Title: APPARATUS AND METHOD FOR AIMING A SURGICAL TOOL

Abstract: An easy to use mechanical apparatus intended for aiming a surgical tool is provided. Embedments of the apparatus offer movement in multiple planes while guaranteeing, given proper placement of the leading end of a locator tool at a target, that the leading end of a second tool be placed at precisely the same target. Methods of using the apparatus as well as kits including the apparatus are also provided.
Published:

— with international search report (Art. 21(3))
APPARATUS AND METHOD FOR AIMING A SURGICAL TOOL

Cross-Reference to Related Application

[0001] This application claims priority from United States Provisional Patent Application Serial Number 61/203,245, filed December 19, 2008, which is incorporated herein by reference.

Technical Field

[0002] The present invention relates to devices and procedures to facilitate accurate placement of hardware. More particularly, accurate positioning of surgical tools is assured through use of the methods and apparatus disclosed.

Background Art

[0003] The effectiveness of most surgical procedures depends in large part on the accuracy with which hardware is introduced. Guide pin and drill guides are very useful in achieving improved accuracy of hardware placement.

[0004] Many current guide or aiming models offer very limited range of motion Many are specifically designed for situations in which a target point is positioned within a more discernible intra-articular space rather than within a bone or other anatomical structure. For many procedures, surgeons must rely on cumbersome C-arm fluoroscopy in the operating room to confirm the location of hardware. This, and other forms of intra-operative x-ray imaging, inevitably leads to excessive radiation exposure as well as increased operating times. There is a need for a single, easy to use, mechanical apparatus that offers movement in multiple planes while guaranteeing, given proper placement of the leading end of a first surgical tool (sometimes described herein as a locator tool) at a target (perhaps not discernibly located within a bone or within a joint), that the leading end of a second surgical tool be placed at precisely the same target.

Summary of the Invention

[0005] Embodiments of the present invention address the need for an easy to use, mechanical apparatus that offers movement in multiple planes while guaranteeing, given proper placement of the leading end of a locator tool at a target (perhaps not discernibly located within a bone or within a joint), that the leading end of a second surgical tool be placed at precisely the same target. A surgical guide for aiming at least one tool toward a surgical
target is provided in a first embodiment. The surgical guide has a base and at least one member that engages with the base. The base has a base thickness disposed orthogonal to and a base width disposed within a plane. A track is cut through the base thickness; the track has a uniform track width and a fixed curvature so as to define a base arc of a base circle. The base circle is oriented within the plane. Further, the base has a base channel cut through the base width, the base channel disposed within the plane. The at least one member of the surgical guide is sized so as to be receivable through the track in order to engage with the base. The at least one member has the same fixed curvature as does the uniform track of the base so as to define a member arc of a member circle, so that, when engaged with the base, the member arc is oriented orthogonal to the plane, the base circle and the member circle define a sphere having a sphere center located at the surgical target. Further, the at least one member has a member channel cut through the member, such that when the at least one member is engaged with the base, both the base channel and the member channel are aligned toward the surgical target.

[0006] In another guide embodiment, the base has an adjustable base arc length. The base has first and second base portions. The first base portion has a first base arc length with a cannula extending along the arc length. The second base portion is sized to be insertable into the cannula to slidingly engage with the first base portion. The second base portion has a second base arc length. When the first and second base portions are engaged, the adjustable base arc length is measurable by adding the first base arc length to an adjustable fraction of the second base arc length. An embodiment may also feature a base locking mechanism to rigidly secure the first and second base portions together at a chosen adjustable base arc length.

[0007] Yet another guide embodiment features the at least one member having an adjustable member arc length. The at least one member has first and second member portions. The first portion has a first member arc length with a cannula extending along the arc length. The second member portion is sized to be insertable into the cannula to slidingly engage with the first member portion. The second member portion has a second member arc length. When the first and second member portions are engaged, the adjustable member arc length is measurable by adding the first member arc length to an adjustable fraction of the second member arc length. An embodiment may also feature a member locking mechanism to rigidly secure the first and second member portions together at a chosen adjustable member arc length.

[0008] A further embodiment for which both the base and the member have adjustable arc lengths is also provided.
In additional guide embodiments, the at least one member (and/or the base) may have a cannulated tool support member (and/or base) extender section. Cannula of the extender section(s) is/are aligned with the member (and/or base) channel(s). The member (and/or base) extender section has an extender section length, the length is slidingly adjustable with the member (and/or base) channel along a radius of the member (and/or base) circle.

Methods for aiming at least one tool toward a surgical target are also provided. A first step is to define a surgical target as a chosen position of a proximal end of a locator tool (the locator tool also has a distal end). An embodiment of the surgical guide is then provided. Its base is engaged with the locator tool by passing the distal end of the locator tool through the base channel. The at least one member of the surgical guide is engaged with the base of the surgical guide; then, the at least one tool is passed through the member channel. The at least one tool will necessarily be aimed at the surgical target.

Methods for adjusting the base arc length of embodiments of the surgical guide are provided. A second portion of a base or a member may slide within the first portion of a base or member to a chosen (extended) arc length. A next step may be engaging a base or member locking mechanism for rigidly securing the second base or member portion within the first base or member portion at a chosen arc length.

A method for selectively orienting the at least one tool within the base of the surgical guide is provided. A first step is to slide the at least one member within the plane and along an arc length of the track disposed within a base of an embodiment of the surgical guide. The at least one member is then slid orthogonal to the plane of the base and along an arc length of the member. The at least one member may be secured within the base of the surgical guide at the selected orientation while remaining aimed at the surgical target.

In further embodiments, a surgical guide kit is provided. The kit contains any of the surgical guide embodiments and an electrical circuit capable of being coupled with the locator tool at one terminus and capable of being coupled with the at least one tool at a second terminus. The kit may also have a sensor in electrical communication with the electrical circuit; the sensor activatable only upon completion of the electrical circuit to indicate that the at least one tool has its proximal end located at the target in electrical communication with the proximal end of the locator tool.

**Brief Description of the Drawings**

FIGS. 1(a) and (b) illustrate the use of a surgical guide embodiment in foot surgery;

FIG. 2(a) shows a surgical guide in accordance with an embodiment; FIG. 2(b)
illustrates a tool holder used in conjunction with the embodiment of FIG. 2(a);
[0016] FIG. 3 shows a surgical guide in accordance with another embodiment;
[0017] FIG. 4 depicts the use of yet another surgical guide embodiment in ankle surgery; and
[0018] FIG. 5 illustrates a surgical guide kit embodiment used in knee surgery; and
[0019] FIG. 6 depicts a surgical guide in accordance with a further embodiment.

Detailed Description of Specific Embodiments
[0020] FIGS. 1(a) and 1(b) show a surgical site, in particular, that of a human foot and
selected associated bones. Locator tool 1 has been drilled (or otherwise inserted) into the foot.
The proximal end of locator tool 1 is lodged within bone at surgical target T. The surgeon
wishes to install tool 2 such that its proximal end will also reside at surgical target T. The
surgeon wishes to insure the accuracy of this placement without the use of ancillary
equipment such as intra-operative x-ray imaging devices to accurately locate surgical target
T.

[0021] Accurate placement of tool 2 is facilitated by the use of surgical guide 100. The
embodiment of surgical guide 100 illustrated in FIGS. 1(a) and 1(b) has base 10 and member
20. Base 10 has track 11 cut through base thickness t. Track 11 is shown as having a uniform
track width; track 11 also has a fixed curvature defining an arc of a base circle. Base 10 also
has base channel 13 cut through base width W. Base channel 13 is sized to accept locator tool
1. In operation, locator tool 1 will be placed before introducing surgical guide 100. Base 10
may then be put into use by first inserting distal end 110 of locator tool 1 into base channel
13. Locator tool 1 may be marked (e.g. laser mark, groove, notch or similar) to identify
proper positioning of base 10 with respect to surgical target T such that track 11 is uniformly
offset from surgical target T. Once base 10 is appropriately placed, the curvature of track 11
will define a base arc of a base circle which will have surgical target T at its center. Member
20 is sized so as to be receivable through track 11 at any position around the base arc.
Member 20 has the same fixed curvature as track 11, thereby defining an arc of a member
circle orthogonal to the base circle, in turn, defining a sphere whose center should accurately
coincide with surgical target T. In the present embodiment, member 20 features a channeled
tool support member extender section 22. Channel 23 is aligned with and extends along
extender section 22. Once the surgeon establishes a desirable position around the base arc
length (formed by track 11) for member 20 to be located, tool 2 is inserted through channel
23 and remains handleable at its distal end 210. Tool 2 may be marked (e.g. laser mark,
groove, notch or similar) along its length to indicate proper insertion depth. The surgeon may
then force or drill tool 2 and be assured of accurately moving the proximal end of tool 2 to surgical target T. Surgical guide 100 is to be made of rigid material capable of maintaining its shape and curvature given the force required to install tool 2 into bone or other structures. [0022] FIG. 2(a) illustrates another surgical guide embodiment. Surgical guide 200 has base 30 and member 40. Base 30 has first base portion 31 and second base portion 32. First base portion 31 has a cannula extending along its length and has track 331 cut through first base portion thickness t. Track 331 has a uniform track width and also has a fixed curvature defining an arc of a base circle of arc length L1. Second base portion 32 has track 332 (having the same uniform track width and fixed curvature as track 331) cut through its thickness (which is of somewhat lesser thickness dimension than first base portion thickness t so as to be receivable within the cannula of first base portion 31) As a result, second base portion 32 is sliddingly engageable with first base portion 31. As shown in FIG. 2(a), much of second base portion 32 remains within the cannula. A telescopic effect is created so that a variable arc length of base 30 may be chosen to be equal to or greater than L1. To facilitate compact storage of base 30 when the guide 200 is not in use or to facilitate initial engagement of base 30 with a locator tool 1 (not shown) through base channel 34 in a surgical procedure area of limited space/accessibility, second base portion 32 may beneficially totally reside within the cannula of first base portion 31. In FIG. 2(a), most of second base portion 32, is shown to reside within the cannula of first base portion 31, adding an operator-adjustable effective arc length L2 of track 332 to arc length L1 of track 331.

[0023] In the present embodiment, member 40 has a fixed length L3. The cross-section of edge 44, as well as that of the entire length L3 are sized to be acceptable into and to sliddingly engage with track 331 (or, equivalently, track 332) to provide both height and angular variation to the entry of tool 2 as tool 2 is to be directed toward surgical target T (not shown) along a radius of a selectable member circle, the member circle oriented orthogonally to the base circle. Member 40 also has extender section 41. Extender section 41 has member channel 410 disposed within it. In this embodiment, member channel 410 is shown as a fixed diameter channel. As mentioned regarding the previously described embodiment, this portion of surgical guide 200 may be subject to high stress during insertion of tool 2. Tool 2 may also be of such small diameter that added stability is mandated to insure accurate placement. FIG. 2(b) (inset) illustrates a generic tool holder 42. Here, tool holder 42 is a cylinder of length Y with channel 420 appropriately sized to hold tool 2 (not shown) therein. Tool holder 42 is sized to be receivable in member channel 410 so that tool 2 is properly directed toward surgical target T. Length Y may vary depending on the particular surgical location. In the
embodiment of FIG. 2(a), length Y may beneficially be somewhat longer than the length of extender section 41 plus the distance between track 331(332) and the point at which tool 2 would enter the body of the surgical subject. The object is to provide sufficient support when pressure and torque are applied along length Y. In FIG. 2(b), tool holder 42 is shown to be tapered (at entry end 421) to, perhaps, provide additional stability, impinging the subject. Other geometries to provide similarly added stability may be utilized. Not presented to be a limiting example, entry end 421 might not be tapered as is shown in the figure but might be serrated or otherwise shaped for stability when impinging the subject.

[0024] FIG. 3 illustrates another surgical guide 300 embodiment. Base 30 has the same elements as did the base shown in FIG. 2(a). In FIG. 3, most of second base portion 32 is shown to reside outside the cannula of first base portion 31, adding a much larger operator-adjustable effective arc length L2 of track 332 to arc length Li of track 331. Member 50 is shown to be slidingly engaged through track 332. While the details of tool 2, inserted in tool holder 42, in turn, inserted through member channel 410 are the same for member 50 as in the previously described embodiment (for member 40), member 50 has two portions: slider portion 53 and holder portion 55. Slider portion 53 is slidingly engageable with holder portion 55 so that a variable arc length of member 50 may be chosen. To facilitate compact storage of member 50 when the guide 300 is not in use or to facilitate initial engagement of member 50 with base 30 followed by increased operator flexibility in a surgical procedure area of limited space/accessibility, slider portion 53 may beneficially totally reside within holder portion 55 so that the location of edge 54 of slider portion 53 does not extend beyond holder portion 55. As one of skill in the art can readily see, the availability to an operator of variable arc length capability of both track 331(332) and member 50 greatly increases the flexibility in procedural details (in particular in the numerous spatial approaches) without sacrificing tool placement accuracy.

[0025] It is to be understood that guide embodiments shown are, with respect to the slidingly engageable components, relying on interference or frictional fits to provide rigidity and stability during operation. If such frictional designs are insufficient in specific circumstances, locking mechanisms known to all skilled in the art are considered to be incorporated for each component having selectable positions.

[0026] FIG. 4 illustrates another variation of surgical guide 400 placed in an ankle surgery environment. Surgical guide 400 has base 60 and member 70. Base 60 has first base portion 61 and second base portion 62. First base portion 61 has a cannula extending along its length and has track 631 cut through first base portion thickness t. Track 631 has a uniform track
width and also has a fixed curvature defining an arc of a base circle. Second base portion 62
has track 632 (having the same uniform track width and fixed curvature as track 631) cut
through its thickness (which is of somewhat lesser thickness dimension than first base portion
thickness so as to be receivable within the cannula of first base portion 61). As a result,
second base portion 62 is slingly engageable with first base portion 61. Much of second
base portion 62 remains within the cannula. A telescopic effect is created so that a variable
arc length of base 60 has been chosen by the operator. Second base portion 62 is shown to be
held in place (with first base portion 61) only by frictional or interference fit. Base channel 64
is sized to accept locator tool holder 65 through which locator tool 1 passes in the direction of
surgical target T located inside tibia 6000. Leading edge 650 of locator tool holder 65 is
serrated and makes firm contact with outer cortex of tibia 6000. A serrated edge may provide
greater stability to a tool and/or tool holder, and may reduce or prevent damage to soft tissue
at a surgical site. Note is then made by the operator as to various distances related to the
position of locator tool holder 65 relative to track 631 and starting length of locator tool 1. Set
screw (locking mechanism) 66 is tightened to secure the position of locator tool holder 65
and, possibly, of locator tool 1. While guide 400 insures that both locator tool 1 and tool 2 are
aimed at surgical target T, the position of holder 65 noted above will, based on the reference
sphere created (with center T) determine when insertion of tool 2 will reach target T.

[0027] Member 70 is shown having a single element with a defined member arc length. The
cross-section of edge 73, as well that of the entire length of member 70 are sized to be
acceptable into and to slingly engage with track 631 (or, equivalently, and in this case track
632) to provide both height and angular variation to the entry of tool 2 as tool 2 is to be
directed toward surgical target T along a radius of the reference sphere. In this embodiment,
the desired height and angular position are determined, member 70 is held by set screw
701 to member stop 702. Member stop 702 is sized so as to rest upon and not pass through
track 632. Member 70 also has extender section 71. Member 70 has member channel 74
disposed within it. In this embodiment, member channel 74 is shown as a fixed diameter
channel sized to accept tool holder 75. As mentioned regarding the previously described
embodiment, this portion of surgical guide 400 may be subject to high stress during insertion
of tool 2. Tool 2 may also be of such small diameter that added stability is mandated to insure
accurate placement. In this embodiment, tool 2 is shown inserted into extender section 71 and
directed toward surgical target T through tool holder 75. Leading edge 710 of tool holder 75
is serrated and makes firm contact with outer cortex of fibula 7000. A comparison of the
distances between member 70 proximate to member channel 74 and the initial lengths of
locator tool 1 and tool 2 indicates to the operator when, upon forcing or drilling tool 2 in the direction, the leading edge of tool 2 will reach surgical target T.

[0028] FIG. 5 illustrates an embodiment of a surgical guide kit 500. Assuming that locator tool 1 and tool 2 are significantly more electrically conductive than the other elements of surgical guide 400 and the contacted anatomical parts, putting the trailing ends of these tools into an electrical circuit will, when their leading ends couple at surgical target T, complete the circuit. Light or other sensor 1000 would then be activated. This would then complete the surgeon's task without resorting to expensive and potentially detrimental imaging techniques.

[0029] FIG. 6 illustrates another surgical guide 600 embodiment for aiming a tool (not shown) toward a surgical target T. Base 80 has the same elements as did the base shown in FIG. 1(b). In FIG. 6, the base 80 has a reduced base arc length. Member 90 is shown to be slidingly engaged with base 80 through track 802, as in previous embodiments. Member 90 includes track 92 so as to prevent obstruction by locator tool 810 while operator is selectively orienting member 90 within base 80. The details of tool holder 93, inserted through member channel 91 are the same for member 90 as in previously described embodiments (FIG. 3 tool holder 42 and member channel 410 in member 50). As one of skill in the art can readily see, the reduced size of base 80 may be suitable for surgical procedures performed on smaller anatomical regions (hand and/or foot) or when the at least one tool need not be significantly offset from the locator tool 810 within the plane of base 80.

[0030] It is to be understood that any and all of the surgical guide embodiments may include more than one member element to be used simultaneously during a procedure. In particular, utilization of locking mechanisms for these member elements facilitates sequential or serial placements. Alternatively, member elements may be designed to be removable without removing the entire guide from the procedural area.

[0031] Although the invention has been described with reference to several embodiments, it will be understood by one of ordinary skill in the art that various modifications can be made and extension to other types of surgical guides can be made without departing from the spirit and the scope of the invention, as set forth in the claims.
What is claimed is:

1. A surgical guide for aiming at least one tool toward a surgical target, the surgical guide comprising:

   a base having a base thickness disposed orthogonal to and a base width disposed within a plane, the base having a track cut through the base thickness, the track having a uniform track width, the track having a fixed curvature so as to define a base arc of a base circle, the base circle oriented within the plane, the base having a base channel cut through the base width, the base channel disposed within the plane; and

   at least one member sized so as to be receivable through the track to engage with the base, the at least one member having the fixed curvature so as to define a member arc of a member circle, so that, when engaged with the base, the member arc is oriented orthogonal to the plane, the base circle and the member circle defining a sphere having a sphere center located at the surgical target, the at least one member having a member channel cut through the member, such that when the at least one member is engaged with the base, both the base channel and the member channel are aligned toward the surgical target.

2. The surgical guide of claim 1, the base having an adjustable base arc length, the base comprising:

   a first base portion having a first base arc length and having a cannula extending along the first base arc length; and

   a second base portion; the second base portion sized to be insertable into the cannula to slidingly engage with the first base portion, the second base portion having a second base arc length, such that when the first and second base portions are engaged, the adjustable base arc length is measurable by adding the first base arc length to an adjustable fraction of the second base arc length.

3. The surgical guide of claim 2 further comprising:

   a base locking mechanism to rigidly secure the first and second base portions together at a chosen adjustable base arc length.

4. The surgical guide of claim 1, the at least one member having an adjustable member arc length, the at least one member comprising:
a first member portion having a first member arc length and having a cannula extending along the first member arc length; and

a second member portion; the second member portion sized to be insertable into the cannula to slidingly engage with the first member portion, the second member portion having a second member arc length, such that when the first and second member portions are engaged the adjustable member arc length is measurable by adding the first member arc length to an adjustable fraction of the second member arc length.

5. The surgical guide of claim 4 further comprising:
   a member locking mechanism to rigidly secure the first and second member portions together at a chosen adjustable member arc length.

6. The surgical guide of claim 3, the at least one member having an adjustable member arc length, the at least one member comprising:
   a first member portion having a first member arc length and having a cannula extending along the first member arc length; and
   a second member portion; the second member portion sized to be insertable into the cannula to slidingly engage with the first member portion, the second member portion having a second member arc length, such that when the first and second member portions are engaged, the adjustable member arc length is measurable by adding the first member arc length to an adjustable fraction of the second member arc length.

7. The surgical guide of claim 6 further comprising:
   a member locking mechanism to rigidly secure the first and second member portions together at a chosen adjustable member arc length.

8. The surgical guide of any of claims 1-7, the at least one member further comprising:
   a channeled tool support member extender section, a channel of the extender section aligned with the member channel, the member extender section having an extender section length slidingly adjustable along a radius of the member circle.

9. The surgical guide of any of claims 1-8, the base further comprising:
a channeled tool support base extender section, a channel of the extender section aligned with the base channel, the base extender section slidingly adjustable along a radius of the base circle.

10. A method for aiming at least one tool toward a surgical target, the method comprising:
   defining a surgical target as a position of a proximal end of a locator tool, the locator tool also having a distal end;
   providing the surgical guide of any of claims 1-9;
   engaging the base of the surgical guide with the locator tool by passing the distal end of the locator tool through the base channel;
   engaging the at least one member of the surgical guide with the base of the surgical guide; and
   passing the at least one tool through the member channel.

11. A method for adjusting the base arc length of the surgical guide of any of claims 2-9, the method comprising:
   sliding the second base portion within the first base portion to a chosen base arc length.

12. A method for rigidly securing an adjustable base arc length of the surgical guide of any of claims 3-9, the method comprising:
   sliding the second base portion within the first base portion to a chosen base arc length; and
   engaging a base locking mechanism.

13. A method for adjusting the at least one member arc length of the surgical guide of any of claims 4-9, the method comprising:
   sliding the second member portion within the first member portion to a chosen member arc length.

14. A method for rigidly securing an adjustable base arc length of the surgical guide of any of claims 5-9, the method comprising:
15. A method for selectively orienting the at least one tool within the base of the surgical guide of any of claims 1-9, the method comprising:
   sliding the at least one member within the plane and along an arc length of the track disposed within a base of a surgical guide;
   sliding the at least one member orthogonal to the plane of the base and along an arc length of the member of the surgical guide;
   securing the at least one member within the base of the surgical guide at the selected orientation.

16. A surgical guide kit, the kit comprising:
   the surgical guide of any of claims 1-9; and
   an electrical circuit capable of being coupled with a locator tool at one terminus and capable of being coupled with the at least one tool at a second terminus.

17. The surgical guide kit of claim 16 further comprising:
   a sensor in electrical communication with the electrical circuit; the sensor activatable only upon completion of the electrical circuit.
**INTERNATIONAL SEARCH REPORT**

**International application No**

PCT/US2009/068612

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**A. CLASSIFICATION**

**INV. A61B 1/17**

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**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

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**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

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<td>EP 0 428 452 A1 (CENDIS MEDICAL SARL [FR]) 22 May 1991 (1991-05-22) column 3, line 25 - line 56; figure 1</td>
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**Further documents are listed in the continuation of Box C**

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**Date of the actual completion of the international search**

9 March 2010

**Date of mailing of the international search report**

15/03/2010

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**Name and mailing address of the ISA/ European Patent Office, P B 5818 Patentlaan 2 NL - 2280 HV Rijswijk**

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Fourcade, Olivier

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<td>US 2006/069394 Al (WEILER ANDREAS [DE] ET AL) 30 March 2006 (2006-03-30) figures 1, 3</td>
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**INTERNATIONAL SEARCH REPORT**

**International application No**

PCT/US2009/068612

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<td>☐ Claims Nos 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</td>
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<td>☐ Claims Nos because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)</td>
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<td>☐ 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</td>
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**Remark on Protest**

☐ The additional search fees were accompanied by the applicant’s protest and, where applicable, the payment of a protest fee

☐ The additional search fees were accompanied by the applicant’s protest but the applicable protest fee was not paid within the time limit specified in the invitation

☐ No protest accompanied the payment of additional search fees
Continuation of Box II.1

Claims Nos.: 10

Claim 10 relates to subject-matter considered to be covered by the provisions of Rule 39.1(iv) PCT (Method for treatment of the human or animal body by surgery), see in particular step "defining a surgical target as a position of a proximal end of a locator tool". Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of claim 10 which is also not searched.
<table>
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<td>EP 1642538 A2</td>
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