PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	20 DEC 2018
Applicant's or agent's file reference DTP-42852.01	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US18/49450	05 September 2018 (05.09.2018)	07 September 2017 (07.09.2017)

International Patent Classification (IPC) or both national classification and IPC
IPC - A61B 17/00, 17/04, 17/06, 17/062, 17/10 (2018.01)
CPC - A61B 17/00, 17/04, 17/0467, 17/0482, 17/06, 17/06133, 17/062, 17/10

Applicant Dura Tap LLC

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

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

2. **FURTHER ACTION**

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

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

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

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	16 October 2018 (16.10.2018)	Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a)).

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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

1. Statement

Novelty (N)	Claims	1-19	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	3-6, 18	YES
	Claims	1-2, 7-17, 19	NO
Industrial applicability (IA)	Claims	1-19	YES
	Claims	NONE	NO

2. Citations and explanations:

Claims 1-2, 7-11, and 15-17 lack inventive step under PCT Article 33(3) as being obvious over US 2004/0034369 A1 to Sauer et al. (hereinafter "Sauer").

As per claim 1, Sauer discloses a suturing kit (a system 10 for suturing; figure 1; paragraph [0155]) comprising: a suture having a first end and a second, opposite, end (suture material 105 is loaded to form two suture ends 98 of the loop of suture, with the suture ends 98 coupled to ferrules 103; figures 1, 17A-17B; 21-22I; paragraph [0186]); a suture holder including an elongate wall defining a suture receiving passage that is elongated along a longitudinal axis and terminates at a suture exit opening (accessory tube 12 includes tube guide 58 that includes suture track 58c from which the loop of suture extends from via the channel 98d to the sew tip 98 along longitudinal axis 1054 to tissue engaging end 16a; annotated figure 22A; figures 1, 17A-17B; 22A-22I; paragraphs [0173]-[0175], [0186]), the suture receiving passage receiving the suture such that the suture is folded over forming a half loop section spaced from the suture exit opening (tube guide 58 includes suture track 58c from which the loop of suture extends from via the channel 98d to the sew tip 98; figures 1, 17A-17B; 21-22I; paragraph [0186]), a first section extending from the half loop section toward the first end (left free end of the suture loop extends from loop outside of track to suture track 58a of tube guide 58 to the sew tip 98 where the two suture ends are coupled to two ferrules 103; figures 1, 17A-17B; 21-22I; paragraph [0186), and a second section extending from the half loop section toward the second end (right free end of the suture loop extends from loop outside of track to suture track 58a of tube guide 58 to the sew tip 98 where the two suture ends are coupled to two ferrules 103; figures 1, 17A-17B; 21-22I; paragraph [0186), wherein each of the first section and the second section of the suture from adjacent to the half loop section to the suture exit opening within the suture receiving passage are aligned along the longitudinal axis (two free ends of the suture loop extend from suture track 58a of tube guide 58 to the sew tip 98 along the longitudinal axis where the two suture ends are coupled to two ferrules 103; annotated figure 22A; figures 1, 17A-17B; 21-22I; paragraph [0186]), but fails to disclose the receiving passage having a width at least twice the diameter of the suture. Given that the receiving passage disclosed by Sauer contains a looped suture wherein two suture ends travel along the same passage, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Sauer to provide a receiving passage having a width at least twice the diameter of the suture for the advantage of ensuring the looped suture does not get lodged in the receiving passage, thereby preventing the device from deploying the suture as intended.

As per claim 2, Sauer discloses the suturing kit of claim 1. Sauer further discloses comprising a first needle at the first end of the suture (needle tip 122 of needle 34 engages a ferule 103; figure 22D-22E; paragraph [0186]) and at least one suturing device having a portion configured to be inserted into a patient during a surgical procedure (tissue engaging end 16a is shown applying a suture through tissue with needle 34; figures 22A-22I; paragraph [0186]), the at least one suturing device including a first needle holder configured to hold the first needle (guide member 58 includes needle tracks 58a and 58b that hold needles 34 and 35, respectively; paragraph [0175]).

As per claim 7, Sauer discloses the suturing kit of claim 1. Sauer further discloses wherein the elongate wall has a closed cross section normal to the longitudinal axis (a cross-sectional view of tissue engaging section 16a including channel 98d within guide tube 58 is shown clearly normal to longitudinal axis 1054; annotated figure 22A; figures 9, 17, 17A; paragraph [0184]).

As per claim 8, Sauer discloses the suturing kit of claim 7. Sauer further discloses wherein the closed cross section is circular (cross sectional view of tissue engaging section 16a is contained within tip tube 102 that is clearly circular; figures 9, 17, 17A; paragraph [0184]).

As per claim 9, Sauer discloses the suturing kit of claim 1. Sauer further discloses wherein the suture receiving passage terminates at a second opening spaced from the suture exit opening along the longitudinal axis (loop of suture extends from ferrules through suture tracks 58a and 58a of guide members 53 and 58 to suture routing tube 47 and out of opening holes 76 and 76a of the valve 19; figures 13, 17-18A; 19C, 20A; paragraph [0185]).

As per claim 10, Sauer discloses the suturing kit of claim 9. Sauer further discloses wherein the half loop section is located nearer to the second opening as compared to the suture exit opening (loop of suture extends from ferrules through suture tracks 58a and 58a of guide members 53 and 58 to suture routing tube 47 and out of opening holes 76 and 76a of the valve 19, and as shown in the figures is clearly nearer to the second opening 76 of valve 19; figures 13, 17A-18A; 19C, 20A; paragraph [0185]).

As per claim 11, Sauer discloses the suturing kit of claim 1. Sauer further discloses wherein the elongate wall includes a smooth interior surface defining the suture receiving passage (cross sectional view of tissue shaft 16b shows the profile of the suture track 58c containing suture thread with a smooth cross section; figures 1, 9-10, 17-17B; 21-22I; paragraph [0186).

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Supplemental Box

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-***-Continued from Box V: Citations and Explanations-***-
As per claim 15, Sauer discloses a method of assembling a suturing kit, the method comprising: inserting a midsection of a suture, which is positioned between a first end and a second end of the suture, into a suture receiving passage of a suture holder (suture material 105 loop is loaded in sew tip 98 of tissue engaging end 16a of suturing instrument 16 when instrument 16 is removed for deployment into tissue 120; figures 10B, 21B-22I, 29A-29E; paragraphs [0186], [0188]); and drawing the suture through the suture receiving passage such that the suture is within the suture receiving passage when viewed in a plane coincident with the longest dimension of the suture holder (the suturing instrument 16 is removed from tube 12, thereby pulling the suture loop down to tissue engaging end 16a of instrument 16 via channel 98d; figures 19C, 29B-29E; paragraph [0186]), but fails to disclose wherein the suture is looped over having only one turning point. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Sauer to provide a suture that is looped over having only one turning point for the advantage of ensuring the suture does not become knotted at the proximal end, thereby causing a potential failure mode when attempted to deploy the suture. Furthermore, although Sauer fails to explicitly disclose the suture having specifically one turning point, the invention disclosure includes several figures wherein the suture is looped over having one turning point, and therefore such a modification would be considered trivial as it fails to truly add any additional features to the device.

As per claim 16, Sauer discloses the method of claim 15. Sauer further discloses wherein drawing the suture further includes connecting a vacuum source in fluid communication with the suture receiving passage (suction is applied to the gap 104, and the vacuum is communicated to suture track 58d through coupler member 56 to channel 98d; figures 22A-22I, 29B; paragraph [0186]).

As per claim 17, Sauer discloses the method of claim 15. Sauer further discloses wherein the suture is a double-armed suture having a first needle connected at the first end and a second needle connected at the second end (guide member 58 includes needle tracks 58a and 58b that hold needles 34 and 35, respectively, with each needle being used to apply opposite ends of the suture through the tissue 120; figures 16-17, 22A-22I; paragraphs [0175], [0186]).

Claims 1 and 15 lack an inventive step under PCT Article 33(3) as being obvious over an alternate interpretation of Sauer.

As per claim 1, the alternate interpretation of Sauer discloses a suturing kit (a system 10 for suturing; figure 1; paragraph [0155]) comprising: a suture having a first end and a second, opposite, end (loop of suture 105 includes two ends that are cut from suturing instrument 16; figures 29A-29F; paragraph [0220]); a suture holder including an elongate wall defining a suture receiving passage that is elongated along a longitudinal axis and terminates at a suture exit opening (the suturing instrument 16 is removed from the accessory tube 12, which pulls the loop 105a of suture 105 through the stomach tissue, and the end of the suture material is cut from suturing instrument 16, leaving the suture material within the accessory tube 12 before securing instrument 16 is inserted into tube 12; annotated figure 22A; figures 1, 29A-29F; paragraph [0220]), the suture receiving passage receiving the suture such that the suture is folded over forming a half loop section spaced from the suture exit opening (loop 105a of suture 105 is shown through the stomach tissue spaced from tip 26 of accessory tube 12; figures 1, 29A-29F; paragraph [0220]), a first section extending from the half loop section toward the first end, and a second section extending from the half loop section toward the second end (the two ends of suture material cut from instrument 16 remain in tube 12 as shown, and extend from the loop 105a of suture 105 stomach tissue spaced from tip 26 of accessory tube 12; figures 1, 29A-29F; paragraph [0220]), wherein each of the first section and the second section of the suture from adjacent to the half loop section to the suture exit opening within the suture receiving passage are aligned along the longitudinal axis (the ends of suture material cut from instrument 16 remain in tube 12 as shown; figures 1, 29A-29F; paragraph [0220]), but fails to disclose the receiving passage having a width at least twice the diameter of the suture. Given that the receiving passage disclosed by Sauer contains a looped suture wherein two suture ends travel along the same passage, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Sauer to provide a receiving passage having a width at least twice the diameter of the suture for the advantage of ensuring the looped suture does not get lodged in the receiving passage, thereby preventing the device from deploying the suture as intended.

As per claim 15, the alternate interpretation of Sauer discloses a method of assembling a suturing kit, the method comprising: inserting a midsection of a suture, which is positioned between a first end and a second end of the suture, into a suture receiving passage of a suture holder (the suturing instrument 16 is removed from the accessory tube 12, which pulls the loop 105a of suture 105 through the stomach tissue, and the end of the suture material is cut from suturing instrument 16, leaving the suture material within the accessory tube 12 before securing instrument 16 is inserted into tube 12; annotated figure 22A; figures 1, 29A-29F; paragraph [0220]); and drawing the suture through the suture receiving passage such that the suture is within the suture receiving passage when viewed in a plane coincident with the longest dimension of the suture holder (the suturing instrument 16 is removed from tube 12, thereby pulling the suture loop down to tissue engaging end 16a of instrument 16 via channel 98d; figures 19C, 29B-29E; paragraph [0186]), but fails to disclose wherein the suture is looped over having only one turning point. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Sauer to provide a suture that is looped over having only one turning point for the advantage of ensuring the suture does not become knotted at the proximal end, thereby causing a potential failure mode when attempted to deploy the suture. Furthermore, although Sauer fails to explicitly disclose the suture having specifically one turning point, the invention disclosure includes several figures wherein the suture is looped over having one turning point, and therefore such a modification would be considered trivial as it fails to truly add any additional features to the device.

Claims 12-14, and 19 lack inventive step under PCT Article 33(3) as being obvious over the alternate interpretation of Sauer as further evidenced by "Use of titanium knot placement device (TK-5) to secure dorsal vein complex during laparoscopic radical prostatectomy and cystoprostatectomy." by Abreu et al. (hereinafter "Abreu").

As per claim 12, the alternate interpretation of Sauer discloses the suturing kit of claim 1. Sauer further discloses comprising a knot pusher (suture securing instrument 130 that represents the Ti-KNOT® TK•5™ manufactured by LSI Solutions, Inc. which, as evidenced by Abreu, is a knot placement device; figures 24, 29C-29E; paragraphs [0188], [0206]; Abreu; Title; Abstract).
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As per claim 13, the alternate interpretation of Sauer discloses the suturing kit of claim 12. The alternate interpretation of Sauer further discloses wherein the knot pusher is connected with the suture holder (suture securing instrument 130 is inserted into accessory tube 12 down to the tissue through which the suture loop extends, and tube 12 contains suture 105, 105a and instrument 130 is inserted; figures, 27A-27H, 29B-29E; paragraph [0214]).

As per claim 14, the alternate interpretation of Sauer discloses the suturing kit of claim 13. The alternate interpretation of Sauer further discloses wherein the suture receiving passage terminates at a second opening spaced from the suture exit opening along the longitudinal axis and the knot pusher covers the second opening (suture securing instrument 130 is inserted into accessory tube 12 containing suture 105 and 105a via the cannula 20 opening, and is shown covering said cannula 20 opening; figures 27A-27H, 29B-29E; paragraph [0155], [0214]).

As per claim 19, the alternate interpretation of Sauer discloses the method of claim 15. The alternate interpretation of Sauer further discloses comprising connecting a knot pusher to the suture holder (suture securing instrument 130 that represents the Ti-KNOT® TK•5™ manufactured by LSI Solutions, Inc. which, as evidenced by Abreu, is a knot placement device, and is inserted into accessory tube 12 containing suture 105, 105a; figures 24, 27A-27H, 29B-29E; paragraphs [0188], [0206], [0214]; Abreu; Title; Abstract]).

Claim 3 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a second suturing device which is a separate instrument from the first suturing device.

In the closest prior art, Sauer discloses the suturing kit of claim 2, and further discloses wherein the suture is a double - armed suture having a second needle at the second end (guide member 58 includes needle tracks 58a and 58b that hold needles 34 and 35, respectively, with each needle being used to apply opposite ends of the suture through the tissue 120; figures 16-17, 22A-22I; paragraph [0175], [0186]), wherein the at least one suturing device includes a first suturing device including the first needle holder (needle track 58a holds needle 34; figures 16-17, 22A-22I; paragraph [0175]) and a second needle holder configured to hold the second needle (needle track 58b holds needle 35; figures 16-17, 22A-22I; paragraph [0175]).

In the second closest prior art, US 5,860,992 A to Daniel et al. (hereinafter "Daniel") discloses wherein the suture is a double - armed suture having a second needle at the second end (double armed suture with second needle 26 at one end; column 13, lines 46-47; column 14, 25-26), wherein the at least one suturing device includes a first suturing device including the first needle holder (carriage 20 holds needle 22 that is removably held with elongate slot 50 in removable portion 40, and a new portion 40 with a needle may be attached; figure 4, 5, 5A; column 10, lines 66-67; column 11; lines 1-15) and a second needle holder configured to hold the second needle (a second needle can be mounted to a second slot parallel to slot 50 on needle carriage 20; figures 4, 5, 5A; column 11, lines 40-46).

In the third closest prior art, WO 2017/136025 A1 to Dura Tap LLC (hereinafter "Dura Tap LLC") discloses wherein the suture is a double - armed suture (double armed suture 22; figure 4; paragraph [0051]) having a second needle at the second end (second needle 20a at second end of suture 22; figure 4; paragraph [0051]), wherein the at least one suturing device includes a first suturing device including the first needle holder (first needle 20 is loaded into suture device 10a; figure 4; paragraph [0051]) and a second suturing device, which is a separate instrument from the first suturing device, including a second needle holder configured to hold the second needle (second needle 20a is loaded into second suturing device 10a; figure 4; paragraph [0051]).

Sauer, Daniel, Dura Tap LLC, and the references of record fail to disclose a second suturing device which is a separate instrument from the first suturing device in a context consistent with the requirements of claim 2. It would not have been obvious to one of ordinary skill in the art at the time the invention was made to have employed this system, because none of the references uncovered disclosed the nuances of the instant claim in a cumulative manner while still allowing for a plausible motivation to combine said references. While Sauer, Daniel, and Dura Tap LLC all have a first needle holder and first and second needles, only the system of Dura Tap LLC utilizes a separate secondary suturing instrument holding the second needle. While Sauer provides the suturing device of Claims 1 and 2, there is no disclosure of a second suturing device. Furthermore, it would not make sense to modify the device of Sauer to provide a second suturing instrument as the device permits the application of sutures with minimal invasiveness to the patient through endoscopic techniques that allow the suture to be applied through small single incisions, and any additional instruments would require larger or possibly more incisions, thereby increasing the risk of scarring and infection to the patient. The references taken solely, or in combination, fail to provide the required limitations, and modification of any complementary combination of the references of record would be impermissible and not provide any advantages over the present application

Claims 4-6 meet the criteria set out in PCT Article 33(2)-(3), because of its dependency on claim 13.

Claim 18 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest loading the second needle into a separate second suturing device.

As per claim 18, Sauer discloses the method of claim 17. Sauer further discloses comprising loading the first needle in a first suturing device and loading the second needle into the first suturing device (guide member 58 includes needle tracks 58a and 58b that hold needles 34 and 35, respectively, with each needle being used to apply opposite ends of the suture through the tissue 120; figures 16-17, 22A-22I; paragraph [0175], [0186]), wherein the suturing device includes a portion configured to be inserted into a patient during a surgical procedure (tissue engaging end 16a is shown applying a suture through tissue with needle 34; figures 22A-22I; paragraph [0816]).

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In the second closest prior art, Daniel discloses further comprising loading the first needle in a first suturing device (the needle 22 is removably held with elongate slot 50 in removable portion 40, and a new portion 40 with a needle may be attached; figure 4, 5, 5A; column 10, lines 66-67; column 11; lines 1-15) and loading the second needle into a first suturing device (a second needle can be mounted to a second slot parallel to slot 50 on needle carriage 20; figures 4, 5, 5A; column 11, lines 40-46), wherein each suturing device includes a portion configured to be inserted into a patient during a surgical procedure (carriage 20 for placing a mattress Stitch in tissue during surgical procedures; figures 4, 5, 5A; column 9, lines 16-17; column 11, lines 40-46).

In the third closest prior art, Dura Tap LLC discloses further comprising loading the first needle in a first suturing device (first needle 20 is loaded into suture device 10a; figure 4; paragraph [0051]) and loading the second needle into a second suturing device (second needle 20a is loaded into second suturing device 10a; figure 4; paragraph [0051]).

Sauer, Daniel, Dura Tap LLC, and the references of record fail to disclose loading the second needle into a separate second suturing device in a context consistent with the requirements of claim 17. It would not have been obvious to one of ordinary skill in the art at the time the invention was made to have employed this system, because none of the references uncovered disclosed the nuances of the instant claim in a cumulative manner while still allowing for a plausible motivation to combine said references. While Sauer, Daniel, and Dura Tap LLC all disclose loading the first needle and second needle into a first needle holder and, only the system of Dura Tap LLC discloses loading the second needle into a second needle holder, but does not disclose wherein each suturing device is to be inserted into a patient during a surgical procedure. While Sauer provides the suturing device of Claim 17, there is no disclosure of any second suturing device whatsoever. Furthermore, it would not make sense to modify the device of Sauer to provide a second suturing instrument as the device permits the application of sutures with minimal invasiveness to the patient through endoscopic techniques that allow the suture to be applied through small single incisions, and any additional instruments would require larger or possibly more incisions, thereby increasing the risk of scarring and infection to the patient. The references taken solely, or in combination, fail to provide the required limitations, and modification of any complementary combination of the references of record would be impermissible and not provide any advantages over the present application

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

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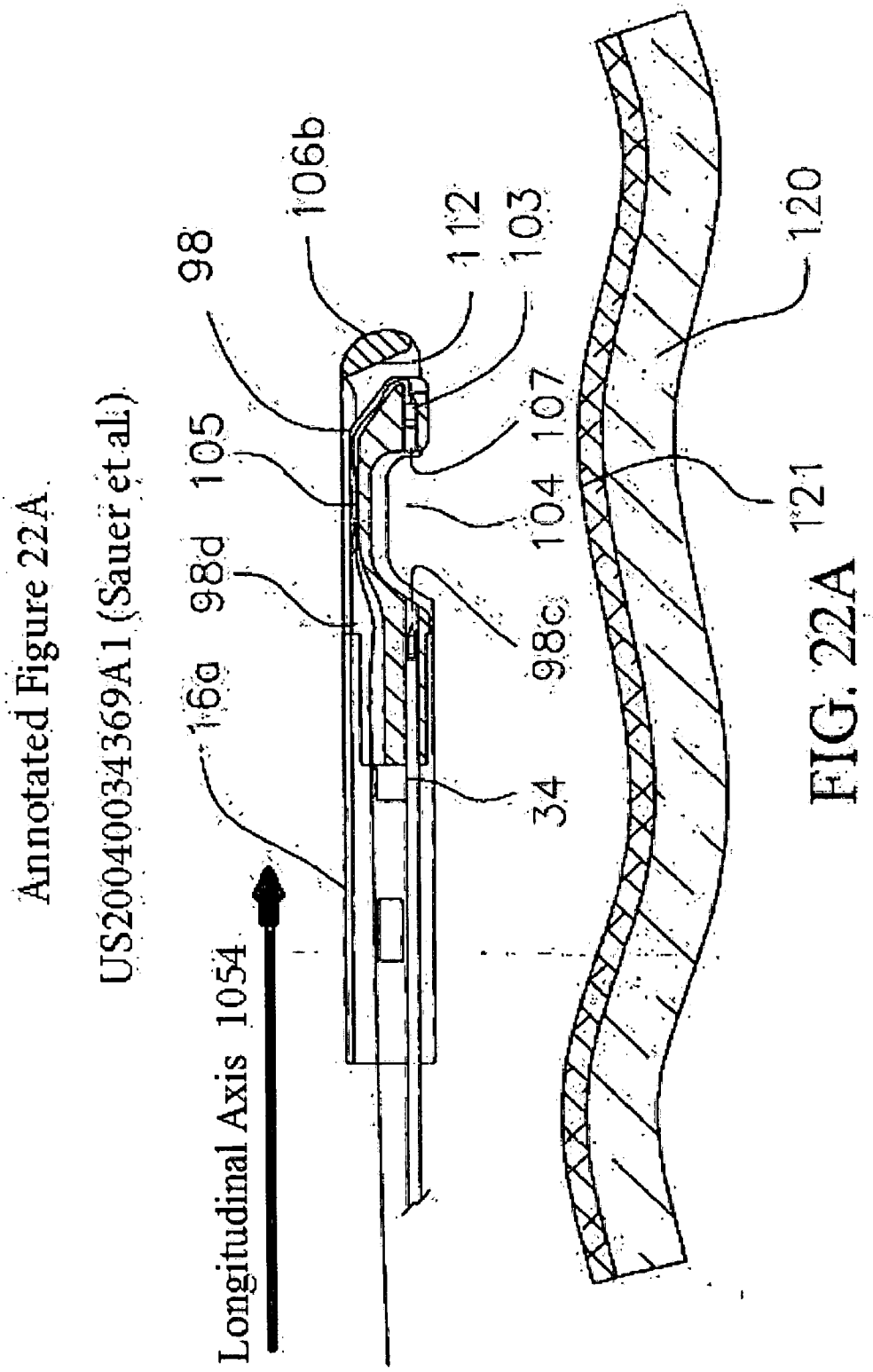

FIG. 22A