from a magnetic material. These particular embodiments are advantageous in that they require a reduced number of individual parts, simplifying the operation and construction of the device whilst also allowing for a reduction in the size of the device.

- 5 -

In a further embodiment, the at least one magnetic element is coupled to the rod and rotatable about an axis parallel to the axis of the rod. Preferably, the converting means further comprises a force multiplying means. Preferably, the force multiplying means comprises a gear linkage between the at least one magnetic element and the rod.

In one embodiment, the at least one magnetic element is rotatable within a static sheath. This has the advantage of reducing the friction encountered by the magnet as it rotates.

Preferably, each of the first and second distraction elements include moveable mounting plates for securing the first and second distraction elements to the first and second parts. This feature provides for versatility in the place of attachment to the parts. Preferably, the moveable mounting plates are attached to the first and second distraction elements via a ball bearing joint.

Preferably, the distraction device is configured to be fully implantable under the skin of a patient.

Preferably, the distraction device is configured to remain implanted after the required distraction has taken place.

Alternatively, the distraction device is configured for removal from a patient after the required distraction has taken place.

Preferably, the distraction device further comprises a sensing means to sense the amount of relative movement between the first and second distraction elements.

### **Brief Description of the Drawings**

Particular embodiments of the invention are illustrated in the accompanying drawings wherein:-

Figure 1A is a schematic representation of a distraction device, according to one embodiment of the invention, in a first position (not to scale);

Figure 1B is a schematic representation of the distraction device of Figure 1A in a second position;

Figure 2A is a schematic representation of a distraction device, according to a second embodiment of the invention, in a first position (not to scale);

Figure 2B is a schematic representation of the distraction device of Figure 2A in a second position;

Figure 3 is a cross-sectional view showing use of a distraction device according to the present invention to distract a patient's jawbone;

Figures 4A through 4C illustrate rotation of an internal magnet of a distraction device according to the present invention, under the influence of an externally rotating magnetic field;

Figure 5 illustrates a variant construction for the external magnetic actuator shown in Figures 4A through 4C;

Figure 6 shows a variant construction of an internal magnet of a distraction device according to the present invention; and



- 7 -

Figure 7 shows a longitudinal cross-sectional representation of a distraction device, according to a third embodiment of the invention (not to scale).

### **Detailed Description of the Invention**

Referring to the drawings, a first embodiment of a distraction device 10, according to the present invention, is shown in Figures 1A and 1B. This distraction device 10 comprises a first distraction element 12 and a second distraction element 13, both of which are mounted on a screw-threaded rod 14. The first distraction element 12 has an internal bore (not shown) through which the rod 14 is fed and allowed to rotate axially within the bore without causing longitudinal movement of the first distraction element 12 along the length of the rod 14. The second distraction element 13 also has a bore (not shown). However, in this case, the bore is threaded such that when the rod 14 is screwed through the bore, axial rotation of the rod 14 causes the second distraction element 13 to move longitudinally along the length of the rod 14. Both of the distraction elements 12, 13 include mounting plates 15 with apertures 16 for receiving attaching means, such as a screw (not shown), when in use. Two slider rods 17 are disposed parallel to the screw-threaded rod 14 and are radially opposed with respect thereto and are spaced apart therefrom. One end of each slider rod 17 is attached to the first distraction element 12 and the other end of each slider rod 17 is passed through a respective bore (not shown) in the second distraction element 13. A magnetic element 11 is axially aligned with and coupled to one end of the screw-threaded rod 14. In the particular distraction device 10 shown, the magnetic element 11 is coupled to the rod 14 at the end adjacent to the first distraction element 12.

- 8 -

In use, the distraction device 10 may be fully implanted within the body of a patient. The first distraction element 12 is attached to a first bone part by use of screws through its apertures 16. Similarly, the second distraction element 13 is attached to a second bone part by use of screws through its apertures 16. An external magnetic field is then applied near to the distraction device 10. As shown in Figure 1A, the external magnetic field may be applied by a rotating magnetic actuator 20 connected to a power source 21. As the external magnetic actuator 20 is rotated it attracts the magnetic element 11 in the distraction device 10 and causes it to rotate also. As the magnetic element 11 is connected to the screw-threaded rod 14, rotation of the magnetic element 11 causes rotation of the rod 14. This in turn causes the second distraction element 13 to move longitudinally along the rod 14 with respect to the first distraction element 12. Thus, depending upon the direction of rotation induced by the external magnetic field, the second distraction element 13 may either be moved apart from or moved towards the first distraction element 12. Therefore, in order to effect distraction of the attached bone parts, the magnetic element 11 is caused to rotate in a direction which moves the second distraction element 13 apart from the first distraction element 12. Conveniently, the external magnetic actuator 20 is calibrated such that an operator can determine how much rotation is required to effect the desired separation of the bone parts. Commonly, bones are distracted by approximately 1mm per day for about 10 days. Further distraction may then be effected after about 1 year.

An alternative construction of a distraction device 30, according to the present invention, is shown in Figures 2A and 2B. Similar components to

- 9 -

those shown in Figures 1A and 1B are numbered accordingly. The main difference between this distraction device 30 and the previous distraction device 10 is that the magnetic element 11 is now axially parallel to the screw-threaded rod 14 and thus, replaces one of the slider rods 17 in the previous device 10. This construction allows for a more compact device 30 and also enables a force multiplying means in the form of a gear linkage to be employed. The first distraction element 12 is positioned at one end of the device 30. Extending from one side of the first distraction element 12 is a fixed slider rod 17, a rotatable screw-threaded rod 14 and a rotatable magnetic element 11. As before, the second distraction element 13 has a threaded bore (not shown) to receive and mate with the thread of the rod 14. The second distraction element 13 also has respective bores (not shown) for the slider rod 17 and magnetic element 11 to pass through and slide therein. The ends, of the slider rod 17, screw-threaded rod 14 and magnetic element 11, opposite to the first distraction element 12, are coupled to an end bracket 32. Disposed towards the ends of the screw-threaded rod 14 and the magnetic element 11, adjacent the end bracket 32, are inter-engaging gear elements 31.

As before, when in use, the distraction device 30 is attached via mounting plates 15 to first and second bone parts. Upon application of an external magnetic field, the magnetic element 11 rotates. This causes the gear element 31 disposed on the magnetic element 11 to also rotate. As it does so, it engages the gear element 31 disposed on the screw-threaded rod 14, thus, causing the rod 14 to also rotate. Consequently, the second distraction element 13 is caused to move longitudinally of the rod 14 as the rod 14 rotates. Thus, the second distraction element 13 may either be moved apart

- 10 -

from or moved towards the first distraction element 12, which in turn either moves apart or together the attached bone parts.

As can be imagined, different sized gear elements 31 may be employed, respectively, on the screw-threaded rod 14 and magnetic element 11 to effect a multiplied, or reduced, force.

Figure 3 illustrates use of a distraction device 40, according to the present invention, being applied to extend a patients jawbone 41. Thus, the device 40 is implanted through an incision 42 in the gum 43 in a patient's mouth. As such, the patient's cheek 44 can hide any resulting scarring of the gum 43, thereby avoiding any external scarring. As illustrated, a rotating external magnetic actuator 20 can be brought close to the device 40 to effect the desired distraction movement. In the example shown, the external magnetic actuator 20 is approximately 8mm from the device 40 when in use.

As can be seen, the external magnetic actuator 20 is disposed at one side of the distraction device 40. This has been termed an asymmetric magnetic linkage as the external magnetic field is not required to be symmetric about the distraction device 40, as is often the case for common distraction devices used on long bones such as in the leg or arm. The asymmetric magnetic linkage is another factor that makes the present distraction device 40 desirable for use with small bones such as the jaw. A further application of the present distraction device 40 is in relation with filling holes in the skull.

Figures 4A through 4C illustrate how the external magnetic field affects the magnetic element 11. Thus a rotating external magnetic actuator 20 is shown

- 11 -

in cross-section adjacent to a magnetic element 11. In this particular example, the rotating external magnetic actuator 20 comprises four permanent magnets 22 disposed equidistant around the perimeter of a rotating drum 23. In other embodiments, many more magnetic elements 22 may be employed. The north poles of each of the magnets 22 and the magnetic element 11 are indicated with an arrow. Some of the magnetic field lines 24 produced by the magnets 22 are also indicated. Thus, as can be seen in Figures 4A, 4B and 4C, the magnetic element 11 in the distraction device 10 rotates to maintain alignment with the applied magnetic field 24, as the external magnetic actuator 20 is rotated. Continued rotation of the drum 23 would effect complete rotation of the magnetic element 11 for only a half turn of the drum 23. Consequently, one full turn of the external magnetic actuator 20 would effect two turns of the magnetic element 11. Thus, the number of magnets 22 (or poles) on the external drive 20 determines the number of turns effected by the internal magnetic element 11, for every turn of the external drive 20.

A variant construction of the external magnetic actuator 20 shown in Figures 4A through 4C is illustrated in Figure 5. Thus, rather than the magnets 22 being orientated with alternate poles facing towards the centre of the drum 23, the magnets 22 in Figure 5 are orientated with their poles aligned tangentially to the drum 23 but facing alternate directions. In both cases, a rotating magnetic field 24 is generated around the circumference of the drum 23 so that as the drum 23 rotates, the magnetic element 11 in the distraction device 10 rotates to align with the applied magnetic field 24.

- 12 -

Figure 6 shows an alternative construction of the magnetic element 11. Thus, two opposed magnets 50 and 51 are disposed adjacent each other, with their respective poles orientated for attraction.

A further construction of a distraction device 60, according to an embodiment of the present invention, is shown in cross-section in Figure 7. Similar components to those shown in Figures 1A and 1B are numbered accordingly. The main difference between this distraction device 60 and the previous distraction device 10 is that the magnetic element 11 is incorporated within the screw-threaded rod 14. This construction therefore provides an encapsulated magnetic element 11 and at the same time allows for a more compact device 60. As previously, the first distraction element 12 is positioned at one end of the device 60. Extending from one side of the first distraction element 12 are two fixed slider rods 17 and a rotatable screw-threaded rod 14 including an embedded magnetic element 11 along its length. As before, the second distraction element 13 has a threaded bore (not shown) to receive and mate with the thread of the rod 14. The second distraction element 13 also has respective bores (not shown) for the two slider rods 17 to pass through and slide therein. The ends, of the slider rods 17 and screw-threaded rod 14, opposite to the first distraction element 12, are coupled to an end retainer bracket 52.

In use, the distraction device 60 operates in substantially the same manner as that of the distraction device 10 described above in relation to Figures 1A and 1B.

- 13 -

The strength of the magnetic element 11, the distance of the magnetic element 11 from the external magnetic actuator 20, and the pitch of the thread on rod 14 determine the distraction force provided by a distraction device according to the present invention. Desirably, the distraction device may provide a distraction force approximately equivalent to 2kg.

Conveniently, the pitch of the thread on rod 14 is small to effect very slow and gradual movement of the distraction elements (i.e. small steps).

In some embodiments, the magnetic element 11 may be disposed within a sheath (not shown) to reducing the friction encountered by the magnetic element 11 as it rotates. If the device is to be used internally, it may be desirable that the sheath and the rods are made from stainless steel.

If desired, more than one distraction device may be used for the distraction of a bone.

The external magnetic field may be generated by a permanent magnet or an electromagnet. The external magnetic field may be a pulsed magnetic field. This may be particularly useful in order to obtain a higher magnetic field, say, to start the distraction process. This is because after a distraction device has been implanted, the patient is normally left for 4 to 5 days in order for them to recover from the surgery. During this time, the bone parts to be distracted may partially heal together and so an extra burst of energy may be required in order to kick start the distraction process.

- 14 -

For the case of distraction of the jaw or skull, the external magnetic actuator 20 may be provided within a removable helmet construction in order to aid in placement of the actuator 20 close to the implanted distraction device 40.

Further embodiments of the distraction device may also be devised in line with the present invention.



- 15 -

CLAIMS:

1. A distraction device comprising:
  - first and second distraction elements capable of being secured, respectively, to first and second parts to be distracted, said first and second distraction elements being relatively moveable so as to effect distraction of the said first and second parts, in use;
  - at least one magnetic element mounted so as to be rotatable under the influence of an external magnetic field; and
  - converting means arranged to effect relative movement of said first and second distraction elements upon rotation of said at least one magnetic element;
  - wherein said relative movement of said first and second distraction elements is permitted in both a direction to draw apart and a direction to draw together said first and second distraction elements.
2. A distraction device according to claim 1 wherein the converting means comprises a screw-threaded rod.
3. A distraction device according to claim 2 wherein the first distraction element is held in a fixed position relative to the rod and the second distraction element is free to move longitudinally along the length of the rod, as the rod is rotated about its longitudinal axis.
4. A distraction device according to claim 2 or 3 wherein the at least one magnetic element is axially coupled to the rod and rotatable about its longitudinal axis.

- 16 -

5. A distraction device according to claim 2 or 3 wherein the at least one magnetic element is incorporated within the rod.
6. A distraction device according to claim 2 or 3 wherein the rod constitutes the at least one magnetic element by being formed from a magnetic material.
7. A distraction device according to claim 2 or 3 wherein the at least one magnetic element is coupled to the rod and rotatable about an axis parallel to the axis of the rod.
8. A distraction device according to any preceding claim wherein the converting means further comprises a force multiplying means.
9. A distraction device according to claim 8, when dependent upon any of claims 2 to 7 wherein the force multiplying means comprises a gear linkage between the at least one magnetic element and the rod.
10. A distraction device according to any of claims 1 to 4 or 7 wherein the at least one magnetic element is rotatable within a static sheath.
11. A distraction device according to any preceding claim wherein each of the first and second distraction elements include moveable mounting plates for securing the first and second distraction elements to the first and second parts.

- 17 -

12. A distraction device according to claim 11 wherein the moveable mounting plates are attached to each of the first and second distraction elements via a ball bearing joint.
13. A distraction device according to any preceding claim wherein the distraction device is configured to be fully implantable under the skin of a patient.
14. A distraction device according to any preceding claim wherein the distraction device is configured to remain implanted after the required distraction has taken place.
15. A distraction device according to any of claims 1 to 13 wherein the distraction device is configured for removal from a patient after the required distraction has taken place.
16. A distraction device according to any preceding claim wherein the distraction device further comprises a sensing means to sense the amount of relative movement between the first and second distraction elements.
17. A distraction device substantially as hereinbefore described with reference to and as shown in any of Figures 1A and 1B, 2A and 2B, or 7.

FIG 1A

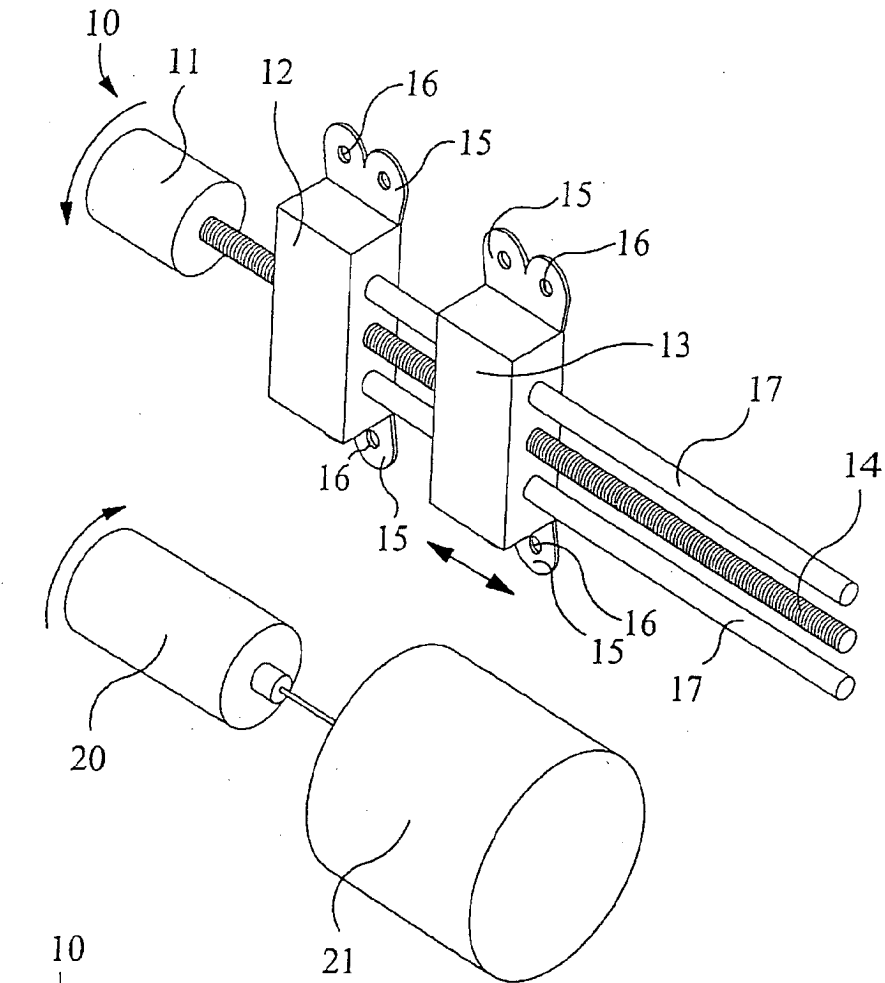


FIG 1B

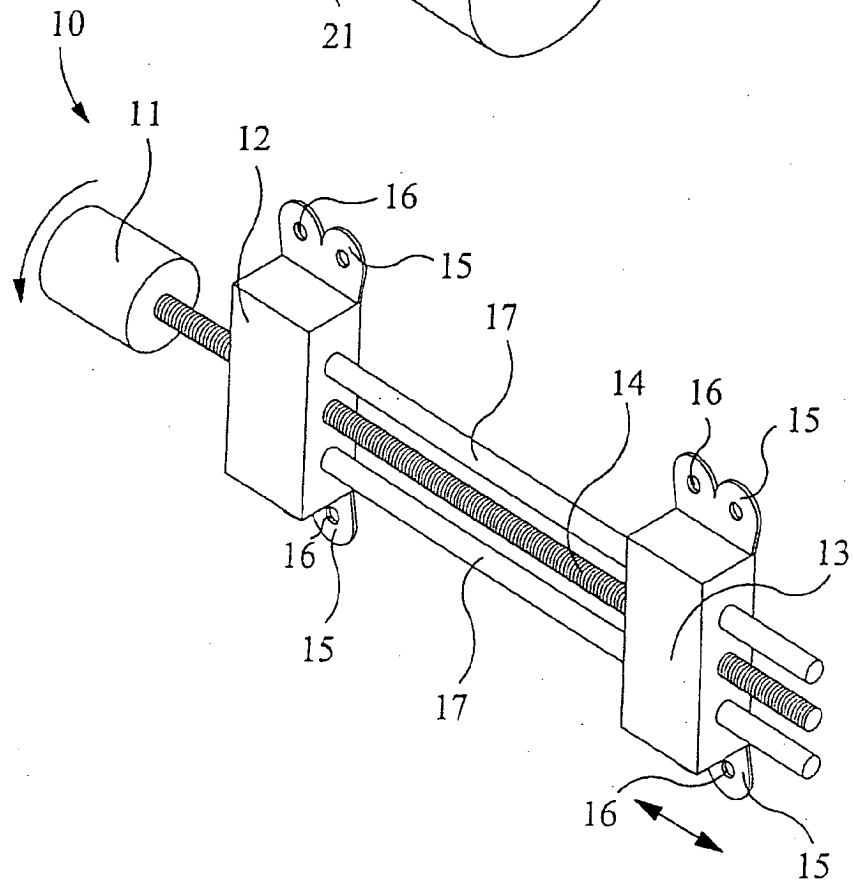


FIG 2A

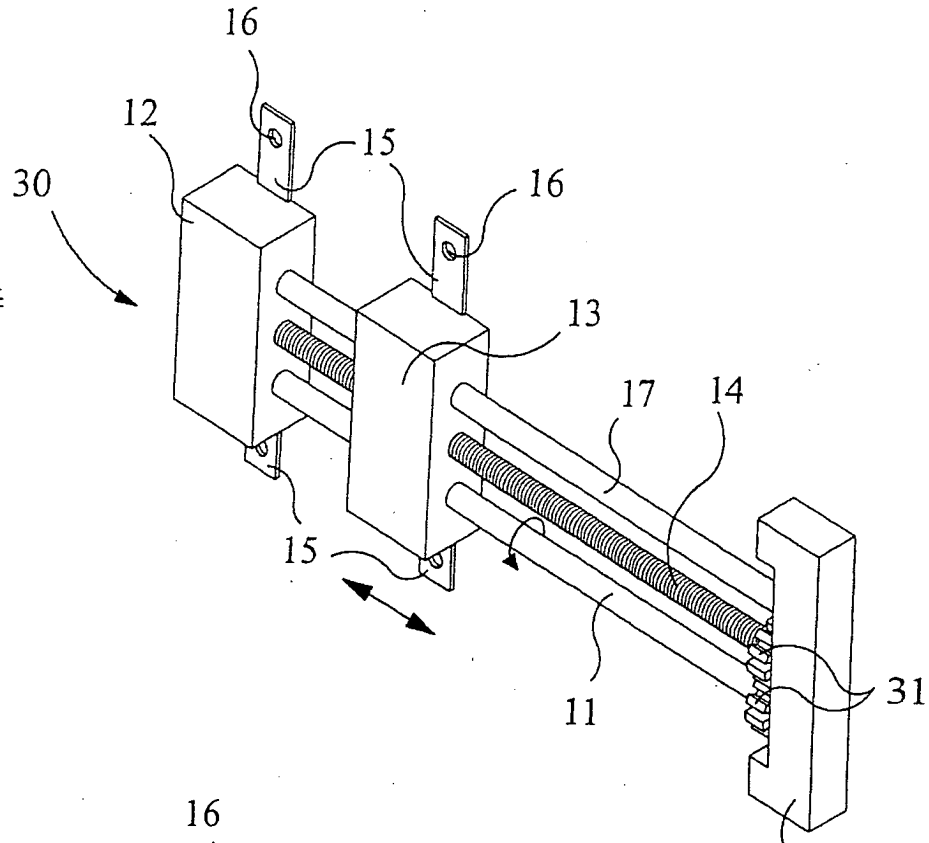
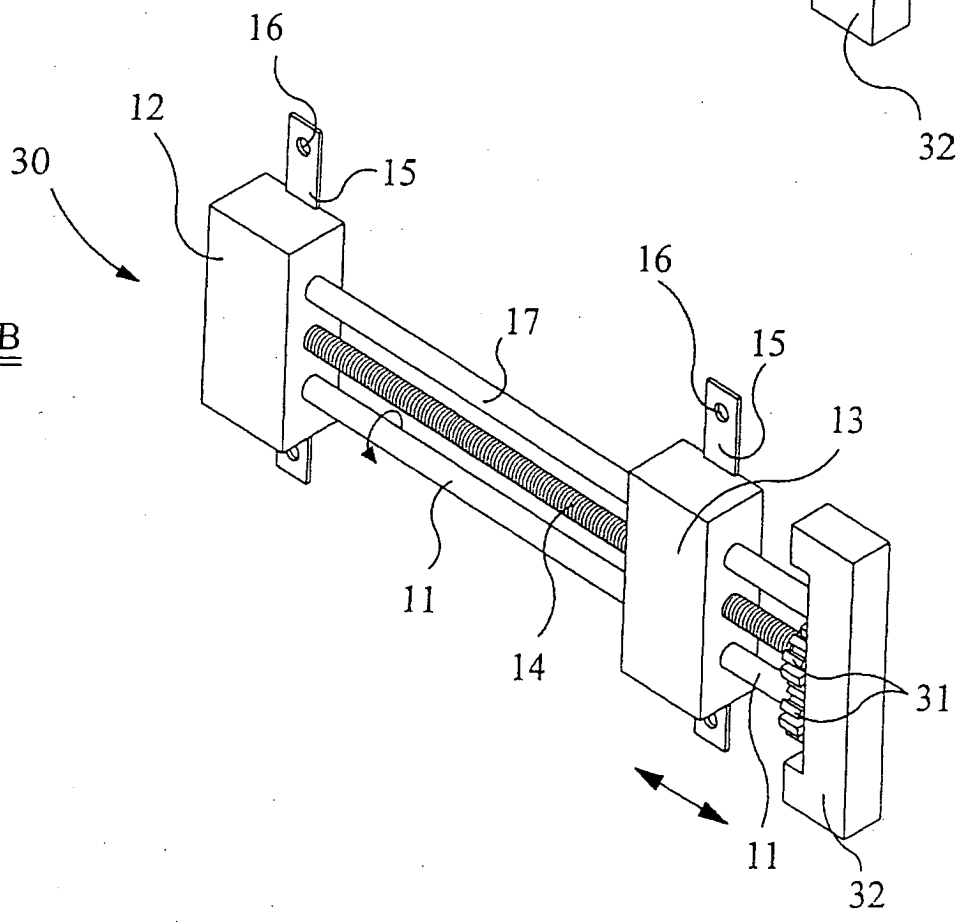


FIG 2B



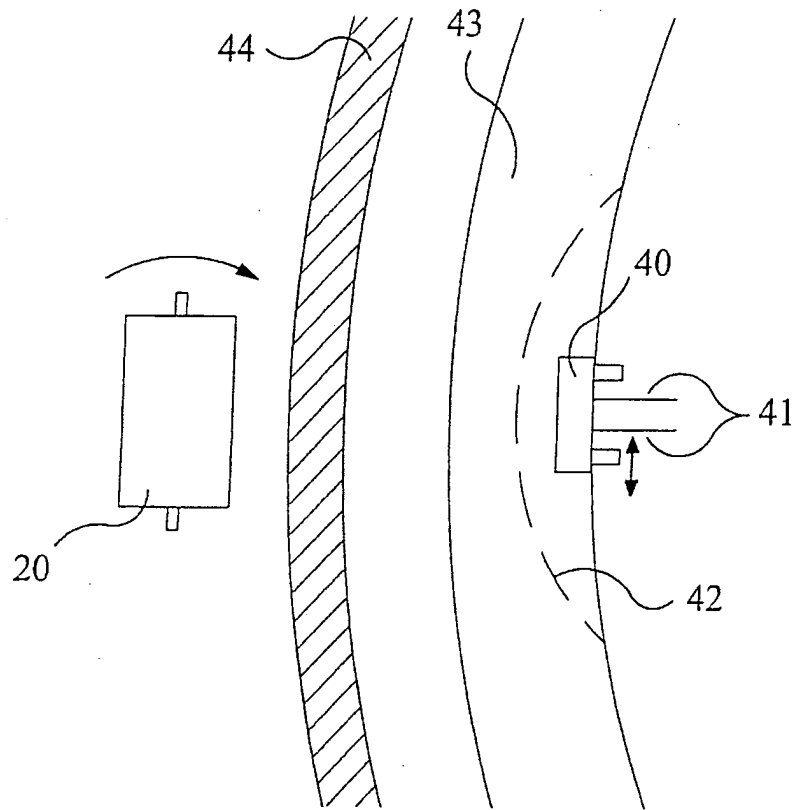


FIG 3

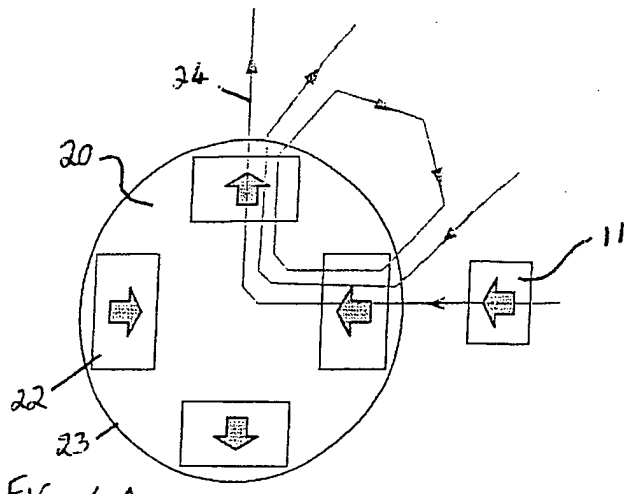


FIG. 4A

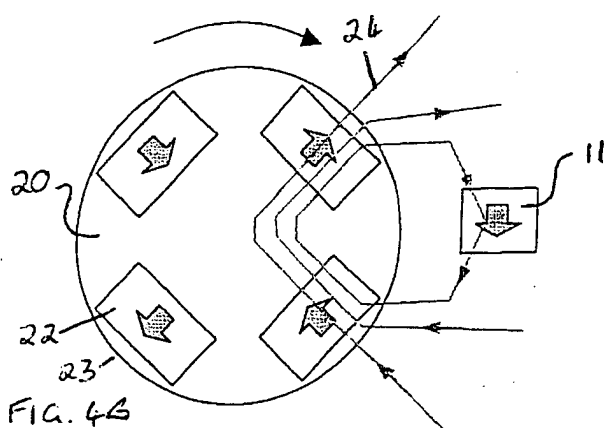


FIG. 4B

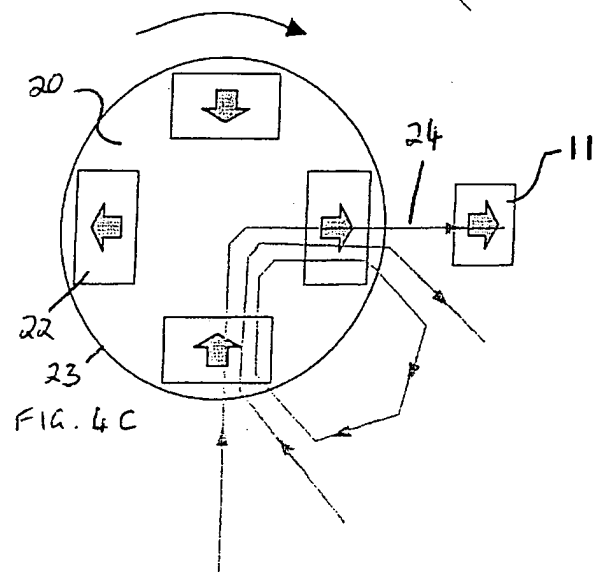


FIG. 4C

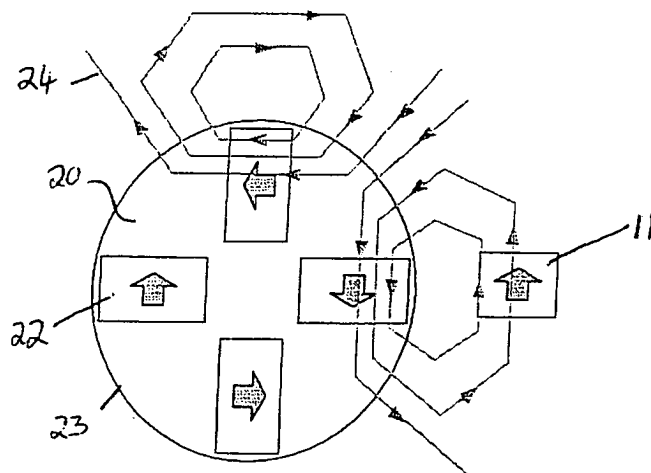


FIG. 5

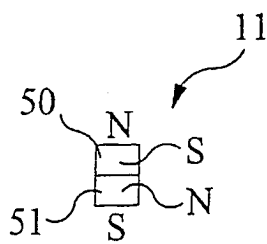


FIG 6



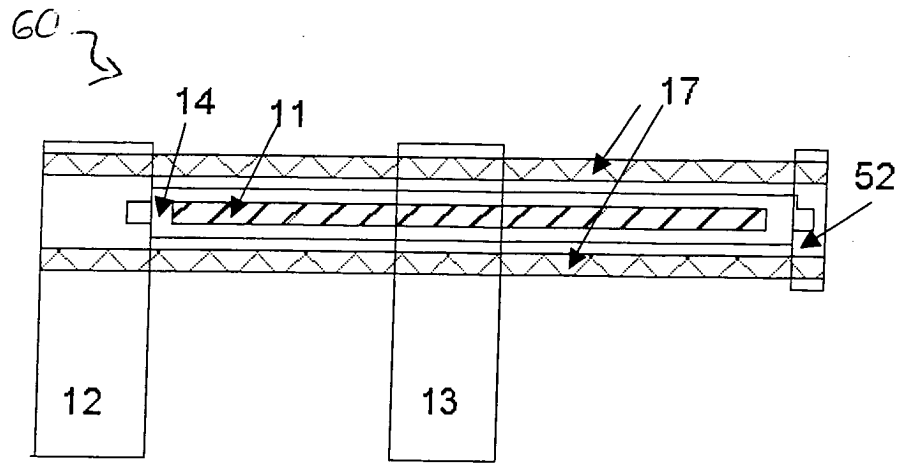


FIG 7

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/GB2007/002481A. CLASSIFICATION OF SUBJECT MATTER  
INV. A61B17/66

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)  
A61B

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 practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/78614 A (UNIV LONDON [GB]) 25 October 2001 (2001-10-25) pages 2-6 - pages 9-10; figures 2-5	1-16
X	US 5 704 939 A (JUSTIN DANIEL F [US]) 6 January 1998 (1998-01-06) column 9, lines 64-67 - column 10, lines 1-34; figure 11	1-6, 10, 13-16
E	US 2007/173837 A1 (CHAN ELAINE [US] ET AL) 26 July 2007 (2007-07-26) paragraphs [0012] - [0087]; figure 1	1, 10, 13-16
X, P	WO 2006/090380 A (ORTHOOGON TECHNOLOGIES 2003 LTD [IL]) 31 August 2006 (2006-08-31)  the whole document	1-4, 7-11, 13-16



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

11 October 2007

Date of mailing of the international search report

24/10/2007

Name and mailing address of the ISA/

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HALLER, E

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/GB2007/002481

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	DE 10 2005 045070 A1 (SIEMENS AG [DE]) 5 April 2007 (2007-04-05)  paragraphs [0026] - [0033]; figure 6 -----	1-4, 8-10, 13-16

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

Continuation of Box II.2

Claims Nos.: 17

No opinion was given as to novelty, inventive step and industrial application in respect to claim 17 due to the fact that claim 17 is unclear. Claim 17 contains references to the drawings. According to Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is not the case here.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/GB2007/002481

## Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

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

1.  Claims Nos.: 17  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claims Nos.: 17  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:  
see FURTHER INFORMATION sheet PCT/ISA/210
  
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
  
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
  
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/GB2007/002481
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