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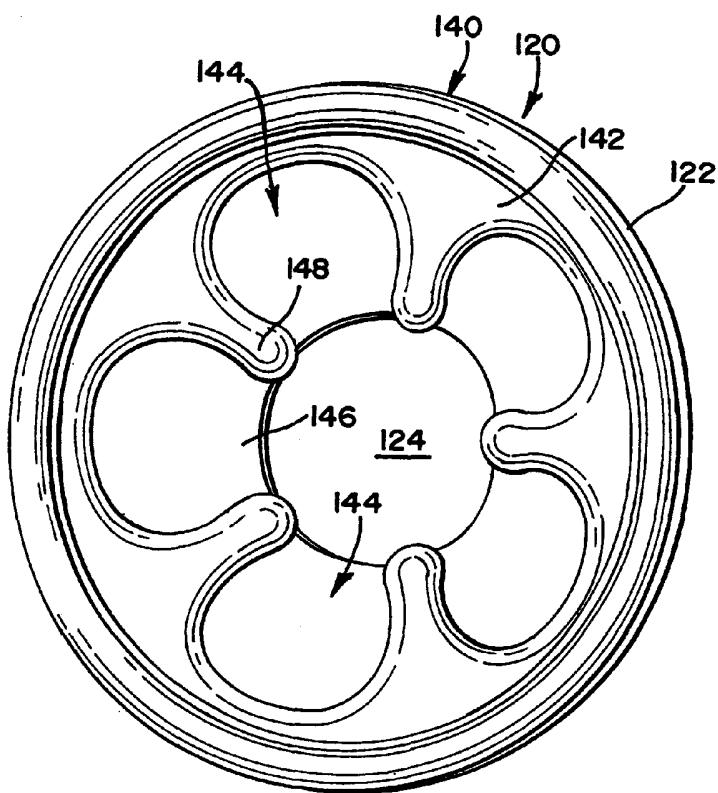
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(54) Title: METHOD OF COLLECTING FLUID WITH A BREASTPUMP MEMBRANE AND NOVEL MEMBRANE COVER  
FOR A BREAST SHIELD



(57) Abstract: A method and apparatus for expressing and collecting mother's milk from a donor utilizing an adapted breastpump assembly. The breast shield is adapted for engagement with a donor's breast to facilitate the expression of mother's milk therefrom. A temporary reservoir is established between the flexible membrane and a portion of the breast shield, the temporary reservoir is provided to initially collect mother's milk upon expression from the donor's breast. This configuration enables the donor to assume a reclined position during the expression process and at least initially collect expressed mother's milk in the temporary fluid reservoir. The membranes disclosed also have unique surface features. A bypass assembly may be provided for conveying mother's milk from the temporary reservoir to a collection receptacle. Utilizing the supplemental configuration, a donor mother need not raise from a reclined position to accommodate any stage of the expression procedure.

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METHOD OF COLLECTING FLUID WITH A BREASTPUMP MEMBRANE AND  
NOVEL MEMBRANE COVER FOR A BREAST SHIELD

5      TECHNICAL FIELD

The present invention relates generally to breastfeeding, and more specifically to an apparatus for preventing leakage during collection of mother's milk, and transferring the collected milk into an infant feeding container.

BACKGROUND OF THE INVENTION

10      Preparation for infant feeding may require the collection of the mother's milk in a container suitable for short-term storage until an appropriate feeding time. There are occasions when it is inconvenient or not possible for mothers to breast feed their infants. At such times the availability of a quantity of mother's milk, in a suitable container, allows an infant the benefit of a familiar source of nourishment. A well known method for the collection of mother's milk utilizes a breast milk pump generally comprising a hood, or shield, that fits over the breast, a vacuum pump connected to the shield for intermittent production of negative pressure within the shield, and a receptacle or container for the expressed milk.

15

United States Patent No. 5,720,722 describes a device and equipment used for breast milk collection, and includes other references to breastpumps. As illustrated, the collection apparatus of U.S. 5,720,722 includes a shield, which covers the breast, becoming engaged to the surface of the breast by suction during intermittent operation of the vacuum pump. Between cycling of the suction, the shield may release from the surface of the breast. This potentially allows expressed

milk to leak from the rim at the perimeter of the shield. The loss of milk may be more pronounced when the shield is made from a relatively rigid material that relies predominantly on formation of a seal by the forward edge of the rim of the shield. To avoid this occurrence, a user of a breastpump may lean slightly forward thereby 5 causing expressed milk to drain from the funnel-shaped shield downwardly into the receiver.

Typically, there is no facility provided that accommodates a mother utilizing the breastpump while in the reclined position. This can be particularly important in a hospital setting after the birth of a child, because this is a time when the mother is 10 normally going to be reclined in bed, or otherwise resting in a reclined position. Furthermore, there is typically no provision for temporary fluid storage in the volume of the shield itself as further facilitation of breast milk collection in a reclined position.

#### SUMMARY OF THE INVENTION

In view of the above-described issues, among others, the present invention 15 has been developed to provide enhancements and further benefits in breastpumps.

Conical or funnel shaped shields, known in the art and used with breastpump arrangements configured according to the present invention, will now allow collection of mother's milk in relative comfort, including reclining posture, without loss of liquid through leakage at the juncture of the arrangement and the surface of the breast. 20 The inventive apparatus and method for leak-free milk collection, even in a reclined position, utilizes in one form a flexible sealing membrane that covers the mouth of the conical shield to provide increased and more consistent surface-to-surface contact between the breast and the incorporating assembly when the breast is positioned at the shield during the pumping process. Furthermore, the sealing

membrane of this design provides accommodation for variations in breast size and shape.

In one contemplated embodiment, the flexible sealing membrane includes an aperture (also referred to herein as a hole, or access port) that is located 5 approximately in the center of the membrane. It is through that aperture that milk passes into the shield's interior and then to the collection container (bottle) attached to the shield. Milk having passed through the aperture, may occupy a temporary reservoir formed between the inner surface of the flexible sealing membrane and the inner wall of the shield. In a reclined position, collected milk may be retained in the 10 temporary reservoir until repositioning of the apparatus causes the milk to drain into the collection container (e.g., the mother sits up).

In another aspect of the present invention, a modification may be made to the wall of the conical shield that conveniently allows continuous transfer of milk from the temporary reservoir into the collection container. This feature obviates the need for 15 the donor to periodically lean forward to drain the temporary reservoir. The modification is preferably made in the form of a bypass tube short-circuiting the normal milk delivery path (through the narrowed portion of the funnel-shaped shield structure) when the angular positioning of the collection assembly prevents natural flow of milk into the receiving container. When the adaptation of the bypass tube is 20 included in the assembly, the mother can remain in, or assume, a reclined position for the entirety of the milk expression procedure.

Conical shields with flexible sealing membranes, according to the present invention allow convenient, comfortable, leak-free, hygienic collection of mother's milk. More specifically, the present invention provides a flexible membrane sized 25 and shaped for releasable engagement with a fluid collecting apparatus of a

breastpump. The flexible membrane includes a flexible body having a sealing portion adapted to achieve releasable engagement upon a fluid collector of a breastpump assembly, and an access port adapted to abut a breast at an exterior side thereof. The access port and flexible body are configured to direct milk expressed from a donor's breast across the flexible membrane to an interior side thereof. In this way, the flexible body is configured to establish a milk retaining space between the interior side and the funnel-shaped shield of a conventionally designed breastpump assembly. The membrane may also be adapted for use on a breastshield separate and apart from its function in making such a reservoir, for which novel designs are provided herein.

In an embodiment, a latex material was used for the flexible membrane. Specifically, a latex condom has been modified by cutting an aperture at the closed end and then stretched about the normally open mouth of the shield to establish the flexible sealing membrane, and the temporary holding reservoir. The condom required no further modification than noted.

The beneficial effects described above apply generally to the exemplary devices and mechanisms disclosed herein for a breastpump assembly. These and other advantages and attributes of the invention will be further understood upon consideration of the following detailed descriptions of certain embodiments, taken in conjunction with the drawings described below.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of a breast milk collecting apparatus according to the present invention.

FIG. 2 is a perspective view of a flexible membrane in a pre-installation 5 tubular configure as utilized in the breastpump assembly of FIG. 1.

FIG. 3 shows a frontal elevational view of an installed flexible membrane of a breast milk collecting apparatus according to the present invention.

FIG. 4 shows a side view of an alternative embodiment of the present breastpump assembly, including a bypass tube that facilitates reclined expression of 10 milk from a mother.

FIG. 5 is a perspective front view of one embodiment of a flexible membrane according to the present invention.

FIG. 6 is a further perspective side view of the flexible membrane of FIG. 5.

FIG. 7 is a rear view of the membrane of FIG. 5.

15 FIG. 8 is a perspective front view of another embodiment of a flexible membrane according to the present invention.

FIG. 9 is a further perspective side view of the flexible membrane of FIG. 8.

FIG. 10 is a rear view of the membrane of FIG. 8.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

It is to be understood that the disclosed embodiments are merely exemplary of the invention that may be embodied in various and alternative forms. The drawings are not necessarily to scale, and some features may be exaggerated or minimized to show details of particular components. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely illustrative and as a representative basis for teaching one skilled in the art to variously employ the present invention.

Referring to FIGS. 1-4, wherein like numbers refer to like parts throughout the several views, FIG. 1 shows a side view of a first embodiment of a fluid collection apparatus or assembly 10 according to the present invention. The primary purpose of the apparatus 10 is the collection of mother's milk. For this purpose, the apparatus 10 uses a conical or substantially funnel-shaped shield 12 of suitable size to extend beyond the nipple area of a human breast. Other shapes for the shield 12 can be used. The conical shield includes a cylindrical nipple tunnel 15 sized and shaped to receive a nipple of a breast and located downstream from the funnel-shaped portion. The conical shield 12, also referred to herein as a fluid collector, is attached to a delivery tube (or tubular extension) 14 to guide the fluid, as it is collected, into a detachable reservoir (not shown, but a bottle, for example) associated with the delivery tube 14 by connecting cover, or collar, 16, which is usually threaded, much like a lid to a jar top. Milk collection is caused by intermittent reduction of the pressure inside the fluid collection apparatus using a suction pump connected to a suction outlet 18, as is well known in the art (see, for instance, U.S. 4,857,051).

To prevent loss of milk during the collection process, the widest dimension, or open mouth, of the conical shield 12 may be covered by a sealing flexible membrane 20 that has an access port 24 (see also FIG. 3) located approximately at the center of the flexible membrane 20. The sealing flexible membrane 20 has sufficient 5 elasticity to allow it to stretch across the mouth of the conical shield 12, extending around its circumferential edge, and held in place by a thickened elastic band 22 that grips the outer surface of the conical shield 12. Before installation upon the funnel-shaped shield 12, the flexible member 20 may exemplarily take the form of a tubular structure 26 having the appearance shown in FIG. 2. From the illustration of FIG. 2, 10 it may be appreciated that conventionally designed condoms may be modified according to the teachings contained herein for providing suitable flexible membranes for apparatus 10.

The tubular structure 26 has the thickened elastic band 22 at the open end and the opening for the access port 24 provided at the normally closed end. It will be 15 appreciated that grasping the thickened elastic band 22 and stretching it evenly around the mouth of the conical shield 12 produces the flexible membrane 20 shown in FIG. 3.

An end view of the mouth of the conical shield 12 appears in FIG. 3 showing the sealing flexible membrane 20 stretched over the mouth of the conical shield 12. 20 The elasticity and flexibility of the sealing flexible membrane 20 allow it to follow the contours of a breast, inserted into the conical shield 12, to provide a surface-to-surface seal that prevents leakage of milk during the collection process. With a modicum of care in positioning the conical shield 12 of the fluid collection apparatus 10, there will be alignment between the nipple and the access port 24 in the flexible 25 membrane 20 for direct transfer of milk into tube 14 then into the collection reservoir

(not shown) that is attached to the connecting cover 16. Formation of a leak-free seal provides a closed volume, subject to reduced pressure, under the influence of a suction pump attached to the suction outlet 18.

FIG. 1 shows that before flowing into the delivery tube 14, a portion of the 5 conical shield 12, shown in this side view as a V-shaped trough portion 28 but which is a three-dimensional crescent shaped sector, will collect fluid until the amount exceeds the volume of the trough portion 28. Having filled trough portion 28, milk will run down the delivery tube 14 into the reservoir attached to the connecting cover 10. The full contents of the reservoir created by trough portion 28 can be emptied by 10 occasionally tilting the assembly 10 to an upright position as shown in FIG. 1. This causes the temporarily collected milk to drain down into the higher volume receiving container.

In an effort to minimize the volume of milk temporarily collected in the reservoir 28, the mother would typically adopt a relatively upright position, or 15 otherwise tip the apparatus. This creates maximum flow to the container, but may be uncomfortable for the mother. At a minimum, it prevents collection of larger quantities of milk without filling the reservoir 28. This can have the negative effect of contributing to leakage between the membrane 20 and the shield 12. Furthermore, if the mother leans back sufficiently, a filled configuration of the reservoir 28 could 20 result in back-flow out of the nipple-receiving aperture.

A solution for when the donor remains reclined during the milk expressing process is shown in FIG. 4. There, it is shown that a relief tube 30 is incorporated into the design of the shield 12 for emptying the portion 28. The relief at shield 12 may be provided merely in the form of an aperture connected directly to a 25 receptacle. Using the relief tube 30 for present purposes, the tube 30 preferably

connects to a relief inlet 32 formed at or near neck 34 between delivery tube 14 and connecting cover 16. A bypass tube, pipe or other conveyance 36 located between the relief tube 30 and the relief inlet 32 completes the supplemental channel that directs milk from portion 28 without going through the delivery tube 14. Collectively, 5 or in various combinations, the bypass conveyance 36, the relief tube 30 and the relief inlet 32 can be referred to as a bypass assembly.

Using this alternative fluid collection apparatus, a mother may assume and maintain a reclined position before, during, and after use of the fluid collection apparatus 10 thereby enjoying greater convenience and comfort during the process 10 of milk collection. Based on positioning and sizing of the relief tube 30, it is possible that the delivery tube 14 may be omitted in favor of the bypass tube or pipe 36. In either situation, that is whether the bypass configuration is provided singularly, or in combination with a conventional delivery tube 14, the relief tube 30 is typically arranged as an aperture through shield 12, and is preferably located proximate to the 15 open mouth of shield 12, where the flexible membrane 20 may be additionally installed.

To prevent any potential loss of suction through the bypass assembly, a one-way valve may be installed across the passage of the bypass and oriented so that when suction is applied, the valve closes and prevents the back-flow of air which 20 might compromise the required vacuum. When suction is released, the valve opens and permits drainage of expressed milk from the reservoir 28 to the collection receptacle.

The present invention further takes the form of a method including the provision of the fluid collection apparatus 10 that incorporates at least the sealing 25 flexible membrane 20. The V-shaped trough portion 28 is established for at least

temporarily receiving expressed milk. The mother commences the process either in an upright or reclined position. If a bypass tube 36 is not provided, the mother may desire to at least sit up occasionally to move collected milk from the reservoir 28 into the permanent collection receptacle through the delivery tube 14. If a bypass tube 5 36 is provided, the mother will not be required to sit up at any time during the expression process. That is, not only may she be reclined when the process begins, but she may remain reclined throughout the procedure and even after its completion. The reason that the reclined position is uniformly accommodated is that the bypass tube facilitates substantially continuous draining of expressed milk from the reservoir 10 area 28 to the permanent receiving container.

Referring to FIGS. 5-7, wherein like numbers refer to like parts throughout the several views, FIGS. 5 and 6 show an embodiment of a membrane 120 according to the present invention including outer surface 142. The membrane 120 may be formed of any suitable flexible elastomeric material, for example, a natural or 15 synthetic rubber. The membrane 120 is generally disk-shaped and includes an elastic band 122 formed about an outer periphery 140 of the membrane. The elastic portion or band 122 is sized and shaped to releasably engage the mouth of the conical shield 12 (FIG. 1). The membrane 120 further includes an access port 124, which is an opening formed at the center of the membrane.

20 On the outer surface 142 of the membrane are formed a plurality of spaced concave impressions 144 that have a generally circular shape. An inner edge 146 of each of the concave impressions 144 is formed without a sidewall, such that the inner edge 146 is in communication with the port 124. In the illustrated embodiment, the membrane 120 includes five impressions 144 on the outer surface 142 thereof.

The present invention contemplates any suitable number of impressions, for example, from three to ten impressions.

Defined between each of the plurality of spaced impressions 144 is a convex ridge 148, which extends from the elastic band 122 toward the port 124.

5 The inner surface 150 of the membrane 120 is illustrated in FIG. 7, wherein it can be seen that the inner side of concave impressions 144 define gently convex features thereon.

Referring to FIGS. 8-10, wherein like numbers refer to like parts throughout the several views, FIGS. 8 and 9 show another embodiment of a membrane 220 10 according to the present invention including outer surface 242. The membrane 220 is generally disk-shaped and includes an elastic band 222 formed about an outer periphery 240 of the membrane. The elastic band 222 is sized and shaped to releasably engage the mouth of the conical shield 12 (FIG. 1). The membrane 220 further includes an access port 224, which is an opening formed at the center of the 15 membrane.

On the outer surface 242 of the membrane are formed a plurality of spaced concave impressions 244 that have a generally rectangular shape with arcuate corners. An inner edge 246 of each of the concave impressions 244 is formed without a sidewall, such that the inner edge 246 is in communication with the port 20 224. In the illustrated embodiment, the membrane 220 includes five impressions 244 on the outer surface 242 thereof. The present invention contemplates any suitable number of impressions, for example, from three to ten impressions.

Defined between each of the plurality of spaced impressions 244 is a convex ridge 248, which extends from the elastic band 222 toward the port 224. Each of the

convex ridges 248 taper from the outer periphery 240 toward the port 224. In addition, each of the convex ridges 248 includes a convex droplet-shaped feature 260. Each of the droplet-shaped features 260 is most narrow at a point adjacent the outer periphery 240.

5 The inner surface 250 of the membrane 220 is illustrated in FIG. 10, wherein it can be seen that the inner side of concave impressions 244 define gently convex features thereon.

When the membrane (120, 220) is positioned upon the conical shield 12 the membrane is held away from the breastshield inner wall by the elastic nature of the 10 membrane material. When a mother contacts a breast against the outer surface (142, 242) of the membrane, the material of the membrane deflects to contact the breastshield inner wall. Upon removal of the breast from the membrane, the membrane returns to its initial position and functions to prevent expressed breastmilk from exiting outwardly from the funnel and potentially out of the shield portion of the 15 breastshield onto the user. Further, the membrane is sized and shaped so as to prevent the membrane from being drawn into the nipple tunnel 15 (FIG. 1). Therefore, the diameter of the nipple tunnel is not reduced. Additionally, the membrane does not negatively affect the movement between the areola and the nipple of the mother's breast resulting from the vacuum from the pump.

20 European Patent Application No. 0198651 A2 discloses a flexible diaphragm (2) associated with the cup member (1) of a vacuum apparatus as illustrated in FIG. 6 of that application. It is explained that the flexible diaphragm (2) is fitted over the mouth of the cup member and is maintained in position by one or more elastic rings which force the edge of the diaphragm sufficiently into the grooves so as to form an 25 airtight connection between the outer wall of the cup and the diaphragm. What is

absent from this disclosure, however, is the provision of the temporary collection reservoir as disclosed according to applicant's present invention. This is particularly evident from the description at page 5, line 17 of European Patent Application No. 0198651 A2 where it is explained that "the nipple will be drawn gently, but firmly, to 5 the rear of the cup member" when the source of vacuum is applied.

Moreover, the method of collecting milk with the donor in a reclined position, including temporarily acting as a reservoir for expressed milk in the space between the membrane and the conical shield, is not disclosed, taught or suggested in European Patent Application No. 0198651 A2.

10 A fluid collection apparatus in the form of a breastpump, and its method of provision and utilization have been described. These and other variations, which will be appreciated by those skilled in the art, are within the intended scope of this invention as claimed below. As previously stated, detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the 15 disclosed embodiments are merely exemplary of the invention that may be embodied in various forms.

I Claim:

1. A method for expressing and collecting mother's milk utilizing a breastpump assembly, said method comprising:
  - providing a breastpump assembly having a flexible membrane engaged upon a breast shield of said breastpump assembly, said breast shield sized and shaped to engage with a breast to facilitate the expression of mother's milk therefrom;
  - 5 establishing a temporary fluid reservoir between said flexible membrane and a portion of said breast shield, said temporary fluid reservoir provided to initially collect mother's milk upon expression from the breast; and thereby
  - 10 enabling the collection of some expressed mother's milk in said temporary fluid reservoir in a reclined position.

2. The method of Claim 1, further comprising:
  - providing a bypass for conveying mother's milk from said temporary fluid reservoir to a collection receptacle.

3. The method of Claim 2, further comprising:
  - using said breastpump assembly in a reclined position during an entire expression process.

4. The method of Claim 1, said method further comprising:

constructing said flexible membrane to include:

a flexible body having a sealing portion adapted to achieve releasable

engagement upon said fluid collector; and

5 an access port configured to abut a human breast at an exterior side of said flexible body, said access port and said flexible body configured to direct expressed milk across said flexible body to said temporary collection reservoir at an interior side of said flexible body.

10 5. A method for expressing mother's milk comprising:

providing a breastpump assembly having a flexible membrane engaged upon a breast shield of the breastpump assembly, wherein a temporary fluid reservoir is provided between the flexible membrane and the breast shield; and

assuming a reclined position during a period in the expression process,

15 whereby expressed mother's milk is collected in the temporary fluid reservoir.

6. The method of Claim 5 further comprising:

providing a bypass assembly for conveying mother's milk from the temporary fluid reservoir to a collection receptacle.

7. A breastpump shield assembly comprising:

a breast shield having an opening sized and shaped to receive a human breast therethrough; and

5 a flexible membrane engaged upon said breast shield, wherein a temporary fluid reservoir is thereby defined between the flexible membrane and the breast shield, and wherein the flexible membrane includes an access port configured to abut the human breast at an exterior side of said flexible membrane such that a nipple of the human breast passes through the access port, and expressed milk is collectable in the temporary reservoir.

10

8. The breastpump shield assembly of Claim 7, wherein said membrane includes an elastic band formed about a periphery of said membrane, said elastic band sized and shaped to releasably engage a mouth of said breast shield.

15

9. The breastpump shield assembly of Claim 7, wherein said membrane includes a plurality of spaced features, each of said features being one of a concave impression and a convex feature and formed in an outer surface of said membrane arranged about said access port

20

10. The breastpump shield assembly of Claim 7, wherein said membrane includes a plurality of spaced concave impressions formed in an outer surface of said membrane arranged about said access port.

11. The breastpump shield assembly of Claim 10, wherein each of said plurality of spaced concave impressions includes an inner edge in communication with said access port.

5 12. The breastpump shield assembly of Claim 10, wherein adjacent pairs of said plurality of spaced concave impressions define a convex ridge therebetween.

10 13. The breastpump shield assembly of Claim 12, wherein each said convex ridge extends from a periphery of said membrane to a point adjacent said access port.

14. The breastpump shield assembly of Claim 12, wherein each said convex ridge includes a convex droplet-shaped feature.

15 15. The breastpump shield assembly of Claim 7, further comprising: a one-way valve for accommodating alternating suction action applied to said temporary reservoir and drainage action of expressed mother's milk from said temporary reservoir.

20 16. The breastpump shield assembly of Claim 7, further comprising a bypass conveyance for conveying mother's milk from said temporary reservoir to a collection receptacle.

17. The breastpump shield assembly of Claim 16, further comprising an aperture to said bypass conveyance at said temporary reservoir.

18. The breastpump shield assembly of Claim 16, wherein said bypass 5 conveyance further comprises a conduit extending from a bottom part of said temporary reservoir and communicating with a collection container.

19. The breastpump shield assembly of Claim 7, wherein said flexible membrane flexes to contact an interior surface of said flexible membrane to an inner 10 surface of said breast shield when the human breast is contacted with said flexible membrane.

20. A breastpump assembly comprising:  
a conical breast shield having an opening sized and shaped to receive a 15 human breast; and  
a bypass conveyance for conveying mother's milk from a reservoir between said human breast and said conical breast shield to a collection receptacle.

21. A flexible membrane for use with a breast shield comprising:  
an essentially planar flexible membrane including an elastic portion formed  
about a periphery of said flexible membrane, said elastic portion sized and shaped to  
releasably engage the breast shield and an access port formed in said flexible  
membrane positioned to receive a nipple of a human breast and wherein said flexible  
membrane when contacted with the human breast is sized and shaped to define a  
temporary reservoir with the breast shield.

22. The flexible membrane of Claim 21, wherein said membrane includes a  
plurality of spaced features, each of said features being one of a concave impression  
and a convex feature and formed in an outer surface of said membrane arranged  
about said access port

23. The flexible membrane of Claim 21, wherein said membrane includes a  
plurality of spaced concave impressions formed in an outer surface of said  
membrane arranged about said access port.

24. The flexible membrane of Claim 23, wherein each of said plurality of  
spaced concave impressions includes an inner edge in communication with said  
access port.

25. The flexible membrane of Claim 23, wherein adjacent pairs of said  
plurality of spaced concave impressions define a convex ridge therebetween.

26. The flexible membrane of Claim 25, wherein each said convex ridge extends from a periphery of said membrane to a point adjacent said access port.

5 27. The flexible membrane of Claim 25, wherein each said convex ridge includes a convex droplet-shaped feature.

28. The flexible membrane of Claim 21, wherein said flexible membrane flexes to contact an interior surface of said flexible membrane to an inner surface of  
10 said breast shield when the human breast is contacted with said flexible membrane.

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# FIG. I

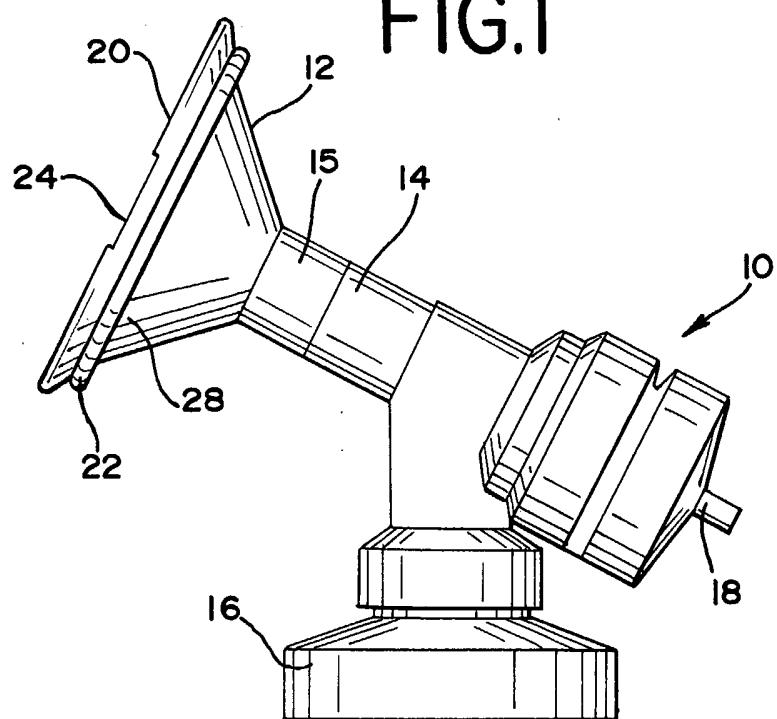
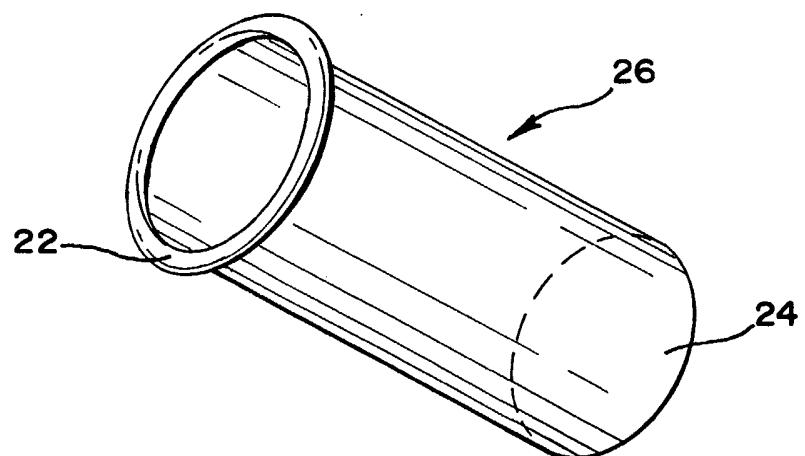


FIG. 2



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FIG.3

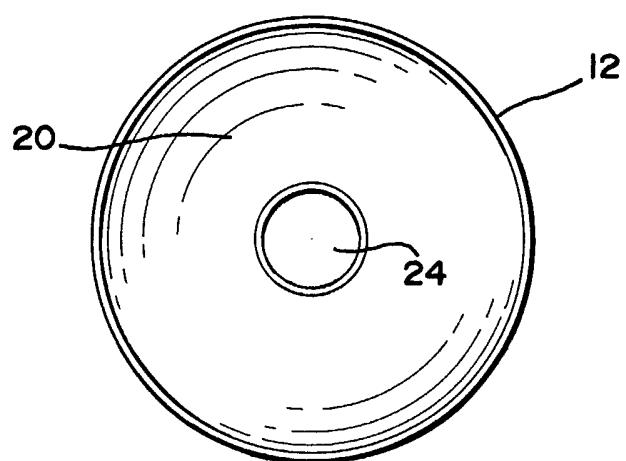
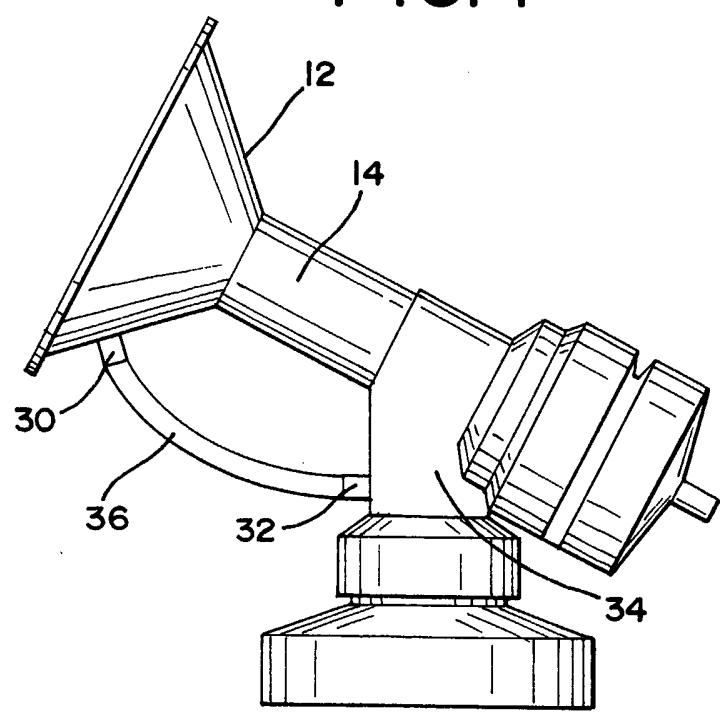


FIG.4



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FIG. 6

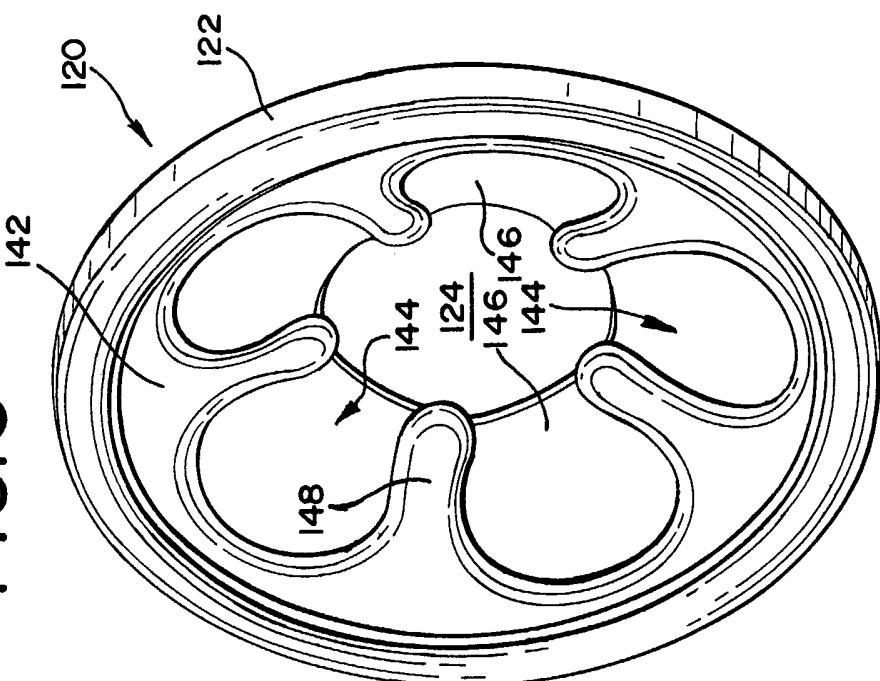


FIG. 5

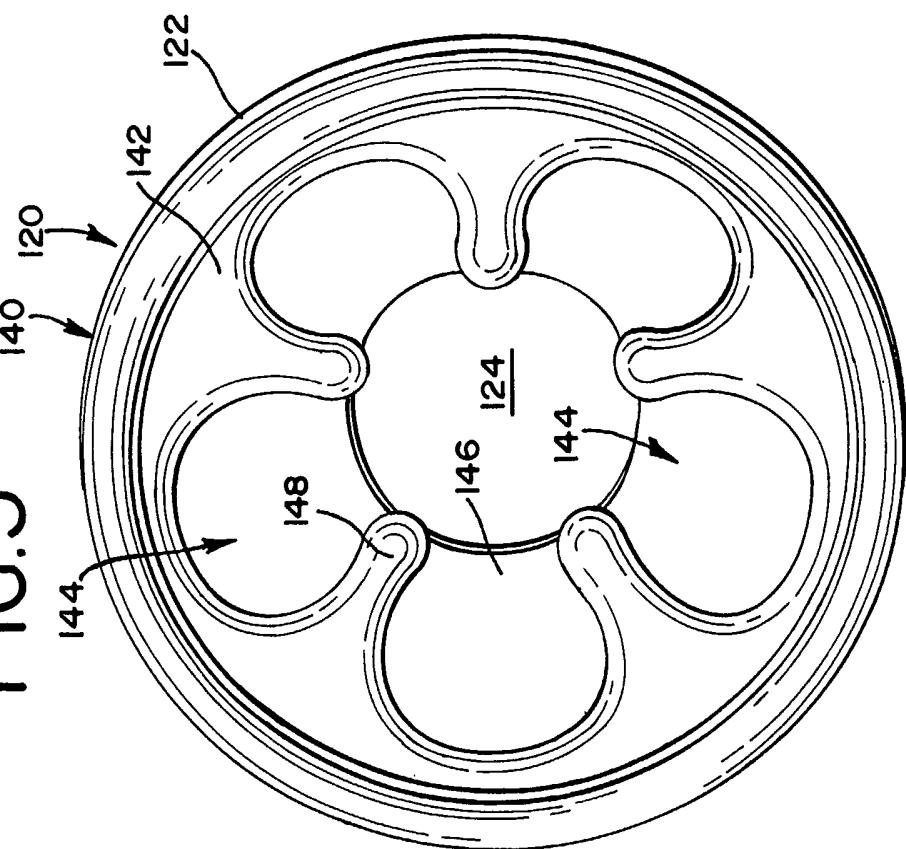


FIG. 7

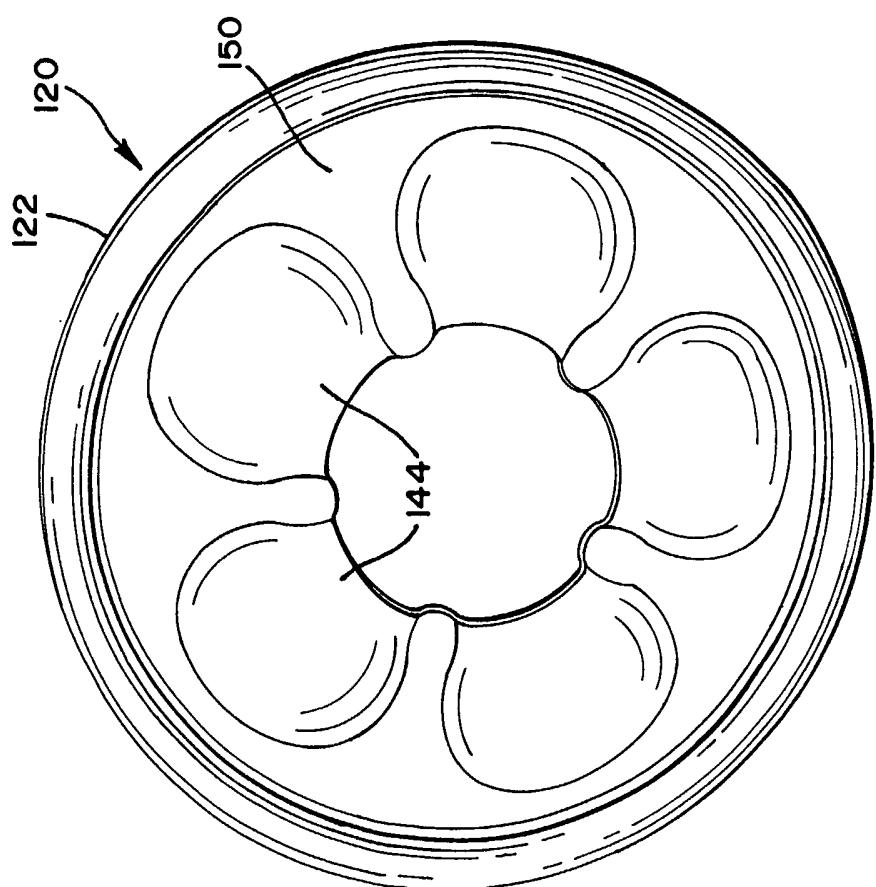


FIG. 8

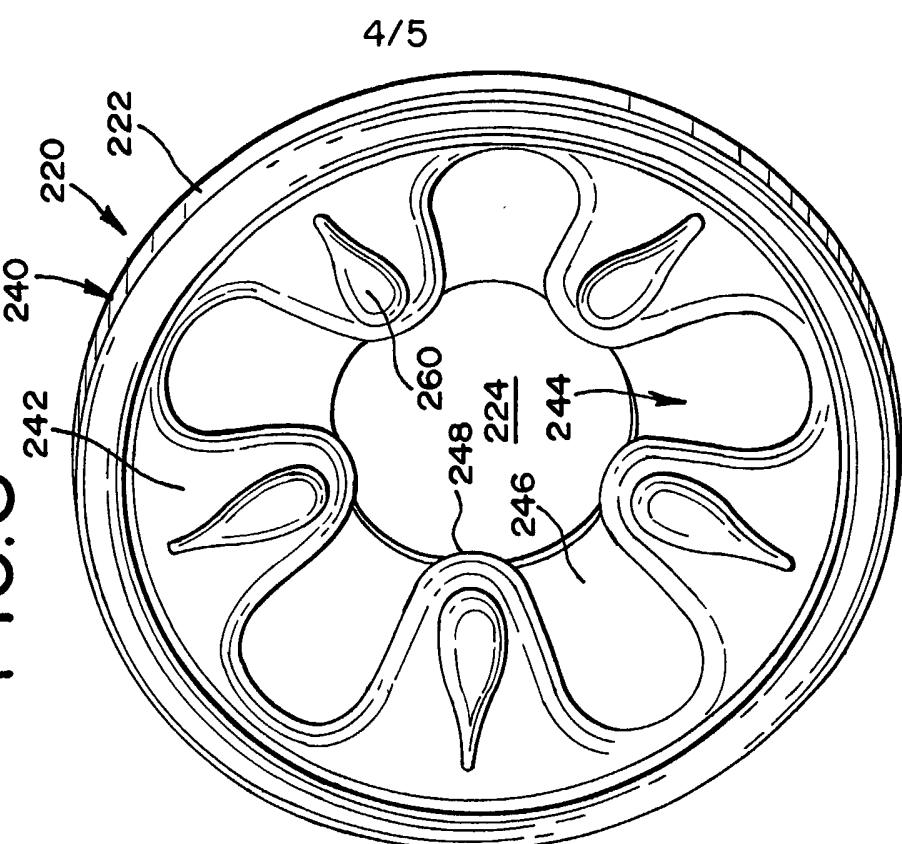


FIG. 9

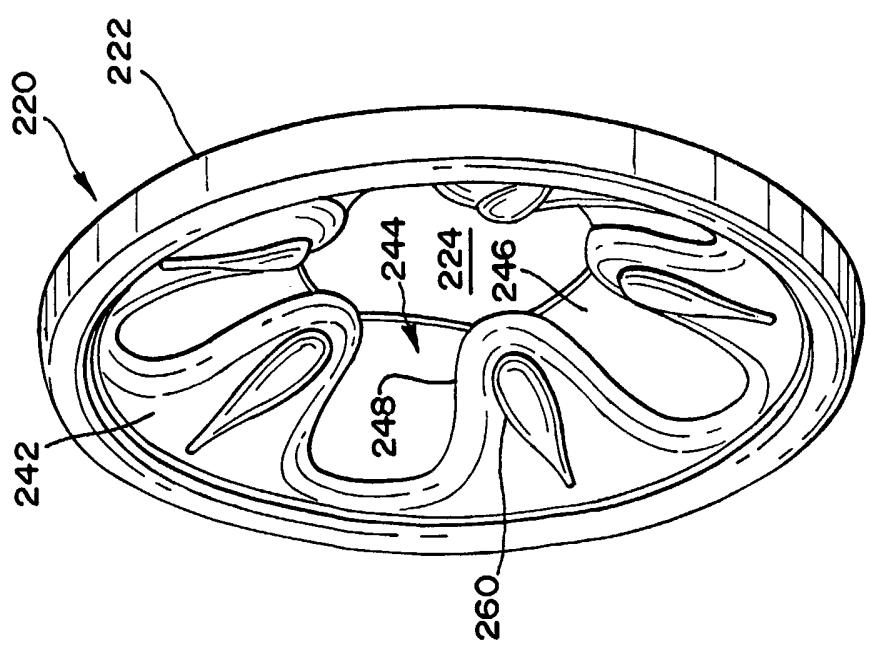


FIG. 10

