

|                                                                                                                                                                                                                                             |                                           |                                           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|-------------------------------------------|
| <b>PTO/SB/08A (08-03)</b><br>U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE<br>Substitute for Form 1449A/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br><i>(Use as many sheets as necessary)</i> | <b>APPLICATION NO.:</b><br>17/314,845     | <b>FILING DATE:</b><br>05/07/2021         |
|                                                                                                                                                                                                                                             | <b>INVENTOR(S):</b><br>Matthew J. Allaway | <b>ART UNIT:</b><br>3793                  |
|                                                                                                                                                                                                                                             | <b>EXAMINER NAME:</b><br>Sanjay Cattungal | <b>ATTY. DOCKET NO.:</b><br>083003-620553 |

### U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIALS* | Cite<br>No. <sup>1</sup> | PATENT<br>NUMBER                              | ISSUE<br>DATE | Name of Patentee of Cited<br>Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|-----------------------|--------------------------|-----------------------------------------------|---------------|---------------------------------------|---------------------------------------------------------------------------------|
|                       |                          | Number – Kind Code <sup>2</sup><br>(if known) | MM-DD-YYYY    |                                       |                                                                                 |
|                       |                          |                                               |               |                                       |                                                                                 |

### U.S. PUBLICATION DOCUMENTS

| EXAMINER<br>INITIALS* | Cite<br>No. <sup>1</sup> | PUBLICATION<br>NUMBER                         | PUBLICATION<br>DATE | Name of Inventor(s) of Cited<br>Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|-----------------------|--------------------------|-----------------------------------------------|---------------------|------------------------------------------|---------------------------------------------------------------------------------|
|                       |                          | Number – Kind Code <sup>2</sup><br>(if known) | MM-DD-YYYY          |                                          |                                                                                 |
|                       | 1.                       | 2008/0027007 A1                               | 1/31/2008           | Benner                                   |                                                                                 |
|                       | 2.                       | 2008/0039889 A1                               | 2/14/2008           | Lamson et al.                            |                                                                                 |
|                       | 3.                       | 2010/0160711 A1                               | 6/24/2010           | Noyes                                    |                                                                                 |
|                       | 4.                       | 2016/0081736 A1                               | 3/24/2016           | Hoey et al.                              |                                                                                 |
|                       | 5.                       | 2016/0243232 A1                               | 8/25/2016           | Pickett                                  |                                                                                 |

### FOREIGN PATENT DOCUMENTS

| EXAMINER<br>INITIALS* | Cite<br>No. <sup>1</sup> | DOCUMENT<br>NUMBER                                                                        | PUBLICATION<br>DATE | Name of Patentee or Applicant<br>of Cited Document | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear | T <sup>6</sup> |
|-----------------------|--------------------------|-------------------------------------------------------------------------------------------|---------------------|----------------------------------------------------|------------------------------------------------------------------------------------|----------------|
|                       |                          | Country Code <sup>3</sup> –<br>Number <sup>4</sup> – Kind<br>Code <sup>5</sup> (if known) | MM-DD-YYYY          |                                                    |                                                                                    |                |
|                       |                          |                                                                                           |                     |                                                    |                                                                                    |                |

### OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

| EXAMINER<br>INITIALS*                                                                                                                                                                                                                          | Cite<br>No. <sup>1</sup> | Include name of Author, title of the article (when appropriate), title of the item (book, magazine, journal,<br>serial, symposium, catalog, etc.), volume-issue number(s), publisher, page(s) and date. | T <sup>6</sup>         |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
|                                                                                                                                                                                                                                                | 6.                       | International Search Report and Written Opinion, PCT/US2021/025946, dated 8-23-2021                                                                                                                     |                        |
| <b>EXAMINER</b>                                                                                                                                                                                                                                |                          |                                                                                                                                                                                                         | <b>DATE CONSIDERED</b> |
| <b>EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</b> |                          |                                                                                                                                                                                                         |                        |

\* EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

# PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

## PCT

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT AND  
THE WRITTEN OPINION OF THE INTERNATIONAL  
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

|                                                                                              |                                                                                        |
|----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| To: Joshua J. Pranckun<br>Polsinelli PC<br>1401 Lawrence St., Suite 2300<br>Denver, CO 80202 | <div style="text-align: right; font-weight: bold; font-size: 1.2em;">AUG 23 2021</div> |
| Applicant's or agent's file reference<br>083003-686948                                       | <b>FOR FURTHER ACTION</b> See paragraphs 1 and 4 below                                 |
| International application No.<br>PCT/US21/25946                                              | International filing date<br>(day/month/year) 06 April 2021 (06.04.2021)               |
| Applicant Corbin Clinical Resources, LLC                                                     |                                                                                        |

|    |                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|----|-------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. | <input checked="" type="checkbox"/> | The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.<br><b>Filing of amendments and statement under Article 19:</b><br>The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):<br><b>When?</b> The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.<br><b>How?</b> Directly to the International Bureau preferably through ePCT, or on paper to:<br>The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland<br><br>For more detailed instructions, see the <i>PCT Applicant's Guide</i> , International Phase, paragraphs 9.004 – 9.011.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 2. | <input type="checkbox"/>            | The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 3. | <input type="checkbox"/>            | <b>With regard to any protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:</b><br><input type="checkbox"/> the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.<br><input type="checkbox"/> no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 4. |                                     | <b>Reminders</b><br>The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.<br>Shortly after the expiration of <b>18 months from the priority date, the international application will be published</b> by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90bis.1 and 90bis.3).<br>Within <b>19 months</b> from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase <b>until 30 months</b> from the priority date (in some Offices even later); otherwise, the applicant must, <b>within 20 months</b> from the priority date, perform the prescribed acts for <b>entry into the national phase</b> before those designated Offices. In respect of other designated Offices, the time limit of <b>30 months</b> (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see <a href="http://www.wipo.int/pct/en/texts/time_limits.html">www.wipo.int/pct/en/texts/time_limits.html</a> and the <i>PCT Applicant's Guide</i> , National Chapters.<br>Within <b>22 months from the priority date, the applicant may request that a supplementary international search be carried out</b> by a different International Searching Authority that offers this service (Rule 45bis.1). The procedure for requesting supplementary international search is described in the <i>PCT Applicant's Guide</i> , International Phase, paragraphs 8.006-8.032. |

|                                                                                                                                                                                 |                                                                                                                                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|
| Name and mailing address of the ISA/<br>Mail Stop PCT, Attn: ISA/US<br>Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-8300 | Authorized officer<br><div style="text-align: center; font-weight: bold;">Shane Thomas</div> Telephone No. PCT Helpdesk: 571-272-4300 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|

Form PCT/ISA/220 (revised January 2020)

CORBIN\_CLINICAL-001403

Advance Medical Designs, Inc. - EX1020

Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041

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## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

|                                                        |                                                                                   |                                                                                               |  |
|--------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|--|
| Applicant's or agent's file reference<br>083003-686948 |                                                                                   | <b>FOR FURTHER ACTION</b><br>see Form PCT/ISA/220 as well as, where applicable, item 5 below. |  |
| International application No.<br>PCT/US21/25946        | International filing date ( <i>day/month/year</i> )<br>06 April 2021 (06.04.2021) | (Earliest) Priority Date ( <i>day/month/year</i> )<br>06 April 2020 (06.04.2020)              |  |
| Applicant<br>Corbin Clinical Resources, LLC            |                                                                                   |                                                                                               |  |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed.  
☐ a translation of the international application into \_\_\_\_\_ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☒ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant.  
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant.  
☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 40  
☒ as suggested by the applicant.  
☐ as selected by this Authority, because the applicant failed to suggest a figure.  
☐ as selected by this Authority, because this figure better characterizes the invention.
- b. ☐ none of the figures is to be published with the abstract.

Form PCT/ISA/210 (first sheet) (July 2019)

CORBIN\_CLINICAL-001404

Advance Medical Designs, Inc. - EX1020

Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041

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# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US21/25946

## Box No. 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.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ 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:
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 No. 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:  
-\*\*\*-Please See Supplemental Page-\*\*\*-

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 additional fees, this Authority did not invite payment of additional fees.
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.:  
Group I: Claims 1-10 and 19-23

### 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.

Form PCT/ISA/210 (continuation of first sheet (2)) (July 2019)

CORBIN\_CLINICAL-001405

Advance Medical Designs, Inc. - EX1020

Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041

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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US21/25946

## A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 18/04; A61B 10/02; A61B 17/34 (2021.01)

CPC - A61B 10/0241; A61K 9/0031; A61B 2017/00274; A61B 2017/3413; A61B 2018/00547; A61B 2018/048; A61N 2005/1094

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)

See Search History document

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

See Search History document

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

See Search History document

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages                                          | Relevant to claim No. |
|-----------|-----------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Y         | US 2019/0231386 A1 (CORBIN CLINICAL RESOURCES, LLC) 01 August 2019; paragraphs [0124]-[0125], [0130]-[0131], [0135], [0141] | 1-10, 19-23           |
| Y         | US 2010/0160711 A1 (NOYES, WR) 24 June 2010; paragraphs [0007], [0016], [0025], [0040]                                      | 1-10                  |
| Y         | US 2016/0081736 A1 (HOEY, M et. al) 24 March 2016; paragraph [0013]                                                         | 19-23                 |
| A         | US 2016/0243232 A1 (GALDERMA S.A.) 25 August 2016; see entire document                                                      | 1-10, 19-23           |
| A         | US 2008/0027007 A1 (BENNER, R) 31 January 2008; see entire document                                                         | 1-10, 19-23           |
| A         | US 2008/0039889 A1 (LAMSON, TC et. al) 14 February 2008; see entire document                                                | 1-10, 19-23           |

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&amp;" document member of the same patent family

Date of the actual completion of the international search

03 August 2021 (03.08.2021)

Date of mailing of the international search report

AUG 23 2021

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents  
P.O. Box 1450, Alexandria, Virginia 22313-1450  
Facsimile No. 571-273-8300

Authorized officer

Shane Thomas

Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

CORBIN\_CLINICAL-001406

Advance Medical Designs, Inc. - EX1020

Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041

Page 685 of 806

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US21/25946

\*\*\*Continued From Box No. III: Observations where unity of invention is lacking.\*\*\*

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fee must be paid.

Group I: Claims 1-10 and 19-23 are directed towards a method of performing a therapy on a prostate of a patient via transperineal access, the therapy using an ultrasound probe, the patient including a rectum and a perineum, the method comprising: sliding the platform and the access needle relative to the pair of stabilization members and the ultrasound probe so the access needle extends into the perineum.

Group II: Claims 11-18 are directed towards a method of performing a therapy on a prostate of a patient via transperineal access, the therapy using an ultrasound probe, the patient including a rectum and a perineum, the method comprising: inserting an access needle through the perineum, the access needle engaged with a displacement member that is configured to slide on a pair of stabilization members of a biopsy guide.

The inventions listed as Groups I-II do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

The special technical features of Group I are at least positioning a pair of stabilization members of a needle guide adjacent the perineum, the pair of stabilization members spaced apart from each other and supporting a platform configured to slide along a portion of a length of the pair of stabilization members, the needle guide coupled to the ultrasound probe; coupling an access needle to the platform; sliding the platform and the access needle relative to the pair of stabilization members and the ultrasound probe so the access needle extends into the perineum, which are not present in Group II.

The special technical features of Group II are at least inserting an access needle through the perineum, the access needle engaged with a displacement member that is configured to slide on a pair of stabilization members of a biopsy guide, the access needle being centrally positioned between the pair of stabilization members when the access needle is engaged with the displacement member, which are not present in Group I.

The common technical features of Groups I and II are towards a method of performing a therapy on a prostate of a patient via transperineal access, the therapy using an ultrasound probe, the patient including a rectum and a perineum, the method comprising: a pair of stabilization members, forming a radiation barrier in a space between the prostate and the rectum by injecting a radiation blocking substance through the access needle and into the space, which are previously disclosed by US 2008/0039889 A1 to NEOTRACT INC. (hereinafter "NEOTRACT").

NEOTRACT discloses a method of performing a therapy on a prostate of a patient via transperineal access (a method of performing a medical procedure on a prostate of a patient via transperineal access; figure 2), the therapy using an ultrasound probe (ultrasound transducer is used in the exam; paragraph [0289]), the patient including a rectum and a perineum (figure 1), the method comprising: a pair of stabilization members (a pair of anchors 376; figure 3G), forming a radiation barrier in a space between the prostate and the rectum by injecting a radiation blocking substance through the access needle and into the space (hydrogels (radiation blocking substance) is injected in a space spatially between the prostate and the rectum through the needle; paragraph [0264]).

Since the common technical features are previously disclosed by NEOTRACT, these common features are not special and so Groups I-II lack unity.

Form PCT/ISA/210 (extra sheet) (July 2019)

CORBIN\_CLINICAL-001407

Advance Medical Designs, Inc. - EX1020

Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041

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# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

# PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

To: Joshua J. Pranckun  
Polsinelli PC  
1401 Lawrence St., Suite 2300  
Denver, CO 80202

Date of mailing  
(day/month/year)

**AUG 23 2021**

Applicant's or agent's file reference

083003-686948

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

PCT/US21/25946

International filing date (day/month/year)

06 April 2021 (06.04.2021)

Priority date (day/month/year)

06 April 2020 (06.04.2020)

International Patent Classification (IPC) or both national classification and IPC

IPC - A61B 18/04; A61B 10/02; A61B 17/34 (2021.01)

CPC - A61B 10/0241; A61K 9/0031; A61B 2017/00274; A61B 2017/3413; A61B 2018/00547; A61B 2018/048; A61N 2005/1094

Applicant Corbin Clinical Resources, LLC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US  
Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450, Alexandria, Virginia 22313-1450  
Facsimile No. 571-273-8300

Date of completion of this opinion

03 August 2021 (03.08.2021)

Authorized officer

Shane Thomas

PCT Help Desk

Telephone No. 571-272-4300

Form PCT/ISA/237 (cover sheet) (revised January 2019)

CORBIN\_CLINICAL-001408

Advance Medical Designs, Inc. - EX1020

Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041

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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US21/25946

**Box No. I      Basis of this opinion**

1. With regard to the **language**, this opinion has been established on the basis of:  
☒ the international application in the language in which it was filed.  
☐ a translation of the international application into \_\_\_\_\_ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43**bis**.1(b)).
3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
  - a. ☐ forming part of the international application as filed:  
☐ in the form of an Annex C/ST.25 text file.  
☐ on paper or in the form of an image file.
  - b. ☐ furnished together with the international application under PCT Rule 13**ter**.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
  - c. ☐ furnished subsequent to the international filing date for the purposes of international search only:  
☐ in the form of an Annex C/ST.25 text file (Rule 13**ter**.1(a)).  
☐ on paper or in the form of an image file (Rule 13**ter**.1(b) and Administrative Instructions, Section 713).
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

Form PCT/ISA/237 (Box No. I) (revised January 2019)

CORBIN\_CLINICAL-001409

Advance Medical Designs, Inc. - EX1020

Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041

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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US21/25946

**Box No. IV    Lack of unity of invention**

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☐ paid additional fees.
- ☐ paid additional fees under protest and, where applicable, the protest fee.
- ☐ paid additional fees under protest but the applicable protest fee was not paid.
- ☒ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fee must be paid.

Group I: Claims 1-10 and 19-23 are directed towards a method of performing a therapy on a prostate of a patient via transperineal access, the therapy using an ultrasound probe, the patient including a rectum and a perineum, the method comprising: sliding the platform and the access needle relative to the pair of stabilization members and the ultrasound probe so the access needle extends into the perineum.

Group II: Claims 11-18 are directed towards a method of performing a therapy on a prostate of a patient via transperineal access, the therapy using an ultrasound probe, the patient including a rectum and a perineum, the method comprising: inserting an access needle through the perineum, the access needle engaged with a displacement member that is configured to slide on a pair of stabilization members of a biopsy guide.

The inventions listed as Groups I-II do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

The special technical features of Group I are at least positioning a pair of stabilization members of a needle guide adjacent the perineum, the pair of stabilization members spaced apart from each other and supporting a platform configured to slide along a portion of a length of the pair of stabilization members, the needle guide coupled to the ultrasound probe; coupling an access needle to the platform; sliding the platform and the access needle relative to the pair of stabilization members and the ultrasound probe so the access needle extends into the perineum, which are not present in Group II.

The special technical features of Group II are at least inserting an access needle through the perineum, the access needle engaged with a displacement member that is configured to slide on a pair of stabilization members of a biopsy guide, the access needle being centrally positioned between the pair of stabilization members when the access needle is engaged with the displacement member, which are not present in Group I.

The common technical features of Groups I and II are towards a method of performing a therapy on a prostate of a patient via transperineal access, the therapy using an ultrasound probe, the patient including a rectum and a perineum, the method comprising: a pair of stabilization members, forming a radiation barrier in a space between the prostate and the rectum by injecting a radiation blocking substance through the access needle and into the space, which are previously disclosed by US 2008/0039889 A1 to NEOTRACT INC. (hereinafter "NEOTRACT").

NEOTRACT discloses a method of performing a therapy on a prostate of a patient via transperineal access (a method of performing a medical procedure on a prostate of a patient via transperineal access; figure 2), the therapy using an ultrasound probe (ultrasound transducer is used in the exam; paragraph [0289]), the patient including a rectum and a perineum (figure 1), the method comprising: a pair of stabilization members (a pair of anchors 376; figure 3G), forming a radiation barrier in a space between the prostate and the rectum by injecting a radiation blocking substance through the access needle and into the space (hydrogels (radiation blocking substance) is injected in a space spatially between the prostate and the rectum through the needle; paragraph [0264]).

Since the common technical features are previously disclosed by NEOTRACT, these common features are not special and so Groups I-II lack unity.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

☐ all parts.

☒ the parts relating to claims Nos. Group I: Claims 1-10 and 19-23

Form PCT/ISA/237 (Box No. IV) (revised January 2019)

CORBIN\_CLINICAL-001410

Advance Medical Designs, Inc. - EX1020

Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041

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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US21/25946

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement**

**1. Statement**

|                               |        |             |     |
|-------------------------------|--------|-------------|-----|
| Novelty (N)                   | Claims | 1-10, 19-23 | YES |
|                               | Claims | NONE        | NO  |
| Inventive step (IS)           | Claims | NONE        | YES |
|                               | Claims | 1-10, 19-23 | NO  |
| Industrial applicability (IA) | Claims | 1-10, 19-23 | YES |
|                               | Claims | NONE        | NO  |

**2. Citations and explanations:**

Claims 1-10 lack an inventive step under PCT Article 33(3) as being obvious over US 2019/0231386 A1 to CORBIN CLINICAL RESOURCES, LLC (hereinafter 'CORBIN') in view of US 2010/0160711 A1 (NOYES).

As per claim 1, CORBIN discloses a method of performing a therapy on a prostate of a patient via transperineal access (a method of performing a therapy on a prostate of a patient via transperineal access; paragraphs [0124]-[0125], [0135]), the therapy using an ultrasound probe (the method is performed using an ultrasound probe; paragraphs [0123], [0135]), the patient including a rectum and a perineum (the ultrasound probe is a transrectal ultrasound probe, wherein the procedure is a transperineal procedure; paragraphs [0009], [0130]), the method comprising: positioning a pair of stabilization members of a needle guide adjacent the perineum (a pair of stabilization bars of a needle guide are positioned adjacent the perineum to hold the perineal skin; paragraph [0123]), the pair of stabilization members spaced apart from each other and supporting a platform configured to slide along a portion of a length of the pair of stabilization members (the stabilization bars have grooves for accommodating a sliding platform that is shorter in length than the stabilization bars. The grooves being configured to allow the platform to slide forward and backward along the stabilization bars; wherein the stabilization bars 101 are shown spaced apart from one another; figure 4; paragraph [0131]), the needle guide coupled to the ultrasound probe (the needle guide is coupled to a transrectal ultrasound probe; paragraph [0130]); coupling an access needle to the platform (an access needle is coupled to the platform; paragraphs [0123], [0133]); sliding the platform and the access needle relative to the pair of stabilization members and the ultrasound probe so the access needle extends into the perineum (the position of the access needle is facilitated by locking the access needle into the subcutaneous tissue of the perineum using a sliding platform that allows a user, such as a medical practitioner or patient caregiver, to place the access needle along a sagittal transducer plane at optimal positions for obtaining prostate biopsies; wherein the platform slides along the stabilization bars and the procedure is a transperineal procedure; paragraphs [0123], [0141]); and using the access needle as a conduit, injecting a substance (a biopsy gun may be inserted into the access needle in order to reach a targeted area, wherein the biopsy gun is used to insert any substance through the lumen of the access needle; paragraphs [0190], [0200]). CORBIN does not disclose injecting a radiation blocking substance between the rectum and the prostate. NOYES discloses injecting a radiation blocking substance between the rectum and the prostate (a method of improving radiological outcomes by introducing a filler between the rectum and the prostate, wherein the filler reduces the passage of radiation into the rectum and comprises an agent that blocks radiation; paragraphs [0025], [0040]). Since CORBIN discloses wherein the guide can be used for any instrument to treat the cancerous area of the prostate (CORBIN; paragraphs [0125], [0135]), and wherein any substance can be inserted via the access needle (CORBIN; paragraph [0190]), it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the method of CORBIN, with injecting a radiation blocking substance between the rectum and the prostate, as taught by NOYES, for the advantage of decreasing radiation treatment-induced side effects on sensitive organs resulting from radiation treatment to the prostate (NOYES; paragraphs [0007], [0016]).

As per claim 2, the combination of CORBIN and NOYES discloses the method of claim 1. CORBIN does not disclose further comprising: providing radiation therapy to the prostate. NOYES discloses providing radiation therapy to the prostate (radiation therapy is provided to the patient; paragraph [0025]). Since CORBIN discloses wherein the guide can be used for any instrument to treat the cancerous area of the prostate (CORBIN; paragraphs [0125], [0135]), it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the method of CORBIN, with providing radiation therapy to the prostate, as taught by NOYES, for the advantage of treating the cancerous prostate (NOYES; paragraphs [0007], [0016]).

As per claim 3, the combination of CORBIN and NOYES discloses the method of claim 1. CORBIN does not disclose wherein the radiation blocking substance comprises a hydrogel. NOYES discloses wherein the radiation blocking substance comprises a hydrogel (the filler for reducing the passage of radiation comprises a hydrogel; paragraphs [0025], [0029], [0040]). Since CORBIN discloses wherein the guide can be used for any instrument to treat the cancerous area of the prostate (CORBIN; paragraphs [0125], [0135]), and wherein any substance can be inserted via the access needle (CORBIN; paragraph [0190]), it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the method of CORBIN, with injecting a radiation blocking substance comprising a hydrogel between the rectum and the prostate, as taught by NOYES, for the advantage of decreasing radiation treatment-induced side effects on sensitive organs resulting from radiation treatment to the prostate (NOYES; paragraphs [0007], [0016]).

As per claim 4, the combination of CORBIN and NOYES discloses the method of claim 1. Modified CORBIN further discloses inserting a needle through the access needle (a needle of a biopsy gun is inserted through the access needle; paragraphs [0123], [0190]). CORBIN

---Continued in Supplemental Box---

Form PCT/ISA/237 (Box No. V) (revised January 2019)

CORBIN\_CLINICAL-001411

Advance Medical Designs, Inc. - EX1020

Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041

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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US21/25946

**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 10 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claim 10 is indefinite for the following reason(s):

Claim 10 refers to "the biopsy guide" in line 2. There is a lack of antecedent basis for this limitation in the claim. For the purpose of this opinion, as best understood, claim 10 is interpreted to read "the needle guide".

Form PCT/ISA/237 (Box No. VIII) (revised January 2019)

CORBIN\_CLINICAL-001412

Advance Medical Designs, Inc. - EX1020

Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041

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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

\*\*\*\*Continued From Box V. 2: Citations and Explanations\*\*\*\*

does not disclose the radiation blocking substance being injected through the needle. NOYES discloses the radiation blocking substance being injected through the needle (a method of improving radiological outcomes by injecting a filler between the rectum and the prostate using a needle, wherein the filler reduces the passage of radiation into the rectum and also comprises an agent that blocks radiation; paragraphs [0025], [0040], [0046]). Since CORBIN discloses wherein the guide can be used for any instrument to treat the cancerous area of the prostate (CORBIN; paragraphs [0125], [0135]), and wherein any substance can be inserted via the access needle (CORBIN; paragraph [0190]), it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the method of CORBIN, with the radiation blocking substance being injected through the needle, as taught by NOYES, for the advantage of decreasing radiation treatment-induced side effects on sensitive organs resulting from radiation treatment to the prostate (NOYES; paragraphs [0007], [0016]).

As per claim 5, the combination of CORBIN and NOYES discloses the method of claim 1. CORBIN does not disclose wherein injecting the radiation blocking substance between the rectum and the prostate spaces the rectum and the prostate apart from each other. NOYES discloses wherein injecting the radiation blocking substance between the rectum and the prostate spaces the rectum and the prostate apart from each other (the filler is injected into the space between the prostate and the rectum to increase a distance between the prostate and the rectum; paragraphs [0025], [0044]). Since CORBIN discloses wherein the guide can be used for any instrument to treat the cancerous area of the prostate (CORBIN; paragraphs [0125], [0135]), and wherein any substance can be inserted via the access needle (CORBIN; paragraph [0190]), it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the method of CORBIN, wherein injecting the radiation blocking substance between the rectum and the prostate spaces the rectum and the prostate apart from each other, as taught by NOYES, for the advantage of decreasing radiation treatment-induced side effects on sensitive organs resulting from radiation treatment to the prostate (NOYES; paragraphs [0007], [0016]).

As per claim 6, the combination of CORBIN and NOYES discloses the method of claim 1. Modified CORBIN further discloses inserting a needle through the access needle and into a first location within the prostate (a needle of a biopsy gun is inserted through the access needle to a desired location within the prostate; paragraphs [0123], [0190]).

As per claim 7, the combination of CORBIN and NOYES discloses the method of claim 6. Modified CORBIN further discloses inserting the needle through the access needle and into a second location within the prostate, the second location being different than the first location (the method comprises allowing multiple extractions of tissue or cell specimens from the prostate using the biopsy needle, wherein the method comprises repositioning the access needle in different planes to obtain cell specimens from different regions of the prostate, and thus the method necessarily comprises inserting the needle through the access needle and into a second location within the prostate, the second location being different than the first location; paragraphs [0123]-[0124], [0141], [0148]).

As per claim 8, the combination of CORBIN and NOYES discloses the method of claim 7. Modified CORBIN further discloses wherein the access needle remains positioned within the perineum during the insertion of the needle into both of the first and second locations (the method comprises allowing multiple extractions of tissue or cell specimens from the prostate using the biopsy needle, wherein the method comprises repositioning the access needle in different planes without retrieving the access needle to obtain cell specimens from different regions of the prostate, and thus the method necessarily comprises wherein the access needle remains positioned within the perineum during the insertion of the needle into both of the first and second locations; paragraphs [0123]-[0124], [0141], [0148]).

As per claim 9, the combination of CORBIN and NOYES discloses the method of claim 1. Modified CORBIN further discloses wherein positioning the pair of stabilization members of the needle guide proximate of the perineum comprises contacting a distal end of the pair of stabilization members with a perineal skin of the patient (a pair of stabilization bars of a needle guide are positioned adjacent the perineum to hold the perineal skin, and thus the stabilization bars necessarily contact and hold the perineal skin; paragraph [0123]).

As per claim 10, the combination of CORBIN and NOYES discloses the method of claim 1. Modified CORBIN further discloses wherein the access needle is generally parallel to a longitudinal axis of the ultrasound probe when the needle guide is secured to the ultrasound probe (as shown in in figures 4-6, the access needle that is inserted through drilled hole 302 of the platform will be parallel to a longitudinal axis of the ultrasound probe 103 when the guide is secured to the ultrasound probe 103; figures 4-6; paragraphs [0135], [0159]), and the pair of stabilization members are laterally spaced apart from each other and from a plane intersecting the access needle and the longitudinal axis of the ultrasound probe (the pair of stabilization bars 101 are shown spaced apart from each other and from a plane intersecting the access needle that is inserted through drilled hole 302 and the longitudinal axis of the ultrasound probe; figures 4-6; paragraphs [0135], [0159]).

Claims 19-23 lack an inventive step under PCT Article 33(3) as being obvious over CORBIN in view of US 2016/0081736 A1 to HOEY et al. (hereinafter 'HOEY').

As per claim 19, CORBIN discloses a method of performing a therapy on a prostate of a patient via transperineal access (a method of performing a therapy on a prostate of a patient via transperineal access; paragraphs [0124]-[0125], [0135]), the therapy using an ultrasound probe (the method is performed using an ultrasound probe; paragraphs [0123], [0135]), the patient including a rectum and a perineum (the ultrasound probe is a transrectal ultrasound probe, wherein the procedure is a transperineal procedure; paragraphs [0009], [0130]), the method comprising: positioning a pair of stabilization members of a needle guide adjacent the perineum (a pair of stabilization bars of a needle guide are positioned adjacent the perineum to hold the perineal skin; paragraph [0123]), the pair of stabilization members spaced apart from each other and supporting a platform configured to slide along a portion of a length of the pair of stabilization members (the stabilization bars have grooves for accommodating a sliding platform that is shorter in length than the stabilization bars. The grooves being configured to allow the platform to slide forward and backward along the stabilization bars; wherein the stabilization bars 101 are shown spaced apart from one another; figure 4; paragraph [0131]), the needle guide coupled to the ultrasound probe (the needle guide is coupled to a transrectal ultrasound probe; paragraph [0130]); coupling an access needle to the platform (an access needle is coupled to the

\*\*\*\*Continued Within the Next Supplemental Box\*\*\*\*

Form PCT/ISA/237 (Supplemental Box) (revised January 2019)

CORBIN\_CLINICAL-001413

Advance Medical Designs, Inc. - EX1020

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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US21/25946

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

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platform; paragraphs [0123], [0133]); sliding the platform and the access needle relative to the pair of stabilization members and the ultrasound probe so the access needle extends into the perineum (the position of the access needle is facilitated by locking the access needle into the subcutaneous tissue of the perineum using a sliding platform that allows a user, such as a medical practitioner or patient caregiver, to place the access needle along a sagittal transducer plane at optimal positions for obtaining prostate biopsies; wherein the platform slides along the stabilization bars and the procedure is a transperineal procedure; paragraphs [0123], [0141]); using the access needle as a guide, inserting a tip of a conduit through the access needle and into the prostate (a biopsy needle of a biopsy gun is inserted through the access needle and into the prostate; paragraphs [0123], [0190]). CORBIN does not disclose injecting water vapor into the prostate via the conduit. HOEY discloses injecting water vapor into the prostate via the conduit (a method of treating the prostate comprises injecting water vapor into the prostate via a vapor delivery needle; paragraph [0013]). Since CORBIN discloses wherein the guide can be used for any instrument to treat the cancerous area of the prostate, such as a thermotherapy instrument (CORBIN; paragraphs [0125], [0135]), and wherein any substance can be inserted via the access needle (CORBIN; paragraph [0190]), it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the method of CORBIN, with injecting water vapor into the prostate via the conduit, as taught by HOEY, for the advantage of delivering a heated water vapor to the prostate to ablate target regions (HOEY; paragraph [0013]).

As per claim 20, the combination of CORBIN and HOEY discloses the method of claim 19. CORBIN does not disclose wherein the water vapor is delivered in bursts of about nine seconds. HOEY discloses wherein the water vapor is delivered in bursts of about nine seconds (each treatment interval consisted of 10 seconds (about 9 seconds) of vapor delivery at each of six locations; paragraph [0117]). Since CORBIN discloses wherein the guide can be used for any instrument to treat the cancerous area of the prostate, such as a thermotherapy instrument (CORBIN; paragraphs [0125], [0135]), and wherein any substance can be inserted via the access needle (CORBIN; paragraph [0190]), it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the method of CORBIN, with injecting water vapor into the prostate via the conduit and wherein the water vapor is delivered in bursts of about nine seconds, as taught by HOEY, for the advantage of delivering a heated water vapor to the prostate to ablate target regions (HOEY; paragraph [0013]) and to prevent thermal diffusion to peripheral locations of the prostate lobes (HOEY; paragraph [0120]).

As per claim 21, the combination of CORBIN and HOEY discloses the method of claim 19. CORBIN does not disclose wherein the conduit is part of a water vapor delivery system including a control system and a water reservoir. HOEY discloses wherein the conduit is part of a water vapor delivery system including a control system and a water reservoir (a vapor delivery system comprising a controller 255 and a water vapor source 250, wherein the water vapor source 250 will necessarily comprise a water reservoir for generating the water vapor; figure 4; paragraphs [0102]). Since CORBIN discloses wherein the guide can be used for any instrument to treat the cancerous area of the prostate, such as a thermotherapy instrument (CORBIN; paragraphs [0125], [0135]), and wherein any substance can be inserted via the access needle (CORBIN; paragraph [0190]), it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the method of CORBIN, wherein the conduit is part of a water vapor delivery system including a control system and a water reservoir, as taught by HOEY, for the advantage of delivering a heated water vapor to the prostate to ablate target regions (HOEY; paragraph [0013]).

As per claim 22, the combination of CORBIN and HOEY discloses the method of claim 19. CORBIN does not disclose retracting the conduit from the prostate, repositioning the access needle within the perineum, inserting the tip of the conduit through the access needle and into the prostate a second time, and injecting water vapor into the prostate via the conduit a second time. However, since CORBIN discloses wherein the method comprises repositioning the access needle in different planes without retrieving the access needle from the prostate (CORBIN; paragraphs [0141], [0148]), it would have been obvious to one of ordinary skill in the art, at the time of invention, to have modified the method of CORBIN, with retracting the conduit from the prostate, repositioning the access needle within the perineum, inserting the tip of the conduit through the access needle and into the prostate a second time, for the advantage of inserting the instrument within the access cannula to deliver the substance at different locations without further perforating the skin of the patient at multiple locations (CORBIN; paragraphs [0148], [0190]). HOEY discloses injecting water vapor into the prostate via the conduit a second time (each treatment interval consisted of 10 seconds (about 9 seconds) of vapor delivery at each of six locations; paragraph [0117]). Since CORBIN discloses wherein the guide can be used for any instrument to treat the cancerous area of the prostate, such as a thermotherapy instrument (CORBIN; paragraphs [0125], [0135]), and wherein any substance can be inserted via the access needle (CORBIN; paragraph [0190]), it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the method of CORBIN, with injecting water vapor into the prostate via the conduit a second time, as taught by HOEY, for the advantage of delivering a heated water vapor to the prostate to ablate target regions (HOEY; paragraph [0013]).

As per claim 23, the combination of CORBIN and HOEY discloses the method of claim 22. Modified CORBIN further discloses wherein the access needle is not removed from the perineum during repositioning the access needle within the perineum (the method comprises allowing multiple extractions of tissue or cell specimens from the prostate using the biopsy needle, wherein the method comprises repositioning the access needle in different planes without retrieving the access needle to obtain cell specimens from different regions of the prostate; paragraphs [0123]-[0124], [0141], [0148]).

Claims 1-10 and 19-23 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.

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CORBIN\_CLINICAL-001414

Advance Medical Designs, Inc. - EX1020

Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041

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## PCT Recordation of Search History

### PCT Recordation of Search History

Case/PCT Application Number: PCT/US21/25946

CLIN Number/Technical Field of PCT Application: 0002 Life Sciences

Date(s) during which the search was conducted: 02 August 2021 to 03 August 2021

Date of Completion of Recordation of Search History Form: 03 August 2021

Research Analyst Initials: KMB

Search Approval Official (SAO) Initials: MWS

### Field of Search/Classification Information:

CPC Classification(s): A61B10/0241; A61B2017/00274; A61B17/3403; A61B2017/3405; A61B2017/3409; A61B2017/3411; A61B2017/3413; A61B2018/00547; A61B18/04; A61B2018/048; A61K9/0019; A61K9/0031; A61N5/00; A61N2005/1094; A61P39/00; A61P43/00

IPC(8) Classification(s): A61B10/02; A61B17/34; A61B18/04; A61P39/00; A61P43/00 (2021.01)

### Database(s) Searched (patent and Non-Patent Literature (NPL), Including Sub-Databases and Files Searched) and Search Terms Used:

PatSeer (US, EP, WO, JP, CN, KR, CA, DE, FR, GB, ES, AU, IN, CH, AT, BR, TH, RU, PH, SE, NO, DK, FI, BE, NL, LU, INPADOC Data); EBSCO; Google Scholar; Pubmed/Medline

Search Terms Used: prostate, ultrasound, needle, perineum, transperineal, inject, infuse, administer, deliver, radiation, block, shield, protect, water, vapor

### Database Search String Recordation (Including Dates of Searches):

#### Patent Database Search Strategy/Results

PatSeer (US, EP, WO, JP, CN, KR, CA, DE, FR, GB, ES, AU, IN, CH, AT, BR, TH, RU, PH, SE, NO, DK, FI, BE, NL, LU, INPADOC Data)

| ID  | Search String                                                                        | Deduped | Records | Created Date   |
|-----|--------------------------------------------------------------------------------------|---------|---------|----------------|
| L26 | <b>Search String:</b><br>AC: A61N2005/1094 AND TACD: (prostat* OR rectum OR rectal*) | SFAM    | 122     | 03 August 2021 |
| L25 | <b>Search String:</b><br>AC: A61B2018/00547 AND TACD: (water W5 vapor)               | SFAM    | 49      | 03 August 2021 |

|     |                                                                                                                                                                                                                                                                                                                                                                           |      |     |                |
|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|-----|----------------|
| L24 | <b>Search String:</b><br>AC: A61B2018/00547 AND TACD: (radiat* OR<br>radio*) W10 (block* OR shield* OR protect* OR<br>prevent* OR reduc*)                                                                                                                                                                                                                                 | SFAM | 186 | 03 August 2021 |
| L23 | <b>Search String:</b><br>AC: A61B2018/00547                                                                                                                                                                                                                                                                                                                               | SFAM | 952 | 03 August 2021 |
| L22 | <b>Search String:</b><br>AC: A61B2017/3413 AND TACD: (prostat*)                                                                                                                                                                                                                                                                                                           | SFAM | 164 | 03 August 2021 |
| L21 | <b>Search String:</b><br>AC: A61B10/0241                                                                                                                                                                                                                                                                                                                                  | SFAM | 197 | 03 August 2021 |
| L20 | <b>Search String:</b><br>AC: A61B2017/00274 AND TACD: (water W5<br>vapor)                                                                                                                                                                                                                                                                                                 | SFAM | 25  | 03 August 2021 |
| L19 | <b>Search String:</b><br>AC: A61B2017/00274 AND TACD: (radiat* OR<br>radio*) W10 (block* OR shield* OR protect* OR<br>prevent* OR reduc*)                                                                                                                                                                                                                                 | SFAM | 130 | 03 August 2021 |
| L18 | <b>Search String:</b><br>AC: A61B2017/00274                                                                                                                                                                                                                                                                                                                               | SFAM | 748 | 03 August 2021 |
| L17 | <b>Search String:</b><br>FCT: (US2019231386A1 OR<br>US20150038572A1 OR US20080027007A1 OR<br>US20160243232A1 OR US20100160711A1 OR<br>US20160081736A1 OR US20100145326A1 OR<br>US20130123888A1) OR BCT:<br>(US2019231386A1 OR US20150038572A1 OR<br>US20080027007A1 OR US20160243232A1 OR<br>US20100160711A1 OR US20160081736A1 OR<br>US20100145326A1 OR US20130123888A1) | SFAM | 52  | 03 August 2021 |

|     |                                                                                                                                                                                                                                              |      |      |                |
|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|------|----------------|
| L16 | <b>Search String:</b><br>L8 AND TACD: (prostat*) AND (transperine* OR perine*) AND (needle) AND (inject* OR infus*) AND (water W5 vapor*)                                                                                                    | SFAM | 30   | 02 August 2021 |
| L15 | <b>Search String:</b><br>TACD: (prostat*) AND (transperine* OR perine*) AND (needle) AND (inject* OR infus*) AND (water W5 vapor*)                                                                                                           | SFAM | 71   | 02 August 2021 |
| L14 | <b>Search String:</b><br>TAC: (prostate) AND (transperine* OR perine*) AND (needle) AND (inject* OR infus*) AND (water W5 vapor*)                                                                                                            | SFAM | 0    | 02 August 2021 |
| L13 | <b>Search String:</b><br>TA: (prostate) AND (transperine* OR perine*) AND (needle) AND (inject* OR infus*) AND (water W5 vapor*)                                                                                                             | SFAM | 0    | 02 August 2021 |
| L12 | <b>Search String:</b><br>L8 AND TACD: (prostat*) AND (needle OR biops* OR sharp* OR penetrat* OR punctur* OR cannula) AND (inject* OR infus* OR administer*) W10 (radiat*) W10 (block* OR shield* OR protect*)                               | SFAM | 115  | 02 August 2021 |
| L11 | <b>Search String:</b><br>L8 AND TACD: (prostat*) AND (needle OR biops* OR sharp* OR penetrat* OR punctur* OR cannula) AND (inject* OR infus* OR administer*) AND (radiat*) W10 (block* OR shield* OR protect*)                               | SFAM | 1100 | 02 August 2021 |
| L10 | <b>Search String:</b><br>L8 AND TACD: (prostat*) AND (transperine* OR perine*) AND (needle OR biops* OR sharp* OR penetrat* OR punctur* OR cannula) AND (inject* OR infus* OR administer*) AND (radiat*) W10 (block* OR shield* OR protect*) | SFAM | 70   | 02 August 2021 |

|    |                                                                                                                                                                                                                                                                                                        |      |        |                |
|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|--------|----------------|
| L9 | <b>Search String:</b><br>L8 AND TACD: (prostat*) AND (transperine*<br>OR perine*) AND (needle OR biops* OR sharp*<br>OR penetrat* OR punctur* OR cannula) AND<br>(inject* OR infus* OR administer*) W10<br>(radiat*) W10 (block* OR shield* OR protect*)                                               | SFAM | 6      | 02 August 2021 |
| L8 | <b>Search String:</b><br>AC: (A61B10/0241 OR A61B2017/00274 OR<br>A61B17/3403 OR A61B2017/3405 OR<br>A61B2017/3409 OR A61B2017/3411 OR<br>A61B2017/3413 OR A61B2018/00547 OR<br>A61B18/04 OR A61B2018/048 OR A61K9/0019<br>OR A61K9/0031 OR A61N5/00 OR<br>A61N2005/1094 OR A61P39/00 OR<br>A61P43/00) | SFAM | 196537 | 02 August 2021 |
| L7 | <b>Search String:</b><br>TACD: (prostate) AND (transperine* OR<br>perine*) AND (needle) AND (inject* OR infus*)<br>W10 (radiat*) W10 (block* OR shield* OR<br>protect*)                                                                                                                                | SFAM | 3      | 02 August 2021 |
| L6 | <b>Search String:</b><br>TACD: (prostate) AND (transperine* OR<br>perine*) AND (needle) AND (inject* OR infus*)<br>AND (radiat*) W10 (block* OR shield* OR<br>protect*)                                                                                                                                | SFAM | 113    | 02 August 2021 |
| L5 | <b>Search String:</b><br>TAC: (prostate) AND (transperine* OR perine*)<br>AND (needle) AND (inject* OR infus*) AND<br>(radiat*) AND (block* OR shield* OR protect*)                                                                                                                                    | SFAM | 5      | 02 August 2021 |
| L4 | <b>Search String:</b><br>TAC: (prostate) AND (transperine* OR perine*)<br>AND (needle) AND (inject* OR infus*) AND<br>(radiat*)                                                                                                                                                                        | SFAM | 7      | 02 August 2021 |

|    |                                                                                                                                |      |   |                |
|----|--------------------------------------------------------------------------------------------------------------------------------|------|---|----------------|
| L3 | <b>Search String:</b><br>TA: (prostate) AND (transperine* OR perine*)<br>AND (needle) AND (inject* OR infus*) AND<br>(radiat*) | SFAM | 0 | 02 August 2021 |
| L2 | <b>Search String:</b><br>INV: (MATT* W2 ALLAWAY)                                                                               | SFAM | 2 | 02 August 2021 |
| L1 | <b>Search String:</b><br>AASN: CORBIN W2 CLINIC*                                                                               | SFAM | 2 | 02 August 2021 |

## Non-Patent Literature (NPL) Search Strategy/Results

### EBSCO

02 August 2021

|                                                                        |
|------------------------------------------------------------------------|
| prostate ultrasound probe transperineal needle guide radiation blocker |
| prostate ultrasound transperineal needle radiation shield              |
| prostate perineum radiation blocker                                    |
| prostate ultrasound probe transperineal needle guide water vapor       |
| prostate ultrasound transperineal needle water vapor                   |
| prostate water vapor                                                   |

### Google Scholar

02 August 2021

|                                                                                        |
|----------------------------------------------------------------------------------------|
| prostate ultrasound probe transperineal access needle guide platform radiation blocker |
| prostate inject rectum radiation shield                                                |
| prostate perineum Inject radiation blocker                                             |
| prostate ultrasound probe transperineal needle guide water vapor                       |
| prostate ultrasound transperineal needle water vapor                                   |
| prostate water vapor                                                                   |

### Pubmed/Medline

02 August 2021

|                                                                           |
|---------------------------------------------------------------------------|
| prostate ultrasound perineum rectum access needle guide radiation blocker |
| prostate ultrasound transperineal needle radiation protection hydrogel    |
| prostate perineum radiation blocker hydrogel                              |
| prostate ultrasound perineum cannula water vapor                          |
| prostate ultrasound transperineal needle water vapor                      |
| prostate water vapor                                                      |



## ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #  
**17/314,845**

RECEIPT DATE / TIME  
**09/08/2021 06:50:06 PM ET**

ATTORNEY DOCKET #  
**083003-620553**

### Title of Invention

METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING GUIDED AND FREE-HANDED TRANSPERINEAL PROSTATE BIOPSIES

### Application Information

APPLICATION TYPE Utility - Nonprovisional Application  
under 35 USC 111(a)

PATENT # -

CONFIRMATION # 1007

FILED BY Donna Carrera

PATENT CENTER # 60306411

FILING DATE 05/07/2021

CUSTOMER # 24030

FIRST NAMED INVENTOR Matthew J. ALLAWAY

CORRESPONDENCE ADDRESS -

AUTHORIZED BY Josh Prackun

### Documents

**TOTAL DOCUMENTS: 3**

| DOCUMENT                               | PAGES | DESCRIPTION                                        | SIZE (KB) |
|----------------------------------------|-------|----------------------------------------------------|-----------|
| 17314845_IDS_TransmittalLetter.pdf     | 5     | Transmittal Letter                                 | 149 KB    |
| 2021-08-23_ISR-WO_PCTUS2021-025946.pdf | 18    | Other Reference-Patent/App/Search documents        | 1134 KB   |
| 17314845_IDS_PTOSB08A.pdf              | 1     | Information Disclosure Statement (IDS) Form (SB08) | 147 KB    |

Warning: This is not a USPTO supplied IDS fillable form. Data in the form cannot be automatically loaded to other USPTO systems.

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**Digest**

| <b>DOCUMENT</b>                        | <b>MESSAGE DIGEST(SHA-512)</b>                                                                                                           |
|----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
| 17314845_IDS_TransmittalLetter.pdf     | 6864395AA5F51DB28FC82D7A0EB5CDEAAEFDC8BE9C5E68A<br>1600C6BCD5AC4F2FE597CA6512027AF06120E12B1231BB00D<br>BB702EFBC0BE74199C5F0ADCAABC4A02 |
| 2021-08-23_ISR-WO_PCTUS2021-025946.pdf | 4BC386A7FA2B43759F6FA92AEAA1D57413903CF30FB9BE02C<br>68B0961CEB142977FEB420FA12799B0C6CA3524750B33BED7<br>0D9BA00F3C8FF19004F81BD0C8F93E |
| 17314845_IDS_PTOSB08A.pdf              | CFFF09631F3F857EFC94F34BAE6DD3B8EFA94C2142DE0C59<br>AE25717DD1F617A46634B27E88D31D5E0072FF8DD4997104B<br>CF71973906A942608FDA829955CEAC4 |

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

**New Applications Under 35 U.S.C. 111**

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

**National Stage of an International Application under 35 U.S.C. 371**

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

**New International Application Filed with the USPTO as a Receiving Office**

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

|                                                                                                                               |                                   |
|-------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| Inventor(s): Matthew J. Allaway                                                                                               |                                   |
| App. No.: 17/314,845                                                                                                          | Con. No.: 1007                    |
| Filed: May 7, 2021                                                                                                            | Art Unit: 3793                    |
| Title: Method, System, and Device for<br>Planning and Performing Guided<br>and Free-Handed Transperineal<br>Prostate Biopsies | Examiner: Sanjay Cattungal        |
|                                                                                                                               | Attorney Docket No. 083003-620553 |

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT  
PURSUANT TO 37 C.F.R. §§ 1.56, 1.97, AND 1.98**

Dear Commissioner:

The Examiner is respectfully requested to consider the patents, patent applications, publications, or other information cataloged on the enclosed Form PTO/SB/08A during examination of the above-identified patent application. The order of presentation of the references should not be construed as an indication of importance. These references are submitted for the Examiner's consideration and are submitted pursuant to an Applicant's duty of disclosure under 37 C.F.R. § 1.56.

Copies of all of the cited documents

☐ are enclosed unless otherwise indicated on the enclosed Form PTO/SB/08a.

☐ have been previously furnished to the Office in prior application No. \_\_\_\_\_, filed \_\_\_\_\_, which the present application relies upon for an earlier effective filing date under 35 U.S.C. § 120. Therefore, no copies of the cited documents are included herewith pursuant to 37 C.F.R. § 1.98(d); MPEP § 609(III)(A)(2).

☒ are enclosed unless they are U.S. patents or U.S. patent application publications pursuant to 37 C.F.R. § 1.98(a).

**I**  
**BASIS**

This information disclosure statement is filed pursuant to

- ☐ 37 C.F.R. § 1.97(b).  
This information disclosure statement is filed either (1) within three months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. § 1.53(d); (2) within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application; (3) before the mailing date of a first Office action on the merits; or (4) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. § 1.114, whichever event occurs last.

Accordingly, this information disclosure statement requires no fee and no certification.

- ☒ 37 C.F.R. § 1.97(c).  
This information disclosure statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing date of any of (1) a final action under 37 C.F.R. § 1.113; (2) a notice of allowance under 37 C.F.R. § 1.311; or (3) an action that otherwise closes prosecution in the application.

Accordingly, this information disclosure statement requires either the fee specified in 37 C.F.R. § 1.17(p) for submission of an information disclosure statement under 37 C.F.R. § 1.97(c), or a statement under 37 C.F.R. § 1.97(e).

- ☐ 37 C.F.R. § 1.97(d).  
This information disclosure statement is filed after the period specified in 37 C.F.R. § 1.97(c) since a

☐ final action under 37 C.F.R. § 1.113

☐ notice of allowance under 37 C.F.R. § 1.311

was mailed to the Applicant(s) on \_\_\_\_\_. The issue fee has not been paid herein.

Accordingly, this information disclosure statement requires the fee set forth in 37 C.F.R. § 1.17(p) to consider an information disclosure statement under 37 C.F.R. § 1.97(d), and a statement under 37 C.F.R. § 1.97(e).

If this statement crosses in the mail with an Office action, or is otherwise not in the indicated category of 37 C.F.R. § 1.97, it is respectfully requested that this statement be treated in the next appropriate category and made of record. To the extent required, please treat this paper as a conditional petition for acceptance of the information disclosure statement.

## **II FEES**

Any required fee is being paid as indicated below by an enclosed check or our deposit account.

- ☒ No fee is due.
- ☐ The \$ \_\_\_\_\_ fee specified in 37 C.F.R. § 1.17(p) for submission of an information disclosure statement under 37 C.F.R. § 1.97(c) or (d) is due.
- ☐ A check is enclosed for the required fee.
- ☐ Payment by credit card is submitted simultaneously herewith for the required fee.
- ☐ Please charge the required fee to our deposit account no. 50-1662.
- ☐ The Commissioner is hereby authorized to charge any additional required fees or credit any overpayments associated with this information disclosure statement to our deposit account no. 50-1662.

## **III CERTIFICATION**

Pursuant to 37 C.F.R. § 1.97(e), I state as follows:

- ☐ No statement is necessary.
- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement. 37 C.F.R. § 1.97(e)(1).
- ☒ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this information disclosure statement. 37 C.F.R. § 1.97(e)(2).

Pursuant to 37 C.F.R. § 1.704(d), I state as follows:

- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application, and this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this information disclosure statement.

#### IV FOREIGN LANGUAGE REFERENCES

Pursuant to 37 C.F.R. § 1.98(a)(3)(i), any information disclosure statement filed under 37 C.F.R. § 1.97 shall include a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language. The concise explanation may be either separate from the specification or incorporated therein. In compliance with the rules, the Applicant states as follows:

- ☒ No concise explanation is required since all cited references are in English.
- ☐ A concise explanation of the relevance of one or more foreign language references is attached.
- ☐ According to the procedural policy adopted by the PTO with regard to disclosure requirements, the Applicant is satisfying the disclosure requirement pursuant to MPEP § 609.04(a)(III) by submitting herewith the following:
  - ☐ An English language version of one or more non-English language documents.
  - ☐ An English language equivalent application or patent of one or more non-English language applications or patents.
  - ☐ An English language version of one or more search reports or other actions by one or more foreign patent offices in one or more counterpart foreign applications, which indicate the degree of relevance found by the foreign office(s).
  - ☐ An English language abstract of one or more non-English language references.

The Applicant has not analyzed these documents and, therefore, declines to comment on their relevance at this time.

#### V REMARKS

- ☐ Pursuant to the doctrines established by the Court of Appeals for the Federal Circuit in *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, 487 F.3d 897 (Fed. Cir. 2007) and *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358 (Fed. Cir. 2003), Applicant(s) submit documents herewith reflecting the prosecution history of applications that Applicant(s) believe may be considered related to the present application.
- ☐ In satisfaction of the duty of disclosure under 37 C.F.R. § 1.56, and as required by M.P.E.P. § 2001.06(b), the Examiner is requested to consider the pending U.S.

patent applications listed in "Attachment A," which are owned by the Assignee of the present application. The pending patent applications may include subject matter similar to that of the present application.

It is respectfully requested that

- (1) the Examiner sign the enclosed Form PTO/SB/08a and Attachment A to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application; and
- (2) the citations for the cited information be printed on any patent that issues from this application.

The submission of this information disclosure statement by the Applicant(s) shall not be construed as a representation that a search has been performed or that no other material information under 37 C.F.R. § 1.56 exists. See 37 C.F.R. § 1.97(g).

The submission of this information disclosure statement by the Applicant(s) shall not be construed as an admission that any information cited or referred to herein is, or is considered to be, material to the patentability of one or more of the pending claims in this application pursuant to 37 C.F.R. § 1.56(b), unless specifically designated by the Applicant(s) as such. See 37 C.F.R. § 1.97(h).

The submission of this information disclosure statement by the Applicant(s) shall not be construed as an admission that any information cited or referred to herein is, or is considered to be, or even qualifies as "prior art" under 35 U.S.C. § 102 with respect to this invention, unless specifically designated by the Applicant(s) as such.

Notwithstanding any statements by the Applicant(s), the Examiner is urged to form his or her own conclusion regarding the relevance of the cited information.

## VI CONCLUSION

The Examiner is encouraged to contact the undersigned attorney to discuss any questions concerning this information disclosure statement or any of the information cited or referred to herein.

Respectfully submitted this 8<sup>th</sup> day of September 2021.

/Joshua J. Prackun/  
Joshua J. Prackun, Registration No. 70712  
Customer No. 24030  
POL SINELLI PC  
TEL: 303-583-8269

| PATENT APPLICATION FEE DETERMINATION RECORD<br>Substitute for Form PTO-875                                                      |                                                                                          |                                                                                                                                                                                                                               |                            | Application or Docket Number<br>17/314,845 |               | Filing Date<br>05/07/2021 |  | <input type="checkbox"/> To be Mailed |  |
|---------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------------------------------|---------------|---------------------------|--|---------------------------------------|--|
| ENTITY: <input type="checkbox"/> LARGE <input checked="" type="checkbox"/> SMALL <input type="checkbox"/> MICRO                 |                                                                                          |                                                                                                                                                                                                                               |                            |                                            |               |                           |  |                                       |  |
| APPLICATION AS FILED - PART I                                                                                                   |                                                                                          |                                                                                                                                                                                                                               |                            |                                            |               |                           |  |                                       |  |
| FOR                                                                                                                             |                                                                                          | (Column 1)<br>NUMBER FILED                                                                                                                                                                                                    | (Column 2)<br>NUMBER EXTRA |                                            |               | RATE (\$)                 |  | FEE (\$)                              |  |
| <input type="checkbox"/> BASIC FEE<br>(37 CFR 1.16(a), (b), or (c))                                                             |                                                                                          | N/A                                                                                                                                                                                                                           | N/A                        |                                            |               | N/A                       |  |                                       |  |
| <input type="checkbox"/> SEARCH FEE<br>(37 CFR 1.16(k), (i), or (m))                                                            |                                                                                          | N/A                                                                                                                                                                                                                           | N/A                        |                                            |               | N/A                       |  |                                       |  |
| <input type="checkbox"/> EXAMINATION FEE<br>(37 CFR 1.16(o), (p), or (q))                                                       |                                                                                          | N/A                                                                                                                                                                                                                           | N/A                        |                                            |               | N/A                       |  |                                       |  |
| TOTAL CLAIMS<br>(37 CFR 1.16(i))                                                                                                |                                                                                          | minus 20 =                                                                                                                                                                                                                    | *                          |                                            |               | x \$50 =                  |  |                                       |  |
| INDEPENDENT CLAIMS<br>(37 CFR 1.16(h))                                                                                          |                                                                                          | minus 3 =                                                                                                                                                                                                                     | *                          |                                            |               | x \$240 =                 |  |                                       |  |
| <input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))                                                                  |                                                                                          | If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s). |                            |                                            |               |                           |  |                                       |  |
| <input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))                                                      |                                                                                          |                                                                                                                                                                                                                               |                            |                                            |               |                           |  |                                       |  |
| * If the difference in column 1 is less than zero, enter "0" in column 2.                                                       |                                                                                          |                                                                                                                                                                                                                               |                            |                                            |               | TOTAL                     |  |                                       |  |
| APPLICATION AS AMENDED - PART II                                                                                                |                                                                                          |                                                                                                                                                                                                                               |                            |                                            |               |                           |  |                                       |  |
| AMENDMENT                                                                                                                       | 09/08/2021                                                                               | CLAIMS REMAINING AFTER AMENDMENT                                                                                                                                                                                              |                            | HIGHEST NUMBER PREVIOUSLY PAID FOR         | PRESENT EXTRA | RATE (\$)                 |  | ADDITIONAL FEE (\$)                   |  |
|                                                                                                                                 | Total<br>(37 CFR 1.16(i))                                                                | * 29                                                                                                                                                                                                                          | Minus                      | ** 29                                      | = 0           | x \$ 50 =                 |  | 0                                     |  |
|                                                                                                                                 | Independent<br>(37 CFR 1.16(h))                                                          | * 3                                                                                                                                                                                                                           | Minus                      | *** 3                                      | = 0           | x \$ 240 =                |  | 0                                     |  |
|                                                                                                                                 | <input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))                           |                                                                                                                                                                                                                               |                            |                                            |               |                           |  |                                       |  |
|                                                                                                                                 | <input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) |                                                                                                                                                                                                                               |                            |                                            |               |                           |  |                                       |  |
|                                                                                                                                 |                                                                                          |                                                                                                                                                                                                                               |                            |                                            |               | TOTAL ADD'L FEE           |  | 0                                     |  |
| AMENDMENT                                                                                                                       |                                                                                          | CLAIMS REMAINING AFTER AMENDMENT                                                                                                                                                                                              |                            | HIGHEST NUMBER PREVIOUSLY PAID FOR         | PRESENT EXTRA | RATE (\$)                 |  | ADDITIONAL FEE (\$)                   |  |
|                                                                                                                                 | Total<br>(37 CFR 1.16(i))                                                                | *                                                                                                                                                                                                                             | Minus                      | **                                         | =             | x \$ 0 =                  |  |                                       |  |
|                                                                                                                                 | Independent<br>(37 CFR 1.16(h))                                                          | *                                                                                                                                                                                                                             | Minus                      | ***                                        | =             | x \$ 0 =                  |  |                                       |  |
|                                                                                                                                 | <input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))                           |                                                                                                                                                                                                                               |                            |                                            |               |                           |  |                                       |  |
|                                                                                                                                 | <input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) |                                                                                                                                                                                                                               |                            |                                            |               |                           |  |                                       |  |
|                                                                                                                                 |                                                                                          |                                                                                                                                                                                                                               |                            |                                            |               | TOTAL ADD'L FEE           |  |                                       |  |
| * If the entry in column 1 is less than the entry in column 2, write "0" in column 3.                                           |                                                                                          |                                                                                                                                                                                                                               |                            |                                            |               | LIE                       |  |                                       |  |
| ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".                                       |                                                                                          |                                                                                                                                                                                                                               |                            |                                            |               | /LASHAWN R MORGAN/        |  |                                       |  |
| *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".                                        |                                                                                          |                                                                                                                                                                                                                               |                            |                                            |               |                           |  |                                       |  |
| The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1. |                                                                                          |                                                                                                                                                                                                                               |                            |                                            |               |                           |  |                                       |  |

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**  
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**Cc:** PAIR\_eOfficeAction@uspto.gov  
**Subject:** Private PAIR Correspondence Notification for Customer Number 24030

Aug 27, 2021 05:01:17 AM

Dear PAIR Customer:

POLSINELLI PC  
900 WEST 48TH PLACE  
SUITE 900  
KANSAS CITY, MO 64112-1895  
UNITED STATES

The following USPTO patent application(s) associated with your Customer Number, 24030 , have new outgoing correspondence. This correspondence is now available for viewing in Private PAIR.

The official date of notification of the outgoing correspondence will be indicated on the form PTOL-90 accompanying the correspondence.

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The list of documents shown below is provided as a courtesy and is not part of the official file wrapper. The content of the images shown in PAIR is the official record.

| Application | Document | Mailroom Date | Attorney Docket No. |
|-------------|----------|---------------|---------------------|
| 17314845    | NTC.PUB  | 08/26/2021    | 083003-620553       |

To view your correspondence online or update your email addresses, please visit us anytime at <https://sportal.uspto.gov/secure/myportal/privatepair>.

If you have any questions, please email the Electronic Business Center (EBC) at [EBC@uspto.gov](mailto:EBC@uspto.gov) with 'e-Office Action' on the subject line or call 1-866-217-9197 during the following hours:

Monday - Friday 6:00 a.m. to 12:00 a.m.

Thank you for prompt attention to this notice,

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CORBIN\_CLINICAL-001429



UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office  
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P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NUMBER | FILING OR 371(C) DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO./TITLE |
|--------------------|-----------------------|-----------------------|------------------------|
| 17/314,845         | 05/07/2021            | Matthew J. ALLAWAY    | 083003-620553          |

**CONFIRMATION NO. 1007**

**PUBLICATION NOTICE**



\*OC000000127987821\*

24030  
POL SINELLI PC  
900 WEST 48TH PLACE  
SUITE 900  
KANSAS CITY, MO 64112-1895

**Title:**METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING GUIDED AND FREE-HANDED  
TRANSPERINEAL PROSTATE BIOPSIES

**Publication No.**US-2021-0259801-A1

**Publication Date:**08/26/2021

**NOTICE OF PUBLICATION OF APPLICATION**

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at [www.uspto.gov](http://www.uspto.gov). The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at [www.uspto.gov](http://www.uspto.gov) using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently <https://portal.uspto.gov/pair/PublicPair>. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101



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| APPLICATION NO.            | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------|-------------|----------------------|---------------------|------------------|
| 17/314,845                 | 05/07/2021  | Matthew J. ALLAWAY   | 083003-620553       | 1007             |
| 24030                      | 7590        | 07/22/2021           | EXAMINER            |                  |
| POL SINELLI PC             |             |                      | CATTUNGAL, SANJAY   |                  |
| 900 WEST 48TH PLACE        |             |                      |                     |                  |
| SUITE 900                  |             |                      |                     |                  |
| KANSAS CITY, MO 64112-1895 |             |                      |                     |                  |
|                            |             |                      | ART UNIT            | PAPER NUMBER     |
|                            |             |                      | 3793                |                  |
|                            |             |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|                            |             |                      | 07/22/2021          | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspt@polsinelli.com



## DETAILED ACTION

### ***Notice of Pre-AIA or AIA Status***

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

### ***Double Patenting***

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a

result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit [www.uspto.gov/patent/patents-forms](http://www.uspto.gov/patent/patents-forms). The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to [www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp](http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp).

3. Claims 1-29 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 10,064,681. Although the claims at issue are not identical, they are not patentably distinct from each other because both application and patent claim an apparatus for use with a transrectal transducer in performing free-handed transperineal prostate biopsies.

4. Claims 1-29 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 21-63 of U.S. Application No. 16/115180. Although the claims at issue are not identical, they are not patentably distinct from each other because both application and patent claim an apparatus for use with a transrectal transducer in performing free-handed transperineal prostate biopsies.

5. Claims 1-29 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 10,064,681. Although the claims at issue are not identical, they are not patentably distinct from each other because both application and patent claim an apparatus for use with a transrectal transducer in performing free-handed transperineal prostate biopsies.

6.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

(a)(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

8. Claim(s) 1, 2, 4, 6-9, 21, 22, and 24-27 is/are rejected under 35 U.S.C. 102a1/a2 as being anticipated by U. S. Publication No. 5,494,039 to Onik et al.

9. Regarding claims 1 and 21, Onik teaches an apparatus for use with a transrectal transducer in performing free-handed transperineal prostate biopsies, the apparatus comprising: a biopsy guide configured to couple to the transrectal transducer and comprising a base portion (fig. 1-4 element 4 teaches a base portion), and a platform slidably engageable with the base portion (fig. 1 element 16 is a platform slidably engageable with the base portion), the platform including a plurality of needle guides (Fig. 1 element 18 are plurality of needle guides) that are sized to support an access

needle comprising a lumen sized to receive a biopsy needle there through, the plurality of needle guides aligning with a sagittal transducer plane of the transrectal probe when the biopsy guide is coupled to the transrectal probe (fig. 1 element 2).

10. Regarding claim 2 and 22, Onik teaches that the plurality of needle guides are holes defined in the platform (fig. 1 element 18 teaches multiple holes/needle guides on the platform element 16).

11. Regarding claims 4 and 24, Onik teaches further comprising the access needle (col. 7 lines 28-32 teaches a biopsy needle).

12. Regarding claim 6 and 25, Onik teaches that the biopsy guide is coupled to the transrectal probe and when the access needle is supported by one of the plurality of needle guides, movement of the access needle is fixed relative to a movement of the transrectal transducer (fig. 1 element 21 can be fixed relative to transrectal probe element 2).

13. Regarding claims 7 and 26, Onik teaches that the biopsy guide and transrectal transducer are freely moveable in operation (fig. 1 element 21 can be fixed/freely movable relative to transrectal probe element 2).

14. Regarding claims 8 and 27, Onik teaches that the platform is shorter in length than the base portion (fig. 1 teaches the platform 16 is shorter than the base element 4).

15. Regarding claim 9, Onik teaches that the base portion comprises a mount configured to releasably secure the biopsy guide to the transrectal probe (fig. 1 element 17 is a mount to secure the biopsy guide [secured to the platform] to the transrectal probe [secured to the base]).

***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claim 3 is/are rejected under 35 U.S.C. 103 as being unpatentable over U. S.

Publication No. 5,494,039 to Onik et al. in view of U. S. Publication No. 2009/0234369 to Bax et al.

18. Regarding Claim 3, Onik teaches all of the above claimed limitations but does not expressly teach that the plurality of needle guides are sized to support the access needle having a needle size of 14 gauge, 15 gauge, 16 gauge, or 18 gauge.

19. Bax teaches that the plurality of needle guides are sized to support the access needle having a needle size of 14 gauge, 15 gauge, 16 gauge, or 18 gauge (para 0078 teaches a needle guide to constrain an 18gauge needle).

20. It would be obvious to one of ordinary skill in the art at the time of filing to modify Onik with a setup such that the needle guides are sized to support the access needle having a needle size of 14 gauge, 15 gauge, 16 gauge, or 18 gauge as taught by Bax, since such a setup would result in a needle guide capable of supporting common needle sizes; furthermore different needle guides capable of supporting different needle sizes are obvious variants.

***Conclusion***

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SANJAY CATTUNGAL whose telephone number is (571)272-1306. The examiner can normally be reached on M-F 9-5 EST.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Raymond can be reached on (571) 270-1790. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <https://ppair-my.uspto.gov/pair/PrivatePair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit: 3793

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/SANJAY CATTUNGAL/  
Primary Examiner, Art Unit 3793

|                                   |                                       |  |                                                                   |             |
|-----------------------------------|---------------------------------------|--|-------------------------------------------------------------------|-------------|
| <b>Notice of References Cited</b> | Application/Control No.<br>17/314,845 |  | Applicant(s)/Patent Under<br>Reexamination<br>ALLAWAY, Matthew J. |             |
|                                   | Examiner<br>SANJAY CATTUNGAL          |  | Art Unit<br>3793                                                  | Page 1 of 2 |

#### U.S. PATENT DOCUMENTS

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Name                  | CPC Classification | US Classification |
|---|---|--------------------------------------------------|-----------------|-----------------------|--------------------|-------------------|
| * | A | US-5494039-A                                     | 02-1996         | Onik; Gary            | A61B17/3403        | 600/461           |
| * | B | US-20150366544-A1                                | 12-2015         | YAP; Chew Loong       | A61B8/4209         | 600/464           |
| * | C | US-20150119715-A1                                | 04-2015         | Baumann; Michael      | A61B8/0841         | 600/444           |
| * | D | US-20140039314-A1                                | 02-2014         | Stoianovici; Dan      | A61B34/30          | 600/439           |
| * | E | US-20110319759-A1                                | 12-2011         | Liu; Hanli            | A61B10/0241        | 600/439           |
| * | F | US-20110071380-A1                                | 03-2011         | GOLDENBERG; Andrew A. | A61B8/0841         | 600/411           |
| * | G | US-20090030339-A1                                | 01-2009         | Cheng; Wai Sam C.     | A61B8/0841         | 600/562           |
| * | H | US-20080004481-A1                                | 01-2008         | Bax; Jeffrey          | A61N5/1001         | 600/7             |
| * | I | US-20120245455-A1                                | 09-2012         | Bauman; Michael       | A61B17/3403        | 600/424           |
| * | J | US-20050159676-A1                                | 07-2005         | Taylor, James D.      | A61B10/0275        | 600/567           |
| * | K | US-20070043291-A1                                | 02-2007         | Fidel; Howard F.      | A61N5/1048         | 600/439           |
| * | L | US-20040162458-A1                                | 08-2004         | Green, Thomas C.      | A61N5/1007         | 600/7             |
| * | M | US-20030153850-A1                                | 08-2003         | Davis, Brian J.       | A61B8/4209         | 601/2             |

#### FOREIGN PATENT DOCUMENTS

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Country | Name | CPC Classification |
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#### NON-PATENT DOCUMENTS

| * |   | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) |
|---|---|-------------------------------------------------------------------------------------------|
|   | U |                                                                                           |
|   | V |                                                                                           |
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Notice of References Cited

Part of Paper No. 20210717

|                                          |                                       |  |                                                                   |             |
|------------------------------------------|---------------------------------------|--|-------------------------------------------------------------------|-------------|
| <b><i>Notice of References Cited</i></b> | Application/Control No.<br>17/314,845 |  | Applicant(s)/Patent Under<br>Reexamination<br>ALLAWAY, Matthew J. |             |
|                                          | Examiner<br>SANJAY CATTUNGAL          |  | Art Unit<br>3793                                                  | Page 2 of 2 |

**U.S. PATENT DOCUMENTS**

| * |   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Name         | CPC Classification | US Classification |
|---|---|--------------------------------------------------|-----------------|--------------|--------------------|-------------------|
| * | A | US-20130142875-A1                                | 06-2013         | SHEMI; Amotz | C12N15/111         | 424/484           |
| * | B | US-20090234369-A1                                | 09-2009         | Bax; Jeffrey | A61B17/3403        | 606/130           |
|   | C |                                                  |                 |              |                    |                   |
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**FOREIGN PATENT DOCUMENTS**

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**Notice of References Cited**

Part of Paper No. 20210717

|                                                                                                                    |                                              |                                                                       |
|--------------------------------------------------------------------------------------------------------------------|----------------------------------------------|-----------------------------------------------------------------------|
| <b><i>Index of Claims</i></b><br> | <b>Application/Control No.</b><br>17/314,845 | <b>Applicant(s)/Patent Under Reexamination</b><br>ALLAWAY, Matthew J. |
|                                                                                                                    | <b>Examiner</b><br>SANJAY CATTUNGAL          | <b>Art Unit</b><br>3793                                               |

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| ✓ | <b>Rejected</b> | - | <b>Cancelled</b>  | N | <b>Non-Elected</b>  | A | <b>Appeal</b>   |
| = | <b>Allowed</b>  | ÷ | <b>Restricted</b> | I | <b>Interference</b> | O | <b>Objected</b> |

| CLAIMS                                                                                 |          |            |  |  |                              |  |                               |  |                                 |  |
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| <input type="checkbox"/> Claims renumbered in the same order as presented by applicant |          |            |  |  | <input type="checkbox"/> CPA |  | <input type="checkbox"/> T.D. |  | <input type="checkbox"/> R.1.47 |  |
| CLAIM                                                                                  |          | DATE       |  |  |                              |  |                               |  |                                 |  |
| Final                                                                                  | Original | 07/17/2021 |  |  |                              |  |                               |  |                                 |  |
|                                                                                        | 1        | ✓          |  |  |                              |  |                               |  |                                 |  |
|                                                                                        | 2        | ✓          |  |  |                              |  |                               |  |                                 |  |
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|                                                                                        | 8        | ✓          |  |  |                              |  |                               |  |                                 |  |
|                                                                                        | 9        | ✓          |  |  |                              |  |                               |  |                                 |  |
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|                                                                                        | 14       | ✓          |  |  |                              |  |                               |  |                                 |  |
|                                                                                        | 15       | ✓          |  |  |                              |  |                               |  |                                 |  |
|                                                                                        | 16       | ✓          |  |  |                              |  |                               |  |                                 |  |
|                                                                                        | 17       | ✓          |  |  |                              |  |                               |  |                                 |  |
|                                                                                        | 18       | ✓          |  |  |                              |  |                               |  |                                 |  |
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|                                                                                        | 20       | ✓          |  |  |                              |  |                               |  |                                 |  |
|                                                                                        | 21       | ✓          |  |  |                              |  |                               |  |                                 |  |
|                                                                                        | 22       | ✓          |  |  |                              |  |                               |  |                                 |  |
|                                                                                        | 23       | ✓          |  |  |                              |  |                               |  |                                 |  |
|                                                                                        | 24       | ✓          |  |  |                              |  |                               |  |                                 |  |
|                                                                                        | 25       | ✓          |  |  |                              |  |                               |  |                                 |  |
|                                                                                        | 26       | ✓          |  |  |                              |  |                               |  |                                 |  |
|                                                                                        | 27       | ✓          |  |  |                              |  |                               |  |                                 |  |
|                                                                                        | 28       | ✓          |  |  |                              |  |                               |  |                                 |  |
|                                                                                        | 29       | ✓          |  |  |                              |  |                               |  |                                 |  |

|                                                                                                          |                                              |                                                                       |
|----------------------------------------------------------------------------------------------------------|----------------------------------------------|-----------------------------------------------------------------------|
| <b>Search Notes</b><br> | <b>Application/Control No.</b><br>17/314,845 | <b>Applicant(s)/Patent Under Reexamination</b><br>ALLAWAY, Matthew J. |
|                                                                                                          | <b>Examiner</b><br>SANJAY CATTUNGAL          | <b>Art Unit</b><br>3793                                               |

| CPC - Searched*                                                                                                                                                         |            |          |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|----------|
| Symbol                                                                                                                                                                  | Date       | Examiner |
| A61B90/39; A61B8/0841; A61B17/3403; A61B8/12; A61B10/0241; A61B10/04; A61B2018/00547; A61B2017/00274; A61B2010/045; A61B2017/00477; A61B18/12; A61B2017/3413; A61B18/02 | 07/17/2021 | SC       |

| CPC Combination Sets - Searched* |      |          |
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| Symbol                           | Date | Examiner |
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| US Classification - Searched* |          |      |          |
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| Class                         | Subclass | Date | Examiner |
|                               |          |      |          |

\* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

| Search Notes             |            |          |
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| Search Notes             | Date       | Examiner |
| Text and Inventor Search | 07/17/2021 | SC       |

| Interference Search |                       |      |          |
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| US Class/CPC Symbol | US Subclass/CPC Group | Date | Examiner |
|                     |                       |      |          |

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| /SANJAY CATTUNGAL/<br>Primary Examiner, Art Unit 3793 |  |
|-------------------------------------------------------|--|

## EAST Search History

### EAST Search History (Prior Art)

| Ref # | Hits | Search Query                                                                                                                                                                                                                                                                                  | DBs             | Default Operator | Plurals | Time Stamp       |
|-------|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|------------------|---------|------------------|
| S266  | 55   | (needle with (trans\$1rectal or rectal) with gauge)                                                                                                                                                                                                                                           | US-PGPUB; USPAT | OR               | ON      | 2021/07/16 18:50 |
| S265  | 1    | "15465148"                                                                                                                                                                                                                                                                                    | USPAT           | OR               | OFF     | 2021/07/16 11:08 |
| S262  | 72   | (needle with (trans\$1rectal or rectal)).clm.                                                                                                                                                                                                                                                 | US-PGPUB; USPAT | OR               | ON      | 2021/06/01 20:38 |
| S261  | 4    | S259 and rectal                                                                                                                                                                                                                                                                               | US-PGPUB; USPAT | OR               | ON      | 2021/06/01 20:31 |
| S260  | 17   | S258 S259                                                                                                                                                                                                                                                                                     | US-PGPUB; USPAT | OR               | ON      | 2021/06/01 20:31 |
| S259  | 15   | (US-0031721-\$   US-0176759-\$   US-0220444-\$   US-0221453-\$   US-0245455-\$   US-0310680-\$   US-20030176759-\$   US-20040031721-\$   US-20040220444-\$   US-20080221453-\$   US-20120245455-\$   US-20130310680-\$   US-5494039-\$   US-5931786-\$   US-52704752-\$   US-8403842-\$).DID. | US-PGPUB; USPAT | OR               | ON      | 2021/06/01 20:31 |
| S258  | 2    | "20160022309"                                                                                                                                                                                                                                                                                 | US-PGPUB; USPAT | OR               | ON      | 2021/06/01 20:31 |
| S257  | 0    | S256 and (attach\$3 with skin)                                                                                                                                                                                                                                                                | US-PGPUB; USPAT | OR               | OFF     | 2021/06/01 20:31 |
| S256  | 7    | S252 or S255                                                                                                                                                                                                                                                                                  | US-PGPUB; USPAT | OR               | OFF     | 2021/06/01 20:31 |
| S255  | 3    | S253 S254                                                                                                                                                                                                                                                                                     | US-PGPUB; USPAT | OR               | ON      | 2021/06/01 20:31 |
| S254  | 1    | "20060241477"                                                                                                                                                                                                                                                                                 | US-PGPUB; USPAT | OR               | ON      | 2021/06/01 20:31 |
| S253  | 2    | "20090093715"                                                                                                                                                                                                                                                                                 | US-PGPUB; USPAT | OR               | ON      | 2021/06/01 20:31 |
| S252  | 4    | S249 S250 S251                                                                                                                                                                                                                                                                                | US-PGPUB; USPAT | OR               | OFF     | 2021/06/01 20:31 |
| S251  | 1    | ("5494039").PN.                                                                                                                                                                                                                                                                               | USPAT; USOCR    | OR               | OFF     | 2021/06/01 20:31 |
| S250  | 1    | "20090292224"                                                                                                                                                                                                                                                                                 | US-PGPUB; USPAT | OR               | OFF     | 2021/06/01 20:31 |
| S249  | 2    | "20040167542"                                                                                                                                                                                                                                                                                 | US-PGPUB; USPAT | OR               | OFF     | 2021/06/01 20:31 |

CORBIN\_CLINICAL-001444

|      |        |                                                                                                                                                                                                                                                                                               |                    |    |     |                     |
|------|--------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|----|-----|---------------------|
| S248 | 1      | "20060241477"                                                                                                                                                                                                                                                                                 | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:31 |
| S247 | 2      | "20090093715"                                                                                                                                                                                                                                                                                 | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:31 |
| S246 | 38,106 | (A61B90/39 or A61B8/0841 or A61B8/12 or A61B10/0241 or A61B10/04 or A61B17/3403 or A61B18/02 or A61B18/12 or A61B2017/00274 or A61B2018/00547 or A61B2017/00477 or A61B2010/045 or A61B2017/3413).cpc.                                                                                        | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:31 |
| S245 | 446    | base\$1line with score with application                                                                                                                                                                                                                                                       | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:31 |
| S244 | 0      | "20140136607" and average                                                                                                                                                                                                                                                                     | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:31 |
| S243 | 0      | "20140136607" and baseline                                                                                                                                                                                                                                                                    | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:31 |
| S242 | 13     | "20030153850"                                                                                                                                                                                                                                                                                 | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:31 |
| S241 | 1      | ("5494039").PN.                                                                                                                                                                                                                                                                               | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:31 |
| S240 | 1      | ("5494039").PN.                                                                                                                                                                                                                                                                               | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:31 |
| S239 | 13     | "20030153850"                                                                                                                                                                                                                                                                                 | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:31 |
| S238 | 1,766  | (bar) and ((trans\$1rectal or rectal) WITH PROBE)                                                                                                                                                                                                                                             | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:31 |
| S237 | 2,125  | needle with (trans\$1rectal or rectal)                                                                                                                                                                                                                                                        | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:31 |
| S236 | 590    | S235 and (lower with upper)                                                                                                                                                                                                                                                                   | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:31 |
| S235 | 2,125  | needle with (trans\$1rectal or rectal)                                                                                                                                                                                                                                                        | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:31 |
| S234 | 4      | S232 and rectal                                                                                                                                                                                                                                                                               | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:31 |
| S233 | 17     | S231 S232                                                                                                                                                                                                                                                                                     | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:31 |
| S232 | 15     | (US-0031721-\$   US-0176759-\$   US-0220444-\$   US-0221453-\$   US-0245455-\$   US-0310680-\$   US-20030176759-\$   US-20040031721-\$   US-20040220444-\$   US-20080221453-\$   US-20120245455-\$   US-20130310680-\$   US-5494039-\$   US-5931786-\$   US-52704752-\$   US-8403842-\$).DID. | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:31 |

CORBIN\_CLINICAL-001445

|      |        |                                                                                                                                                                                                                          |                                                       |    |     |                     |
|------|--------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|----|-----|---------------------|
| S231 | 2      | "20160022309"                                                                                                                                                                                                            | US-PGPUB;<br>USPAT                                    | OR | ON  | 2021/06/01<br>20:31 |
| S230 | 10     | ((("ALLAWAY") near3<br>("Matthew"))).INV.                                                                                                                                                                                | US-PGPUB;<br>USPAT;<br>USOCR;<br>EPO; JPO;<br>DERWENT | OR | OFF | 2021/06/01<br>20:31 |
| S229 | 3      | S185 S186                                                                                                                                                                                                                | US-PGPUB;<br>USPAT                                    | OR | ON  | 2021/06/01<br>20:31 |
| S228 | 1      | "20060241477"                                                                                                                                                                                                            | US-PGPUB;<br>USPAT                                    | OR | ON  | 2021/06/01<br>20:31 |
| S227 | 2      | "20090093715"                                                                                                                                                                                                            | US-PGPUB;<br>USPAT                                    | OR | ON  | 2021/06/01<br>20:31 |
| S226 | 3      | (US-10743909-\$ or US-10743910-\$ or<br>US-10743911-\$).did.                                                                                                                                                             | USPAT                                                 | OR | OFF | 2021/06/01<br>20:31 |
| S225 | 15     | (bar) with ((trans\$1rectal or rectal)<br>WITH PROBE)                                                                                                                                                                    | US-PGPUB;<br>USPAT                                    | OR | ON  | 2021/06/01<br>20:31 |
| S224 | 38,106 | (A61B90/39 or A61B8/0841 or<br>A61B8/12 or A61B10/0241 or<br>A61B10/04 or A61B17/3403 or<br>A61B18/02 or A61B18/12 or<br>A61B2017/00274 or A61B2018/00547<br>or A61B2017/00477 or A61B2010/045<br>or A61B2017/3413).cpc. | US-PGPUB;<br>USPAT                                    | OR | OFF | 2021/06/01<br>20:31 |
| S223 | 2      | ((("8971995") or ("9408586"))).PN.                                                                                                                                                                                       | US-PGPUB;<br>USPAT                                    | OR | OFF | 2021/06/01<br>20:31 |
| S222 | 15     | base\$1line with rank\$3 with application<br>with user                                                                                                                                                                   | US-PGPUB;<br>USPAT                                    | OR | ON  | 2021/06/01<br>20:31 |
| S221 | 78     | base\$1line with score with application<br>with user                                                                                                                                                                     | US-PGPUB;<br>USPAT                                    | OR | ON  | 2021/06/01<br>20:31 |
| S220 | 446    | base\$1line with score with application                                                                                                                                                                                  | US-PGPUB;<br>USPAT                                    | OR | ON  | 2021/06/01<br>20:31 |
| S219 | 0      | "20140136607" and average                                                                                                                                                                                                | US-PGPUB;<br>USPAT                                    | OR | ON  | 2021/06/01<br>20:31 |
| S218 | 0      | "20140136607" and baseline                                                                                                                                                                                               | US-PGPUB;<br>USPAT                                    | OR | ON  | 2021/06/01<br>20:30 |
| S217 | 1      | "20140136607"                                                                                                                                                                                                            | US-PGPUB;<br>USPAT                                    | OR | ON  | 2021/06/01<br>20:30 |
| S216 | 14     | S214 S215                                                                                                                                                                                                                | US-PGPUB;<br>USPAT                                    | OR | ON  | 2021/06/01<br>20:30 |
| S215 | 13     | "20030153850"                                                                                                                                                                                                            | US-PGPUB;<br>USPAT                                    | OR | ON  | 2021/06/01<br>20:30 |
| S214 | 1      | ("5494039").PN.                                                                                                                                                                                                          | US-PGPUB;<br>USPAT                                    | OR | OFF | 2021/06/01<br>20:30 |

CORBIN\_CLINICAL-001446

|      |       |                                                                                                                                                                                                                             |                    |    |     |                     |
|------|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|----|-----|---------------------|
| S213 | 1     | S212 and (user near2 behavior)                                                                                                                                                                                              | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S212 | 1     | ("9326189").PN.                                                                                                                                                                                                             | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:30 |
| S211 | 14    | S209 S210                                                                                                                                                                                                                   | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S210 | 1     | ("5494039").PN.                                                                                                                                                                                                             | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:30 |
| S209 | 13    | "20030153850"                                                                                                                                                                                                               | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S208 | 307   | needle with (trans\$1rectal or rectal)<br>with probe                                                                                                                                                                        | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S207 | 1,766 | (bar) and ((trans\$1rectal or rectal)<br>WITH PROBE)                                                                                                                                                                        | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S206 | 1     | ((stable or stablization) near2 bar) and<br>((trans\$1rectal or rectal) WITH PROBE)                                                                                                                                         | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S205 | 2     | "20140059703"                                                                                                                                                                                                               | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S204 | 93    | S202 and ((holder) with needle)                                                                                                                                                                                             | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S203 | 28    | S202 and ((mount) with needle)                                                                                                                                                                                              | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S202 | 2,125 | needle with (trans\$1rectal or rectal)                                                                                                                                                                                      | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S201 | 25    | S199 and ((lower with upper) with<br>needle)                                                                                                                                                                                | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S200 | 590   | S199 and (lower with upper)                                                                                                                                                                                                 | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S199 | 2,125 | needle with (trans\$1rectal or rectal)                                                                                                                                                                                      | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S198 | 7     | S194 and (trans\$1rectal or rectal)                                                                                                                                                                                         | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S197 | 4     | S194 and rectal                                                                                                                                                                                                             | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S196 | 10    | "14677286"                                                                                                                                                                                                                  | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S195 | 17    | S193 S194                                                                                                                                                                                                                   | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S194 | 15    | (US-0031721-\$   US-0176759-\$   US-<br>0220444-\$   US-0221453-\$   US-<br>0245455-\$   US-0310680-\$   US-<br>20030176759-\$   US-20040031721-\$  <br>US-20040220444-\$   US-20080221453-<br>\$   US-20120245455-\$   US- | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |

CORBIN\_CLINICAL-001447

|      |    |                                                                                                                                                                                                                                                                                         |                    |    |     |                     |
|------|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|----|-----|---------------------|
|      |    | 20130310680-\$   US-5494039-\$   US-5931786-\$   US-52704752-\$   US-8403842-\$).DID.                                                                                                                                                                                                   |                    |    |     |                     |
| S193 | 2  | "20160022309"                                                                                                                                                                                                                                                                           | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S192 | 4  | S191 and (attach\$3 with (body or patient or subject))                                                                                                                                                                                                                                  | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:30 |
| S191 | 13 | (US-20150366544-\$ or US-20150119715-\$ or US-20140039314-\$ or US-20110319759-\$ or US-20110071380-\$ or US-20090030339-\$ or US-20080004481-\$ or US-20120245455-\$ or US-20050159676-\$ or US-20070043291-\$ or US-20040162458-\$ or US-20030153850-\$).did. or (US-5494039-\$).did. | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:30 |
| S190 | 1  | S188 and (attach\$3 with (body or patient or subject))                                                                                                                                                                                                                                  | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:30 |
| S189 | 0  | S188 and (attach\$3 with skin)                                                                                                                                                                                                                                                          | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:30 |
| S188 | 7  | S184 or S187                                                                                                                                                                                                                                                                            | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:30 |
| S187 | 3  | S185 S186                                                                                                                                                                                                                                                                               | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S186 | 1  | "20060241477"                                                                                                                                                                                                                                                                           | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S185 | 2  | "20090093715"                                                                                                                                                                                                                                                                           | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S184 | 4  | S181 S182 S183                                                                                                                                                                                                                                                                          | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:30 |
| S183 | 1  | ("5494039").PN.                                                                                                                                                                                                                                                                         | USPAT;<br>USOCR    | OR | OFF | 2021/06/01<br>20:30 |
| S182 | 1  | "20090292224"                                                                                                                                                                                                                                                                           | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:30 |
| S181 | 2  | "20040167542"                                                                                                                                                                                                                                                                           | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:30 |
| S180 | 3  | S178 S179                                                                                                                                                                                                                                                                               | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S179 | 1  | "20060241477"                                                                                                                                                                                                                                                                           | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S178 | 2  | "20090093715"                                                                                                                                                                                                                                                                           | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S177 | 3  | (US-10743909-\$ or US-10743910-\$ or US-10743911-\$).did.                                                                                                                                                                                                                               | USPAT              | OR | OFF | 2021/06/01<br>20:30 |

CORBIN\_CLINICAL-001448

|      |        |                                                                                                                                                                                                        |                    |    |     |                     |
|------|--------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|----|-----|---------------------|
| S176 | 15     | (bar) with ((trans\$1rectal or rectal) WITH PROBE)                                                                                                                                                     | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S175 | 38,106 | (A61B90/39 or A61B8/0841 or A61B8/12 or A61B10/0241 or A61B10/04 or A61B17/3403 or A61B18/02 or A61B18/12 or A61B2017/00274 or A61B2018/00547 or A61B2017/00477 or A61B2010/045 or A61B2017/3413).cpc. | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:30 |
| S174 | 2      | ((("8971995") or ("9408586"))).PN.                                                                                                                                                                     | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:30 |
| S173 | 15     | base\$1line with rank\$3 with application with user                                                                                                                                                    | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S172 | 78     | base\$1line with score with application with user                                                                                                                                                      | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S171 | 446    | base\$1line with score with application                                                                                                                                                                | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S170 | 0      | "20140136607" and average                                                                                                                                                                              | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S169 | 0      | "20140136607" and baseline                                                                                                                                                                             | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S168 | 1      | "20140136607"                                                                                                                                                                                          | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S167 | 14     | S165 S166                                                                                                                                                                                              | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S166 | 13     | "20030153850"                                                                                                                                                                                          | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S165 | 1      | ("5494039").PN.                                                                                                                                                                                        | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:30 |
| S164 | 1      | S163 and (user near2 behavior)                                                                                                                                                                         | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S163 | 1      | ("9326189").PN.                                                                                                                                                                                        | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:30 |
| S162 | 14     | S160 S161                                                                                                                                                                                              | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S161 | 1      | ("5494039").PN.                                                                                                                                                                                        | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:30 |
| S160 | 13     | "20030153850"                                                                                                                                                                                          | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S159 | 307    | needle with (trans\$1rectal or rectal) with probe                                                                                                                                                      | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |
| S158 | 1,766  | (bar) and ((trans\$1rectal or rectal) WITH PROBE)                                                                                                                                                      | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:30 |

|      |       |                                                                                                                                                                                                                                                                                               |                 |    |    |                  |
|------|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|----|----|------------------|
| S157 | 1     | ((stable or stablization) near2 bar) and ((trans\$1rectal or rectal) WITH PROBE)                                                                                                                                                                                                              | US-PGPUB; USPAT | OR | ON | 2021/06/01 20:30 |
| S156 | 2     | "20140059703"                                                                                                                                                                                                                                                                                 | US-PGPUB; USPAT | OR | ON | 2021/06/01 20:30 |
| S155 | 93    | S153 and ((holder) with needle)                                                                                                                                                                                                                                                               | US-PGPUB; USPAT | OR | ON | 2021/06/01 20:30 |
| S154 | 28    | S153 and ((mount) with needle)                                                                                                                                                                                                                                                                | US-PGPUB; USPAT | OR | ON | 2021/06/01 20:30 |
| S153 | 2,125 | needle with (trans\$1rectal or rectal)                                                                                                                                                                                                                                                        | US-PGPUB; USPAT | OR | ON | 2021/06/01 20:30 |
| S152 | 25    | S150 and ((lower with upper) with needle)                                                                                                                                                                                                                                                     | US-PGPUB; USPAT | OR | ON | 2021/06/01 20:30 |
| S151 | 590   | S150 and (lower with upper)                                                                                                                                                                                                                                                                   | US-PGPUB; USPAT | OR | ON | 2021/06/01 20:30 |
| S150 | 2,125 | needle with (trans\$1rectal or rectal)                                                                                                                                                                                                                                                        | US-PGPUB; USPAT | OR | ON | 2021/06/01 20:30 |
| S149 | 7     | S145 and (trans\$1rectal or rectal)                                                                                                                                                                                                                                                           | US-PGPUB; USPAT | OR | ON | 2021/06/01 20:30 |
| S148 | 4     | S145 and rectal                                                                                                                                                                                                                                                                               | US-PGPUB; USPAT | OR | ON | 2021/06/01 20:30 |
| S147 | 10    | "14677286"                                                                                                                                                                                                                                                                                    | US-PGPUB; USPAT | OR | ON | 2021/06/01 20:30 |
| S146 | 17    | S144 S145                                                                                                                                                                                                                                                                                     | US-PGPUB; USPAT | OR | ON | 2021/06/01 20:30 |
| S145 | 15    | (US-0031721-\$   US-0176759-\$   US-0220444-\$   US-0221453-\$   US-0245455-\$   US-0310680-\$   US-20030176759-\$   US-20040031721-\$   US-20040220444-\$   US-20080221453-\$   US-20120245455-\$   US-20130310680-\$   US-5494039-\$   US-5931786-\$   US-52704752-\$   US-8403842-\$).DID. | US-PGPUB; USPAT | OR | ON | 2021/06/01 20:30 |
| S144 | 2     | "20160022309"                                                                                                                                                                                                                                                                                 | US-PGPUB; USPAT | OR | ON | 2021/06/01 20:30 |
| S141 | 4     | S138 and rectal                                                                                                                                                                                                                                                                               | US-PGPUB; USPAT | OR | ON | 2021/06/01 20:27 |
| S139 | 17    | S137 S138                                                                                                                                                                                                                                                                                     | US-PGPUB; USPAT | OR | ON | 2021/06/01 20:27 |
| S138 | 15    | (US-0031721-\$   US-0176759-\$   US-0220444-\$   US-0221453-\$   US-0245455-\$   US-0310680-\$   US-20030176759-\$   US-20040031721-\$   US-20040220444-\$   US-20080221453-\$   US-20120245455-\$   US-20130310680-\$   US-5494039-\$   US-                                                  | US-PGPUB; USPAT | OR | ON | 2021/06/01 20:27 |

CORBIN\_CLINICAL-001450

|      |        |                                                                                                                                                                                                        |                    |    |     |                     |
|------|--------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|----|-----|---------------------|
|      |        | 5931786-\$   US-52704752-\$   US-8403842-\$).DID.                                                                                                                                                      |                    |    |     |                     |
| S137 | 2      | "20160022309"                                                                                                                                                                                          | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:27 |
| S133 | 0      | S132 and (attach\$3 with skin)                                                                                                                                                                         | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:27 |
| S131 | 3      | S129 S130                                                                                                                                                                                              | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:27 |
| S130 | 1      | "20060241477"                                                                                                                                                                                          | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:27 |
| S129 | 2      | "20090093715"                                                                                                                                                                                          | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:27 |
| S128 | 4      | S125 S126 S127                                                                                                                                                                                         | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:27 |
| S126 | 1      | "20090292224"                                                                                                                                                                                          | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:27 |
| S125 | 2      | "20040167542"                                                                                                                                                                                          | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:27 |
| S123 | 1      | "20060241477"                                                                                                                                                                                          | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:27 |
| S122 | 2      | "20090093715"                                                                                                                                                                                          | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:27 |
| S119 | 38,106 | (A61B90/39 or A61B8/0841 or A61B8/12 or A61B10/0241 or A61B10/04 or A61B17/3403 or A61B18/02 or A61B18/12 or A61B2017/00274 or A61B2018/00547 or A61B2017/00477 or A61B2010/045 or A61B2017/3413).cpc. | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:27 |
| S115 | 446    | base\$1line with score with application                                                                                                                                                                | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:27 |
| S114 | 0      | "20140136607" and average                                                                                                                                                                              | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:27 |
| S113 | 0      | "20140136607" and baseline                                                                                                                                                                             | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:27 |
| S110 | 13     | "20030153850"                                                                                                                                                                                          | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:27 |
| S109 | 1      | ("5494039").PN.                                                                                                                                                                                        | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:27 |
| S105 | 1      | ("5494039").PN.                                                                                                                                                                                        | US-PGPUB;<br>USPAT | OR | OFF | 2021/06/01<br>20:27 |
| S104 | 13     | "20030153850"                                                                                                                                                                                          | US-PGPUB;<br>USPAT | OR | ON  | 2021/06/01<br>20:27 |

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|      |        |                                                                                                                                                                                                                                                                                               |                                           |    |     |                  |
|------|--------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|----|-----|------------------|
| S102 | 1,766  | (bar) and ((trans\$1rectal or rectal) WITH PROBE)                                                                                                                                                                                                                                             | US-PGPUB; USPAT                           | OR | ON  | 2021/06/01 20:27 |
| S97  | 2,125  | needle with (trans\$1rectal or rectal)                                                                                                                                                                                                                                                        | US-PGPUB; USPAT                           | OR | ON  | 2021/06/01 20:27 |
| S95  | 590    | S94 and (lower with upper)                                                                                                                                                                                                                                                                    | US-PGPUB; USPAT                           | OR | ON  | 2021/06/01 20:27 |
| S94  | 2,125  | needle with (trans\$1rectal or rectal)                                                                                                                                                                                                                                                        | US-PGPUB; USPAT                           | OR | ON  | 2021/06/01 20:27 |
| S92  | 4      | S89 and rectal                                                                                                                                                                                                                                                                                | US-PGPUB; USPAT                           | OR | ON  | 2021/06/01 20:27 |
| S90  | 17     | S88 S89                                                                                                                                                                                                                                                                                       | US-PGPUB; USPAT                           | OR | ON  | 2021/06/01 20:27 |
| S89  | 15     | (US-0031721-\$   US-0176759-\$   US-0220444-\$   US-0221453-\$   US-0245455-\$   US-0310680-\$   US-20030176759-\$   US-20040031721-\$   US-20040220444-\$   US-20080221453-\$   US-20120245455-\$   US-20130310680-\$   US-5494039-\$   US-5931786-\$   US-52704752-\$   US-8403842-\$).DID. | US-PGPUB; USPAT                           | OR | ON  | 2021/06/01 20:27 |
| S88  | 2      | "20160022309"                                                                                                                                                                                                                                                                                 | US-PGPUB; USPAT                           | OR | ON  | 2021/06/01 20:27 |
| S87  | 10     | ((("ALLAWAY") near3 ("Matthew"))).INV.                                                                                                                                                                                                                                                        | US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT | OR | OFF | 2021/04/10 17:58 |
| S86  | 3      | S42 S43                                                                                                                                                                                                                                                                                       | US-PGPUB; USPAT                           | OR | ON  | 2021/04/10 17:38 |
| S85  | 1      | "20060241477"                                                                                                                                                                                                                                                                                 | US-PGPUB; USPAT                           | OR | ON  | 2021/04/10 17:38 |
| S84  | 2      | "20090093715"                                                                                                                                                                                                                                                                                 | US-PGPUB; USPAT                           | OR | ON  | 2021/04/10 17:38 |
| S83  | 3      | (US-10743909-\$ or US-10743910-\$ or US-10743911-\$).did.                                                                                                                                                                                                                                     | USPAT                                     | OR | OFF | 2021/04/10 17:38 |
| S82  | 15     | (bar) with ((trans\$1rectal or rectal) WITH PROBE)                                                                                                                                                                                                                                            | US-PGPUB; USPAT                           | OR | ON  | 2021/04/10 17:38 |
| S81  | 37,593 | (A61B90/39 or A61B8/0841 or A61B8/12 or A61B10/0241 or A61B10/04 or A61B17/3403 or A61B18/02 or A61B18/12 or A61B2017/00274 or A61B2018/00547 or A61B2017/00477 or A61B2010/045 or A61B2017/3413).cpc.                                                                                        | US-PGPUB; USPAT                           | OR | OFF | 2021/04/10 17:38 |

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|     |       |                                                                                     |                    |    |     |                     |
|-----|-------|-------------------------------------------------------------------------------------|--------------------|----|-----|---------------------|
| S80 | 2     | ((("8971995") or ("9408586"))).PN.                                                  | US-PGPUB;<br>USPAT | OR | OFF | 2021/04/10<br>17:38 |
| S79 | 15    | base\$1line with rank\$3 with application<br>with user                              | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>17:38 |
| S78 | 76    | base\$1line with score with application<br>with user                                | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>17:38 |
| S77 | 437   | base\$1line with score with application                                             | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>17:38 |
| S76 | 0     | "20140136607" and average                                                           | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>17:38 |
| S75 | 0     | "20140136607" and baseline                                                          | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>17:38 |
| S74 | 1     | "20140136607"                                                                       | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>17:38 |
| S73 | 14    | S71 S72                                                                             | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>17:38 |
| S72 | 13    | "20030153850"                                                                       | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>17:38 |
| S71 | 1     | ("5494039").PN.                                                                     | US-PGPUB;<br>USPAT | OR | OFF | 2021/04/10<br>17:38 |
| S70 | 1     | S69 and (user near2 behavior)                                                       | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>17:38 |
| S69 | 1     | ("9326189").PN.                                                                     | US-PGPUB;<br>USPAT | OR | OFF | 2021/04/10<br>17:38 |
| S68 | 14    | S66 S67                                                                             | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>17:38 |
| S67 | 1     | ("5494039").PN.                                                                     | US-PGPUB;<br>USPAT | OR | OFF | 2021/04/10<br>17:38 |
| S66 | 13    | "20030153850"                                                                       | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>17:38 |
| S65 | 303   | needle with (trans\$1rectal or rectal)<br>with probe                                | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>17:38 |
| S64 | 1,752 | (bar) and ((trans\$1rectal or rectal)<br>WITH PROBE)                                | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>17:38 |
| S63 | 1     | ((stable or stablization) near2 bar) and<br>((trans\$1rectal or rectal) WITH PROBE) | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>17:38 |
| S62 | 2     | "20140059703"                                                                       | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>17:38 |
| S61 | 93    | S59 and ((holder) with needle)                                                      | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>17:38 |
| S60 | 28    | S59 and ((mount) with needle)                                                       | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>17:38 |
| S59 | 2,107 | needle with (trans\$1rectal or rectal)                                              | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>17:38 |

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|     |       |                                                                                                                                                                                                                                                                                               |                 |    |     |                  |
|-----|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|----|-----|------------------|
| S58 | 25    | S56 and ((lower with upper) with needle)                                                                                                                                                                                                                                                      | US-PGPUB; USPAT | OR | ON  | 2021/04/10 17:38 |
| S57 | 582   | S56 and (lower with upper)                                                                                                                                                                                                                                                                    | US-PGPUB; USPAT | OR | ON  | 2021/04/10 17:38 |
| S56 | 2,107 | needle with (trans\$1rectal or rectal)                                                                                                                                                                                                                                                        | US-PGPUB; USPAT | OR | ON  | 2021/04/10 17:38 |
| S55 | 7     | S51 and (trans\$1rectal or rectal)                                                                                                                                                                                                                                                            | US-PGPUB; USPAT | OR | ON  | 2021/04/10 17:38 |
| S54 | 4     | S51 and rectal                                                                                                                                                                                                                                                                                | US-PGPUB; USPAT | OR | ON  | 2021/04/10 17:38 |
| S53 | 10    | "14677286"                                                                                                                                                                                                                                                                                    | US-PGPUB; USPAT | OR | ON  | 2021/04/10 17:38 |
| S52 | 17    | S50 S51                                                                                                                                                                                                                                                                                       | US-PGPUB; USPAT | OR | ON  | 2021/04/10 17:38 |
| S51 | 15    | (US-0031721-\$   US-0176759-\$   US-0220444-\$   US-0221453-\$   US-0245455-\$   US-0310680-\$   US-20030176759-\$   US-20040031721-\$   US-20040220444-\$   US-20080221453-\$   US-20120245455-\$   US-20130310680-\$   US-5494039-\$   US-5931786-\$   US-52704752-\$   US-8403842-\$).DID. | US-PGPUB; USPAT | OR | ON  | 2021/04/10 17:38 |
| S50 | 2     | "20160022309"                                                                                                                                                                                                                                                                                 | US-PGPUB; USPAT | OR | ON  | 2021/04/10 17:38 |
| S49 | 4     | S48 and (attach\$3 with (body or patient or subject))                                                                                                                                                                                                                                         | US-PGPUB; USPAT | OR | OFF | 2021/04/10 17:11 |
| S48 | 13    | (US-20150366544-\$ or US-20150119715-\$ or US-20140039314-\$ or US-20110319759-\$ or US-20110071380-\$ or US-20090030339-\$ or US-20080004481-\$ or US-20120245455-\$ or US-20050159676-\$ or US-20070043291-\$ or US-20040162458-\$ or US-20030153850-\$).did. or (US-5494039-\$).did.       | US-PGPUB; USPAT | OR | OFF | 2021/04/10 17:11 |
| S47 | 1     | S45 and (attach\$3 with (body or patient or subject))                                                                                                                                                                                                                                         | US-PGPUB; USPAT | OR | OFF | 2021/04/10 17:06 |
| S46 | 0     | S45 and (attach\$3 with skin)                                                                                                                                                                                                                                                                 | US-PGPUB; USPAT | OR | OFF | 2021/04/10 17:06 |
| S45 | 7     | S41 or S44                                                                                                                                                                                                                                                                                    | US-PGPUB; USPAT | OR | OFF | 2021/04/10 16:56 |
| S44 | 3     | S42 S43                                                                                                                                                                                                                                                                                       | US-PGPUB; USPAT | OR | ON  | 2021/04/10 16:56 |
| S43 | 1     | "20060241477"                                                                                                                                                                                                                                                                                 | US-PGPUB; USPAT | OR | ON  | 2021/04/10 16:56 |

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|     |        |                                                                                                                                                                                                                          |                    |    |     |                     |
|-----|--------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|----|-----|---------------------|
| S42 | 2      | "20090093715"                                                                                                                                                                                                            | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>16:56 |
| S41 | 4      | S38 S39 S40                                                                                                                                                                                                              | US-PGPUB;<br>USPAT | OR | OFF | 2021/04/10<br>16:56 |
| S40 | 1      | ("5494039").PN.                                                                                                                                                                                                          | USPAT;<br>USOCR    | OR | OFF | 2021/04/10<br>16:55 |
| S39 | 1      | "20090292224"                                                                                                                                                                                                            | US-PGPUB;<br>USPAT | OR | OFF | 2021/04/10<br>16:55 |
| S38 | 2      | "20040167542"                                                                                                                                                                                                            | US-PGPUB;<br>USPAT | OR | OFF | 2021/04/10<br>16:55 |
| S37 | 3      | S35 S36                                                                                                                                                                                                                  | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>13:58 |
| S36 | 1      | "20060241477"                                                                                                                                                                                                            | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>13:58 |
| S35 | 2      | "20090093715"                                                                                                                                                                                                            | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>13:58 |
| S34 | 3      | (US-10743909-\$ or US-10743910-\$ or<br>US-10743911-\$).did.                                                                                                                                                             | USPAT              | OR | OFF | 2021/04/10<br>13:58 |
| S33 | 15     | (bar) with ((trans\$1rectal or rectal)<br>WITH PROBE)                                                                                                                                                                    | US-PGPUB;<br>USPAT | OR | ON  | 2021/04/10<br>12:11 |
| S32 | 37,593 | (A61B90/39 or A61B8/0841 or<br>A61B8/12 or A61B10/0241 or<br>A61B10/04 or A61B17/3403 or<br>A61B18/02 or A61B18/12 or<br>A61B2017/00274 or A61B2018/00547<br>or A61B2017/00477 or A61B2010/045<br>or A61B2017/3413).cpc. | US-PGPUB;<br>USPAT | OR | OFF | 2021/04/10<br>12:11 |
| S31 | 2      | ((("8971995") or ("9408586"))).PN.                                                                                                                                                                                       | US-PGPUB;<br>USPAT | OR | OFF | 2018/03/26<br>21:57 |
| S30 | 9      | base\$1line with rank\$3 with application<br>with user                                                                                                                                                                   | US-PGPUB;<br>USPAT | OR | ON  | 2018/03/26<br>20:06 |
| S29 | 32     | base\$1line with score with application<br>with user                                                                                                                                                                     | US-PGPUB;<br>USPAT | OR | ON  | 2018/03/26<br>19:53 |
| S28 | 246    | base\$1line with score with application                                                                                                                                                                                  | US-PGPUB;<br>USPAT | OR | ON  | 2018/03/26<br>19:53 |
| S27 | 0      | "20140136607" and average                                                                                                                                                                                                | US-PGPUB;<br>USPAT | OR | ON  | 2018/03/26<br>19:52 |
| S26 | 0      | "20140136607" and baseline                                                                                                                                                                                               | US-PGPUB;<br>USPAT | OR | ON  | 2018/03/26<br>19:52 |
| S25 | 1      | "20140136607"                                                                                                                                                                                                            | US-PGPUB;<br>USPAT | OR | ON  | 2018/03/26<br>19:51 |
| S24 | 6      | S22 S23                                                                                                                                                                                                                  | US-PGPUB;<br>USPAT | OR | ON  | 2018/03/26<br>16:19 |

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|     |       |                                                                                     |                    |    |     |                     |
|-----|-------|-------------------------------------------------------------------------------------|--------------------|----|-----|---------------------|
| S23 | 5     | "20030153850"                                                                       | US-PGPUB;<br>USPAT | OR | ON  | 2018/03/26<br>16:08 |
| S22 | 1     | ("5494039").PN.                                                                     | US-PGPUB;<br>USPAT | OR | OFF | 2018/03/26<br>16:08 |
| S21 | 1     | S20 and (user near2 behavior)                                                       | US-PGPUB;<br>USPAT | OR | ON  | 2018/03/26<br>13:15 |
| S20 | 1     | ("9326189").PN.                                                                     | US-PGPUB;<br>USPAT | OR | OFF | 2018/03/26<br>13:14 |
| S19 | 6     | S17 S18                                                                             | US-PGPUB;<br>USPAT | OR | ON  | 2018/02/11<br>00:03 |
| S18 | 1     | ("5494039").PN.                                                                     | US-PGPUB;<br>USPAT | OR | OFF | 2018/02/11<br>00:03 |
| S17 | 5     | "20030153850"                                                                       | US-PGPUB;<br>USPAT | OR | ON  | 2018/02/10<br>23:41 |
| S16 | 243   | needle with (trans\$1rectal or rectal)<br>with probe                                | US-PGPUB;<br>USPAT | OR | ON  | 2017/10/02<br>01:34 |
| S15 | 1,377 | (bar) and ((trans\$1rectal or rectal)<br>WITH PROBE)                                | US-PGPUB;<br>USPAT | OR | ON  | 2017/10/02<br>01:27 |
| S14 | 1     | ((stable or stablization) near2 bar) and<br>((trans\$1rectal or rectal) WITH PROBE) | US-PGPUB;<br>USPAT | OR | ON  | 2017/10/02<br>01:25 |
| S13 | 2     | "20140059703"                                                                       | US-PGPUB;<br>USPAT | OR | ON  | 2017/09/28<br>13:20 |
| S12 | 64    | S10 and ((holder) with needle)                                                      | US-PGPUB;<br>USPAT | OR | ON  | 2017/09/28<br>11:10 |
| S11 | 13    | S10 and ((mount) with needle)                                                       | US-PGPUB;<br>USPAT | OR | ON  | 2017/09/28<br>11:02 |
| S10 | 1,623 | needle with (trans\$1rectal or rectal)                                              | US-PGPUB;<br>USPAT | OR | ON  | 2017/09/28<br>11:02 |
| S9  | 9     | S7 and ((lower with upper) with needle)                                             | US-PGPUB;<br>USPAT | OR | ON  | 2017/09/28<br>02:12 |
| S8  | 416   | S7 and (lower with upper)                                                           | US-PGPUB;<br>USPAT | OR | ON  | 2017/09/28<br>01:56 |
| S7  | 1,623 | needle with (trans\$1rectal or rectal)                                              | US-PGPUB;<br>USPAT | OR | ON  | 2017/09/28<br>01:52 |
| S6  | 7     | S2 and (trans\$1rectal or rectal)                                                   | US-PGPUB;<br>USPAT | OR | ON  | 2017/09/28<br>01:40 |
| S5  | 4     | S2 and rectal                                                                       | US-PGPUB;<br>USPAT | OR | ON  | 2017/09/28<br>01:40 |
| S4  | 2     | "14677286"                                                                          | US-PGPUB;<br>USPAT | OR | ON  | 2017/09/28<br>01:20 |
| S3  | 16    | S1 S2                                                                               | US-PGPUB;<br>USPAT | OR | ON  | 2017/09/28<br>01:05 |
| S2  | 15    | (US-0031721-\$   US-0176759-\$   US-<br>0220444-\$   US-0221453-\$   US-            | US-PGPUB;<br>USPAT | OR | ON  | 2017/09/28<br>01:04 |

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|    |   |                                                                                                                                                                                                                           |                    |    |    |                     |
|----|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|----|----|---------------------|
|    |   | 0245455-\$   US-0310680-\$   US-20030176759-\$   US-20040031721-\$   US-20040220444-\$   US-20080221453-\$   US-20120245455-\$   US-20130310680-\$   US-5494039-\$   US-5931786-\$   US-52704752-\$   US-8403842-\$).DID. |                    |    |    |                     |
| S1 | 1 | "20160022309"                                                                                                                                                                                                             | US-PGPUB;<br>USPAT | OR | ON | 2017/09/28<br>01:01 |

#### EAST Search History (Interference)

| Ref # | Hits   | Search Query                                                                                                                                                                                           | DBs   | Default Operator | Plurals | Time Stamp          |
|-------|--------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|------------------|---------|---------------------|
| S264  | 12     | (needle with (trans\$1rectal or rectal)).clm. and S263                                                                                                                                                 | USPAT | OR               | ON      | 2021/06/01<br>20:39 |
| S263  | 15,959 | (A61B90/39 or A61B8/0841 or A61B8/12 or A61B10/0241 or A61B10/04 or A61B17/3403 or A61B18/02 or A61B18/12 or A61B2017/00274 or A61B2018/00547 or A61B2017/00477 or A61B2010/045 or A61B2017/3413).cpc. | USPAT | OR               | OFF     | 2021/06/01<br>20:33 |

7/17/2021 7:21:58 PM

C:\Users\scattungal\Documents\EAST\Workspaces\17314845.wsp

CORBIN\_CLINICAL-001457

## Bibliographic Data

Application No: 17/314,845

Foreign Priority claimed: ☐ Yes ☒ No

35 USC 119 (a-d) conditions met: ☐ Yes ☒ No ☐ Met After Allowance

Verified and Acknowledged:

/SANJAY CATTUNGAL/

Examiner's Signature

Initials

Title:

METHOD, SYSTEM, AND DEVICE FOR PLANNING AND  
PERFORMING GUIDED AND FREE-HANDED TRANSPERINEAL  
PROSTATE BIOPSIES

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| FILING or 371(c) DATE | CLASS | GROUP ART UNIT | ATTORNEY DOCKET NO. |
|-----------------------|-------|----------------|---------------------|
| 05/07/2021            | 600   | 3793           | 083003-620553       |
| RULE                  |       |                |                     |

### APPLICANTS

Corbin Clinical Resources, LLC, Cumberland, MD,

### INVENTORS

Matthew J. ALLAWAY, Cumberland, MD, UNITED STATES

### CONTINUING DATA

This application is a CON of 16115180 08/28/2018

16115180 is a CON of 14677286 04/02/2015 PAT 10064681

14677286 has PRO of 61974826 04/03/2014

### FOREIGN APPLICATIONS

#### IF REQUIRED, FOREIGN LICENSE GRANTED\*\*

05/14/2021

\*\* SMALL ENTITY \*\*

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Advance Medical Designs, Inc. - EX1020

Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041

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|-------------|----------|---------------|---------------------|
| 17314845    | CTNF     | 07/22/2021    | 083003-620553       |
|             | 892      | 07/22/2021    | 083003-620553       |

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**Cc:** PAIR\_eOfficeAction@uspto.gov  
**Subject:** Private PAIR Correspondence Notification for Customer Number 24030

Jun 26, 2021 09:46:11 AM

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SUITE 900  
KANSAS CITY, MO 64112-1895  
UNITED STATES

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| Application | Document     | Mailroom Date | Attorney Docket No. |
|-------------|--------------|---------------|---------------------|
| 17314845    | TRACK1.GRANT | 06/25/2021    | 083003-620553       |

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United States Patent and Trademark Office  
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P.O. Box 1450  
Alexandria, Virginia 22313-1450  
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| APPLICATION NO.                                                                  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 17/314,845                                                                       | 05/07/2021  | Matthew J. ALLAWAY   | 083003-620553       | 1007             |
| 24030                                                                            | 7590        | 06/25/2021           | EXAMINER            |                  |
| POL SINELLI PC<br>900 WEST 48TH PLACE<br>SUITE 900<br>KANSAS CITY, MO 64112-1895 |             |                      | ART UNIT            | PAPER NUMBER     |
|                                                                                  |             |                      | 3793                |                  |
|                                                                                  |             |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|                                                                                  |             |                      | 06/25/2021          | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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uspt@polsinelli.com

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                      |                                            |                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------------------------------|---------------------------------|
| <b><i>Decision Granting Request for Prioritized Examination (Track I)</i></b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <b>Application No.</b><br>17/314,845 | <b>Applicant(s)</b><br>ALLAWAY, Matthew J. |                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Examiner</b><br>DIANE C GOODWYN   | <b>Art Unit</b><br>OPET                    | <b>AIA (FITF) Status</b><br>Yes |
| <p>1. THE REQUEST FILED <u>07 May 2021</u> IS <b>GRANTED</b> .</p> <p>The above-identified application has met the requirements for prioritized examination</p> <p>A. <input checked="" type="checkbox"/> for an original nonprovisional application (Track I).</p> <p>B. <input type="checkbox"/> for an application undergoing continued examination (RCE).</p> <p>2. <b>The above-identified application will undergo prioritized examination.</b> The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:</p> <p>A. filing a <b><u>petition for extension of time</u></b> to extend the time period for filing a reply;</p> <p>B. filing an <b><u>amendment to amend the application to contain more than four independent claims, more than thirty total claims</u></b>, or a multiple dependent claim;</p> <p>C. filing a <b><u>request for continued examination</u></b> ;</p> <p>D. filing a notice of appeal;</p> <p>E. filing a request for suspension of action;</p> <p>F. mailing of a notice of allowance;</p> <p>G. mailing of a final Office action;</p> <p>H. completion of examination as defined in 37 CFR 41.102; or</p> <p>I. abandonment of the application.</p> <p>Telephone inquiries with regard to this decision should be directed to DIANE GOODWYN at (571) 272-6735. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.</p> |                                      |                                            |                                 |
| /DIANE C GOODWYN/<br>Paralegal Specialist, OPET                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                      |                                            |                                 |

U.S. Patent and Trademark Office  
PTO-2298 (Rev. 02-2012)

| <b>PATENT APPLICATION FEE DETERMINATION RECORD</b><br>Substitute for Form PTO-875                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                               |                                  |            |                                    |               | Application or Docket Number<br>17/314,845 |                    |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|------------|------------------------------------|---------------|--------------------------------------------|--------------------|
| <b>APPLICATION AS FILED - PART I</b>                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                               |                                  |            |                                    |               |                                            |                    |
| (Column 1)                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                               | (Column 2)                       |            | SMALL ENTITY                       |               | OTHER THAN SMALL ENTITY                    |                    |
| FOR                                                                                                                                                                                                                                                                                                                                                                                                        | NUMBER FILED                                                                                                                                                                                                                  | NUMBER EXTRA                     | RATE(\$)   | FEE(\$)                            |               | RATE(\$)                                   | FEE(\$)            |
| BASIC FEE<br><small>(37 CFR 1.16(a), (b), or (c))</small>                                                                                                                                                                                                                                                                                                                                                  | N/A                                                                                                                                                                                                                           | N/A                              | N/A        | 80                                 |               | N/A                                        |                    |
| SEARCH FEE<br><small>(37 CFR 1.16(k), (l), or (m))</small>                                                                                                                                                                                                                                                                                                                                                 | N/A                                                                                                                                                                                                                           | N/A                              | N/A        | 350                                |               | N/A                                        |                    |
| EXAMINATION FEE<br><small>(37 CFR 1.16(o), (p), or (q))</small>                                                                                                                                                                                                                                                                                                                                            | N/A                                                                                                                                                                                                                           | N/A                              | N/A        | 400                                |               | N/A                                        |                    |
| TOTAL CLAIMS<br><small>(37 CFR 1.16(j))</small>                                                                                                                                                                                                                                                                                                                                                            | 29                                                                                                                                                                                                                            | minus 20 = 9                     | x 50 =     | 450                                | OR            |                                            |                    |
| INDEPENDENT CLAIMS<br><small>(37 CFR 1.16(h))</small>                                                                                                                                                                                                                                                                                                                                                      | 3                                                                                                                                                                                                                             | minus 3 =                        | x 240 =    | 0.00                               |               |                                            |                    |
| APPLICATION SIZE FEE<br><small>(37 CFR 1.16(s))</small>                                                                                                                                                                                                                                                                                                                                                    | If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s). |                                  |            | 0.00                               |               |                                            |                    |
| MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                               |                                  |            | 0.00                               |               |                                            |                    |
| * If the difference in column 1 is less than zero, enter "0" in column 2.                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                               |                                  | TOTAL      | 1280                               |               | TOTAL                                      |                    |
| <b>APPLICATION AS AMENDED - PART II</b>                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                               |                                  |            |                                    |               |                                            |                    |
| AMENDMENT A                                                                                                                                                                                                                                                                                                                                                                                                | (Column 1)                                                                                                                                                                                                                    |                                  | (Column 2) |                                    | (Column 3)    |                                            | SMALL ENTITY       |
|                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                               | CLAIMS REMAINING AFTER AMENDMENT |            | HIGHEST NUMBER PREVIOUSLY PAID FOR | PRESENT EXTRA |                                            | RATE(\$)           |
|                                                                                                                                                                                                                                                                                                                                                                                                            | Total<br><small>(37 CFR 1.16(i))</small>                                                                                                                                                                                      | *                                | Minus      | **                                 | =             |                                            | ADDITIONAL FEE(\$) |
|                                                                                                                                                                                                                                                                                                                                                                                                            | Independent<br><small>(37 CFR 1.16(h))</small>                                                                                                                                                                                | *                                | Minus      | ***                                | =             |                                            |                    |
|                                                                                                                                                                                                                                                                                                                                                                                                            | Application Size Fee (37 CFR 1.16(s))                                                                                                                                                                                         |                                  |            |                                    |               |                                            |                    |
|                                                                                                                                                                                                                                                                                                                                                                                                            | FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))                                                                                                                                                               |                                  |            |                                    |               |                                            |                    |
| TOTAL ADD'L FEE                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                               |                                  |            |                                    |               |                                            |                    |
| AMENDMENT B                                                                                                                                                                                                                                                                                                                                                                                                | (Column 1)                                                                                                                                                                                                                    |                                  | (Column 2) |                                    | (Column 3)    |                                            | SMALL ENTITY       |
|                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                               | CLAIMS REMAINING AFTER AMENDMENT |            | HIGHEST NUMBER PREVIOUSLY PAID FOR | PRESENT EXTRA |                                            | RATE(\$)           |
|                                                                                                                                                                                                                                                                                                                                                                                                            | Total<br><small>(37 CFR 1.16(i))</small>                                                                                                                                                                                      | *                                | Minus      | **                                 | =             |                                            | ADDITIONAL FEE(\$) |
|                                                                                                                                                                                                                                                                                                                                                                                                            | Independent<br><small>(37 CFR 1.16(h))</small>                                                                                                                                                                                | *                                | Minus      | ***                                | =             |                                            |                    |
|                                                                                                                                                                                                                                                                                                                                                                                                            | Application Size Fee (37 CFR 1.16(s))                                                                                                                                                                                         |                                  |            |                                    |               |                                            |                    |
|                                                                                                                                                                                                                                                                                                                                                                                                            | FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))                                                                                                                                                               |                                  |            |                                    |               |                                            |                    |
| TOTAL ADD'L FEE                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                               |                                  |            |                                    |               |                                            |                    |
| * If the entry in column 1 is less than the entry in column 2, write "0" in column 3.<br>** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".<br>*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".<br>The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1. |                                                                                                                                                                                                                               |                                  |            |                                    |               |                                            |                    |

CORBIN\_CLINICAL-001463

Advance Medical Designs, Inc. - EX1020

Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041

Page 742 of 806



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| APPLICATION<br>NUMBER | FILING or<br>371(c) DATE | GRP ART<br>UNIT | FIL FEE REC'D | ATTY. DOCKET NO. | TOT CLAIMS | IND CLAIMS |
|-----------------------|--------------------------|-----------------|---------------|------------------|------------|------------|
| 17/314,845            | 05/07/2021               |                 | 1280          | 083003-620553    | 29         | 3          |

**CONFIRMATION NO. 1007**

## FILING RECEIPT

24030  
POL SINELLI PC  
900 WEST 48TH PLACE  
SUITE 900  
KANSAS CITY, MO 64112-1895



Date Mailed: 05/17/2021

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

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### Inventor(s)

Matthew J. ALLAWAY, Cumberland, MD;

### Applicant(s)

Corbin Clinical Resources, LLC, Cumberland, MD;

### Assignment For Published Patent Application

Corbin Clinical Resources, LLC, Cumberland, MD

**Power of Attorney:** The patent practitioners associated with Customer Number 24030

### Domestic Priority data as claimed by applicant

This application is a CON of 16/115,180 08/28/2018  
which is a CON of 14/677,286 04/02/2015 PAT 10064681  
which claims benefit of 61/974,826 04/03/2014

**Foreign Applications** for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.) - None.

*Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.*

**Permission to Access Application via Priority Document Exchange:** Yes

**Permission to Access Search Results:** Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

**If Required, Foreign Filing License Granted:** 05/14/2021

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/314,845**

**Projected Publication Date:** 08/26/2021

**Non-Publication Request:** No

**Early Publication Request:** No

**\*\* SMALL ENTITY \*\***

**Title**

METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING GUIDED AND  
FREE-HANDED TRANSPERINEAL PROSTATE BIOPSIES

**Preliminary Class**

**Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications:** No

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page 2 of 4

CORBIN\_CLINICAL-001465

Advance Medical Designs, Inc. - EX1020

Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041

Page 744 of 806

countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

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**To:** uspt@polsinelli.com,,  
**From:** PAIR\_eOfficeAction@uspto.gov  
**Cc:** PAIR\_eOfficeAction@uspto.gov  
**Subject:** Private PAIR Correspondence Notification for Customer Number 24030

May 17, 2021 03:55:00 AM

Dear PAIR Customer:

POLSINELLI PC  
900 WEST 48TH PLACE  
SUITE 900  
KANSAS CITY, MO 64112-1895  
UNITED STATES

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| Application | Document     | Mailroom Date | Attorney Docket No. |
|-------------|--------------|---------------|---------------------|
| 17314845    | APP.FILE.REC | 05/17/2021    | 083003-620553       |

To view your correspondence online or update your email addresses, please visit us anytime at <https://sportal.uspto.gov/secure/myportal/privatepair>.

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|-------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|------------------------------------------------------------------|
| <b>UTILITY<br/>PATENT APPLICATION<br/>TRANSMITTAL</b><br><br><i>(Only for new nonprovisional applications under 37 CFR 1.53(b))</i> | Attorney Docket No.              | 083003-620553                                                    |
|                                                                                                                                     | First Named Inventor             | Matthew J. Allaway                                               |
|                                                                                                                                     | Title                            | METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING GUIDED AN |
|                                                                                                                                     | Priority Mail Express® Label No. | EFS-WEB                                                          |

|                                                                                                            |                                                                                             |
|------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| <b>APPLICATION ELEMENTS</b><br><i>See MPEP chapter 600 concerning utility patent application contents.</i> | <b>Commissioner for Patents</b><br><b>P.O. Box 1450</b><br><b>Alexandria, VA 22313-1450</b> |
|------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1.</b> <input type="checkbox"/> <b>Fee Transmittal Form</b><br>(PTO/SB/17 or equivalent)<br><b>2.</b> <input checked="" type="checkbox"/> <b>Applicant asserts small entity status.</b><br>See 37 CFR 1.27<br><b>3.</b> <input type="checkbox"/> <b>Applicant certifies micro entity status.</b> See 37 CFR 1.29.<br>Applicant must attach form PTO/SB/15A or B or equivalent.<br><b>4.</b> <input checked="" type="checkbox"/> <b>Specification</b> [Total Pages <u>27</u> ]<br>Both the claims and abstract must start on a new page.<br>(See MPEP § 608.01(a) for information on the preferred arrangement)<br><b>5.</b> <input checked="" type="checkbox"/> <b>Drawing(s)</b> (35 U.S.C. 113) [Total Sheets <u>12</u> ]<br><b>6.</b> <b>Inventor's Oath or Declaration</b> [Total Pages <u>1</u> ]<br>(including substitute statements under 37 CFR 1.64 and assignments<br>serving as an oath or declaration under 37 CFR 1.63(e))<br>a. <input type="checkbox"/> Newly executed (original or copy)<br>b. <input checked="" type="checkbox"/> A copy from a prior application (37 CFR 1.63(d))<br><b>7.</b> <input checked="" type="checkbox"/> <b>Application Data Sheet</b> * See note below.<br>See 37 CFR 1.76 (PTO/AIA/14 or equivalent)<br><b>8.</b> <b>CD-ROM or CD-R</b><br>in duplicate, large table, or Computer Program (Appendix)<br><input type="checkbox"/> Landscape Table on CD<br><b>9. Nucleotide and/or Amino Acid Sequence Submission</b><br>(if applicable, items a. - c. are required)<br>a. <input type="checkbox"/> Computer Readable Form (CRF)<br>b. <input type="checkbox"/> Specification Sequence Listing on:<br>i. <input type="checkbox"/> CD-ROM or CD-R (2 copies); or<br>ii. <input type="checkbox"/> Paper<br>c. <input type="checkbox"/> Statements verifying identity of above copies | <b>ACCOMPANYING APPLICATION PAPERS</b><br><b>10.</b> <input checked="" type="checkbox"/> <b>Assignment Papers</b><br>(cover sheet & document(s))<br>Name of Assignee <u>Corbin Clinical Resources, LLC</u><br><b>11.</b> <input type="checkbox"/> <b>37 CFR 3.73(c) Statement</b> <input checked="" type="checkbox"/> <b>Power of Attorney</b><br>(when there is an assignee)<br><b>12.</b> <input type="checkbox"/> <b>English Translation Document</b><br>(if applicable)<br><b>13.</b> <input type="checkbox"/> <b>Information Disclosure Statement</b><br>(PTO/SB/08 or PTO-1449)<br><input type="checkbox"/> Copies of citations attached<br><b>14.</b> <input type="checkbox"/> <b>Preliminary Amendment</b><br><b>15.</b> <input type="checkbox"/> <b>Return Receipt Postcard</b><br>(MPEP § 503) (Should be specifically itemized)<br><b>16.</b> <input type="checkbox"/> <b>Certified Copy of Priority Document(s)</b><br>(if foreign priority is claimed)<br><b>17.</b> <input type="checkbox"/> <b>Nonpublication Request</b><br>Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35<br>or equivalent.<br><b>18.</b> <input checked="" type="checkbox"/> <b>Other:</b> <u>Track One Request for Prioritized Examination</u><br><br><br><br><br> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

\*Note: (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 must be included in an Application Data Sheet (ADS).  
 (2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

|                                                                                                                                                        |                            |  |  |                                   |                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|--|--|-----------------------------------|-------------------|
| <b>19. CORRESPONDENCE ADDRESS</b>                                                                                                                      |                            |  |  |                                   |                   |
| <input checked="" type="checkbox"/> The address associated with Customer Number: <u>24030</u> OR <input type="checkbox"/> Correspondence address below |                            |  |  |                                   |                   |
| Name                                                                                                                                                   |                            |  |  |                                   |                   |
| Address                                                                                                                                                |                            |  |  |                                   |                   |
| City                                                                                                                                                   | State                      |  |  | Zip Code                          |                   |
| Country                                                                                                                                                | Telephone                  |  |  | Email                             |                   |
| Signature                                                                                                                                              | <u>/Joshua J. Prancun/</u> |  |  | Date                              | <u>05/07/2021</u> |
| Name (Print/Type)                                                                                                                                      | <u>Joshua J. Prancun</u>   |  |  | Registration No. (Attorney/Agent) | <u>70712</u>      |

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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Advance Medical Designs, Inc. - EX1020

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| Electronic Patent Application Fee Transmittal                                                    |          |                                                                                                               |        |                      |
|--------------------------------------------------------------------------------------------------|----------|---------------------------------------------------------------------------------------------------------------|--------|----------------------|
| Application Number:                                                                              |          |                                                                                                               |        |                      |
| Filing Date:                                                                                     |          |                                                                                                               |        |                      |
| Title of Invention:                                                                              |          | METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING GUIDED AND FREE-HANDED TRANSPERINEAL PROSTATE BIOPSIES |        |                      |
| First Named Inventor/Applicant Name:                                                             |          | Matthew J. ALLAWAY                                                                                            |        |                      |
| Filer:                                                                                           |          | Joshua Prancun/Donna Carrera                                                                                  |        |                      |
| Attorney Docket Number:                                                                          |          | 083003-620553                                                                                                 |        |                      |
| Filed as Small Entity                                                                            |          |                                                                                                               |        |                      |
| Filing Fees for Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a) |          |                                                                                                               |        |                      |
| Description                                                                                      | Fee Code | Quantity                                                                                                      | Amount | Sub-Total in USD(\$) |
| <b>Basic Filing:</b>                                                                             |          |                                                                                                               |        |                      |
| UTILITY FILING FEE (ELECTRONIC FILING)                                                           | 4011     | 1                                                                                                             | 80     | 80                   |
| UTILITY SEARCH FEE                                                                               | 2111     | 1                                                                                                             | 350    | 350                  |
| UTILITY EXAMINATION FEE                                                                          | 2311     | 1                                                                                                             | 400    | 400                  |
| REQUEST FOR PRIORITIZED EXAMINATION                                                              | 2817     | 1                                                                                                             | 2100   | 2100                 |
| <b>Pages:</b>                                                                                    |          |                                                                                                               |        |                      |
| <b>Claims:</b>                                                                                   |          |                                                                                                               |        |                      |
| CLAIMS IN EXCESS OF 20                                                                           | 2202     | 9                                                                                                             | 50     | 450                  |
| <b>Miscellaneous-Filing:</b>                                                                     |          |                                                                                                               |        |                      |

| <b>Description</b>                       | <b>Fee Code</b> | <b>Quantity</b> | <b>Amount</b> | <b>Sub-Total in USD(\$)</b> |
|------------------------------------------|-----------------|-----------------|---------------|-----------------------------|
| PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL   | 1504            | 1               | 0             | 0                           |
| PROCESSING FEE, EXCEPT PROV. APPLS.      | 2830            | 1               | 70            | 70                          |
| <b>Petition:</b>                         |                 |                 |               |                             |
| <b>Patent-Appeals-and-Interference:</b>  |                 |                 |               |                             |
| <b>Post-Allowance-and-Post-Issuance:</b> |                 |                 |               |                             |
| <b>Extension-of-Time:</b>                |                 |                 |               |                             |
| <b>Miscellaneous:</b>                    |                 |                 |               |                             |
| <b>Total in USD (\$)</b>                 |                 |                 |               | <b>3450</b>                 |

| Electronic Acknowledgement Receipt          |                                                                                                               |
|---------------------------------------------|---------------------------------------------------------------------------------------------------------------|
| <b>EFS ID:</b>                              | 42659067                                                                                                      |
| <b>Application Number:</b>                  | 17314845                                                                                                      |
| <b>International Application Number:</b>    |                                                                                                               |
| <b>Confirmation Number:</b>                 | 1007                                                                                                          |
| <b>Title of Invention:</b>                  | METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING GUIDED AND FREE-HANDED TRANSPERINEAL PROSTATE BIOPSIES |
| <b>First Named Inventor/Applicant Name:</b> | Matthew J. ALLAWAY                                                                                            |
| <b>Customer Number:</b>                     | 24030                                                                                                         |
| <b>Filer:</b>                               | Joshua Prackun/Donna Carrera                                                                                  |
| <b>Filer Authorized By:</b>                 | Joshua Prackun                                                                                                |
| <b>Attorney Docket Number:</b>              | 083003-620553                                                                                                 |
| <b>Receipt Date:</b>                        | 07-MAY-2021                                                                                                   |
| <b>Filing Date:</b>                         |                                                                                                               |
| <b>Time Stamp:</b>                          | 16:48:40                                                                                                      |
| <b>Application Type:</b>                    | Utility under 35 USC 111(a)                                                                                   |

### Payment information:

|                                                                                                                                                                                                                                                                                |                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| Submitted with Payment                                                                                                                                                                                                                                                         | yes              |
| Payment Type                                                                                                                                                                                                                                                                   | DA               |
| Payment was successfully received in RAM                                                                                                                                                                                                                                       | \$3450           |
| RAM confirmation Number                                                                                                                                                                                                                                                        | E202157G49234206 |
| Deposit Account                                                                                                                                                                                                                                                                | 501662           |
| Authorized User                                                                                                                                                                                                                                                                | Donna Carrera    |
| <p>The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:</p> <p>37 CFR 1.16 (National application filing, search, and examination fees)</p> <p>37 CFR 1.17 (Patent application and reexamination processing fees)</p> |                  |

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Advance Medical Designs, Inc. - EX1020

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|                                              |                                                     |                               |                                          |                  |                  |
|----------------------------------------------|-----------------------------------------------------|-------------------------------|------------------------------------------|------------------|------------------|
| 37 CFR 1.19 (Document supply fees)           |                                                     |                               |                                          |                  |                  |
| 37 CFR 1.20 (Post Issuance fees)             |                                                     |                               |                                          |                  |                  |
| 37 CFR 1.21 (Miscellaneous fees and charges) |                                                     |                               |                                          |                  |                  |
| File Listing:                                |                                                     |                               |                                          |                  |                  |
| Document Number                              | Document Description                                | File Name                     | File Size(Bytes)/ Message Digest         | Multi Part /.zip | Pages (if appl.) |
| 1                                            | Application Data Sheet                              | WebADS.pdf                    | 123890                                   | no               | 8                |
|                                              |                                                     |                               | a8eeff98ada332083d68e8b4409f3b42a07977d5 |                  |                  |
| Warnings:                                    |                                                     |                               |                                          |                  |                  |
| Information:                                 |                                                     |                               |                                          |                  |                  |
| 2                                            | Oath or Declaration filed                           | 620553_Declaration_signed.pdf | 571580                                   | no               | 1                |
|                                              |                                                     |                               | ff8a2511233522e050b8dc6b430d1df5863d151b |                  |                  |
| Warnings:                                    |                                                     |                               |                                          |                  |                  |
| Information:                                 |                                                     |                               |                                          |                  |                  |
| 3                                            | Drawings-only black and white line drawings         | 620553_Drawings.pdf           | 191137                                   | no               | 12               |
|                                              |                                                     |                               | 41b0c00aa59c00d353684793e9af99f37b336571 |                  |                  |
| Warnings:                                    |                                                     |                               |                                          |                  |                  |
| Information:                                 |                                                     |                               |                                          |                  |                  |
| 4                                            |                                                     | 620553_Specification.pdf      | 187131                                   | yes              | 27               |
|                                              |                                                     |                               | 5ba55c9d094d9482cb442d626d5ace772685265b |                  |                  |
|                                              | Multipart Description/PDF files in .zip description |                               |                                          |                  |                  |
|                                              | Document Description                                | Start                         | End                                      |                  |                  |
|                                              | Specification                                       | 1                             | 22                                       |                  |                  |
|                                              | Claims                                              | 23                            | 26                                       |                  |                  |
|                                              | Abstract                                            | 27                            | 27                                       |                  |                  |
| Warnings:                                    |                                                     |                               |                                          |                  |                  |
| Information:                                 |                                                     |                               |                                          |                  |                  |
| 5                                            | TrackOne Request                                    | 620553_TrackOneRequest.pdf    | 64867                                    | no               | 1                |
|                                              |                                                     |                               | 80663e1acaec00dbef722c86396ccbcdfda9b8c1 |                  |                  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                |                              |                                                   |    |   |
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| <b>Warnings:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                |                              |                                                   |    |   |
| <b>Information:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                |                              |                                                   |    |   |
| 6                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Transmittal of New Application | 620553_TransmittalLetter.pdf | 101835<br>7be2223503dd71ecc49258e4d03c38b383d8f06 | no | 1 |
| <b>Warnings:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                |                              |                                                   |    |   |
| <b>Information:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                |                              |                                                   |    |   |
| 7                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Fee Worksheet (SB06)           | fee-info.pdf                 | 41952<br>5065ba30d80b589bee2f26615875122dd0d859bb | no | 2 |
| <b>Warnings:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                |                              |                                                   |    |   |
| <b>Information:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                |                              |                                                   |    |   |
| <b>Total Files Size (in bytes):</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                |                              | 1282392                                           |    |   |
| <p><b>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</b></p> <p><b><u>New Applications Under 35 U.S.C. 111</u></b><br/> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><b><u>National Stage of an International Application under 35 U.S.C. 371</u></b><br/> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><b><u>New International Application Filed with the USPTO as a Receiving Office</u></b><br/> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p> |                                |                              |                                                   |    |   |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                               |                        |               |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|------------------------|---------------|
| <b>Application Data Sheet 37 CFR 1.76</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                               | Attorney Docket Number | 083003-620553 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                               | Application Number     |               |
| Title of Invention                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING GUIDED AND FREE-HANDED TRANSPERINEAL PROSTATE BIOPSIES |                        |               |
| <p>The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.</p> <p>This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.</p> |                                                                                                               |                        |               |

## Secrecy Order 37 CFR 5.2:

|                          |                                                                                                                                                                                                                                       |
|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> | Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.) |
|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## Inventor Information:

|                                                                                                                                                                                                                      |                     |                                                                                                                                       |                    |                                             |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|---------------------------------------------------------------------------------------------------------------------------------------|--------------------|---------------------------------------------|
| <b>Inventor 1</b>                                                                                                                                                                                                    |                     |                                                                                                                                       |                    |                                             |
| <b>Legal Name</b>                                                                                                                                                                                                    |                     |                                                                                                                                       |                    |                                             |
| <b>Prefix</b>                                                                                                                                                                                                        | <b>Given Name</b>   | <b>Middle Name</b>                                                                                                                    | <b>Family Name</b> | <b>Suffix</b>                               |
|                                                                                                                                                                                                                      | Matthew             | J.                                                                                                                                    | ALLAWAY            |                                             |
| <b>Residence Information (Select One)</b>                                                                                                                                                                            |                     | <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service |                    |                                             |
| <b>City</b>                                                                                                                                                                                                          | Cumberland          | <b>State/Province</b>                                                                                                                 | MD                 | <b>Country of Residence <sup>i</sup></b> US |
| <b>Mailing Address of Inventor:</b>                                                                                                                                                                                  |                     |                                                                                                                                       |                    |                                             |
| <b>Address 1</b>                                                                                                                                                                                                     | 12234 Williams Road |                                                                                                                                       |                    |                                             |
| <b>Address 2</b>                                                                                                                                                                                                     |                     |                                                                                                                                       |                    |                                             |
| <b>City</b>                                                                                                                                                                                                          | Cumberland          | <b>State/Province</b>                                                                                                                 | MD                 |                                             |
| <b>Postal Code</b>                                                                                                                                                                                                   | 21502               | <b>Country <sup>i</sup></b>                                                                                                           | US                 |                                             |
| All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the <b>Add</b> button. <div style="text-align: right;"><input type="button" value="Add"/></div> |                     |                                                                                                                                       |                    |                                             |

## Correspondence Information:

|                                                                                                                                       |                                                                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Enter either Customer Number or complete the Correspondence Information section below.<br>For further information see 37 CFR 1.33(a). |                                                                                                                                             |
| <input type="checkbox"/> An Address is being provided for the correspondence information of this application.                         |                                                                                                                                             |
| <b>Customer Number</b>                                                                                                                | 24030                                                                                                                                       |
| <b>Email Address</b>                                                                                                                  | uspt@polsinelli.com <div style="float: right;"> <input type="button" value="Add Email"/> <input type="button" value="Remove Email"/> </div> |

## Application Information:

|                                                |                                                                                                               |                                                  |                                     |
|------------------------------------------------|---------------------------------------------------------------------------------------------------------------|--------------------------------------------------|-------------------------------------|
| <b>Title of the Invention</b>                  | METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING GUIDED AND FREE-HANDED TRANSPERINEAL PROSTATE BIOPSIES |                                                  |                                     |
| <b>Attorney Docket Number</b>                  | 083003-620553                                                                                                 | <b>Small Entity Status Claimed</b>               | <input checked="" type="checkbox"/> |
| <b>Application Type</b>                        | Nonprovisional                                                                                                |                                                  |                                     |
| <b>Subject Matter</b>                          | Utility                                                                                                       |                                                  |                                     |
| <b>Total Number of Drawing Sheets (if any)</b> | 12                                                                                                            | <b>Suggested Figure for Publication (if any)</b> | 8                                   |

|                                           |                                                                                                               |                        |               |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------|------------------------|---------------|
| <b>Application Data Sheet 37 CFR 1.76</b> |                                                                                                               | Attorney Docket Number | 083003-620553 |
|                                           |                                                                                                               | Application Number     |               |
| Title of Invention                        | METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING GUIDED AND FREE-HANDED TRANSPERINEAL PROSTATE BIOPSIES |                        |               |

**Filing By Reference:**

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

|                                                        |                          |                                            |
|--------------------------------------------------------|--------------------------|--------------------------------------------|
| Application number of the previously filed application | Filing date (YYYY-MM-DD) | Intellectual Property Authority or Country |
|                                                        |                          |                                            |

**Publication Information:**

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

**Representative Information:**

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

|                                                                                                                    |            |             |             |        |                                       |                                                  |                                              |                                                         |
|--------------------------------------------------------------------------------------------------------------------|------------|-------------|-------------|--------|---------------------------------------|--------------------------------------------------|----------------------------------------------|---------------------------------------------------------|
| Please Select One:                                                                                                 |            |             |             |        |                                       | <input checked="" type="radio"/> Customer Number | <input type="radio"/> US Patent Practitioner | <input type="radio"/> Limited Recognition (37 CFR 11.9) |
| Customer Number                                                                                                    |            | 24030       |             |        |                                       |                                                  |                                              |                                                         |
| Prefix                                                                                                             | Given Name | Middle Name | Family Name | Suffix | <input type="button" value="Remove"/> |                                                  |                                              |                                                         |
|                                                                                                                    |            |             |             |        |                                       |                                                  |                                              |                                                         |
| Registration Number                                                                                                |            |             |             |        |                                       |                                                  |                                              |                                                         |
| Prefix                                                                                                             | Given Name | Middle Name | Family Name | Suffix | <input type="button" value="Remove"/> |                                                  |                                              |                                                         |
|                                                                                                                    |            |             |             |        |                                       |                                                  |                                              |                                                         |
| Registration Number                                                                                                |            |             |             |        |                                       |                                                  |                                              |                                                         |
| Additional Representative Information blocks may be generated within this form by selecting the <b>Add</b> button. |            |             |             |        |                                       |                                                  |                                              |                                                         |

|                                           |                                                                                                               |                        |               |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------|------------------------|---------------|
| <b>Application Data Sheet 37 CFR 1.76</b> |                                                                                                               | Attorney Docket Number | 083003-620553 |
|                                           |                                                                                                               | Application Number     |               |
| Title of Invention                        | METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING GUIDED AND FREE-HANDED TRANSPERINEAL PROSTATE BIOPSIES |                        |               |

### Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

When referring to the current application, please leave the "Application Number" field blank.

|                                                                                                                       |                               |                          |                                    |                        |                         |
|-----------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------------|------------------------------------|------------------------|-------------------------|
| Prior Application Status                                                                                              |                               | Pending                  |                                    | <a href="#">Remove</a> |                         |
| Application Number                                                                                                    | Continuity Type               | Prior Application Number | Filing or 371(c) Date (YYYY-MM-DD) |                        |                         |
|                                                                                                                       | Continuation of               | 16115180                 | 2018-08-28                         |                        |                         |
| Prior Application Status                                                                                              |                               | Patented                 |                                    | <a href="#">Remove</a> |                         |
| Application Number                                                                                                    | Continuity Type               | Prior Application Number | Filing Date (YYYY-MM-DD)           | Patent Number          | Issue Date (YYYY-MM-DD) |
| 16115180                                                                                                              | Continuation of               | 14677286                 | 2015-04-02                         | 10064681               | 2018-09-04              |
| Prior Application Status                                                                                              |                               | Expired                  |                                    | <a href="#">Remove</a> |                         |
| Application Number                                                                                                    | Continuity Type               | Prior Application Number | Filing or 371(c) Date (YYYY-MM-DD) |                        |                         |
| 14677286                                                                                                              | Claims benefit of provisional | 61974826                 | 2014-04-03                         |                        |                         |
| Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the <b>Add</b> button. |                               |                          |                                    |                        |                         |

### Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

|                                                                                                        |                      |                          |                                          |
|--------------------------------------------------------------------------------------------------------|----------------------|--------------------------|------------------------------------------|
| Application Number                                                                                     | Country <sup>i</sup> | Filing Date (YYYY-MM-DD) | Access Code <sup>i</sup> (if applicable) |
|                                                                                                        |                      |                          |                                          |
| Additional Foreign Priority Data may be generated within this form by selecting the <b>Add</b> button. |                      |                          |                                          |

### Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

|                                           |                                                                                                               |                        |               |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------|------------------------|---------------|
| <b>Application Data Sheet 37 CFR 1.76</b> |                                                                                                               | Attorney Docket Number | 083003-620553 |
|                                           |                                                                                                               | Application Number     |               |
| Title of Invention                        | METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING GUIDED AND FREE-HANDED TRANSPERINEAL PROSTATE BIOPSIES |                        |               |

This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.



NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

|                                           |                                                                                                               |                        |               |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------|------------------------|---------------|
| <b>Application Data Sheet 37 CFR 1.76</b> |                                                                                                               | Attorney Docket Number | 083003-620553 |
|                                           |                                                                                                               | Application Number     |               |
| Title of Invention                        | METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING GUIDED AND FREE-HANDED TRANSPERINEAL PROSTATE BIOPSIES |                        |               |

## Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

**NOTE:** This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

### 1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

**A. Priority Document Exchange (PDX)** - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

**B. Search Results from U.S. Application to EPO** - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

### 2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

**NOTE:** Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

|                                           |                                                                                                               |                        |               |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------|------------------------|---------------|
| <b>Application Data Sheet 37 CFR 1.76</b> |                                                                                                               | Attorney Docket Number | 083003-620553 |
|                                           |                                                                                                               | Application Number     |               |
| Title of Invention                        | METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING GUIDED AND FREE-HANDED TRANSPERINEAL PROSTATE BIOPSIES |                        |               |

## Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

**Applicant 1**

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

☒ Assignee
 ☐ Legal Representative under 35 U.S.C. 117
 ☐ Joint Inventor

☐ Person to whom the inventor is obligated to assign.
 ☐ Person who shows sufficient proprietary interest

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name

**Mailing Address Information For Applicant:**

|                      |            |                     |       |
|----------------------|------------|---------------------|-------|
| Address 1            |            | 12234 Williams Road |       |
| Address 2            |            |                     |       |
| City                 | Cumberland | State/Province      | MD    |
| Country <sup>1</sup> | US         | Postal Code         | 21502 |
| Phone Number         |            | Fax Number          |       |
| Email Address        |            |                     |       |

Additional Applicant Data may be generated within this form by selecting the Add button.

|                                           |                                                                                                               |                        |               |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------|------------------------|---------------|
| <b>Application Data Sheet 37 CFR 1.76</b> |                                                                                                               | Attorney Docket Number | 083003-620553 |
|                                           |                                                                                                               | Application Number     |               |
| Title of Invention                        | METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING GUIDED AND FREE-HANDED TRANSPERINEAL PROSTATE BIOPSIES |                        |               |

## Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                |                |       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------|-------|
| <b>Assignee 1</b>                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                |                |       |
| Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication. |                                |                |       |
| If the Assignee or Non-Applicant Assignee is an Organization check here. <input checked="" type="checkbox"/>                                                                                                                                                                                                                                                                                                                                           |                                |                |       |
| Organization Name                                                                                                                                                                                                                                                                                                                                                                                                                                      | Corbin Clinical Resources, LLC |                |       |
| <b>Mailing Address Information For Assignee including Non-Applicant Assignee:</b>                                                                                                                                                                                                                                                                                                                                                                      |                                |                |       |
| Address 1                                                                                                                                                                                                                                                                                                                                                                                                                                              | 12234 Williams Road            |                |       |
| Address 2                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                |                |       |
| City                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Cumberland                     | State/Province | MD    |
| Country i                                                                                                                                                                                                                                                                                                                                                                                                                                              | US                             | Postal Code    | 21502 |
| Phone Number                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                | Fax Number     |       |
| Email Address                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                |                |       |
| Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.                                                                                                                                                                                                                                                                                                                                      |                                |                |       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                |                |       |

|                                           |                                                                                                               |                        |               |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------|------------------------|---------------|
| <b>Application Data Sheet 37 CFR 1.76</b> |                                                                                                               | Attorney Docket Number | 083003-620553 |
|                                           |                                                                                                               | Application Number     |               |
| Title of Invention                        | METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING GUIDED AND FREE-HANDED TRANSPERINEAL PROSTATE BIOPSIES |                        |               |

**Signature:**

**NOTE:** This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

|                                                                                     |                     |           |         |                     |       |
|-------------------------------------------------------------------------------------|---------------------|-----------|---------|---------------------|-------|
| <b>Signature</b>                                                                    | /Joshua J. Prackun/ |           |         | Date (YYYY-MM-DD)   |       |
| First Name                                                                          | Joshua              | Last Name | Prackun | Registration Number | 70712 |
| Additional Signature may be generated within this form by selecting the Add button. |                     |           |         |                     |       |

# DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

|                    |                                                                                                                |
|--------------------|----------------------------------------------------------------------------------------------------------------|
| Title of Invention | METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING, GUIDED AND FREE-HANDED TRANSPERINEAL PROSTATE BIOPSIES |
|--------------------|----------------------------------------------------------------------------------------------------------------|

As the below named inventor, I hereby declare that:

This declaration is directed to:



The attached application, or



United States application or PCT international application number \_\_\_\_\_  
filed on \_\_\_\_\_.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

## WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

## LEGAL NAME OF INVENTOR

Inventor: Matthew J. Allaway

Date (Optional):

8/28/18

Signature:

*Matthew J. Allaway*

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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Advance Medical Designs, Inc. - EX1020

Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041

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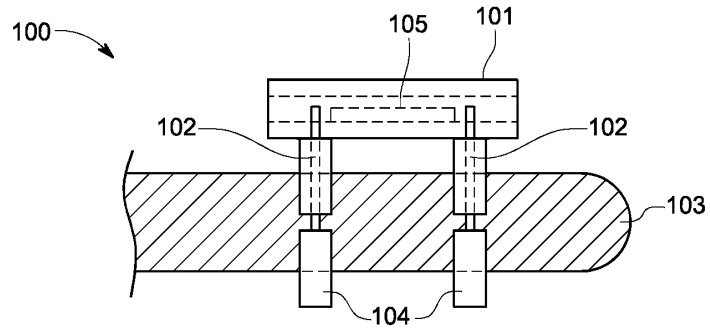


FIG. 1

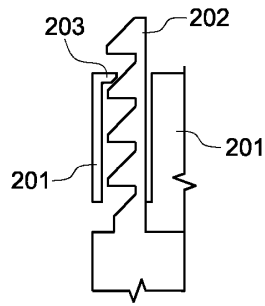


FIG. 2A

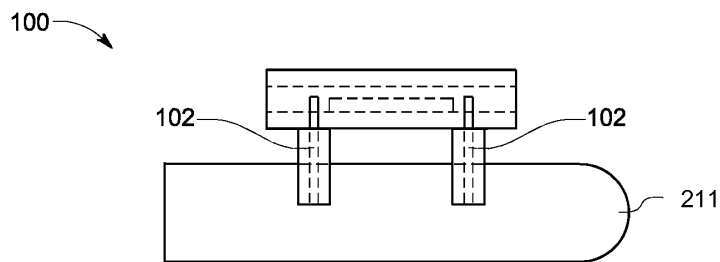


FIG. 2B

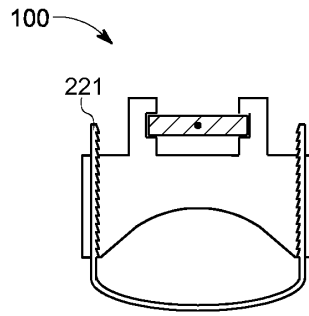


FIG. 2C

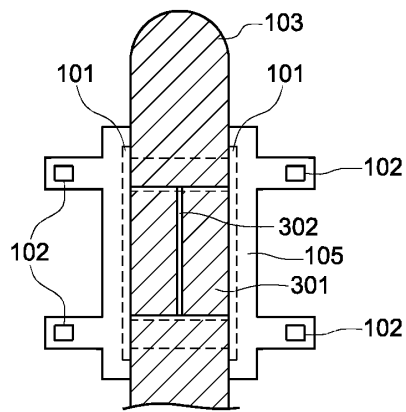


FIG. 3

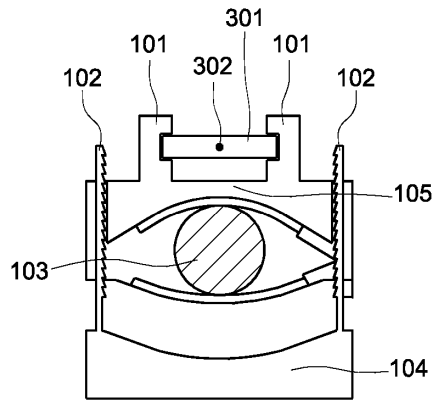


FIG. 4

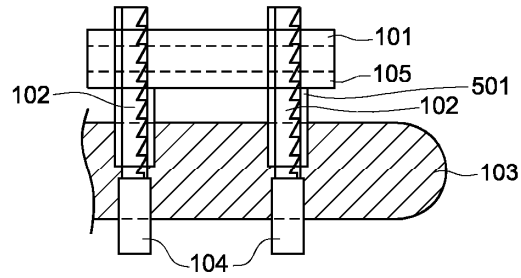


FIG. 5

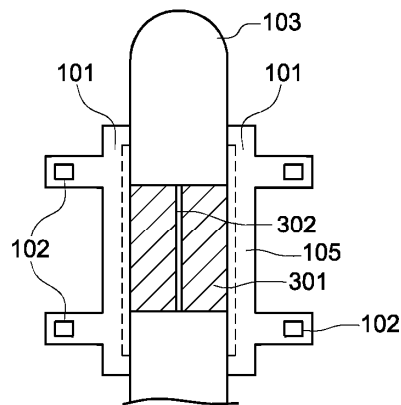


FIG. 6

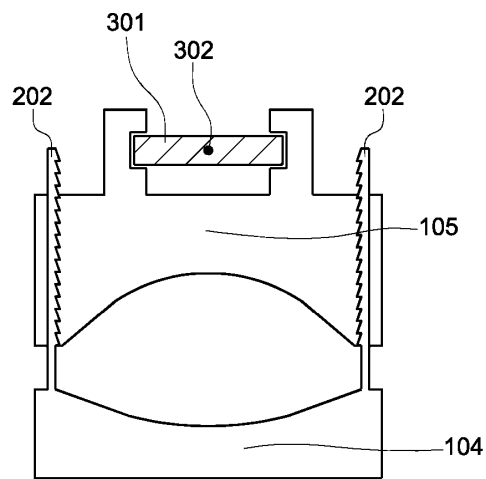


FIG. 7

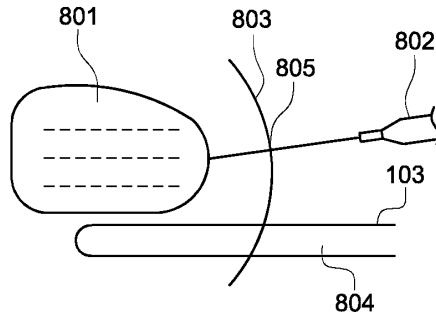


FIG. 8

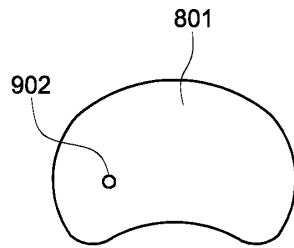


FIG. 9

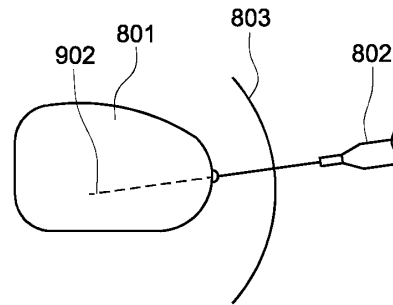


FIG. 10

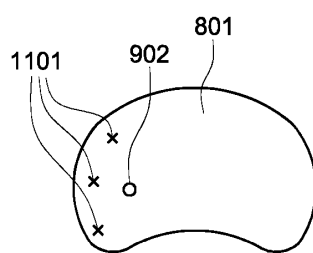


FIG. 11

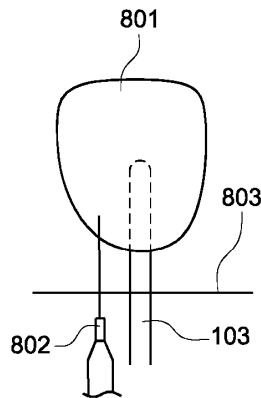


FIG. 12

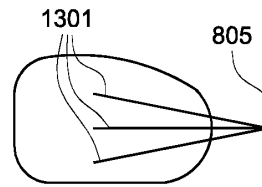


FIG. 13

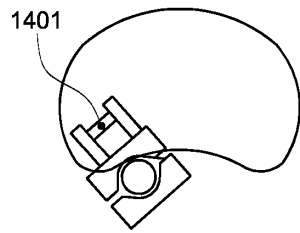


FIG. 14

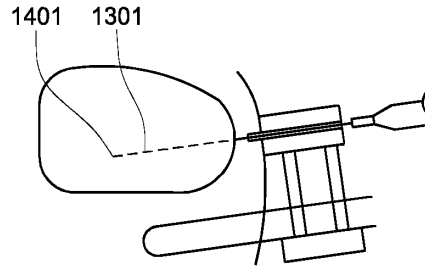


FIG. 15

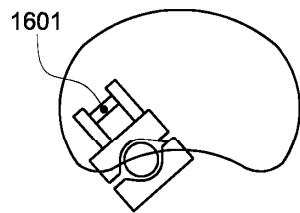


FIG. 16

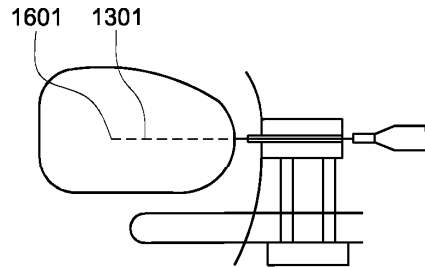


FIG. 17

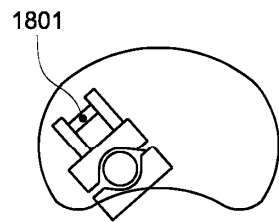


FIG. 18

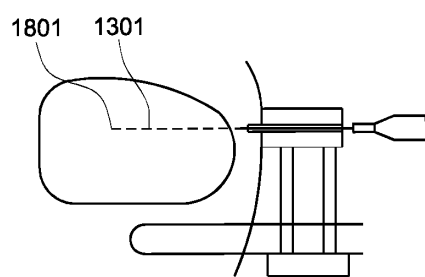


FIG. 19

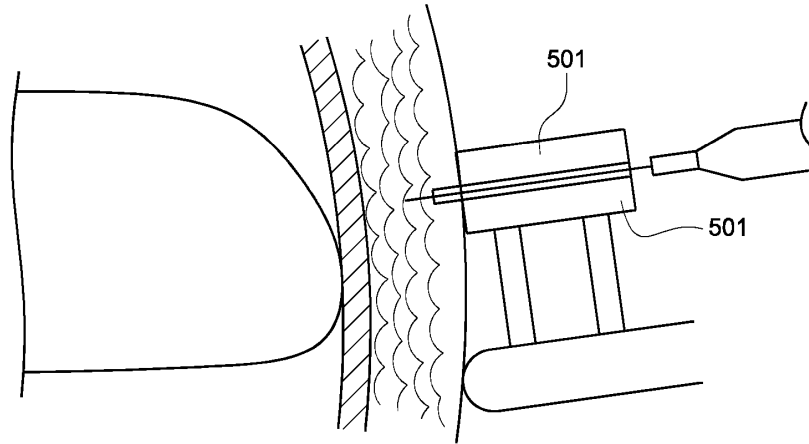


FIG. 20

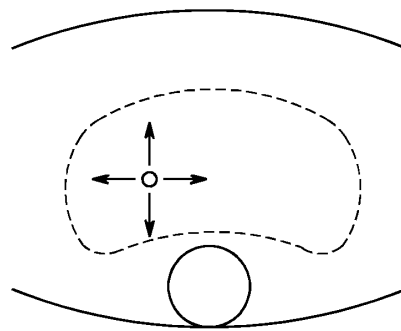


FIG. 21

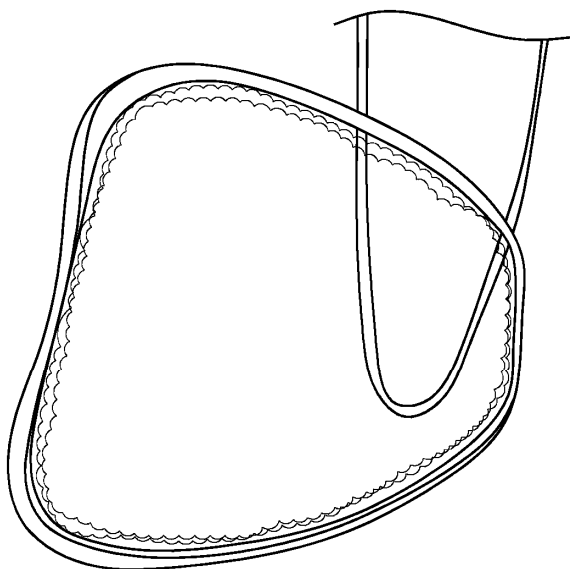


FIG. 22

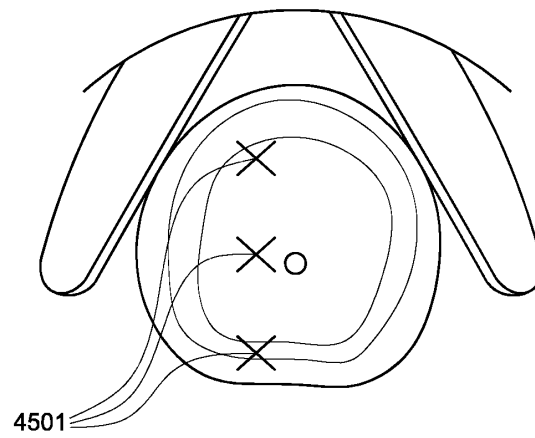
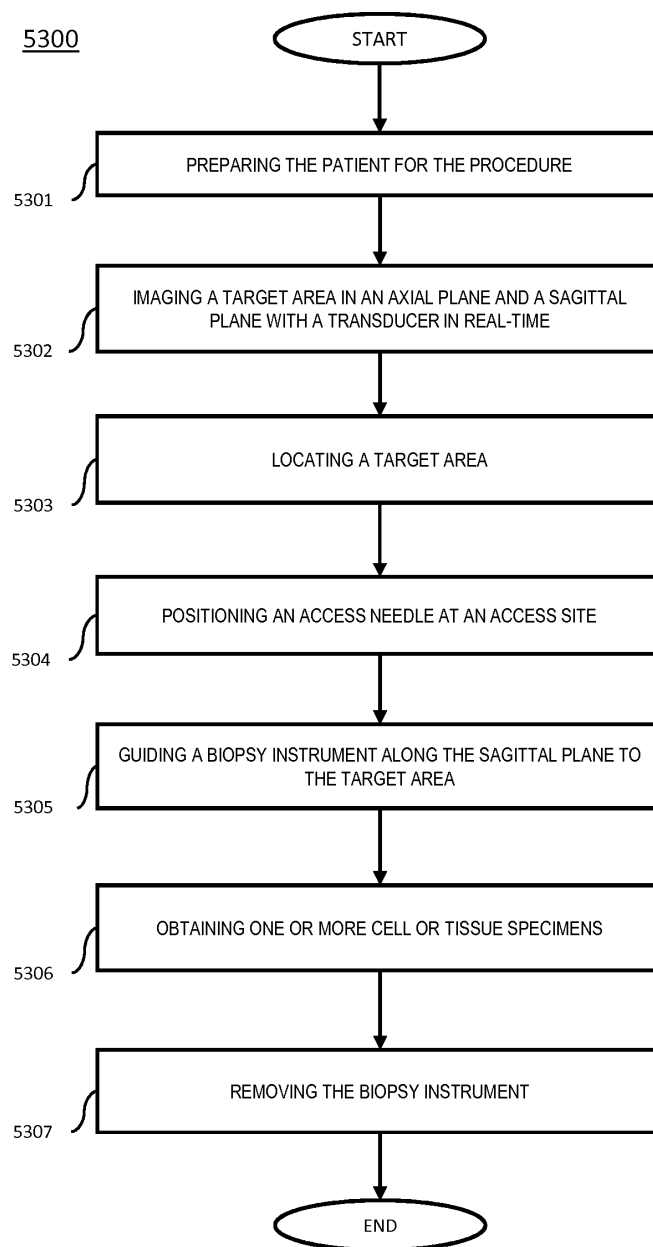


FIG. 23

FIG. 24



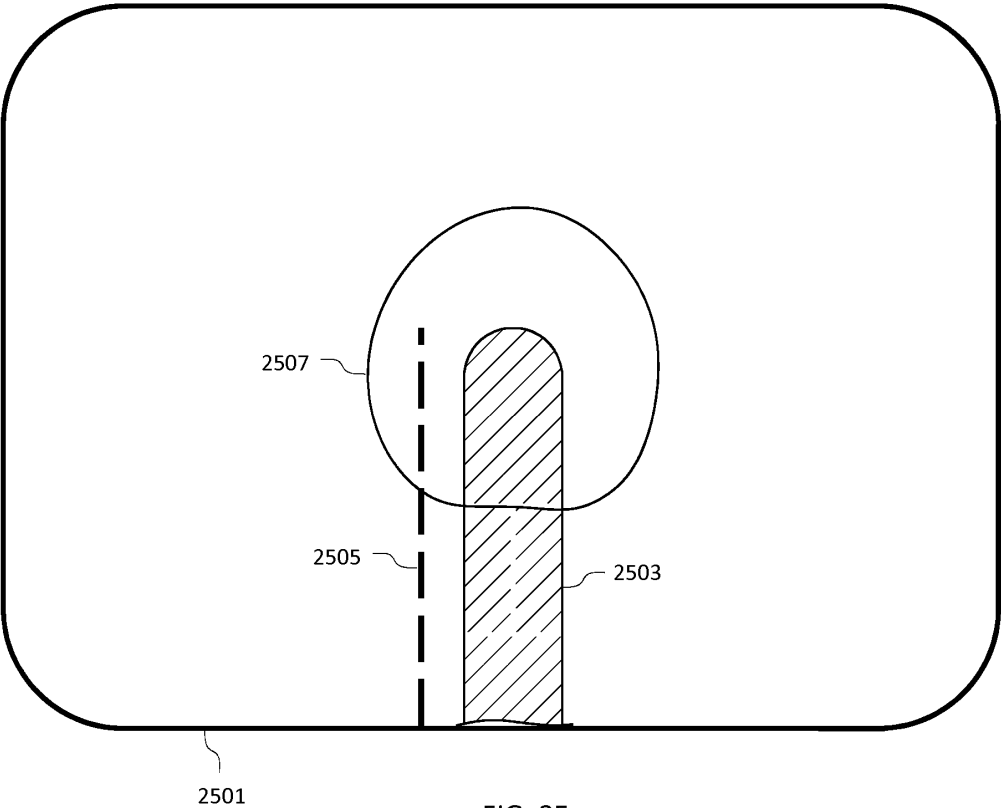


FIG. 25

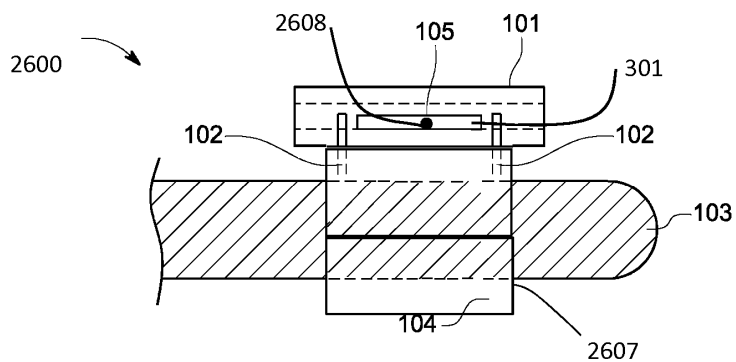


FIG. 26A

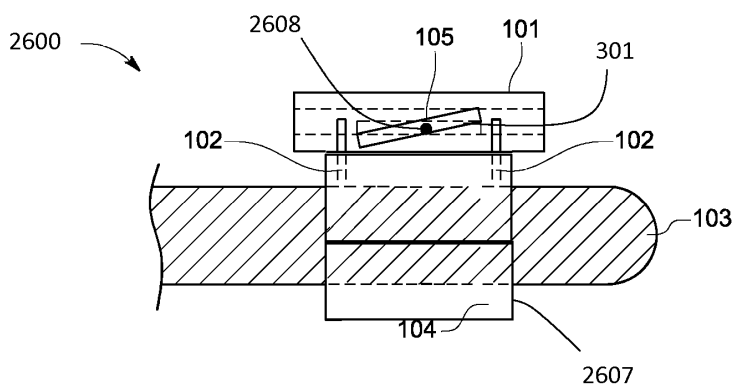


FIG. 26B

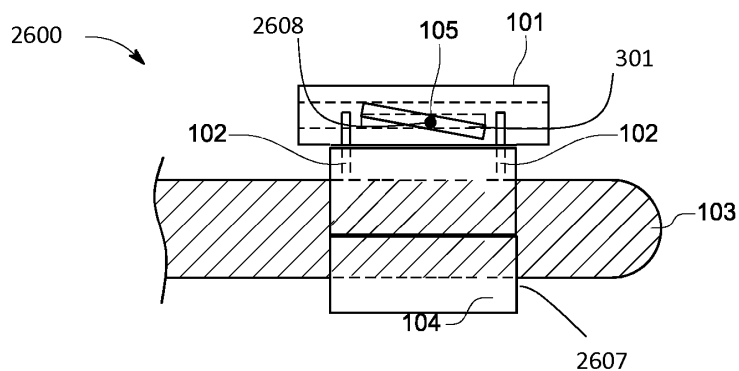


FIG. 26C

**METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING GUIDED  
AND FREE-HANDED TRANSPERINEAL PROSTATE BIOPSIES**

**CROSS-REFERENCE TO RELATED APPLICATIONS**

[0001] This application is a continuation application of U.S. Application No. 16/115,180 filed August 28, 2018, which application is a continuation of U.S. Application No. 14/677,286 filed Apr. 2, 2015, now U.S. Patent No. 10,064,681, which application claims the benefit of U.S. Provisional Patent Application No. 61/974,826, titled “METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING GUIDED AND FREE-HANDED TRANSPERINEAL PROSTATE BIOPSIES”, filed Apr. 3, 2014. The entire disclosure of each application referenced above is hereby incorporated by reference herein.

**FIELD**

[0002] The disclosure relates to biopsy procedures and systems. In particular, the disclosure relates to methods, systems, and apparatus useful for planning and performing guided and free-handed transperineal prostate biopsies.

**BACKGROUND**

[0003] A biopsy is a medical procedure that involves sampling and removing tissues or cells from a living body for further examination and analysis. A prostate biopsy may be performed by a care provider for diagnosis and treatment of a patient's prostate. For example, the vast majority of patients with an abnormal prostate specific antigen (PSA) or suspicious results from a digital rectal examination (DRE) undergo biopsy. Typical biopsy procedures include transrectal ultrasound-guided (TRUS) biopsies and transperineal ultrasound-guided (TPUS) biopsies.

[0004] TRUS involves obtaining tissue or cell specimens by passing a biopsy needle or other biopsy instruments through the rectal wall and into the prostate at various locations using a sagittal imaging plane. The biopsy needle or other biopsy instruments may be guided by ultrasound in a sagittal plane. There are disadvantages associated with TRUS. In particular, the patient may be required to take antibiotics prior to the procedure to reduce the risk of infections. Also, TRUS requires the patient to perform bowel preparation, which is a procedure usually undertaken before the biopsy, for cleansing the intestines of fecal matter and secretions. Further, the passage of the biopsy needle through the rectal wall may introduce bacteria from the rectum

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into the prostate, such as coliform bacteria that may lead to an infection or other complications. Additionally, many clinically significant prostate cancers are found in locations of the prostate that are often too difficult to access when using the transrectal approach.

[0005] TPUS includes obtaining tissue or cells specimens by passing one or more biopsy needles through the perineum and into the prostate. TRUS has been favored over TPUS. Unlike TRUS, TPUS does not require a patient to take antibiotics prior to the procedure or to undergo the bowel preparation for lowering the risk of bacterial issues. Further, TPUS uses a more effective route to access the prostate and is capable of accessing target locations that may be difficult to access utilizing the transrectal approach in comparison with TRUS. In addition, the needle does not pass through the rectal wall which eliminates the risk associated with TRUS of coliform bacteria entering the prostate or the bloodstream.

[0006] Systems configured for TPUS include a biopsy grid that may be fixed to, for example, a floor, platform, or table on which the patient receiving the biopsy lies. The biopsy grid may provide multiple apertures through which a biopsy needle or other biopsy instruments may be inserted. An ultrasound probe is fixed directly to the apparatus and is used to axially guide the biopsy needle or other instruments, for example other biopsy instruments. Thus, TPUS systems require imaging in an axial plane of the ultrasound or a transverse transducer for positioning the biopsy needle.

#### SOME EXAMPLE EMBODIMENTS

[0007] Related art systems and prostate biopsy TPUS methods do not allow free-hand movement of the ultrasound probe, and heavily rely on the axial ultrasound plane to confirm positioning of the biopsy needle or other instruments. Moreover, such systems and methods include extracting prostate tissue specimens by delivering separate punctures into the transperineal tissue. Also, a care provider executing TPUS procedure using related art systems may experience substantial difficulty in freely handling and positioning a biopsy needle at a desired target location of the prostate relying on the sagittal plane in using the TRUS methods.

[0008] An apparatus in accordance with an embodiment may include an upper mount and a lower mount. The lower mount may be configured to connect with the upper mount to secure a transrectal probe therebetween. The upper mount may be configured to support an access needle,

the access needle configured for perforation of subcutaneous tissue of a perineum at an access site of a target area of a patient. The upper mount may be configured to guide the access needle whereby movement of the access needle is fixed relative to movement of the transrectal probe.

[0009] A system in accordance with an embodiment may include a biopsy guide and a transrectal transducer fixed to the biopsy guide. The biopsy guide may be configured to guide an access needle to perforate an access site in subcutaneous tissue of a perineum, whereby movement of the access needle is fixed relative to a movement of the transrectal transducer.

[0010] A method of performing a prostate biopsy in accordance with an embodiment may include imaging a prostate in an axial plane and a sagittal plane with a transducer providing a real-time image, locating a target area of the prostate, and positioning an access needle and an access site in subcutaneous tissue of a perineum wherein the access site is at a midpoint between a lateral edge of the prostate and a urethra along a first axis and a midpoint between an anterior capsule and a posterior capsule along a second axis. The method may include guiding a biopsy instrument along a sagittal plane to the target using the real-time image, and obtaining one or more specimens of the prostate through the access needle with a biopsy instrument.

[0011] Accordingly, there is a demand for transperineal biopsy methods, systems, and apparatus that enables a biopsy that is less burdensome for the patient and for the practitioner performing the biopsy, increased guidance of needle or other biopsy instruments, and with a higher rate of efficacy and lower rate of health risk than related art TPUS and TRUS systems and methods. Apparatus, systems, and methods disclosed herein satisfy these demands.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0012] Various exemplary embodiments are illustrated by way of example, and not by way of limitation, in the figures of the accompanying drawings in which like reference numerals refer to similar elements and in which:

[0013] FIG. 1 shows a side view of a guide secured to a probe in accordance with an embodiment;

[0014] FIG. 2A shows an internal view of a guide fastener in accordance with an embodiment;

[0015] FIG. 2B shows a sheath-based guide fastener in accordance with an embodiment;

[0016] FIG. 2C shows a zip-tie-based guide fastener in accordance with an embodiment;

[0017] FIG. 3 shows a top view of a guide secured to a probe in accordance with an embodiment;

[0018] FIG. 4 shows a cross-sectional view of the back of a guide secured to a probe in accordance with an embodiment.

[0019] FIG. 5 shows a magnified view of a guide secured to a probe in accordance with an embodiment;

[0020] FIG. 6 is a magnified top view of a guide fastener in accordance with an embodiment;

[0021] FIG. 7 is a magnified view of a guide in accordance with an embodiment;

[0022] FIG. 8 is a side view of a biopsy instrument that has penetrated the prostate in accordance with an embodiment;

[0023] FIG. 9 is a front view of a designated area of the prostate where a biopsy instrument will penetrate in accordance with an embodiment;

[0024] FIG. 10 is a side view of a biopsy instrument penetrating the prostate in accordance with an embodiment;

[0025] FIG. 11 is a front view of a designated area of the prostate where a biopsy instrument will penetrate with areas in which the cell or tissue specimen has already been extracted in accordance with an embodiment;

[0026] FIG. 12 is a top view of a biopsy instrument that has penetrated the prostate in accordance with an embodiment;

[0027] FIG. 13 is a side view of a prostate and the path of the biopsy instrument;

[0028] FIG. 14 is a front view of a guide positioned at a designated area of the prostate in accordance with an embodiment;

[0029] FIG. 15 is a side view of a guide positioned at a designated area of the prostate in accordance with an embodiment;

[0030] FIG. 16 is a front view of a guide positioned at another designated area of the prostate in accordance with an embodiment;

[0031] FIG. 17 is a side view of a guide positioned at another designated area of the prostate;

[0032] FIG. 18 is a front view of a guide positioned at a higher designated area of the prostate, according to one embodiment;

[0033] FIG. 19 is a right side view of a guide positioned at a higher designated area of the prostate in comparison with that shown in FIGS. 14-17 in accordance with an embodiment;

[0034] FIG. 20 is a side view of a guide and a biopsy instrument firmly penetrating a fat plane and perineum skin of a patient in accordance with an embodiment;

[0035] FIG. 21 is a view of an access needle positioned at the access site in accordance with an embodiment;

[0036] FIG. 22 is a magnified view of the right side of a prostate and a biopsy instrument in accordance with an embodiment;

[0037] FIG. 23 is an image of the front side of a prostate and a biopsy instrument being retrieved from the prostate, and other targeted areas in accordance with an embodiment;

[0038] FIG. 24 shows a method for performing a prostate biopsy in accordance with an embodiment;

[0039] FIG. 25 is an ultrasound image showing a transducer, access needle path extending from an access point at a perineal site to a prostate, and a prostate; and

[0040] FIGS. 26A-26C show side views of a guide configured with a pivoting mount in accordance with an embodiment.

## DESCRIPTION OF SOME EMBODIMENTS

[0041] The apparatus, systems, and methods provided herein enable real-time visualization, free-handed, guided, and multi-sample transperineal methods for performing a biopsy. The methods, systems, and apparatus provided herein also enable a complete biopsy of the prostate with only one perforation, or with minimal perforations of a patient's skin by way of an initial access site, such that the access needle is freely moveable. The biopsy guide may be placed on or fitted to an assortment of ultrasound probes of different sizes and shapes due to an adjustable mounting system. The guide may be configured to fit to the probe using any suitably configured fastening system. For example, the guide may be configured as a sleeve that is formed to slide over an end of a probe and into an operable position. Alternatively, the guide may be configured to fit to a probe using screws, flanges, zip ties, or other temporary, permanent, or semi-permanent fastening systems.

[0042] In one embodiment, the guide allows biopsies of one or more tissue or cell samples to be obtained through an initial access needle, while providing direct, real-time ultrasound visualization by, for instance, fixing a position of the access needle relative to an ultrasound probe to provide. For example, the guide is fixed to an ultrasound probe that is not fixed and may be freely moveable in operation. Stabilization bars that are built into the guide facilitate the positioning and holding of the perineal skin and subcutaneous tissue to allow positioning of the access needle. The position of the access needle is facilitated by locking the access needle into the subcutaneous tissue of the perineum using a sliding platform that allows a user, such as a medical practitioner or patient caregiver, to place the access needle along a sagittal transducer plane at optimal positions for obtaining prostate biopsies. In some embodiments, upon placement of the access needle into a locked position, for example, in the pelvic floor, a user may then pass a biopsy needle through the access needle to a desired location of the prostate. In yet further embodiments, the passing of the biopsy needle through the access needle and to the prostate may be facilitated by direct sagittal plane visualization based on the alignment of the access needle.

[0043] Methods and systems provided herein do not require a patient to take antibiotics at any point prior to the biopsy procedure, nor do they require a patient to undergo bowel preparation in advance of the procedure. Methods, systems, and apparatus can reduce or eliminate multiple skin perforations by using a single access location or access site, while allowing multiple extractions

of tissue or cell specimens from the prostate. Methods, systems, and apparatus in accordance with embodiments allow for real-time visualization during a free-handed, guided, transperineal approach, while also facilitating a complete assessment of the prostate with, for example, only one perforation of the patient's skin wherein the access needle is freely moveable in each plane.

[0044] Methods, systems, and apparatus of embodiments may include and facilitate treatment that uses a cryoablation probe for focal therapy of prostate cancer, a radiofrequency instrument, a thermotherapy instrument, any instrument for treatment of the cancerous area, or a combination of any of these instruments.

[0045] Methods, systems, and apparatus of embodiments enable planning and performing the free-hand transperineal prostate biopsies under the guidance of a device and of a real-time transducer in the sagittal imaging plane.

[0046] The biopsy is performed using a system that includes a biopsy guide, a transducer, an access needle, and a biopsy instrument. The access needle may allow the anesthesia to be injected into the patient, and the tissue or cell specimens of the prostate to be extracted. If anesthesia is used, a syringe may be included in the system. The transducer may be an ultrasound probe or any other type of device that is capable of causing a visualization of the prostate in a display device. In embodiments, the biopsy guide may be disposable. In embodiments, the biopsy guide may be formed of materials intended for a single use. In other embodiments, the biopsy guide is reusable. In some embodiments, the biopsy guide may be formed of materials intended for multiple uses.

[0047] The guide may include a sliding platform, stabilization bars, one or more upper and lower mounts, and a fastener. The upper and lower mounts may be curvilinear in shape. The upper and lower mounts may be positioned proximally or distally along an ultrasound probe, such as a transrectal ultrasound probe. The configuration and positioning of the upper and lower mounts are adjustable based on the shape of the ultrasound probe and the patient's body habitus.

[0048] The guide may be made of any material such as a plastic or metallic material. The guide may be disposable and made of a biodegradable plastic material. In other embodiments, the guide may be reusable and made of stainless steel. The dimensions, for example, the length,

width, height, depth, and breadth of the sliding platform, stabilization bars, upper and lower mounts, and the fastener may vary and may be adjustable. The variable and adjustable dimensions, for example, of the stabilization bars, provide a user with flexibility in achieving and maintaining the guide in an appropriate ultrasound plane while performing biopsy procedures, while the user's patients may vary in size and levels of perineal subcutaneous tissue and fat. In a patient with an excessive amount of perineal subcutaneous tissue and fat, a larger stabilization bar will assist in locking the guide in the proper ultrasound plane.

[0049] The adjustable stabilization bars and mounts may be curvilinear in shape, allowing the guide to be placed proximally or distally along any cylindrical instrument, such as the transrectal ultrasound probe, which is determined by the surgeon based on the shape of the probe and the patient's body habitus. This allows the guide to be mounted to any assortment of ultrasound probes. Similarly, the platform may, for example, have various thicknesses.

[0050] The stabilization bars may be fixed to a top portion of the upper curvilinear mounts of the guide, and may extend beyond the front edge of the upper mounts. The stabilization bars may extend beyond the front edge of the upper curvilinear mount by approximately 8 mm. The guide may be approximately 60 mm wide, or the guide may be approximately 50 mm long, for example. The stabilization bars may have grooves for accommodating a sliding platform that is shorter in length than the stabilization bars. The grooves being configured to allow the platform to slide forward and backward along the stabilization bars.

[0051] An inner portion of the stabilization bars may have built-in grooves. The grooves accommodate a sliding platform which is shorter in length than the stabilization bars. This allows the sliding platform to slide from the back to the front of the stabilization bars. The stabilization bars may include a resistance as to prevent the sliding bar to freely move back and forth on the stabilization bar. This resistance may be introduced by the sliding platform or both the stabilization bar and the sliding platform. The resistance may be provided by a strip of rubber or any other material capable of providing friction or other. The strip may be curvilinear. The resistance may be generated by a mechanical system, such as a spring mechanism.

[0052] The sliding platform may have a hole through the platform. In some embodiments, the hole is drilled in the center of the platform. The hole can accommodate various types of needles,

including access needles having various diameters, for example, spinal needles having a gauge in the range of 14-18. The hole can also accommodate needles having various lengths. The lengths of the needle may depend, in part, on the body habitus. The needle may be a reusable needle, such as a reusable spinal needle. The needle may be a disposable needle, such as a disposable spinal needle.

[0053] A flange of the guide secures the placement of the access needle to the guide. The flange may be configured to snap into the guide to secure the needle. The flange may be secured to the guide by other securing mechanisms. The flange can be of various shapes and configurations. For example, the flange may be u-shaped. As another example, the flange may have a thin or slim configuration. The guide assists in providing the appropriate angle of penetration and direction of the access needle, or other instruments that may be used in combination with the guide.

[0054] The hole in the guide is placed so that once the guide is mounted to the ultrasound probe, the drilled hole will be parallel to the sagittal transducer. The drilled hole may also accommodate the tip of a biopsy gun, or any other biopsy instrument. The sliding platform may be interchangeable and may be removed to allow placement of another sliding platform with a different sized to permit different sizes of needles and other instruments. The hole may be configured to accommodate a cryoablation instrument, a radiofrequency instrument, thermotherapy instrument, or any other instrument for diagnosis and treatment of a bodily tissue, including a cancerous area of a prostate.

[0055] The platform may have or define a predrilled hole in the center of the platform that can accommodate various sizes of needles and instruments. For example, the hole may be configured to accommodate a needle having a range of 14-18 gauges, such as a reusable 14 gauge spinal needle. Central hole placement on the platform provides enables alignment of the hole with a sagittal transducer when the guide is mounted to an ultrasound probe. The platform may have multiple holes to accommodate various applications and body habitus. Further, the platform may be of various thicknesses.

[0056] Once the one or more upper curvilinear mounts are placed at the desired location on the transrectal ultrasound probe, the access hole for a needle, such as a 14 gauge reusable spinal

needle, will remain a fixed distance from the ultrasound probe. In embodiments, having one or more lower curvilinear mounts, the mounts may be positioned to cradle an upper aspect of the ultrasound probe.

[0057] At least two lower mounts are provided and may be individually positioned to accommodate various types of probes, which may have variable diameters along their shafts. In embodiments, a probe, such as a transrectal ultrasound probe, may have one or more diameters along the probe's shaft. In yet further embodiments, one end of the guide may be fixed at a location of the probe having a different diameter than the location where the other end of the guide is fixed. The separate lower mounts allow for the fixation of the guide, even with varying probe diameters.

[0058] The lower mount of the guide may include a lower right mount and a lower left mount connected by an adjustable mid joint or fastener. The adjustable mid joint or fastener allows the guide to be secured to the probe even if the diameter of the shaft of the probe is longer than the width of the lower mount. The mid joint or fastener may be flexible to allow the right lower mount to form an acute angle with the left lower mount. This also allows for fixation of the guide to a probe shaft that is not circular in shape.

[0059] The lateral edges on both ends of the lower mounts may contain a notched post. Corresponding locations of the upper mounts contain holes, such as square shaped holes, to accommodate the notched post of a corresponding lower mount. An upper aspect of each hole includes a flange for locking the notched post in a fixed position. This configuration allows the lower mounts and the upper mounts to be secured to each other and to the probe.

[0060] Methods may include locating a suspicious area, positioning an access needle, and obtaining one or more tissue or cell specimens from an accurate point in the prostate. The method allows for multiple tissue or cell specimens to be obtained from a bodily organ, such as the prostate, and permits access to the prostate from different angles through a single initial access needle. The method may include calculating the volume of the prostate by positioning the access needle at a mid point in the x axis from the lateral edge of the prostate to the urethra.

[0061] Methods may be performed using no anesthesia. Alternatively, an anesthetic may be used. For example, the anesthetic may be lidocaine, or any type of local anesthetic. The lidocaine may include 1 or 2% of a lidocaine solution.

[0062] The suspicious area or bodily organ may be located by using a transducer. The transducer may be any type of probe for accessing and viewing a targeted site or object, such as an ultrasound probe, or any type of transducer capable of providing visualization of the prostate and/or instruments and devices for diagnosis and treatment of the tissue. The biopsy may be performed using a biopsy gun, a suction device, or any type of instrument that is small enough to be introduced through the access needle and capable of extracting the tissue or cell specimen. The biopsy may be performed while the patient is in a dorsal lobother position, prone position, or any position that allows for access to the perineal area.

[0063] Methods may include applying an antiseptic solution to the perineal area. The antiseptic solution may include betadine, or any other substance that reduces the possibility of infection, sepsis, or putrefaction. Methods may include applying bacitracin to the skin at the puncture site or any other type of topical preparation for preventing the possibility of infection.

[0064] Methods may include attaching a needle to a luer lock syringe, which may contain an anesthetic, or any other type of device capable of retaining its contents and dispensing its contents through the needle. A biopsy gun or any other instrument that may be attached to the needle and used for inserting or extracting any substance thru the lumen of the access needle.

[0065] Methods may include releasing the syringe from the needle after the anesthetic is injected. Methods may include dividing the prostate in three different regions and designating lateral, mid, apical prostate, and may include labeling the tissue or cell specimen containers, which will identify the tissue or cell specimens.

[0066] Methods may include securing the guide to the probe. This will permit the practitioner to take the biopsy gun as many times as necessary using his/her other hand, and, consequently, extract multiple tissue or cell specimens. It is contemplated that this can be done without assistance of any other person, and that the biopsy gun may also be attached to the guide in order to permit the surgeon to, for example, label the container with the tissue or cell specimen while

performing the biopsy. Methods may also include monitoring all the actions in the prostate by way of a display device that provides images captured by the probe.

[0067] Methods may include moving the needle in x, y, and z planes. By being able to move the needle in x, y, and z planes, the surgeon is capable of extracting tissue or cell specimens from several different areas of the prostate without having to retrieve the needle and preventing other perforation of the patient's skin. In embodiments, movement of the needle within the patient's body is facilitated by using a display device.

[0068] Methods may include removing the access needle from the perineal area. This may be done while the biopsy gun is secured to the access needle or after the biopsy gun has been detached from the access needle.

[0069] Methods may include realigning the needle in the desired prostate region. If the surgeon wishes to start at the right lateral prostate region and notices that the needle tip is not directed at the lateral region, the surgeon rolls the ultrasound probe slightly and to note that the needle tip is directed to the desired region, then the surgeon may realign the needle to obtain tissue or cell specimen. The surgeon may realign the needle using one hand while having the needle attached to the biopsy gun, which may be attached to the probe through the guide.

[0070] Methods may include identifying the areas in which biopsy have already been performed. After each extraction of tissue or cell specimen during the biopsy, a hyperechoic streak remains visible on ultrasound display. This allows the surgeon to identify the area of the prostate and that an extraction has been made, as to allow the surgeon to prevent overlap of extractions.

[0071] In another embodiment, the method includes identifying the path of the urethra. This allows the surgeon from preventing passing the biopsy needle thru or into this path.

[0072] FIG. 1 is a side view of a guide 100 secured to a probe including a stabilization bar 101, fasteners 102, probe 103, lower mounts 104, and an upper mount 105. The stabilization bar 101 is an extension of the upper mount 105, as further discussed in FIG. 4. In embodiments, the distance between the fasteners 102 and the upper mount 105 may be adjustable to accommodate various applications and body habitus.

[0073] FIG. 2A is an internal view of a guide's fastener, including an aperture 201, teeth 202, and a flange 203. The flange 203 may be an extension of the aperture 201, which is part of the upper mount 105. Aperture 201 will allow the teeth 202 to be inserted into the upper mount 105, and the flange 203 will lock the teeth 202, which is connected to lower mount 104, to the upper mount 105. The aperture 201 with flange 203 and teeth 202 allows for adjusting the height of the guide 100.

[0074] In one embodiment, the fastener (e.g., via the aperture 201, flange 203, and/or the teeth 202) can be configured to fasten the guide 100 to the probe 103 with, e.g., varying levels of tension to provide for adjustments of the relative positions of the guide 100 and the probe 103 even after the guide 100 has been mounted to the probe 103. For example, the fastener 102 can provide a first level of tension sufficient to hold the position of an access needle (e.g., introduced through a hole or other needle mount of the guide 100) rotationally fixed to the probe 103 while still allowing for a forward or reverse sliding of the probe 103 with respect to the guide 100. By way of example, the forward or reverse sliding adjustment can be performed to adjust the penetration depth of the probe 103 with respect to the patient depending on a size of the patient. Once the final adjustment is made, the fastener can be actuated to final position or tension that will then lock further adjustments of the positioning of the guide 101 relative to the probe 103.

[0075] It is noted that the guide's fastener as described above is one example embodiment among other possible example fasteners that are applicable to various embodiments of the guide 100. Accordingly, it is contemplated that various embodiments of the guide 100 may use any now known or later developed fastening system that can secure the guide 100 to the probe 103.

[0076] By way illustration and not limitation, examples of two fasteners are discussed with respect to FIGS. 2B and 2C. FIG. 2B shows a sheath-based fastener whereby the fasteners 102 are attached to a sheath 211 that is configured to slide over an end of a probe 103 and into an operable position. Although the sheath 211 is shown as a closed sheath, in another embodiment, the sheath 211 can be configured as a sleeve that is open-ended to slide over the probe 103. By way of example, the sheath 211 can be made of a flexible material (e.g., rubber) to provide for stretching and tension on probe 103.

[0077] In another embodiment, as shown in FIG. 2C, the guide 100 can be configured with a zip-tie style fastener in place of a lower mount mechanism to secure the guide 100 to the probe 100. In other embodiments (now shown), the guide 100 may be configured to fit to the probe 100 using screws, flanges, or other temporary, permanent, or semi-permanent fastening systems. In addition, although the fasteners 102 of the guide 100 may be configured as generic and adjustable fasteners that can support probes of a variety sizes and shapes, it is also contemplated that the fasteners can be fit to specific models of probes for customized applications.

[0078] FIG. 3 is a top view of a guide secured to a probe. This figure includes a sliding platform 301, a drilled hole 302, stabilization bars 101, fasteners 102, an upper mount 105, and a probe 103. As previously described, in one embodiment, the drilled hole 102 can accommodate or support various sizes and/or configurations of needles (e.g., straight needles, curved needles, etc.) and instruments for performing a biopsy so that the needle can be aligned relative to the probe 103, thereby, also providing an alignment between the needle and an image produced by the ultrasound probe 103. In one embodiment, the drilled hole 102 can support an access needle through which a biopsy needle or other instrument can be introduced at a known alignment with respect to the probe 103. In addition, although the hole 102 to support, e.g., an access needle or other instrument is showed in a central midline position, the location of the hole can be configured at any position of the guide 100.

[0079] FIG. 4 is a cross-section view of the back of a guide secured to a probe including a sliding platform 301, drilled hole 302, stabilization bars 101, lower mount 104, upper mount 105, fasteners 102, and probe 103.

[0080] FIG. 5 is a magnified view of FIG. 1. FIG. 5 demonstrates minimum dimensions of preferred embodiments, which includes stabilization bars 101 and upper mount 105 from 30 mm to 50 mm long; the upper mount 105 with a height ranging from 10 mm to 15 mm; the stabilization bars 101 with a height that is about 1/3 of the height of the upper mount 105; fasteners 102 with a height of about 25 mm and 10 mm wide; a lower mount 104 10 mm wide. Additionally, the off-set 501 from the distal point of the stabilization bar 105 to the fasteners 102 may be 5 mm. It is contemplated that any of these dimensions may vary, including the stabilization bar 101, which may be longer than the upper mount 105.

[0081] FIG. 6 is a magnified internal view of the guide fastener shown in FIG. 2. FIG. 6 demonstrates minimum dimensions of preferred embodiments. The fasteners 102 may have an aperture 201 to accommodate teeth 202, wherein the fastener 102 is 5 mm to 10 mm wide. Additionally, the sliding platform 301, which may be from 12 mm to 25 mm wide, is slightly shorter than the distance between the two stabilization bars 101 as to accommodate the sliding platform while also securing it to the guide 100.

[0082] FIG. 7 is a magnified view of the guide depicted FIG. 3, without the probe 103. FIG. 7 also demonstrates minimum dimensions of preferred embodiments, wherein the height of the upper mount 105 ranges from 5 mm to 10 mm; and the teeth 202 is from 5 mm to 8 mm wide.

[0083] FIG. 8 is a side view of a biopsy instrument that is about to penetrate the prostate, including a prostate 801, a probe 103, a biopsy instrument 802, a perineum skin 803, an anus 804, and a perforation point 805. The probe 103 is inserted into the anus 804 to provide real-time images of the biopsy, including images of the biopsy instrument 802 and the prostate 801. It is contemplated that the biopsy instrument 802 includes a needle and any other instrument capable of performing a biopsy.

[0084] FIG. 9 is a front view of a targeted area 902 of the prostate 801. FIG. 10 is a side view of a biopsy instrument penetrating the prostate 801, including a targeted area 902 of the prostate 801. The targeted area 902 is reached by biopsy instrument 802 after perforating perineum skin 803.

[0085] FIG. 11 is a front view of a targeted area of the prostate where a biopsy instrument will penetrate with areas in which the cell or tissue specimen has already been extracted. FIG. 11 depicts both an extracted area 1101 and a targeted area 902. The possibility of viewing the area in which the cell or tissue specimen has already been extracted permits the practitioner to avoid placing the access needle in an area that cell or tissue specimen has already been extracted. This allows the biopsy to be more efficient and more accurate.

[0086] FIG. 12 is a top view of FIG. 8, depicting a prostate 801, perineum skin 803, a probe 103, and a biopsy instrument 802. FIG. 13 is a right side view of a prostate and the path of the biopsy instrument including the path of the biopsy instrument 1301 and the perforation point 805. FIG.

13 illustrates that only one initial perforation to the skin of the patient is necessary in order to extract one or more cell or tissue specimens.

[0087] FIG. 14 is a front view of a guide determining a lower targeted or suspicious area 1401 of the prostate in which to penetrate the biopsy instrument, a prostate, and a probe. FIG. 16 is a front view of a guide determining a mid target or suspicious area 1601 of the prostate in which to penetrate the biopsy instrument, a prostate, and a probe. FIG. 18 is a front view of a guide determining a higher targeted or suspicious area 1801 of the prostate in which to penetrate the biopsy instrument, a prostate, a probe. FIGS. 14, 16, and 18 demonstrates the variety of angles and positions in which a guide may be positioned in order to reach several regions of the prostate, such as the lateral region, mid region, and apical region. In order to be able to reach these areas, FIGS. 14, 16, and 18 demonstrate how the upper mount 105, the stabilization bars 101, or a combination of thereof can adjust in order to reach a lower targeted or suspicious area 1401, a mid targeted or suspicious area 1601, or a higher targeted or suspicious area 1801 of the prostate.

[0088] FIGS. 15, 17, and 19 demonstrate a side view of FIGS. 14, 16, and 18 and the paths of the biopsy instrument 1301 taken by a biopsy instrument to reach lower targeted or suspicious area 1401, a mid targeted or suspicious area 1601, or a higher targeted or suspicious area 1801 of the prostate.

[0089] FIG. 20 is a right side view of a guide, and a biopsy instrument firmly penetrating a fat plane of perineum skin, including offset 501 of a stabilization bar 101. This allows for stabilization in a patient with an excessive amount of perineal subcutaneous tissue, fat, or a combination thereof. A larger stabilization bar 101 will assist in locking the guide in the proper ultrasound plane. Accordingly, the offset 501 may longer than 5 mm for these purposes.

[0090] FIG. 21 is a front view of a prostate, a probe, a targeted or suspicious area, wherein the biopsy instrument may reach any area of the prostate. FIG. 21 demonstrates that the biopsy instrument can reach the entire prostate while using only one perforation point 805. After obtaining one cell or tissue specimen, the biopsy instrument 802 may be partially retrieved from the perineum area at a point in which the distal point of the biopsy instrument 802 is redirected to another targeted or suspicious area. Then, the biopsy instrument (usually the needle of the biopsy

instrument) is inserted to the second targeted or suspicious area for obtaining a cell or tissue specimen of another area of the prostate.

[0091] FIG. 22 is a magnified view of the right side of a prostate and a biopsy instrument. FIG. 22 depicts the location of the biopsy instrument inside the prostate and the other paths in which the biopsy instrument may take utilize for additional samples or retrieval. In embodiments, the biopsy needle or other instruments do not reach the initial part of the penis, which is in a different plane from the prostate.

[0092] FIG. 23 is an image of the front side of a prostate and a biopsy instrument being retrieved from the prostate, and other targeted areas. FIG. 23 shows a procedure being applied to the apical region of the prostate.

[0093] The urethra should be avoided in any part of the procedure, but it is mostly important when extracting cell or tissue specimens from the apical region of the prostate, when the chances of perforation is greater. After several extractions, the practitioner is able to see the blood streak from where the cell or tissue specimen was taken so as to avoid overlapping.

[0094] After this procedure, the patient may be put with restriction for no more than 1 day. If the patient is put on restriction for 1 day, after the one-day-restriction, no restriction is made.

[0095] In an embodiment, the biopsy system performs the processes 2400 of FIG. 24. At 2401, a patient is prepared for the biopsy procedure by having the patient get into a lithotomic position, prone position, or any position that allows for access to the perineal area. The biopsy procedure may be a prostate biopsy. In some embodiments, the patient's scrotum is elevated using, for example, two strips of plastic tape. The perineum is prepared with an antiseptic solution to the perineal area, for example, the antiseptic solution may include betadine.

[0096] At 2402, a target area or object, such as the prostate, is imaged. Imaging may be performed with a transducer, such as an ultrasound probe. Imaging of a target area may be in a sagittal and/or axial plane and may be performed in real-time with direct visualization. Utilizing the real-time image, a user can identify areas of interest, e.g. suspicious areas or the target area or object at 2403.

[0097] The user may determine an access site for positioning an access needle. At 2404, an access needle is positioned at an access site in subcutaneous tissue of the perineum. The access site may be at a midpoint between a lateral edge of the prostate and the urethra along an x axis, and a midpoint between an anterior capsule and a posterior capsule along a y axis. The access needle is guided and positioned at the access site by using the guide.

[0098] At 2405, a biopsy instrument is guided to the target or suspicious areas or object. The biopsy instrument may include a biopsy needle. The guiding of the biopsy instrument can be facilitated by using the real-time visualization provided by the transducer. Real-time visualization also facilitates obtaining tissue or cell specimens from an accurate point in the prostate, for example. The method allows for one or more tissue or cell specimens to be obtained from a bodily organ, such as the prostate at 2406, and permits access to the prostate from different angles through a single initial access needle.

[0099] At 2407, the biopsy instrument may be retrieved and removed from the patient. The method may include calculating the volume of the prostate by positioning the access needle at a mid point in x axis from the lateral edge of the prostate to the urethra.

[0100] FIG. 25 shows an ultrasound 2501 showing a transrectal probe 2503 and an access needle guide line 2505. The needle guide line enables the practitioner to observe a needle path whereby the access needle has contacted the prostate 2507, thereby enabling the practitioner to avoid overlapping sampling, and to avoid perforating the prostate.

[0101] FIGS. 26A-26C show side views of an alternative embodiment of a guide 2600 secured to a probe including a stabilization bar 101, fasteners 102, probe 103, lower mount 104, and an upper mount 105. The stabilization bar 101 is an extension of the upper mount 105, as further discussed in FIG. 4. In embodiments, the distance between the fasteners 102 and the upper mount 105 may be adjustable to accommodate various applications and body habitus.

[0102] The guide 2600 includes a sliding platform 301. The guide is fitted to the probe 103 by a sleeve 2607. The sleeve 2607 is formed by the lower mount 104 and the upper mount 105. The sleeve 2607 may be configured to slide over an end of the probe 103 into an operable position as

shown in FIGS. 26A-26C. The sleeve 2607 is a partial sleeve that has an opening at both ends of the sleeve 2607 to enable slidable mounting to and removal from the probe 103.

[0103] The sliding platform 301 of the guide 2600 may be pivotably mounted to enable movement in a direction perpendicular to a longitudinal axis of the probe 103, as shown in FIGS. 26A-26C. In particular FIGS. 26A-26C show that the sliding platform 103 is fixed to the guide at a pivot point 2608. The sliding platform 103 is configured to pivot at pivot point 2608 to enable, for example, normal or vertical adjustment of an access needle (not shown) in directions perpendicular to a longitudinal axis of the probe 103 while ensuring that a longitudinal axis of the access needle (not shown) remains parallel to the longitudinal axis of the probe 103.

[0104] For example, FIG. 26A shows a sliding platform 301 in a first position at which a lateral planar surface of the platform 301 extends in a direction parallel to the longitudinal axis of the probe 103. FIG. 26B shows the sliding platform 301 pivoted to a second position wherein a front end the platform 301 is disposed a distance from the probe 103 that is greater than a distance between an opposite rear portion of the platform 301 and the probe 103. FIG. 26C shows the sliding platform 301 pivoted to a third position wherein the rear end of the platform 301 is disposed a distance from the probe 103 that is greater than a distance between the opposite front end of the platform 301 and the probe 103.

[0105] In another embodiment, the method may be performed without the patient taking antibiotics or undergoing bowel preparation before having the procedure. During the procedure, the practitioner may administer an anesthetic to the patient, for example, lidocaine, or any type of local, anesthetic. The lidocaine may be included in a solution having 1% of lidocaine.

[0106] In an embodiment, the suspicious area is located by using a transducer. The transducer may be any type of transrectal robe for prostate cancer, such as an ultrasound probe, or any type of transducer capable of imaging the prostate and the extraction device. The biopsy may be performed using a biopsy gun, a suction-mechanism, or any type of instrument that is small enough to be introduced through the access needle and capable of extracting the tissue or cell specimen. The biopsy may be performed while the patient is in a lithotomy position, prone position, or any position that allows for access to the perineal area.

[0107] In another embodiment, methods may include applying an antiseptic solution to the perineal area such as betadine, or any other substance that reduces the possibility of infection, sepsis, or putrefaction.

[0108] In another embodiment, the ultrasound probe may be a B&K 8848 transrectal ultrasound probe, or any other ultrasound capable of causing visualization of the prostate and the extraction device. The frequency range may be 5-12 MHZ, and the focal range may be 3-60 mm. The ultrasound probe may be able to cause the visualization of the prostate and extraction devices at least in the axial plane, sagittal plane, or a combination thereof.

[0109] In another embodiment, methods may include attaching a needle to a luer lock syringe, which may contain an anesthetic, or any other type of device capable of retaining its contents and to dispense its contents through the needle. A biopsy gun or any other instrument may be attached to the needle for inserting or extracting any substance through the lumen of the access needle.

[0110] In another embodiment, the method includes releasing the syringe from the needle after the anesthetic is injected. The method may include dividing the prostate in three different regions and designating lateral, mid, apical prostate, and may include labeling the tissue or cell specimen containers, which will identify the tissue or cell specimens.

[0111] In another embodiment, a biopsy gun may be an 18 gauge biopsy gun, or any other size that is capable of being coaxially inserted thru the lumen of the access needle.

[0112] In another embodiment, methods may include securing the guide to the probe. This will permit the practitioner to take the biopsy gun as many times as necessary using his or her other hand, and, consequently, extract multiple tissue or cell specimens. It is contemplated that this can be done without assistance of any other person, and that the biopsy gun may also be attached to the guide in order to permit the surgeon to e.g. label the container with the tissue or cell specimen while performing the biopsy. The method may also include monitoring all the actions in the prostate thru a display device, which will transmit images captured by the probe.

[0113] In another embodiment, methods may include moving the needle in x, y, and z planes. By being able to move the need in x, y, and z planes, the surgeon is capable of extracting tissue or

cell specimens from several different areas of the prostate without having to retrieve the needle and preventing other perforation of the patient's skin.

[0114] Methods may further include removing the access needle from the perennial area.

Removal of the access needle may be performed while the biopsy gun is secured to the access needle or after the biopsy gun has been detached from the access needle.

[0115] Methods may include realigning the needle in the desired prostate region. If the surgeon wishes to start at the right lateral prostate region and notices that the needle tip is not directed at the lateral region, the surgeon rolls the ultrasound probe slightly and to note that the needle tip is directed to the desired region, then the surgeon may realign the needle to obtain tissue or cell specimen. The surgeon may realign the needle using one hand while having the needle attached to the biopsy gun, which may be attached to the probe through the guide.

[0116] Methods may include identifying the area in which a biopsy has already been performed. After each extraction of tissue or cell specimen during the biopsy, a hyperechoic streak remains visible on ultrasound display. This allows the surgeon to identify the area of the prostate and that an extraction has been made, as to allow the surgeon to prevent overlap of extractions.

[0117] In another embodiment, methods may include identifying the path of the urethra. This allows the surgeon from preventing passing the biopsy needle thru or into this path. In another embodiment, the method includes pressuring the perineum. In yet another embodiment, the method includes applying bacitracin to the skin at the puncture site or any other type of topical preparation for preventing the possibility of infection. In another embodiment, positioning the access needle is performed without the need of a biopsy grip, wherein the guide provides the precise point for the biopsy.

[0118] An apparatus and system in accordance with embodiments discussed above is used to carry out these methods. In an alternative embodiment of apparatus and systems, a guide may not include a lower mount, and may include an access needle. The guide includes a stabilization bar, sliding platform, a hole located in approximately the center of the platform, an upper mount, teeth, aperture, arms, and a connector. The access needle includes a hub and is secured to the guide. The teeth may be part of, or may be attached to, a lower mount. The teeth may be inserted

into the aperture in order to secure the guide to a probe, for example. It is contemplated that the combination of the aperture and the teeth may form a fastener mechanism. In embodiments, connector is part of, or may be attached to, an access needle, and may be secured to the upper mount in order to provide stabilization of the access needle and to allow the practitioner to move the access needle by merely moving, for example, a probe that may be secured to the guide.

[0119] A connector and a hub permit the use of various other instruments such as, for example, a non-biopsy instrument, to be secured. A biopsy instrument may be inserted into the access needle in order to reach a targeted area. The upper mount may include arms. In embodiments, the arms may be shorter, longer, or may not exist, in which case the aperture is disposed directly in the upper mount. When the aperture is directly in the upper mount, upper mount may be longer, thicker, or a combination thereof.

[0120] In some embodiments, the guide may include lower mounts that have teeth. Arms may extend from the upper mount to allow the height of the guide to be adjusted and to be placed farther from or closer to the probe. The arms permit the access needle to be maintained at a certain distance from a probe. In embodiments, the material of the guide may be a plastic or any other material, including other plastic materials, or any other material that is cost effective. In embodiments, the guide may be reusable and may be formed with a stainless steel. The lower mount may be curvilinear and flexible to allow the lower mount to bend if necessary to secure the guide to the probe.

[0121] While the invention has been described in connection with a number of embodiments and implementations, the invention is not so limited but covers various obvious modifications and equivalent arrangements, which fall within the purview of the appended claims. Although features of the invention are expressed in certain combinations among the claims, it is contemplated that these features can be arranged in any combination and order.

## CLAIMS

1. An apparatus for use with a transrectal transducer in performing free-handed transperineal prostate biopsies, the apparatus comprising:

a biopsy guide configured to couple to the transrectal transducer and comprising a base portion, and a platform slidably engageable with the base portion, the platform including a plurality of needle guides that are sized to support an access needle comprising a lumen sized to receive a biopsy needle there through, the plurality of needle guides aligning with a sagittal transducer plane of the transrectal probe when the biopsy guide is coupled to the transrectal probe.

2. The apparatus of claim 1, wherein the plurality of needle guides are holes defined in the platform.

3. The apparatus of claim 1, wherein the plurality of needle guides are sized to support the access needle having a needle size of 14 gauge, 15 gauge, 16 gauge, or 18 gauge.

4. The apparatus of claim 1, further comprising the access needle.

5. The apparatus of claim 1, wherein the platform is configured to slide relative to a pair of stabilization members of the base portion.

6. The apparatus of claim 1, whereby, when the biopsy guide is coupled to the transrectal probe and when the access needle is supported by one of the plurality of needle guides, movement of the access needle is fixed relative to a movement of the transrectal transducer.

7. The apparatus of claim 1, wherein the biopsy guide and transrectal transducer are freely moveable in operation.

8. The apparatus of claim 1, wherein the platform is shorter in length than the base portion.

9. The apparatus of claim 1, wherein the base portion comprises a mount configured to releasably secure the biopsy guide to the transrectal probe.

10. The apparatus of claim 1, wherein the base portion comprises a pair of stabilization members spaced apart from each other, the platform configured to slide in frictional contact on the pair of stabilization members.

11. The apparatus of claim 10, wherein a distal point of the plurality of stabilization members is offset from a fastener of the base portion that is configured to connect the biopsy guide to the transrectal transducer.

12. An apparatus for use with a transrectal transducer in performing free-handed transperineal prostate biopsies, the apparatus comprising:

a biopsy guide configured to couple to the transrectal transducer and comprising a base portion including a pair of stabilization members having inner surfaces that oppose each other, and a platform including a pair of lateral surfaces opposite each other, and a plurality of needle guides that are sized to support an access needle comprising a lumen sized to receive a biopsy needle there through, the plurality of needle guides aligning with a sagittal transducer plane of the transrectal probe when the biopsy guide is coupled to the transrectal probe, the platform configured to slide relative to the pair of stabilization members with the pair of lateral surfaces of the platform in frictional engagement with the inner surfaces of the pair of stabilization members.

13. The apparatus of claim 12, wherein the plurality of needle guides are holes defined in the platform.

14. The apparatus of claim 12, wherein the plurality of needle guides are sized to support the access needle having a needle size of 14 gauge, 15 gauge, 16 gauge, or 18 gauge.

15. The apparatus of claim 12, further comprising the access needle.

16. The apparatus of claim 12, whereby, when the biopsy guide is coupled to the transrectal probe and when the access needle is supported by one of the plurality of needle guides, movement of the access needle is fixed relative to a movement of the transrectal transducer.

17. The apparatus of claim 12, wherein the biopsy guide and transrectal transducer are freely moveable in operation.

18. The apparatus of claim 12, wherein the platform is shorter in length than the base portion.
19. The apparatus of claim 12, wherein the base portion comprises a mount configured to releasably secure the biopsy guide to the transrectal probe.
20. The apparatus of claim 12, wherein a distal point of the plurality of stabilization members is offset from a fastener of the base portion that is configured to connect the biopsy guide to the transrectal transducer.
21. An apparatus for use with a transrectal transducer in performing free-handed transperineal prostate biopsies, the transrectal transducer configured to image in a sagittal plane and having a cylindrical portion, the apparatus comprising:
- a biopsy guide configured to couple to the transrectal transducer and comprising a base portion and a platform, the base portion including a channel portion, and a mount coupled to the channel portion and configured to releasably couple to the cylindrical portion of the transrectal transducer, the platform configured to slide within the channel portion of the base portion, the platform including a plurality of needle guides that are sized to support an access needle comprising a lumen sized to receive a biopsy needle there through, the plurality of needle guides aligning with a sagittal transducer plane of the transrectal probe when the biopsy guide is coupled to the transrectal probe.
22. The apparatus of claim 21, wherein the plurality of needle guides are holes defined in the platform.
23. The apparatus of claim 21, wherein the plurality of needle guides are sized to support the access needle having a needle size of 14 gauge, 15 gauge, 16 gauge, or 18 gauge.
24. The apparatus of claim 21, further comprising the access needle.
25. The apparatus of claim 21, whereby, when the biopsy guide is coupled to the transrectal probe and when the access needle is supported by one of the plurality of needle guides, movement of the access needle is fixed relative to a movement of the transrectal transducer.
26. The apparatus of claim 21, wherein the biopsy guide and transrectal transducer are freely moveable in operation.

27. The apparatus of claim 21, wherein the platform is shorter in length than the base portion.
28. The apparatus of claim 21, wherein the channel portion is defined by a pair of stabilization members spaced apart from each other, the platform configured to slide in frictional contact on the pair of stabilization members.
29. The apparatus of claim 28, wherein a distal point of the plurality of stabilization members is offset from the mount of the base portion that is configured to connect the biopsy guide to the transrectal transducer.

## ABSTRACT

A system for planning and performing a guided and free-handed transperineal prostate biopsy includes a transrectal ultrasound probe, an access needle configured to perforate a perineal access site of a patient, a biopsy gun, and a guide. The guide includes a sliding platform, stabilization bars, upper and lower mounts, and fasteners. The system and guide apparatus is used for locating a target area using the ultrasound probe, positioning the ultrasound and the access needle at respective designated points, precisely measuring the distance to a designated point, and obtaining specimens from a precise point in the prostate, wherein the method is performed free-handed, and multiple tissue or cell specimens may be obtained from the prostate through an initial access needle.

**CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION  
UNDER 37 CFR 1.102(e) (Page 1 of 1)**

|                       |                                                                                                               |                                               |  |
|-----------------------|---------------------------------------------------------------------------------------------------------------|-----------------------------------------------|--|
| First Named Inventor: | Matthew J. Allaway                                                                                            | Nonprovisional Application Number (if known): |  |
| Title of Invention:   | METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING GUIDED AND FREE-HANDED TRANSPERINEAL PROSTATE BIOPSIES |                                               |  |

**APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.**

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently \$0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.
2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.
3. The applicable box is checked below:

**I. ☒ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)**

- i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.  
---OR---
- (b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.
- ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, or the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

**II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)**

- i. A request for continued examination has been filed with, or prior to, this form.
- ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
- iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
- iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
- v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

|                                                                                                                                                                                                       |                                               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| Signature <u>/Joshua J. Pranckun/</u>                                                                                                                                                                 | Date <u>05/07/2021</u>                        |
| Name (Print/Typed) <u>Joshua J. Pranckun</u>                                                                                                                                                          | Practitioner Registration Number <u>70712</u> |
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|                        |                                                                                                               |
|------------------------|---------------------------------------------------------------------------------------------------------------|
| Application Number     | 17/314,845                                                                                                    |
| Filing Date            | 05/07/2021                                                                                                    |
| First Named Inventor   | Matthew J. Allaway                                                                                            |
| Title                  | METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING GUIDED AND FREE-HANDED TRANSPERINEAL PROSTATE BIOPSIES |
| Art Unit               |                                                                                                               |
| Examiner Name          |                                                                                                               |
| Attorney Docket Number | 083003-620553                                                                                                 |

| SIGNATURE of Applicant or Patent Practitioner                                                                                                                                                 |                                |                     |            |
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| Signature                                                                                                                                                                                     | /Joshua J. Pranckun/           | Date (Optional)     | 05/07/2021 |
| Name                                                                                                                                                                                          | Joshua J. Pranckun             | Registration Number | 70712      |
| Title (if Applicant is a juristic entity)                                                                                                                                                     | Attorney for Applicant         |                     |            |
| Applicant Name (if Applicant is a juristic entity)                                                                                                                                            | Corbin Clinical Resources, LLC |                     |            |
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Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041

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|                                                                                                                                                                                                                                                                                                                                                                                                        |                    |             |            |            |  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-------------|------------|------------|--|
| I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.                                                                                                                                                                                                                                                      |                    |             |            |            |  |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">Application Number</td> <td style="padding: 2px;">Filing Date</td> </tr> <tr> <td style="text-align: center; padding: 5px;">16/115,180</td> <td style="text-align: center; padding: 5px;">08/28/2018</td> </tr> </table>                                                                             | Application Number | Filing Date | 16/115,180 | 08/28/2018 |  |
| Application Number                                                                                                                                                                                                                                                                                                                                                                                     | Filing Date        |             |            |            |  |
| 16/115,180                                                                                                                                                                                                                                                                                                                                                                                             | 08/28/2018         |             |            |            |  |
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| <div style="border: 1px solid black; padding: 5px; min-height: 20px;">Corbin Clinical Resources, LLC</div>                                                                                                                                                                                                                                                                                             |                    |             |            |            |  |
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| <input type="checkbox"/> Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)                                                                                                                                                                                                                                                                               |                    |             |            |            |  |
| <input checked="" type="checkbox"/> Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)                                                                                                                                                                                                                                |                    |             |            |            |  |
| <input type="checkbox"/> Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)                                                                                                                             |                    |             |            |            |  |
| <b>SIGNATURE of Applicant for Patent</b>                                                                                                                                                                                                                                                                                                                                                               |                    |             |            |            |  |
| The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).                                                                                                                                                                                                                                                      |                    |             |            |            |  |
| Signature                                                                                                                                                                                                                                                                                                                                                                                              | Date (Optional)    |             |            |            |  |
| Name                                                                                                                                                                                                                                                                                                                                                                                                   | Matthew J. Aglikey |             |            |            |  |
| Title                                                                                                                                                                                                                                                                                                                                                                                                  | President/CEO      |             |            |            |  |
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| Electronic Acknowledgement Receipt          |                                                                                                                             |
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| <b>EFS ID:</b>                              | 42669699                                                                                                                    |
| <b>Application Number:</b>                  | 17314845                                                                                                                    |
| <b>International Application Number:</b>    |                                                                                                                             |
| <b>Confirmation Number:</b>                 | 1007                                                                                                                        |
| <b>Title of Invention:</b>                  | METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING GUIDED AND FREE-HANDED TRANSPERINEAL PROSTATE BIOPSIES               |
| <b>First Named Inventor/Applicant Name:</b> | Matthew J. ALLAWAY                                                                                                          |
| <b>Correspondence Address:</b>              | POLSINELLI PC<br>-<br>900 WEST 48TH PLACE<br>SUITE 900<br>KANSAS CITY MO 64112-1895<br>US 8167531000<br>uspt@polsinelli.com |
| <b>Filer:</b>                               | Joshua Prancun/Donna Carrera                                                                                                |
| <b>Filer Authorized By:</b>                 | Joshua Prancun                                                                                                              |
| <b>Attorney Docket Number:</b>              | 083003-620553                                                                                                               |
| <b>Receipt Date:</b>                        | 07-MAY-2021                                                                                                                 |
| <b>Filing Date:</b>                         |                                                                                                                             |
| <b>Time Stamp:</b>                          | 16:55:56                                                                                                                    |
| <b>Application Type:</b>                    | Utility under 35 USC 111(a)                                                                                                 |
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| Submitted with Payment                      | no                                                                                                                          |
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| Information:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                      |                            |                                          |                  |                  |
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| <p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><b><u>New Applications Under 35 U.S.C. 111</u></b><br/>If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><b><u>National Stage of an International Application under 35 U.S.C. 371</u></b><br/>If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><b><u>New International Application Filed with the USPTO as a Receiving Office</u></b><br/>If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p> |                      |                            |                                          |                  |                  |