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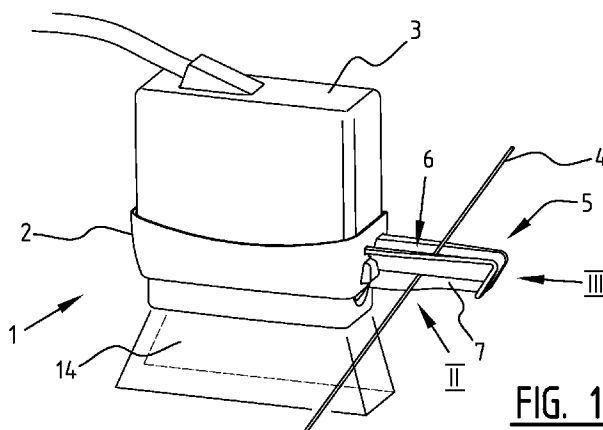


FIG. 1

(57) Abstract: The present invention relates to a device (1) for guiding a invasive medical instrument (4), such a needle, a syringe, a bioppter, or the like, relative to an imaging apparatus (3). The imaging apparatus is essentially non-invasive. The device of the invention comprises an accommodation (2) for the imaging apparatus. Also the device has a guide (5) adjacent the accommodation for guiding the medical device relative to the imaging apparatus. Thus accurate positioning of the medical instrument is enabled, while keeping the needle in the line of sight of the imaging apparatus. In particular a guide surface (7) is defined, and where opposite the guide surface at least partially resilient press means (8) are provided, which in use press the medical instrument against the guide surface. Thus medical instruments having different sizes or diameters can be employed and maneuvered within a plane of use corresponding with a line or field of sight of an imaging apparatus. The risk of any such medical instrument, like a needle, breaking is greatly reduced, while the freedom of operating the instruments is increased. The medical instrument can even temporarily be released by the physician or operator to perform additional therapeutic or diagnostic steps.

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DEVICE FOR GUIDING AN INVASIVE MEDICAL INSTRUMENT

The present invention relates to a device for guiding an
invasive medical instrument, such a needle, a syringe, a
5 biopter, or the like, relative to an imaging apparatus,
which is essentially non-invasive. The imaging apparatus
serves to obtain a view and exact position of the medical
instrument or at least the tip thereof with or on the
imaging apparatus, when maneuvering the medical instrument
10 in use thereof.

It is noted that through forming images of the interior
of a patient with the aid of the imaging apparatus and
viewing the formed images, an operator or physician
utilising the medical instrument is better able to position
15 the medical device in the interior of a body of a patient,
since on the basis of the formed images, the operator is
accurately informed of the position reached by the medical
device operated by the operator. Especially in relation to
organs or other sub-dermal locations accurate positioning of
20 the medical instrument is often highly relevant or extremely
important. For example, continuous visualisation of a needle
or other invasive instrument, such as during anaesthesia,
during ultrasound guided interventions is highly important
when inserting the invasive device into tissues which may be
25 in close proximity to vessels, pleura or nerves. Without
accurate identification and more in particular localization
of the needle damage to collateral structures may be caused.
Thus the effectiveness of use of the invasive medical
instruments is improved, when used in conjunction with an
30 imaging instrument.

As examples of imaging instruments here are mentioned
ultrasound probes, computed tomography scanners (CT
Scanners), and magnetic resonance imagers (MRI). Such non-

invasive imaging devices have enabled considerable improvements in the effectivity of diagnostics and accuracy of medical procedures.

For example, ultrasound probes and other imaging
5 instruments are also being more and more used for a variety of purposes, such imaging a fetus, identifying the existence, location, and size of tumors, as well as the existence of other medical conditions. Ultrasound probes are also known to be used when inserting catheters into blood
10 vessels and organs.

For many imaging applications, it is desirable that an invasive instrument or device is used to apply actual therapeutic treatment, the medical device comprising a needle, biopsy instrument, a biopier, a catheter, or other
15 more or less thin invasive instrument. In view of the common invasive nature of such medical instruments, these may herein below generally be referred to as needles, although these may be used to perform different medical applications, other than to just inject or retract fluid. For instance the
20 needles can be inserted into the body of a patient in order to remove a biopsy sample.

Thus it is normally desirable that the needle be guided to a specific position within the body of the patient. Often such a specific position is located using conventional
25 diagnostics methods or even the imaging apparatus.

Nonetheless, operators or physician have in the past been left to deal with this matter for themselves in that have had to manoeuvre the needle while handling the imaging device to obtain images of the position reached by the (tip
30 of the) medical instrument.

Having to simultaneously handle the imaging apparatus and maneuver the medical instrument, both manually and individually, requires skill and is still highly cumbersome.

Often the medical instrument is lost from view on a monitor connected with the imaging apparatus for forming the images, especially with so-called IP or in-plane technique. The risk of this happening is particularly, though not exclusively, present with imaging apparatuses that form images in a narrow cross section and for instance diverging in a direction perpendicular to the cross section. If this happens the operator or physician has the possibility of retracting the medical instrument and start all over again, with all evident discomfort to the patient as a direct result. Also the imaging apparatus can be displaced to find the (tip of the) medical instrument again, which is something that arouses suspicion with the patient, since the operator or physician would then evidently be looking for a lost needle, at least in the perception of the patient.

It is noted that for positioning the medical instrument relative to an imaging apparatus two methods are predominantly employed. One of these is a so-called in-plane (IP) technique, mentioned directly above, in which the entire needle and the tip can be visualised, and another technique is the out-of-plane (OOP) technique. The OOP technique results in the needle being imaged on cross-section, which has the disadvantage that the needle will cross the ultrasound beam only once. The major obstacle for the in-plane IP technique is to keep the needle exact in the path of the for instance narrow and diverging ultrasound beam.

From WO-A-00/040.155 a device is known, having an accommodation for a non-invasive imaging apparatus. At a predefined position relative to the accommodation, the known device is provided with a guide for guiding a medical instrument during invasive diagnostics or treatment. The

guide in the known device comprises rigid and opposing surfaces for a medical instrument to pass there between.

In WO-A-00/040.155 reference is made to the disclosure of US-A-5.235.987, in which latter disclosure a guide for
5 guiding movement of a medical instrument is formed by lips encompassing or embracing a channel dimensioned for a medical instrument of specific size or diameter. Between the lips a slit is provided, and the lips are to some extent resilient to allow the medical instrument to escape
10 therefrom. The lips and the channel accommodated therein define the direction of invasive movement of the medical device, relative to the imaging device. Another operating angle for the medical instrument than the direction of movement defined by the lips and channel is not provided
15 for.

In US-A-5.052.396 a device comprises an accommodation for an imaging apparatus and a guide at a predefined position relative to the accommodation for guiding a medical instrument. The guide comprises a number of passages between
20 essentially rigid guide surfaces for the medical instrument, wherein all passages define essentially the same direction of movement for the medical instrument. Different diameters or sizes of medical instruments than those of the passages are not provided for, and neither are other working angles
25 or directions of movement for the medical instrument than those defined in or by the guide.

The present invention has for an object to obviate or at least reduce drawbacks of the prior art, for which a guiding device is proposed herein in accordance with the present
30 invention, as defined in the appended independent claim.

With a device according to the present invention it has become possible to maintain the medical instrument, and more particularly any medical instrument with respect to the size

or thickness thereof, within the imaging zone corresponding with the imaging apparatus, such as an ultrasound device. As a result of the positional relationship between the imaging apparatus and the invasive medical instrument, keeping the (tip of the) medical instrument within the line or field of sight of the imaging apparatus has been considerably improved. Also, by virtue of the combination of the guide surface and the press means extending in the defined direction, i.e. across the direction of use of the medical instrument, e.g. for invasive insertion thereof, the medical instrument can be maneuvered to any desired angle of inclination, without limitation to any predefined orientation, which is determined by the channels or passages of the prior art devices. Nonetheless, the press means keep the instrument firmly pressed against the guide surface and thus maintain the (tip of) the medical instrument within line or field of sight of the imaging apparatus. Moreover, variation in thickness of the medical instrument is possible without having to use another device from a range of devices all made suitable for specific medical instrument diameters or sizes: the invention allows for use of the device with different medical instrument diameters or sizes. The guide surface itself is oriented in correspondence with the line or field of sight of the imaging apparatus, so that the medical instrument when pressed against the guide surface can be freely maneuvered within said field of sight, even when this is thin (and is optionally diverging in a direction perpendicular to the thinness of the field of sight).

Further, the invention exhibits yet another considerable advantage over the prior art, in that the medical instrument is - as it were - engaged in use by the press means. As a result the operator or physician can release his grip

temporarily on the medical instrument during positioning thereof or after the desired position has been reached, for instance to perform another medical procedure, such as to perform an injection or the like. For instance, where the
5 medical device is a catheter, a separate device can be attached thereto by the operator or physician with his free hand, while maintaining his hold on the device of the invention with the imaging apparatus and the engaged medical instrument with the other hand. Normally at least one
10 assistant would have been required to perform the extra steps.

Within the bounds of the present invention as defined in the appended independent claim, several preferred embodiments are possible, which are noted herein below as
15 well, however without presenting such preferred embodiments as limiting the invention in any way.

For instance it is possible, that the guide comprises a slot, which is oriented in such a direction to pass the medical instrument there through for maneuvering the medical
20 instrument essentially in an imaging zone corresponding with the imaging apparatus. Providing a slot for maneuvering the medical instrument has for an advantage, that maneuvering can be restricted essentially to a plane in the centre below the imaging apparatus, thus restricting the freedom of
25 movement of the medical instrument to said plane. Such a slot may be beneficially employed to keep the medical instrument inside a field of sight of the imaging apparatus.

In a further preferred embodiment, the guide comprises at least one guide surface defining an area for at least a
30 part of the medical instrument to abut there against. Rather than defining a slot, or in addition thereto, such an abutment surface provided for the medical instrument can allow for some degree a freedom when deviations from the

centre plane relative to the imaging apparatus are desired. Nonetheless, if centralization of the medical instrument is desired, abutment against the guide surface can provide the desired guidance in the desired orientation within the plane
5 or centre plane corresponding with the imaging apparatus. However, if only a guide surface having a guide area is provided, then it may be desirable to provide an additional guide surface. This may, in combination with the first guide surface, form a slot or any other shape to keep the medical
10 instrument in the space between the two guide surfaces. However, additionally or alternatively opposite the provided guide surface having the guidance area at least partially resilient press means are provided, which in use press the medical instrument against the guide surface. The feature,
15 that the press means are at least partially resilient, allows for the use of different medical instruments, having different thicknesses or diameters. Thus it has become possible in this embodiment to employ a single device according to the present invention in combination with
20 different medical instruments each having its own particular thickness and/or size and/or other characteristics. Otherwise, different devices according to the invention, each having the capacity to be employed in combination with a medical instrument having a specific thickness or
25 diameter, would have to be provided. In an embodiment with press means, these could comprise as a non-limiting example a leg extending over essentially the same length as the guide surface in a direction away from the accommodation. Thus it possible to maneuver the medical instrument within a
30 range of movement, defined by the combination of the leg and the guide surface or area, and precisely corresponding with the line or field of view of the imaging apparatus. Such press means serve as a inventive solution to yet another

problem, which is that of safety. An invasive medical instrument, like a needle, is rigid and breakable. If during insertion thereof through a stiff slot, e.g. enclosed on opposite sides by inflexible walls, the needle follows an oblique path relative to the angle of insertion, which 5 determined by the stiff slot, the needle could break, causing all kinds of harm in the process. This is effectively prevented by a resilient press means which are suitable for allowing the needle to bend or be deflected, without breaking. Also or alternatively, the press means 10 could comprise a leg extending under an angle relative to the direction of the medical instruments passing along the guide surface. With the leg inclined towards the guide surface, the function of the press means to keep the medical instrument forced against the guide surface or area is 15 improved. Further, in such an embodiment, it is possible that the leg is fixed relative to the guide surface at a position at a larger distance from the guide surface than the angled portions of the leg. This could provide the desired resilience to the leg and thus form efficient press 20 means, which could be embodied in a unitary form, together with the guide surface and preferably also with the accommodation for the imaging apparatus. Especially, when the angled portions of the leg form a cantilever, this function could be optimized. 25

Herein below a preferred embodiment of a device according to the present invention is described in conjunction with the accompanying drawings, where it is noted that the shown and described embodiment is not 30 limiting upon the invention as defined in the claims, and where the same or similar elements, component and features are designated with the same reference numbers. In the drawings:

Figure 1 shows a perspective view of the device according to the present invention in use;

Figure 2 shows a detail in figure 1 in accordance with arrow II;

5 Figure 3 shows an elevated front view in accordance with arrow III in figure 1;

Figure 4 shows the device of figure 1 in isolation; and

Figure 5 shows a view from below on the device in accordance with figure 4 along arrow V in figure 4.

10 In the figures a device 1 according to the present invention is shown in use, comprising a holder 2 forming an accommodation for an imaging apparatus, such as an ultrasound probe 3. The ultrasound probe 3 is used in conjunction with a schematically shown medical instrument 4,
15 such as a syringe, a needle, a cavitator, a biopter, etc. For optimal positioning of the medical instrument 4 relative to the often narrow field of view 14 created by the ultrasound probe 3, the holder 2 is connected with a guide 5, and preferably forms a unitary structure therewith. The guide 5
20 defines a slot 6 for introducing the medical instrument 4 there through. It is noted here that field of view 14 is shown in rather an exaggerated dimensioning: normally the width or breadth of the field of view 14 in a direction essentially perpendicular to slot 6 is in the order of 0,3
25 mm or even less, and most often at most no more than 1 mm. The field of view 14 retains this width or breadth also at greater depth in the body of a person to be treated. From this it is immediately apparent what problems a physician faces when maneuvering the medical instrument to remain
30 within such a small width or breadth field of view 14, while attempting to reach a desired locus of interest within the body of the person to be treated.

Moreover, the plane at least approximately defined by the field of view 14 extends through and in a parallel direction to this slot 6 for optimal imaging when introducing and/or positioning the medical instrument 4. The
5 plane defined by the field of view 14 more preferably extends centrally through the slot 6 or even more preferably skims a guide surface 7 in a direction parallel thereto.

More in particular, the guide 5 comprises this guide surface 7, against which a portion of the length of the
10 medical instrument 4 can abut. By keeping the portion of the medical instrument 4 abutted against the guide surface 7, alignment of the medical instrument 4 in relation to the field of view of the ultrasound probe 3 is achieved.

In specific embodiments the slot 6 can be defined by two
15 opposite guide surfaces 7.

As shown in figures 2 and 3, in the shown and below described embodiment, a cantilever plate 8 is provided opposite the guide surface 7, which plate 8 is inclined, in a relaxed state, toward the guide surface 7. A medical
20 instrument 4, introduced in the slot 6, is thereby pressed against the guide surface 7. The cantilever plate 8, which is resiliently suspended from an attachment 9, between the cantilever plate 8 and the holder 2, thus forms press means in a sense that the medical instrument 4 when introduced
25 into and through the slot 6 is pressed over a specific length against the guide surface 7. The medical instrument is thus kept in the often narrow field of view 14 of the imaging apparatus, while still being able to be maneuvered within this field of view, since the guide surface is
30 oriented in correspondence with this field of view 14 of the imaging apparatus. With the medical device engaged between the guide surface 7 and the leg 8 the physician is able to let go of the medical device during positioning or after a

desired position is reached by the (tip of the) medical device, for instance to perform an additional diagnostic or therapeutic step, such as to inject a person to be treated or connect the medical instrument to some additional apparatus or device. Other resilient or spring based press means are equally well suited to be embodied in a device according to the invention.

As shown in more detail in figure 2, the cantilever plate 8 is defined between and by cuts 10 and 11, whereby the cantilever plate 8 is provided with a desired degree of resilience to allow for medical instruments of different sizes to be introduced there through, and to allow for deflection of plate 8 when the instrument is bent or forced sideways. The attachment 9 is, in the embodiment of figure 3, farthest away from the guide surface 7.

In figure 4, the device 1 of figure 1 is shown in isolation i.e. without the ultrasound probe 3 and without the medical instrument 4. At the distal end of the guide relative to the holder 2, the leg 13 from which the cantilever plate 8 is suspended, is shown to be attached to the guide surface 7 at a connection 12. Thus, the leg 13 with the cantilever plate 8 suspended therefrom will be prevented from diverging away from the guide surface 7, when a relatively thick medical instrument 4 is introduced into the slot between the guide surface 7 and the cantilever plate 8. The connection 12 is again more clearly represented in figure 5, which also makes abundantly clear that the bottom of the holder 2 is open for the ultrasound probe to be able to emit waves and receive reflections in order to be able to form images from a received response on a monitoring device (not shown).

After having disclosed the present invention, at least a single embodiment thereof, in the description above in

conjunction with the accompanying drawings, many additional and alternative embodiments will have become apparent to the skilled person. Thus, it is evident that many alternative and additional embodiments are possible within the framework of the present invention as defined in the accompanying 5 claims, especially the independent claim, and should only then be accepted as anything other than embodiments of the present invention, if such alternative and/or additional variants depart from the letter or spirit of the appended 10 claims. For instance, the underside of the holder 2 is described as open. In an alternative embodiment the holder 2 could comprise at the bottom thereof, which bottom - when in use - is directed at the patient, be provided with a preferably thin foil, or any other type of component for 15 closing the bottom of holder 2 while still be able to allow waves (radio, ultrasound or other waves) to pass there through. With such a feature, resembling a membrane or the like, is that such a sheet or membrane can extend over the sides of the imaging apparatus and of the holder. Thus 20 sterile conditions can be maintained and ensured.

The imaging apparatus needs to be used, in many forms and shapes of such imaging apparatuses, sterile. Normally a sheet or protective member is arranged over the imaging apparatus, by way of an adhesive or the like, on one side of 25 such a sheet or protective member. According to the invention, such a protective sheet or member can be provided as an integral part of the device and/or form the foil, sheet or membrane mentioned directly above. In fact, the device according to the invention can itself be integrated 30 as a unit with the imaging apparatus. In a space defined by holder 2, imaging apparatus 3 and a protective sheet or membrane a material conductive to the waves of the imaging apparatus can be introduced. Also a protective sheet or

membrane can be provided all around the device according to the invention, and thus enclose the conductive material, to be opened at the upper side of the device just prior to use. Thereafter the imaging apparatus can be introduced into the holder on the opened upper side thereof and into the conductive material. The protective sheet could even be arranged on the device with or without the conductive material, to be entirely removed just prior to use, and to open also the lower side of the device of the invention just prior to use. However, the sheet on this lower side could just as well remain to close off the lower side of the apparatus in use also. Further, two opposite guide surfaces can also be used rather than employing press means, for instance in the form of the resilient cantilever plate. The cantilever plate 8 could be made from a material, which is in itself more resilient than other parts of the device, to optimally enclose inserted medical instrument 4 of different diameters optimally between the cantilever plate and the guide surface 7. In such an embodiment with another material, or in embodiment with sufficiently resilient material, the cuts 10, 11 can be obsolete and omitted. Moreover, any configuration pressingly engaging the medical instrument to position the instrument in a desired orientation in at least one direction relative to the imaging apparatus can be considered as an embodiment of the invention with press means, even a simple spring based configuration. A similar guide as the one shown in the figures, can also be provided along the longer side of the holder 2 forming an accommodation for an imaging apparatus, or can extend therefrom.

CLAIMS

1. Device (1) for guiding a invasive medical instrument (4), such a needle, a syringe, a biopter, or the like, relative to an imaging apparatus (3), which is essentially non-invasive, the device (1) comprising:
- an accommodation (2) for the imaging apparatus (3); and
 - a guide (5) adjacent the accommodation (2) for guiding the medical device (4) relative to the imaging apparatus (3),
- 10 wherein the guide (5) comprises:
- a guide surface (7) defining a plane for at least a portion of the medical instrument in use to abut there against and defining a larger plane of use for the medical instrument (4), said larger plane at least corresponding
- 15 with an imaging zone of the imaging apparatus (3); and
- elongate press means (8) extending along the guide surface in at least one direction which essentially crosses a direction of use of the medical instrument to in use act on the medical instrument (4) at any location along the
- 20 length of the press means (8) for pressing against the guide surface (7).
2. Device as claimed in claim 1, wherein the guide (5, 7, 8) defines a slot (6) which is oriented in such a direction to pass the medical instrument (4) therethrough
- 25 for maneuvering the medical instrument (4) essentially in an imaging zone corresponding with the imaging apparatus (3).
3. Device as claimed in claim 1 or 2, wherein opposite the guide surface (7) an additional guide surface is provided, where the additional guide surface forms a carrier
- 30 for the press means (8).
4. Device as claimed in claim 1, 2 or 3,

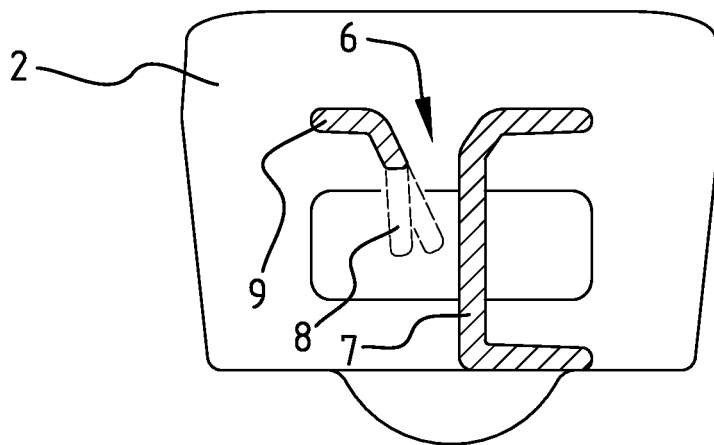
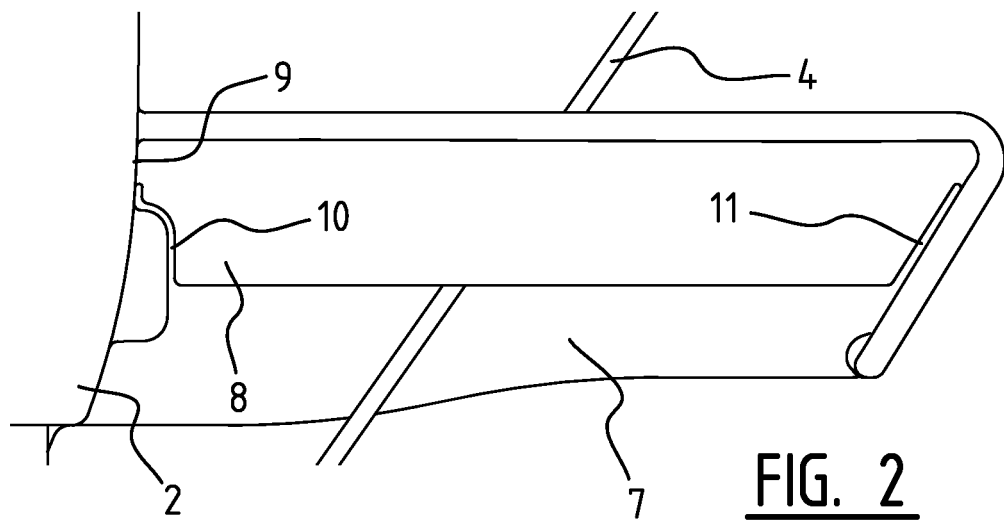
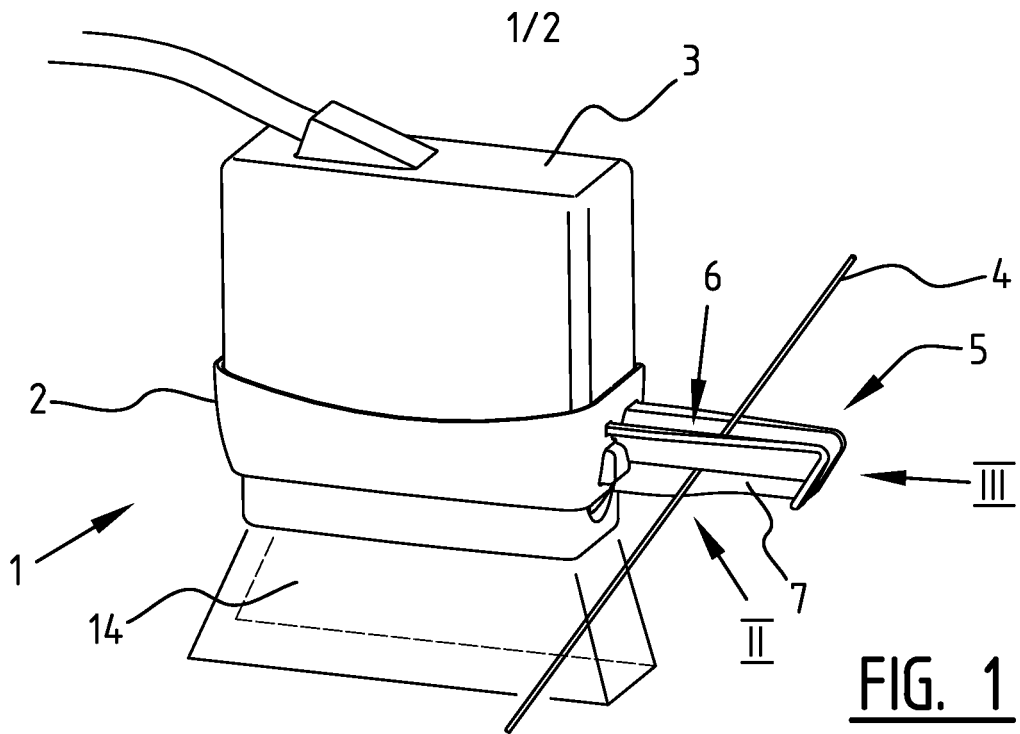
wherein the elongate press means comprise a leg (8) extending over essentially the same length as the guide surface (7) in a direction away from the accommodation (3).

5 5. Device as claimed in any one of the preceding claims, wherein the press means comprise a leg (8) extending under an angle relative to the direction of a medical instrument passing along the guide surface.

10 6. Device as claimed in claim 5, wherein the leg is fixed relative to the guide surface at a position at a larger distance from the guide surface than the angled portions of the leg.

 7. Device as claimed in claim 5 or 6, wherein the angled portions of the leg form a cantilever.

15 8. Device as claimed in any one of the preceding claims, wherein the bottom of the holder is closed with a member made from a material to allow waves from the imaging apparatus to pass there through.



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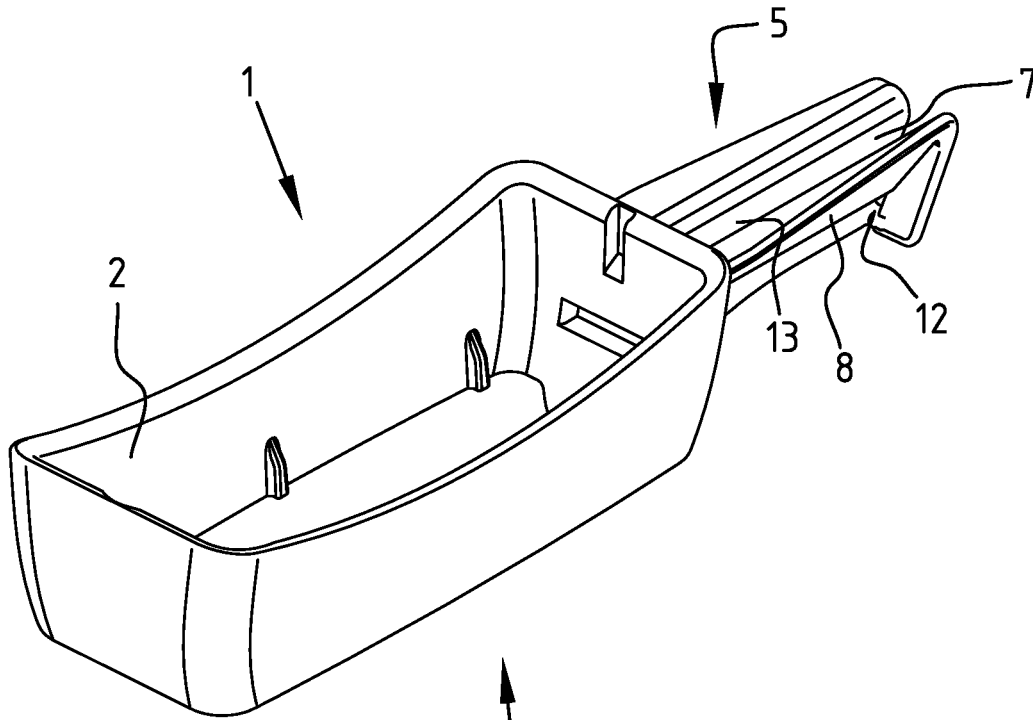


FIG. 4

V

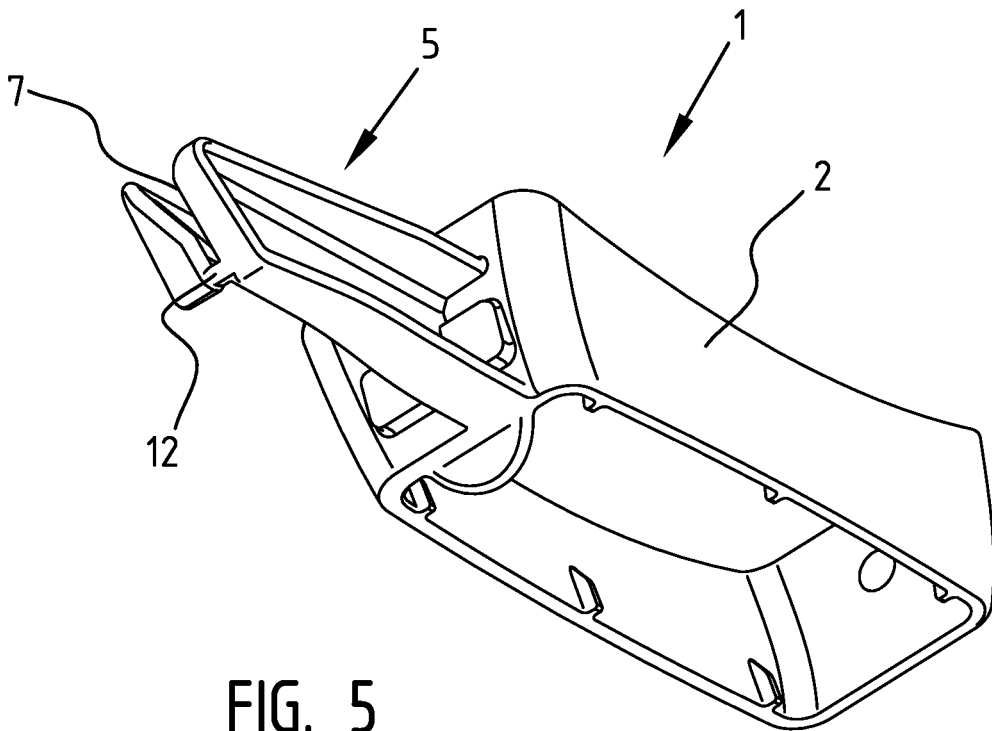


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No
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A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61B8/08 A61B17/34
 ADD. A61B1/00

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	US 6 379 307 B1 (FILLY ROY [US] ET AL) 30 April 2002 (2002-04-30) figures 1-7 column 6, paragraph 5 column 7, paragraph 1	1-8
X	WO 00/40155 A (DYMAX CORP [US]) 13 July 2000 (2000-07-13) figures 4,5 page 6, paragraph 1 page 5, lines 15-20 & US 5 235 987 A (WOLFE JEROME K [US]) 17 August 1993 (1993-08-17) referred to in WO 00/40155 on page 5 figure 2	1-7

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

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Date of the actual completion of the international search

8 April 2009

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06/05/2009

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Schießl, Werner

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2009/050450

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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