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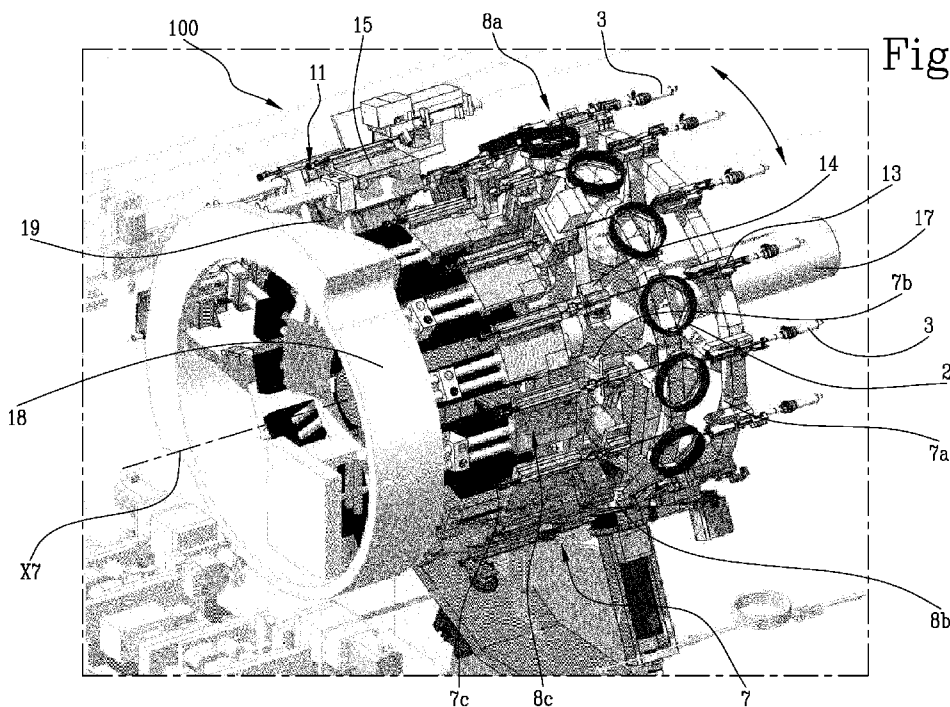


Fig. 3

(57) Abstract: A machine for the assembly of medical devices, such as infusion catheters (1), each having a plurality of components which comprising: a drum (7) which rotates about a horizontal axis (X7) and which has a cylindrical surface subdivided into a first section (7a), a second section (7b) and a third section (7c) which rotate in a synchronous fashion with each other about the horizontal axis (X7); each first (7a), second (7b) and third (7b) section has a corresponding first (8a), second (8b) and third (8b) plurality of assembly stations for the assembly of the components of the catheter (1), uniformly distributed along the cylindrical surface and along its entire extension; each of the trios consisting of a first (8a), second (8b) and third (8b) assembly station defines a single assembly line, parallel to the horizontal axis (X7) of rotation, in such a way as to configure a single assembly station for a single catheter (1); a plurality of operating stations (9) positioned around the rotating drum (7) and in positions which are angularly different from each



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other, with reference to the horizontal axis (X7) of rotation; each station (9) is configured to intercept a first (8a) or a second (8b) or a third (8c) assembly station, according to a predetermined sequence and following at least a partial rotation of the drum (7), to position one of the components of the catheter (1) in a corresponding first (8a) or second (8b) or third (8c) station, or to connect to one another at least two components of the catheter (1) positioned in the corresponding first (8a) or second (8b) or third (8c) station.

## MACHINE FOR THE ASSEMBLY OF MEDICAL DEVICES

The present invention concerns a machine for the assembly of medical devices.

More particularly, these are medical devices called infusion catheters for the medical treatment of patients requiring fluid drainage, to administer medication, or for diagnostic purposes (generally used in dialysis treatment, controlled infusions of liquid solutions, etc.).

The infusion catheter in question basically comprises:

- a first flexible tube having a first end and a second end;
- a drip chamber for the controlled administration of a product; the chamber is connected to the first end of the first tube;
- a first flow control valve associated in a point of the first tube;
- a second connecting valve connected to the second end of the first tube;
- a second flexible tube having a first end connected to the second valve and a second end;
- a connector, associated with the second end of the second tube, for the attachment of the device to medical instruments.

It should be observed that the first and the second flexible tube that are used can be of different diameters and variable lengths, depending on the use and purpose of the device.

Analogously, the second connecting valve that is used can be of different functional types (Y valve, air separator, etc.) depending on the use and purpose of the device.

Also the connector that is used can be of different types depending on the use and the type of medical instrument that is to be connected.

Presently, to assemble infusion catheters of this kind semi-automatic machines are used that comprise a work plane that extends along a longitudinal axis, above or

alongside of which single operating stations are located that carry out the positioning or assembly of a corresponding component of the catheter.

Each operating station located along the work plane is connected to a supply receptacle for the assembly component in question, placed lateral to the work  
5 plane.

However, this type of machine has a number of drawbacks.

The structure with the longitudinally extending work plane is an extremely unwieldy structure of considerable width and length, also in relation to the number of components that have to be assembled.

10 With such a single line of operation the productivity of the machine in relation to the size of that machine is low.

The machine with such a structure has less operational flexibility whenever it is necessary to modify the type of tube, valve or connector, which have to be replaced from time to time in the corresponding receptacles by an operator.

15 The aim of the present invention is to provide a machine for the assembly of medical devices, such as infusion catheters, which overcomes the above-mentioned drawbacks. More particularly, the aim of the present invention is to provide a machine for the assembly of medical devices, such as infusion catheters, which is able to assemble the devices with speed and accuracy, but occupying  
20 much less space for its operation. Further aim of the present invention is to provide a machine for the assembly of medical devices, such as infusion catheters, which is able to increase productivity and that has higher operational flexibility, and in which the components can be substituted rapidly and easily, depending on production needs.

25 Said aims are fully obtained by the machine for the assembly of medical devices, such as infusion catheters, of the present invention, which is characterised by the features as defined in the claims below.

These and other characteristics will become clear from the following description of a preferred embodiment, illustrated by the enclosed figures provided by way of non-limiting example, wherein:

- 5 - figure 1 illustrates a machine for the assembly of medical devices, such as infusion catheters, that is the subject of the present invention, in a perspective view with some parts removed in order to highlight others;
- figure 2 illustrates a rotating drum that is part of the machine of figure 1, in a perspective front view and with some parts removed in order to highlight others ;
- figure 3 illustrates the rotating drum of figure 2 in a perspective rear view with regard to figure 2 and with some parts removed in order to highlight others;
- 10 - figure 4 illustrates the components that together form an infusion catheter which can be assembled in the machine illustrated in the previous figures, and in a perspective view;
- figure 5 illustrates a part of the machine illustrated in figures 1 to 3 in a schematic front view with some parts removed in order to highlight others ;
- 15 - figure 6 illustrates a detail of the drum of figure 2 in a schematic side view with some parts removed in order to highlight others.

With reference to the enclosed figures, in particular figure 1, the machine which is the subject of the present invention and which is generally indicated by the number 100, is used for the assembly of medical devices such as infusion catheters 1, for example the catheter illustrated in figure 4.

Each infusion catheter 1 essentially consists of a plurality of components (refer to figure 1):

- 25 - a first flexible tube 2a (which can have various diameters and lengths depending on its intended purpose) having a first end and a second end;
- a drip chamber 3 connected to the first end of the first tube 2a;
- a first flow control valve 4 associated in a point of the first tube 2a;

- a second connecting valve 5 (of various types, shapes or geometries, depending on the intended purpose) connected to the second end of the first tube 2a;
- a second flexible tube 2b (which can have various diameters and lengths depending on its intended purpose) having a first end connected to the second valve 5 and a second end; and
- a connector 6 (of various types, shapes or geometries, depending on the intended purpose) associated to the second end of the second tube 2b.

According to the illustrations (see figures 1-3 and 5 and 6) the machine 100 comprises a drum 7 which rotates about a horizontal axis X7.

- 10 The drum 7 has a cylindrical surface which is subdivided in a first section 7a, a second section 7b, and a third section 7c rotating in synchronised fashion with each other about the horizontal axis X7.

Each first 7a, second 7b and third 7b section has a corresponding first 8a, second 8b and third 8c plurality of stations for the assembly of the components of the catheter 1, uniformly distributed along the cylindrical surface and along its entire extension.

Each of the trios composed of a first 8a, a second 8b, and a third 8b assembly station defines a single assembly line, parallel to the horizontal axis X7 of rotation, in such a way as to configure a single assembly station for a single catheter 1.

- 20 The machine 100 also comprises a plurality of operating stations 9a-9g positioned around the rotating drum 7 and in positions which are angularly different from each other, with reference to the horizontal axis X7 of rotation.

Each station 9a-9g is configured to intercept a first 8a or a second 8b or a third 8c assembly station, according to a predetermined sequence and following at least a partial rotation of the drum 7, to position one of the components of the catheter 1 in a corresponding first 8a, second 8b, or third 8c station, or to connect to one another at least two components of the catheter 1 positioned in the corresponding first 8a, or second 8b, or third 8c station.

In other words, the drum defines a plurality of assembly stations for corresponding catheters, along an arc of 360 degrees, each of which works in synchronous fashion with the operating stations located around the drum.

By this it is possible to have a machine that as a whole occupies less space and that combines an increased operational productivity with great flexibility also when it comes to switching to other types of catheters, i.e. with tubes of different lengths and diameters to assemble, different valves, etc..

Preferably, for illustrative purposes, the drum 7 rotates in a counterclockwise direction and preferably in a discontinuous motion to allow the individual stations to perform their steps.

It should be observed that the machine 100 comprises a plurality of supply receptacles 10 for the corresponding components of the catheter 1 at corresponding operating stations 9a-9g or directly at a first 8a or second 8b or third 8c assembly station.

The plurality of receptacles 10 are positioned each at different heights with regard to a load-bearing reference surface P (see figure 5 in particular).

The term load-bearing surface P refers to the surface on which the support frame of the drum 7 rests.

Preferably, at least one of the first 7a, second 7b, and third 7c sections comprises first means 11 for movement of the corresponding first 8a or second 8b or third 8c assembly station configured for moving the first 8a, or second 8b, or third 8c station parallel to the horizontal axis X7, in both directions towards or away from an adjacent station of one of the other sections 7a or 7b or 7c. Preferably, again at least one of the first 7a, second 7b, and third 7c sections comprises second means 12 for movement of the corresponding first 8a or second 8b or third 8c assembly station configured for moving the first 8a, or second 8b, or third 8c station transversely to the horizontal axis X7, in both directions towards or away from the horizontal surface, in order to move towards or away from at least one of the operating stations 9a-9g.

Preferably the first 11 and second 12 means of movement are interconnected with each other on the first 7a or second 7b or third 7c section (here, for illustrative purposes, it is the third section 7c) in order to allow for a combined movement along two axes – parallel and transversal to the horizontal axis X7 – of the first 8a  
5 or second 8b or third 8c station (here, for illustrative purposes, it is the third station 8c).

It should be observed that each of the first 7a, second 7b and third 7c section of the drum 7 defines cylindrical portions that are independent from each other, with a corresponding cylindrical surface, and connected by means of a joint rotary  
10 support shaft 17.

In this light the first section 7a is substantially a carousel connected to the rotary shaft 17 and provided with first stations 8a.

In this light the first section 7a, or carousel, has two subsections 7a1, 7a2 on which the first assembly stations 8a are positioned, defining two corresponding  
15 substations 8a1, 8a2.

The first subsection 7a1 comprises a plurality of substations 8a1 defining a stationary collecting device to collect a working quantity of flexible tube 2, intended to become (subsequently) the first 2a and the second 2b flexible tube.

The substation 8a1 is configured to collect the flexible tube 2 between a first  
20 stretch of flexible tube 2 and a second stretch of flexible tube 2.

The second subsection 7a2 comprises a plurality of subsections 8a2 having a device 13 for gripping and stationary positioning the first stretch of flexible tube 2 defining also the first end of the first flexible tube 2a of the drip chamber 3, when applied by a relative operating station 9a-9g to the first end of the flexible tube 2,  
25 and of the first flow control valve 4 when applied to the flexible tube 2 by a relative operating station 9.

In a preferred but non-limiting embodiment the flexible tube 2 can be supplied parallel to the axis X7 of rotation in such a manner as to be positioned along the



three stations 8a, 8b, 8c, through a receptacle 10a having spools onto which the tube 2 is wound (figure 1).

Once the flexible tube 2 is positioned along the trio of stations 8a, 8b, 8c which define the single assembly station of a catheter 1, an apposite operating station 9a-  
5 9g (illustrated here by a block, indicated by 9a) unwinds the tube 2 from the receptacle 10a until the length of flexible tube 2 is equal to the sum of the first 2a and the second 2b flexible tube to be used, and positions it, rolled up, on the substation 8a1 of the first section 7a1.

The first stretch of the unwound flexible tube 2 is held by the second substation  
10 7a2, while the second stretch is positioned along the second 8b and third 8c stations for further operations and assembly (as will be described in more detail below).

During the rotation of the drum 7, the substation 8a2 of the second subsection 7a2 arrives at several operating stations 9a-9g (indicated here by 9b and 9c) which  
15 supply and connect, on the first stretch of flexible tube 2, the drip chamber 3 to the end of the flexible tube 2 and the first flow control valve 4 along the first stretch of the tube 2. These two operating stations 9b and 9c are connected to corresponding receptacles 10b and 10c located overhead and supplying, respectively, the drip chamber 3 and the first flow control valve 4.

20 Preferably the second section 7b (intermediate between the other two sections 7a, 7c) has a plurality of second stations 8b each having gripping members 14 to hold a part of the second stretch of the flexible tube 2.

Preferably, the third section 7c has a plurality of third stations 8c each comprising  
25 a slide 15 provided with a gripping device 16 to hold a part of the second stretch of flexible tube 2.

Each slide 15 is at least movable in the two directions parallel to the horizontal axis X7 of rotation, at least between a first operational position near the corresponding second station 8b (figures 2 and 3 and the upper portion of 6) and a second operational position away from the corresponding second station 8b

following the separation of the second stretch of flexible tube 2, performed by a relative operating station 9, in order to create the second flexible tube 2b, held by the slide 15, and the second end of the first flexible tube 2a, held by the second station 8b and onto which, subsequent to the separation from the second stretch of flexible tube 2, the second connecting valve 5 is applied by a relative operating station 9a-9g and following a rotation of the drum about the horizontal axis X7.

In this light, the slide 15 is also transversely movable with regard to the horizontal axis X7 of rotation between a first operational position, which is raised with respect to the second station 8b, and a second operational position which is on the same plane as the second station 8b, in such a manner as to arrive, in sequence and following the corresponding rotations of the drum 7 about the horizontal axis X7 of rotation, at at least two operating stations 9a-9g for the application of the connector 6 to the second end of the flexible tube 2b and, respectively, of the second connecting valve 5 to the first end of the second flexible tube 2b.

In other words the slide 15 is connected to the above-mentioned first and second means 11, 12 of movement to allow the slide 15 to move in a parallel and in a transverse direction with respect to the axis X7 of rotation.

For the purpose of a non-limiting constructive example, the first means 11 of movement comprise a combination of an actuator 11a (illustrated as a block) and cylinders 11b connected to the slide 15. The cylinders 11b are arranged in parallel to the axis X7 and allow the slide to move in the two directions.

The second means 12 of movement comprise a combination of an actuator 12a (illustrated as a block) and cylinders 12b connected to the slide 15. The cylinders 12b are arranged radially to the axis X7 and allow the slide to move upwards and downwards.

It should be observed that posterior to the third section 7c a ring 18 is located which is fixed with respect to the third section 7c. This ring 18 has an annular counter-surface 19 for the cylinders 11b of the first means 11 of movement passing over, configured with a variable profile to allow for the stable backwards

and forwards motion of the cylinders 11b, as well as for their stability when raised overhead when the cylinders 12b raise the slide 15.

Basically, the phases provided by each second and third station 8b and 8c, could essentially be the following, during corresponding rotations of the drum 7:

- 5 - separation of the second stretch of flexible tube 2 between the second station 8b and the slide 15, in order to create the second end of the first flexible tube 2a (on the second station 8b) and the second flexible tube 2b (on the slide 15) in a station 9d;
- distancing of the slide 15 away from the second station 8b;
- 10 - positioning and application of the second connecting valve 5 onto the second end of the first flexible tube 2a in a corresponding station 9e with the component being supplied from receptacle 10d;
- positioning and application of the connector 6 onto the second end of the second tube 2b placed on the slide 15 in the retracted and raised position and by means of
- 15 an operating station 9f with the component supplied from receptacle 10e;
- lowering and advancement of the slide 15 towards the second station 8b;
- application of the second connecting valve 5 onto the first end of the second flexible tube 2b in a corresponding station 9g.

Once the catheter 1 is completed with all its components in place, it is released

20 onto a conveyer belt 20.

Thanks to this machine, therefore, the aims described earlier are obtained, namely a machine that as a whole occupies less space but that provides high operational productivity.

The structure of the stations, the operating stations and the architecture of the

25 receptacles provide a high level of operational flexibility and a rapid switching of catheter types, i.e. the lengths and diameters of the flexible tubes that are to be assembled, the types of valves, etc..

### CLAIMS

1. Machine for the assembly of medical devices, such as infusion catheters (1), each having a plurality of components comprising: a first flexible tube (2a) having a first end and a second end; a drip chamber (3) connected to the first end of the first tube (2a); a first flow control valve (4) associated in a point of the first tube (2a); a second connecting valve (5) connected to the second end of the first tube (2a); a second flexible tube (2b) having a first end connected to the second valve (5) and a second end; a connector (6) associated with the second end of the second tube (2b); characterised in that it comprises:
- 10 - a drum (7) which rotates about a horizontal axis (X7); the drum (7) having a cylindrical surface divided into a first section (7a), a second section (7b) and a third section (7c) which rotate in a synchronous fashion with each other about the horizontal axis (X7); each first (7a), second (7b) and third (7b) section having a corresponding first (8a), second (8b) and third (8c) plurality of stations for the assembly of the components of the catheter (1), uniformly distributed along the cylindrical surface and along its entire extension; each of the trios consisting of a first (8a), second (8b) and third (8b) assembly station defining a single assembly line, parallel to the horizontal axis (X7) of rotation, in such a way as to configure a single assembly station for a single catheter (1);
- 15 - a plurality of operating stations (9a-9g) positioned around the rotating drum (7) and in positions which are angularly different from each other, with reference to the horizontal axis (X7) of rotation; each station (9a-9g) being configured to intercept a first (8a) or a second (8b) or a third (8c) assembly station, according to a predetermined sequence and following at least a partial rotation of the drum (7),
- 20 to position one of the components of the catheter (1) in a corresponding first (8a) or second (8b) or third (8c) station, or to connect to one another at least two components of the catheter (1) positioned in the corresponding first (8a) or second (8b) or third (8c) station.
2. The machine according to claim 1, comprising a plurality of receptacles (10) to supply the corresponding components of the catheter (1) to corresponding
- 30

operating stations (9a-9g) or directly to a first (8a) or second (8b) or third (8c) assembly station; the plurality of receptacles (10) being positioned each at different heights with regard to a load-bearing reference surface (P).

3. The machine according to claim 1 or 2, wherein at least one of either the first  
5 (7a), second (7b) and third (7c) section comprises first means (11) for movement of the corresponding first (8a) or second (8b) or third (8c) assembly station, configured for moving the first (8a) or second (8b) or third (8c) station parallel to the horizontal axis (X7), in both directions, towards or away from an adjacent station of one of the other sections (7a or 7b or 7c).

10 4. The machine according to any one of the preceding claims, wherein at least one of either the first (7a), second (7b) and third (7c) section comprises second means (12) for movement of the corresponding first (8a) or second (8b) or third (8c) assembly station, configured for moving the first (8a) or second (8b) or third (8c) station transversely to the horizontal axis (X7), in both directions, towards or  
15 away from the horizontal surface, so as to move towards or away from at least one of the operating stations (9a-9g).

5. The machine according to claims 3 and 4, wherein the first (11) and second (12) means of movement are interconnected with each other on the first (7a) or second (7b) or third (7b) section in such a way as to allow a combined movement along  
20 two axes, parallel and transversal to the horizontal axis (X7), of the first (8a) or second (8b) or third (8c) station.

6. The machine according to any one of the preceding claims, wherein each of the first (7a), second (7b) and third (7c) section of the drum (7) defines cylindrical portions that are independent from each other, with a corresponding cylindrical  
25 surface, and connected by means of a joint rotary support shaft (17).

7. The machine according to any one of the preceding claims, wherein the first section (7a) has two subsections (7a1, 7a2) on which the first assembly stations (8a) are positioned, defining two corresponding substations (8a1, 8a2); a first subsection (7a1) comprising a plurality of substations (8a1) defining a stable

collecting device to collect a working quantity of flexible tube (2), intended to become the first (2a) and second (2b) flexible tube, between a first stretch of flexible tube (2) and a second stretch of flexible tube (2); a second substation (7a2) comprising a plurality of substations (8a2) having a device (13) for gripping and stably positioning the first stretch of flexible tube (2) defining also the first end of the first flexible tube (2a) of the drip chamber (3), when applied by a relative operating station (9a-9g) to the first end of the flexible tube (2), and of the first flow control valve (4) when applied to the flexible tube (2) by a relative operating station (9).

10 8. The machine according to claim 7, wherein the second section (7b) has a plurality of second stations (8b) each having gripping members (14) to hold a part of the second stretch of the flexible tube (2).

9. The machine according to claim 7 or 8, wherein the third section (7c) has a plurality of third stations (8c) each comprising a slide (15) provided with a gripping device (16) to hold a part of the second stretch of flexible tube (2); each slide (15) being at least movable in the two directions parallel to the horizontal axis (X7) of rotation, at least between a first operating station near the corresponding second station (8b) and a second operational position away from the corresponding second station (8b) following a separation of the second stretch of flexible tube (2) performed by a relative operating station (9), in order to create the second flexible tube (2b), held by the slide (15), and the second end of the first flexible tube (2a), held by the second station (8b) and onto which, subsequent to the separation from the second stretch of flexible tube (2), the second connecting valve (5) is applied by a relative operating station (9a-9g) and after to a rotation of the drum about the horizontal axis (X7).

10. The machine according to claim 9, wherein the slide (15) is also transversely movable with regard to the horizontal axis (X7) of rotation between a first operational position, which is raised with respect to the second station (8b), and a second operational position which is on the same plane as the second station (8b), in such a way as to arrive, in sequence and following corresponding rotations of

the drum (7) about the horizontal axis (X7), at at least two operating stations (9a-9g) for the application of the connector (6) to the second end of the second flexible tube (2b) and, respectively, the second connecting valve (5) to the first end of the second flexible tube (2b).

Fig.1

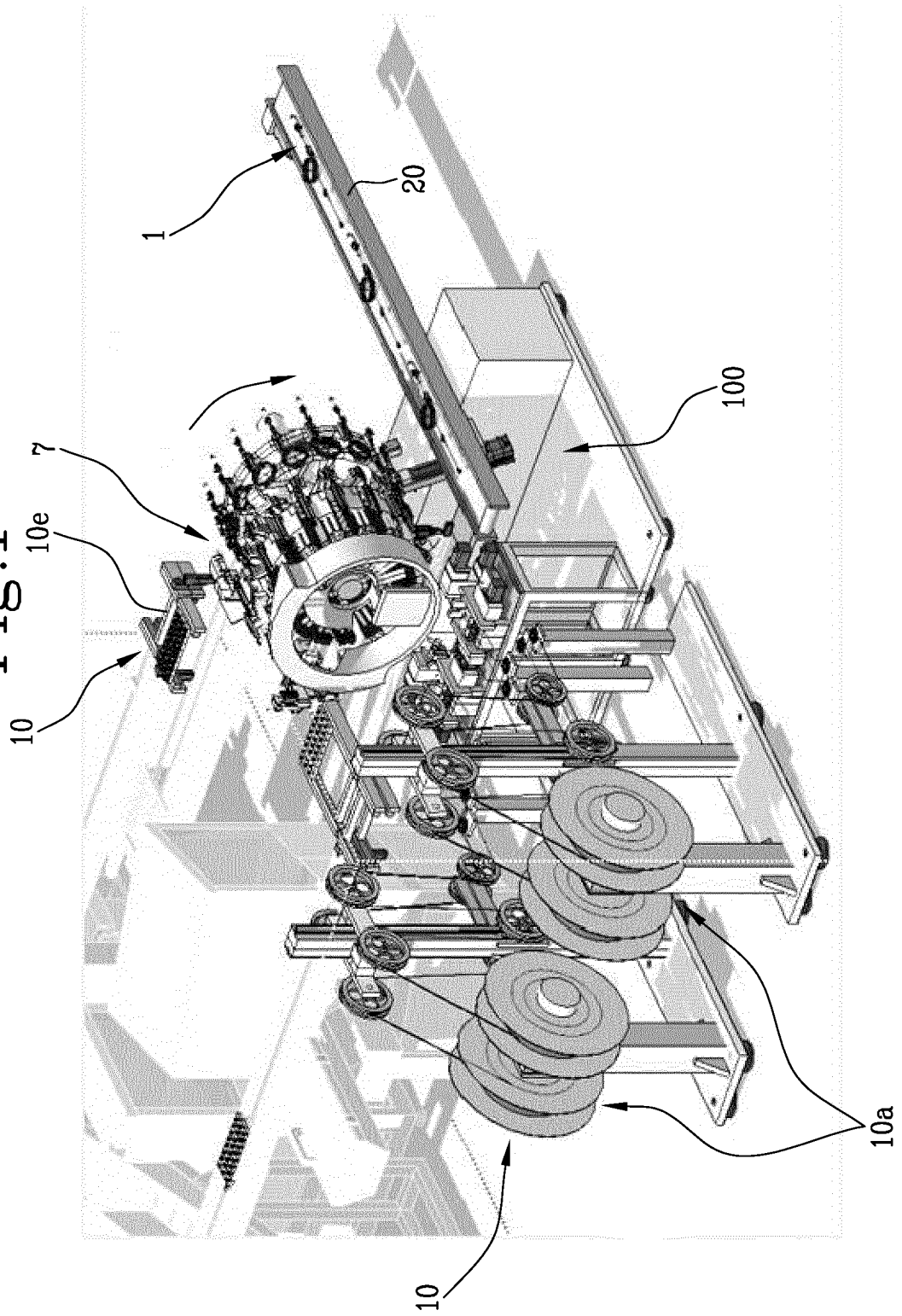




Fig. 2

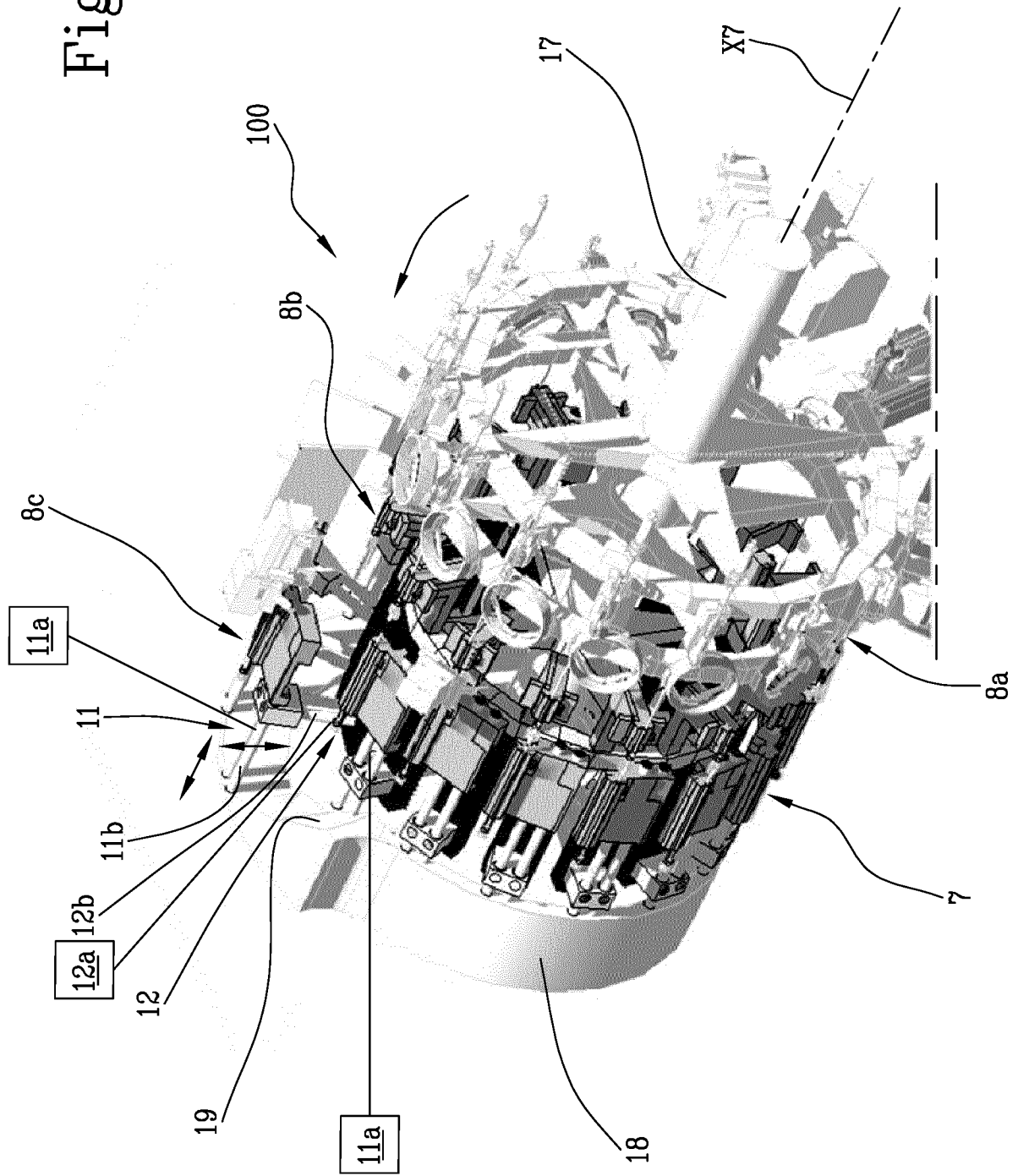


Fig. 3

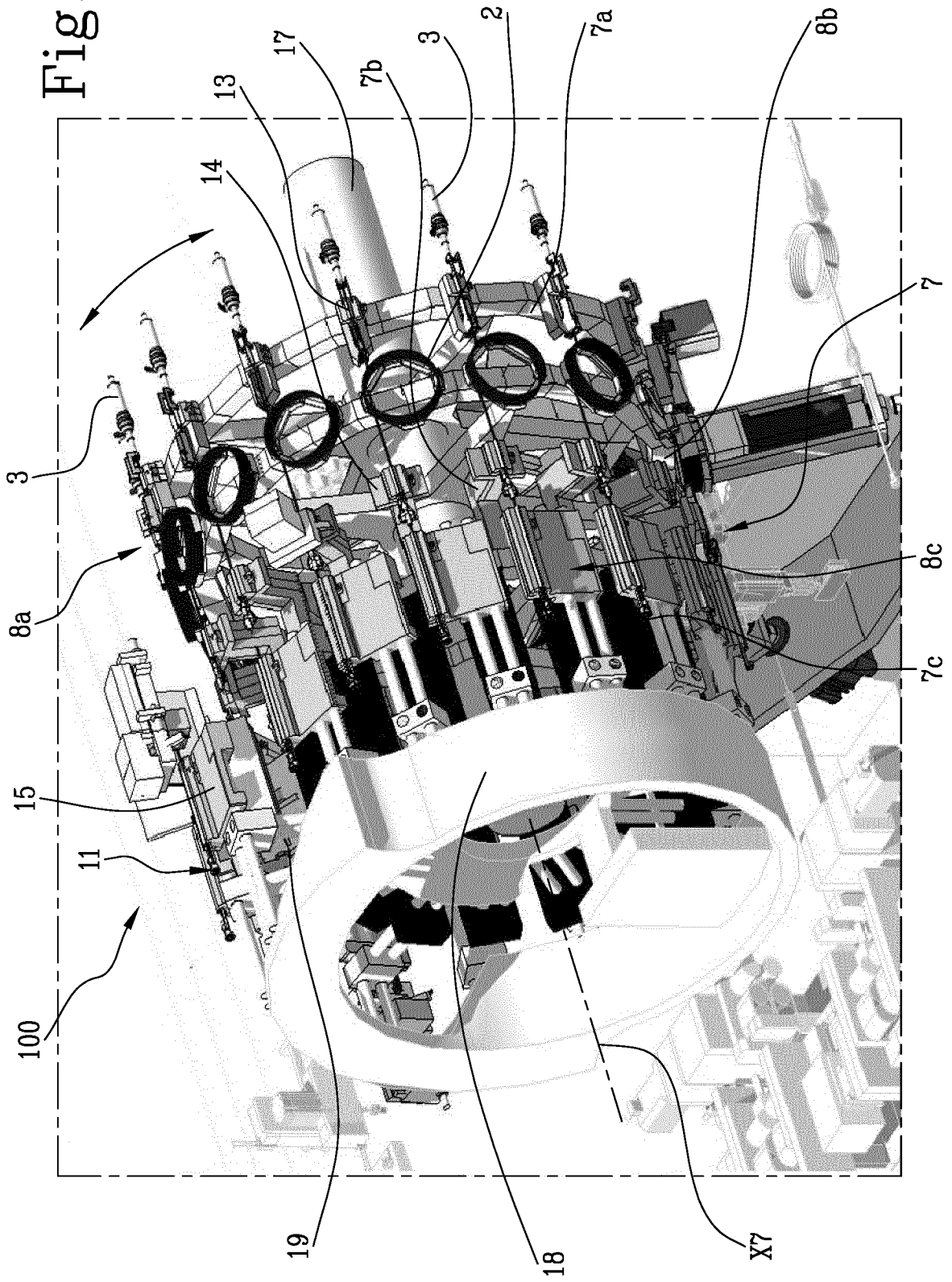


Fig.4

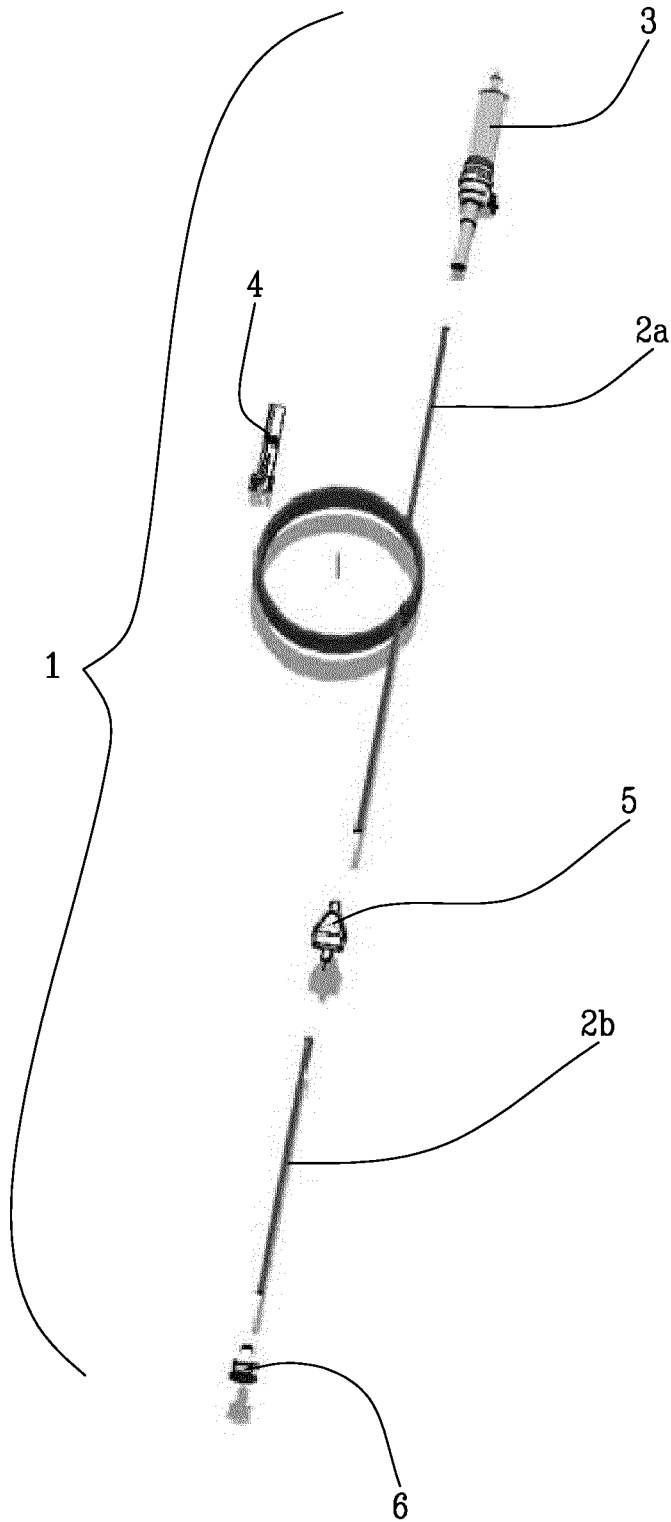


Fig.5

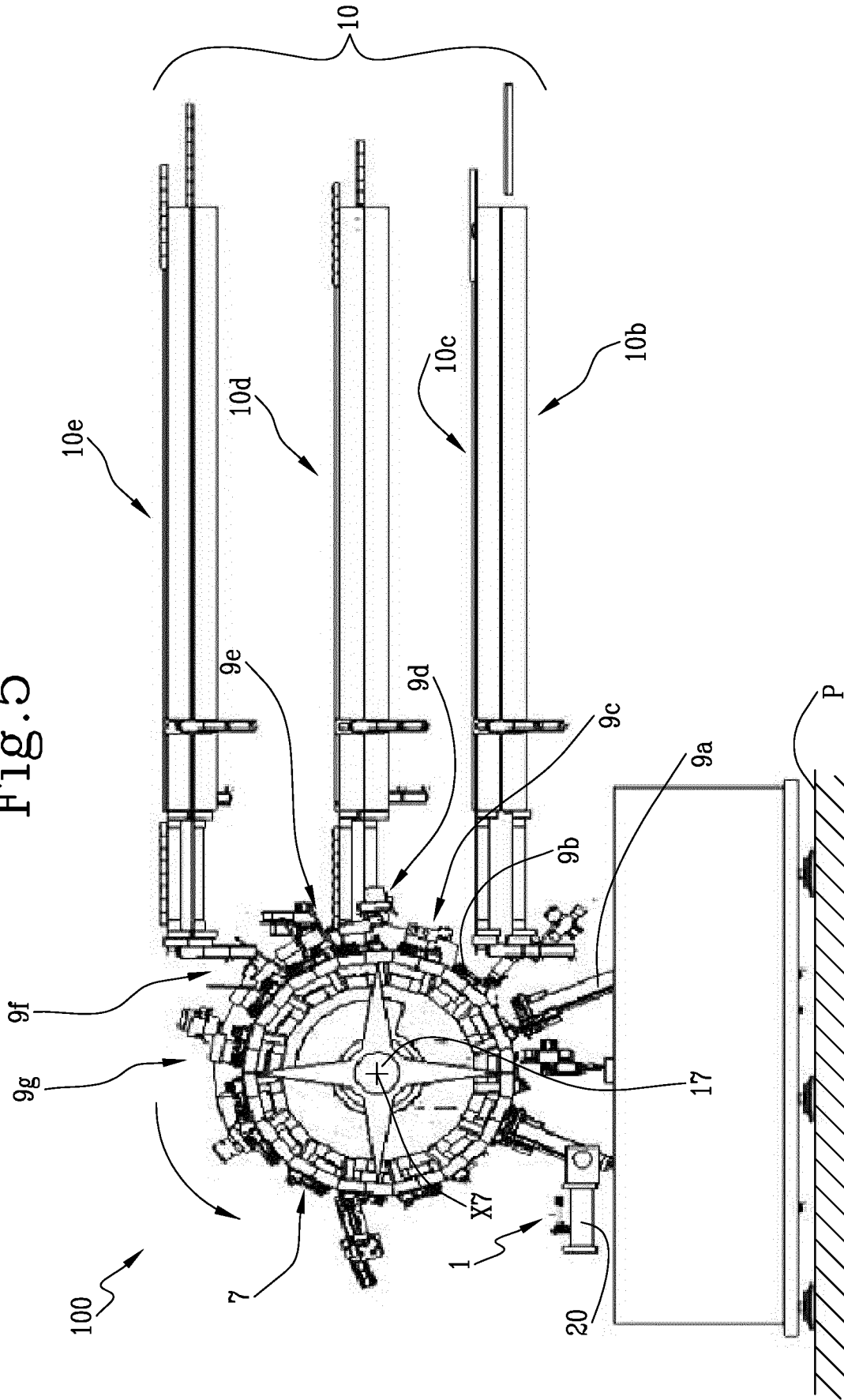
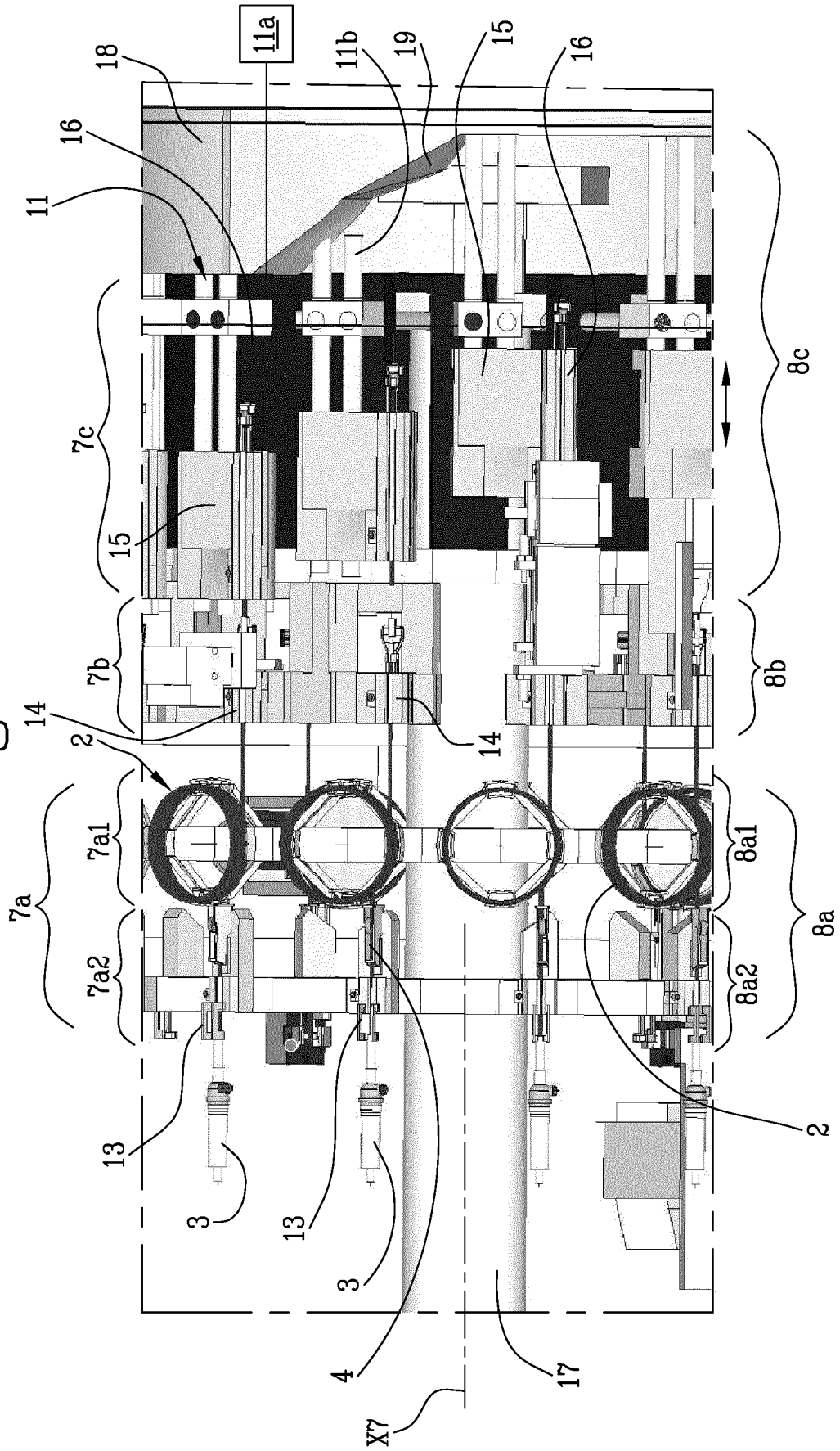


Fig. 6



INTERNATIONAL SEARCH REPORT

International application No  
PCT/EP2018/077581

A. CLASSIFICATION OF SUBJECT MATTER  
INV. B23P21/00 A61M25/00  
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)  
B23P A61M

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.
A	DATABASE WPI Week 201677 Thomson Scientific, London, GB; AN 2016-705990 XP002782033, -& CN 106 064 306 A (LIANG Q) 2 November 2016 (2016-11-02) abstract; figures -----	1-10
A	DATABASE WPI Week 201677 Thomson Scientific, London, GB; AN 2016-683814 XP002782034, -& CN 106 039 542 A (LIANG Q) 26 October 2016 (2016-10-26) abstract; figures ----- -/--	1-10

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See patent family annex.

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Date of the actual completion of the international search  6 March 2019	Date of mailing of the international search report  15/03/2019
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  Plastiras, Dimitrios

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International application No  
PCT/EP2018/077581

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