

(CONVENTION. By one or more persons and/or a Company.)

7 /  
Form 4.

COMMONWEALTH OF AUSTRALIA

Patents Act 1952-1969

636624

### CONVENTION APPLICATION FOR A PATENT

(1) Here insert (in full) Name or Names of Applicant or Applicants, followed by Address(es).

X (1) DOW CORNING FRANCE S.A.  
We .....  
.....of.....Route des Cretes, Sophia Antipolis, 06561 Valbonne,.....  
.....France.....  
.....  
.....

(2) Here insert Title of Invention.

hereby apply for the grant of a Patent for an invention entitled: (2) .....  
.....MEANS FOR SURGICAL TREATMENT.....  
.....  
.....

(3) Here insert number(s) of basic application(s).

which is described in the accompanying complete specification. This applications is a Covention application and is based on the application numbered (3) .....  
.....89.09101.....

(4) Here insert Name of basic Country or Countries, and basic date or dates.

for a patent or similar protection made in (4) .....France.....  
.....on 6th July 1989.....  
.....  
.....

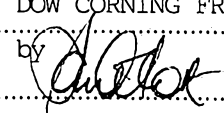
My  
Our address for service is WATERMARK PATENT & TRADEMARK ATTORNEYS  
290 Burwood Road, Hawthorn, Victoria, Australia.

DATED this .....4th..... day of .....July.....19..90.....

F017675

05/07/90

(5) Signa-  
ture(s) of  
Applicant(s)  
or  
Seal of  
Company and  
Signatures of  
its Officers as  
prescribed by  
its Articles of  
Association.

(5) DOW CORNING FRANCE S.A.  
by   
.....  
Ian A. Scott  
.....  
Registered Patent Attorney

To: THE COMMISSIONER OF PATENTS.

COMMONWEALTH OF AUSTRALIA

Patents Act 1952-1969

DECLARATION IN SUPPORT OF A CONVENTION APPLICATION FOR A PATENT OR PATENT OF ADDITION

(1) Here insert (in full) Name of Company.

In support of the Convention Application made by(1) DOW CORNING FRANCE S.A. of Route des Cretes, Sophia Antipolis, 06561 Valbonne, France (hereinafter referred to as the applicant) for a Patent

(2) Here insert title of Invention.

for an invention entitled:(2) MEANS FOR SURGICAL TREATMENT

(3) Here insert full Name and Address, of Company official authorized to make declaration.

I,(3) ALAIN F. JOACHIM, President Directeur General of Rue General de Gaulle 62, 1310 La Hulpe, Belgium

do solemnly and sincerely declare as follows:

1. I am authorised by the applicant for the patent to make this declaration on its behalf.

(4) Here insert basic Country or Countries followed by date or dates and basic Applicant or Applicants.

2. The basic application as defined by Section 141 of the Act was made in(4) France on the 6th day of July 1989, by DOW CORNING FRANCE S.A. ~~on the xxx day of xxx~~ ~~xxxxxx~~

(5) Here insert (in full) Name and Address of Actual Inventor or Inventors.

3.(5) JEROME JEAN-CLAUDE HENRI VERMOT of 22 Place des Arcades, 06250 Mougins-Le-Haut, France

is/~~are~~ the actual inventor of the invention and the facts upon which the applicant is entitled to make the application are as follow:

The applicant is the assignee of the invention from the said actual inventor

4. The basic application referred to in paragraph 2 of this Declaration was the first application made in a Convention country in respect of the invention the subject of the application.

DECLARED at Brussels, Belgium



AU9058699

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**(12) PATENT ABRIDGMENT (11) Document No. AU-B-58699/90**  
**(19) AUSTRALIAN PATENT OFFICE (10) Acceptance No. 636624**

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- (54) Title  
**MEANS FOR SURGICAL TREATMENT**
- International Patent Classification(s)  
(51)<sup>5</sup> **A61M 029/02 A61B 017/00**
- (21) Application No. : **58699/90** (22) Application Date : **05.07.90**
- (30) Priority Data
- (31) Number (32) Date (33) Country  
**89 09101 06.07.89 FR FRANCE**
- (43) Publication Date : **10.01.91**
- (44) Publication Date of Accepted Application : **06.05.93**
- (71) Applicant(s)  
**DOW CORNING FRANCE S.A.**
- (72) Inventor(s)  
**JEROME JEAN-CLAUDE HENRI VERMOT**
- (74) Attorney or Agent  
**WATERMARK PATENT & TRADEMARK ATTORNEYS , Locked Bag 5, HAWTHORN VIC 3122**
- (56) Prior Art Documents  
**GB 512456**  
**US 4648383**
- (57) Claim

1. A flexible article intended for disposition subcutaneously in the human or animal body characterised in that said article comprises an envelope having upon its outer surface receptor means provided by a pocket comprising an abutment portion against which an end portion of a tool intended for inserting the article into a subcutaneous cavity provided in the body may bear during the insertion process and positioning means whereby said end portion of the tool is retained in contact with the abutment portion during insertion and which is capable of releasing the tool when the article has been inserted subcutaneously in a human or animal body.

6. A method of forming a flap of tissue on a human or animal body characterised in that said method comprises inserting an implement through the skin and working the implement to induce a subcutaneous cavity, withdrawing the implement from the body, inserting into the cavity a tool of sufficient length that its distal end portion can penetrate the cavity to its furthest extremity, the tool having a tissue expander according to Claim 4 mounted upon its distal end portion by means of the receptor means upon the surface of the envelope,

(11) AU-B-58699/90  
(10) 636624

-2-

urging the distal end portion of the tool through the cavity until the distal end portion meets the furthestmost extremity of the cavity, disengaging the distal end portion of the tool from the receptor means, removing the tool from the cavity and inflating the envelope of the tissue expander progressively to induce formation of flap tissue.

636624

Form 10

COMMONWEALTH OF AUSTRALIA

PATENTS ACT 1952-69

# COMPLETE SPECIFICATION

(ORIGINAL)

Class

Int. Class

Application Number:

Lodged:

Complete Specification Lodged:

Accepted:

Published:

Priority :

Related Art :

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Name of Applicant : DOW CORNING FRANCE S.A.

Address of Applicant : Route des Cretes, Sophia Antipolis, 06561 Valbonne, France

Actual Inventor : JEROME JEAN-CLAUDE HENRI VERMOT

Address for Service : WATERMARK PATENT & TRADEMARK ATTORNEYS.  
LOCKED BAG NO. 5, HAWTHORN, VICTORIA 3122, AUSTRALIA

Complete Specification for the invention entitled:

MEANS FOR SURGICAL TREATMENT

The following statement is a full description of this invention, including the best method of performing it known to :-

us

MEANS FOR SURGICAL TREATMENT

This invention is concerned with means for surgical treatment of the human or animal body.

In the surgical treatment of the human body it is a practice to insert into the body articles of a flaccid nature, for example certain prostheses which are placed to  
5 mimic natural organs, and tissue expanders which are used to generate a flap of tissue which may be required for treatment of the body, or to generate a cavity into which a prosthesis may be inserted. There are many designs of  
10 prostheses available some of which comprise a flexible envelope at least partially filled with a fluid which inherently is not shape retaining but which are intended to be inflated using, for example, saline fluid. Various designs of tissue expander are available. Generally they  
15 comprise an inflatable envelope which is implanted in the body and progressively inflated over an extended period of time, for example a period of several weeks or months. The envelope is generally of a flaccid nature and, especially when collapsed i.e. completely deflated, is highly  
20 flexible. The steps of insertion of such articles into a cavity formed to accept it in the body and manipulation of the article within the cavity to obtain correct location can be difficult due to the flexibility of the article. The operation is especially difficult when there are  
25 limitations on the visibility of the operation or on space for handling of the article within the cavity. Such limitations may arise for example from the location or dimensions, for example extreme length, of the cavity into which the article is placed or from a restricted incision  
30 through which it is to be inserted into the cavity. The difficulties are important in relation to placement of, for

example partially filled prostheses, where the desired cosmetic effect influences the decision to employ a small entry incision, but are especially evident in the case of tissue expanders employed to expand tissue required for provision of a flap of unscarred tissue, where the need for unscarred tissue precludes  
5 placement of the expander through an incision which would lie within the flap.

We have now found that one may insert and dispose a flaccid article subcutaneously into the human or animal body for inflation more readily than was possible hereto-fore by providing the article with means adapted to receive a tool by means of which the article may be urged through an incision in  
10 the body to locate the article in the body.

The present invention provides in one of its aspects a flexible article intended for disposition subcutaneously in the human or animal body characterised in that said article comprises an envelope having upon its outer surface receptor means provided by a pocket comprising an abutment portion  
15 against which an end portion of a tool intended for inserting the article into a subcutaneous cavity provided in the body may bear during the insertion process and positioning means whereby said end portion of the tool is retained in contact with the abutment portion during insertion and which is capable of releasing the tool when the article has been inserted subcutaneously in a  
20 human or animal body.

A flexible article according to the invention is initially flaccid and floppy and is adapted to be inflated and swelled to a desired shape and volume in the body and may be, for example, a prosthesis or a tissue expander. A prosthesis according to the invention may contain some gel like material or  
25 saline fluid and may be constructed so that when inflated it mimics, for example a female breast. Means are provided for inflating the prosthesis when in the body. A tissue expander according to the invention may comprise an envelope which is intended to be inflated for example with saline fluid. The envelope of an article according to the invention may be formed from any of those



biocompatible materials, for example a biocompatible silicone elastomer, employed in the commercially available tissue expanders. The envelope may be formed in known manner, for example by deposition of a silicone material on a mandrel followed by curing of the silicone to an elastomeric state. The envelope may be designed to assume any desired shape when filled. In an article according to the invention in the form of a tissue expander, hereinafter described to illustrate the invention, the envelope is of an elongate shape and is suitable for insertion in an elongate cavity open at one end only thereof. Such expanders are in demand, for example for use in provision of an elongate flap of body tissue at the extremity of a limb for reconstructive surgery.

An article according to the invention has receptor means adapted to receive a portion of a tool intended for inserting the article into a subcutaneous cavity in the body and capable of releasing the tool when the article has been inserted subcutaneously in a human or animal body. Preferably, the receptor means comprises an abutment portion against which an end portion of the tool may bear during insertion of the article into the cavity, and a location means whereby said end portion of the tool is restrained in contact with the abutment portion during the insertion. The abutment portion serves to allow the article to be pushed into the cavity by pushing on the tool which contacts the abutment portion. The location means may comprise for example, wall elements upstanding from the envelope and which are spaced apart sufficiently to receive the tool between them, but not so far apart that the tool is allowed to disengage from the abutment portion whilst pressure is being exerted on the tool to insert the article in the cavity. When the article is elongate the receptor

means is preferably located adjacent an end portion of the envelope with the abutment portion located nearer to said end portion than said location means. In the illustrative article, the receptor means is provided by a pocket  
5 integral with the surface of the envelope and which comprises two side edges, which are at least substantially parallel to each other, and an end wall extending between them. In this embodiment an end wall of the pocket provides said abutment means and the inner surface of the  
10 pocket, together with the enclosed outer surface of the envelope, provide said location means. The side edges are spaced apart so that the end portion of the tool is snugly received in the pocket to an extent sufficient to retain the tool in the pocket during the stage of urging the  
15 article into the cavity. Conveniently, the pocket is located adjacent an edge or end portion of the envelope with an open mouth portion of the pocket directed away from that end portion. The pocket may be formed by securing a portion of a foil of biocompatible silicone elastomer to  
20 the envelope in the desired location. This may conveniently be done by locating a foil of uncured silicone elastomer upon the envelope before the envelope is cured and then curing the silicone elastomer of the envelope and the foil simultaneously.

25 An article according to the invention, e.g. in the form of a tissue expander, is provided with valve means through which inflating medium under pressure may be introduced from time to time into the envelope by means of a syringe or pump. The valve means may comprise, for  
30 example, a permanently attached self sealing valve secured in the envelope wall, or a remote self-sealing valve connected with the envelope by means of a feeder tube permanently attached to the valve and envelope.

An article according to the invention may be introduced through a small incision into a cavity prepared in the body by inserting through the incision a tool of sufficient length that its distal end portion can penetrate the cavity to its furthestmost extremity, the tool having an article according to the invention mounted upon its distal end portion by means of the receptor means upon the surface of the envelope, urging the distal end portion of the tool into the cavity until the distal end portion is adjacent the furthestmost extremity of the cavity, disengaging the distal end portion of the tool from the receptor means and removing the tool from the cavity .

An article according to the invention in the form of a tissue expander may be used, for example to form a flap of tissue on a human or animal body by a procedure which includes, inter alia, inserting an implement through the skin and working the implement to induce a subcutaneous cavity, withdrawing the implement from the body, inserting into the cavity a tool of sufficient length that its distal end portion can penetrate the cavity to its furthestmost extremity, the tool having a tissue expander according to the invention mounted upon its distal end portion by means of the receptor means upon the surface of the envelope, urging the distal end portion of the tool through the cavity until the distal end portion is adjacent the furthestmost extremity of the cavity, disengaging the distal end portion of the tool from the receptor means, removing the tool from the cavity and inflating the envelope of the tissue expander progressively to induce formation of flap tissue.

In order that the invention may become more clear, there now follows a detailed description to be read with the accompanying drawings of the illustrative article and

of tools for use therewith. In the drawings:

Figure 1 is an elevation of the illustrative article,

Figure 2 is an elevation of a first tool,

Figure 3 is an elevation of a second tool and

5 Figure 4 is an elevation of a third tool.

The illustrative article is a tissue expander and comprises a flexible envelope (10) and a remote self-sealing valve (12) connected with the envelope by means of a feeder tube (14) permanently attached to the envelope and the valve. The envelope (10) is intended to be expanded by periodic inflation with saline fluid. It is formed from a biocompatible silicone elastomer by deposition of a silicone material on a mandrel followed by curing of the silicone to an elastomeric state. The envelope is of an elongate shape and is suitable for insertion in an elongate cavity open at one end only thereof.

Receptor means in the form of a pocket (16) is formed on the surface of the envelope adjacent one end thereof. The pocket, which is pod-like and has a part circular opening for receiving a tool, is bounded by two upstanding side walls which are joined together and subtend from edges (18,20) which are at least substantially parallel to each other, and an end wall (22) extending between them. The end wall of the pocket provides abutment means against which a tool may bear during insertion of the article into the cavity. The inner surface of the pocket side walls, together with the enclosed outer surface of the envelope, provide location means whereby the end portion of the tool is restrained in contact with the end wall during the insertion. The side edges (18, 20) are spaced apart so that the end portion of the tool is snugly received in the pocket between the side walls to an extent sufficient to retain the end portion of the tool in the pocket during the

stage of urging the article into the cavity. The pocket is located adjacent an end portion of the envelope with its open mouth directed away from that end portion. The pocket is formed by securing a portion of a foil of uncured  
5 silicone elastomer upon the envelope before the envelope is cured, and then curing the silicone elastomer of the envelope and the foil simultaneously.

In Figures 2, 3 and 4 there are shown tools suitable for use with an article according to the invention. Each  
10 of the tools is formed from stainless steel and comprises a handle portion (30, 32, 34) and a probe portion. The probe portions are at least substantially rigid, have curved end portions, are free of sharp edges and have smoothly rounded distal ends (42, 44, 46). As is apparent from the drawings  
15 the curvatures of end portions of each of the probes differ one from another. The curvature of the probe of the tool shown in Figure 2 is selected to facilitate placement of an article according to the invention in the extremity of a leg or arm. The curvature of the probe of the tool shown  
20 in Figure 3 is selected to facilitate placement of an article according to the invention in the thorax. The curvature of the probe of the tool shown in Figure 4 is selected to facilitate placement of an article according to the invention in the head or neck.

25 In one method of using the illustrative tissue expander according to the invention, an implement (for example one of the tools shown in Figures 2, 3 and 4) is inserted through an incision in the skin and worked around, beneath the skin, to cause the implement to induce a subcu-  
30 taneous cavity extending for several centimetres. When a cavity of sufficient length has been made the implement is withdrawn from the body, through the incision, and the same instrument or another used as a tool for insertion of the

article into the cavity. When the cavity is formed at the end of an arm or leg we prefer to employ the tool shown in Figure 2. The illustrative tissue expander is mounted upon the distal end of the tool by means of the pocket (16) and the end portion of the tool thrust into the cavity. The tool is then pushed further into the cavity to push the pocket forward and to draw trailing portions of the article into the cavity. Pressure is exerted until the distal end portion of the tool is adjacent the furthestmost extremity of the cavity. The distal end portion of the tool is disengaged from the pocket and the tool is removed from the cavity. The valve may then be located on the body and saline solution introduced by means of a hypodermic needle through the valve to the tube (14) and thence to the envelope. Inflation of the envelope is accomplished by introduction of saline solution to the envelope from time to time over a period of several weeks. When sufficient flap tissue has been induced the envelope is deflated and removed from the cavity ready for incision of the tissue.

## THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A flexible article intended for disposition subcutaneously in the human or animal body characterised in that said article comprises an envelope having upon its outer surface receptor means provided by a pocket comprising an abutment portion against which an end portion of a tool intended for inserting the article into a subcutaneous cavity provided in the body may bear during the insertion process and positioning means whereby said end portion of the tool is retained in contact with the abutment portion during insertion and which is capable of releasing the tool when the article has been inserted subcutaneously in a human or animal body.

2. An article according to Claim 1 characterised in that the envelope is elongate and wherein the receptor means is located adjacent an end portion of the envelope with the abutment portion located nearer to said end portion than said positioning means.

3. An article according to either one of the preceding claims characterised in that the envelope and receptor means are formed of a biocompatible silicone elastomer.

4. An article according to any one of the preceding claims characterised in that said article is made in the form of a tissue expander.

5. A set characterised in that said set is composed of an article according to any one of the preceding claims and a tool having a probe which is at least substantially rigid, has a curved end portion, is free of sharp edges and has a rounded end without any unevenness.

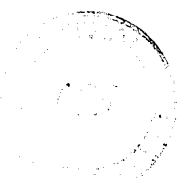
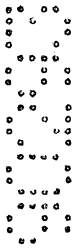
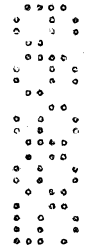


6. A method of forming a flap of tissue on a human or animal body characterised in that said method comprises inserting an implement through the skin and working the implement to induce a subcutaneous cavity, withdrawing the implement from the body, inserting into the cavity a tool of sufficient length that its distal end portion can penetrate the cavity to its furthest extremity, the tool having a tissue expander according to Claim 4 mounted upon its distal end portion by means of the receptor means upon the surface of the envelope, urging the distal end portion of the tool through the cavity until the distal end portion meets the furthest extremity of the cavity, disengaging the distal end portion of the tool from the receptor means, removing the tool from the cavity and inflating the envelope of the tissue expander progressively to induce formation of flap tissue.

DATED this 27th day of January, 1993

DOW CORNING FRANCE S.A

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290 BURWOOD ROAD  
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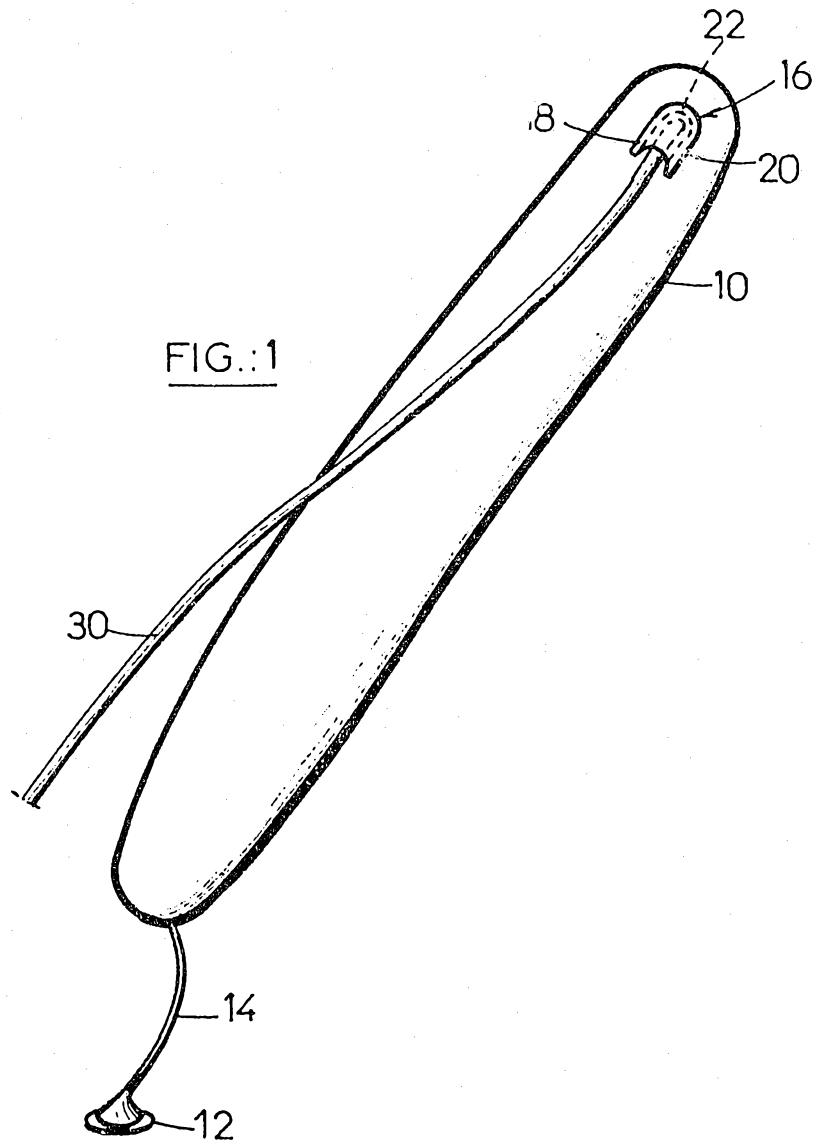


FIG.:1

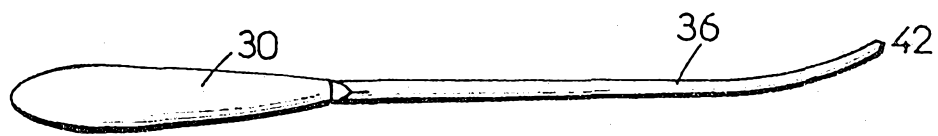


FIG.:2

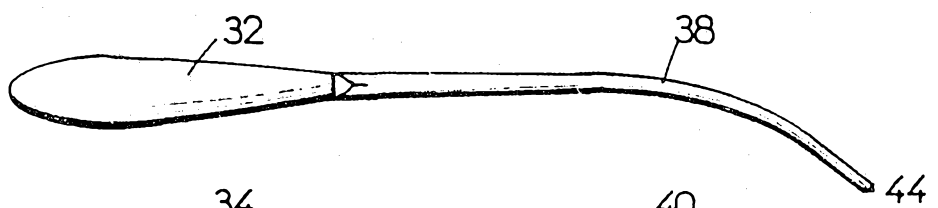


FIG.:3

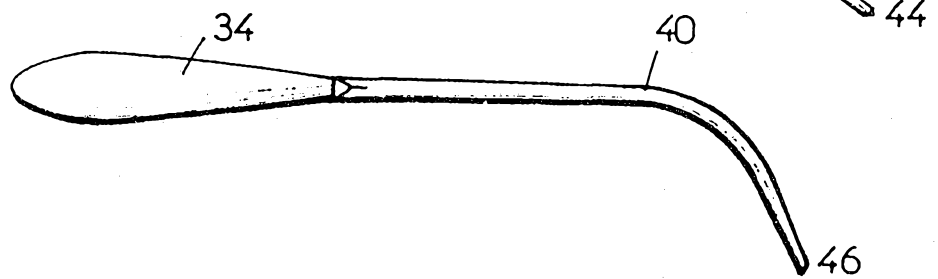


FIG.:4

