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)*	14 FEB 2020
Applicant's or agent's file reference EMPRESS002WO	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 19/64030	02 December 2019 (02.12.2019)	02 December 2018 (02.12.2018)

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

IPC - A61B 17/12 (2020.01)

CPC - A61B 17/12002

Applicant
EMPRESS MEDICAL, INC.

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	29 January 2020	Lee Young PCT Help Desk Telephone No. 571-272-4300

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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(b)).

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

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

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

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

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

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

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

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

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

5. Additional comments:

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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	1-36	YES
	Claims	None	NO
Inventive step (IS)	Claims	3, 12, 15-18, 24-36	YES
	Claims	1-2, 4-11, 13-14, 19-23	NO
Industrial applicability (IA)	Claims	1-36	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-2, 4-11, 13-14, and 19-23 lack an inventive step under PCT Article 33(2) as being obvious over US 2017/0128062 A1 to Nagasaki University (hereinafter 'Nagasaki') in view of US 2004/0010273 A1 to Diduch et al. (hereinafter 'Diduch').

Regarding 1, Nagasaki teaches an apparatus for passing a tension member around a volumetric region of an organ (instrument for delivering a surgical thread, Abstract; Fig. 6, para. [0047]-[0059]), the apparatus comprising:

a rigid outer tube (outer cylinder 70, Fig. 1, para. [0027]) comprising a sharp outer tube tip (end 72, Fig. 1; end 72 penetrate between the peritoneum and the extra peritoneal tissue, para. [0052]) and an outer tube lumen (the main body portion having the lumen receiving needle 80, Fig. 1, 6, para. [0033]) with an outer tube opening in proximity to the outer tube tip (distal opening through which needle 80 extends, Fig. 1, 6);

an inner needle (hollow needle 80, Fig. 1, para. [0033]) [comprising an elastic needle body curved at least in part thereof], the inner needle ending with a sharp needle tip (tip 82 has a sharp shape, Fig. 1, para. [0033]) and enclosing an inner needle lumen (the lumen that receives loop 90, Fig. 1, 6, para. [0037]) with an inner needle opening being in proximity to the needle tip (distal opening through which loop 90 extends, Fig. 1, 6), the inner needle body being configured to pass straightened through the outer tube lumen (Fig. 7b) and to partially protrude via the outer tube opening (Fig. 7a), [such that a protruding portion of the inner needle body is allowed to voluntarily flex to a curved form having diameter equal to or greater than diameter of the volumetric region]; and

a tension member passer (loop 90, Fig. 1, 6, para. [0037]) comprising a tension member passer body, sized for passing through the inner needle lumen (wire 68, Fig. 1, para. [0037]), and a tension member pulling portion configured for engaging with a portion of the tension member and for continuously applying a pulling force to the engaged portion of the tension member when the tension member is withdrawn with the tension member passer (central aperture of loop 90, Fig. 1, 6; ligature 92 is pass through the loop 90 in advance, pulling the loop 90 inside the hollow needle 80 results in drawing the loop 90 inside of the hollow needle 80 so as to sandwich the ligature 92, para. [0037]);

wherein the apparatus is configured for forming a passage through the organ (passage of ligature 92 through abdominal cavity, Fig. 6i), the passage extending along a plane crossing the volumetric region from an entry point at a surface of the organ located in front of a first side of the volumetric region (entry point on right side of hernia gate 14, Fig. 6), to an exit point at the surface of the organ, located in front of a second side of the volumetric portion opposite to the first side (exits on left side of hernia gate 14, Fig. 6), and the apparatus is further configured for passing the tension member around the volumetric region by pulling the tension member from the exit point to the entry point through the passage (Fig. 6l, para. [0054]-[0057]).

Nagasaki fails to teach the inner needle comprising an elastic needle body curved at least in part thereof, such that a protruding portion of the inner needle body is allowed to voluntarily flex to a curved form having diameter equal to or greater than diameter of the volumetric region.

Diduch teaches a surgical device for passing a suture (Abstract) comprising an inner needle (tube raw material 38 formed into the preformed geometry and cut to define a sharpened tip 8, Fig. 8, para. [0070]) comprising an elastic needle body curved at least in part thereof (superleastic snare, para. [0070; curved, Fig. 8a-8d), such that a protruding portion of the inner needle body is allowed to voluntarily flex to a curved form having diameter equal to or greater than diameter of the volumetric region (Fig. 8a-8d, para. [0070]; thermally formed into a desired shape). It would have been obvious to one of ordinary skill in the art that the device of Nagasaki could have been modified as claimed in view of Diduch to change the geometry of the needle for multiple applications with different shapes.

Regarding claim 2, Nagasaki in view of Diduch teaches an apparatus according to claim 1. While Nagasaki fails to specifically teach wherein the volumetric region of the organ includes a tissue mass comprising at least a portion of a tumor, it would have been obvious to one of ordinary skill in the art that the apparatus of Nagasaki could have been been employed in any number of surgical procedures, including the removal of tumors.

Regarding claim 4, Nagasaki in view of Diduch teach an apparatus according to claim 1. Diduch further teaches the needle body includes a first segment having a first centerline (external portion of tube 38 adjacent straightening tube 20, Fig. 8b), and a second segment having a second centerline (external portion of tube 38 adjacent tip 8, Fig. 8b), the second segment adjoins with a proximal end thereof to a distal end of the first segment (Fig. 8b) and with a distal end thereof to a proximal end of a tip segment (Fig. 8b) , wherein, when the needle body is in an unstressed relaxed form, the first centerline has a first radius of curvature, at least along a portion thereof being adjacent to the first segment distal end (radius of curvature of proximal curve of external portion 38, Fig. 8b), and the second centerline has a second radius of curvature, at least along a portion thereof being adjacent to the second segment proximal end (radius of curvature of distal portion of tube 38, Fig. 8b), the second radius of curvature is smaller than the first radius of curvature (Fig. 8b).

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In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
-*-Box V.2 - Citations and Explanations-*-

Regarding claim 5, Nagasaki in view of Diduch teach an apparatus according to claim 4. While the prior art fails to specifically teach wherein a ratio between the second radius of curvature and the first radius of curvature is within a range of 1/10 to 1/3, it would have been obvious to one of ordinary skill in the art that the apparatus of Nagasaki in view of Diduch could have been modified as claimed, through routine experimentation to provide a needle with the desired curvature.

Regarding claim 6, Nagasaki in view of Diduch teach an apparatus according to claim 4. Diduch further teaches wherein, when the needle body is in the unstressed relaxed form, the first segment subtends a first subtended angle and/or the second segment subtends a second subtended angle (subtended angles of first and second portions, Fig. 8b), wherein the second subtended angle is smaller than the first subtended angle (Fig. 8b).

Regarding claim 7, Nagasaki in view of Diduch teach an apparatus according to claim 6. While Diduch fails to specifically teaches wherein the first subtended angle is within a range of 200 [degrees] to 300 [degrees], and/or the second subtended angle is within a range of 10 [degrees] to 80 [degrees], Diduch teaches a subtended angle of the first segment greater than 180 [degrees] (Fig. 8b). It would have been obvious to one of ordinary skill in the art that the apparatus of Nagasaki in view of Diduch could have been modified as claimed, through routine experimentation to provide a needle with the desired curvature.

Regarding claim 8, Nagasaki in view of Diduch teach an apparatus according to claim 4. Diduch further teaches wherein the first radius of curvature is within a range of 15 mm to 45 mm when the needle body is in the unstressed relaxed state (diameter of 4 mm, para. [0073]; having at least one curve with a radius of curvature greater than or equal to 3 times the diameter of the superelastic puncturing component, para. [0052]; thus can be within 15 to 45 mm).

Regarding claim 9, Nagasaki in view of Diduch teach an apparatus according to claim 1. While the prior art fails to specifically teach wherein the elastic needle body is configured with elastic resistance to straightening within a range of 2 N to 20 N, Diduch teaches superelastic puncturing components of the suture passing devices return towards their preformed, resting, enlarged shape upon removal of the compressive forces required to reduce their profiles thereby enabling the advancement or retraction of one or more sutures through soft tissue despite limited access to the soft tissue (para. [0027]). It would have been obvious to one of ordinary skill in the art that the apparatus of Nagasaki in view of Diduch could have been modified as claimed, through routine experimentation to provide a needle with the a resistance to straightening as claimed.

Regarding claim 10, Nagasaki in view of Diduch teaches an apparatus according to claim 1. While the prior art fails to specifically teach the apparatus configured such that the protruding portion exits the outer tube opening with a needle exit angle within a range of 10 [degrees] to 80 [degrees], relative to the outer tube, Diduch teaches an exit angle relative to the the outer tube (Fig. 8c). It would have been obvious to one of ordinary skill in the art that the apparatus of Nagaski in view of Diduch could have been modified as claimed, through routine experimentation, to provide an exit angle within a range of 10 [degrees] to 80 [degrees] for desired deployment of the inner needle around the target tissue.

Regarding claim 11, Nagasaki in view of Diduch teach an apparatus according to claim 1. Nagasaki further teaches wherein the tension member passer body is flexible and elastic (loop 90, Fig. 1, 6, para. [0037])

Regarding claim 13, Nagaski in view of Diduch teach an apparatus according to claim 1. Diduch further teaches wherein the tension member passer body has a curved or bent portion forming a deviated distal end portion inclined relative to remainder of the tension member passer body (curved portion of wire 40 inclined relative to body of wire, Fig. 8, para. [0070]). It would have been obvious to one of ordinary skill in the art that the device of Nagasaki could have been modified as claimed in view of Diduch to better grasp the suture.

Regarding claim 14, Nagaski in view of Diduch teach an apparatus according to claim 13. Diduch further teaches wherein the deviated tension member passer distal end portion forms with rest of the tension member passer body a deviation angle within a range of 15 [degrees] to 55 [degrees] (Fig. 8c).

Regarding claim 19, Nagasaki in view of Diduch teach an apparatus according to claim 13. While Diduch fails to specifically teach wherein the curved or bent portion of the tension member passer body is configured with elastic resistance to straightening within a range of 0.1 N to 1 N, the curved or bent portion inherently exhibits resistance to straightening. It would have been obvious to one of ordinary skill in the art that the apparatus of Nagasaki in view of Diduch could have been modified as claimed, through routine experimentation, to provide a desired deployment shape.

Regarding claim 20, Nagasaki in view of Diduch teach an apparatus according to claim 1. Nagasaki teaches the apparatus further comprising a console, optionally formed as a handheld device (grip 10, Fig. 1, para. [0027]).

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-*-Supplemental Box - Box V.2 - Citations and Explanations-*-

Regarding claim 21, Nagasaki in view of Diduch teach an apparatus according to claim 1. Nagasaki teaches the apparatus further comprising an inner needle protrusion controller configured to operatively control advancement of the inner needle within the outer tube (needle position adjuster 50, Fig. 1, para. [0041]).

Regarding claim 22, Nagasaki in view of Diduch teach an apparatus according to claim 1. Nagasaki further teaches the apparatus further comprising a tension member passer protrusion controller configured to operatively control advancement of the tension member passer body within the inner needle (loop opening and closing portion 60, Fig. 3, para. [0037]).

Regarding claim 23, Nagasaki in view of Diduch teach an apparatus according to claim 20. Diduch teaches the apparatus further comprising a forceps head fixedly positioned distally to the console (upper jaw, lower jaw, Fig. 9, para.[0071]) and activatable via the console (stylet actuator 56 rotates the upper jaw 46 relative to a pivot connector to the lower jaw 48, and is manipulated by a proximal handle, para. [0071]), configured for selective grasping of the organ adjacent to the entry point and/or the exit point, for holding the grasped organ at a fixed distance relative to the console (intended use; once soft tissue is captured between the upper and low jaws, the superelastic puncturing component is advanced through the soft tissue, para. [0071]). It would have been obvious to one of ordinary skill in the art that the apparatus of Nagasaki could have been modified as claimed in view of Diduch to provide manipulation of the target tissue.

Claims 3, 12, 15-18, and 24-36 meet the criteria of PCT Article 33(2)-33(3) because the prior art fails to teach or fairly suggest the limitations as claimed.

The prior art is exemplified by (1) Nagasaki; (2) Diduch; (3) US 2010/0198235 A1 to Pierce et al. (hereinafter 'Pierce').

Regarding claim 3, Nagasaki in view of Diduch teach an apparatus according to claim 1, but fail to teach wherein the outer tube is movable relative to a covering portion of the apparatus until the outer tube tip extends a chosen uncovered length from a distal edge of the covering portion, the distal edge is configured to resist penetration into soft tissue to inhibit insertion of the outer tube to a depth greater than the uncovered length.
Pierce teaches a suture placement system (Abstract) wherein the outer tube is movable relative to a covering portion of the apparatus (slidable shaft assembly 35 is slidably disposed on elongated cannula 10, Fig. 1, para. [0093]). Pierce and the prior art fail to teach the outer tube movable until the outer tube tip extends a chosen uncovered length from a distal edge of the covering portion, the distal edge is configured to resist penetration into soft tissue to inhibit insertion of the outer tube to a depth greater than the uncovered length.

Regarding claim 12, Nagasaki in view of Diduch teach an apparatus according to claim 1. The prior art fails to teach wherein the tension member pulling portion includes a securing member forming a loop with the tension member passer body.

Regarding claim 15, Nagasaki in view of Diduch teach an apparatus according to claim 13. Diduch fails to teach wherein the tension member pulling portion includes a securing wire portion extending from a first location on the tension member passer body, distally to the curved or bent portion, to a second location on the tension member passer body, proximally to the curved or bent portion.

Regarding claims 16-18, the prior art fails to teach or fairly suggest the limitations as claimed because they depend from claim 15.

Regarding claim 24, Nagasaki in view of Diduch teach an apparatus according to claim 23. Diduch fails to teach wherein the forceps head is configured in a form of tenaculum having two hinged tenaculum arms, each tenaculum arm includes a slender sharppointed hook configured to penetrate through the organ surface into the organ when the forceps head is operated to grasp the organ surface.

Regarding claim 25, Nagasaki in view of Diduch teach an apparatus according to claim 23. Diduch fails to teach wherein the outer tube is slidable distally relative to the forceps head such that the outer tube tip is extendable distally beyond the forceps head, wherein the apparatus is configured to prevent extension of the outer tube tip distally beyond the forceps head over a predetermined maximal penetration depth.
Pierce teaches a suture placement system (Abstract) wherein the outer tube is movable relative to a covering portion of the apparatus (slidable shaft assembly 35 is slidably disposed on elongated cannula 10, Fig. 1, para. [0093]). Pierce and the prior art fail to teach the outer tube is slidable distally relative to the forceps head such that the outer tube tip is extendable distally beyond the forceps head, wherein the apparatus is configured to prevent extension of the outer tube tip distally beyond the forceps head over a predetermined maximal penetration depth.

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Regarding claim 26, Nagasaki teaches a method for passing a tension member around a volumetric region of an organ (Fig. 6, para. [0047]-[0059]), the method comprising:
using a rigid outer tube (outer cylinder 70, Fig. 6, para. [0058]), comprising a sharp outer tube tip (end 72 of outer cylinder 70 has a rigidity enough to penetrate between the peritoneum and the extra peritoneal tissue, para. [0052]) and an outer tube lumen (lumen of cylinder 70, Fig. 1, 6) with an outer tube opening in proximity to the outer tube tip (opening of end 72, Fig. 1, 6),
penetrating into the organ such that the outer tube tip reaches a penetration depth (the skin 12 is punctured by the tip 82 of the hollow needle 80, and the hollow needle 80 and the outer cylinder 70 is inserted in to the body through the skin and the fascia, para. [0049]);
passing an inner needle in the outer tube lumen (Fig. 6; hollow needle 80 is housed into the outer cylinder 70 , para. [0050]), [the inner needle includes an elastic needle body curved at least in part thereof], ending with a sharp needle tip (sharp portion of the tip 82 of the hollow needle 80, Fig. 6, para. [0053]) and enclosing an inner needle lumen (lumen of hollow needle 80, Fig. 6) with an inner needle opening in proximity to the needle tip (distal opening of tip 82, Fig. 1, 6);
piercing a [curved] passage with the needle tip around the volumetric region with a protrusion length of a protruding portion of the inner needle body, by pushing the inner needle via the outer tube opening (the skin 12 is punctured by the tip 82 of the hollow needle 80, and the hollow needle 80 and the outer cylinder 70 is inserted in to the body through the skin and the fascia, para. [0049]) [and allowing the protruding portion to voluntarily flex to a curved form having diameter equal to or greater than diameter of the volumetric region];
Nagasaki fails to teach the inner needle includes an elastic needle body curved at least in part thereof, advancing a curved passage, and allowing the protruding portion to voluntarily flex to a curved form having diameter equal to or greater than diameter of the volumetric region.
Diduch teaches a surgical device for passing a suture (Abstract) comprising an inner needle (tube raw material 38 formed into the preformed geometry and cut to define a sharpened tip 8, Fig. 8, para. [0070]) comprising an elastic needle body curved at least in part thereof (superleastic snare, para. [0070; curved, Fig. 8a-8d), such that a protruding portion of the inner needle body is allowed to voluntarily flex [to a curved form having diameter equal to or greater than diameter of the volumetric region] (Fig. 8a-8d, para. [0070]; thermally formed into a desired shape). It would have been obvious to one of ordinary skill in the art that the device of Nagasaki could have been modified as claimed in view of Diduch to change the geometry of the needle for multiple applications with different shapes.
Nagaski further teaches advancing a tension member passer comprising a tension member passer body and a tension member pulling portion, in the inner needle lumen and via the inner needle opening (loop is further moved to the inside of the outer cylinder 70, Fig. 6, para. [0051]), but fails to teach advancing the tension member passer until the tension member pulling portion exits the organ at an exit point opposing the entry point relative to the volumetric region; and
drawing the tension member into and through the curved passage by pulling the tension member passer with the secured tension member..
Pierce teaches a suture placement system (Abstract) comprising advancing a tension member passer until the tension member pulling portion exits the organ at an exit point (suture capturing mechanism 70 is projected out of sharp distal tip 25, Fig. 14, para. [0116]) opposing the entry point relative to the volumetric region (exits opposite entry point of tip 25, Fig. 14); and
drawing the tension member into and through the curved passage by pulling the tension member passer with the secured tension member. (Fig. 16-18, para. [0116]).
However, it would not have been obvious to one of ordinary skill in the art to modify the method of Nagasaki in view of Pierce as the method of Pierce requires a separate device for tension member delivery.

Regarding claims 27-36, the prior art fails to teach or fairly suggest the limitations as claimed because they depend from claim 26.

Claims 1-36 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.