

BREAST SHIELD**Priority Cross-Reference**

[001] The present application claims priority from Australian Provisional Patent Application No. 2020900501 filed 21 February 2020 and Australian Provisional Patent
5 Application No. 2020902945 filed 18 August 2020 the contents and disclosure of which are incorporated into this specification by this reference.

Technical Field

[0001] The present invention relates to a breast shield for use in mechanical breast pumps for expressing human breastmilk from lactating mothers.

10 Background of Invention

[0002] The discussion of the background to the invention that follows is intended to facilitate an understanding of the invention. However, it should be appreciated that the discussion is not an acknowledgement or admission that any aspect of the discussion was part of the common general knowledge as at the priority date of the
15 application.

[0003] Breast pumps are known in the prior art and comprise manually operated and motor driven units. The motor driven units can be connected to a mains electricity supply or can be battery-operated. The motor driven units include a vacuum pump and one or two breast shields for placement on the mother's breast or
20 breasts. Breast pumps aim to simulate to the extent possible, the manner in which a baby suckles a mother's breast. The closer a breast pump can approach that simulation, the more likely that milk will be drawn from a mother's breast and the more likely the mother will be comfortable in expressing her breast milk. Breast pumps thus have typically been developed to pump in a cyclic manner using vacuum to apply and
25 release pressure to the breast and nipple through the breast shield and to create a vacuum within the or each breast shield to draw milk from the mother's breast.

[0004] The breast shield component of a breast pump is provided in a large number of different shapes and forms which are intended to ensure a comfortable fitting on different sized and shaped breasts and nipples. Generally, breast shields
30 have a circular funnel opening that is large enough to receive a nipple and to press

and seal against the breast about the nipple. Some breast shields comprise a single shield into which a nipple is inserted and that seals against the skin of the breast about the nipple, and cyclic vacuum is applied within the shield to extend and relax the nipple, drawing breast milk from the breast. Other breast shields have both a
5 hard or rigid outer liner or shell (sometimes known as an outer “shield”) and a flexible inner liner within the outer liner. In some of these breast shields, a generally constant vacuum is applied within the inner liner while a cyclic vacuum is applied between the inner and outer liners, while in other breast shields, the vacuum applied within the inner liner is not constant. The constant vacuum within the inner liner draws milk from
10 the mother’s breast, while the cyclic vacuum applied between the inner and outer liners causes the inner liner to apply pressure to (squeeze) the nipple and to relax or release the nipple in a way that is considered a better simulation of the manner in which a baby suckles a mother’s breast. The squeezing and release of the nipple in this way is thought to promote good milk flow through the nipple, with reduced
15 propensity for blocked milk ducts and the formation of oedema, at good comfort levels for the mother. These are very beneficial outcomes.

[0005] A significant hurdle in successful milk expression is in the initial commencement of milk expression (often referred to as “let-down”) and the continuation of milk expression beyond let-down. The similarity of the feel of the
20 breast pumping process to that of a suckling baby and the comfort the mother experiences during breast pumping are significant factors in successful milk expression over multiple pumping sessions. Improved comfort to the mother in particular has the beneficial effect that mothers are more likely to successfully express breastmilk and so to continue to do so over a longer period post birth to the
25 benefit of the newborn infant, rather than reverting to milk formula.

[0006] US Patent No 7,166,087 which is a patent of a related corporate entity of the present applicant, relates to breastmilk pumps, and discloses arrangements for delivering pressure into breast shields, either positive or negative, which can be independently applied in varying degrees and/or zones of the breast shields in order
30 to provide improved simulation of the natural suckling action of a baby. US 7,166,087 also discloses that the breast shields can be constructed and pressure can be applied in a manner that massages the nipple and breast of a lactating mother. Some of the arrangements disclosed in US 7,166,087 include the use of ribs or bulges in breast

shields for massaging purposes. The ribs or bulges can be permanently formed in surface sections of the breast shields that are in contact with the skin surface of the breast and nipple, or they can be sections that form as a result of the pressure that is delivered to the breast shield. That is, they can be transitional in nature, expanding and contracting based on the pressure delivered to the breast shield. Other arrangements disclosed in US 7,166,087 include single wall breast shields that pulse in a manner to massage the breast and nipple and inner and outer liner arrangements in which a chamber is formed between the liners and positive pressure is employed to enlarge the chamber cyclically to press against or squeeze the breast and nipple to massage the breast and nipple.

[0007] Australian patent application 2016421331 discloses breast shields that are intended to stimulate the nipple of a breast by massage. Breast shields that are disclosed in Application 2016421331 can engage the breast tissue about the nipple, but there is no teaching of actual massage of the breast tissue.

[0008] The present invention aims to provide a breast shield that provides improved milk expression comfort levels for a mother, or which provides benefits in reaching let-down and continuing milk expression beyond let-down, or which provides an alternative to existing breast shields in order to provide better choice for consumers.

Summary of the Invention

[0009] The present invention thus uniquely provides a breast shield that is operable to massage both the nipple and the areola during human breast milk expression.

[0010] The present invention is provided in one form in a breast shield for expressing human breast milk, in which the breast shield comprises an outer housing and a flexible inner liner within the outer housing, wherein in use, with the breast shield applied to a breast, the inner liner is in contact with the surface of both the areola and nipple of the breast, the breast shield further comprising an outer chamber between the outer housing and the inner liner and an inner chamber within the inner liner, in use, the inner and outer chambers being subjectable to differential pressure

and the differential pressure being operable to cause the inner liner to exert a massaging effect against the surface of both the areola and nipple of a breast.

[0011] In the above form of the invention, the breast shield can have an entry end which in use, bears against the surface of the areola of a breast and which applies the massaging effect to the areola. The construction of the breast shield to create the massaging effect at the areola can comprise that the outer housing and the inner liner both extend to the entry end, and the outer chamber extends between the inner liner and the outer housing at the entry end.

[0012] In a more specific form of the present invention there is provided a breast shield for expressing human breast milk, the breast shield comprising:

a rigid outer housing and a flexible inner liner within the outer housing,
the inner liner defining an inner chamber for receiving the nipple of a human breast and an annular outer chamber being defined between the outer housing and the inner liner, the inner and outer chambers being subjectable to differential pressure,

the breast shield having an entry end which in use, bears against the surface of the areola of a breast, the outer housing and the inner liner extending to the entry end so that in use, the inner liner bears against the surface of the areola about the nipple,

the inner liner having a compression section which is inboard of the entry end for receiving a nipple,

in use, the application of differential pressure to the inner and outer chambers is operable to cause the inner liner at the entry end to move relative to the outer housing to create a massaging effect against the surface of the areola and for the compression section of the inner liner to expand and contract relative to an inserted nipple to create a massaging effect against the surface of the nipple.

[0013] The present invention can thus provide breast shields that are operable to massage both the nipple and the areola by the application of differential pressure to the inner and outer chambers.

[0014] The present invention also provides a method for operating a breast pump unit for expression of human breastmilk using the breast shield described above, the method including applying a generally constant vacuum pressure P_1 to the inner chamber, and thereafter adjusting the vacuum pressure in the outer chamber so that the operating vacuum pressure P_o in the outer chamber oscillates about the vacuum pressure P_1 in the inner chamber so that:

- a. the compression section of the inner liner expands and contracts relative to the nipple inserted into it to create the massaging effect against the side surface of the nipple, and
- 10 b. the inner liner at the entry end moves relative to the outer housing to create the massaging effect against the surface of the areola.

[0015] A breast shield according to the present invention specifically targets both the nipple and the areola region of a breast for massage. This arrangement has been developed following research conducted by the present applicant and its related corporate bodies, along with other research organisations and personnel engaged by the present applicant and its related corporate bodies, that indicates that the initial commencement of milk expression (let-down) can be assisted by massaging the areola region of the breast. The research also indicates that there is benefit in continued massage of the areola region as well as massaging of the nipple as this can assist the continuation of milk expression beyond let down. A major benefit is that the volume of milk being expressed is at a level that allows a good quantity of the mother's breast to be drained in an acceptable timeframe. That is, the research suggests that continued massage of the areola region following the commencement of milk expression provides positive outcomes in terms of maximising the volume of milk expressed in a period of pumping and minimising the time taken for that volume to be expressed. This provides improved convenience and satisfaction for the lactating mother and also provides mental health benefits to the mother, given that the lactation stage of a new birth for mothers is already normally quite stressful and that poor pumping outcomes can increase that stress. Failure to successfully express breast milk can also lead to mothers commencing use of milk formula and this can have negative mental health outcomes if the mother would prefer to continue with breast milk for the health of her infant, but is not successfully expressing milk via the pumping process.

[0016] Another benefit is that the pumping action of a breast shield according to the present invention has been established to be very comfortable to the mother and so this likewise promotes the likelihood that the mother will continue to express breast milk for a longer period, both in a single pumping sitting as well as over a longer
5 period of the early stages of a baby or infant's life.

[0017] It is notable that while US 7,166,087 refers to arrangements that are described to massage the breast and/or the nipple for improved milk expression, the disclosure of US 7,166,087 does not recognise the benefits of specifically massaging the areola region of the breast. US 7,166,087 discloses breast and nipple massage
10 to facilitate milk expression but is not prescriptive in terms of how milk expression is improved by breast massage or the type of massage that achieves this. Likewise, Application 2016421331 discloses engagement of the breast tissue about the nipple, but there is no teaching of actual massage of the breast tissue, in particular the areola about the nipple.

[0018] The research referred to above that has been conducted since the priority date of US 7,166,087 has led to the development of new breast shield configurations which are the subject of this application. These new breast shield configurations specifically target both the nipple and areola region for massage in a manner that is intended to assist the commencement and continuation of milk expression. It has
15 also been found, surprisingly, that the massage of the areola region is also beneficial for reducing, like the nipple, the propensity for blocked milk ducts in the areola region and the formation of oedema and for more closely simulating the action of a suckling infant.

[0019] The entry end of the breast shield can have a generally conical or funnel
25 shaped portion. This can comprise complementary funnel shaped portions of the inner liner and the outer housing whereby the funnel shaped portion of the inner liner presents for bearing engagement against the surface of the areola. The outer chamber can also extend to the entry end between the funnel shaped portions of the inner liner and the outer housing so that the application of differential pressure to the
30 inner and outer chambers causes the funnel shaped portion of the inner liner to move relative to the funnel shaped portion of the outer housing. The funnel shaped portion

of the inner liner will thus be movable relative to the funnel shaped portion of the outer housing for massaging the surface of the areola.

[0020] The massaging effect that is created against the areola can be the same as, or different to the effect applied to the nipple. For example, the massaging effect created against the nipple can be by compression and expansion of the compression section of the inner liner which applies a force or load generally perpendicular to the side surface of the nipple to press and pull the side surface. The force applied to the surface of the nipple is thus generally a single component force only. Similarly, the entry end of the breast shield might be arranged so that inner liner at the entry end applies only a compression and expansion force to the surface of the areola, so that likewise the force applied to the surface of the areola generally has only a single component.

[0021] In different arrangements, the inner liner can be arranged to apply a force to the surface of the areola that has two or more components. In these arrangements, the force applied to the surface of the areola can apply both compressive and shear force or stress to the surface. Thus, in some forms of the invention, the nipple is subject to compressive force or stress only and the areola is subject to both compressive and shear force or stress. In some forms of the invention, there can be three components of force comprising compressive and shear force or stress, and lateral force or stress. The components can for example be in 3-dimensions in the X, Y and Z axes comprising radial, axial and lateral loading.

[0022] The generation of compressive force against the surface of the nipple can be by contraction and expansion (or release or relaxation) of the compression section of the inner liner against the nipple surface. The compression section can be generally circular in cross-section so that contraction and expansion of the compression section against the nipple applies a generally perpendicular force against the nipple. In this respect, during milk expression, typical nipples will have a generally cylindrical section between the areola and the nipple tip, although often with a slight taper from the areola to the nipple tip, so that contraction of the compression section against the nipple will typically apply an even compressive load along the length of the cylindrical section. In other forms of the invention, the compression section can be generally circular in cross-section but tapered from the entry end from

a larger diameter to a smaller diameter. The tapering will be slight but can facilitate easy entry of a nipple into the compression section and should still apply load evenly along the side surface of the nipple given that nipples normally have the slight taper referred to above from the areola to the nipple tip. The tapering of the compression
5 section can also resist entry of tissue from the areola into the compression section.

[0023] The compression section can be contracted against the surface of the nipple by reducing the operating vacuum pressure P_o within the outer chamber relative to the generally constant vacuum pressure P_i within the inner chamber. Expansion of the compression section can be by increasing the operating vacuum
10 pressure P_o relative to the vacuum pressure P_i within the inner chamber.

[0024] The constant vacuum pressure P_i in the inner chamber can be approximately -70 to -350mmHg, more preferably -120 to -250mmHg, more preferably -200mmHg. In some forms of the invention, the vacuum pressure P_i in the inner chamber is approximately -200mmHg and the initial vacuum pressure P_i in the outer
15 chamber is approximately -250mmHg. In some forms of the invention, operating vacuum pressure P_o within the outer chamber is set to oscillate between atmosphere and up to about -400mmHg, i.e. to about twice the constant vacuum pressure in the inner chamber.

[0025] In some forms of the present invention, the compression section of the
20 inner chamber can have a natural or relaxed state in which the inner diameter of the compression section is less than the outer diameter of the nipple that the breast shield is intended for use with. An arrangement of this form means that in the application of the breast shield to the breast of a mother, the application of differential pressure to the inner and outer chambers is such as to expand the compression
25 section to allow insertion of a nipple. Once inserted, the compression section can return to the natural or relaxed state in which it applies compressive pressure to the nipple. In these forms of the invention, consumers will purchase an appropriate size of breast shield, or an appropriate size of inner liner, that suits their own nipple size and the method of the invention will be such that an initial vacuum pressure P_i will be
30 applied to the outer chamber which is greater than the vacuum pressure of the inner chamber. The vacuum pressure P_i might be applied when the inner chamber is at atmosphere, or the vacuum pressure P_i might be applied when the inner chamber has

already been evacuated to the generally constant vacuum pressure P_1 . In either case, the initial vacuum pressure P_1 will be greater than, i.e. more negative than the vacuum pressure within the inner chamber, so that the compression section of the inner chamber expands for receiving a nipple. Once the nipple is received into the compression section, the operating vacuum pressure P_o in the outer chamber can be oscillated about the vacuum pressure P_1 in the inner chamber to produce the massaging effects against the nipple and the areola.

[0026] A benefit of the above arrangement is that the breast shield attaches to the nipple immediately the compression section is returned to the natural or relaxed state, or a compressed state. Then, when a vacuum pressure is applied to the inner chamber with the breast shield in place in touching or pressing engagement with the areola, the breast shield remains firmly attached to the breast and in contact with the surface of the nipple and areola. Once the differential pressure is then applied to the inner and outer chambers, the beneficial massaging effect is created against the nipple and the areola.

[0027] The compression section of the inner chamber can alternatively have a natural or relaxed state in which the inner diameter of the compression section is greater than the outer diameter of the nipple that the breast shield is intended for use with. An arrangement of this form means that a nipple can be inserted into the compression section without the application of differential pressure to the inner and outer chambers, so that for example, the inner liner can be placed over a breast before the breast shield is operated. In this form of the invention, with a nipple already inserted into the compression section, the compression section is brought into compression engagement with the nipple for massaging purposes by the application of a pressure in the outer chamber that is more positive than the pressure in the inner chamber. For example, for compression of the nipple for massaging purposes, with the pressure in the inner chamber being -200mmHg, the pressure in the outer chamber can oscillate between a negative or vacuum pressure such as a pressure between -200mmHg and atmosphere, and positive pressure above atmosphere, such as +100mmHg. At -200mmHg in both the inner and outer chambers, the inner diameter of the compression section of the inner liner will be relaxed and so will be greater than the outer diameter of the nipple and so the nipple will be released from

compression, but compression will commence as the pressure in the outer chamber increases from -200mmHg towards and beyond atmosphere, such as to +100mmHg.

[0028] The differential pressure that is applied to the inner and outer chambers is also operable to create the massaging effect against the surface of the areola. In some forms of the invention, the massaging effect can be as a result of movement of the inner liner in the region of the entry end of the breast shield in a direction forward and away from the surface of the areola. That forward and away movement can occur while the inner liner remains attached to or in contact with the surface of the areola, so that the surface of the areola moves with the inner liner. While there can also be sliding or rubbing movement of the inner liner laterally relative to the surface of the areola, or across the surface, that movement is not preferred. Preferred movement is lateral pulling and pushing movement whereby the inner liner attaches to the surface of the areola as a result of vacuum pressure within the inner chamber and the application of differential pressure to the inner and outer chambers is operable to pull on the surface of the areola and to push against it. There can be a combination of sliding movement and pulling and pushing movement, but again, the preference is for non-sliding or non-rubbing movement only.

[0029] The massaging effect can thus be produced by a mixture of movements of the inner liner with the surface of the areola, whether being movement either relative to the surface of the areola (non-preferred) or in attachment to the areola surface (preferred), which include one or more of back and forth movement, orbiting or circular movement, lifting and pressing movement, or a combination of two or more of these types of movement. The movement may be programmed to change during milk expression, or it may naturally change as the milk expression activity proceeds due to changes in the values of the vacuum pressures applied within the inner and outer chambers, or due to changes in the frequency of the oscillation of the vacuum pressure in the outer chamber about the vacuum pressure in the inner chamber, or due to a combination of both.

[0030] The movement may also change depending on the physiology of the breast under expression, for example between the commencement of milk expression when the breast is substantially full and the surface of the breast or the outer skin layer of the breast is relatively tight or taut, as compared to the mid-way through an

expression or toward the end of an expression when a significant portion of the volume of breast milk has already been expressed and so the surface of the breast or the outer skin layer of the breast is more relaxed or supple. Changes in the temperature of the breast may also have an effect on the movement that occurs on or
5 over the areola.

[0031] As indicated above, in some forms of the invention, the movement and thus the forces that are applied to the areola can be different to the movement and forces applied to the nipple in order to apply a different massaging effect to the areola and nipple. This different application of movement is anticipated to have a positive
10 influence on milk flow through the milk ducts of the areola and the nipple with no increased discomfort to the mother, but rather, with an expected increase in comfort. This outcome is both surprising and beneficial.

[0032] Some of the movement generated in the entry end of the breast shield by the inner liner against the surface of the areola can be as a result of inward and
15 outward movement of the inner liner within and relative to the outer housing, as the vacuum pressure in the outer chamber oscillates relative to the vacuum pressure in the inner chamber. In some forms of the invention, the inner liner can be pulled in a direction toward the tip of the nipple when the vacuum pressure in the outer chamber is less than the vacuum pressure in the inner chamber and that shift can occur as the
20 inner liner is in contact with the surface of the nipple and/or the areola. The areola and nipple are thus pulled further into the outer housing until the vacuum pressure in the outer chamber is returns to a greater vacuum pressure than in the inner chamber wherein the areola and nipple can move outwardly relative to the outer housing. This outward movement can be recovery movement by recovery of the areola and nipple
25 from stretched conditions to relaxed or more relaxed conditions.

[0033] In some forms of the invention, the compression section extends to an end section that is collapsible over the tip of the nipple (the tip being the end surface of the nipple which is generally perpendicular to the length of or the side surfaces of the nipple) under sufficient differential pressure between the inner and outer chambers.
30 Thus, when the vacuum pressure within the inner chamber is greater than the vacuum pressure within the outer chamber so that the compression section is applying a compressive or contracting force against the surface of the nipple, the end

section can collapse into engagement with the tip of the nipple to apply pressure to or across the nipple tip. The end section can collapse into engagement with the tip of the nipple each time the vacuum pressure within the inner chamber is greater than the vacuum pressure within the outer chamber so that the end section cyclically
5 engages and disengages the nipple tip. The massaging effect applied to the breast is thus applied to each of the areola, the side of the nipple and the end or tip of the nipple. That pressure can have the same or similar benefits at the tip of the nipple as the massage that is applied along the length of the nipple and at the areola. Improved milk expression and reduced blockage of milk ducts are expected
10 outcomes.

[0034] The inner liner can collapse in any suitable manner that provides engagement of the nipple tip. In some forms of the invention, the collapse is three-fold or star-shaped collapse. In other forms of the invention, the collapse is two-fold or bow-tie shaped collapse.

15 [0035] To promote collapse in a three-fold form, the end section can be formed to have a three-sided polygonal shape in a relaxed or resting state. Such a polygonal shape will form three apexes in the relaxed or resting state and these form the three folds when the end section collapses. Three further inner folds will be formed between the apex folds as the end section collapses and these inner folds converge
20 towards each other and towards the centre line of the inner liner. The inner folds can converge to the point at which they meet and engage and at which point the side walls of the end section close over the nipple tip and into engagement with the nipple tip. In this form of the invention, the end section can expand to a circular form or shape in the expanded shape of the inner liner when the vacuum pressure in the
25 outer chamber exceeds, i.e. is more negative than, the vacuum pressure in the inner chamber.

[0036] To promote collapse in a two-fold form the end section can be formed to have diametrically opposed thicker wall sections, or diametrically opposed thinner wall sections. The collapse will have the end section form into a bow-tie shape with two
30 end folds and two inner folds between the end folds. The inner folds can converge to the point at which they meet and engage and at which point the side walls of the end

section close over the nipple tip and into engagement with the nipple tip the wall of the polygonal section of the inner liner has closed over the nipple.

[0037] The inner liner can be formed of any suitable material, however the preferred material currently is Silicone / Liquid Silicone Rubber (LSR). The preferred hardness is Shore 40. However, alternatives include: rubber, thermoplastic elastomer (TPE), Latex, Nitrile butadiene rubber (NBR), Neoprene, HCR Silicone (Heat Cured Rubber). The preferred Shore hardness is from 20 to 80, more preferably from 40 to 60.

[0038] The flexible wall of the inner liner can have any suitable construction. In some forms of the invention, the wall of the inner liner is of generally constant wall thickness. In other forms of the invention, different sections of the inner liner have generally constant wall thicknesses. For example, the wall thickness of the entry end may be different from the wall thickness of the compression section and the end section. In other forms of the invention, the wall thickness of the liner can be of irregular thickness or cross-section in one or more sections of the inner liner. This irregular thickness or cross-section can be provided to unevenly distribute pressure and/or movement to different sections or regions of the areola and nipple. This can also alter the massaging effect that is produced on those sections or regions of the areola and nipple.

[0039] Irregular thicknesses or cross-sections can comprise discrete thick sections formed in the liner wall. Four equidistantly spaced thick sections can be provided for example in a liner of otherwise even wall thickness. The thick sections can extend longitudinally of the inner liner, such as in one or more sections of the inner liner, such as the compression section. These thick sections will resist circular expansion of the liner so that the liner expands in a non-circular shape. The shape might be a generally square expanded shape. Greater expansion will occur in the region between the thick sections of the expanded liner as compared to at the thick sections, so that different areas of the areola and nipple will be massaged differently or will be affected differently under liner expansion. This different treatment means that some regions of the areola and nipple will be subject to more liner movement than others and more or less compression or stress than others. That different

treatment can enhance the massaging effect by the exerting a less uniform and more random pressure/movement distribution to the areola and nipple.

[0040] Three equidistantly spaced thick sections could alternatively be provided so that a generally triangular expansion occurs of the inner liner. Again, greater
5 expansion will occur in the region between the thick sections.

[0041] In other forms of the invention, the inner liner can have an uneven wall thickness that progressively increases in thickness from a minimum thickness to a maximum thickness, which is diametrically opposite the minimum thickness, and back to the minimum thickness. In this form of the invention, greater expansion occurs in
10 the thinner regions of the expanded liner as compared to the thicker regions.

[0042] In some forms of the invention, the thicker wall sections can be elongate and thus can extend in straight lines generally in the direction of the axis of the liner, or they can be formed in a spiral or helix manner about the axis of the liner, or they can extend in random, non-uniform paths. The thicker wall sections result in some
15 regions of the areola and nipple being subject to more liner movement than others and more or less compression or stress than others. This can enhance the massaging effect by the exerting a less uniform and more random pressure/movement distribution to the areola and nipple. The thicker wall sections can have uniform cross-section throughout the length of the sections, or the cross-
20 sections of the thicker wall sections can change along the length, such as tapering at one or each end of the section. Where a plurality of thicker wall sections is provided, the sections can be all of the same length or of different lengths, and the thickness of the thicker wall sections can also be the same or different.

[0043] The use of elongate thicker wall sections can also be combined with a liner
25 wall thickness that progressively increases in thickness from a minimum thickness to a maximum thickness.

[0044] Other parts of a breast shield according to the invention can also be arranged to apply uneven pressure or movement against the areola or nipple. Suitable profiles can be formed in the funnel or entry end of an inner liner, to form
30 recesses or projections, such as localised recesses or projections. These can include part spherical projections and elongate recesses. The projections can form massage

spots or elevations, while the recesses can form suction areas. The projections can apply localised increased or concentrated pressure, while the recesses can redistribute suction pressure to different areas of the entry end. The result can be to create local variations in the movement of the entry end of the inner liner against the surface of the areola, in order to affect the amplitude of the cyclic compression force on the areola. The effect can also be to guide or move the suction applied to the breast/areola to a larger diameter to increase the holding force of the breast shield on the breast. This increases the security with which the breast shield attaches to the breast.

10 Brief Description of the Drawings

[0045] In order that the invention may be more fully understood, some embodiments will now be described with reference to the figures in which:

[0046] Figure 1 shows a cross-sectional view of a breast shield according to one aspect of the present invention.

15 [0047] Figure 2 is a schematic representation of a breast and of the forces that are applied to the areola and the nipple of the breast by the inner liner of a breast shield according to the invention.

[0048] Figures 3 to 8 illustrate an example of the pressure that is applied to an areola and nipple by a breast shield according to the present invention.

20 [0049] Figure 9 shows an example pressure distribution within the inner and outer chambers of a breast shield according to the present invention.

[0050] Figure 10 illustrates the inner liner of a breast shield according to the invention.

[0051] Figure 11 is a cross-section through section 11-11 of the inner liner of
25 Figure 10 showing three states of collapse and recovery.

[0052] Figure 12 is a cross-sectional view showing two different configurations of liner collapse.

[0053] Figures 13 to 15 show alternative wall constructions of the inner liner.

[0054] Figures 16 to 22 show further alternative wall constructions of the inner liner.

Detailed Description of the Drawings

[0055] Figure 1 shows a cross-sectional view of a breast shield according to one aspect of the present invention. The breast shield 10 has a rigid outer housing 12 and a flexible inner liner 14. The inner liner 14 has a funnel shaped entry end 16 and the edge 17 of the entry end 16 is in sealing engagement with a proximal portion of the outer housing 12. The outer housing 12 is shown square in cross-section in Figure 1, although the wall will be circular. The outer housing 12 could be alternatively shaped and in some forms of the present invention, the outer housing 12 has a shape that is similar to that of the inner liner 14.

[0056] The opposite end of the outer housing 12 also seals with the inner liner 14, although the construction of the seal at the opposite end is not shown in Figure 1. The seal can be through an end connection or manifold through which vacuum pressure can be delivered and a suitable arrangement is shown in part cross-section in Figures 3 to 8.

[0057] The inner liner 14 defines an inner chamber 18 for receiving the nipple of a human breast, while an annular outer chamber 20 is defined between the outer housing 12 and the inner liner 14. The inner and outer chambers 18 and 20 are connected to vacuum sources during use of the breast shield 10 to evacuate the respective chambers 18 and 20 to below atmospheric pressures. Vacuum lines 22 and 24 communicate with the respective chambers 18 and 20 and extend to vacuum pumps (not shown).

[0058] The outer housing 12 can have any suitable shape to connect with the inner liner 14 and to create the outer chamber 20 between them.

[0059] The inner liner 14 has a compression section 26 that extends from an inboard end of the entry end 16. The compression section 26 is generally cylindrical, although slightly tapered from a larger diameter at the entry end 16 to a smaller diameter remote from the entry end 16, and is provided to exert pressure on a nipple that is inserted into the inner liner 14. As will be explained later herein, in some forms

of the invention, the internal diameter of the compression section 26 is less than the outer diameter of the nipple the breast shield is intended for use with, so that a nipple that is inserted into the compression section 26 is compressed by the inner liner 14 when the inner liner 14 is in a relaxed state. In other forms of the invention, the
5 compression section 26 can have a natural or relaxed state in which the internal diameter of the compression section is greater than the outer diameter of the nipple that the breast shield is intended for use with.

[0060] The inner liner 14 has a collapsible section 28 that extends from an inboard end of the compression section 26. The collapsible section 28 has a structure that
10 allows it to collapse against or close over the surface of the tip of the nipple, to apply pressure to the nipple tip. This will be discussed later herein in relation to Figures 11 to 15.

[0061] In use, the entry end 16 is placed against the surface of breast about the nipple. The entry end 16 thus is placed against or bears against the surface of the
15 areola of a breast. By placing the entry end 16 against the surface of the areola, the nipple of the breast extends into the inner chamber 18 and into the compression section 26 of the inner liner 14. Where the outer diameter of the nipple is less than the inner diameter of the compression section 26, the nipple will enter the compression section 26 without resistance. However, where the outer diameter of the
20 nipple is greater than the inner diameter of the compression section 26, the compression section 26 will resist insertion of the nipple and so a vacuum may need to be applied to the outer chamber 20 to expand the compression section 26 to allow the nipple to enter the compression section 26, to avoid having to force the nipple into the compression section 26.

[0062] Arranging for the inner diameter of the compression section 26 to be
25 generally smaller than the outer diameter of the nipple for which the inner liner 14 is intended to be used, is considered to be beneficial given the intention of the invention to apply a compression load or force to the nipple during milk expression. Thus, the inner liner 14 can be arranged to apply compression to the nipple when the liner is
30 relaxed and this means that the effort required to apply increased compression to the nipple is reduced and can be initiated quickly.

[0063] The outer chamber 20 extends from the edge 17 of the entry end 16 and extends past the compression section 26 and the collapsible section 28. The application of differential pressure to the inner and outer chambers 18 and 20 is thus operable to cause movement in the inner liner 14 from adjacent the edge 17 fully
5 along the funnel shaped entry end 16 and through the compression section 26 and the collapsible section 28. This movement of the inner liner 14 is such as to create a massaging effect against the areola and the nipple, including the nipple tip. Movement is created in each of the entry end 16, the compression section 26 and the collapsible section 28 and the movement in each of these parts of the inner liner 14 is
10 different to the other parts.

[0064] The method of operating the breast shield 10 involves attaching the breast shield 10 to a breast with the entry end 16 seated against the areola of the breast. If the breast shield 10 is of a form in which the outer diameter of the nipple is less than the inner diameter of the compression section 26, then, as discussed above, the
15 nipple will enter the compression section 26 without resistance. However, if the outer diameter of the nipple is greater than the inner diameter of the compression section 26, it will likely be necessary as a first step, to apply a vacuum to the outer chamber 20 to expand the inner liner 14 at the compression section 26 so that the nipple can enter the compression section 26. This step can be initiated before or after vacuum is
20 applied to the inner chamber 18. If this step is initiated after vacuum is applied to the inner chamber 18, then the vacuum that needs to be applied to the outer chamber 20 to expand the compression section 26 needs to be greater than the vacuum applied to the inner chamber 18.

[0065] It is preferred that the vacuum pressure that is applied to the inner
25 chamber 18 be a generally constant vacuum, while the vacuum pressure that is applied to the outer chamber 20 be variable to cycle, oscillate or pulsate above and below the vacuum pressure in the inner chamber 18. In some prototype testing, the vacuum pressure within the inner chamber 18 is maintained at about -200mmHg. In this prototype testing, the compression section of the inner chamber 18 has a natural
30 or relaxed state in which the inner diameter of the compression section 26 is less than the outer diameter of the nipple that the breast shield is intended for use with and the outer chamber 20 has been set to oscillate between atmosphere and up to about -400mmHg, i.e. to about twice the constant vacuum pressure in the inner chamber 18.

[0066] Alternatively, where the compression section of the inner chamber has a natural or relaxed state in which the inner diameter of the compression section is greater than the outer diameter of the nipple that the breast shield is intended for use with, the vacuum pressure that is applied to the inner chamber 18 can still be a
5 generally constant vacuum of about -200mmHg, and the outer chamber 20 can be set to oscillate between a negative pressure value, such as a value or point between -200mmHg and atmosphere and a positive pressure value, such as a value or point between atmosphere and +100mmHg.

[0067] The outer housing 12 is a rigid housing so that the vacuum pressure within
10 the outer chamber 20 does not distort or deflect the outer housing 12 in any noticeable manner. Thus, it is only the flexible inner liner 14 that distorts, deflects, moves, shifts or vibrates as the vacuum pressure in the outer chamber 20 oscillates about the vacuum pressure within the inner chamber 18.

[0068] Figure 1 shows in broken line the outline of a breast 30 that the breast
15 shield 10 has been applied to. The areola 32 of the breast 30 is seated against the entry end 16 of the inner liner 14, while the nipple 34 is within the compression section 26 and, while not apparent in Figure 1, the nipple 34 is under compression by the inside wall of the compression section 26. The breast shield 10 is in a non-activated state in which the internal pressure within each of the inner and outer
20 chambers 18 and 20 is atmosphere. The inner liner 14 is therefore near a relaxed state or condition while exerting a squeeze load on the nipple 34.

[0069] Upon activation of the breast shield 10, the vacuum pressure within the inner chamber 18 is taken to about -200mmHg. This may take several seconds to reach that vacuum. The vacuum pressure within the outer chamber 20 can remain at
25 atmosphere until the inner chamber 18 reaches the pre-selected vacuum pressure, or the vacuum pressure within the outer chamber 20 can also be generated as the inner chamber 18 is being evacuated.

[0070] As indicated above, when the breast shield is operating, the vacuum pressure within the outer chamber 20 will oscillate about the constant pressure within
30 the inner chamber 18 to create the movement required of the inner liner 14. Figure 2 is a schematic representation of the breast 30 and of the loads or forces that are

applied to the areola 32 and the nipple 34 of the breast 30 by the inner liner 14 of the breast shield 10 during oscillation of the vacuum pressure within the outer chamber 20 about the constant pressure vacuum within the inner chamber 18. The forces that are applied to the areola 32 and the nipple 34 are shown by the arrows of Figure 2 and while the arrows point in one direction only, the forces are applied in the directions shown as well as in the opposite directions. The forces can thus be compressive and pulling forces.

[0071] In Figure 2, the forces applied to the areola are shown to have components of radial and axial compression. That is, the forces are applied generally perpendicular to the inclined or curved surface of the areola and so the areola is subject to both radial and axial compression. In contrast, the forces applied to the nipple are generally perpendicular to a cylindrical surface and so the forces applied to the nipple are generally radial compression forces. There is generally no axial component to the forces applied to the nipple. Of course lactating mothers' breasts vary significantly, so that the schematic representation of Figure 2 is to be understood as being a very generalised illustration of a breast and the forces applied to it, but the testing that has been undertaken to date shows that despite the variations in breast size and shape, the forces that are applied to the areola and nipple are generally consistent with the schematic representation of Figure 2.

[0072] The forces that are applied to the areola 32 can be described as comprising both compressive and shear forces or stresses. The resultant movement of the entry end 16 of the inner liner 14 against the areola 32 involves the two component forces discussed above so that the entry end 16 of the inner liner 14 tends to either 1) shift on the surface of the areola 32, producing the massaging effect, or 2) the entry end 16 tends to shift the outer skin layer of the breast relative to inner layers of the breast to again produce the massaging effect, or 3) the massaging effect is produced as a combination of both. The movement of the entry end 16 can be a back and forth movement, or an orbiting or circular movement, or a lifting and pressing movement for example, or a combination of two or more of these types of movement. The movement of the entry end 16 on or relative to the areola 32 may also change between these types of movement as the milk expression activity proceeds due to, for example, changes in the values of the vacuum pressures applied within the inner and outer chambers 18 and 20, or due to changes in the frequency of the oscillation of the

vacuum pressure in the outer chamber 20 about the vacuum pressure in the inner chamber 18, or due to a combination of both.

[0073] The movement of the entry end 16 on or relative to the areola 32 may also change depending on the physiology of the breast under expression, for example
5 between the commencement of milk expression when the breast is substantially full and the surface of the breast or the outer skin layer of the breast is relatively tight or taut, as compared to the mid-way through an expression or toward the end of an expression when a significant portion of the volume of breast milk has already been expressed and so the surface of the breast or the outer skin layer of the breast is
10 more relaxed or supple.

[0074] Importantly, the forces that are applied to the areola 32 are different to the forces applied to the nipple 34 and the massaging effect that is created is therefore different between the areola 32 and the nipple 34. The outcome of this difference has been found through testing and experimentation to have a positive influence on milk
15 flow through the milk ducts of the areola 32 and the nipple 34 and yet with no increased discomfort to the mother, but rather, with an expected increase in comfort. This outcome is both surprising and beneficial.

[0075] Figures 3 to 8 illustrate an example of inner liner movement relative to an areola and nipple in a breast shield according to the present invention. Figures 3 to 8
20 show a portion of an inner liner 40 of a breast shield in the region bound by the dashed line in Figure 1, so that the liner portion 40 shown is inboard of the edge 17 and extends into the collapsible section 28. Movement of the liner portion 40 correlates to the pressure distribution shown Figure 9, which is the distribution applied or generated within the inner and outer chambers 18 and 20 of the breast shield 10.
25 A constant vacuum is applied within the inner chamber 18 and a variable or pulsating vacuum being applied within the outer chamber 20. The Y axis of the graph of Figure 9 is thus an increasing vacuum value (that is, becoming more negative moving upwardly), while the X axis represents time. Numbered stages 1 to 6 appear in Figure 9 and these relate to the state of the inner liner in Figures 3 to 8.

30 [0076] With reference to Figure 3, this shows the initial state of the liner portion 40 in which the respective pressures within the inner and outer chambers 18 and 20 are

at atmosphere. Figure 9 graphs this initial state at stage 1. The broken line 44 represents the shape of the inner surface 46 of the liner portion 40 in this zero and equal pressure state and the broken line 44 is maintained throughout Figures 4 to 8 to show deviation of the inner surface 46 during pressure application within the inner and outer chambers 18 and 20.

[0077] From the initial zero pressure state of Figure 3, a vacuum is produced in the inner chamber 18 by evacuation through the vacuum line 22 (see Figure 1) and so, as shown in Figure 4, the liner portion 40 collapses into firm surface engagement or connection with the areola and the nipple shown schematically in outline by reference numerals 42 and 43. The liner portion 40 collapses into surface engagement with the side surfaces of the nipple 43 and also the end surface or tip of the nipple 43. The constant vacuum produced in the inner chamber 18 is identified by the "const Vac" line in Figure 9 and constant vacuum is reached at stage 2 of Figure 9. At stage 2 of Figure 9, the vacuum within the outer chamber 20 is only just commencing generation.

[0078] In Figure 5, the constant vacuum in the inner chamber 18 is retained and the pulsating vacuum of the outer chamber 20, identified by the "puls Vac" line in Figure 9, has increased as shown through stages 2 to 4. As a result, the pressure differential between the inner and outer chambers 18 and 20 reduces and as the vacuum pressure within the outer chamber 20 increases, the liner portion 40 tends to pull the areola 42 inwardly. This can be seen in the region marked R₁ in Figure 5 where the liner portion 40 has shifted so that the inner surface 46 of the liner portion 40 has moved away from the broken line 44 representing the initial shape of the inner surface 46 at atmospheric pressure as shown in Figure 3. The nipple 43 remains under a compression load as shown by the liner portion 40 at the arrow C₁ but the compression load has been reduced.

[0079] Figure 6 shows the state of the liner portion 40 when the pulsating vacuum of the outer chamber 20 is at about the same vacuum pressure as the constant vacuum of the inner chamber 18. This is represented by stage 4 of Figure 9. At this stage, the liner portion 40 is continuing to pull the areola 42 inwardly (see region R₂) while the nipple 43 is still under compression, but at a further reduced compression compared to Figure 5.

[0080] Figure 7 shows the state of the liner portion 40 when the pulsating vacuum is significantly greater than the constant vacuum. This is represented by stage 5 of Figure 9. The liner portion 40 is continuing to pull the areola 42 inwardly (see region R₃) while the compression load applied to the nipple 43 has been reduced further compared to Figure 6 so that the nipple 43 is actually released from compression loading. The nipple 43 is thus relaxed. The point at which the liner portion 40 releases the nipple 43 from compression is dependent on the pressure differential between the inner and outer chambers 18 and 20, as well as the construction of the liner portion 40, such as the wall thickness of the liner portion 40, as well as the flexibility of the material from which the liner portion 40 is created. The material from which the inner liner 14 and thus the liner portion 40 can be created is discussed later herein.

[0081] The peak or maximum pulsating vacuum is shown in Figure 8 and in the example given, this is about twice the constant vacuum generated in the inner chamber 20. This is represented by stage 6 of Figure 9. At stage 6, the liner portion 40 is continuing to pull the areola 43 inwardly while the liner portion 40 is also now pulling the nipple 43 inwardly (see region R₄). Importantly, the nipple 43 is no longer under radial compression, but is now under radial expansion.

[0082] The pulsating vacuum starts to reduce following the peak reached at stage 6 of Figure 9 and takes a sinusoidal path whereby it reduces back to atmosphere and then increases back through the path described above in relation to Figures 3 to 9. As the pulsating vacuum within the outer chamber 20 reduces from the peak or maximum pulsating vacuum, the liner portion 40 will return through the stages 5 to 2. Through these stages, the vacuum within the inner chamber 18 will remain constant. Stage 1 of Figure 9 will not be reached given that this requires the vacuum within the inner chamber 18 to be returned to atmosphere. This will only happen when the breast shield 10 is switched off. Thus, as the pulsating vacuum within the outer chamber 20 reduces, the liner portion 40 will push against the areola 42 in the stages described above in which it pulls against the areola 42. Likewise, the liner portion 40 will be released from the pulling load of stage 6 and will pass through the relaxed stage 5 and onto the compression in stages 4 to 2. The cycle thus imposes alternating pull and push loads on the areola 42 and the nipple 43. The frequency of this cycle can be in the range of 0.5 to 2Hz, such as in the order of about 1Hz.

[0083] The inner liner 14 of Figure 1 is shown in isolation in Figure 10. In Figure 10, cross-sectional shapes (not to scale) of the liner 14 are shown at several points between the entry end 16 and the liner tip 50. From this it can be seen that the funnel portion of the entry end 16 is generally circular, while the compression section 26 is also generally circular. The compression section 26 does taper slightly from the entry end 16 towards the liner tip 50 for the reasons discussed above. The liner tip 50 comprises a polygonal section 52 and a circular tip end 54. The liner tip 50 is intended to collapse over the tip of a nipple that is inserted into the inner liner 14 and to apply pressure to the nipple tip during that collapse. This form of collapse can be seen in Figure 4 in particular, but also Figure 5, in which the liner portion 40 pushes inwardly against the side surface of the nipple and over the top or tip of the nipple. The collapse is a cyclic collapse so that the liner tip 50 cycles through collapse and recovery as the pressure distribution within the inner and outer chambers 18 and 20 cycles through the curve shown in Figure 9. Thus, the liner tip 50 applies and releases pressure to the nipple tip, which, like the massaging effect applied to the areola and the side surface of the nipple, has been found to provide reduced blockage of milk ducts and thus improved milk expression.

[0084] The particular construction of the inner liner 14 provides for three fold or star-shaped collapse of the liner tip 50 into engagement with a nipple tip. Figure 11 is a cross-section through the polygonal section 52 towards the junction with the tip end 54 shows three states of the polygonal section 52 within the cycle of collapse and recovery. The first and left-hand image in Figure 11 is the polygonal form of the section 52 in a relaxed state of the inner liner 14. The second and middle image in Figure 11 is the expanded circular state of the section 52 when the vacuum within the outer chamber 20 exceeds or is greater than the vacuum within the inner chamber 18, such as at stages 5 and 6 of the vacuum curve of Figure 9. The third and right-hand image in Figure 11 is the collapsed "three-fold" shape of the section 52 when the vacuum within the inner chamber 18 exceeds or is greater than the vacuum within the outer chamber 20, such as at stages 2 and 3 of the vacuum curve of Figure 9.

[0085] The circular tip end 54 also collapses when the polygonal section 52 collapses, but the form of the collapse of the tip end 54 is not particularly important given that it is the polygonal section 52 that collapses into engagement with the nipple tip.

[0086] The collapsed “three-fold” shape of the section 52 is also shown in Figure 12 but that figure also shows an alternative collapsible shape of the section 52 which is different to the three-fold shape. The views in Figure 12 are cross-sectional views through the polygonal section 52 towards the compression section 26 and the views are of two different liner tips, the first being the liner tip 50 showing the section 52 in partial collapse. The three folds 56 are clearly evident in Figure 11, but as these folds form, inner folds 58 are also formed that converge towards each other and towards the centre line of the liner tip 50 and the inner liner 14. The inner folds 58 can converge to the point at which they meet and engage and at which point the wall of the polygonal section 52 of the inner liner 14 has closed over the nipple tip and is in engagement with the nipple tip.

[0087] The second liner tip 60 of Figure 12 folds in a “bow tie” shape and has four folds, being two end folds 62 and two middle folds 64. Again, the middle folds 64 can converge to the point at which they meet and engage and at which point the wall of the polygonal section 52 of the inner liner 14 has closed over the nipple tip and is in engagement with the nipple tip.

[0088] Figure 12 illustrates that the liner tip can be differently shaped but still collapse in the required manner into engagement with the nipple tip.

[0089] The inner liner 14 can be formed of any suitable material, such as the materials listed earlier herein.

[0090] Figures 13 to 15 show alternative wall constructions for the flexible wall of the inner liner. While the wall of the inner liner can be of constant thickness like the inner liner 14, it can also be of irregular thickness or cross-section in order to unevenly distribute pressure and/or movement to different sections or regions of the areola and nipple. This can also alter the massaging effect that is produced on those sections or regions of the areola and nipple. Each of Figures 13 to 15 shows an inner liner that has a compression section which is generally circular but which has an irregular cross-section. As described below, the inner liners all expand to exert uneven pressure or movement relative to the surface of the areola and/or nipple with which they are in contact.

[0091] Figure 13 shows that the inner liner 70 has four equidistantly spaced thick sections 72. These sections 72 can be short, discrete sections that are formed in particular parts of the liner or they can be longer sections that extend fully through one or more sections of the liner. The sections 72 might for example, be provided
5 only in the compression section of the liner, but may extend through the full length of that section, or through a portion of that section. The sections 72 can extend in straight lines generally in the direction of the axis of the liner, or they can be formed in a spiral or helix manner about the axis of the liner.

[0092] The sections 72 resist circular expansion of the liner 70 so that a non-
10 circular or in this case, a generally square expansion occurs. The size of the arrows in the expanded image of the liner 70 indicate the level of movement of the liner 70 under expansion and shows that greater expansion occurs in the region of the corners of the expanded liner 70 as compared to the region of the thick sections 72, so that different areas of the areola and nipple will be massaged differently or will be
15 affected differently under liner expansion. This different treatment means that some regions of the areola and nipple will be subject to more liner movement than others and more or less compression or stress than others. That different treatment can enhance the massaging effect by the exerting a less uniform and more random pressure/movement distribution to the areola and nipple.

[0093] Figure 14 shows an inner liner 74 that has three equidistantly spaced thick sections 76 that resist circular expansion of the liner 74 so that non-circular expansion occurs, and in Figure 14, a generally triangular expansion occurs. Again however, greater expansion occurs in the region of the corners of the expanded liner 74 as compared to the region of the thick sections 76.

[0094] Figure 15 shows an inner liner 78 that has an uneven wall thickness that progressively increases in thickness from a minimum thickness at region 80 to a maximum thickness at region 82, which is diametrically opposite region 80, and then back to the minimum thickness at region 80. Figure 15 differs from Figures 13 and 14 in that the greatest and least movement of the liner occurs in diametrically opposite
25 regions of the liner 78 and the change in movement gradually increases and decreases between the opposite regions 80 and 82. Greater expansion occurs in the thinner regions of the expanded liner 78 as compared to the thicker regions.
30

[0095] Figure 16 shows the arrangement of Figure 14 applied to a liner 90, specifically to the compression section 92 of the liner 90. It can be seen that the thick sections 76 of Figure 14 are formed as elongate spiral ridges that extend for the full length or height of the compression section 92. It can be seen that the ridges 76 taper at opposite ends and this is readily apparent in the differing cross-sections B-B compared to C-C.

[0096] Figure 17 shows an alternative arrangement to Figure 16, in which the liner 94 includes a compression section 96 that has an increased number of thick sections or ridges 98. The ridges 98 are formed in the same spiral manner as the ridges 76 of Figure 16 and likewise taper at opposite ends thereof. The ridges 98 each extend for the full height or length of the compression section 96.

[0097] Figure 18 illustrates a further alternative arrangement in which the liner 100 has a compression section 102 that includes a plurality of thick sections or ridges 104, but not all of the ridges 104 extend for the full height or length of the compression section 102. As shown in Figure 18, the ridge 106 terminates within the compression section 102.

[0098] Finally, Figures 19 and 20 show an arrangement in which the wall thickness of the compression section varies like that shown in Figure 15, but the compression section also includes thick sections similar to that provided in Figure 14. Thus, Figure 19 shows a liner 104 that has a compression section 106 that has three thick sections or elongate ridges 108. The ridges 108 are formed similar to the ridges 76 of the liner 90 of Figure 16, but they have been applied to a liner that has an uneven wall thickness of the kind shown in Figure 15 by liner 78. Figure 20 shows the basic amalgamation of the constructions of the liners 74 and 78 to arrive at the compression section 106 of the liner 104.

[0099] The examples given in Figures 13 to 20 show how liner construction can be used to influence the manner in which the liner reacts to the pressure differential applied to the inner and outer chambers 18 and 20 and thus the manner in which the liner applies pressure to and moves against the areola and nipple.

[0100] Other parts of a breast shield according to the invention can also be arranged to apply uneven pressure or movement against the areola or nipple.

Figures 21 and 22 show profiles formed in the funnel or entry end of an inner liner, to form localised recesses or projections. The inner liner 110 has an entry end 112 which is formed in a funnel formation like the entry end 16 of the inner liner 14 of the earlier figures and the entry end 112 includes part spherical projections 114 and
5 elongate recesses 116.

[0101] The projections 114 form massage spots or elevations, while the recesses 116 form suction areas. The projections 114 can apply localised increased or concentrated pressure, while the recesses 116 can redistribute suction pressure to different areas of the entry end 112. The result can be to create local variations in the
10 movement of the entry end 112 of the inner liner 110 against the surface of the areola, in order to affect the amplitude of the cyclic compression force on the areola. The effect can also be to guide or move the suction applied to the breast/areola to a larger diameter to increase the holding force of the breast shield on the breast. This increases the security with which the breast shield attaches to the breast.

15 [0102] The movement of the inner liners described and shown in the figures is movement that applies pressure to the areola and nipple as the pressure in the outer chamber of the breast shield cycles about the constant pressure in the inner chamber. That movement produces the massaging effect against the tissue surface of the areola and the nipple. As shown in Figure 2, and it is this difference in effect that
20 produces the surprising and beneficial effects described herein.

[0103] Where any or all of the terms "comprise", "comprises", "comprised" or "comprising" are used in this specification (including the claims) they are to be interpreted as specifying the presence of the stated features, integers, steps or components, but not precluding the presence of one or more other features, integers,
25 steps or components.

[0104] Those skilled in the art will appreciate that the invention described herein is susceptible to variations and modifications other than those specifically described. It is understood that the invention includes all such variations and modifications which fall within the spirit and scope of the present invention.

30 [0105] Future patent applications may be filed in Australia or overseas on the basis of or claiming priority from the present application. It is to be understood that

the following provisional claims are provided by way of example only, and are not intended to limit the scope of what may be claimed in any such future application. Features may be added to or omitted from the provisional claims at a later date so as to further define or re-define the invention or inventions.