United States Patent [19]

Armao

[11] **3,786,814**

[45] **Jan. 22, 1974**

[54] **METHOD OF PREVENTING CRYOADHESION OF CRYOSURGICAL INSTRUMENTS AND CRYOSURGICAL INSTRUMENTS**

[76] Inventor: **Thomas A. Armao,** 1242 56th St., Brooklyn, N.Y. 11219

[22] Filed: **Dec. 15, 1972**

[21] Appl. No.: **315,314**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 213,380, Dec. 29, 1971, abandoned.

[52] **U.S. Cl.** ..... **128/303.1,** 128/2 B, 128/269, 128/305

[51] **Int. Cl.** **A61b 17/36**

[58] **Field of Search** ..... 128/305, 303.1, 314, 260, 28/239.2 B; 134/42; 62/293; 260/2 EP

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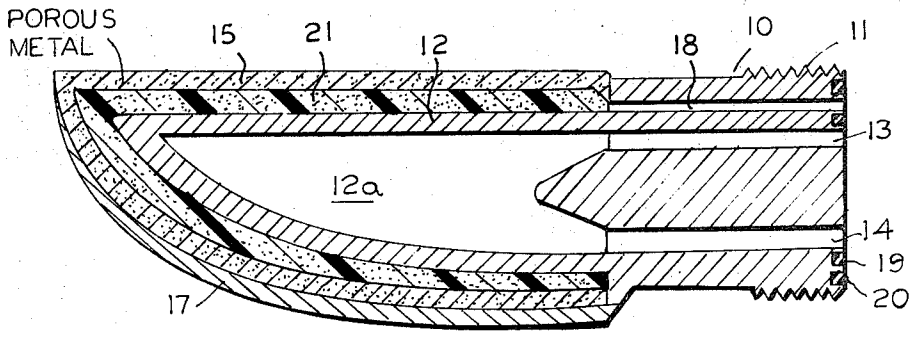
Primary Examiner—Aldrich F. Medbery

[57] **ABSTRACT**

A method of preventing cryoadhesion of cryosurgical instruments comprises placing on the surface of the instrument which comes in contact with tissue a coating of a fluorocarbon anti-cryoadhesion material which is a good heat conducting material which is liquid at ambient temperatures and remains a liquid at cryogenic temperatures and which is non-toxic to tissue. A cryosurgical instrument which prevents cryoadhesion has a hollow inner portion of a good heat conducting material having a cryogenic fluid inlet passage opening into the hollow interior thereof and a cryogenic outlet passage opening out of the hollow interior thereof. A sheath is provided which is of a good heat conducting material, at least a portion of which is porous. The sheath is positioned around the inner portion and spaced therefrom to define an enclosed space between the sheath and the inner portion. The instrument has an anti-cryoadhesion inlet passage therethrough opening into the enclosed space for anti-cryoadhesion material to flow into the space and through the porous portion of the sheath so that it is always present on the surface of the instrument during its use.

38 Claims, 22 Drawing Figures



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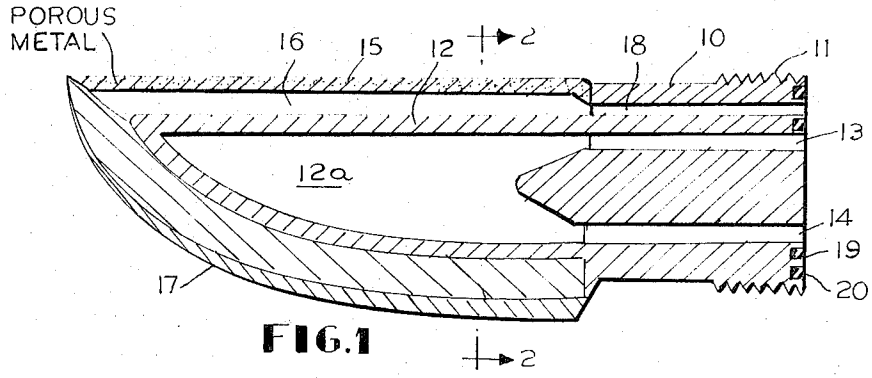


FIG. 1

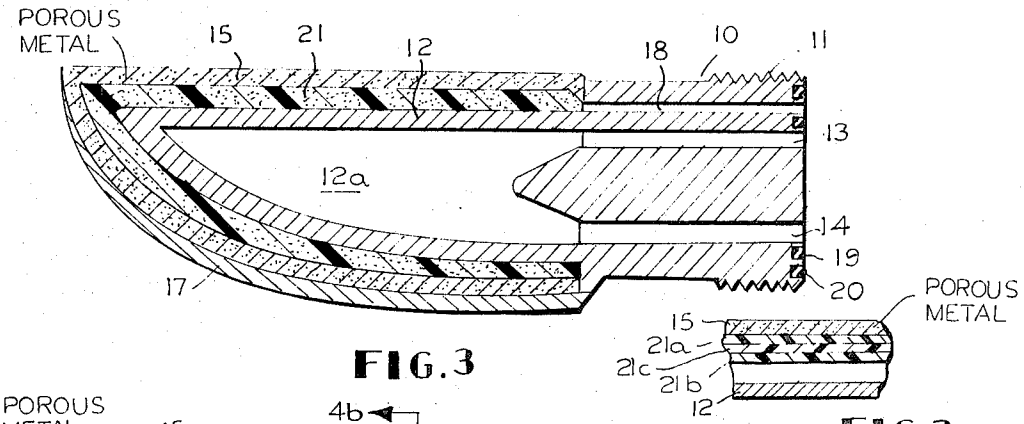


FIG. 3

FIG. 3a

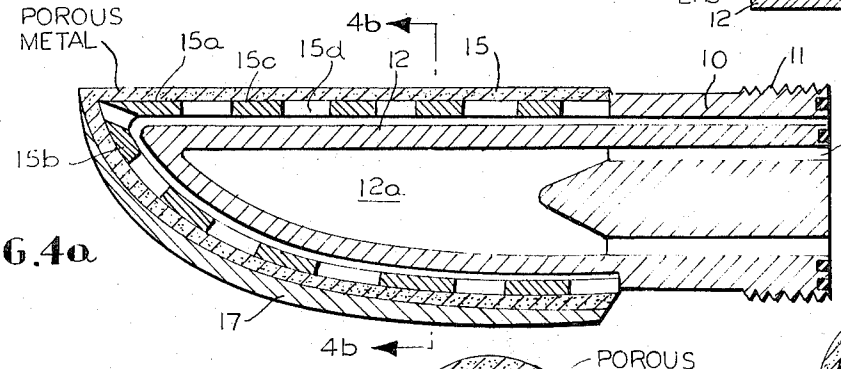


FIG. 4a

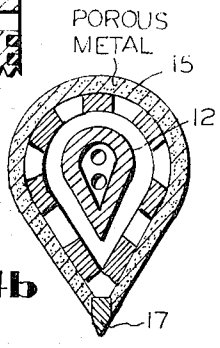


FIG. 4b

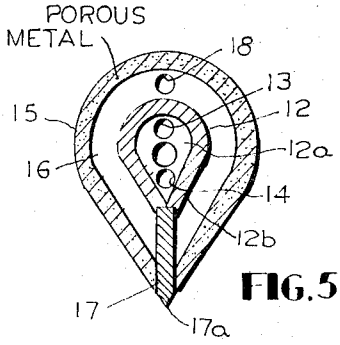
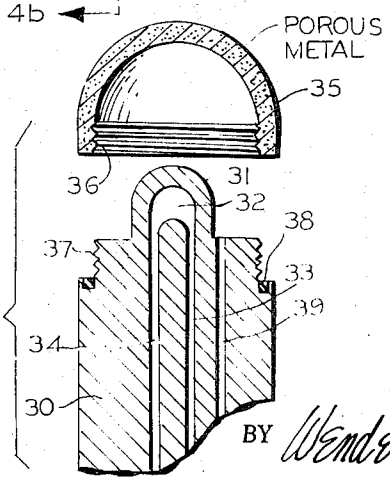


FIG. 5

FIG. 2



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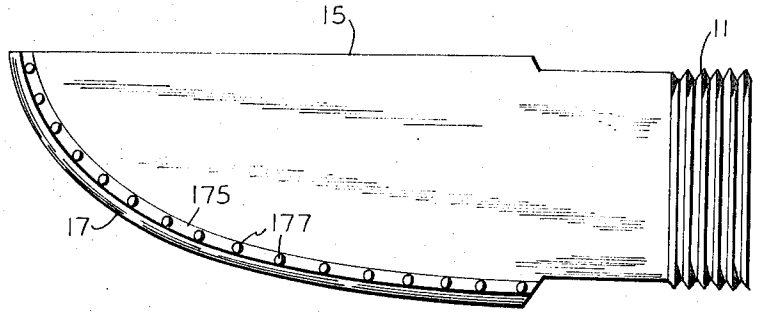


FIG. 4c

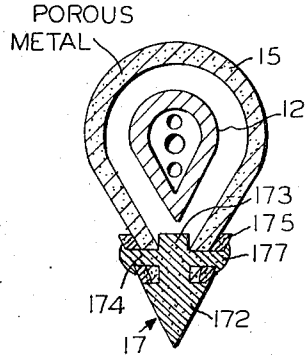


FIG. 4d

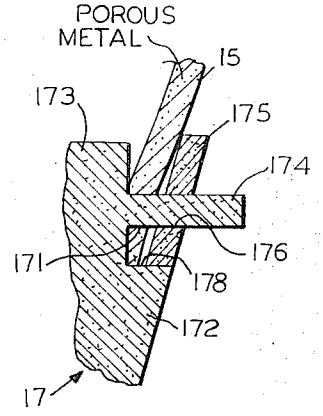


FIG. 4e

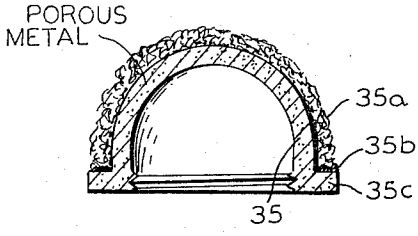


FIG. 5a

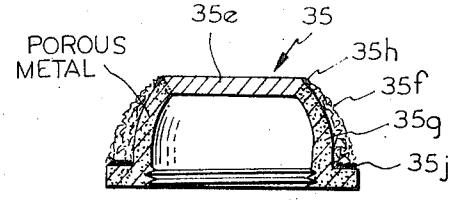


FIG. 5b

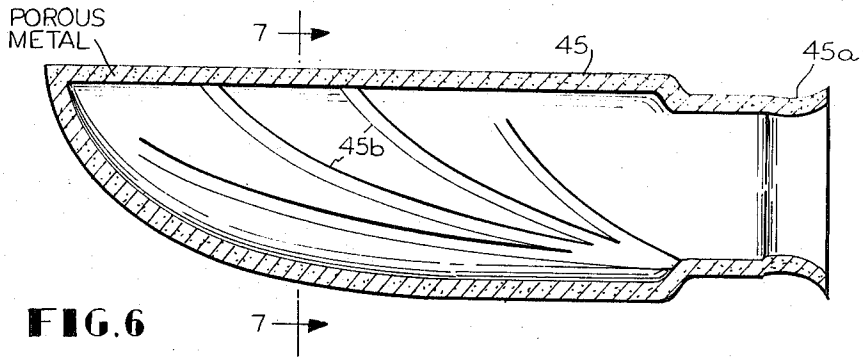


FIG. 6

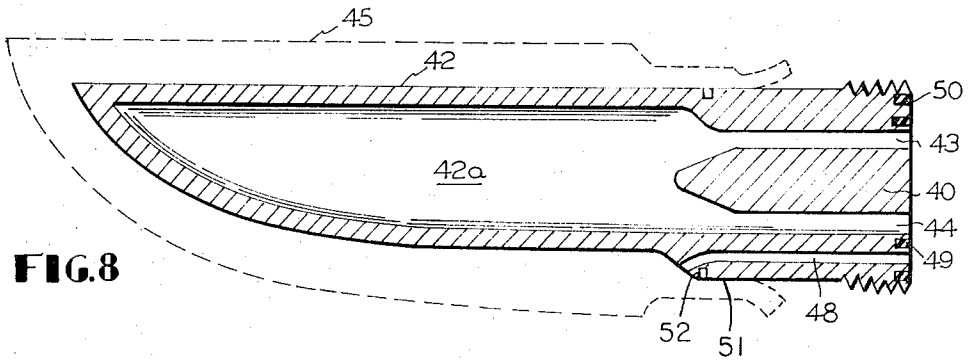


FIG. 8

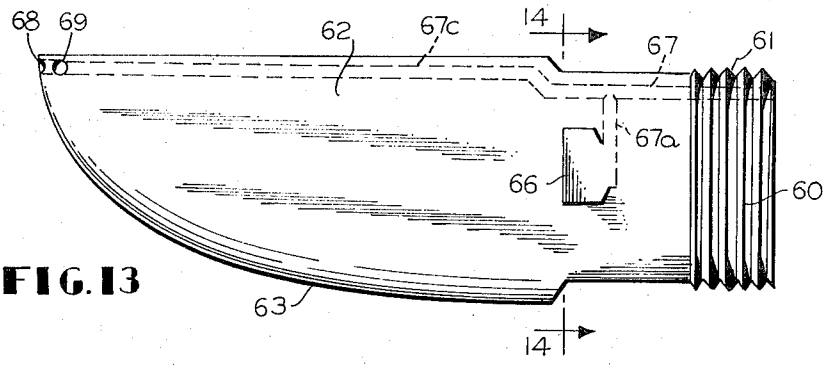


FIG. 13

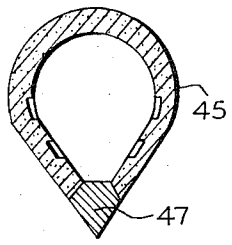


FIG. 7

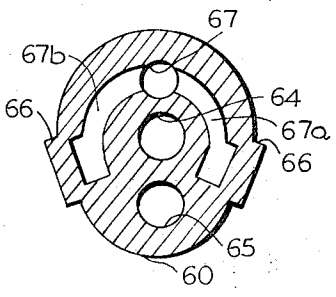


FIG. 14

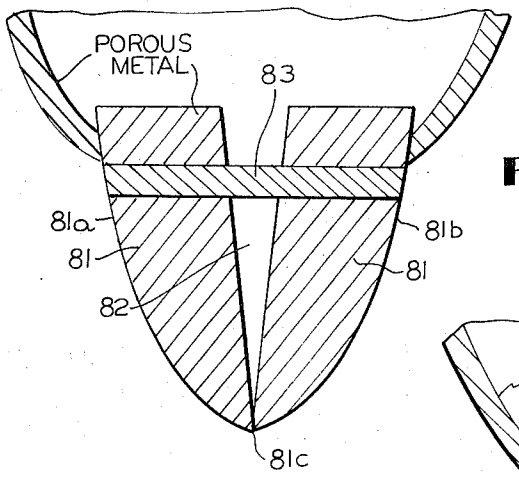


FIG.9

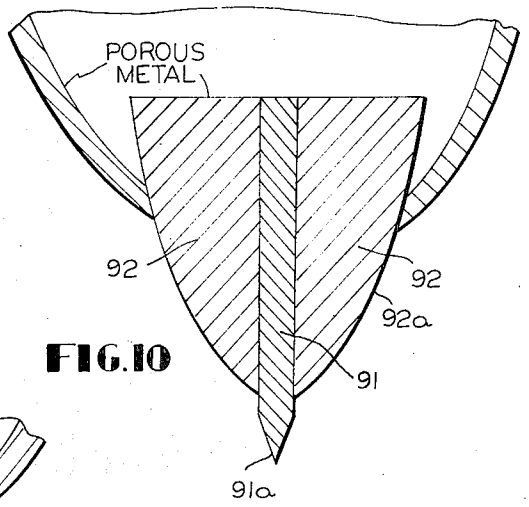


FIG.10

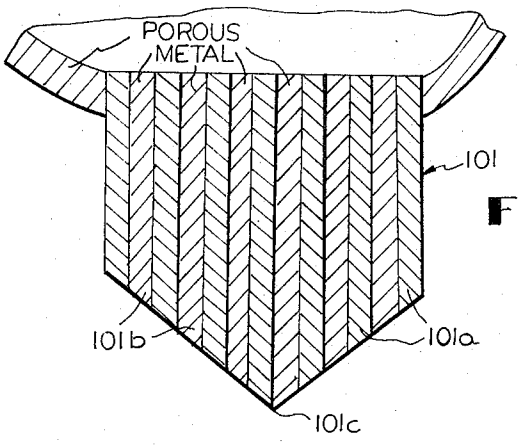


FIG.11

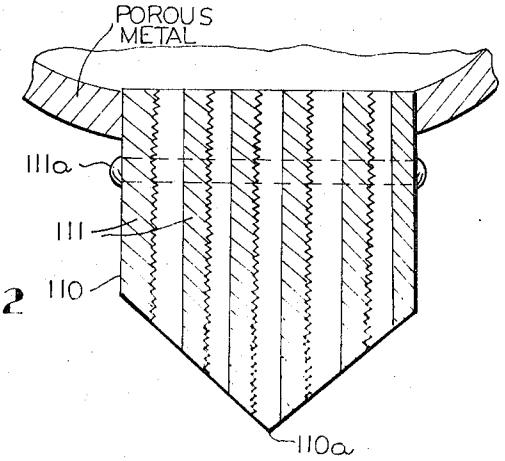


FIG.12

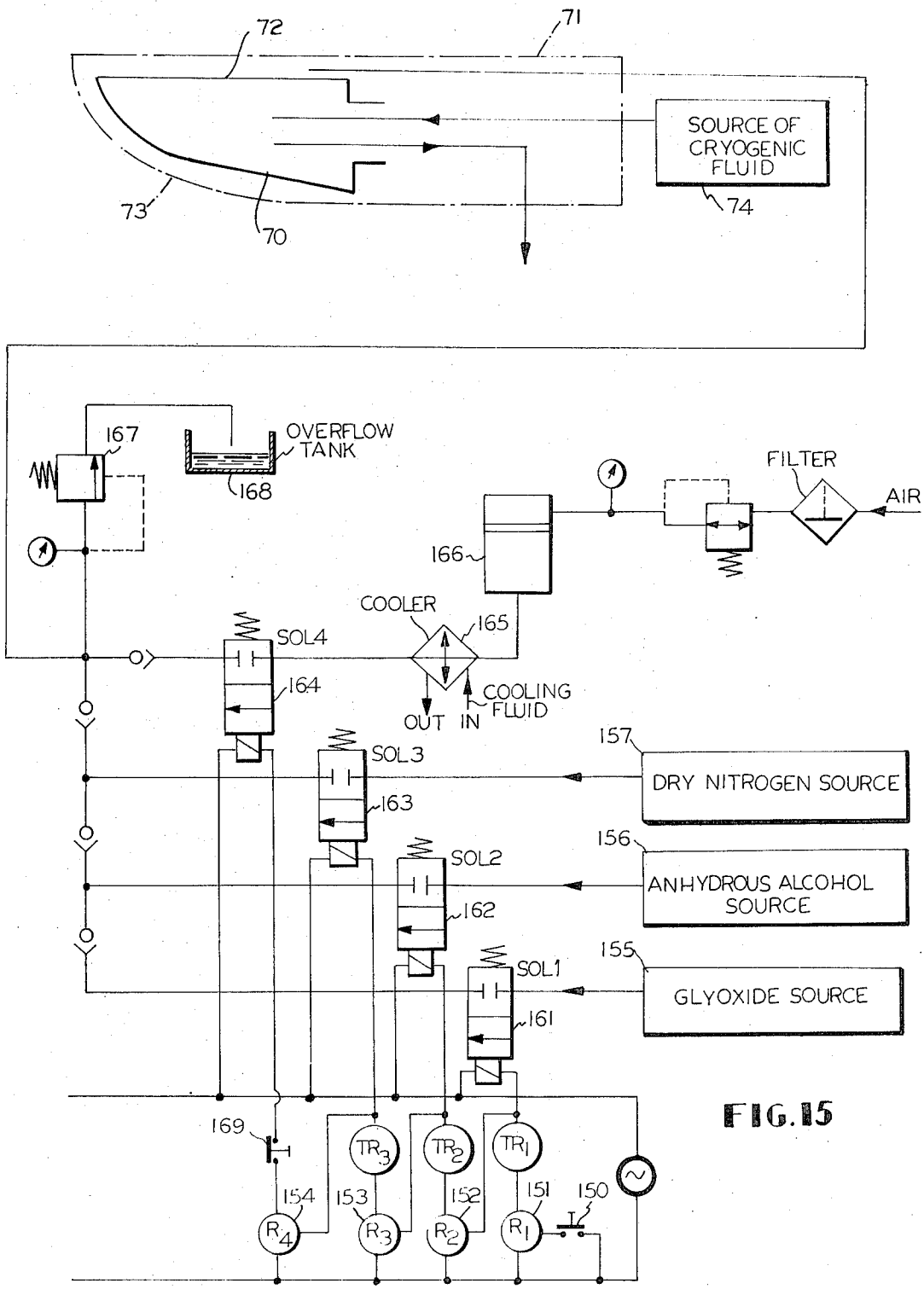

72
71
SOURCE OF CRYOGENIC FLUID
74
73
70
167
OVERFLOW TANK
168
FILTER
AIR
166
COOLER
165
SOL4
164
OUT
IN
COOLING FLUID
157
SOL3
DRY NITROGEN SOURCE
163
156
SOL2
ANHYDROUS ALCOHOL SOURCE
162
155
SOL1
GLYOXIDE SOURCE
161
169
TR3
TR2
TR1
154
153
152
151
150
R4
R3
R2
R1

FIG. 15

METHOD OF PREVENTING CRYOADHESION OF CRYOSURGICAL INSTRUMENTS AND CRYOSURGICAL INSTRUMENTS

This application is a continuation-in-part of Ser. No. 213,380 filed Dec. 29, 1971 and now abandoned.

This invention relates to a method of carrying out cryosurgery so as to prevent cryoadhesion, and to special surgical instruments used in carrying out the method.

BACKGROUND OF THE INVENTION

There has recently been considerable development of techniques and instrumentation for use in cryosurgery, i.e. surgery which involves the use of cryogenic instruments cooled to cryogenic temperatures. A characteristic of all of these techniques is the cryoadhesion between tissue and the metal of the instrument being used. This is, of course, desirable in such surgical procedures as cataract removal or the removal of chlosterol plaques from blood vessel walls, and, in fact, is what makes these techniques workable. However, in other areas, cryoadhesion has limited the use of cryosurgical techniques to probes of various designs and shapes. Even here, when it is necessary to treat tissue cryogenically and thereafter remove the probe, it is necessary to apply heat in some manner to overcome the cryoadhesion. This is usually accomplished by passing a heating fluid through the instrument or providing miniature heating devices in the instrument. Such measures are not only crude, but more important, they are time consuming and thus can be dangerous where rapid withdrawal of the instrument becomes necessary.

A further disadvantage of the necessity of providing some source of heat to overcome the cryoadhesion of the surgical instrument to tissue is that it is not at all useful in a surgical instrument which must be moved during use, such as a surgical knife. Manifestly, it is impossible to both cool cryogenically to obtain the benefits of the cryogenic temperatures, and, at the same time, heat to avoid or overcome cryoadhesion.

My prior U.S. Pat. No. 3,391,690 has recognized that tissue will adhere to cryogenically active surgical instruments. The disclosure in this patent states that cryoadhesion can be prevented by the simple application of a viscous lubricant to the tissue contacting components of said instruments.

However, permanent coverings or coatings of Paralene, Kel-F, Teflon Silicones and Lubrichrome, etc. have proved to be of insufficient practical value in the prevention of cryoadhesion of tissue to the cryogenically active surgical instruments. It is recognized by those skilled in the art that even minute tabs or shreads of tissue that will adhere or freeze to the activated instrument will cause stripping away of the cryogenically treated tissue adjacent to the instrument upon its withdrawal or movement. This stripping away or disturbance of the cryosurgically treated zone of tissue will expose a raw denuded highly vascular area and invariably leads to profuse hemorrhaging, thus negating any beneficial effects of cryogenic surgery.

OBJECTS AND SUMMARY OF THE INVENTION

It is an object of the present invention to provide a method of carrying out cryosurgical procedures in such a manner as to overcome the problem of cryoadhesion and thereby make possible instantaneous removal of probes and the like, and the performance of cryosurgical cutting techniques.

It is a further object of the present invention to provide cryosurgical instruments for use in carrying out such cryosurgical techniques, and further to provide cryosurgical instruments which can be converted from use in such a manner as to avoid or overcome cryoadhesion to use in such a manner as to take advantage of cryoadhesion.

These objects are achieved by providing an anti-cryoadhesion material on the surgical instrument which is non-toxic to living tissue and prevents sticking of the material of the instrument to the tissue. One specific material is fluorinated polyether. The material can be applied by first drying the outside surface of the instrument and then simply dipping it in the anti-cryoadhesion material, or by spraying the anti-cryoadhesion material on the outside surface of the surgical instrument before and during its use. It has been found that the anti-cryoadhesion material is particularly effective when it is used in instruments according to the invention which have a porous sheath over the cryogenic fluid containing portion of the instrument through which sheath the anti-cryoadhesion material is forced during the use of the instrument. According to the invention, such porous sheaths can be removable, thereby making the instruments usable in techniques which take advantage of cryoadhesion.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be described in greater detail hereinafter in connection with the accompanying drawings, in which:

FIG. 1 is a sectional view of a cryoscalpel according to the present invention;

FIG. 2 is a sectional view taken along line 2—2 of FIG. 1;

FIGS. 3 and 3*a* are views similar to FIG. 1 and 2 showing a slightly modified embodiment of the cryoscalpel;

FIGS. 4*a* and 4*b* are views similar to FIGS. 1 and 2 showing a further embodiment of the cryoscalpel;

FIGS. 4*c*–4*e* are respectively a side elevation, a section on line 4*d*—4*d*, and an enlarged fragmentary section of a further embodiment of the cryoscalpel;

FIG. 5 is a sectional view of a cryogenic probe according to the present invention with a removable sheath member thereon;

FIGS. 5*a* and 5*b* are sectional views of modified forms of tips therefor;

FIG. 6 is a sectional view of a disposable cryoscalpel blade according to the present invention;

FIG. 7 is a section taken on line 7—7 of FIG. 6;

FIG. 8 is a section of a core portion of a cryoscalpel which uses the disposable blade shown in FIG. 6;

FIGS. 9–12 are sectional views similar to FIG. 7 of specific forms of blade portions;

FIG. 13 is elevation view of a further embodiment of a cryoscalpel according to the present invention;

FIG. 14 is a section taken along line 14—14 of FIG. 13; and

FIG. 15 is a diagrammatic view of a cryosurgical system using the cryosurgical instrument according to the present invention.

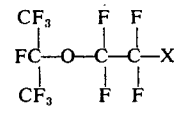
DETAILED DESCRIPTION OF THE INVENTION

In its most elementary form, the method of the pres-

ent invention comprises placing on the portion of the cryosurgical instrument a film layer of anti-cryoadhesion material which will remain between the metal of the instrument and the tissue being acted on by the instrument to prevent cryoadhesion. The simplest method of placing the material on the instrument is to first degrease and clean the portion of the instrument which is to contact tissue with a material which will remove blood and serum exudate, such as a mixture of carbamide peroxide and anhydrous glycerol. One such material is sold under the trademark GLY-OXIDE by International Pharmaceutical Corporation, Warrington, Penna. Thereafter the cleaned portion is dipped in a 100% anhydrous alcohol and then a stream of dry nitrogen is directed thereagainst to thoroughly dry it. Then the portion of the instrument is dipped in a bath of the anti-cryoadhesion material and the temperature of the tissue contacting portion is lowered. Lowering the temperature of the tissue contacting portion after application of the anti-cryoadhesion material lowers the vapor pressure of the anti-cryoadhesion material. This simple application of the material will suffice where the tissue is simply to be touched by a probe or a small incision is to be made in a short time.

The anti-cryoadhesion material should be a material which is liquid at ambient temperatures and remains liquid at cryogenic temperatures, e.g. down to about −180° C so that it overcomes the adhesion between the metal of the cryosurgical instrument and the tissue contacted thereby, and it should also be a material which has good thermal conductivity so that heat can be conducted through the film of the material from the tissue to the metal of the cyrosurgical instrument. Otherwise, the efficiency of heat conduction becomes poor and the carrying out of the cyrogenic aspects of the surgical procedure is reduced. Moreover, the material should be inert and non-toxic, since it will come in contact with tissue during the carrying out of the surgical procedures.

One group of such materials are non-toxic, inert liquid fluorocarbons which remain liquid at cryogenic temperatures, which fluorocarbons are applied to cryosurgical instruments and, as a result of the use of such instruments in cryosurgical treatments, are applied topically to cryosurgically treated tissue. The primary function of the fluorocarbon is to prevent cryoadhesion of the tissue to the cryogenically active instrument. As the temperature drops, these materials do not crystallize but only become increasingly viscous. These materials are available from several sources. One source is the fluoro-carbon chemical sold under the trademark MEDIFLOR by 3M Company. One specific fluorocarbon is designated FC47 and is a polyfluorinated tertiary alkyl amine having the general formula $(C_4F_9)_3N$ and has a pour point of −58° F. Another specific fluorocarbon designated FC80 is a cyclic perfluorinated ether and has the general formula $c\text{-}C_8F_{16}O$ had has a pour point of −135° F. Another is designated FC88 and has a pour point of approximately −115° C. Another source is the fluorocarbon chemicals sold under the trademark FLUORONETS by Allied Chemical Company. The fluorocarbon chemicals with the designations P-1F, P-1H, P-1C, P-1D and P-11C have pour points from −85° to −125° C. Among these materials, the materials with the designations P-1F, P-1H and P-1C are polyfluorinated ethers having the general formula:

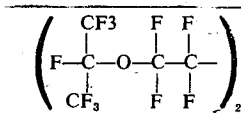


(1)

where X is fluorine, hydrogen or chlorine. The material designated P-11C is a polyfluorinated ether having the formula:

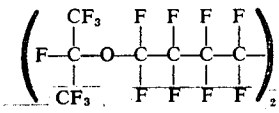
(2)

The materials with designations P-1D and P-11D are perfluorinated polyethers having the formulae:



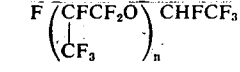
(3)

and



(4)

Another specific material which can be used as the anti-cryoadhesion material is one of a family of polyfluorinated polyethers having the general formula:



where *n* is a whole number in the range of 1-11 inclusive. The materials have pour points from −46° C down, depending on the value of *n*. This material is available from E.I. DuPont de Nemours Co. as FREON E Series Fluorocarbons. The characteristics of the members of the series from one to four of the material which are pertinent to the present invention are as set forth in Table I. It will be seen from this data that the thermal conductivity is such that the material conducts heat very satisfactorily, yet it remains liquid to very low temperatures. Because of the low boiling point, especially of the lowest viscosity form of the material, it is desirable that it be kept cooled for use as the anti-cryoadhesion material. It is preferable that it be cooled to a temperature of −5° to −15° C, for example by packing the container in dry ice. In the above described simplest method of placing the material on the instrument by dipping the instrument in the material, the material can simply be provided in a cooled open top container into which the instrument can be dipped manually.

The anti-cryogenic materials described above can be used individually, or then can be blended to obtain viscosities and pour point temperatures intermediate the viscosities and pour points of the individual materials.

Anti-cryoadhesion material placed on the instrument simply by dipping the instrument in the material will be wiped off after the instrument has moved a short distance through tissue. In order to make it possible to use a cryosurgical instrument to make a relatively long in-

cision or move over tissue for relatively long distances, special surgical instruments have been devised which provide a constant flow of anti-cryogenic material to the surface thereof which will be in contact with the tissue. Some embodiments of these instruments will be described hereinafter. It should be understood, however, that while the description is of several forms of scalpels and one form of a probe, the same type of structures can be used in clamps, biopsy instruments, and the like without departing from the scope of the present invention. Examples of other such instruments are found in my U.S. Pat. Nos. 3,391,690 and 3,369,550.

Referring to FIGS. 1 and 2, there is shown a cryoscalpel which has a neck 10 having threads 11 thereon to enable it to be removably attached to a handle. Projecting from the neck 10 is a hollow inner portion 12 for containing cryogenic fluid, and a cryogenic fluid inlet 13 extends through the neck into the hollow interior 12*a* of the inner portion 12 and a cryogenic fluid outlet passage 14 extends through the neck out of the hollow interior 12*a*. Surrounding the inner portion 12 is a sheath 15 which is attached to the neck and which has the inner surface thereof spaced from the outer surface of the inner portion 12 so as to leave a space 16 therebetween. The sheath has a blade portion 17 extending through the bottom edge thereof with a sharp surgical knife edge 17*a* along the lower portion thereof. The back edge is seated in groove 12*b* in the inner portion for stability and good heat conduction. The material of the sheath is porous so that anti-cryoadhesion material can flow or diffuse through it slowly, if the material is kept under pressure. The blade portion 17 can be attached to the porous sheath by being welded or force fitted into a groove along the bottom edge of the sheath. The blade portion can also be porous, such as sintered porous stainless steel or titanium, such as beta structure titanium which takes a good cutting edge, sintered platinum-iridium alloy, or any other metal or alloy which can be shaped to a knife edge. It is preferable to sinter a sintered material blade to the sheath, thus omitting a non-porous weld portion in the blade. It is also preferred, where the blade or any part thereof is porous, that the pore size be greater than the pore size of the sheath material, so that fluid will initially flow more readily through the blade than through the sheath. Opening into the space 16 through the neck 10 is an anti-cryoadhesion material passage 18. On the free end of the neck 10 are two ring gaskets, a gasket 19 around the cryogenic fluid inlet and outlet passages, and a gasket 20 between the anti-cryoadhesion material passage 18 and the periphery of the neck.

The handle (not shown) to which the scalpel is designed to be attached has a threaded socket into which the threads 11 engage, and in which said gaskets 19 and 20 seal. The handle has passages opening into this socket for the feed and discharge of the cryogenic fluid and for the feed of the anti-cryoadhesion material. Appropriate conduits extend from the handle to equipment for feeding and controlling the flow of the cryogenic fluid and the anti-cryoadhesion material. The equipment for the cryogenic fluid is conventional and will not be described here. The equipment for the supply of the anti-cryoadhesion material can consist simply of a reservoir and a pump.

The hollow inner portion of the scalpel is preferably made of a good heat conducting low thermal expansion metal. One good metal is a high nickel-iron alloy sold under the trademark INVAR by Carpenter Steel Company. It can be nickel plated to increase corrosion resistance. Stainless steel, which resists staining during use and can be cleaned and sterilized readily, can also be used. Use of such a metal makes possible rapid transfer of heat from the tissue to the cryogenic fluid. The sheath is preferably thin stainless steel which has been made mircoporous, for example by the process disclosed in U.S. Pat. No. 3,352,679 which comprises connecting the stainless steel as an anode in a cell containing a non-polarizing electrolyte and discharging direct current through the cell. The gaskets are silicone rubber, which will withstand cryogenic temperatures.

It will be understood that the sizes of the pores in the stainless steel sheath can be varied, and that anti-cryoadhesive materials are available with different viscosities. Those skilled in the art will be able to provide the proper combination of pore size and viscosity of the anti-cryoadhesive material with a minimum amount of difficulty to give optimum results.

An alternative form of porous material for the sheath is a woven stainless steel wire cloth known as MICROWEAVE which is available from Microporous Filter Division of Circle Seal Development Corporation, Anaheim, Calif. This material is woven from stainless steel wire drawn to a diamter of as small as 0.001 inch and then heat treated to restore the ductility and corrosion resistance. To form this material or the above described materials into a sheath, a die in the shape of the casing is made, and the material is shaped to this die in a four slide forming machine.

In use, the instrument is first dried thoroughly for example by dipping in a 100 percent anhydrous alcohol solution and purging with dry nitrogen gas. Then the anti-cryoadhesion material is pumped through the passage 18 into the space 16, and, due to the pressure it is under, it is forced through the porous sheath 15 so as to form a film on the outer surface of the sheath. Thereupon the flow of cryogenic fluid is increased to cool the instrument to the desired temperature, and it is then ready for use.

During the cutting action of the surgical knife edge 17, the anti-cryoadhesion material will prevent the metal of the scalpel from sticking to the tissue being cut by providing a physical layer of the material between the tissue and the sheath and also due to the hydraulic pressure of the material which acts to force the tissue away from the surface of the sheath. This action will, of course, be a minimum along the edge 17, so that the cutting action is not impaired.

Thus the scalpel can be drawn through tissue in the same manner as a room temperature scalpel is drawn through tissue, thereby removing any restrictions on the use of the instrument because of the occurrence of cryoadhesion. At the same time, due to the heat conductivity properties of the anti-cryoadhesion material, heat is removed from the tissue being cut so that the benefits of cryogenic surgery can be obtained.

In the use of the surgical device of the present invention and the fluorocarbon anti-cryoadhesive materials disclosed, it has been discovered that whatever toxicity these materials have can be reduced by passing them through a microporous filter, such as a Gelman microporous filter made by Fisher Scientific Company, 711 Forbes Avenue, Pittsburgh, Pa. 15219. Moreover, if it is anticipated that large amounts of the fluorocarbon

anti-cryoadhesive material are to be used on an individual patient, it may be advantageous to lower the general body temperature of the patient to about 85° F or lower by known hypothermia techniques. This will suppress the general vapor pressure of the fluorocarbon material that will come into contact with the tissue being acted upon.

The embodiment of the scalpel shown in FIG. 3 is substantially the same as that of FIGS. 1 and 2, but with the addition to the space 16 between the sheath 15 and the inner portion 12 of a porous metal structure 21, the pores of which are interconnected. One such material is sold by Linde Division, Union Carbide Company, under the trademark KORO-TEX. Such an arrangement makes it possible to control the flow of the anti-cryoadhesion material better, so as to slow the flow through the porous sheath, and is especially useful for such materials which have a low viscosity.

Another such material is stainless steel filter devices, for example stainless steel flat or pleated MICROWEAVE filters, which can be fabricated so as to have a mean filter rating of as low as 2 microns. Such filters are sold by Circle Seal Development Corporation, Microporous Filter Division, Anaheim, Calif. They can be readily sterilized by autoclaving along with the rest of the parts of the instrument.

In a preferred embodiment, shown in FIG. 3*a*, the layer 21 is a laminated structure of two layers 21*a* and 21*b* of the stainless steel filter material between which is a layer 21*c* of a molecular sieve material, for example synthetically produced crystalline metal aluminasilicates that have been activated for adsorption by removing their water of hydration. Several types of such material are available from Union Carbide Corporation as Linde molecular sieves. The molecular sieve material can be in powder or wafer or pellet form between the two layers of stainless steel filter material. The inner surface of the laminated structure 21 is spaced from the inner portion 12, while the outer surface thereof can be in contact with the inner surface of the sheath. The instrument of this embodiment can be used down to about −150° C. This arrangement has a number of specific advantages. In addition to providing control of the flow of the anti-cryoadhesion material, the molecular sieve material will adsorb water. The space in the instrument between the inner portion 12 and the layer 21 can be purged of moisture prior to use of the instrument by a blast of dry nitrogen gas, which drives the moisture into the sieve material where it is bound. The outside of the instrument can be dried at the same time. Thereafter, the anti-cryoadhesion material can pass through the sieve material without picking up the moisture bound in the sieve material. Moreover, such a laminated structure would insure that no moisture from the tissue being treated or the atmosphere will get into the anti-cryoadhesion material in the instrument, because any such moisture will be absorbed in the sieve material. A still further advantage of this embodiment is that the molecular sieve material reduces the vapor pressure of the anti-cryoadhesion material. This is especially desirable when the specific anti-cryoadhesion material described above is used, because this material tends to have a relatively high vapor pressure until it reaches cryogenic temperatures. The instrument with the laminated structure of the layer 21 is therefore especially suited for use with the above described anti-cryoadhesion material.

FIGS. 4*a* and 4*b* show a further alternative in which the sheath 15*a* is formed of an apertured metal portion 15 which is a good heat conductor having adhered to the outer surface thereof a porous metal material 15*c* which covers the surface of portion 15*b*, as well as the apertures 15d. A blade portion 17 is inserted into the lower edge in the same manner as in FIGS. 1–3. Otherwise the structure is the same as that of FIGS. 1–3. The effect of this construction is substantially the same as that of FIG. 3, i.e. the porous metal material 15*c* controls the flow of anti-cryoadhesion material out of the space 16.

A further modification of the cryoscalpel is shown in FIGS. 4*c*–4*e*, in which the surgical cutting blade is snap fitted to the sheath. The sheath 15 is generally the same as in FIGS. 1–4*b*, being made of the same porous materials, and being fitted over the core 12. The lower edges, however, where they abut the blade portion 17 have a row of holes 17 therealong which are preferably reinforced by metal rings or eyelets, and fitted between the lower edges is a porous blade portion 17 which has a lower portion 172 with a pointed cutting edge therealong, an upper portion 173 extending upwardly from the lower pointed portion into the space between the lower edges of the sheath, and which has laterally extending projections 174 extending therefrom. These projections extend through the reinforced holes 171. A fastening strip 175 extends along each side of the lower edge of the sheath which is also of porous material the same as the sheath, and which has a series of holes 176 therealong corresponding to the holes 171 in the sheath edges. The fastening strips 175 are placed over the projections 174 in the position shown in FIG. 4*e*, and the ends of the projections are hammered into rivet heads 177 to secure the strips 175 in fluid tight engagement to the sides of the sheath 15 and to hold the blade 17 in position on the sheath. Preferably the strips 175 are shaped so that they fit tightly against the upper surface 178 of the lower portion 172 of the blade portion 17, and if desired, the upper edges of the strips can be smoothed into the surface of the sheath after the fastening of the blade portion 17 to the sheath 15 is completed.

The manner in which the present invention can be adapted for a probe is shown in FIG. 5. A probe body 30 has a hollow probe end 31 thereon into the hollow interior 32 of which opens a cryogenic fluid feed passage 33, and out of which opens a cryogenic fluid discharge passage 34. Detachably secured over the probe end 31 is a sheath 35 which is shaped so that when it is in position over the probe end there is a space between the outer surface of the probe end and the inner surface of the sheath. The edge of the sheath has a threaded portion 36 which is threadedly engageable with mating threads 37 around the probe end. A gasket 38 is provided in the surface against which the edge of the sheath engages for sealing the space between the probe end 31 and the sheath 35. Extending through the body 30 and opening into the space between the probe end and the sheath is an anti-cryoadhesion material feed passage 39.

To the other end of the probe body 30 are attached conduits for the feed and discharge of the cryogenic fluid and a conduit for the feed of the anti-cryoadhesion material, which conduits extend to appropriate equipment for the feed of these materials.

The materials of the probe are preferably the same as the corresponding parts of the scalpel, i.e. stainless steel or Invar for the body **30** and the probe end **31**, and porous stainless steel for the sheath **35**.

The steps in the use of the probe with the sheath **35** attached are the same as those in the use of the scalpel, except of course that the probe does not make an incision in the manner that the scalpel does. If it is desired to take advantage of cryoadhesion, such as in the removal of a cataract, the sheath **35** is removed by unthreading it from the probe body **30**, and the anticryoadhesion material is not fed through the passage **39**. The probe is then a simple cryogenic probe, such as is already in use in the art.

The detachable sheath on the end of the probe can be modified to enable it to be used by inserting it into cavities in the body. The modified forms are shown in FIGS. **5***a* and **5***b*. It is one of the techniques of surgical treatment to insert a probe into a body cavity, for example the cervix. However, unless the tissue surrounding and defining the cavity is relatively flexible or stretchable, or unless the probe is specially shaped, it is often necessary to force the probe into the cavity. Particularly in the treatment of the cervix with a conventional probe, it is often necessary to exert considerable force on the probe to cause it to enter the cervix.

In the embodiment shown in FIG. **5***a*, there has been added to the outside of the sheath **35** a covering **35***a* of loosely tangled fine stainless steel filaments the same as those used in making the MICROWEAVE filters described above, the material being formed into a steel wool-like form, and the lower edge welded or soldered at **35***b* to the base edge of the sheath **35**. A ledge **35***c* may be provided around the base of the sheath to accommodate the weld or solder joint. With the sheath **35** covered with the loosely tangled fine steel filament cover **35***a*, the probe will positively adapt itself to the walls of a body cavity, such as the cervix, and the anticryoadhesion material would first be diffused through the porous sheath **35** and then through the covering **35***a* onto the internal wall of the cavity, thereby preventing sticking of the probe to the tissue around the cavity. A probe of this type would cause a minimal amount of pressure, distension and distortion of the cervix.

A further modified form of the sheath is shown in FIG. **5***b*, in which the top portion of the sheath at **35***e* has been made non-porous, while a wide ring **35***f* of the stainless steel wool-like material is placed around the porous part **35***g* of the sheath and welded or soldered at the top **35***h* and the bottom **35***j* of the material to secure it to the sheath. The advantage of this embodiment is that the anticryoadhesion material is forced only through the porous part **35***g* of the sheath and through the material **35***f* at the sides of the sheath, while no material is forced out of the top of the sheath. Thus, when using the instrument in, for example, the cervix, no material is forced ahead of the probe further into the cervix and then into the uterus.

It will be appreciated that these embodiments of the probe can be used to treat the tissue around the cavities with other than cryogenic treatments. For example, the probes of FIGS. **5***a* and **5***b* lend themselves particularly well to the treatment of cervicitis, in which a medicament is pumped into the probe instead of the anticryoadhesion material, and is diffused through the sheath **35** and the steel wool-like covering on the sheath.

Referring to FIGS. **6–8**, there is shown a cryoscalpel with a replaceable blade and sheath. The inner portion of the cryoscalpel as shown in FIG. **8** is similar to the inner portion of the cryoscalpel shown in FIGS. **1** and **2**, in that it has a neck **40** with threads **41** on one end thereof for attachment into a socket in a handle, and a hollow inner portion **42** having a hollow interior **42***a*. Cryogenic fluid feed passage **43** extends through the neck into the hollow interior **42***a* and cryogenic fluid exhaust passage **44** extends out of the hollow interior **42a** through the neck. A shoulder **51** is provided around the inner end of the neck **40** adjacent the start of the inner portion **42**, and an anti-cryoadhesion material passage **48** extends through the bottom of the neck **40** and opens out of the face of the shoulder **51** in the direction of the inner portion **42**. A gasket **52** is provided in the other face of the shoulder, i.e. the face toward the neck **40**. Gaskets **49** and **50** are provided in the end face of the neck **40**.

A removable sheath **45** is provided which has the upper portion and side walls of porous material, and has a solid knife blade portion **47** along the lower edge thereof. The sheath **45** is shaped so that it fits around the inner portion **42** so as to leave a space between the outer surface of the inner portion and the inner surface of the sheath. The open end of the sheath has a female snap flange **45***a* thereon which forms a snap fit over the shoulder **51** with the surface of the flange sealing against the gasket **52**. With the sheath **45** in this position, the anti-cryoadhesion material passage **48** opens into the bottom of the space between the sheath and the inner portion. The anti-cryoadhesion material will thus flow more readily out of the bottom portion of the sheath and upwardly along the sides during cutting. In order to aid distribution of the anticryoadhesion material, grooves **45b** can be provided in the inner surface of the sheath **45** extending along the surface from the point where the passage **48** opens into the sheath. This modification can be used on other sheaths as well.

The materials of which the various parts are made correspond to the materials described in connection with FIGS. **1** and **2**. The blade portion **47** can be of sintered porous stainless steel or tungsten, sintered porous platinum-iridium alloy, or any other porous metal or alloy which can be shaped to a cutting edge. Alternatively, all the blade portions and other tissue contacting components of the cryosurgical instruments can be superfinished. This process or method of finishing metals reduces surface scratches or marrings to a minimum and thus augments the liquid anticroadhesive material, in that it aids its free flow. Superfinishing further prevents or minimizes microscopic mechanical ice locks between the metal, film of liquid anticryoadhesive material and the tissue being treated or acted upon.

The scalpel of FIGS. **6–8** is used in the same manner as that of FIGS. **1** and **2**. However, when the sheath becomes worn or otherwise damaged, it can be replaced. Moreover, by removing the sheath and stopping the feed of the anti-cryoadhesion material, the device can be used as a probe or the like with cryoadhesion taking place between the inner portion and the tissue contacted thereby.

Although it is not specifically illustrated, the inner surface of the sheath **45** of FIGS. **6** and **7** could be lined with porous metal material so as to fill the space be-

tween the sheath **45** and the inner portion **42**, so that when assembled, the device of FIGS. **6–8** would be the same as that shown in FIG. **3**.

Where sintered stainless steel, titanium or platinum-iridium is used for the blade **17** or **47**, when the cutting edge is formed, it will have fine serrations therealong. Any ripping effect which might be caused by these serrations as the blade is moved through tissue will be minimized or substantially eliminated by the presence of the anti-cryogenic material which will be present in a film between the cutting edge of the blade and the tissue being cut.

However, if it is desired to have a substantially smooth cutting edge, the blade can first be formed with a cutting edge and then the surgical cutting edge plated with a stainless material, such as nickel, by a conventional electroless plating process, and then the thus plated edge honed to surgical sharpness.

Forms of blades which can be sharpened to a good edge yet which deliver anti-cryogenic liquid to the blade edge are shown in FIGS. **9–12**. In FIG. **9** there is shown a split blade. The blade is formed of two blade halves **81** which are solid metal or alloy, such as stainless steel, and which abut each other at the blade edge **81***a* along the longitudinal center plane of the blade. The outer surfaces **81**b taper upwardly in the shape of a conventional blade, and the opposed inner surfaces **81***c* are inclined away from each other to leave a V-shaped groove **82** between the blade halves. The upper portions of the blade halves **81** are attached to each other so as to keep them spaced apart by welds **83** or rivets or the like, so that the groove **83** is open to the space **16** between the sheath **15** and the inner portion **12**, aS in FIGS. **1** and **2**, or to the space between the sheath **45** and the inner portion **42**, as shown in FIGS. **6** and **7**.

In operation, the pressure of the anti-cryogenic liquid in the space between the inner portion and the sheath will be forced through the groove **82** and between the blade edges **81***a* during the use of the device, and will flow back along the outer surfaces **81***b* as the blade is moved through tissue.

Another form of blade is shown in FIG. **10**, which is comprised of a blade core **91** having a sharpened edge **91**a and blade covering portions **92** on opposite surfaces of the blade core **91** and having the outer surfaces **92***a* tapering in the shape of a conventional blade. The blade covering portions **92** are of a porous metal or alloy, such as sintered porous stainless steel. Particularly useful for such portions is a 420 sintered porous stainless steel which is available from Union Carbide Company in the UCAR porous metal products. It is advantageous to flame spray the cutting edge of the blade core with a carbide to provide a better, longer lasting cutting edge.

In operation, the pressure of the anti-cryogenic liquid in the space between the inner portion and the sheath will be forced through the porous covering portions **92** to a point immediately adjacent the tip of the cutting edge of the blade core **91** and will form the desired film on this cutting edge. This form of blade is particularly useful in the embodiment of FIGS. **1** and **2**, since the lateral faces of the blade covering portions **92** are exposed to the space between the sheath and the inner portion, even though the base of the blade is seated in the groove in the inner portions.

Still another form of blade is shown in FIG. **11**. In this form, the blade **101** is a laminated blade having alternating thin sheets **101***a* of solid stainless steel and thin sheets **101***b* of sintered porous stainless steel bonded to the solid stainless steel sheets **101***a* by sintering. The sheets lie generally parallel to the plane of the blade. The lower portion of the blade is shaped to a pointed cutting edge **101***c*, and preferably the point of the cutting edge lies on a joint between a sheet **101***a* and a sheet **101***b*.

In operation, the pressure of the anti-cryogenic liquid in the space between the inner portion and the sheet will be forced through the porous thin sheets **101***b*, and since they alternate with the solid sheets **101***a*, the fluid will be delivered to all of the outer surface of the blade.

Another form of blade is shown in FIG. **12** in which a plurality of non-porous stainless steel sheets **111** are laminated to each other to form the blade **110** and the bottom is sharpened into an edge **110***a*. Prior to assembling the sheets **111**, one surface of each sheet is peened, preferably by glass particle peening, a process similar to shot peening, to form minute depressions in the surfaces of the sheets. The sheets are then coated with a thin layer of plastic to fill the depressions. After the sheets are assembled, the assembly is heated to burn off the plastic, the depressions forming fine passages between the sheets. The sheets are held in the assembled condition by rivets **111***a* or welds.

FIGS. **13** and **14** show a cryosurgical instrument which is somewhat less complex than those described above, in which means are provided to direct a spray of anti-cryoadhesion material along the surface of the surgical element thereof during its use. The instrument comprises a neck **60** having screw threads **61** on one end thereof for attachment into a socket on a handle in the same manner as for the device of FIGS. **1** and **2**. A hollow surgical element **62**, here shown as a scalpel blade, is provided on the neck **60** and has a surgically sharp cutting edge **63** along one side thereof, and cryogenic fluid feed and discharge passages **64** and **65** are provided through the neck **60** to the hollow interior of the blade **62**. Spray heads **66** are formed integrally with the neck **60** at the end of the blade **62** where it joins the neck, the spray heads **66** having spray outlets directed along the surface of the blade **62**. Within the neck is an anti-cryoadhesion material feed passage **67** having two branches **62***a* and **67***b* extending to the spray heads **66**. A third branch **67***c* extends along the top edge of the sheath and has openings **68** and **69** at the end thereof to provide a flow of anticryogenic material along the blade of the sheath when the sheath is pushed through tissue, from right to left in the figure. Gaskets are provided in the end of the neck **60** in the same manner as in the device of FIGS. **1** and **2**, and the handle is equipped with means to supply a cryogenic fluid and an anti-cryoadhesive material also in the same manner as in the device of FIGS. **1** and **2**.

The use of the device of FIGS. **13** and **14** is generally the same as that of FIGS. **1** and **2**. During cutting, however, the anti-cryoadhesive material, instead of being forced through the porous sheath, is simply sprayed along the surface of the blade.

As pointed out above, it is desirable to clean and degrease the surgical instrument, then dry it by using anhydrous alcohol followed by purging with dry nitrogen, and then to pre-cool the anti-cryoadhesion material be-

fore it is supplied to the blade. Means can be provided in the feed system for the anti-cryoadhesion material to provide these effects. As shown diagrammatically in FIG. 15, a cryosurgical instrument 70, such as the scalpel shown in FIGS. 1 and 2, attached to a handle 71 having the inner portion 72 and the sheath 73, has connected to it a source 74 of cryogenic fluid, including appropriate controls (not shown) for controlling the flow of the cryogenic fluid. Also connected to the handle 71 is a source of anti-cryoadhesion material 166 which, in this arrangement, is a pressure vessel having pressure creating means therein driven by air under pressure supplied through a pressure regulator 168. In the line from the source 166 to the instrument 70 is a cooler 167 cooled by a cooling fluid, and a solenoid valve 164. A pressure relief valve 167 and an overflow container 168 are connected to the feed line for the anti-cryoadhesion material downstream of the solenoid valve 164.

Also connected into the feed line for the anti-cryoadhesion material through a series of feed lines and check valves is a course 155 of a cleaning material, such as GLYOXIDE, a source 156 of anhydrous alcohol, and a source 157 of dry nitrogen. The feed lines for these sources have solenoid valves 162, 163 and 164 therein, respectively. The solenoid valves 161–163 are controlled by a series of timers TR-1, TR-2 and TR-3 which are connected in series across a source of power with relays 151, 152, 153, respectively, while solenoid valve is controlled by relay 154 and break switch 169. The relays are connected so as to energize the next successive timer when a given timer times out. The first relay 151 is energized by a starter button 150. It will be understood that the various parts and their connections have been shown only schematically. Practical circuits can be provided by using conventional arrangements.

In operation, the starter button 150 is actuated which starts the timer TR-1 running through the relay 151. This opens solenoid valve 161 to permit passage of the glyoxide through the space between the sheath 73 and inner portion 72, and hence through the porous sheath, to clean and degrease the sheath. After an appropriate time, the timer TR-1 times out, and the solenoid valve 161 is closed. At the same time the timer TR-2 is actuated through the relay 153, and solenoid valve 162 is opened, and anhydrous alcohol is passed through the sheath 73 to dry it. After an appropriate time, timer TR-2 times out, closing solenoid valve 162, and timer TR-3 is actuated through relay 153 to open solenoid valve 163. This passes dry nitrogen through the sheath 73 to complete the drying process. Again, after an appropriate time the timer TR-3 times out, closing solenoid valve 163, and relay 154 is actuated. This opens solenoid valve 164 to feed cooled anticryogenic material to the sheath 73. When the use of the scalpel is finished, the solenoid valve 164 is deenergized by actuating break switch 169. Any overpressure in the system will be relieved through the relief valve 167.

It will be appreciated that the operation of the above system should be tied into the operation of the supply system for the cryogenic fluid so that cryogenic fluid is supplied after the cleaning and drying steps.

The surgical instrument of the present invention will be particularly useful in the recently developed techniques of performing surgery in hyperbaric units, i.e. units in which the atmosphere is pure oxygen at elevated pressure. Obviously, it is extremely dangerous to use electrical cauterization devices in such an atmosphere in which potentially explosive anesthetics are often used. The cryosurgical instrument of the present invention, with the supply of cryosurgical liquid and the anticryoadhesion material piped into the hyperbaric unit from outside, can readily be used for surgery in which cauterization is carried out following the surgical step or steps. In addition, by providing means to saturate the anticryoadhesion material with oxygen and feed it to the sheath concurrently with or after the end of the flow of the cryogenic liquid, the area of the surgical treatment can be subjected to a highly oxygenated material for treatment of anaerobic bacteria such as cause gas gangrene which is now being treated in hyperbaric units. Furthermore, these oxygen or gas saturated materials can be used in cryosurgical instruments to treat the tissues of body or bodily regions undergoing neoplastic surgery.

It is thought that the invention and its advantages will be understood from the foregoing description, and it is apparent that various changes may be made in the from construction and arrangement of the parts without departing from the spirit and scope of the invention or sacrificing its material advantages, the forms hereinbefore described and illustrated in the drawings being merely preferred embodiments thereof.

TABLE I

n	1	2	3	4
Boiling Point °C	39	101	153	193
Thermal Conductivity J/(m)(sec)(°C)	311	311	311	311
Vapor Pressure at 52°C psia	21.7	2.03	0.023	0.82
Viscosity at 25°C CS	0.03	0.6	1.3	2.3

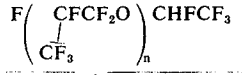
What is claimed is:

1. A method of preventing cryoadhesion of cryosurgical instruments comprising placing on the surface of the instrument which comes in contact with tissue a coating of anti-cryoadhesion material which is a good heat conducting material which is liquid at cryogenic temperature and which is non-toxic to tissue and which is taken from the group consisting of polyfluorinated polyethers, polyflurinated ethers, polyfluorinated tertiary alkyl amines and cyclic perfluorinated ether and mixtures thereof.

2. A method as claimed in claim 1 in which the step of placing the anti-cryoadhesion material on the instrument comprises dipping the instrument in the material.

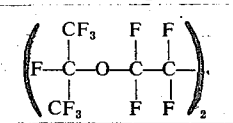
3. A method as claimed in claim 1 in which the instrument is first dried by dipping in a 100 percent anhydrous alcohol solution and then a stream of dry nitrogen gas is directed thereover.

4. A method as claimed in claim 1 in which the polyfluorinated polyether has the general formula:

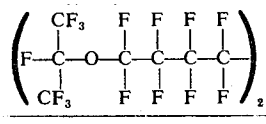


where *n* is a whole number in the range of 1 to 11.

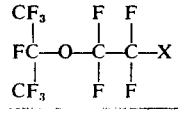
5. A method as claimed in claim 1 in which the polyfluorinated polyether has the general formula:



6. A method as claimed in claim 1 in which the polyfluorinated polyether has the general formula:

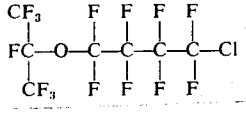


7. A method as claimed in claim 1 in which the polyfluorinated ether has the general formula:



where X is fluorine, hydrogen or chlorine.

8. A method as claimed in claim 1 in which the polyfluorinated ether has the general formula:



9. A method as claimed in claim 1 in which the anti-cryoadhesion material is a polyfluorinated tertiary alkyl amine having the general formula $(C_4F_9)_3N$.

10. A method as claimed in claim 1 in which the anti-cryoadhesion material is a cyclic perfluorinated ether having the general formula $C\text{-}C_8F_{16}O$.

11. A cryosurgical instrument comprising a hollow inner portion of a good heat conducting material having a cryogenic fluid inlet passage opening into the hollow interior thereof and a cryogenic outlet passage opening out of the hollow interior thereof, and a sheath comprised of a good heat conducting material at least a portion of which is porous, said sheath being around said inner portion and spaced therefrom to define an enclosed space between said sheath and said inner portion, said instrument having an anti-cryoadhesion inlet passage therethrough opening into said enclosed space, whereby liquid anti-cryoadhesion material can flow from said anti-cryogenic inlet passage through said space and out through said porous sheath.

12. A cryosurgical instrument as claimed in claim 11 in which said enclosed space is filled with a porous metal material, the pores of which are interconnected.

13. A cryosurgical instrument as claimed in claim 11 in which the material of the sheath is a porous stainless steel.

14. A cryosurgical instrument as claimed in claim 11 in which the material of said sheath is woven stainless steel wire.

15. A cryosurgical instrument as claimed in claim 11 further including a supply means connected to said surgical instrument for supplying anti-cryoadhesion material, said supply means having a cooling means for precooling the anti-cryoadhesion material.

16. A cryosurgical instrument as claimed in claim 11 in which the sheath is detachably mounted on the instrument.

17. A cryosurgical instrument as claimed in claim 11 in which the sheath is in the form of a blade and has a blade portion along the lower edge thereof.

18. A cryosurgical instrument as claimed in claim 17 in which said blade portion is of a porous metal.

19. A cryosurgical instrument as claimed in claim 18 in which the edge of said blade is plated with a solid stainless metal material.

20. A cryosurgical instrument as claimed in claim 17 in which said blade portion is comprised of two blade halves having the edges at the cutting edge against each other and the halves diverging to define a V-shaped groove between them through which anti-cryoadhesion material can flow and escape between the edges at the cutting edge of the blade portion.

21. A cryosurgical instrument as claimed in claim 17 in which said blade portion is comprised of alternate sheets of porous stainless metal material and non-porous stainless metal material extending generally parallel to the plane of the blade, anti-cryoadhesion material flowing through the porous laminations toward the cutting edge of the blade portion.

22. A cryosurgical instrument as claimed in claim 21 in which there is a joint between a porous sheet and a non-porous sheet lying along the cutting edge of the blade portion.

23. A cryosurgical instrument as claimed in claim 17 in which said blade portion is comprised of a blade core having a sharpened edge, and a blade covering portion of porous stainless metal material on opposite sides of said blade core.

24. A cryosurgical instrument as claimed in claim 17 in which said blade portion is comprised of a plurality of sheets of non-porous stainless metal material each having a side with a series of depressions therein against a smooth side of an adjacent sheet for leaving fine passages between sheets.

25. A cryosurgical instrument as claimed in claim 16 in which said sheath has a non-porous blade portion extending along one edge, the remainder of the sheath being of porous material.

26. A cryosurgical instrument as claimed in claim 11 in which said instrument includes a neck portion on which said inner portion and said sheath are mounted and through which said passages extend, said neck portion having means thereon for detachably mounting the instrument on a handle.

27. A cryosurgical instrument as claimed in claim 26 in which said sheath is in the form of a blade and has a blade portion along the lower edge thereof.

28. A cryosurgical instrument as claimed in claim 11 in which said instrument includes an elongated body portion on which said inner portion and said sheath are mounted and through which said passages extend, said body portion being in the shape of the body of a probe, and said inner portion and said sheath being in the shape of the tip of a probe.

29. A cryosurgical instrument as claimed in claim 28 in which said sheath has on at least a portion of the outside thereof a covering of a steel wool-like material of fine filaments of stainless steel.

30. A cryosurgical instrument as claimed in claim 29 in which the whole of the sheath is porous, and said covering covers the whole of the sheath.

31. A cryosurgical instrument as claimed in claim 28 in which said sheath has a non-porous portion on the free end portion thereof, and said covering is in the

shape of a ring around the remainder of said sheath.

32. A cryosurgical instrument as claimed in claim 11 in which the sheath is in the form of a blade and has a blade portion receiving space along the bottom edge thereof and a plurality of holes along the sheath on the opposite sides of the blade portion receiving space, and a blade portion of porous metal positioned in said space and having a cutting edge along the lower portion and an upper portion between the edges of the sheath and a plurality of laterally extending porous projections extending through the holes in the sheath, and a porous fastening strip having a plurality of holes therealong placed over the projections on each side of the sheath, the ends of the lateral projections being in the shape of rivet heads and holding the fastening strips, the sheath and the blade portion in tight engagement.

33. A cryosurgical instrument as claimed in claim 11 in which said sheath has a plurality of grooves in the inside surface thereof extending from the point at which the said inlet passage opens into said sheath and outwardly from said point over the inside surface of the sheath.

34. A cryosurgical instrument as claimed in claim 11 in which said sheath is comprised of an apertured good heat conducting portion and a good heat conducting porous metal material on the outer surface of said apertured portion covering the surface thereof and the apparatus.

35. A cryosurgical instrument as claimed in claim 11 in which said enclosed space has therein a laminated structure comprised of two layers of a stainless steel filter material and an intermediate layer of molecular sieve material, the inner surface of said laminated structure being spaced from the outer surface of said inner portion and the outer surface of said laminated structure being against the inner surface of said sheath.

36. A cryosurgical instrument comprising a hollow surgical element of a good heat conducting material having a cryogenic fluid inlet passage opening into the hollow interior thereof and a cryogenic outlet passage opening out of the hollow interior thereof, and spray means on said instrument directed along said surgical element, said instrument having an anti-cryoadhesion material inlet passage therein extending to said spray means, whereby liquid anti-cryoadhesion material can be sprayed along said surgical element.

37. A cryosurgical instrument as claimed in claim 36 in which said surgical element is a blade, and said spray means comprise a spray head on each side of said instrument at the base of said blade and directed along the side surface of the blade, and spray openings at the tip of said blade.

38. A method of preventing cryoadhesion of cryosurgical instruments comprising placing on the surface of the instrument which comes in contact with tissue a coating of anti-cryoadhesion material, said material being one of the viscous fluorocarbons which is a good heat conducting material which is liquid at cryogenic temperature and which is non-toxic, and then lowering the temperature of the tissue contacting component of the instrument to the cryogenic temperature prior to the application thereof to the tissue.

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