PATENT SPECIFICATION (11) 1 570 087

1 570 087

(21) Application No. 50683/76 (22) Filed 6 Dec. 1976
(31) Convention Application No. 638 884
(32) Filed 8 Dec. 1975 in
(33) United States of America (US)
(44) Complete Specification published 25 June 1980
(51) INT CL³ A61F 1/00//A61M 1/00; A61N 1/36
(52) Index at acceptance A5R 85D6 85F1 AR

(72) Inventors WAYNE HARPER STATT, GERARD GUIRAUDON and FORREST OTTO STARK

(19)

(54) SURGICAL IMPLANTABLE DEVICES

(71) We, DOW CORNING CORPORATION of Midland, Michigan, United States of America, a corporation organized under the laws of the State of Michigan, United States of America do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The present invention relates to surgically implantable devices and particularly to devices which include elongated members such as tubing or electrical conductors.

For some time, it has been common practice to implant lengths of tubing or lengths of electrical conductors within living bodies for various therapeutic purposes. For example, in the treatment of hydrocephalus, shunts are implanted to provide an artificial pathway for cerebro-spinal fluids from the brain to either the blood circulatory system or to the peritoneal cavity. Similarly, in the use of heart pacers, electrically conductive members are used to transmit electrical energy from a power source to the heart. The heart or cardiac pacer generally comprises electrical circuitry which is connected by a lead or leads to one or more electrodes, the electrodes adapted to be connected to a desired spot within the human body. One problem which has been encountered and is known to those skilled in the art involves pediatric implants where a substantial growth of the body in which the implantation is made can be expected. Obviously, leads which are of the desired length at the time of a pediatric implant will become too short as body growth occurs. Successive implantation of leads and related devices with increased length is undesirable because of the multiple surgery involved. To implant a device with extra lead length is unsatisfactory because normal body movement may cause the extended length of lead to entwine itself around portions of the body interfering therewith and probably causing malfunctioning of the device and/or the body portion. Furthermore, normal body reactions tend to encapsulate foreign materials and thereby prevent the extension intended. Several methods have been used to overcome the above mentioned pediatric implant problem. U.S. Patent No. 3,492,996 directed to a ventriculoatrial shunt used in the treatment of pediatric hydrocephalics suggests that the implant ventricular conduit include a pair of telescoping portions to provide adjustability. U.S. Patent 3,598,128 suggests the use of a reel type lead storing spacer which permits leads stored in the reel to unwind providing lead lengths for growth while isolating the stored lead from the body. U.S. Patent No. 3,623,484 suggests an implantable telescoping shunt system for drainage or unwanted fluids in the body such as in hydrocephalics.

British Patent Specification No. 1,408,216 described and claims a surgically implantable device comprising an elongated member designed to interconnect two separate parts of the body in which the device is to be implanted, and a hollow capsule surrounding a midportion of said elongated member such that end portions of said elongated member pass through the walls of said capsule, a length portion of said elongated member being contained within the hollow of said capsule which length portion is substantially longer than said hollow, at least one end portion of said elongated member having a cross-sectional dimension which corresponds to the dimension of the opening in the capsule wall through which that end portion of the elongated member passes, in a manner such that the elongated member is freely slidable through said capsule wall when tension is applied between opposite end of the elongated member. Typically, the elongated member is a hollow tube.

One of the disadvantages of the adjustment systems available prior to the present invention is that tissue ingrowth can occur around and in the moving parts interfering with their efficient operation and in some cases stopping the adjustment action completely. This ingrowth is particularly apt to occur at the apertures through which the movable members pass.

We have sought to provide an improved surgically implantable device, for transferring fluids or energy between two separated parts

of the body, which device will accommodate growth of the animal body in which it is implanted.

Accordingly, the present invention provides a surgically implantable device for transfer of fluids or energy comprising an elongated member designed to interconnect two separated parts of the body in which the device is to be implanted and a hollow capsule containing a mid portion of the elongated member there within which portion is substantially longer than the hollow; the capsule having at least one opening such that the elongated member is slidable through the opening when tension is applied between opposite ends of the member, the opening or openings having viscous material (as herein defined) positioned in relation thereto such that the elongated member passes through the viscous material (as herein defined) prior to passing through the opening.

By the term "viscous material" as used herein and throughout the specification and claims is meant a material which is sufficiently viscous to prevent leakage thereof through the opening or openings of the capsule but which is sufficiently soft and flowable not to impede movement of the elongated member through said opening or openings. Preferably, the viscous material (as herein defined) is a soft gel-like material, for example a silicone gel although other materials fulfilling the above requirements such as a grease or heavy fluid may be used. Thus, as the child grows, the length portion of the member which is in the capsule is gradually pulled out of the capsule allowing controlled extension of the length of the elongated member. The elongated member can be either a hollow tube such as that used in a hydrocephalus shunt or alternatively, can be an electrically conductive element such as that used in a heart pacer lead. The capsule is generally filled with the viscous material (as herein defined) and said material effectively seals the opening or openings of the capsule against tissue ingrowth or interfering buildup avoiding the disadvantages of prior art devices.

The present invention is further illustrated by the accompanying drawings wherein:

Fig. 1 is a perspective view of a surgically implantable variable length device made in accordance with the present invention;

Fig. 2 is a vertical cross-section through the device of Fig. 1; and

Fig. 3 is a vertical cross-section through a modification of the device shown in Fig. 1.

Referring now to the drawing wherein like reference characters designate like parts throughout the figures thereof, there is shown in Fig. 1 a surgically implantable, expandable length device for transfer of fluids or energy having an elongated member 10 which may be either a hollow tube such as a hydrocephalus shunt or alternatively, may be an electrically conductive element such as in a heart pacer lead. Surrounding a portion of the elongated member 10 is a hollow capsule 12 through which the elongated member 10 passes. The point of entry of the elongated member 10 into the hollow of the capsule 12 is designated by the letter A and the point of exit is designated by the letter B in Fig. 2. The length portion of the elongated member 10 which extends between the points A and B is substantially longer than the length of the hollow in the capsule 12. This length is preferably accommodated by coiling that portion of the member 10 within the hollow but other configurations such as zig-zags or serpentine folds may also be provided. If desired, the capsule 12 may have the configuration of a hollow disc or may be formed in any configuration which will provide a container for the coiled portion of the elongated member and viscous material (as herein defined).

The capsule 12 is filled with a viscous material (as herein defined) such as a soft gel 14 of such consistency that leakage through the openings at points A and B is prevented while movement of the elongated member 10 is allowed. An excellent filling material is a silicone gel made in accordance with the disclosure of U.S. Patent No. 3,020,260, the consistency of which is adjusted to meet the requirements set forth herein. The soft gel 14 can be made by vulcanizing a liquid methylsilicone resin blended with a dimethylsilicone fluid. The resin contains $R_3SiO_{1/2}$ units, R_2SiO units and SiO_2 units where R represents methyl radicals. The ratio of the groups one to the other determines the consistency of the gel. It should be understood, however, that the silicone gel can be prepared in other ways such as, for example, by injecting a mixture of a hydroxylated siloxane and ethylsilicate into the container along with a suitable catalyst such as stannous octoate. The fluid will then set in place forming a soft silicone gel. Regardless of the type of gel employed it is preferred that the gel have a soft consistency.

Preferably at both points A and B but in any case at one of the points A and B the cross-sectional dimension of the elongated member 10 must generally correspond to the dimension of the opening in the capsule wall through which that end of the elongated member passes in a manner such that the elongated member is freely slidable through the capsule wall when tension is applied between opposite ends of the elongated member 10. In this manner when tension is applied between the ends, additional portions of the elongated member which were originally positioned between A and B are pulled from the interior of the capsule. Thus, as a body grows and the ends of the member 10 are placed in tension, additional portions of the member 10 are pulled from the capsule causing the overall device in effect to grow in length and accommodate such growth. Tissue attachment tabs may be extended from the outer surface of the capsule 12 for fixing

of the device in place by either surgical sutures or tissue infiltration.

Another embodiment of the device includes a hollow capsule 12a having a point of entry, of the elongated member 10a, designated by the letter and number A1 and a point of exit designated by the letter and number B1 is shown in Fig. 3. The entry point A1 and the exit point B1 are partially blocked by hollow discs 16 each having a first aperture designated by the letter C and a second aperture designated by the letter D. The apertures C and D are in spaced relation and have a common axis, although such axial relationship may be varied. The discs 16 are filled with a soft gel 14a having the same composition and viscosity as the gel 14. The discs 16 are adhered to the inner surface of the hollow capsule 12a with the apertures C and D of one disc 16 axially aligned with the axis of the entry A1 on one side of the hollow capsule 12a and the apertures C, D of the other disc 16 axially aligned with the exit point B1 on the other side of the capsule 12a. The elongated member 10a is similar to elongated member 10 and is passed through the hollow capsule 12a and through the apertures C and D of the discs 16 as shown in Fig. 3. As in the case of the elongated member 10, the length portion of the elongated member 10a extending between the points A1 and B1 is substantially longer than the distance between those two points and the additional length is accommodated by coiling a portion thereof. The portions of the elongated member 10a passed through the discs 16 are not coiled. This embodiment leaves the major portion of the hollow of the capsule 12a in effect empty so that it could be filled with air or saline solution which may include drugs that could be dispersed to the animal body if the wall of the capsule 12 was permeable thereto. The elongated member 10a is freely slidable through the points A1, B1 and through the apertures C and D providing a device which operates the same as or very similar to the filled capsule 12 and which has its advantages.

It must be understood that while in the preferred embodiments described above, the elongated member has been referred to simply in terms of a tube or electrical conductor various types of valves and connectors may be applied to the ends thereof without departing from the scope of the invention. The entire device with the exception of electrically conductive elements is preferably made of silicone rubber although it should be understood that suitable reinforcement fabrics or tissue ingrowth means may be applied to the silicone rubber for added strength or maintenance of position of the device should that be surgically desirable, one embodiment of which has been mentioned herein as tissue attachment tabs.

WHAT WE CLAIM IS:—

1. A surgically implantable device for transfer of fluids or energy comprising:

an elongated member designed to interconnect two separated parts of the body in which the device is to be implanted, and

a hollow capsule containing a mid portion of the elongated member there within which portion is substantially longer than the hollow; the capsule having at least one opening such that the elongated member is slidable through the opening when tension is applied between opposite ends of the member, the opening or openings having viscous material (as herein defined) positioned in relation thereto such that the elongated member passes through the viscous material (as herein defined) prior to passing through the opening.

2. A surgically implantable device as claimed in claim 1 wherein the whole of the hollow device is filled with viscous material (as herein defined).

3. A surgically implantable device as claimed in claim 1 wherein the viscous material (as herein defined) is within a disc within the capsule, the disc having a first and second aperture in spaced coaxial relation to each other and with the opening of the capsule, and the elongated member is slidable through the first and second apertures and the opening.

4. A surgically implantable device as claimed in any of claims 1 to 3 wherein the hollow is filled with a soft gel.

5. A surgically implantable device as claimed in claim 4 wherein the soft gel is a silicone gel.

6. A surgically implantable device as claimed in any of claims 1 to 5 wherein the elongated member is a hollow tube.

7. A surgically implantable device as claimed in any of claims 1 to 5 wherein the elongated member is an electrically conductive element.

8. A surgically implantable device as claimed in claim 1 substantially as described with reference to the accompanying drawing.

ELKINGTON & FIFE,
Chartered Patent Agents,
High Holborn House,
52—54 High Holborn,
London WC1V 6SH.
Agents for the Applicants.

Printed for Her Majesty's Stationery Office by the Courier Press, Leamington Spa, 1980.
Published by the Patent Office, 25 Southampton Buildings, London, WC2A 1AY, from which copies may be obtained.

1570087 COMPLETE SPECIFICATION
1 SHEET This drawing is a reproduction of the Original on a reduced scale

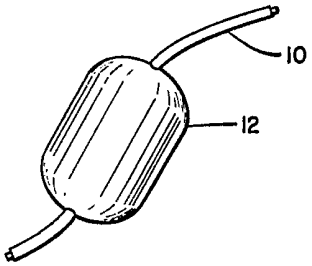

Fig. 1

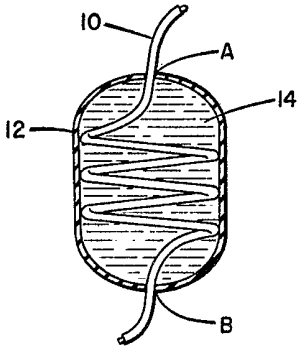

Fig. 2

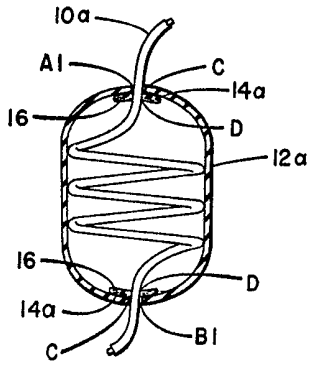

Fig. 3