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[33] **Germany**
[31] **1,566,111**

[54] **CRYOSURGICAL APPLIANCE**
16 Claims, 6 Drawing Figs.

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

[56] **References Cited**

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ABSTRACT: A cryosurgical appliance having a thermally insulated probe with a handle member and a separate container attached to the latter. The probe has a conductive nose for a cooling liquid and the separate container is attached directly to the handle member and also the latter has indicating means provided thereon.

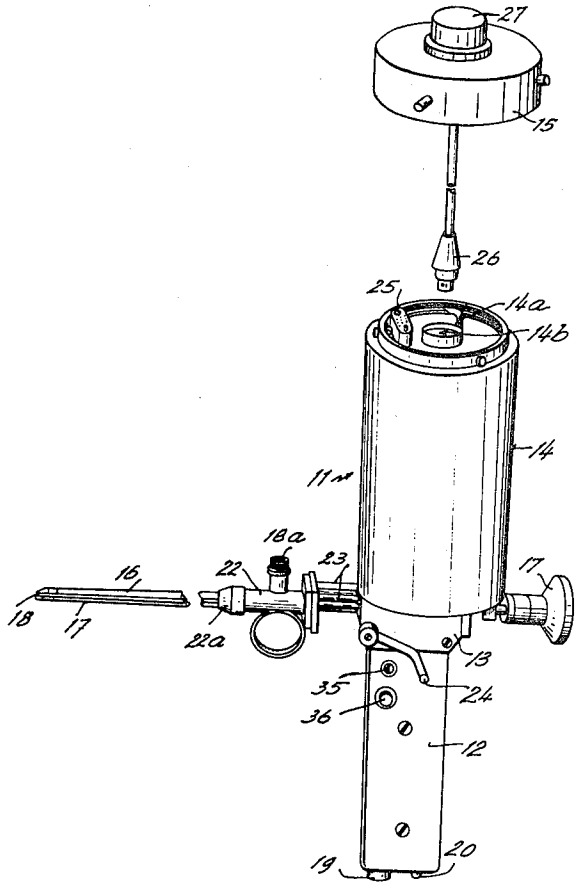

FIG. 1

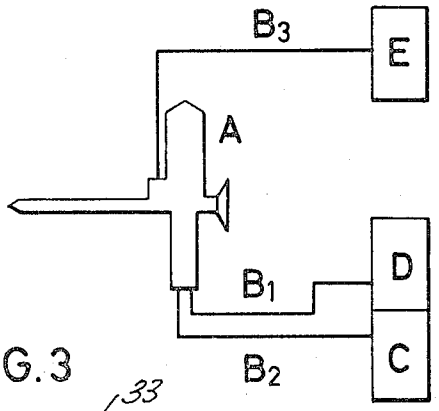

FIG. 3

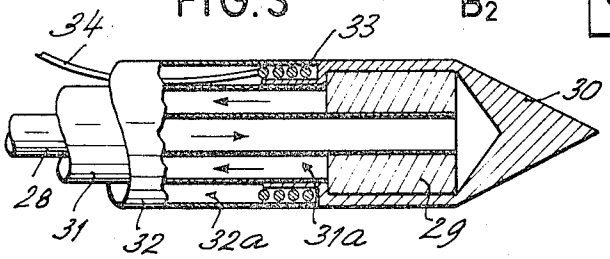

FIG. 4

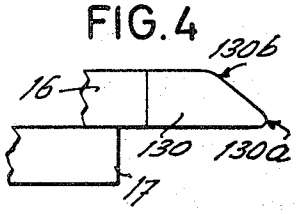

FIG. 5

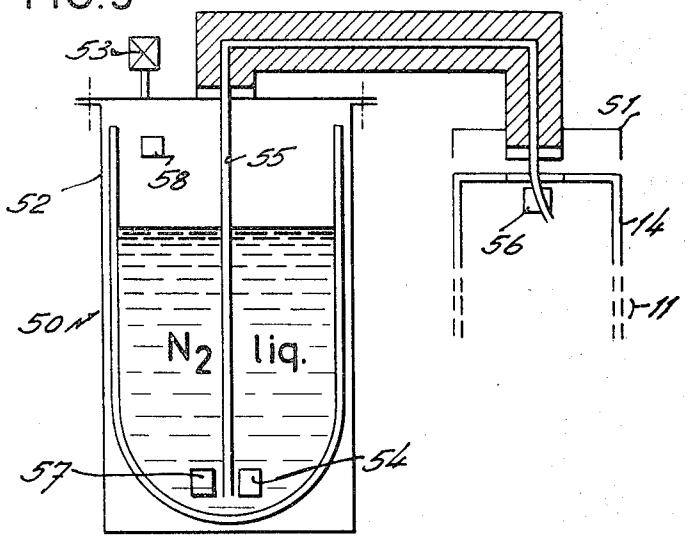

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FIG. 2

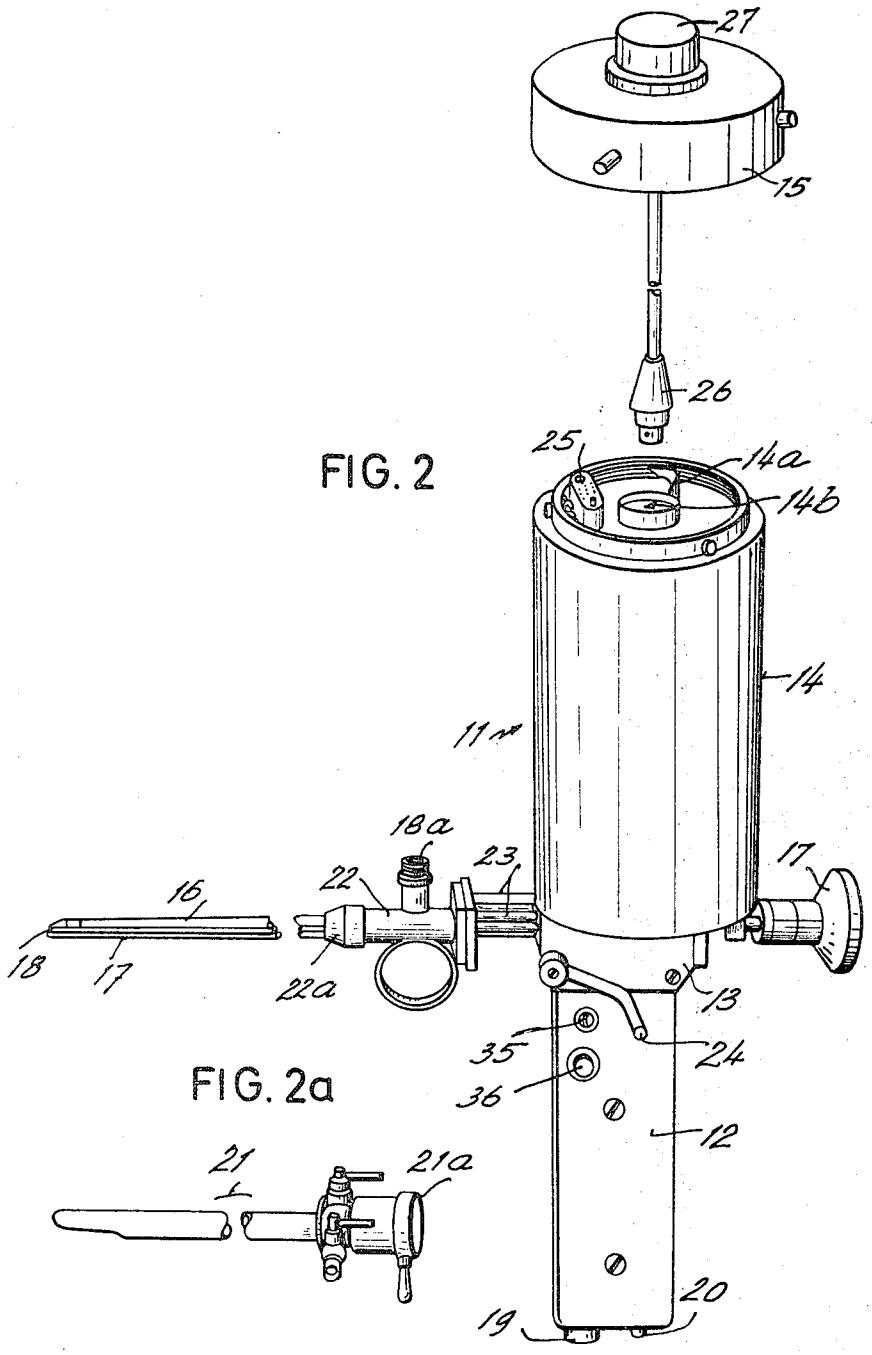

FIG. 2a

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CRYOSURGICAL APPLICANCE

This invention relates to a cryosurgical appliance. In medicine, the destruction and removal of proud, diseased or undesirable tissue by intense supercooling has already been carried out frequently with good success. As compared with other known methods such as, for example, cutting, burning, and the use of electrical sparks or arcs, the possibility of bleeding occurring is reduced and the time taken to heal is shortened.

If supercooling is to be carried out at easily accessible parts of the body such as for example, the torso, arms or legs, this can easily be achieved by spraying-on a coolant or by contact with a suitable cooled metal tool, whose total volume may be large in relation to the area to be cooled. If, on the other hand, it is necessary to treat by cooling a region of tissue or organ situated in the interior of the body (prostate, tonsils, for example), a small cooling element arranged on the end of a probe and given a suitable shape must first of all be introduced at body temperature and brought into the correct position. Then the cooling or freezing can be carried out.

Cryosurgical appliances have already been described, constructed and used. Liquid nitrogen is used inter alia as coolant, having a boiling point of −196°C. In one known appliance the coolant is stored in a stationary container containing several litres, and it is connected to the actual cryosurgical probe by means of a metallic corrugated tube. In the corrugated tube there is disposed a hose which conducts the coolant to the evaporator situated in the point of the coolant to the evaporator situated in the point of the cryosurgical probe, and a second hose which discharges the gas produced at evaporation. Pressure-regulating and pressure-measuring devices are also provided so that the coolant is fed in correct quantities to the evaporator from the supply vessel which is under a pressure of about 2 atmospheres excess pressure. It is also known for the gas produced to be removed by suction. Since all known materials suitable for low temperatures such as for example, "Teflon" become hard and brittle at the temperature of the liquid nitrogen, the corrugated tube can only be slightly flexible and cannot be twisted. The treatment of the patient is considerably hampered and restricted thereby, since the patient must substantially be aligned relatively to the operating appliance and not the other way around, as would be desirable.

An arrangement with a hand appliance separate from the stationary coolant supply container is also known. The coolant used is nitrous oxide (N_2O) under high pressure. The coolant in the supply container is at room temperature and is fed to the manual appliance by way of a flexible pressure hose. By expanding the coolant to normal pressure in the point of the manual appliance, the cooling effect is achieved. This method of operation is advantageous inasmuch as the coolant is at room temperature during supply to the manual appliance and therefore it is possible to use hoses made of plastics material, rubber and the like without prejudicing the flexibility thereof. On the other hand, it is only possible with this appliance to achieve a lower limit temperature of about −90°C., as compared with a lower limit temperature of −196°C. when using liquid nitrogen as coolant.

But when tissue is to be destroyed by supercooling the lowest possible temperature is necessary. Irreversible destruction of tissue occurs only after cooling to temperatures below −50°C. Within a ball of ice formed in the tissue by supercooling, the temperature (even after a long cooling time) increases with increasing distance from the cooling tip. Thus, cell death is achieved only in the innermost part in a ball of ice of this kind. Therefore, the percentage of destroyed tissue volume relative to the total volume of frozen tissue is substantially more advantageous with a lower limit temperature.

It is an object of the present invention to provide a simple, handy and easily operated operating appliance which, after the supercooling or freezing of a limited region of tissue, can quickly be removed and, if necessary, repositioned.

Starting with a cryosurgical appliance having a probe in whose thermally conductive nose a cooling liquid is evaporated which is fed from a supply container through the thermally insulated probe shank and conducted back again in the evaporated state, the solution of the aforesaid problem is characterized in that the supply container is attached directly to a handle member to which the probe, contact means for the operation thereof and indicating means for supervision of the appliance, are also arranged. An appliance of this type can be constructed for example for carrying out transurethral operations, the supply container arranged at the handle member being designed for a capacity of about 300 cm.^{3} of liquid nitrogen. This supply of coolant is sufficient for a freezing time of about 8 minutes, or for producing 6 to 8 balls of frozen tissue each of about 15 mm. diameter from water at room temperature. The total weight of an appliance of this kind in the filled state is between 1,000 and 1,500 grammes.

In the preferred form of embodiment of the appliance a viewing optical system is arranged interchangeably adjacent the probe shank, and preferably a lighting device also. Suitable viewing optical systems and lighting devices, more particularly cold light projectors, are known per se more particularly for resection instruments also. Therefore, in further development of the present invention there is provided at the handle member of the operating appliance a connection for a so-called treatment shank which accommodates probe, optical system and lighting device. The treatment shank is a component of the aforesaid resection appliance which is widely used in urological operating techniques and is used in such cases to accommodate the actual operating probe and at the same time an optical system for viewing and lighting, or can serve for the introduction, after removal of the operating appliance, of a larger-diameter optical system intended merely for viewing the operating zone. According to a further feature it serves for better viewing of the operating zone if the cooling probe and treatment shank are arranged to be axially displaceable relative to one another in the handle member and in such a manner that they can be locked in position. The viewing optical system and the lighting device are fixed rigidly to the handle member. The surgeon can first of all view the operating zone and then move the probe nose out of the front end of the treatment shank and retract it again, as needed. In order to prevent injury to tissue outside the visible region of the optical system, the probe nose according to a further feature of the invention is shaped so as not to damage tissue at regions which are not visible. The probe nose can also be arranged to be interchangeable in order to permit of fitting a suitably shaped nose in accordance with the object of the operation.

In order to meet the need for a handy appliance, the supply container may be given only a limited capacity. Although it has been found that many kinds of operations can be carried out with a filling of for example 300 cm.^{3} of N_2, it promotes the usefulness of the appliance to provide a device which indicates acoustically and/or optically when the supply container is empty or emptied apart from a specific reserve. A still further object of the invention resides in that there can be associated with the operating appliance, a replenishing device on which the operating appliance can be set in an operation pause or after emptying of the supply container, and automatically replenished from a storage container. The handiness aimed at according to the invention, that is more particularly easy mobility of the operating appliance, is promoted in that according to an additional feature of the invention electric heating is provided in the handle member which heats the gas flowing from the evaporator to a temperature at which the flexibility of a discharge gas hose connected to the handle member is guaranteed. As is known per se, at the end of the discharge gas hose, which leads to a conveniently electronically operating control device arranged outside the operating area, a control valve is provided which is opened by means of a contact means arranged on the handle member when an operation step is to be carried out, said valve effecting the

passage of cooling liquid from the supply container subjected to slight positive pressure (about 2 atmospheres excess pressure) through the probe and back through the handle and the discharge gas hose, and closing again at the end of the operating step. In further development of this underlying idea of the invention the control of the valve and the control of the electrical heating in the handle member are so coupled that the heating is effected only when the valve is opened. In order to permit of removing the probe nose quickly from the frozen tissue after carrying out a freezing, electrical heating device is provided in the immediate vicinity of the evaporator and the probe nose.

Further features and advantages of the invention will be apparent from the following description of an example of embodiment, the drawing and claims. The drawings show an appliance for carrying out transurethral operations, and in the drawings:

FIG. **1** is a block schematic diagram of the operating manual applicance and its supply devices;

FIG. **2** is a side perspective view showing manual appliance with the cover of the supply container lifted;

FIG. **2***a* is a perspective view of a treatment shank which can be fitted on the probe of the operating manual appliance;

FIG. **3** is a sectional view on a larger scale of the probe nose;

FIG. **4** is a side view of a particular embodiment of the probe nose; and

FIG. **5** is a side sectional view diagrammatically showing the replenishing device for the operating manual appliance.

The construction of a complete operating apparatus layout according to the invention is shown in FIG. **1**, in which A designates the actual operating manual appliance, B_1, B_2 and B_3, supply and control lines of which B_1 leads to the low-tension device D, B_2 to the suction pump C and B_3 to the cold light projector E.

The manual appliance given the general reference numeral **11** in FIG. **2** comprises substantially a handle member **12**, a connecting member **13**, the supply container **14** which is fixed to the member **13** and comprises a cover **15**, and the probe **16**. Also belonging to the probe are the viewing optical system **17** and the cold light fibre-optical system **18**, the connecting member of which is designated as **18***a*. Also provided at the handle member **12** is a connection **19** for electrical current supply and the monitoring electronics, and a discharge gas union **20** to which there is connected a flexible high-vacuum rubber hose, not shown, leading to the suction pump (C in FIG. **1**). In transurethral operations, the procedure is conveniently carried out with the treatment shank, illustrated in FIG. **2***a*, of a conventional resection instrument, otherwise not shown. The treatment shank is designated as **21**, and it has a bayonet joint member **21***a* with which it can be fixed to a connecting cone **22***a* of the finger rest **22** of the manual appliance. The finger rest **22** is axially displaceable in relation to the handle member **12**, a parallel guide **23** being provided between the two parts. The viewing optical system **17** is fixed, whereas by means of the finger rest **22**, the treatment shank **21** and the cooling probe **16** can be displaced axially relatively to one another. If the optical system **17** is not required, it can be removed from the central member **13** after release of a plug and socket connection (not shown). A securing toggle or lever **24** on the connecting member **13** is used for fixing the cooling probe **16** in the desired position.

The coolant supply container **14**, from which a communicating duct leads to the probe **16** in the interior of the intermediate member **13**, is expediently provided with an evacuatable jacket. A pump union **14***a* for evacuation of the jacket is accessible when the cover **15** is removed. The liquid coolant is introduced into the supply container through the union **14***b*. Situated above on the body of the supply container **14** is one half **25** of a plug contact arrangement whose other half, not shown, in the drawing, is fixed to the inner side of the cover. This contact arrangement serves for electrical connection between the thermoelectric device of pickup **25** arranged on the cover **15**, and monitoring means of an acoustic and/or optical type which can be arranged at the manual appliance itself or at the electronic control and supply device to show the surgeon using the hand appliance when the supply container **14** is completely empty or is empty apart from a predetermined reserve quantity. At the same time the plug contact half **25** arranged on the body of the supply container **14** serves for connecting the hand appliance to the replenishing device which will be described hereinafter and on which there is situated a matching contact half. A pressure relief and safety valve with adjusting screw **27** is situated on the cover **15**.

The probe which is given the general reference numeral **16** consists of three coaxially disposed, thin-walled tubes of mechanically strong material which is a poor conductor of heat and is corrosion-resistant, such as for example stainless steel. In the innermost tube **28**, the liquid coolant fed from the supply container **14** flows to the evaporator **29** which can consist of a thermally conductive wire coil, a multiple perforated metal cylinder or a metal wire gauze, which establishes a good thermal contact between the evaporating coolant and the probe nose **30** surrounding the evaporator. The probe nose consists of a material which is a good conductor of heat such as for example, silver. The probe nose **30** can be unscrewed from the probe shank and replaced by other noses appropriate in shape to the particular object of the operation. The gas produced in the evaporation of the liquid nitrogen escapes through the space **31***a* between the innermost tube **28** and the central tube **31**. The space **32***a* between the central tube **31** and the other outer shank tube **32** of the probe **16** is used for thermal insulation and is evacuated for this purpose, direct contact with the central tube **31** being prevented by suitable means such as, for example, plastics material filament spirally wound thereon. In the immediate vicinity of the evaporator **29** and the probe nose **30** there is provided a heating coil **33** to which current is supplied thereto by a wire **34** situated between the central tube **31** and the outer shank tube **32**. By means of the heating coil **33**, the probe nose **30** can be heated quickly in order to remove it again from the frozen tissue.

When using the optical system **17** during an operation the probe nose **130**, FIG. **4**, can be given such a shape that its piercing portion **130***a* is in the visible region of the optical system, whereas, the invisible portions **130***b* of the probe nose are so shaped and rounded that tissue cannot be injured.

Situated at the handle member **12** are the members for controlling the operation of the appliance, namely a switch **35** for "freezing" and a switch **36** for "thawing". When operating the "freezing" switch **35**, an electromagnetic valve, not shown, at the end of the discharge gas hose connected at **20** and upstream of the suction pump C, (FIG. **1**), is opened. As a result, gas can escape from the system and thus liquid coolant can be forced from the supply container **14**, which is kept at a pressure of about 2 atmospheres excess pressure, into the evaporator **29**, evaporated therein, and flow out through the probe shank **31***a* and the handle member **12**. When the "freezing" switch **35** is operated, an electrical heating device built into the handle member **12** is brought into operation at the same time, thus serving for heating the outflowing gas to about room temperature so that the flexibility of the high-vacuum rubber hose, not shown, connected at **20** to the handle member is not effected. There can be arranged at the handle member **12**, not shown in the drawings, telltale lamps which indicate when freezing and thawing are switched-on at **35** and **36**. It will be understood that suitable interlocking means may be provided in order to eliminate faulty switching.

For replenishment, the manual appliance **11** is attached to the replenishing device which is given the general reference numeral **50** and is shown diagrammatically in FIG. **5**, when the cover **15** is removed. Arranged on the housing **51** provided for this purpose on the replenishing device, are contact halves not shown, which match the contact half **25** on the manual appliance; electrical control lines end here, whereby the following is effected: the electromagnetic valve **53** is closed, which is arranged on the pressure-tight storage container **52**; this valve serves as a pressure-relief and outlet valve outside filling

times. At the same time, a heating resistance **54** situated in the storage container **52** is switched on. As a result some liquid nitrogen is evaporated and a slight positive pressure occurs in the storage container **52**, so that liquid nitrogen can flow into the supply container of the hand appliance **11** through the siphon pipe **55**. At the housing **51** of the replenishing device there is situated a temperature-responsive element **56** in such a position relative to the supply container of the hand appliance that when the desired degree of fullness is reached, through the agency of the temperature-sensitive element, the opening of the electromagnetic valve **53** and the switching off of the heating device **54** at the storage container **52** is initiated. The replenishing device **50** serves at the same time for depositing the manual appliance during an operation pause. The arrangement of the temperature-responsive element **56** guarantees that the hand appliance is kept constantly filled even if replenished liquid nitrogen is partly evaporated again during a relatively long pause. Finally, temperature-responsive elements **57** and **58** can be arranged at the storage container **52** to indicate appropriately the full and empty situations.

We claim:

1. Cryosurgical appliance comprising a thermally insulated probe, a handle member, a supply container attached directly to the handle member, said probe having a thermally conductive nose in which a cooling liquid is evaporated which is fed from the supply container through the thermally insulated probe and is conducted back again in the evaporated state, the supply container being attached directly to the handle member at which the probe is arranged, contact means for the operation of the probe, and indicating means for the supervision of the appliance mounted on the handle member.

2. Cryosurgical appliance according to claim **1**, in which a viewing optical system is provided interchangeably mounted on the handle member adjacent the probe.

3. Cryosurgical appliance according to claim **1**, in which a lighting device is provided arranged on the handle member adjacent a probe shank.

4. Cryosurgical appliance according to claim **1** in which a connection for a treatment shank is provided on the handle member which accommodates the probe as well as an optical system and lighting device.

5. Cryosurgical appliance according to claim **1** in which a treatment shank is provided with the probe and treatment shank arranged to be axially displaceable relatively to one another and fixable in a desired position.

6. Cryosurgical appliance according to claim **1**, in which the nose of the probe is adapted to be interchanged with noses of different shape in accordance with the object of the particular operation being carried out.

7. Cryosurgical appliance according to claim **1**, in which a viewing optical system is provided interchangeably mounted on the handle member adjacent the probe, the probe nose being shaped so that tissue will be undamaged outside the region of vision of the optical system.

8. Cryosurgical appliance according to claim **1** in which a device is provided to automatically indicate the "empty" state of the supply container.

9. Cryosurgical appliance according to claim **1** in which a device is provided to automatically indicate the "empty" state of the supply container, and in which the supply container comprises a removable cover to which a thermoelectric pickup is arranged for indicating degree of fullness which projects into the supply container, and between the cover and the container body and fixed to the handle member there are arranged contacts so that a replenishing device having an attaching device for housing the appliance when the cover is removed, and similar contact halves on the cover which lead to a thermoelectric pickup for indicating degree of fullness, which indicates the "full" state for the supply container and in which a device is provided for transferring the cooling liquid from a container into the supply container, and a device for rendering the transfer operative and inoperative, which is switched on when the operating appliance is attached to the replenishing device and is switched off by a fullness pickup at the replenishing device at "full".

10. Cryosurgical appliance according to claim **1** in which a replenishing device is provided having a coolant container which is closed in a pressure-tight manner, and a controllable valve, an electrical heat source and a replenishing device are provided for the production of the necessary replenishing pressure and which are in operative connection with an attaching device for the appliance at the replenishing device and the degree of fullness pickup of the replenishing device.

11. Cryosurgical appliance according to claim **1**, in which the jacket is provided for the supply container for thermal insulation, and in which an evacuating union is provided freely accessible when a container cover is removed.

12. Cryosurgical appliance according to claim **1** in which a cover is provided to close the supply container in pressure-tight manner, and in which a controllable pressure regulating valve is provided and a safety valve in the cover.

13. Cryosurgical appliance according to claim **1** in which an electrical heating device is provided in the handle member for heating the evaporated coolant flowing back from an evaporator to a temperature which is not harmful to the flexibility of the discharge gas hose connected to the handle member.

14. Cryosurgical appliance according to claim **1** in which a valve is provided to control the through-flow of coolant from the supply container through an evaporator to a gas outlet, the control being connected so that a handle member heating device is brought into action also when the valve is opened.

15. Cryosurgical appliance according to claim **1**, in which the supply container is designed for a capacity of about 300 $cm.^3$ of cooling liquid, adequate for a freezing time of about 8 minutes, and for producing 6 to 8 balls of ice each of about 15 mm. diameter from water at room temperature when operating with liquid nitrogen.

16. Cryosurgical appliance according to claim **1**, in which the immediate vicinity of the evaporator and the probe nose is provided with an electrical heating device for releasing the probe nose from frozen tissue.