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(54) Title: MEDICAL DEVICE AND PROCESS FOR MANUFACTURING

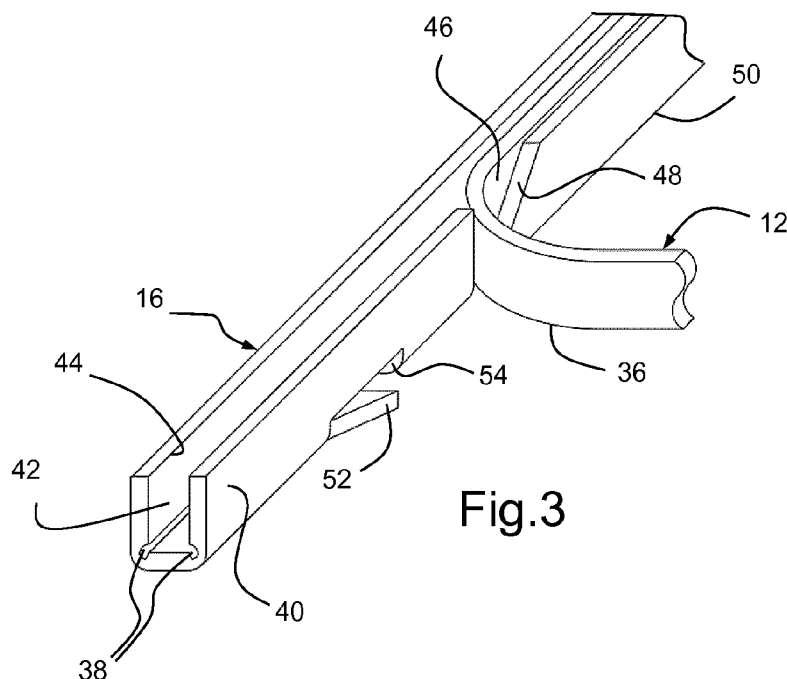


Fig.3

(57) Abstract: The invention concerns a medical device and a method for its production, wherein the device comprises a cannula (14) having an elongated hollow shaft (16) and a sharp tip (18) provided at a distal end of the shaft (16), wherein the shaft (16) is formed as a bent part from a sheet material and confines an interior passage (42) which has a lateral slit opening (44), and wherein the shaft (16) has at least one longitudinal pre-bending channel (38) provided in the sheet material, wherein the thickness of the sheet material is reduced along the pre-bending channel (38) and a sidewall (40) of the shaft (16) is folded over the pre-bending channel (38).



TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

Published:

— *with international search report (Art. 21(3))*

Medical device and process for manufacturing

Description

5 The invention concerns a medical device, in particular for insertion or
implanting of a sensor or an infusion set into the skin or subcutaneous tissue
of a human or mammal, comprising a cannula having an elongated hollow
shaft and a sharp tip provided at a distal end of the shaft, wherein the shaft is
formed as a bent part from a sheet material and confines an interior passage
10 which has a lateral slit opening. The invention further concerns a method for
manufacturing of such a device.

The document US 2012/0184835 discloses a sensor arrangement including a
cannula that can be used to insert the sensor electrodes into the body of a
15 patient for transcutaneous measurement. The cannula has a slit that extends
along its longitudinal direction and in which the sensor shaft is arranged to be
upright. The sensor head including the contact field is offset by an acute
angle between with respect to the sensor shaft. This is achieved by an
angled layout of a substrate, which is however more difficult to produce.

20

On this basis the object of the invention is to further improve the known
devices and production methods and to define a design which allows cost-
effective manufacture and simplified system integration and use while
reducing injuries upon insertion.

25

The combination of features stated in the independent claims is proposed to
achieve this object. Advantageous embodiments and further developments of
the invention are derived from the dependent claims.

30 A first aspect of the invention is based on the idea of forming a hollow
cannula from flat material including etched structures. Thus, it is proposed
according to the invention that the shaft has at least one longitudinal pre-
bending channel provided in the sheet material, wherein the thickness of the

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sheet material is reduced along the pre-bending channel and a sidewall of the shaft is folded (angled by lengthwise bending) over the pre-bending channel. The pre-bending channel(s) which define bending lines reduce the necessary bending forces and increase the tool life in the manufacturing process. Furthermore, the bending easily allows to produce a slotted shaft, while maintaining a flat distal tip. Thereby it is possible to produce miniaturized parts in very high volumes in a cost efficient way.

Advantageously, the shaft has one of a V-shaped profile along a single pre-bending channel or a trapezoidal- or square- or U-shaped profile along two parallel pre-bending channels. In this way, a concave interior is easily created to simplify mounting of a sensor.

According to a preferred implementation, the at least one pre-bending channel is formed as an etched channel in the sheet material. It is also conceivable that the pre-bending channel(s) is/are formed by punching (die-cutting) or by laser-engraving.

Preferably, the at least one pre-bending channel is arranged on the inside (inner side) of the hollow shaft such that smooth outer contours are achieved. In case of more narrow cannulas, it is also conceivable that the pre-bending channel is arranged on the outside.

It is also preferred that the sidewall of the shaft includes a bend angle through which the sheet material is bent having an apex in the pre-bending channel, and wherein the bend angle is in the range of 60° to 120°.

Another aspect of the invention is directed to a cutout in a folded sidewall of the shaft, wherein the cutout adjoins the slit opening and provides a side-outlet of the interior passage. In this way, it is possible to guide a generally straight bendable sensor in a proximal section of the shaft without the need of an angled sensor layout.

According to another preferred implementation, the distal side of the cutout is bordered by a transverse edge of the sidewall which is inclined towards the distal end of the shaft. Thereby, a start-up slope is created which facilitates a sensor removal out of the cannula.

5

Another improvement provides that a catch is formed at the outside of the shaft for fixation of the cannula on a carriage. This improves efficiency of assembly and simplifies system integration.

- 10 For further manufacturing improvement it is advantageous when the catch is a deflected segment of the sheet material of the shaft and the segment is formed by a transection of the sheet material preferably made by etching.

- 15 A particular embodiment further comprises that the cutting edges are formed as a sloped blade by under-etching the sheet material, such that the sloped blade is laterally protruding over an adjacent edge section of the shaft. These measures benefit a sharp tip design while reducing skin damage during insertion.

- 20 Another improvement in this direction is achieved when the tip is a flat shaped part of the sheet material bounded by tapered cutting edges.

- 25 Preferably the at least one pre-bending channel has a distal section which ends in a distance proximal of the tip being formed as a flat shaped part, such that unwanted through-etching is avoided and the tip remains unaffected by the bending of the shaft.

- 30 Another aspect of the invention concerns a system including an electrochemical sensor having electrodes and conducting paths, wherein at least a proximal section of the sensor is provided in the interior passage for insertion into the skin.

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For further design improvement it is advantageous when the sensor comprises a flexible linear sensor substrate which in the mounted state is angled by flexible bending and is guided out of the interior passage through the cutout in the folded sidewall of the shaft. In this way, it is possible to use
5 a simple linear strip sensor without a complicated sensor layout.

Still another aspect of the invention concerns an inserter system further comprising a carriage for manipulation of the cannula by means of an inserter, wherein a proximal part of the cannula is snap-locked in the
10 carriage.

In this connection it is further advantageous when the carriage has a back tapered recess and the shaft has a protruding catch which engages the recess.
15

The invention further concerns a process for manufacturing a medical device, comprising pre-forming a sheet material to provide a proximal shaft part and a distal tip part, forming preferably by chemical etching at least one pre-bending channel having a reduced material thickness along the shaft part, and folding the shaft part over the pre-bending channel to form an angled
20 sidewall of a shaft which confines a concave interior passage.

In this connection, it is also advantageous when pre-forming of the sheet material and forming of the channel is achieved in one step by chemical
25 etching.

In the following, the invention is further elucidated on the basis of an embodiment example shown schematically in the drawings, where

30 Fig. 1 is a side view of a medical device including a folded cannula for sensor implantation into skin;

Fig. 2 is a top view of a skin-insertable electrochemical sensor;

Fig. 3 is a partial perspective view of a proximal portion of the cannula and the sensor received therein;

5 Fig. 4 is a plan view of the tip of the cannula;

Fig. 5 is a cross-sectional view of the tip along the line 5 – 5 in Fig. 4;

Fig. 6 is a flat preform of the cannula photo-etched from sheet metal;

10

Fig. 7 and 8 is plan view of a photomask image for the top and bottom surface of the photo-etched preform shown in Fig. 6; and

Fig. 9 is a view of the proximal endface of the preform shown in Fig. 6.

15

Fig. 1 shows a medical device 10 provided for insertion of a sensor 12 into the skin of a human or mammal to continuously measure an analyte in bodily fluid, e.g. glucose in blood. The device 10 comprises a cannula 14 having an elongated folded shaft 16 and a tip 18 provided at the distal (free) end of the shaft 16. The shaft 16 is firmly connected to a carriage 20 of an inserter which allows an automatically driven reciprocating movement for sensor implantation. Thereby, the free sensor end 22 is placed in the puncture, while the sensor shaft 24 laterally leaves the cannula 14 during retraction through a longitudinal slit 26 in the folded shaft 16.

25

As shown in more detail in Fig. 2, the sensor 12 has a head 28 which bears contact fields 30 to be connected to a measuring unit (not shown). For a transcutaneous measurement by electrochemical means, the free sensor end 22 carries electrodes 32 which are connected to the contact fields 20 by means of conducting paths 34. At least the sensor shaft 24 is formed from a flat substrate 36 as a straight strip. In the mounted state the flexible substrate 36 is angled by flexible bending such that the narrow side appears curved by 90° as shown in Fig. 1.

30

Fig. 3 shows the configuration of the folded shaft 16 of the cannula 14 including the sensor 12. The shaft 16 has square-shaped profile along two parallel pre-bending channels 38 which serve as bending lines for forming the shaft as a bent component from sheet metal, as will be explained in more detail below. Thereby, the sidewall 40 of the shaft 16 is angled over the pre-bending channels 38 to assume a U-shaped configuration which confines an interior passage 42 having a lateral slit opening 44 along its length. Generally, the bend angle may be less or larger than 90° and may vary in different sections of the shaft 16. In case of a relatively wide interior passage 42, it is preferred that the pre-bending channels 38 are arranged on the inner side of the shaft 16.

As further apparent from Fig. 3, a cutout 46 is provided in an upstanding flank of the folded sidewall 40 for guiding the bent substrate 36 of the sensor 12. The cutout 46 adjoins the slit opening 44 at the edge of the sidewall 40 and tapers to the base of the U-Profile in a generally trapezoid-like shape. Preferably, the clearance at the base is at least adapted to the thickness of the sensor substrate 36. The height of the cutout 46 may be equal to the height of the upstanding flank or may be less in order to improve bending stiffness of the shaft 16.

The combination of the slit opening 44 and the cutout 46 allows to mount the sensor 12 by lateral insertion movement of a few millimeters. In contrast, the conventional design of slotted needles requires an infeed from the distal end over the whole needle length.

In order to support a self-acting pull out of the sensor 12 out of the interior passage 42 during retraction of the cannula 14, the distal side of the cutout 46 is bordered by a sloped transverse edge 48 which is inclined towards the distal end of the shaft 16 and thereby forms a start-up slope. The slope angle as included between the edge transverse 48 and the base edge 50 lies in the range of 3° to 45°, preferably 8° to 30° and most preferred 18° to 22°.

For simplification of assembly, the shaft 16 is provided with a catch 52 protruding at the outside and allowing a snap-lock in the carriage 20. The catch 52 is provided as a deflected base segment of the shaft 16 which is produced by a transection 54 of the sheet material. It is also conceivable to create the catch by the upstanding proximal section of the sidewall 40 bordering the cutout 46 and having a reduced bend angle as compared to a distal section. To allow simple connection assembly, the carriage 20 has a back tapered recess or plugin channel 56 (Fig. 1), wherein the catch 52 engages inseparably.

Fig. 4 shows the tip 18 which has a generally flat configuration shaped photo-chemical etching. The tip 18 remains unaffected by the metal working or bending of the shaft 16. Thus, the pre-bending channels 38 end at a distance proximal of the tip 18. Advantageously, the sharp tip 18 in top-view includes an angle of 30° to 40° and an apex radius of preferred 5 to 30 µm.

The tip 18 is defined by tapered cutting edges 56 which are laterally protruding over a proximally adjacent edge section 58. As illustrated in the sectional view of Fig. 5, the cutting edges 56 are formed as a blade sloped to one side of the sheet metal - in the case shown to the bottom side. This can be achieved by lateral under-etching of the sheet material, as explained below. In tests carried out with artificial skin, it has been found that such a tip geometry significantly reduces skin damage as compared to an integrated blade which does not protrude over the edge section 58.

Fig. 6 shows a flat preform 60 of the cannula as produced by photo-etching (also referred to as chemical milling or photo chemical machining) from sheet metal in a cost efficient way. This method allows a high degree of freedom in the layout design without the need for additional cutting work. The flat preform 60 includes the tip 18 and the section of the shaft 16 provided with the pre-bending channels 38, the cutout 46 and the U-shaped transection 54 for producing the catch 52.

All these elements can be shaped by photomask images for the top and bottom surface of the sheet metal as shown in Fig. 7 and 8. The respective photomasks 62, 64 are not exact mirror images, but differ in the channel forming portions 38' for the channels 38 and the blade forming portions 56', 56'' for the blades 56 of the tip 18. The masks 62, 64 are positioned above each other by means of index points 66 as to make them in perfect alignment.

- 10 The sheet metal is preferably medical-grade stainless steel with a thickness in the range of 80 to 200 μm , preferably 100 to 130 μm .

An etching agent to the sheet metal is subsequently applied over the double-sided mask generated in this manner so that the masked areas are etched away according to the desired basic shape. In the case of an isotropic etching action, the depth of the removed material corresponds to the lateral etching rate for the undercutting of edge contours. The etching process can also take place anisotropically due to external influencing parameters or material properties of the substrate i.e. the lateral undercutting rate is then larger or smaller than the depth etching rate. The etching allows to separate workpieces in very large numbers from a ribbon-like sheet material 68 without need for additional tools and handling/machining of individual parts. Usually in uncritical positions at least one junction between a workpiece and a ribbon-like sheet holds the workpiece in place. This junction, which is not shown, may be provided with an etched predetermined breaking line to allow the final separation of individual parts even without tools just by breaking, for instance by bending the individual part along the breaking line.

Fig. 9 shows the pre-bending channels 38 produced by chemical etching in the flat preform 60. The width of the channels is larger than the depth. The depth should be designed such that the material is sufficiently weakened for simplified bending, but remains still sufficiently thick to guarantee an adequate stiffness of the bent cannula. The pre-bending channels 38 are

terminated before the tip area, in order to avoid unwanted through-etching which would lead to increased injuries in the skin puncture.

5 The process of chemical etching or milling leads to sharp edges, specifically in along the blades 56 which may lead to increased skin tearing. Such unwanted effects can be avoided by rounding the edges by means of electrochemical polishing. In this process step, the preform 60 is immersed in a bath of electrolyte and serves as the anode. A current passes from the anode, where metal on the surface is oxidized and dissolved in the
10 electrolyte. Thereby, the protruding parts of an edge profile dissolve faster than the recesses. It is also possible to partly mask or cover areas like the sharp tip which should not be further rounded.

When conducting pricking tests in artificial skin, it could be demonstrated that
15 electro-polishing leads to enhanced surface properties and reduces the punctures grooves to an area which is up to 5 times smaller in comparison to untreated workpieces. Apparently, the tip 18 opens the skin, while the blunt electro-polished blades 56 aid to displace the tissue without additional trauma.

20

Thereafter, the cannula 14 is finished by bending the preform 60 in a suitable tool. This can be achieved by a die block which presses the sheet material to form the U-shape as shown in Fig. 3. The residual stress may cause the material to spring back, so the sheet must be over-bent to achieve the proper
25 bend angle. If the width of the slit opening 44 is larger than the base width, the insertion of the sensor is simplified, though the overall cross section is increased. In any case, the pre-bending channels 38 reduce the necessary bending forces and protect the necessary bending tooling from early wear.

Patent Claims

1. Medical device, in particular for subcutaneous insertion of a sensor (12) or an infusion set, comprising a cannula (14) having an elongated
5 hollow shaft (16) and a sharp tip (18) provided at a distal end of the shaft (16), wherein the shaft (16) is formed as a bent part from a sheet material and confines an interior passage (42) which has a lateral slit opening (44), characterized in that the shaft (16) has at least one longitudinal pre-bending channel (38) provided in the sheet material,
10 wherein the thickness of the sheet material is reduced along the pre-bending channel (38) and a sidewall (40) of the shaft (16) is folded over the pre-bending channel (38).
2. The device of claim 1, wherein the shaft (16) has one of a V-shaped
15 profile along a single pre-bending channel (38), or a trapezoidal-shaped or square-shaped profile along two parallel pre-bending channels (38).
3. The device of claim 1 or 2, wherein the at least one pre-bending
20 channel (38) is formed as an etched channel in the sheet material.
4. The device according to any of claims 1 to 3, wherein the sidewall (40)
includes a bend angle through which the sheet material is bent having an apex in the pre-bending channel (38), and wherein the bend angle is in the range of 60° to 120°.
25
5. The device according to any of claims 1 to 4, further comprising a cutout (46) in the folded sidewall (40) of the shaft (16), wherein the cutout (46) adjoins the slit opening (44) and provides a side-outlet of the interior passage (42) preferably for guiding the sensor (12) in a proximal
30 section of the shaft (16).

6. Medical device, in particular for subcutaneous insertion of a sensor (12) or an infusion set, comprising a cannula (14) having an elongated hollow shaft (16) and a sharp tip (18) provided at a distal end of the shaft (16), wherein the shaft (16) is formed as a bent part from a sheet material and confines an interior passage (42) which has a lateral slit opening (44), characterized by a cutout (46) in a folded sidewall (40) of the shaft (16), wherein the cutout (46) adjoins the slit opening (44) and provides a side-outlet of the interior passage (42).
5
- 10 7. The device of claim 5 or 6, wherein the distal side of the cutout (46) is bordered by a transverse edge (48) of the sidewall (40) which is inclined towards the distal end of the shaft (16).
- 15 8. The device according to any of claims 5 to 7, further comprising a sensor (12) formed as a strip, wherein the sensor (12) has a flexible substrate (36) which is guided in a bent section through the cutout (46) out of the interior passage (42).
- 20 9. The device according to any of claims 1 to 8, further comprising a catch (52) formed at the outside of the shaft (16) for fixation of the cannula (14) on a carriage (20).
- 25 10. The device of claim 9, wherein the catch (52) is a deflected segment of the sheet material of the shaft (16) and the segment is formed by a transection (54) of the sheet material preferably made by etching.
- 30 11. The device according to any of claims 1 to 10, wherein the tip (18) is a flat shaped part of the sheet material bounded by tapered cutting edges (56).
12. The device of claim 11, wherein the cutting edges (56) are formed as a sloped blade by under-etching the sheet material, and wherein the

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sloped blade is laterally protruding over an adjacent edge section (58) of the shaft (16).

13. The device according to any of claims 1 to 12, wherein the at least one
5 pre-bending channel (38) has a distal section which ends in a distance proximal of the tip (18) formed as a flat shaped part.
14. The device according to any of claims 1 to 13, further comprising an
10 electrochemical sensor (12) having electrodes (32) and conducting paths (34), wherein at least a proximal section of the sensor (12) is provided in the interior passage (42) for insertion into the skin.
15. The device according to any of claims 1 to 14, further comprising a
15 carriage (20) for manipulation of the cannula (14) by means of an inserter, wherein a proximal part of the cannula (14) is snap-locked in the carriage (20).
16. The device of claim 15, wherein the carriage (20) has a back tapered
20 recess (36) and the shaft (16) has a protruding catch (52) which engages the recess (36).
17. A process for manufacturing a medical device (10) according to any one
25 of the previous claims, comprising pre-forming a sheet material (68) to provide a proximal shaft part and a distal tip part, forming preferably by chemical etching at least one pre-bending channel (38) having a reduced material thickness along the shaft part, and folding the shaft part over the pre-bending channel (38) to form an angled sidewall (40) of a shaft (16) which confines a concave interior passage (42).

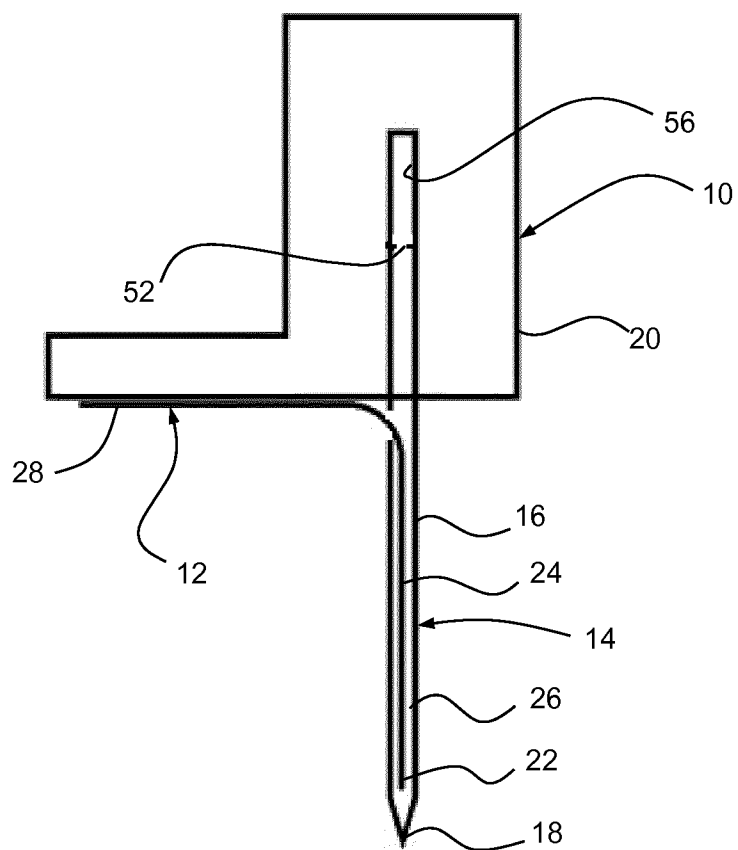


Fig.1

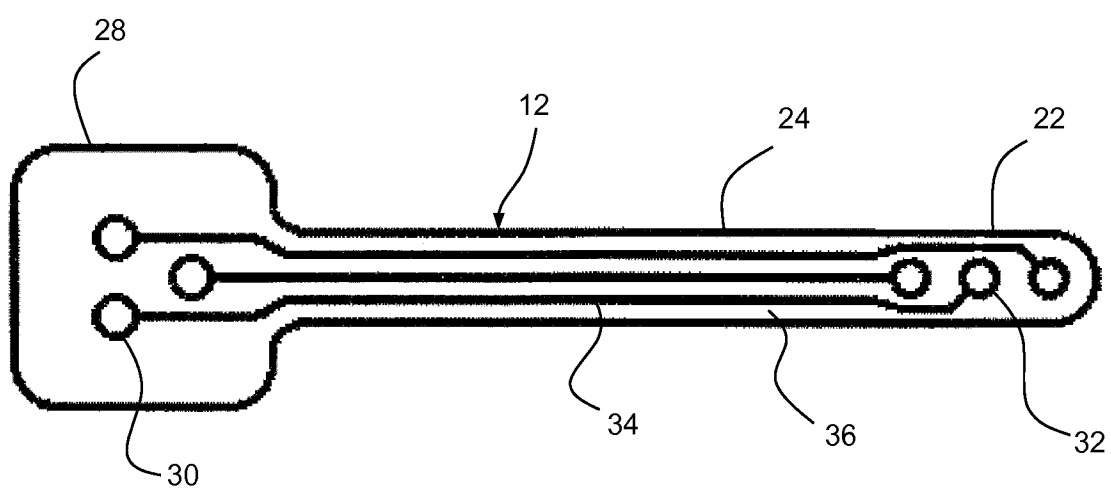


Fig.2

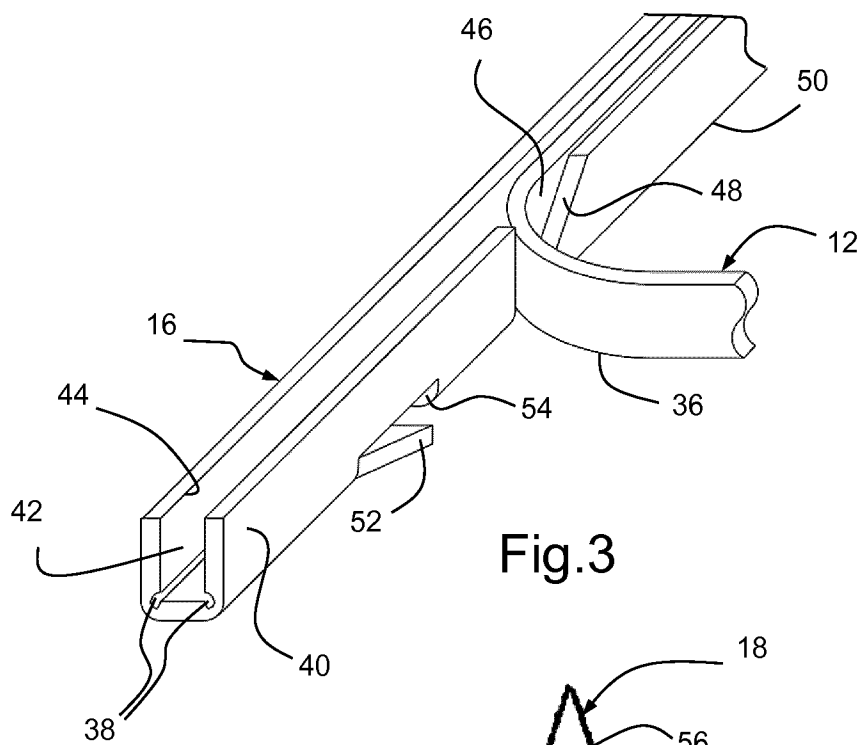


Fig.3

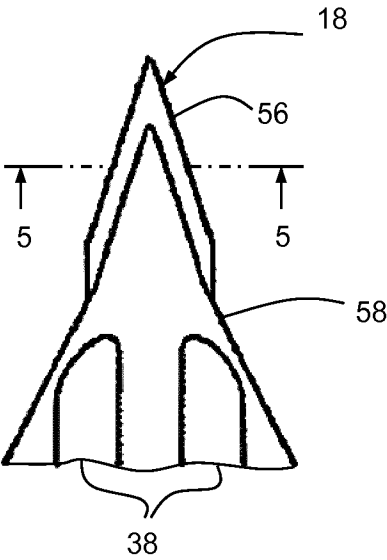


Fig.4

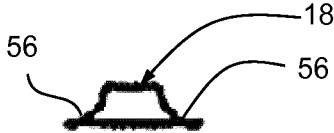


Fig.5

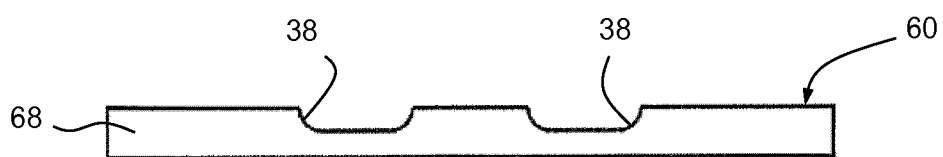
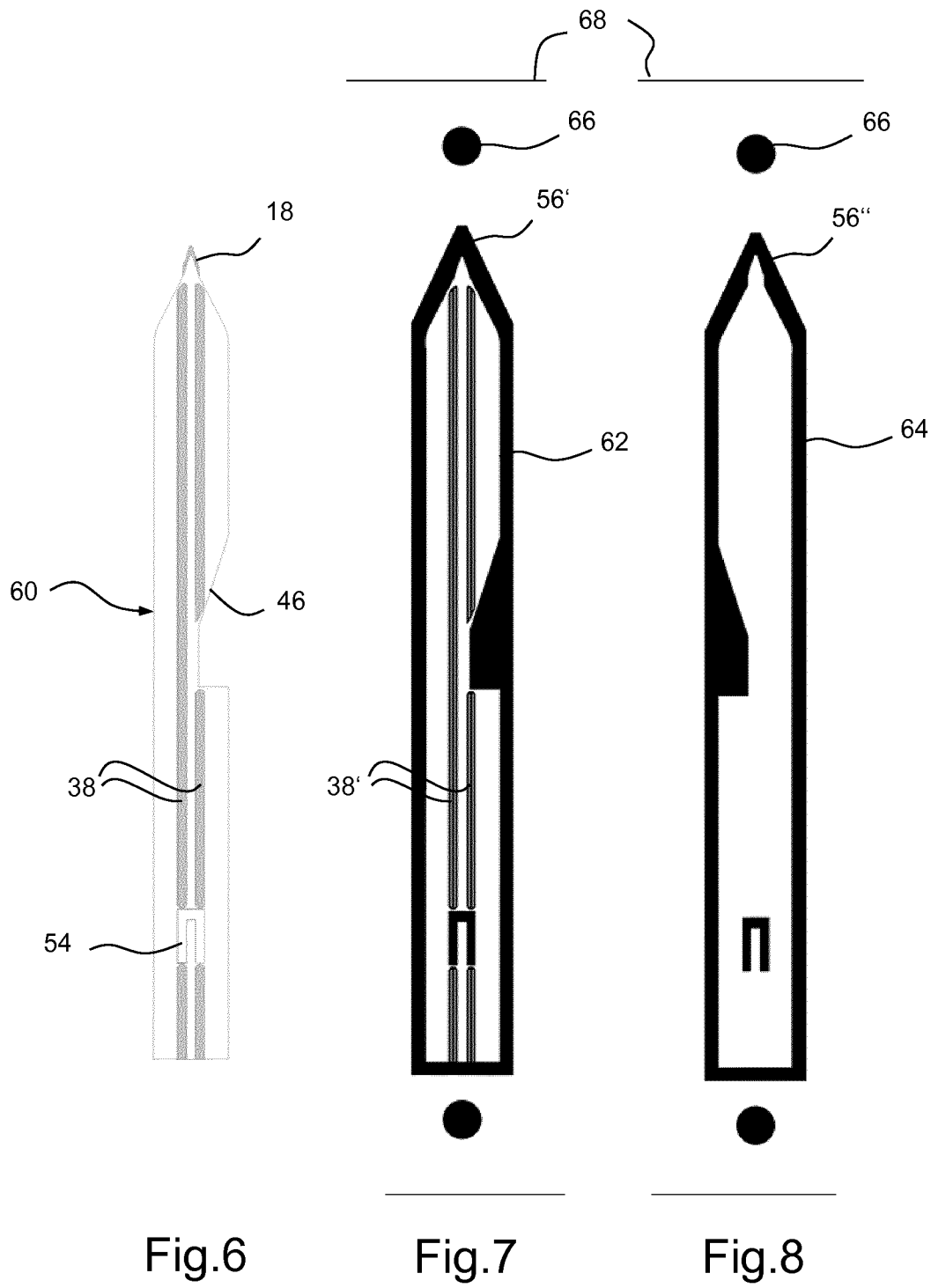


Fig.9

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/051490

A. CLASSIFICATION OF SUBJECT MATTER		
INV.	A61M5/158 A61M25/00	A61B17/34 A61B5/15
	A61B5/00	A61B5/1486 A61M25/01
ADD.		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) A61M A61B		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012/197222 A1 (DONNAY MANUEL LUIS [US] ET AL) 2 August 2012 (2012-08-02) paragraphs [0162] - [0166]; figures 8-17 -----	1-4,8-17
X	US 2007/060814 A1 (STAFFORD GARY A [US]) 15 March 2007 (2007-03-15) paragraphs [0017] - [0028]; figures 5-6 -----	1,5-7, 9-17
A	WO 2013/136968 A1 (OLYMPUS CORP) 19 September 2013 (2013-09-19) figures 2-4, 10-13 & US 2016/008028 A9 (MATSUMOTO ATSUSHI [JP] ET AL) 14 January 2016 (2016-01-14) paragraphs [0063] - [0075]; figures 2-4, 10-13 ----- -/-	1-17
☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 28 February 2017		Date of mailing of the international search report 13/03/2017
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Ioanovici, T

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2017/051490

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-17

Cannula comprising a sheet material bending along etched pre-bending channels and Cannula comprising a bent sheet material with a sidewall cutout adjoining the a lateral slit opening

1.1. claims: 1-4, 13, 17

Cannula comprising a sheet material bending along etched pre-bending channels

1.2. claims: 5-12, 14-16

Cannula comprising a bent sheet material with a sidewall cutout adjoining the a lateral slit opening

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/051490

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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