United States Patent

Delgado

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[54] **FLUID-CONDUCTING INSTRUMENT INSERTABLE IN LIVING ORGANISMS**

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[52] **U.S. Cl.** ....**128/2 R,** 128/2 F, 128/2.1, 128/213, 128/260, 128/348

[51] **Int. Cl.** **A61b 5/00**

[58] **Field of Search**......................128/2, 2.05, 2.1, 213, 214, 128/260, 261, 348–351, 240–241, 239; 424/16, 19; 3/1

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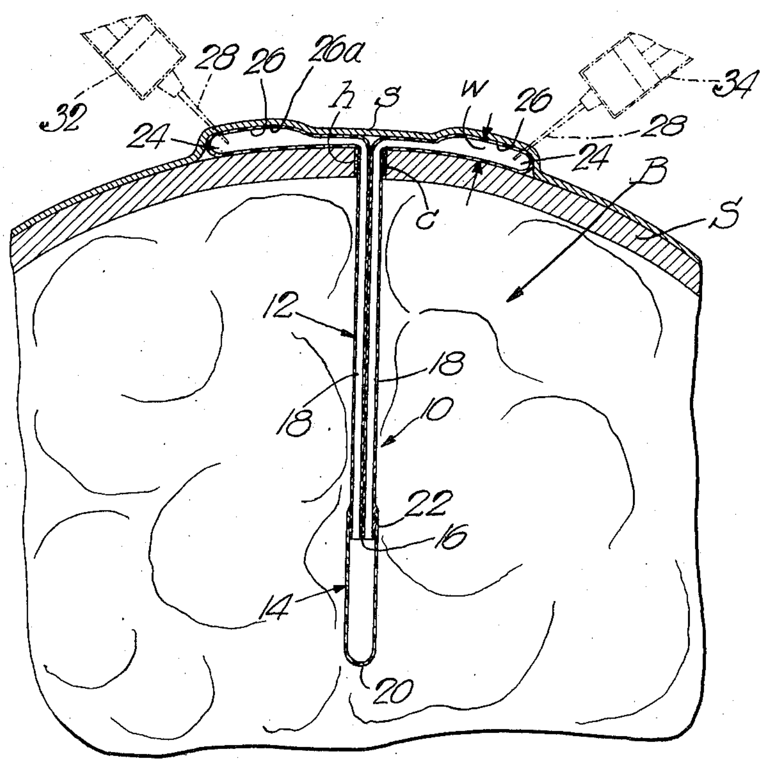
[57] **ABSTRACT**

An instrument for insertion in living organisms, having two flexible fluid-impermeable tubes open at one end and provided at the other end with enlarged bag formations which are self-sealing after being punctured with a needle, and a porous bag closed except for an open end with which the open tube ends communicate, with the latter being received in and attached to the open bag end and sealed from the outside of the bag.

5 Claims, 3 Drawing Figures



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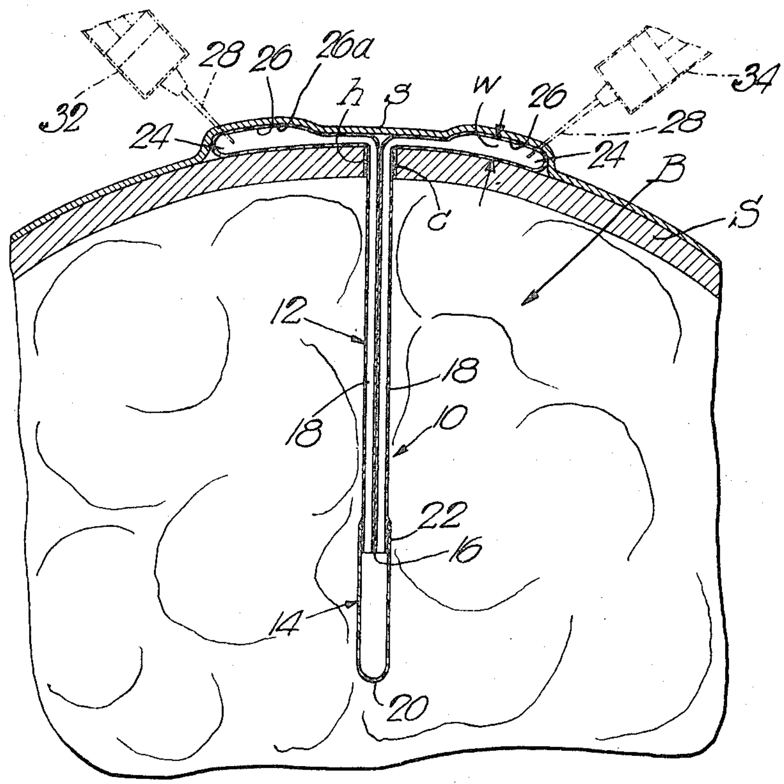

Fig. 1

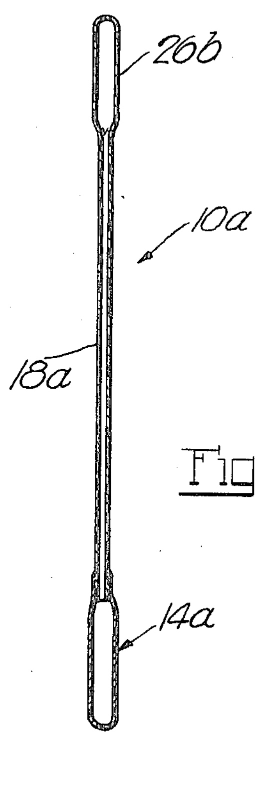

Fig. 2

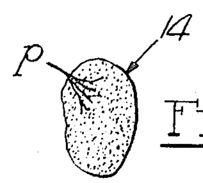

Fig. 3

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FLUID-CONDUCTING INSTRUMENT INSERTABLE IN LIVING ORGANISMS

This invention relates to medical instruments in general, and to instruments for passing fluids into and from living organisms in particular.

The present invention is concerned with instruments that are insertable or implantable in living organisms for passing fluids therefrom and/or thereinto for medical-scientific and therapeutic purposes. Prior instruments of this type are known, but these are mostly in the form of needles or cannulae which, while serving for highly useful purposes, are limited in their applications. Particularly lacking among these prior instruments is one single instrument which readily lends itself to any of various procedures involved in medical techniques, such as supplying a liquid medium to a localized part of a living organism at a prescribed rate over a desired, including relatively long, time span with or without human supervision, extracting matter in liquid form from a localized part of a living organism, and circulating liquid medium through a localized part of a living organism for any desired length of time. Further, in using prior instruments of this type in living organisms, there is always the risk of introducing micro-organisms into, and thus contaminating, these organisms.

It is among the objects of the present invention to provide an instrument of this type which not only lends itself readily to any of the aforementioned various procedures involved in medical techniques, but the use of which in any part of a living organism does not involve any risk of introducing micro-organisms into the organism dealt with.

It is another object of the present invention to provide an instrument of this type which for insertion in a living organism includes preferably flexible tubing, and for displacement of fluid into or from an organism provides the tubing with a closed lead end and with a porous wall over a length of the tubing near, and preferably extending to, the closed lead end. With this arrangement, the inserted instrument with its porous wall in a desired location in a living organism, may be attended to at its outer end, either to introduce into the tubing a liquid for its gradual, dosed, seepage through the porous wall and perfusion of the organism, or to draw liquid from the organism through the porous wall into and out of the tubing.

It is a further object of the present invention to provide an instrument of this type in which the porosity of the aforementioned wall of the tubing is such that the pores will block the passage of micro-organisms but will permit the passage of fluids involved in the various medical procedures.

Another object of the present invention is to provide an instrument of this type in which the aforementioned lead end and porous wall of the tubing are formed by a separate porous application bag which is joined and open to the tubing and is preferably flexible and of sufficient volume to hold a substantial quantity of liquid. With this arrangement, the tubing may be of any nonporous material well tolerated by living tissue, such as stainless steel or Teflon, for example, while the application bag may be of any suitable porous material, such as polypropylene sheet of proper pore size, for example, which may readily be joined to the tubing either directly or by a binder. Further, the bag may hold liquid, such as a medicating drug, for instance, in sufficient quantity to perfuse an affected part of a living organism for a relatively long period.

A further object of the present invention is to provide an instrument of this type of which the tubing is in the form of twin tubes side-by-side at least over their insertable length, and the aforementioned porous application bag is joined and open to both tubes. With this arrangement, charging the bag of the inserted instrument with a liquid is expedited as well as facilitated, in that the liquid may be introduced through one tube while the bag is vented through the other tube. Further, the inserted instrument lends itself to the additional procedure of circulating a liquid for any length of time through the affected area within an organism without possible contamination of the latter by micro-organisms. This is achieved by connecting the outer ends of the tube with the outlet and inlet of a pump so as to form through the tubes and bag a circulatory passage via the pump and keep this passage filled with liquid. With the liquid in this circulatory passage being then subjected to the positive and negative pressure from the operating pump, the liquid is displaced from the application bag into the organism and back from the organism into the bag. The inserted instrument also lends itself still further to electric stimulation of, and recording from, a living organism, such as the brain, for example, by introducing through the tubing an insulated conductor with its bare conductive tip extending into the application bag, and filling the bag with an electrolite, such as spinal fluid, which by its perfusion of the cerebral tissue around the bag establishes electrical contact between the tissue and conductor.

It is another object of the present invention to provide an instrument of this type of which the outer ends of the twin tubes are closed, and are preferably formed as enlarged reservoir bags of a material which allows repeated puncturing with a needle without giving rise to leakage after retraction of the needle. With this arrangement, the instrument lends itself particularly well, though not exclusively, to implantation, with the reservoir bags being arranged subcutaneously but readily accessible with needles through the skin overlying these bags, so that the instrument lends itself to any and all of the aforementioned procedures. Further, with the entire instrument closed except for the pores in the application bag, the rate of seepage of a liquid from the application bag into a living organism, or vice versa, may be varied considerably by superatmospheric or subatmospheric air or gas pressure applied to the closed instrument through a needle into either of the reservoir bags.

Further objects and advantages will appear to those skilled in the art from the following, considered in conjunction with the accompanying drawings.

In the accompanying drawings, in which certain modes of carrying out the present invention are shown for illustrative purposes:

FIG. 1 is a section through an instrument embodying the present invention, with the instrument shown in this instance implanted in a living organism;

FIG. 2 is a section through an instrument embodying the invention in a modified manner; and

FIG. 3 is a fragmentary enlarged view of a prominent part of either instrument of FIG. 1 or FIG. 2.

Referring to the drawings, and more particularly to FIG. 1 thereof, the reference numeral **10** designates an instrument which is insertable into living organisms for passing fluids therefrom and/or thereinto for medical-scientific and therapeutic purposes. The present instrument is shown in this instance inserted, and more particularly implanted, in a living brain B beneath a skull S. The instrument is adapted for injecting into, or retracting from, a living organism fluid, and more particularly various liquids. To this end, the instrument has as its major components fluid-conducting tubing **12** and an application bag **14** at the inner end **16** of the tubing **12**. The tubing **12** consists of a plurality of tubes **18**, two in this instance, which are of a material that is impermeable to fluids and well tolerated by the tissue, such as Teflon or some other suitable plastic, or stainless steel. Some of these materials lend flexibility to various desired degrees to the tubes.

The application bag **14**, which is preferably a separate part, is in this instance elongated and is closed at its lead-in end **20** and open at its other end **22**. The tubes **18** project with their open ends **16** into the open end **22** of the bag **14** and are there suitably attached to each other so that the tubes and bag are sealed from the outside of the bag. In accordance with an important aspect of the invention, the application bag **14** is porous for the displacement of fluid, and especially liquids, thereinto and therefrom. The bag **14** may be formed of any suitable porous material, such as polypropylene, polysulfone or cellulose acetate, for example. The tube ends **16** may be attached to each other and to the surrounding bag end **22** by any known method of bonding plastic to plastic or stainless steel, depending on the materials used. The remainder of the tubes **18** are preferably unattached to each other so that they may be separated, for example to diverge with their outer ends 24 in the fashion shown in FIG. 1.

The outer ends 24 of the tubes 18 may be open for injection or retraction of fluid into or from the tubes. Preferably and advantageously, however, the outer ends 24 of the tubes 18 are formed as closed reservoirs in the form of bags 26 which may be formed integrally with, or suitably joined to, the respective tubes 18. These bags 26 are of any suitable material which allows repeated puncturing with a needle 28 and self-seals after each needle retraction. Among such suitable materials is silicone rubber, for example.

While dimensions of the tubes 18, application bag 14 and reservoir bags 26 may obviously vary for applications of the instrument to different living organisms, there are given, by way of example only, the dimensions of a specific instrument actually implanted in a living brain as shown. Thus, each of the tubes 18 had an outer diameter of about 0.9 mm., the application bag 14 measured about 1.8 mm. in diameter and about 5 mm. in length, while each of the reservoir bags measured about 5 mm. in width *w* and about 10 mm. in diameter. The instrument was implanted in the brain B by conventional surgical procedure, with the tubes 18 being secured in the drilled hole *h* in the skull S with a suitable cement *c*, in this instance acrylic cement, and the reservoir bags 26 being in this instance placed subcutaneously, i.e., below the scalp *s*, as shown, and anchored to the skull S as by the vitallium screws (not shown). In introducing the instrument in the brain, the application bag 14 was directed to the desired location and also depth in the brain with the aid of a fine metallic introductor directed by the micromanipulator of a stereotaxic instrument.

The instrument thus implanted in the exemplary brain B can be used for various purposes. One of these purposes is intracerebral injection of a drug solution. To this end, the needle 28 of a charged syringe 32 is entered through the scalp *s* into the subcutaneous bag 26*a*, for example, whereupon the plunger of the syringe is driven forward to eject the drug charge into the bag 26*a* while the instrument is being simultaneously vented at the other subcutaneous bag 26 through a needle 28 of another syringe 34 (FIG. 1). Drug solution of any desired amount may thus be introduced in the instrument. This drug solution will then enter the brain area around the application bag 14 at a readily controlled volumetric rate. Control over the rate of displacement of the solution from the application bag 14 is achieved by the pores *p* in this bag (FIG. 3) which lend it the desired porosity, by the total volume of drug solution injected into the instrument, by the selective pressure within the instrument, and by the concentration of the drug solution. The particular application bag used in the aforementioned specific instrument had a pore size below 0.2 microns and water permeability above 60 ml./min./cm.^{2}, but these data are given only by way of example and not limitation. Insofar as the pressure within the instrument is concerned, this may be regulated anywhere from the subatmospheric to superatmospheric by proper manipulation of the syringes 32 and 34, as will be readily understood. Further, the higher the concentration of the drug solution, the more rapid will be its displacement from the application bag 14 into the brain regardless of the pressure of the instrument. Thus, even if there is no pressure on the solution in the instrument, i.e., if the pressure therein is approximately atmospheric, the solution will pass from the porous bag 14 into the brain at a rate depending on its concentration. It is thus readily apparent that by means of the present instrument a drug solution may perfuse the brain at a rate and over a time span within relatively wide limits.

The exemplary instrument may serve for numerous other purposes. Thus, it may serve for intracerebral collection. To this end, the instrument is filled with a suitable solution, such as synthetic spinal fluid, for example, and a negative pressure is maintained in the instrument by injecting slowly and placing the collecting syringe below the level of the head, with the negative pressure being proportional to the diameter of the needle used and to the differential levels between the injection and collection syringes.

Another application of the instrument is for recirculation of a fluid. To this end, a pump is interposed between the applied syringes to complete a recirculation path through the instrument, with the collected fluid being reintroduced into the subcutaneous injection bag and recirculated intracerebrally for as long as desired. In this application, for example, neurochemical equilibrium between brain and perfused fluids may be established within a certain period of time, increasing the concentration of neurohumors released from the brain into the synthetic spinal fluid.

Still another exemplary application of the instrument is for electrical stimulation and recording. To this end, one of the subcutaneous bags is punctured with a fine needle, whereupon an insulated Teflon-coated stainless steel wire with a bare conductive tip is through the needle introduced as a stylet to establish electric contact with the cerebral tissues around the application bag through intermediation of an electrolite, such as spinal fluid, in the instrument.

In all of these and still other applications, no micro-organisms may enter the living organ because the pore size of the porous application bag is in any event such as to block the passage of organisms. Pore sizes of below 0.5 microns are recommended to that end.

With the instrument implanted as in the example shown, the same is ready for use at any time, but during periods of rest there is no instrumentation breaking the continuity of the skin.

Short or long term intracerebral injections will have important scientific and therapeutic applications. Following are a few exemplary ones of these applications:

a. to increase the dopamine content of the pallidum in patients with Parkinson's disease,

b. to inhibit the abnormal functioning of localized areas of the brain by slow, chronic infiltration with blocking agents,

c. to administer antiepileptic medication to the site of the origin of disturbed electrical activity in patients with epilepsy, and

d. electrical stimulations and recordings which may provide basic information for diagnostic and therapeutic purposes. In addition, analysis of chemicals released locally by the brain may orient the diagnosis of cerebral disturbances and may guide the administration of drugs.

While the instrument is shown implanted in a brain in the example shown in FIG. 1, it may, of course, be implanted, or merely inserted, in any other living organism with or without requiring surgery for its introduction into the organism.

Reference is now had to FIG. 2 which shows a modified instrument 10*a* that is like the described instrument 10 of FIG. 1, except that there is only one tube 18*a* and one outer bag 26*b*. The application bag 14*a* is porous, the same as the bag 14 of the instrument 10. The present instrument 10*a* lends itself to similar applications as the instrument 10, though with obvious limitations owing to the single tube 18*a* and single outer bag 26*b*.

I claim:

1. An instrument insertable into living organisms, comprising two flexible fluid-impermeable tubes of the same uniform cross-sectional size, with said tubes being open at one end and provided at their other ends with enlarged flexible fluid-impermeable bag formations which are puncturable with a hypodermic needle and self-sealing on needle retractions; and a separate elongated porous bag having an open end and being otherwise closed, and receiving in its open end side-by-side disposed endlengths of said tubes including said open ends thereof, and said tube endlengths being attached to said open bag end and sealed from the outside of said bag, with other endlengths of said tubes including said bag formations being unattached to each other, and said porous bag defining a counterflow path from either of said open tube ends to the other open tube end.

2. An instrument as in claim 1, in which said bag formations are of substantially the same volume.

3. An instrument as in claim 1, in which said tubes are unattached to each other except at their attachment to said open bag end.

4. An instrument as in claim 1, in which said endlengths of said tubes received in said open bag end are of the same length.

5. An instrument as in claim 1, in which the pores of said porous bag are of a size below 0.5 microns.

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