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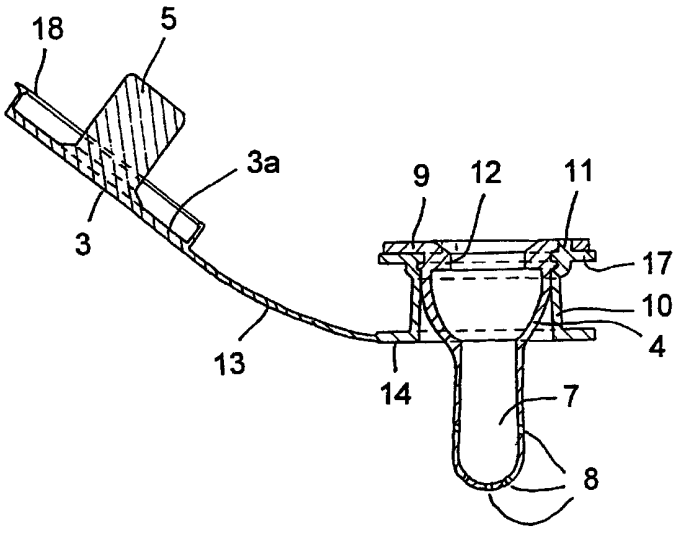
(54) Title: WEANING DEVICE



(57) **Abstract:** The invention relates to a device for weaning an infant from receiving liquids from a baby bottle, the device comprising a flanged pacifier (1), the interior space thereof being adapted to accommodate small amounts of an agent to be dosed to the infant, the agent having a sweet-tasting but not caries-promoting nature to the infant's teeth and further being soluble in the infant's own saliva, the structure of the pacifier (1) having a perforated nipple portion (6) for inflow and outflow of the infant's saliva, a body part (2, 10) surrounding the base of the pacifier (1) and, cooperating with the latter part, a closing cap (3) adapted to seal the central opening of the wide-diameter base of the pacifier (1). The invention is characterized in that the closing cap includes a rim (3a) and a closed-bottom plug portion (5) that in the closed position of the closing cap extends into the void interior of the base (4) of the pacifier so as to occupy a major volume in pacifier interior space and, simultaneously, to prevent the dosed agent from escaping from the interior space of the nipple portion (6) of the pacifier toward the base (4) of the pacifier.

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Weaning device

The present invention relates to a weaning device according to the preamble of claim 1.

Conventionally, a baby bottle is used for feeding small infants. However, administration of beverages sweetened with sugar to an infant from a baby bottle when putting the infant to sleep is very detrimental to the infant's teeth. This is because at the instant of falling asleep, the infant's saliva production is reduced and active swallowing ends. Thence, the last sip of sugar-containing liquid sucked from a baby bottle can remain for a very long time in the infant's buccal cavity thus causing a serious risk of dental decay as the bacteria responsible for caries thrive on sugar. Even mere milk given from a baby bottle may be deleterious if administered at the instant of falling asleep. Indications have been found on an increased risk of middle ear inflammation thereupon, particularly if the infant is fed in a supine position, whereby the liquid sucked by the infant can readily reach the higher portions of the oropharyngeal region thus offering a source of nutrition for the ear infection causing microbes residing therein.

In his article "Mutans streptococci and their specific oral target. New implications to prevent dental caries", published in Swiss periodical "Schweizer Monatsschrift für Zahnmedizin", J. Suhonen has presented theoretical grounds for the advantages of a pacifier-shaped administering device suitable for releasing a medically effective agent at a slow rate into the infant's mouth in a prophylactic sense in order to prevent dental caries. The functionality of a slow-release pacifier *in vitro* is described in a paper titled "Release of preventive agents from pacifiers in vitro" by J. Suhonen et al. in cited periodical "Schweizer Monatsschrift für Zahnmedizin", 1994 (104), pp. 946-951. In a study (performed by Aaltonen AS, Suhonen JT, Tenovuo J, Inkilä-Saari I, paper "The efficacy of a slow-release device containing fluoride, xylitol and sorbitol in preventing mutans streptococcal oral infection and infant caries" published in Acta Odont. Scand., in print), it has been shown that a prototype of a slow-release pacifier as a

means for administering sodium fluoride, xylitol and sorbitol is an effective and viable device for preventing oral and pharyngeal infections in infants. Dental caries and middle ear infections were reduced in a significant manner in infants using a slow-release pacifier as compared to infants receiving the same prophylactic composition by oral administration without using the slow-release pacifier. The daily dose of xylitol used in the study was only a fraction of that needed for prophylaxis of middle ear infections in kindergarten infants of 2 to 5 years of age by way of administering the prophylactic agent in chewing gum or directly orally as a mixture.

Weaning an infant from sucking a sugar-sweetened beverage from a baby bottle may be difficult. Better results can be achieved if the weaning step is carried out using a slow-release pacifier that is filled with a sweetening agent such as xylitol, which is harmless to the teeth. Herein, the parents' motivation may be elevated by the verified fact that a sweetening agent administered via a pacifier has a plurality of beneficial health-promoting effects.

A problem herein, however, may arise from the rejection of a new pacifier presented by many infants when the shape or size of the new pacifier differs from that already accepted by the infants. In these situations, it might be advantageous to make it possible for the infants to use the pacifier portion of their old baby bottle also during the weaning period, e.g., for administering xylitol. However, sweetening a beverage administered from a baby bottle with xylitol would require so massive dosage that it can upset the function of an infant's intestine. Based on Suhonen's findings, this problem may be solved by placing xylitol only into the nipple portion of the pacifier, whereby the base opening is capped and the nipple portion is provided with suitable openings. Then, the infant's own salivary flow will dissolve the xylitol contained in the slow-release device, which xylitol simultaneously will administer slowly into the infant's mouth, yet giving a clearly sweet taste notwithstanding the minimized dosage.

Aaltonen and Suhonen have in Their FI Pat. Appl. No. 955,389 proposed the bottle portion of a baby bottle to be replaced by a cap which is adapted screwably mountable

onto the coupling ring of the baby bottle's pacifier portion. The same idea is also implemented in a device known as CANNON babysafe Mini-Feeder, wherein the base of the pacifier portion can be capped with a planar plastic plate that is mounted on the coupling ring. These arrangements are suited for administration of a liquid medicine mixture, but due to the 7-15 ml volume of the pacifier portion of a conventional baby bottle, a major portion of small doses of medication may not reach the infant's mouth as the medicine agglomerates into the large and empty base portion of the pacifier. In the method of Suhonen, wherein the agent to be administered may be in the form of a powder or a fragile tablet that dissolves in the infant's saliva, the problem is accentuated as the agent accumulates to the base portion of the pacifier without becoming moistened by the infant's saliva.

The nipple portions of baby bottles and the above kinds of slow-release pacifier Embodiments are handicapped by a drawback not permitted in pacifiers, namely that the nipple portion can relatively easily slip out from its coupling member if the nipple portion is pulled outwardly or, particularly, if the pulling force is effected from a sideways oblique direction. While this disadvantage has not been considered to form a safety risk in daily use, such a shortcoming is most undesirable for prolonged use of a pacifier during the night-time. Well known in the art is also a slow-release pacifier with a detachable nipple portion that is disclosed in EP patent publication No. 0 494 904 and FI Pat. Appl. No. 921,411 and wherein the nipple portion is connected with a holding force compliant to safety regulations by way of compressing a narrow rim of the nipple portion against a cap by means of a relatively complicated and fragile, screwably mountable locking mechanism that cooperates with a separate cap. A problem herein is that if the locking of the cap in accordance with the operating instructions of the device remains undone due to Human negligence, the separable parts may land in the infant's mouth thus causing a risk of suffocation.

The safest types of slow-release devices would be those manufactured into a single piece as have been proposed by Aaltonen and Suhonen in FI utility model No. 2797 and in international patent application No. PCT/FI97/00682. In these embodiments,

however, the manufacture of a series of products having a sufficiently versatile range of volume and design for weaning use would become very expensive.

In FI utility model application U960626, Alanen and Söderling describe the use of the nipple portion of a pacifier or a nursing bottle as a slow-release device in such a manner as to introduce the agent to be administered, not into the nipple portion, but instead as a tablet or a shape-retaining slow-release dosing unit into a pocket of the hollow nipple portion or a space formed within the sealed nipple portion. This kind of a design is more difficult to manufacture than such wherein the agent to be administered is placed in a space formed into the actual nipple portion. Furthermore, the design proposed by Alanen and Söderling bears a risk of permitting the tablet to break into relatively large lumps which may reach the infant's windpipe. The shape required from the solid clump of dosage also causes a risk to teethed infants of bite against the clump so that the material of the nipple portion, conventionally silicon rubber, is torn, whereby the lumps released from the nipple portion can reach the infant's windpipe. To minimize this risk, it is a safer technique to fill the slow-release device via a wide base opening, whereby the filling can be made using an agent having a powder-like, liquid, gelled or brittle granular dosing constitution. Then, the biting of the nipple portion does not cause an aspiration risk higher than that associated with the use of a conventional baby bottle.

The effect of prophylactic agents acting locally in the mouth is maximized when the dosing time is extended. A slow-release device intended for prolonged use in the mouth must be lightweight to avoid torsional forces that lead to dislocation of the teeth. Hence, the bottle portion of the device should be abandoned as soon as the infant is ready to give up its use. However, a nipple portion with a closed base should not be left alone into the infant's mouth overnight because of the potential choking risk of the infant in the case that the pacifier with its base should entirely slip into the infant's mouth.

It is an object of the present invention to provide such an accessory for the nipple portion of a pacifier that by virtue of an easily implementable technical solution is capable of overcoming the above-described drawbacks of conventional nipple portions of slow-release devices and baby bottles, simultaneously acting as slow-release device for prophylactic agents and featuring a sufficiently high safety level in use, easy manufacture for rapid commercial deployment at low costs and finding ready acceptability in the group of such infants that can gain the greatest benefit from prophylactic actions, in other words, being most suited for weaning infants accustomed to receive liquids via the nipple portion of a baby bottle from the habit of sucking the contents of a baby bottle. The above-stated goal of the invention is achieved by virtue of the design disclosed in the characterizing part of claim 1.

When used for weaning, the device according to the invention facilitates the use of a conventional nipple portion of a baby bottle in a slow-release method, wherein the infant is weaned from the habit of sucking a caries-causing baby bottle liquid with the help of administering small doses of a sweetening agent that is inhibitory to dental caries.

Furthermore, the weaning device according to the invention features a positive indication of the open/closed positions of the cap closing the device.

By virtue of locking the wide flange of a baby bottle pacifier portion within the knob-like clamping plug member, or body part, of the device, the holding force imposed on the pacifier is increased substantially inasmuch the detachment of the pacifier requires that the pacifier flange must be pulled off from its clamped position under the rim of the device cap via a narrow annular slit remaining between the clamping plug and the body part of the device. Moreover, the insertion length of the clamping plug member serves to almost entirely eliminate the laterally acting components of pulling forces imposed on the pacifier that otherwise tend to detach the pacifier. When the device is used in conjunction with pacifier types not having an annular inner shoulder made at their base portion in order to reduce the diameter of the base opening, the fit between

the inner rim of the device base part upper plane and the clamping plug member is so tight that merely this kind of pacifier clamping may be considered reliable as such. However, secure clamping of baby bottle pacifier portions having a conventional annular flange can be assured according to the present invention with the help of at least one securing pin adapted to penetrate through the pacifier flange.

Given this kind of a sufficiently safe solution to the problem associated with the detachment risk of the pacifier, the possibility of replacing the pacifier portion is evidently an ecological benefit inasmuch the rapidly wearing pacifier portion can be replaced without discarding the entire device. Another undeniable benefit of the present invention can be appreciated in its compatibility with conventionally marketed disposable pacifier portions that can be used as such or with a slight modification in both feeding from a baby bottle and weaning from the use thereof.

The simplest embodiment of the closing cap according to the present invention comprises a thin-profile plastic cap adapted to fit on the bottom of the threaded closing ring of a baby bottle so as to become clamped between the flange of the pacifier portion and the mouth of the baby bottle. This kind of weaning device embodiment can be tested at the transition phase toward weaning from the use of a baby bottle as to find the infant's reaction to the taste of the sweetening agent.

When the pacifier portion is used detached from the baby bottle as a slow-release device, the pacifier base is sealed with a closing cap that has suitable connection means for joining the cap with the base part of the weaning device. For filling, the cap of the slow-release device is designed openable in a manner that an adult but not an infant can manage. The closing cap can be secured in a sufficiently reliable manner by means of, e.g., an elastic rim of the closing cap flange that is adapted to be slippable in a snap-on manner over the respective shoulder of the body part of the device or by providing the closing cap with a locking catch. Obviously, the closing cap may also be secured to the body part of the device by means of a threaded or bayonet connection. To avoid the risk of choking, the weaning device is equipped with a guard similar to

the inhalation shield of pacifiers. The guard is adapted so close to the infant's lips that the torsional forces imposed on the device remain as small as possible. According to CE standards, the guard of pacifiers must have ventilation holes of a specified shape. The same safety standard has also been followed in the design of the present weaning device. The guard is connected to the lower edge of the knob-like body part of the device that in a preferred embodiment is designed to have an elongated, slightly inward-curved shape and is equipped with two slightly elliptical ventilation holes. The closing cap joins to the base part via an elastic plastic strip, either being fabricated integral with the guard and the body part or being connected via a detachable connecting ring. Preferably, the body part and the stem of the guard should be made from a relatively stiff plastic such as polypropylene, while the other parts may be of a more elastic, foodstuff-compatible plastic that is sterilizable by boiling. In conjunction with the device, both natural and silicon rubber pacifier portions can be used in a form properly perforated for use in the present slow-release dosing method.

In the following, the invention will be explained with reference to the appended drawings, in which:

FIG. 1 shows a simple implementation of a weaning device according to the invention to be used in an initial phase of weaning from a baby bottle, in a horizontal longitudinal sectional view;

FIG. 2 shows in a horizontal longitudinal sectional view an example of a weaning device according to the invention, provided with a guard and intended to be used after the baby bottle has been given up;

FIG 3 shows a closing cap of the weaning device of FIG. 2 with its flexible connecting strip and connecting ring in a view separated from the other parts of the weaning device;

FIG. 4 shows another embodiment of a weaning device according to the invention provided with a guard in a vertically sectional view taken along the median plane of the device; and

FIG. 5 shows the weaning device of FIG. 4 in a top view with the pacifier portion removed.

Referring to FIG. 1, the simple implementation of a weaning device shown therein comprises a pacifier portion 1 of a baby bottle with pacifier coupling member 2 having a closing cap 3 adapted thereto. The closing cap 3 is formed by a flange portion 3a and a plug portion 5 adapted to fit into the void base part 4 of a pacifier 1. When mounted in place, the rim 5a of the cylindrical plug portion 5 stays firmly pressed against the wall of the conical portion of the pacifier 1, thus effectively sealing off the connection between the hollow nipple portion 6 and the base part 4 of the pacifier 1. Hence, the agent to be administered, which is dosed into a space 7 formed by the hollow nipple portion 6, is prevented from escaping toward the pacifier base part 4. The agent to be administered dissolves into the saliva that penetrates from the infant's mouth into the space 7 via openings 8 in the pacifier nipple portion 6 and diffuses thereafter gradually back to the mouth via the same openings 8. The flange 9 of the pacifier remains clamped under the flange 3a of the closing cap when the bottle is fixed by rotation to the coupling member 2.

Now referring to FIG. 2, the weaning device shown therein for use after the infant has given up the baby bottle feeding phase has the nipple portion 1 of the baby bottle's pacifier portion inserted into the body part 10 of the weaning device so that the flange 9 of the pacifier portion remains resting on the annular top rim 17 of the body part of the weaning device. The closing cap flange 3a has a fixing rim 18 adapted to slip in a snap-on manner over the upper shoulder 17 of the body part 10 in order to secure the pacifier 1 in its position. In secured position, the bottom edge 5a of the plug portion 5 of the closing cap 3 stays firmly pressed against the wall of the conical portion of the pacifier 1 and reaches maximally about three millimeters from the level of the guard

14 toward the interior of the infant's mouth. The guard 14 is provided with air passage openings 16. The closing cap 3 is secured to the base part 10 via a flexible connecting strip 13 by means of an elastic fixing ring 19 at the end of said strip, which ring can be pushed over the shoulder of the upper rim 17 of the body part 10.

In FIG. 3 is shown the closing cap 3 of the weaning device with its fixing ring 19 in a view detached from the weaning device.

In FIGS. 4 and 5 is shown another embodiment having the upper rim 17 of the body part 10 provided with three upward-projecting securing pins 11, while the flange 9 of the pacifier 1 has securing holes adapted to cooperate with said pins so as to keep the pacifier 1 firmly in place when the weaning device is set into its closed position. The weaning device shown in FIG. 4 has a contraction 12 made to the base part 4 of the pacifier 1, at the base opening thereof, so that the diameter of the plug portion 5 of the closing cap 3 is relatively small. The plug portion 5 has preferably a solid envelope to prevent an infant from sticking a finger therein. In its closed position, the closing cap 3 has its plug portion 5 firmly pressed against the wall of the conical portion of the pacifier base 4 thereby sealing the dosing space 7. The locking of the closing cap 3 is secured by means of an elastic rim 18 of the cap to be slipped in a snap-on manner over the upper shoulder 17 of the body part. In this embodiment, the closing cap 3 is manufactured integral with the base part 10 and is joined to guard 14 of the body part 10 via an elastic plastic strip 13. Advantageously, the guard 14 is equipped with ventilation holes, e.g., comprising two elongated holes 16 of a narrow width (less than 5.5 mm) as shown in FIG. 5.

To those skilled in the art, it is obvious that the applications of the invention are not limited to the exemplifying embodiments described above, but rather, may be varied within the scope and spirit of the appended claims.

Claims:

1. Device for weaning an infant from receiving liquids from a baby bottle, the device comprising a flanged pacifier (1), the interior space thereof being adapted to accommodate small amounts of an agent to be dosed to the infant, the agent having a sweet-tasting but not caries-promoting nature to the infant's teeth and further being soluble in the infant's own saliva, the structure of the pacifier (1) having a perforated nipple portion (6) for inflow and outflow of the infant's saliva, a body part (2, 10) surrounding the base of the pacifier (1) and, cooperating with the latter part, a closing cap (3) adapted to seal the central opening of the wide-diameter base of the pacifier (1), **characterized** in that the closing cap includes a rim (3a) and a closed-bottom plug portion (5) extending into the void interior of the base (4) of the pacifier in the closed position of the closing cap so as to occupy a major volume in pacifier interior space and, simultaneously, preventing the dosed agent from escaping from the interior space of the nipple portion (6) of the pacifier toward the base (4) of the pacifier.

2. Device according to claim 1, **characterized** in that the wide-diameter base (4) of the pacifier is adapted to fit into the interior hole of said base part (10) acting as a locking means of the device, whereby in the closed position of the closing cap the flange (9) of the pacifier base becomes clamped between the rim (3a) of the closing cap (3) and the annular top rim (17) of the body part of the weaning device.

3. Device according to claim 2, **characterized** in that closing cap (3) has safety means (18) not releasable by an infant and serving to keep the cap in its closed position during its use.

4. Device according to any of the previous claims, **characterized** in that the flange (9) of the pacifier (1) has at least one securing hole, while the annular top rim (17) of the body part (10) has compatible securing pin(s) (11) cooperating with said fixing hole(s) so as to lock the pacifier (1) in place.

5. Device according to any of the previous claims, **characterized** in that the end of the body part (10) directed towards the nipple portion (6) is provided with a guard (14) having ventilation holes made therein.

6. Device according to any one of claims 2 - 5, **characterized** in that the closing cap (3) is connected via a flexible strip (13) to the body part (10), either permanently or by means of a fixing ring (19) at the end of the strip (13) pushed around the neck of the body part (10).

7. Device according to claim 1, **characterized** in that the weaning device body part (2) is a member for connecting said pacifier (1) to a baby bottle.

Fig. 1

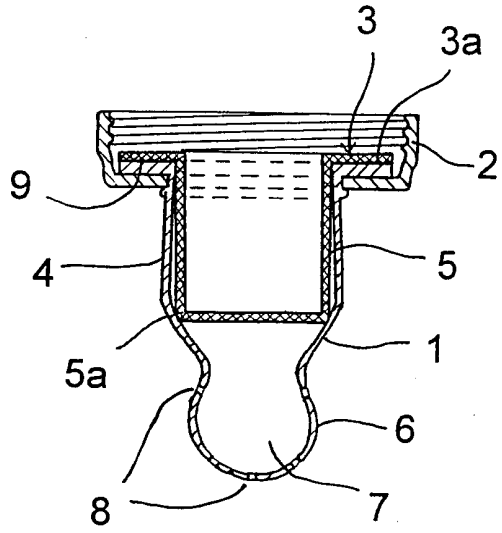


Fig. 2

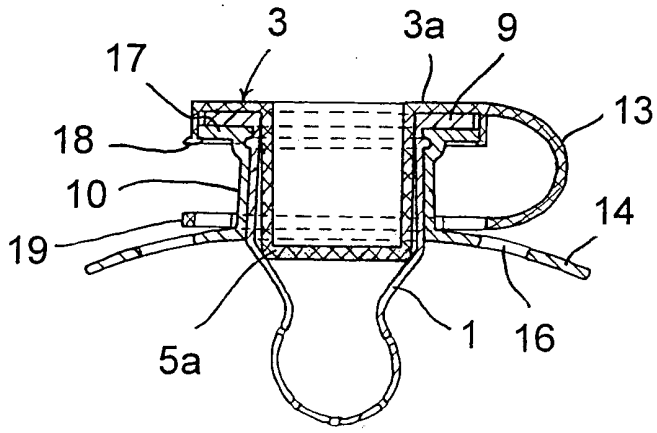
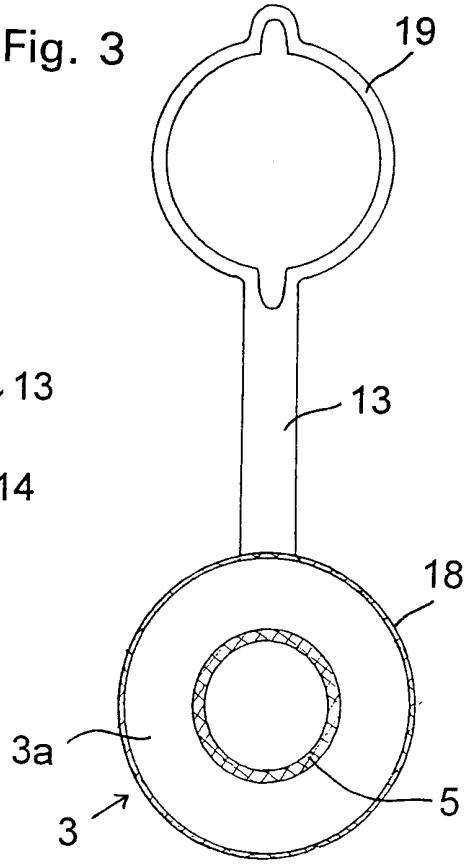


Fig. 3



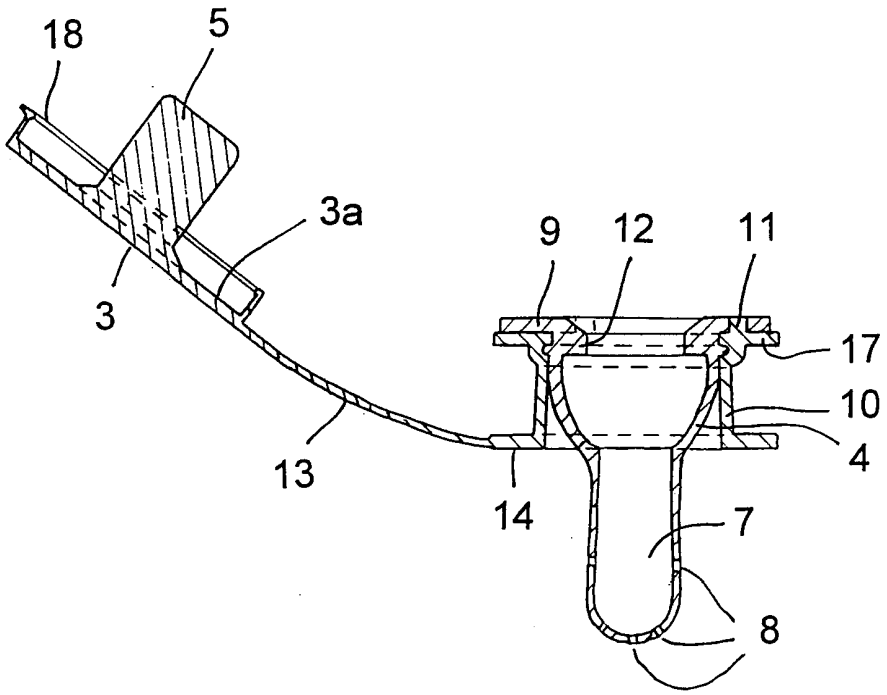


Fig. 4

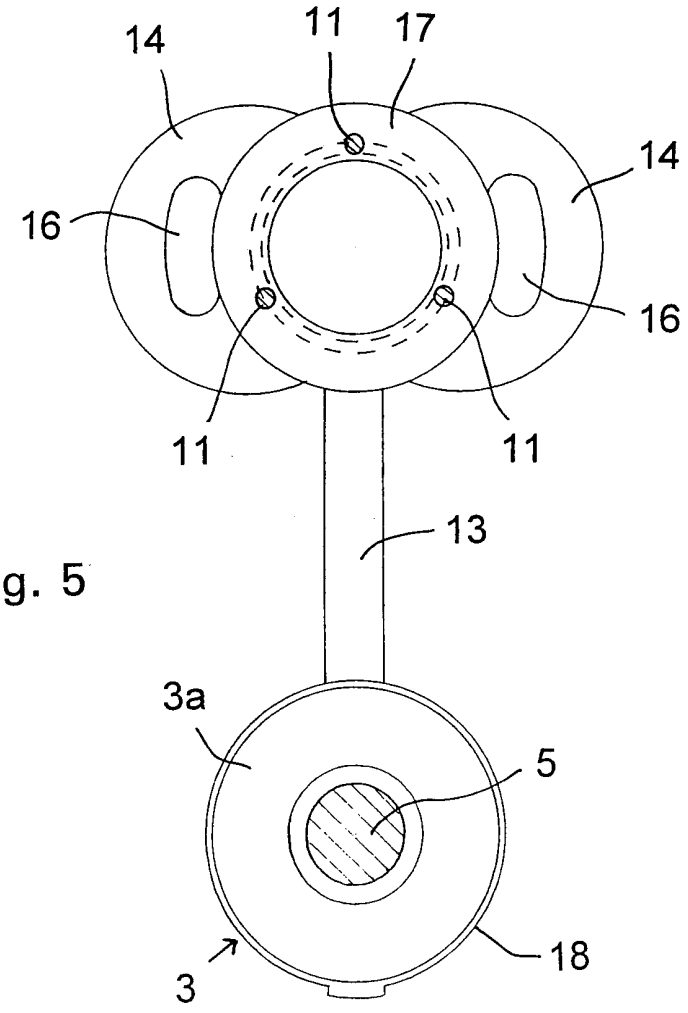


Fig. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/FI 00/00820

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61J 11/00, A61J 17/00
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)

IPC7: A61J

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	GB 2296182 A (HULYA HARBER), 26 June 1996 (26.06.96), figures 1-4, claims 1-6	1-7

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

* Special categories of cited documents:
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Date of the actual completion of the international search	Date of mailing of the international search report
22 November 2000	22 -11- 2000
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Agneta Änggård/Els Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

Information on patent family members

02/11/00

International application No.
PCT/FI 00/00820

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 2296182 A	26/06/96	GB 9510241 D	00/00/00
		GB 9519712 D	00/00/00