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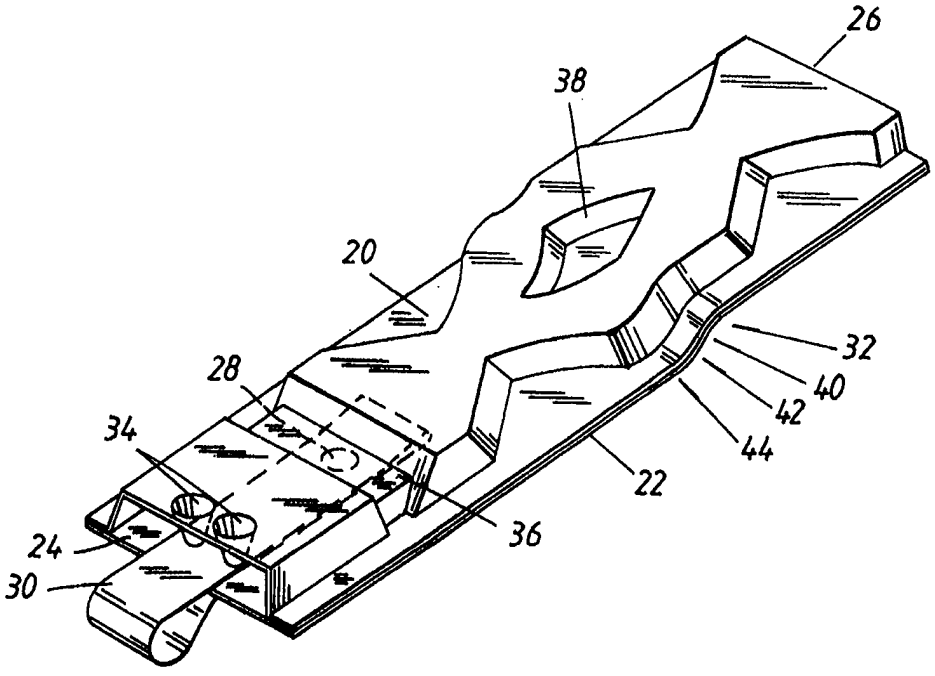
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(54) Title: SINGLE DOSE INHALER II




(57) Abstract

A generally flat elongated inhaler having a bend in its body at a predetermined distance from the outlet so as to ensure that the outlet is inserted sufficiently far into the mouth of the user and a method of ensuring that such an inhaler is inserted sufficiently far into the mouth of a user by providing a bend in the body.

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# SINGLE DOSE INHALER II

The present invention relates to a disposable inhaler, particularly for administering powder by inhalation.

Previously, as described in WO93/17728 and illustrated in Figures 1 to 3 of the accompanying drawings, there was known a disposable inhaler constructed from two parts 1 and 2. The lower part 2 includes a recesses 3 in which a dose of powder is stored and the two parts together define a channel through which a stream of air may be drawn by a user from an air inlet 4 to a mouthpiece 5. A tape 6 is provided to cover the recesses 3 and is additionally bent around the outside of the part 2 to cover an aperture 8 in the bottom of the recess 3. In use, the tape 6 is pulled away from the lower part 2 so as to expose both the aperture 8 and the recess 3. Projections 7 are provided to keep the loose tape out of the way of the air flow and a depression 9 directs the air flow to pick up the powder in the recess 3 more effectively. The channel defined by parts 1 and 2 also includes a deagglomeration section 10 having a section inlet 11, a section outlet 12 and a divider 13. The divider 13 splits the stream of air into two flow paths and powder is caused to impact on internal surfaces. In this way, powder is effectively deagglomerated.

In use, a patent inhales through the mouthpiece 5 causing an air stream to pick up the powder stored in recess 3. As the air/powder mixture flows through the inhaler, powder is deagglomerated, then passes out of the mouthpiece 5 and into the lungs of the patient.

An object of the present invention is to simplify use of the inhaler such that it is more difficult to use the inhaler incorrectly.

The present invention is based on a recognition that it is possible that a user will not insert an inhaler, such as illustrated in Figures 1 to 3, sufficiently far into his or her mouth. This is in contrast to many other types of inhaler where mouthpieces are provided to give the user an indication of how far the inhaler should be inserted to thereby prevent the inhaler being inserted too far. The present invention recognises that, with small flat inhalers of the type illustrated in Figures 1 to 3, it is important that the inhaler outlet passes beyond the tongue, whereas for other larger types of inhaler, when the mouth is opened sufficiently

wide to insert the inhaler, the tongue naturally moves out of the way of the flow of air from the inhaler to the lungs.

According to the present invention, there is provided a method of indicating to a user how far to insert into the mouth an inhaler having a body extending in a first direction between an air inlet and an air/powder outlet, the outer cross-section of the body at substantially every position along the length of the body being elongate in a second direction substantially perpendicular to said first direction, the method comprising displacing the body at a predetermined distance from the air/powder outlet in a third direction perpendicular to said first and second directions.

According to the present invention there is also provided an inhaler for administering powder by inhalation, the inhaler comprising:

a body extending in a first direction between an air inlet and an air/powder outlet, the outer cross-section of the body at substantially every position along the length of the body being elongate in a second direction substantially perpendicular to said first direction; wherein

at a predetermined distance from the air/powder outlet, the body is displaced in a third direction perpendicular to said first and second directions so as to provide a guide to the user as to how far the body should be inserted into the mouth of the user.

In this way, the overall construction, simplicity and effectiveness of the inhaler remains unchanged and yet it is immediately apparent to the user to what extent the inhaler should be inserted into his or her mouth. In particular, where the body of the inhaler is displaced downwardly, it will be immediately apparent to the user that the inhaler should be inserted in to his or her mouth until that downward displacement of the body lies immediately adjacent his or her lower lip.

In this way, it is ensured that the outlet of the inhaler is above the tongue, such that the air powder mixture will travel down into the lungs of the user, rather than be deposited on his or her tongue.

Preferably, the body is shaped such that a plane exists wholly within the body.

In this way, despite the displacement in the body, it is still possible to construct the body from two parts, each having respective portions lying in respect planes for joining together.

Preferably, at a second predetermined distance further than said first predetermined distance from the outlet, the body is bent in a direction opposite to said third direction.

In this way, the inhaler is formed with a gentle S-bend along its length and retains its generally flat planar elongate shape.

Although not directly relevant to the present invention, it should be noted that medicaments suitable for administration by an inhaler using the present invention are any which may be delivered by inhalation. Suitable inhalable medicaments may include for example β2-adrenoreceptor agonists for example salbutamol, terbutaline, rimiterol, fenoterol, reproterol, adrenaline, pirbuterol, isoprenaline, orciprenaline, bitolterol, salmeterol, formoterol, clenbuterol, procaterol, broxaterol, picumeterol, TA-2005, mabuterol and the like, and their pharmacologically acceptable esters and salts; anticholinergic bronchodilators for example ipratropium bromide and the like; glucocorticosteroids for example beclomethasone, fluticasone, budesonide, tipredane, dexamethasone, betamethasone, fluocinolone, triamcinolone acetonide, mometasone, and the like, and their pharmacologically acceptable esters and salts; anti-allergic medicaments for example sodium cromoglycate and nedocromil sodium; expectorants; mucolytics; antihistamines; cyclooxygenase inhibitors; leukotriene synthesis inhibitors; leukotriene antagonists, phospholipase-A2 (PLA2) inhibitors, platelet aggregating factor (PAF) antagonists and prophylactics of asthma; antiarrhythmic medicaments, tranquilisers, cardiac glycosides, hormones, antihypertensive medicaments, antidiabetic- antiparasitic- and anticancer-medicaments, sedatives and analgesic medicaments, antibiotics, antirheumatic medicaments, immunotherapies, antifungal and antihypotension medicaments, vaccines, antiviral medicaments, proteins, polypeptides and peptides for example peptide hormones and growth factors, polypeptides vaccines, enzymes, endorphines, lipoproteins and polypeptides involved in the blood coagulation cascade, vitamins and others, for example cell surface receptor blockers, antioxidants, free radical scavengers and organic salts of N,N'-diacetylcystine.

The present invention will be more clearly understood from the following description, given by way of example only, with reference to the accompanying drawings in which:

Figure 1 illustrates a previous inhaler;

Figure 2 illustrates the previous inhaler of Figure 1 separated into two parts;

Figures 3a, 3b and 3c illustrate a cross-section of the inhaler of Figure 1;

Figure 4 illustrates an inhaler similar to that of Figure 1 embodying the present invention;

Figure 5 illustrates an embodiment of the present invention;

Figure 6 illustrates an embodiment of the present invention; and

Figure 7 illustrates schematically a cross-section of an embodiment of the present invention.

The inhaler illustrated in Figure 4 is similar to that illustrated in Figure 1, but at a position upstream of the inhaler outlet, the inhaler body is displaced downwardly.

The inhaler is constructed from a first part 20 and a second part 22. The first part 20 and second part 22 are preferably moulded from a transparent plastics material such that the channels of the inhaler may be inspected before and after use. The first part 20 and second part 22 are joined together to form the inhaler illustrated in Figure 4.

The inhaler has an air inlet 24 and an outlet 26. Furthermore, like the inhaler of Figure 1, the second part 22 includes a depression 28 for containing a dose of medicament, preferably in powdered form.

A tape 30 is provided to seal the depression 28 and extends out of the air inlet 24.

In use, the tape 30 is pulled out of the air inlet 24 so as to peel it away from the depression 28 and expose the powder contained in that depression. The outlet 26 is then placed into the mouth of the patient and the patient inhales through the inhaler. When the patient inhales, air is drawn in through the air inlet 24 and picks up the powder from the depression 28. The air powder mixture is drawn through the inhaler through a deagglomeration section 32 and out of the outlet 26.

In order to prevent the loose tape 30 from impeding the air flow into the air inlet 24, projections 34 are provided to hold the loose tape close to the inner surface of the lower part 22.

As illustrated, a restriction 36 is provided in the inhalation channel at the position of the depression 28. This is to direct the air flow down towards the depression 28 so as to assist in ensuring that the powder in the depression 28 joins the air flow through the inhaler.

The deagglomeration section 32 is provided to break down any larger powder particles into their constituent fine powder particles. In particular, the deagglomeration section 32 is provided with a divider 38 which divides the air stream into two paths and causes powder carried by the air stream to impact with internal walls of the inhaler.

As illustrated, the inhaler of Figure 4 has a generally flat elongate form. This makes it easy to store and pleasing to patients. It may be constructed with a relatively small overall size which is advantageous to patients, particularly those who have to carry a number of such inhalers with them on a day to day basis. However, although the elongate cross-section and outlet are very pleasing and advantageous to the user, since they may very easily be inserted to the mouth, it is important that the outlet 26 of the inhaler extends beyond the tongue.

With an inhaler of this form, i.e. one which extends in a generally first direction between the air inlet 24 and the outlet 28 and has a generally flat construction such that it extends in an elongate manner in a direction perpendicular to the first direction, a patient does not open his or her mouth to any great extent, such that the tongue is not naturally moved down away from the flow of air between the mouth and the lungs. Thus, as illustrated in Figure 4, unlike previous inhalers of this general form, the inhaler is not completely flat along its length, but, at position 40, is deflected downwards, such that it is displaced in a third direction perpendicular to both the first and second directions. This deflection or displacement provides a downwardly extending wall 42, which, in use, may be pressed against the lower lip of the user. In this way, the user can assuredly insert the inhaler into his or her mouth by the correct amount. Indeed, because of the shape of the inhaler, it will feel strange to insert the inhaler by less than the correct amount.

Thus, in use, the inhaler will be inserted with the outlet 26 over and clear of the user's tongue, rather than a position where the user's tongue could still impede the flow of air/powder from the outlet 26 into his or her lungs.

Since it is desirable that the inhaler retains its generally flat form, at position 44, the inhaler is deflected back upwardly such that it is displaced or bent in a direction opposite to the third direction. In this way, the inhaler may have the required function and yet retain a pleasing gentle S-bend form.

Clearly, as described above, the present invention applies to any inhaler having the generally flat form described above, in particular inhalers where the portion to be inserted into the mouth is generally flat with a shallow elongate cross-section. It is not essential to the invention how medicament is stored or released into the inhalation channel of the inhaler, nor is it essential to the invention that, where the medicament is in powdered form, it is deagglomerated as described above. Nevertheless, it is particularly advantageous with dry powder inhalers of the general form discussed above.

Figures 5 and 6 illustrate two other inhalers embodying the present invention.

Figure 7 illustrates a cross-section of an inhaler according to the present invention. As illustrated, a plane 46 exists which passes within the inhaler. Shaping the inhaler with such a plane is highly advantageous, since, as illustrated, the inhaler can be formed from first 20 and second 22 parts which can still be joined at a flat surface. This makes the moulding and construction steps much more straightforward.

Figure 7 also illustrates some preferred dimensions or inhalers of this type. In general, such inhalers should be between 50mm and 120mm in length, 3mm and 20mm in height and 10mm and 40mm in width. More preferably, they should be between 60mm and 90mm in length, 3mm and 12mm in height and 12mm and 30mm in width or in the region or more preferably still, they should be in the region of 80mm in length, 5mm in height and 20mm in width. Of course, the width to height ratio is of some importance and should be between 2 to 13, 3 to 10 or preferably in the region of 4. Preferably, at position 40, there is an inner radius of curvature 48 of approximately 5mm and an outer radius of curvature 50 of approximately 8mm. Similarly, at position 44, there is an inner radius of curvature 52 of approximately 5mm and an outer radius of curvature 54 of approximately 8mm.

To obtain the correction length of insertion of the outlet 26 into the mouth of a patient, the downwardly extending wall 42 should occur at approximately 30mm from the outlet

26. It may be sufficient to have the downward deflection at a position in the region of 20mm to 60mm, with increasing preference for the ranges 20mm to 50mm, 25mm to 45mm and 25mm to 35mm.

CLAIMS

1. An inhaler for administering powder by inhalation, the inhaler comprising:

a body extending in a first direction between an air inlet and an air/powder outlet, the outer cross-section of the body at substantially every position along the length of the body being elongate in a second direction substantially perpendicular to said first direction; wherein

at a predetermined distance from the air/powder outlet, the body is displaced in a third direction perpendicular to said first and second directions so as to provide a guide to the user as to how far the body should be inserted into the mouth of the user.

2. An inhaler according to claim 1 wherein, at a second predetermined distance further than said first predetermined distance from the outlet, the body is displaced in a direction opposite to said third direction.

3. An inhaler according to claim 2 wherein the body forms a generally S-shaped bend along its length.

4. An inhaler according to claim 1, 2 or 3 wherein the body is shaped such that a plane exists wholly within the body.

5. An inhaler according to any preceding claim wherein, where the body is displaced in the third direction, the outer surface of the body bends with an inner radius of curvature of approximately 5mm and an outer radius of curvature of approximately 8mm.

6. An inhaler according to any preceding claim wherein said predetermined distance from the outlet is within one of the following ranges 20mm to 60mm, 20mm to 50mm, 25mm to 45mm and 25mm to 35mm.

7. An inhaler according to claim 6 wherein said predetermined distance from said outlet is in the region of 30mm.

8. A method of indicating to a user how far to insert into the mouth an inhaler having a body extending in a first direction between an air inlet and an air/powder outlet, the outer cross-section of the body at substantially every position along the length of the body being elongate in a second direction substantially perpendicular to said first direction, the method comprising displacing the body at a predetermined distance from the air/powder outlet in a third direction perpendicular to said first and second directions.

9. Use of an inhaler as described in any of claims 1 to 7 wherein said powder includes a pharmaceutically active substance.

10. Use according to claim 9 wherein the said substance is systemically active.

11. Use according to claim 9 wherein said substance is active in the bronchial area.

12. Use according to claim 11 wherein said substance is used in treatment of a bronchial disease.

13. Use according to claim 12 wherein said substance is used in the treatment of asthma.

Fig. 1

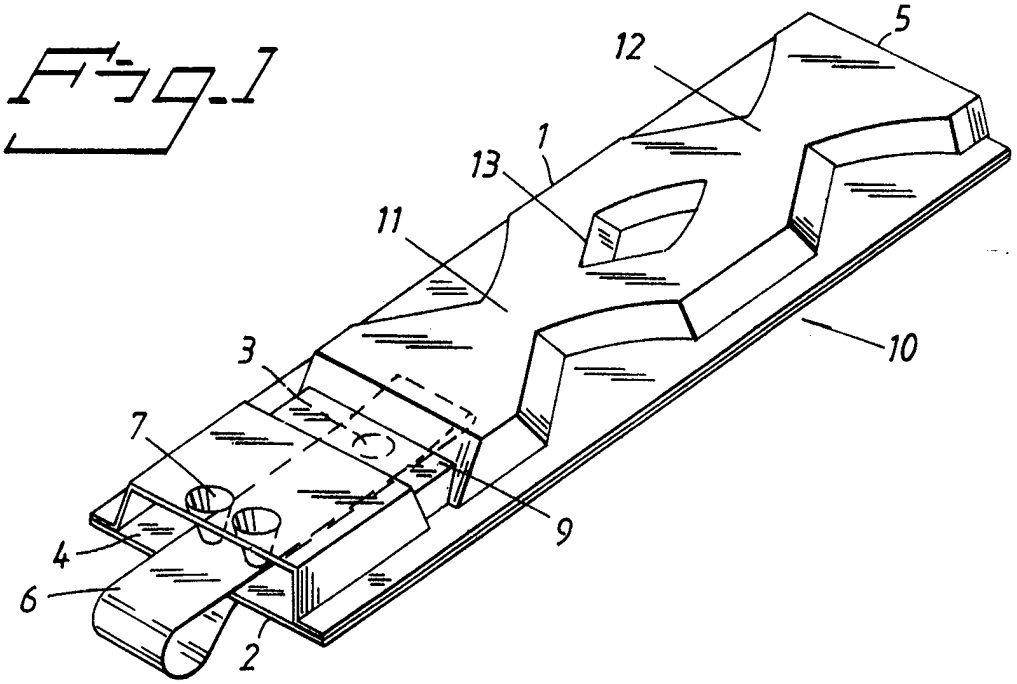



Fig. 2

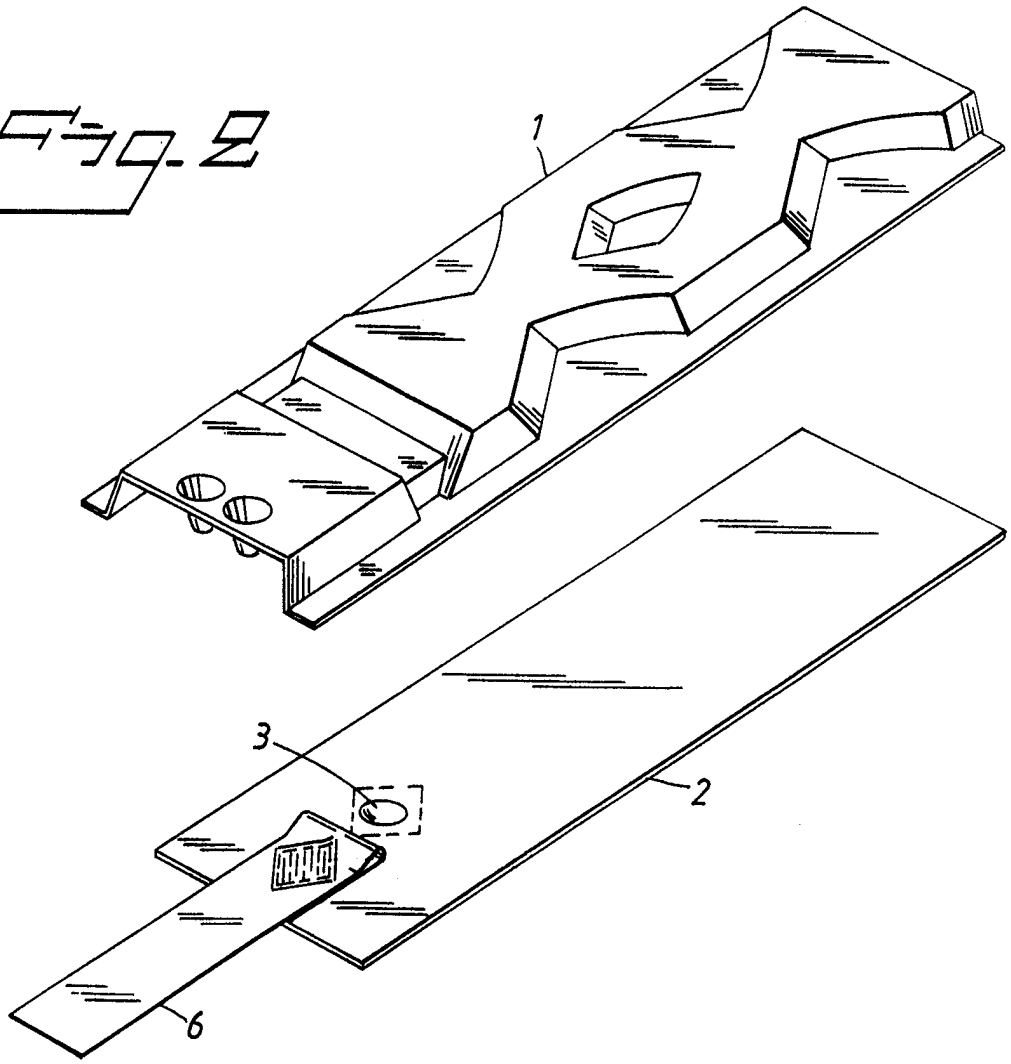


Fig. 3a

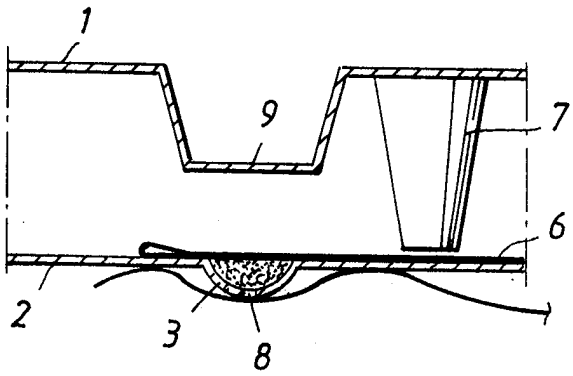



Fig. 3b

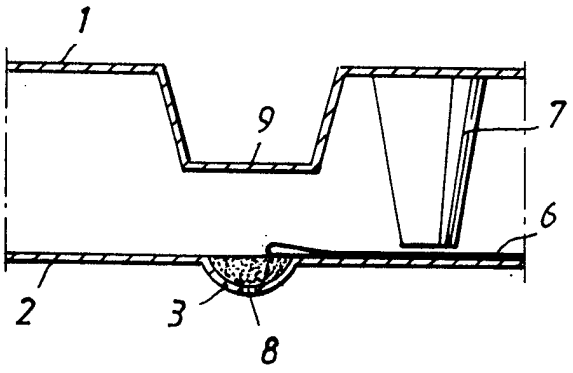



Fig. 3c

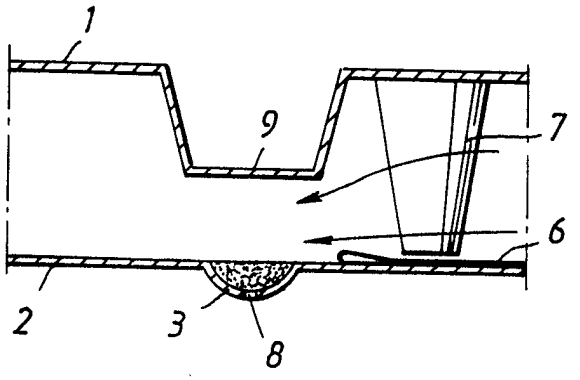


Fig. 4

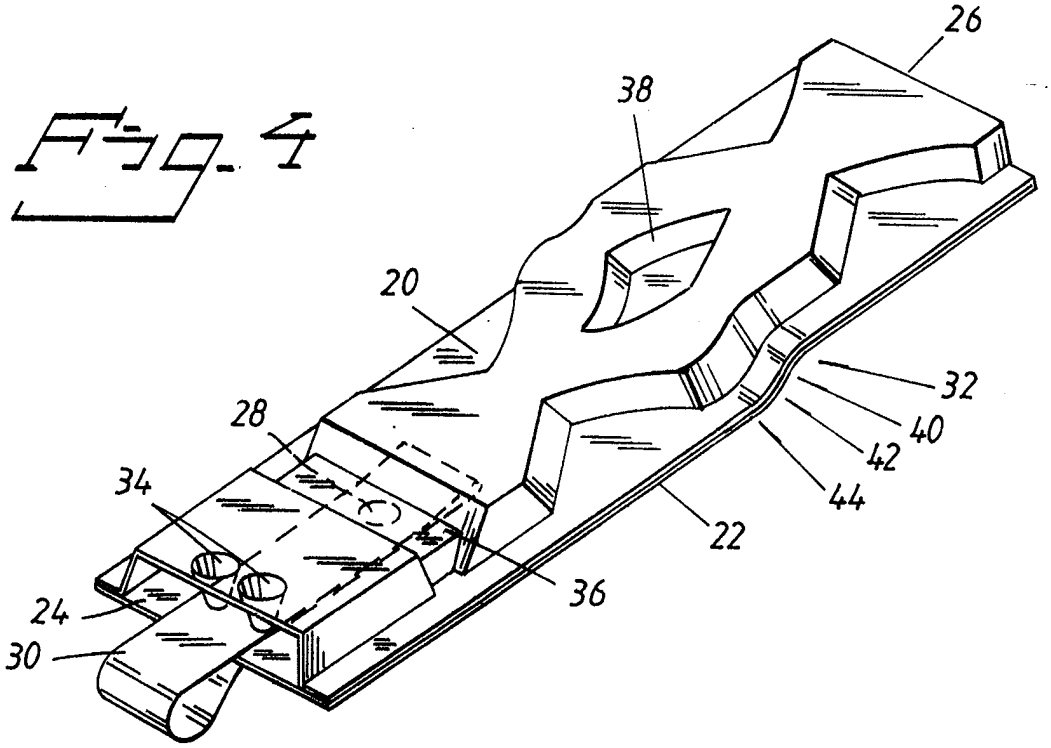



Fig. 7

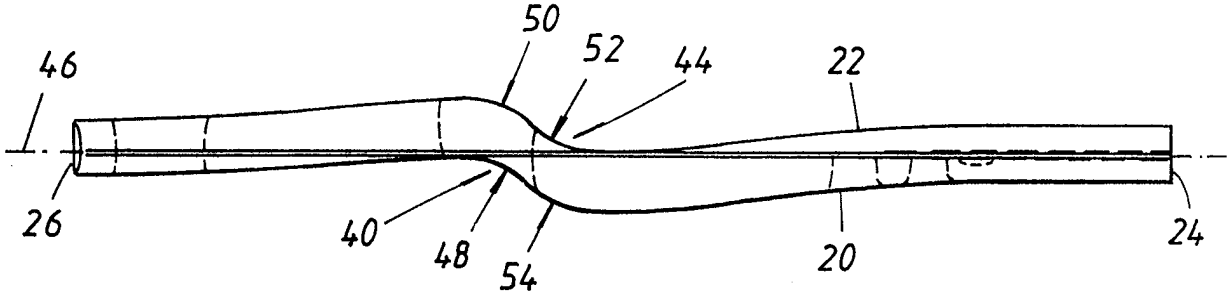


Fig.5

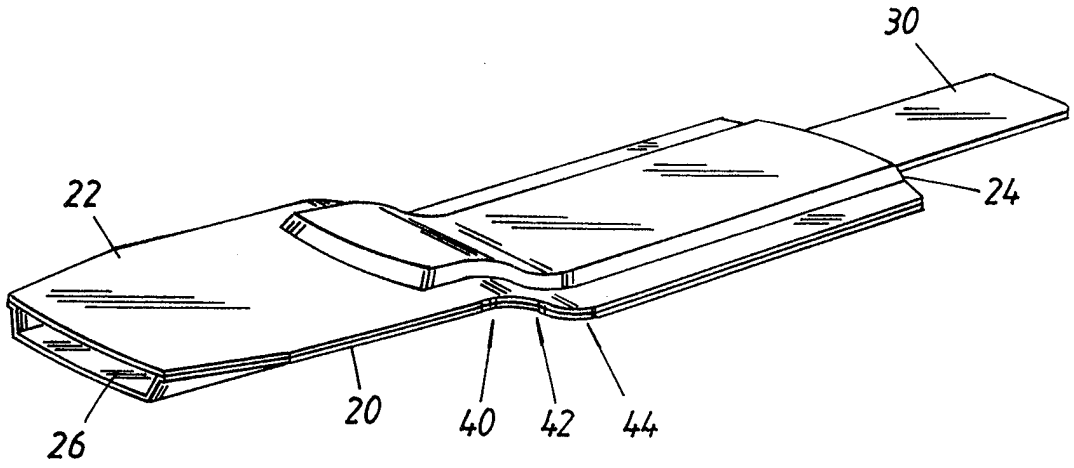
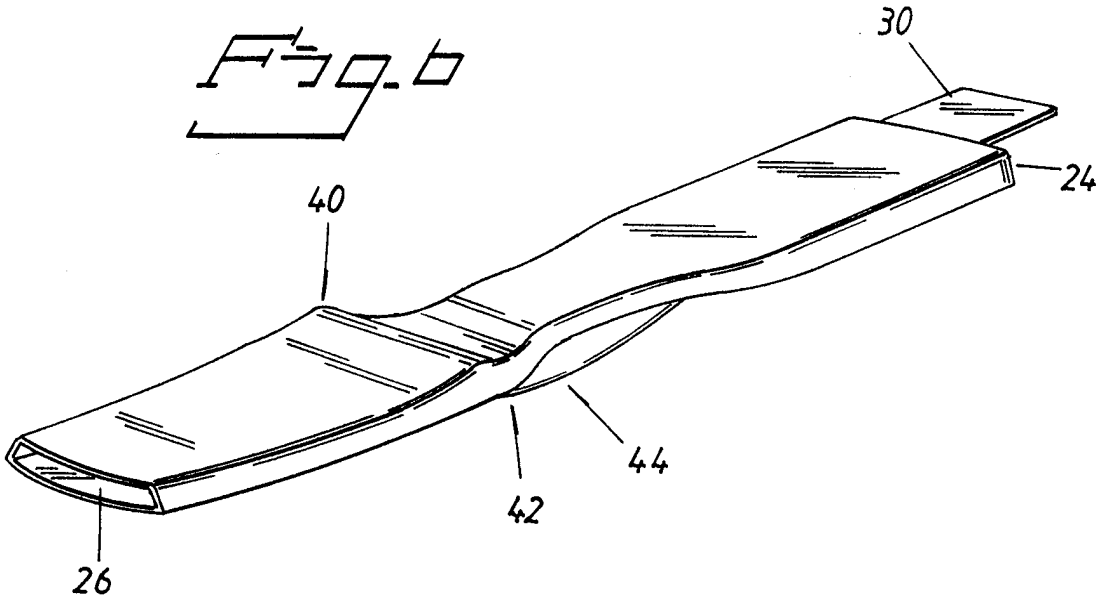



Fig.6



# INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 98/00130

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 15/00
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)

IPC6: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | WO 9622802 A1 (DIRECT-HALER A/S), 1 August 1996 (01.08.96), page 6, line 5 - line 32, figures 8-9 -- | 1-11 |
| A | WO 9503846 A1 (E. HÖRLIN), 9 February 1995 (09.02.95), page 9, line 17 - line 25, figure 1 -- | 1-11 |
| A | WO 9317728 A1 (AKTIEBOLAGET ASTRA), 16 Sept 1993 (16.09.93), figure 1, abstract -- | 1-11 |

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☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 18 May 1998 | 25 -05- 1998 |
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# INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE98/00130

**Box I** Observations where certain claims were found unsearchable (Continuation of item 1 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. [X] Claims Nos.: 12-13
because they relate to subject matter not required to be searched by this Authority, namely:

A method for treatment of the human or animal body by therapy (Article 17(2)(a)(i) and Rule 39.1(iv)).

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 II** Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

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 fee, this Authority did not invite payment of any additional fee.

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.

[ ] No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

29/04/98

International application No.
PCT/SE 98/00130

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