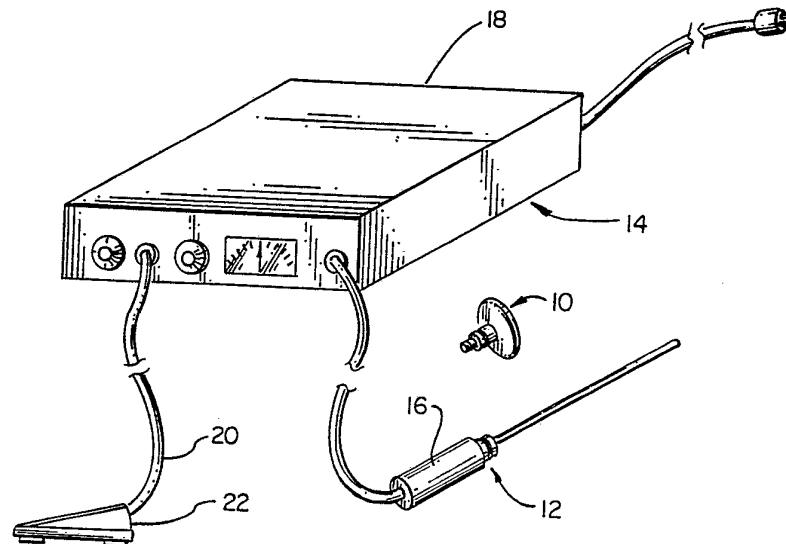


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: METHOD AND APPARATUS FOR TREATING HUMAN FAT TISSUE



(57) Abstract

This invention relates to a method and apparatus for destroying human fat tissue safely, quickly and conveniently by the internal or external application of ultrasonic energy by means of special probes. If the ultrasonic energy is to be applied externally, the special external ultrasonic probe (10) is placed on the skin over the area of fat cells and tissue to be destroyed. Ultrasonic energy is applied to the probe, which destroys the human fat cells and fat tissues in the area under the probe. After the fat cells and fat tissues are ruptured and destroyed by the ultrasonic energy, the probe is removed from the patient. A suction device may be surgically inserted into the area of destruction for removal of the destroyed cells and tissues, if desired. If the ultrasonic energy is to be applied internally, the special internal ultrasonic probe (12) is inserted into the patient's body through a small incision in the area where fat destruction is desired. Ultrasonic energy is applied to the probe, which destroys the human fat cells and fat tissues in the area surrounding the probe. After the fat cells and fat tissues are ruptured and destroyed by the ultrasonic energy, the probe is removed from the patient. A suction device may be surgically inserted into the area of destruction for removal of the destroyed cells and tissues, if desired.

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⁺ Any designation of "SU" has effect in the Russian Federation. It is not yet known whether any such designation has effect in other States of the former Soviet Union.

Method and Apparatus for Treating Human Fat Tissue

This invention relates to a method and apparatus for destroying human fat cells and tissue safely and expeditiously directly inside the body or externally through the skin for ultimate removal or other liposculpturing treatment.

Current plastic surgery techniques for treating obesity of physical appearance requires elimination of human fat cells and tissue. With liposuction, surgical incisions are made and areas of fatty tissue are cut away with surgical instruments and removed with suction devices. Such operations can be traumatic and dangerous if not performed properly.

The present invention provides a novel technique for destroying fat cells and fat tissue areas directly inside the body or externally through the skin, significantly reducing surgical trauma by use of ultrasonic energy. With an ultrasonic probe disposed externally of the body, cavitation can be induced in adjacent fat cells beneath the skin destroying fat tissue without any incision. A small incision may be made and a liposuction device used for sucking out the destroyed fat tissues. Alternatively direct fat cell contact with a long titanium ultrasonic probe through a small incision may be employed to destroy the fat cells. Fat cells and tissue adjacent the probe end can be destroyed.

The use of the present method and apparatus greatly reduces the surgical trauma and risks presently experienced in liposuction and liposculpturing techniques while reducing the time of the procedures.

A method and apparatus for destruction of human fat cells and tissue using ultrasonic energy application either directly within the body or externally through the patients skin. The method broadly encompasses selecting the area of treatment, positioning an ultrasonic probe at the desired treatment location and applying ultrasonic energy to the human fat cells and tissues to be destroyed. The removal of the destroyed fat cells may be done through a small incision

with a liposuction device which sucks out the residual oils and residual fat tissue from the area subjected to ultrasonic energy between 20,000 Hz and 3,000,000 Hz.

For ultrasonic application externally through the skin, a plate-shaped ultrasonic probe of a predetermined size having a smooth, polished surface and centre connector coupled to the ultrasonic generator is utilized. A gel is applied to the outer skin of the patient in the probe contact area. Fat cells below the skin receiving the ultrasonic energy burst due to the application of ultrasonic energy causing their destruction. The probe may be applied with a slow circular motion around the body area to be treated. After the ultrasonic external treatment is finished, if desired although not mandatory, a small incision may be made in the patient's skin and a liposuction device inserted there through which sucks out the destroyed fat cells, tissue and oils and any residual cell material.

Alternatively, the fat cells may be destroyed internally. A long, narrow ultrasonic probe (preferably made of titanium) is connected to an ultrasonic generator. The narrow probe is inserted through a small incision in the patient's skin in the treatment area and the ultrasonic energy applied, thus destroying and bursting fat cells and tissue immediately surrounding the blunt end of the probe. For fat cell removal, liposuction with a suction device is performed through the incision to remove the oil, dead cells and tissue although this is unnecessary as the destroyed material will be reabsorbed by the body.

With the use of the present method and apparatus, fat cells and fat tissues are quickly and efficiently destroyed without surgical trauma to the patient currently experienced with liposuction surgical techniques. In addition, the patient may be treated either externally with the external surgical probe or internally through a small incision using the elongated blunt tip probe, both probes providing ultrasonic energy directed to the fat cells to be treated.

The total time period of ultrasonic energy application will be normally less than one minute for the internal

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device, and quite longer (up to 15 minutes) for the external probe.

The technique and instruments provided are not only useful for abdominal areas of patients but can also be directed to other specific areas such as knees or saddle bags and buttocks in which autogenous collagen may be used for remodelling and in which the destroyed fat tissue materials may be allowed to reabsorb into the body and not be removed by suction after the ultrasonic exposure of the areas.

It is an object of this invention to provide a method for destroying fat cells and fatty tissue especially for liposculpturing also without using surgical trauma and surgical removal of the fat and cells and tissue.

It is another object of this invention to provide a method and apparatus for destroying human fat cells and tissue safely and efficiently.

Yet still another object of this invention is to provide a method and apparatus for performing liposculpturing and lipotription for treating human fat cells and tissue which includes internal or external ultrasonic application respectively.

In accordance with these and other objects which will be apparent hereinafter, the instant invention will now be described with particular reference to the accompanying drawings.

Figure 1 shows a perspective view of an apparatus used in the present invention which includes either an external probe or internal probe connected to the ultrasonic generator.

Figure 2 shows a side elevational view of the external probe used with the present invention.

Figure 3 shows a front elevational view with the probe used with the external application of the present invention.

Figure 4 shows a perspective view of the external probe used with the present invention.

Figure 5 shows a perspective view of an internal probe for internal application of ultrasonic energy in accordance with the present invention.

The method in accordance with the invention is accomplished by locating the fat cell and tissue area to be treated and applying ultrasonic energy to a limited, defined area of human fat cells and tissue, with either a flat ultrasonic probe externally through the skin or with a narrow internal probe typically for the ultimate removal of the destroyed fat cells and tissue or for liposculpturing. The method involves the application of ultrasonic energy in the range of 20,000 Hz to 3,000,000 Hz with the use of specially designed probes for internal or external use. The fat cells are destroyed by the bursting of the cells releasing oil and residual tissue, all of which can be removed by suction quickly and efficiently, or can be left in the body for a progressive reabsorption.

To carry out the method described above, a device as shown in Figure 1 may be used comprising an ultrasonic generating system 18 connected to a standard AC power supply that includes a foot switch 22 connected by wires 20 into the generator 18 for controlling the application of the energy. Also attached to the power supply and generator 18 is a convertor 16 that is used to attach either a probe 10 which is used for external application of ultrasonic energy through the skin of the patient or probe 12 which with a small incision can be inserted into a patient for internal ultrasonic application. Such a device as the VIBRACELL VC 50 is manufactured by Sonics and Materials, Inc., of Danbury, Connecticut.

Referring now to Figures 2, 3 and 4 the external probe is shown comprised of a metal circular disk of an ultrasonic transmitting material (preferably titanium) which is perfectly smooth and polished on outside face 10a and which includes a connector 10c that connects to the converter of the ultrasonic generator and a central flange 10d that transmits the energy into the disk from the converter connection. The probe diameter may be a desired, preferably

8 to 10 cm. The connector 10c includes a threaded connector to converter 16 shown in Figure 1 for the application of ultrasonic energy from 20,000 to 3,000,000 Hz. The probe 10 in conjunction with a gel applied on the skin of the patient can then be slowly moved in a circular motion on the skin around the area of fat cells below the skin which are to be destroyed by the ultrasonic energy. It is believed that cavitation in the fat cells is produced through the skin of the patient and the fat cells burst under the action of the ultrasonic energy. After the ultrasonic energy application is completed, destroying a reasonable number of fat tissue and fat cells desired beneath the skin, the residual is progressively reabsorbed by the body. The device is especially useful for treating small areas such as knees or saddle bags.

To employ the method with an internal ultrasonic application, and referring to Figure 5, an elongated titanium probe 12 is utilised which includes a thin cylindrical shaft portion 12a terminating in a blunt tip 12b from which the ultrasonic energy is transmitted. A threaded connector 12c connects the probe to the convertor 16 of Figure 1 of the ultrasonic energy generator. The probe 12 shown in Figure and shaft portion 12a is circular in cross section and includes an enlarged cylindrical portion 12d which connects the shaft 12a to the connector 12c. The length of the shaft may be between 10 and 30 centimetres and the diameter between 2 and 6 millimetres. To utilize the probe 12 shown in Figure 5 for internal use, a small incision is made in the patient in the desired area for the fat tissue and cell destruction. The probe 12 is inserted through the small incision under the skin into the area of the fat cells to be destroyed. Ultrasonic energy is then applied through the actuation of foot switch 22 shown in Figure 1 so that ultrasonic energy emerges from the blunt tip end and is concentrated in the area for the fat tissue destruction. After the ultrasonic treatment, a small liposuction device may be inserted in the treated area to remove the fat cell oil and dead cells or in some situations

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the oil and fat cells may be left in place for natural reabsorption. In some cases the injection of autologous collagen for remodelling a treated area may be applied.

Through the use of the present method, fat cells and tissue may be precisely and safely destroyed to permit removal or regeneration and liposculpturing in desired areas of the human body eliminating traumatic and dangerous cutting surgical techniques previously used. The invention also provides equipment for performing both external and internal ultrasonic destruction of fat cells and tissue in predetermined areas quickly and safely.

The instant invention has been shown and described herein in what it is considered to be the most practical and preferred embodiment. It is recognised, however, that departures may be made therefrom within the scope of the invention and that obvious modifications will occur to a person skilled in the art.

Claims

1. A method of destroying human fat tissue and fat cells comprising the steps of:-
 - a) selecting an area of the body containing human fat cells to be treated;
 - b) placing an ultrasonic probe adjacent said area containing fat cells to be destroyed; and
 - c) applying ultrasonic energy between 20,000 hz and 3,000,000 hz to the designated area for a predetermined amount of time, destroying the fat cells.
2. A method as in claim 1, which is performed externally to the human body comprising the step of placing said probe externally adjacent to the outer skin of the human body capable of transmitting ultrasonic energy from the probe through the skin to the human fat tissue below the skin destroying the fat tissue.
3. A method as in claim 1, including the step of:
 - providing a small incision in the outer skin of the patient for insertion of said ultrasonic transmitting probe;
 - providing a narrow elongated ultrasonic probe;
 - sliding the probe through the incision directing the probe to areas of human fat tissue to be destroyed; and
 - transmitting ultrasonic energy from said probe tip onto human fat cell tissue destroying the fat tissue.
4. A method as in claim 1, including the step of:
 - removing the dead fat tissue or fat cells from the patient;
5. An apparatus for externally applying ultrasonic energy to human internal fat cells and tissue comprising:
 - a flat plate of a predetermined thickness, said plate having a first connector sized and connected for receiving ultrasonic energy, said plate being capable of transmitting ultrasonic energy through the skin of a patient; and
 - means for generating ultrasonic wave energy of 20,000 hz to 3,000,000 hz connected to said flat plate connector.
6. An apparatus as in claim 5, wherein:
 - said flat plate is circular and has a smooth flat polished surface which contacts the human skin.

7. A device for applying ultrasonic energy internally in a human body to destroy human fat cells and tissue comprising:

an elongated narrow titanium probe capable of transmitting ultrasonic energy, said probe having substantially a blunt end portion through which the ultrasonic energy is transmitted outwardly, and a probe connector;

ultrasonic energy generator connected to said probe for transmitting ultrasonic energy into said probe, said probe sized for insertion through a small incision in the human patient capable of destroying fat cells adjacent to the blunt end tip.

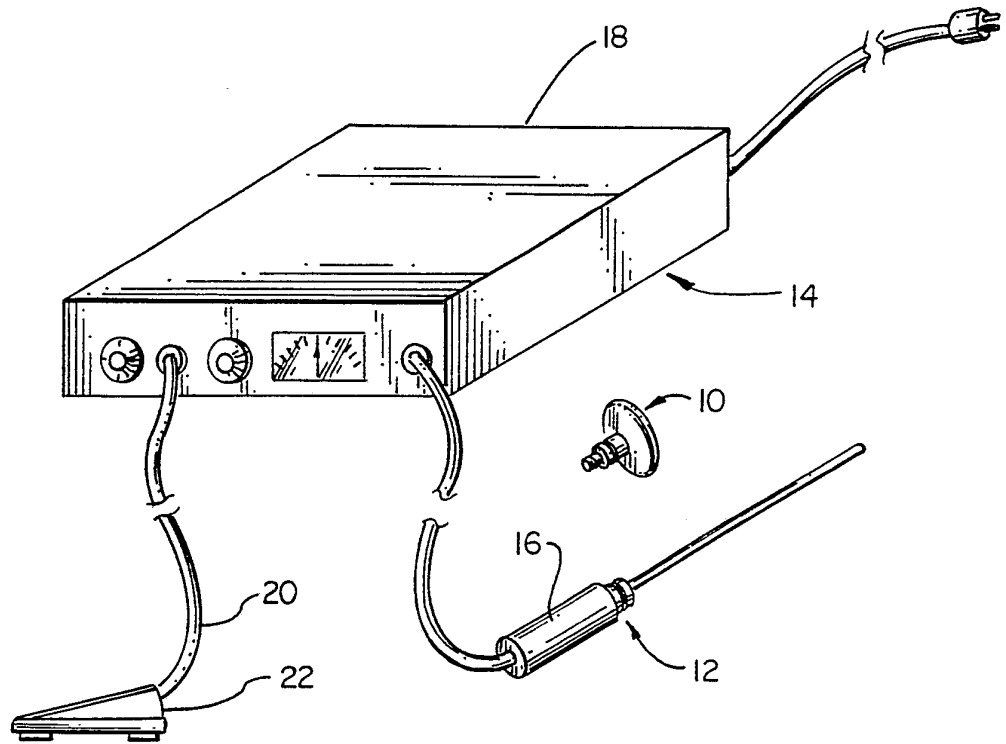


FIG. 1

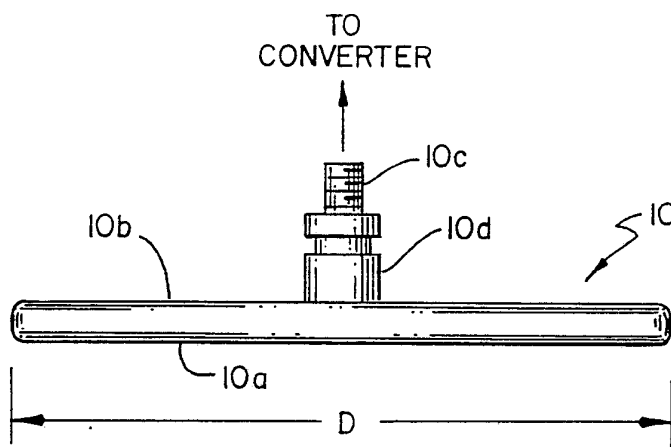


FIG. 2

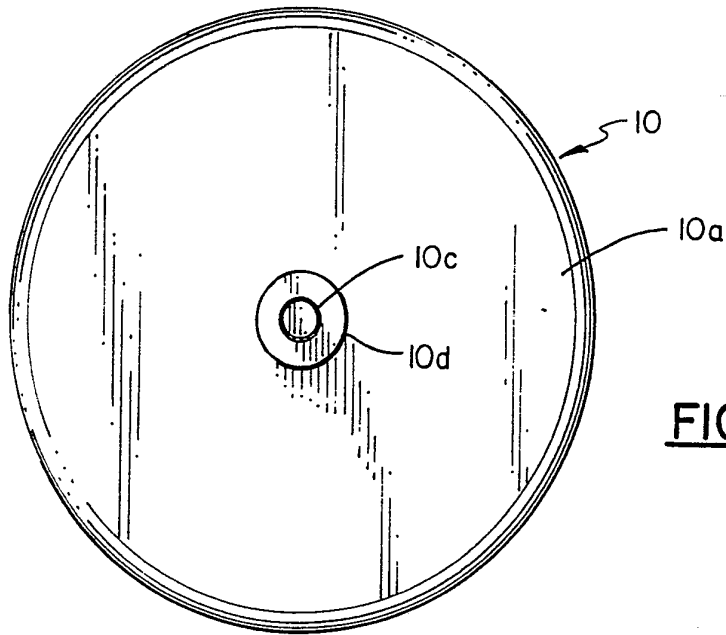


FIG. 3

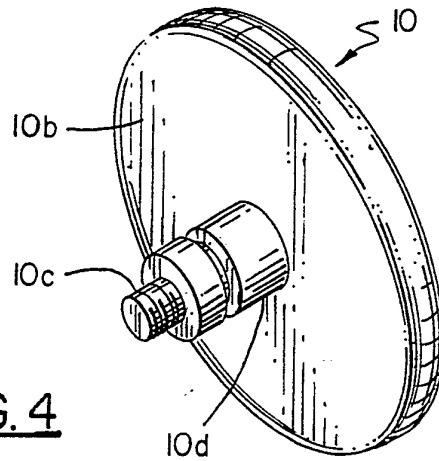


FIG. 4

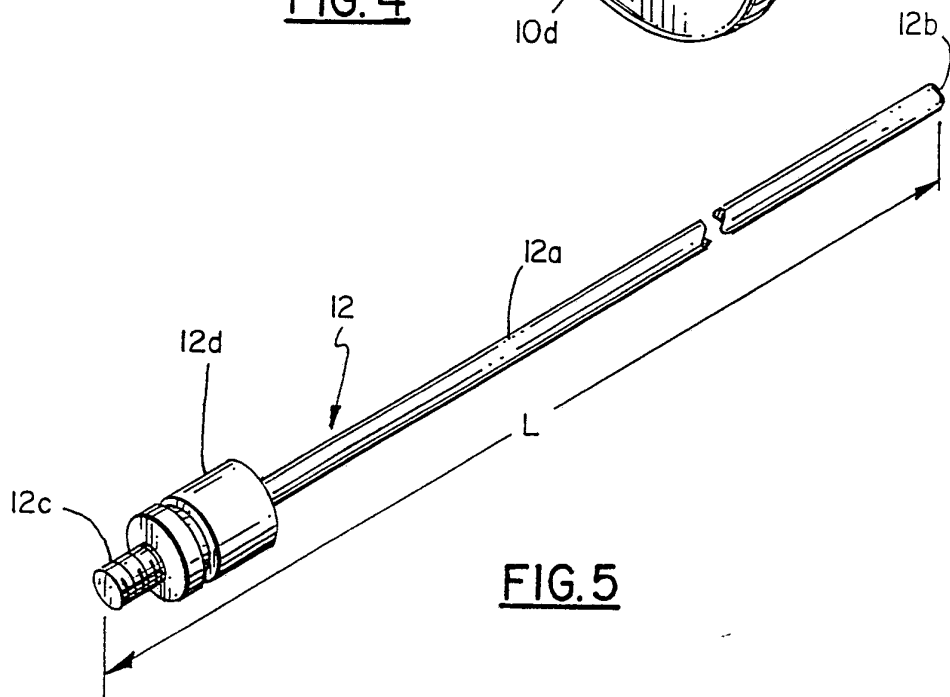
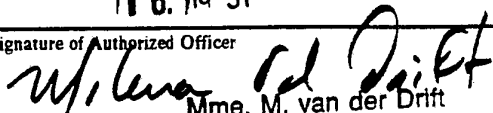


FIG. 5

INTERNATIONAL SEARCH REPORT

International Application No **PCT/EP 9002335**

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)				
According to International Patent Classification (IPC) or to both National Classification and IPC A 61 B 19/00 A 61 B 17/22 A 61 F 7/00				
II. FIELDS SEARCHED				
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Classification System	Classification Symbols			
Int.Cl.5	A 61 B A 61 F			
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸				
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹				
Category ^o	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³		
X	WO-A-8 907 468 (D.G. FELLNER) 24th August 1989, see page 7, line 13 - page 8, line 21; figure 1 ---	5,6		
X	EP-A-0 331 313 (T. PARISI) 6th September 1989, see column 4, line 46 - column 6, line 4; figure 1 ---	7		
A	US-A-4 823 042 (K.W. COFFEY) 18th April 1989, see column 3, lines 37-40; figure 5 -----	5,6		
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top; border: none;"> ^o Special categories of cited documents :¹⁰ "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed </td> <td style="width: 50%; vertical-align: top; border: none;"> "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step "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 </td> </tr> </table>			^o Special categories of cited documents : ¹⁰ "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step "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
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IV. CERTIFICATION				
Date of the Actual Completion of the International Search <div style="text-align: center;">26-07-1991</div>	Date of Mailing of this International Search Report <div style="text-align: center;">19 6. 91</div>			
International Searching Authority <div style="text-align: center;">EUROPEAN PATENT OFFICE</div>	Signature of Authorized Officer <div style="text-align: center;">  Mme. M. van der Drift </div>			

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE ¹

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. Claim numbers 1-4 because they relate to subject matter not required to be searched by this Authority, namely:

Methods for treatment of the human or animal body by surgery
Rule 39.1 (iv)

2. Claim numbers....., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claim numbers....., because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING ²

This International Searching Authority found multiple inventions in this international application as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:
3. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:
4. As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- The additional search fees were accompanied by applicant's protest.
- No protest accompanied the payment of additional search fees.

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

EP 9002335

SA 43655

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 02/09/91
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A- 8907468	24-08-89	None	
EP-A- 0331313	06-09-89	US-A- 4886491	12-12-89
		JP-A- 1262854	19-10-89
US-A- 4823042	18-04-89	None	

EPO FORM P0479

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82