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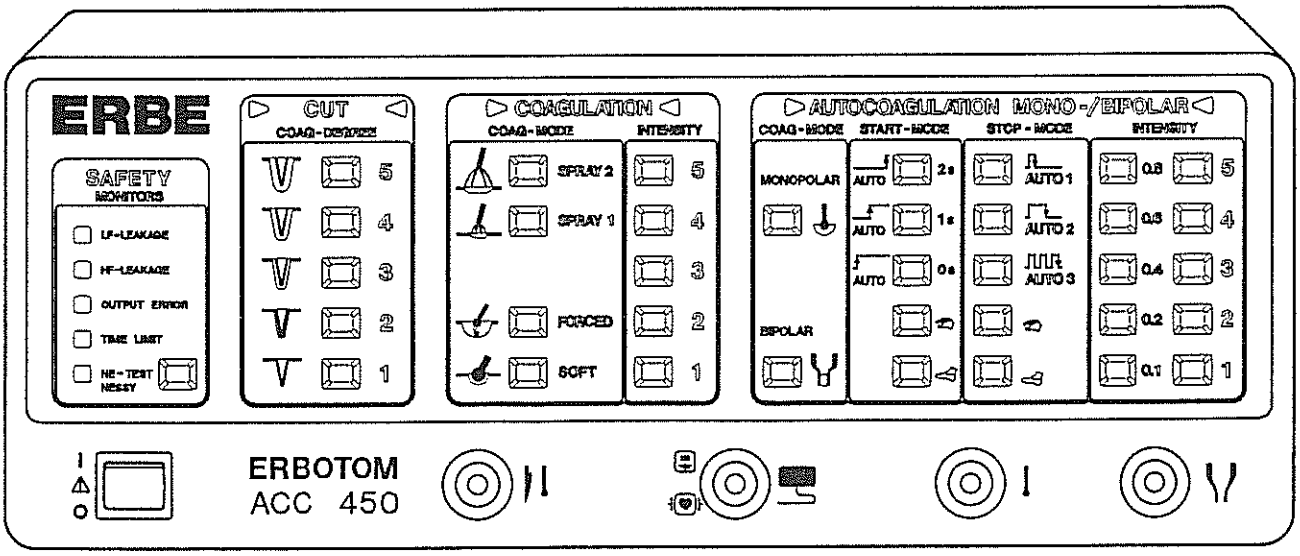

Operating Instructions

ERBOTOM ACC 450

Edition 10.90

Operating Instructions

for the HF Surgical Unit

ERBOTOM ACC 450

ERBE electromedical equipment

Printed in West-Germany

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CONTENTS

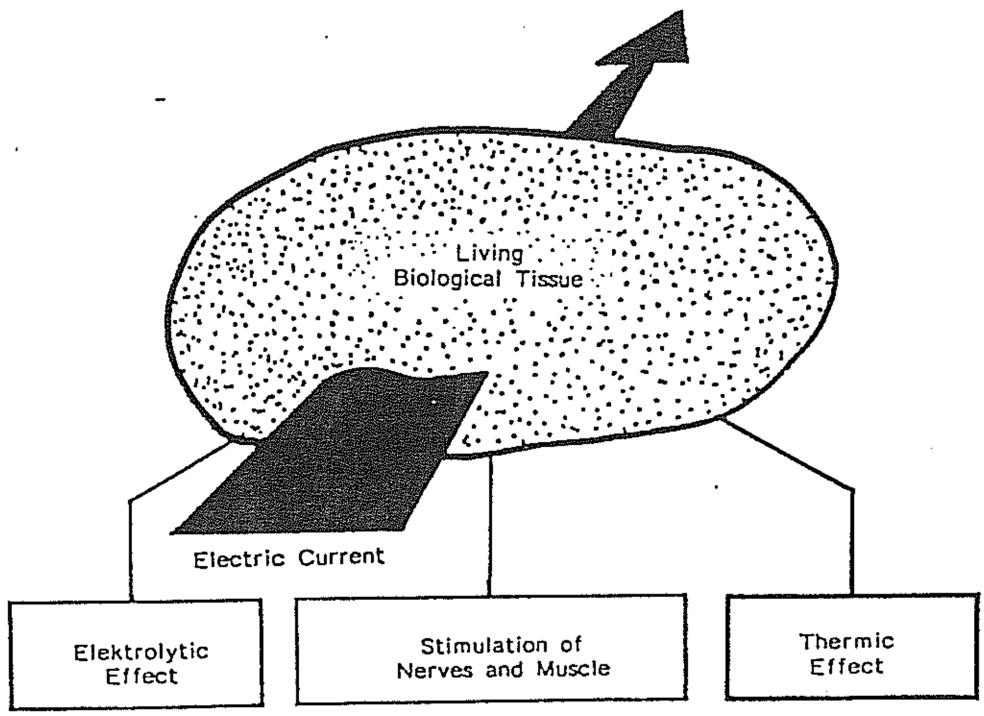
PRINCIPLES OF HIGH FREQUENCY SURGERY

High frequency surgery has been in use for more than 50 years for cutting and/or coagulation of biological tissue, and has become a firmly established operating technique in almost all surgical disciplines. Some surgical indications, such as transurethral resection (TUR), endoscopic polypectomy and papillotomy, are predominantly based on the use of HF surgery.

The different surgical disciplines place different demands on high frequency surgery. To meet the demands of the individual case, the surgeon not only has to select the suitable HF surgical equipment and instruments, but also to familiarize himself with the principles of HF surgery and its applications. **This chapter is intended to familiarize the surgeon with the principles of HF surgery.**

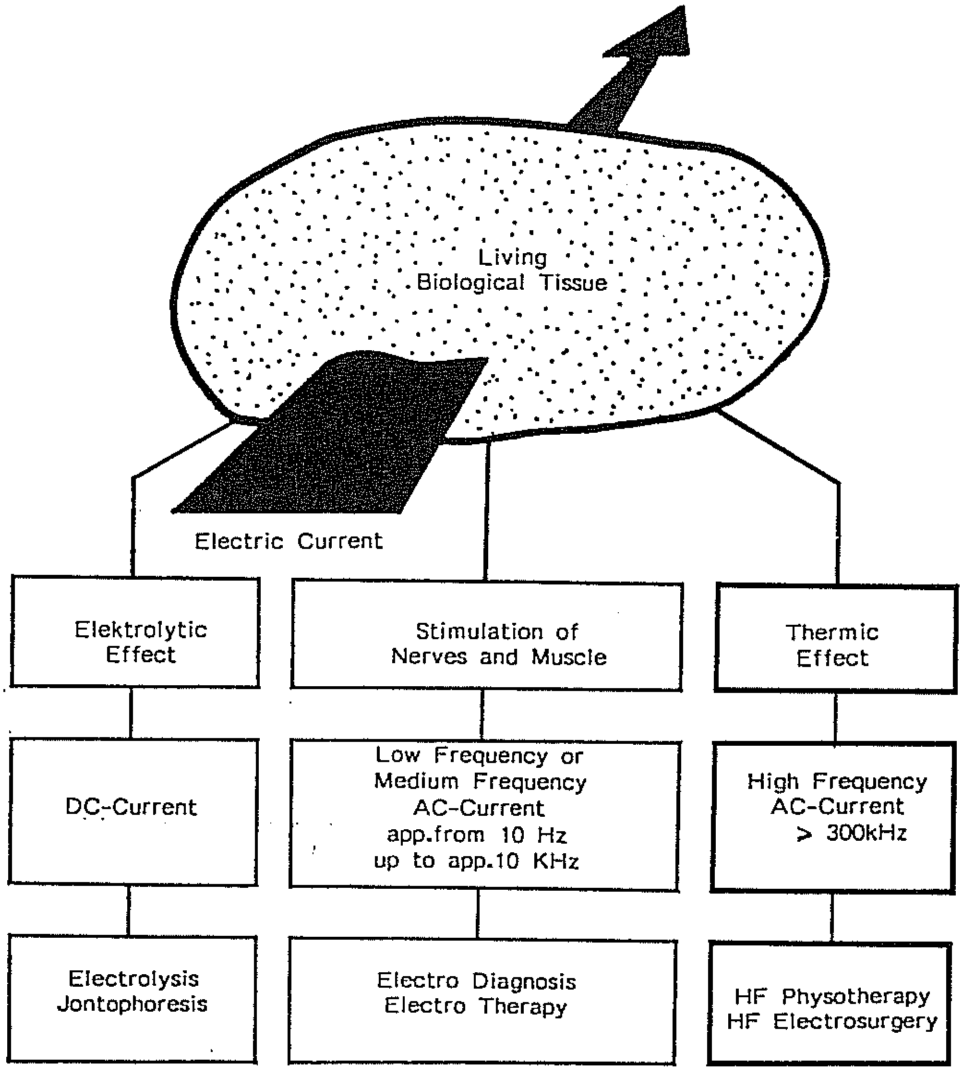
Endogenous effects of electrical current in living biological tissue

Biological tissues are to a greater or lesser extent electrically conductive, depending on their electrolyte content. If electric current flows through a living tissue, three qualitatively different endogenous effects can be observed.



Which one of these effects is dominant depends not only on the type of tissue (muscle, nerve, fat, bone etc.), but also on the quality and intensity of the electric current flowing through that tissue type.

The electrolytic effect is dominant by direct current and low-frequency alternating currents.
The irritation effect on nerves and muscles is dominant by low- and medium-frequency alternating currents or pulsed currents .
The thermal effect is dominant by high-frequency alternating currents.



HF surgery utilizes the thermal effect, which the electric current produces endogenously in tissue, for selective destruction of tissue, while avoiding the undesirable electrolytic and irritation effects on nerves and muscles by using alternating currents with a frequency of a minimum of 300 kHz.

Utilization of the thermal effects in HF surgery

CUTTING

Biological tissue can only be cut when the voltage between the cutting electrode and the tissue to be cut is sufficiently high to produce electric arcs between the cutting electrode and the tissue, effectively concentrating the high-frequency electric current onto specific points of the tissue.

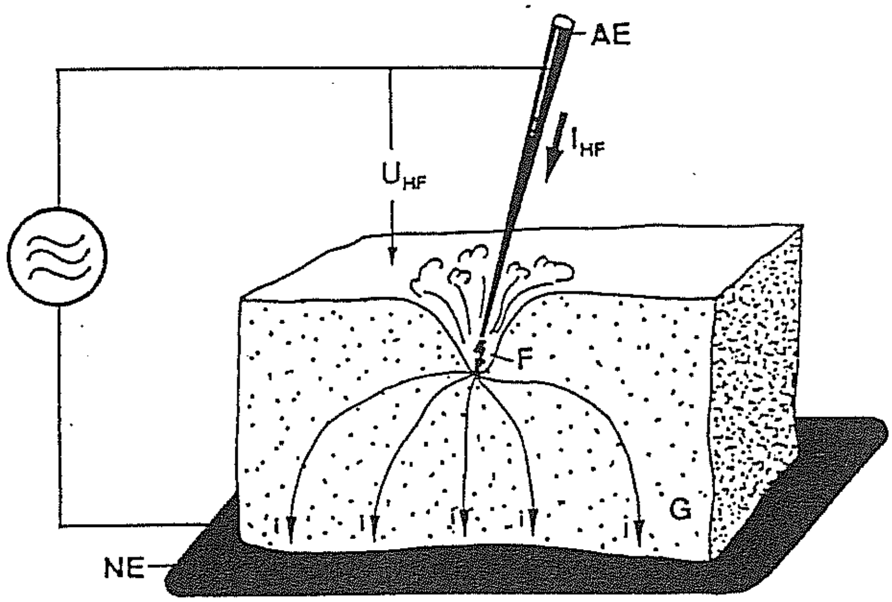


Fig.: If the voltage U_{HF} between active electrode AE and tissue G is sufficiently high, electric arcs F may be produced concentrating the entire current I_{HF} onto a single point so that the tissue at that point is immediately evaporated.

The temperatures produced at those points at which the electric arcs contact the tissue like microscopic flashes of lightning are so high that the tissue is immediately evaporated or burned away. As the active electrode passes through the tissue, electric arcs are stochastically produced wherever the distance between the electrode and the tissue is sufficiently small, producing a cut.

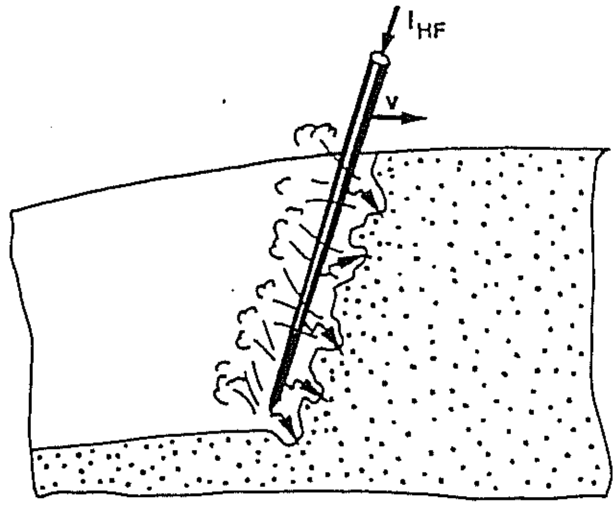


Fig.: A cut is produced when electric arcs contact the tissue near the active electrode and cause it to evaporate.

A peak voltage (U_p) of approx. 200 V_p is required in order to produce the electric arc between a metal electrode and biological tissue. If the voltage is less than 200 V_p, the electric arcs cannot be triggered and the tissue cannot be cut. If it is greater than 200 V_p, the electric arcs increase in proportion to the voltage. Experience has shown that the depth of coagulation (k) along the cut increases with increasing voltage and length or intensity of the electric arc.

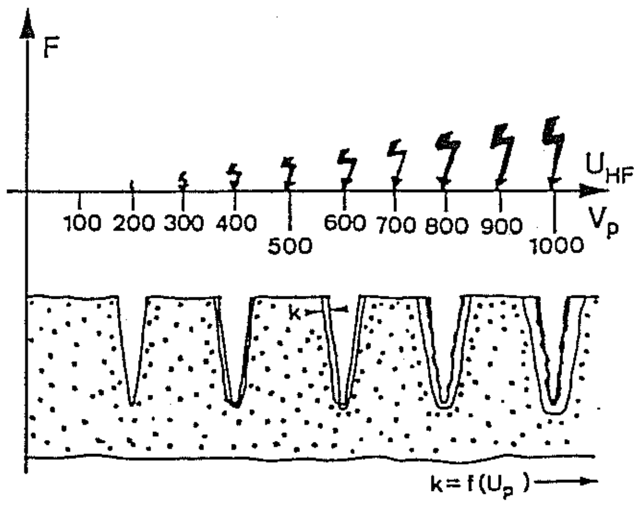


Fig.: Schematic illustration of the relationship between the intensity of the electric arcs F and hence of the coagulation depth k on the voltage U_{HF}.

This relationship between the depth of coagulation and the electric voltage or intensity of the electric arcs between active electrode and biological tissue has for decades been used in the practical application of conventional high-frequency surgical equipment; unmodulated voltages with a relatively small peak value U_p are used to produce cuts with the least possible coagulation necrosis, while voltages with greater or lesser amplitude modulation and a relatively high peak value U_p are used for cuts with a greater or lesser depth of coagulation.

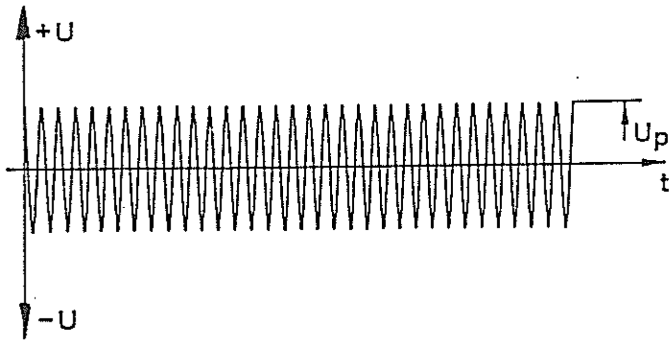


Fig.: Unmodulated high-frequency voltage for cuts with only slight coagulation.

The high-frequency surgical equipment used for this purpose up until around 1980 included a tube generator and a spark-gap generator. The tube generator produced largely unmodulated high-frequency voltages for cuts with little coagulation, the spark-gap generator producing strongly amplitude-modulated high-frequency voltages for cuts with intensive coagulation. The HF output power of the two generators could be adjusted relatively roughly but separately for each unit.

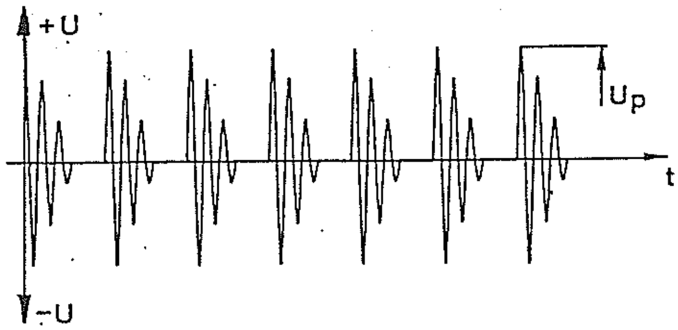


Fig.: Strongly amplitude-modulated high-frequency voltage for cuts with major coagulation.

The depth of coagulation along the cut edges could then be varied to a greater or lesser degree by mixing the HF voltages of the two generators.

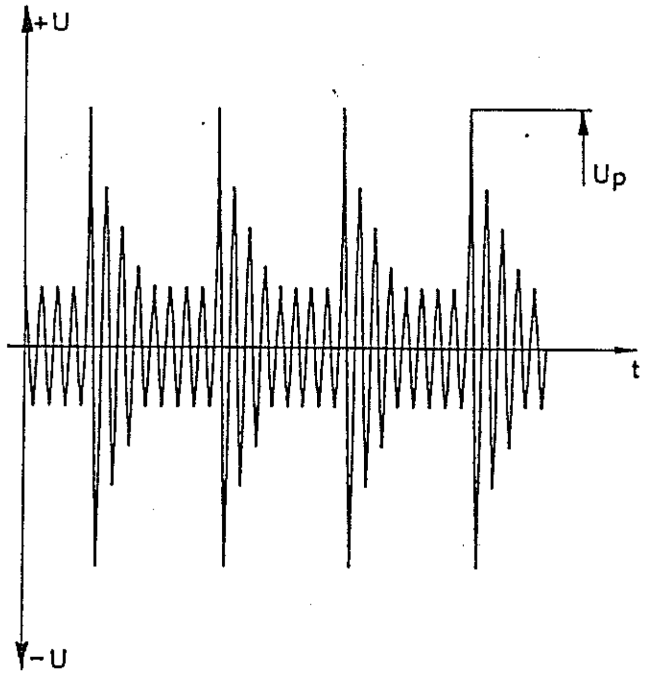


Fig. Mixture of the HF voltages a and b for cuts with a greater or lesser degree of coagulation.

Semiconductor-based high-frequency surgical equipment has been built since roughly 1970. The only difference with regard to cutting properties is that the depth of coagulation is no longer varied by mixing an unmodulated HF voltage produced by a tube generator with a modulated HF voltage produced by a spark-gap generator, but by adjusting the amplitude and degree of modulation of the HF voltage. As in high-frequency surgical equipment with tube and spark-gap generators, the controls for adjusting the degree of modulation are still marked "Mix" or "Blend" on a number of units with transistorized generators.

The purpose of the "MIX" or "BLEND" function is to allow the operator to determine the quality of the cut, i.e. the depth of coagulation, in advance by adjusting the settings on the HF surgical unit.

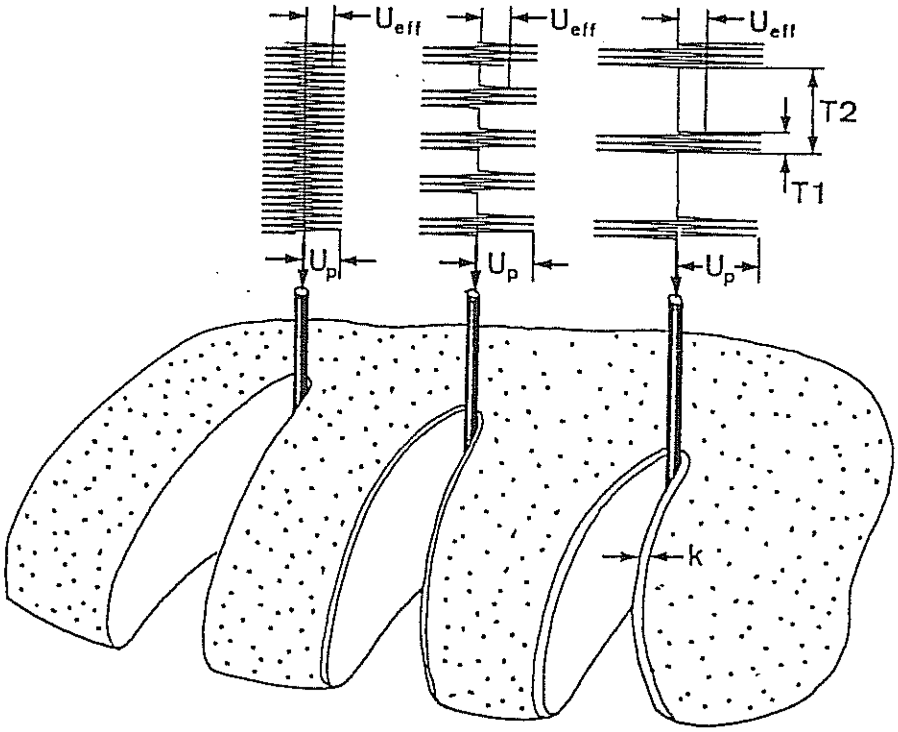


Fig.: Usually, the amplitude U_p and the pulse/pause duty T_2:T_1 of the HF voltage can be varied on conventional HF surgical units. The depth of the coagulation k increases with increasing peak value U_p even with a constant root-mean-square value U_{rms} of the voltage U_{HF}.

One problem with regard to the adjustability, reproducibility and constancy of the depth of coagualtion common to all conventional high-frequency surgical units is the greater or lesser generator impedance R_i making the HF output voltage U_a not only dependent on the generator voltage U_o but more or less on the HF output current I_a as well.

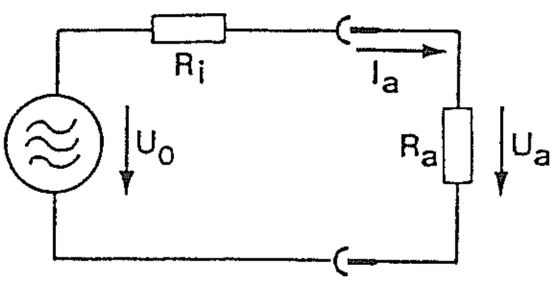


Fig. HF output voltage U_a as a function of the generator voltage U_o and the output current I_a or load resistance R_a.

The greater the generator impedance R_i, the more the HF output voltage U_a depends on the HF output current I_a. Conventional high-frequency surgical equipment has a generator impedance of between 200 and 1000 ohm.

$$U_a = U_o - R_i \cdot I_a$$

$$U_a = \frac{U_o}{R_i + Ra} \cdot R_a$$

The HF output voltage U_a and hence also the intensity of the electric arcs and ultimately the depth of coagulation vary considerably, since the load resistance R_a and current I_a vary from one cut to the next and also during each cutting process as a result of fluctuations in the cutting depth, cutting rate and inhomogeneity of the tissue.

The following figure shows the typical fluctuations in current I(t) and voltage U(t) occurring during a single cut as a result of the inevitable fluctuations in cutting rate, cutting depth and inhomogeneity of the tissue.

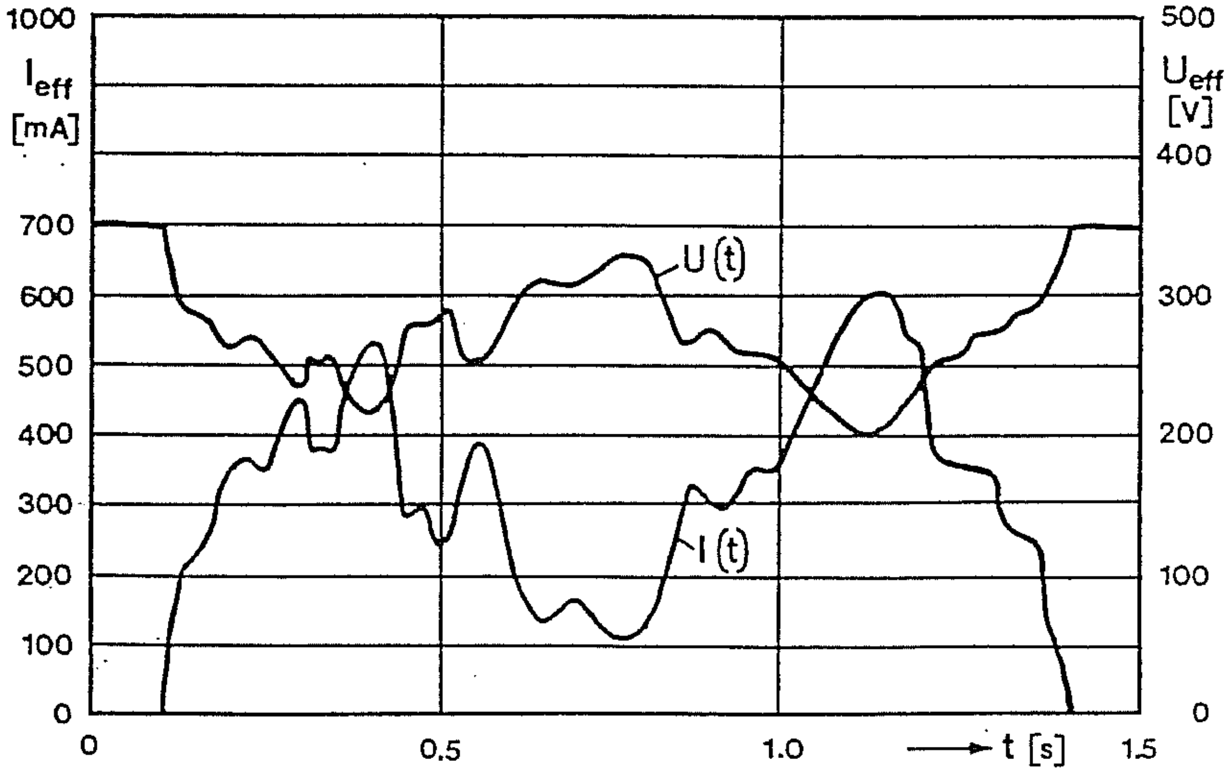


Fig.: Fluctuations in the effective values of the current I(t) and voltage U(t) during a single cut produced in 1.3 s. The HF generator impedance is 250 ohm.

The Figure below shows the effects of the fluctuations in the current I_a on the output voltage U_a, intensity of the electric arc F and coagulation depth k in a conventional high-frequency surgical unit with an impedance of 250 ohm. The voltage suitable for cutting biological tissue ranges between not less than 200 V_p and not more than 500 V_p. If it drops below 200 V_p, the tissue cannot be cut since electric arcs cannot be generated between the cutting electrode and the tissue. If it rises above 500 V_p, the electric arcs become so intense that the tissue is increasingly carbonized and the cutting electrodes my be damaged.

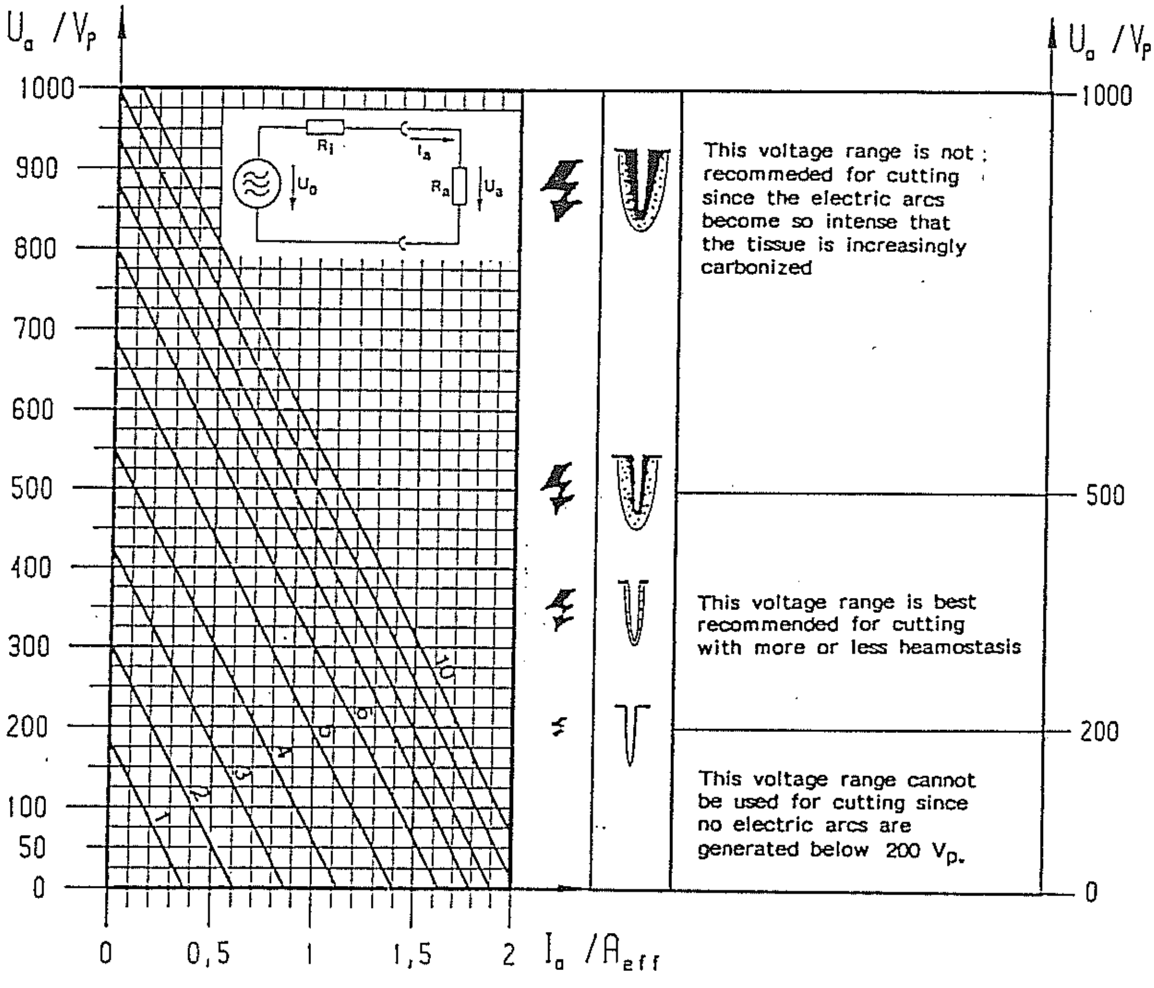


Fig.: HF output voltage U_a versus HF output current I_a of a conventional HF surgical unit with an impedance R_i = 250 ohm. Load resistor R_a = 250 ohm (matched condition). Power settings from 1 to 10.

Parameters 1 to 10 represent the power settings on conventional HF surgical units.

Stage 1 cannot be used for cutting since no electric arcs are generated.

Stage 2 can be used to obtain cuts with only a slight depth of coagulation.
Stage 4 can be used to obtain cuts with heamostasis, although the depth of coagulation varies considerably.
From stage 6 upwards, the risk of tissue carbonization increases if cutting is too slowly, the cutting angle is too shallow and/or the cutting electrode is too thin.

For this reason, practical application of conventional high-frequency surgical equipment demands that the depth of coagulation depends not only on the setting of the HF output power and degree of modulation, but also on the thickness of the cutting electrode, as well as on the cutting rate and depth. This relationship increases with the impedance of the high-frequency generator.

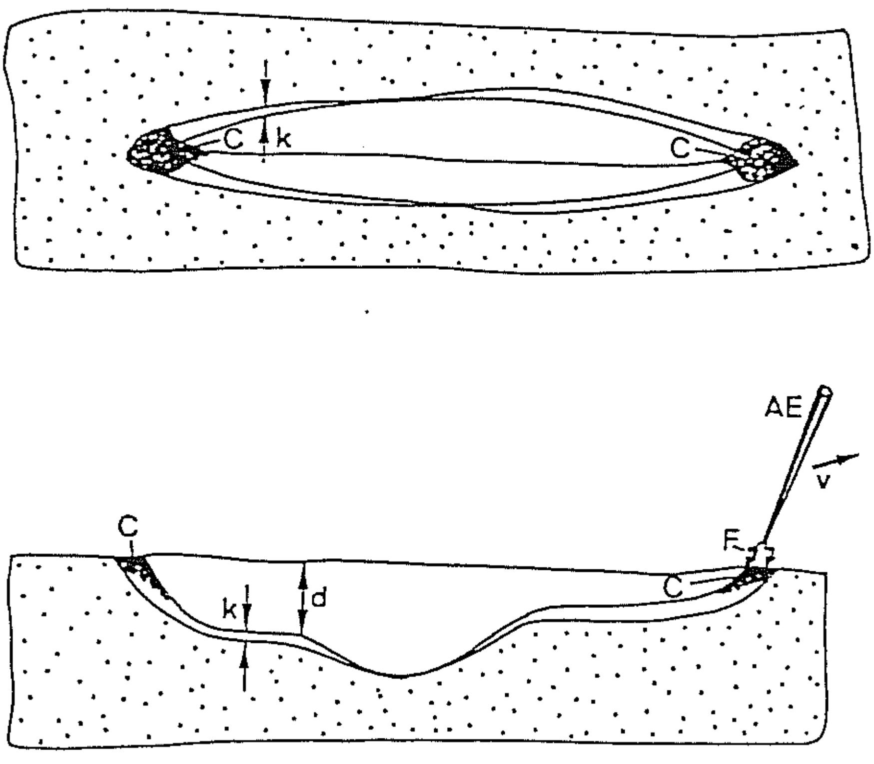


Fig.: Schematic illustration of the irregular coagulation depth k due to the irregular depth d of the cut even with a uniform cutting rate v resulting in carbonization C of the tissue at the beginning and end of the cut produced by the intense electric arcs F.

HF surgical units incorporating automatic control circuits have been available since 1985. These control circuits ensure that the intensity of the electric arcs and/or the peak value U_p of the HF output voltage are kept constant. This makes the depth of coagulation relatively independent of the cutting rate and depth. This characteristic is illustrated below. As shown before, the optimum HF cutting voltage range between 200 V_p and 500 V_p has again been marked.

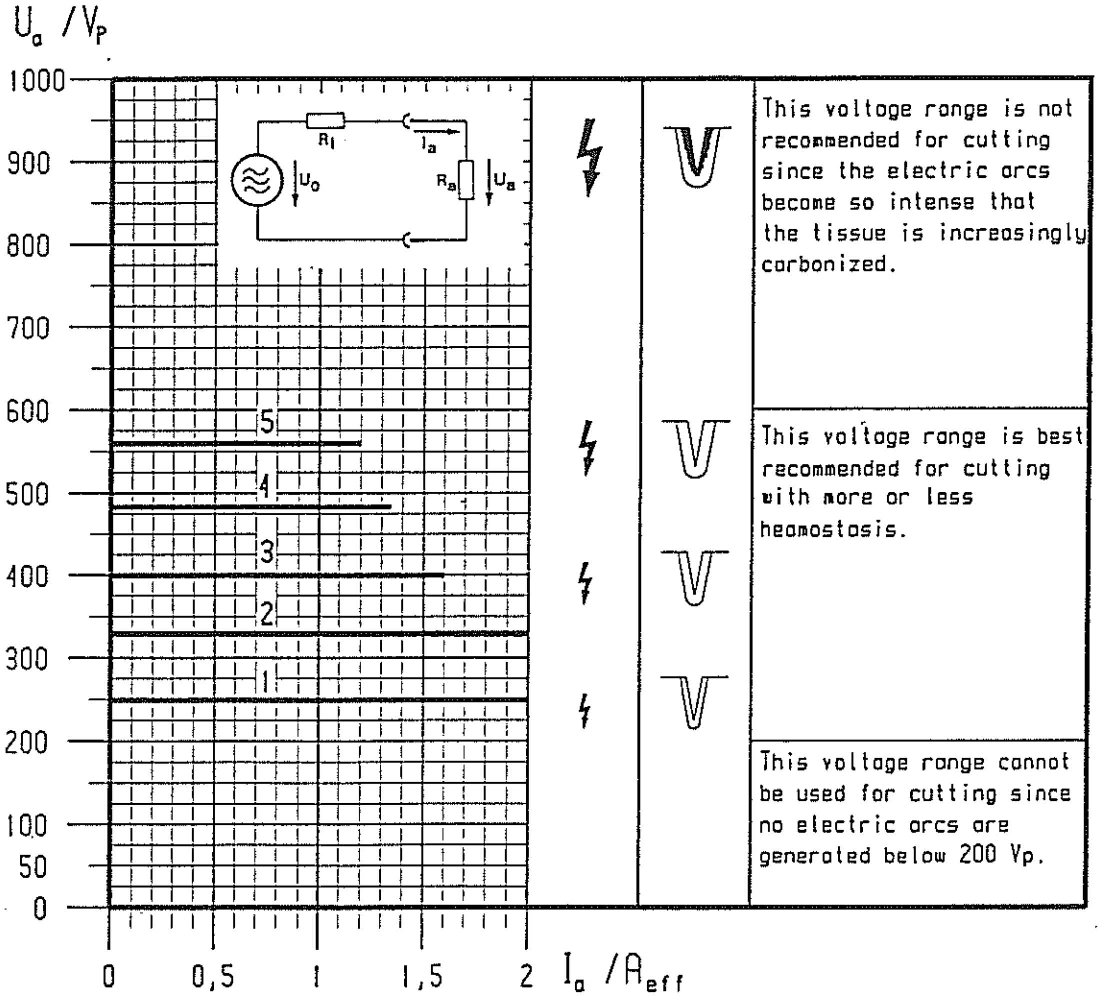


Fig.: Independence between HF output voltage U_a and HF output current I_a in a HF surgical unit with automatic voltage control. HF output voltage settings from 1 to 5.

Parameters 1 to 5 represent the individual adjustable HF voltages and the individual adjustable intensities of the electric arc between cutting electrode and tissue. Automatic control of the HF output voltage U_a or automatic control of the electric arc intensity ensures that the depth of coagulation remains constant for each setting.

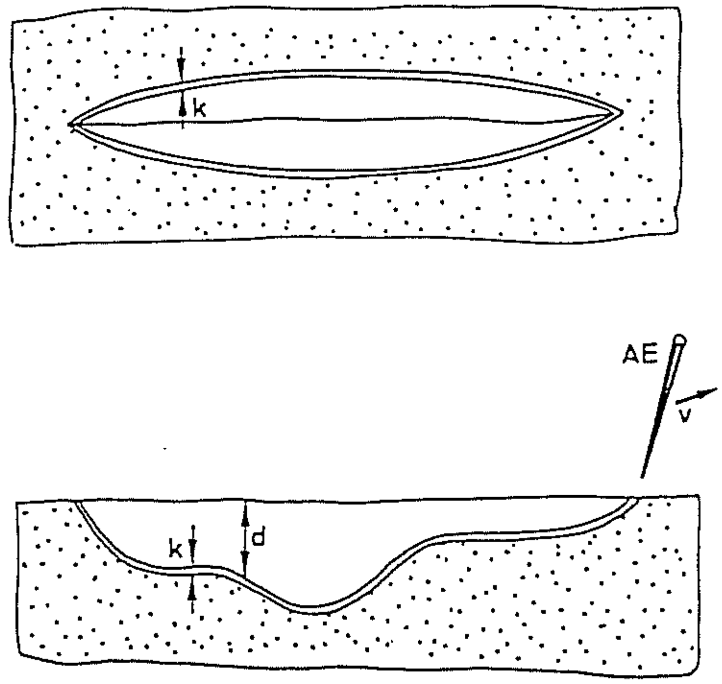


Fig.: Schematic illustration of the relatively constant depth of coagulation k despite the irregular cutting depth d and cutting rate v.

Cutting biological tissue using high-frequency equipment as compared with other cutting or separating methods offers the following advantages, particularly when using equipment with automatic control:

- The cut edges are thermally coagulated to a greater or lesser depth as the cut is produced. This ensures that at least the smaller vessels inevitably opened as a result of the cutting process are sealed off. Larger vessels can be sealed through partial thermal coagulation.

- The use of suitable cutting electrodes, such as needle-type electrodes, gives the operator considerable freedom with regard to both the direction and depth of cutting.

- All soft tissues can be cut without mechanical resistance or mechanical stress on the tissue. However, this also means that larger vessels can be cut into or even separated without any perceptible mechanical resistance; this risk is particularly high when cutting parenchymal organs, such as the liver.

- The use of high-frequency surgical equipment automatically regulating the intensity of the electric arcs and/or amplitude of the HF voltage between cutting electrode and tissue and thus determining the quality of each and every cut guarantees a high degree of elasticity during the cutting process while maintaining a largely constant cutting quality; in other words, the operator can move the cutting electrode through the tissue as quickly or slowly as desired and at any angle without affecting the depth of coagulation to any major extent and without changing the settings on the high-frequency surgical equipment. This makes it possible to produce highly dynamic cuts.

COAGULATION

Biological tissue can only be coagulated by thermal means if the requisite temperature of approx. 70 °C has been built up. Although this effect appears very simple, the problems associated with utilizing the effect to obtain specific denaturation of the tissue or specific haemostasis are extremely complex.

Specific denaturation of the tissue or specific haemostasis means that no more tissue is coagulated than is absolutely required in order to achieve the intended purpose. This requirement is difficult to satisfy, for it is virtually impossible to introduce the heat energy into the tissue in such a way that the tissue to be coagulated is heated to the temperature required for coagulation as uniformly as possible without causing thermal damage to the adjacent tissue. The following critical temperatures must be noted:

Up to approx. 40 °C:	No significant cell damage
Above approx. 40 °C:	Reversible cell damage, depending on the duration of exposure (according to Bender and Schramm, 1968)
Above 49 °C:	Irreversible cell damage = denaturation (according to Bender and Schramm, 1968)
Above approx. 70 °C:	Coagulation (Latin: coagulatio = clotting). Collagens are converted to glucose
Above approx. 100 °C:	Phase transition from liquid to vapour of the intra- and extra-cellular water. The tissue rapidly dries out = desiccation (Latin: ex sico = dehydration). Glucose has an adhesive effect after dehydration.
Above approx. 200 °C:	Carbonization (Latin: carbo = coal; medical pathological burns of the 4th degree).

If the temperature of approx. 50 °C required for denaturation is not obtained or if the temperature of approx. 70 °C required for coagulation is exceeded, additional problems may arise as the coagulum containing glucose dehydrates and carbonizes.

When using a high-frequency electric alternating current for endogenous heating of biological tissue, the tissue temperature T increases until it reaches approx. 100 °C or the boiling point of the tissue liquids in a manner roughly proportional to the specific electric resistance r of the tissue, duration of current flow Δt and square of the root-mean-square value of the electric current density i in the tissue concerned:

$$\Delta T = f\ (r,\ \Delta t,\ i_{rms})$$

The temperature rises at different rates at the various points on account of the inhomogeneity of the electrical and thermal tissue properties and, above all, of the irregular current density distribution within the tissue. As a rule, the density of the electric current is largest in the effective contact area between coagulation electrode and tissue, decreasing with the distance from this contact area.

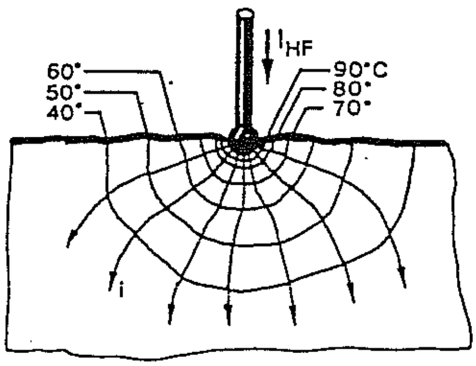


Fig.: Typical temperature profile during monopolar coagulation

On the one hand, this constitutes a problem with regard to controlling the physical size of the coagulation zone, but is simultaneously also the physical prerequisite for ensuring that monopolar coagulation does not continue to any random depth. The following figures illustrate the basic principles underlying the endogenous thermal effects during monopolar and bipolar coagulation over time.

Temperature-dependent effects over time

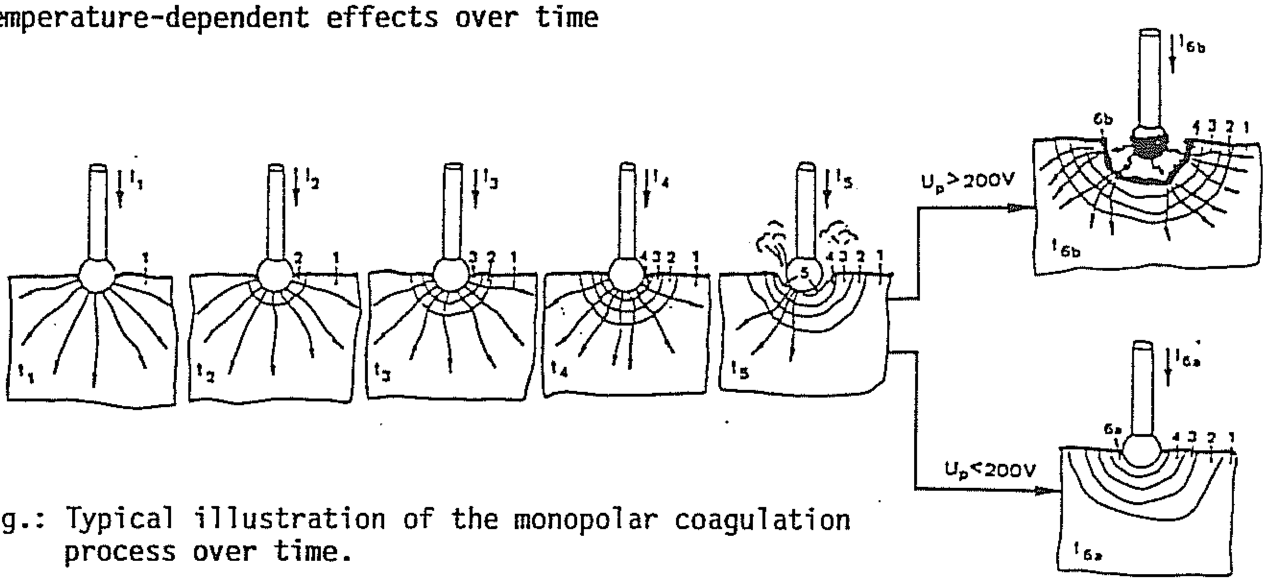


Fig.: Typical illustration of the monopolar coagulation process over time.

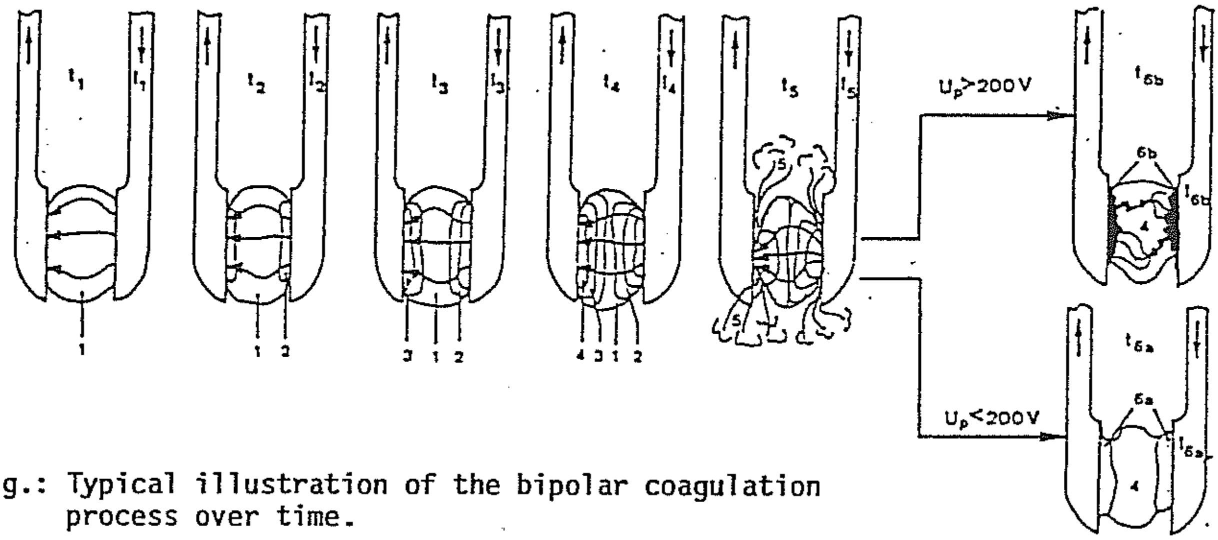


Fig.: Typical illustration of the bipolar coagulation process over time.

When the HF generator is switched on at time t_1, a current I_{HF} flows through a monopolar or bipolar coagulation electrode into the tissue where it is dispersed to a greater or lesser degreee, the current density i decreasing with the distance from the contact surface. Since the rise in tissue temperature is proportional to the square of the current density, the temperature near the contact points increases very much more rapidly than in the deeper tissue layers.

The following zones are produced as the temperature increases during the coagulation process:

Zone 1: No noticeable increase in temperature

Zone 2: Irreversible cell damage due to thermal effects

Zone 3: Coagulation zone

Zone 4: Desiccation zone (thermal dehydration)

Zone 5: Vapour zone

Zone 6a: Dehydrated tissue incapable of conducting electric current may adhere to the coagulation electrode (due to the conversion of collagens to glucose in zone 3 and dehydration in zone 4).

Zone 6b: Carbonization zone

The current I_{HF} can only flow through the tissue unimpeded and the tissue temperature can only increase until the boiling point of the tissue liquids near the contact surface has been reached, as illustrated for time t_5; this produces a vapour layer 5 between coagulation electrode and tissue impeding the current flow to various degrees, depending on the magnitude of the electric voltage between coagulation electrode and tissue. If the voltage has a peak value of less than 200 V_p, the electrically insulating effect of the resultant vapour layer slows down the coagulation process when the boiling point has been reached until the tissue layer 6a near the electrode has dried out to such an extent that virtually no more current can flow. If the current I_{HF} is not switched off and the coagulation process halted by time t_4 at the latest, the coagulum may adhere to the coagulation electrode as from time t_5 onwards.

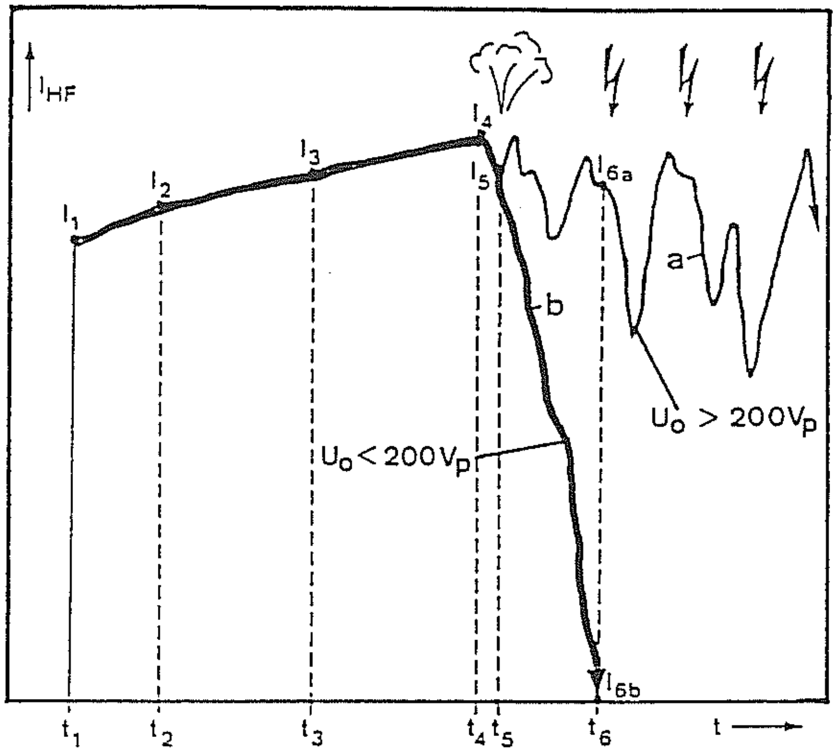


Fig.: Typical change over time t in the intensity of the HF current I_{HF} during monopolar and bipolar coagulation. Although the rate of coagulation up to time t_5 varies with different HF voltages, it is basically always the same. From time t_5 onwards, the current I_{HF} decreases towards zero if $U_p <$ 200 V or electric arcs carbonizing the coagulum are produced if $U_p >$ 200 V.

If the voltage has a peak value of more than 200 V_p, the vapour layer 5 and dried-out tissue layer 6a are punctured by electric arcs causing the coagulation process to continue either until the high-frequency generator is switched off or until the thickness of the dried-out tissue layer is so great that it cannot be punctured by any further electric arcs at the voltage set. The electric arcs produced between the coagulation electrode and the tissue cause the tissue 6b to carbonize, producing not only the unpleasant smell of burning flesh but, but also strongly contaminating the coagulation electrode.

This yields the following general rule:

If the coagulation electrode is to make electrically conducting contact with the tissue to be coagulated, voltages greater than 200 V_p should only be used in exceptional cases in which
- **relatively large coagulation zones must be produced**
- **by relatively small electrodes**
- **within a relatively short period of time and**
- **the risk of carbonization of the coagulum is tolerable.**

Coagulation modes

The physical size of the coagulation zone can be determined both by the application technique and the coagulation rate. In this context, it is essential to differentiate between three different coagulation modes, namely soft coagulation, forced coagulation and spray coagulation.

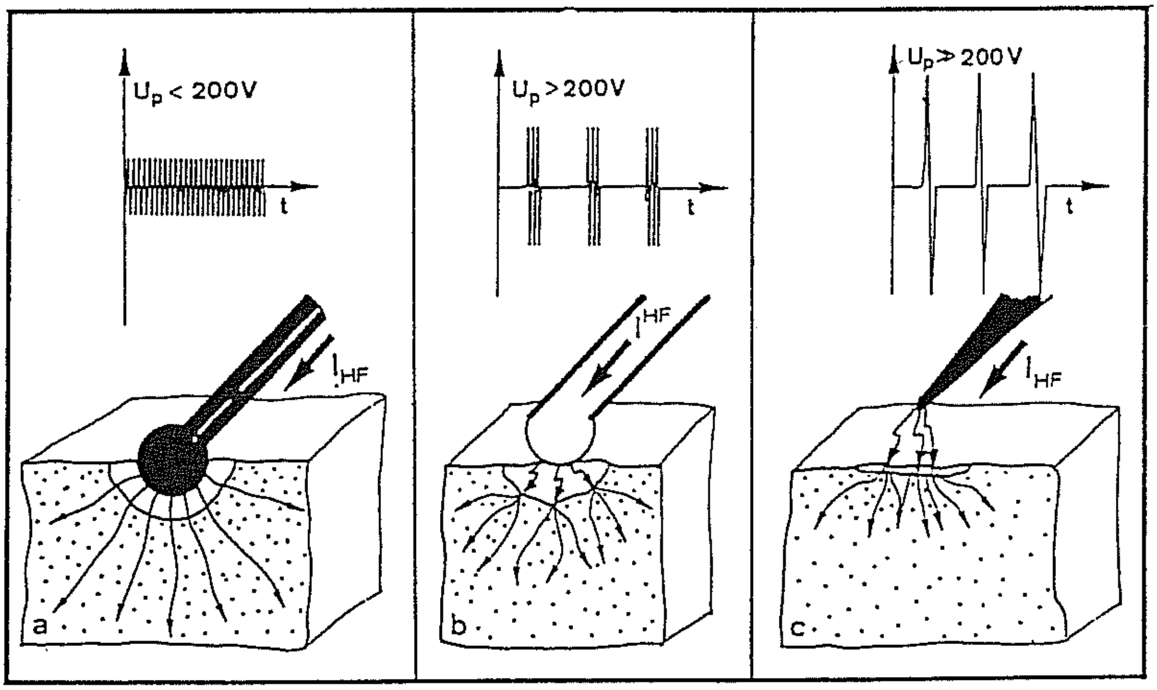


Fig.: a) Soft coagulation b) Forced coagulation c) Spray coagulation

Soft coagulation is characterized by the fact that no electric arcs ignite between the coagualtion electrode and the tissue during the entire coagulation process to prevent the tissue from becoming carbonized. Therefore, unmodulated HF voltages with a peak value below the sparking voltage for electric arcs between coagulation electrode and tissue are recommended for soft coagulation.

Soft coagulation is recommended for all cases in which monopolar or bipolar coagulation electrodes are brought in direct contact with the tissue to be coagulated. But please note: **Voltages greater than 200 V_p** between the coagulation electrode and the tissue **must not be used for soft coagulation.**

Forced coagulation is characterized by the fact that electric arcs are intentionally generated between the coagulation electrode and the tissue in order to obtain deeper coagulation than could be achieved with soft coagulation, particularly when using thinner or smaller electrodes. The risk of tissue carbonization must be tolerated here.

Modulated HF voltages with a peak value sufficiently high to ignite electric arcs of the required length, but with a root-mean-square value sufficiently small to avoid cutting effects are recommended for forced coagulation. **The voltage used for forced coagulation should be of a minimum of 500 V_p.**

Forced coagulation can only be recommended when thin or small electrodes are used to obtain a relatively deep coagulation. One such case, for example, would be the TUR with rinsing fluid, the thin cutting electrode also being used for coagulation.

Spray coagulation is characterized by the fact that such long electric arcs are intentionally generated between spray electrode and tissue as to make any direct contact between electrode and tissue unnecessary. **Strongly modulated HF voltages with peak values of a few kilovolt are recommended for spray coagulation.**

Controlling the physical size of the coagulation zone by varying the application technique for soft coagulation

The physical size of the coagulation zone for soft coagulation depends above all on the distribution of the current density within the tissue to be coagulated. The current density distribution, on the other hand, is primarily dependent on the technique with which the HF current I_{HF} is applied. Basically, a distinction is made between monopolar and bipolar application techniques; these are then further differentiated according to monopolar and bipolar surface application, monopolar and bipolar puncture application and monopolar and bipolar spread application.

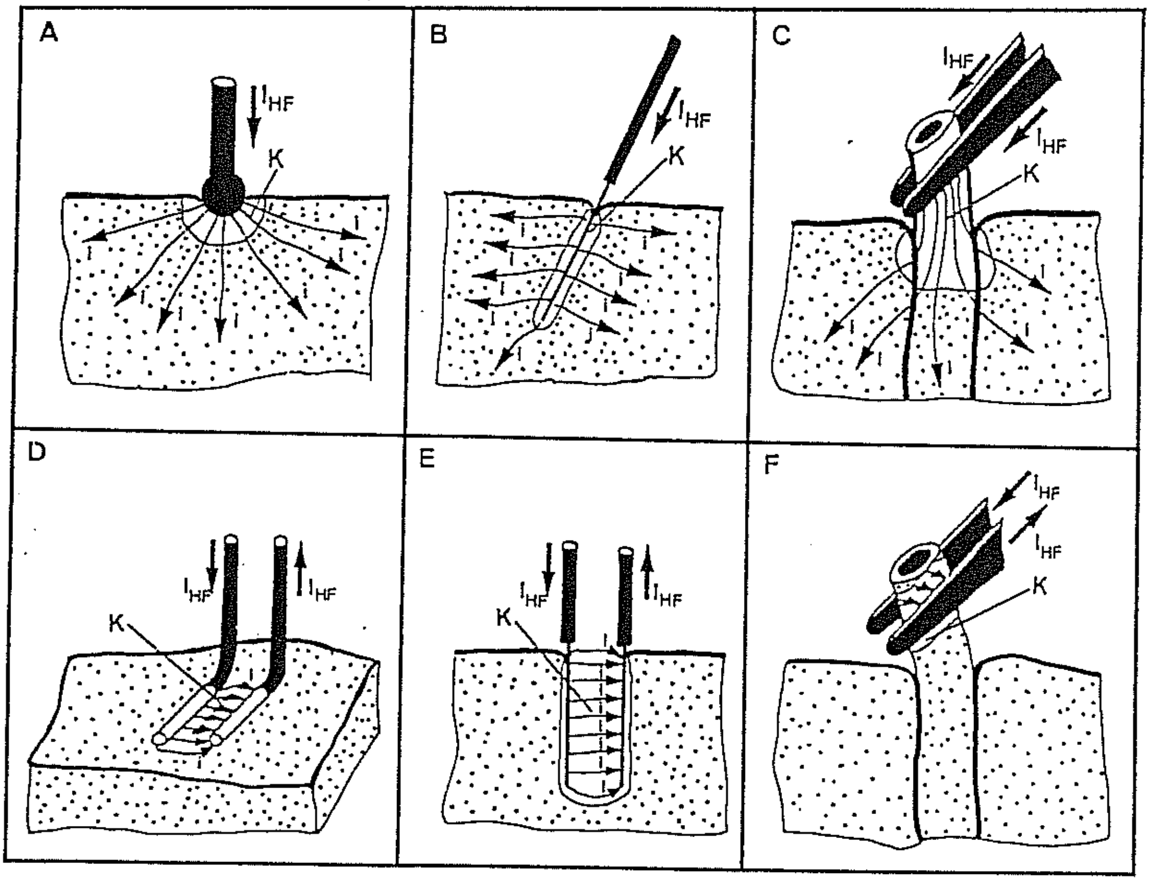


Fig.: Physical size of the coagulum produced by monopolar and bipolar soft-coagulation techniques:

MONOPOLAR

A) Contact coagulation
B) Puncture coagulation
C) Spread coagulation

BIPOLAR

D) Contact coagulation
E) Puncture coagulation
F) Spread coagulation

Spray coagulation is used both for surface coagulation and for haemostasis of vessels not directly accessible to coagulation electrodes, such as those hidden in bone fissures.

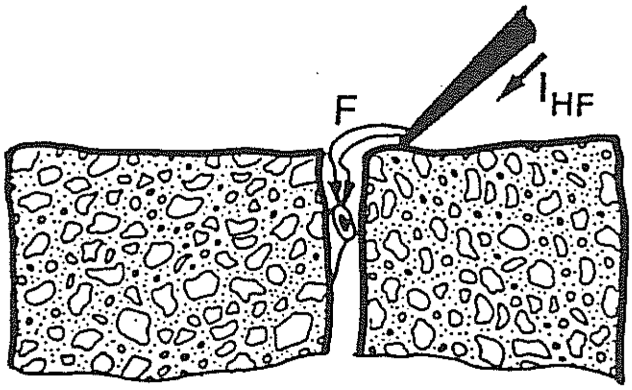


Fig.: Typical application of spray-coagulation to stop the bleeding of vessels hiden in bone fissures.

Since the growth of coagulation mainly depends on the current density distribution within the tissue, the size of the effective contact area between tissue and electrode has a decisive effect on the development and maximum size of the coagulation zone obtained: the smaller the effective contact area the more inhomogeneous the current density distribution near the contact area.

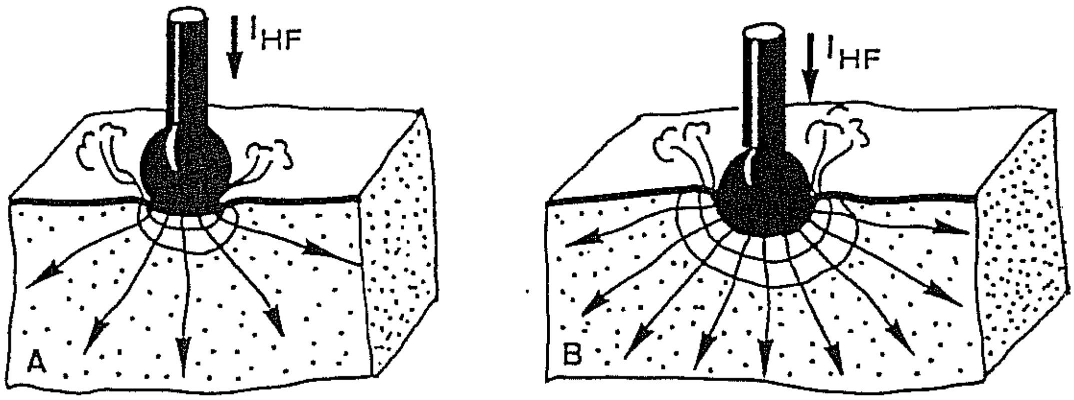


Fig.: Volumetric growth of the coagulum as a function of the effective contact area between electrode and tissue during soft-coagulation:

A) Only small clots are obtained with a small effective contact area

B) Correspondingly large clots are obtained with a large effective contact area

Controlling the physical size of the coagulation zone by varying the soft coagulation rate

With soft coagulation, the coagulation rate remains roughly proportional to the square of the HF current I_{HF} or the square of the HF voltage U_{HF} until the boiling point has been reached. As already described in detail, the temperature increases most rapidly near the point of contact between electrode and tissue, producing a temperature gradient from the contact surface into the tissue. The resultant flow of heat w from the boundary layer between coagulation electrode and tissue towards the deeper tissue layers can be used to control the depth of coagulation. If the HF current or voltage is set so that the amount of heat produced near the coagulation electrode is only marginally greater than that conducted into the deeper tissue layers per unit time, the resultant temperature gradient from the electrode towards the tissue will be flatter and the depth of coagulation correspondingly larger than in the case of more rapid coagulation using a higher HF current or voltage.

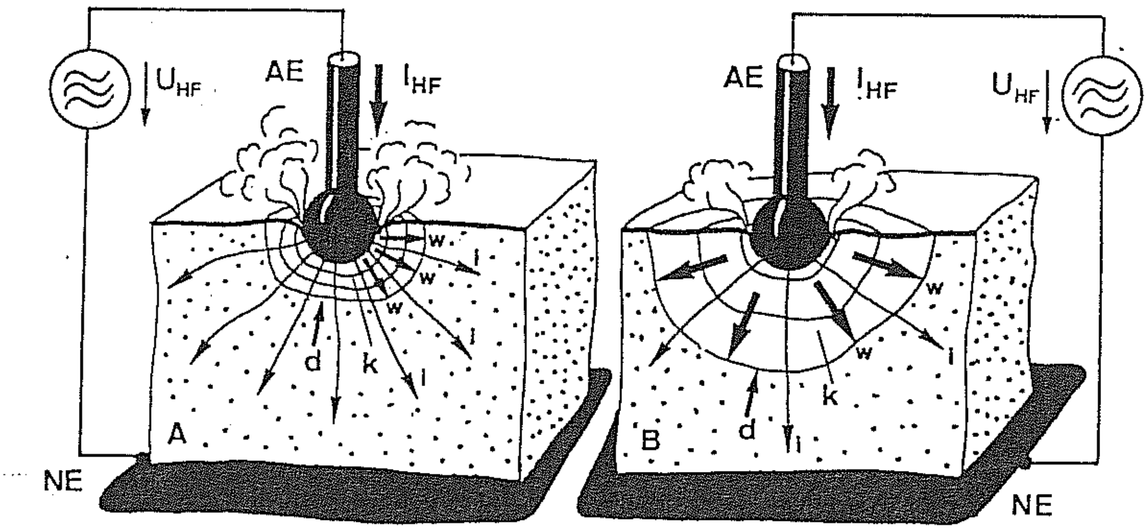


Fig.: The volumetric growth of the coagulum before coagulation is ended by a vapour layer between electrode and tissue is roughly reciprocal to the voltage U_{HF} and current I_{HF}.

This yields the following general rule:

The HF voltage U_{HF} must not be too high if a relatively small coagulation electrode or relatively small effective contact area is to be used to obtain the maximum possible depth of coagulation d, for the higher the HF voltage, the more rapidly an electrically insulating vapour layer will be created between the coagulation electrode and the tissue, ending the coagulation process prematurely. The heat w produced near the coagulation electrode can flow into the deeper tissue layers if a lower HF voltage is used.

In this context, it is often found that high HF voltages are used to obtain great coagulation depths by force, intense electric arcs carbonizing the tissue and contaminating the coagulation electrode in the process. (This does not apply for coagulation using the TUR where water is used for coagulation and other conditions apply.)

However, the coagulation time can only be used as a reliable means of controlling the coagulation depth if the high-frequency surgical equipment used for this purpose has the required characteristics. This applies not only to the ability to define the HF voltage setting, but also the constancy of the set HF voltage over the entire relevant current range. Since the effective contact area between coagulation electrode and tissue can vary considerably from one coagulation to the next, the HF current required for a defined coagulation time will also vary from one coagulation to the next. A constant current density i not dependent on the coagulation electrode and tissue can only be guaranteed if the root-mean-square value of the HF voltage U_a used for coagulation remains constant.

The HF output voltage U_a of a high-frequency generator with a generator impedance of R_i = 350 ohm is plotted as a function of the HF output current I_a for different settings 1 to 10 in Fig.below.For each of the settings 1 to 10, the HF output voltage U_a decreases as the reciprocal value of the effective contact area A_{eff} and current I_a. Consequently, the more the effective contact area A_{eff} varies during an operation, the more difficult it becomes to determine the depth of coagulation d that can be achieved by varying the settings on the HF generator.

If the equipment is set to values for which peak voltages greater than 175 V_p are obtained for I_a = 0, electric arcs may be produced between the coagulation electrode and tissue carbonizing the tissue when using smaller effective contact areas.

Fig.below illustrates the relationship between the HF output voltage U_a of a high-frequency generator with automatic voltage control and the HF output current I_a for different settings 1 to 5 of the HF output voltage U_a. The automatic voltage control function ensures that the HF output voltage U_a remains constant regardless of the current I_a and effective contact area A_{eff}. As a result, the coagulation depth that can be obtained for each setting remains largely independent of the effective contact area A_{eff}.

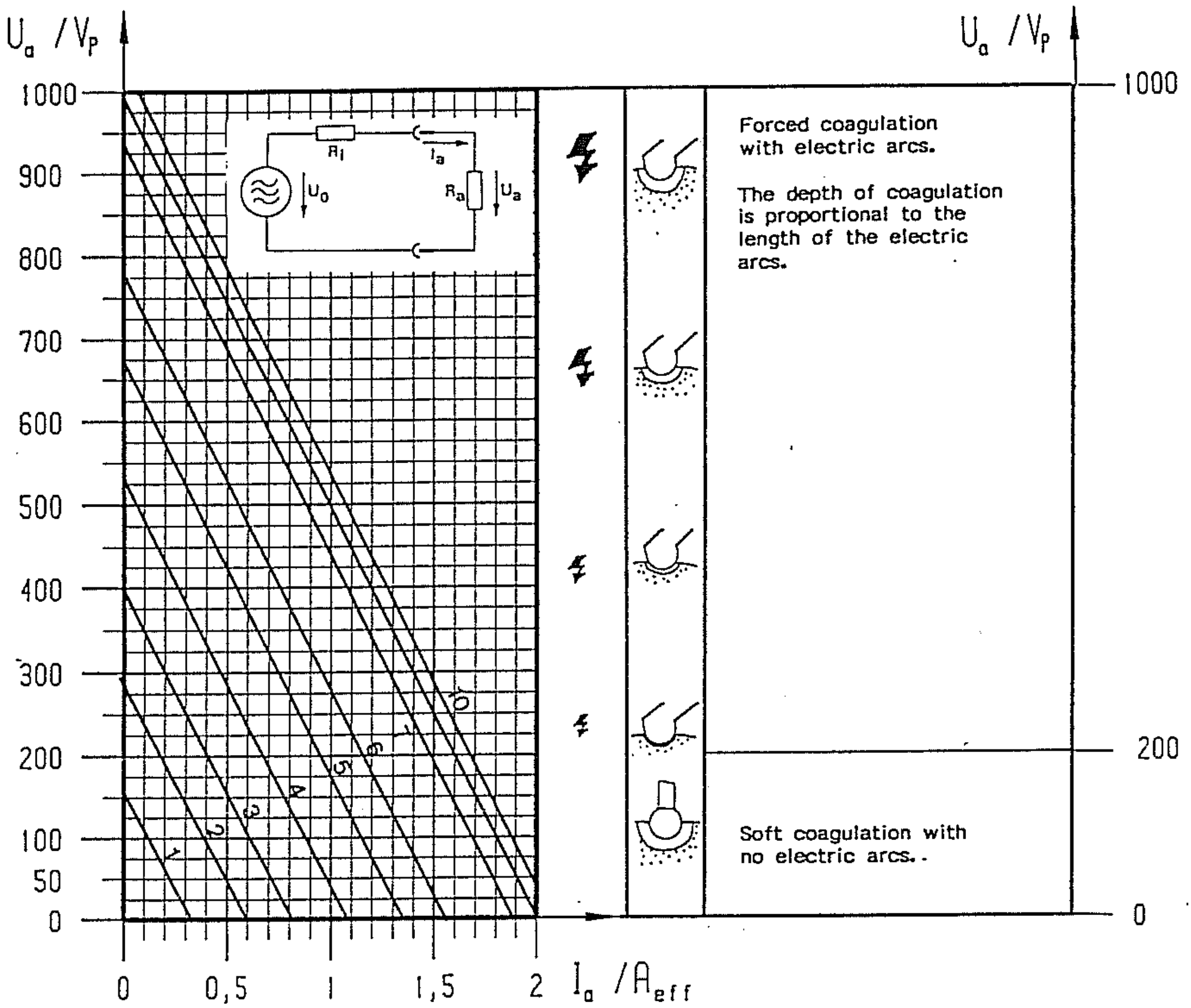


Fig.: Relationship between the HF output voltage U_a and HF output current I_a of a conventional HF surgical unit with an impedance R_i = 350 ohm.
Power settings from 1 to 10.

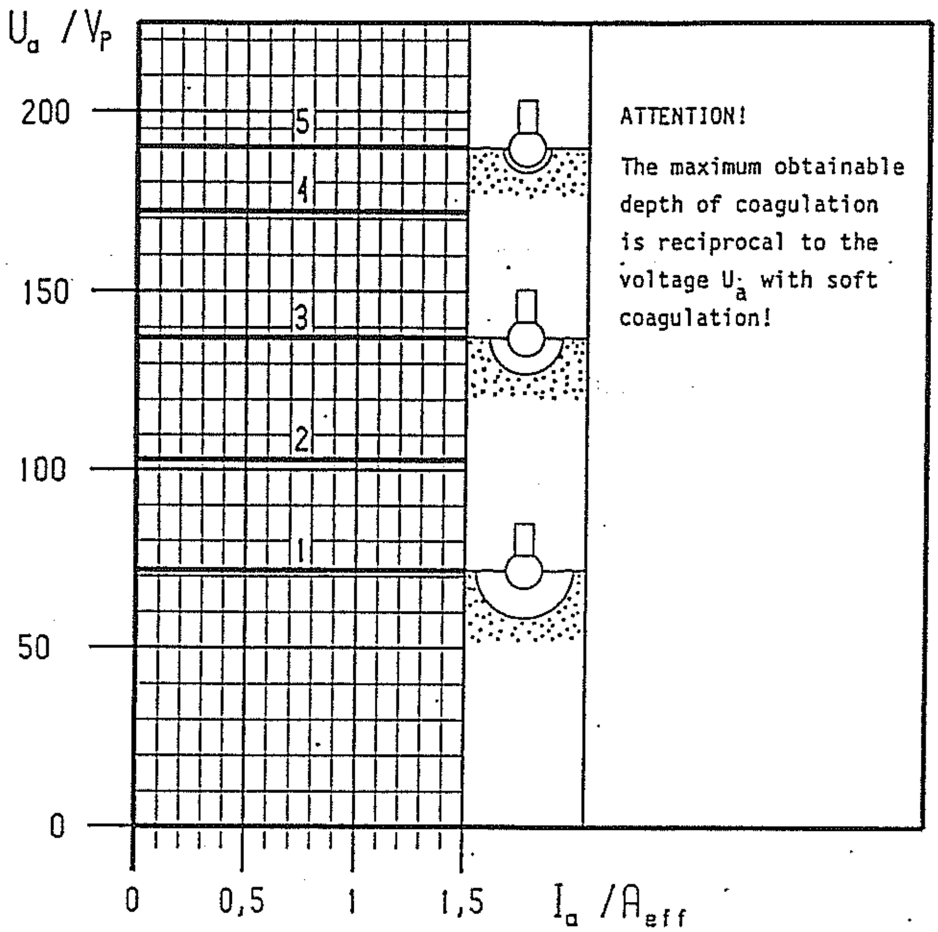


Fig.: Independence between the HF output voltage U_a and HF output current I_a of a HF surgical unit with automatic voltage control for soft coagulation, settings from 1 to 5.

This yields the following general rule for soft coagulation:

The settability and reproducibility of the soft coagulation depth increases as the HF generator impedance decreases. A HF generator with automatic voltage control is ideal for this purpose.

Soft coagulation can only be used to the optimum extent if the coagulation process is stopped when the vapour phase occurs. The coagulation zone effectively ceases to increase from this time onwards, since the vapour formation considerably reduces the current flow. If this particular moment is disregarded or missed, the coagulum, which now contains glucose, will dry out (desiccate) and possibly adhere to the coagulation electrode. When the electrode is then removed from the tissue, the coagulum may be torn away, resulting in inadequate haemostasis.

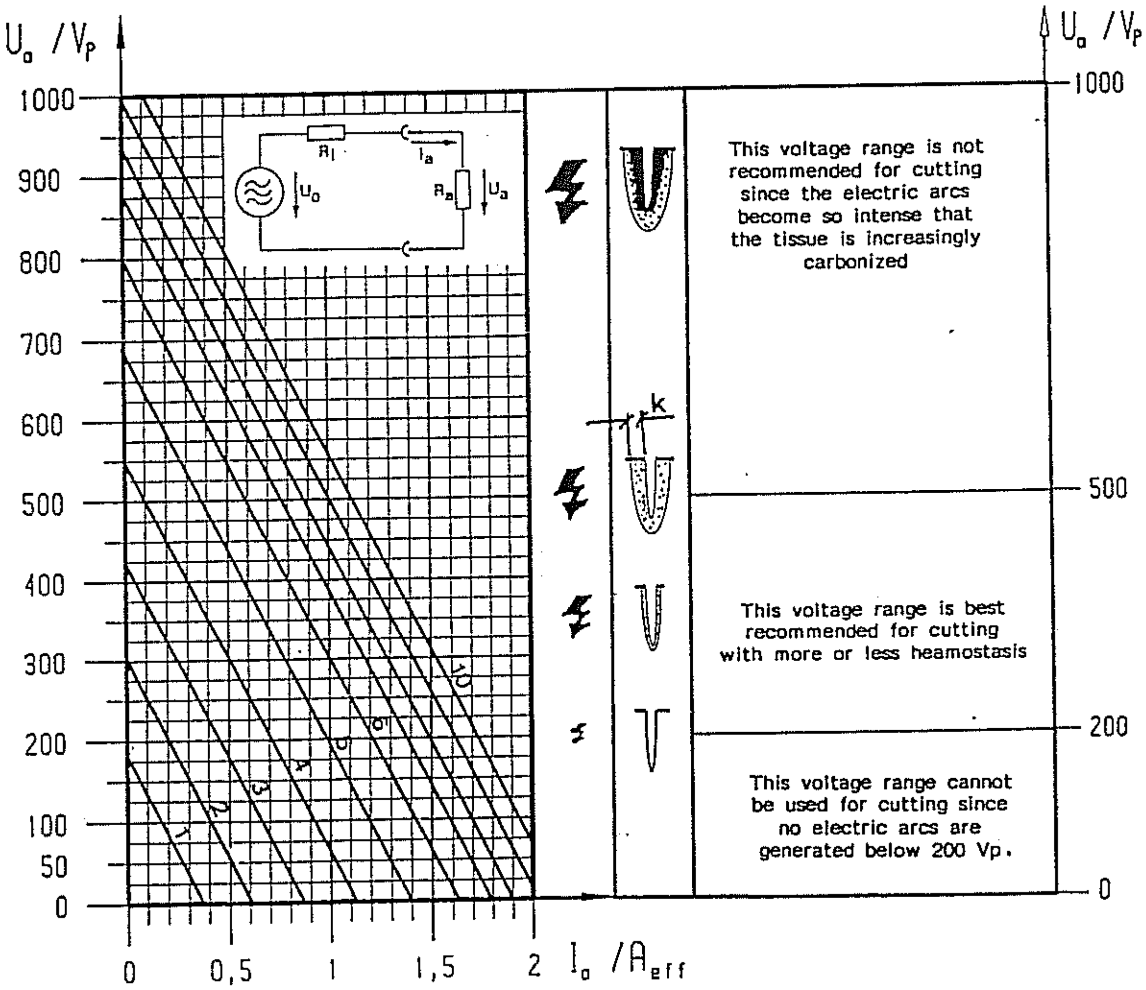
In order to avoid this adhesive effect, soft coagulation should be ended as soon as vapour emerges from the coagulation zone.

2 HF SURGICAL TECHNIQUES

2.1 CUTTING WITH THE ERBOTOM ACC 410 / ACC 430 or ACC 450

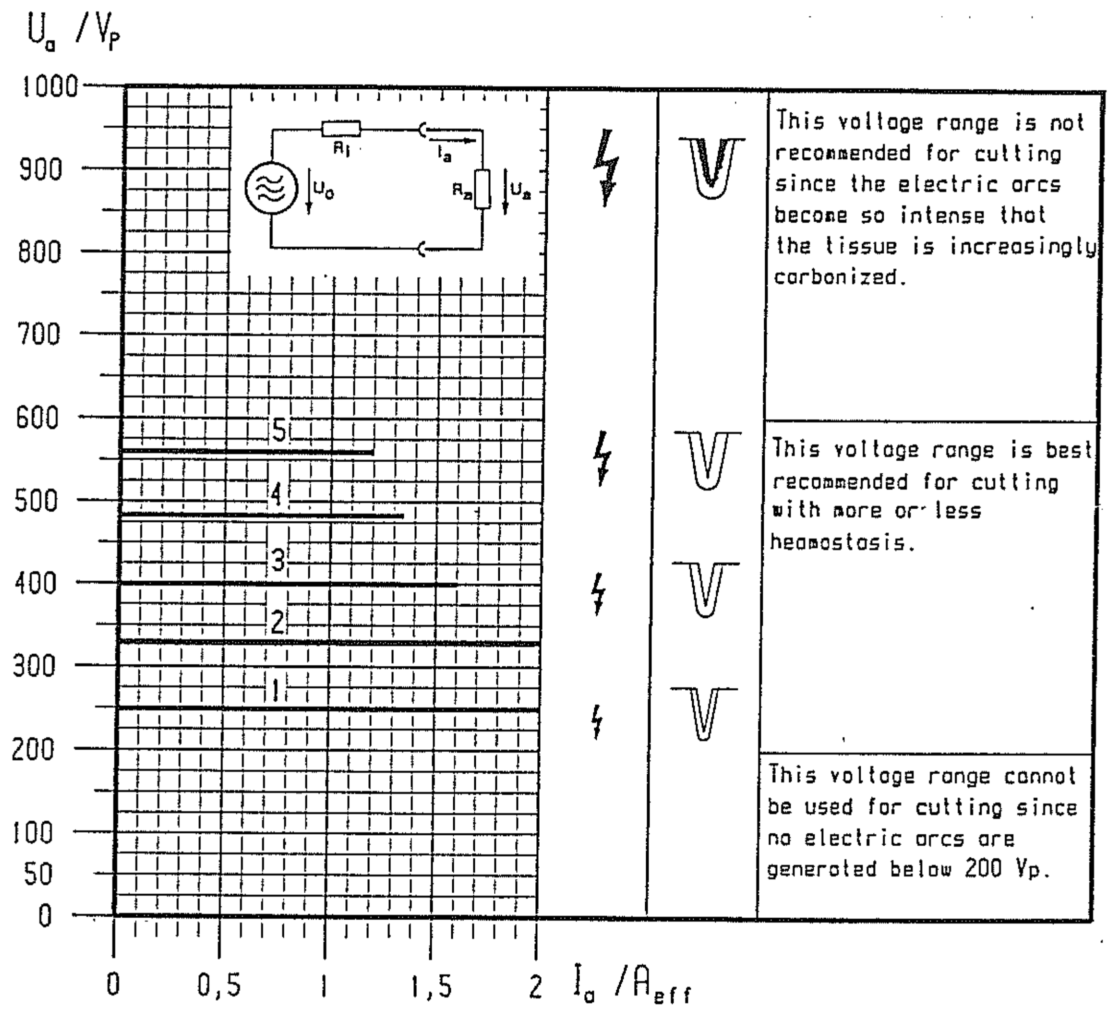
Definition: Biological tissue can only be cut when the voltage between the cutting electrode and the tissue to be cut is sufficiently high to produce electric arcs between the cutting electrode and the tissue, effectively burning away the tissue in the direct vicinity of the electrode.

This produces a coagulation zone (k) of varying depth along the cut surfaces.



In conventional high-frequency surgical instruments, the voltage (U_a) - and hence the intensity of the electric arc - is more or less dependent on the load resistance (R_L) and current (I_a), as well as on the internal impedance of the high-frequency generator. This explains why the thickness of the coagulation zone (k) tends to vary during the cutting process and from one cut to the next. This also explains why conventional high-frequency instruments require a power setting which must be corrected, depending on the shape and size of the cutting electrode used, the intended cutting rate and the depth of the cut.

In the ERBOTOM ACC 410, ACC 430 and ACC 450, the voltage is automatically kept constant so as to make setting of the power unnecessary. The depth of the coagulation zone (k) alongside the cut surfaces is thus largely independent of the size and shape of the cutting electrode, cutting rate and depth of the cut.



Five different automatically regulated HF voltages can be selected at the push of a button on the ERBOTOM ACC ... units, producing coagulation zones (k) of five different depths.

2.2 AUTOMATICALLY CONTROLLED COAGULATION

A new coagulation technique

Thermal coagulation processes employing a high-frequeny alternating electrical current (HF current) are used in surgery to denature specific biological tissues and above all to stop bleeding. The HF current is passed through the tissue to be coagulated, endogenously heating the tissue at the same time. The amount of heat Q produced in the tissue is proportional to the electrical resistance of the tissue R, the duration of current flow Δt and the square of the current intensity I:

$$Q = I^2 \times R \times \Delta t \quad (Ws)$$

As the tissue heats up, its temperature increases in direct proportion to the amount of heat Q and in inverse proportion to the heat capacity of the tissue C:

$$\Delta t = Q/C \quad (K)$$

If the temperature of the biological tissue is then increased from the normal temperature of 36 °C, for example, the following effects of relevance to the surgeon will be triggered successively and partly overlapping:

Up to approx. 40 °C:	No significant cell damage
Above approx. 40 °C:	Reversible cell damage, depending on the duration of exposure (according to BENDER and SCHRAMM, 1968)
Above 49 °C:	Irreversible cell damage = denaturation (according to BENDER and SCHRAMM, 1968)
Above approx. 70 °C:	Coagulation (Latin coagulatio = clotting)
Above approx. 100 °C:	Phase transition from liquid to vapour of the intra- and extra-cellular water. The tissue rapidly dries out = desiccation (Latin ex sico = dehydration).
Above approx. 200 °C:	Carbonization (Latin carbo = coal; medical pathological burns of the 4th degree)

For the tissue to be denatured, it must therefore be heated to at least 50 °C and to at least 70 °C to obtain coagulation. If these temperatures are not achieved, the effect will remain unsatisfactory or there may be none at all. Since it is not usually possible to measure the temperature during the denaturation and coagulation processes, the operator can in effect only look for the following visible and audible warning signs as the tissue warms up:

In a relatively large number of applications for HF coagulation, these signs indicating when the relevant temperature has been reached unfortunately cannot be used by the operator to end the coagulation process at the optimum point, for instance if he cannot see the coagulation process, if the coagulation zone is very small, if the coagulation process takes place very rapidly, if the colour of the tissue does not change clearly during the coagulation process and above all if the operator must concentrate on other, more important details.

The fact that both time and local processes within the overall coagulation process are dependent on a large number of variable and interdependent parameters constitutes a major difficulty for the coagulation process. These parameters include the following:

- Inhomogeneous electrical properties of the tissue to be coagulated
- Geometry of the electrical field within the tissue to be coagulated which is, in turn, dependent on the geometry of the effective contact area between the coagulation electrode and the tissue
- Specific thermal capacity of the various tissue components
- Relationship between the electrical resistance of the various tissue types and temperature, in particular
    - Changes in the electrical conductance of the tissue fluids at the transition from the liquid phase to the vapour phase
    - Thermal conductance of the various tissue types
    - Heat dissipation through the coagulation electrode
    - Performance characteristics of the high-frequency generator

Optimum coagulation is more or less a matter of luck when using conventional high-frequency units. As a rule, the coagulation process will be continued for longer than is actually required in order to ensure that the desired result has indeed been achieved. However, this leads to new problems:

Above 70 °C, collagens in the clot are presumably converted into glucose, producing an adhesive effect and causing the clot to stick to the electrode, particularly if the heating process is continued even after coagulation has taken place. This merely causes the clot and hence the glucose to dry out more and more.
The adhesive effect is particularly undesirable when this coagulation process is used to stop bleeding, since the blood vessel will be opened afresh when the electrode is removed and the haemostasis will be insufficient.

Above 100 °C, the clot may literally explode on account of the high endogenous vapour pressure, making the haemostatic process a failure.

Unnecessarily long and/or intensive coagulation also increases the risk of accidental burns in the patient, as well as the risk of damaging more tissue than is necessary.

Unnecessarily long and/or intensive coagulation furthermore results in carbonization of the clot as a result of electric arcs generated between the coagulation electrode and the clot. This not only contaminates and overheats the electrode unnecessarily, but also destroys the clot which is of such importance in order to stop bleeding.

Automatically controlled high-frequency units for optimum coagulation

The manufacturers of high-frequency surgical equipment have for many years sought a way to improve the coagulation process so as to permit optimum reproducibility of the coagulation quality, i.e.

- Not to destroy more tissue than is necessary.
- To lower the risk of accidental patient burns.
- To make the coagulation quality independent of the exact timing when using pedals or push-buttons.
- To ensure that the coagulation electrode remains clean during coagulation.
- Thus the operator can work more quickly and safely.

Like the familiar and clinically established, automatically controlled high-frequency units ERBOTOM TUR, ERBOTOM AMR and the special-purpose therapy unit for refractory ventricular tachycardia through transvenous detachment of accessory conductors, the ACC 450 (ACC = automatically controlled coagulation) high-frequency unit from ERBE ELEKTROMEDIZIN has opened up new horizons in the development of electrosurgery.

The high-frequency unit ACC 450 offers the following capabilities in addition to those of conventional coagulation techniques:

1. Automatic activation of the HF current with preset, reversible preparation time of 0, 1 or 2 seconds.

2. Automatic control of the intensity of the HF current with preselectable coagulation depth, with automatic compensation of differences in the tissue volume during bipolar coagulation and of the effective contact area during monopolar coagulation. Power settings, such as those required with conventional high-frequency units, are not necessary.

3. Automatic de-activation of the HF current at the end of the coagulation process with a choice of two cutout criteria. The first cutout criterion is based on the change in the electrical resistance of the coagulating tissue as a function of the temperature of that tissue. The second cutout criterion is based on an electric spark triggered between the coagulation electrode and the clot.
In addition, the first criterion can be automatically repeated up to three times.

4. Acoustic signal informing the operator of the moment the coagulation process is automatically ended.

These capabilities give rise to the following advantages over conventional high-frequency units:

- Optimum reproducibility of the denaturation and coagulation processes despite the numerous variable and interdependent parameters; i.e. the coagulation process is not ended too soon or too late.
- The feared adhesive effect is considerably reduced.
- The risk of explosive destruction of the clot is considerably reduced.

3 RISKS AND SAFETY DURING HF SURGERY

High-frequency surgery always entails certain risks for the patient, the staff and the surroundings. In order to avoid these risks in practice, the surgeon and his assistants must be aware of their existence and follow certain rules to prevent damage or injury. These risks are described below, together with the rules to be followed in order to prevent damage or injury.

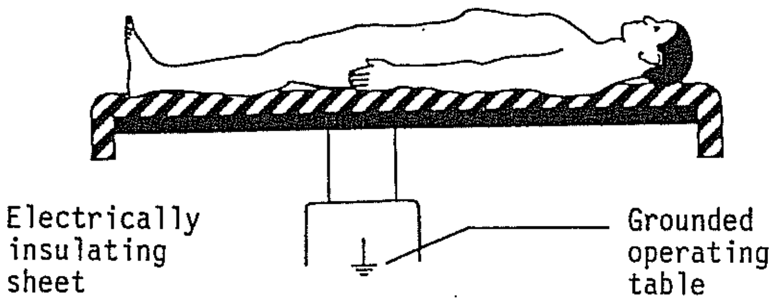
3.1 Accidental burns due to HF leakage currents

The patient inevitably conducts HF electrical voltages to ground during HF surgery. If he comes in contact with electrically conductive objects during surgery, a HF current may flow between that object and the patient which may in turn cause thermal necroses. Not only metal objects conduct electricity: damp and above all wet fabrics are also highly conductive.

The rules for application of high-frequency surgical equipment set out in DIN 57 753 therefore include the folowing requirements:

- The patient's entire body, including all extremities, must be insulated against all grounded metal parts of the operating table during HF surgery.

- Since elastic sheets on the operating table have a certain degree of conductivity in order to discharge any electric charges, they cannot always guarantee simultaneous HF insulation between the patient and any metal parts of the table. Such HF insulation can be achieved by using a sufficient number of additional intermediate layers (sheets).



Positioning the patient

- A waterproof sheet must be used to prevent the intermediate layers providing HF insulation from becoming soaked if moisture, perspiration, etc. is to be expected during the operation.

- Absorbent sheets must be placed between the patient and the waterproof sheet in order to prevent any accumulation of moisture below the patient.

- Additional sheets must be placed between any areas where considerable perspiration is to be expected, between limbs in contact with the torso or where skin-to-skin contact is unavoidable (e.g. between arm and torso, between the legs, below the breasts).

- <u>The following conditions must be satisfied if the patient is connected to the surgical equipment and also to a monitor (e.g. ECG)</u>:

  If both units are operated with grounded neutral electrodes, the neutral ECG cable must be connected to the neutral electrode of the HF surgery unit.

  The active surgical electrode must not be placed in the vicinity of the ECG electrodes (minimum distance 15 cm).

  The use of needle electrodes or injection cannulae is not recommended; the metal cone must never rest on the skin; the same also applies for the monitor cables.

- Urine must be discharged through a catheter.

3.2 **Accidental burns due to improper use**

Preference should generally be given to bipolar coagulation techniques rather than monopolar coagulation. This applies in particular when coagulating long organs in which the HF current flows through long strethes with invariable or increasingly narrow cross-sections.

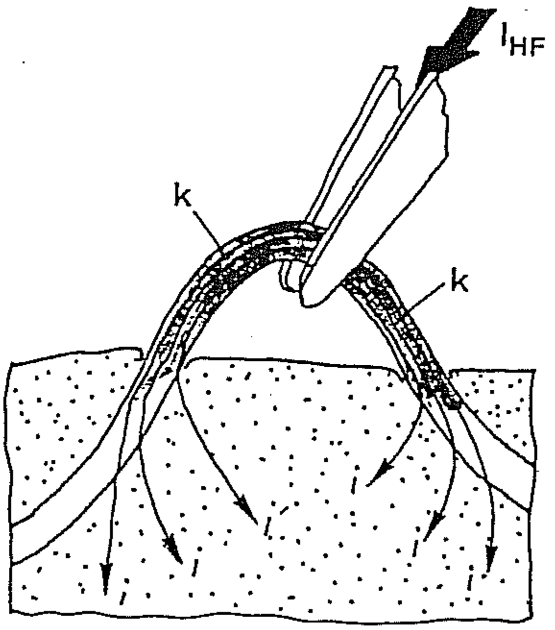


Fig.: If the high-frequency current I_{HF} flows through long tissue parts with the same cross-section when using monopolar techniques, the entire length k will be coagulated.

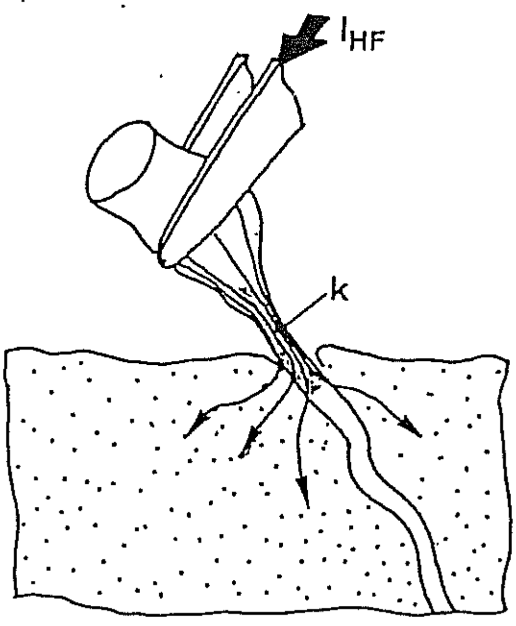


Fig.: If the high-frequency current flows through constrictions in the tissue when using monopolar techniques, the coagulation k starts at the point of constriction <u>and not at the point at which the coagulation electrode touches the tissue</u>.

3.3 Accidental burns due to improper use of the neutral electrode

If the neutral electrode is not applied correctly or is not used at all, there is a very high risk of accidental burns both at the point of application of the neutral electrode and at other points on the patient's body.

The following rules must therefore be observed when applying the neutral electrode:

- The effective contact area and the value of the electrical conductance between neutral electrode and patient must be adequate for the HF output and intensity of the HF current used.

  The effective contact area in this case is the area of the neutral electrode in electrically conductive contact with the patient's skin during HF surgery.

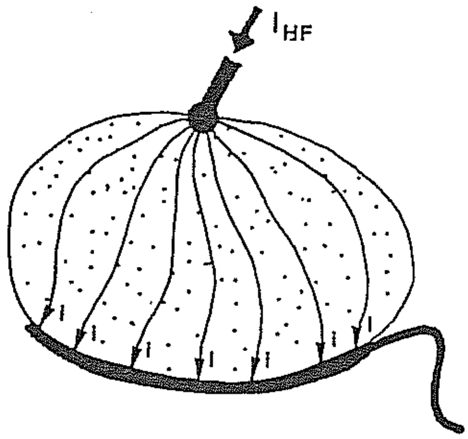


Fig.: The current density at the neutral electrode is only negligibly small if it makes full electrical contact with the patient's skin.

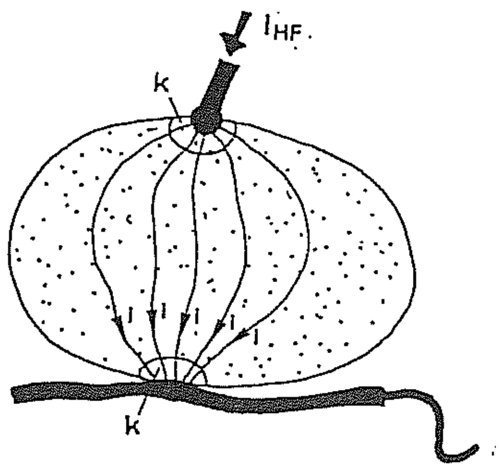


Fig.: If the neutral electrode makes only partial contact with the patient's skin, the current density at this effectively small point can become extremely large and burn the tissue.

Many years of experience have shown that neutral electrodes should be selected and used in accordance with the following criteria:

Neutral electrode of electrically conductive silicone	1.5 W/cm^2_{rms} or 10 mA/cm^2_{rms}
Metal neutral electrode without conductive gel	3.0 W/cm^2_{rms} or 15 mA/cm^2_{rms}
Disposable neutral electrode	5.0 W/cm^2_{rms} or 20 mA/cm^2_{rms}

3.4 Accidental burns due to the use of unsuitable and/or defective accessories

It must be ensured that only faultless accessories are used for high-frequency surgery. Only accessories tested by the manufacturer within the framework of type tests or compatible accessories may be used.

The compatibility of the accessories must be certified in the form of a compatibility certificate issued by an approved test center. This applies for both the active and the neutral electrodes with their respective cables and plug connectors.

The insulation on electrodes, electrode holders, cables, connectors, etc. must be in absolutely perfect condition.

Neutral electrodes must guarantee perfect electrical contact with the patient's skin.

3.5 Accidental burns due to inattentiveness

Like a scalpel, high-frequency surgery is a source of potential danger if applied without exercising due caution.

The cutting or coagulation electrodes must always be handled with extreme care and put aside so that neither the patient nor other people can come in contact with the electrodes when they are not in use.

<u>It is dangerous to leave unused electrode handles or coagulation forceps on or beside the patient or in the artificial folds in the sheets</u>! Patients have been known to suffer burns because their skin was inadvertently pierced by coagulation forceps put down in the folded sheets.

3.6 Accidental burns due to output errors

The risk of accidental burns is directly proportional to the intensity and duty cycle set on the unit for cutting and/or coagulation.

The intensity selected for cutting and/or coagulation should be no more than is actually required for the momentary purpose and should not be switched on for longer than necessary (refer also to the Chapter entitled "SAFETY FEATURES, Output errors").

IMPORTANT: **If normal settings produce an inadequate effect, this may be due to poor contact between skin and neutral electrode, poor contact in the plug connectors, broken wires inside the insulation or encrusted electrodes. These possibilities must be checked before selecting a higher output intensity.**

3.7 Accidental burns due to the ignition of flammable liquids, gases and/or vapors

Sparks are always produced at the active electrode when HF surgical units are in operation. For this reason, particular care must be taken during HF surgery to ensure that anaesthetics, skin cleansers, degreasing agents and disinfectants are neither flammable nor explosive. At the very least, they must be allowed to evaporate completely and taken out of the vicinity of the sparks before switching on the HF surgical equipment.

HF surgery should not be performedin the gastro-intestinal tract since endogenous gases present a potential explosion hazard; this does not apply if the explosive gases are eliminated from these organs, for instance by flushing with inert gases, before and during the high-frequency surgery.

IMPORTANT: H_2O molecules may dissociate to form H_2 and O_2 in the electric arc between resection loop and flushing liquid during transurethral resection (TUR). **These gases may accumulate at the top of the urinary bladder to form a highly explosive mixture. Potentially dangerous explosions may be produced by cutting in such a mixture of gases.**

3.8 Electric shock

An electric shock may be produced if the low-frequency current delivered by the HF surgical unit is too high or if an excessively high low-frequency current flows through the patient and into the HF unit from another voltage source.

The ERBOTOM ACC 430 and ERBOTOM ACC 450 are fitted with a low-frequency leakage current monitor which generates a warning signal if the low-frequency leakage current exceeds 0.05 mA (refer also to the Chapter entitled "Low-frequency leakage current monitor").

3.9 Stimulation of muscles and nerves

Inadvertent stimulation of the patient's muscles and nerves is a familiar risk in high-frequency surgery. Such stimulation may be caused by low-frequency currents originating either in low-frequency current sources (refer to the Chapter entitled "Electric shock") or in electric arcs between the active electrode and the patient's tissue.

Note: An alternating current with a frequency of more than 300 kHz cannot stimulate nerves and muscles.

However, the electric arcs inevitably produced when cutting and during forced or spray coagulation cause part of the high-frequency alternating current to be rectified, thus producing more or less strongly modulated low-frequency current components stimulating those structures capable of electrical stimulation, such as nerves and muscles. This may in turn lead to more or less pronounced twitching and/or muscular contractions.

IMPORTANT: **Muscular contractions must be expected during high-frequency surgery on structures capable of electrical stimulation. Such contractions may occur, for example, during endoscopic surgery in the urinary bladder, near the obturator nerve or near the facial nerve.**

3.10 Interference with other electronic equipment

By their very nature, HF surgical units generate high-frequency voltages and currents which can cause interference in other electronic equipment.

This problem should be taken into account when installing or arranging sensitive electronic equipment in the operating theatre. Sensitive electronic equipment should always be positioned as far away as possible from the HF surgical unit and away from all cables conducting HF currents. Moreover, these cables should be kept as short as possible and must never be routed near and parallel to the cables of sensitive electronic equipment, for no matter how carefully they are shielded, the HF cables have the same effect as a transmission antenna.

On account of the interference in sensitive electronic equipment, the ERBOTOM ACC series of HF surgical units has been equipped with a special generator which outputs relatively low interference levels as compared with conventional HF equipment.

ADDITIONAL IMPORTANT NOTES

UNINTENTIONAL ACTIVATION OF THE HF-GENERATOR

WARNING: Unintentional activation of the high-frequency generator can lead to patient burns when the active electrode touches the patient directly or indirectly through electrically ductile objects or wet cloths.

Unintentional activation of the high-frequency generator can be caused for example by:

- unintended pressing of a footpedal
- unintended pressing of a button on the electrode handle
- short circuit within a cable to the electrode handle with push buttons or to the footswitch
- penetration of electrically ductile fluids into a finger switch, into an electrode handle or into a footswitch. Electrically ductile fluids are for example blood, amniotic fluid **(special care is called for in cesarean section, see under point 1)**, urine, physiological saline, irrigation fluids etc.
- defects within the high-frequency surgical unit

In order to avoid patient burns due to unintended activation of the high-frequency generator, the following rules of application must be observed:

1. **Never place active electrodes on or beside the patient in such a way** that the electrodes can touch the patient directly or via electrically ductile objects or wet cloths.
2. The acoustic signal which indicates the activation of the high-frequency generator **must always be adjusted so that it can be heard.**
3. In operations in which the cutting or coagulation electrode unavoidably remains in contact with the patient even in the unactivated state, e. g. in endoscopic operations, special care is called for. An electrode activated unintentionally owing to a mistake should not be removed without due precautions from the body. In removal of the activated electrode from the body of the patient, burns may arise at all areas within the body which come into contact with the activated electrode. **For this reason, the mains switch of the high-frequency surgical unit must be turned off immediately** before an attempt is made to remove the activated electrode from the body.

UNINTENDED BURNS CAUSED BY HOT ELECTRODES

WARNING: Cutting and/or coagulation electrodes become hot indirectly from the heated tissue and from the electric arc during cutting and/or coagulation processes. Tissue may be unintentionally burned after cutting and/or coagulation when electrodes which are still hot have contact with the tissue. This is to be noted especially in endoscopic operations, for example in pelviscopic coagulation of the Fallopian tube or in endoscopic polypectomy.

4 GENERAL DESCRIPTION OF THE ERBOTOM ACC 450

The ERBOTOM ACC 450 is a high-frequency surgical instrument with the following characteristic features:

<u>Automatically controlled HF output voltage in CUTTING MODE</u>

The HF output voltage of the ERBOTOM ACC 450 remains constant during all relevant applications. This function is realized by a particularly fast-acting automatic control loop making it unnecessary to adjust the power as required for conventional high-frequency surgical equipment.

The cutting quality, i.e. the depth of the coagulation zone of the cut surfaces, is largely independent of the depth and rate at which the cut is produced. It can be selected, definitively and reproducibly, in five stages via push-buttons.

<u>Three different monopolar COAGULATION MODES</u>

1. <u>SOFT COAGULATION</u> is characterized by the fact that no electric arcs are produced between the coagulation electrode and the tissue during the coagulation process. This not only prevents the coagulation electrode from adhering to the coagulated tissue, but also prevents the tissue from carbonizing.

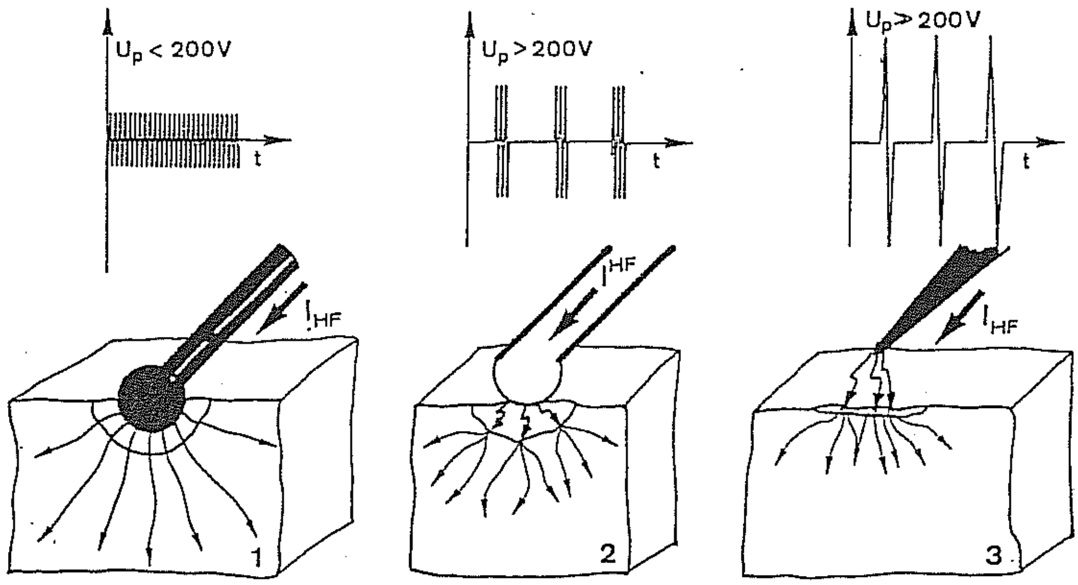
   The HF voltage is automatically kept constant in SOFT COAGULATION MODE, making it unnecessary to adjust the power level.

2. <u>FORCED COAGULATION</u> is characterized by the fact that electric arcs are deliberately produced between the active electrode and the tissue, yielding a considerable coagulation depth in relation to the effective contact area of the active electrode.

   This coagulation mode should be used when relatively large coagulation depths must be obtained using fine or thin active electrodes, i.e. typical cutting electrodes.

3. SPRAY COAGULATION is characterized by the fact that the coagulation electrode need not come in direct contact with the tissue to be coagulated. The HF voltage used for this coagulation mode is so high that an electric arc is produced between the coagulation electrode and the tissue, conducting the coagulation current to that part of the tissue where the conductivity is greatest. As a rule, this will be a blood vessel, which is why SPRAY COAGULATION is particularly suitable for coagulating blood vessels between inaccessible bone fissures.

Both the length and the intensity of the electric arcs can be set definitively on the ERBOTOM ACC 450.



Soft Coagulation Forced Coag. Spray Coagulation

MONO/BIPOLAR AUTOCOAGULATION can not only make the operator's work easier, in that the HF generator is automatically activated and deactivated by the equipment, but can also considerably improve the quality of the monopolar and bipolar coagulation processes.

5 FUNCTION CHECKS

The ERBOTOM ACC 450 includes a number of automatic function checks which are run through very quickly whenever the power is switched on.

The functions required for each application should additionally be checked before the equipment and its accessories are used.

5.1 Automatic function checks

Whenever the power is switched on, the equipment immediately runs through an internal automatic test routine which detects and signals the following faults in the equipment controls and in the accessories connected to the equipment:

1. If one of the keys on the front panel has been shorted due to a fault or if it is pressed when the power is switched on, this fault is indicated acoustically after switching on the power; the digit or word alongside the defective or pressed key flashes to identify the key concerned.

2. If one of the keys on an electrode handle has been shorted due to a fault or has been bridged with low impedance (e.g. due to moisture in the electrode handle) or was pressed when the power is switched on, this fault is indicated acoustically after switching on the power; the triangles in the frame of the corresponding function field flash to identify which key is defective or pressed.

3. If one of the contacts in the foot pedal has been shorted due to a fault, if a pedal has jammed or is pressed when the power is switched on, this fault will be indicated acoustically and the triangles in the frame of the corresponding function field flash to identify which pedal is involved.

5.2 Manual function checks

1. NE test

   The neutral electrode test (NE test) is used to

   - check the correct functioning of the neutral electrode monitor,
   - check that the neutral electrode is correctly connected to the equipment and,

   if neutral electrodes with two contact surfaces are used,

   - to check that the neutral electrode has been applied to the patient (refer also to the Section entitled "NE test").

2. Checking the acoustic signal

   The relevant acoustic signal must always sound whenever a function field is activated.

3. Checking the HF output voltage

   The equipment will generate visual and acoustic alarms if the set HF output voltage differs from that prevailing when a particular operating mode, such as CUTTING or SOFT COAGULATION, is activated (refer to the Section entitled "Output errors").

6 DESCRIPTION OF THE CONTROL ELEMENTS

1 Power switch

Whenever the equipment is switched on, it automatically performs a number of function tests. If these reveal a fault, this is indicated visually and/or acoustically.

If the equipment was only briefly switched off (for up to approx. 15 seconds), the settings previously selected in the function fields CUTTING, COAGULATION, AUTOCOAGULATION MONO/BIPOLAR are saved and the equipment is immediately operational, unless other settings are required.

If it was switched off for more than 15 seconds, the default setting is shown after switching on the equipment again. The LEDs alongside the corresponding keys flash to indicate the selected default setting. If this setting is required, simply press one of the flashing keys. The unit is immediately operational.

If other settings are required, the keys concernced must be pressed to set new values.

IMPORTANT! The functions CUTTING, COAGULATION and AUTOCOAGULATION MONO/BIPOLAR can only be activated by means of the push-button or foot-operated switch or by AUTO-START when the power is switched on and the individual functions have been set completely, i.e. when all the indicators in the function field concerned have stopped flashing.

2-4 Function fields

The function fields CUTTING, COAGULATION, AUTOCOAGULATION MONO/BIPOLAR can be set and used independently of one another.

Although the settings in the function fields can be changed as required, this is not possible while the equipment is activated.

2 **Function field CUTTING**

The automatically controlled cut makes HF power adjustment unnecessary in the ERBOTOM ACC ... series (ACC = automatically controlled cut). The only setting that is required is for the degree of coagulation of the cut. Level 1 corresponds to the minimum coagulation degree, level 5 being the maximum degree.

3 **Function field COAGULATION**

The COAGULATION function field encompasses four different coagulation modes, namely SOFT COAG., FORCED COAG., SPRAY COAG. 1 and SPRAY COAG. 2.

When setting this function field, the COAGULATION MODE must always be set first, and then the required INTENSITY.

4 **Function field MONO/BIPOLAR AUTOCOAGULATION**

This function field can be used for monopolar or bipolar coagulation totally independently of the COAGULATION field (3). It offers a variety of coagulation techniques. It can be activated conventionally via push-button or foot-operated switches (MANUAL or PEDAL), semi-automatically (AUTOSTART) and fully automatically (AUTOSTART/AUTOSTOP).

When setting this function field, always proceed from left (COAG. MODE) to right (INTENSITY). This also applies when altering the settings.

5 **Connecting socket for neutral electrodes**

A suitable neutral electrode must be applied to the patient and connected to the equipment for monopolar coagulation techniques.

The ERBOTOM ACC 450 is equipped with an NEUTRAL ELECTRODE monitoring system (refer to the Section entitled "SAFETY FEATURES, NE MONITOR") which monitors the electrical connection between the neutral electrode and the equipment, as well as between the neutral electrode and the patient. However, the latter is only possible if suitable neutral electrodes with two contact surfaces are used.

This socket is used for all function fields (CUTTING, COAGULATION and MONOPOLAR AUTOCOAGULATION).

IMPORTANT: The ERBOTOM ACC 450 and ACC 430 are equipped with a low-frequency leakage current monitor which monitors any low-frequency leakage currents flowing into or out of the equipment.

In this way, the equipment fulfils the requirements for type CF, although the neutral electrode is grounded via a capacitor.

6 **CUTTING and COAGULATION socket** for the CUTTING and COAGULATION function fields.
Electrode handles with or without push-button switches can be operated via this socket. However, it can also be used to connect other instruments, such as rigid or flexible endoscopes.

Push-button or foot-operated switches can be used for activation.

7 **Monopolar AUTOCOAGULATION socket** for the AUTOCOAGULATION function field
Electrode handles with or without push-button switches can be operated via this socket. However, it can also be used to connect other instruments, such as special-purpose monopolar coagulation electrodes or monopolar coagulation forceps.

Activation is possible via push-button or foot-operated switches or automatically.

WARNING! If two alike electrode handles are connected to the monopolar sockets for CUTTING (6) and AUTOCOAGULATION (7) at the same time, <u>the electrode handles must be put down such that any possible mixing up is avoided. In case of doubt the equipment should be activated for testing but the patient must not be touched by the active electrode.</u>

8 **Bipolar AUTOCOAGULATION socket**

Bipolar coagulation instruments, such as bipolar coagulation forceps, can be connected to this socket.

Activation is possible via foot-operated switch or automatically.

NOTE:

Cables may be connected to both sockets (7) and (8) at the same time. For safety reasons, however, only the monopolar <u>or</u> bipolar socket can be activated depending on which COAGULATION MODE has been selected at the front panel.

NOTE:

In order to prevent any possible thermal damage to bipolar coagulation forceps with fine tips, the INTENSITY should be set to the maximum of 0.8. If a higher INTENSITY is used, it must be taken care that the tips not come into contact with one another.

9 **Monitoring panel**

The HF surgical units ERBOTOM ACC 450 include a variety of safety features designed to protect both the patient and the user against injury due to low-frequency leakage current, HF leakage current, output errors, excessively long unintentional activation of the HF current and burns due to incorrect application of the neutral electrode.

These SAFETY FEATURES are described in detail in Chapter 8.

10 **Socket for foot pedal** (on the rear panel)

Both a single or a double pedal can be connected to this socket. With the yellow pedal only CUTTING can be activated.

NOTE:

Use of the blue pedal for different coagulation modes:
The blue pedal can be used to activate SOFT, FORCED or SPRAY coagulation, as well as for the AUTOCOAGULATION function field.

If the blue pedal is first used for the AUTOCOAGULATION function field and then for SOFT, FORCED or SPRAY coagulation, a different START MODE, such as MANUAL, must be selected in the AUTOCOAGULATION field so that the blue pedal becomes free for SOFT, FORCED or SPRAY coagulation.

11 **Connection for potential equalization** (on the rear panel)

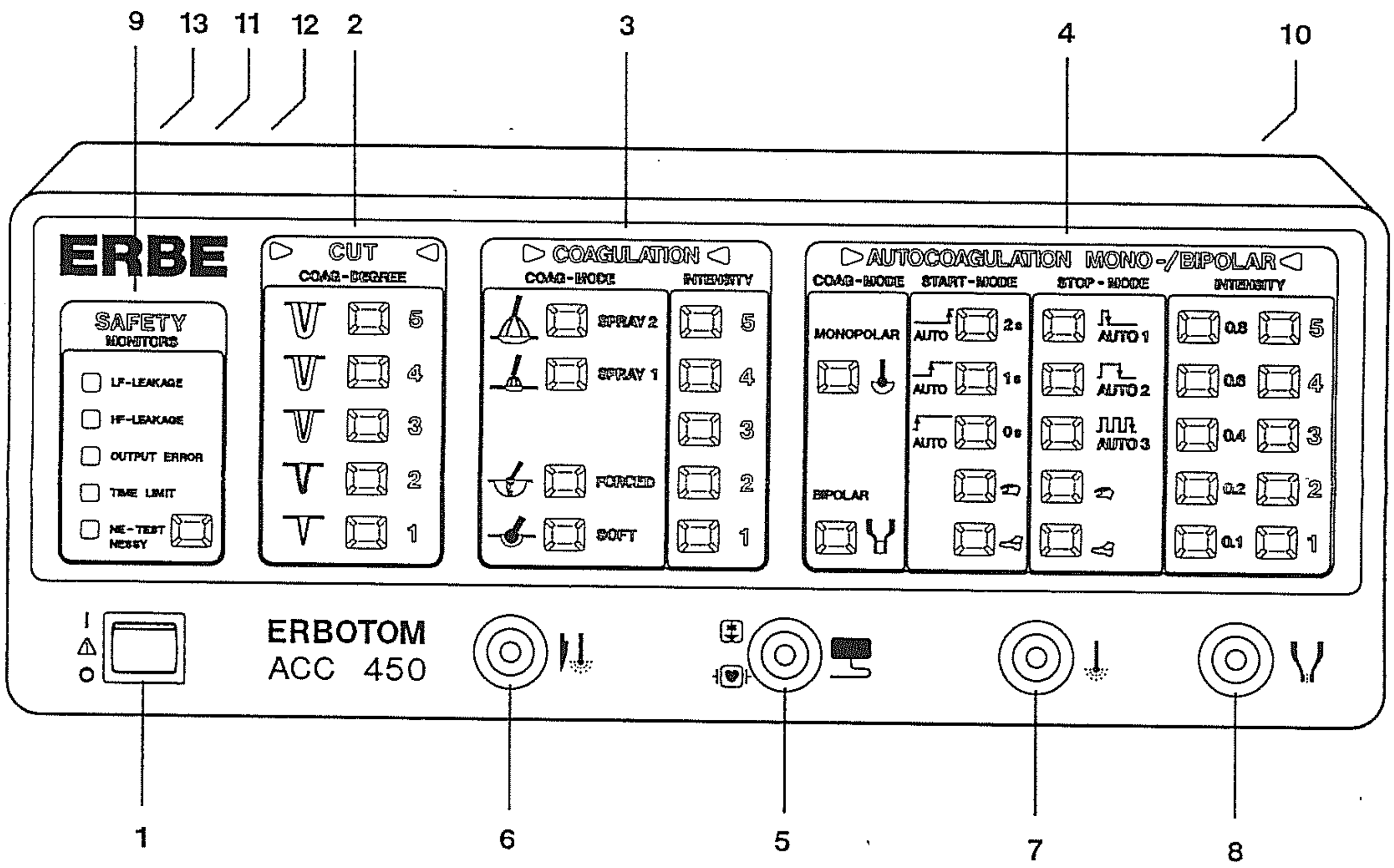
12 **Volume control for the acoustic signal** (on the rear panel)
The volume of the acoustic signal can be adjusted by means of this control during activation of the high-frequency generator.

IMPORTANT: **One of the main purposes of this acoustic signal is to protect both the patient and the staff against burns due to accidental activation of the high-frequency generator.**

13 **Power socket** (on the rear panel)

IMPORTANT: The ERBOTOM ACC 430 and ACC 450 may only be connected to correctly installed earthed sockets using the mains lead supplied by the equipment manufacturer or a lead of the same quality and bearing the national calibration mark. Adapters or extension leads should not be used, for safety reasons. If their use is unavoidable, they must also be fitted with a faultless protective earth conductor.

The mains socket must have a fuse with a rating of at least 10 A.


9
13
11
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4
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ERBE
SAFETY
MONITORS
LF-LEAKAGE
HF-LEAKAGE
OUTPUT ERROR
TIME LIMIT
NE-TEST
NESSY
CUT
COAG-DEGREE
5
4
3
2
1
COAGULATION
COAG-MODE
INTENSITY
SPRAY 2
SPRAY 1
FORCED
SOFT
AUTOCOAGULATION MONO-/BIPOLAR
COAG-MODE
START-MODE
STOP-MODE
INTENSITY
MONOPOLAR
BIPOLAR
AUTO
2s
1s
0s
AUTO 1
AUTO 2
AUTO 3
0.8
0.6
0.4
0.2
0.1
ERBOTOM
ACC 450
1
6
5
7
8

7 SETTING THE ERBOTOM ACC 450

The equipment can be set most easily if the preprogrammed default setting can be used. In this case, simply press one of the flashing keys after switching on the mains switch, thus confirming that the default setting is required.

If the default setting is to be changed, it can be programmed as follows:

1. Switch off the equipment by the mains switch.

2. Press keys 1 and 2 in the function field CUTTING and simultaneously switch on the mains switch.

3. The LEDs alongside keys 1, 2 and 5 in the function field CUTTING now light up.

4. Press key 5. The equipment is now set to programming mode. This is indicated by a continuous acoustic signal.

5. The setting which is to replace the default setting can now be effected on the front panel by pressing the appropriate keys.

   IMPORTANT! Any plausible setting can be stored in the equipment as its default setting. Individual function fields or even the entire front panel can be set to OFF and stored as the default setting.

6. This setting is saved in the equipment as the new default setting by switching off the mains switch.

If a differnt setting is to be used in place of the default setting, it can be programmed by pressing the appropriate keys as follows:

- CUTTING

  Simply select the required coagulation degree for cutting (degree of haemostasis during the cutting process). The power is adjusted automatically.

- COAGULATION

  First select the coagulation mode, i.e. either
  SPRAY COAGULATION 2 or
  SPRAY COAGULATION 1 or
  FORCED COAGULATION or
  SOFT COAGULATION.
  The intensity levels then flash as a reminder to input the required intensity for the mode selected: 1 = minimum intensity, 5 = maximum intensity.

- AUTOCOAGULATION MONO/BIPOLAR

  1. Select COAG.-MODE, i.e. either
     MONOPOLAR or
     BIPOLAR

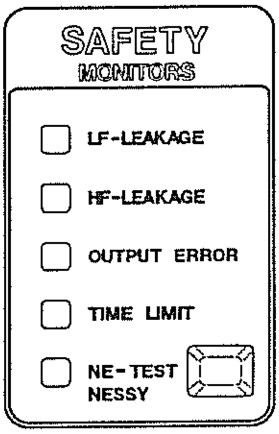
  2. Select the START-MODE, i.e. either
     AUTO 2 seconds or
     AUTO 1 s or
     AUTO 0 s or
     FINGERSWITCH or
     FOOTSWITCH

  3. Select the required STOP-MODE, i.e. either
     AUTO 1 or
     AUTO 2 or
     AUTO 3 or
     FINGERSWITCH or
     FOOTSWITCH

  4. Select the required INTENSITY

As a rule, only three different modes will be required for an operation, so that the equipment can be set **quickly and reliably.**

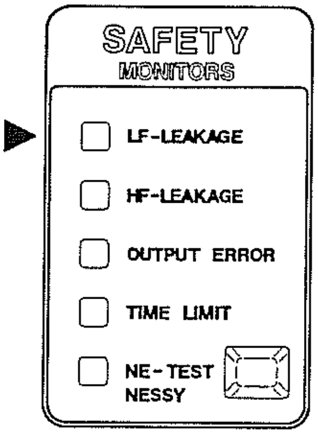
8 SAFETY FEATURES OF THE ERBOTOM ACC 430 and ACC 450



The high-frequency surgical units ERBOTOM ACC 430 and ACC 450 include a variety of safety features reducing the risks entailed in high-frequency surgery for both the patient and the user.

These safety features are described in detail on the following pages.

8.1 LOW-FREQUENCY LEAKAGE CURRENT MONITOR



Definition: Low-frequency leakage current (VDE 0750, Part 1, and IEC 601, Part 1, refer to patient leakage current) is the current flowing from the applied part of a high-frequency surgical unit via the patient to earth; it also refers to the current from an external current source with which the patient is in contact and flowing via the patient, the applied part and the high-frequency surgical unit to earth (refer to VDE 0750, Part 1, Section 19).

During high-frequency surgery, the patient and sometimes also the operator come in electrically conducting contact with the applied part of one or more electrical appliances and instruments. The most important is the high-frequency surgical unit itself. In this way, low-frequency currents can accidentally flow through and endanger the patient and/or operator.

The maximum permissible values for long-term leakage currents are specified in DIN/IEC 601, Part 1, and VDE 0750, Part 1/05.82, Section 19. Three safety levels are defined, namely types B, BF and CF.

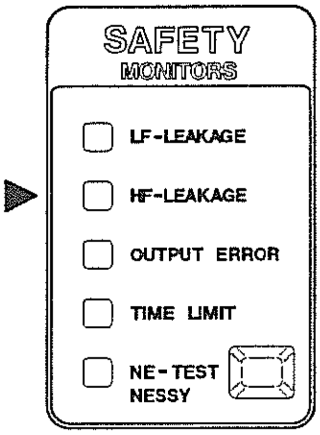
According to DIN/IEC 601, Part 2-2, and VDE 0750, Part 202, high-frequency surgical units must correspond to type BF at least; in other words, the low-frequency leakage current flowing through the patient from the unit's applied part must not exceed max. 0.1 mA in normal operation and max. 0.5 mA when the first fault occurs. If the high-frequency unit is used for cardiac surgery, it must correspond to type CF, i.e. the maximum permissible leakage current from the unit's applied part must not exceed 0.01 mA in normal operation and 0.05 mA when the first fault occurs.

The ERBOTOM ACC 430 and ACC 450 include a low-frequency leakage current monitor which **automatically monitors the low-frequency leakage current** flowing from the applied part of the high-frequency surgical unit via the patient.

If this current rises above 0.05 mA, the monitor automatically disconnects the capacitive grounding of the neutral electrode inside the unit, reducing the leakage current to less than 0.05 mA, switching off the HF generator. The fault is optically indicated on the front panel.

This protects both the operator and the patient against electric shocks.

8.2 HIGH-FREQUENCY LEAKAGE CURRENT MONITOR



Definition: High-frequency leakage current is the current unintentionally flowing from the applied part and patient through other electrically conductive connections outside the applied part (refer to VDE 0750, Part 202, Section 19.101).

HF leakage currents are unavoidable in high-frequency electrosurgery. This applies in particular for all monopolar application techniques.

In order to prevent the uncontrolled flow of HF leakage currents through the patient and accidentally causing burns, it must be ensured that the patient does not come in contact with electrically conductive objects during the operation. This applies above all for objects with inductive or capacitive grounding. Burns due to HF leakage currents can be avoided by observing this rule.

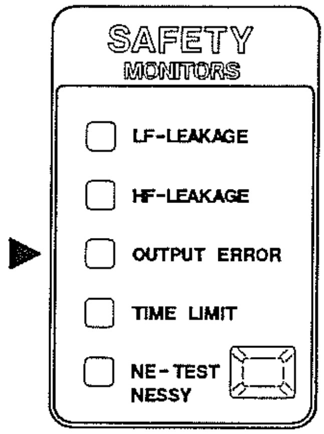
DIN/IEC 601, Part 2-2, and VDE 0750, Part 202, Section 19.101, set the maximum permissible leakage current not capable of significantly burning the patient at 150 mA.

In spite of carefully positioning the patient on the operating table, he or she can nevertheless accidentally come in contact with electrically conducting objects. Such contacts are unavoidable in some operations.

The ERBOTOM ACC 430 and ACC 450 are fitted with a high-frequency leakage current monitor which automatically monitors the HF leakage current and generates an optical alarm when the HF leakage current rises above 150 mA. It generates an additional acoustic alarm when the HF leakage current exceeds 300 mA.

In this event the surgeon should only proceed with cutting or coagulating if this is absolutely necessary.

8.3 OUTPUT ERROR MONITORING



Definition: According to Section 3, Para. 2 of the regulations governing medical equipment (MedGV), medical equipment classed in group 1 or 3 for the metered output of energy or drugs must include an alarm in case of metering errors due to the equipment.

An output error in this particular instance refers to every deviation of the HF output voltage (actual value) of an HF unit from the HF output voltage (required value) set on that unit insofar as the deviation is caused by the equipment itself.

If the actual value of the HF output voltage is lower than the required value set on the unit, the desired effect will only be achieved to an unsatisfactory extent or not at all.

If the actual value of the HF output voltage is greater than the required value set on the unit, more tissue will be damaged than is necessary to achieve the desired effect; undesired effects may also result.

The ERBOTOM ACC 410, ACC 430 and ACC 450 include automatic monitoring of the HF output voltage which monitors any deviations of the actual value from the required value set for the HF output voltage and which generates an alarm and/or disconnects the HF generator when the deviation becomes so great as to jeopardize the desired quality of the effect (cutting, soft coagulation or auto-coagulation).

For the operator, the advantage of indicating an output error due to the equipment is that he can immediately verify whether or not discrepancies or even the absence of a desired effect are due to a defect in the equipment.

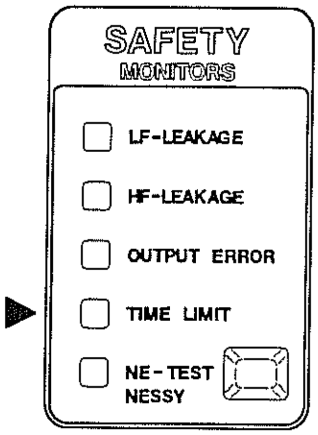
Discrepancies between the actual and required HF output voltages can only occur in the ERBOTOM ACC 410, ACC 430 and ACC 450 if the connected loads have an excessively low impedance (e.g. coagulation electrodes too large, short circuit between active and neutral electrodes, fault in the unit).

Effect \ Signal	Optical signal	Optical + acoustic signal + HF generator off
Cutting	over ± 20%	over +40%, -80%
Soft coagulation	over ± 20%	over +40%, -80%
* Forced coagulation	over approx. ± 15%	over -80%
* Spray coagulation	over approx. ± 15%	over -80%
Auto coagulation	over +20%	over +40%

Maximum deviation of the actual value from the set required value of the HF output voltage in the ERBOTOM ACC 410, ACC 430 and ACC 450, above which an optical alarm is generated; if the deviation becomes greater, an acoustic signal is also output and the HF generator deactivated.

* When using SPRAY- or FORCED COAG. not the HF output voltage but the supply voltage of the HF generator is monitored.

8.4 DUTY MONITOR



Definition: The duty cycle in this case refers to the time during which the high-frequency generator of a high-frequency surgical instrument is continuously switched on.

When used for its intended purpose, the high-frequency generator will only be switched on briefly by means of the push-button, pedal switch or automatic activation in order to carry out a cutting or coagulation process. As a rule, this will only take a few seconds.

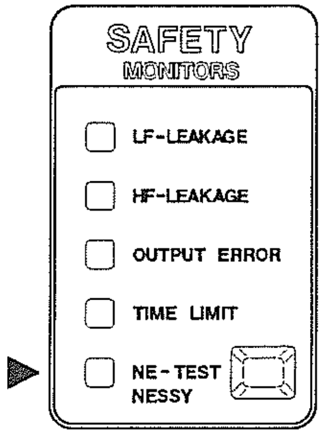
The high-frequency generator may be switched on unintentionally as a result of a fault in the equipment or accessories or as a result of an operator error. In order to prevent major damage due to such accidental activation of the HF generator, the **ERBOTOM ACC 410, ACC 430 and ACC 450 are fitted with a monitor which automatically monitors the duty cycles of the high-frequency generator.** *When a preset time is exceeded, the monitor generates an optical and acoustic alarm. If the HF generator is not then switched off, it is automatically deactivated by the monitor upon expiry of a further preset time. **

The high-frequency generator can be restarted at any time and the duty cycle is again monitored automatically.

This prevents major damage due to unintentional activation of the high-frequency generator for indefinite periods of time.

* 15 Seconds
** 10 Seconds

8.5 NEUTRAL ELECTRODE MONITOR



Definition: According to DIN/VDE 0750, Part 202, Section 2.1.104, a neutral electrode is an electrode with a relatively large surface area to be positioned on the patient in order to allow the high-frequency current to flow back with such a low current intensity in the body tissue as to prevent any physical effects, such as undesired burns.

The ERBOTOM ACC 410, ACC 430 and ACC 450 are fitted with a safety monitor for the neutral electrode which can monitor both the electrical connection between the equipment and the neutral electrode, as well as application of the neutral electrode on the patient.

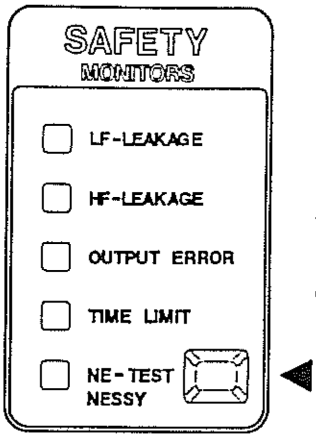
Only the electrical connection between the equipment and the neutral electrode is automatically monitored when a neutral electrode with only one contact surface is used. If this connection is interrupted, the red indicator lights up and an intermittent alarm sounds. **The high-frequency generator cannot be activated in this case.**

Both the electrical connection between the equipment and the neutral electrode and application of the neutral electrode on the patient are automatically monitored when a neutral electrode with two contact surfaces is used. If the electrical connection between the equipment and the neutral electrode is interrupted or if the neutral electrode is inappropriately positioned on the patient or not applied at all, the red indicator lights up and an intermittent alarm sounds.

The ERBOTOM ACC 430 and ACC 450 are additionally fitted with a neutral electrode safety system (NESSY) ideally satisfying the requirements of DIN/VDE 0750, Part 202, Section 2.1.104, as it automatically and continuously monitors the contact area and electrical conductance between the neutral electrode and the patient's skin in relation to the intensity of the high-frequency current.

The advantage of NESSY is that it only outputs an alarm if and when the intensity of the high-frequency current rises above the value permitted for the electrical conductance prevailing between the electrode and the patient. This reduces the risk of faulty alarms unnecessarily interrupting the operation. NESSY also makes it possible to use various neutral electrode models, as it is not restricted to one particular model. NESSY can also be used in conjunction with small neutral electrodes, such as those used for small children.

8.6 NE TEST



Definition: The neutral electrode test (NE test) is used to check the correct functioning of the neutral electrode monitor, connection of the neutral electrode to the equipment and whether the neutral electrode has been applied to the patient (when using neutral electrodes with two contact surfaces).

- **Checking the correct functioning of the neutral electrode monitor**

  The red indicator must flash and an intermittent acoustic alarm sound when the NE Test button is pressed while there is no neutral electrode connected to the equipment or a neutral electrode with two contact surfaces is incorrectly applied to the patient.
  If the NE Test button is pressed when a neutral electrode is connected to the equipment and neutral electrodes with two contact surfaces are correctly applied to the patient, only the acoustic signal must sound.

  Any other reaction indicates a fault in the neutral electrode monitor.

- **Checking the electrical connection between the neutral electrode and the equipment, as well as the application of neutral electrodes with two contact surfaces on the patient**

  When the patient has been prepared for high-frequency electrosurgery and before starting the operation, the NE Test button can be pressed to check that an electrical connection has been made between the neutral electrode and the equipment.

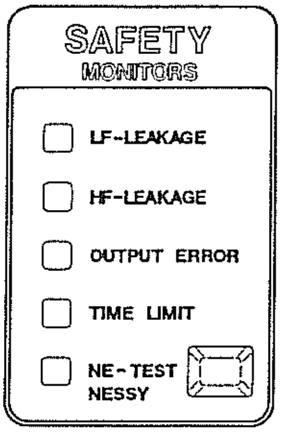
  The electrical connection between the neutral electrode and the patient has been correctly established when the acoustic signal sounds continuously and the red indicator alongside the NE TEST button does not light. When using a neutral electrode with two contact surfaces, this also indicates that the neutral electrode has been applied to the patient.

  The electrical connection is defective if the red indicator alongside the NE Test button flashes and an intermittent acoustic alarm sounds.

  When using a neutral electrode with two contact surfaces, this can also indicate that the neutral electrode has not been applied to the patient or that it has been applied incorrectly.

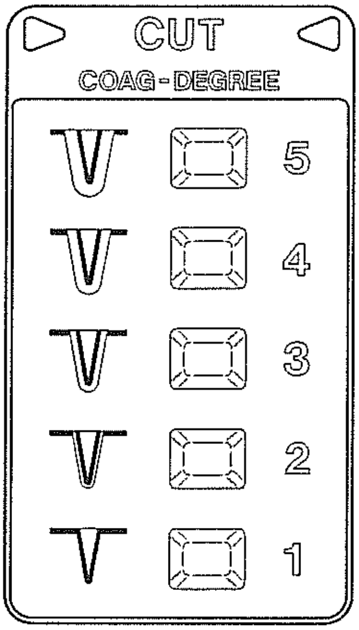
8.7 SAFETY AGAINST OPERATOR ERRORS

The front panel of the ERBOTOM ACC 450 is subdivided into a monitoring panel, three mutually independent function fields, a socket panel and a power switch. The sockets for pedals, power lead and potential equalization, as well as the volume control, are all located on the rear panel, as they are operated relatively infrequently.

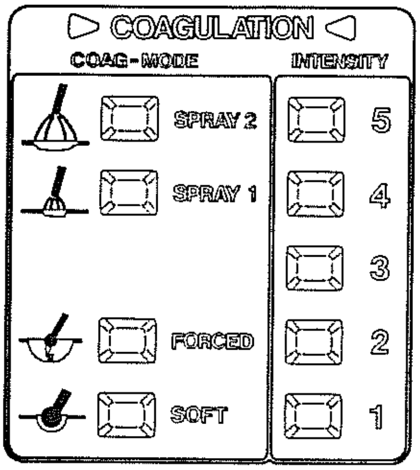


The monitoring panel (grey) contains all the main safety monitors. If any of these monitors detects a fault or hazardous condition, the user is warned by means of visual and acoustic alarms.

(Refer to the Section "SAFETY FEATURES OF THE ERBOTOM ACC 430 and ACC 450").



The function field CUTTING (yellow) can be set very easily, thanks to the precise graduation and automatically controlled HF output voltage. Only one button need be pressed in order to set one of the five cut qualities. Conventional HF surgical equipment normally requires two separate settings for power and degree of coagulation.

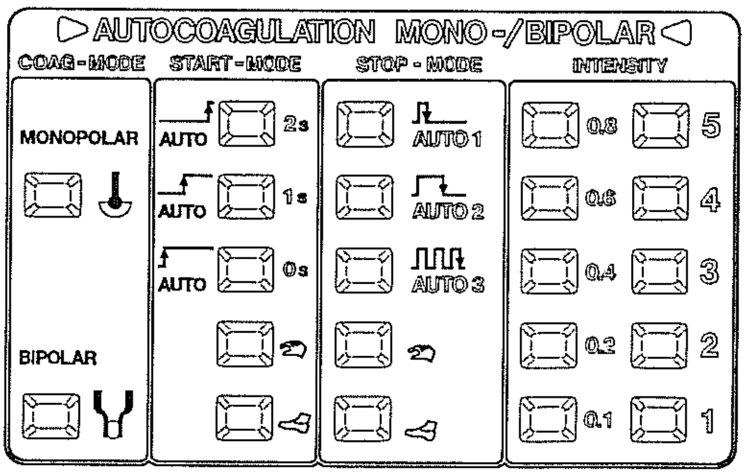


The function field COAGULATION (blue) contains two (ERBOTOM ACC 410 and ERBOTOM ACC 430) or four (ERBOTOM ACC 450) monopolar coagulation modes. Each coagulation mode can be set very quickly by pressing the corresponding COAGULATION MODE key and the required INTENSITY key.

In order to ensure that the required intensity is not forgotten after setting or changing the COAGULATION MODE, the digits alongside the INTENSITY keys flash until an INTENSITY has been selected after every change of COAGULATION MODE.

The required COAGULATION MODE can <u>only</u> be activated by push-button or pedal if the corresponding COAGULATION MODE and INTENSITY have definitively been set.

IMPORTANT: **If the blue button on the electrode handle or the blue pedal switch is pressed without first setting this function field or if the setting is incomplete, the equipment will generate an intermittent acoustic alarm and the two triangles in the field's frame will flash.**



The function field MONO/ BIPOLAR AUTOCOAGULATION (blue) contains all the keys required for monopolar and bipolar coagulation. Four steps are required for every coagulation technique:

1. Select COAG.-Mode, MONOPOLAR or BIPOLAR

2. How is the coagulation process to be started?
   Select the START MODE!

3. How is the coagulation process to be stopped?
   Select the STOP MODE!

4. Is coagulation to take place quickly or slowly?
   Select the required INTENSITY!

IMPORTANT: **The coagulation depth that can be achieved varies in inverse proportion to the coagulation rate. The more slowly coagulation proceeds, the larger the clot will be.**

A variety of coagulation techniques are possible using the ERBOTOM ACC 450. In order to prevent operator errors in what appears at first glance to be a complex function field, the field has been designed in such a way that illogical and/or incomplete settings are monitored and signalled automatically. Coagulation can only be started if the settings for the coagulation technique in question are complete.

IMPORTANT: **Coagulation processes can only be started if a coagulation technique has been correctly set in this field, i.e. if none of the indicators in this field are flashing. If an attempt is made to start before the coagulation technique is set or before the setting is complete (those keys which have not yet been set continue to flash), the equipment will generate an intermittent acoustic alarm and the two triangles in the field's frame will flash.**

All the sockets for the application section of the equipment are located in the **socket panel** below the front panel.

These sockets are designed so that they will only accept the plug connector of the correct accessory (provided that only accessories supplied or recommended by the equipment manufacturer are used).

NOTE:

The monopolar and bipolar sockets for the **MONO/BIPOLAR AUTOCOAGULATION function field are electronically interlocked in such a way that the HF generator can only be activated if either the monopolar <u>or</u> the bipolar socket is used.**

Whenever the power is switched on, the equipment immediately runs through an internal **automatic test routine** which detects and signals the following faults in the equipment controls and in the accessories connected to the equipment:

1. If one of the keys on the front panel has been shorted due to a fault or if it is pressed when the power is switched on, this fault is indicated acoustically after switching on the power; the digit or word alongside the defective or pressed key flashes to identify the key concerned.

2. If one of the keys on an electrode handle has been shorted due to a fault or has been bridged with low impedance (e.g. due to moisture in the electrode handle) or was pressed when the power is switched on, this fault is indicated acoustically after switching on the power; the triangles in the frame of the corresponding function field flash to identify which key is defective or pressed.

3. If one of the contacts in the foot pedal has been shorted due to a fault, if a pedal has jammed or is pressed when the power is

switched on, this fault will be indicated acoustically and the triangles in the frame of the corresponding function field flash to identify which pedal is involved.

SAVING THE SETTINGS on the front panel during a power failure or when the power is switched off.

Whenever the equipment is switched on, it automatically performs a number of function tests. If these reveal a fault, this is indicated visually and/or acoustically.

If the equipment was only briefly switched off (for up to approx. 15 seconds), the settings previously selected in the function fields CUTTING, COAGULATION, AUTOCOAGULATION MONO/BIPOLAR are saved and the equipment is immediately operational, unless other settings are required.

If it was switched off longer than 15 seconds, the default setting is shown after switching on the equipment again. The LEDs alongside the corresponding keys flash to indicate the selected default setting. If this setting is required, simply press one of the flashing keys. The unit is immediately operational.

If other settings are required, the keys concernced must be pressed to set new values.

IMPORTANT! The functions CUTTING, COAGULATION and AUTOCOAGULATION MONO/BIPOLAR can only be activated by means of the push-button or foot-operated switch or by AUTO-START when the power is switched on and the individual functions have been set completely, i.e. when all the indicators in the function field concerned have stopped flashing.

9 TECHNICAL DATA OF THE ERBOTOM ACC 450

Mains connection

Mains voltage	220 V ± 20% / 50 Hz ± 5%, switchable to 110 V ± 20% / 60 Hz ± 5%
Protection class to DIN/IEC 601-1	I
Type according to DIN/IEC 601-1	CF
Mains fuses	In both poles of the mains line, fusible inserts to DIN 41 662, 4 A slow-blow (220 V), 8 A slow-blow (110 V), fuse holders in the rear panel
Mains lead	With PE conductor, with earthed mains plug connector to DIN 49 441 and CEE 7, Sheet VII, with earthed jack on the equipment side to DIN 49 457, Sheet 1, plug connector and jack vulcanized onto the lead, 3 m long
Potential equalization	Plug connector to DIN
Power consumption	600 W

Operating modes

Cutting

Rated output	460W at 350 ohm
Rated frequency	350 kHz
Output voltage	Sine-wave AC voltage
Power adjustment	Automatic
Voltage regulation during cutting	Automatic
Degree of coagulation of the cut surfaces	Choice of 5 coagulation degrees
Power reduction during a coagulating cutting process	None

Soft coagulation

Rated output	200 W at 90 ohm 140 W at 125 ohm
Rated frequency	350 kHz
Output voltage	Without harmonics, sine-wave AC voltage, unmodulated 5 degrees can be set between 50 V_{eff} and 134 V_{eff}
Power adjustment	Automatic
Max. HF current	1.5 A_{rms}

Forced coagulation

Rated output	150 W at 500 ohm
Rated frequency	350 kHz
Max. output voltage	1000 V_p Sine-wave AC voltage, pulse-modulated
Power adjustment	Automatic
Depth of coagulation	Choice of 5 different relative depths

Spray coagulation (fulguration)

Spray 1: Max. rated output	85 W at 500 ohm
Max. output voltage	3000 V_p
Spray 2: Max. rated output	120 W at 500 ohm
Max. output voltage	4000 V_p
Intensity of the electric arc	Choice of 5 different intensities

Auto-coagulation

Rated output: monopolar and bipolar	120 W at 125 ohm

Activation

Cutting	Push-button or pedal Colour code as per DIN/IEC 601, Part 2-2: yellow
Soft coagulation	Push-button or pedal Colour code as per DIN/IEC 601, Part 2-2: blue
Forced coagulation	Push-button or pedal Colour code as per DIN/IEC 601, Part 2-2: blue
Spray coagulation	Push-button or pedal Colour code as per DIN/IEC 601, Part 2-2: blue
Automatic coagulation	Activated via push-button, pedal or automatically; automatic de-activation

Labelling

Language	German or English plus pictograms
Colour code	As per DIN/IEC 601-2-2 Cutting channel: yellow, left Coagulation channel: blue, right

Optical and acoustic signals

see encl. list

External dimensions	W x H x D: 410 x 152 x 368 mm
Weight	12.5 kg

OPTICAL and ACOUSTIC SIGNALS at:	ERBOTOM ACC 410			ERBOTOM ACC 430			ERBOTOM ACC 450		
	OPTICAL	ACOUS.	HF OFF	OPTICAL	ACOUS.	HF OFF	OPTICAL	ACOUS.	HF OFF
Power ON	x			x			x		
HF Generator ON	x	x		x	x		x	x	
NF-Leakage current exceeding 0.05 mA				x		x	x	x	x
HF-Leakage current exceeding 150 mA				x			x		
HF-Leakage current exceeding 300 mA				x	x	x	x	x	
OUTPUT Error	x	x	x	x	x	x	x	x	x
Max. Duty duration if	x	x		x	x		x	x	
Max. Duty duration ignored, then	x	x	x	x	x	x	x	x	x
NE Safety Monitor	x	x	x	x	x	x	x	x	x
NESSY				x	x	x	x	x	x
NE-Test	x	x		x	x		x	x	
AUTO-STOP at AUTO COAG								x	x
Opera[illegible] Er[illegible]	x	[illegible]		x	x	x	x	x	[illegible]

10.4 Potential equalization

DIN 57 753 Part 2/VDE 0753 Part 2 specifies that all equipment used for intracardiac operations must be connected to the potential equalization of the room. The purpose of this requirement is to prevent any danger to the patient due to low-frequency currents, such as the low-frequency leakage currents in a defective protective earth conductor.

In order to satisfy this requirement, the ERBOTOM ACC units all have a potential equalization connector to DIN 42 801 on their rear panel. The units can be connected to the potential equalization system in the room by means of an equipotential cable plugged into this socket.

10.5 Protection against explosion hazards

High-frequency surgical equipment naturally produces electric arcs between the active electrode and the tissue. Electric arcs may also be produced inside the equipment. **HF surgical equipment must therefore not be used in explosion-hazard areas.**

The entire area up to 20 cm above the floor, as well as the area around and below the operating table are potentially explosive areas if flammable or explosive cleansers, disinfectants, anaesthetics, etc. are used. This is illustrated in the following diagram showing the potentially dangerous areas of an operating theatre when using ignitable anaesthesia gas mixtures.

10 INSTALLATION

10.1 Spatial requirements

HF surgical equipment may only be operated in rooms used for medical purposes if these rooms satisfy the requirements set out in DIN 57 107 (VDE 0107).

With regard to the electrical installations, these requirements concern, for example, the protective earth system, potential equalization and leakage current protection.

Refer also to the Chapter entitled "Protection against explosion hazards".

10.2 Possibilities for installation in operating rooms

The ERBOTOM ACC units can basically be set up on tables, brackets suspended from the ceiling or wall-mounted brackets, as well as on special-purpose equipment trolleys.

10.3 Line connection

The power outlet must be fitted with a fuse with a minimum rating of 10 A.

10.6 Protection against moisture

The ERBOTOM ACC series of HF surgical units is protected against the ingress of moisture and splash-water as required by DIN/IEC 601 Part 2-2/VDE 0750 Part 202.

Nevertheless, the equipment should not be installed near hoses or vessels containing liquids. Do not place any liquids above or on the equipment itself.

<u>Only use waterproof pedal switches in accordance with DIN/IEC 601 Part 2-2/VDE 0750 Part 202, Section 44.6 aa), draft edition</u>.

<u>Only use waterproof electrode handles with push-button switches in accordance with DIN/IEC 601 Part 2-2/VDE 0750 Part 202, Section 44.6 bb), draft edition</u>. If electrode handles are used which are not waterproof, care must be taken to ensure that no moisture enters the handles during use (refer also to the Chapter entitled "Accidental activation of the equipment").

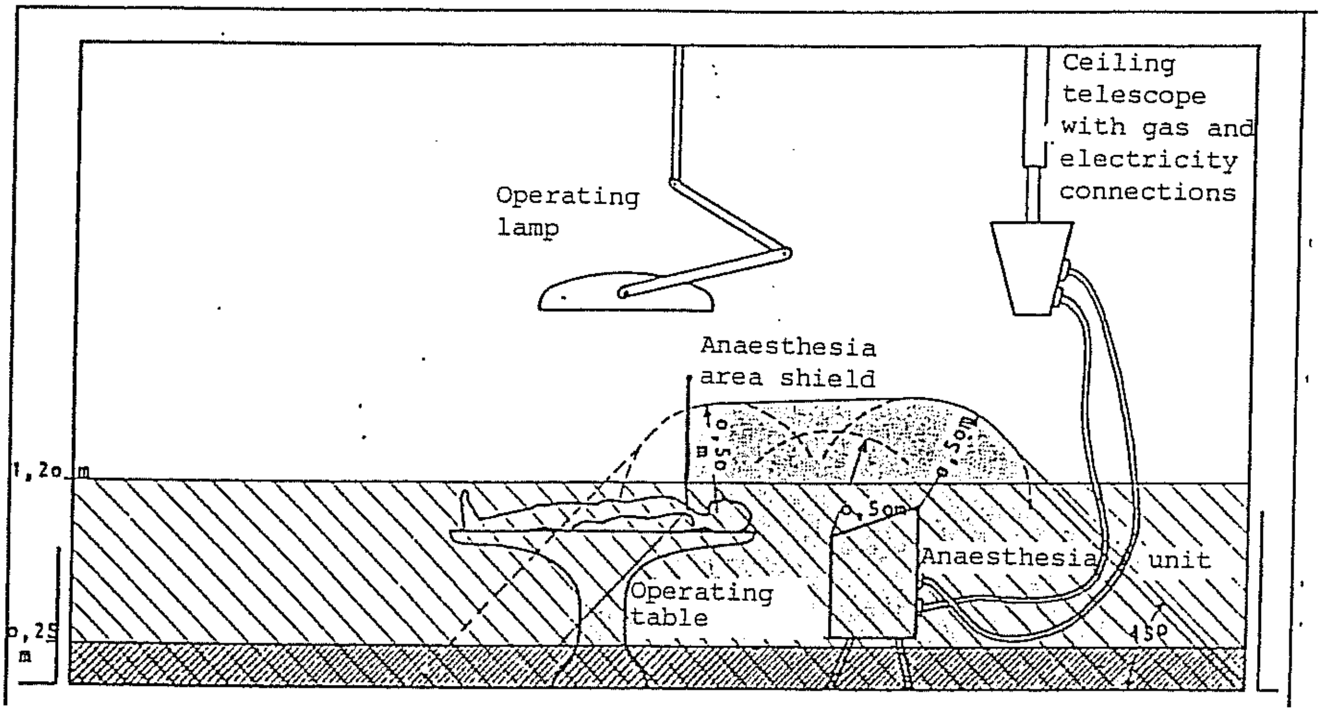
10.7 Cooling

The ERBOTOM ACC units must be set up in such a way as to ensure an unobstructed flow of air around the housing. <u>They must not be installed in small niches, shelves, etc.</u>!

10.8 HF interference

High-frequency surgical units naturally generate high-frequency voltages and currents. The fact that they may cause interference in other electromedical equipment must be taken into account when they are installed and during operation.

<u>Note</u>: Because they are equipped with a harmonics-free HF generator and automatic voltage regulator, the ERBOTOM ACC series of HF surgical units generate considerably less HF interference than conventional units of this type. This is particularly advantageous when they are used in combination with video monitors.



(diagonal cross-hatching, fine)	Must always be considered an explosion-hazard area for stationary and movable electrical wiring and equipment, as well as electromedical equipment.
(diagonal hatching, wide)	Must always be considered an explosion-hazard area for stationary electrical wiring and equipment, as well as stationary electromedical equipment.
(stippled)	Temporary explosion-hazard area when using ignitable inhalation anaesthetics.

Fig.: Explosion-hazard areas in the operating theatre (source: Guidelines on protection against explosions [Ex-RL] issued by the employers' liability insurance association for the chemical industry).

High-frequency surgical equipment is normally installed outside the area marked as an explosion-hazard zone.

IMPORTANT: **Pedal switches must, however, always be used in the explosion-hazard area and must be correspondingly explosion-proofed.**

11 SAFETY CHECKS FOR THE ERBOTOM ACC 450

- Check the labelling and user manual.

- Inspect the equipment and accessories to ensure they are not damaged.

- Check the electrical safety as required by DIN VDE 0751, Part 1
  a) Protective earth conductor
  b) Leakage current
  The leakage currents can alternatively be measured and assessed in accordance with DIN IEC 601/VDE 0750, Part 1.

- Check the correct functioning of all switches and indicators on the equipment.

- Check the safety monitors.

- Check the automatic start mode.

- Check the automatic stop mode.
  a) AUTO 1
  b) AUTO 2
  c) AUTO 3

- Measure the high-frequency voltages for CUTTING mode.

- Measure the high-frequency voltages for SOFT COAGULATION mode.

- Measure the high-frequency voltages for FORCED COAGULATION mode.

- Measure the high-frequency voltages for SPRAY COAGULATION mode.

The results of these checks must be recorded and filed with the equipment log.

ATTENTION!

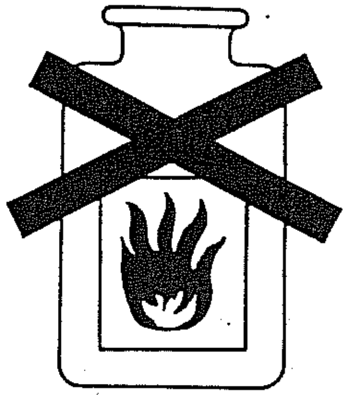
If these safety checks reveal any defects capable of endangering patients, staff or third parties, the equipment must be withdrawn from service until the defects have been eliminated through correct technical servicing.

12 FIRE AND EXPLOSION HAZARDS

The ERBOTOM ACC 450 surgical unit is not intended for operation in explosion-hazard areas.

Sparking at active electrodes is unavoidable in HF surgery. Because of the danger of fire and explosion, HF surgery must not be used in areas where flammable or explosive agents are present, e. g. anesthetics, skin cleansing agents, degreasants and disinfectants as well as endogenous gases, e. g. in the gastro-intestinal tract.

When using HF surgery, the agents indicated above must neither be flammable nor explosive, or at least completely evaporated or removed from the area of spark formation before the HF surgical unit is switched on.



13 CARE OF THE UNIT

13.1 PREVENTING DAMAGE

Apart from proper operation and maintenance, effective protection of the unit against damage is achieved by secure positioning of the unit. This involves not only securely mounting the HF surgical unit on its base but also protecting it against damp, contamination and contact with flammable and explosive substances. In order to ensure good dissipation of the heat generated during operation, it must be ensured that cooling slots and heat sinks are open to good air circulation.

13.2 CLEANING AND DISINFECTION

Cleaning and disinfection of the unit should only be undertaken with nonflammable and nonexplosive agents. In this respect, make sure that no moisture or detergents enter the unit.

If cleaning or disinfection of the unit with flammable or explosive agents is unavoidable, these must be completely evaporated from the HF surgical unit before it is switched on.

ATTENTION!

Alcohol must never be used to clean and disinfect the front panel. We recommend that the panel be disinfected by spraying or wiping. However, it is essential to follow the manufacturer's directions regarding concentration of the disinfectant used and the time it is allowed to act.

14 CARE OF THE ACCESSORIES

14.1 PREVENTING DAMAGE

In order to protect accessories from premature wear and tear, the following instructions should be observed:

- **Active electrodes** must always be handled and stored so that they are not damaged.
- **Monopolar and bipolar coagulation forceps** must always be handled and stored so that the forceps tips are not damaged. These forceps should be kept and transported in special cases.

  Forceps with insulated legs must not be cleaned and kept with other hard or pointed instruments which could damage the insulation.

  The legs of the forceps must not be forced apart, since this can chip the insulating layer from the legs.
- **Electrode handles.** Do not wrap the cable of the electrode handles around the handles, since this will deform the cable.
- **Patient plates of metal** must not be bent excessively and not kinked.
- Do not carry the **footswitch** by the cable. Do not wind the cable tightly around the footswitch.
- Do not coil the **cable** too tightly, kink it or bend it.
- Unplug the **plugs** from the unit sockets and accessories by gradually pulling on the plug shaft and not by strongly tugging on the cable.

14.2 CLEANING, DISINFECTION AND STERILIZATION

- **Monopolar and bipolar electrodes**

  Cleaning: Tissue residue can be removed from the active electrodes with steel or copper wool. No scalpel, scissors or similar pointed objects must be used for cleaning the electrodes, since they will damage the electrode surface. Such damage increases adhesion of tissue to the surfaces of the electrodes during use.

  Disinfection: Always clean and disinfect the electrodes in a disinfecting solution prior to sterilizing them. All commercially available disinfectants may be used.

  Sterilization: All ERBE active electrodes are autoclavable.

- **Electrode handles with cables and plugs**

  These accessories may be cleaned and disinfected by spraying or wiping over with disinfectant. It is also possible to dip them into a disinfectant solution or to sterilize them in an autoclave up to 134° C, if necessary or to clean them in the washing machine at up to 95° C.

  Note: Because of their better material compatibility, aldehyde preparations are more suitable for
  - ▶ disinfection of the accessories than phenolic preparations, since they have less corrosive effect on the plastics used.
  - ▶ To prevent premature wear to cable and plug, be sure to comply with the manufacturer's instructions concerning concentration of the disinfectant used and the time it is allowed to act on the objects being disinfected.
  - ▶ Always ensure that the disinfectant is thoroughly rinsed off.

- **Patient plates with cables, plugs and rubber straps**

  Patient plates along with their cables, plugs and rubber straps should be cleaned and disinfected before and after use.

- **Footswitches and footswitch boards**

  Non explosion-proof footswitches, must not be cleaned or disinfected with flammable or explosive agents because of the existing fire and explosion hazards.

  Any disinfectant can be used for surface disinfection of explosion-proof footswitches.

Recommendations on Cleaning, Desinfection and Sterilization of Accessories for the ERBE HF surgical unit

ERBE

		Cleaning				Desinfection		Drying	Sterilisation			
										Steam		
		mechanical cleaning	chemical cleaning	ultrasonic cleaning	Washing machine up to 95 °C	Spray-Desinfection	Solution	Hot air up to 120° C	Germicidal Gases	120° C 1,1 bar	134° C 2,1 bar	Hot air 180° C
Active electrodes	non-insulated	●	●	●	●	●	●	●	●	●	●	●
	insulated	●	●	●	●	●	●	●	–	●	●	–
Electrode handles		●	●	●	●	●	●	●	–	●	●	–
Forceps		●	●	●	●	●	●	●	–	●	●	–
Patient plates	flexible metal plate	●	●	●	–	●	●	–	–	–	–	–
	Silicone plate	●	●	●		●	●	●	–	●	●	–
Foot-switches	explosion-proof	●	●	●	–	●	●	–	–	–	–	–
	non-explosion proof	●	●	–	–	●	–	–	–	–	–	–
Cables with plugs		●	●	●	●	●	●	●	–	●	●	–

APPENDIX

WARRANTY CONDITIONS

TRANSPORT DAMAGE

The unit and accessories must be inspected immediately on receipt for deficiencies and transport damage. In this respect, claims for compensation can only be enforced when the seller or carrier are notified without delay. A damage report must be compiled.

EQUIPMENT WARRANTY

The warranty period for the unit is 1 year from the date of delivery.

Claims under warranty are valid only when the warranty certificate has been properly completed. The warranty covers free repair of the unit provided that the deficiency has been caused by material or manufacturing faults. Other claims, particularly claims for compensation are excluded.

Repairs may only by carried out by us, our representatives or by authorized service agents. Claims under warranty are invalidated if improper modifications or repairs have been undertaken.

Work carried out under the warranty neither extends nor renews the warranty.

RELEVANT STANDARDS

IEC Publication 601-1
Safety of medical electrical equipment

Part 1: General requirements

Part 2-2: Medical electrical equipment
Particular requirements for the safety of high frequency surgical equipment

UL 544
Standard for medical and dental equipment

ADDRESS

ERBE

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West Germany
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Telex 7262839

For guarantee claims and servicing contact the nearest ERBE branch office.

Contents

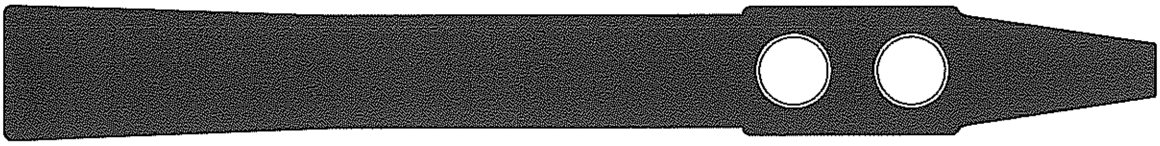
Sterilizable up to 134 °C

Cleaning in washing machine up to 95 °C

Electrode handles

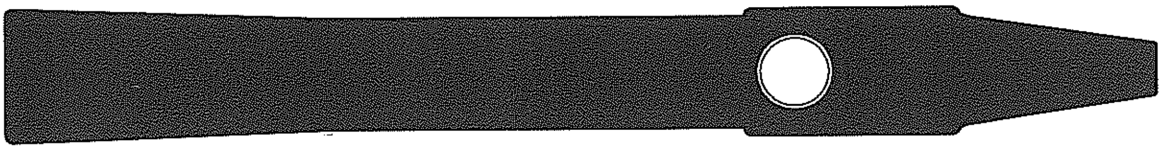
Electrode handles

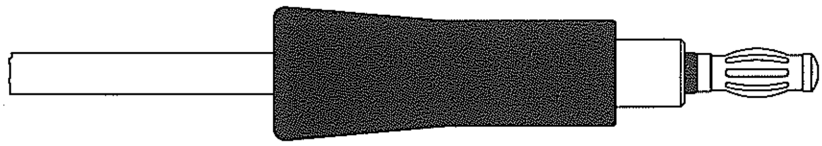
- The electrode handles are used for the fitting of monopolar active electrodes, which can be fitted in various positions in the appropriate handle, secure against rotation.
- ERBE electrode handles consist of glass-fibre reinforced, electrically-insulated plastic material, and can be sterilized using all steam sterilization procedures up to 134° C, including connecting cables and plugs.
- The electrode handles are water-tight according to DIN IEC 601, part 2–2, 44.6.bb. This prevents the handles from being accidentally switched on through penetration by liquid.



Electrode handle with 2 buttons

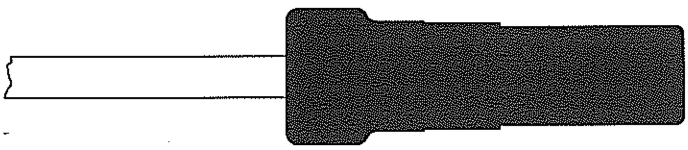
The electrode handle with 2 buttons allows direct actuation of the monopolar generator. The yellow button switches on the HF current for cutting and the blue button switches on the HF current for coagulation.
No. 20190-038





Electrode handle with 1 button

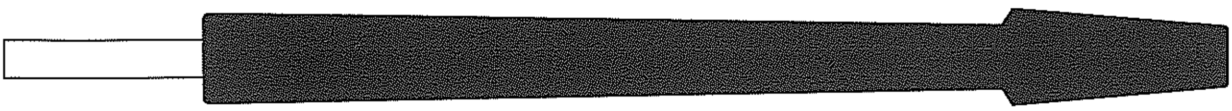
The electrode handle with one button allows direct actuation of the FH current for coagulation.
No. 20190-039

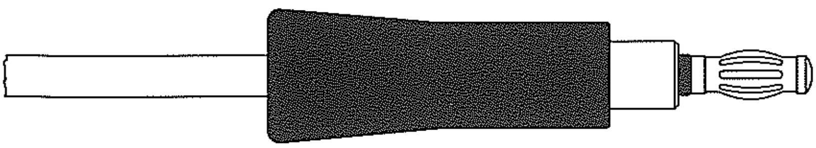


Connecting cable for electrode handle ACC

in compliance with IEC 601, part 2–2, 101.3

Cable 3 m long No. 20192-026
Cable 5 m long No. 20192-027



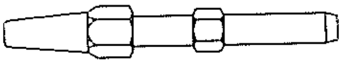


Electrode handle without button

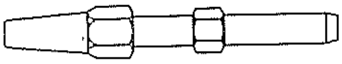
The generator is activated by the footswitch.
No. 20190-047

Chucks

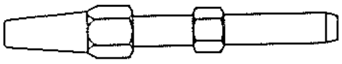
Shaft extension, 4.0 mm diameter
with insulated shaft, 10 cm
No. 20191-119



Chuck, 1.6 mm diameter for
microelectrodes
No. 20191-113



Chuck, 1.0 mm diameter for
insulated epilation needles
No. 20191-013

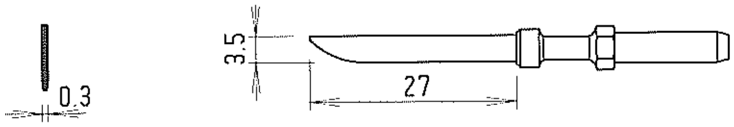


Chuck, 0.3 mm diameter for
uninsulated epilation needles
No. 20191-012

Sterilizable up to 134 °C

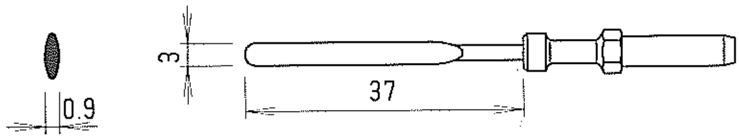
Cleaning in washing machine up to 95 °C

Monopolar Electrodes
Cutting electrodes

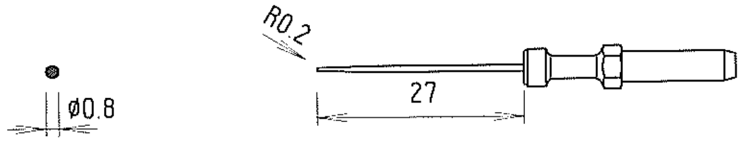


Knife electrode, straight,
after Kirschner
No. 20191-007

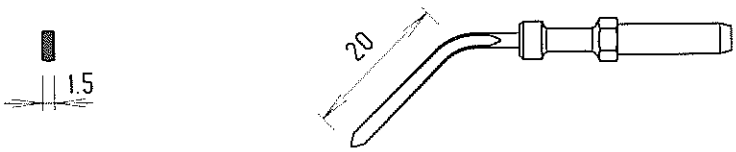
Knife electrode, straight,
lancet-shaped
No. 20191-009



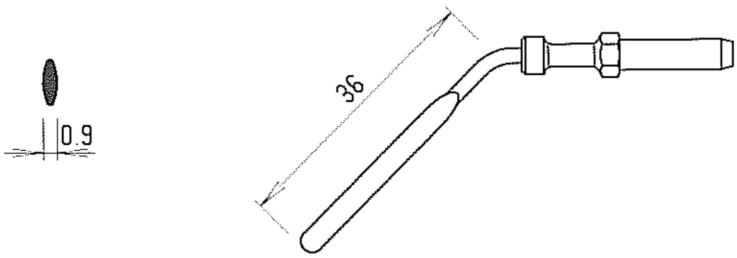
Spatular electrode, straight
No. 20191-126



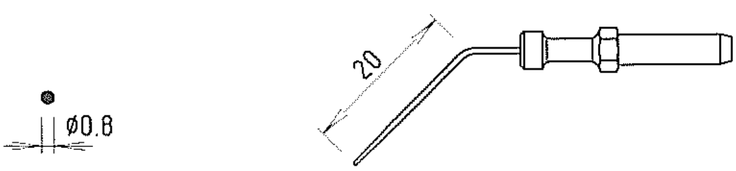
Needle electrode, straight
No. 20191-011



Knife electrode, curved,
after Magenau
No. 20191-008



Spatular electrode, curved
No. 20191-125

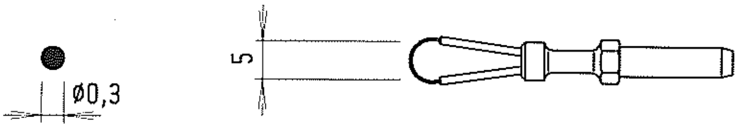


Needle electrode, curved
No. 20191-124

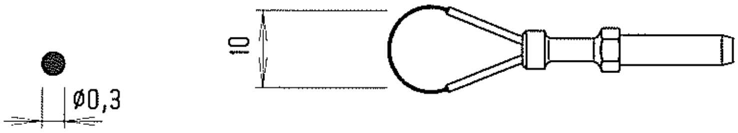
Sterilizable up to 134°C

Cleaning in washing machine up to 95°C

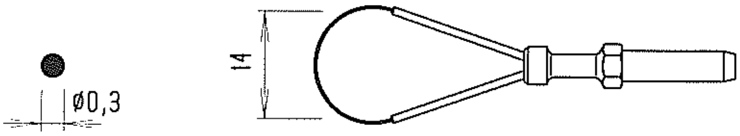
Loop Electrodes



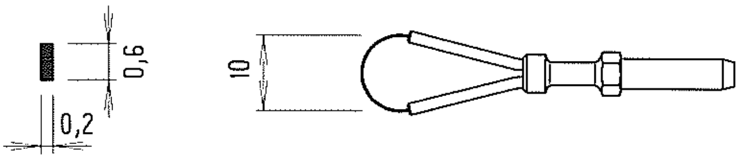
Wire loop electrode,
diameter 5 mm
No. 20191-014



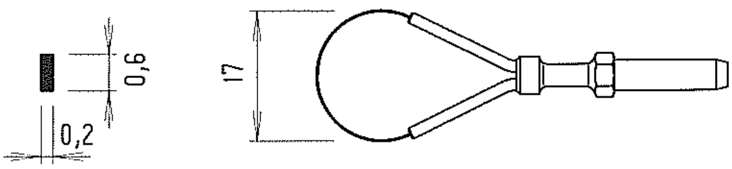
Wire loop electrode,
diameter 10 mm
Nr. 20191-015



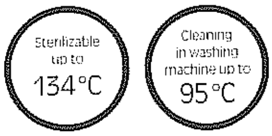
Wire loop electrode,
diameter 14 mm
No. 20191-016



Band loop electrode,
diameter 10 mm
No. 20191-017

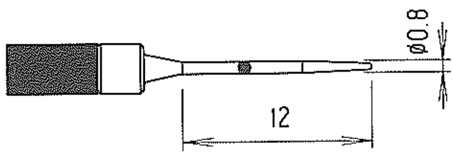


Band loop electrode,
diameter 17 mm
No. 20191-018

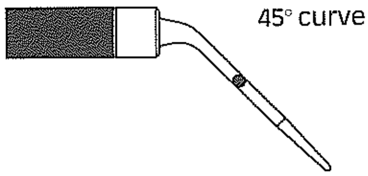


Cutting electrodes with insulated shaft for body cavities

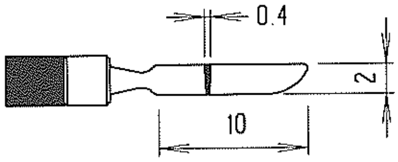
in compliance with IEC 601, part 2–2, 101.3.2



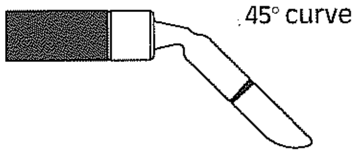
Needle electrode, straight
0.8 × 12 mm, with insulated shaft,
10 cm long
No. 20191-027



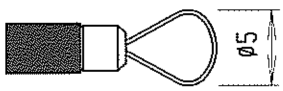
Needle electrode, curved,
0.8 × 12 mm, with insulated shaft,
10 cm long
No. 20191-122



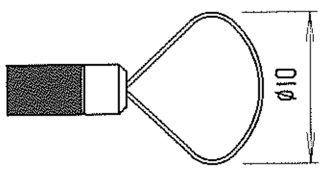
Knife electrode, straight,
0.4 × 10 mm, with insulated shaft,
10 cm long
No. 20191-028



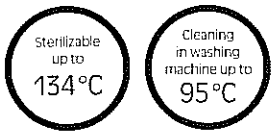
Knife electrode, curved,
0.4 × 10 mm, with insulated shaft,
10 cm long
No. 20191-123



Wire loop electrode, straight
5 mm, with insulated shaft,
10 cm long
No. 20191-031



Wire loop electrode, straight
10 mm, with insulated shaft,
10 cm long
No. 20191-032



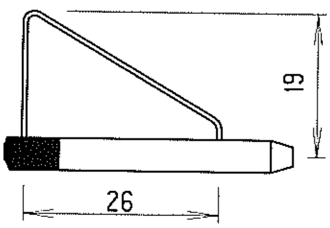
Cutting electrodes for conization of the cervical portio

Loop-electrode, 20 × 20 mm,
shaft 90 mm long, insulated
No. 20191-132

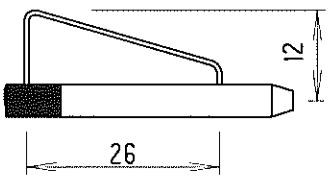
Loop-electrode, 20 × 15 mm,
shaft 90 mm long, insulated
No. 20191-133

Loop-electrode, 10 × 10 mm,
shaft 90 mm long, insulated
No. 20191-134

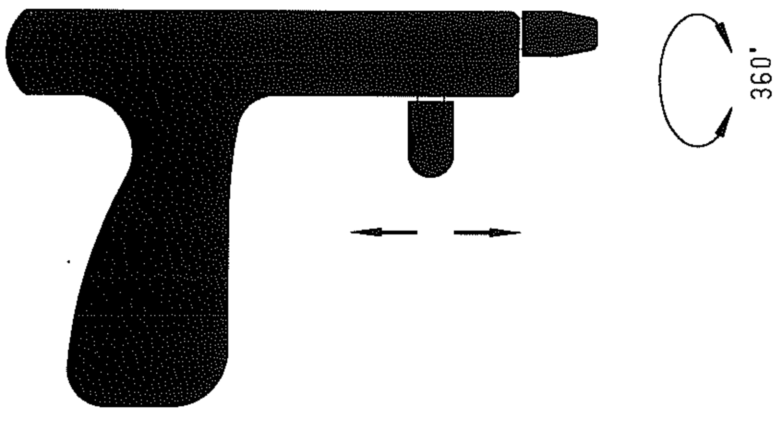
Loop holder
with variable loops,
19 mm and 12 mm,
with insulated shaft, 116 mm long
No. 20191-075



Loop, 12 mm
No. 20191-076

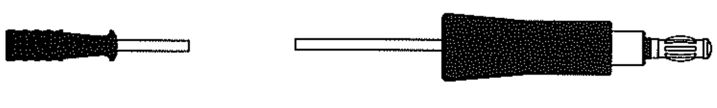


Loop, 19 mm
No. 20191-077

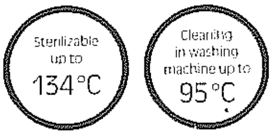


Pistol-shaped handle

The conization electrodes are secured against rotation in the handle by the use of a screw cap. The electrodes can be turned through 360°. (The HF connection is 4 mm in diameter.)
No. 20191-041

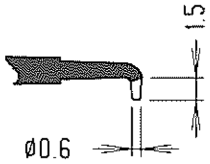


Connecting cable for monopolar electrodes
Cable 3 m long
No. 20192-030

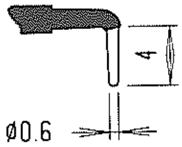


Cutting electrodes for arthroscopic meniscus resection

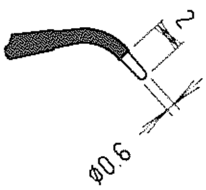
with insulated shaft, in compliance with IEC 601, part 2–2, 101.3.2



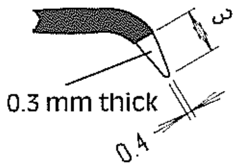
Needle electrode
Shaft straight,
needle angle 90°, 1.5 mm
No. 20191-108



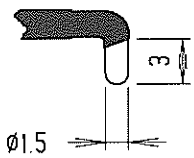
Needle electrode
Shaft straight,
needle angle 90°, 4.0 mm
No. 20191-109



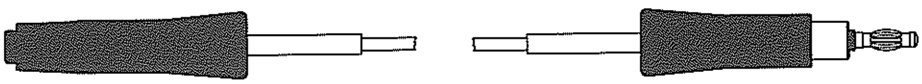
Needle electrode
Shaft straight,
needle offset 45°
No. 20191-111



Knife electrode
Shaft straight,
knife offset 45°
No. 20191-112



Palpation electrode
Shaft straight,
tip angle 90°
No. 20191-110

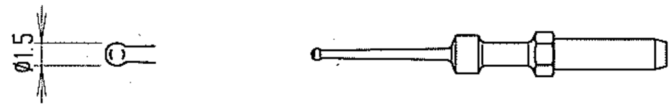


Connecting cable for arthroscopy electrodes
in compliance with IEC 601,
part 2–2, 101.3
3 m long No. 20192-031
5 m long No. 20192-032

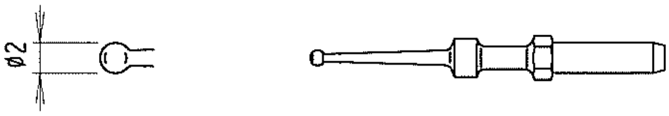
Sterilizable up to 134 °C

Cleaning in washing machine up to 95 °C

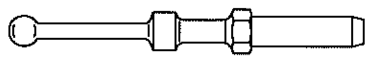
Coagulation electrodes



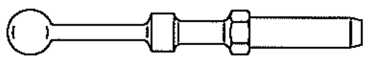
Ball electrode, straight,
diameter 1.5 mm
No. 20191-019



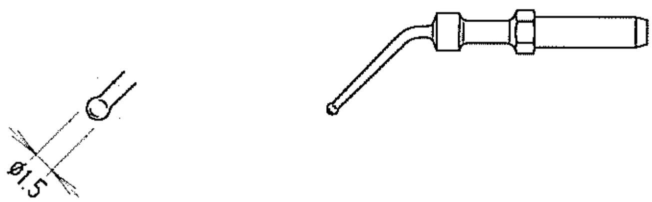
Ball electrode, straight,
diameter 2 mm
No. 20191-020



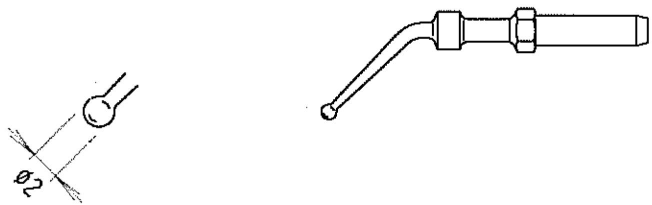
Ball electrode, straight,
diameter 4 mm
No. 20191-021



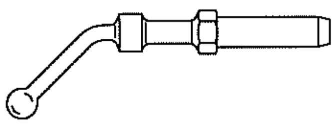
Ball electrode, straight,
diameter 6 mm
No. 20191-022



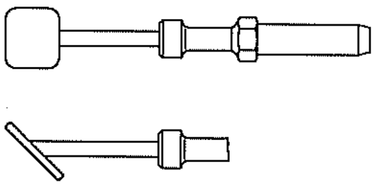
Ball electrode, curved,
diameter 1.5 mm
No. 20191-129



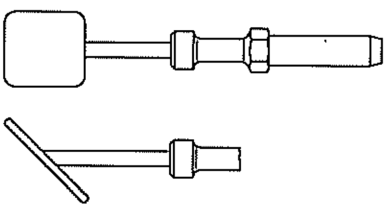
Ball electrode, curved,
diameter 2 mm
No. 20191-130



Ball electrode, curved,
diameter 4 mm
No. 20191-131



Flat electrode, straight,
8 × 10 mm
No. 20191-023



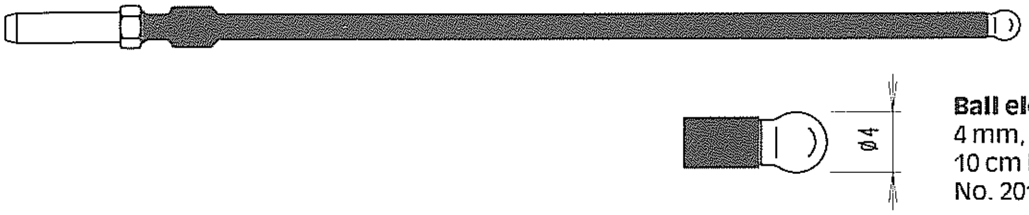
Flat electrode, straight,
10 × 15 mm
No. 20191-024

Sterilizable up to 134 °C

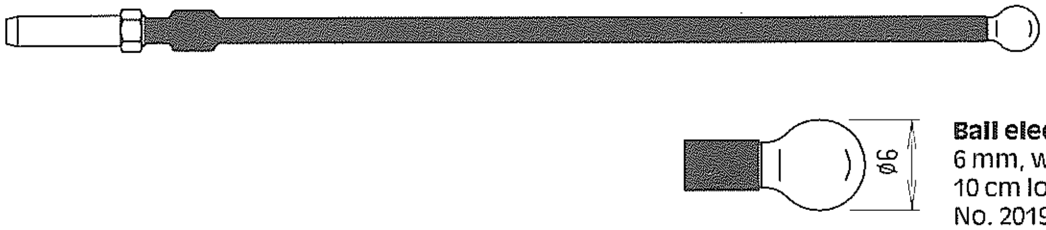
Cleaning in washing machine up to 95 °C

Coagulation electrodes with insulated shaft for body cavities

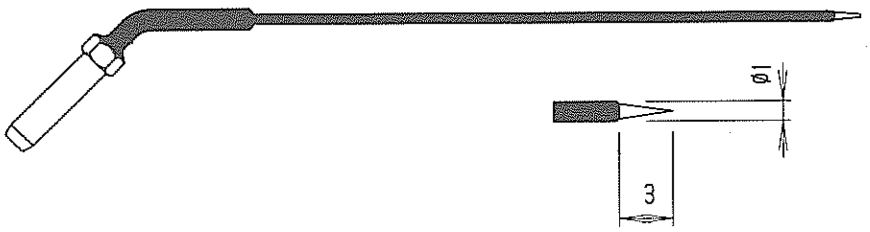
in compliance with IEC 601, part 2–2, 101.3.2



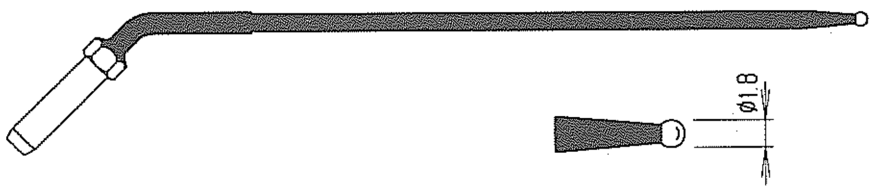
Ball electrode, straight, diameter 4 mm, with insulated shaft,
10 cm long
No. 20191-029



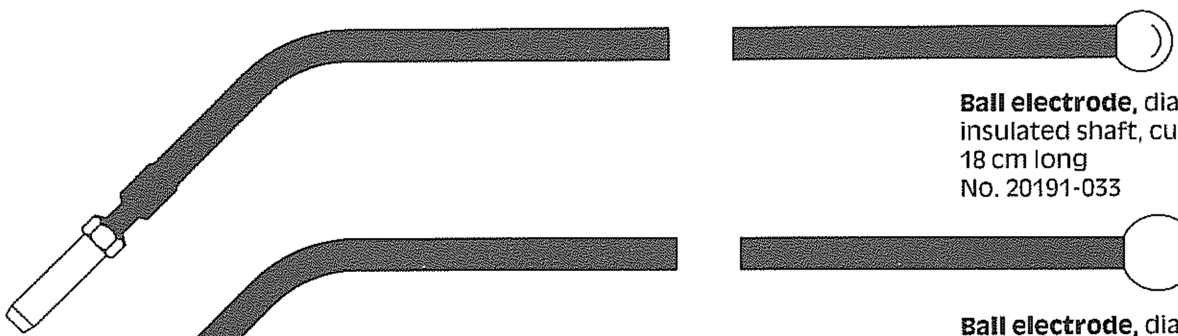
Ball electrode, straight, diameter 6 mm, with insulated shaft,
10 cm long
No. 20191-030



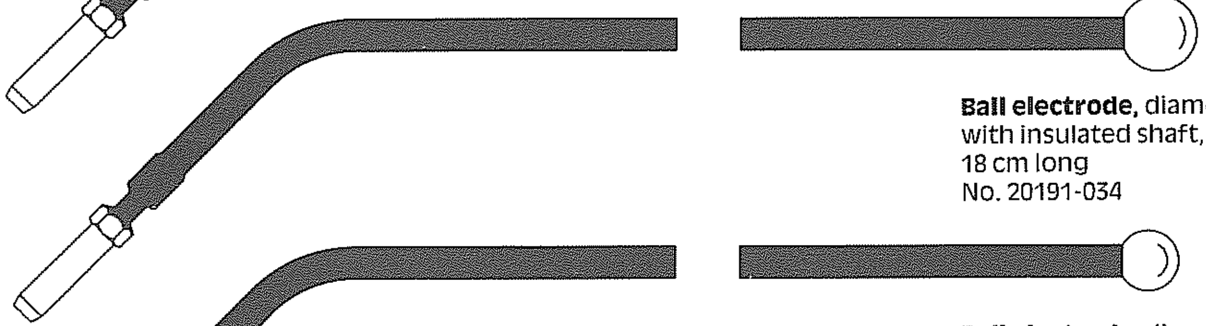
Coagulation needle, 1 × 3 mm, after Mittenmaier, for incision coagulation of the concha nasalis, with insulated shaft, curved,
10 cm long
No. 20191-039



Ball electrode, diameter 1.8 mm, with insulated shaft, curved,
10 cm long
No. 20191-114



Ball electrode, diameter 8 mm, with insulated shaft, curved,
18 cm long
No. 20191-033



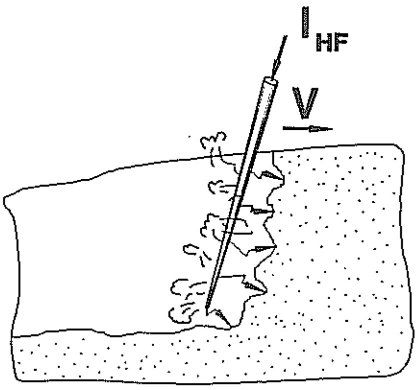
Ball electrode, diameter 10 mm, with insulated shaft, curved,
18 cm long
No. 20191-034

Ball electrode, diameter 8 mm, with insulated shaft, curved,
23 cm long
No. 20191-036

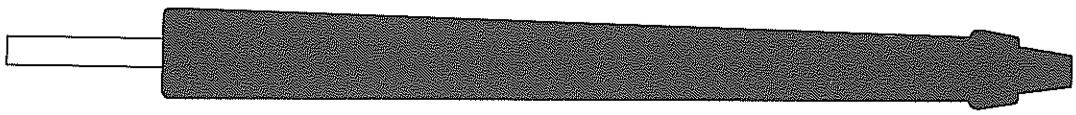
Sterilizable up to 134 °C

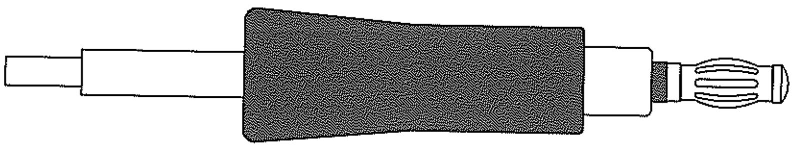
Cleaning in washing machine up to 95 °C

Electrode handle for microsurgery



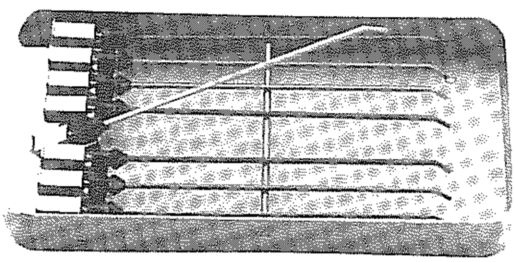
Microsurgery
It is only through the development of voltage or arc regulated high-frequency surgical equipment, that it is possible to regulate the intensity of the electric arc to a minimum between the electrode and tissue.
The degree of coagulation or coagulation depth when making incisions is therefore no longer dependent on the depth and speed of incision. Regulation of the arc prevents erosion of the active cutting electrode.





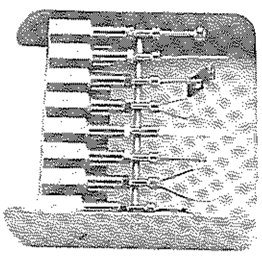
Electrode handle
without button, with 3 m long cable, in compliance with IEC 601, part 2–2, 101.3 No. 20197-000

- Activation via the footswitch.
- The active electrodes are simply inserted in the handle.
- The electrodes are held securely and prevented from rotating by the elastic and coneshaped connector.



Rack for microelectrodes, long
stainless steel for 8 electrodes, diameter 1.6
190 × 96 × 25 mm
No. 20197-030

Rack for microelectrodes, short
stainless steel for 8 electrodes, diameter 1.6
96 × 96 × 25 mm
No. 20197-029 not illustrated



Rack for monopolar electrodes
stainless steel for 8 electrodes
diameter 4
No. 20191-137

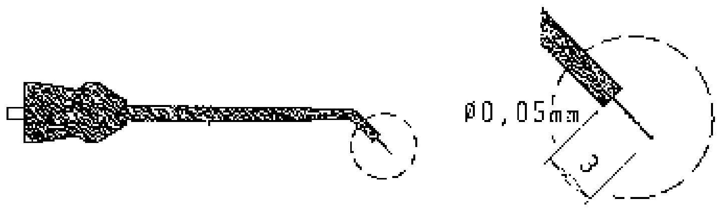
134°C

95°C

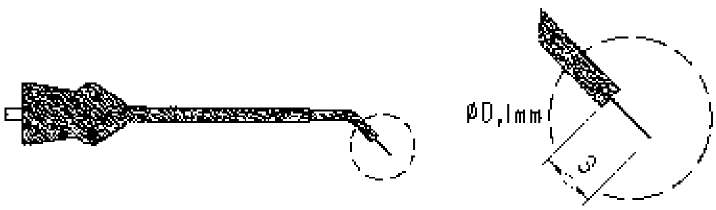
Monopolar electrodes for microsurgery

Cutting electrodes

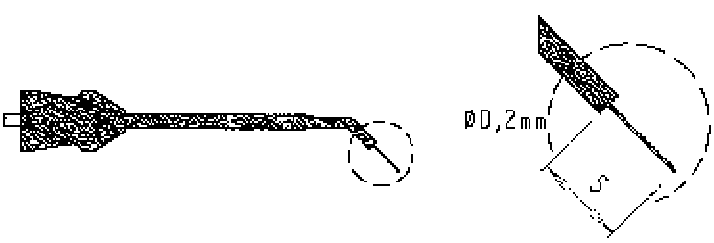
with insulated shaft in compliance with IEC 601, part 2–2, 101.3.2



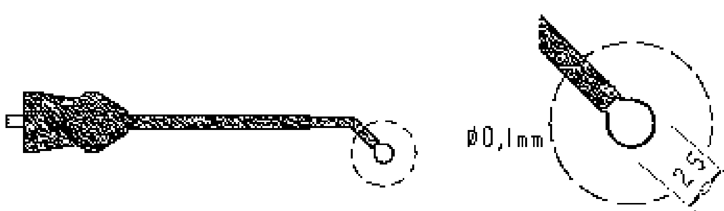
Needle, extremely fine,
diameter 0.05 mm,
with insulated shaft, angled,
40 mm long, colour: red
No. 20197-021



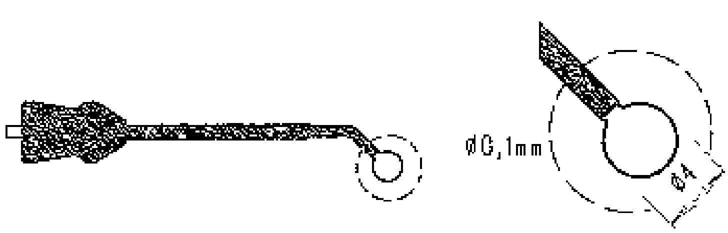
Needle, fine, diameter 0.1 mm,
with insulated shaft, angled,
40 mm long, colour: green
No. 20197-022



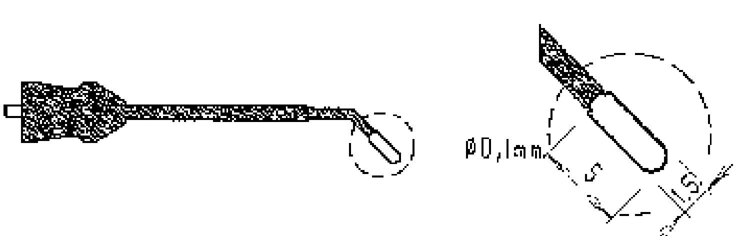
Needle, diameter 0.2 mm
with insulated shaft, angled,
40 mm long, colour: brown
No. 20197-023



Wire loop, fine,
diameter 2.5 mm,
with insulated shaft, angled,
40 mm long, colour: yellow
No. 20197-024



Wire loop, fine, diameter 4 mm
with insulated shaft, angled,
40 mm long, colour: orange
No. 20197-025

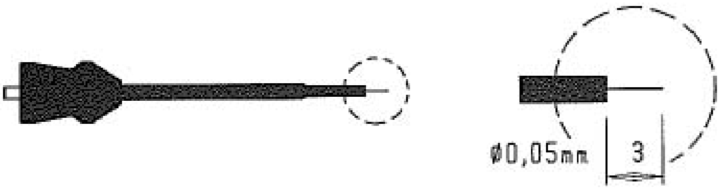


Wire loop, fine, 1.5 × 5 mm,
with insulated shaft, angled,
40 mm long, colour: violet
No. 20197-026

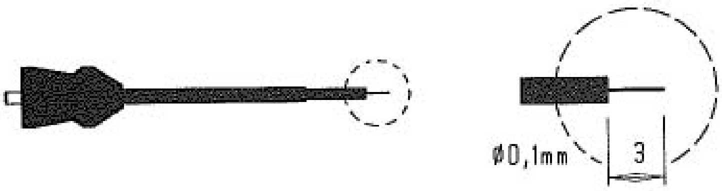
Sterilizable up to 134 °C

Cleaning in washing machine up to 95 °C

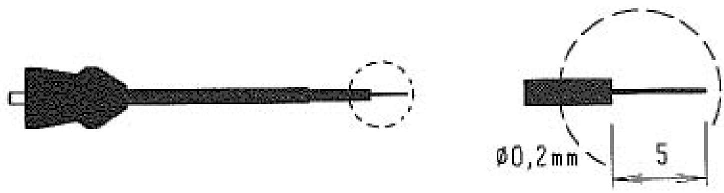
Cutting electrodes



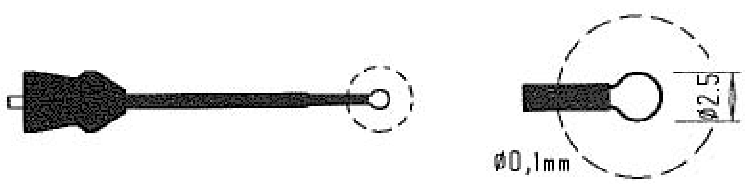
Needle, extremely fine,
diameter 0.05 mm,
with insulated shaft, straight,
40 mm long, colour: red
No. 20197-007



Needle, fine, diameter 0.1 mm,
with insulated shaft, straight,
40 mm long, colour: green
No. 20197-008

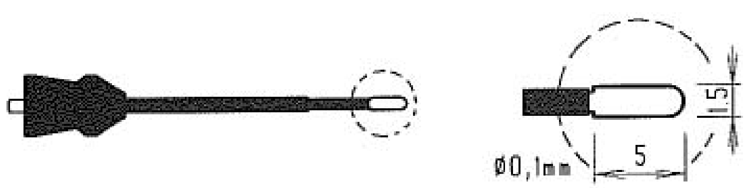


Needle, diameter 0.2 mm,
with insulated shaft, straight,
40 mm long, colour: brown
No. 20197-009

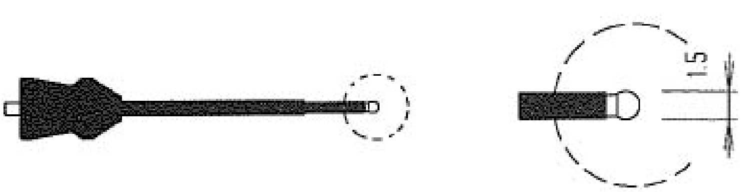


Wire loop, fine,
diameter 2.5 mm,
with insulated shaft, straight,
40 mm long, colour: yellow
Nr. 20197-010

Wire loop, fine, diameter 4 mm,
with insulated shaft, straight,
40 mm long, colour: orange
No. 20197-019



Wire loop, fine, 1.5 × 5 mm,
with insulated shaft, straight,
40 mm long, colour: violet
No. 20197-020

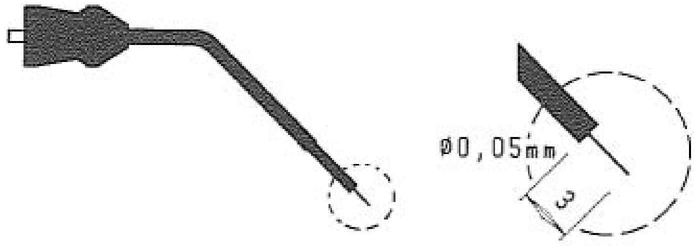


Ball, fine, diameter 1.5 mm,
with insulated shaft, straight,
40 mm long, colour: blue
No. 20197-011

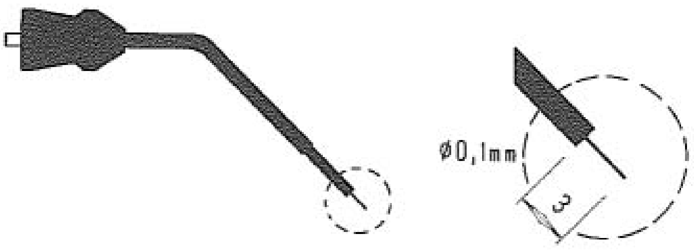
Sterilizable up to 134°C

Cleaning in washing machine up to 95°C

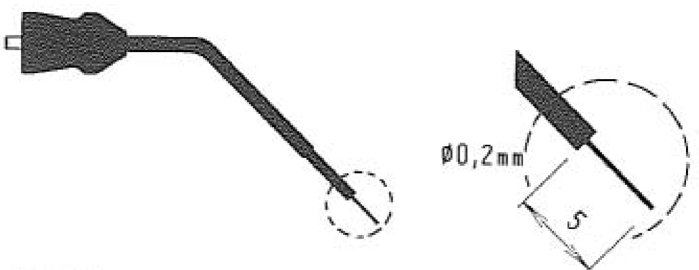
Cutting electrodes



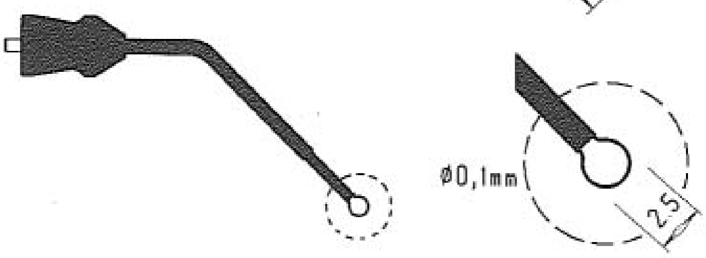
Needle, extremely fine, diameter 0.05 mm, with insulated shaft, curved, colour: red
No. 20197-001



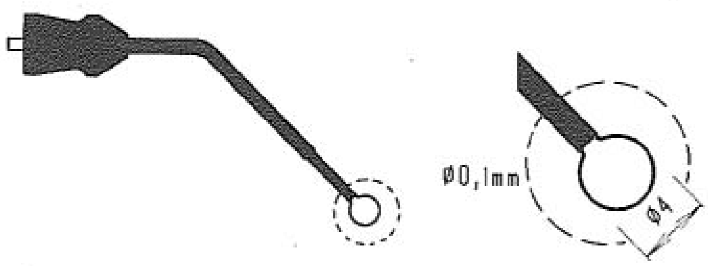
Needle, fine, diameter 0.1 mm, with insulated shaft, curved, colour: green
No. 20197-003



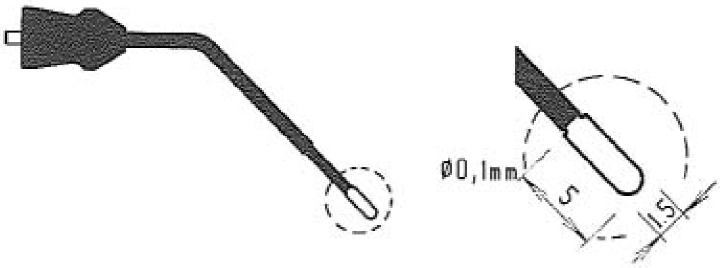
Needle, diameter 0.2 mm, with insulated shaft, curved, colour: brown
No. 20197-002



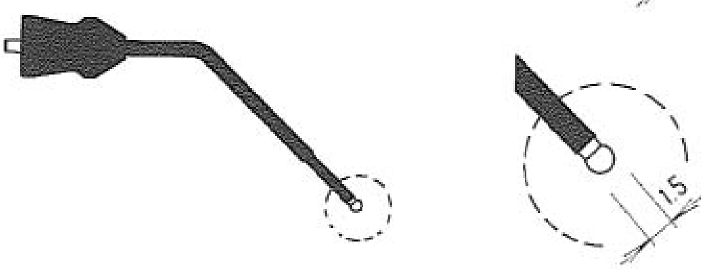
Wire loop, fine, diameter 2.5 mm, with insulated shaft, curved, colour: yellow
No. 20197-004



Wire loop, fine, diameter 4 mm, with insulated shaft, curved, colour: orange
No. 20197-027



Wire loop, fine, 1.5 × 5 mm, with insulated shaft, curved, colour: violet
No. 20197-028

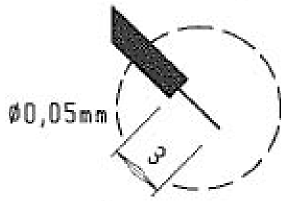


Ball, fine, diameter 1.5 mm, with insulated shaft, curved, colour: blue
No. 20197-005

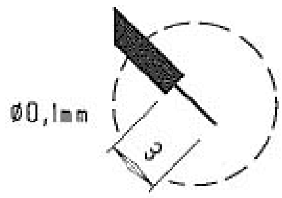
Sterilizable up to 134°C

Cleaning in washing machine up to 95°C

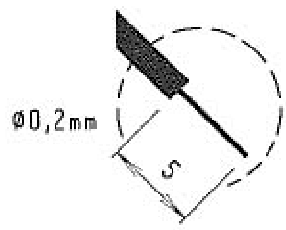
Cutting electrodes, long, for body cavities



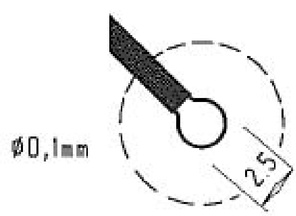
Needle, extremely fine,
diameter 0.05 mm,
with insulated shaft, 110 mm long,
colour: red
No. 20197-012



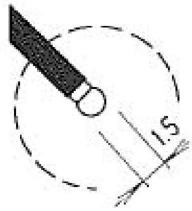
Needle, fine, diameter 0.1 mm,
with insulated shaft, 110 mm long,
colour: green
No. 20197-013



Needle, diameter 0.2 mm,
with insulated shaft, 110 mm long,
colour: brown
No. 20197-014



Wire loop, fine, diameter 2.5 mm,
with insulated shaft, 110 mm long,
colour: yellow
No. 20197-015

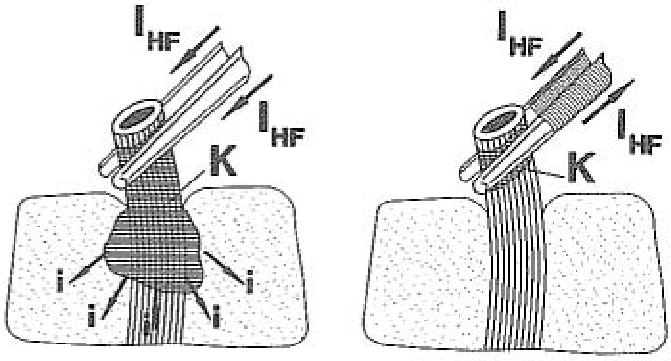


Ball, fine, diameter 1.5 mm,
with insulated shaft, 110 mm long,
colour: blue
No. 20197-016

Bipolar coagulation electrodes

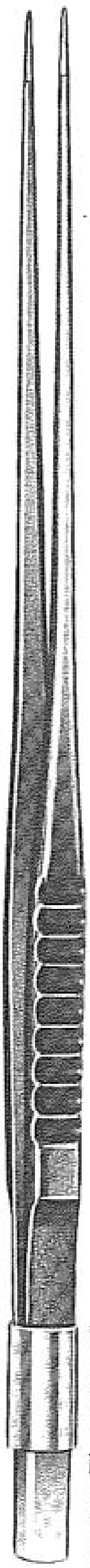
Bipolar forceps

insulated, in compliance with IEC 601, part 2–2, 101.3.2



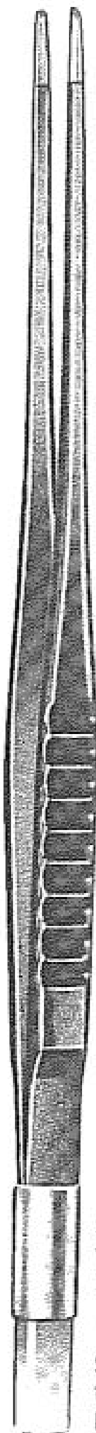
Dimensions of the coagulate in monopolar and bipolar technique of SOFT coagulation with forceps.

Macro



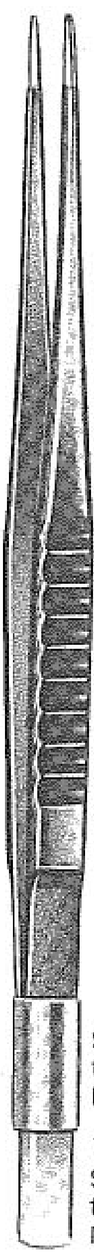
Straight, 22 cm
tip 2 mm, blunt
No. 20195-030*

Straight, 22 cm
tip 1 mm, blunt
No. 20195-041*



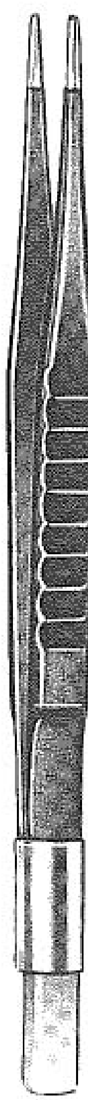
Straight, 19.5 cm
tip 2 mm, blunt
No. 20195-029*

Straight, 19.5 cm
tip 1 mm, blunt
No. 20195-040



Straight, 16.5 cm
tip 2 mm, blunt
No. 20195-028*

Straight, 16.5 cm
tip 1 mm, blunt
No. 20195-039*



Straight, 14.5 cm
tip 2 mm, blunt
No. 20195-027*

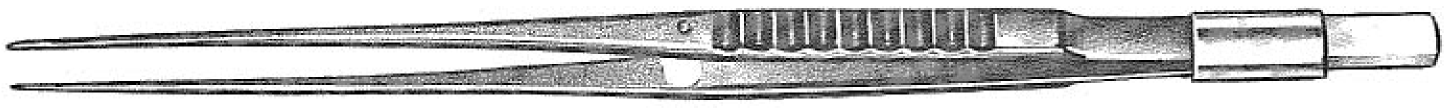
Straight, 14.5 cm
tip 1 mm, blunt
No. 20195-038*

* Delivery time: on request

Sterilizable up to 134 °C

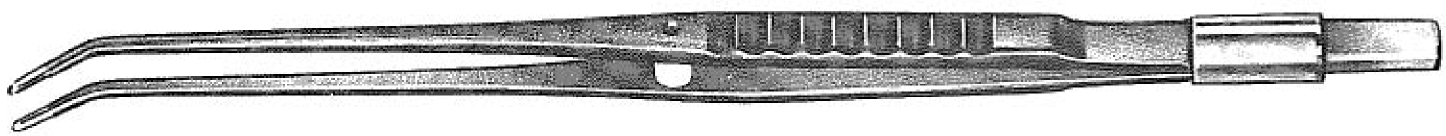
Cleaning in washing machine up to 95 °C

Bipolar forceps



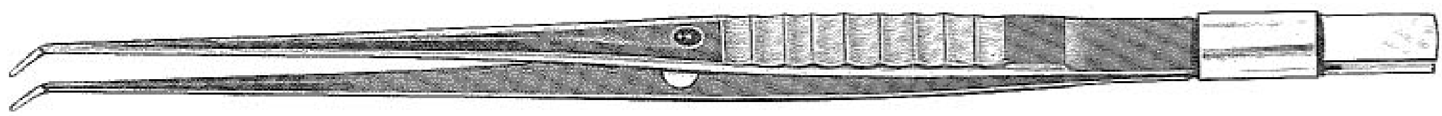
Straight, 19.5 cm, tip 1 mm, blunt
No. 20195-000

Straight, 19.5 cm, tip 1 mm, pointed
No. 20195-037*



Angled, 19.5 cm, tip 2 mm, blunt
No. 20195-007*

Angled, 19.5 cm, tip 1 mm, blunt
No. 20195-001



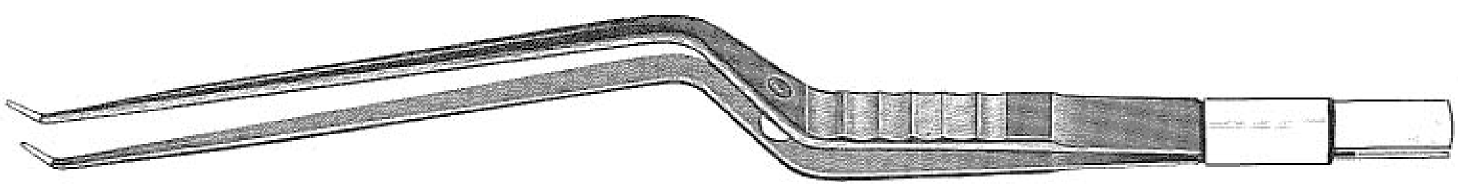
for difficult access

Short-angled, 19.5 cm,
tip 1 mm, blunt
No. 20195-065*

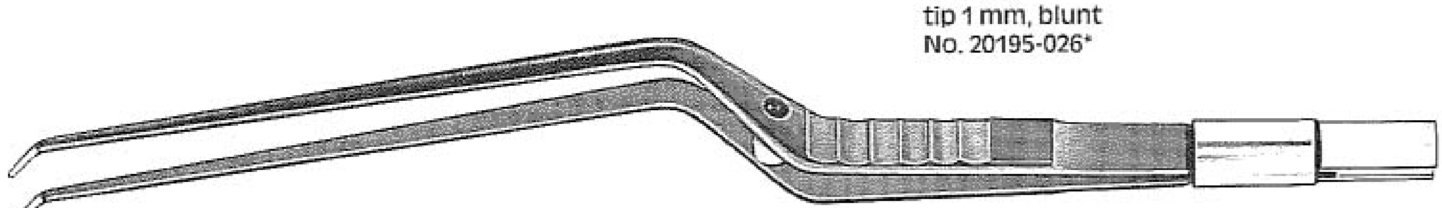
Bayonet, 19.5 cm, tip 2 mm, blunt
No. 20195-034*

Bayonet, 19.5 cm, tip 1 mm, blunt
No. 20195-002

Bayonet, 19.5 cm, tip 1 mm, pointed
No. 20195-008*



Bayonet, short-angled upwards,
19.5 cm,
tip 1 mm, blunt
No. 20195-026*



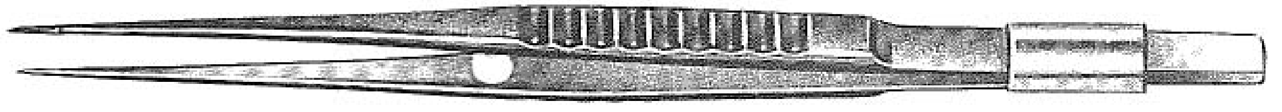
Bayonet, short-angled downwards,
19.5 cm,
tip 1 mm, blunt
No. 20195-009*

* Delivery time: on request

Sterilizable up to 134 °C

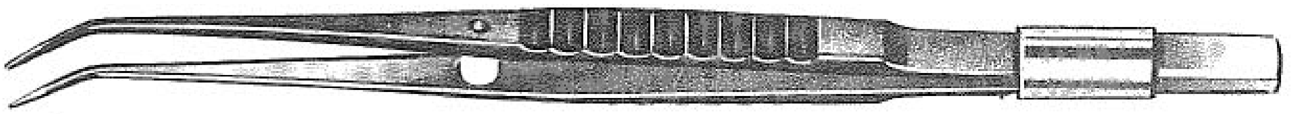
Cleaning in washing machine up to 95 °C

Bipolar forceps



Straight, 16.5 cm, tip 1 mm, blunt
No. 20195-010*

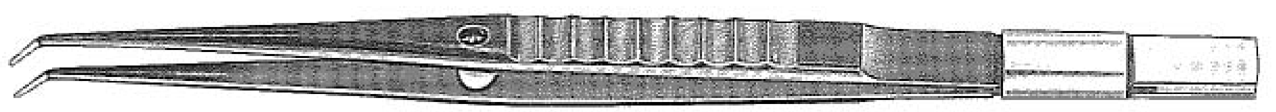
Straight, 16.5 cm, tip 1 mm, pointed
No. 20195-011*



Angled, 16.5 cm, tip 1 mm, blunt
No. 20195-014*

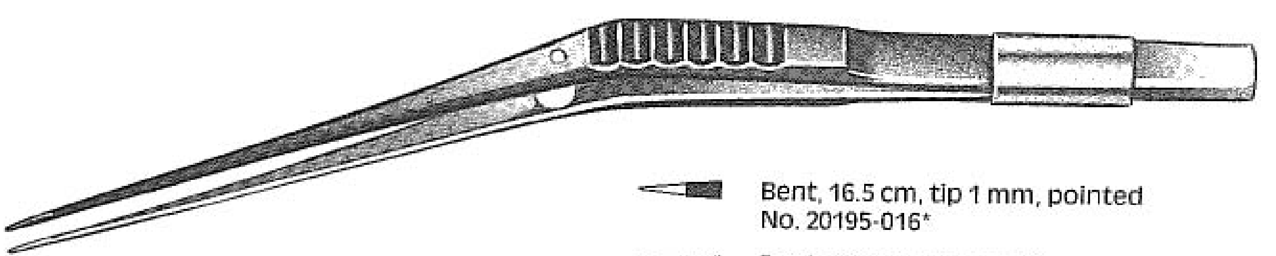
Angled, 16.5 cm, tip 1 mm, pointed
No. 20195-013*

Angled, 16.5 cm, tip very fine
No. 20195-036*



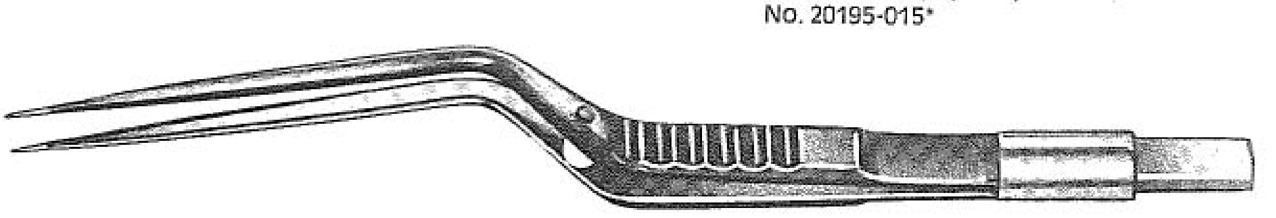
for difficult access

Short-angled, 16.5 cm,
tip 1 mm, blunt
No. 20195-066*



Bent, 16.5 cm, tip 1 mm, pointed
No. 20195-016*

Bent, 16.5 cm, tip very fine
No. 20195-015*



Bayonet, 16.5 cm, tip 1 mm, blunt
No. 20195-018*

Bayonet, 16.5 cm, tip 1 mm, pointed
No. 20195-017*

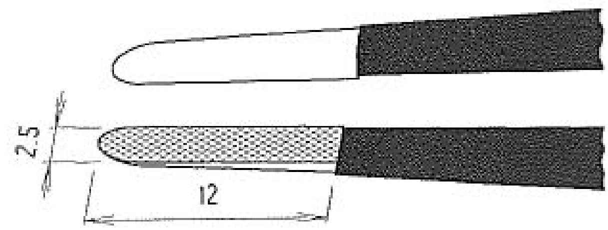
Bayonet, 16.5 cm, tip very fine
No. 20195-033*

* Delivery time: on request

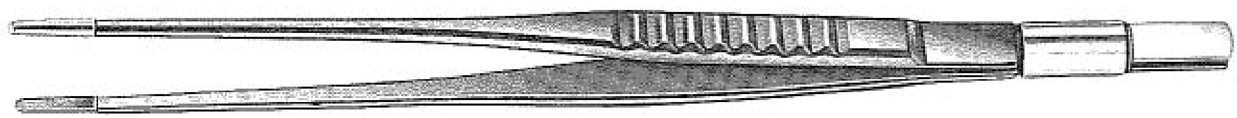
Sterilizable up to 134 °C

Cleaning in washing machine up to 95 °C

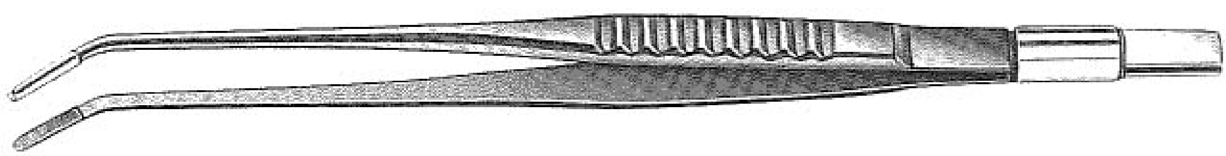
Bipolar forceps with gripping surfaces



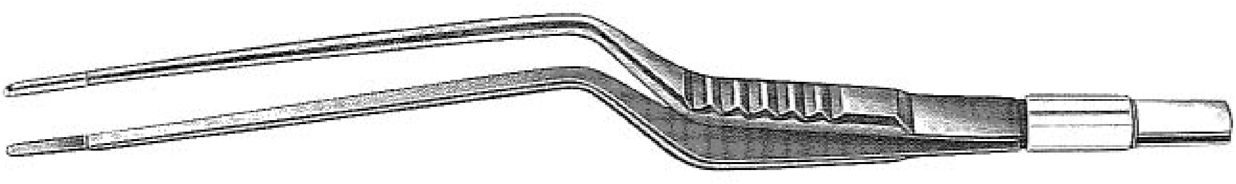
Bipolar forceps for general surgery and orthopaedics with structured (similar to knurling) coagulation surfaces for safe gripping, preparation and preservation coagulation in SOFT coagulation.



Straight, 19 cm, tip 2.5 mm, blunt
No. 20195-057*



Angled, 19 cm, tip 2.5 mm, blunt
No. 20195-058*



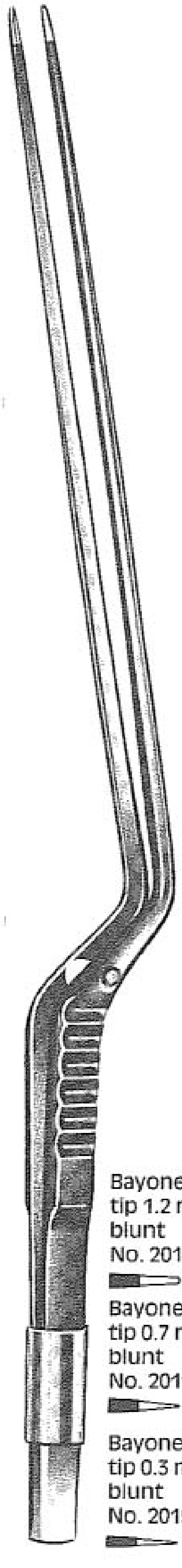
Bayonet, 19 cm, tip 2.5 mm, blunt
No. 20195-059*

* Delivery time: on request

Sterilizable up to 134 °C

Cleaning in washing machine up to 95 °C

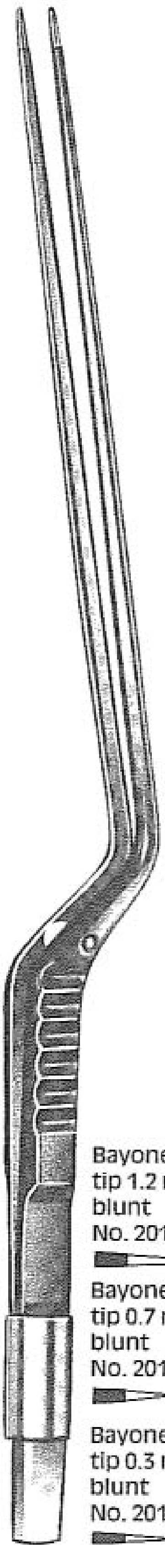
Bipolar forceps



Bayonet, 24 cm
tip 1.2 mm,
blunt
No. 20195-032*

Bayonet, 24 cm,
tip 0.7 mm,
blunt
No. 20195-043*

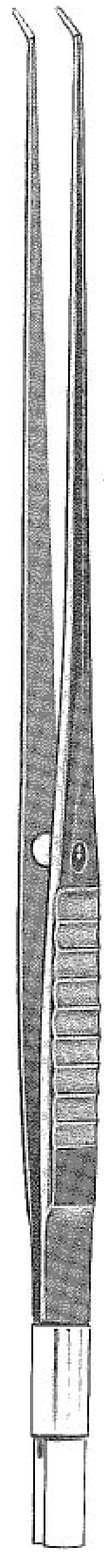
Bayonet, 24 cm,
tip 0.3 mm,
blunt
No. 20195-042*



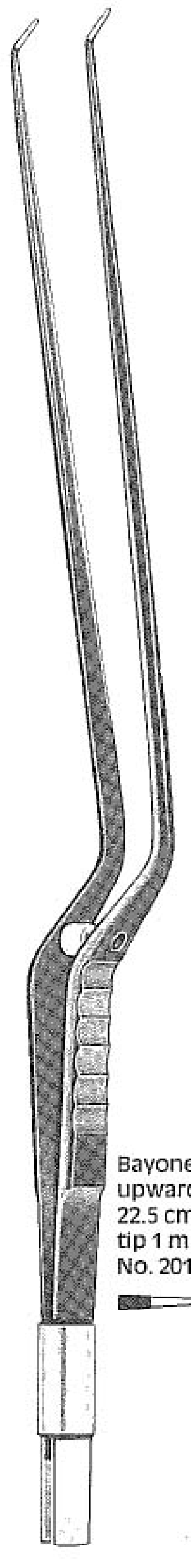
Bayonet, 22.5 cm,
tip 1.2 mm,
blunt
No. 20195-031*

Bayonet, 22.5 cm,
tip 0.7 mm,
blunt
No. 20195-045*

Bayonet, 22.5 cm,
tip 0.3 mm,
blunt
No. 20195-044*



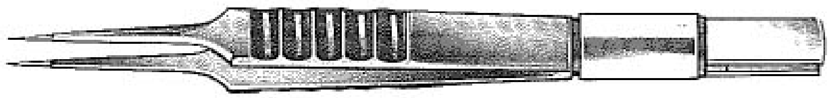
Short-angled,
22.5 cm,
tip 1 mm, blunt
No. 20195-064*



Bayonet, short-angled
upwards,
22.5 cm,
tip 1 mm, blunt
No. 20195-063*

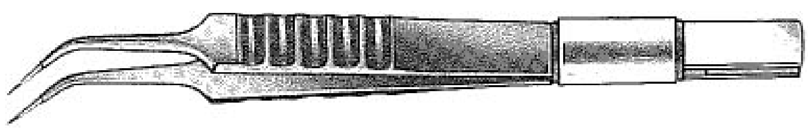
* Delivery time: on request

Bipolar forceps



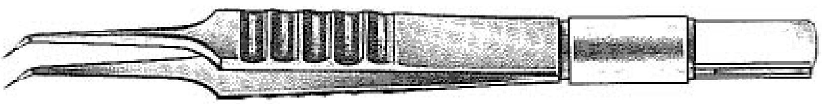

Straight, 11 cm, tip 0.7 mm, blunt
No. 20195-020*


Straight, 11 cm, tip 0.7 mm, pointed
No. 20195-019*

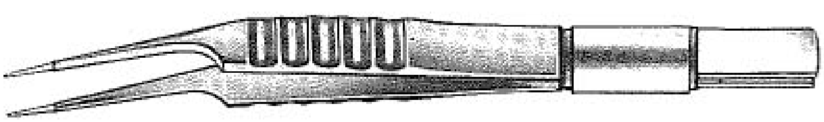



Angled, 11 cm, tip 0.7 mm, blunt
No. 20195-021*


Angled, 11 cm, tip 0.7 mm, pointed
No. 20195-023*




Short-angled, 11 cm,
tip 0.7 mm, pointed
No. 20195-022*




Bent, 11 cm, tip 0.7 mm, pointed
No. 20195-035*

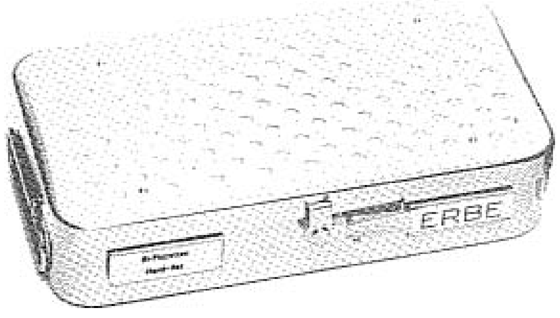
Connecting cable for bipolar forceps
in compliance with IEC 601, part 2–2, 101.3
5 m long No. 20196-000
3 m long No. 20196-001

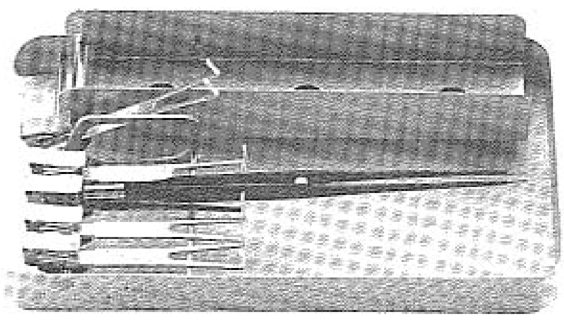
* Delivery time: on request

Sterilizable up to 134 °C

Cleaning in washing machine up to 95 °C

Forceps rack and sets





Container, large size
stainless steel with perforated bottom for sterilization
No. 20195-049

Container, small size, stainless steel
No. 20195-052

Forceps-Rack, small size
stainless steel
No. 20195-053

Forceps rack, stainless steel
to hold 5 forceps. The forceps are simple to place in the raised position (removal position)
226 × 125 × 40 mm
No. 20195-050

Bipolar forceps set,
for microsurgery, ENT, consisting of rack and following forceps:
20195-011, -014, -018, -016
No. 20195-048 not illustrated

Bipolar forceps set,
for ophthalmology, plastic surgery, experimental surgery, consisting of rack and following forceps:
20195-019, -020, -022, -021, -035
No. 20195-051 not illustrated

Bipolar forceps set,
for neurosurgery, consisting of rack and following forceps:
20195-008, -002, -034, -026
No. 20195-047 not illustrated

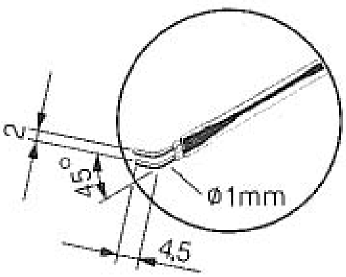
Bipolar forceps set,
for gynaecology, ENT, tonsillar surgery, consisting of rack and following forceps:
20195-000, -001, -007
No. 20195-046 not illustrated

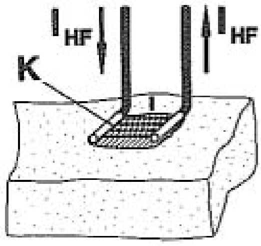
Connecting cable for bipolar forceps,
in compliance with IEC, part 2–2, 101.3
5 m long No. 20196-000
3 m long No. 20196-001

Sterilizable up to 134 °C

Cleaning in washing machine up to 95 °C

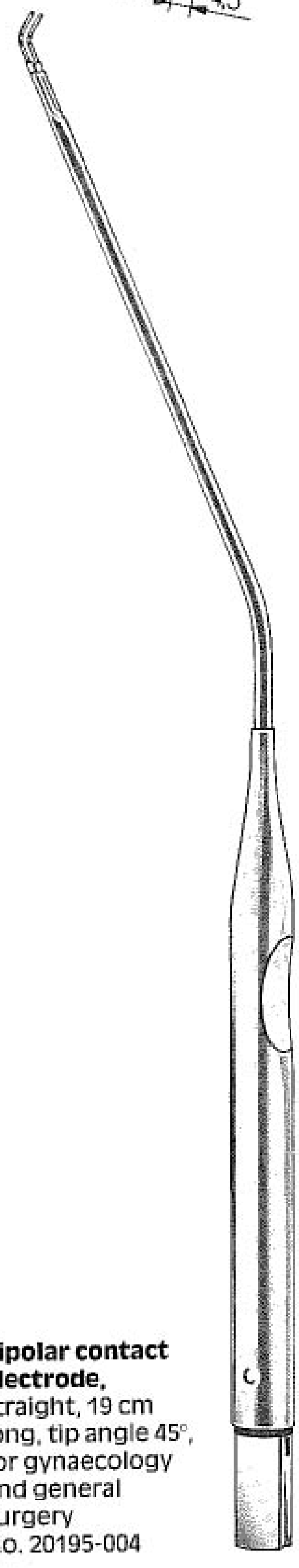
Bipolar contact electrodes



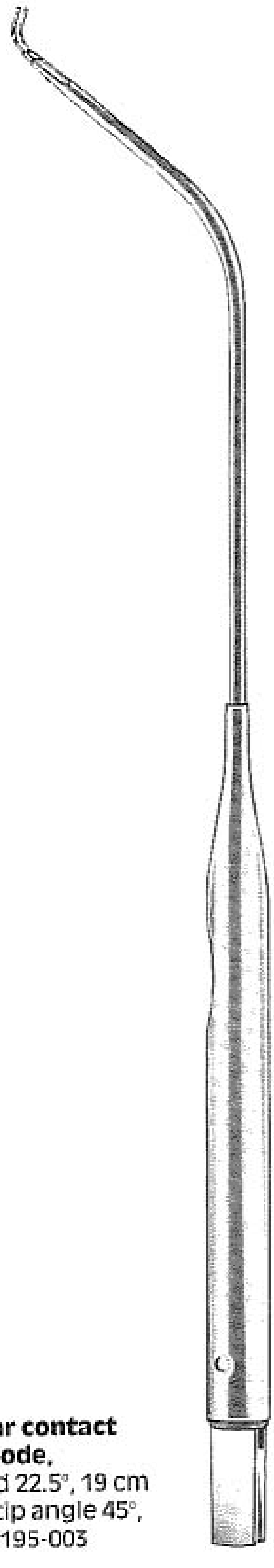


Bipolar contact electrodes are suitable for large-area surface coagulation. Coagulation only takes place between the two contact electrodes.

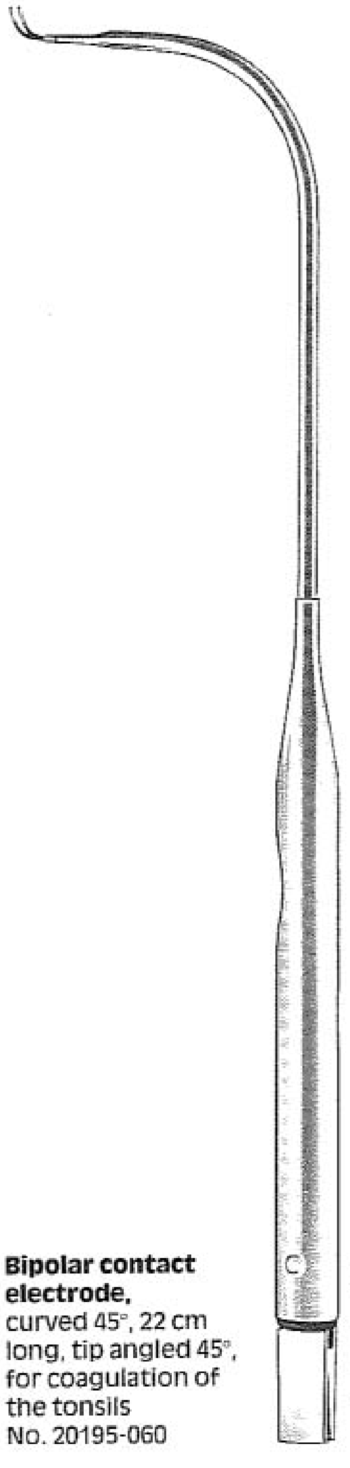
Bipolar contact electrode, straight, 19 cm long, tip angle 45°, for gynaecology and general surgery
No. 20195-004



Bipolar contact electrode, curved 22.5°, 19 cm long, tip angle 45°,
No. 20195-003

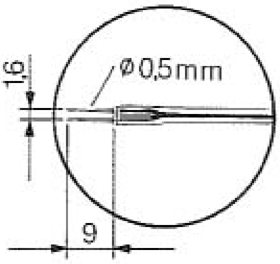


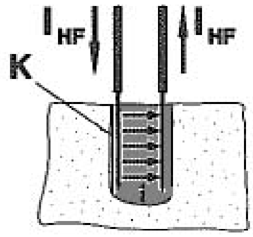
Bipolar contact electrode, curved 45°, 22 cm long, tip angled 45°, for coagulation of the tonsils
No. 20195-060



Bipolar contact electrode, curved 90°, 22 cm long, tip angle 45°, for coagulation of the tonsils
No. 20195-061

Bipolar puncture electrodes

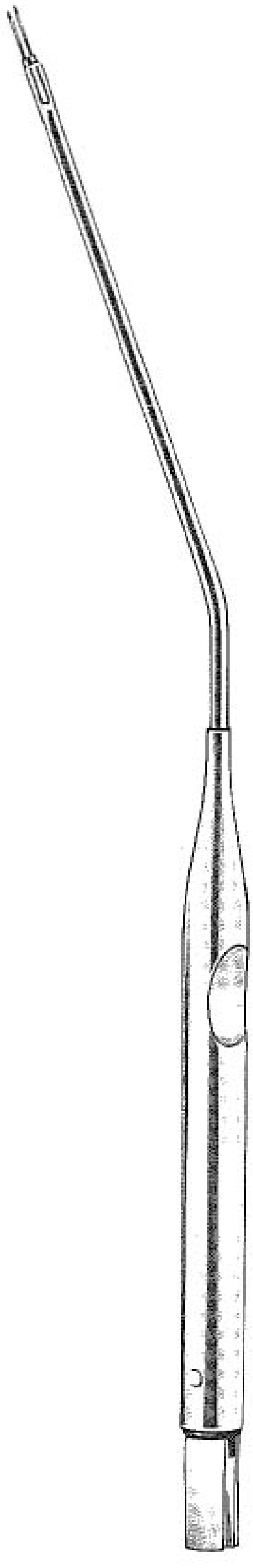




Spread of coagulation in bipolar puncture coagulation.

In rhinopathy,
the bipolar method allows coagulation of the nasal concha without patient plate.

Advantage:
In coagulation of the lower nasal concha (cauterization) with the bipolar coagulation electrode, no puncture bleeding occurs. This gives the surgeon a very good view and allows him to perform several selective posterior to anterior coagulations of the lower nasal concha. In addition, the absence of the patient plate provides the surgeon with a relaxed patient.



Bipolar coagulation needle,
curved 22.5°, 19 cm long, tip 1.6 × 9 mm, for puncture coagulation of the nasal concha.
No. 20195-025

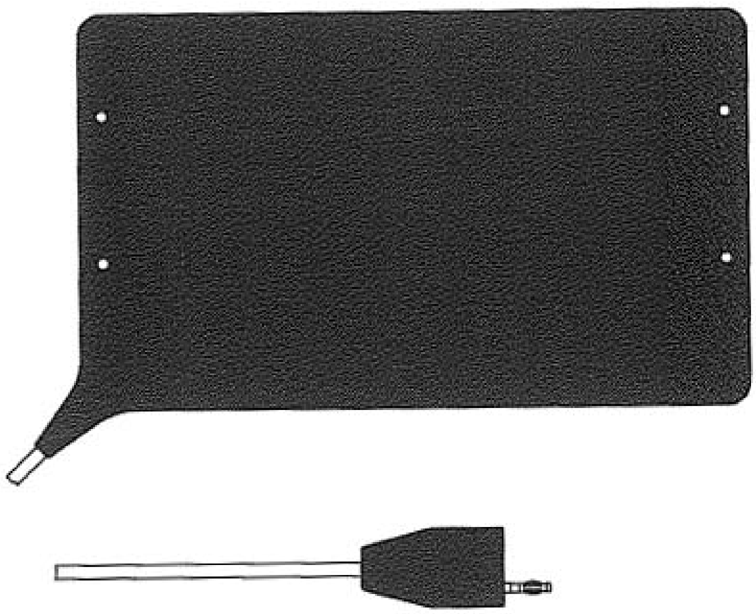
Patient plates

Patient plates reusable single-surface

in compliance with IEC 601, part 2–2, 101.4

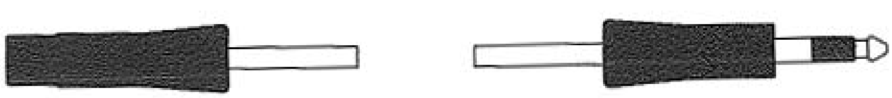
Patient plate of conductive silicone

- The patient plate supplied by ERBE consists of soft, flexible and electrically conductive silicone material, which adapts well to the anatomical shape of the patient in the area of application.
- An elastic and perforated rubber strap fastens the patient plate securely to the patient.
- The patient plate has a short cable with a connector for ECG.

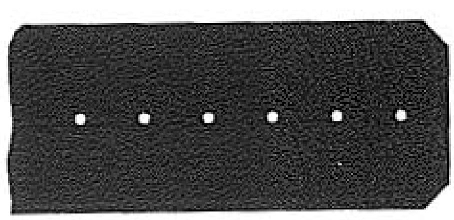


Patient plate of conductive silicone
with short connecting cable, 40 cm long, ECG connection 4 mm diameter, with 2 rubber fastening straps, contact area 516 cm^2
No. 20193-008

Patient plate of conductive silicone
with short connecting cable, 40 cm long, ECG connection 4 mm diameter, with 1 rubber fastening strap, contact area 187 cm^2, for children
No. 20193-016



Connecting cable for patient plates
reusable, for Erbotom series T, ACC, sterilizable up to 134 °C
Cable 3 m long No. 20194-000
Cable 5 m long No. 20194-001



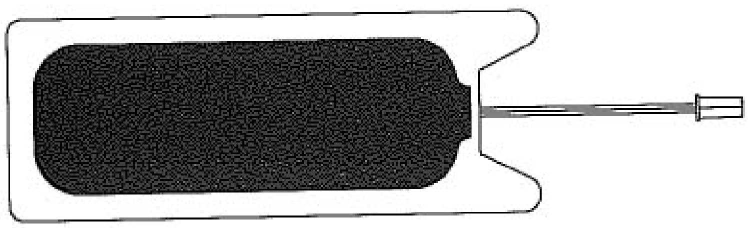
Rubber strap, elastic
with fastening stud, 6 cm wide, perforated strap,
non-sterilizable.
0.55 m long No. 20592-009
1.25 m long No. 20592-011

Fastening stud
No. 40592-003

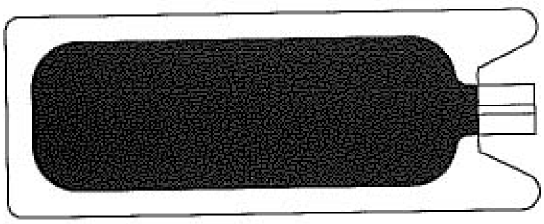
Patient plates, disposable, single-surface

Disposable patient plate

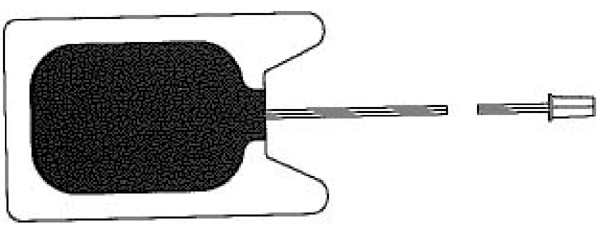
- The supporting material of the patient plate from ERBE consists of flexible and elastic plastic, which adapts well to the anatomical form of the patient in the area of application.
- The contact surface carries an electrically conductive coating of adhesive (Polyhesive).
- Simple and safe handling by applying the patient plate like a plaster.



Disposable patient plate
Version: single contact surface,
A = 125 cm², with short connecting cable, 40 cm long,
adhesive: electrically conductive
No. 20193-018

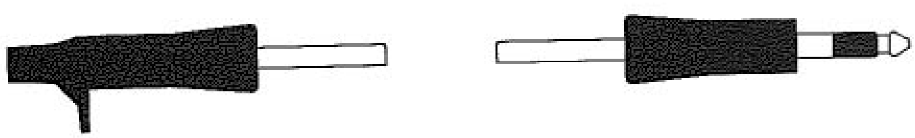


Disposable patient plate
Version: single contact surface,
A = 125 cm², without cable,
adhesive: electrically conductive
No. 20193-020

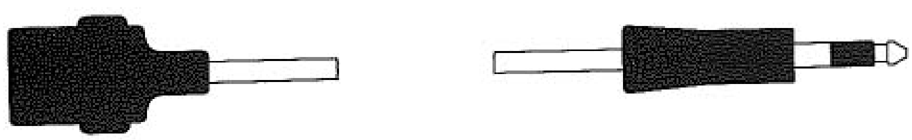


Disposable patient plate for children up to 15 kg
Version: single contact surface,
A = 60 cm², with short connecting cable, 40 cm long,
adhesive: electrically conductive
No. 20193-019

Connecting cable for disposable patient plates



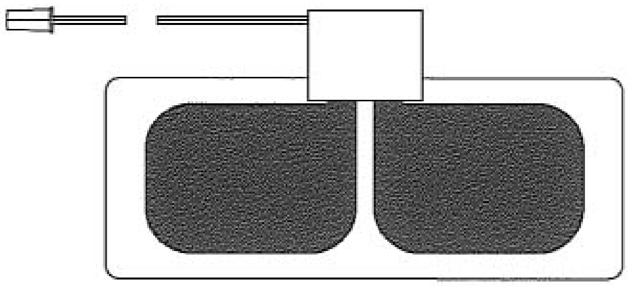
Disposable patient plate, with short cable,
sterilizable up to 134 °C
3 m No. 20194-026
5 m No. 20194-027



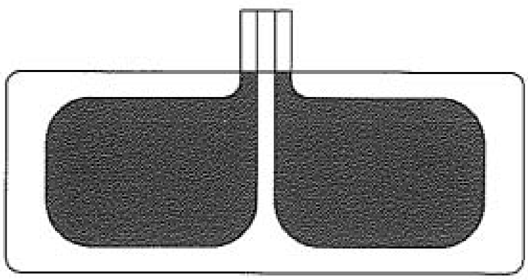
Disposable patient plate, without cable,
non-sterilizable
3 m No. 20194-042
5 m No. 20194-038

Disposable patient plate, double-surface

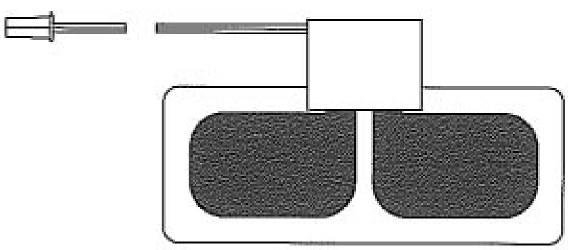
- The correct and safe application of the patient plate is checked and guaranteed by using patient plates with two separate contact surfaces and by a suitable »Neutral Electrode Safety System« type NESSY.



Disposable patient plate
Version: two separate contact surfaces, A = 125 cm², with short connecting cable, 40 cm long, adhesive: electrically conductive
No. 20193-021



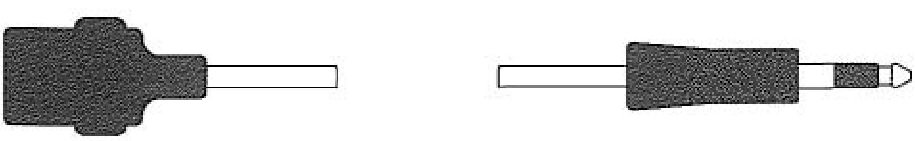
Disposable patient plate
Version: two separate contact surfaces, A = 125 cm², without cable, adhesive: electrically conductive
No. 20193-022



Disposable patient plate for children up to 15 kg
Version: two separate contact surfaces, A = 60 cm², with cable, adhesive: electrically conductive
No. 20193-023

Connecting cable for disposable patient plates

Disposable patient plate, with short cable,
sterilizable up to 134 °C
3 m No. 20194-026
5 m No. 20194-027

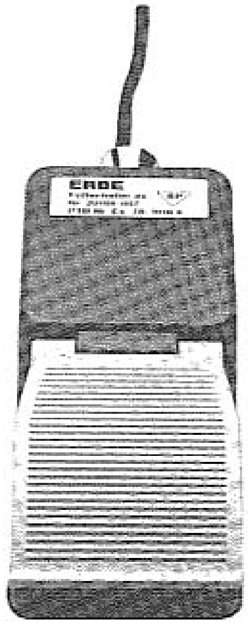


Disposable patient plate, without cable,
non-sterilizable
3 m No. 20194-042
5 m No. 20194-038

Footswitch

Footswitch, explosion-protected

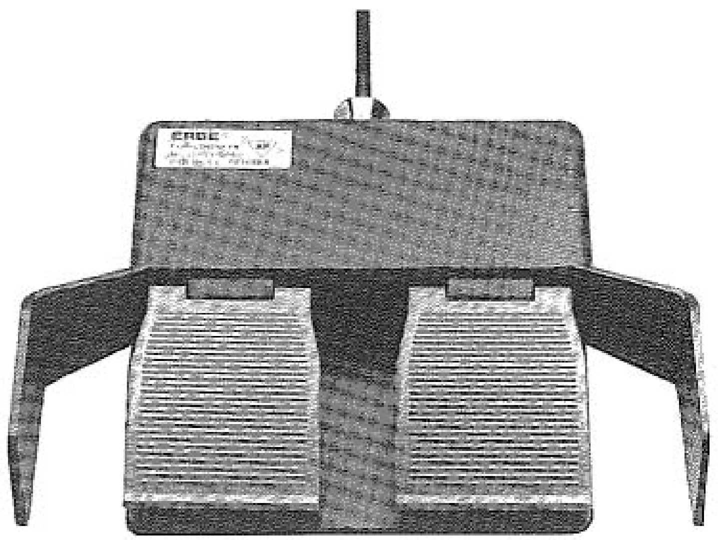
- The casing of the explosion-protected footswitch is made of aluminium die-casting, it es watertight, according to IEC 601, part 2–2, subclause 44.6 and complies with the requirements of IEC 601, part 1, clause 6, Protection against Explosion Hazards PTB No. Ex-79/1016X. The footswitches are designed for universal application.
- The footswitch is provided with slip-proof rubber feet.
- The footswitch can be subjected to surface disinfection using any disinfectant.
- The footswitch is fitted with a 5 m long connecting cable as standard.



Single-pedal footswitch, explosion-protected

No. 20188-007

The single-pedal footswitch activates the generator for monopolar and bipolar coagulation.



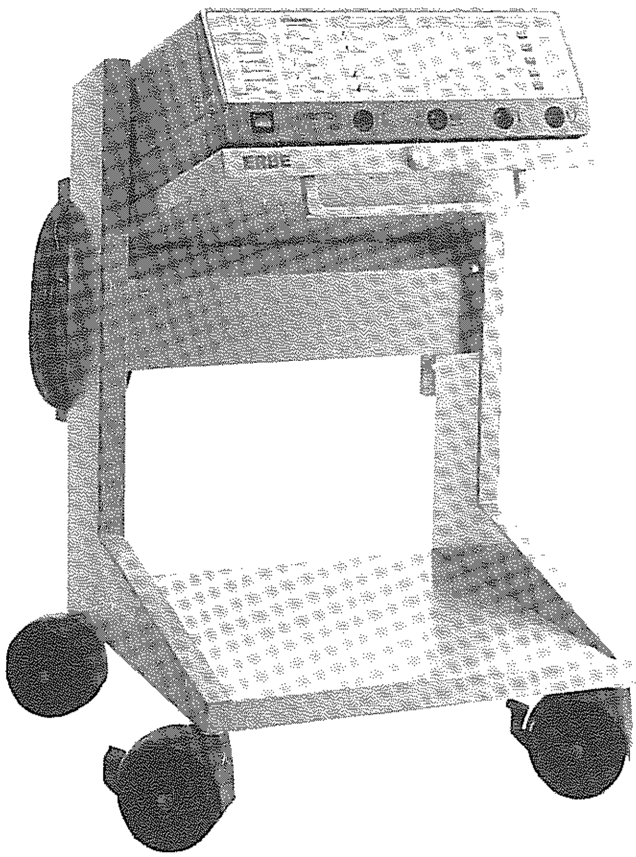
Double-pedal footswitch, explosion-protected

No. 20189-009

The double-pedal footswitch activates the monopolar and bipolar generator for cutting and coagulation.

Connecting cable for footswitches
with angled plug,
0.5 m long
No. 20189-014 not illustrated

Equipment trolley



Equipment trolley ACC

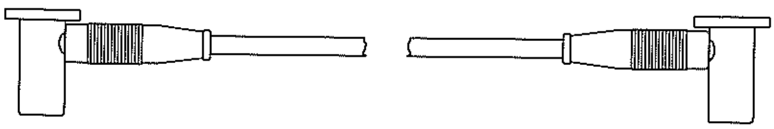
- A practical trolley holding 2 units, the HF electrosurgical unit ACC and a cold-light source placed under the electrosurgical unit.
- The trolley equipment shelf is tilted slightly to the rear. This provides a clear view of the display elements and good accessibility for setting the individual parameters via the control panel keys.
- The equipment trolley is fitted as standard with two spray-water protected sockets and a 5 m long power cord along with 3 equipotential conductor pins.
- The footswitch, for example, can be placed on the bottom shelf of the trolley.
- The four large dual steering casters facilitate simple and safe movement of the trolley. The casters are made of electrically conductive material thus preventing the build-up of an electrostatic charge on the trolley. The two front casters can be locked.
- The trolley is open on all sides and easy to clean. Conventional disinfectant can be used for cleaning purposes.

Equipment trolley ACC

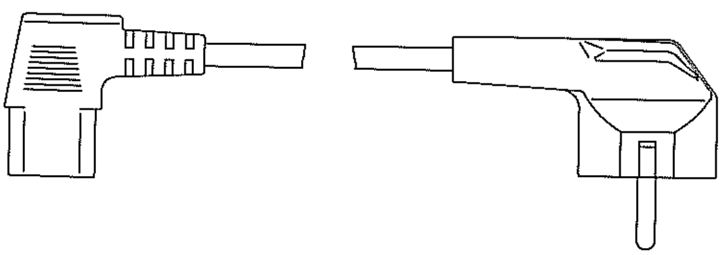
No. 20185-005

Fastening set for Erbotom ACC only
No. 20121-003 not illustrated

Fastening set for cold-light and Erbotom ACC
No. 20121-004 not illustrated



Equipotential bonding cable
with connections according to DIN 42801
No. 30312-184



Power cord
according to IEC 601, part 1, 57
No. 30185-009