United States Patent

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[54] **SUPERCOOLED SURGICAL INSTRUMENT**
11 Claims, 13 Drawing Figs.

[52] U.S. Cl. 128/303.1
[51] Int. Cl. A61b 17/36
[50] Field of Search 128/303.1, 400, 401

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Primary Examiner—L. W. Trapp
Attorney—Kenneth S. Goldfarb

ABSTRACT: A supercooled surgical instrument comprising a heat conductive surgical tool having a hollow thin walled body of heat conductive material of low icing capacity and a thermally insulative handle connected to the body. A reservoir containing a cryogenic liquid including means for injecting a precooled nontoxic inert gas into the cryogenic liquid so that the said gas and said liquid are supercooled by expansion during passage through the cryogenic liquid, and outlet means located above the liquid level of the cryogenic liquid for removing the supercooled gas from the reservoir is interconnected with the body through means disposed in the handle of the tool or by venting said gas along the outer contour of the instrument in order to increase the cooling of the instrument and to prevent icing by repelling the water molecules of the surrounding air.

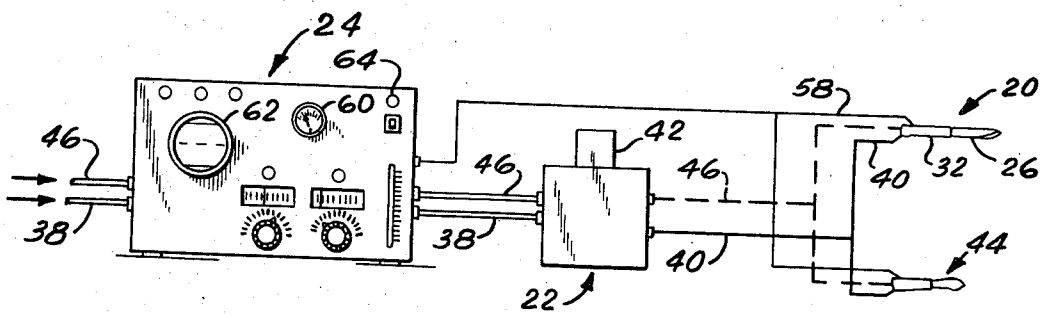
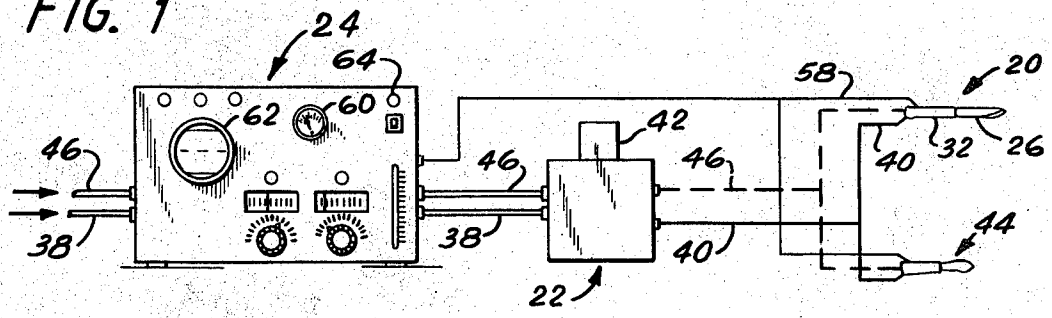


FIG. 1



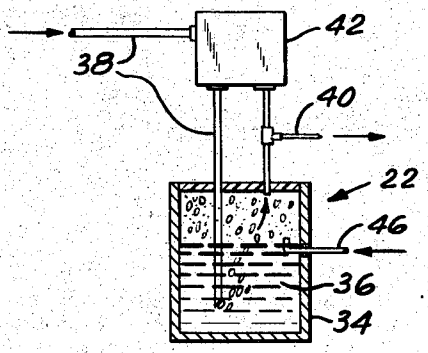
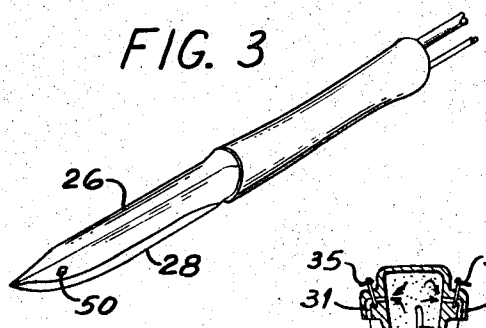


FIG. 2

FIG. 3



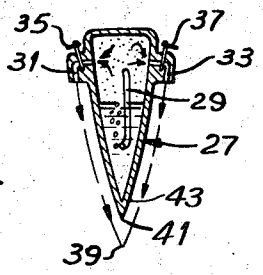


FIG. 5

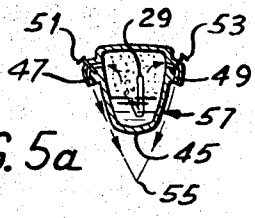
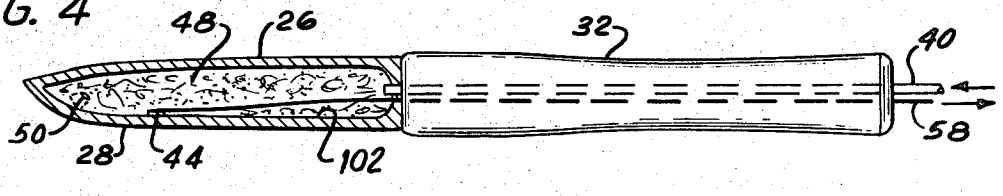


FIG. 5a

FIG. 4



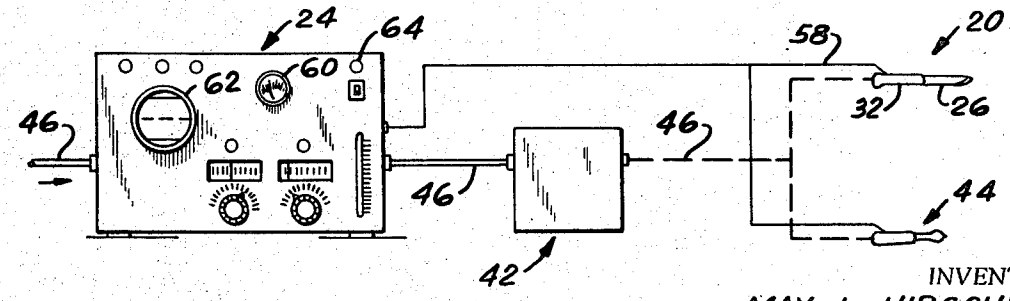


FIG. 1a

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FIG. 6

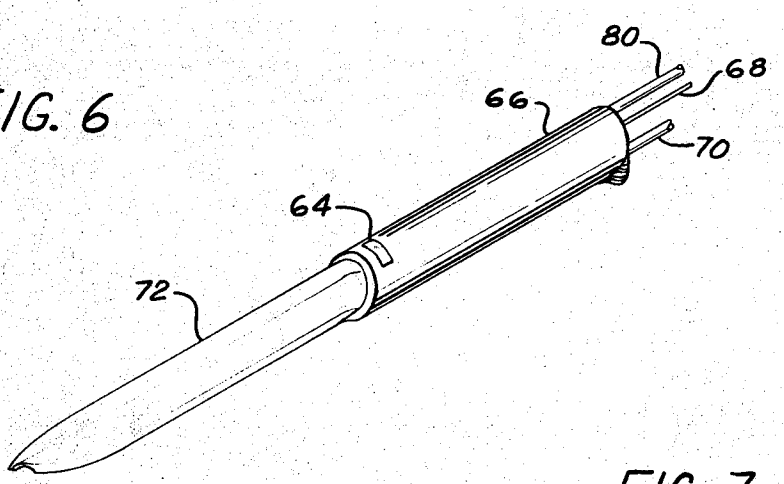
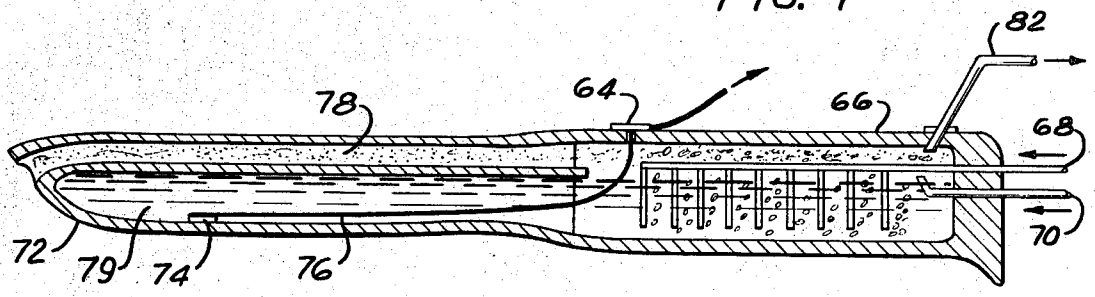


FIG. 7



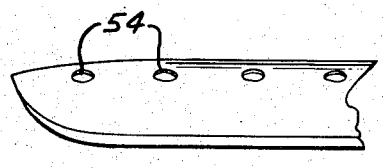


FIG. 8

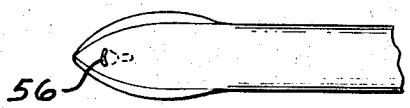


FIG. 9

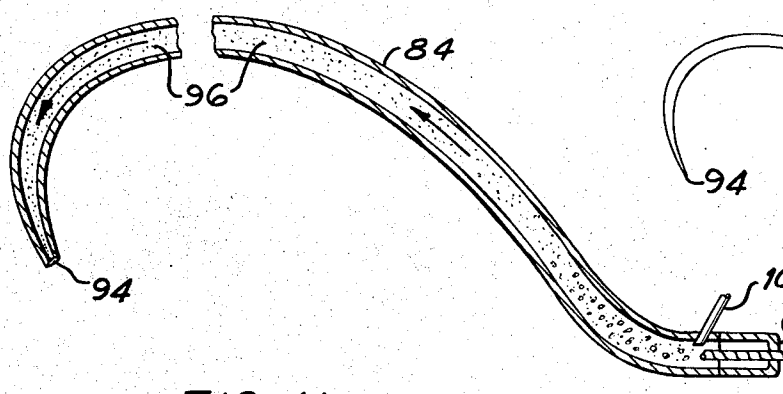


FIG. 11

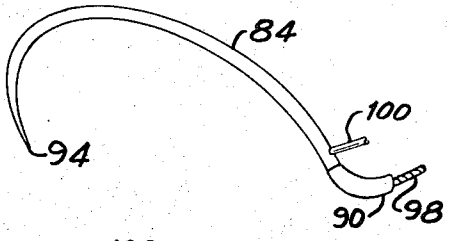


FIG. 10

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SUPERCOOLED SURGICAL INSTRUMENT

This invention relates to surgical instruments and more particularly to a cryogenically cooled surgical instrument.

At the present time it is known to perform certain operative techniques whereby parts of the body are cooled to reduce local body metabolism so as to locally reduce the flow of blood, eliminate pain, and preserve the viability of tissue by reducing its local metabolic needs. Generally, in the past surgery has been performed using knives, probes, biopsy scoops and other instruments which are applied directly to body tissue, the temperature of the tissue having been lowered by external means, for example, by application of ethyl chloride to the skin to freeze it by evaporation prior to incision in the general area of the local surgery.

Until now the use of surgical instruments for cutting or piercing body tissue having been subjected to local freezing was limited by the fact that the instrument adhered to the cooled flesh at the point of incision. In order to remove the instrument from the cooled flesh without causing severe damage to surrounding tissue it was necessary to heat the instrument, for example, by heating coils located in its interior. Therefore, the use of such surgical instruments were restricted to a single cutting motion, then waiting for a lengthy period for renewed deep cooling of the blade before continuing with the operation. The blade would be covered with ice and be insufficient since it would not have a clean cutting edge if renewed deep cooling were not allowed and after the initial incision was made, resort was had to conventional implements for continuous surgical movements.

Under certain circumstances the necessity of performing the major portion of the operation with conventional surgical instruments is particularly disadvantageous. In the case of cancer surgery, an attempt to selectively remove cancerous tissue is not without danger of transmitting the cancer cells to the blood stream and thereafter to other areas of the body by way of the circulatory system. In like manner, surgery of infected areas may cause subsequent spread of infection organisms and capillary bleeding is likewise prevented.

The surgical technique requiring preliminary cooling of the body is beset with many problems. Some of these difficulties stem from the fact that there is no way of controlling the temperature of the flesh at any given time during the operative procedure due to the rapid rate at which heat is exchanged between the ambient and the portion of the body being operated upon.

It is therefore a primary object of the present invention to provide a surgical instrument having a cutting edge or tool which may be accurately and continuously cooled below ambient room temperature, wherein the degree of cooling can be closely controlled at all times during the surgical procedure. The cooled edge acts to reduce the local body tissue metabolism at the point of and immediately surrounding the area of incision thereby reducing the local bleeding and spread of cancer cells or other infecting organisms to the circulatory system, at the same time it modifies the metabolic rate of local tissues to a degree of total destruction if so desired.

It is still another object of this invention to provide a supercooled surgical instrument which can move and sever body tissue at the surgeon's desired speed of movement, cooling being continuously applied by the body of the instrument to the body tissue.

It is a further object of this invention to provide a supercooled surgical instrument which can easily be maintained at a substantially uniform temperature throughout the entire surgical process, the surgical instrument being maintained at a temperature so low as to render the surgical instrument self-sterilizing.

It is also an object of this invention to provide a coolable surgical instrument having means to constantly control the temperature of the ambient proximate to the area being operated upon.

It is still another object of the present invention to provide a surgical instrument, which instrument is constructed from

thermally conductive material which will not adhere to the body tissue being penetrated by it or closely situated to the incised area at the required temperature.

Another object of this invention resides in the provision of a surgical instrument having a handle which is thermally insulated by novel insulation materials.

In accordance with the aforesaid objects of the invention a supercooled surgical instrument is provided having a body portion cooled by an external or internal cryogenic cooling system. A plurality of thermally conductive surgical tools and implements may be removably inserted into the end of the handle. Preferably, the body or handle portion is provided with a temperature sensing and control apparatus so that the temperature of the surgical tools and implements may be predetermined and maintained constant.

Other objects and features of the present invention will become apparent as the following description proceeds, several preferred embodiments of which have been illustrated in the accompanying drawings, wherein:

FIG. 1 is a diagrammatic view of one embodiment of the surgical instrument in accordance with the concepts of the present invention showing the manner in which a plurality of surgical tools are externally connected to a source of cryogenic cooling and temperature control panel;

FIG. 1*a* is a diagramatic view of a second embodiment of the surgical instrument in which the surgical tools are externally connected to a source of cryogenic liquid and temperature control panel;

FIG. 2 is a vertical sectional view of the source of cryogenic cooling shown in FIG. 1;

FIG. 3 is a perspective view of a surgical tool in accordance with the present invention;

FIG. 4 is an enlarged detailed longitudinal sectional view of the surgical tool illustrated in FIG. 3 showing the manner in which the tool is connected to the cryogenic cooling system and the internal circuitry for monitoring the temperature of the tool;

FIG. 5 is a fragmentary top plan view of a surgical implement which may be removably mounted into the end of a handle in accordance with the concepts of the present invention;

FIG. 5*a* is a fragmentary top plan view of a modified version of the surgical implement shown in FIG. 5;

FIG. 6 is a perspective view of another surgical tool in accordance with the concepts of this invention;

FIG. 7 is an enlarged detailed longitudinal sectional view of the surgical tool illustrated by FIG. 6 showing an internal cryogenic cooling system disposed within the handle and body of the tool;

FIG. 8 is a fragmentary side elevational view of a surgical implement which may be removably mounted into the end of the handle of the surgical instrument.

FIG. 9 is a fragmentary top plan view of another surgical implement which may be removably mounted into the end of the handle;

FIG. 10 is a perspective side view of a further surgical implement which may be removably mounted into the end of the handle; and

FIG. 11 is a detailed fragmentary longitudinal sectional view of the surgical implement shown in FIG. 10.

With continuing reference to the accompanying drawings, wherein like reference numerals designate similar parts throughout the various views, reference numeral 20 is used to generally designate the surgical tool of the present invention. In one embodiment of the invention the surgical tool 20 is connected to a source of cryogenic cooling 22 and a temperature sensing and control panel 24. The surgical tool 20 includes a body 26 having at least one honed cutting edge 28 or a piercing member, for example, the needle 30 illustrated in FIGS. 10 and 11, which may be removably inserted into a thermally insulative handle 32. The source of cryogenic cooling 22 comprises an insulated reservoir 34 containing a cryogenic liquid 36, a conduit 38 for injecting a precooled nontoxic inert gas into the cryogenic liquid contained in the

reservoir and another tube or conduit **40** located above the liquid level of the cryogenic liquid for removal of supercooled gas. In one embodiment of this invention a gas compression pump and/or gas flow regulator generally indicated at **42** is disposed between gas injection conduit or inlet **38** and gas removal conduit or outlet **40** for recycling and condensing supercooled gas, thereby increasing the efficiency of the cooling system. There may also be provided a temperature control panel **24** which monitors the temperature of the body portion **26** of surgical tool **20** by means of a temperature sensing device **44**, for example, a thermistor (see FIG. **4**) or thermocouple embedded close to the outside surface of body **26**. The cooling system of this invention may be readily adapted to cool more than one surgical tool at a time, as for example the pair of implements **20** and **44** shown in FIG. **1**.

The source of cryogenic cooling **22** operates by injection of a precooled inert gas through conduit **38** into a cryogenic liquid in which the inert gas is insoluble or only very slightly soluble, *i.e.* the gas bubbles through the liquid at an accelerating rate, the gas molecules moving away from one another and occupying a greater volume with a concurrent increase in the size of the bubbles. Although no attempt is made here to explain the resulting cooling effect of the passage of the gas through the liquid, the expansion of the gas bubbles decreases the vapor pressure of the gas within the bubbles so that molecules of liquid having above average kinetic energies evaporate into the gas bubbles, thereby extracting heat from the liquid and cooling the liquid. If it is desired to utilize the supercooled gas without subsequent recycling through compression pumps **22**, the liquid may be replenished through conduit **46**.

The cryogenic liquid may be any nonexplodable, nontoxic, low molecular weight substance. Of those substances meeting the aforementioned requirements, the choice of liquid will depend upon the temperature at which the surgeon chooses to perform the operation. Typically, these temperatures will be in the range of about 63°K. to about 200°K. Preferred cryogenic liquids are: nitrogen (freezing point, 63.3°K.; boiling point, 77.4°K.) and freon **14** (freezing point, 128°K.; boiling point, 145°K.). Dry ice sublimes at 194.7°K. and may be utilized in place of a cryogenic liquid.

The supercooled gas leaves the reservoir through conduit **40** which passes through handle of the surgical tool **20** and then into an evaporating chamber **48** formed by hollow thin walled body **26**. Vents **50** and **52** are provided for removal of supercooled gas from evaporating chamber **48**. If desired the surgical implement may be vented in other manners, as in FIG. **8**, where a plurality of vents **54** are located in the top or in FIG. **9** where a single vent **56** is located in the body. It should be noted that vents **50** and **52** permit the supercooled gas to circulate around the contour of the body on which they are located thereby controlling the temperature of the ambient immediately surrounding area of incision. Therefore, it is preferable that the gas have a low heat capacity. Since the supercooled gases come into contact with body tissue they must be nontoxic as well as insoluble or only slightly soluble in the cryogenic liquid or other cryogenic substance, such as has been previously mentioned. It is possible to use any inert gas meeting the above requirements, although helium is preferred.

Although certain ambients can rapidly absorb heat, the rate of transference of heat or cold through such mediums is very slow. Therefore, it is necessary in the instant invention to operate at very low temperatures. Furthermore, the surgical implement itself must, in addition to being a good thermal conductor, have as small a thermal mass as possible to permit rapid heat exchange with the ambient and for maximum efficiency.

This invention further provides the novel use of sapphire and zirconium oxide or materials having similar physical characteristics from which the body of the surgical tool is fabricated. Desirably, sapphire and zirconium oxide are extremely hard, are excellent thermal conductors, and are electrically nonconductive. Electrical nonconductivity renders the use of these materials particularly attractive since there is no electrical discharge which would injure the body tissue being operated upon. In some cases this might even be fatal. Equally important is the fact that sapphire and zirconium oxide surgical implements will not freeze into the incised area even at the very low temperatures being used in this invention.

The handle of the surgical tool utilizes a novel form of insulation material. The material is manufactured by superposing several layers of plastic material, such as polystyrene, upon one another. The superposed layers are heated in a vacuum chamber, causing the layers to incompletely join because of low pressure vacuoles created at the interfaces of successive layers, thereby forming an unevenly constructed wafer. Not only do such materials exhibit very poor thermal conductivity, but they also have great tensile strength. Moreover, the elasticity of the material will help to maintain the low atmospheric pressure within the vacuoles. This material is particularly useful in cryogenic applications because of the severely low temperatures involved.

It is also desired that the temperature of the body of the surgical tool be controllable. For this purpose a thermistor **44** or thermocouple, no shown, may be embedded at the interface of the body wall and the evaporating chamber. Suitably the thermistor may be made from sapphire. The thermistor **44** is connected to a wire **58** which passes through the handle **32** of the instrument. From the handle the wire passes to control panel **24** where by means of various temperature reading gauges the temperature can be monitored. Thus, the flow of gas into conduit **38** and flow of liquid into conduit **46** can be regulated to achieve any desired temperature. If it is desired that the surgeon be constantly advised of the temperature at which he is working and oscillator **62** may be connected to the panel **24**. Alternatively, an amber light **64** may be incorporated in the panel or on the handle, as indicated in FIG. **6**, which will light up when the temperature of the body of the surgical instrument has reached its present value.

FIG. **1***a* illustrates a preferred embodiment of the invention. Cryogenic liquid travels from a source, not shown, through a conduit **46** which passes through a thermally insulated handle **32** of the surgical tool **20**. As the liquid approaches the tip of conduit **46** which communicates with the hollow chamber of a body **26** in all respects identical to the body of FIG. **4**, it instantaneously evaporates, concurrently supercooling the body of the tool. The gas may either be vented, as previously described, or be recycled through a compression pump **42**. Temperature monitoring means disposed within the body may be conveniently connected by a wire **58** to a temperature control panel **24**.

In another embodiment of the invention, illustrated in FIGS. **6** and **7**, a thermally insulative handle **66** which communicates with a body **72** in such a manner that handle **66** and body **72** jointly form a reservoir for the cryogenic liquid. Gas inlet tubes **68** pass into the interior of the handle **66** and inject cryogenic liquid which may be continuously replenished through inlet **70**. A thermistor **74** is disposed at the interface of the body wall with reservoir chamber **79** and is connected by a wire **76** to an amber light **64** and finally to a temperature control panel **24**. Supercooled gas may be removed from evaporating chamber **78** through gas outlet tubes **80** or **82**, illustrated by FIGS. **6** and **7**, respectively. The gas may then be recycled through a compression pump, not shown, or merely permitted to escape into the atmosphere.

FIGS. **5** and **5***a* relate to a further important teaching of this invention and consists of a jet stream arrangement of the supercooled gases venting from the surgical scalpel downward along the sides of the instrument causing the H_2O molecules in the approximate air space to be dispelled and thus tending to prevent additionally the condensation of water vapor upon the instrument or icing. The inert cooled gases can be forced through the vents by very high pressure at an acute angle. The gas streams would meet and join forces a very short distance from the cutting edge of the instrument. The gas stream would then assume a downward direction. Such cooled air stream

will cool and destroy the tissues in a linear fashion before the cutting edge of the supercooled scalpel reaches the tissue. This embodiment will therefore enhance the efficiency of the cooled blade and allow greater operative speed to the surgeon. The gas stream will substantially further prevent tissue fluid condensation or freezing of the instrument into the tissues by tending to shield the cutting blade from the water molecules of the severed tissues.

A novel application for bone surgery consists of the reservoir containing the cryogenic liquid, and the supercooled helium gas jet striking down in an acute angle in a linear or point confluence pattern. The reservoir does not necessarily possess a cutting edge and may be constructed of any suitable material.

This embodiment will eminently serve for cutting bone or cartilage and give all advantage of controlled freezing.

More particularly with reference to FIG. 5, there is provided a surgical implement having a tapered hollow body **27**, tip **41** and cutting edge **43**. The body is provided with cryogenic fluid inlet tubes **29** for cryogenic liquid and/or gas so that when inert gas is passed into the cryogenic liquid, the gas and liquid become supercooled. Supercooled inert gas is removed from the body at vents **31** and **33** designed to permit the vented gas to travel along the tapered contours of the body and meet at a point **39** in advance of the tip **41** of the implement. The pressure of the supercooled gas vented from the body is regulated by jet control valves **35** and **37** located at vents **31** and **33** at a value on the order of 0.25 atm. The supercooled gas stream will cool the air proximate to the tip **41** of the implement and cool and destroy body tissues in a linear fashion before the cutting edge **43** of the supercooled implement reaches the body tissue. The supercooled gas stream will also substantially minimize condensation of tissue fluid and tend to prevent the cutting blade of the instrument from freezing into severed tissues.

In the embodiment depicted in FIG. *5a* the hollow body **57** has a blunt tip **45**. The vents **47** and **49**, including jet control valves **51** and **53**, are regulated to direct inert gas to flow around the body contours, the inert gas stream meeting in advance of tip **45** at a point **45**. The gas stream is controlled at a substantially greater pressure (for example, multiples of 0.25 atm.) than in the embodiment shown in FIG. 5 permitting the inert gas stream to cut bone or cartilage as it strikes the tissue in a linear or point confluence pattern.

FIGS. **10** and **11** depict a further surgical implement according to this invention. Needle or piercing implement **84** is connected to a handle, not shown, and to a source of cryogenic liquid by a conduit **100** located at the base of the implement and a length of surgical thread **98** passing through an aperture located in the end wall **90** of the implement. Cryogenic liquid which flows into the gas evaporating chamber **96** through conduit **100** is evaporated as hereinbefore described and may be vented at outlet **100**.

It is further contemplated by this invention to reinforce the interior of hollow thin walled sapphire or zirconium oxide with a thin layer of heat conductive metal **102** for rigidifying the structure of the body.

It is to be understood that the disclosed supercooling apparatus can be utilized to supercool any suitable body to desired temperatures. It is within the concept of the invention to utilize the apparatus for supercooling transmission lines, electrical conduits, conductors and the like.

A latitude of modification, substitution and change, is intended in the foregoing disclosure, and in some instances some features of the present invention may be employed without a corresponding use of other features. Accordingly, it is appropriate that the appended claims be construed broadly and in a manner consistent with the spirit and scope of the invention herein.

I claim:

1. A supercooled surgical instrument comprising a heat conductive surgical tool having a hollow thin walled body of heat conductive material selected from the class of materials consisting of sapphire and zirconium oxide, a thermally insulative handle connected to said body, a reservoir containing a cryogenic liquid, means for injecting a precooled nontoxic inert gas into said cryogenic liquid in said reservoir so that said gas is supercooled by expansion during passage through said cryogenic liquid thereby supercooling said cryogenic liquid, said reservoir having outlet means located above the liquid level of said cryogenic liquid for removing the supercooled gas from said reservoir, said handle having means interconnecting said body with said outlet means.

2. A supercooled surgical instrument according to claim **1**, including reinforcing means for rigidifying the interior of said body, said means being a thin layer of thermally conductive material.

3. A supercooled surgical instrument according to claim **1**, wherein a thermally responsive means is embedded in said body for monitoring the temperature of said body.

4. A supercooled surgical instrument according to claim **3**, wherein said thermally responsive means is a sapphire thermistor.

5. A supercooled surgical instrument according to claim **1**, wherein said body is provided with outlet means for removing said supercooled gas from said body, and outlet means being located above the liquid level of said cryogenic liquid in said body, and compression pump means for recycling said supercooled gas to said handle.

6. A supercooled surgical instrument according to claim **1**, wherein said body is provided with vent means for removal of said supercooled gas.

7. A supercooled surgical instrument according to claim **6**, wherein said reservoir includes inlet means for replenishing said cryogenic liquid in said reservoir.

8. A supercooled surgical instrument according to claim **7**, wherein said vent means direct supercooled gas along the outside contours of said body.

9. A supercooled surgical instrument according to claim **1**, wherein said handle and said body are interconnected to jointly form said reservoir, said means for injecting said gas being located in said handle.

10. An apparatus for supercooling bodies comprising a reservoir containing a cryogenic liquid, means for injecting a precooled nontoxic inert gas into said cryogenic liquid in said reservoir so that said gas and said cryogenic liquid are supercooled by expansion of said gas during passage through said cryogenic liquid, said reservoir having outlet means located above the liquid level of said cryogenic liquid for removing the supercooled gas from said reservoir, and means for interconnecting a body to be supercooled with said outlet means.

11. A supercooled surgical instrument comprising a heat conductive surgical tool having a hollow thin walled body, a thermally insulative handle connected to said body, a reservoir containing a cryogenic fluid disposed in the body of said tool, means for injecting a precooled nontoxic inert gas into said cryogenic fluid in said reservoir so that said gas is supercooled by expansion during passage through said cryogenic fluid thereby supercooling said cryogenic fluid, and means on said body communicating with said reservoir for directing flow of supercooled gas outwardly of said body and in a path substantially conforming to the contours of said body so that said gases meet in advance of said body.