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Defendant/Counter-Plaintiff Corbin Clinical Resources, LLC, (“Corbin”), through counsel, submits Corbin’s Amended Responsive Claim Construction Brief pursuant to Local Rule 805(1)(h) and the Second Amended Scheduling Order [Dkt. 73], including supporting evidence rebutting Plaintiff Advance Medical Designs, Inc.’s Updated Opening Claim Construction Brief [Dkt. 76] (“AMD Brief”). In further support of its claim construction positions, Corbin states as follows:

I. INTRODUCTION

Defendant Advance Medical Designs, Inc. (“AMD”) proposes construing nine terms found in U.S. Patent No. 10,064,681 (“’681 Patent”), **Exhibit A** [Dkt. 75-1], U.S. Patent No. 11,096,762 (the “’762 Patent”) **Exhibit B** [Dkt. 75-2], 11,246,677 (the “’677 Patent”) **Exhibit C** [Dkt. 75-3], U.S. Patent No. 11,446,056 (the “’056 Patent”) **Exhibit D** [Dkt. 75-4], and 11,547,436 (the “’436 Patent”) **Exhibit E** [Dkt. 75-5] (together the “Asserted Patents”). These terms are comprised of common everyday words readily understood by a person of ordinary skill in the art (“POSITA”). The terms do not need construing because their meaning and scope is clear from a simple reading of the patent claims. The inventor never offered alternate definitions of the disputed terms, never identified a clear intent to modify the meaning of such terms, and never provided any indication that the plain and ordinary meaning of the terms are not sufficient. These are not technical terms of art, such as those terms proposed by Corbin. There is nothing that strikes against the presumption that the plain and ordinary meaning of the claims shall apply. *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1363 (Fed. Cir. 1999) (the plain and ordinary meaning is presumed to apply).

AMD improperly attempts to re-write certain claim terms to advance theories of non-infringement. *See, e.g., Eon Corp. IP Holdings LLC v. Silver Spring Network, Inc.*, 815 F.3d 1314, 1319 (Fed. Cir. 2016) (it is well settled that claim construction “should not resolve questions that do not go to claim scope, but instead go to infringement . . . or improper attorney argument.”).

AMD's proposed constructions are also confusing and unsupported by the intrinsic record. *See generally* AMD Brief. Those arbitrary constructions do not comport with their plain and ordinary meaning, violate well-settled claim construction principles, inject more uncertainty than they resolve, and improperly rely on misleading extrinsic evidence. In some instances, AMD deletes clear requirements of the claims. In other instances, AMD attempts to commit the “cardinal sin” of importing limitations into the claims to escape infringement. *SciMed Life Sys., Inc. v. Adv. Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1340 (Fed. Cir. 2001). In doing so, AMD relies very little on the claims and specifications of the Asserted Patents. *See generally* AMD Brief; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 1303) (quoting *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985)) (the Federal circuit has long emphasized that the specification is “the primary basis for construing claims.”).

There are only two exceptions to the general rule that claim terms are given their ordinary and customary meaning: “1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution.” *Thorner v. Sony Computer Entertainment America LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). In this case, there is no suggestion in the claims, specification or prosecution history that the inventor assigned a unique definition to these terms, or otherwise disavowed the full scope of the claims. Therefore, the plain and ordinary meaning of the terms should govern. *See, e.g., DSW, Inc. v. Shoe Pavilion, Inc.*, 537 F.3d 1342, 1347 (Fed. Cir. 2008) (stating that “absent contravening evidence from the specification or prosecution history, plain and unambiguous claim language controls the construction analysis”).

AMD's other arguments are similarly flawed. For example, AMD claims that two terms found in the '677 Patent are indefinite “due to ambiguity/lack of written support.” However, the

identified terms use simple, ordinary language and their meaning is clear. The claims, read in light of the specification, clearly inform, with reasonable certainty, a POSITA about the scope of the invention. Therefore, they are not indefinite.

II. DICTIONARIES

AMD attaches various dictionary definitions as Exhibits J through O [Dkt. 58-10 – Dkt. 58-15] to the AMD Brief, though it minimally relies on the same in making its argument. Where “the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996). “The claims, specification, and file history, rather than extrinsic evidence, constitute the public record of the patentee’s claim, a record on which the public is entitled to rely.” *Id.* That is, “competitors are entitled to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee’s claimed invention and, thus, design around the claimed invention.” *Id.* “Allowing the public record to be altered or changed by extrinsic evidence would make this right meaningless.” *Id.*

The problems associated with the reliance on extrinsic evidence in claim construction are particularly true for dictionary definitions. The Federal Circuit has explained that in claim construction, “[t]he main problem with elevating the dictionary to such prominence is that it focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent.” *Phillips*, 415 F.3d at 1321. As the Federal Circuit has explained:

Dictionaries, by their nature, provide an expansive array of definitions. General dictionaries, in particular, strive to collect all uses of particular words, from the common to the obscure. By design, general dictionaries collect the definitions of a term as used not only in a particular art field, but in many different settings. In such circumstances, it is inevitable that the multiple dictionary definitions for a term will extend beyond the construction of the patent [that] is confirmed by the avowed understanding of the patentee, expressed by him, or on his behalf, when his application for the original patent was pending.

Id. at 1321-22 (citing *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222, 227 (1880)). Thus, “the use of the dictionary may extend patent protection beyond what should properly be afforded by the inventor’s patent.” *Id.* at 1322. The Court went on:

Moreover, different dictionaries may contain somewhat different sets of definitions for the same words. A claim should not rise or fall based upon the preferences of a particular dictionary editor, or the court’s independent decision, uninformed by the specification, to rely on one dictionary rather than another. Finally, the authors of dictionaries or treatises may simplify ideas to communicate them most effectively to the public and may thus choose a meaning that is not pertinent to the understanding of particular claim language.

Id. at 1322 (internal citations omitted).

Even if considered, the Court in claim construction must ascertain the ordinary meaning of claim terms as of the earliest effective filing date of a patent. *See Helmsderfer v. Bobrick Washroom Equipment, Inc.*, 527 F.3d 1379, 1381 (Fed. Cir. 2008) (“To construe a claim term, a court must determine the meaning of any disputed words from the perspective of one of ordinary skill in the pertinent art at the time of filing.”). In this case, it appears that the proposed definitions are more current definitions updated on August 18, 2022, not those existing on April 3, 2014. AMD Ex. J, p. 5 of 10. Therefore, they are irrelevant for the purposes of this analysis.

III. CORBIN’S PROPOSED TERMS

Term 1 “pair of stabilization members”:

(’762 Patent Claims 1, 5, 6, 9, 10-13, 16-19, 27, 28, 32, 34, 36 and 39; ’677 Patent Claims 9, 10, 13, 21, 28 and 29; ’056 Patent Claims 16 and 17; ’436 Patent Claim 27)

Corbin’s Proposal	AMD’s Proposal
“two stabilization bars or other structures able to resist movement of the platform or displacement member in all directions except along the length of the probe”	Plain and ordinary meaning

Term 2 “pair of stabilization bars:**(’681 Patent Claims 1-5, 7, 8, 12, 19 and 20)**

Corbin’s Proposal	AMD’s Proposal
“two bars able to resist movement of the platform or displacement member in all directions except along the length of the probe”	Plain and ordinary meaning

AMD claims that Term 1 and Term 2 are not in dispute and therefore do not need construing. AMD Brief, pp. 5-6. In doing so, it ignores the claims and specification of the Asserted Patents, and the unique meaning the inventor assigned to those terms. Indeed, “stabilization bars” are not ordinary words commonly used by ordinary people. If the terms are not defined, then a trier of fact risks assigning an overly broad meaning to them, taking the claims outside the scope of the invention as described by the inventor. For the reasons stated in Corbin’s Amended Opening Claim Construction Brief [Dkt. 75] (“Opening Brief”), pp. 5-13, Corbin respectfully requests that this Court adopt its proposed definitions of Term 1 and Term 2.

Term 3: “Biopsy Needle”

(’681 Claims 16; ’762 Patent Claims 2-4, 13-15, 17, 20, 27, 33, 36-38, and 40; ’677 Patent Claims 1, 11-13, 17, 22, and 30; ’056 Patent Claims 11, 12, 27, 28; ’436 Patent Claims 1, 3, 4, 5, 12, 13, 15-17, 23, 24, 28, and 29)

Corbin’s Proposal	AMD’s Proposal
“a needle system capable of obtaining tissue or cell specimens”	“a needle or needle system capable of obtaining tissue or cell specimens”

In its Opening Brief, Corbin explains why an ordinary “needle” is not sufficient to meet the requirement for a “biopsy needle.” See Opening Brief, pp. 13-16. The AMD Brief cites portions of the specification referencing a biopsy “instrument,” and concludes that a biopsy instrument may be a biopsy system, even though the specification never says that. AMD Brief, p. 6-7. Instead, patents generally use the terms “biopsy instrument” and “biopsy needle” interchangeably. See, e.g., ’436 Patent, 2:15-17 (“The biopsy grid may provide multiple apertures through which a

biopsy needle or other biopsy instruments may be inserted.”). AMD makes no arguments that strike against Corbin’s proposed definition.

Term 4: “Access Needle”

(’681 Patent Claims 1, 2, 5, 10, 13, 14, 17, 19, and 20; ’762 Patent Claims 1-4, 6, 7, 12-19, 21, 24, 26-29, 32, 33, 36-39, and 41; ’677 Patent Claims 1, 3, 4, 13, 16, 22, and 25; ’056 Patent Claims 1, 6, 9, 10, 13, 14, 16, 21, 25, 26, 29 and 30; ’436 Patent Claims 1, 6, 10, 11, 13, 18, 22-26, and 28-30)

Corbin’s Proposal	AMD’s Proposal
“a needle providing access to the body comprising a lumen sized to receive a biopsy needle or other instrument therethrough”	“a needle providing access to the body”

The term “access needle” is not an ordinary word commonly used by ordinary people; rather, it is a term unique to this invention. In its Opening Brief, Corbin explains why an “access needle” is more than just a needle that provides access to the body, and that it is comprised of a lumen sized to receive a biopsy needle or other instrument therethrough. See Opening Brief, pp. 16-22. Therefore, it may be properly construed by this court.

AMD claims that the doctrine of claim differentiation precludes Corbin’s proposed construction because independent claim 16 of the ’681 Patent requires that “the access needle is configured to receive a biopsy needle therethrough.” AMD Brief, pp. 7-9. That is not true. Dependent claims narrow the scope of independent claims and therefore have a different scope than the independent claims. In this case, Corbin advocates for a construction of “access needle” wherein the needle has a “lumen sized to receive a biopsy needle or other instrument therethrough.” (emphasis added). If that definition is adopted, then claim 16 of the ’681 Patent and claim 2 of the ’762 Patent would naturally narrow the claim to include only a “biopsy needle,” excluding other biopsy instruments. Clearly, the specification contemplates biopsy instruments other than a biopsy needle, thus requiring the broader definition proposed by Corbin. See ’436

Patent, 2:1-3 (referring to “a biopsy needle or other biopsy instruments”). The same is true with respect to the claims of the ’677 Patent, the ’056 Patent, and the ’436 Patent, none of which require a lumen capable of receiving an “other biopsy instrument,” as contemplated by the specification. Rather, they narrow the scope of Term 4 to receive only a biopsy needle, precluding any alleged redundancy or claim construction arguments.

IV. AMD’S PROPOSED TERMS DO NOT REQUIRE CONSTRUCTION

The terms proposed to be construed by AMD are common everyday words that a person of ordinary skill in the art (“POSITA”) – or even lay jurors – would readily understand in the context of the patents and their claims. AMD proposes constructions that depart from their plain and ordinary meaning, even though the inventor never suggested an alternate meaning. In doing so, they introduce more confusion than clarity, improperly import limitations into the claims, and rely on misleading extrinsic evidence. Therefore, they should be rejected.

Term 5: “an upper mount and a lower mount configured to couple to each other, the lower mount configured to engage the transrectal probe” (’681 Patent Claim 1)

Corbin’s Proposal	AMD’s Proposal
No construction required – plain and ordinary meaning	“an upper mount and a lower mount configured to: Independently engage a transrectal probe; and couple to an upper mount”

1. AMD’s Proposed Construction of Term 5 is Arbitrary and Unsupported

AMD proposes to redraft a simple, clear claim limitation that plainly describes the invention with the hopes of escaping infringement. In doing so, it re-arranges the phrase, deletes the requirement that the upper and lower mount be configured to “couple to each other,” and adds a requirement for the lower mount to “independently engage” a transrectal probe. However, claim 1 has no requirement that the lower mount independently engage the transrectal probe. Instead, the lower mount and the upper mount couple “to each other” to engage the transrectal probe. *See* ’681

Patent, 15:17-20. In particular, Claim 1 requires “an upper mount and a lower mount ***configured to couple to each other***, the lower mount configured to engage the transrectal probe ***and secure the upper mount relative to the transrectal probe.***” *Id.* (emphasis added). This claim language is supported by the intrinsic record and would in fact exclude the disclosed embodiments of the claims. For example, Figure 1 illustrates a lower mount and an upper mount coupled together to secure the probe. *See id.* at Fig. 1; 8:38-45.

The dependent claims further strike against AMD’s proposed construction. Claims 6 and 14 depend from Claim 1, each of which require that “the upper mount and lower mount are configured to be secured to the transrectal probe by a fastener.” *See id.* at 15:46-48, 16:13-17. All requirements of Claim 1 are also requirements of Claims 6 and 14. It would be impossible to require that the lower mount be “configured to independently engage a transrectal probe” and also require that the upper mount ***and*** lower mount be secured to the transrectal probe by a fastener.

Nowhere in the intrinsic record does the inventor even suggest that the lower mount must be configured to “independently engage” a transrectal probe. In fact, the word “independently” is not found anywhere in the ’681 Patent. Therefore, a requirement that a lower mount independently engage the transrectal probe should not be added to Claim 1 of the ’681 Patent.

Even if the Patents disclosed a preferred embodiment with this feature, it is well-settled law that preferred embodiments should not be used to read limitations into the claim. *See Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 418 (1908) (“An inventor must describe what he conceives to be the best mode, but he is not confined to that. If this were so most patents would be of little worth.”). It is a “cardinal sin” to import extraneous limitations from the specification into the claims. *SciMed Life Sys.*, 242 F.3d at 1340. Just because the specification discloses a particular embodiment, the claims should not be construed as being limited to that

embodiment. *Gemstar-TV Guide Intern., Inc., v. International Trade Com’n*, 383 F.3d 1352, 1366 (Fed. Cir. 2004). Similarly, courts must avoid importing limitations disclosed in the preferred embodiment into broader patent claims. *See, e.g., Conoco, Inc. v. Energy & Environmental Int’l, L.C.*, 460 F.3d 1349, 1357-58 (Fed. Cir. 2006); *McCarty v. Lehigh Valley R.R. Co.*, 160 U.S. 110, 116 (1895) (“if we once begin to include elements not mentioned in the claim, in order to limit such claim . . . , we should never know where to stop”); *Texas Digital Systems, Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed. Cir. 2002) (“unless compelled otherwise, a court will give a claim term the full range of its ordinary meaning”). While “the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.” *Phillips*, 415 F.3d at 1323.

AMD’s proposed construction would also exclude the preferred embodiments, as none of them depict a lower mount configured to “independently engage” a transrectal probe; rather, they all depict an upper mount that is engaged with the transrectal probe. *See generally* ’681 Patent. For that reason alone, the Court cannot accept AMD’s proposed construction of this term. *See, e.g., Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1305 (Fed. Cir. 2007) (rejecting proposed claim interpretation that would exclude disclosed examples in the specification); *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1369 (Fed. Cir. 2003) (finding district court’s claim construction erroneously excluded an embodiment described in an example in the specification, where the prosecution history showed no disavowal of claim scope); *see also Vitronics*, 90 F.3d at 1583 (finding that a claim interpretation that excludes a preferred embodiment is “rarely, if ever, correct”).

The specification describes multiple ways of engaging the transrectal probe utilizing both the lower and upper mounts. *See, e.g.,* ’681 Patent, Figs. 1, 2A, 2B, 2C, 3, 4, 5, 6, and 7; 8:38-

9:40. For example, Figure 2C shows a zip-tie fastener connected to the upper mount. *See id.* at 9:25-35. Figure 4 shows a fastener connecting the lower mount to the upper mount to engage the transrectal probe. *See id.* at 9:54-57. Figures 26A through 26C show a guide fitted to a probe by a sleeve which is “formed by the lower mount 104 and the upper mount 105.” *See id.* at 12:35-42. AMD provides no support for its suggestion that Claim 1 should be re-written in this manner. Indeed, the inventor never made such a suggestion. Not only is AMD’s modification to the claim language unnecessary and unsupported, it adds confusion, which is contrary to the purpose of claim construction.

The proposed construction also replaces the requirement for “an upper mount and a lower mount configured to couple to each other” with a requirement that the lower mount “couple to an upper mount.” That defies both the claim language and various descriptions in the specification. *See, e.g., id.* at 8:42-45 (“[i]n embodiments, the distance between the fasteners 102 and the upper mount 105 may be adjustable to accommodate various applications and body habitus.”); 8:46-52 (describing a connection between the upper and lower mounts relative to the guide).

Because its construction is wholly unsupported by the claims and specification, the Court should reject it in favor of its plain and ordinary meaning.

2. Prosecution History Estoppel Does Not Apply to Term 5

The doctrine of prosecution disclaimer is ‘well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution.’ *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003). In this case, AMD argues that “the ’681 Patent disavowed the claim scope of a lower mount that secured the upper mount relative to the transrectal probe but did not, itself, engage the transrectal probe.” AMD Brief, p. 9. However, the doctrine of prosecution history estoppel has no

applicability whatsoever when a party advocates against construing the terms of a patent claim, as is the case here.

The prosecution history represents a dialogue between the patent examiner and prosecuting attorney that resulted in the issuance of claims. *See, e.g., In Re Buszard*, 504 F.3d 1364, 1366-67 (Fed. Cir. 2007) (“The patent examiner and the applicant, in the give and take of rejection and response, work toward defining the metes and bounds of the invention to be patented.”). Prosecution history estoppel applies if a party attempts to advocate for a construction that differs from the claim language, such as a construction that would broaden the scope of the patent to cover material disclaimed during prosecution. *See, e.g., Kranos IP Corporation v. Riddell*, 339 F.Supp.3d 850, 857 (N.D. Ill. 2018) (rejecting an argument that the plaintiff is prosecution-history-estopped from claiming the plain and ordinary meaning of a disputed claim term, even when the limitation was adopted in an amendment to overcome an obviousness rejection.”).

The metes and bounds of the invention are set forth in its claims. In this case, arguing for the plain and ordinary meaning of those claims does not, and cannot, invoke prosecution history estoppel because the inventor is not advocating for a deviation from the duly issued claims. Rather, it is seeking to stay true to the claims that issued during prosecution. AMD’s statement that “Corbin cannot explain how the plain and ordinary meaning of this claim term would exclude the configuration of Onik, as required.” AMD Brief, p. 12. That statement is nonsensical, as ***the issued claims*** are the result of the dialogue between the examiner and the inventor.

3. There Was No Disavowal Of Claim Scope During Prosecution

Even if prosecution history estoppel did apply, there was no disavowal of claim scope in this case. Prosecution history estoppel “can occur in two ways: ‘either (1) by making a narrowing amendment to the claim (‘amendment-based estoppel’) or (2) by surrendering claim scope through argument to the patent examiner (‘argument-based estoppel’).” *Pharma Tech Solutions, Inc. v.*

LifeScan, 942 F.3d 1372, 1380-81 (Fed. Cir. 2019) (quoting *Conoco*, 460 F.3d at 1363. Regarding amendment-based prosecution history estoppel, “the Supreme Court has recognized that a ‘patentee’s decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim.’” *Id.* (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 740 (2002)). With “argument-based prosecution history estoppel, “the prosecution history must evidence clear and unmistakable surrender of subject matter.”” *Id.* (citing *Conoco, Inc.*, 460 F.3d at 1364). “To invoke argument-based estoppel ... the prosecution history must evince a clear and unmistakable surrender of subject matter.”” *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1367 (Fed. Cir. 2007) (citing *Conoco, Inc.*, 460 F.3d at 1364).

In this case, AMD claims that the inventor disavowed claim scope in arguments made to overcome prior art reference U.S. Patent No. 5,494,039 to Onik (“Onik”). AMD Brief, pp. 9-13. While it is true that the Examiner initially identified the Onik reference as potential prior art, that reference was quickly disregarded and the application for the ’681 Patent issued with minimal argument. And rightfully so. Onik describes a totally different invention with a different structure. *See* Onik, Plaintiff Ex. E [Dkt. 58-5]. Onik is not even used for transperineal biopsies; rather, it is a cryosurgical device used after biopsies are taken. *See id.* It is clear that the block **16** of Onik is nothing like the “upper mount” in the ’681 Patent. *See* AMD Brief, p. 11. The block is not comprised of the alleged platform and does not have a pair of stabilization bars, as required by the ’681 Patent. *Id.* In making its arguments to the examiner, the inventor never made a clear and unmistakable surrender of subject matter. Indeed, it never surrendered any subject matter to gain allowance.

AMD references an interview on May 4, 2018, wherein the inventor discussed Onik with the Examiner. AMD Brief, p. 12. It notes that, during that conversation, the inventor stated that “Examiner suggested amending claims to clarify lower mount to overcome the cited reference.” *Id.* This statement is not helpful to AMD’s argument. First, an Applicant cannot disavow claim scope merely by noting an Examiner’s statement and such does not constitute an express disavowal of claim scope.

Second, AMD only quotes a portion of that statement. The whole statement is as follows: “Examiner suggested amending claims to clarify lower mount to overcome cited reference. ***Examiner stated a new search needs to be conducted to determine allowability, no agreement was reached.***” (emphasis added). May 4, Interview, Plaintiff Ex. F [Dkt. 58-6]. Clearly, there was no agreement to amend the claims to overcome Onik. In fact, as noted four days later in the Applicant’s May 8, 2018 Office Action Response, the Examiner stated he would “remove the reference to Onik as applied to the current claims ***based on our previously submitted arguments***, among other reasons.” (emphasis added). May 8, 2018, Office Action Response, p. 6-8, Plaintiff Ex. G [Dkt. 58-07]. The arguments regarding Onik presented in the May 8, 2018, Office Action Response are the same as the *previously submitted arguments* on pages 5-7 the January 3, 2018, Office Action Response. *See* Response to Oct. 6, 2017 Office Action, attached as **Exhibit H**; Response to April 2, 2018 Office Action, attached as **Exhibit I**. Thus, the inclusion of the “upper mount” in the claims in the May 8, 2018 Office Action Response was merely for clarity, and had no bearing on the arguments presented to distinguish the claims from Onik because the previously submitted arguments, along with a discussion of the same during the Interview, were sufficient to change the Examiner’s opinion regarding the allowability of the claims. In response to that Office

Action Response, the USPTO issued a Notice of Allowance on July 24, 2018. Notice of Allowance, attached as **Exhibit J**.

The Notice of Allowance stated that Applicant's arguments "have been fully considered and are persuasive. The rejection of claims 21-40 has been withdrawn." See Notice of Allowance, Detailed Action, p. 2, **Ex. J**. Nothing in the Notice of Allowance indicated that the Examiner was issuing the '681 Patent based on statements of estoppel; rather, the Examiner stated that ***Onik does not alone or in combination teach the limitations of the independent claim.*** *Id.* In the Comments on Statement of Reasons for Allowance submitted on June 26, 2018 ("Comments"), the Applicant reaffirmed his understanding that there was no prosecution history estoppel:

Applicant expressly traverses the Examiner's Statement of Reasons of Allowance to the extent that any statement is intended to or has the intended effect of limiting a claim scope, explicitly or implicitly, by not reciting verbatim the respective claim language, or is intended to or has the effect of limiting a claim scope by stating or implying that all the reasons for patentability are in any way fully enumerated. The Applicant specifically does not acquiesce or agree in any manner as to any assertion in Examiner's statements that may be interpreted to narrow the claims to less than their recited scope.

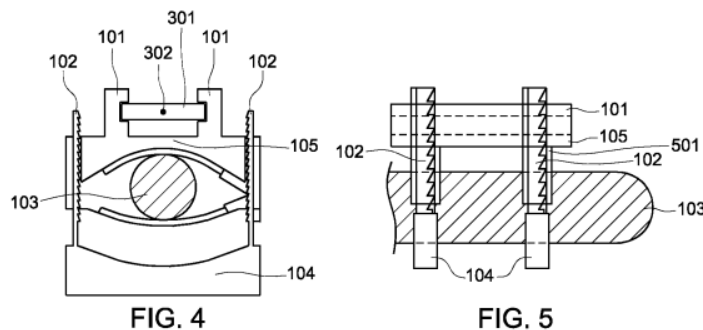
See Comments, p. 1, attached as **Exhibit K**.

The inventor never disclaimed any subject matter to overcome Onik. The statements that were made simply clarified Onik but did not rise to the level of prosecution history disclaimer. Tellingly, AMD cites no express disavowal of claim scope. It merely references the addition of the language "... and a lower mount configured to couple to each other, the lower mount configured to engage the transrectal probe and secure the upper mount relative to ..." AMD Brief, p. 12. However, that language does not support the argument that the lower mount can "independently engage" the transrectal probe. If anything, that language clarifies that the upper mount needs the lower mount in order to engage the transrectal probe. Nothing indicates that this language was added "to distinguish the upper mount and lower mount of Onik from the upper and

lower mount claimed in the '681 Patent" as claimed by AMD. *Id.*; see *Warner-Jenkins Co., Inc., v. Hilton Davis Chemical Co.*, 520 U.S. 17 (1997) ("[o]ur prior cases have consistently applied prosecution history estoppel only where claims have been amended for a limited set of reasons, and we see no substantial cause for requiring a more rigid rule invoking an estoppel regardless of the reasons for a change.").

AMD claims that "the '681 Patent disavowed the claim scope of a lower mount that secured the upper mount relative to the transrectal probe but did not, itself, engage the transrectal probe." *Id.* No such disavowal was made. Such a statement would be non-sensical, as every embodiment of the '681 Patent shows the upper mount engaging the transrectal probe and such a disavowal would remove all embodiments. See *generally* '681 Patent.

AMD claims that the prosecution history and specification emphasize the fact that the lower mount is configured to engage the transrectal probe directly and not through an intermediate structure such as the upper mount. AMD Brief at p. 12-13. To support that argument, AMD cites Figures 1 and 5. However, every embodiment, including those in Figures 1 and 5, shows the lower mount – in combination with the upper mount – engaging the transrectal probe. Figure 4 shows the structure of Figures 1 and 5 from a different angle, which clearly shows the upper mount 105 and the lower mount 104 directly contacting the probe 103 by use of the fasteners 102:



'681 Patent, 9:54-57. Every embodiment shows the upper mount and lower mount working together to engage the transrectal probe.

4. The Disavowal Claimed By AMD Still Would Not Support Its Proposed Construction

The inventor never assigned a special meaning to the term “an upper mount and a lower mount configured to couple to each other, the lower mount configured to engage the transrectal probe” or otherwise suggested a deviation from its plain and ordinary meaning. Even if the inventor did make the disavowals claimed by AMD, they would still not substantiate a construction of a lower mount “configured to independently engage a transrectal probe.” The inventor never suggested that the lower mount must independently engage the probe. *See, e.g., Biotras, LLC v. Clear Ballistics, LLC*, 3:16-CV-00566-K, 2017 WL 1509304, at *9 (N.D. Tex. April 27, 2017) (“even if estoppel had occurred, which appears unlikely, the file wrapper cited by the Defendants does not support their proposed constructions because the attorney arguments and examiner comments do not address the limitations that the Defendant now wants to impose upon these claims.”).

Term 6 “platform configured to slide (on the [a] pair of stabilization bars [members] relative to the base, relative to the pair of stabilization members, within the channel)” (’681 Patent Claim 1; ’762 Patent Claims 13 and 36; ’677 Patent Claims 1, 13, and 22)

Corbin’s Proposal	AMD’s Proposal
No construction required – plain and ordinary meaning	“a platform configured to slide (on the pair of stabilization bars [members], relative to the pair of stabilization members, within the channel) while the access needle is engaged with the platform”

Term 7 “so as to displace the access needle along the at least a portion of the length” (’681 Patent Claim 1)

Corbin’s Proposal	AMD’s Proposal
No construction required – plain and ordinary meaning	“so as to displace the entire platform supporting the access needle between the front portion and the back portion of the stabilization bars”

In its brief, AMD spends time describing statements made during the prosecution of the various patents, but never points to any statement in the claims, specification, or prosecution history that suggest a deviation from the plain and ordinary meaning of Terms 6 and 7. *MEMS Technology Berhad v. International Trade Com’n*, No. 2010-2018, 2011 WL 2214091, *7 (Fed. Cir. June 3, 2011) (declining to construe a term where “[n]owhere in the specification is the claimed electrical coupling described as ‘direct,’ and nothing in the claim language or specification suggests that ‘electrically coupled’ should have any interpretation other than its plain meaning.”).

1. AMD’s Proposed Definition Of Term 6 Is Arbitrary And Unsupported

For its proposed construction of “platform configured to slide,” AMD merely adds a requirement that the platform be configured to slide “while the access needle is engaged with the platform.” This is not a proposed definition of a claim term; rather, it is a proposal to **add to** the claim term and improperly import a limitation that does not exist. Term 6 is clear and unambiguous. Nowhere does the inventor indicate that the term “platform configured to slide” has a special meaning, or that adding the words “while the access needle is engaged with the platform” is required. None of the claims of the Asserted Patents have a requirement that the platform be configured to slide “while the access needle is engaged with the platform.” See ’681 Patent, 15:11-16:53; ’762 Patent, 15:10-18:35; ’677 Patent, 15:10-17:12, ’056 Patent, 35:32-38:27; ’436 Patent, 35:45-38:44. The intrinsic record provides no support to AMD’s suggestion that these requirements should be added to the claims of any Asserted Patent. Had the inventor wanted to add those words to the claims, he would have done so. That limitation simply does not exist and it would be improper to import such a requirement into the claims.

2. AMD’s Proposed Construction Of Term 7 Is Arbitrary And Unsupported

In its proposed construction of Term 7, AMD asks this court to substitute the phrase “the access needle along the at least a portion of the length” with “the entire platform supporting the

access needle between the front portion and the back portion of the stabilization bars.” However, there is no support in the intrinsic record for this change, nor is any cited by AMD. Similarly, AMD provides no extrinsic evidence to support its position.

Even worse, AMD’s proposed construction is contrary to the preferred embodiments and therefore improper. *See, e.g., Verizon Servs.*, 503 F.3d at 1305 (rejecting proposed claim interpretation that would exclude preferred embodiments). Claim 1 of the ’681 Patent requires that the platform be “configured to support the access needle and the platform configured to slide on the pair of stabilization bars along at least a portion of the length so as to displace the access needle along the at least a portion of the length.” ’681 Patent, 15:28-33. The only requirement of the claim language is that the platform be configured to slide such that the access needle is displaced along “at least a portion of the length” of the stabilization bars. *Id.* AMD’s proposed definition attempts to improperly add the requirement that the platform, in its entirety, be displaced between the front portion and the back portion of the stabilization bars. However, there is no requirement that the movement of the “entire platform” be confined to the front and back portions of the stabilization bars, much less the access needle. *Id.* The specification never even mentions the words “entire” or “entire platform,” or otherwise imposes a limitation on the movement of the platform relative to the stabilization bars. *See generally* ’681 Patent. The inventor meant what was said in Claim 1 of the ’681 Patent: “so as to displace the access needle along the at least a portion of the length.”

Not only is AMD’s proposal unsupported by the specification, but it is also inconsistent with it. The specification broadly describes the structure of the guide as follows:

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.

Id. at 5:24-39. There is no limitation on the movement of the guide. *See also id.* at 5:54-58 (“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.”); 5:58-65 (“The grooves accommodate a sliding platform which is shorter in length than the stabilization bars”). These excerpts imply that a sliding platform that is longer in length than the stabilization bars is a possibility, undercutting the definition proposed by AMD. There is no suggestion that the movement of the platform be limited as proposed by AMD.

AMD references the prosecution history of the ’681 Patent, but it fails to cite any statements that support its argument. To the contrary, the cited portions of the prosecution history merely state that the Onik prior art reference does not disclose a guide configured to “displace a needle along at least a portion of its length.” Response to April 2, 2018, Office Action, 6-8, **Ex. I**. The argument was that Onik fails to disclose an access needle and so it follows that it does not disclose displacing an access needle. *Id.* There was no discussion regarding the front and back portion of the stabilization bars, or any other suggestion that the movement of the platform be limited.

Accordingly, the Court should reject AMD’s proposed construction of this Claim Term 7 and afford it its plain and ordinary meaning.

3. Prosecution History Estoppel/Disclaimer Does Not Apply To Terms 6 and 7

Prosecution history estoppel “‘is a ‘rule of patent construction’ that ensures that claims are interpreted by reference to those ‘that have been cancelled or rejected.’” *Festo*, 535 U.S. at 733 (quoting *Schriber-Schroth Co. v. Clevelant Trust Co.*, 311 U.S. 211, 220-221 (1940)). That doctrine is inapplicable here because Corbin is not proposing its own definitions; rather it is asking

this court to *decline* to construe these terms and instead to allow the trier of fact to rely on the plain and ordinary meaning of the claim language. Therefore, prosecution history estoppel does not apply to either Term 6 or Term 7.

4. The Inventor Did Not Disavow the Claim Scope

AMD’s argument that the inventor somehow made a disclaimer of all other subject matter is futile. AMD claims that the ’681 Patent distinguished its claim language from Onik by arguing that Onik does not describe a “platform configured to support the access needle and platform configured to slide on the pair of stabilization bars along at least a portion of the length so as to displace the access needle along at least a portion of the length.” AMD Brief, p. 15. In doing so, AMD argues that “Onik did not disclose this claim language because of the timing of when Onik’s ‘platform’ moved relative to when the access needle was inserted into the platform.” AMD Brief, p. 15. AMD noted that the inventor stated that “Onik uses a biopsy needle, which is inserted through the notch 31 of the needle holder assembly 28 **once the guide 1 is set in position against the patient’s body.**” *Id.* on p. 15-16 and 18 (emphasis added in AMD Brief). However, AMD misses the mark.

The point the inventor was making was that Onik describes a biopsy needle insertion guide for cryosurgery that does not have an *access needle*. Response to Oct. 6, 2018 Office Action, p. 5-6, **Ex. H**. In fact, the statement relied on by AMD is part of an “overview” discussion of Onik that includes multiple citations and quotations from Onik that describe its general uses. It is only at the last sentence of this paragraph that the inventor contrasts Onik with the claim language by stating, “Onik’s guide is not used with an access needle and is not configured to ‘displace the access needle along the at least a portion of the length’ of a pair of stabilization bars.” *Id.* at 6. The inventor goes on to state in the next paragraph that his “apparatus, on the other hand, is configured for use with an access needle through which a biopsy needle can be inserted.” *Id.* To further distinguish Onik,

the inventor argued that “[t]he needle holder assembly 28 cannot be considered claim 21’s ‘platform’ because it does not ‘slide’ on anything that could be considered ‘a pair of stabilization bars.’” *Id.* He went on “[c]learly, the needle holder assembly 28 does not ‘slide’ on the shafts 27’ because they are fixed together.” *Id.* These statements clarify the requirement for an access needle. They do not support a requirement for the language “while the access needle is engaged with the platform.”

AMD states that these same arguments were advanced in relation to U.S. App. No. 16,377,754, which became U.S. Pat. No. 10,743,911 (the “’911 Patent”). AMD Brief, p. 16-17. However, the ’911 Patent is different for numerous reasons. It has method claims wherein the ’681 Patent has apparatus claims. More importantly, the claims of the ’911 Patent *specifically require* inserting an access needle into the perineal access site of the patient by sliding a displacement member (including a platform) of the biopsy guide relative to the guide member of the biopsy guide. See ’911 Patent, 35:33-38:27 [Dkt. No. 58-9]. Thus, while Onik is discussed during prosecution of both the ’911 Patent and the ’681 Patent, the purpose and context are vastly different because the claim language is vastly different. In addition to the difference in type and scope of claims, the ’911 Patent also has a different disclosure than the Asserted Patents and includes numerous other different embodiments. Therefore, any statements made by the inventor in pursuit of the ’911 Patent would not constitute estoppel with respect to the ’681 Patent.

AMD argues that “[t]he claim language of the ’762 and ’677 Patents both indicate that the applicant understood ‘a platform that is configured to slide’ is one that slides after the access needle engages it.” AMD Brief, p. 17. In stark contrast to the ’911 Patent, nothing in the Asserted Patents or their prosecution histories indicate that the platform is configured to slide only “while the access

needle is engaged with the platform.” *That is a claimed feature of the ’911 Patent*, not the Asserted Patents. *See* ’911 Patent, 35:33-38:27.

AMD references a May 2, 2018, letter to the European Patent Office (“EPO Letter”) in regard to a *foreign* patent application. In doing so, it argued that “Corbin emphasized that Onik’s ‘guide is affixed to an ultrasound probe and advanced until the needle holder assembly 28 engages and bears firmly against the patient’s perineum’ and then a biopsy needle is ‘placed in the notch 31, and the surgeon advances the needle into the patient with the guide maintained in position.’” AMD Brief, p. 16; EPO Letter, [Dkt. No. 58-16]. This statement is taken out of context within the EPO Letter and does not support AMD’s position. The paragraph from the EPO letter is merely an introduction and overview of Onik, not an emphasis on distinguishable characteristics of Onik as compared with the claims. *See* EPO Letter, pp. 8-9. The paragraph in the EPO letter begins by saying, “[Onik] describes a biopsy needle insertion guide for use in cryosurgery. [Onik’s] guide is used” There are no statements in this paragraph about what Onik does *not* teach – it is merely background information on Onik’s teachings. This is setting the stage for the arguments in the next paragraph, which begins with “[Onik] does not disclose” It is in those paragraphs in which the inventor seeks to distinguish Onik. *See* EPO Letter, pp. 8-9.

AMD argues that, in the EPO prosecution, “Corbin emphasized that a distinguishing feature between Onik and its claims was the fact that Onik’s needle holder assembly moves prior to insertion of the biopsy needle whereas the claimed ‘platform’ slides with the access needle already inserted.” AMD Brief, p. 16. This was not what the EPO letter states. It discussed the timing of the insertion of the biopsy needle only in the introductory paragraph describing Onik’s general teachings. EPO Letter, pp. 8-9. The inventor distinguishes Onik in the subsequent paragraphs that state that “[Onik] does not describe” However, those paragraphs do not mention

the timing of insertion of the biopsy needle. *Id.* The focus of the inventor's arguments was that Onik "does not describe 'a first stabilization bar (101) and a second stabilization bar (101)' and a 'sliding platform (301) [that] is configured to slide from a back to a front of the first and second stabilization bars (101).'" *Id.* at p. 9. The inventor also argues that the needle holder assembly 28 cannot slide relative to its shafts 27 because they are "**fixed** to the proximal end of shaft 27." *Id.* (emphasis in original).

AMD makes reference to the May 2, 2018 EPO Letter wherein "the applicant argued that its claims were novel over Onik 'because [Onik] does not describe a sliding platform that is configured to slide from a back to a front of first and second stabilization bars.'" AMD Brief, p. 16. However, the foregoing language was a near exact recitation of the language of the EPO claims, which state "wherein the sliding platform (301) is configured to slide from a back to a front of the first and second stabilization bars (101)." *See* EPO Letter, p. 2, [Dkt. 58-16]. The reason the inventor used these words in the EPO letter was because it closely followed the language of the EPO claims. In contrast, the U.S. claim in the '681 Patent state that "the pair of stabilization bars including a back portion, a front portion, and a length extending along a longitudinal axis between the back and front portions, [...] the platform configured to slide on the pair of stabilization bars along at least a portion of the length so as to displace the access needle along the at least a portion of the length." '681 Patent, 15:22-33. Thus, AMD's reliance on statements in the EPO Letter to supposedly alter the claim language in the '681 Patent is misplaced since the inventor merely restated the EPO claim language.

AMD makes no substantive argument relating to Term 7 and provides no support for its definition. While the specification states that "[t]he stabilization bars may have grooves for accommodating a sliding platform that is shorter in length than the stabilization bars," that is not

a requirement. *See, e.g.*, '681 Patent, 5:54-56 (emphasis added); *see also Glaukos Corp. v. Ivantis Inc.*, Case No. SACV 18-620 JVS (JDEx), 2019 WL 8955768 *5 (C.D. Cal. Aug. 16, 2019) (declining to construe “distal portion” as “sits in Schlemm’s canal” because “the claims do not require placement of the ‘distal portion’ anywhere, much less ‘entirely within’ Schlemm’s canal; rather, the claims describe a device with portions ‘sized and shaped to be received within a portion of Schlemm’s canal.’). In this case, there is no requirement that the platform “is configured to slide from a back to a front of the first and second stabilization bars.” Therefore, these statements can in no way limit the claims of the '681 Patent.

It is also worthy to note that the language of the EPO claims relate to directional movement - from a back to a front – not the confinement of movement between two points as advocated by AMD in its proposed claim construction, i.e. “displace the entire platform supporting the access needle between the front portion and the back portion of the stabilization bars.” Therefore, even if it was limiting, it bears no relevance to the construction advocated by AMD.

5. AMD’s Proposed Construction Of Term 7 Violates The Doctrine Of Claim Differentiation

The term “claim differentiation” refers to the presumption that an independent claim should not be construed as requiring a limitation added by a dependent claim. *See Nazomi Commc’ns, Inc. v. Arm Holdings, PLC.*, 403 F.3d 1364, 1370 (Fed. Cir. 2005) (“[C]laim differentiation normally means that limitations stated in dependent claims are not to be read into the independent claim from which they depend.”) (quoting *Karlin Tech., Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971-72 (Fed. Cir. 1999)). The statute also stresses that a dependent claim must add a limitation to those recited in the independent claim. *See* 35 U.S.C. § 112(d) (“[A] claim in dependent form shall contain a reference to a claim previously set forth and then specify *a further limitation of the subject matter claimed.*”) (emphasis added).

In this case, AMD notes that dependent claim 18 of the '762 Patent requires "[t]he method of claim 13, wherein inserting the access needle into the perineal access site comprises sliding the access needle and platform along a portion of a length of the pair of stabilization members." See AMD Brief, p. 13-14; '762 Patent, 16:34-37 [Dkt. 75-2]. Through the doctrine of claim differentiation, that means that a requirement for "sliding the access needle and platform along a portion of a length of the pair of stabilization members" **is not** within the scope of the claims from which they depend. Rather, the independent claims have a broader scope. Accordingly, the language of those dependent claims support Corbin's argument against importing the limitation "while the access needle is engaged with the platform" into the independent claims of at least the '762 Patent.

Term 8: "the access needle being centrally positioned between the pair of stabilization members when the access needle is engaged with the platform" ('762 Patent, Claim 13)

Corbin's Proposal	AMD's Proposal
No construction required – plain and ordinary meaning	"the access needle being centrally positioned in the space separating the pair of stabilization members when the access needle is engaged with the platform"

1. AMD's Proposed Construction Of Term 8 Is Arbitrary And Unsupported

The Court does not need to construe Term 8 because a POSITA would understand the meaning and scope of the term from its context within in the claims and specification. This term is clear and unambiguous and the inventor never conveyed an intent to deviate from its plain and ordinary meaning.

In its proposed construction, AMD merely substitutes the word "between" with "in the space separating" to create the following sentence: "the access needle being centrally positioned ***in the space separating*** the pair of stabilization members when the access needle is engaged with the platform." Again, there is no support in the intrinsic record to warrant this modification to the

claim language. The inventor was clear that the needle must be held in a central position “between” the pair of stabilization members. *See* ’762 Patent, Claim 13. The proposed modification adds confusion to an otherwise clear and straight forward term. For example, it is unclear what is meant by the term “space separating” the pair of stabilization bars.

Nowhere does the ’762 Patent even mention the term “space separating” or even the word “separating.” *See generally* ’762 Patent. The only mention of the word “space” is in Claim 1, which states that “the pair of stabilization members spaced apart from each other ...” *Id.* at 15:16-17. The word “between” was never defined by the inventor, and he never provided any indication that one should deviate from the plain and ordinary meaning of that term. The concept of requiring the access needle to be positioned in the space separating the stabilization bars is similarly not described anywhere in the ’762 Patent. Instead, the specification describes guiding the access needle along a sagittal plane to the target. *See, e.g., id.* at 4:35-41 (the sliding platform allows a user to “place the access needle along a sagittal transducer plane at optimal positions for obtaining prostate biopsies.”); 5:1-5 (“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 plane.”); 6:28-30 (the needle hole is “parallel to the sagittal transducer.”). The sagittal plane extends from the transducer along a plane. It is important to position the needle in a central position between the pair of stabilization members so the needle is positioned within the plane. *See, e.g., id.* at 2:42-50 (The needle can be positioned at various heights within the sagittal plane without being in the “space separating” the pair of stabilization members.).

As one example, the ’762 Patent describes an embodiment at Figures 26A-26C in which “[t]he 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.” *Id.* at 12:48-53. In this particular embodiment of a platform with vertical adjustment of an access needle that ensures the access needle and probe remain parallel, the needle could be positioned outside of the “space separating” the pair of stabilization members. In another example, the ’762 Patent states that the “platform may have multiple holes to accommodate various applications and body habitus.” *Id.* at 6:47-50; *see also* 15:59-67. Given the importance that the access needle be positioned within the sagittal transducer plane, the multiple holes would logically be positioned vertically so that holes would guide the access needle in the sagittal plane. As with the embodiment in Figures 26A-26C, the embodiment with multiple holes may require the needle to be positioned outside of the “space separating” the pair of stabilization members. As such, AMD’s proposed construction would exclude certain embodiments from the claim language, violating an important rule of claim construction.

Because the stabilization members stabilize the platform and needle, it is necessary for them to be “centrally positioned between the pair of stabilization members.” If they were not, then the needle guide would not effectively guide the needle. However, there are no further requirements. The specification states that “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.***” *Id.* at 9:38-54 (emphasis added). While the platform must slide on the stabilization bars, there is no requirement that the needle be situated in the “space separating” the pair of stabilization bars, as opposed to above the stabilization bars.

Note that Claim 1 requires that the pair of stabilization members be spaced apart. *Id.* at 15:15-17. No such requirement appears in Claim 13. *Id.* at 16:5-17. The inventor omitted the “spaced apart” requirement, opting to instead to only require that the needle be “centrally positioned” between them. The specification reinforces the notion that the needle does not need to be in the space separating the stabilization members.

AMD’s proposed construction is also contrary to the requirements of the claims. For example, the requirement that the access needle be “centrally positioned in the space separating the pair of stabilization members” could be read, in literal terms, to prevent the scenario wherein the access needle extend beyond the front (distal) end of the stabilization members “wherein the access needle remains positioned within the perineal access site of the prostate,” as required by Claim 15. *Id.* at 16:22-25. This could not happen if the access needle was constrained to being in the space separating the stabilization members. Even if the stabilization members were positioned against the perineal skin, the access needle would still necessarily have to extend beyond that point and into the perineum. *See* FIG. 20 below.

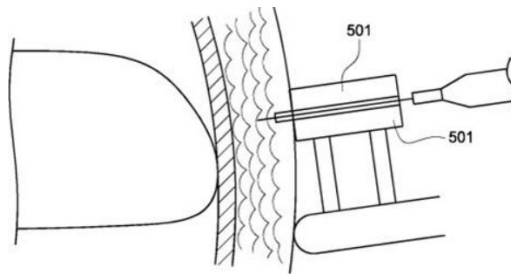


FIG. 20

With its proposed definition, AMD tries to import structural limitations from a disclosed embodiment to escape infringement, but such limitations are contrary to the clear meaning of the claims and disclosure in the patent. *See, e.g., DSW, Inc.*, 537 F.3d at 1348 (concluding “trial court did not construe or clarify the meaning of actual words in the claims[,] but improperly read into

them a new limitation not required by the claim language, specification, or prosecution history”); *Phillips*, 415 F.3d at 1323 (“[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.”).

AMD identifies no statements in the claims or specification of the ’762 Patent, or any Asserted Patent, wherein the inventor conveyed a requirement that the access needle be centrally positioned in the “space separating” the pair of stabilization members when the access needle is engaged with the platform. AMD Brief, pp. 18-19. It provides no citation to any statement that indicates that the inventor did not intend for the plain and ordinary meaning of the words of that limitation to apply. Indeed, the inventor never redefined this phrase.

AMD’s only argument is that the inventor made limiting statements during the prosecution of the related ’681 Patent; however, that argument fails because (1) prosecution history estoppel does not apply because Corbin is merely advocating for the issued claim language agreed upon by the examiner and the inventor, as opposed to some deviation from that language, and (2) even if prosecution history estoppel did apply, no statements were made that would have required the additional language proposed by AMD. Rather, the express wording of the claim is the result of the back and forth between the examiner and the prosecuting attorney.

2. The Statements Made During Prosecution Are Not Limiting

AMD claims that the statement made to “distinguish Onik from the platform ‘support[ing] the access needle in a central position between the pair of stabilization bars’” during the prosecution of the ’681 Patent constitutes a disavowal of claim scope in the ’762 Patent. AMD Brief, p. 15. First, the ’681 Patent has apparatus claims that are unique and different than the method claims of the ’762 Patent. Second, the cited statement does not disavowal claim scope; rather, it merely quotes the language of the *claim*. Third, even if it did, the notion of supporting a

needle in a central position between a pair of stabilization bars does not require the addition of the “space separating” language. Rather, the claim language “being centrally positioned between the pair of stabilization members” is sufficient and, in fact, is true to the language made to the examiner of the ’681 Patent.

AMD relies on a dictionary definition defining “between” as “in the time, space, or interval that separates.” *See* AMD Brief, p. 19 (citing Ex. J). That definition does not support the definition of “space separating.” That same Merriam-Webster dictionary also defines “between” as “in intermediate relation to” and “from one to another of.” *Id.* AMD provides no reason why one definition should apply, but the other one should not. Regardless, none of those definitions are helpful, as they are not medical definitions from a medical dictionary, and they are not from the time of the priority date of the first filed Asserted Patent. Further, the dictionary definition is divorced from the patent at issue and is otherwise inherently problematic in claim construction. *See supra* Section II. In this case, the inventor never defined “between” nor provided any indication that its plain and ordinary meaning should not apply.

Lastly, AMD points to a statement in the ’762 Patent wherein the inventor says that the hole 102 “is showed in a central midline position” to support its construction, but AMD fails to quote the entire statement. The quoted statement actually says that “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 along the guide 100.***” AMD Brief, p. 19; ’762 Patent, 9:51-54 (emphasis added). The actual statement strikes against AMD’s proposed construction by explicitly providing for other configurations.

AMD then states that “[w]hat the ’762 Patent specification defines as the ‘central’ position is not laterally ahead of or behind the stabilization bars, but directly between them.” *See* AMD

Brief, p. 19. That position is non-sensical and contrary to the express requirements of the patent, as the access needle must necessarily move laterally ahead of the stabilization bars in order to make contact with, and penetrate, the perineum. *See, e.g.*, '762 Claim 1, 15:25-27 (“sliding the platform ... so the access needle extends into the perineal access site.”); *Id.* at Claim 13, 16:8-9 (“inserting an access needle into a perineal access site...”); *id.* at Claim 36, 18:3-5 (“inserting an access needle into a perineal access site...”); *id.* at FIGS 15, 17, 19, and 20. The construction proposed by AMD is contrary to the express requirements of every claim of the '762 Patent, as well as multiple embodiments. It would be physically impossible to confine the access needle to the space separating the pair of stabilization members.

Term 11: “coupling [securing] the access needle to the one of the plurality of needle receiving ports of the displacement member of the transperineal biopsy guide such that a position and angle of the access needle relative to the displacement member is retained [maintained]” ('436 Patent, Claims 1, 13, 24)

Corbin’s Proposal	AMD’s Proposal
No construction required – plain and ordinary meaning	“inserting the access needle into one of the plurality of needle receiving ports, wherein the needle receiving port is configured to support the access needle at an angle and position relative to the displacement member”

The definition proposed by AMD is technically imprecise and unsupported by any intrinsic or extrinsic evidence. In some instances, AMD reads-out important requirements of the claim including “coupling” and “securing.” AMD Brief, p. 26. That is improper. *See, e.g., Bio-Rad Lab, Inc. v. ITC*, 998 F.3d 1320, 1331 (Fed. Cir. 2021) (rejecting the patentee's attempt to effectively rewrite the claim and broaden it by reading out the functional aspects); *Callicrate v. Wadsworth Mfg., Inc.*, 427 F.3d 1361, 1369 (Fed. Cir. 2005) (ruling that district court erred in construing claim limitation “preformed endless loop” in a manner that read out the requirement of being “preformed”); *Flex-Rest, LLC v. Steelcase, Inc.*, 455 F.3d 1351, 1361 (Fed. Cir. 2006) (rejecting

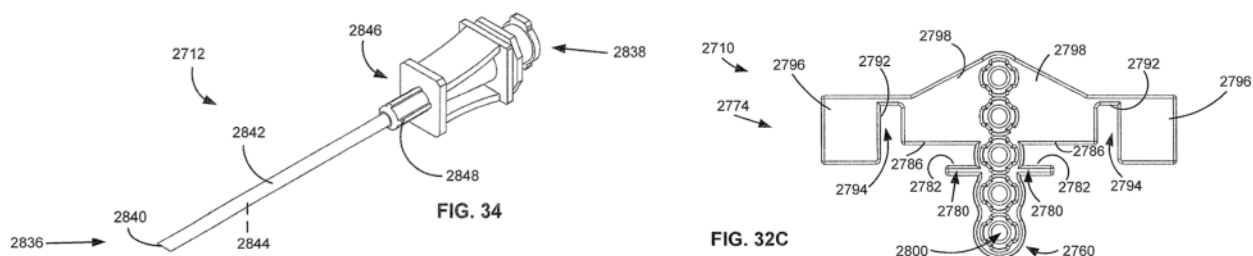
patentee's attempt to read-out a sidewall limitation contained in a claim directed to a computer keyboard stand, in part because that would make the sidewall superfluous).

While independent claims 1, 13, and 24 recite similar steps of “coupling” and “securing,” the claims are not the same. Moreover, the definition proposed by AMD ignores that each of the independent claims require “inserting” an access needle and separately “coupling” or “securing” the access needle. For example, independent claim 1 requires the step of “inserting at least a portion of the tubular shaft of the access needle into one of a plurality of needle receiving ports” and separately requires the step of “coupling the access needle to the one of the plurality of needle receiving ports of the displacement member...” ’436 Patent, 35:58-60; 36:1-3. Independent claim 13 requires “inserting an access needle into one of a plurality of needle receiving ports of a displacement member...” and separately requires the step of “securing the access needle to the displacement member...” ’436 Patent, 36:47-48; 36:59-60. Lastly, independent claim 24 requires the step of “inserting an access needle into one of a plurality of needle receiving ports of a displacement member...” and separately includes the step of “securing the access needle to the one of a plurality of needle receiving ports...” ’436 Patent, 37:39-40; 38:3-4. Hence, the access needle must be coupled or secured “to” the receiving port or displacement member. AMD deletes this requirement and merely reiterates the requirement of “inserting.” Clearly, the inventor intended the “coupling” and “securing” limitations to mean something different than merely “inserting.”

As described in the Abstract, the invention is comprised of “inserting an access needle into one of a plurality of needle receiving ports of a displacement member of a transperineal biopsy guide that is secured to the transrectal ultrasound probe; securing the access needle to the displacement member such that a position of the access needle relative to the displacement member

is maintained.” *Id.* at Abstract. Each independent claim requires the access needle to be either “secured” or “coupled” to the displacement member. *Id.* at 36:1-2; 36:59-61; 38:3-4. In particular, claims 10, 22 and 25 are dependent claims describing how the “coupling” or “securing” may occur. Claim 10 states “wherein coupling the access needle to one of the plurality of needle receiving ports of the displacement member of the transperineal biopsy guide comprises inserting a portion of the hub into one of the plurality of needle receiving ports.” *Id.* at 36:32-36. The “hub” is the specific method of “coupling” the access needle to the needle receiving port of Claim 1. Claim 22 similarly describes that “securing” the access needle to the displacement member is comprised of “inserting a portion of the hub into one of the plurality of needle receiving ports.” *Id.* at 37:26-29. Claim 25 describes a similar requirement, but does not specify that a “hub” effectuates the securing of the access needle. *Id.* at 38:14-19.

An example of a “hub” is shown as **2846** in Figure 34. *See* below. The hub may have “ridges **2848**” that “engage with corresponding and negatively shaped features on the proximal side **2800** of the needle receiving ports **2768**.” *Id.* at 25:8-13; *see* Figures 34 and 32C below. This demonstrates that “coupling” or “securing” is more than just “inserting.”



The specification further describes the “coupling” and “securing” limitations. There are 53 references to the root word of “secure” (including “securing”) describing that “securing” is not the same as “inserting.” For example, the specification states that “[i]n certain embodiments, the access needle **2712** may be secured to the displacement member **2710** by, for example, a threaded

features on the hub **2846** and openings **2770** of the ports **2768** such that the needle **2712** and the displacement member **2710** may be threadably engaged and disengaged with each other.” *Id.* at 26:2-7. This passage describes how a securing mechanism may work and reaffirms that the word “securing” is not the same as “inserting” as used in the patent. Numerous other references reinforce this notion. *See, e.g., id.* at 12:8-10 (“[t]his configuration allows the lower mounts and the upper mounts to be secured to each other and to the probe.”); 11:12-14 (“[t]he flange may be configured to snap into the guide to secure the needle.”).

Similarly, the word “coupling” is not the same as “inserting.” There are 82 references to the root word “couple” (including “coupling” and “couples”) describing that “coupling” means more than just “inserting.” *See, e.g., id.* at 5:9-13 (“[i]n certain embodiments, the guide member may operably couple with the transrectal probe via at least one of a sheath arrangement, a ratchet arrangement, a biased collar arrangement, a flexible strap arrangement, a clamping arrangement, or a clamshell collar arrangement.”); 24:16-18 (“[t]he platform 2766 is coupled with the probe coupling mechanism 2706, which, as seen in the figures, may be a snap-grip or snap-clip type of hose or tube clamp.”). The inventor even noted that “[j]oiner references (e.g., attached, coupled, connected, and the like) are to be construed broadly.” *Id.* at 35:15-16.

In its proposed construction, AMD also arbitrarily deletes the language “... of the displacement member of the transperineal biopsy guide.” While that language may be implied, it is an explicit requirement of the claim that cannot be ignored. *Flex-Rest*, 455 F.3d at 1361.

AMD then replaces the term “such that a position and angle of the access needle relative to the displacement member is retained [maintained]” with “wherein the needle receiving port is configured to support the access needle at an angle and position relative to the displacement member.” AMD Brief, p. 26. Again, this construction is unsupported, arbitrary and contrary to the

precise wording of the claims. For example, it reads out the requirement that the position and angle of the access needle relative to the displacement member be “retained” or “maintained.” No such concept is articulated in AMD’s proposed re-write of the claim language. As a result, any angle and position of the access needle would meet the requirement, even if it was subsequently changed.

AMD claims that its construction clarifies that “neither ‘coupling’ nor ‘securing’ require locking the access needle in place to completely prevent any movement of the access needle.” AMD Brief, p. 26. First, the claim language is clear and unambiguous, and nothing needs “clarifying.” Second, even if such clarification was necessary, AMD’s proposed definition only adds confusion without providing any supposed clarification on that point. Its proposed definition does not even mention “locking.”

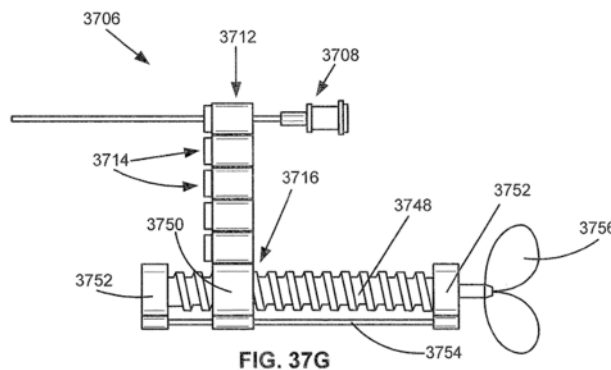
Term 12: “wherein securing the access needle to the one of a plurality of needle receiving ports of the displacement member includes inserting a structure that is engaged with the tubular shaft of the access needle into the one of a plurality of needle receiving ports” (’436 Patent, Claim 25)

Corbin’s Proposal	AMD’s Proposal
No construction required – plain and ordinary meaning	“a portion of the access needle other than the tubular shaft is inserted into a corresponding feature within one of the plurality of needle receiving ports such that the access needle remains coupled with the displacement member”

AMD also attempts to re-write Term 12, modifying the precise language that was specifically chosen by the inventor – and considered by the examiner during prosecution – while adding confusion and ambiguity. AMD Brief, pp. 27-29. Claim term 12 is clear and unambiguous, comprised of plain and ordinary terms. For example, AMD ignores the definitional format of dependent claim 25 wherein it further describes, and thus narrows, the requirement for “securing the access needle to the one of a plurality of needle receiving ports” found in claim 24. In doing

so, it further requires that “a structure that is engaged with the tubular shaft of the access needle” be inserted into a needle receiving port. ’436 Patent, 37:33-38:19.

AMD’s definition is consistent with its attempt to read out the “securing” requirement of claim 24. It contorts the language “inserting a structure that is engaged with the tubular shaft of the access needle into one of the plurality of needle receiving ports” into “a portion of the access needle other than the tubular shaft is inserted into a corresponding feature within one of the plurality of needle receiving ports.” There is no requirement that the tubular shaft not be inserted into the needle receiving ports. In fact, the tubular shaft is meant to be inserted into the needle receiving ports until the structure engaged with it comes in contact with the needle receiving port. There is no other way the invention could work. An example of this embodiment is found in Figure 37G (showing the tubular shaft of the access needle inserted into the needle receiving ports with the structure attached):



See also *id.* at 29:33-61 (describing the embodiment).

There are other flaws in AMD’s construction. It requires a “corresponding feature within one of the plurality of needle receiving ports,” which appears to be an attempt to import a requirement for some kind of feature within the needle receiving port, which is not a requirement of the claim. The interface between the “structure” and the needle receiving ports - whether it be a threaded feature, a snap feature, or other mating structure – is simply not part of claim 25. AMD

then seeks to add the “coupling” requirement it proposed deleting in dependent claim 1 into dependent claim 25.

Term 13: “wherein securing the access needle to the one of a plurality of needle receiving ports of the displacement member restricts rotation of the access needle relative to the displacement member” (’436 Patent, Claim 30)

Corbin’s Proposal	AMD’s Proposal
No construction required – plain and ordinary meaning	“wherein a portion of the access needle engages corresponding features of the one of the plurality of needle receiving ports of the displacement member such that the access needle is restrained from rotating”

AMD completely ignores the claim language quoted in Term 13, and instead writes a whole new definition. AMD Brief, p. 29. In doing so, AMD again ignores the requirement for “securing the access needle,” which it attempts to read-out of the independent claims. This claim term merely adds to, and thus narrows, the requirement of “securing the access needle to the one of a plurality of needle receiving ports” found in claim 24. *See* ’436 Patent, 38:3-5. AMD then adds a requirement that “a portion of the access needle engages with corresponding features of the one of the plurality of needle receiving ports of the displacement member such that the access needle is restrained from rotating.” The claim does not recite “a portion of the access needle,” and does not require such a portion to “engage” with “corresponding features” of the needle receiving ports. The proposed definition imports the requirement for structure that is not present in the claim language. The claim merely requires “securing the access needle” and, when secured, that it “restricts rotation of the access needle relative to the displacement member.” AMD also includes a requirement that the needle be “restrained from rotating,” while reading out the requirement that the “securing” of the access needle “restricts rotation” of the needle “relative to the displacement member.”

V. THE CLAIM TERMS OF THE '677 PATENT ARE NOT INDEFINITE

A. *Legal Standard for Indefiniteness*

The specification of every patent must “conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” 35 U.S.C. § 112(b). The Supreme Court has said that “a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 909-10 (2014). A patent is presumed valid, and the burden of establishing invalidity as to any claim of a patent rests upon the party asserting such invalidity. 35 U.S.C. § 282. Clear and convincing evidence is required to invalidate the claim of a patent. *TypeRight Keyboard Corp. v. Microsoft Corp.*, 374 F.3d 1151, 1157 (Fed. Cir. 2004).

Proof of indefiniteness must meet an exacting standard. *Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776, 783 (Fed. Cir. 2010). That standard “entails a delicate balance” of “competing concerns.” *Nautilus*, 572 U.S. at 901. While the definiteness requirement mandates clarity, it recognizes “that absolute precision is unattainable” and it “must take into account the inherent limitations of language.” *Id.* “Some modicum of uncertainty” is expected, and it is important to “bear in mind . . . that patents are not addressed to lawyers, or even to the public generally, but rather to those skilled in the relevant art.” *Id.*

In a pre-*Nautilus* decision, the Federal Circuit aptly noted that:

In determining whether that standard is met, i.e., whether “the claims at issue [are] sufficiently precise to permit a potential competitor to determine whether or not he is infringing,” ... we have not held that a claim is indefinite merely because it poses a difficult issue of claim construction. We engage in claim construction every day, and cases frequently present close questions of claim construction on which expert witnesses, trial courts, and even the judges of this court may disagree. Under a broad concept of indefiniteness, all but the clearest claim construction issues could

be regarded as giving rise to invalidating indefiniteness in the claims at issue. But we have not adopted that approach to the law of indefiniteness. We have not insisted that claims be plain on their face in order to avoid condemnation for indefiniteness; rather, what we have asked is that the claims be amenable to construction, however difficult that task may be. If a claim is insolubly ambiguous, and no narrowing construction can properly be adopted, we have held the claim indefinite. If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds.

Exxon Research & Eng'g Co. v. U.S., 265 F.3d 1371, 1375 (Fed. Cir. 2001).

When a “word of degree” is used, the court must determine whether the patent provides “some standard for measuring that degree.” *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1332 (Fed. Cir. 2010). “Claim language employing terms of degree has long been found definite where it provided enough certainty to one of skill in the art when read in the context of the invention.” *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 2014) (citing *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 65-66 (1923) (finding “substantial pitch” sufficiently definite because one skilled in the art “had no difficulty . . . in determining what was the substantial pitch needed” to practice the invention); *Enzo Biochem*, 599 F.3d at 1335 (holding phrase “not interfering substantially” was not indefinite even though the construction “define[d] the term without reference to a precise numerical measurement”); *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1384 (Fed. Cir. 2005) (“[A] patentee need not define his invention with mathematical precision in order to comply with the definiteness requirement.”)).

In this case, AMD claims that two terms of the '677 Patent are indefinite. *See* AMD Brief, pp. 20-25. In doing so, it presents them divorced from the context of the claims and specification of the '677 Patent. However, each of these terms, read in light of their respective specifications and prosecution histories, inform, with reasonable certainty, those skilled in the art about the scope

of the invention. The scope of the '677 Patent is clear, and a POSITA would know how to practice its claims.

B. Terms 9 and 10 are not Indefinite

Term 9: “lumen sized to receive a biopsy needle there through”

AMD claims that the term “lumen sized to receive a biopsy needle there through” is indefinite. AMD’s argument is futile. *See* AMD Brief, p. 20. The claim language itself defines the scope of this limitation. The lumen merely needs to be “sized to receive a biopsy needle there through.” *See* '677 Patent, 15:13-14; 15:67-16:2; 16:38-39. Further, dependent claims 3, 4, 11, 12, 15, 24, 25, and 30 all describe various sizes of the access needle. *See id.* at 15:30-34, 15:55-58, 16:12-15; 16:58-62; 17:11-13. For example, Claim 4 requires that “the access needle has a needle size of 15 gauge or 16 gauge.” *Id.* at 15:33-34. A POSITA would know what size a lumen would need to be in order to receive a biopsy needle.

The specification provides further descriptions to enlighten a POSITA. *See, e.g.,* '677 Patent, 7:55-58 (“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.”); *id.* at 13:32-35 (same); *id.* at 13:42-44 (“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.”). Figures 15, 17, 19, and 20 depict a biopsy needle received through a lumen. *See also* 11:1-13.

Notwithstanding the foregoing, a “question about the state of the knowledge of a skilled artisan is a question of fact.” *Dow Chem. Co. v. Nova Chems. Corp. (Canada)*, 809 F.3d 1223, 1225 (Fed. Cir. 2015). Therefore, to the extent it is not obvious that one of ordinary skill in the art would understand the meaning of this term, the determination of indefiniteness should not be decided at this early stage.

A “lumen” is generally known as a cavity or channel within a hollow tube or tubular structure. Allaway Declaration (“Allaway Decl.”), ¶ 25, attached as **Exhibit L**. AMD argues that the term “lumen sized to receive a biopsy needle there through” is indefinite because “nothing in the specification defines either the size of a biopsy needle or the size a lumen needs to be to receive said biopsy needle.” AMD Brief, p. 20. In this case, AMD’s arguments fail for at least three reasons. First, neither the size of the lumen or the size of the needle is a requirement of the independent claims at issue. *See* ’677 Patent, 15:10-17:11; *see also e.g., EcoServices, LLC, v. Certified Aviation Services, LLC*, 830 Fed.Appx. 634, 649 (Fed. Cir. 2020) (holding that “although the claim does not state a percentage of the liquid that must be in the claimed particle size, the claim makes clear that “small quantities” of liquid must follow the gas path.”). The only thing claimed is the “a lumen sized to receive a biopsy needle.” ’677 Patent, 15:13-14; 16:1-2; 16:38-39. If the lumen can receive a biopsy needle, it infringes. Allaway Decl., ¶ 26. If it cannot, it does not infringe. *Id.* Courts have construed “lumen” without specifying the size of the needle. *See, e.g., Medtronic Vascular, Inc., v. Boston Scientific Corp.*, 526 F.Supp.2d 612, 619 (E.D.Tex. 2007) (giving the plain meaning to the term “the lumen having a first diameter for the distal portion of the guide wire tube and a second diameter larger than the first diameter for the proximal portion of the guide wire tube.”).

Second, while the definiteness requirement mandates clarity, it recognizes “that absolute precision is unattainable” and it “must take into account the inherent limitations of language.” *Nautilus, Inc.*, 572 U.S. at 909-10. When a “word of degree” is used, the court must determine whether the patent provides “some standard for measuring that degree.” *Enzo*, 599 F.3d at 1332. “Claim language employing terms of degree has long been found definite where it provided enough certainty to one of skill in the art when read in the context of the invention.” *Interval*

Licensing LLC, 766 F.3d at 1370 (citing *Eibel Process Co.*, 261 U.S. at 65-66 (finding “substantial pitch” sufficiently definite because one skilled in the art “had no difficulty . . . in determining what was the substantial pitch needed” to practice the invention); *Invitrogen, L.P.*, 424 F.3d at 1384 (“[A] patentee need not define his invention with mathematical precision in order to comply with the definiteness requirement.”)). Therefore, Corbin is not required to claim the dimensions of the needles with precision.

Third, even if such a requirement existed, the dependent claims and specification do precisely identify the size of both a biopsy needle and an access needle. *See* ’677 Patent, 15:30-34, 55-58; 16:12-15, 56-62; 17:11-12. For example, dependent claims 11, 12, and 30 require that “the biopsy needle has a needle size of 18 gauge.” *Id.* Further dependent claims 3, 4, 15, 24, and 25 require an access needle of 14, 15, or 16 gauge. *Id.* The specification provides additional clarity. Allaway Decl., ¶¶ 27-32. In one passage, it states that “[t]he 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.” ’677 Patent, 6:9-12; *see also* 6:42-44. The specification also states that the “biopsy gun may be an 18-gauge biopsy gun, or any other size that is capable of being coaxially inserted through the lumen of the access needle.” *Id.* at 13:42-44. On page 22 of the AMD Brief, AMD claims that the foregoing 18-gauge reference relates to the gun, not the needle. Clearly that is not the case. The 18-gauge element referred to in the foregoing passage is a biopsy needle inserted using a gun, as it would be impossible to coaxially insert the gun itself through the lumen (as suggested by AMD). *See generally* ’677 Patent; Allaway Decl., ¶ 31.

Even if the patent did not provide specific examples of needle sizes, a POSITA would know that the lumen merely needs to be a size large enough to accommodate a biopsy needle. Allaway Decl., ¶¶ 23-32. AMD claims that a POSITA is a doctor with “at least five years of

experience taking transperineal prostate biopsies, and at least a year's experience developing medical devices used in needle biopsies." AMD Brief, p. 4. A person with that experience could read the claims of the '677 Patent and understand that, to practice the invention, the lumen must be big enough that one can slide a biopsy needle there through. Allaway Decl., ¶¶ 23-32. That is how the invention is practiced.

Term 10 “distal point of the pair of stabilization members is offset from (a fastener of the base portion, the mount of the base)”

The terms “distal” and “offset” are common medical and engineering terms known by a POSITA. The term “Distal” refers to the most forward point in a distal direction. The term “offset” means a positional difference between two points. Claim 10 requires an apparatus of Claim 1 “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.” '677 Patent, 15:51-54. This simply means that a distant point of the stabilization members is offset from the fastener of the base portion. Claim 29 similarly requires that the “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.” *Id.* at 17:7-10. Figure 20 below shows this offset. *See also* 11:6-8 (“FIG. 20 is a right side view of a guide, and a biopsy instrument firmly penetrating a fat plane of the perineum skin, including a offset 501 of a stabilization bar 101.”)

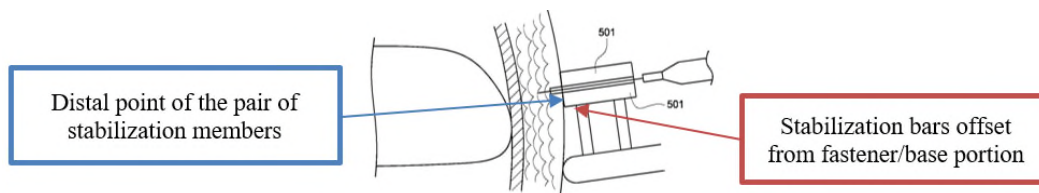


FIG. 20

The term “distal” has been determined to inform a POSITA and is not indefinite. *See, e.g., SignalQuest, Inc. v. Chou*, Civil No. 11-cv-392-JL, 2016 WL 3248246 *9 (D.N.H. June 13, 2016)

(“the terms ‘distal end,’ ‘distal portion,’ ‘distal surface,’ ‘proximate end,’ ‘proximate portion,’ and ‘proximate surface’ are not indefinite.”); *Advanced Cardiovascular Systems, Inc. v. Scimed Life Systems*, 96 F.Supp.2d 1006, 1008 (N.D. Cal. 2000) (holding that the term “distal section” is sufficiently clear for a person of ordinary skill in the art to identify that section); *Abiomed, Inc. v. Maquet Cardiovascular LLC*, 329 F.Supp.3d 1, 52 (D. Mass. 2018) (giving “distal tip member” its plain and ordinary meaning).

The term “distal point of the pair of stabilization members is offset from” is clear from the reading of the patent and is clearly understood by a POSITA. AMD again relies on an outdated, out-of-context dictionary definition, with no other intrinsic or extrinsic support. Therefore, AMD cannot meet its burden to prove by clear and convincing evidence that this term is indefinite.

The term “distal point of the pair of stabilization members is offset from,” viewed in light of the claims, specification, and prosecution history, adequately informs those skilled in the art about the scope of the invention with reasonable certainty. Allaway Decl., ¶¶ 33-42. Claims 10 and 21 of the ’677 Patent require “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.” ’677 Patent, 15:51-54; 16:30-33. Hence, the distal point of the stabilization members must be offset from the fastener. The claims and the specification further describe this limitation.

The term “distal” is a commonly known medical term. Allaway Decl., ¶ 34. A medical professional would understand that the “distal point” of the stabilization members is that point that most closely faces the perineum. *Id.* Referencing Figure 5, the specification states that “the off-set 501 from the distal point of the stabilization bar 105 to the fasteners 102 may be 5 mm.” *Id.* at ¶ 35. Figure 5 clearly shows the offset on the distal side of the stabilization bars:

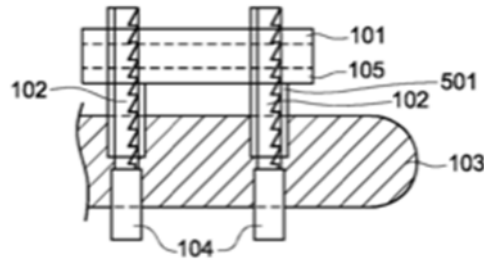


FIG. 5

The specification provides further support and context for the term “distal,” as well as the term “proximal,” which is well understood to mean the opposite of distal. Allaway Decl., ¶ 36. As one example, the specification states that “[a]fter 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.” ‘677 Patent, 11:18-22. Figure 12 shows 802 at the end closest to the patient:

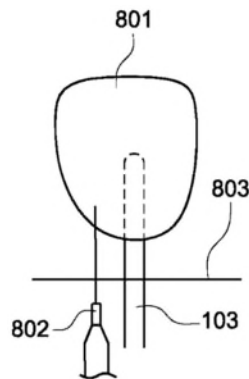


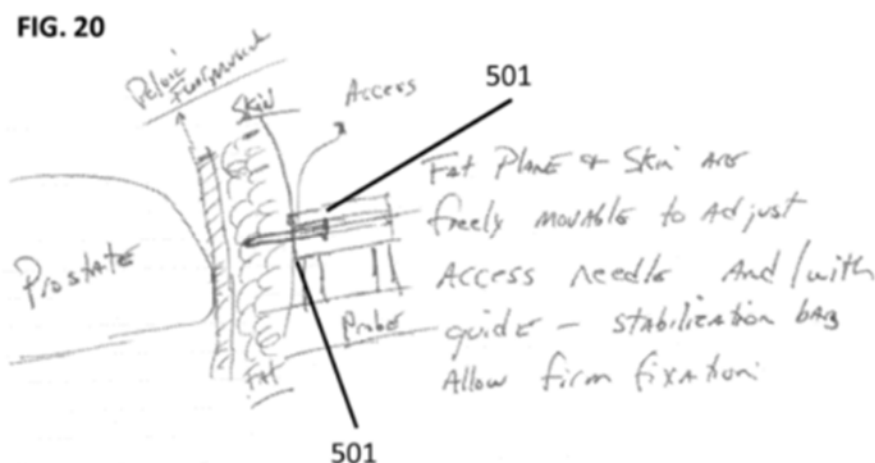
FIG. 12

In this passage, the “distal point of the biopsy instrument” is the tip of the needle as this is the part that can be redirected for insertion into another targeted area for obtaining a cell or tissue specimen. Allaway Decl., ¶ 37. This interpretation is consistent with common usage of “distal” and “distal point.” *Id.* As another example, the specification states that “[t]he upper and lower mounts may be positioned proximally or distally along an ultrasound probe, such as a transrectal ultrasound probe.” ‘681 Patent, 5:19-21. In this passage, both distal and proximal are used

consistently with common usage and with the preceding example of the “distal point of the biopsy instrument.” Allaway Decl., ¶ 37. The foregoing examples provide additional clarity to one of ordinary skill in the art as to the meaning of the well understood term “distal point.” *Id.*

AMD’s dramatization of Figure 1 ignores the use of the term “distal” within the claims and specification. See AMD Brief, p. 24. It also ignores Figures 5 and 12 above. To support its argument, AMD cites two dictionary definitions, neither of which are medical or engineering dictionaries and are otherwise not specific to the art at issue in this case. *Id.* at 23.

AMD also identifies an apparent inconsistency in the labeling of the offset 501 in Figures 5 and 20 of the ‘677 Patent. *Id.* at 24-25. The apparent inconsistency with labeling of the offset 501 in Figure 20 appears to be a misplaced reference line, which was correctly shown in U.S. Provisional Patent Application No. 61/974,826, filed April 3, 2014. See Provisional Application, Fig. 20, **Exhibit M**; Allaway Decl., ¶ 38. As seen in Figure 20 from Provisional Application 61/974,826, reproduced below, the offset 501 on the left of the image correctly identifies the location of the offset with the accompanying text explaining the function of the offset: “stabilization bars allow firm fixation[.]”



While reference to the stabilization bars 101 is incorrectly labeled as 501 on the upper right of Figure 20 of Provisional Application 61/974,826, it is clear with reference to the other figures

(e.g., Figure 5) and to the accompanying portions of the specification that this reference line was intended to refer to the stabilization bars 101. Allaway Decl., ¶ 39. The specification provides clarity to the offset 501 with reference to Figure 20 by stating, “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. *Id.* at ¶ 40. This allows for stabilization in a patient with an excessive amount of perineal subcutaneous tissue, fat, or a combination thereof.” ‘681 Patent, 11:6-10. As seen in Figure 20, the distal point of the stabilization bars 101 is the part of the device that contacts and penetrates the fat plane of perineum skin. *Id.* at Fig. 20; Allaway Decl., ¶ 41. The offset 501 allows for stabilizing the device with the patient. *Id.* As such, Figure 20 from Provisional Application 61/974,826, provides a consistent interpretation of the offset and the distal point with Figure 5, and a consistent interpretation with common usage of the terms offset and distal. *Id.*

Numerous courts have construed terms with the word “distal,” none of which deemed that term indefinite or otherwise indicated that the term fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention. *See, e.g., Rawcar Group, LLC, v. Grace Medical, Inc.*, No. 13-cv-1105 H(BLM), 2014 WL 2925209 *7 -8 (S.D. Cal. March 14, 2014) (construing the term “two side portions disposed between said proximal and distal portions on laterally opposing sides of the upper sterile portion”); *Medtronic*, 526 F.Supp.2d at 619 (giving the plain meaning to the term “the lumen having a first diameter for the distal portion of the guide wire tube and a second diameter larger than the first diameter for the proximal portion of the guide wire tube.”); *Intuitive Surgical, Inc., v. Auris Health, Inc.*, C.A. No. 18-1359 (MN), 2019 WL 6840327 *8 (D. Del. Dec. 16, 2019) (giving the plain and ordinary meaning to the term “hold or return the distal tip of the catheter to the desired working configuration.”); *Abiomed, Inc.*, 329 F.Supp.3d at 52 (giving “distal tip member” its plain and ordinary meaning); *Medtronic AVE, Inc., v. Cordis*

Corp., 516 F.Supp.2d 741, 750 (E.D. Tex. 2007) (Construing the term “a less viscous anticoagulant is allowed to coat the surface of the guide wire within the distal portion of the guide wire lumen” as “an anticoagulant composition, having less resistance to flow than blood, in the proximal portion of the guide wire tube is allowed to coat the surface of the guide wire in the distal portion of the guide wire tube.”).

Other courts have explicitly held that the term “distal” is not indefinite. *See, e.g., SignalQuest, Inc.*, 2016 WL 3248246 at *9 (“the terms ‘distal end,’ ‘distal portion,’ ‘distal surface,’ ‘proximate end,’ ‘proximate portion,’ and ‘proximate surface’ are not indefinite.”); *Advanced Cardiovascular*, 96 F.Supp.2d at 1008 (holding that the term “distal section” is sufficiently clear to a person of ordinary skill in the art.). Counsel is not aware of any decisions wherein a court found the term “distal” or “distal point” to be indefinite. Therefore, this court should decline to hold the term “distal” to be indefinite.

The term “offset” is equally clear. Courts have construed terms using the word “offset” without finding them to be indefinite. *See, e.g., Focus Products Group Int’l, LLC, v. Kartri Sales Co., Inc.*, 15 Civ. 10154 (PAE), 2018 WL 3773986 *11 (S.D.N.Y. Aug. 8, 2018) (defining “offset from said top” as “to a side of the top.”); *Varian Medical Syst., Inc. v. ViewRay*, Case No. 19-cv-05697-SI, 2020 WL 4260714 *9 (N.D.Cal. June 24, 2020) (construing the term “a pair of leaves in the first set close at a first location, a corresponding pair of leaves in the second set close at a second location, and the first and second locations are offset from a beam's point of view.”). AMD fails to cite any case indicating that the term “offset” is indefinite.

C. *If There is a Real Question of Indefiniteness, the Court Should Not Rule on the Issue at the Claim Construction Stage*

To the extent that this Court has any concern regarding the definiteness of the foregoing terms, then Corbin respectfully requests that it defer such ruling until a time after depositions and

expert disclosures. “Generally, ‘the weight of the jurisprudence disfavors indefiniteness determinations at the *Markman* stage of patent litigation.’” *Gilead Sciences, Inc. v. Mylan, Inc.*, No. 1:14CV99, 2015 WL 1534067 *2 (N.D.W.V. April 6, 2015) (quoting *CBS-System Intern. Inc.*, 2011 WL 3240838 at *17, 20, fn. 16.); *see also STX, Inc. v. Brine*, 37 F.Supp.2d 740, 754 (D. Md. 1999) (“it would be error to collapse claim construction (for purposes of anticipation, obviousness or infringement analysis) into a statutory indefiniteness analysis and I decline STX’s invitation to do so.”).

“[S]everal principles mitigate against ruling on indefiniteness at the *Markman* stage: first, the high burden of proof on the party challenging a patent claim for indefiniteness; second, the fact that a claim is not indefinite merely because the parties dispute its meaning; and, finally, the dispositive effect of a ruling on indefiniteness, which invalidates the claim entirely.” *Broadnet Teleservices, LLC v. Shoutpoint, Inc.*, 2015 WL 13614122, at *4 (D. Col. Jul. 15, 2015) (citing *CBS-System Intern. Inc. v. SAP America, Inc.*, No. 10–2156, 2011 WL 3240838, at *17–18 (E.D. Pa. July 28, 2011)). For the foregoing reasons, “many judges have elected to wait and tackle indefiniteness at the summary judgment stage.” *Id.* (citing *CBS-Systems Intern.*, 2011 WL 3240783 at *2 (denying the defendant’s indefiniteness argument without prejudice, subject to renewal during summary judgment); *Mannatech, Inc. v. TechMedia Health, Inc.*, 2009 WL 3614359 at *15 (N.D. Tex. Oct. 29, 2009) (determining that consideration of the indefiniteness issue was not appropriate at the claim construction phase).

VI. CLAIM CONSTRUCTION HEARING WITNESSES

Corbin presently intends to call Dr. Matthew Allaway as a witness at the Claim Construction Hearing on behalf of Corbin.

VII. CONCLUSION

For the reasons stated herein, Corbin respectfully requests that the Court adopt its proposed constructions and decline to adopt AMD's proposed constructions and instead allow AMD's proposed terms to be interpreted according to their plain and ordinary meaning. Corbin also requests that this Court decline to find that any term of the Asserted Patents are indefinite.

Dated: September 15, 2023.

Respectfully submitted,

By: /s/ D. Jack Blum

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CERTIFICATE OF SERVICE

I hereby certify that on this 15th day of September 2023, a true and correct copy of the foregoing was electronically served on counsel for all parties properly registered to receive notice via the Court's CM/ECF system.

/s/ D. Jack Blum

Counsel for Corbin Clinical Resources, LLC

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EXHIBIT H

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Inventor(s): Matthew J. Allaway	
App. No.: 14/677,286	Con. No.: 6607
Filed: Apr. 2, 2015	Art Unit: 3768
Title: Method, System, and Device for Planning and Performing, Guided and Free-Handed Transperineal Prostate Biopsies	Examiner: Sanjay Cattungal

AMENDMENT AND RESPONSE TO NON-FINAL OFFICE ACTION

MAIL STOP Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

In response to the Office action dated October 6, 2017, please consider the following remarks and amend the above-identified application as follows:

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 5 of this paper.

Amendments to the Claims:

The listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-20. (Canceled)

21. (New) An apparatus configured to couple with a transrectal probe and for use in guiding an access needle in a transperineal prostate biopsy procedure, the access needle configured to perforate and be positioned within subcutaneous tissue of a perineum at an access site of a target area of a patient, the apparatus comprising:

an upper mount configured to be secured to the transrectal probe, the upper mount comprising a platform and a pair of stabilization bars spaced-apart from each other, the pair of stabilization bars including a back portion, a front portion, and a length extending along a longitudinal axis between the back and front portions, the longitudinal axis of the pair of stabilization bars being generally parallel with a longitudinal axis of the transrectal probe when the upper mount is secured to the transrectal probe, the platform configured to support the access needle and the platform configured to slide on the pair of stabilization bars along at least a portion of the length so as to displace the access needle along the at least a portion of the length.

22. (New) The apparatus of claim 21, wherein the platform is configured to support the access needle in a central position between the pair of stabilization bars.

23. (New) The apparatus of claim 21, wherein each of the pair of stabilization bars include grooves on an inner portion that allow the platform to slide thereon.

24. (New) The apparatus of claim 21, wherein the pair of stabilization bars comprises a feature that secures the platform into position at the front portion.

25. (New) The apparatus of claim 21, wherein the access needle extends beyond the front portion of the pair of stabilization bars when the access needle is displaced to the front portion.
26. (New) The apparatus of claim 21, wherein the upper mount is configured to be secured to the transrectal probe by a fastener.
27. (New) The apparatus of claim 26, wherein the pair of stabilization bars extends longitudinally beyond a front longitudinal edge of the fastener.
28. (New) The apparatus of claim 21, wherein the platform is removably coupled with the pair of stabilization bars.
29. (New) The apparatus of claim 28, wherein the platform is interchangeable with alternate platforms of different sizes.
30. (New) The apparatus of claim 21, wherein the platform includes at least one hole configured to receive the access needle therethrough.
31. (New) The apparatus of claim 30, wherein the at least one hole includes multiple holes of different diameters.
32. (New) The apparatus of claim 21, wherein the platform comprises a hole that is generally parallel with a longitudinal axis of the transrectal probe when the upper mount is secured to the transrectal probe and when the platform is supported by the pair of stabilization bars.
33. (New) The apparatus of claim 21, wherein the platform is configured to pivot at a pivot point to enable angular adjustment of the access needle.
34. (New) The apparatus of claim 33, wherein, when the upper mount is secured to the transrectal probe, the access needle is configured to pivot while maintaining a longitudinal axis of the access needle parallel with the longitudinal axis of the transrectal probe.

35. (New) The apparatus of claim 21, wherein the upper mount is configured to be secured to the transrectal probe by a fastener, the fastener is a portion of a curvilinear and flexible lower mount.

36. (New) The apparatus of claim 21, wherein the access needle is configured to receive a biopsy needle therethrough.

37. (New) The apparatus of claim 21, further comprising the access needle.

38. (New) The apparatus of claim 21, further comprising the transrectal probe.

39. (New) An apparatus configured to couple with a transrectal probe and for use in guiding an access needle in a transperineal prostate biopsy procedure, the access needle configured to perforate and be positioned within subcutaneous tissue of a perineum at an access site of a target area of a patient, the apparatus comprising:

an upper mount comprising a pair of stabilization bars and a platform, the pair of stabilization bars extending a length between a front portion and a back portion and being laterally spaced-apart from each other, the pair of stabilization bars configured to support the platform, the platform configured to support the access needle in a central position between the pair of stabilization bars, the platform configured to slide along at least a portion of the length of the pair of stabilization bars so as to displace the access needle along the at least a portion of the length; and

a lower mount configured to engage with the transrectal probe and to couple to the upper mount via a fastener.

40. (New) The apparatus of claim 39, wherein the platform includes a hole configured to receive the access needle therethrough, the hole having an axis generally parallel with a longitudinal axis of the transrectal probe when the upper and lower mounts are coupled together and to the transrectal probe, and when the platform is supported by the pair of stabilization bars.

REMARKS

This paper is submitted in response to the Office action mailed on October 6, 2017.

I. Status of Claims

Claims 1-20 are rejected. This paper cancels claims 1-20, and adds new claims 21-40. No claims are amended. Accordingly, after entry of this Amendment and Response, claims 21-40 will be pending. No new matter is added with the addition of claim 21-40. Rather, all claims are fully supported by the original application.

II. Claim Rejections Under 35 U.S.C. § 102

Claims 1-20 are rejected under 35 U.S.C. § 102a1/a2 as being anticipated by U.S. Patent No. 5,494,039 to Onik et al. ("Onik"). The Applicant respectfully traverses the rejection for at least the reason claims 1-20 are canceled with this paper; thus, the rejections are moot. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejections.

While the rejections of claims 1-20 under 35 U.S.C. § 102 in view of Onik are moot, Onik will be discussed with reference to the new claims in the subsequent section.

III. New Claims

New claims 21-40 are added with this paper. No new matter is added with the claims. The claims are patentable in view of Onik for at least the following reasons.

- a. Independent claim 21 is patentable because Onik does not describe an apparatus with a platform configured to support an access needle, where the platform is configured to slide on a pair of stabilization bars so as to displace the access needle.*

Independent claim 21 recites a "platform configured to support the access needle and the platform configured to slide on the pair of stabilization bars along at least a portion of the length so as to displace the access needle along the at least a portion of the length." Onik does not describe these limitations for at least the following reasons.

As an overview, Onik describes a biopsy needle insertion guide for use in cryosurgery. *Onik, Title*. Onik's guide is used in a cryosurgical procedure where the guide is affixed to an

ultrasound probe and advanced till the needle holder assembly 28 engages and bears firmly against the patient's perineum. *Id. at col. 7, ll. 15-22.* "The surgeon need then only maintain a firm grip and slight proximal pressure on ultrasound probe 2 to keep insert guide 1 in position thereby providing a firm and stable guide *for the insertion of a biopsy needle.*" *Id. at col. 7, ll. 24-27; italics added.* A biopsy needle is then placed in the notch 31, and the surgeon advances the needle into the patient with the guide maintained in position. *Id. at col. 7, l. 28.* Stated differently, Onik's guide is not used with an access needle, and it is not configured to "displace the access needle along the at least a portion of the length" of a pair of stabilization bars.

Applicant's apparatus, on the other hand, is configured for use with an access needle through which a biopsy needle can be inserted. More particularly, Applicant's apparatus is configured to "displace the access needle" along a length of "a pair of stabilization bars," as required by claim 21. Onik uses a biopsy needle, which is inserted through the notch 31 of the needle holder assembly 28 *once the guide 1 is set in position against the patient's body.* That is, the guide does not displace a biopsy needle, an access needle, or any other type of needle for that matter. For at least these reasons, claim 21 is patentable.

Beyond not describing displacing an access needle, Onik does not describe "a pair of stabilization bars" and a "platform configured to slide on the pair of stabilization bars along at least a portion of the length." The needle holder assembly 28 cannot be considered claim 21's "platform" because it does not "slide" on anything that could be considered "a pair of stabilization bars." Onik describes the guide block 29 of the needle holder assembly 28 as "fixed to the proximal end of shaft 27'." *Id. at col. 5, ll. 38-39.* Clearly, the needle holder assembly 28 does *not* "slide" on the shafts 27' because they are fixed together. For at least these reasons, independent claim 21 is patentable because Onik does not describe "a pair of stabilization bars" and a "platform configured to slide on the pair of stabilization bars along at least a portion of the length."

Dependent claims 22-38 are patentable for at least the reason they each depend from and incorporate the limitations from independent claim 21, which is patentable in view of Onik. This statement is made without addressing the individual patentable limitations of the dependent

claims and such an argument is reserved by Applicant. Accordingly, Applicant respectfully submits claims 22-38 are patentable.

b. Independent claim 39 is patentable for the reasons independent claim 21 is patentable and because Onik does not describe the platform supporting an access needle in a central position between the pair of stabilization bars.

Independent claim 39 recites “the platform configured to support the access needle in a central position between the pair of stabilization bars, the platform configured to slide along at least a portion of the length of the pair of stabilization bars so as to displace the access needle along the at least a portion of the length.” Onik does not describe these limitations for at least the following reasons.

As described with reference to independent claim 21, Onik does not describe an apparatus that displaces an access needle, or an apparatus that includes a platform configured to slide along at least a portion of a length of a pair of stabilization bars. Additionally, Onik does not describe a platform configured to “support the access needle in a central position between the pair of stabilization bars,” as required by claim 39. For at least these reasons, independent claim 39 is patentable in view of Onik.

Dependent claim 40 is patentable for at least the reason it depends from and incorporates the limitations from independent claim 39, which is patentable in view of Onik. This statement is made without addressing the individual patentable limitations of the dependent claim and such an argument is reserved by Applicant. Accordingly, Applicant respectfully submits claim 40 is patentable.

IV. Conclusion

The Applicant thanks the Examiner for his thorough review of the application. The Applicant respectfully submits the present application, as amended, is in condition for allowance and respectfully requests the issuance of a Notice of Allowability as soon as practicable.

The Applicant believes no fees or petitions are due with this filing. However, should any such fees or petitions be required, please consider this a request therefor and authorization to charge Deposit Account No. 50-1662 as necessary.

If the Examiner should require any additional information or amendment, please contact the undersigned attorney.

Dated: 1/3/18

Respectfully submitted,



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EXHIBIT I

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Inventor(s): Matthew J. Allaway	
App. No.: 14/677,286	Con. No.: 6607
Filed: Apr. 2, 2015	Art Unit: 3768
Title: Method, System, and Device for Planning and Performing, Guided and Free-Handed Transperineal Prostate Biopsies	Examiner: Sanjay Cattungal

AMENDMENT AND RESPONSE TO FINAL OFFICE ACTION

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

In response to the Office action dated April 2, 2018 please consider the following remarks and amend the above-identified application as follows:

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 6 of this paper.

Amendments to the Claims:

The listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-20. (Canceled)

21. (Currently Amended) An apparatus configured to couple with a transrectal probe and for use in guiding an access needle in a transperineal prostate biopsy procedure, the access needle configured to perforate and be positioned within subcutaneous tissue of a perineum at an access site of a target area of a patient, the apparatus comprising:

an upper mount and a lower mount configured to couple to each other, the lower mount configured to engage the transrectal probe and secure the upper mount relative to ~~configured to be secured to the~~ transrectal probe, the upper mount comprising a platform and a pair of stabilization bars spaced-apart from each other, the pair of stabilization bars including a back portion, a front portion, and a length extending along a longitudinal axis between the back and front portions, the longitudinal axis of the pair of stabilization bars being generally parallel with a longitudinal axis of the transrectal probe when the upper mount is secured to the transrectal probe, the platform configured to support the access needle and the platform configured to slide on the pair of stabilization bars along at least a portion of the length so as to displace the access needle along the at least a portion of the length.

22. (Previously Presented) The apparatus of claim 21, wherein the platform is configured to support the access needle in a central position between the pair of stabilization bars.

23. (Previously Presented) The apparatus of claim 21, wherein each of the pair of stabilization bars include grooves on an inner portion that allow the platform to slide thereon.

24. (Previously Presented) The apparatus of claim 21, wherein the pair of stabilization bars comprises a feature that secures the platform into position at the front portion.
25. (Previously Presented) The apparatus of claim 21, wherein the access needle extends beyond the front portion of the pair of stabilization bars when the access needle is displaced to the front portion.
26. (Currently Amended) The apparatus of claim 21, wherein the upper mount and lower mount are [[is]] configured to be secured to the transrectal probe by a fastener.
27. (Currently Amended) The apparatus of claim 26, wherein the pair of stabilization bars extends longitudinally beyond a front longitudinal edge of the fastener.
28. (Previously Presented) The apparatus of claim 21, wherein the platform is removably coupled with the pair of stabilization bars.
29. (Previously Presented) The apparatus of claim 28, wherein the platform is interchangeable with alternate platforms of different sizes.
30. (Previously Presented) The apparatus of claim 21, wherein the platform includes at least one hole configured to receive the access needle therethrough.
31. (Previously Presented) The apparatus of claim 30, wherein the at least one hole includes multiple holes of different diameters.
32. (Previously Presented) The apparatus of claim 21, wherein the platform comprises a hole that is generally parallel with a longitudinal axis of the transrectal probe when the upper mount is secured to the transrectal probe and when the platform is supported by the pair of stabilization bars.

33. (Previously Presented) The apparatus of claim 21, wherein the platform is configured to pivot at a pivot point to enable angular adjustment of the access needle.

34. (Previously Presented) The apparatus of claim 33, wherein, when the upper mount is secured to the transrectal probe, the access needle is configured to pivot while maintaining a longitudinal axis of the access needle parallel with the longitudinal axis of the transrectal probe.

35. (Currently Amended) The apparatus of claim 21, wherein the upper mount and lower mount are ~~are~~ configured to be secured to the transrectal probe by a fastener, the fastener is a portion of a curvilinear and flexible portion of the lower mount.

36. (Previously Presented) The apparatus of claim 21, wherein the access needle is configured to receive a biopsy needle therethrough.

37. (Previously Presented) The apparatus of claim 21, further comprising the access needle.

38. (Previously Presented) The apparatus of claim 21, further comprising the transrectal probe.

39. (Previously Presented) An apparatus configured to couple with a transrectal probe and for use in guiding an access needle in a transperineal prostate biopsy procedure, the access needle configured to perforate and be positioned within subcutaneous tissue of a perineum at an access site of a target area of a patient, the apparatus comprising:

an upper mount comprising a pair of stabilization bars and a platform, the pair of stabilization bars extending a length between a front portion and a back portion and being laterally spaced-apart from each other, the pair of stabilization bars configured to support the platform, the platform configured to support the access needle in a central position between the pair of stabilization bars, the platform configured to slide along at least a portion of the length of the pair of stabilization bars so as to displace the access needle along the at least a portion of the length; and

a lower mount configured to engage with the transrectal probe and to couple to the upper mount via a fastener.

40. (Previously Presented) The apparatus of claim 39, wherein the platform includes a hole configured to receive the access needle therethrough, the hole having an axis generally parallel with a longitudinal axis of the transrectal probe when the upper and lower mounts are coupled together and to the transrectal probe, and when the platform is supported by the pair of stabilization bars.

REMARKS

This paper is submitted in response to the Office action mailed on April 2, 2018.

I. Status of Claims

Claims 21-40 are rejected. This paper amends claims 21, 26-27, and 35, but does not add or cancel any claims. Accordingly, after entry of this Amendment and Response, claims 21-40 will remain pending. No new matter is added with the amendments to the claims. Rather, the amendments are fully supported by the original application.

II. Examiner Interview

On May 4, 2018, Attorney for Applicant and Examiner Cattungal discussed this case over the telephone. Examiner Cattungal stated he would remove the reference to Onik as applied to the current claims based on our previously submitted arguments, among other reasons. The Examiner asked that the “lower mount” be amended into independent claim 21, and such an amendment is included in this paper in order to expedite prosecution to an allowance. The Examiner is thanked for the reconsideration and for taking the time to discuss this case.

III. Claim Rejections Under 35 U.S.C. § 102

Claims 21-40 are rejected under 35 U.S.C. § 102a1/a2 as being anticipated by U.S. Patent No. 5,494,039 to Onik et al. (“Onik”). The Applicant respectfully traverses the rejection for at least the following reasons.

- a. Independent claim 21 is patentable because Onik does not describe an apparatus with a platform configured to support an access needle, where the platform is configured to slide on a pair of stabilization bars so as to displace the access needle.*

Independent claim 21 recites a “platform configured to support the access needle and the platform configured to slide on the pair of stabilization bars along at least a portion of the length so as to displace the access needle along the at least a portion of the length.” Onik does not describe these limitations for at least the following reasons.

As an overview, Onik describes a biopsy needle insertion guide for use in cryosurgery. *Onik, Title*. Onik's guide is used in a cryosurgical procedure where the guide is affixed to an ultrasound probe and advanced till the needle holder assembly 28 engages and bears firmly against the patient's perineum. *Id. at col. 7, ll. 15-22*. "The surgeon need then only maintain a firm grip and slight proximal pressure on ultrasound probe 2 to keep insert guide 1 in position thereby providing a firm and stable guide *for the insertion of a biopsy needle*." *Id. at col. 7, ll. 24-27; italics added*. A biopsy needle is then placed in the notch 31, and the surgeon advances the needle into the patient with the guide maintained in position. *Id. at col. 7, l. 28*. Stated differently, Onik's guide is not used with an access needle, and it is not configured to "displace the access needle along the at least a portion of the length" of a pair of stabilization bars.

Applicant's apparatus, on the other hand, is configured for use with an access needle through which a biopsy needle can be inserted. More particularly, Applicant's apparatus is configured to "displace the access needle" along a length of "a pair of stabilization bars," as required by claim 21. Onik uses a biopsy needle, which is inserted through the notch 31 of the needle holder assembly 28 *once the guide 1 is set in position against the patient's body*. That is, the guide does not displace a biopsy needle, an access needle, or any other type of needle for that matter. For at least these reasons, claim 21 is patentable.

Beyond not describing displacing an access needle, Onik does not describe "a pair of stabilization bars" and a "platform configured to slide on the pair of stabilization bars along at least a portion of the length." The needle holder assembly 28 cannot be considered claim 21's "platform" because it does not "slide" on anything that could be considered "a pair of stabilization bars." Onik describes the guide block 29 of the needle holder assembly 28 as "fixed to the proximal end of shaft 27'." *Id. at col. 5, ll. 38-39*. Clearly, the needle holder assembly 28 does *not* "slide" on the shafts 27' because they are fixed together. For at least these reasons, independent claim 21 is patentable because Onik does not describe "a pair of stabilization bars" and a "platform configured to slide on the pair of stabilization bars along at least a portion of the length."

Dependent claims 22-38 are patentable for at least the reason they each depend from and incorporate the limitations from independent claim 21, which is patentable in view of Onik. This

statement is made without addressing the individual patentable limitations of the dependent claims and such an argument is reserved by Applicant. Accordingly, Applicant respectfully submits claims 22-38 are patentable.

b. Independent claim 39 is patentable for the reasons independent claim 21 is patentable and because Onik does not describe the platform supporting an access needle in a central position between the pair of stabilization bars.

Independent claim 39 recites “the platform configured to support the access needle in a central position between the pair of stabilization bars, the platform configured to slide along at least a portion of the length of the pair of stabilization bars so as to displace the access needle along the at least a portion of the length.” Onik does not describe these limitations for at least the following reasons.

As described with reference to independent claim 21, Onik does not describe an apparatus that displaces an access needle, or an apparatus that includes a platform configured to slide along at least a portion of a length of a pair of stabilization bars. Additionally, Onik does not describe a platform configured to “support the access needle in a central position between the pair of stabilization bars,” as required by claim 39. For at least these reasons, independent claim 39 is patentable in view of Onik.

Dependent claim 40 is patentable for at least the reason is depends from and incorporates the limitations from independent claim 39, which is patentable in view of Onik. This statement is made without addressing the individual patentable limitations of the dependent claim and such an argument is reserved by Applicant. Accordingly, Applicant respectfully submits claim 40 is patentable.

IV. Conclusion

The Applicant thanks the Examiner for his thorough review of the application. The Applicant respectfully submits the present application, as amended, is in condition for allowance and respectfully requests the issuance of a Notice of Allowability as soon as practicable.

The Applicant believes no fees or petitions are due with this filing. However, should any such fees or petitions be required, please consider this a request therefor and authorization to charge Deposit Account No. 50-1662 as necessary.

If the Examiner should require any additional information or amendment, please contact the undersigned attorney.

Dated: 5/8/18

Respectfully submitted,



Joshua J. Pranckun, Registration No. 70712
Attorney for Applicant
USPTO Customer No. 24030

POLSINELLI PC
900 West 48th Place, Suite 900
Kansas City, MO 64112
uspt@polsinelli.com
Tel: 303-583-8269
Fax: 816-753-1536

EXHIBIT J



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

24030 7590 07/24/2018
POL SINELLI PC
900 West 48th Place
Suite 900
KANSAS CITY, MO 64112-1895

EXAMINER

CATTUNGAL, SANJAY

ART UNIT

PAPER NUMBER

3737

DATE MAILED: 07/24/2018

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/677,286	04/02/2015	Matthew J. ALLAWAY	083003-499696	6607

TITLE OF INVENTION: METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING, GUIDED AND FREE-HANDED
TRANSPERINEAL PROSTATE BIOPSIES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$500	\$0	\$0	\$500	10/24/2018

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail****Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

24030 7590 07/24/2018
POLSINELLI PC
 900 West 48th Place
 Suite 900
 KANSAS CITY, MO 64112-1895

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/677,286	04/02/2015	Matthew J. ALLAWAY	083003-499696	6607

TITLE OF INVENTION: METHOD, SYSTEM, AND DEVICE FOR PLANNING AND PERFORMING, GUIDED AND FREE-HANDED TRANSFERINEAL PROSTATE BIOPSIES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$500	\$0	\$0	\$500	10/24/2018

EXAMINER	ART UNIT	CLASS-SUBCLASS
CATTUNGAL, SANJAY	3737	600-464000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a **Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1. _____
 2. _____
 3. _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
☐ Applicant asserting small entity status. See 37 CFR 1.27
☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/677,286	04/02/2015	Matthew J. ALLAWAY	083003-499696	6607
24030 7590 07/24/2018 POLSINELLI PC 900 West 48th Place Suite 900 KANSAS CITY, MO 64112-1895				
EXAMINER CATTUNGAL, SANJAY				
ART UNIT PAPER NUMBER 3737				
DATE MAILED: 07/24/2018				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. 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, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/677,286	Applicant(s) ALLAWAY, MATTHEW J.	
	Examiner SANJAY CATTUNGAL	Art Unit 3737	AIA (First Inventor to File) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/8/18.
☐ A declaration(s)/affidavit(s) under 37 CFR 1.130(b) was/were filed on _____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 21-40. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some *c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 20180617.
5. ☐ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☒ Other pto2323.

/SANJAY CATTUNGAL/
Primary Examiner, Art Unit 3737

Application/Control Number: 14/677,286
Art Unit: 3737

Page 2

DETAILED ACTION

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

Response to Arguments

2. Applicant's arguments, see Remarks, filed 05/08/18, with respect to claims 21-40 have been fully considered and are persuasive. The rejection of claims 21-40 has been withdrawn.

Allowable Subject Matter

3. Claims 21-40 are allowed.

4. The following is an examiner's statement of reasons for allowance: the closest prior art of record are U. S. Patent No. 5,494,039 to Onik et al.; U. S. Publication No. 2015/0119715 to Baumann; and U. S. Publication No. 2011/0319759 to Liu none of the prior art alone or in combination teaches the limitations of the independent claim specifically "an upper mount and a lower mount configured to couple to each other, the lower mount configured to engage the transrectal probe and secure the upper mount relative to the transrectal probe, the upper mount comprising a platform and a pair of stabilization bars spaced-apart from each other, the pair of stabilization bars including a back portion, a front portion, and a length extending along a longitudinal axis between the back and front portions, the longitudinal axis of the pair of stabilization bars being

Application/Control Number: 14/677,286
Art Unit: 3737

Page 3

generally parallel with a longitudinal axis of the transrectal probe when the upper mount is secured to the transrectal probe, the platform configured to support the access needle and the platform configured to slide on the pair of stabilization bars along at least a portion of the length so as to displace the access needle along the at least a portion of the length”.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

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 Monday-Friday 9-5.

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, Pascal Bui-Pho can be reached on (571) 272-2714. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 14/677,286
Art Unit: 3737

Page 4

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 <http://pair-direct.uspto.gov>. 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.

/SANJAY CATTUNGAL/
Primary Examiner, Art Unit 3737

EXHIBIT K

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 14/677,286	Confirmation No.	: 6607
First Applicant	: Matthew J. Allaway	Art Unit	: 3737
Filed	: 04/02/2015	Examiner	: Sanjay Cattungal
Title	: Method, System, and Device for Planning and Performing, Guided and Free-Handed Transperineal Prostate Biopsies		
Docket No.	: 083003-499696		
Customer No.	: 24030		

COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE

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

Dear Commissioner:

The Applicant acknowledges with appreciation the allowance of claims 21-40 in the captioned application by the Examiner. The Applicant agrees with the Examiner's Statement of Reasons for Allowance to the extent that claims 21-40 are patentable over the references in the record.

Applicant expressly traverses the Examiner's Statement of Reasons for Allowance to the extent that any statement is intended to or has the intended effect of limiting a claim scope, explicitly or implicitly, by not reciting verbatim the respective claim language, or is intended to or has the effect of limiting a claim scope by stating or implying that all the reasons for patentability are in any way fully enumerated. The Applicant specifically does not acquiesce or agree in any manner as to any assertion in Examiner's statements that may be interpreted to narrow the claims to less than their recited scope.

Applicant asserts that claims 21-40 are patentable as presented and the scope of the allowed claims should in no way be limited by the rationale cited by the Examiner or in view of the prior art. If there are any questions, please contact the undersigned attorney.

Respectfully submitted this 26 day of July 2018.

Respectfully submitted,



Joshua J. Pranckun, Registration No. 70712
Attorney for Applicant
USPTO Customer No. 24030

POLSINELLI PC
900 West 48th Place, Suite 900
Kansas City, MO 64112
uspt@polsinelli.com
Tel: 303-583-8269
Fax: 816-753-1536

EXHIBIT L

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

**ADVANCE MEDICAL
DESIGNS, INC.,**

Plaintiff,

V.

CASE NO. 1:22-cv-0789-SAG

**CORBIN CLINICAL
RESOURCES, LLC**

Defendant.

**DECLARATION OF MATTHEW J. ALLAWAY IN SUPPORT OF
CORBIN'S AMENDED RESPONSIVE CLAIM CONSTRUCTION BRIEF**

I, Matthew J. Allaway, of lawful age declare under penalty of perjury as follows:

A. Background

1. I am an actively practicing urologist in Maryland.
2. I graduated from the Chicago College of Osteopathic Medicine in 1996 and subsequently attended West Virginia University where I completed my residency in General Surgery in 1998, and my residency in Urology in 2002.
3. After my residency, I moved to Maryland where I set up Urology Associates. I have been practicing there as a urologist for almost 20 years. A special focus of my practice is prostate cancer.
4. During the course of my practice, it is often necessary for me to perform prostate biopsies to sample and remove tissues or cells for further examination and analysis. These prostate biopsies are important to diagnose and treat prostate cancer and other pathologies of the prostate.

5. Two types of prostate biopsies are transrectal prostate biopsies and transperineal prostate biopsies. I have been performing both types of these biopsies throughout the course of my 20-year career.

6. Transrectal prostate biopsies are a common method of conducting prostate biopsies. However, increased rates of antibiotic-resistant transrectal induced bacteria and the risk of infection make such procedures increasingly risky. Because of the risks of fecal bacteria, the transperineal prostate biopsies had a significant benefit over the transrectal prostate biopsies.

7. An early technique of taking transperineal prostate biopsies included using a grid/template approach wherein the biopsy trajectory is determined by the grid hole and not the geometrical configuration of the zones of the prostate where prostate cancer originates. One would often need to take three biopsies to cover a region of interest. For each biopsy sample taken, the biopsy needle traverses through the skin, subcutaneous tissue, and the prostate. A total of around 50-60 core samples are needed to sample the entire prostate. Although the cancer detection is optimal, the procedure requires general anaesthesia and significant resources of the operating physician. Since the prostate biopsy is performed on over 3 million men worldwide each year, this is not a suitable approach for the mainstream adoption.

8. Another early transperineal technique did not use a guide for the needle at all. Instead, the urologist would maneuver an ultrasonic probe with one hand while independently maneuvering the biopsy needle with the other hand. This requires a high degree of skill and dexterity on the part of the clinician. It is a technique which has a long learning curve and is relatively difficult to master.

9. It was later discovered that patient comfort could be improved by keeping the access point open with the use of a coaxial needle, then passing the biopsy needle through the coaxial needle. The advantage of using a coaxial needle is to reduce trauma by avoiding multiple insertions of the biopsy needle into the same perforation.

10. In this early technique, the coaxial needle was always manipulated wholly independently of the probe. Accordingly, the urologist would be required to maneuver the probe with one hand, and independently maneuver (using his or her other hand) the biopsy needle through the coaxial needle.

11. This is sometimes described as a “*double free-handed*” approach. Each hand is acting freely, without being guided by a template, and without the device that is held in one hand being attached to the device that is held in the other. This is a difficult maneuver and slightly desynchronous movements often lead to the loss of vision of the biopsy needle on the ultrasound screen. The free-hand technique has been around for over 20 years. Prior to development of the PrecisionPoint™ prostate biopsy, I utilized this approach.

12. The free-hand technique had some notable limitations. For example, through this single access point, one is simply pivoting on a fulcrum and based on the variable size of the prostate, one is not able to adequately sample the entire prostate. One will often need to make multiple punctures in the perineum to properly sample the anterior/apical prostate. In addition, the biopsy trajectory is not unique for each core. One is typically overlapping a prior biopsy path repeatedly. Thus, the cancer detection is suboptimal compared with the grid/template transperineal biopsy. The technique was also challenging for the urologist to learn because of the need to

monitor the ultrasound probe separately from the biopsy gun. Thus, standardization and reproducibility were seriously lacking.

13. With the double handed, free-hand approach, I was unable to separate each biopsy from subsequent cores. The biopsy needle typically passes through the zones of the prostate where cancer does not originate, and I was unable to keep the biopsy needle entirely in the relevant zones of the prostate. Other urologists that I attempted to train were typically unable to reproduce the method because they could not properly coordinate manipulating the probe with one hand and guiding the biopsy gun into the target with the other hand. As a result, many of these urologists were detecting cancer at a rate lower than those obtained using the transrectal technique.

14. Faced with the difficulties of existing techniques, I realised there was a need for a device allowing the benefits of the two different approaches for transperineal biopsies. Driven by the clinical and technical challenges that I encountered in the practice of taking prostate biopsies, I started working on solving this problem and developing a device and method to foster mainstream adoption of the transperineal approach. Since then, I have spent over 8 years designing medical technologies using needles to perform transperineal prostate biopsies. During that time, I developed the PrecisionPoint® Transperineal Access System.

15. In this process, I came to understand that key to the solution is to anchor an access trocar into the perineum with the stability to withstand the counter forces of the anatomy as the access trocar is shifted to various positions in the x,y and z coordinates. With such a device, the access trocar can be repositioned to a unique and definable point to access the most relevant zones of the prostate for ideal cancer detection. Another key element was that the device be coupled to the ultrasound probe so the biopsy needle trajectory can be constantly monitored.

16. Through the development process, I created over two dozen iterations of the design. Each detail of the device was engineered with this very specific purpose. As one moves from one biopsy position to the next, the hand on the ultrasound probe is shifted in a multitude of directions, and the PrecisionPoint® moves in tandem.

17. The combination of a device for mounting onto a transrectal probe and the device being equipped with a coaxial access needle for carrying out transperineal biopsies was new.

18. PrecisionPoint® is the only FDA cleared, CE marked, Class Ila medical device for performing freehand transperineal prostate biopsies. This new system provides a significant improvement over the prior systems and significantly reduces the risks associated with such procedures.

19. I founded Corbin Clinical Resources, LLC, d/b/a PERINEOLOGIC® (“Corbin”) in 2009 to commercialize PrecisionPoint® and to continue my focus of addressing a growing concern regarding the high rate of infections and missed cancer diagnoses associated with the then-current state of the art transrectal ultrasound-guided biopsy. I am currently the President and Chairman of Corbin.

20. The PrecisionPoint® system is covered by seven issued patents in the United States, five of which are the subject of this lawsuit. I am the named inventor on these patents, which include U.S. Patent No. 10,064,681 (“681 Patent”), U.S. Patent No. 11,096,762 (the “762 Patent”), 11,246,677 (the “677 Patent”), U.S. Patent No. 11,446,056 (the “056 Patent”), and 11,547,436 (the “436 Patent”) (together the “Asserted Patents”). Corbin holds the intellectual property associated with these inventions.

21. I have reviewed Plaintiff Advance Medical Designs, Inc.’s Updated Opening Claim Construction Brief (“Brief”) and am prepared to make the following opinions and comments in response. I understand that my statements will be relied on in the claim construction proceedings and I confirm that what is set out here is true to the best of my knowledge and belief and that the opinions expressed herein are truly held. I am prepared to confirm the contents of this statement under oath.

22. From the outset, I note that I agree that one of ordinary skill in the art is someone with an advanced medical degree, including a Doctor of Medicine or a Doctor of Osteopathic Medicine, with at least five years of experience taking transperineal prostate biopsies. Such person may also have experience developing medical devices such as the PrecisionPoint or other medical devices used within the field of urology for taking prostate biopsies.

B. “lumen sized to receive a biopsy needle there through” is not indefinite

23. AMD argues that the term “lumen sized to receive a biopsy needle there through” is indefinite because “nothing in the specification defines either the size of a biopsy needle or the size a lumen needs to be to receive said biopsy needle.”

24. The ’677 Patent covers an apparatus for use with a transrectal transducer in performing free-handed transperineal prostate biopsies. The procedure includes locating a target area using an ultrasound probe, positioning the ultrasound and the access needle at respective designated points, and obtaining specimens from a precise point in the prostate. Multiple tissue or cell specimens may be obtained from the prostate through an access needle.

25. A “lumen” is generally known as a cavity or channel within a hollow tube or tubular structure. In this case, the lumen is the hollow interior cavity of the access needle. The

claims of the '677 Patent require that the lumen of the access needle be sized to receive a biopsy needle therethrough. One of ordinary skill in the art would know that the lumen would have to be large enough that one could insert a biopsy needle through the lumen. This would require that the lumen be larger than the diameter of the biopsy needle.

26. One of ordinary skill in the art would have experience taking transperineal prostate biopsies. AMD concedes this fact. That person would therefore know that, in order to obtain the tissue or cell specimens in performing a transperineal prostate biopsy using a biopsy needle and an access needle, that the lumen could be any size that would allow a biopsy needle to be coaxially inserted into the access needle. If the lumen is too small to receive the biopsy needle, then it does not meet the limitations of this claim element. If the lumen is large enough to receive a biopsy needle, then it meets the claim limitation. One of ordinary skill in the art would clearly know whether a lumen is sized to receive a biopsy needle there through.

27. Even if the term “lumen sized to receive a biopsy needle there through” itself does not adequately inform one of ordinary skill in the art about the scope of the invention with reasonable certainty, the dependent claims and specification provide additional certainty.

28. For example, dependent claims 3, 4, 15, 24, and 25 require an access needle of 14, 15, or 16 gauge. Those gauges have exact dimensions associated with them and provide one of ordinary skill in the art with specific examples of sizes of access needles that would suffice. Hence, a practitioner could practice the invention with a 14-gauge access needle.

29. Further, dependent claims 11, 12, and 30 require that “the biopsy needle has a needle size of 18 gauge.” A 14, 15, or 16 gauge access needle can receive the smaller 18 gauge biopsy needle.

30. These examples take any guesswork out of the selection of an access needle or a biopsy needle and precisely inform one of ordinary skill in the art.

31. The specification also states that the “biopsy gun may be an 18-gauge biopsy gun, or any other size that is capable of being coaxially inserted through the lumen of the access needle.” That reference means that the biopsy gun can be used with an 18-gauge biopsy needle.

32. I believe that the term “lumen sized to receive a biopsy needle there through,” viewed in light of the claims, specification, and prosecution history, adequately informs those skilled in the art about the scope of the invention with reasonable certainty.

C. The Term “distal point of the pair of stabilization members is offset from” is not indefinite

33. I understand that AMD claims that the term “distal point of the pair of stabilization members is offset from” is indefinite. I disagree for the following reasons.

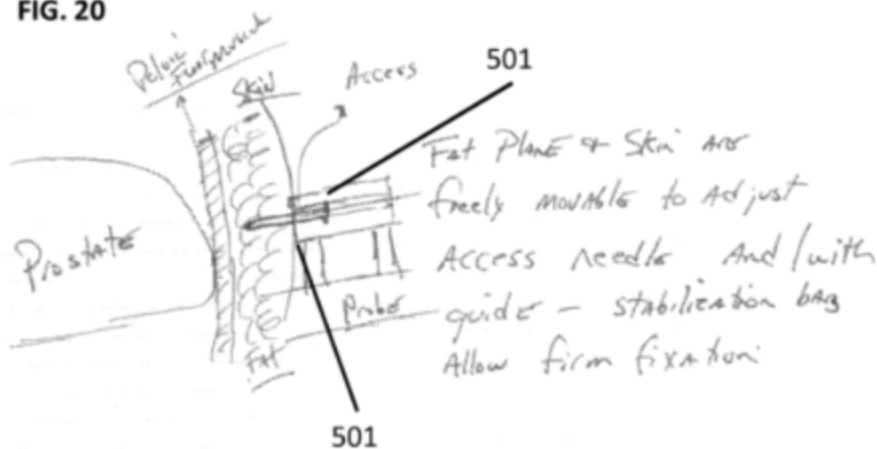
34. “Distal” is a commonly known term in the medical device industry. In this case, a medical professional would understand that the “distal point” of the stabilization members is that point that most closely faces the perineum when the biopsy is being performed. This is consistent with how the term is commonly used in medicine, i.e. the distal end is the end opposite of where the structure is attached. For example, the fingers represent the distal end of an arm, which is opposite from the proximal end where the arm is attached to the body.

35. The specification provides more clarity. For example, referencing Figure 5, the specification states that “the off-set 501 from the distal point of the stabilization bar 105 to the fasteners 102 may be 5 mm.” ‘677 Patent, 9:67-10:1. The term “offset” means a positional difference between two points. Figure 5 clearly shows the offset on the distal side of the stabilization bars.

36. The specification provides further support and context for the term “distal,” as well as the term “proximal,” which is well understood to mean the opposite of distal. As one example, the specification states that “[a]fter 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.” ‘677 Patent, 11:18-22. Figure 12 shows 802 clearly at the end closest to the patient.

37. In this passage, the “distal point of the biopsy instrument” is the tip of the needle that is used for obtaining cell or tissue specimens from the patient. This interpretation is consistent with common usage of “distal” and “distal point.” As another example, the specification states that “[t]he upper and lower mounts may be positioned proximally or distally along an ultrasound probe, such as a transrectal ultrasound probe.” ‘681 Patent, 5:19-21. In this passage, both distal and proximal are used consistently with common usage and with the preceding example of the “distal point of the biopsy instrument.” The foregoing examples provide additional clarity to one of ordinary skill in the art as to the meaning of the well understood term “distal point.”

38. AMD identifies an apparent inconsistency in the labeling of the offset 501 in Figures 5 and 20 of the ‘677 Patent. The apparent inconsistency with labeling of the offset 501 in Figure 20 appears to be a misplaced reference line. This line was in the correct position in U.S. Provisional Patent Application No. 61/974,826, filed April 3, 2014. As seen in Figure 20 from Provisional Application 61/974,826, reproduced below, the offset 501 on the left of the image correctly identifies the location of the offset with the accompanying text explaining the function of the offset: “stabilization bars allow firm fixation[.]”

FIG. 20

39. Reference to the stabilization bars 101 is incorrectly labeled as 501 on the upper right of Figure 20 of Provisional Application 61/974,826. That reference line was intended to refer to the stabilization bars 101.

40. The specification provides clarity to the offset 501 with reference to Figure 20 by stating, “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.” ‘681 Patent, 11:6-10.

41. As seen in Figure 20, the distal point of the stabilization bars 101 is the part of the device that contacts and penetrates the fat plane of perineum skin. *Id.* at Fig. 20. The offset 501 allows for stabilizing the device with the patient. As such, Figure 20 from Provisional Application 61/974,826, provides a consistent interpretation of the offset and the distal point with Figure 5, as well as a consistent interpretation with common usage of the terms offset and distal.

42. In light of the foregoing, I believe that the term “distal point of the pair of stabilization members is offset from,” viewed in light of the claims, specification, and prosecution

history, adequately informs those skilled in the art about the scope of the invention with reasonable certainty.

43. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct, and that this declaration was executed on September 15, 2023, in Allegany, County Maryland.



Matthew Allaway, Declarant

EXHIBIT M

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

BACKGROUND

[0001] A biopsy is a medical procedure that commonly involves sampling and removing tissues or cells from a living body for further examination of potentially abnormal conditions. For example, a prostate biopsy may be performed for diagnosis and/or treatment of a patient's prostate. Moreover, the vast majority of patients with an abnormal prostate specific antigen (PSA) or suspicious digital rectal examination (DRE) undergo biopsy. The biopsy is normally performed by transrectal ultrasound-guided (TRUS) biopsies or transperineal ultrasound-guided (TPUS) biopsies.

[0002] The transrectal approach obtains 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. Systems and approaches using the transrectal approach commonly include guiding the biopsy needle or other biopsy instruments by ultrasound in a sagittal plane. However, there are several disadvantages of the transrectal approach. Initially, the patient is commonly required to take antibiotics prior to the procedure to reduce the risk of infections. Also, the transrectal approach requires the patient to perform bowel preparation, which is a procedure usually undertaken before the biopsy, for cleansing of the intestines of fecal matter and secretions. Further, the passage of the biopsy needle through the rectal wall may introduce bacteria from the rectum 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.

[0003] The transperineal approach obtains tissue or cells specimens by passing one or more biopsy needles through the perineum and into the prostate. Currently in practice, the transrectal approach is mostly favored over the transperineal approach. Contrary to the transrectal approach, the transperineal approach 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, the

transperineal approach utilizes 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 addition, the needle does not pass through the rectal wall which eliminates the risk of coliform bacteria entering the prostate or the bloodstream.

[0004] Systems using the transperineal approach for performing prostate biopsies mostly utilize a biopsy grid that is fixed to an apparatus. The apparatus is fixed to the floor or to a platform/table on which the patient lies. The biopsy grid provides a plurality of 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, these systems require imaging in an axial plane of the ultrasound or a transverse transducer for positioning the biopsy needle.

[0005] The above systems and approaches using the transperineal approach do not allow free-hand movement of the ultrasound probe, heavily rely on the axial ultrasound plane to confirm positioning of the biopsy needle or other instruments. Using such systems and approaches, each extraction of prostate tissue specimens involve separate punctures into the transperineal tissue. Similarly, one is not able to freely handle and position the needle to the desired target location of the prostate relying on the sagittal plane in using the transrectal approach, which is commonly the favored imaging approach.

[0006] Accordingly, there is a demand for a transperineal biopsy method, system, and device that provides 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 than traditional transperineal and transrectal approaches. The method, system, and device herein provided satisfy this demand.

SOME EXAMPLE EMBODIMENTS

[0007] The method, system, and device herein provided allow a real-time visualization, free-handed, guided, and multi-sample transperineal approach to performing a biopsy. The method, system, and device herein provided also allow for a complete biopsy of the prostate with only one or a minimum perforations of the patient's skin via an initial access site, such that the access needle is freely moveable. The biopsy guide can be placed on an assortment of ultrasound probes of different sizes and shapes due to an adjustable mounting system. 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.

[0008] In embodiments, the guide is fixed to an ultrasound probe that is not fixed and freely moveable. 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 (e.g., a practitioner) to place the access needle along a sagittal transducer plane at optimal positions for obtaining prostate biopsies. In further 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.

[0009] In embodiments, the method and system herein provided do not require a patient to take antibiotics at any point prior to the biopsy procedure, nor do they require a patient to undergo any form of bowel preparation in advance of the procedure. In embodiments, the method and system can reduce and/or eliminate multiple skin perforations by utilizing a single access location and/or access site, while allowing multiple extractions of tissue or cell specimens from the prostate. It is contemplated that the device herein provided allows for a real-time visualization, free-handed, guided, transperineal approach, while allowing for a complete assessment of the prostate with only one perforation of the patient's skin, wherein the access needle is freely moveable in each plane. In embodiments, the method, system, and device may include and/or facilitate treatment that includes the use of 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.

[0010] In embodiments, methods, systems, and devices for 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.

[0011] In one embodiment, the biopsy is performed using a system that includes a biopsy guide, a transducer, an access needle, and a biopsy instrument. The access needle will allow the anesthesia to be injected in the patient as well as the tissue or cell specimens of the prostate to be

extracted. If anesthesia is used, it is also contemplated that a syringe is 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 is disposable. In embodiments, the biopsy guide is formed of materials intended for a single use. In other embodiments, the biopsy guide is reusable. In embodiments, the biopsy guide is formed of materials intended for multiple uses.

[0012] In yet another embodiment, the guide includes a sliding platform, stabilization bars, one or more upper and lower mounts, and a fastener. In embodiments, the upper and lower mounts may be curvilinear in shape. In further embodiments, 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. In embodiments, the mounts may be formed, in part, with rubber.

[0013] In embodiments, the guide may be made of any material such as a plastic or metallic material. In embodiments, the guide may be disposable and made of a biodegradable plastic material. In other embodiments, the guide may be reusable and made of a stainless steel. The dimensions, for example, the length, width, height, depth, and breadth, of the sliding platform, stabilization bars, upper and a lower mounts, and the fastener may vary and/or are adjustable, according to embodiments. 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. In yet further embodiments, 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 patients' body habitus. This allows the guide to be mounted to any assortment of ultrasound probes. Similarly, in further embodiments, the platform may, for example, have various thicknesses.

[0014] In another embodiment, the stabilization bars are 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 8mm, according to embodiments. In further embodiments, the guide may be approximately 60 mm wide, and the guide may be approximately 50 mm long. According to further embodiments, 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.

[0015] In yet further embodiments, an inner portion of the stabilization bars 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 in the stabilization bar. This resistance may be introduced by the sliding platform or both the stabilization bar and the sliding platform. In embodiments, the resistance may be provided by a strip of rubber or any other material capable of providing friction or other. In yet further embodiments, the strip may be curvilinear. In embodiments, the resistance may be generated by a mechanical system, such as a spring mechanism.

[0016] According to embodiments, the sliding platform may have a hole through the platform. In further 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. In yet further embodiments, the needle may be a reusable needle, such as a reusable spinal needle. In yet other embodiments, the needle may be a disposable needle, such as a disposable spinal needle.

[0017] In embodiments, a flange of the guide secures the placement of the access needle to the guide. In further embodiments, the flange snaps into the guide to secure the needle. In yet further embodiments, the flange can be secured to the guide by other securing mechanisms. The flange can be of various shapes and configurations. For example, the flange can be u-shaped. As another example, the flange can be thinly configured. 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.

[0018] 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. In embodiments, the sliding platform is 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. In further embodiments, the hole can 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.

[0019] In further embodiments, the platform has a predrilled hole in the center of the platform that can accommodate various sizes of needles and/or instruments. In embodiments, the hole can accommodate a needle having a range of 14-18 gauges. For example, a reusable 14 gauge spinal needle. Having the placement of the hole centered on the platform provides that once the guide is mounted to an ultrasound probe, the hole may be aligned in parallel with a sagittal transducer. In yet further embodiments, the platform may have multiple holes to accommodate various applications and body habitus. The embodiments, the platform may also be various thicknesses.

[0020] In embodiments, 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, the one or more lower curvilinear mounts are positioned after positioning of the one or more upper curvilinear mounts are cradling an upper aspect of the ultrasound probe.

[0021] In another embodiment, at least two lower mounts are provided and may be individually positioned to accommodate various types of probes, as some probes have variable diameters along their shafts. In embodiments, the 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.

[0022] In another embodiment, the lower mount of the guide comprises a lower right mount and lower left mount connected by an adjustable mid-joint or fastener. This 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 as 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.

[0023] In another embodiment, the lateral edges on both ends of the lower mounts 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.

[0024] According to one embodiment, a method includes 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 x axis from the lateral edge of the prostate to the urethra shown in FIG 51.

[0025] In embodiments, the method maybe performed using no anesthesia. In yet further embodiments, an anesthetic may be used. For example, the anesthetic may be lidocaine, or any type of local anesthetic. The lidocaine may be include 1 or 2% of a lidocaine solution.

[0026] According to another embodiment, the suspicious area or bodily organ is 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, some type of 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 lobothy position, prone position, or any position that allows for access to the perineal area.

[0027] In embodiments, the method includes 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. 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.

[0028] In another embodiment, the method includes 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. It is also contemplated that a biopsy gun or any other instrument that may be attached to the needle for inserting or extracting any substance thru the lumen of the access needle.

[0029] 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.

[0030] In another embodiment, the method includes 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 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 via a display device that provides images captured by the probe.

[0031] In further embodiment, the method includes 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.

[0032] In another embodiment, the method includes removing the access needle from the perennial 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.

[0033] In another embodiment, the method includes 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.

[0034] In further embodiments, the method includes 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.

[0035] 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.

BRIEF DESCRIPTION OF THE DRAWINGS

[0036] 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:

[0037] FIG. 1 is a right side view of a guide secured to a probe, according to one embodiment;

[0038] FIG. 2 is an internal view of a guide's fastener, according to one embodiment;

[0039] FIG. 3 is a top view of a guide secured to a probe, according to one embodiment;

[0040] FIG. 4 is a cross-section view of the back of a guide secured to a probe, according to one embodiment.

[0041] FIG. 5 is a close-up view of a guide secured to a probe, according to one embodiment;

[0042] FIG. 6 is a magnified view of a guide's fastener, according to one embodiment;

[0043] FIG. 7 is a magnified view of a guide, according to one embodiment;

[0044] FIG. 8 is a right side view of a biopsy instrument that has penetrated the prostate, according to one embodiment;

[0045] FIG. 9 is a front view of a designated area of the prostate where a biopsy instrument will penetrate, according to one embodiment;

[0046] FIG. 10 is a right side view of a biopsy instrument penetrating the prostate, according to one embodiment;

[0047] 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, according to one embodiment;

[0048] FIG. 12 is a top view of a biopsy instrument that has penetrated the prostate, according to one embodiment;

[0049] FIG. 13 is a right side view of a prostate and the path of the biopsy instrument;

[0050] FIG. 14 is a front view of a guide positioned at a designated area of the prostate, according to one embodiment;

[0051] FIG. 15 is a right side view of a guide positioned at a designated area of the prostate, according to one embodiment;

[0052] FIG. 16 is a front view of a guide positioned at another designated area of the prostate, according to one embodiment;

[0053] FIG. 17 is a right side view of a guide positioned at another designated area of the prostate;

[0054] FIG. 18 is a front view of a guide positioned at a higher designated area of the prostate, according to one embodiment;

[0055] FIG. 19 is a right side view of a guide positioned at a higher designated area of the prostate, according to one embodiment;

[0056] FIG. 20 is a right side view of a guide, and a biopsy instrument firmly penetrating a fat plane and perineum skin;

[0057] FIG. 21 is a view of an access needle positioned at the access site, according to one embodiment;

[0058] FIG. 22 is a front view of a patient in a dorsal lithotomy position, according to one embodiment;

[0059] FIG. 23 is an ultrasound image of the prostate, according to one embodiment;

[0060] FIG. 24 is a front view of the prostate and the initial part of the penis, according to one embodiment;

[0061] FIG. 25 is an ultrasound image of the front view of the prostate with a computer generated measuring line in the screen, according to one embodiment;

[0062] FIG. 26 is an image of a front view of the prostate and the initial part of the penis, according to one embodiment;

[0063] FIG. 27 is an ultrasound image of the suspicious points from which the biopsy instrument will take cell or tissue specimens, according to one embodiment;

[0064] FIG. 28 is an image of the right side view of the prostate and an initial part of the penis, according to one embodiment;

[0065] FIG. 29 is an ultrasound of the point of the extracted cell or tissue specimen, according to one embodiment;

[0066] FIG. 30 is image of the right side view of a perforation path of the biopsy instrument, prostate, and an initial part of the penis, according to one embodiment;

[0067] FIG. 31 is image of the front view of a perforation path of a biopsy instrument, a designated point, prostate, an initial part of the penis, according to one embodiment;

[0068] FIG. 32 is an ultrasound image of the prostate, according to one embodiment;

[0069] FIG. 33 is another ultrasound image of the prostate, according to one embodiment;

[0070] FIG. 34 is an ultrasound image of a prostate and a biopsy instrument, according to one embodiment;

[0071] FIG. 35 is an ultrasound image of a prostate and a biopsy instrument being inserted into the prostate, according to one embodiment;

[0072] FIG. 36 is an image of the right side of a prostate and a biopsy instrument, according to one embodiment;

[0073] FIG. 37 is an image of the front side of a prostate and a biopsy instrument, according to one embodiment;

[0074] FIG. 38 is a magnified view of the right side of a prostate and a biopsy instrument, according to one embodiment;

[0075] FIG. 39 is an ultrasound image of a prostate and a biopsy instrument being retrieved from the prostate, according to one embodiment;

[0076] FIG. 40 is an image of the right side of a prostate and a biopsy instrument being retrieved from the prostate, and other targeted areas, according to one embodiment;

[0077] FIG. 41 is an image of the front side of a prostate and a biopsy instrument being retrieved from the prostate, and other targeted areas, according to one embodiment;

[0078] FIG. 42 is a magnified image of the right side of a prostate and a biopsy instrument being retrieved from the prostate, and other targeted areas, according to one embodiment;

[0079] FIG. 43 is an ultrasound image of the prostate and biopsy instrument, according to one embodiment;

[0080] FIG. 44 is an image of the right side of a prostate and a biopsy instrument being retrieved from the prostate, and other targeted areas, according to one embodiment;

[0081] FIG. 45 is an image of the front side of a prostate and a biopsy instrument being retrieved from the prostate, and other targeted areas, according to one embodiment;

[0082] FIG. 46 is a magnified image of the right side of a prostate and a biopsy instrument being retrieved from the prostate, and other targeted areas, according to one embodiment;

[0083] FIG. 47 is an image of the practitioner labeling the containers with specimens, according to one embodiment;

[0084] FIG. 48 is an ultrasound image of the prostate and biopsy instrument, according to one embodiment;

[0085] FIG. 49 is an image of the right side of the prostate, initial part of the penis, and biopsy instrument path, according to one embodiment;

[0086] FIG. 50 is an image of the front side of a prostate, a biopsy instrument, and other targeted areas, according to one embodiment;

[0087] FIG. 51 is an ultrasound image of the prostate, biopsy instrument, and urethra, according to one embodiment;

[0088] FIG. 52 is an image of the practitioner pressuring the perineum region of the patient, according to one embodiment;

[0089] FIG. 53 is a flowchart of a process for performing a biopsy, according to one embodiment;

[0090] FIG. 54 is an image of a guide made of a synthetic material without the lower mount, and an access needle, according to an embodiment; and

[0091] FIG. 55 is a guide made of a synthetic material, a lower mount, and an access needle, according to an embodiment.

DESCRIPTION OF SOME EMBODIMENTS

[0092] FIG. 1 is a right 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. Further embodiments are shown in FIG. 54 and FIG. 55. In embodiments, the distance between the fasteners 102 and the upper mount 105 be adjustable to accommodate various applications and body habitus.

[0093] FIG. 2 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.

[0094] 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. 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.

[0095] 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 30mm to 50mm long; the upper mount 105 with a height ranging from 10mm to 15mm; 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 25mm and 10mm wide; a lower mount 104 10mm wide. Additionally, the offset 501 from the distal point of the stabilization bar 105 to the fasteners 102 may be 5mm. It is contemplated that any of these dimensions may vary, including the stabilization bar 101, which may be longer than the upper mount 105.

[0096] FIG. 6 is a magnified internal view of a guide's fastener depicted 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 5mm to 10mm wide. Additionally, the sliding platform 301, which may be from 12mm to 25mm 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.

[0097] 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 5mm to 10mm; and the teeth 202 is from 5mm to 8mm wide.

[0098] FIG. 8 is a right 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.

[0099] FIG. 9 is a front view of a targeted area 902 of the prostate 801. FIG. 10 is a right 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.

[00100] 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. In embodiments, the access needle.

[00101] 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.

[00102] 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 targeted 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.

[00103] 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.

[00104] 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 5mm for these purposes.

[00105] 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 utilizing 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 usually 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.

[00106] FIG. 22 is a front view a right leg of a patient in a dorsal lithotomy position. At this point the patient's scrotum is elevated by e.g. two simple strips of plastic tape, and the perineum is prepared with an antiseptic solution to the perineal area such as a betadine, according to step 5201 shown in FIG. 53.

[00107] FIG. 23 is an ultrasound image of the prostate, wherein the image allows for the practitioner to follow the procedure. FIG. 24 is an image of the front view of the prostate and the initial part of the penis. At this point, only the transducer, such as an ultrasound probe may be inserted into the patient.

[00108] FIG. 25 is an ultrasound image of the front view of the prostate. FIG. 25 demonstrates the dimensions of the prostate. This will allows the practitioner to determine the exact volume of the prostate, and to establish a targeted or suspicious area or areas in which a cell or tissue specimen will be extracted from. The volume can be determined by e.g. a transrectal ultrasound that is displayed in an interactive screen.

[00109] FIG. 26 is an image of the front view of the prostate. At this stage, the practitioner is looking carefully at any suspicious area of the prostate, as shown in FIG. 53. FIG. 27 is an ultrasound image of the suspicious points from which the biopsy instrument will take cell or

tissue specimens. At this stage, the practitioner determines the specific point in which to target at the time of the extraction, also as shown in FIG. 53.

[00110] FIG. 28 is an image of the right side view of the prostate and the initial part of the penis. It is contemplated that another transducer device may be used to provide both the image of a side of the prostate and of the front of the prostate.

[00111] FIG. 29 is an ultrasound of the point of the extracted cell or tissue specimen. The practitioner is estimating the position of the access needle 2901 will reach. Here, the guide will help the practitioner to identify the mid line location of e.g. a sagittal transducer is located, and e.g. the distance from the probe to the mid prostate level, and ultimately the location in which to position the access needle 2901.

[00112] FIG. 30 is image of the right side view of the perforation path of the biopsy instrument, prostate, and the initial part of the penis. FIG. 31 is image of the front view of the perforation path of the biopsy instrument, the targeted or suspicious point, prostate, and the initial part of the penis. At this point, the practitioner may insert an access needle into the perineum area of the patient. The access needle may be inserted with a syringe attached to it, in accordance with FIG. 53.

[00113] FIGS. 32 and 33 are an ultrasound image of the prostate. FIG. 33 is an ultrasound image. If the patient is not under sedation, a local anesthesia may be applied to the patient. The sedative may be lidocaine. Here, the access needle may also be positioned in order to receive the biopsy instrument, and may be detached from a syringe that the practitioner may have used. The access needle may be later used with the biopsy instrument to extract cell or tissue specimen.

[00114] FIG. 34 is an ultrasound image of a prostate and a biopsy instrument. At this point, the biopsy instrument has been inserted into the body of the patient, but the biopsy instrument has not reached the prostate. FIG. 35 is an ultrasound image of a prostate and a biopsy instrument being inserted into the prostate. At this stage, the biopsy instrument has been inserted into the prostate, according to FIG. 53. FIG. 36 is an image of the right side of a prostate and a biopsy instrument. FIG. 36 shows the biopsy instrument into the prostate and other paths in which the biopsy instrument may take.

[00115] FIG. 37 is an image of the front side of a prostate and a biopsy instrument. FIG. 37 show the biopsy instrument into the prostate and other paths in which the biopsy instrument may take in a different angle. FIGS. 35, 36, and 37 shows a procedure being applied to the lateral

region 3701 of the prostate. It is contemplated that any other region of the prostate may be sampled.

[00116] FIG. 38 is a magnified view of the right side of a prostate and a biopsy instrument, as depicted in FIG. 36. FIG. 38 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 and/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.

[00117] FIG. 39 is an ultrasound image of a prostate and a biopsy instrument being retrieved from the prostate. FIG. 40 is an image of the right side of a prostate and a biopsy instrument being retrieved from the prostate, and other targeted areas. FIG. 41 is an image of the front side of a prostate and a biopsy instrument being retrieved from the prostate, and other targeted areas, according to FIG. 53. FIG. 39, 40, and 41 show a procedure being applied to the mid region 4101 of the prostate. FIG. 42 is a magnified image of the right side of the prostate and biopsy instrument, as shown in FIG. 40

[00118] FIG. 43 is an ultrasound image of the prostate and biopsy instrument. At this point the urethra 5101 is located so the practitioner may avoid perforating the urethra 5101. FIG. 44 40 is an image of the right side of a prostate and a biopsy instrument being retrieved from the prostate, and other targeted areas, per FIG. 53. FIG. 45 is an image of the front side of a prostate and a biopsy instrument being retrieved from the prostate, and other targeted areas. FIGS. 43, 44, and 45 show a procedure being applied to the apical region of the prostate, according to FIG. 53. FIG. 46 is a magnified image of the right side of a prostate and a biopsy instrument, as depicted in FIG. 44.

[00119] FIG. 47 is an image of the practitioner labeling the containers with specimens. This is done either by the practitioner or by an assistant so the practitioner knows where a specific cell or tissue specimen comes from, i.e. from the lateral region of the prostate, the mid region of the prostate, or apical region of the prostate.

[00120] FIG. 48 is an ultrasound image of the prostate and biopsy instrument. FIG. 49 is an image of the right side of the prostate, initial part of the penis, and biopsy instrument path. FIG. 50 is an image of the front side of a prostate, a biopsy instrument, and other targeted areas. FIGS. 48, 49, and 50 shows that the same procedure described above may be applied to the other side of the prostate, in accordance with FIG. 53. The procedure on the other side of the prostate

may be done either through the same perforation or through a second perforation on the other side of the perineum.

[00121] FIG. 51 is an ultrasound image of the prostate, biopsy instrument, and urethra. The urethra 5101 should be avoided in any part of the procedure, but it is mostly important to when extracting cell or tissue specimen 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.

[00122] FIG. 52 is an image of the practitioner pressuring the perineum region of the patient. 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.

[00123] In one embodiment, the biopsy system performs the processes 5300 of FIG. 53. In one embodiment, per step 5301, 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. In embodiments, the biopsy procedure a prostate biopsy. In further embodiments, the patient's scrotum is elevated with, 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.

[00124] In one embodiment, a target area or object is imaged, such as the prostate, per step 5302. In embodiments, imaging can be performed with a transducer, such as an ultrasound probe. Imaging of target area can be in sagittal and/or axial plane and performed in real-time with direct visualization. Utilizing the real-time image, a user can identify areas of interest, e.g. suspicious areas of the target area or object, per step 5303.

[00125] In embodiments, the user determines an access site for positioning an access needle. Per step 5304, an access needle is positioned at an access site in subcutaneous tissue of the perineum. According to embodiments, the access site is 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. In further embodiments, the access needle is guided and positioned at the access site by using the guide.

[00126] In embodiments, per step 5305 a biopsy instrument is guided to the targeted and/or suspicious areas or object. In further embodiments, the biopsy instrument includes a biopsy needle. The guiding of the biopsy instrument can be facilitated by utilizing the real-time

visualization provided by the transducer. and obtaining tissue or cell specimens from an accurate point in the prostate. The method allows for one or more tissue or cell specimens to be obtained from a bodily organ, such as the prostate, per step 5306, and permits access to the prostate from different angles through a single initial access needle. Per step 5307, 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 shown in FIG 51.

[00127] In yet another embodiment, the method maybe 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.

[00128] In embodiments, the suspicious area is located by using a transducer. The transducer may be any type of probe 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.

[00129] In another embodiment, the method includes applying an antiseptic solution to the perineal area such as betadine, or any other substance that reduces the possibility of infection, sepsis, or putrefaction.

[00130] 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 3-60mm. 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.

[00131] In another embodiment, the method includes 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. It is also contemplated that a biopsy

gun or any other instrument that may be attached to the needle for inserting or extracting any substance thru the lumen of the access needle.

[00132] 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.

[00133] In another embodiment, a biopsy gun may be 18 gauge biopsy gun, or any other size that is capable of being coaxially inserted thru the lumen of the access needle.

[00134] In another embodiment, the method includes 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 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.

[00135] In another embodiment, the method includes 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.

[00136] The method further includes a step of 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.

[00137] The method includes 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.

[00138] In another embodiment, the method includes 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.

[00139] 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. 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.

[00140] FIG. 54 depicts a guide 5400 without a lower mount, and an access needle 2901, according to some embodiments. The guide 5400 includes a stabilization bar 101, sliding platform 301, a hole 302 in approximately the center of the platform 301, an upper mount 105, teeth 202, aperture 201, arms 5401, and a connector 5402. The access needle 2901 includes a hub 5403 and is secured to the guide. The teeth 202 may be part of, or may be attached to, a lower mount. The teeth 202 may be inserted into the aperture 201 in order to secure the guide to e.g. a probe. It is contemplated that the combination of aperture 201 and the teeth 202 may form a fastener mechanism. In embodiments, connector 5402 is part of, or may be attached to, an access needle 2901, and may be secured to the upper mount 105 in order to provide stabilization of the access needle 2901 and to allow the practitioner to move the access needle by merely moving, for example, a probe that may be secured to the guide. Connector 5402 and hub 5403 permits the usage of various other instruments, for example, a non-biopsy instrument to be secured. A biopsy instrument may be inserted into the access needle 2901 in order to reach a targeted area. Upper mount 105 may include arms 5401. In embodiments, arms 5401 may be shorter, longer, or may not exist, in which case the aperture 201 is directly in the upper mount 105. When the aperture 201 is directly in the upper mount 105, upper mount 105 may be longer, thicker, or a combination thereof.

[00141] Similar to FIG. 54, FIG. 55 depicts a guide 5500 and an access needle 2901, according to some embodiments. FIG 55 also depicts detached lower mounts 104 with teeth 202. Arms 5401 are part of the upper mount 105 s in FIG. 55, in order to allow the height of the guide 100 to be adjusted and to be placed farther or closer to the probe 103. The arms 5401, as depicted in FIG. 55, permit the access needle 2901 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 is reusable and may be formed with a stainless steel. Lower mount 104 may be curvilinear and flexible to allow lower mount 104 to bend if necessary to secure the guide to the probe.

[00142] 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

WHAT IS CLAIMED

1. A method of performing a prostate biopsy comprising:
imagining a prostate in an axial plane and a sagittal plane with a transducer providing a real-time image;
locating a suspicious area of the prostate;
positioning an access needle at 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;
guiding a biopsy instrument along the sagittal plane to the target and/or suspicious areas using the real-time image; and
obtaining one or more specimens of the prostate through the access needle with a biopsy instrument.

ABSTRACT

Method, system, and device for planning and performing a guided and free-handed transperineal prostate biopsy is provided herein, wherein the method, system, and device allows for a real-time feedback, for performing multiple biopsies utilizing an initial access needle, and for sampling of precise and different parts of the prostate. It is contemplated that the device herein provided allows for testing and the treatment of a bodily tissue, including a cancerous area of a prostate. The system may include an ultrasound probe, an access needle, a biopsy gun and a guide. The guide may include a sliding platform, stabilization bars, upper and lower mounts, and fasteners. The method may include locating a suspicious 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 and/or cell specimens may be obtained from the prostate through an initial access needle.

FIG. 1

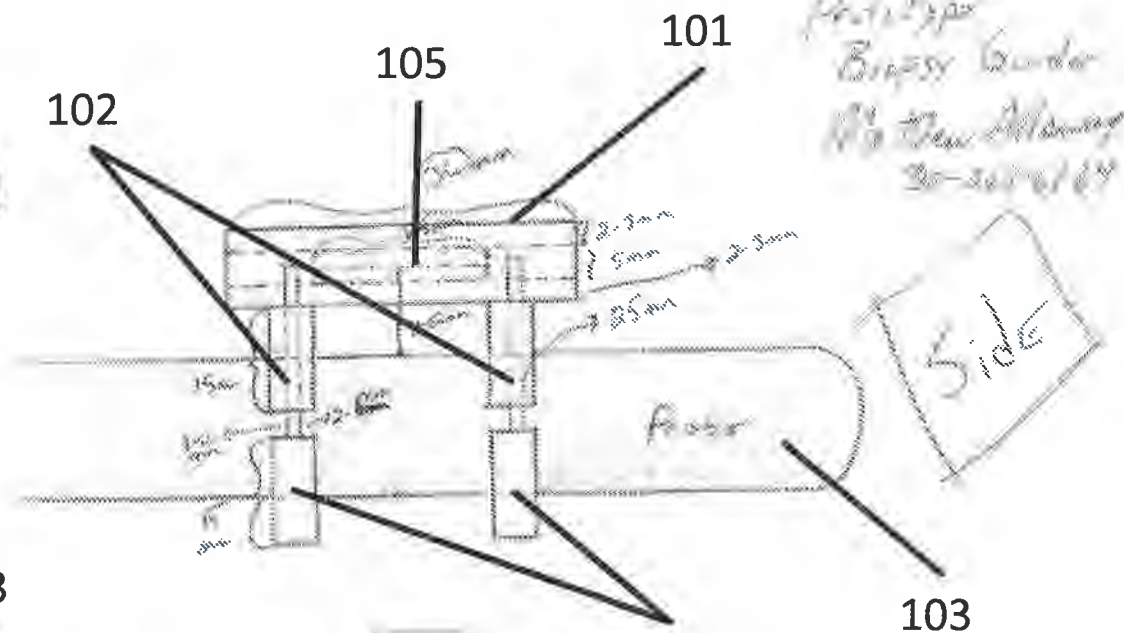


FIG. 2

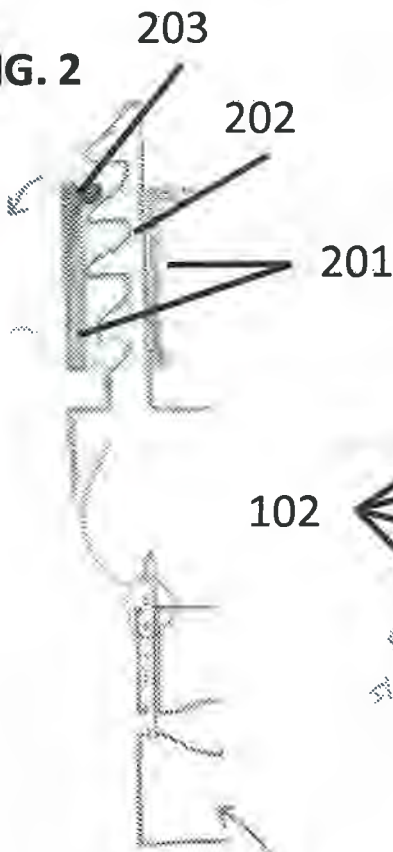


FIG. 3

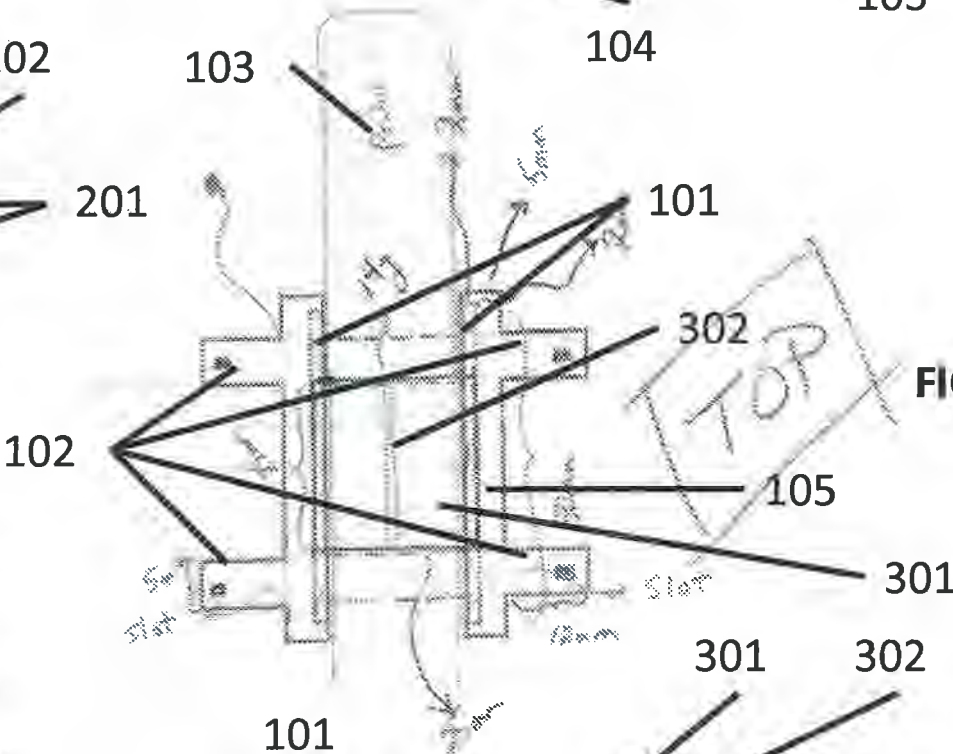


FIG. 4

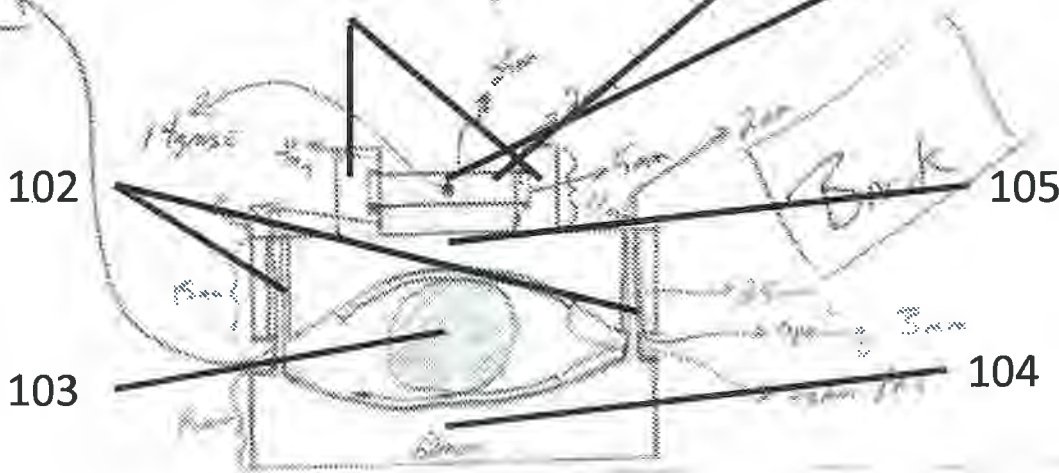


FIG. 5

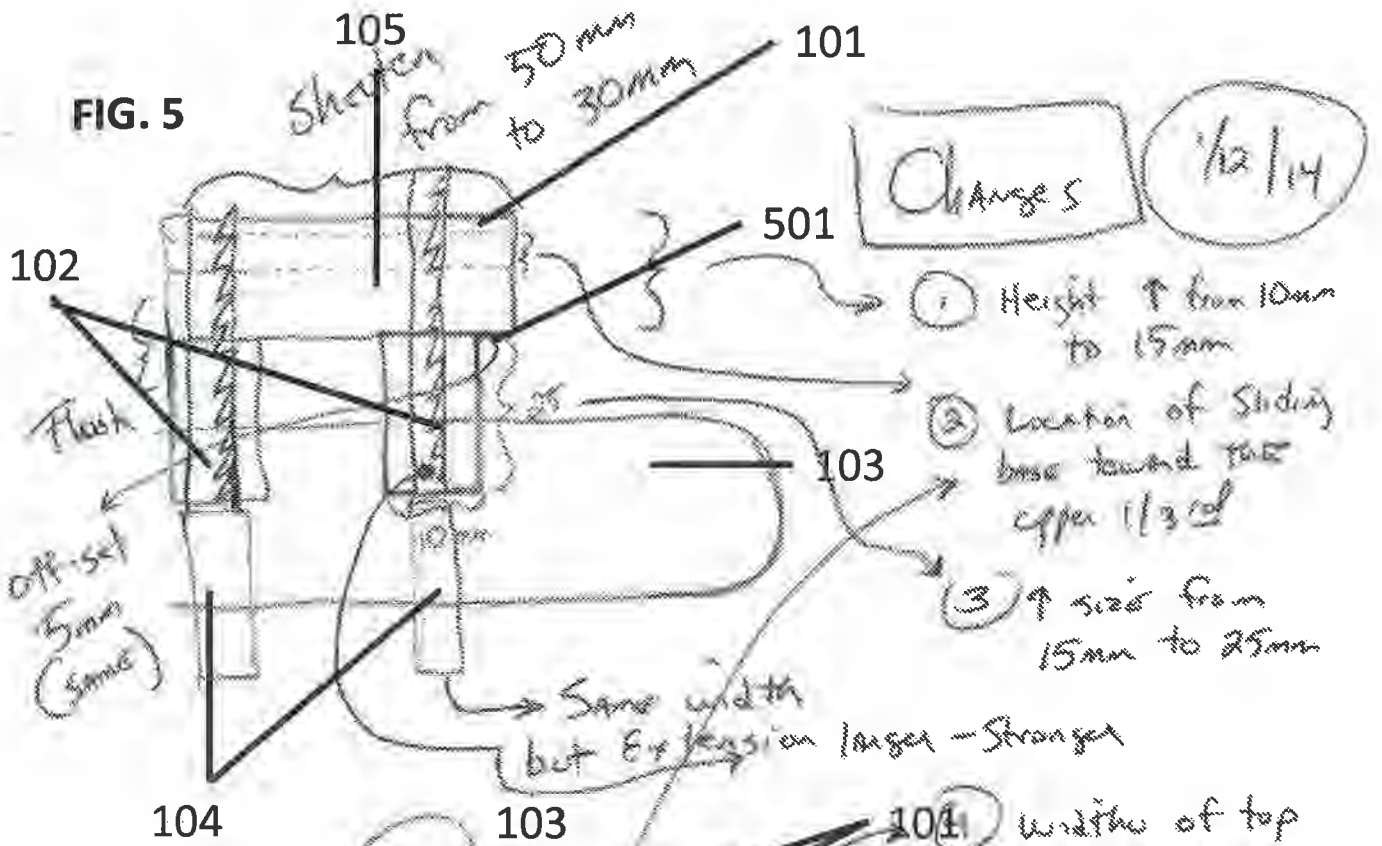
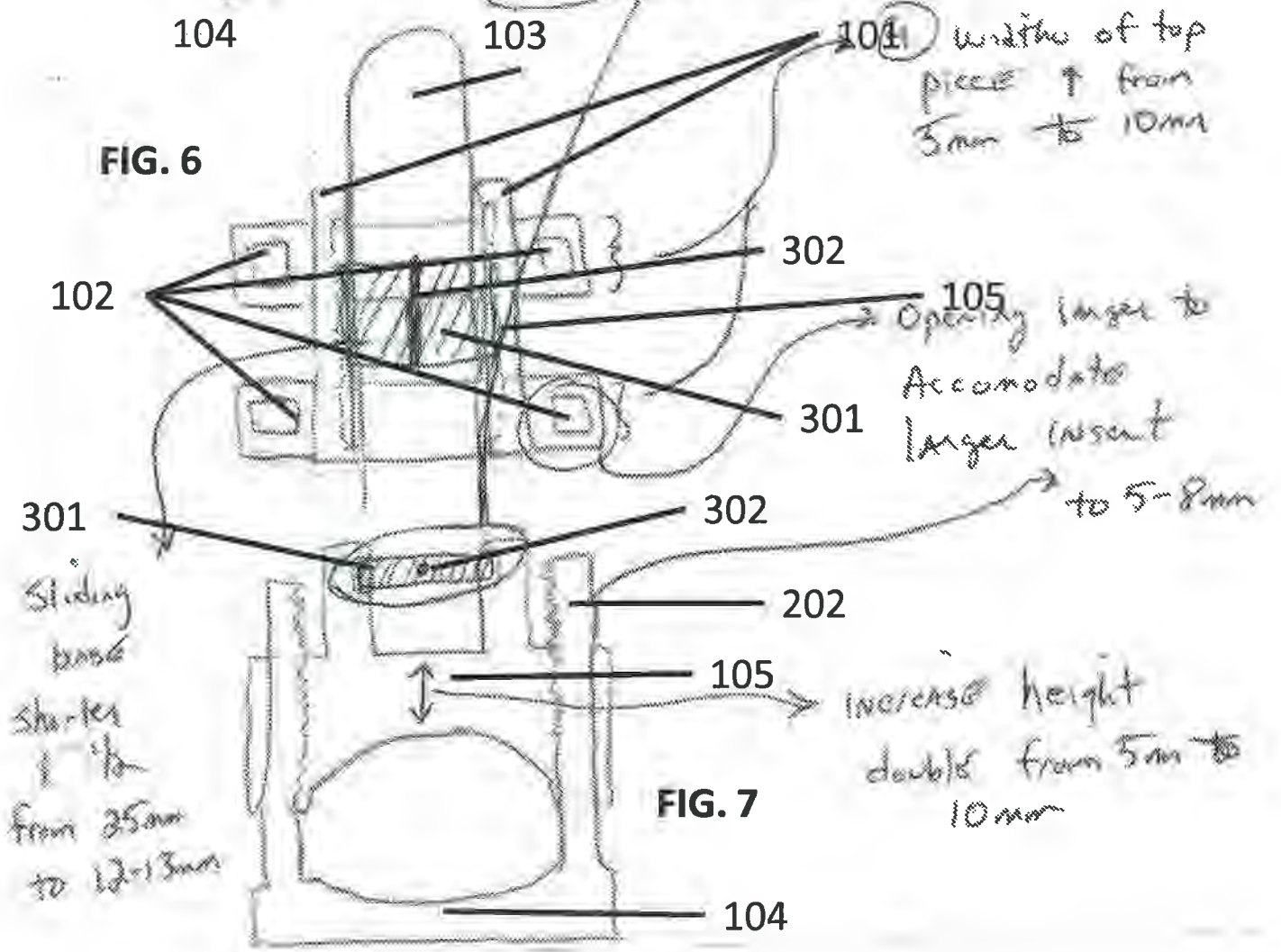
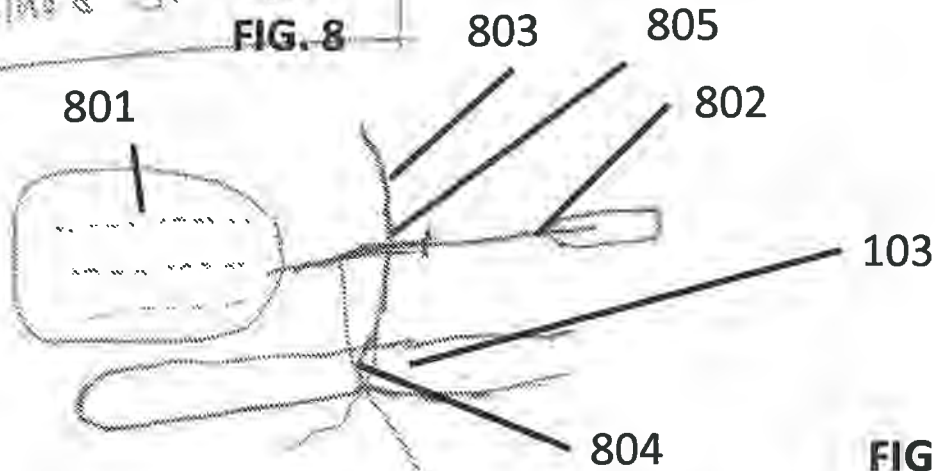


FIG. 6



Method Sketches

FIG. 8



902

FIG. 9

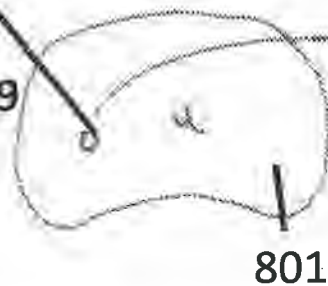


FIG. 10

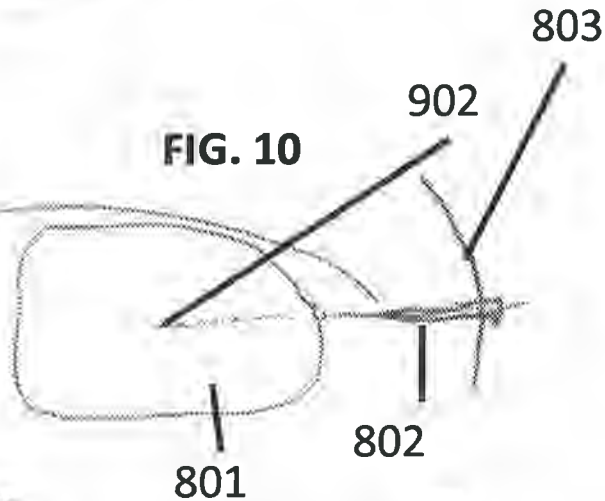


FIG. 12

Top

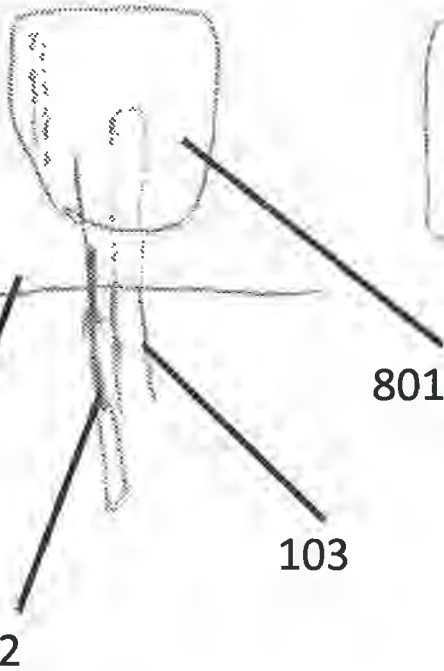


FIG. 13

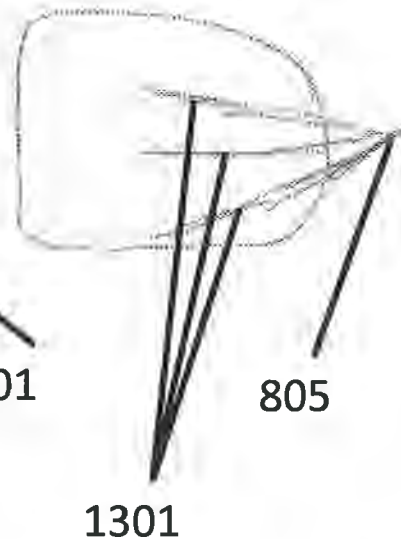
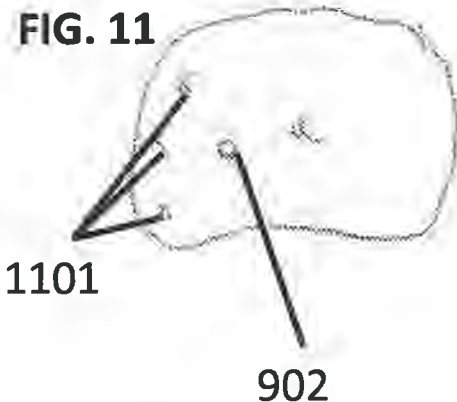


FIG. 11



Guide Sketch

FIG. 14



FIG. 16



FIG. 18

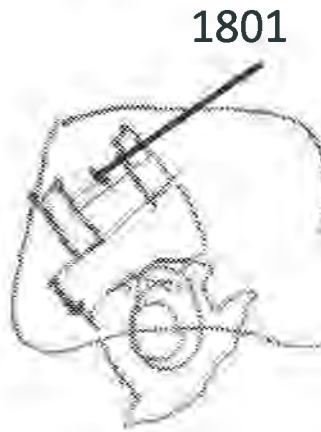


FIG. 15

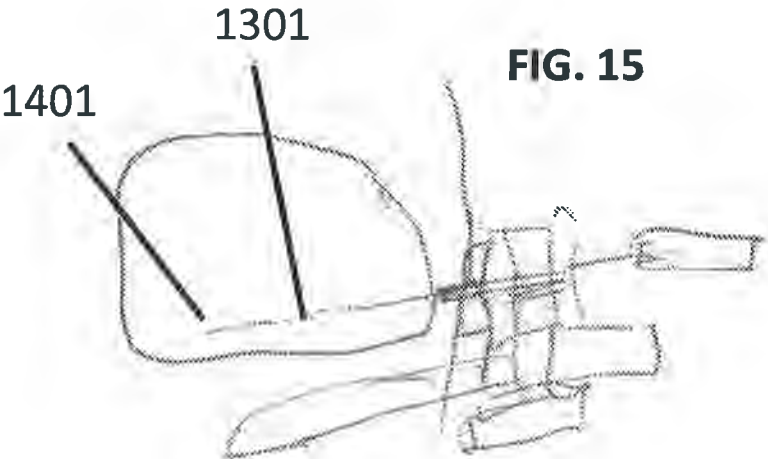


FIG. 17

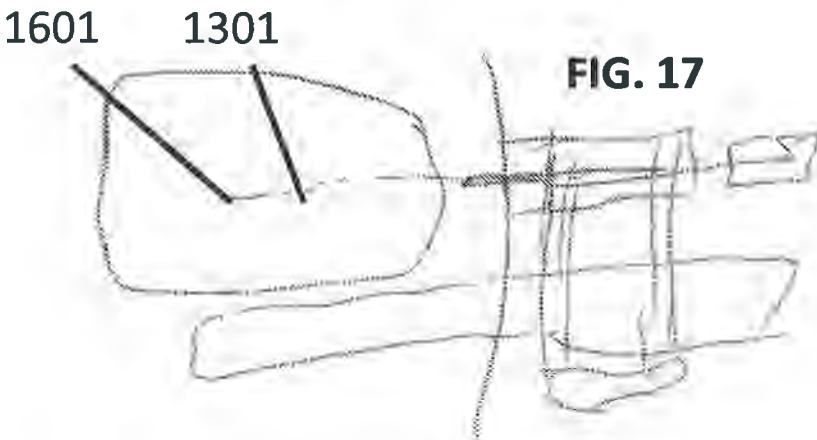


FIG. 19

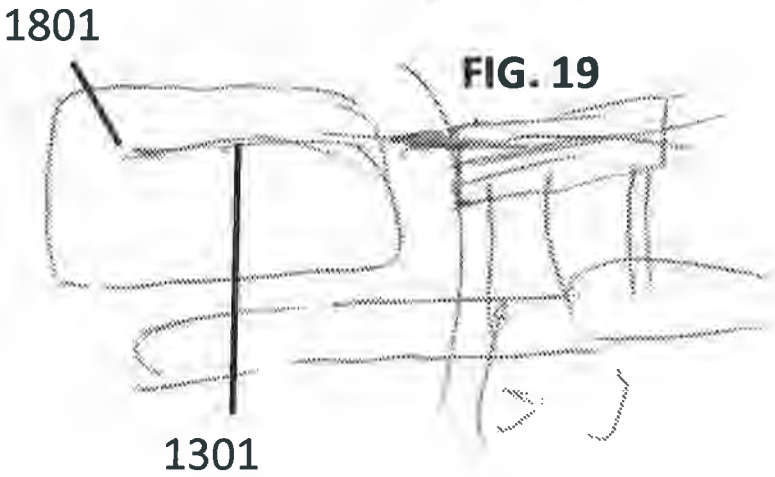


FIG. 20

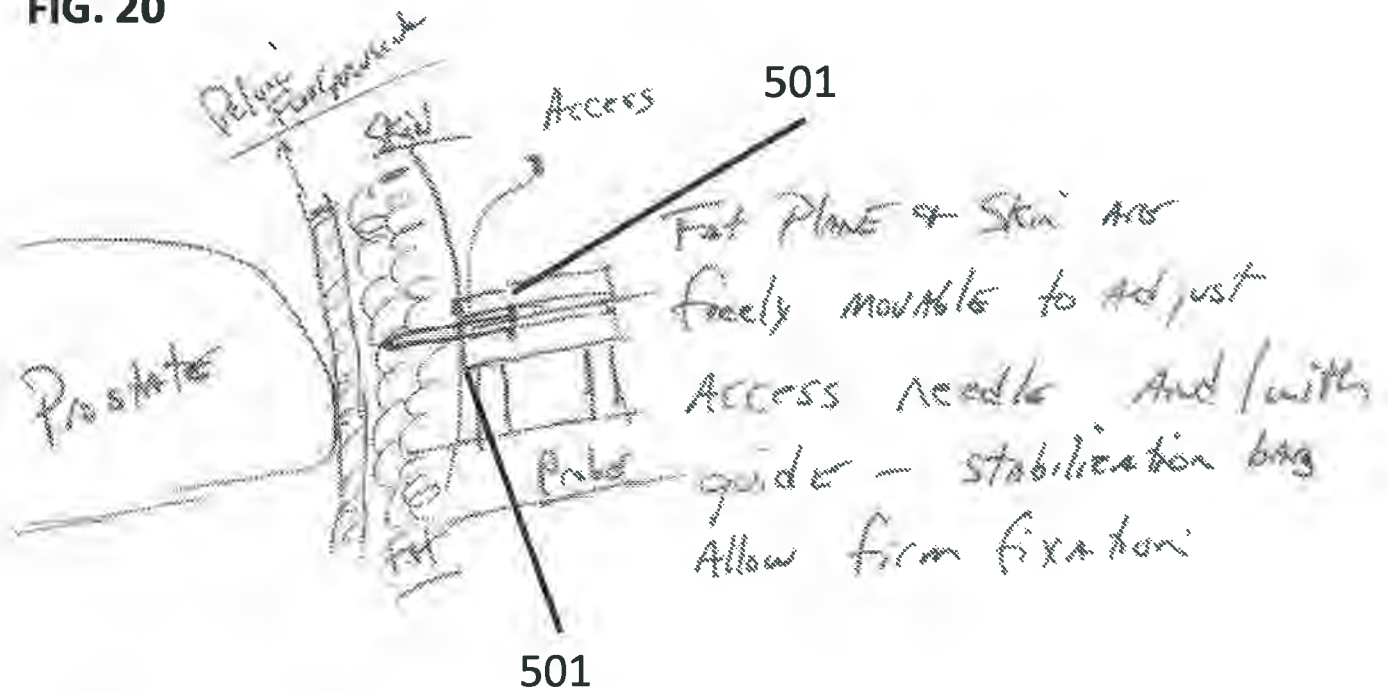


FIG. 21

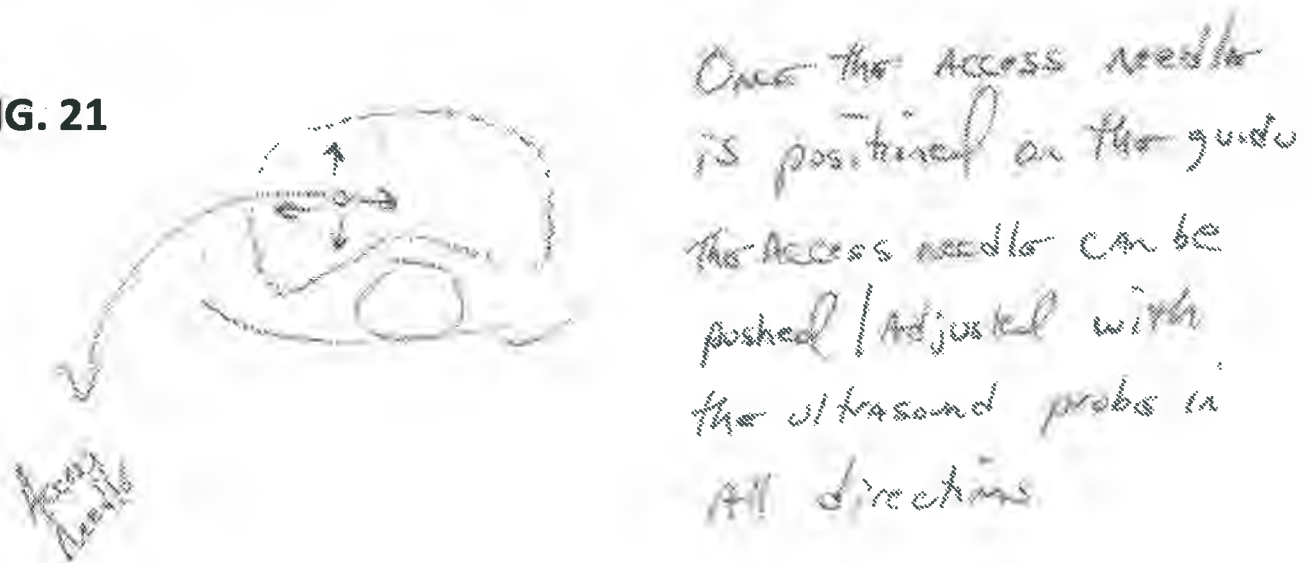


FIG. 22

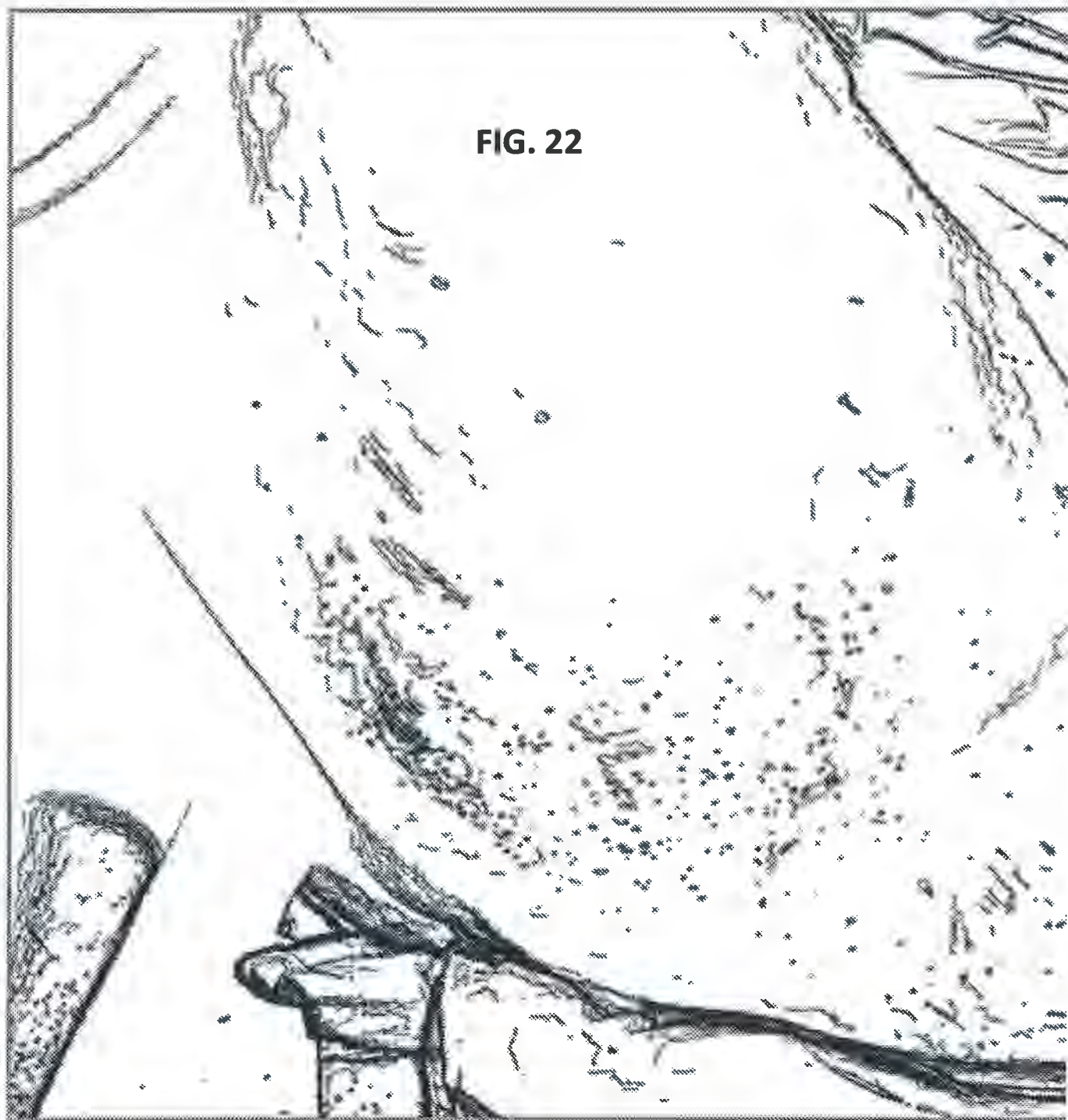


FIG. 23

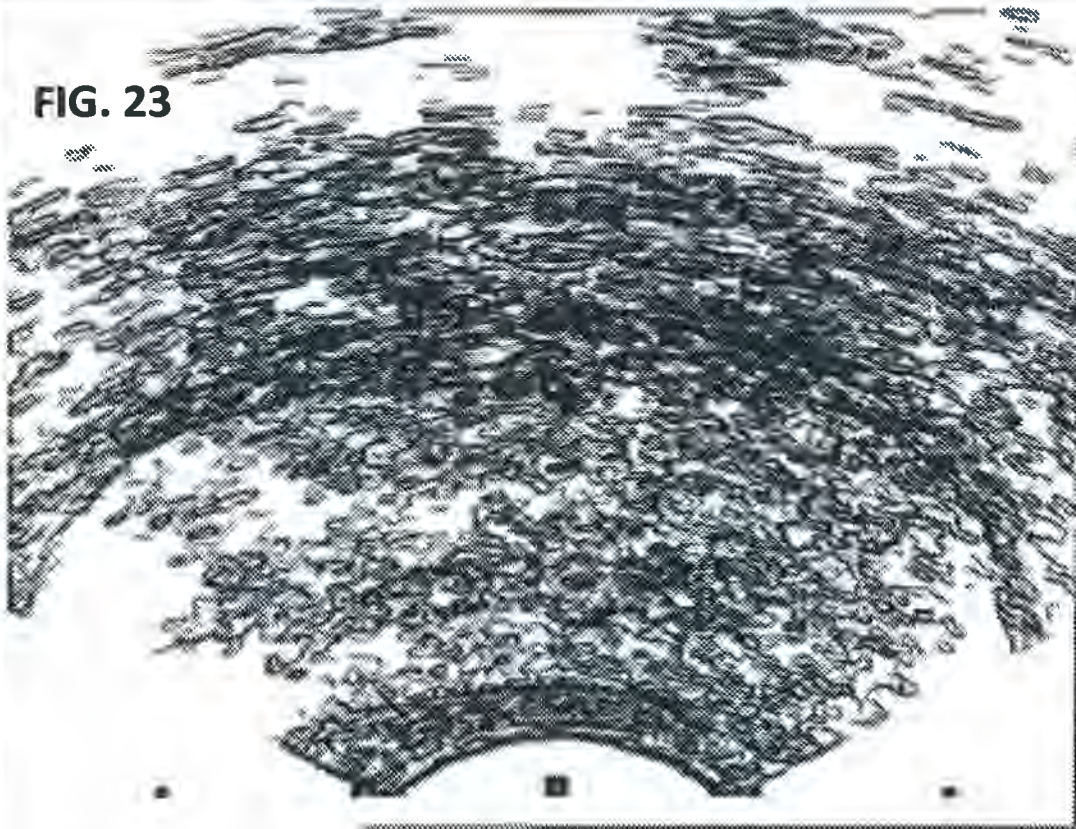
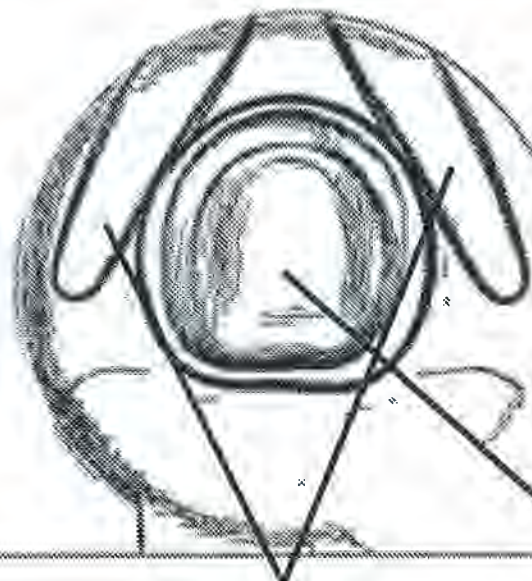


FIG. 24



2401

801

FIG. 25

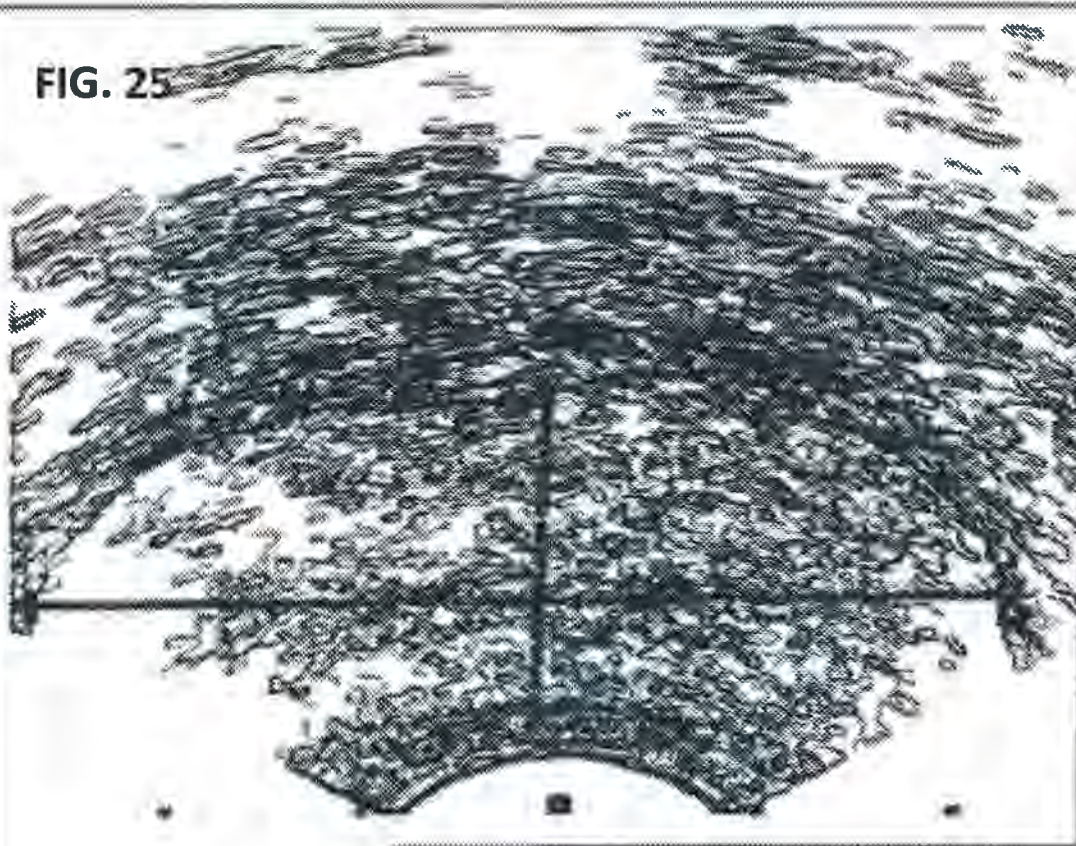


FIG. 26



FIG. 27

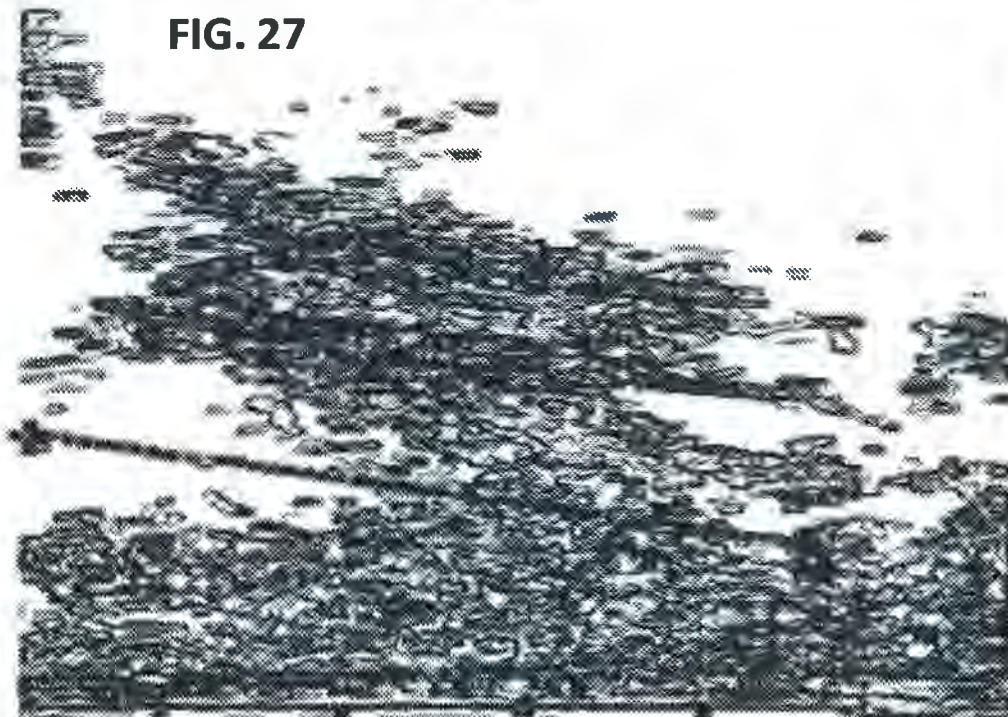
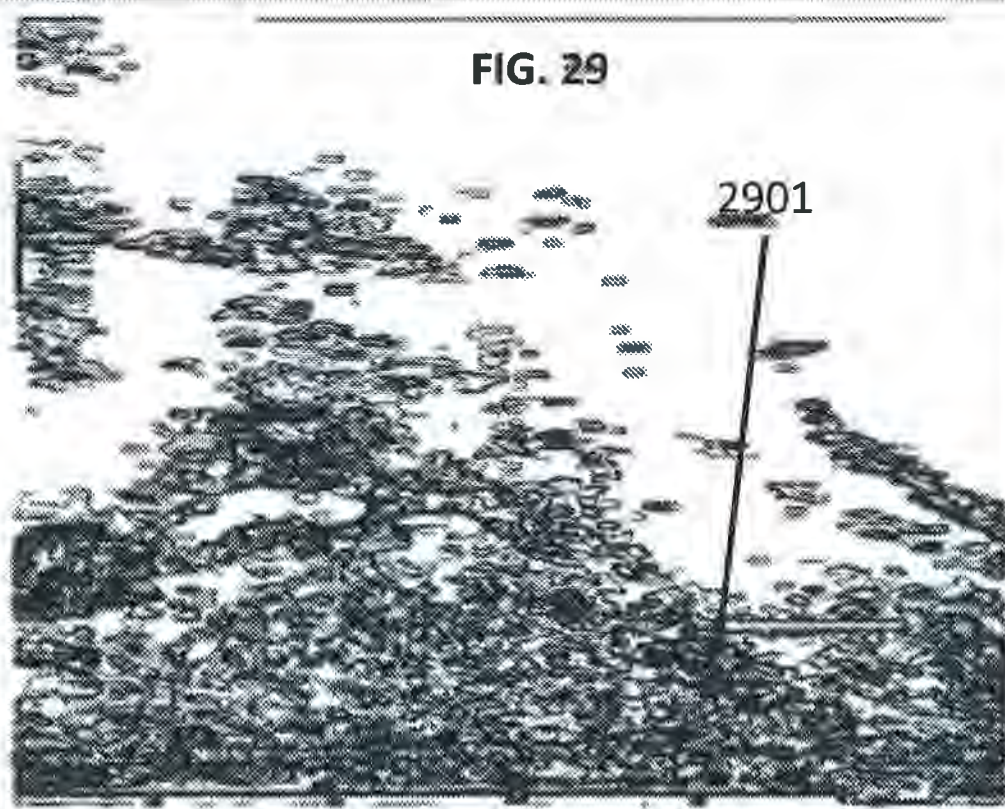


FIG. 28



FIG. 29



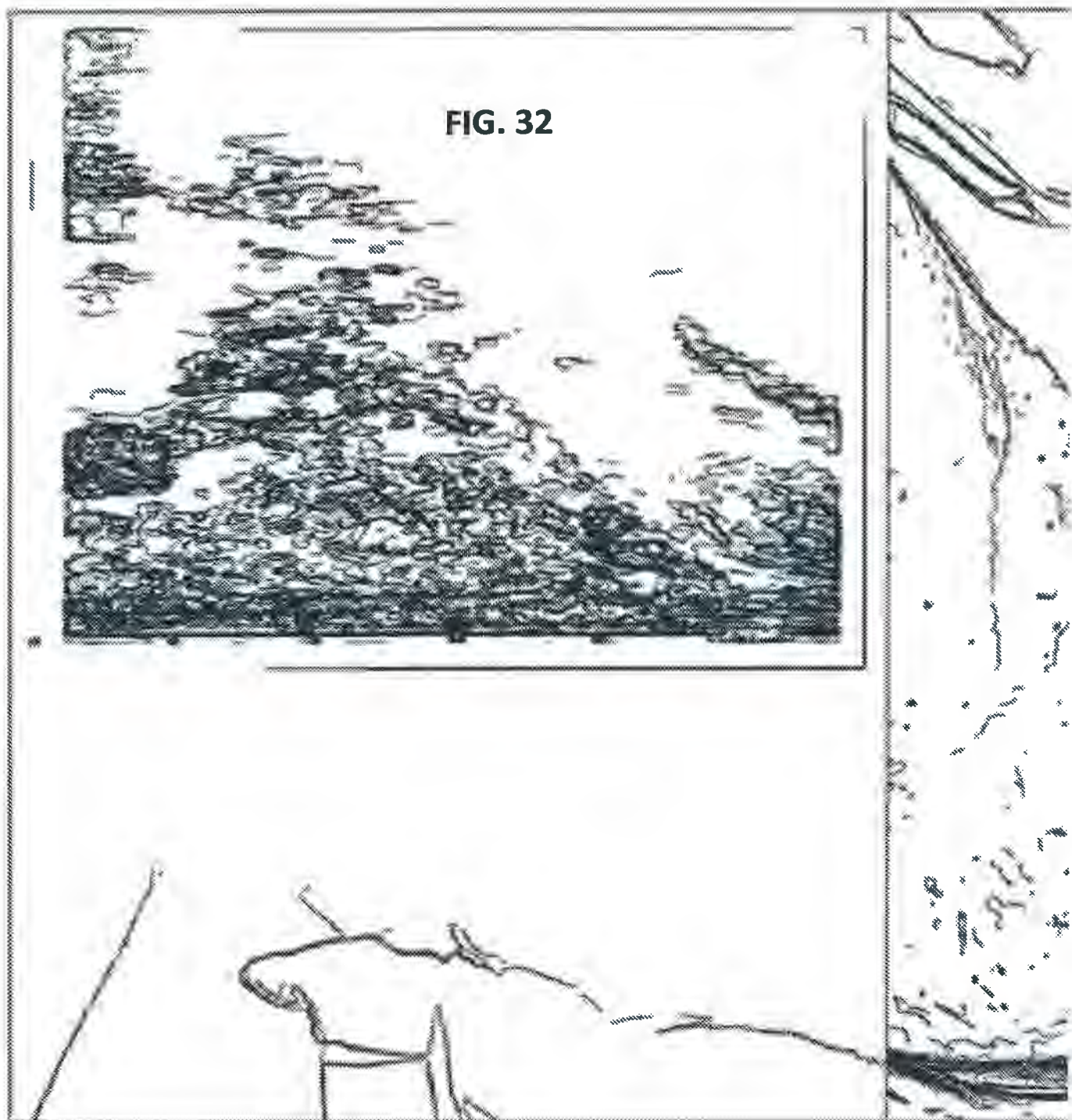
2901

FIG. 30



FIG. 31





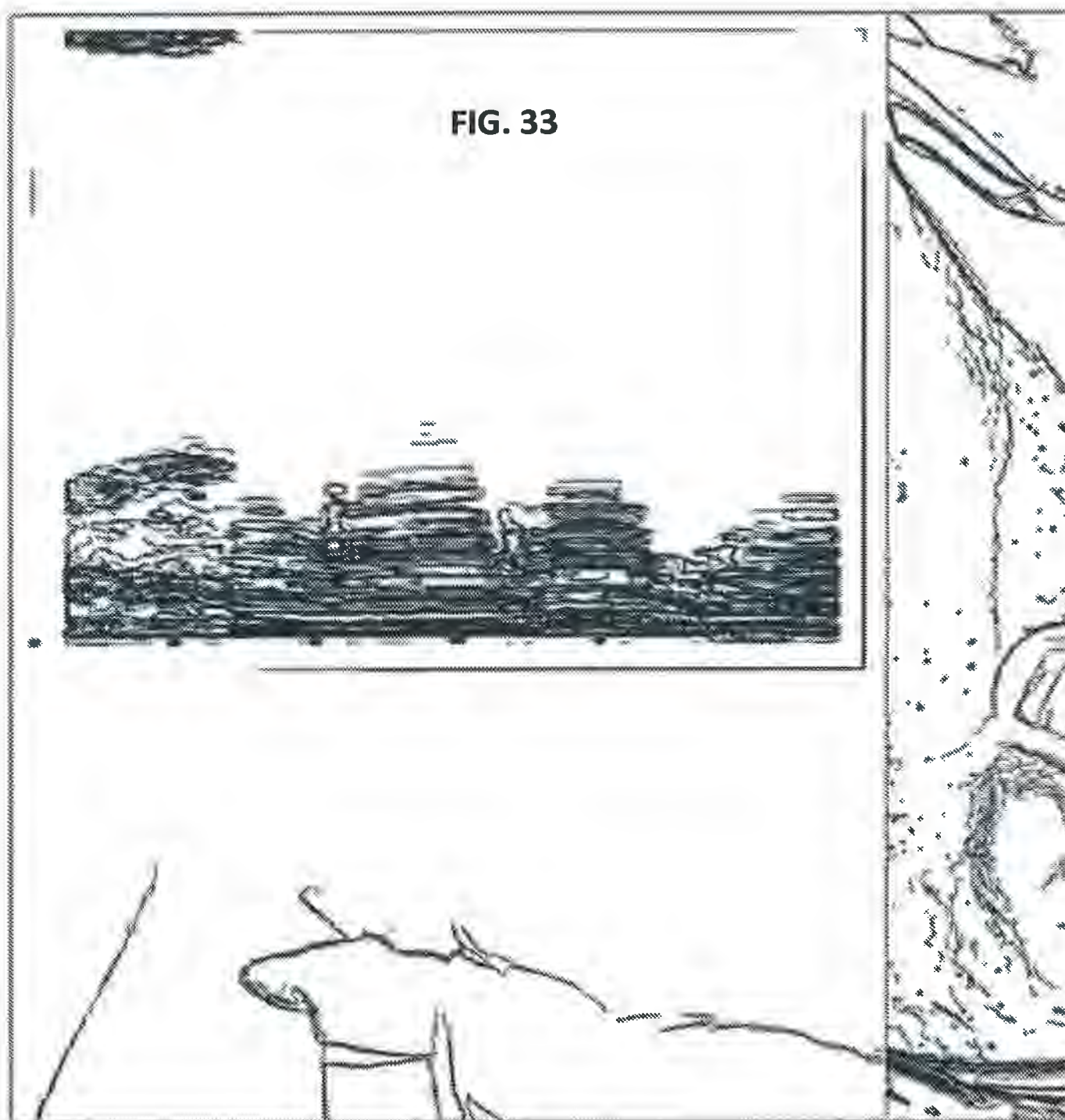


FIG. 34

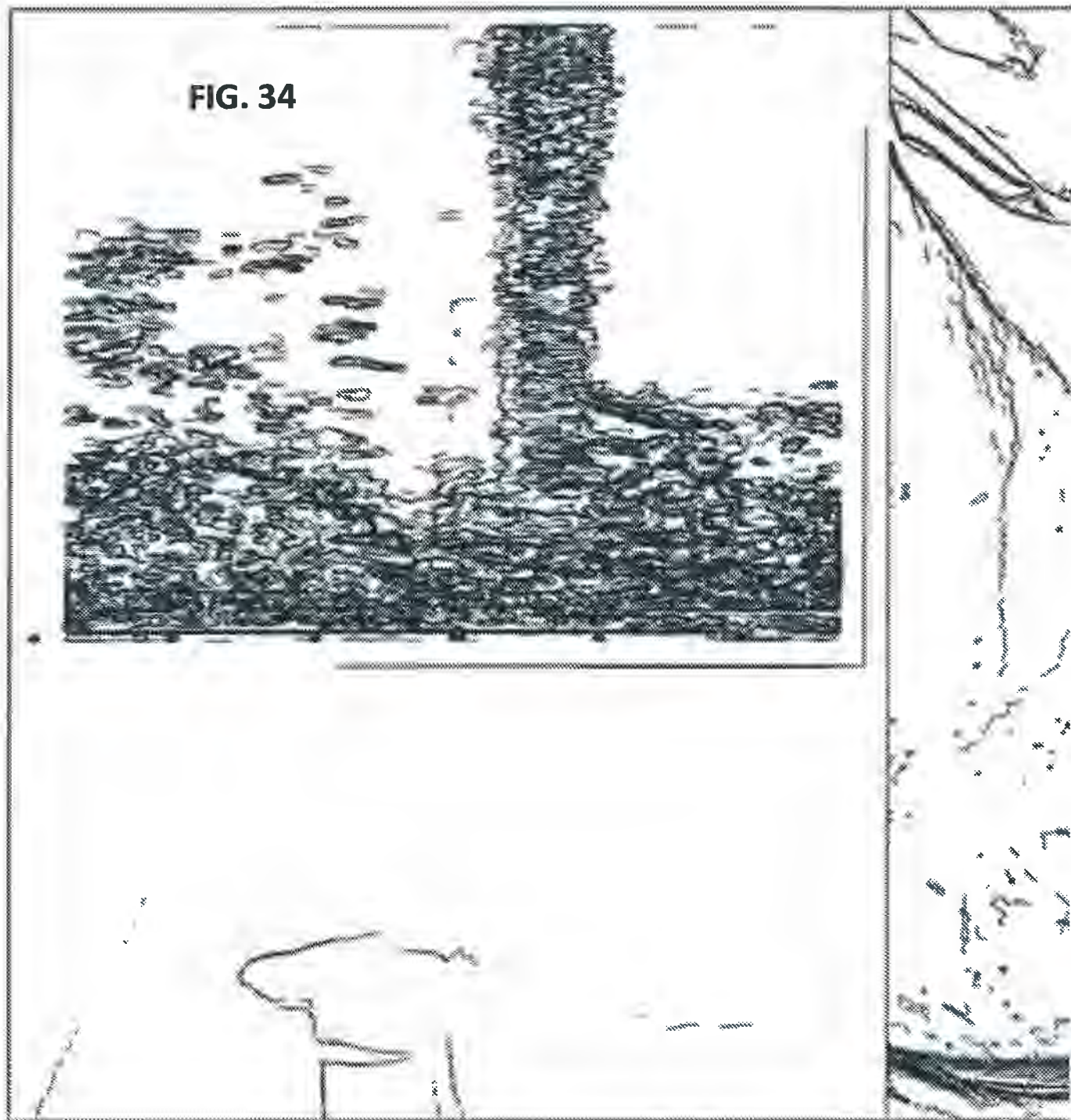


FIG. 35

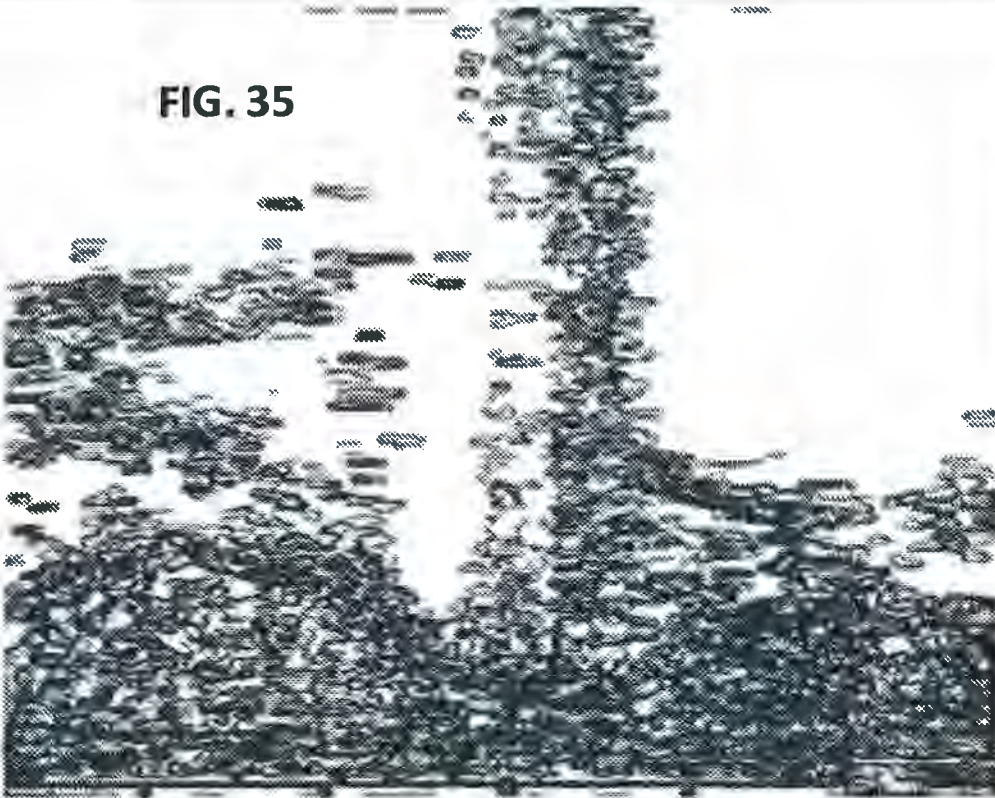


FIG. 36



FIG. 37

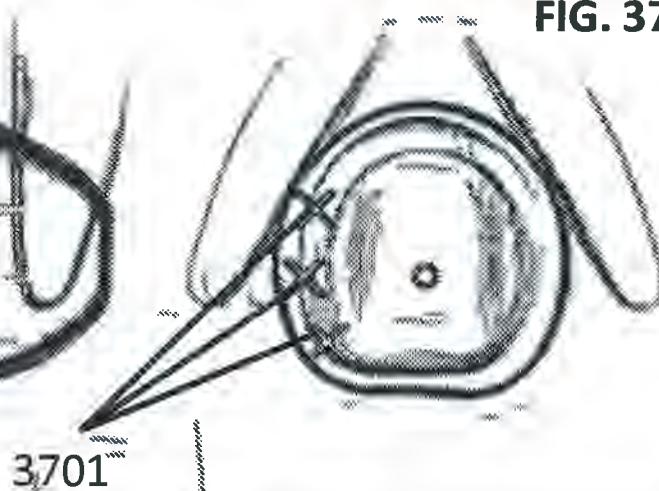


FIG. 38

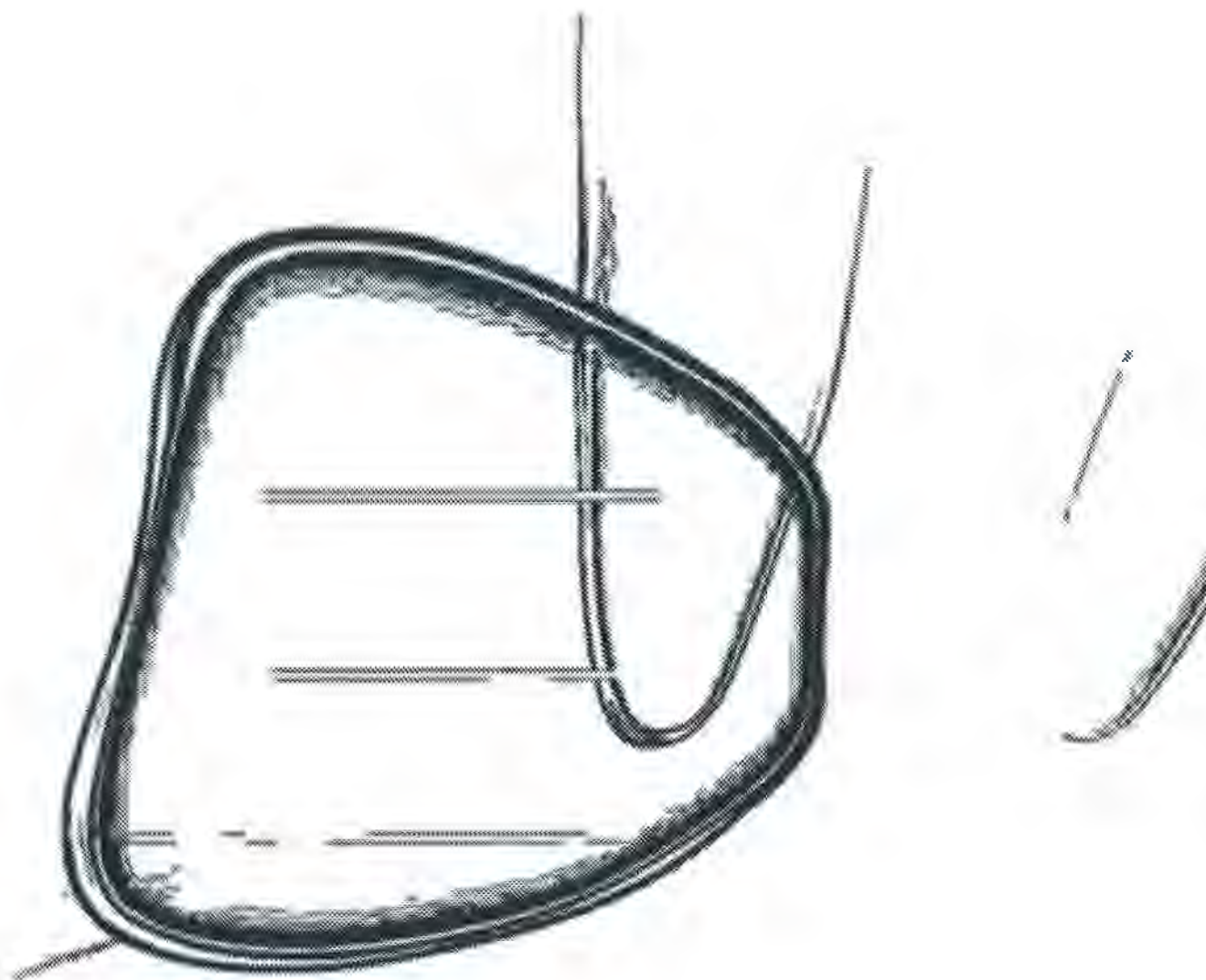


FIG. 39



FIG. 40



FIG. 41

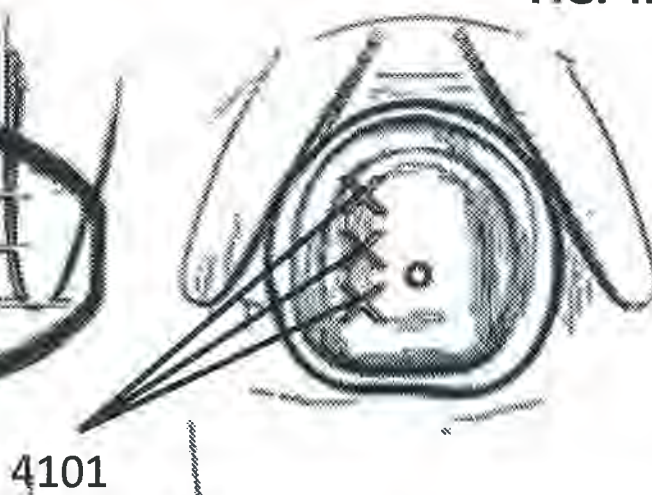


FIG. 42

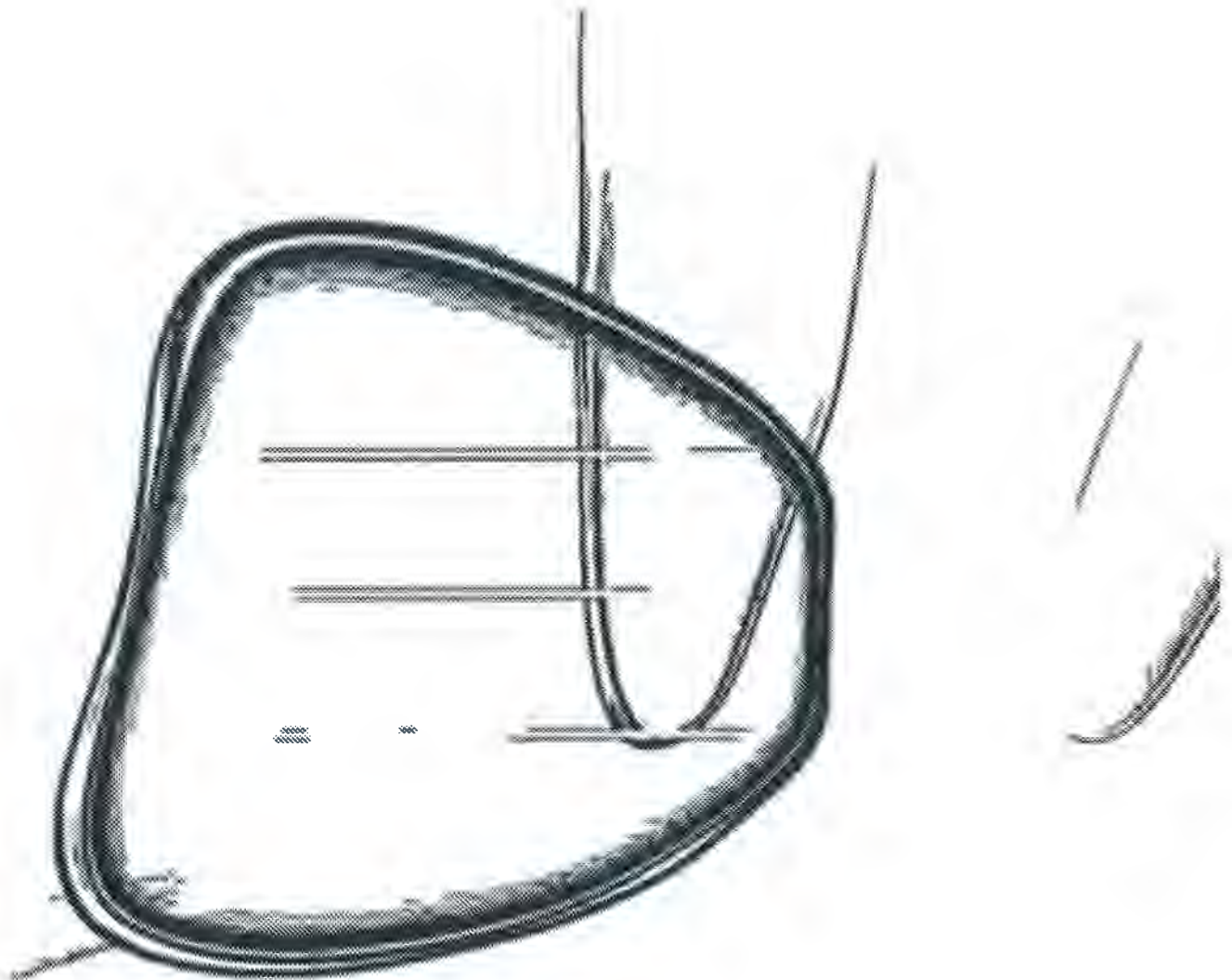


FIG. 43

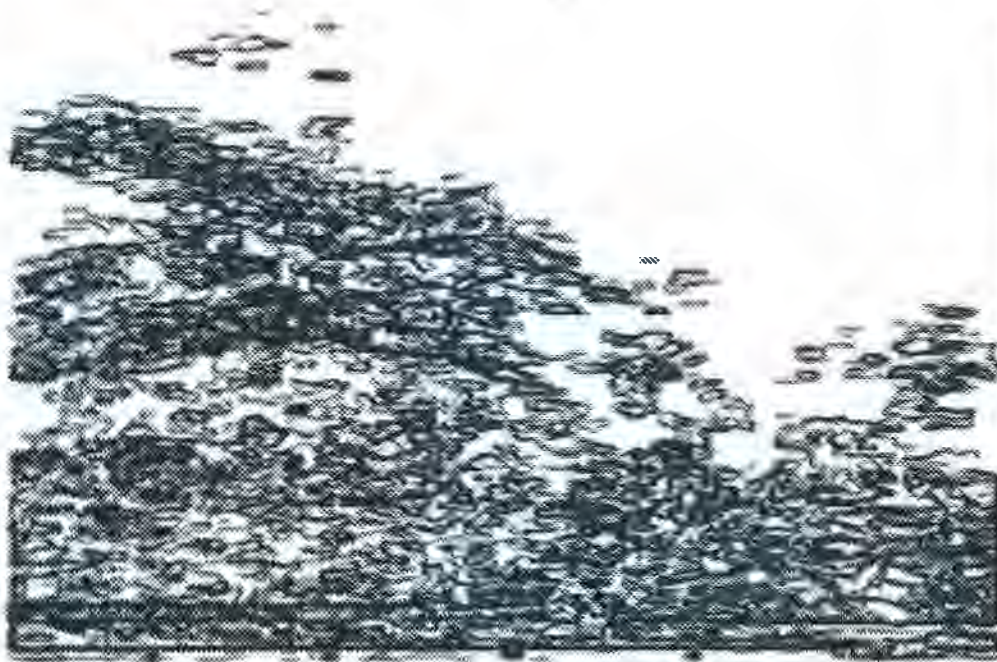


FIG. 44



FIG. 45

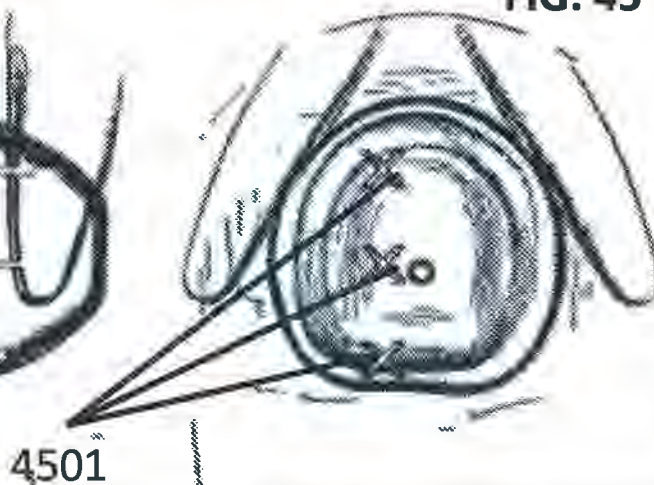


FIG. 46

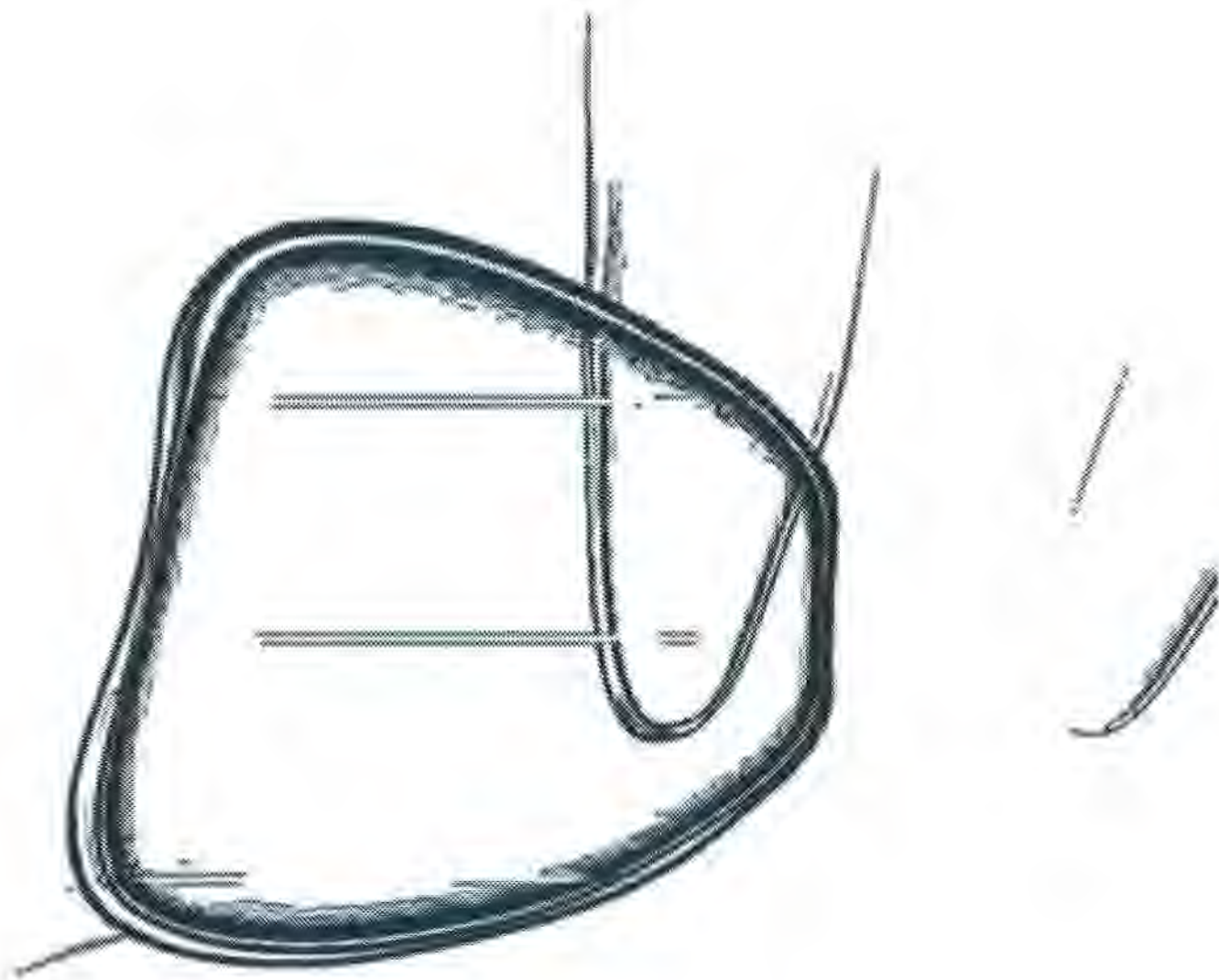




FIG. 48

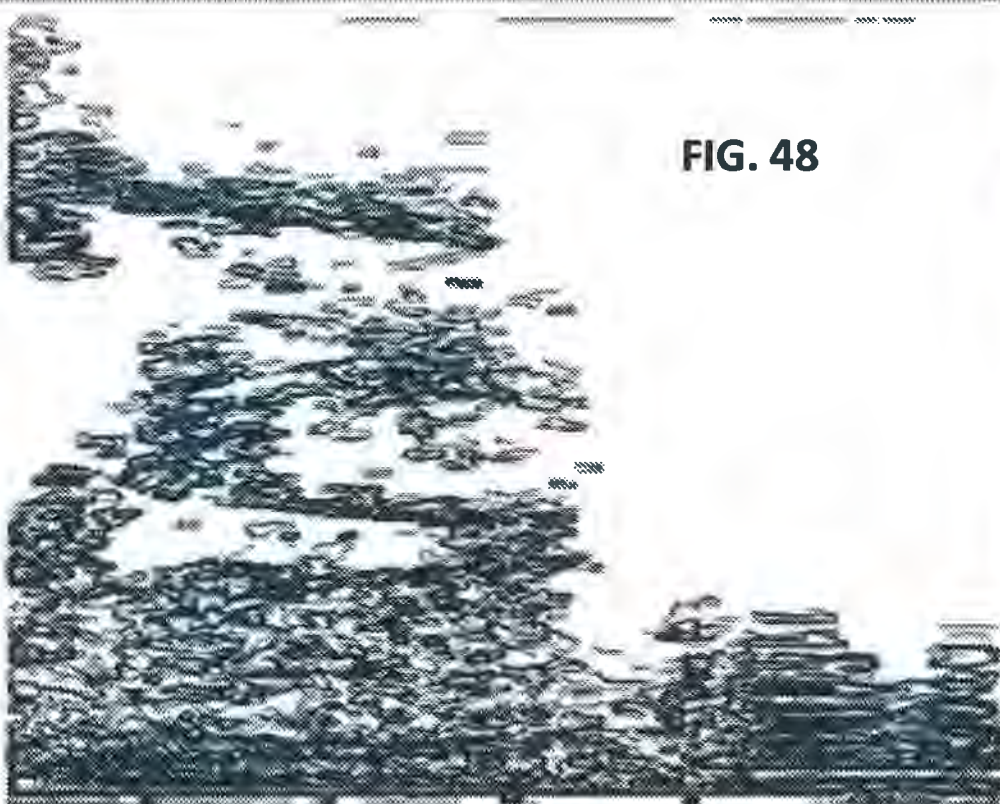
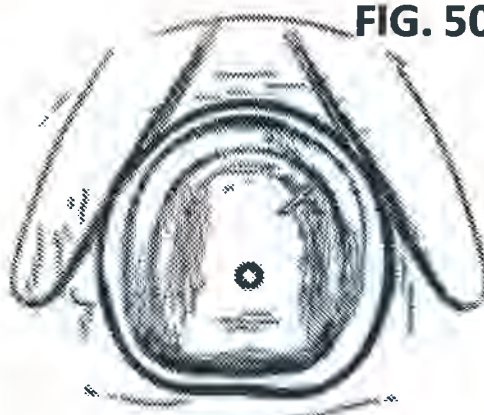


FIG. 49



FIG. 50



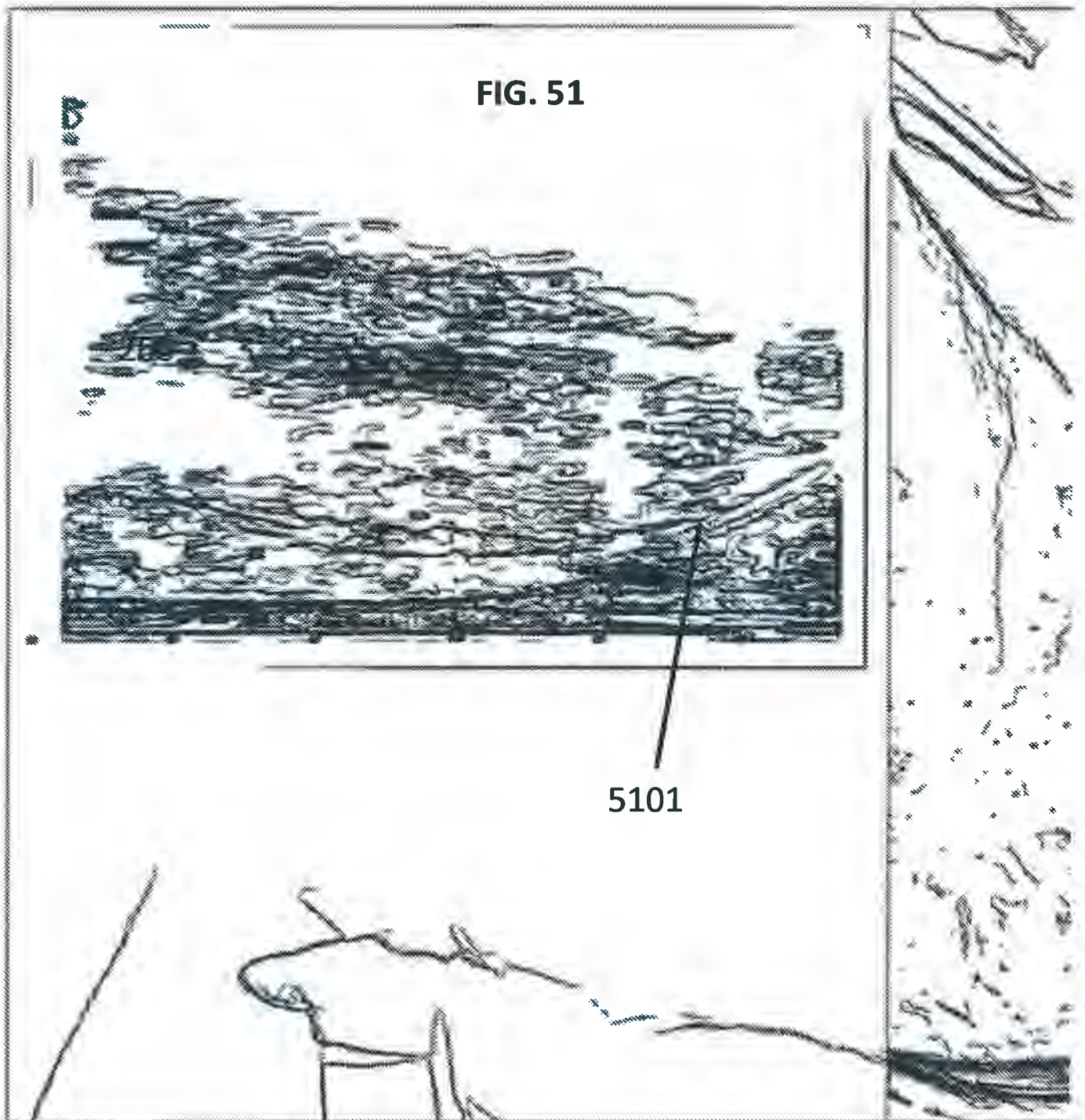


FIG. 52



FIG. 53

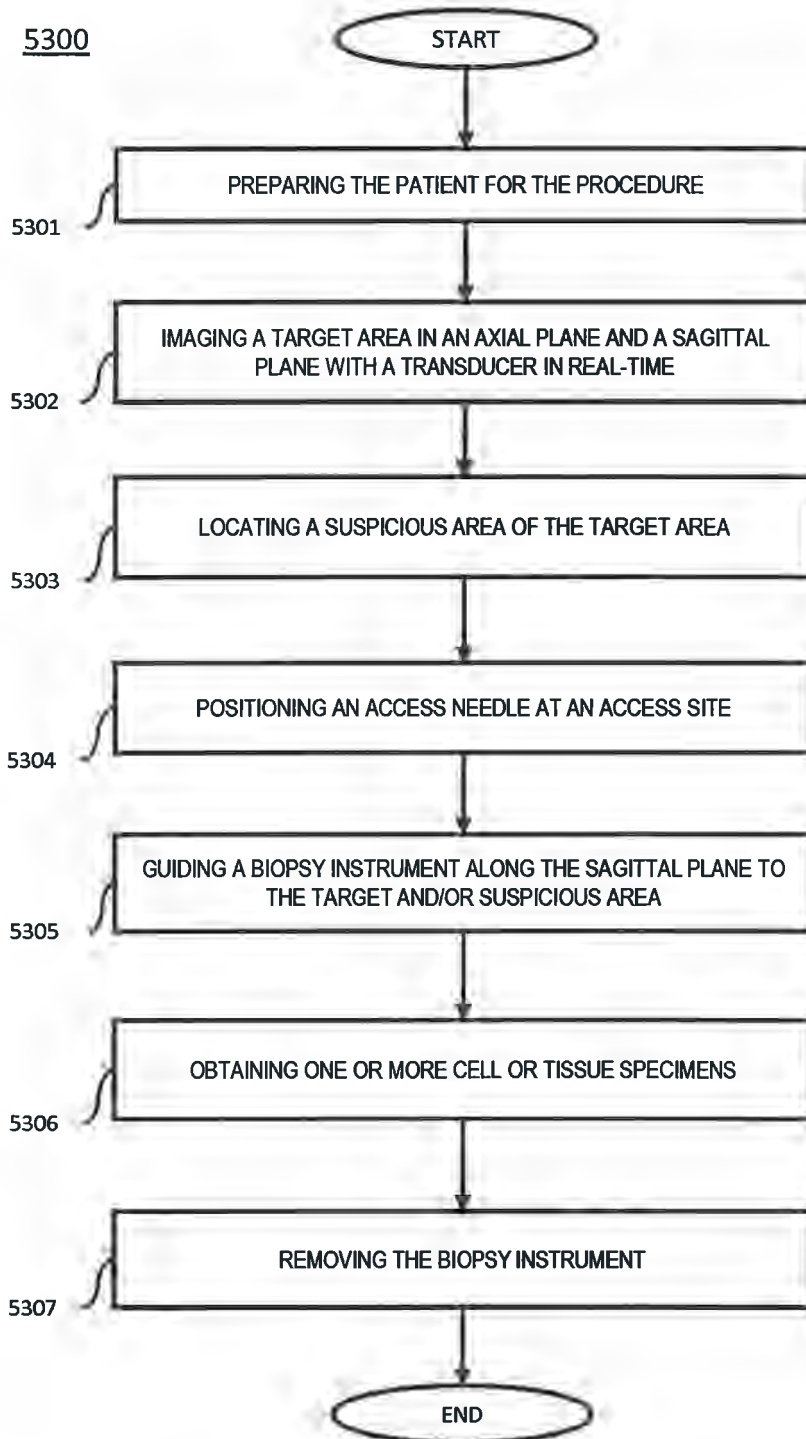


FIG. 54

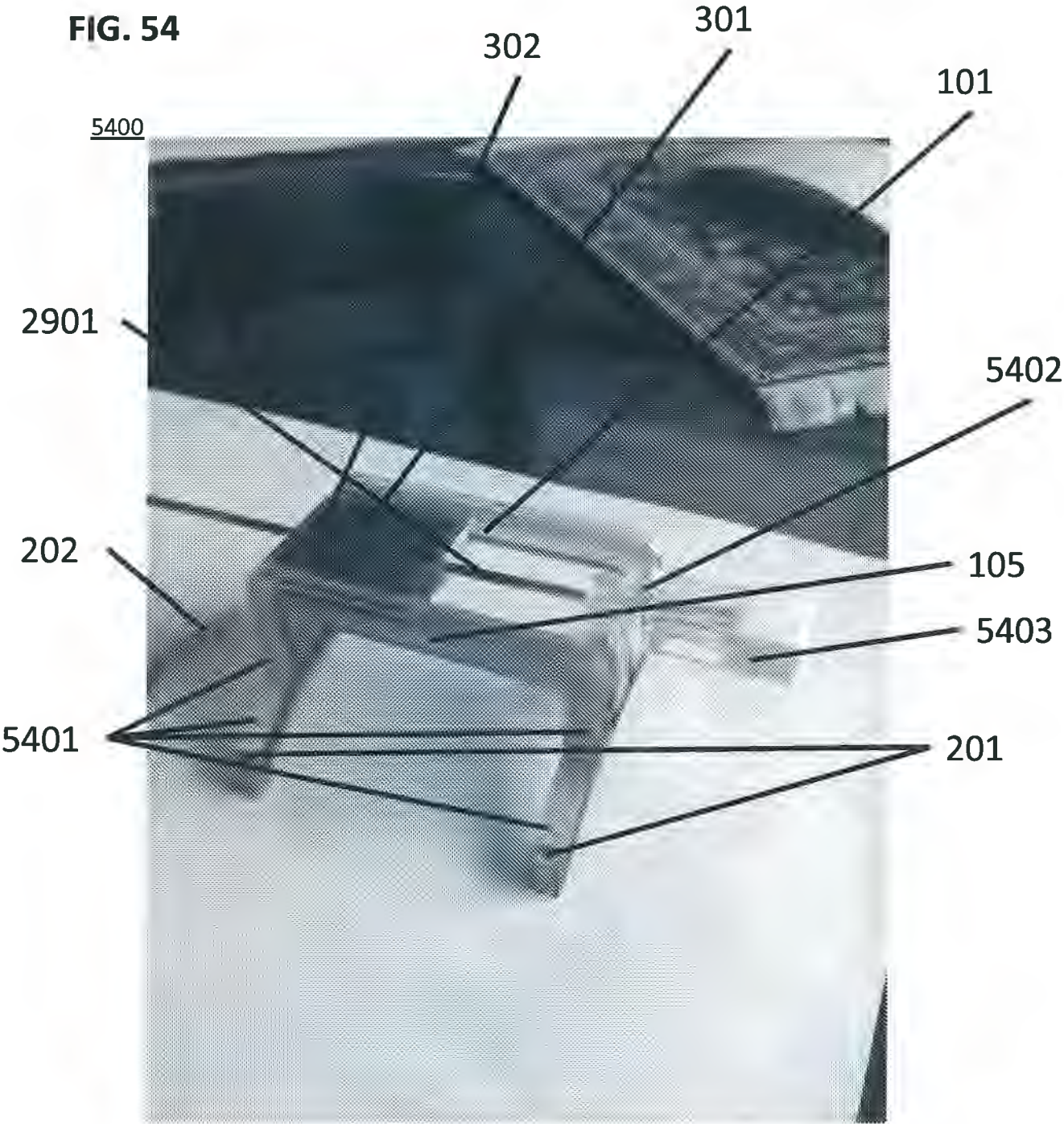


FIG. 55

