Special Medical Technology, Ltd.

Cryosurgical System

CRYOCAUTER

SMT KCH 450A

Operating Instructions

CONTENT:

Manufacturer:

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Device classification class: .....**II a**
Device service life: .....**7 years**

1. Operating Instructions

1.1. Product: .....Cryosurgical System - CRYOCAUTER

1.2. Type Specification: .....KCH 450A - Automat

1.3. Designation:

The Cryocauter **KCH 450Automat** is designated for ambulatory and clinical applications to minimal invasive treatment of tumorous diseases in **all medical branches**. (Nevertheless also usual routine benign warts – in Dermathology for inst. - can be treated with this device.) The coolant is Liquid Nitrogen with a boiling temperature -196°C.(-321°F) KCH 450A operating temperature is automatically set on -190°C (-310°F).

1.4. Principle of Operation:

The Cryocauter KCH 450A function is based on rapid freezing of the tissue followed by slow controlled warming back to initial temperature. The patological cells are so safety damaged and the new - healthy ones grows step by step on their place.

Warnings:

1) Do not hold the pedal – Footswitch pressed if there is no Liquid Nitrogen in the Dewar vessel of the system KCH. The system could overheat the exchangers in the operating instrument and the

instrument could be damaged. Do not put any heavy objects on the pedal instead of your foot!

2) During the phase of influence of the fast electric transitional phenomena / the sets of impulses to instrument main network, the switching of the electromagnetic valve may occur in the frequency of these phenomena /sets of impulses.

This phenomenon passes away just after this external influence subsided, and the instrument completely recovers its normal functions.

This state, however, does not reduce the safety nor the usability of the instrument.

2. INSTRUMENT AND SUPPLIED BASIC ACCESSORIES

2.1. Electronic part - OVJ (electronic control unit) KCH 450A ..... 1 piece

2.2. Contact part (operating tool KNU 12 or KNC 12 and/or KNC 8) ..... 1 piece

2.3. Contact part (operating apparatus, i.e. corpus with reservoir) ..... 1 piece

2.4. Pneumatic foot-operated switch ..... 1 piece

2.5. Set of basic operating probes (tips) SET 5 (surgical set) :

- 2.5.1. Finger shaped operating probe with shield, diam. 5 mm . 1 piece
- 2.5.2. Conical operating probe, diam. 4 mm ..... 1 piece
- 2.5.3. Flat operating probe, diam. 12 mm ..... 1 piece
- 2.5.4. Flat operating probe, diam. 20 mm ..... 1 piece
- 2.5.5. Conical tubular operating probe I, diam. 4 mm ..... 1 piece
- 2.5.6. Conical tubular operating probe II, diam. 6 mm ..... 1 piece
- 2.5.7. Hemispherical operating probe, diam. 12 mm ..... 1 piece
- 2.5.8. Bevelled operating probe, diam. 12 mm, sloping edge to the right, left, down or up..... 4 pieces
- 2.5.9. Pointed (forked) operating probe, diam. 12 mm..... 1 piece

2.6. Liquid nitrogen withdrawal device PIPE 1 and/or UPZ 1 ..... 1 piece

2.7. Operating apparatus holder - Plastic STAND type 3 or 4 ..... 1 piece

2.8. Transport package:

2.8.1. Special box with padding that protects the electronic part1 piece
2.8.2. Special transport suitcase for the apparatus, tool, operating probes and accessories..... 1 piece

2.9. Operating Instructions

2.10. The Indemnity Agreement

2.11. End User Registration Card

2.12. SUPPLIED ADDITIONAL ACCESSORIES (to special order):

The instrument can be furnished with extra sets of Operating probes supplied to special order:
The set of operating probes for gynaecology SAD 6, containing. 6 pieces.
The set of operating probes for dermatology SAD 8, containing 12 pieces.
The set of operating probes for ophthalmology SAD 9, containing.....
..... 6 pieces.
The set of special shank operating probes SAD 16, containing... 6 pieces.
The set of special - oncological - operating probes SAD 15, containing....
..... 6 pieces.
The detailed information about accessories for working with liquid nitrogen are listed in firm catalogue.
The system can be furnished with the external Liquid Nitrogen Container 7, 20 or 32

3. TECHNICAL DESCRIPTION

3.1. The electronic part of the system KCH 450A is an automatic control unit that ensures the safe automatic operation of all operational functions and the continuous evaluation of the temperature and pressure data. The basic data are clearly arranged on the panel display. The control unit is installed in a box made of resistant insulating plastics. The switch is pneumatic, foot-operated, without any electric parts. So the highest safety is ensured.

The indicators on the front panel indicate (from the left): The level of nitrogen reserves, pressure of the nitrogen in reservoir, operational temperature, and cooling time. Everything is operated automatically after pressing-down the foot-operated switch (and after filling the

system up with liquid nitrogen). Thus, the extent of cryodestruction is given by the automatically adjusted OPTIMAL PARAMETERS and by the TIME PERIOD of pressing the switch, which is operated by a physician. There are also a shortened Operating Manual and the pictures and realistic curves of typical cryosurgical uses on the front panel.

On the rear panel, there is a coupler plug of power cord, power-supply switch, plug contact for the operating instrument, screw-coupling for the connection of foot-operated switch, and a label with technical data and a serial number.

3.2. The contact part (surgical apparatus) consists of a surgical tool (upper part) and a reservoir of liquid nitrogen with a handpiece (lower part). The clothing of the surgical tool and the clothing of the reservoir are evacuated and vacuum-tight sealed. The liquid nitrogen in the reservoir is under weak overpressure of 45 kPa, that is held by a valve inbuilt in the body of the surgical instrument. The liquid nitrogen level is measured by three level indicators. The winding, that serves to possible warming of the reservoir content and thereby reaching operational pressure, is at the butt-end of the tube through which the liquid nitrogen is driven out to the surgical tool and tip. After pressing-down the foot switch that opens the electromagnetic valve, liquid nitrogen passes into the heat exchanger in applicator, which is in the end of the surgical tool, and cools down the operating probe screwed on its end. The gaseous nitrogen passes through the heater of leaving gas and it is given off quite notelessly to atmosphere. Thanks to an exceptional efficiency of the heat exchanger in the instrument KCH 450A, the volume of this gas is so small, that no special precaution is required.

3.3. The foot-operated switch is pneumatic. There are not any electric parts, so the operation is entirely safe. The pneumatic chamber inside the electronic part transmits the opening of the electromagnetic valve in operating apparatus when the foot switch is pressed down.

3.4. The operating probes are active (the tool KNU 12 only) and passive (others). The active probes are equipped with the own heat exchanger. This enables a considerable enhancement of the cold conduction to the contact with tissue. This advantage is useful particularly when applying the probes of larger diameters, 20 - 30 mm. The active probes can be used only with the universal instrument, marked KNU 12. The passive probes allow conducting cold generated

in the applicator to tissue. These probes are supplied in the number of designs, that differ in shape of the tool face and in the size. This makes it possible to choose such a type, that attaches efficiently the treated tissue.

4. BASIC TECHNICAL SPECIFICATIONS

The operating system KCH 450A consists of an operating apparatus with surgical tool that ends in operating probes and an electronic unit that has indicator and control functions. These two basic parts are attached by a flexible cable.

4.1. Electronic Part

Dimensions.....height 80 mm, width 290 mm, depth 250 mm
Weight.....3,5 kg
Power requirements.....230 V 50 (60) Hz
Power supply transformer .....TRONIC 9804413 160 VA
Insulation ..... instrument class II
Operation.....uninterrupted
Degree of moisture-proof enclosure ..... IP 21

Cautions of necessity to observe safety regulations when working with liquid nitrogen, specified in the Operating Instructions

The contact part..... type B

4.2. Contact Part - Basic Operating Tool KNC 12 or KNU 12

Dimensions.....height 265 mm, width 20 mm, length 370 mm
Weight.....0.2 kg
Working diameter ..... 12 mm
Insulation .....vacuum

-.Operating Tool KNC 8

Dimensions.....height 265 mm, width 20 mm, length 450 mm
Weight.....0.2 kg
Working diameter ..... 8 mm
Insulation .....vacuum

4.3. Contact Part - Apparatus with Handle and Reservoir

Dimensions.....height 280 mm, width 150 mm, depth 90 mm
Weight.....1 kg

Container capacity ..... 400 and/or 300 ml
Freezing medium ..... liquid nitrogen LN2
Operating temperature ..... -190°C (-310°F)
Working pressure ..... 45 kPa
Heating ..... heater winding - Manganin conductor,
..... diam. 0.1 mm,
..... braided with cotton,
..... length 350 mm
Insulation ..... vacuum

4.4. Pneumatic Foot-Operated Switch (without any electric parts)

Dimensions ..... diam. 110 mm, length of coupling hose 3 m
Weight ..... 0.25 kg

5. SELF-CONTAINED OPERATING APPARATUS (Contact part)

The operating apparatus consists of the dismountable surgical tool, the vertical part of which is immersed in the reservoir with liquid nitrogen. The neck of the reservoir goes through the handpiece of apparatus. The clothing of the surgical tool and the clothing of the reservoir are sucked and vacuum sealed by the suction adapters (the adapter on surgical instrument is placed from under of the front part of the widen horizontal tube, the adapter on reservoir is placed on the conical upper cover just beside the filling hole cap). The screw in each of these suction adapters is tightened by the manufacturer and it must not be loosened or turned. (It can be loosened only by a trained technician, who can re-suck and reseal the instrument or the reservoir by a vacuum pump and a special pumping connecting adapter).

The pressure of liquid nitrogen in reservoir is automatically held at moderate atmospheric pressure 45 kPa (0,45 atmosphere), so, after the electromagnetic valve opens, the liquid coolant gets in the inner tubule of the surgical tool, and proceeds through this tubule to the heat exchanger in applicator (cylindrical front part of the surgical tool). This heat exchanger is a constituent part of surgical tool, with the efficiency exceeding 95 %, that allows reaching the temperature drop on the applicator surface extremely fast, even in the case, when the applicator, including operating probe, is fully immersed in the tumorous tissue. In such case the applicator reaches the cooling power output 200 watts

and cools itself down to the required operational temperature (e.g. -190° C [-310°F]) within 10-25 seconds. Then, the gaseous nitrogen goes away through the tube of the tool into the widen part. There is an analogical, but larger heat exchanger. The electric heating automatically heats this exchanger to such temperature that holds the gas passing along to the electromagnetic regulation valve at room temperature.

The operating apparatus is fastened to the reservoir and to the handpiece by a cap nut, that secures the thrust of the gas-tight connections onto rubber packing. The liquid nitrogen is poured into the reservoir by a filling neck, which is on the upper part of conical reservoir and is closed by a closure cap.

The electric connection of operating tool with the lower part of the apparatus is arranged by the jack plugged in the rear face of the tool. The whole operating apparatus is connected up with indicator and control functions of the electronic unit by the insertion of the connector (at the end connection cable) in the corresponding coupler socket on the right edge of the electronic unit rear panel. Diameter of the operating tool base version is 12 mm. The surgeon, who performs the operative intervention, can choose from additional accessories of operating tool - i.e. from the set of operating probes. These probes can be attached to the applicator by the right-hand thread. Each of these probes should adapt the shape of the applicator in such a way, that it allows reaching the best possible contact with the treated locality. You must realize, however, that such probe creates some thermal resistance between the tissue and the applicator, and the temperature gradient is formed on it during an actual operation. It follows from thermodynamics that with the increasing heat flow on some resistance, value of which remains invariable, the temperature gradient grows. As the heat flow grows with the growing difference in temperatures on the thermal resistance, then, it is possible to say, that the lower temperature applied for the cryosurgery operation, the bigger temperature gradient on the probe. Nevertheless, it is important to realize, that at a given value of the thermal resistance (i.e. for a particular operating probe) and at a given initial temperature of operated tissue, the lowermost temperature of the operating probe in the steady state is reached only then, when the temperature of applicator is the lowest possible - that is, in the concrete case of the system cooled down by liquid nitrogen, this temperature approaches to -196°C (-321°F) (the boiling point of liquid nitrogen at atmospheric pressure). At the same time you must consider that at an adjusted temperature of the operation only the applicator can

reach this temperature (i.e. the cylindrical front part of the operating tube). So that, at a given adjusted temperature of the applicator, the less heat flow on the operating probe (that is the less contact surface with tissue), the closer surface temperature of operating probe to the temperature of the applicator.

A characteristic feature of the applicator in the existing shape is that its temperature in a steady state corresponds to the adjusted temperature practically every time and it is independent of the area of the contact surface with cured tissue (the cooling power output of the applicator is automatically controlled and the operating temperature on the applicator surface is held invariable). However, when applying operating probes, it is necessary to consider that the temperature of an operating probe at an adjusted (e.g. the lowest possible) temperature of the applicator differs from this adjusted temperature (is warmer). The larger surface of the operating probe is applied in surgical operation, the bigger difference in temperatures this is. From this follows, that the large diameter operating probes are applicable to shallow cryotherapeutical operations (e.g. circular probe diameter 20 mm), while the fork or sharp conical operating probes are applicable to deep cryodestruction, where it is necessary to stick the probe into the tumorous tissue and at the same time to start the cryotherapeutical intervention.

6. OPERATION OF ELECTRONIC UNIT DURING SURGICAL INTERVENTION

Successive steps of system connection:

a/ Plug the electric cord in the main network socket 220-230 V/50Hz and in the connector on the rear panel of electronic unit, right down.

b/ Plug the elongated connector of the connection cable that connects electronic unit with operating apparatus in the connector on the rear panel, left. Attach the pneumatic foot-operated switch in the screw-coupling on the rear panel, left.

c/ Switch the instrument on by the power switch button on the rear panel, right up.

d/ Fill the reservoir with liquid nitrogen up to the required level. The level indicator shows three heights of liquid nitrogen surface (the first indicator on the front left).

e/ After closing the cover of reservoir, pressure inside starts rising. When the pressure light signal lights up (the second indicator on

the front panel left), the needed working pressure is reached, and the apparatus is ready to operate.

f/ Then, screw chosen operating probe (tip) on the applicator.

The most efficient is the lowest possible temperature. The cryosurgery apparatus KCH 450A sets up this temperature automatically on -190°C (-310°F). Centigrade (the third indicator on the front panel from left) and the actual operation is controlled by the time period of application.

7. FILLING LIQUID NITROGEN RESERVOIR IN OPERATING APPARATUS

7.1. The most simple way of filling is to bring liquid nitrogen from another place of the hospital directly in the withdrawal device PRE 68. The filling of the operating apparatus (the instrument reservoir) see in 7.3.

7.2. The comfortable filling of the reservoir with coolant is possible by using Special withdrawal pump PIPE 1, supplied by the manufacturer on special order. This transfer equipment is hermetically attached to a newly delivered vessel (Container) of liquid nitrogen simply by screwing it on. After reaching required pressure, it is continuously ready to filling as long as any liquid nitrogen is in the vessel. If you press down the head of the PIPE 1, liquid nitrogen flows out, if you release it, the filling stops.

If this original withdrawal equipment PIPE 1 is not at disposal, you can use a Discharger and the withdrawal device PRE 68 for pouring liquid nitrogen over.

7.3. Filling with Discharger and the withdrawal device PRE 68

Insert the discharger slowly into stationary vessel of liquid nitrogen (Dewar flask) and screw the holding-down nut on its neck. Insert the air pipe tip of the foot-operated inflater into the opening above the neck of the vessel and displace the ring of the lower horizontal cylindrical part of the discharger in such a way, that it covers the outlet hole of evaporated gas. Put the transport stainless steel bowl PRE 68 with polystyrene lining (alternatively another polystyrene or vacuum insulated stainless steel container) under the discharge tube of the discharger. Then slowly press-down the foot operated inflater. Liquid nitrogen starts discharging out to the bottom of the container (where it

gasifies and goes out along the filling pipe of the discharger; atmospheric moisture condenses on the cold gas and forms mist). But after several tens of seconds, polystyrene lining of the bowl cools down and the level of liquid nitrogen in bowl starts rising. Pump till the transport container PRE 68 is filled up. After that remove the cover of the enclosure of operating instrument, close the transport container with the lid (after the insertion of packing), and insert its discharge pipe into the filling opening of the cryosurgery instrument. Then close tightly the opening in the plastic head of stainless steel transport container by hand. The content of the container discharges into the instrument reservoir.

The filling is usually finished after the third (upper-most) signal light of the level indicator goes off. This allows to work in the cooling operating mode for the time period of about 15 up to 30 minutes. The volume of the original transport container is just equal to one complete refilling of the instrument.

7.4. Filling with Funnel

If you have only a usual polystyrene bowl and a funnel, specially intended to this application, insert the funnel into the reservoir of operating apparatus. Pour slowly the liquid nitrogen over from the polystyrene bowl by the help of the funnel into the reservoir till the liquid nitrogen level reaches the required height - the upper-most signal light of the level indicator on panel goes off. When the filling is over, screw on and tighten carefully the cover of the filling neck and wait till the system reaches working overpressure (several seconds). Surgeon is informed about the volume of remaining liquid nitrogen in reservoir as follows: If the upper-most light signal of the liquid nitrogen level indicator lights up, it means that a quarter of the liquid nitrogen volume of initially full reservoir was consumed; if the middle light signal lights up, one half of liquid nitrogen was consumed; if the lowest light signal lights up (that is all three light signals are on) the rest of liquid nitrogen in reservoir is sufficient just for three to four minutes of operation. These specifications are valid if the operating instrument is at least 15 seconds in such position that the angle of deviation of operating tube from the horizontal position is less than plus minus 30°. The technique of refilling the reservoir is the same as at the first filling, but from the very beginning it can be done more quickly than in the case, when the reservoir has not been cooled down yet.

8. NOTES ON USE

The cryocauter is not designed for the work in the environment of combustible anaesthetic agents.

Refrigeration and Rewarming Modes

As mentioned in the introduction, the maximal therapeutical effect is achieved in any part of the tissue only then, when cooling down to the temperature below -25°C is the quickest possible, but the subsequent rewarming is very slow. That is the reason why you must pay the close attention to the selection of an operating probe and to its tightening up with the applicator (the thread on the applicator is mostly made of pure silver, so you must pay the attention to it, that the operating probe axis is parallel with the applicator axis when screwing them on, that there is not even a tiny impurity between the conical surfaces of the applicator and the probe, and that you do the final tightening very gently by free hand, in order not to distort the relatively soft thread). If possible, prefer the direct contact between the tissue and the applicator because only the applicator surface can reach the lowest temperature. During the phase of rewarming, do not hasten the detachment of the tool from the tissue to avoid any injury of the tissue and subsequent bleeding. The temperature delay in the contact zone between operating probe and the tissue versus the indication of the applicator temperature on panel is caused partly by thermal resistance of the operating probe (the temperature of the applicator is measured on its surface, not on the surface of operating probe), and partly by the heat capacity of the frozen tissue (the operating probe is cooled down from the heat capacity of the total volume of frozen tissue relatively long time during rewarming phase).

The Problem of Heat Contact

You must arrange for the optimal heat contact between the applicator and the largest possible area of the operated tissue, in order to reach the maximal cooling rate in a certain locality of tissue. Some larger volumes (in particular if deeper layers of tissue are involved) can be operated from inside, i.e. by the application of inserted operating probes, e.g. a sharp conical probe that enables even the insertion of the applicator. In case when you use the contact operating probes, it is necessary:

a/ to apply the operating probe to tissue without its cooling down previously, and only after assuring good heat contact, to start cooling down (applying already cooled down tool to tissue is not effective as during the cooling period the atmospheric moisture condenses and freezes on its surface; this might create additional thermal resistance between the tissue and the applicator).

b/ to see to it that the surface of operating probe copies and follows the surface of the operated tissue, and that these contact surfaces are parallel.

c/ to press the operating probe against the tissue to ensure the best possible contact.

d/ in case of some unevenness of the tissue surface, that cannot be copied and followed by any probe, you must use sterile vaseline or gel in order to get better heat transfer.

If an undesirable separation of the tool from the tissue happens during a surgical operation (e.g. by the loss of adhesive power with the subsequent lateral pressure on the tool), first, you must wait till the tissue and the tool entirely thaw out, and only after that it is possible to renew the heat contact. In practice, renewing any good heat contact between two hard surfaces that are not entirely even and smooth is not possible. That is why you must unconditionally wait till the tissue completely thaws out when performing two- or multi- times repeated surgical intervention on the same locality.

Adhesive Power Effect

The phenomenon of the firm adhesion of operating probe surface to the tissue surface occurs at low temperatures, but disappears at the moment when the temperature of the cold object drops below -80°C. The dry tissue that contacts the overcooled surface (temperature lower than -80°C) loses its adhesive power to it. This may result in the detachment of the tool from the operated locality, even at a negligible lateral pressure to this contact locality. Therefore it is important to keep the operating instrument still during the cryosurgery intervention (and of course patient must be still too).

The Danger of Breaking Frozen Tissue

When using inserted operating probes (but also at the application of contact operating probes as far as the adhesive power is effective), you

must avoid any torque in the contact locality between tissue and cryocauter (eliminate any wrench, even slight). The frozen tissue is very fragile. In case of any „break“, profuse bleeding may occur after thawing out.

Homeostatic Effect

There is no reason to be afraid of any profuse bleeding after intervention if the tissue is not traumatized (e.g. by above mentioned technique). It is caused by the vascular stasis, thrombotic closure of minute capillaries, while main vessels remain intact. The profuse bleeding (in particular arterial) stops as long as the operated locality is frozen down. During its thawing out, bleeding occurs - at the beginning only oozing, but then it comes back to the initial intensity. Only during antiseptic inflammation and formation of total coagulative necrosis the locality of cryosurgery intervention becomes in most cases avascular and during incision does not occur any bleeding.

Analgesic Effect

Cryosurgery interventions performed at the high rate of cooling are actually painless. This consists in the functional lesion of sensitive nerve cells by coolness. Only during the phase of thawing out, the mild burning or some similar sensation can occur in the locality of intervention. But this usually disappears after several minutes. That is why, in many cases, it is possible not to dose any local anaesthetic before a cryosurgery intervention. A patient can sometimes feel more intensive pain during freezing some cornified formations e.g. verrucae, because the hard formation cannot be easily put in good contact with the metallic probe and then the freezing phase is much slower.

Effect of Demarcation

During a cryosurgery intervention performed at the locality under visual control you can observe the growth of an icy formation in the contact area of the cryocauter with the tissue. You must calculate with it, that the boundary-line of this clearly seen white area corresponds to null isotherm (a line connecting the points having the same temperature 0°C), and not to the isotherm of necrosis (it is generally -25°C isotherm), which is always shifted inside the icy area. If only a rough estimation is sufficient, then it can be presumed that the distance of the surface of the -25°C isotherm under the contact surface of operating probe with the tissue is situated approximately in the 4/5 of the distance of the icy boundary-line from the contact surface of operating probe.

This means, that the depth of the real congelation is about 20 % smaller than the spread of the icy border-line.

Precautions Taken to Secure Operating Apparatus Safety

The delicate porous medium of the heat exchangers must be attentively protected from any contamination and from the condensation of moisture, which might be sources of the limitation of the heat exchangers clearness, and by that the consecutive reduction of the efficiency of the operating instrument, or, perhaps, even its temporary putting out of operation. The contamination of heat exchangers can be prevented by the consistent re-filling of reservoir through a fine filter screen (such filter screen is in the transfer pump PIPE 1 and it is also placed in the reduced metallic part of the discharger). It is necessary to clean it out periodically. (Liquid nitrogen may contain particles of impurities or some drops of frozen oil.) The same attention must be given to the sieve screwed on the bottom inlet to operating instrument. You must prevent any penetration of moisture or even water (or another liquid substance) into the operating instrument or into the reservoir of liquid nitrogen. Failing this, the inlet of liquid nitrogen would cause entire freeze-up of the instrument in presence of such substances after starting operation. This relates also to the too early dismantling of operating instrument from reservoir, before its parts get rewarmed back to temperature above zero. In such case, the cold metallic surfaces exposed to atmosphere freeze out the atmospheric moisture and get covered with ice. The danger, mentioned above, impends if this moisture does not evaporate till the next cooling of the instrument. If the cryosurgery apparatus is installed in a health-service, then, after finishing an entire operation programme, it is optimum to leave the system in the state it was in after the last operation and disconnect it only (of course after its cleaning and appropriate surface disinfecting).

9. THE PRINCIPLES OF SAFE MANIPULATING LIQUID NITROGEN

It is important to realize that one litre of liquid nitrogen produces almost thousand times larger volume of gas. This means that a considerable volume of gas arises by warming-up liquid nitrogen, and this gas must escape. That is why the stationary container of liquid nitrogen (Dewar vessel) must be closed with the perforated stopper that is supplied by the manufacturer (unless the convenient transfer pump

PIPE 1 is installed there). The entire closure of the filling neck with e.g. rubber stopper could result even in its dangerous „shooting off“. The filling neck must be covered with the supplied cap that does not allow the moisture to enter the vessel (which would condense and freeze out inside). Design of the stationary container does not allow tilting, that would facilitate to pour the liquid out (e.g. into a polystyrene bowl). The inner vessel is surrounded by a vacuum covering and is hanged on the long thin-walled filling neck that could break off at tilting the vessel, what might be followed by an explosion and a possible injury of the operator. The staff that manipulate the operating reservoir and the stationary container must be trained in observing the rules of the safe manipulating liquid gases, and must pass the examination to prove thus gained knowledge (e.g. the Czech Standards CSN 69 00 10, 69 00 12, 07 83 05 and CSN 07 85 09). The fundamental rule at manipulating such liquid gases is that at least two trained persons must do this work together. Let´s mention only one of possible dangers as an example - i.e. asphyxia - an insufficient supply of oxygen to the body. This might happen by e.g. the evaporation of a larger amount of liquid nitrogen in an unventilated room, resulting in the decrease in the atmospheric oxygen concentration. The critical limit of oxygen concentration is about 13 %, but this greatly depends on the loading of the organism. If the concentration of the oxygen in atmosphere decreases slowly, the symptoms of difficult breathing can be covered up by euphoria. This offers the false feelings of safety to victims, and by that hinders their instinct of self-preservation. Therefore, you must see to it that there is a good ventilation in room where you work with the cryosurgery instrument and in rooms where liquid nitrogen is kept. To specify better the danger vs. the quantity of evaporated nitrogen, we can say that the fluent evaporation of five litres of liquid nitrogen within 12 hours in a room with the ventilation at intervals is entirely harmless. Burning the tissue with liquid nitrogen is very dangerous as well, particularly by contacting fabric soaked with liquid nitrogen, or, if liquid nitrogen gets into e.g. shoes. Also any contact of liquid nitrogen with the ring, that is on finger and gets cold very quickly, causes the injury comparable to burning. On the contrary a short-time contact of liquid nitrogen with the tissue is not dangerous because a gas cushion with a very low thermal conductivity is formed on the tissue and the liquid cannot wet it directly. However, the sensitive organs, e.g. eyes, can be injured even at very momentary contact with a drop of liquid nitrogen; therefore, it is advisable to use transparent eye shield when working with liquid nitrogen. You must avoid any contact with metallic under-cooled parts

(e.g. the cryocauter applicator during operation), where, in case of some faster holding, the skin freezes onto the surface of such under-cooled parts instantly, and, at an attempt to tear it off, you might suffer even a deeper injury.

If one uses e.g. a polystyrene bowl for pouring liquid nitrogen over, this liquid must never stay in it longer than several minutes. The concentration of oxygen there increases by condensation of atmospheric oxygen (oxygen condenses at higher temperature than the boiling point of liquid nitrogen), and in an extreme case this liquid may become explosive, in particular when in contact with some organic substances, such as oil or some other grease. Liquid nitrogen is entirely transparent liquid. By the condensation of the atmospheric oxygen it gets gradually bluish tone, which signalizes the higher concentration of oxygen.

10. STERILIZATION AND DISINFECTION

To keep the operating system on operational standby and for its disinfection and sterilization, it is necessary to divide the instrument into four parts:

1. The electronic part. Its maintenance is the same as the maintenance of other instruments in operating room that are not directly applied in an operation.
2. The operating apparatus. The handpiece with the reservoir of liquid nitrogen.
3. The operation tool.
4. The operating probes (tips).

There are several factors that influence the selection of sterilization and disinfection techniques which are used for the maintenance of operating tool and operating probes. Firstly, it is necessary to respect the materials they are made of. Secondly, one must also take into account the number of operating interventions performed with one operating apparatus, with one tool, and with one set of operating probes during one operation programme.

The sterilization of operating probes can be done by any techniques.

However, the classical methods of sterilization, such as autoclave or hot air, are not acceptable either for the tool or for the apparatus because they use too high temperatures. The technique that satisfies these requirements is that one with ETOXEN - the ethyl oxide. This microbicide gas is effective at relatively low temperatures and practically normal pressure. It is efficient for all used materials.

However, its great disadvantage is the long time period needed for the degasification of objects after sterilization (minimum 48 hours). Another technique that uses the high energy electromagnetic radiation at minimal dose 2.5 Mrad is also commendable, however, it is extremely time-consuming. This makes its application practically impossible, in particular at the scheduled repeated use of the instrument.

The sterilization by formaldehyde proved to be a suitable method for the clinical operation of the cryosurgery instrument, but only at observing certain conditions - such as sealing all the openings on the instrument or tool. (The active operating probes must be sealed before starting sterilization as well.)

These are the reasons why to apply new methods of disinfection, in particular those with the short time of exposure and with the high bacteriostatic activity. But one must always remember that even the best disinfection cannot entirely replace the sterilization, and in cases when the nature of operation requires highly sterile environment, we cannot do without above mentioned techniques of sterilization.

Before disinfection, it is important to insist on the thorough cleaning of the complete apparatus and operating probes. A usual detergent is recommendable. Recently, it has been recommended to apply a detergent in combination with a disinfecting agent at strict observing directions about dilution. One must see to it that the solution of detergent does not get into any opening on the instrument; otherwise liquid nitrogen could cause formation of icy plugs and that way make its functioning impossible during the next operation of the instrument. In order to prevent the penetration of the washing detergent solution under the shields of the instrument and by that to its electric components, you must wipe the lower part of the operating tool, especially its upper section, only with a damp gauze. The sterilization by formaldehyde proved to be a suitable method for the clinical operation of instrument, especially for the operating tool, alternatively for the operating apparatus (handpiece with reservoir) including tool.

11. THE FULFILMENT OF LEGISLATIVE REQUIREMENTS

The conformity was reviewed with the product.

The manufacturer declares at its own responsibility exclusively that the product fulfils basic requirements stated in Annex 1 of Regulations of the Czech Government No. 336/2004 Coll. (93/42/EEC) in the relevant valid readings.

For the review were used these harmonised standards in a valid reading:

EN ISO 13485
EN 60601-1
EN 60601-1-2

The examination of the conformity was carried out in participation of the Authoritative person – Notified Body No. 1014.

The Manufacturer issued a Declaration of Conformity on this matter.

12. PREVENTATIVE INSPECTIONS

The end user must see to it that the preventative inspections of the cryosurgery system are performed minimum bi-yearly by the manufacturer or his service agent. The manufacturer supplies the system in two special transport boxes: one is for the electronic part, the other is for the operating apparatus and accessories (contact parts). These boxes should be used for dispatching cryosurgery system to preventative inspections. They are labelled with the caution mark and notice „BREAKABLE“.

13. INSTRUCTIONS FOR THE REALIZATION OF GUARANTEE REPAIR

Forward or transport personally the cryosurgery instrument, duly packed in original transport boxes (see above), with the enclosed Indemnity Agreement and description of the failure, to the address of manufacturer, or, after the previous telephonic or written agreement with the manufacturer, to the address of the nearest relevant service organization.

INDEMNITY AGREEMENT

Product: CRYOCAUTER KCH 450A

Serial number:

Date of sale:

Stamp and signature of expedition:

Guarantee Conditions:

a) At observing Operating Instructions the manufacturer guarantees that the product shall have characteristics assessed by the relevant technical conditions and standards for the duration of 24 months from the date of sale.

b) In case of failure in function of the product within the guarantee period, not caused by the end user or by an inevitable event, the product will be repaired free of charge.

c) The free of charge repair within the guarantee period will be done by an accredited service or by the manufacturer, whose address is in heading, after the presentation of the Indemnity Agreement.

d) The guarantee period shall be extended for a term of the guarantee repair.

e) The Indemnity Agreement is at the same time „The Certificate of the Quality and Completeness of the Product“.

RECORDS OF REPAIRS

Date of reception:

Description of malfunction:

Completion date:

Signature and stamp of the service

Date of reception:

Description of malfunction:

Completion date:

Signature and stamp of the service

Date of reception:

Description of malfunction:

Completion date:

Signature and stamp of the service

Date of reception:

Description of malfunction:

Completion date:

Signature and stamp of the service

Date of reception:

Description of malfunction:

Completion date:

Signature and stamp of the service

END USER REGISTRATION CARD

PRODUCT: CRYOCAUTER KCH 450A

Serial number:

Sales clerk:

User:

Name:

Organization:

Address:

Telephone: Fax:

Herewith I confirm that I have got acquainted with the Operating Instructions and with the Guarantee Conditions and I will observe them.

Date:

Signature:

Dear customers,

will you tear this registration card out and forward it to the address: SMT Ltd., Papírenská 114/5, 160 00 Prague 6, Czech Republic, EU.

The objective of this registration is, partly, to improve the quality of services our firm offers to its customers, and, partly, to observe strict requirements of standards ISO 13485:2003 that our firm conforms and that the user of medical technology must be acquainted with.

In the next 3-9 months we will contact you again and will ask you for the filling of another our form (blank) - the “Feed Back”- which will be, thanks to your special opinions, a very good base for further development of our products. Thank you in advance for your kind cooperation.

Yours,
Special Medical Technology, Co.

Specialni Medicinska Technologie, s.r.o.
/Special Medical Technology, Ltd./

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