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(54) Title: MANUFACTURING METHOD AND PRODUCT

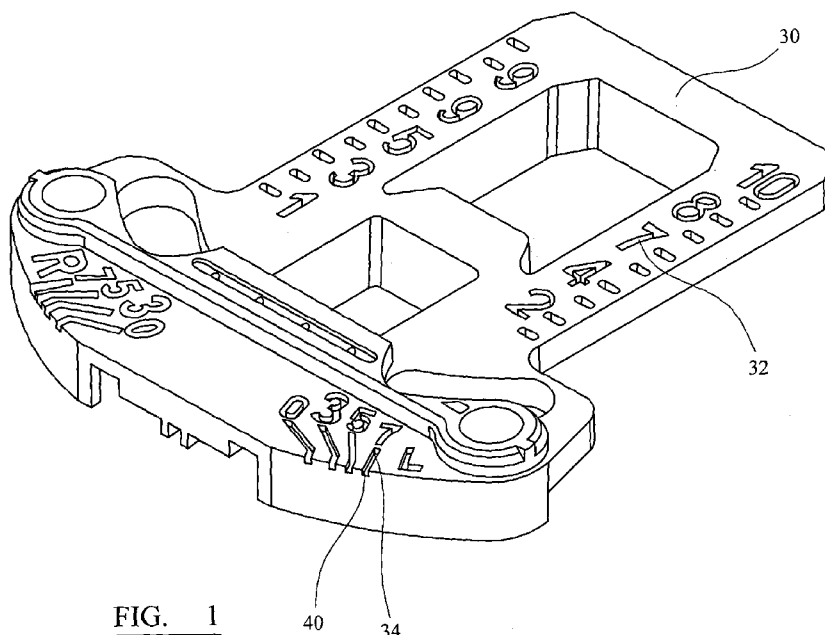


FIG. 1

(57) Abstract: A method of manufacturing a surgical instrument or prosthesis and an injection moulded surgical instrument or prosthesis are described. A first material is injected into a first mould to form an interim component. A second material is injected into a second mould containing at least part of the interim component to form the surgical instrument or prosthesis such that portions of the first and second materials are exposed at the external surface of the surgical instrument or prosthesis. The first and second materials are visually distinct such that at least one exposed portion of the first or second material adjacent to an exposed portion of the other material forms a marking which is visible to a user.

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Manufacturing Method and Product

The present invention relates to a manufacturing method and a product produced by the manufacturing method. In particular, the present invention relates to methods of making
5 surgical instruments and prostheses.

Surgical instruments and prostheses are typically formed from a relatively small number of materials, which are selected for their properties, including biocompatibility, strength and resilience. Typical materials include metals such as stainless steel and plastics. The
10 chosen materials, and the methods by which the instruments are formed, vary according to the particular function of the instrument or prosthesis.

It is a common requirement of surgical instruments and prostheses that they are provided with markings to aid their use by surgeons. Markings may include gauge lines, numerals,
15 letters or any other form of symbol. For components formed from plastic it is known to form markings by applying dyes or paints to the surface of the instrument, or into recesses within the surface. Alternatively, markings may be etched onto the instrument. Such additional processing steps increase the cost of manufacturing surgical instruments. Additionally, the markings produced may be prone to damage during cleaning, which may
20 make the instrument or prosthesis hard to clean.

It is an object of embodiments of the present invention to obviate or mitigate one or more of the problems associated with the prior art, whether identified herein or elsewhere.

25 According to a first aspect of the present invention there is provided a method of manufacturing a surgical instrument or prosthesis comprising: injecting a first material into a first mould to form an interim component; and injecting a second material into a second mould containing at least part of the interim component to form the surgical instrument or prosthesis such that portions of the first and second materials are exposed at the external
30 surface of the surgical instrument or prosthesis; wherein the first and second materials are visually distinct such that at least one exposed portion of the first or second material

adjacent to an exposed portion of the other material forms a marking which is visible to a user.

5 An advantage of the first aspect of the present invention is that markings may be produced on a surface of a surgical instrument or prosthesis that are relatively resilient to damage caused when cleaning the instrument or prosthesis. This is because the markings are formed from a similar plastic to the remainder of the instrument and so form an integral part of the instrument, in contrast to markings applied to the surface of an instrument using a dye or paint, which may be erased during cleaning. As the plastics used are visually
10 distinct, for instance different colours, the markings may be highly visible to a surgeon.

In the step of injecting a second material into a second mould the second material may partially or fully surround at least one portion of the interim component such that the first material in that portion forms a marking.

15

In the step of injecting a second material into a second mould the second material may be deposited upon a selected portion of the surface of the interim component such that the second material in that portion forms a marking.

20 The interim component may incorporate at least one aperture extending through a portion of the interim component, and wherein said step of injecting the second material comprises the second material flowing through the aperture to the selected portion of the surface of the interim component.

25 The interim component may comprise at least one channel arranged to direct the flow of the second material during the step of injecting the second material, the at least one channel communicating with the at least one aperture.

The selected portion of the surface of the interim component may comprise a recess
30 arranged to receive the second material to form the marking.

The recess may further comprise at least one blind hole spaced apart from the surface of the interim component surrounding the recess, the blind hole being arranged to receive gas within the recess during the step of injecting a second material into a second mould.

- 5 The selected portion of the surface of the interim component may be on an exterior surface of the interim component.

The second mould may be arranged to seal to the interim component surrounding the selected portion of the surface of the interim component to define the edge of the marking.

10

The first and second materials may be different colours.

The marking may be arranged to be recessed, flush or proud of the surrounding external surface of the surgical instrument or prosthesis.

15

The first and second materials may comprise plastics. The first and second plastics may have substantially similar structural properties. The first and second plastics may comprise the same plastic. At least one of the first and second plastics may further comprise at least one additive. The or each plastic may comprise a high or ultra high performance polymer, or silicone.

20

According to a second aspect of the present invention there is provided an injection moulded surgical instrument or prosthesis comprising: an injection moulded body having an external surface, said external surface comprising at least one exposed first portion formed from a first material in a first injection moulding step and at least one exposed second portion formed from a second material in a second injection moulding step; wherein the first and second materials are visually distinct such that at least one of said first and second portions forms a marking which is visible to a user.

25

- 30 The present invention will now be described, by way of example only, with reference to the accompanying figures, in which:

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Figure 1 is a perspective view of part of an interim component formed using a manufacturing method in accordance with an embodiment of the present invention;

Figure 2 is a top view of the interim component of figure 1;

5

Figure 3 is a bottom view of the interim component of figure 1;

Figure 4 is a cross sectional view of the interim component of figure 2 along the line 4:4 in the direction of the arrows;

10

Figure 5 is a cross sectional view of the interim component of figure 2 along the line 5:5 in the direction of the arrows;

Figure 6 is an enlargement of region 6 of figure 5;

15

Figure 7 is an enlargement of region 7 of figure 4;

Figure 8 is an enlargement of region 8 of figure 4;

20 Figure 9 is an enlarged view of some of the markings shown in figure 2;

Figure 10 is a view of part of the top of a surgical instrument formed from the interim component of figure 1; and

25 Figure 11 is a view of part of the bottom of a surgical instrument formed from the interim component of figure 1.

It is known to manufacture products, including surgical instruments and prostheses, through injection moulding. A material such as thermoplastic or thermosetting plastic is
30 heated and mixed to ensure a uniform consistency. The molten material is forced under pressure into a mould cavity where it cools and hardens. The amount of material required to fill the cavities of the mould is called a shot.

It is known to use injection moulding to apply a layer of a plastic material over part or the whole of an existing interim component. This technique may be referred to as over-moulding or two shot moulding. One known application of this is to couple together two different forms of plastic having different material properties. For example, a toothbrush may comprise a first, stiff plastic forming the body of a handle, and a second, softer plastic forming a hand grip. Two shot moulding is also known for coating other materials such as metals with plastic, and for joining together two separate components.

10 In accordance with an embodiment of the present invention, a two shot injection moulding process can be used to generate markings on surgical instruments or prostheses which are visible to a user and resistant to damage during routine cleaning. In a first injection moulding step an interim component comprising the body of the instrument or prosthesis is formed. In a second injection moulding step, part or the whole of the interim component is

15 inserted into a second mould which seals to the interim component and defines regions on the surface of the interim component where marks such as symbols and lines are to be formed. A plastic material which is visually distinct from the plastic material used in the first injection moulding step is injected into the mould in the region of the markings.

20 It may be that exactly the same plastic is used in the first and second injection moulding steps, albeit treated in some way to be visually distinct, for instance by being a different colour. However, it may be that different, though similar, plastics are used. In certain applications, dissimilar plastics may be used, though typically the same or similar plastics will be required for functional reasons associated with the use of the instrument or

25 prosthesis. By “similar” it is intended that the plastics used in each injection moulding step are generally the same, with similar chemical, structural or function properties. In particular embodiments of the present invention, where different but similar plastics are used, each plastic may be within the group of plastics known in the plastics industry as “high performance polymers” and “ultra high performance polymers” as these generally

30 have high resistance to chemicals, moisture and temperature as well as high stiffness. Alternatively, types of silicone may be used. One option for using two shot moulding to form markings is to form the body of the instrument or prosthesis from a glass filled plastic

and the marking from the same plastic, without glass fill. Alternatively, the plastics may be substantially the same as one another, differing only in the particular dye which is incorporated into the plastic mix.

- 5 The regions where markings are to be formed upon the surface of the interim component may be selected portions of a flat surface of the interim component. The shape and size of the region (including the height of the marking above the surrounding surface of the interim component) may be defined by the shape of the mould and how it seals to the interim component. Alternatively, the marking regions may be partly or fully defined by
- 10 recesses in the surface of the interim component. Where recesses are used, the mould may seal to the interim component such that the second plastic material is recessed relative to the surrounding surface of the interim component. Alternatively, the markings may be flush with the surrounding surface or stand proud of the surrounding surface.
- 15 In order to ensure that the second plastic material can pass to the required regions on the surface of the interim component, one or more channel may be defined within the interim component leading to the marking regions. For instance, where a marking is to be formed on a first surface, a channel may be formed on a reverse surface of the interim component, passing underneath the marking region. A fill hole may connect the channel to the
- 20 marking region such that injected plastic supplied to the channel can pass through the fill hole to the marking region. Advantageously, a single channel may be provided with multiple fill holes coupling to respective marking regions such that a single injection port in the second injection moulding step can be used to form multiple markings.
- 25 Referring now to figure 1, this illustrates a perspective view of an interim component part way through a manufacturing process in accordance with an embodiment of the invention. The interim component comprises an injection moulding plastic component that is intended to be over-moulded to form a surgical instrument or prostheses. It can be seen that the interim component of figure 1 comprises a single body 30 which may generally
- 30 comprise the majority of the structure of the surgical instrument (or at least that part of the whole surgical instrument formed through injection moulding). Set into the surface of the body 30 are a series of recesses, for instance recess 32. It can be seen that some of the

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recesses 32 form numbers and letters, and some form lines and other shapes. The recesses 32 define regions on the surface of body 30 where markings are to be formed.

At the base of each recess 32 is at least one fill hole 34. It will be appreciated that fill
5 holes 34 are only visible in certain of the recesses 32 in the view of figure 1 owing to the perspective view of the interim component. Additionally, some or all of the recesses 32 may comprises blind holes 40. Fill holes 32 extend fully through the interim component 30. The blind holes 40 are closed at one end and from smaller recesses at the base of the marking recesses 32. One fill hole 32 and one blind hole 40 are identified in figure 1. It
10 will be appreciated that in the perspective view of figure 1 and the plane view of figure 2 the fill holes 32 and the blind holes 40 are hard to distinguish. The difference between the fill holes 32 and the blind holes 40 can be more clearly seen in the cross sectional views of figures 4 to 8 described below.

15 Referring also to the top view of the interim component in figure 2, it can be seen that each recess 32 connects with at least one fill hole 34. Referring to figure 3, this is a bottom view of the interim component 30 of figure 1. The base of the interim component 30 defines a number of channels 36 which each extend from the exterior edge 38 of the interim component to a group of fill holes 34. In alternative embodiments of the present
20 invention a channel 36 could connect with only a single fill hole. Each channel 36 is open on one face (which will be closed off by the side of the second mould during the second injection moulding step) and is of sufficient depth to allow plastic to flow through to each fill hole 34, and hence to each recess 32.

25 Figures 4 and 5, together with the enlargements of figures 6 and 7, illustrate cross sectional views of the interim component. It can be seen particularly in the enlargement of figure 7 that the channels 36 extend through a significant depth of the body 30, and the fill holes 34 are narrower and shallower than the channels 36 before opening out into the recesses 32. Figure 7 illustrates in an enlarged view a portion of the cross section of figure 4 in which
30 the relative dimensions of the channel 36, the fill hole 34 recess marking 32 can be clearly seen. Figure 6 illustrates in an enlarged view a portion of the cross section of figure 5 showing part of a channel 36 passing through a region of the interim component 30 which

does not include any marking recesses 32. It will be understood that the channels 36 must extend from an exterior edge 38 of the interim component 30 to wherever markings are required. Figure 3 illustrates that multiple channels 36 may be required to supply plastic to all of the marking recesses 32 in the second injection moulding step. In alternative
5 embodiments of the present invention, the mould for the second injection moulding step may be arranged to supply plastic directly to a face of the interim component 30 and so it may not be necessary to have the channels extending all of the way to the edge 38 of the interim component 30.

10 Referring now to figure 8, this illustrates an enlarged portion of the cross section of figure 4 allowing a pair of blind holes 40 to be seen adjacent to a fill hole 34. During the second injection moulding step air within the recesses 32 is generally driven out between the surface of the mould and the interim component 30. However, if air is trapped this could prevent a recess 32 from being correctly filled with the second plastic. This could prevent
15 a continuous surface formed from the second plastic being formed for that particular marking in the finished surgical instrument or prosthesis. A blind hole 40 accommodates the trapped air and allows the second plastic to fully flow throughout the recess 32. It will be appreciated that blind holes 40 may not be required for all recesses 32, particularly small recesses or large recesses with separate air escape channels. Referring to figure 9,
20 this illustrates an enlarged portion of the top view of the interim component of figure 2. Five recesses 32 are illustrated, including two numerals and three dashes. Each recess includes at least one fill hole 34 and at least one blind hole 40. It has been found that blind holes 40 are particularly useful in the case of recesses 32 having two fill holes 34 filling the recess from either end (for example, numeral "3") or where the recess 32 is elongated
25 and is filled by a fill hole 32 towards one end (for example, numeral "1").

Referring to figures 10 and 11 this respectively illustrate portions of a top surface and a bottom surface of a surgical instrument formed in accordance with an embodiment of the present invention using the interim component 30 of figure 1 in a second injection
30 moulding step. In figure 10 markings 42 are visible, including two numerals and dashes. It can be seen that a first marking (numeral "5") is flush with the surrounding instrument. Specifically, the first marking was formed by injecting the second plastic through a fill

hole into a recess that was sealed flush to the surrounding first plastic by the second mould having a flat portion. A second marking (numeral "3") stands proud with the surrounding instrument as the mould in the second injection moulding step was sealed to the surrounding first plastic, and the second mould includes a recess having the shape of the numeral. In figure 11 two filled channels 44 are visible where the second plastic material has been injected into a portion of the second mould along an edge 38 of the mould such that the second plastic flows to portions of the channel 36 where fill holes 34 are provided. For comparison, one channel 36 is shown unfilled with the second plastic material.

10 The visual quality of the markings on a completed surgical instrument or prosthesis are affected by a ranged of factors. These include the particular materials used, the width and depth of the markings (that is, the recesses and / or the portion of the marking protruding from the surrounding plastic), the dimensions, positions and number of the fill holes, the dimensions of the channels, the dimensions, positions and number of the blind holes and
15 the wall thickness and accuracy of the interim component formed in the first injection moulding step.

As an example of suitable plastics, Avaspire (RTM) AV 651 GF30 BK95 may be used in the first injection moulding step to form the interim component. This is

20 Polyaryletherketone reinforced with 30% glass fibre manufactured by Solvay Advanced Polymers and coloured black. Avaspire (RTM) AV 651 GF30 BG20 may be used in the second injection moulding step to form the markings. This is generally the same as the first plastic except coloured beige.

25 It has been found that good quality markings can be formed if they have a minimum width of no less than 0.25mm, for instance approximately 0.43mm. Similarly, it has been found that a suitable maximum marking width is no more than 2mm, for instance approximately 1mm. It has been found that good quality markings can be formed if they have a minimum depth of no less than 0.1mm, for instance approximately 0.24mm.

30

It has been found that to ensure adequate flow of plastic to the markings the fill holes should have a maximum ratio of diameter to length of 2, for example a diameter of 0.5mm

and a length of 0.25mm. The maximum diameter of the fill hole is limited by the shape and size of the recess to be filled in the second injection moulding step. However, it is desirable to ensure that within the recess the fill hole is spaced apart from the sides of the recess to ensure good mechanical retention of the material injected in the second injection moulding step. The fill holes may have a minimum diameter of no less than 0.25mm, for example approximately 0.3mm. The fill holes may have a maximum diameter of no more than 0.75mm, for instance approximately 0.530mm. The fill holes may have a minimum length of no less than 0.25mm, for instance approximately 0.35mm. The fill holes may have a maximum length of no more than 2mm, for instance approximately 1.0mm. It will be appreciated that the dimensions, number and positions of the fill holes are largely dependent upon the shape of the marking to be formed and the volume of material required to form the markings, in combination with the parameters of the second injection moulding step, including the injection pressure.

In an alternative embodiment, it may be that the interim component formed from the first plastic includes at least one marking and the second injection moulding step is arranged to form the external structure of the instrument or prosthesis surrounding the marking and leaving the marking uncovered. The second plastic may be arranged to partially or fully surround the marking. Markings may also be formed from portions of both the first and second plastics which are exposed at the external surface of the instrument or prosthesis and visible relative to the surrounding second or first plastic respectively.

While the embodiment of the present invention described above relates to a surgical instrument and a method of manufacturing such an instrument, the invention defined by the claims is not limited to this. The same manufacturing technique may also be applied to manufacturing surgical prostheses. In particular, the manufacturing technique described above is generally applicable wherever there is a need to apply robust markings to plastic surgical instruments or prostheses.

Other applications of, and modifications to, the present invention will be readily apparent to the appropriately skilled person from the teaching herein, without departing from the scope of the appended claims.

CLAIMS:

1. A method of manufacturing a surgical instrument or prosthesis comprising:
injecting a first material into a first mould to form an interim component; and
5 injecting a second material into a second mould containing at least part of the
interim component to form the surgical instrument or prosthesis such that portions of the
first and second materials are exposed at the external surface of the surgical instrument or
prosthesis;
wherein the first and second materials are visually distinct such that at least one
10 exposed portion of the first or second material adjacent to an exposed portion of the other
material forms a marking which is visible to a user.
2. A method according to claim 1, wherein in the step of injecting a second material
into a second mould the second material partially or fully surrounds at least one portion of
15 the interim component such that the first material in that portion forms a marking.
3. A method according to claim 1, wherein in the step of injecting a second material
into a second mould the second material is deposited upon a selected portion of the surface
of the interim component such that the second material in that portion forms a marking.
20
4. A method according to claim 3, wherein the interim component incorporates at
least one aperture extending through a portion of the interim component, and wherein said
step of injecting the second material comprises the second material flowing through the
aperture to the selected portion of the surface of the interim component.
25
5. A method according to claim 4, wherein the interim component comprises at least
one channel arranged to direct the flow of the second material during the step of injecting
the second material, the at least one channel communicating with the at least one aperture.
- 30 6. A method according to any one of claims 3 to 5, wherein the selected portion of
the surface of the interim component comprises a recess arranged to receive the second
material to form the marking.

7. A method according to claim 6, wherein the recess further comprises at least one blind hole spaced apart from the surface of the interim component surrounding the recess, the blind hole being arranged to receive gas within the recess during the step of injecting a
5 second material into a second mould.
8. A method according to any one of claims 3 to 7, wherein the selected portion of the surface of the interim component is on an exterior surface of the interim component.
- 10 9. A method according to any one of claims 3 to 8, wherein the second mould is arranged to seal to the interim component surrounding the selected portion of the surface of the interim component to define the edge of the marking.
10. A method according to any one of the preceding claims, wherein the first and
15 second materials are different colours.
11. A method according to any one of the preceding claims, wherein the marking is arranged to be recessed, flush or proud of the surrounding external surface of the surgical instrument or prosthesis.
20
12. A method according to any one of the preceding claims, wherein the first and second materials comprise plastics.
13. A method according to claim 12, wherein the first and second plastics comprise
25 the same plastic.
14. A method according to claim 13, wherein the first and second plastics comprise the same plastic.
- 30 15. A method according to claim 14, wherein at least one of the first and second plastics further comprise at least one additive.

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16. A method according to any one of claims 12 to 15, wherein the or each plastic comprises a high or ultra high performance polymer, or silicone.

17. An injection moulded surgical instrument or prosthesis comprising:

5 an injection moulded body having an external surface, said external surface comprising at least one exposed first portion formed from a first material in a first injection moulding step and at least one exposed second portion formed from a second material in a second injection moulding step;

10 wherein the first and second materials are visually distinct such that at least one of said first and second portions forms a marking which is visible to a user.

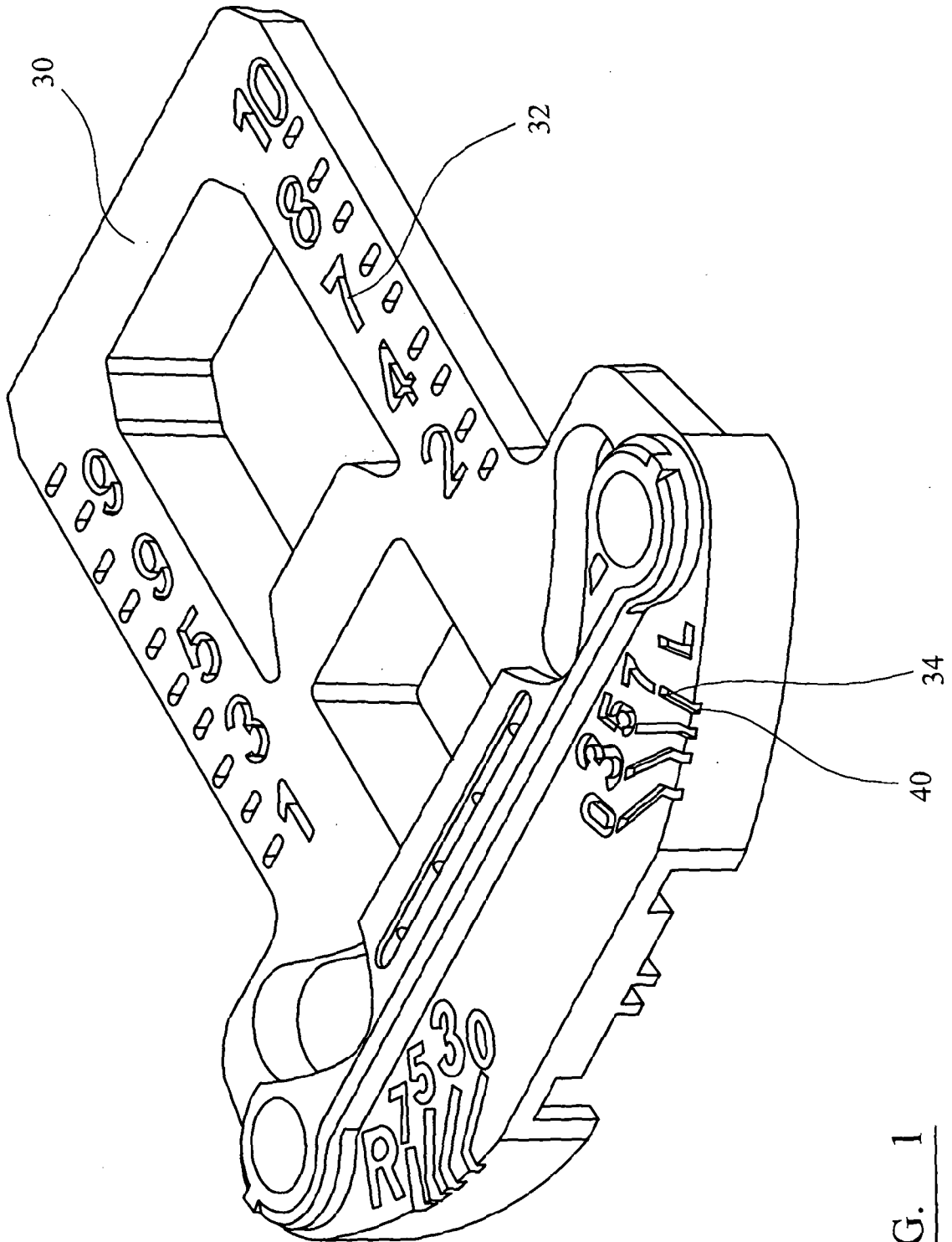


FIG. 1

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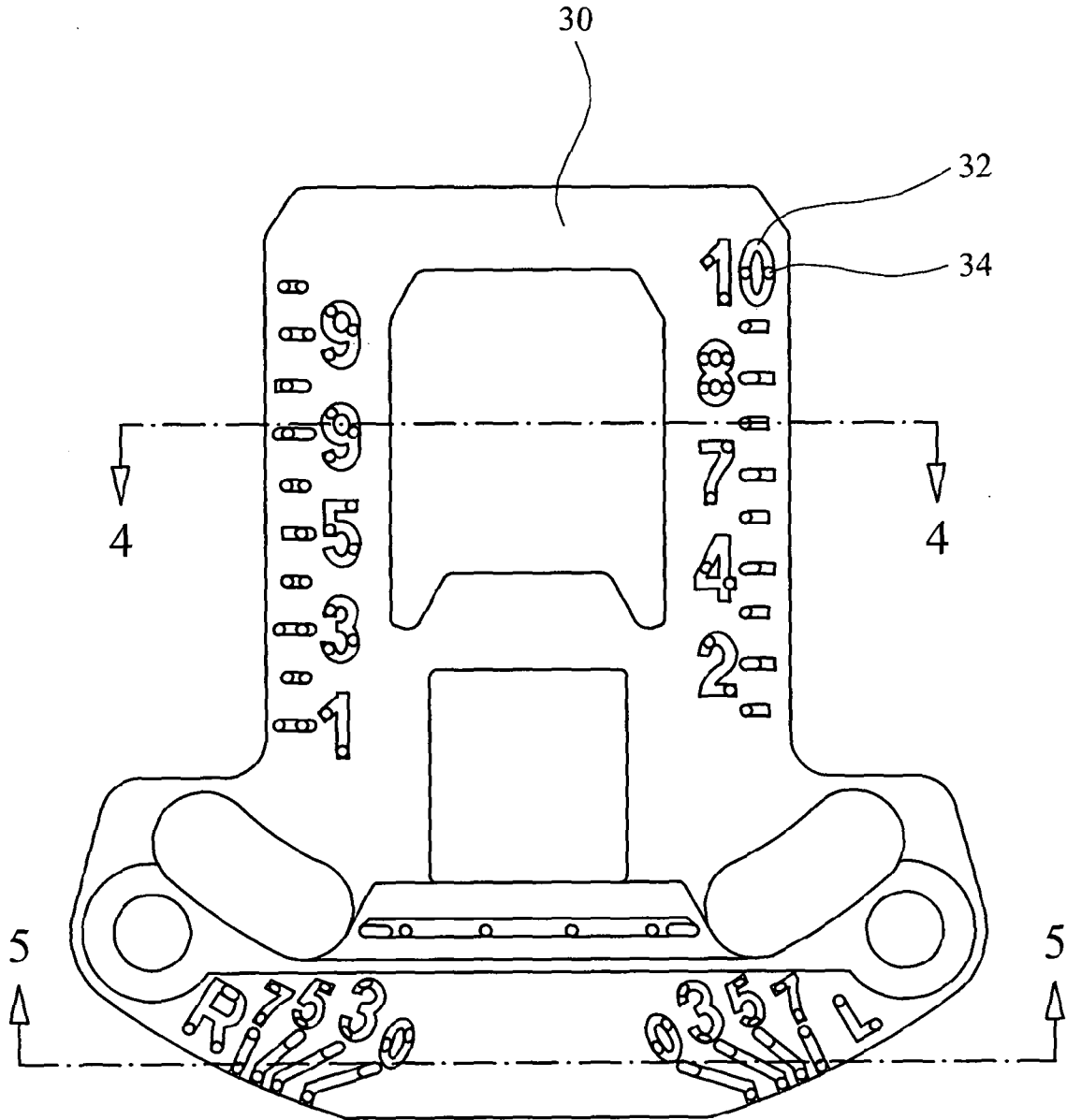


FIG. 2

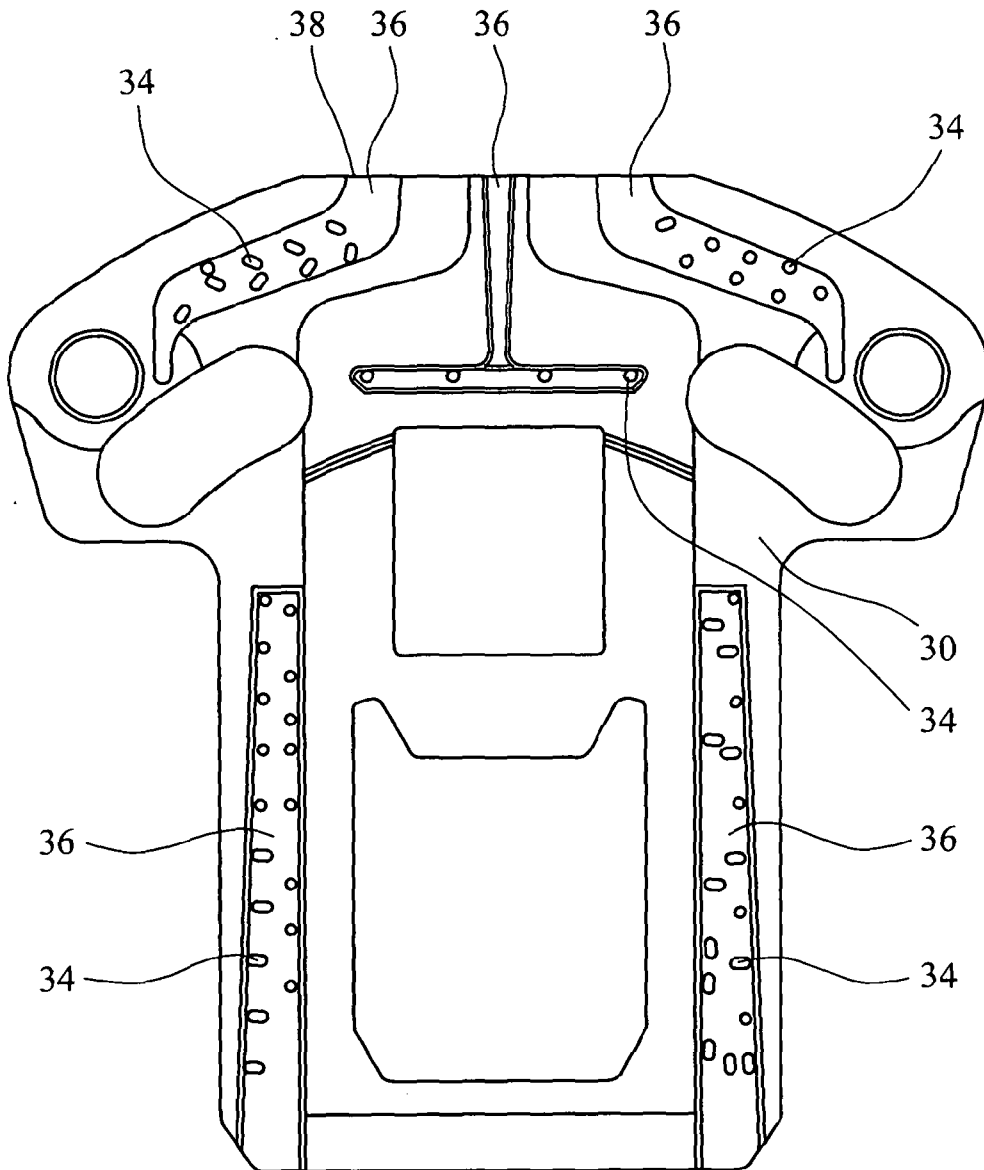


FIG. 3

-4/5-

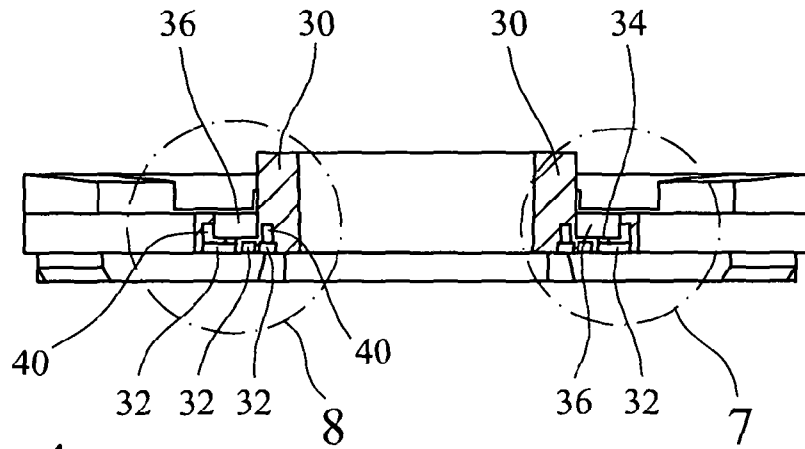


FIG. 4

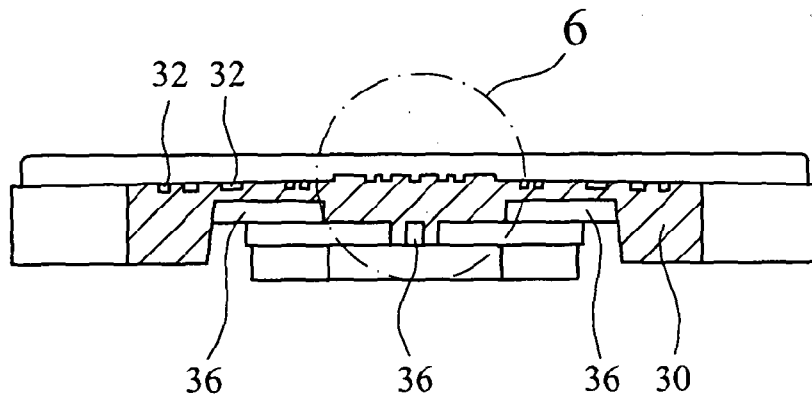


FIG. 5

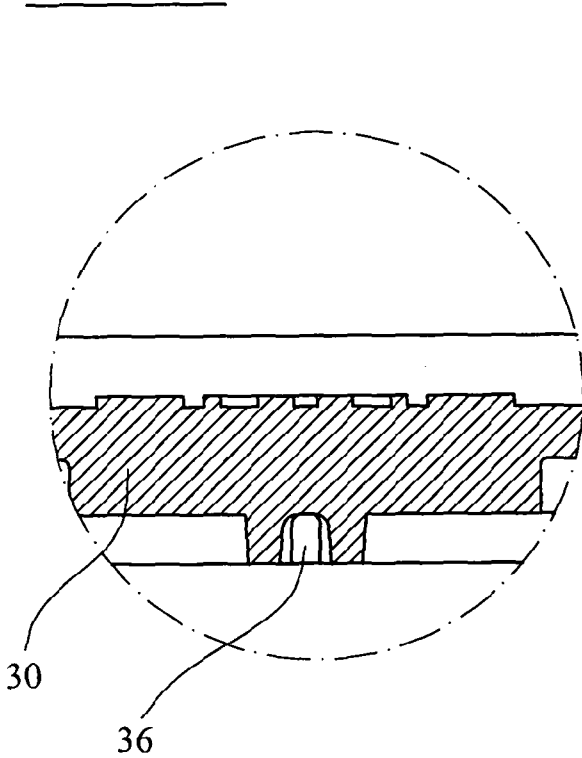


FIG. 6

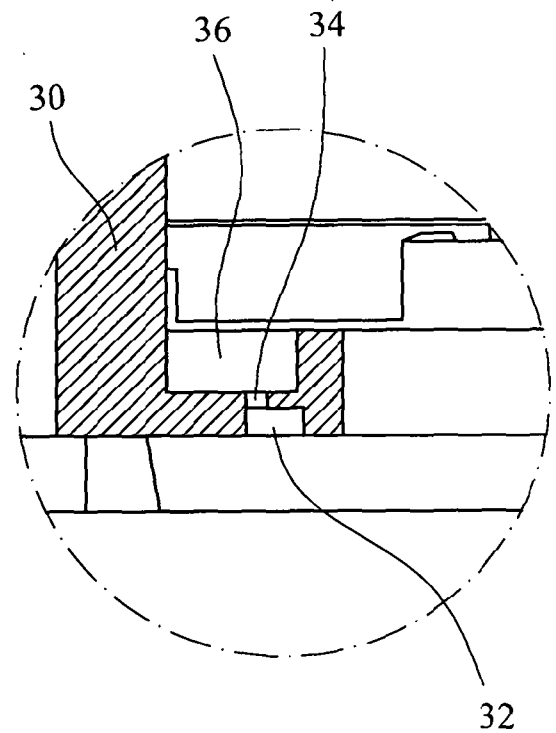


FIG. 7

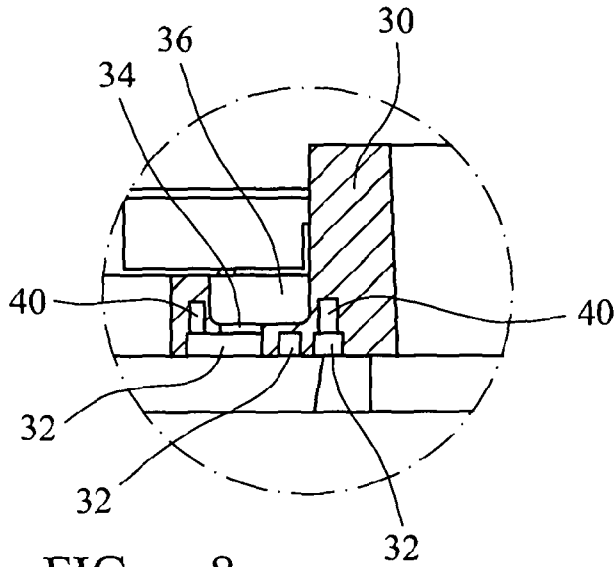


FIG. 8

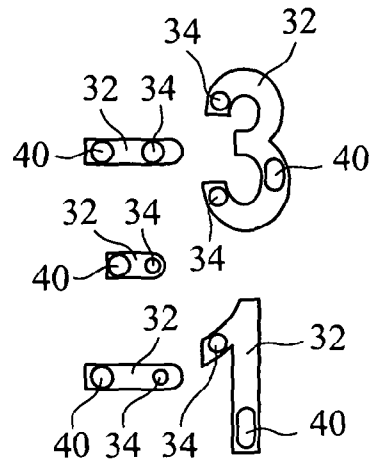


FIG. 9

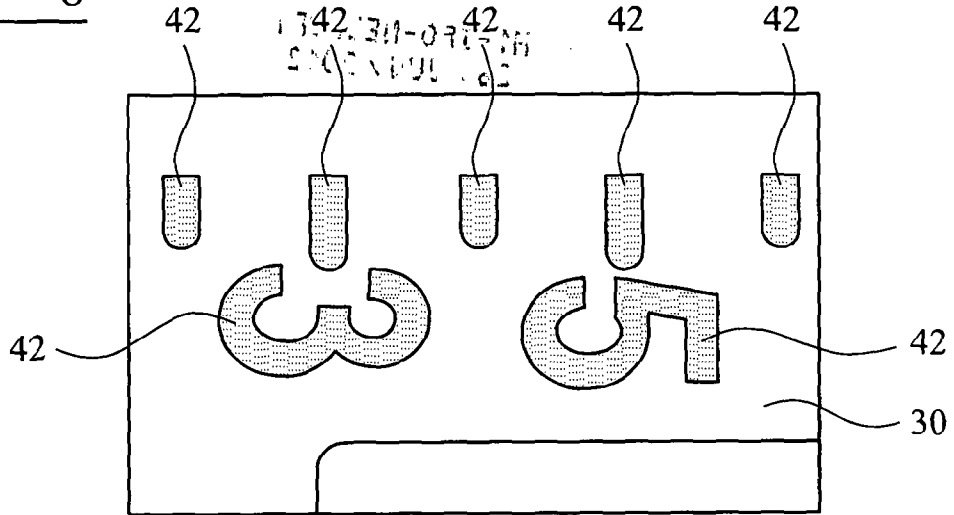


FIG. 10

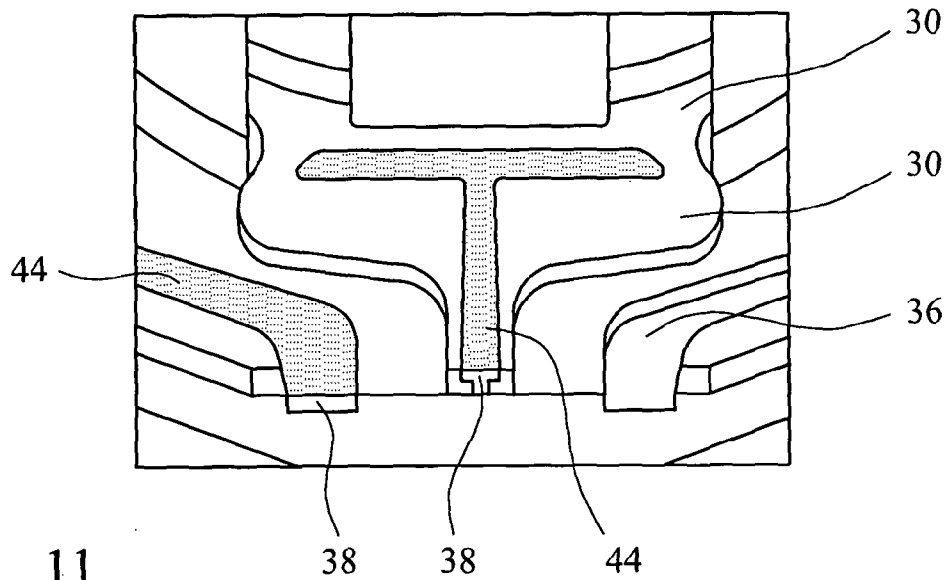


FIG. 11

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2012/051061

A. CLASSIFICATION OF SUBJECT MATTER
INV. B29C45/16
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)
B29L B29C

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 2010/180400 A1 (PELL RANDOLPH W [US]) 22 July 2010 (2010-07-22)	1,2, 10-12, 16,17
Y	paragraph [0017] - paragraph [0018] -----	3-9
Y	GB 2 110 586 A (FATTORINI THOMAS) 22 June 1983 (1983-06-22) page 1, line 93 - page 2, line 41; figures -----	3-9
Y	WO 97/34740 A1 (SANDVIK AB [SE]; JANSSON CONNY [SE]; HIMBERT HANS [SE]; BERGKVIST HAAK) 25 September 1997 (1997-09-25) page 2, lines 16-24; figures -----	3-6,8,9
Y	JP 58 076243 A (TOYODA GOSEI KK) 9 May 1983 (1983-05-09) abstract; figures -----	3-6,8,9
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Further documents are listed in the continuation of Box C.

See patent family annex.

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