CORRECTED VERSION

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference<br>4082-0008WO10 | **FOR FURTHER ACTION** | See Form PCT/IPEA/416 |
|---|---|---|
| International application No.<br>PCT/IB2022/058030 | International filing date *(day/month/year)*<br>26 Aug 2022 | Priority date *(day/month/year)*<br>27 Aug 2021 |
| International Patent Classification (IPC) or national classification and IPC<br>IPC: A61B 1/00, A61B 1/05, A61B 17/34<br>CPC: A61B 1/00066 (20130101), A61B 1/00101 (20130101), A61B 1/00105 (20130101), A61B 1/00121 (20130101), A61B 1/05 (20130101), A61B 17/34 (20130101) | | |
| Applicant<br>PSIP2 LLC | | |

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ a total of 17 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and/or sheets containing rectifications authorized by this Authority, unless those sheets were superseded or cancelled, and any accompanying letters (see Rules 46.5, 66.8, 70.16, 91.2, and Section 607 of the Administrative Instructions).
      ☐ sheets containing rectifications, where the decision was made by this Authority not to take them into account because they were not authorized by or notified to this Authority at the time when this Authority began to draw up this report, and any accompanying letters (Rules 66.4 *bis*, 70.2(e), 70.16 and 91.2).
      ☐ superseded sheets and any accompanying letters, where this Authority either considers that the superseding sheets contain an amendment that goes beyond the disclosure in the international application as filed, or the superseding sheets were not accompanied by a latter indicating the basis for the amendments in the application as filed, as indicated in item 4 of Box No. I and the Supplemental Box (see Rule 70.16(b)).
   b. ☐ a separate electronic file containing a sequence listing *(sent to the International Bureau only)*.

4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ 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 Article 35(2) 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

| Date of submission of the demand | Date of completion of this report |
|---|---|
| 19 Mar 2023 | 24 Dec 2023 |
| Name and mailing address of the IPEA/<br>Israel Patent Office<br><br>Email address: pctoffice@justice.gov.il | Authorized officer<br>SEGAL Liviu<br><br>Telephone No. 972-73-3927134 |

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

International application No.
PCT/IB2022/058030

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on:

☒ 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)).

☐ publication of the international application (Rule 12.4(a)).

☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a) and (b)).

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)* :

☐ the international application as originally filed/furnished.

☒ the description: pages 1-30 as originally filed/furnished.

pages * _____ received by this Authority on _____

pages * _____ received by this Authority on _____

☒ the claims: Nos. _____ as originally filed/furnished.

Nos. * _____ as amended (together with any statement) under Article 19

Nos. * 1-21 received by this Authority on 19 Mar 2023

☒ the drawings: pages 1-48 as originally filed/furnished.

pages * _____ received by this Authority on _____

pages * _____ received by this Authority on _____

☐ a sequence listing - see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☒ the claims, Nos. 19-21

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since either they are considered to go beyond the disclosure as filed, or they were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in the Supplemental Box (Rules 70.2(c) and (c-*bis*)):

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

5. ☐ This report has been established:

☐ taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rules 66.1(d- *bis*) and 70.2(e)).

☐ without taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91(Rules 66.4 *bis* and 70.2(e)).

6. With regard to top-up searches (Rules 66.1*ter* and 70.2(f)):

☐ A top-up search was carried out by this Authority on _____

☐ Additional relevant documents have been discovered during the top-up search.

☒ No top-up search was carried out by this Authority because it would serve no useful purpose.

7. ☐ Supplementary international search report(s) from Authority(ies) _____ has/have been received and taken into account in establishing this report (Rule 45*bis*.8(b) and (c)).

** If item 4 applies, some or all of those sheets may be marked "superseded."*

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

International application No.
PCT/IB2022/058030

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

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has, within the applicable time limit:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest and, where applicable, the protest fee.

   ☐ paid additional fees under protest but the applicable protest fee was not paid.

   ☐ neither restricted the claims nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

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

   ☐ complied with.

   ☒ not complied with for the following reasons:

   The following separate inventions have been identified:

   Invention 1: Claims 1-8, which refer to an endoscope, wherein the handle and its components being formed of biocompatible material and designed with no metal fasteners, no adhesives, and no detachable parts small enough to travel though fluid passages of the insertion shaft.
   Invention 2: Claims 9-15, which refer to an endoscope, wherein the handle is formed of inner and outer shells concentric with each other.
   Invention 3: Claims 16-21, which refer to an endoscope set, comprising an endoscope, cannula and obturator.

   The common matter between the independent claims 1, 9 and 16 is an endoscope having a handle and an insertion shaft with a camera at its distal end, the handle having retained within a circuit board for control of and receipt signals from the camera. Devices including these features are, however, well-known in the field (see for example, documents D1-D4). In conclusion, the claimed inventions are not linked by common or corresponding special technical features and define 3 different inventions not linked by a single inventive concept. Consequently, the requirement of unity is not fulfilled, according to Rules 13 PCT.

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

   ☒ all parts.

   ☐ the parts relating to claims Nos. _____

**Box No. V** **Reasoned statement under Article 35(2) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | 1-21 | YES |
| | Claims | | NO |
| Inventive step (IS) | Claims | 1-21 | YES |
| | Claims | | NO |
| Industrial applicability (IA) | Claims | 1-21 | YES |
| | Claims | | NO |

2. Citations and explanations (Rule 70.7)

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2.1 Reference is made to the following documents:

**D1** US 2019/0328217 A1 (Deka Products Ltd. Partnership [US]) 31 October 2019
**D2** US 2018/0168442 A1 (Cook Medical Technologies [US]) 21 June 2018
**D3** US 2019/0374095 A1 (Pristine Surgical LLC [US]) 12 December 2019
**D4** US 2020/0397232 A1 (Karl Storz Se & Co. KG [DE]) 24 December 2020

**Novelty and Inventive step**

**Invention 1**

2.2 INDEPENDENT CLAIM 1

The subject-matter of claim 1 seems to meet the requirements of Article 33(2) and 33(3) PCT with respect to novelty and inventive step, *notwithstanding the clarity objections mentioned at Box VIII below*.

Document **D1** may be considered to be a prior art closest to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document):

An endoscope (endoscope 10, see fig. 3B; see also Abstract), comprising:

a handle (section 16) and an insertion shaft (insertion shaft/section 14), the insertion shaft having at its distal end a solid state camera (camera assembly 350, see par. [0246] and fig. 23), the handle having retained within a circuit board with circuitry (enclosed circuit board 431, see fig. 9B) for control of and receipt of signals from the camera (see e.g. par. [0080]); the handle and components of the handle being formed of biocompatible material (see par. [0136], last six lines "rubber or other elastomer").

However, neither D1 nor any other available prior art (see in particular, document **D2** cited in the search report) appears to disclose or suggest, alone or in combination, that said handle and components thereof are designed with no metal fasteners except those encapsulated sufficiently to ensure no loosening, escape or contact with fluids that flow into a patient, and no detachable parts small enough to travel through fluid passage of the insertion shaft, and with no adhesives except those encapsulated to ensure no contact with fluids that flow into a patient.

It is maintained, that designing the endoscope using techniques that avoid small components that can fall off and fall into a patient and without toxic adhesives or solvents that may contaminate fluids that flow into a patient, provide an improved structure that increase patient safety during surgery while reduce costs of assembly and manufacturing steps.

Claim 1 is therefore new and inventive over cited prior art.

2.3 DEPENDENT CLAIMS 2-8

Claims 2-8 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

**Invention 2**

2.4 INDEPENDENT CLAIM 9

The subject-matter of claim 9 seems to meet the requirements of Article 33(2) and 33(3) PCT with respect to novelty and inventive step, *notwithstanding the objections mentioned at Box VIII below.*

None of the available prior art (taking into account document **D1**, see in particular pars. [0143], [0154] and fig. 3B, as representing the closest prior art) appears to disclose or suggest, individually or in combination, an endoscope comprising a handle being formed of inner and outer shells concentric with each other, wherein rotation of the shells relative to each other is controlled via one or more resilient components frictionally engaged between the respective shells.

It is maintained, that employing an inner and outer handle shells, configured to rotate relative to each other, provides an improving solution that allows a surgeon to adjust the endoscope's field of view, using magnetic Hall effect sensors disposed within the handle.

Claim 9 is therefore new and inventive over cited prior art.

2.5 DEPENDENT CLAIMS 10-15

Claims 10-15 are dependent on claim 9 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

**Invention 3**

2.6 INDEPENDENT CLAIM 16

The subject-matter of claim 16 seems to meet the requirements of Article 33(2) and 33(3) PCT with respect to novelty and inventive step.

Document **D1** may be considered to be a prior art closest to the subject-matter of claim 16, and discloses (the references in parentheses applying to this document):

An endoscope set, comprising:

an endoscope (10, see fig. 3B), cannula (trocar or cannula 318, see fig. 16A-B) and obturator (319, see fig. 19); the endoscope having a handle (section 16) and an insertion shaft (insertion shaft/section 14), the insertion shaft having at its distal end a solid state camera (camera assembly 350, see par. [0246] and fig. 23), the handle having retained within a circuit board with circuitry (enclosed circuit board 431, see fig. 9B) for control of and receipt of signals from the camera (see e.g. par. [0080]); the obturator designed to pierce tissue (via pointed end 323) for introduction of the endoscope (see par. [0237]); the cannula being a tube (see fig. 16) to accept passage of the endoscope insertion shaft and to offer structural protection to

the insertion shaft (see e.g. par. [0229]); the cannula having a connector and locking feature (e.g. cannula mount 300, see figs. 16, 17) designed to engage with the mating connectors and locking features of the obturator (via base portion 325, see par. [0237]) and locking features of the endoscope handle (via handle section 30, see pars. [0230], [0234] and fig. 18), the connector and locking feature of the cannula designed to engage with both the obturator and endoscope handle successively.

However, neither D1 nor any other available prior art (see in particular, document **D2** cited in the search report) appears to disclose or suggest, alone or in combination, that the connector and locking features of the cannula, obturator and endoscope handle having *a slope* tending to draw the cannula and obturator, and cannula and endoscope handle, together for fluid leak-resistant locking.

It is maintained, that this differentiating feature provides an improved coupling and handling between the components of the endoscope set during surgery, while ensuring watertight-ness or leak-proof-ness.

Claim 16 is therefore new and inventive over cited prior art.

2.7 DEPENDENT CLAIMS 17-21

Claims 17-21 are dependent on independent claim 16, and as such also meet the requirements of the PCT with respect to novelty and inventive step.

**Industrial Applicability**

The invention defined in the claims 1-21 is considered to meet the requirements of industrial applicability under Article 33(4) of the PCT.

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

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

The present application does not meet the requirements of Article 6 PCT, due to the following reasons:

The present set of claims contains 21 claims, of which 3 have been drafted as separate independent claims. Therefore, the present set of claims offend the requirements as to CONCISENESS and CLARITY, because a doubt remains to which the protection is sought.

In claim 1 the matter for which protection is sought is not clearly defined. Thus, some of the features in the DEVICE claim 1 (see, in particular, the last paragraph: "DESIGNED with no metal fasteners … except those encapsulated by overmolding or melt-fusing … and with no adhesives") relate more to a METHOD of manufacturing the device rather than clearly defining the device in terms of its structural features as required in device claims. The intended limitations are therefore not clear from this claim, contrary to the requirements of Article 6 PCT.

The term "sufficiently" used in claim 1 is unclear, since it is a relative term with no well-defining meaning in the technical field. Consequently the scope of the claim is unclear.

It is clear from the description that the features of "one or more magnets and one or more Hall effect sensors arranged on the inner and outer shells to provide a sensor signal indicating location of the magnet(s) and Hall sensor(s) relative to each other, thereby to permit computational orientation of the inner and outer shells relative to each other" are ESSENTIAL to the definition and functioning of the invention. Since independent claim 9 does not contain these features, it does not meet the requirement following from Article 6 PCT and PCT-Guidelines 5.33, that any independent claim must contain all the technical features essential to the definition of the invention.

Dependent claims 4 and 12 define the device (endoscope) comprising several components (cannula, obturator). Therefore, the subject-matter of claims 1 and 9 should be amended to an endoscope set (see for example, the correspondent claim 16).

DOCKET NO. 4082-0008WO10

**IN THE INTERNATIONAL BUREAU OF WIPO**

| | | |
|---|---|---|
| Applicant: | PSIP2 LLC | Examiner: Liviu SEGAL |
| Serial No.: | PCT/IB2022/058030 | |
| Filed: | 26 August 2022 | |
| Title: | Endoscope | |

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**AMENDMENT UNDER ARTICLE 34**

**AMENDMENTS TO THE CLAIMS** begin on page **2** of this paper.

**REMARKS/ARGUMENTS** begin on page **7** of this paper.

## AMENDMENTS TO THE CLAIMS

Kindly amend the claims as follows.

1. (Currently amended) An endoscope, comprising:

a handle and an insertion shaft, the insertion shaft having at its distal end a solid state camera, the handle having retained within a circuit board with circuitry for control of and receipt of signals from the camera;

the handle and [[its]] components of the handle being formed of biocompatible materials, and designed with no metal fasteners except those encapsulated sufficiently to ensure no loosening, escape, or contact with fluids that flow into a patient, ~~no adhesives,~~ and no detachable parts small enough to travel though fluid passages of the insertion shaft, except those encapsulated by overmolding or melt-fusing to prevent dislodgement, and with no adhesives except those encapsulated to ensure no contact with fluids that flow into a patient.

2. (Previously presented) The endoscope of claim 1:

the handle being formed of inner and outer shells concentric with each other, rotation of the shells relative to each controlled via one or more resilient components frictionally engaged between the two respective shells.

3. (Currently amended) The endoscope of any one of claims 1 or 2, wherein [[the]] inner and outer shells of the handle are formed of plastic components, the components having resilient clips designed to held the components to each other before joining into unitary structure via melting.

4. (Currently amended) The endoscope of claim 1, further comprising:

a cannula and obturator;

the obturator designed to pierce tissue for introduction of the endoscope;

the cannula being a tube designed to accept passage of the endoscope insertion shaft and to offer structural protection to the insertion shaft;

the cannula having a connector and locking feature designed to engage with mating connectors and locking features of the obturator and locking features of the

endoscope handle, the connector and locking feature of the cannula designed to engage with both the obturator and endoscope handle successively.

5. (New) The endoscope of claim 4, wherein:

the connector and locking features of the cannula, obturator, and endoscope handle have a slope tending to draw the cannula and obturator, and cannula and endoscope handle, together for fluid leak-restistant locking.

6 [[5]]. (Currently amended) The endoscope of any one of claims 1, 2, or 4, wherein one or more control buttons of the endoscope are molded with projections that function as return springs, the projections to be adhered into the endoscope handle via melting.

7 [[6]]. (Currently amended) The endoscope of any one of claims 1, 2, or 4, wherein the circuit board is overmolded by plastic that encapsulates the circuit board from contact with water

8 [[7]]. (Currently amended) The endoscope of any one of claims 1, 2, or 4, wherein components of the handle are joined to each other into a unitary structure via melting.

9 [[8]]. (Previously presented) An endoscope, comprising:

a handle and an insertion shaft, the insertion shaft having at its distal end a solid state camera, the handle having retained within a circuit board with circuitry for control of and receipt of signals from the camera;

the handle being formed of inner and outer shells concentric with each other, rotation of the shells relative to each other controlled via one or more resilient components frictionally engaged between the respective shells.

10 [[9]]. (Currently amended) The endoscope of claim 9 [[8]], wherein:

the resilient components include O-rings.

11 [[10]]. (Currently amended) The endoscope of claim 9 [[8]]:

the handle and its components being formed of biocompatible materials, and designed with no metal fasteners except those encapsulated sufficiently to ensure no loosening, escape, or contact with fluids that flow into a patient, ~~no adhesives,~~ and no detachable parts small enough to travel though fluid passages of the insertion shaft, except those encapsulated by overmolding or melt-fusing to prevent dislodgement, and with no adhesives except those encapsulated to ensure no contact with fluids that flow into a patient.

12 [[11]]. (Currently amended) The endoscope of claim 9 [[8]], further comprising:

a cannula and obturator;

the obturator designed to pierce tissue for introduction of the endoscope;

the cannula being a tube designed to accept passage of the endoscope insertion shaft and to offer structural protection to the insertion shaft;

the cannula having a connector and locking feature designed to engage with mating connectors and locking features of the obturator and locking features of the endoscope handle, the connector and locking feature of the cannula designed to engage with both the obturator and endoscope handle successively;

13. (New) The endoscope of claim 12, wherein:

the connector and locking features of the cannula, obturator, and endoscope handle have a slope tending to draw the cannula and obturator, and cannula and endoscope handle, together for fluid leak-restistant locking.

14 [[12]]. (Currently amended) The endoscope of any one of claims 9 [[8]], 10, 11, or 12, wherein:

the outer shell of the handle having an overmolded layer of a high-friction elastomer.

15. (New) The endoscope of any one of claims 9-12, further comprising:

one or more magnets and one or more Hall effect sensors, arranged on the inner and outer shells to provide a sensor signal indicating location of the maget(s) and Hall effect sensor(s) relative to each other, thereby to permit computation of rotational orientation of the inner and outer shells relative to each other.

16 [[13]]. (Currently amended) An endoscope set, comprising:

an endoscope, cannula, and obturator;

the endoscope having a handle and an insertion shaft, the insertion shaft having at its distal end a solid state camera, the handle having retained within a circuit board with circuitry for control of and receipt of signals from the camera;

an obturator designed to pierce tissue for introduction of the endoscope;

the cannula being a tube designed to accept passage of the endoscope insertion shaft and to offer structural protection to the insertion shaft;

the cannula having a connector and locking feature designed to engage with mating connectors and locking features of the obturator and locking features of the endoscope handle, the connector and locking feature of the cannula designed to engage with both the obturator and endoscope handle successively;

the connector and locking features of the cannula, obturator, and endoscope handle having a slope tending to draw the cannula and obturator, and cannula and endoscope handle, together for fluid leak-restistant locking.

17 [[14]]. (Currently amended) The endoscope set of claim 16 [[13]]:

the handle and its components being formed of biocompatible materials, and designed with no metal fasteners except those encapsulated sufficiently to ensure no loosening, escape, or contact with fluids that flow into a patient, ~~no adhesives,~~ and no detachable parts small enough to travel though fluid passages of the insertion shaft, except those encapsulated by overmolding or melt-fusing to prevent dislodgement, and with no adhesives except those encapsulated to ensure no contact with fluids that flow into a patient.

18 [[15]]. (Currently amended) The endoscope set of claim 16 [[13]]:

the handle being formed of inner and outer shells concentric with each other, rotation of the shells relative to each other controlled via one or more resilient components frictionally engaged between the respective shells.

19 [[16]]. (Currently amended) The endoscope set of any one of claims 16 [[13]], 17 [[14]], or 18 [[15]]:

the locking features of the obturator and endoscope being engageable by twisting of the endoscope relative to the cannula.

20 [[17]]. (Currently amended) The endoscope set of any one of claims 16 [[13]], 17 [[14]], or 18 [[15]]:

the connectors of the endoscope and cannula being watertight, molded for an interference seal without O-rings.

21 [[18]]. (Currently amended) The endoscope set of claim 20 [[17]]:

the connectors being formed as two frusta of cones in interference fit.

**REMARKS/ARGUMENTS**

By this paper, Applicant replies to the Search Report and Written Opinion of 19 December 2022 and respectfully requests reconsideration of the application.

Claims 1-19 are now pending. Claims 1, 9, and 16 are independent. Applicant requests entry of the amendment under Article 34, and a favorable Written Opinion and Preliminary Examination Report.

## Amendments to the claims

The following table clarifies the relationship of the claims before amendment to the claims after amendment:

| new claim | corresponds to old claim (as originally filed) |
|---|---|
| 1 | claim 1, amendment supported at ¶¶ [0070] to [0077] and [0083] |
| 2-3 | original claims 2-3 |
| 4 | original claim 4, amendment supported at ¶¶ [0070] to [0077] and [0083] |
| 5 | New, supported at ¶ [0092] |
| 6-8 | original claims 5-7 |
| 9 | original claim 8 |
| 10 | original claim 9 |
| 11 | original claim 10, amendment supported at ¶¶ [0070] to [0077] and [0083] |
| 12 | original claim 11 |
| 13 | New, amendment supported at ¶ [0092] |
| 14 | original claim 12 |
| 15 | New, supported at ¶¶ [0056] and [0078] |
| 16 | original claim 13, amendment supported at ¶ [0092] |
| 17 | old claim 14; amendment supported at ¶¶ [0070] to [0077] and [0083] |
| 18-21 | original claims 15-18 |

## Claim 1: novelty and inventive step

The Written Opinion compares claim 1 to D1 DEKA/Moreau US 2019/0328217 A1 ("D1 Moreau '217") and to D2 Cook/Schaeffer US 2018/0168442 A1 ("D2 Schaeffer '442"). Claim 1 recites as follows:

1. An endoscope, comprising:

a handle and an insertion shaft, the insertion shaft having at its distal end a solid state camera, the handle having retained within a circuit board with circuitry for control of and receipt of signals from the camera;

the handle and components of the handle being formed of biocompatible materials, and designed with **no metal fasteners except those encapsulated sufficiently to ensure no loosening, escape, or contact with fluids that flow into a patient**, and no detachable parts small enough to travel though fluid passages of the insertion shaft, except those encapsulated by overmolding or melt-fusing to prevent dislodgement, and with **no adhesives except those encapsulated to ensure no contact with fluids that flow into a patient**.

Paragraphs [0070] to [0077] and [0083] of the application explain why the highlighted language is important and inventive: patient safety may be improved if the endoscope design avoids small parts that can fall off and fall into a patient, and avoids adhesives that may contaminate fluids that flow into a patient.

D1 Moreau '217 communicates no recognition that design techniques must be *restricted* to achieve these aspects fo patient safety. In fact, D1 Moreau '217 does the opposite, stating that "*any* suitable means" of fabrication technique may be used, with no recognition of patient safety concerns:

- D1 Moreau '217 teaches repeatedly that "screws" and "various fasteners" may be used. ¶¶ [0137], [0139], [0143], [0155], [0165], with no recognition that encapsulation or other capture is important to avoid compromising patient safety
- D1 Moreau '217 teaches that "any … adhesive" may be used, ¶ [0137], with no recognition that it is important to ensure that adhesives cannot leach into fluids that flow into a patient

D2 Schaeffer '442 is similarly silent. To the degree D2 Schaeffer '442 mentions anything relevant, D2 Schaeffer '442 goes against the claim, by repeatedly allowing "any" design technique, even those that might compromise patient saftety:

- D2 Schaeffer '442 ¶¶ [0075], [0078], [0079], [0099], [0114], [0115], [0221], [0222], [0230] teach use of "adhesive," a "clip," and "threaded fasteners" (screws) to attach components, without recognition of what must be done to keep the patient safe from contamination or dislodgement
- D2 Schaeffer '442 ¶ [0071], [0091], [0112], [0185], [0222] teach use of "biocompatible" materials, but only for the large structural compents such as the "elongate member" "handle," and "wire member." However, D2 Schaeffer '442 fails to recognize that patient safety must extend to the fabrication techniques used to put those parts together, not just the parts themselves.

For reasons of completeness, Applicant has reviewed D3 US 2019/0374095 A1 Pristine Surgical / Lord and D4 US 2020/0397232 A1 Karl Storz / Ulmschneider, and they are no more relevant than D1 Moreau '217 or D2 Schaeffer '442. Neither D3 Lord

'095 nor D4 Ulmschneider '232 recognize that choices of design and fabrication techniques must be *restricted* to ensure patient safety.

In view of these remarks, Applicant respectfully submits that claim 1 is novel and inventive.

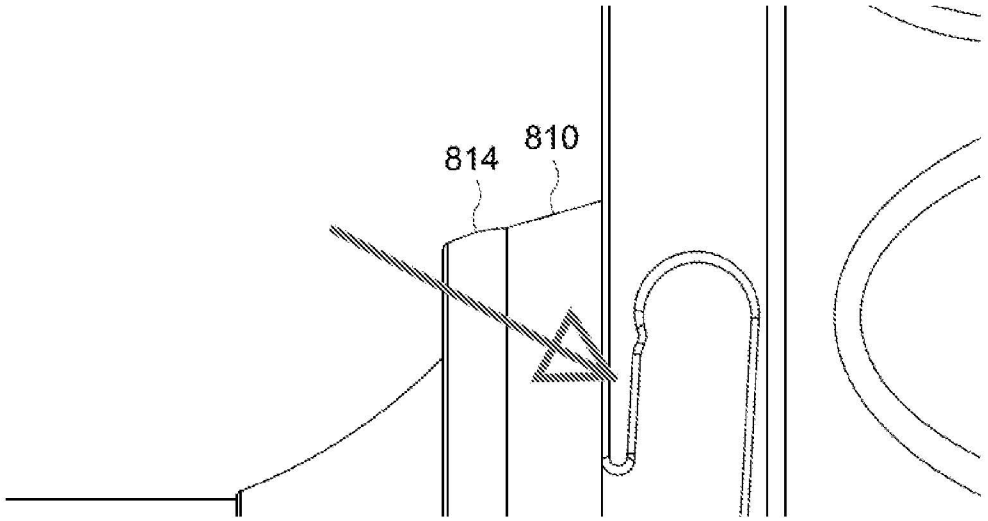
## Claim 14: novelty and inventive step

The Written Opinion compares claim 13 (now claim 14) to D1 DEKA/Moreau US 2019/0328217 A1 ("D1 Moreau '217"). Claim 14 recites as follows:

14. An endoscope set, comprising:
an endoscope, cannula, and obturator;
the endoscope having a handle and an insertion shaft, the insertion shaft having at its distal end a solid state camera, the handle having retained within a circuit board with circuitry for control of and receipt of signals from the camera;
an obturator designed to pierce tissue for introduction of the endoscope;
the cannula being a tube designed to accept passage of the endoscope insertion shaft and to offer structural protection to the insertion shaft;
the cannula having a connector and locking feature designed to engage with mating connectors and locking features of the obturator and locking features of the endoscope handle, the connector and locking feature of the cannula designed to engage with both the obturator and endoscope handle successively;
**the connector and locking features of the cannula, obturator, and endoscope handle having a slope tending to draw the cannula and obturator, and cannula and endoscope handle, together for fluid leak-restistant locking**.

As shown in FIG. 1D to 1H of this application as filed, claim 14 is directed to a cannula that may be used during piercing or other entry into the surgical site with an obturator inserted, then the obturator may be withdrawn, and an endoscope locked into the cannula to provide visibility during endoscoping surgery. For endoscopes that provide water or other insufflation fluid to the endoscope tip, it is important that the coupling between the endoscope and cannula be watertight.

In claim 14, and as shown in FIG. 6D, the coupling has a slope that tends to draw the coupling together as it locks either the cannula and obturator, or cannula and endoscope handle together:




D1 Moreau '217 does not mention watertightness or leak-proof-ness as important properties to be implemented via the "locking device," let alone teach a slope in the coupling to improve watertightness or leak-proof-ness.

## Clarity and conciseness

The Written Opinion suggest that claims 1 and 8 "appear to relate effectively to the SAME subject-matter and to differ from each other only with the regard to the definition of the subject-matter for which protection is sought."

The Written Opinon is confusing: the two halves of this sentence are mutually contradictory. Claims 1 and 8 define different subject matter, as specified in the words of the two claims. The Written Opinion recognizes that the subject matter is different, in opinining that claim 8 satisfies novelty and inventive step, while raising questions as to claim 1.

The Written Opinion writes "Thus, the term 'no' used in [claim 1] is a negative limitation. A claim's subject-matter has to be defined in terms of positive features indicating that certain technical elements are present."

First, the Written Opinion identifies no applicable rule. Neither the PCT Treaty nor the Regulations state any rule requiring "positive features" or forbidding "negative limitations." Most national patent systems abolished rules against negative limitations decades ago, and Applicant requests examination under that international norm.

Second, claim 1 is clear. It recites that an endoscope is designed by *restricitng* design techniques that might degrade patient safety. Paragraphs [0070] to [0077] and [0083] explain the degree of avoidance of use of metal fasteners, small parts, and adhesives. The scope of claim 1 is clear.

The Written Opinion wrtes "claims 4 and 11 (which are dependent on claims 1 and 8, respectively) define the device (endoscope) comprising several components (cannula, obturator). Therefore, the subject-matter of claims 1 and 8 should be amended to an endoscope set."

First, the Written Opinion identifies no applicable rule. Neither the PCT Treaty nor the Regulations state any rule relating to claim preambles in the manner suggested.

Second, claims 1 and 8 are properly written as "An endoscope." It would render claims 1 and 8 *unclear* to change the preamble to "endoscope set" when the two claim bodies recite components of an endoscope.

Claims 4 and 11 use the language "further comprising" indicating that the endsoscope of claims 1 and 8 is accompanied by something in addition. This is conventional claim drafting in most PCT member states.

The claims as drafted conform to international norms. Applicant requests that they be considered under those norms.

Nonetheless, as an accommodation to the Examiner's preference, claim 15 is added to recite the Hall effect sensors and magnets.

The Written Opinion writes "Claim 8 is missing essential features which are necessary for adequately define the invention."

First, the PCT Treaty text and PCT regulations state no rule relating to "essential features" being required in a claim.

Second, claim 8 is complete as it stands. The "Hall effect magnet sensors, rotation collar)" are not necessary to "achieve the intended scope" of claim 8. The components necessary to achieve the intended scope of claim 8 are the handle, the insertion shaft, the solid state camera, the circuit board, the inner and outer shells of the handle, and the one or more resilient components frictionally engaged between the respective shells.

In view of these amendments and remarks, Applicant respectfully submits that the claims are in condition for a favorable Written Opinion and Preliminary Examination Report. The Examiner is urged to telephone Applicant's undersigned counsel at the number noted

below if it will advance the prosecution of this application, or with any suggestion to resolve any condition that would impede allowance.

Respectfully submitted,

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Dated: 19 March 2023

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**REPLACEMENT SHEET**

# CLAIMS

1. An endoscope, comprising:

a handle and an insertion shaft, the insertion shaft having at its distal end a solid state camera, the handle having retained within a circuit board with circuitry for control of and receipt of signals from the camera;

the handle and components of the handle being formed of biocompatible materials, and designed with no metal fasteners except those encapsulated sufficiently to ensure no loosening, escape, or contact with fluids that flow into a patient, and no detachable parts small enough to travel though fluid passages of the insertion shaft, except those encapsulated by overmolding or melt-fusing to prevent dislodgement, and with no adhesives except those encapsulated to ensure no contact with fluids that flow into a patient.

2. The endoscope of claim 1:

the handle being formed of inner and outer shells concentric with each other, rotation of the shells relative to each controlled via one or more resilient components frictionally engaged between the two respective shells.

3. The endoscope of any one of claims 1 or 2, wherein inner and outer shells of the handle are formed of plastic components, the components having resilient clips designed to held the components to each other before joining into unitary structure via melting.

4. The endoscope of claim 1, further comprising:

a cannula and obturator;

the obturator designed to pierce tissue for introduction of the endoscope;

the cannula being a tube designed to accept passage of the endoscope insertion shaft and to offer structural protection to the insertion shaft;

the cannula having a connector and locking feature designed to engage with mating connectors and locking features of the obturator and locking features of the endoscope handle, the connector and locking feature of the cannula designed to engage with both the obturator and endoscope handle successively.

5. The endoscope of claim 4, wherein:

the connector and locking features of the cannula, obturator, and endoscope handle have a slope tending to draw the cannula and obturator, and cannula and endoscope handle, together for fluid leak-restistant locking.

6. The endoscope of any one of claims 1, 2, or 4, wherein one or more control buttons of the endoscope are molded with projections that function as return springs, the projections to be adhered into the endoscope handle via melting.

7. The endoscope of any one of claims 1, 2, or 4, wherein the circuit board is overmolded by plastic that encapsulates the circuit board from contact with water

8. The endoscope of any one of claims 1, 2, or 4, wherein components of the handle are joined to each other into a unitary structure via melting.

9. An endoscope, comprising:

a handle and an insertion shaft, the insertion shaft having at its distal end a solid state camera, the handle having retained within a circuit board with circuitry for control of and receipt of signals from the camera;

the handle being formed of inner and outer shells concentric with each other, rotation of the shells relative to each other controlled via one or more resilient components frictionally engaged between the respective shells.

10. The endoscope of claim 9, wherein:

the resilient components include O-rings.

11. The endoscope of claim 9:

the handle and its components being formed of biocompatible materials, and designed with no metal fasteners except those encapsulated sufficiently to ensure no

loosening, escape, or contact with fluids that flow into a patient, and no detachable parts small enough to travel though fluid passages of the insertion shaft, except those encapsulated by overmolding or melt-fusing to prevent dislodgement, and with no adhesives except those encapsulated to ensure no contact with fluids that flow into a patient.

12. The endoscope of claim 9, further comprising:

a cannula and obturator;

the obturator designed to pierce tissue for introduction of the endoscope;

the cannula being a tube designed to accept passage of the endoscope insertion shaft and to offer structural protection to the insertion shaft;

the cannula having a connector and locking feature designed to engage with mating connectors and locking features of the obturator and locking features of the endoscope handle, the connector and locking feature of the cannula designed to engage with both the obturator and endoscope handle successively;

13. The endoscope of claim 12, wherein:

the connector and locking features of the cannula, obturator, and endoscope handle have a slope tending to draw the cannula and obturator, and cannula and endoscope handle, together for fluid leak-restistant locking.

14. The endoscope of any one of claims 9, 10, 11, or 12, wherein:

the outer shell of the handle having an overmolded layer of a high-friction elastomer.

15. The endoscope of any one of claims 9-14, further comprising:

one or more magnets and one or more Hall effect sensors, arranged on the inner and outer shells to provide a sensor signal indicating location of the maget(s) and Hall effect sensor(s) relative to each other, thereby to permit computation of rotational orientation of the inner and outer shells relative to each other.

16. An endoscope set, comprising:

an endoscope, cannula, and obturator;

the endoscope having a handle and an insertion shaft, the insertion shaft having at its distal end a solid state camera, the handle having retained within a circuit board with circuitry for control of and receipt of signals from the camera;

an obturator designed to pierce tissue for introduction of the endoscope;

the cannula being a tube designed to accept passage of the endoscope insertion shaft and to offer structural protection to the insertion shaft;

the cannula having a connector and locking feature designed to engage with mating connectors and locking features of the obturator and locking features of the endoscope handle, the connector and locking feature of the cannula designed to engage with both the obturator and endoscope handle successively;

the connector and locking features of the cannula, obturator, and endoscope handle having a slope tending to draw the cannula and obturator, and cannula and endoscope handle, together for fluid leak-restistant locking.

17. The endoscope set of claim 16:

the handle and its components being formed of biocompatible materials, and designed with no metal fasteners except those encapsulated sufficiently to ensure no loosening, escape, or contact with fluids that flow into a patient, and no detachable parts small enough to travel though fluid passages of the insertion shaft, except those encapsulated by overmolding or melt-fusing to prevent dislodgement, and with no adhesives except those encapsulated to ensure no contact with fluids that flow into a patient.

18. The endoscope set of claim 16:

the handle being formed of inner and outer shells concentric with each other, rotation of the shells relative to each other controlled via one or more resilient components frictionally engaged between the respective shells.

19. The endoscope set of any one of claims 16, 17, or 18:

the locking features of the obturator and endoscope being engageable by twisting of the endoscope relative to the cannula.

20. The endoscope set of any one of claims 16, 17, or 18:

the connectors of the endoscope and cannula being watertight, molded for an interference seal without O-rings.

21. The endoscope set of claim 20:

the connectors being formed as two frusta of cones in interference fit.