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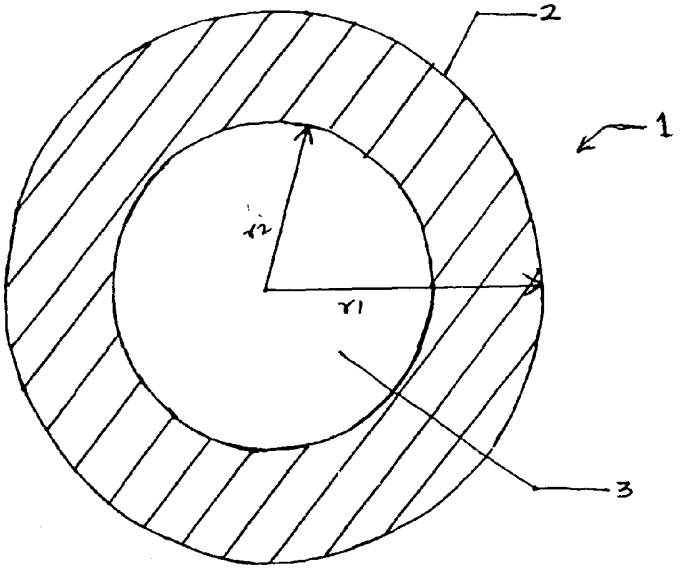
(54) Title: HOLLOW SPHERE ALLOY IMPLANT FOR FACIAL AND BREAST PROSTHESIS AND A METHOD OF IMPLANTING THE SAME



(57) Abstract: The present invention discloses an inventive implant (1) for soft tissue implantation, especially, but not limited to, facial and breast tissue implantation. The tissue implant (1) comprises one or more filler elements (1) made out of a material which is inert to the body fluid associated with the implant(1). The material of the filler element (1) is preferably Vitallium or 19-9 stainless steel. The filler elements (1) are preferably configured as hollow spheres each having an outer diameter to suit the patient's need. For breast implantation, the outer diameter of the tiller element (1) is in the range of 1 to 6 inches, preferably one inch, and for facial implantation, the outer diameter of the tiller element (1) is less than or equal to 3 mm.

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TITLE :

HOLLOW SPHERE ALLOY IMPLANT FOR FACIAL AND BREAST PROSTHESES AND A METHOD OF IMPLANTING THE SAME.

FIELD OF THE INVENTION:-

The present invention relates to the field of tissue implant and more particularly to the field of soft tissue implant for use in plastic and reconstructive surgery generally known as augmentation mammoplasty. The present invention might be particularly useful in subcutaneous reconstructive implant procedures for augmenting or reconstructing certain soft tissue in human body, particularly but not limited to female breast and facial tissue.

BACKGROUND ART :-

The use of breast and facial implants has been in existence since early 1960.

One of the known forms of breast implant is a silicone shell filled with silicone gel.

Another known form of breast implant is the use of a polyester balloon filled with salt water known as normal (0.9%) saline.

Numerous attempts have been made to provide improved versions of such tissue implants, more particularly the breast and facial implants.

In the recent years, controversy has surrounded the materials used to fill these physiological shells. The use of silicone gel is associated with a number of problems, for example, silicone gel is not sufficiently radiolucent and can thus provide obscure mammographic signs of

breast cancer. In fact, some researchers have suggested that breast implants containing silicone gel fillers prevent early detection of breast cancer and hence reduce the probability of a promising prognosis once cancer is detected. Because an estimated one in nine women will develop breast cancer, and, with cancer recurring in another 1 in 3, the risk of delay of detection caused by silicone gel implants is quite significant. Another problem with silicone gel fillers is that the body is unable to metabolize or excrete the silicone gel. The presence of free liquid silicone whether by injection or rupture of silicone implant has had serious local and systemic side effects, particularly migration of the free liquid silicone and collection of silicone in major body organs, such as liver, where an undesirable body reaction can ensue, thereby requiring surgical removal or other treatment.

The presence of free silicone has incited autoimmune responses in many patients causing a severely debilitated state. More particularly, the anti-immune responses include diseases such as Fibromyalgia, chronic fatigue syndrome and Scleroderma. The use of silicone filled implants has now been discontinued in all the cases except for breast reconstruction necessitated by mastectomy for cancer treatment. The problem of side effects caused by silicone can be eliminated by filling the polymer sac with physiological saline solution or less harmful filler constituents known in the art.

Eventhough saline has supplemented silicone gels as the most prevalent implant filler material, saline is also ill-suited for use as an implant filler material. Significantly, saline has a relatively low

viscosity and is a poor lubricant thereby resulting in an excessively soft implant that is prone to rippling, fold flaws and spontaneous deflation. Saline fillers also suffer from resulting of an unnatural "feel."

While the saline implant has generally eliminated immune system problems, saline filled sacs have been subjected to partial deflation and even cosmetically less appealing. The long term cosmetic effects of the saline implant have thus been generally unsatisfactory, making the partially deflated sac crinkling, with a wave–like effect being felt instead of a full soft breast. The reason for this deflation is speculated as being osmotic pressure, aggravated by a tendency on the part of implanting surgeons to over inflate the sac with saline.

However, it is known that the silicon sac itself interferes with mammography, and therefore utilizing of less interfering filler does not completely solve the mammography problem.

An attempt which has been known to increase the breast size is by the use of oestrogens. This has a tendency to cause breast cancer and uterine cancer.

Further, the use of synthetic or herbal products is also known in the art for enhancing breast size. However there exists a need for a better filler material to enable safe and satisfactory implantation within the human body.

As regards the facial implant, dimples and crevices of the skin of the face have been filled by fat fillers which are known to be made of a variety of materials.

Conventionally, a protein like material usually collagen, is introduced into the skin crevices to obtain a face-lift. But in due course of time, collagen is found to be absorbed due to the defense mechanism of the body and therefore such application was found to be of temporary use.

Another form of the facial prosthesis is the use of silicone gel which is injected into the skin crevices to reshape the facial tissue. However the silicone gel has now become notorious for it causes anti-immune diseases.

Another form of facial prosthesis is by the use of fat cells. In this method, tissue obtained by liposuction is centrifuged and the fat cells are separated.

These fat cells are introduced into the dimples of the facial skin. Even though the fat cells last for a longer time period than that of the collagen, there is a likelihood of being absorbed by the human body defense mechanism in the long run.

In view of the safety problems and more nearly unsatisfactory results associated with the tissue implants may it be a breast implant or a facial implant as presented in the foregoing discussion, the search for a safe replacement material for use as implant filler material has become an important requirement in the present days.

OBJECTS OF THE INVENTION

It is an object of the present invention to provide a new and novel implant for augmenting certain soft tissue in the human body, especially the breast and the facial tissue, which would replace the

existing polymer implants such as polymer sacs and silicone sacs in particular that are known to use liquid filler materials and which may cause safety related problems during the course of run.

An object of the present invention is to provide a breast / facial implant that would eliminate the need for use of liquid filler material such as liquid silicone and saline solution in particular, which is known to cause delirious effects resulting from leakage and bare weight.

Another object of the invention is to provide a tissue implant which may be permanently implanted and which would replicate, as nearly as possible, the natural characteristics over long term especially within the facial and breast tissue.

An object of the present invention is to provide an implant whereby the selection and controlled use of implant material is possible to obtain true and natural feel after the surgery, but retaining a better cosmetic effect and desired body contour than the prior art implants.

An object of the present invention is to provide an implant whereby excessive softness, rippling, fold flaws and spontaneous deflation are eliminated and also, reduction in breast reconstruction volume after pregnancy and difference in breast size are corrected effectively.

An object of the present invention is to provide an implant whereby the implant materials can be injected into the portion of the body requiring the treatment and can be adopted for replacement of small as well as large amount of tissue.

A further object of the present invention is to provide a reliable implant whereby inciting of anti-immune responses in patients, or causage of severe debilitated state is totally eliminated.

SUMMARY OF THE INVENTION

The present invention discloses a novel tissue implant for use in soft tissue prostheses particularly breast and facial prostheses in the humans. According to the present invention, the implant comprises one or more filler elements such filler elements each having a shape and size and made of a material which is substantially inert with the body fluid associated with the said implant. The material of the implant is preferably Vitallium or 19-9 stainless steel. Alternatively, any other metal, alloy, non-metal or any inter–metallic material or any combination of them which is proven to be inert in the human tissue may also be used as the material of the filler element.

Preferably, each filler element is configured as a hollow sphere with the interior filled preferably with atmospheric air and the outer surface shaped to a perfectly spherical profile.

The density of each filler element is equal to the density of body fat associated with the said implant.

May it be a breast or facial prosthesis, the filler elements are introduced into the tissue which requires treatment, by making a tunnel preferably in curved form using special tools and techniques.

As regards the breast prosthesis a curved tunnel is made using a specially configured tunnel making device which has substantially a long knife with a sharp and triangular tip at one end. The body of the

knife is flat, with the edges substantially blunt. The tunnel is made so as to pass through a location away from the core of the glandular tissue of the breast, starting from the areola of the breast to the surface of the chest wall. The filler elements are then introduced into the tunnel for embedment in the tissue. The outer diameter of each filler element used for embedment in the breast tissue is in the range of 1 inch to 6 inch, preferably 1 inch. The bleeding points of the artery generated during making of the tunnel are identified and viewed using a specially designed viewing tube and then cauterized using an electrocaturery device. The open end of the tunnel is then occluded by suture.

As regards the facial prosthesis, a tunnel is made from a location adjacent to the margin of a skin dimple which requires raising treatment, such that the tunnel leads to the under side of the said dimple. The filler elements of outer diameter less than or equal to3 mm, preferably of diameter 1.5 mm are introduced into the tunnel. The filler elements are further pushed by a substantially long and hollow blunt probe and after the filler elements are placed in position, the probe is removed and the tunnel is occluded at one end by suture.

BRIEF DESCRIPTION OF THE DRAWINGS

To complement the description that is being given and in order to promote a better understanding of the characteristics of the invention in accordance with a practical embodiment of the same and as an integral part of the said description a set of drawings accompany it in

which, in an illustrative and non-restrictive way, the following are represented:-

Fig. 1 shows an enlarged cross section of a single filler element according to the preferred embodiment of the present invention.

Fig 2A Shows the perspective and cross sectional views of view of the tunnel making device according to the present invention.

Fig 2B Shows the front view of the hollow viewing tube of the tunnel making device.

Fig 3A Shows the side sectional view of the breast, with the hollow spherical implant embedded inside.

Fig 3B Shows the cross section of the hollow spherical implants embedded in the breast and as seen from the front.

Fig 4A Shows the side view of the tunnel as it progresses from the areola to the chest wall of the breast.

Fig 4B Shows the front view of the tunnel with the hollow spherical implants being pushed into position.

Fig 5 illustrates the stillet at the left and the blunt probe at the right.

Fig 6A shows the cut view of a portion of the skin with a dimple on the surface.

Fig 6B illustrates the stillet used for making a tunnel under the dimple.

Fig 6C shows the cross section of the skin with the hollow spherical implant embedded underneath the dimple.

DETAILED DESCRIPTION OF THE INVENTION

The present invention discloses an implant for subcutaneous reconstructive implant procedures for augmenting or reconstructing soft tissue in human body, particularly but not limited to female breast and facial tissue. The present invention preferably uses filler elements that have a shape and a size unlike the prior art filler materials that are either in liquid or gel form. Preferably the filler elements are in the form of a hollow sphere (1) as shown in Fig1. The filler elements are preferably made of an alloy known as Vitallium, and are embedded in the tissue. Alternatively, 19-9 stainless steel, any other material / alloy may it be a metal or non-metal or even an inter-metallic material or any combination of them, which remains inert in the human tissue, i.e which does not corrode within the human tissue environment and which could function as implant material may also be used as a material of the filler element.

PRIOR USE OF VITALLIUM

Vitallium is an alloy used in orthopedic surgery as bone plates and screws. During 1947, "The U.S Committee on the treatment of fractures" of the American College of surgeons established specifications for implantable material for use as bone plates and screws. The material then recommended were Vitallium and "19-9 stainless steel". Vitallium is an alloy containing 65% cobalt, 30% chromium and 5% molybdenum.

The 19-9 stainless steel contains 19% chromium and 9% molybdenum. These alloys are inert and isoelectric with the body

fluids i.e. the alloys have the same pH as that of the tissue. They do not corrode in the living tissue environment. They have been safely used in orthopedics for over 50 years. The above alloys are also used for making dental implants. Other dental implant materials include Dacron, Dexon, Medpure, Propast I, Proplast II, Vicryl and various other low density materilals.

BEST MODE OF CARRYING OUT THE INVENTION

The present invention discloses an implant for augmenting and /,or reconstructing soft tissue in the human body particularly but not limited to female breast and facial tissue. The inventive implant as disclosed by the present invention comprises a plurality of filler elements and such filler elements have a shape and size unlike the prior art implants. The shape of the filler elements may be an object of revolution preferably in the form of hollow sphere, an ellipsoid or the shape of a river rock. The filler elements are made of either metal or metal alloy or non-metallic materials or any inter-metallic material or á combination thereof that are proven to be inert to the body fluids and which do not corrode within the human body tissue environment. Preferably, the filler elements are made of metal alloys such as Vitallium and 19-9 stainless steel etc which are being used in orthopedics since long time.

In the present application, the term hollow sphere is used only for the purposes of illustration of the filler elements. Therefore, it is to be construed that the preferred appearance of the filler elements is not only limited to spherical shape but also includes any shape which

may find suitability for use in the tissue prostheses as disclosed by the present invention.

May it be facial or breast prosthesis, the diameter of each hollow sphere is selected accordingly. The outer surface (2) of each hollow sphere is shaped to a perfectly spherical profile and the interior (3) of the said hollow sphere is kept hollow. The hollow interior of the said hollow sphere may be filled with atmospheric air and the weight of each hollow sphere is kept equal to the weight of the body fat i.e., the density of each hollow sphere is maintained equal to the density of the body fat by virtue of the hollow interior. This ensures that the hollow spheres sit comfortably in the body fat and do not tend to migrate into the lower parts of the body due to their weight. Assuming the shape of each filler element to of hollow spherical profile, the thickness of such sphere may be computed using the following set of equations.

Considering the volume of sphere (V) for a sphere of any arbitrary radius r, to be

$V = 4/3\ \pi\ r^3$.

And the equation $(4/3\ \pi\ r_1^3 - 4/3\ \pi\ r_2^3)\ d_1 = d_2$

Where r_1 is the outer radius of the ball r_2 is the inner radius of the hollow interior, d_1 the density of the filler material, d_2 the density of the body fat. The difference in radii $(r_1 - r_2)$ gives the thickness of the hollow sphere.

BREAST PROSTHESIS

Multiple hollow spheres as described in the foregoing discussion, preferably three to six in number, are deposited in the deeper layer of the breast so as to improve the size and shape of the breast, by a special kind of surgery. The outer diameter of each hollow sphere used for embedment in the breast tissue ranges from 1 inch to 6 inch. Preferably, the outer diameter of said each hollow sphere is 1 inch. The softness of the fat tissue and glandular tissue of the breast mask the hardness of the hollow spheres implanted therein. The surgical procedure as regards the breast prosthesis using the hollow spheres according to the present invention is disclosed in the following description.

SURGERY FOR BREAST IMPLANT

The surgical procedure for the said breast prosthesis involves use of the instruments and techniques as described herein:

THE TUNNEL MAKER

Referring to Fig 2A, the tunnel maker is a long flat surgical knife (4), which is curved along the flat side, and is made available in different sizes. The reason why the knife is curved is because the incision is to be done in the areola (9) shown in fig 3A, of the breast and a tunnel has to be made to the surface of the chest wall.

The tip (5) of the knife (4) is usually triangular and is sharp. The edges (6,7) on the body (8) of the knife are maintained blunt. The flat body of the knife has equal width at either of the blunt edges. The flat portion of the body may be reinforced with a thick rib in the middle

(not illustrated in the figure).The purpose of the knife is to make a tunnel in the breast to introduce the hollow spheres. Cut sections of the knife (4) are shown in Fig 2A of the drawings that accompany this specification.

Referring to Figs 3A and 3B, using the tip (5) of the said knife (4), an incision is made at the meeting portion of the areola (9) and the skin (10), at the inferolateral part of the areola (9). The anesthesia provided to the patient at this time may be preferably a local anesthesia infiltration, with a sedative.

Referring to Figs 4A and 4B, by applying a gentle jerk to the said knife (4), a curved tunnel (12) of 1 ½ inch diameter is made from the margin (21) of the areola (9) to the surface of the chest wall (11) as shown in Fig 3A.

Definition of " Margin of the Areola

The colored skin surrounding the nipple (22) of the breasts is called the Areola. In Caucasians (White Race), the Areola is pink in color. The location where the areola meets the skin of the breast is the margin (21) of the areola. If a surgical incision is made at this margin (21) the resultant scar will be invisible.

The tunnel (12) passes through a location away from the middle core of glandular tissue (13) of Fig 3A. The knife (4) may be gently jerked back and forth while being introduced into the tissue (13) to facilitate cutting into the deeper part of the tissue (13).

When the tissue is cut, there is bleeding from the cut arteries. These bleeding points are viewed, identified and cauterized using electrocautery device.

The final scar (23) in the breasts is preferably a 1 ½ inch linear scar at the line where the areola (9) meets the skin (10)

THE VIEWING TUBE

The viewing tube (14) illustrated in Fig 2A, is a long hollow transparent plastic tube with blunt edges and is used to view the interior of the tunnel. The length of the viewing tube is preferably 10 inch and the diameter is 1.5 inch. The tissue associated with the implant is soft and therefore curved tunnel in the breast would reshape into a straight tunnel if a hollow straight tube is introduced. Bleeding in the tissue can be visualized as the tube is gradually withdrawn. Every inch of the wall of the tunnel will pop into view. As the tube is withdrawn from the depth step by step at the terminal circular viewing area of the tube. The blood is mopped by towel holders and the bleeders are cauterized by electrocautery. As the tube is gradually withdrawn more and more areas of the walls of the tunnel appear into view. The bleeding points are then one by one cauterized.

Finally the viewing tube (14) is once again reintroduced into the tunnel and the hollow spheres are introduced into the depth of the tunnel. An obturator like the piston of a syringe may be used to push the hollow spheres into the depth of the tunnel. Once the balls are in place, the viewing tube is withdrawn in steps and the tunnel is

occluded by a helical suture. Finally the incision at the margin of the areola is closed. The final scar (23) is usually a 1.5 inch line at the margin of the areola.

FACIAL PROSTHESIS:-

The facial prosthesis according to the present invention involves using a plurality of hollow spheres made of vitallium or other implantable materials proven to be innocuous to body tissue by traditional use in orthopedics. Other materials as disclosed in the earlier part of the description may also be used as the material of the filler element.

Such hollow spheres are made into 0.5 to 3 millimeter outer diameter with a hollow interior so that they have the same weight or density as the body fat. The hollow interior is filled with atmospheric air and therefore they do not tend to migrate into the lower parts by their own weight. Vitallium is isoelectric with body fluids and is innocuous to human tissue. The filler elements made of Vitallium remain permanant since they are not absorbed by the body tissue.

The skin implants are introduced into the subcutaneous tissue of the skin. They can be inserted for many purposes.

1. To raise the skin dimple left at the site of a scar of old acne.

2. To raise the furrow of the nasolabial fold.

3. To improve the contour and shape of a lip. The lip can be made fuller and more thicker.

The use of any solid inert alloy or other substances for use as breast skin implant also comes under the jurisprudence of this invention. These substances are common for dental/ orthopedic implant.

The implant put inside the breast or skin need not be perfectly spherical. The implant may be oval, elliptical or irregularly shaped as in cosmetic stores or shaped like a river rock.

The implant need not be hollow. A dental implant such as Dacron may have low specific gravity and may be nearly weightless in tissue without being hollow.

This invention covers other solid implants as which are implanted into the tissue to increase its volume as a "Filler" of space, because they are inert in tissue and body fluids.

Thus, while there have been shown and described and pointed out fundamental novel features of the present invention as applied to preferred embodiments thereof, it will be understood that various omissions and substitutions and changes in the form and details of the methods described may be made by those skilled in the art without departing from the spirit of the present invention. For example, it is expressly intended that all combinations of those elements and/or method steps which perform substantially the same function in substantially the same way to achieve the same results are within the scope of the invention. Substitutions of elements from one described embodiment to another are also fully intended and contemplated. It is the intention, therefore, to be limited only as indicated by the scope of the claims appended hereto.

CLAIMS

1. A tissue implant for use in breast, facial prosthesis comprising :

one or more filler elements for embedment into a tissue;

said each filler element having a shape;

wherein said each filler element is made of a material which is substantially inert with the body fluid associated with the said implant.

2. The tissue implant according to claim 1 wherein the material of the filler element is selected either individually or in combination from the group comprising a metal, an alloy, a non-metal and an inter- metallic compound.

3. The tissue implant according to claim 1 wherein the material of the filler element is Vitallium.

4. The tissue implant according to claim 1 wherein the material of filler element is 19-9 stainless steel.

5. The tissue implant according to claim 1 wherein the shape the filler element is identical to that of a river rock.

6. The tissue implant according to claim 1 wherein each filler element has a shape of an object of revolution.

7. The tissue implant according to claim 6 wherein the object of revolution is a sphere.

8. The tissue implant according to claim 6 wherein the object of revolution is an ellipsoid.

9. The tissue implant according to claim 6 wherein the sphere has a hollow interior filled preferably with air.

10. The tissue implant according to claim 9 wherein the outer surface of the sphere has a perfectly spherical profile.

11. The tissue implant according to any foregoing claim wherein each filler element has a density equal to the density of the body fat associated with the said implant.

12. The tissue implant according to claim 1 or 2 wherein the material of filler element is selected from the group of materials which are suitable for use in dental and orthopedic implants.

13. The tissue implant according to claim 12 wherein the material of filler element is selected from one or more among the group comprising Dacron, Dexon, Medpure, Proplast 1, Proplast 2, Vinyl and similar low density material.

14. A method of performing breast prosthesis using the tissue implant as claimed in claim 1 comprising the steps of

(i). making a tunnel from the aerola of the breast, to the surface of the chest wall;

(ii). cauterizing the bleeding points of the artery generated at the time of making the said tunnel;

(iii). introducing filler elements into the said tunnel; and

(iv). occluding the tunnel end by suture.

15. The method according to claim 14 wherein the tunnel is formed to substantially curved shape, so as to pass through a location away from the middle core of the glandular tissue of the breast.

16. The method according to claim 14 or 15 wherein the bleeding points of the artery are cauterized by electro cautery device.

17. The method according to claim 14 wherein the outer diameter of each filler element is in the range of 1 to 6 inch.

18. The method according to claim 17 wherein the outer diameter is 1 inch.

19. A tunnel making device for performing the breast prosthesis as claimed in claim 14 comprising :

a substantially long knife with a flat sided body;

the said body having blunt edges on the said flat side and a sharp cutting tip wherein;

the body of the said knife is curved on the flat side so as to enable making a tunnel from the aerola of the breast to the surface of the chest wall.

20. A tube for viewing the interior of the tunnel made using the tunnel making device as claimed in claim 19 comprising :

a substantially long straight body having a diameter;

the said body made of a transparent material preferably of plastic.

21. The tube according to claim 20 wherein the diameter is preferably 1.5 inch.

22. A method of performing facial prosthesis using the tissue implant as claimed in claim 1 comprising:

making a substantially small tunnel leading towards underside of a skin dimple from a location adjacent to the said skin dimple;

introducing and thereby pushing-in one or more filler elements into the said tunnel; and

occluding the outer end of the said tunnel by suture.

23. The method according to claim 22 wherein the diameter of each filler element is less than or equal to 3 mm.

24. The method according to claim 23 wherein the diameter of the filler element is preferably 1.5 mm.

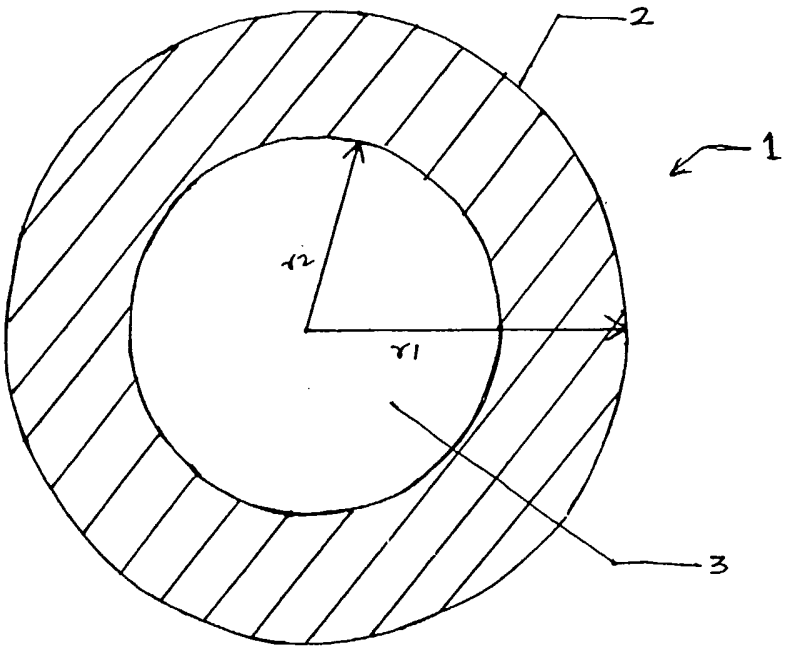

FIGURE 1

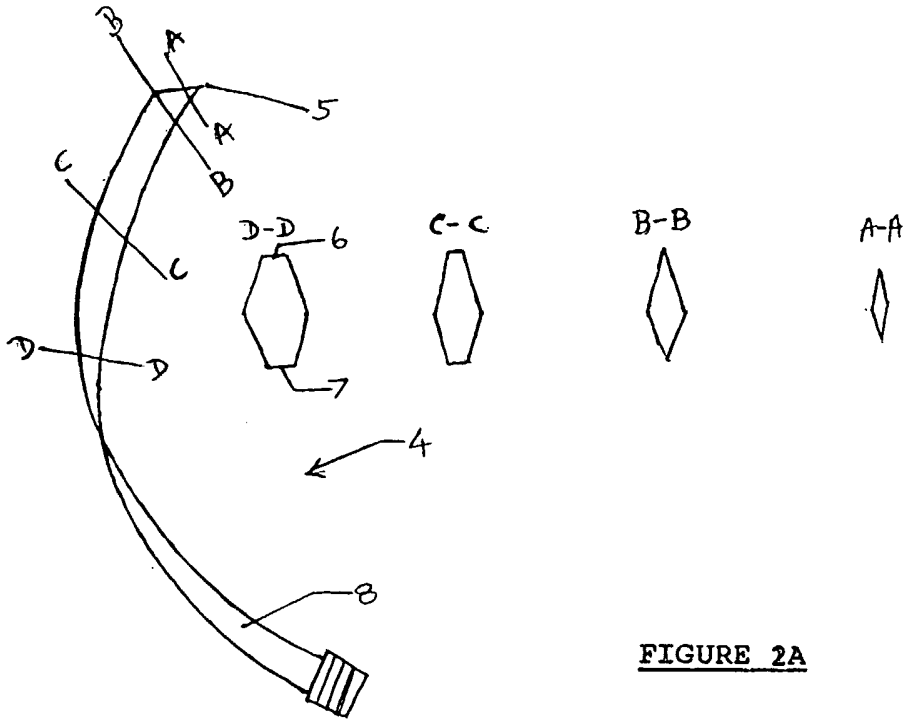

FIGURE 2A

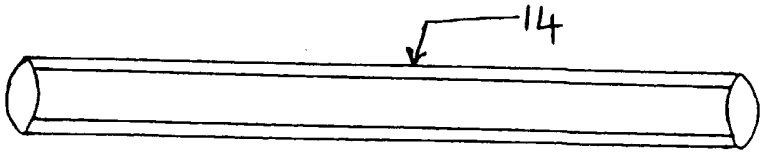

FIGURE 2B

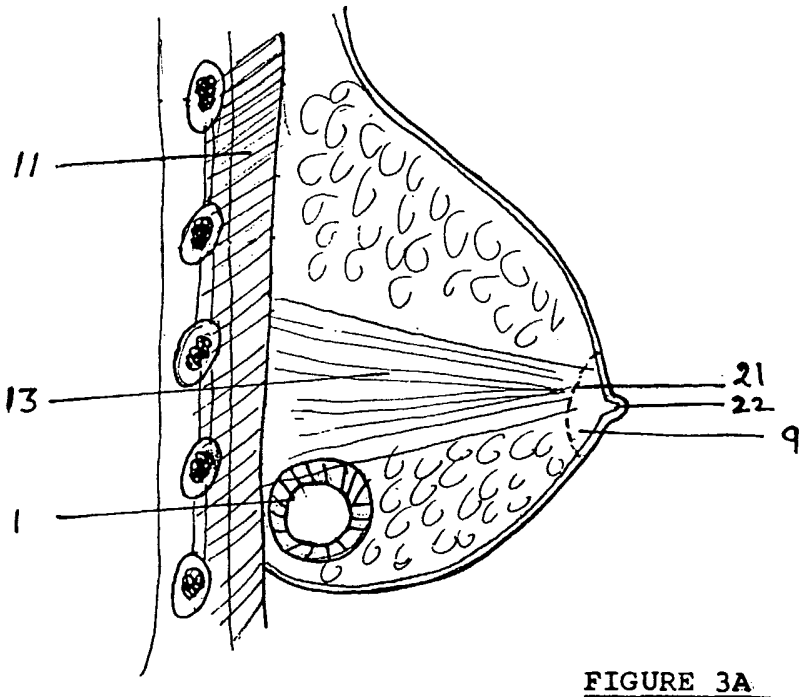

FIGURE 3A

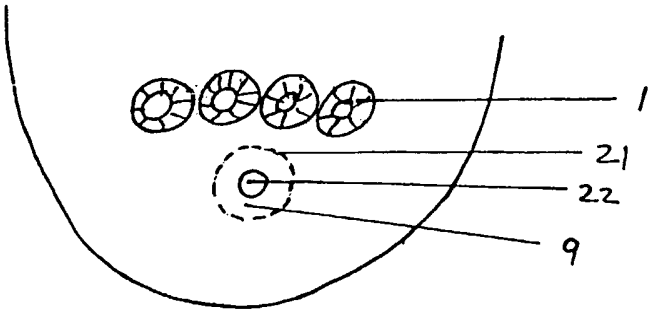

FIGURE 3B

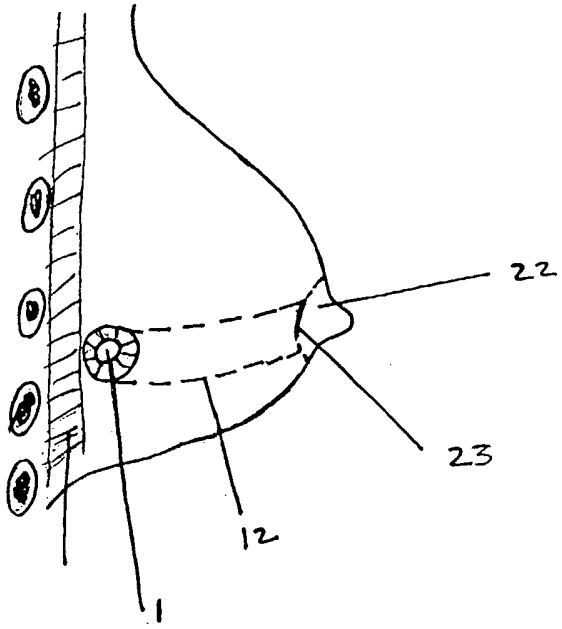

FIGURE 4A

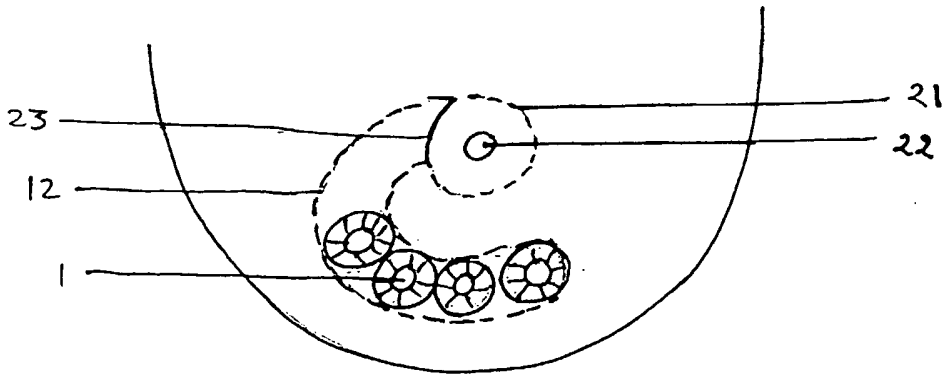

FIGURE 4B

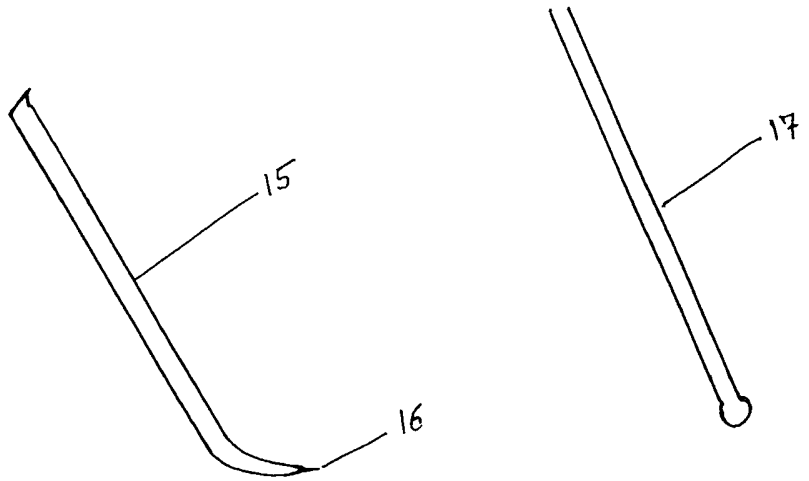

FIGURE 5

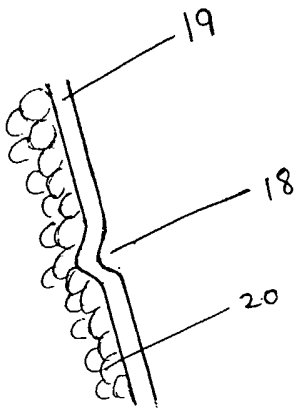

FIGURE 6A

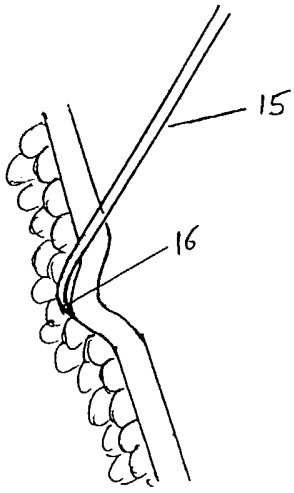

FIGURE 6B

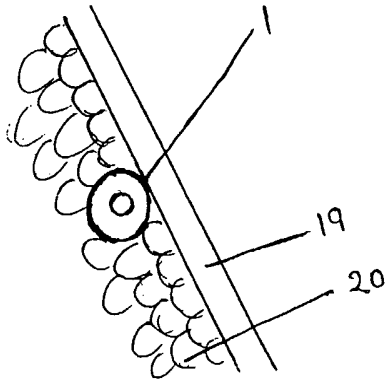

FIGURE 6C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB02/05003

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/02
US CL : 623/23.72

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/23.72, 8, 11.11, 17.11, 17.16; 606/170,184; 600/114 (with transparent)

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 4,963,848 A (BAGBY) 26 June 1990 (26.06.1990), see Figures 1, 2, 5 and 10 as well as column 4, lines 5-13.	1, 2, 5, 6, 7, 9, 10, and 12 --- 3,4,8
X --- A	US 5,258,026 A (JOHNSON et al) 02 November 1993 (02.11.1993), see Figures 10 to 17, column 9, lines 55-62, and column 8, lines 25-64.	1,2,5,6,9,12,and 13 --- 14 and 16
A	US 4,807,593 A (ITO) 28 February 1989 (28.02.1989), see the abstract and column 3, lines 4-28.	20
A	US 5,292,329 A (WERNER) 08 March 1994 (08.03.1994), see Figures 1 and 2.	19

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

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"A" document defining the general state of the art which is not considered to be of particular relevance

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
08 May 2003 (08.05.2003)	09 JUL 2003
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer Paul B. Prebilic Diane Smith for Telephone No. (703) 308-0858

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