



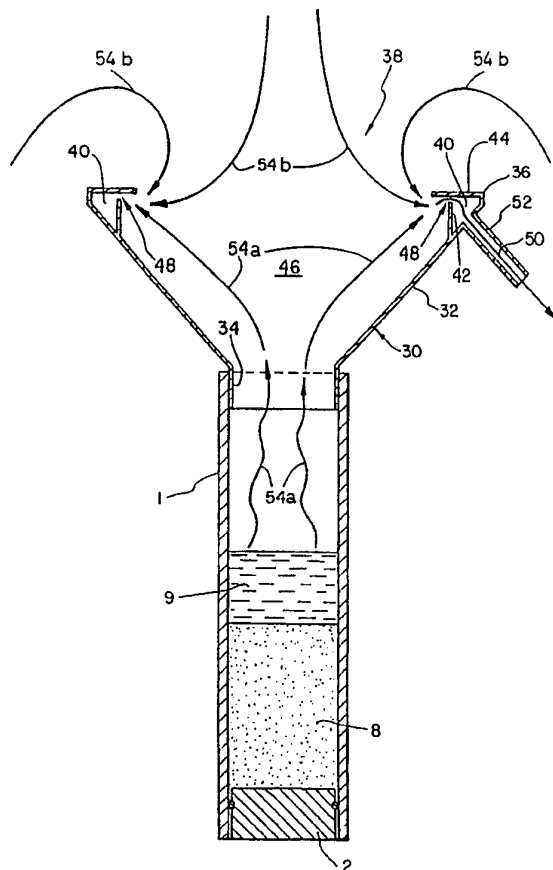
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(21) International Application Number: PCT/SE94/00593 (22) International Filing Date: 16 June 1994 (16.06.94) (30) Priority Data: 08/081,445 21 June 1993 (21.06.93) US (71) Applicant: CEMVAC SYSTEM AB [SE/SE]; Åkarevägen 17, S-311 23 Falkenberg (SE). (72) Inventor: JONSSON, Sören; Rönnhagsvägen 38, S-582 70 Linköping (SE). (74) Agent: WILLQUIST, Bo; Albihn Willquist AB, S:t Larsgatan 23, S-582 24 Linköping (SE).		(81) Designated States: AU, CA, FI, JP, KR, NO, RU, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>

(54) Title: APPARATUS FOR THE PREPARATION OF BONE CEMENT

(57) Abstract

The invention is directed to an apparatus for manufacturing bone cement by mixing a plurality of constituent components within a mixing cylinder (1). A bottom (2) is axially movable within the cylinder (1), and a funnel (30) is attachable to the cylinder (1) for introducing the plurality of constituent components therein. An evacuation channel (50) is disposed in the funnel (30) for drawing gas from the funnel. The evacuation channel (50) is connectable to an evacuation source.



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Apparatus for the preparation of bone cement

BACKGROUND OF THE INVENTION

5 The present invention relates to an arrangement for the
manufacture of bone cement by mixing together its
constituent components comprising a mixing cylinder in the
form of a tube with a bottom and a lid and inside the
mixing cylinder an axially movable agitator in the form of
10 a piston-like agitator disc, which is perforated by
channels, through which the components of the bone cement
are caused to flow during the mixing procedure and an
agitator rod resembling a piston rod operatively connected
to the agitator disc and supported in the lid in such a way
15 that it is free to slide.

Bone cement is used in hip-joint operations, for example.
When manufacturing bone cement, for which purpose a
component in the form of a powder and a liquid component
20 require to be mixed, it is important that the mixture
should be as homogeneous as possible, and that gases which
occur during the mixing procedure are removed to the
greatest extent possible. Any lack of homogeneity and gas
inclusions have the effect of reducing the strength of the
bone cement, which can result in a shorter service life for
25 the implanted prothesis. Furthermore, the gases which occur
during manufacture may be unhealthy, for which reasons
steps must be taken to ensure that they do not escape into
the operating theatre.

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SUMMARY OF THE INVENTION

The object of the present invention is to make available a
preparation apparatus for bone cement, which is intended to

be disposable and capable of being manufactured efficiently and at a low cost, and which also contributes to meeting the requirements stipulated above in respect of the prepared bone cement. The invention comprises an apparatus
5 for manufacturing bone cement by mixing a plurality of constituent components within a mixing cylinder. A bottom is axially removable within the cylinder, and a funnel is attachable to the cylinder for introducing the plurality of constituent components therein.

10

This object is met in that an evacuation channel is disposed in the funnel for drawing gas from the funnel. The evacuation channel is connectable to an evacuation source.

15 BRIEF DESCRIPTION OF THE DRAWINGS

The above-mentioned and other features and advantages of this invention, and the manner of attaining them, will become more apparent and the invention will be better
20 understood by reference to the following description of an embodiment of the invention taken in conjunction with the accompanying drawings, wherein:

Fig. 1 illustrates an embodiment having a funnel which is
25 removably attached to the mixing cylinder and includes an evacuation channel;

Fig. 2 illustrates another embodiment having a funnel which is removably attached to the mixing cylinder, and which
30 defines an annular space fluid communication with the evacuation channel;

Fig. 3 illustrates another embodiment having a funnel removably attached to the mixing cylinder and including an evacuation channel;

5 Figs. 4a and 4b illustrate another embodiment having a removable lid with an evacuation channel and a funnel having a second evacuation channel removably attached to the lid.

10 Corresponding reference characters indicate corresponding parts throughout the several views. The exemplification set out herein illustrates one preferred embodiment of the invention, in one form, and such exemplification is not to be construed as limiting the scope of the invention in any
15 manner.

DETAILED DESCRIPTION OF THE INVENTION

The designation 1 is used in the drawing for a mixing
20 cylinder, and 2 for a bottom which is inserted in a sealing fashion into one end of the mixing cylinder 1. The mixing cylinder 1 is preferably made from a transparent material. The bottom 2, can be held in its position in different ways for example with a locking pin not shown or by a bayonet
25 coupling.

A dot screen and the designation 8 are used in the drawing to indicate a powder, and the designation 9 and a pattern of dashes to indicate a liquid, which are components of the
30 bone cement and have been introduced into the mixing cylinder 1 via a funnel mounted to the opening which is intended to be closed off by means of a lid 3 threadingly

engaged with the cylinder and integrated with an emptying tube, or as shown with an arrangement according to Fig 3. In the interests of clarity, these components are omitted from the other Figures.

5

The mixing procedure itself and the further use of the prepared bone cement in a syringe mechanism of the kind which is customarily used for the extrusion of sealing compound or similar is disclosed in the form of a bead and will not be explained further.

10

Fig. 1 illustrates an embodiment of the present invention having a funnel 30 which is removably attachable to mixing cylinder 1 for introducing a plurality of constituent components 8, 9 into mixing cylinder 1. Funnel 30 includes a frustoconical portion 32 and a smaller diameter portion 34. Smaller diameter portion 34 has an external diameter which is slightly less than the internal diameter of mixing cylinder 1. Smaller diameter portion 34 therefore may be slid within mixing cylinder 1, whereby smaller diameter portion 34 is disposed within and radially adjacent mixing cylinder 1.

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Funnel 30 includes a larger diameter base portion 36 disposed at an inlet 38 of funnel 30, i.e., at the base portion of frustoconical portion 32. An air flow conduit 40, which is generally disposed at base portion 36 and defined by transversely extending walls 42 and 44, is in fluid communication with an interior 46 of funnel 30 via a gap 48, and is in further fluid communication with evacuation channel 50. Evacuation channel 50 is defined by a tube 52 attached to frustoconical portion 32, and adapted

for connection to an evacuation source (not shown).

5 The plurality of constituent components 8, 9 may be poured into funnel 30 through inlet 38 for subsequent mixing within mixing cylinder 1. Gases produced by constituent components 8, 9 are drawn into air flow conduit 40 through gap 48 and are exhausted via evacuation channel 50. Directional arrows 54a, shown in Fig. 1, indicate the flow of gases within mixing cylinder 1 and funnel 30 which are
10 drawn into air flow conduit 40.

Arrows 54b indicate the flow ambient air drawn into the funnel thus forming a barrier preventing gases 54 from escaping into the operating theatre.

15

Fig. 2 illustrates another embodiment of the present invention having a funnel 30 which is removably attached to mixing cylinder 1. Funnel 30 includes a larger diameter portion 56 which is disposed radially outward from smaller diameter portion 34. Larger diameter portion 56 includes an
20 inner diameter which is slightly larger than the exterior diameter of mixing cylinder 1 and is disposed radially adjacent mixing cylinder 1 when in an installed position. Larger diameter portion 56 and smaller diameter portion 34 define an annular space 58 therebetween which is in fluid
25 communication with interior 60 of mixing cylinder 1 and interior 46 of funnel 30. Annular space 58 is further in fluid communication with evacuation channel 50 defined by tube 52. Gases within interior 46 of funnel 30 and interior
30 60 of mixing cylinder 1, as indicated by directional arrows 54a, are drawn together with ambient air 54b into annular space 58 and exhausted out evacuation channel 50.

Fig. 3 discloses another embodiment of the present invention including a funnel 30 having a frustoconical portion 32 and a smaller diameter portion 34. The exterior of smaller diameter portion 34 includes a first cylindrical portion 62 having a diameter substantially the same as the inner diameter of mixing cylinder 1, and a second cylindrical portion 64 having a diameter which is less than the inner diameter of mixing cylinder 1. Disposed radially outward from smaller diameter portion 34 is a larger diameter portion 56 having female threads 66 which threadingly engage male threads 68 formed in mixing cylinder 1. Smaller diameter portion 34 and larger diameter portion 56 define an annular space 58 therebetween.

In the embodiment shown in Fig. 3, larger diameter portion 56 is formed separately from funnel 30 and includes an O-ring 70 for sealingly engaging funnel 30. Those skilled in the art will recognize, however, that larger diameter portion 56 may be monolithically formed with funnel 30. A tube 52 defining an evacuation channel 50 is disposed in larger diameter portion 56 and is connectable to an evacuation source (not shown). Gases 54a within interior 60 of mixing cylinder 1 and interior 46 of funnel 30 are drawn together with ambient air 54 through annular space 57 and exhausted through tube 52.

Fig. 4a illustrates another embodiment of the invention having a lid 3 with female threads 72 which engage male threads 68 formed on mixing cylinder 1. A funnel 30 having a larger diameter portion 56 and smaller diameter portion 34 defines an annular space 58 therebetween which is in fluid communication with interior 60 of mixing cylinder 1.

A tube 52 defining an evacuation channel 50 is attached to larger diameter portion 56 and in fluid communication with annular space 58. Tube 52 is adapted to be connected to an evacuation source (not shown) for drawing gases from interior 60 of mixing cylinder 1 and interior 46 of funnel 30.

After that the constituent components 8 and 9 have been drawn into mixing cylinder 1 through funnel 30 under the influence of the negative pressure created by the evacuation of air within the cylinder. This is accomplished via annular space 58 arranged between portions 56 and 34, funnel 30 may be thereafter removed and the associated opening formed in lid 3 filled with a suitably shaped plug (not shown). To remove gases which exist within mixing cylinder 1 during the mixing process, lid 3 is formed with an upstanding tubular portion 76 adapted to receive a removable evacuation tube 74. Removable evacuation tube 74 includes a first portion 78 having an exterior diameter which is slightly less than the interior diameter of upstanding tubular portion 76, and a second portion 80 adapted for connection to a vacuum source (not shown). Removable evacuation tube 74 defines an evacuation channel 50 therein, and includes an O-ring 82 for sealingly engaging upstanding tubular portion 76. A shoulder 84 allows removable evacuation tube 74 to be seated against upstanding tubular portion 76.

After mixing of constituent components 8, 9 with agitator 4 is complete, removable evacuation tube 74 is removed from upstanding tubular portion 76 and a tube 86 (Fig. 4b), having female threads 88 is screwed onto upstanding tubular

portion 76 whereby male threads 90 engage female threads 88. Bottom 2 is then moved in an axial direction toward lid 3, and the mixed constituent components 8, 9 are expelled through tube 86.

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The present invention, as described above, includes a number of advantages over previously known apparatus for preparing bone cement. For example, the invention does not require premeasured components. Rather, the amount of components required can be decided in situ, i.e., in the hospital operating room.

Furthermore the type of constituent components can be selected as desired to permit total flexibility by the surgeon in selecting both the types and quantities of constituent components. In addition, by drawing gas through the cylinder and drawing the constituent components into the cylinder and forming a negative pressure at the point of entry into the cylinder for the constituent components, noxious fumes generated by the constituent components will be drawn into the cylinder and will not be admitted into the hospital operating room. This is particularly important when such fumes may be harmful to personnel in the hospital operating room and where several batches of bone cement need to be mixed within a relatively short period of time, thereby preventing unnecessary exposure of personnel to such fumes. Moreover, the present invention permits the creation of a partial vacuum within the cylinder to prevent the formation of air bubbles in the mixed bone cement, thereby preventing porosity of the bone cement and ensuring its effectiveness.

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While this invention has been described as having a preferred design, the present invention can be further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the invention using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practise in the art to which this invention pertains and which fall within the limits of the appended claims.

Patent Claims

1. An apparatus for manufacturing bone cement by mixing a plurality of constituent components, said apparatus comprising:
5 a mixing cylinder (1);
a bottom (2) which is axially movable within said cylinder;
a funnel (30) attachable to said cylinder (1) for
10 introducing said plurality of constituent components into said cylinder (1), c h a r a c t e r i z e d in that said apparatus further comprising:
an evacuation channel (50) disposed in said funnel (30) for drawing gas from said funnel (30) and from
15 said cylinder (1); and
means for connecting said evacuation channel to an evacuation source.
2. The apparatus of Claim 1, c h a r a c t e r i z e d
20 in that said funnel (30) includes a frustoconical portion (32) and a smaller diameter portion (34), said smaller diameter adapted to be disposed within and radially adjacent said cylinder (1).
- 25 3. The apparatus of claim 2, c h a r a c t e r i z e d in that said smaller diameter portion (34) engages said cylinder (1).
- 30 4. The apparatus of claim 2, c h a r a c t e r i z e d in that said funnel (30) further includes a larger diameter portion (56) disposed radially outward from said smaller diameter portion (34), said larger

diameter portion (56) engaging said cylinder (1).

5 5. The apparatus of claim 4, c h a r a c t e r i z e d
in that said larger diameter portion (56) threadingly
engages said cylinder (1).

10 6. The apparatus of claim 4, c h a r a c t e r i z e d
in that said larger diameter portion (56) includes
female threads on the interior thereof, and said
cylinder (1) includes male threads on the exterior
thereof.

15 7. The apparatus of claim 4, c h a r a c t e r i z e d
in that said larger diameter portion (56) and said
smaller diameter portion (34) define an annular space
(58) therebetween, said annular space (58) in fluid
communication with said cylinder (1) and said
evacuation channel (50).

20 8. The apparatus of claim 4, c h a r a c t e r i z e d
in that said larger diameter portion (56) forms an
adapter between said funnel (30) and said cylinder.

25 9. The apparatus of claim 2, c h a r a c t e r i z e d
in that said frustoconical portion (32) includes a
larger diameter base portion disposed at an inlet to
said funnel (30), and an air flow conduit (40)
disposed at said base portion, said air flow conduit
(40) in fluid communication with an interior of said
30 funnel (30) and said evacuation channel (50).

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FIG 1

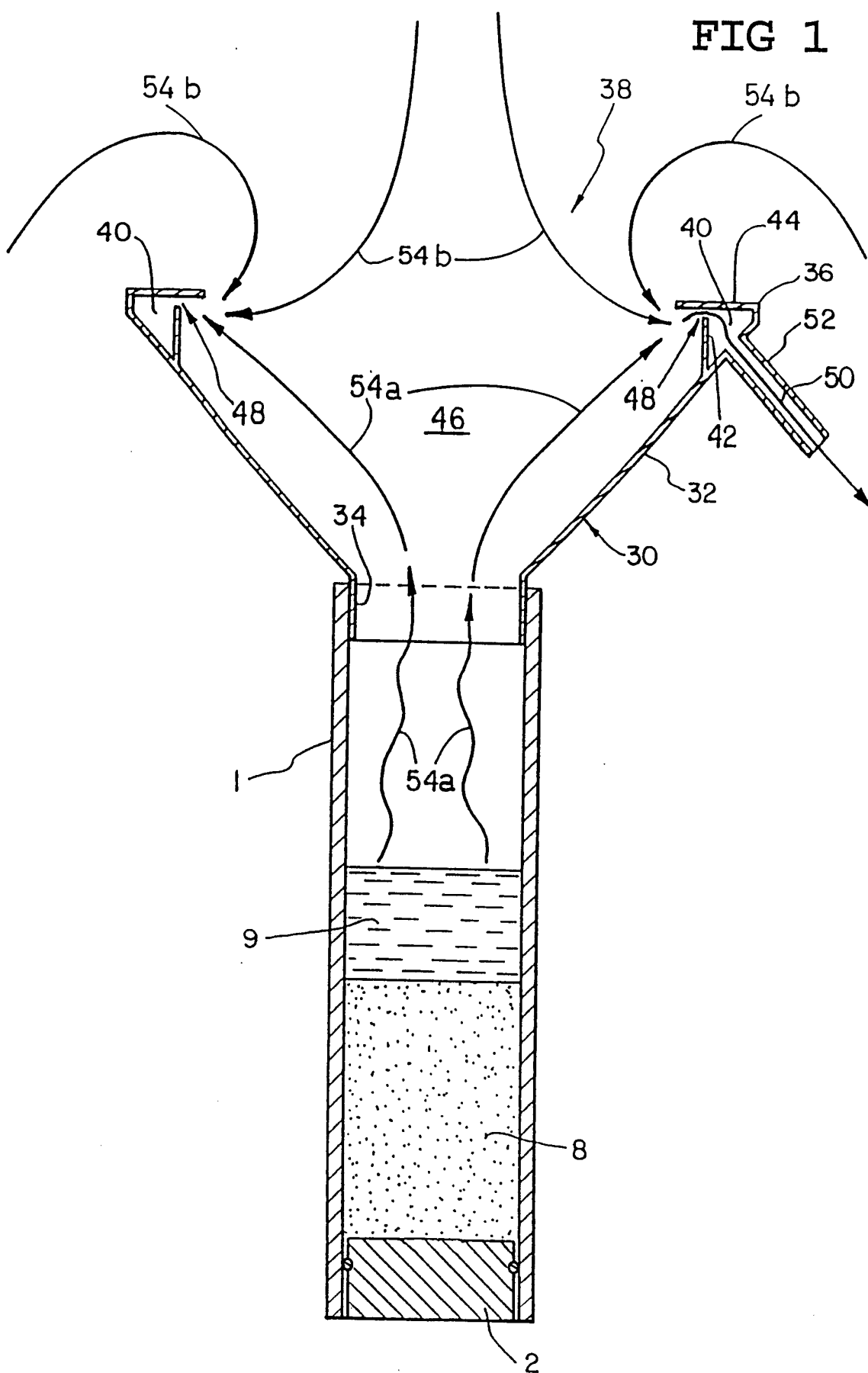


FIG 2

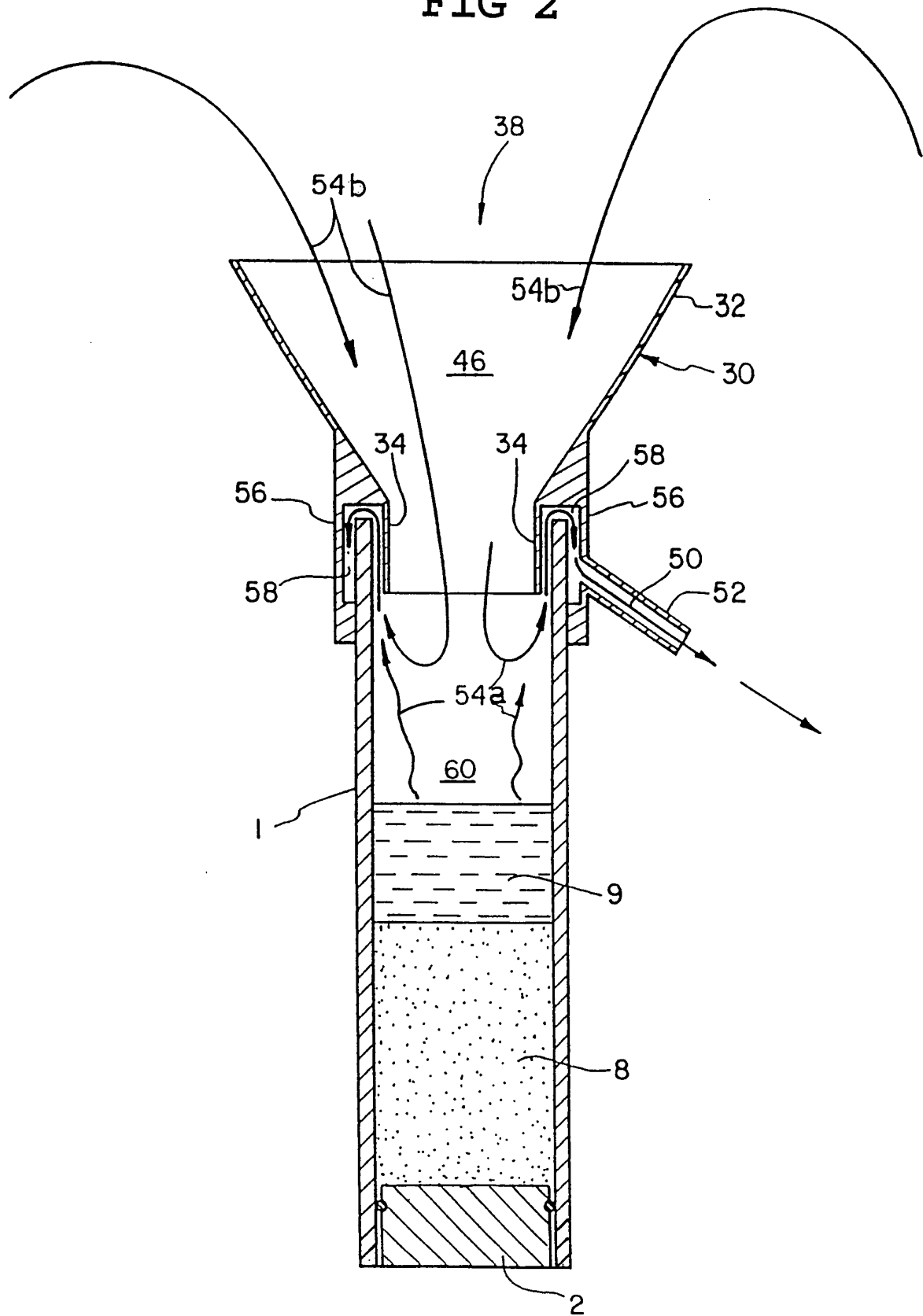


FIG 3

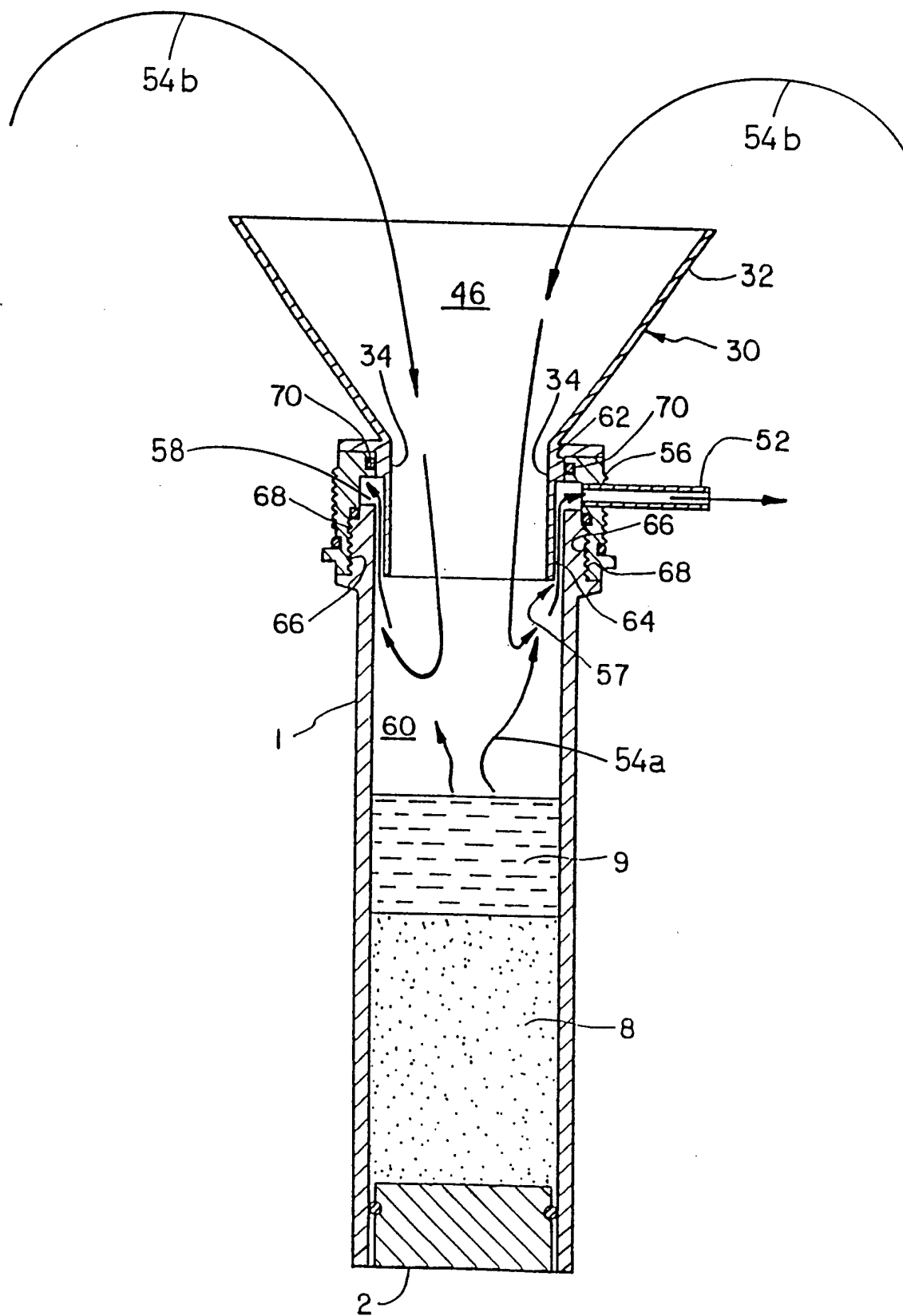


FIG 4a

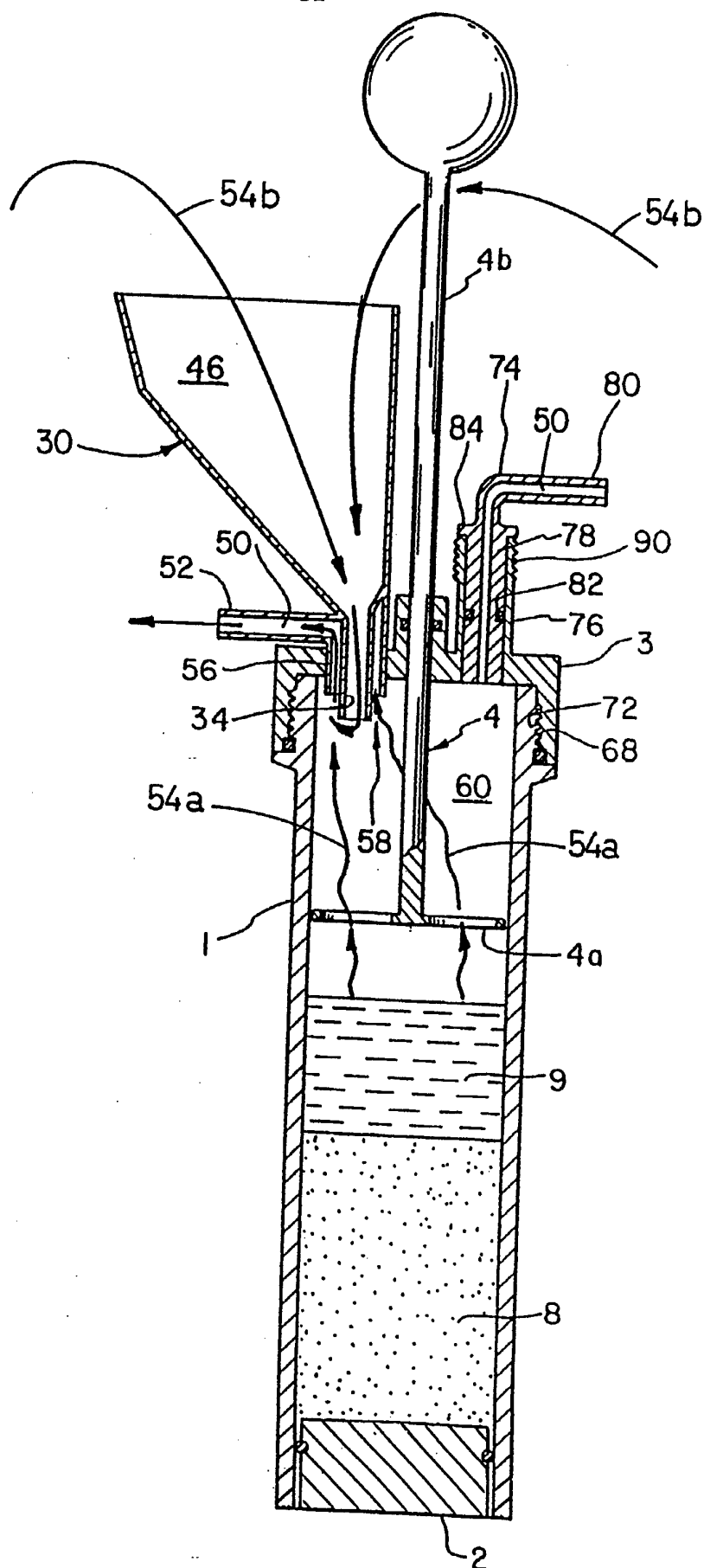
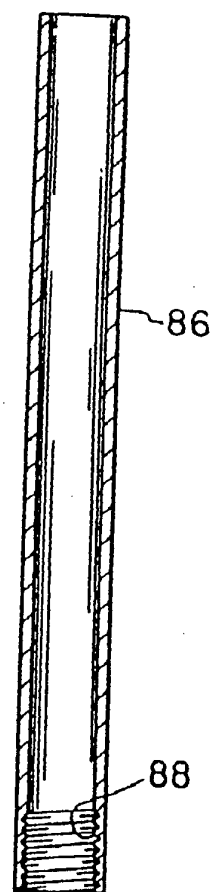


FIG 4b



INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 94/00593

A. CLASSIFICATION OF SUBJECT MATTER

IPC5: B01F 3/12, B01F 13/06, A61F 2/46

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)

IPC5: B01F, A61F

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)

DIALOG

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	SE, B, 462315 (SURGITEC AB), 11 June 1990 (11.06.90), figure 2, abstract --	1
P,A	WO, A1, 9322041 (CEMVAC SYSTEM AB), 11 November 1993 (11.11.93), figures 1,5, abstract -- -----	1-9

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Further documents are listed in the continuation of Box C.

☒

See patent family annex.

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Date of the actual completion of the international search

19 Sept 1994

Date of mailing of the international search report

27 -09- 1994

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INTERNATIONAL SEARCH REPORT
Information on patent family members

27/08/94

International application No.
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
SE-B- 462315	11/06/90	AU-B- 633058	21/01/93
		AU-A- 5155190	29/11/90
		EP-A- 0470959	19/02/92
		JP-T- 4507200	17/12/92
		US-A- 5252301	12/10/93
		WO-A- 9013264	15/11/90
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