DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 1998

Mr. Thomas J. Gilloway
Executive Vice President
Valley Forge Scientific Corporation
136 Green Tree Road
Oaks, Pennsylvania 19456

Re: K982229
Trade Name: Bi-Dent
Regulatory Class: II
Product Code: EKZ
Dated: May 14, 1998
Received: May 15, 1998

Dear Mr. Gilloway:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT F

510(k) NUMBER (IF KNOWN): K982229

DEVICE NAME: Bi-Dent Bipolar Surgical System

INDICATIONS FOR USE:

The Valley Forge Bi-Dent Electrosurgical System is intended for the Dental Practitioner for the cutting and coagulation of oral tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ______ (Per 21 CFR 801.109) OR Over-The-Counter-Use ______ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K982229

AUG 13 1998

K982229

EXHIBIT VI
PAGE 1 of 9

SUMMARY OF SAFETY AND EFFECTIVE INFORMATION

Dr. Leonard I. Malis, former Chairman of the Department of Neurosurgery at Mount Sinai School of Medicine, New York, NY and Neurosurgeon - in - Chief and Director of Neurosurgery of Mount Sinai Medical Center, first introduced his electrosurgical Bipolar Coagulator in the 1960's for use in micro and general surgery. The system utilized an aperiodic waveform with spark gap technology. The random spike components of the waveform produced excellent coagulation because there was no tissue destruction due to molecular resonance as produced by the periodic synchronous waveforms of monopolar electrosurgical systems. However, the overvoltage of the first spike in each pulse train of the original Malis system caused undesirable sparking at the forceps tips which results in excessive tissue charring, eschar (coagulum) build-up, and sticking at the forceps tips. This problem was overcome with the advent of microprocessor technology utilized in Dr. Malis' second generation solid state Bipolar Coagulator and Bipolar Cutting System CMC-II introduced in 1983 and the Malis Bipolar Coagulator and Cutter System CMC-III introduced in 1990. (Please see the attached articles by Leonard I. Malis, M.D.)

Through bipolar coagulation surgeons have been effectively sealing vessels and coagulating tissue for over thirty years. One of the advantages of bipolar coagulation is the ability to coagulate under irrigation in the surgical field. Initially, surgeons used a bulb syringe to continuously irrigate the field. In 1985, a controlled Irrigation Module was introduced as an accessory product to be used with the Malis coagulation systems. This enables the surgeon to irrigate while coagulating without the assistance of a second surgical assistant working the bulb syringe. (Please see the attached article, "The Value of Irrigation During Bipolar Coagulation").

Valley Forge Scientific Corporation, the manufacturer of the Malis solid state Bipolar Coagulator/Cutting Sustems and the Irrigation System, has now combined the two separate generators into one functioning Bipolar Coagulator/Cutting System with integrated irrigation. This new system incorporates the effectiveness and safety features of bipolar coagulation/cutting and irrigation packaged into one functional unit. Some of the effective safety features of the Bipolar Coagulator/Cutting System are:

*Bipolar Technology eliminates the need for grounding pads and the possibility of patient burns.

*Bipolar Cutting/Coagulation minimizes damage to adjacent tissue since the patient is no longer the return path for the electrical current.

*Bipolar Technology works at voltages approximately 1/10th the voltage required for monopolar technique.

*Localized Bipolar Cutting/Coagulation gives the surgeon precise control of the electric current at the tissue site.

*The System's patented waveform and exceedingly low Output Impedance provide superior Cutting/Coagulation and the absence of charring and sticking even in a dry field.

*Because of the high output impedance of monopolar and other bipolar systems, instruments short-out in an irrigated or bloody field.

*The Bipolar Coagulator/Cutting System offers an Irrigation Delivery System to keep tissue moist and cool during coagulation.

*Because of the System's ability to work in a wet field, tissue samples removed for biopsy are not charred or desiccated.

*Unlike monopolar systems, the Bipolar Coagulator/Cutting System provides smooth, progressive coagulation with precise flow-controlled irrigation.

*The System permits the physician to cut and coagulate in an Irrigated Field thereby minimizing heat build-up or thermal damage to adjacent tissues.

*The waveform parameters of the Bipolar Coagulator/Cutting System are programed for the smoothest, most gentle, precise and efficient coagulation and cutting of tissue during any surgical procedure.

New Trends in Microsurgery and Applied Technology

L. I. Malis

Dr. Yasargil suggested to me that it might be good if I spent more time talking about coagulation than anything else, and since I am deeply interested in that and since it does not come up elsewhere in the program, I thought I would finish with a rather more detailed discussion of coagulation. An electrosurgical device with a spark generator was first brought into an operating room in 1910. It had a motor-driven rotating-disc as a static generator with a spark gap, a Leyden jar as a capacitor and a resonating coil. It put out a powerful discharge with which one could almost cook living tissue but which was not generally used. In 1928, W. T. Bovie, a physicist and one of the earliest biophysicists, developed an electrosurgical unit in which a spark gap generator provided an output of damped irregular waveforms of about a megahertz in frequency which permitted coagulation, and with a synchronous resonating circuit, also providing cutting ability. Cushing used this machine to revolutionize some of his removals in areas where bleeding had not been controllable before. Cushing's first publication began with a note by Bovie which is remarkably erudite now more than 65 years later.

Let me take a moment for basic principles. Direct current has a voltage level which stays constant through time. Alternating current on the other hand changes its direction with each side of the circuit changing from positive to negative, and the time it takes to do this is the frequency of the alternating current. Our ordinary power line current is either 50 or 60 cycles per second (Hertz). The amplitude up from the zero line is the voltage and this is the same as pressure in a hydraulic system. The current, which is measured in amperes, is a measure of how many electrons have passed through in a unit of time. The total power is the volts times the amperes but that applies only to direct current. The power line alternating current describes a sinusoidal wave form.

The amount of current that can flow at a given voltage depends upon the resistance of the material through which it flows. Resistance is a direct current term. Impedance is its equivalent for alternating current since other factors determine how alternating current can go through a material. Those are frequency and phase shift which I will not go into today because of time constraints. Constant current stimulators are the ones most frequently used for electrophysiology today. This is the diametric opposite of power distribution for our cities. If constant current were used, the current, whether one lamp or a million were turned on, would be the same. There would be no light from the million bulbs and the one bulb would disappear in a flash of smoke. With a constant voltage system, which is what is used, no matter how many bulbs you put in, no matter how many air conditioners run, since the voltage remains constant, all bulbs stay at the same brightness and appliances at the same level. For the coagulator nothing could be more important than constant voltage. In a constant current system, if you had saline over the field virtually nothing would be left for the coagulation at the tip since most of the current would flow through the saline, whereas in a constant voltage system, the closer the voltage is regulated, the lower will be the effect of the shunting of the saline and the more will the voltage and the power at the tip remain the same to go through the tissue.

The constant voltage is determined by the generator impedance. The lowest possible impedance in the generator gives you the best regulation of the voltage and the most constant voltage so that the current flowing is going to rise if the tissue impedance is low, and the voltage across the tissue will remain the same regardless of the impedance, regardless of the forceps area. Engineers will tell you that for transferring power, the generator impedance and the load impedance should match and that is perfectly true if your problem is the transfer of power with the highest efficiency. We are totally uninterested in efficiency. We have power to waste and what we want is for the power to be always available at the forcep tip. So the matching load idea in the system is for us totally without reason. Current must flow across at the tips of the forceps despite the fact that it is immersed in saline all the way, which requires a very low generator impedance as close as possible to a constant voltage system.

As Bovie pointed out, there is a difference between cutting and coagulating current. Cutting is performed with a constant sine wave, from a perfectly smooth resonant system. It also requires only a small tissue area to be involved. It is generally done with a fairly high voltage so that a tiny spark ahead of the electrode actually divides the tissue by molecular resonance. At one megahertz the macromolecules of tissue resonat[illegible] thly in synchrony, fall apart and separate, and so the current cuts. Coagulating is done with bursts of damped waves, and a somewhat larger tissue area for the amount of power.

The important factor is the arrhythmicity. A coagulating waveform is an arrhythmic wave form where not 2 cycles are alike, where there can be no true resonance i.e. no molecular resonance and the lowest division of tissue. The two requirements for coagulating are an arrhythmic waveform and damping, which means the voltage will come in bursts and each burst will go downward and then recur again so that any resonance that takes place will be stopped between the bursts.

If you use a human and put an electrode on the brain and a ground plate on the back, the impedance between the two at about a megahertz is about 1500 ohms. The impedance between the tips of the bipolar forceps on the brain is about 80 ohms. Now under those circumstances, if you look at the power required, you realize that only 5% or so of the generator power is needed to coagulate the surface with the bipolar at that point on the brain than would be needed with the monopolar and ground plate.

When Greenwood first developed bipolar coagulation back in about 1939, he used it by putting one side of the forceps to each side of the Bovie machine and just disconnecting his ground plate so that he had a very high leakage from one side of his forceps to any ground on the patient. But if you look at it this way, the impedance between his forceps tips was 80 ohms; his impedance to ground at the best 1500 or so. Only 5% of the current was leaking away, i.e. 1/20th. So despite the fact that his system was totally without isolation, he only had a 5% leakage current and that isn't too bad and it did indeed work for him.

With the separate isolated bipolar unit, there is only the flow between the forcep tips and virtually none any other way, which does indeed prevent leakage current. If you use a unipolar forceps and just touch it with the Bovie, the best return path to ground is through the blood in the parent vessel and you may very well damage the parent vessel. With the bipolar, there is no flow into the parent vessel and, of course, you can seal just the branch you want, preserving the main trunk.

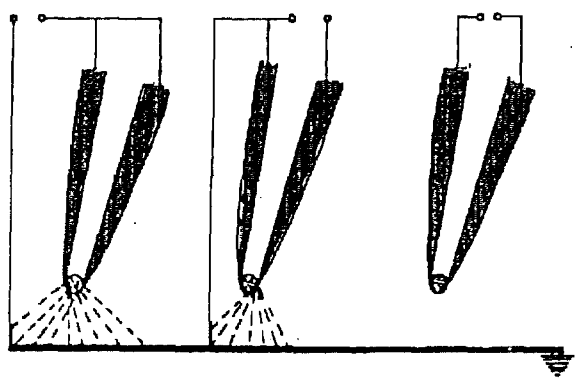


Fig. 14. On the *left* the unipolar coagulator. Current flows from the forceps to the dispersive electrode or ground plate. *Center section;* unisolated bipolar connection. Most of the current flows between the tips of the forceps but leakage current flows from the active electrode to the dispersive ·ound plate. On the *right* the isolated bipolar connection with the current flowing on' ·veen the ·rceps tips

To summarize this, you have the Bovie unit with the unipolar unit going to ground, the bipolar unisolated unit as Greenwood used it with 5% leakage in the human, and finally, the true isolated bipolar unit with all the power going through the forceps tips and no leakage to going ground (Fig. 14). Now when you go to repeat this experiment in the rat, you get a very different most misleading result. There have been papers in the literature saying that based on rat studies the leakage of some of the commercial units is too great to be safe. When you use a Bovie unit on a rat, the impedance is 150 ohms, so half the current will go to the ground plate; if you use an unisolated generator with bipolar forceps instead of 1/20 of the current as in the human. So you must take the rat leakage current studies and divide them by 10 in order to have any meaning for the human. To put it simply, the leakage current in any commercial bipolar, no matter how badly built, is not high enough to be a problem, no matter which company has made it. Reducing leakage current is helpful in avoiding interference with monitoring equipment and television cameras.

The way to determine leakage and its damage – if you are really worried about it – is to put one forcep blade of the bipolar on the surface of the rat brain and turn the power all the way up keeping it on for a minute or so. Then inject the live animal with methylene blue and if it doesn't stain, there is no significant damage. It is not the measurement of current that is important, it is what happens to the brain.

Another comparison between bipolar and unipolar coagulation: one side of the brain is stroked with the unipolar at the lowest power setting that will coagulate all the surface vessels; the other side with the bipolar under the same circumstances and then the methylene blue injection is given. There is indeed damage going deep with the unipolar which is the result of heat spread, and there is superficial damage from the bipolar, essentially the result of destroying the cortical vascular supply, and the

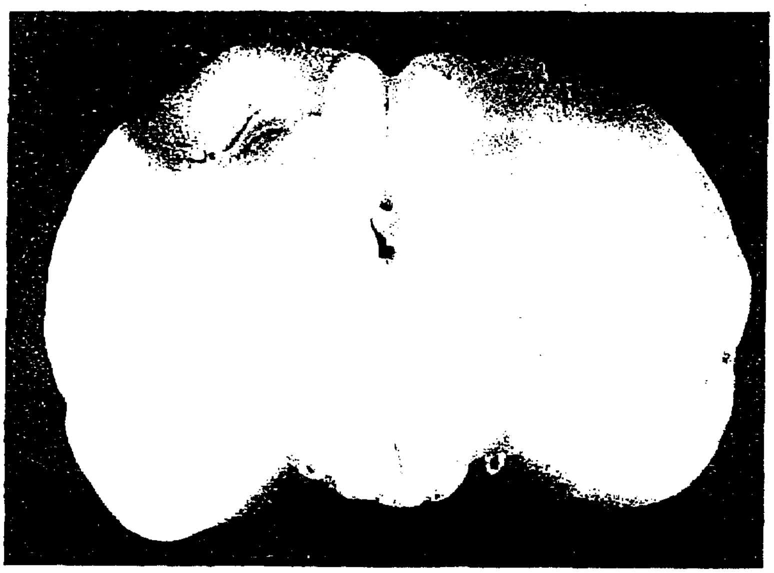


Fig. 15. On the *left* the deep necrosis caused by unipolar coagulation of surface vessels. On the *right* superficial ch[illegible] ·fter bipolar coagulation of surface vessels

marked difference between the two is seen consistently (Fig. 15). Now if you set both unipolar and bipolar coagulators at the same power level you can blow the brain apart on the bipolar treated side because so much less power is required for coagulation than with the unipolar connection because the return, i.e., the ground plate, is at a distance. So the coagulators must be matched to the lowest power for each to coagulate for this to be meaningful.

The fact that we irrigate and do our coagulating under saline, since there is no current spread, allows us to keep tissue cool. I have had my assistant irrigate with a simple bulb syringe of saline. In the laboratory many years ago, when I had no assistant, I used to keep a needle cemented to my bipolar forceps and run saline through it (Fig. 16). We are going back to that again as progressive cost cutting leaves us without an assistant much of the time so that we now have available a forceps with an irrigating tube controlled to go on and off with the bipolar which makes the assistant unnecessary.

Different forceps sizes are essential, as part of your surgical armamentarium. You do not attempt to coagulate a vascular malformation with a fine pointed tip or you can indeed perforate it by getting too high a current density at the tip. You use a rounded, flat, broader blade which will allow you to shrink and bring down a vessel. The fine tip is superb for sealing a tiny branch of an artery which must be pre-

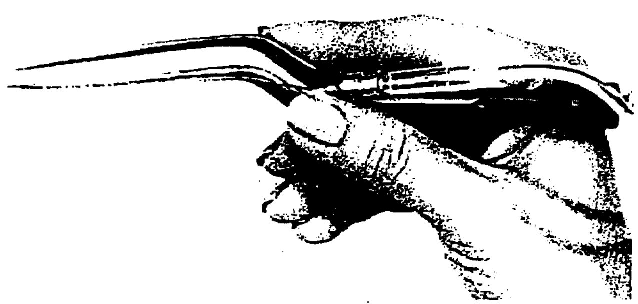


Fig. 16. Spinal needles cemented to side of bipolar forceps to provide irrigation

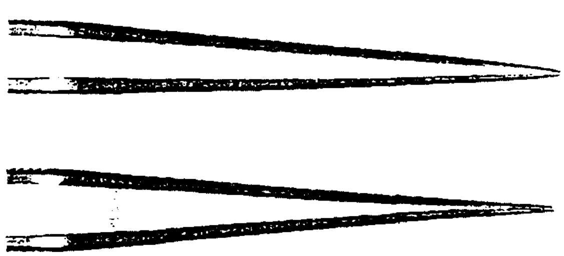


Fig. 17. Correct alignment of forceps blades in *upper half* of photograph, incorrect alignment with short circuiting proximal to the tips in the *lower* illustration

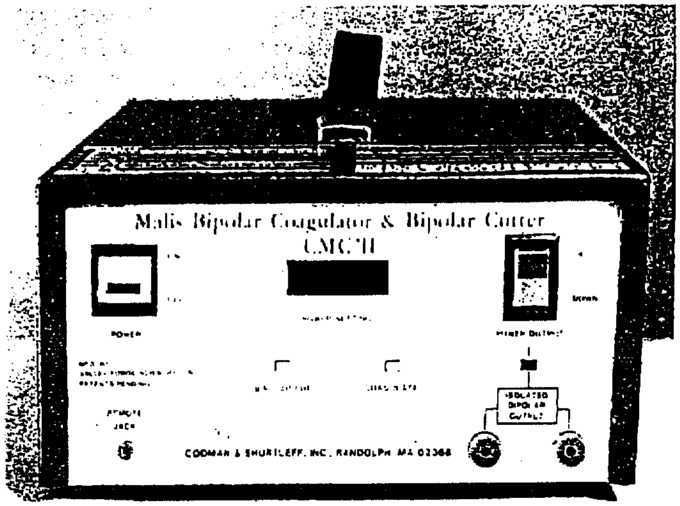


Fig. 18. The new solid state microprocessor controlled coagulator

Fig. 19. A right acoustic neuromas with the forceps tips applied to the capsule

served, for working against a tumor capsule or taking a minute vessel off the facial nerve without damaging the nerve.

It is essential that the forceps not touch each other as you work because if the forceps tips are in contact, the current just goes through the metal and coagulates nothing. Forcer come through from the factories with the blades straight. When

Fig. 20. Same patient as Figure 19. The bipolar cutting current is being used to core the tumor

they pick up a vessel at the tip, they are shorted well back of the tip. The forceps blades should be concave enough to meet so that you can hold the vessel without shorting (Fig. 17). It is also essential that the surface be clean and polished. I polish them myself with an electrical hone between cases since I do not trust them any other way.

The spark generator puts out a completely asynchronous highly random damped series of spikes in each burst. In some commercial solid state coagulators, a damped sinewave is generated. Because it does resonate in part, it has higher cutting and higher bursting of vessels. It is rhythmic and resonant despite the fact that it is damped. We were finally able with the advent of microprocessor technology to program a microprocessor to change the height and width of each spike of the damped wave, to change the interspike interval and so the frequency of each spike separately thus producing an asyncronous, arrhythmic damped wave with solid-state equipment. This has an advantage in that it does not have the high first spike of the spark generator. It begins with a gentle start and so there is almost no sparking when you use it on the tissue. This is the basis of my new solid-state unit which I personally find has a tremendous advantage over the old spark gap device. This is purely the result of microprocessor technology (Fig. 18).

Additionally, the new solid state bipolar unit incorporates a pure sinusoidal wave form for use as a bipolar cutting instrument. This again is a low impedence, relatively low voltage technique. It cuts by molecular resonance without the high voltage arc to the tissue. As such it works only under saline irrigation. It is effective and efficient for coring tumors but not so good for dividing avascular fibrous tissue. I now use the cutting mode in virtually all neoplasm surgery (Figs. 19, 20, 21). It does indeed decrease for me the difficulty and duration of the surgical procedures

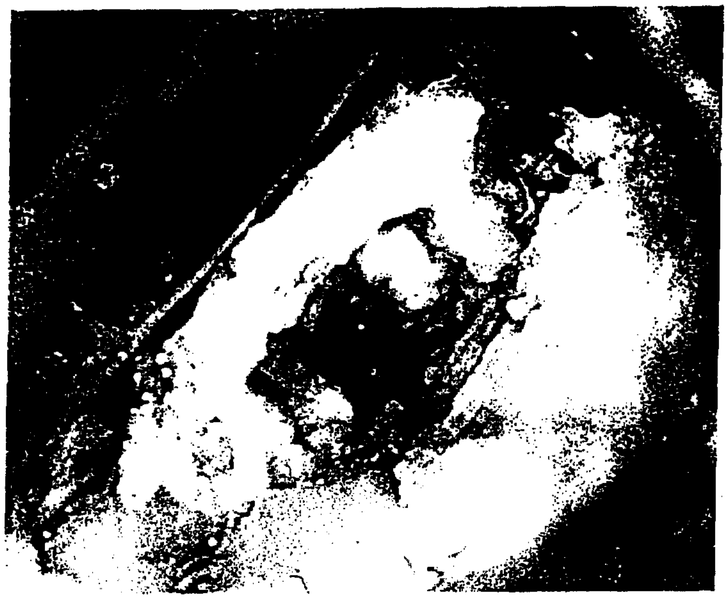


Fig. 21. Same patient as in Figs. 19 and 20. A large segment of the tumor has been removed bloodlessy with the bipolar cutting current

Finally, I have mentioned several times the problem with engineers and surgical instruments. Bovie brought to Cushing one day a pistol-grip with a trigger and a Bovie ball on the end of it and suggested that Cushing coagulate with it instead of the little pencil instrument and the foot switch. Cushing looked at it and commented that it was very nice, and suggested that Bovie go and put a pencil in the muzzle of a pistol and write his name with it, and then he would see why surgeons rather than engineers should design surgical equipment.

Background
by Leonard Malis, M.D.

The original monopolar and the MALIS Bipolar Coagulators used spark-gap generators to produce their coagulating waveform. The aperiodic waveform and random spike components of the spark-generated waveform produced good coagulation. However, the initial spike of each damped train is always much higher in voltage than the rest of the train, as a requirement for striking the arc in the internal spark gap of the generator. This high voltage initial spike is responsible for the undesirable sparking at the forceps tips and interference with television and monitoring equipment.

Previous electronic tube or solid state coagulators generally provided either damped trains of sine or square waves, or simply repetitive pulses. The synchronizing of these pulses or waves increased undesirable cutting or perforation of vessels being coagulated, as a result of molecular resonance. For this reason, the original MALIS Bipolar Coagulator and its present day version, the MALIS Bipolar Coagulator CMC-I (catalog no. 80-1114) continue to be the choice of most microsurgeons.

The MALIS Bipolar Coagulator and Bipolar Cutter System CMC-II simulated the aperiodic waveform of the spark gap systems, but the leading spike has now been reduced and is proportional to the remainder of the damped asynchronous train. The aperiodic waveform results in the elimination of molecular resonance while control of the first spike of each train results in marked reduction of sparking of the forceps and interference with other equipment. In addition, the waveform parameters are specifically programmed for smoother coagulation, and reduced neuromuscular stimulation, charring, sticking, and vascular perforation.

Bipolar coagulation has been part of microsurgical technique from the very beginning. The old standard unipolar machines worked from a single active electrode to a return plate through a large ground plate or dispersive electrode. A considerable total current, distributed roughly in a geometric cone from the active electrode to the ground plate, had its highest power per tissue volume at the active electrode, but a fair amount of current was distributed in adjacent tissues. The most conductive path to the ground had the highest current density. This could be through the blood in the small vessel being coagulated, thereby inadvertently coagulating the parent vessel. Use of the unipolar coagulator under saline irrigation was not feasible, as the saline, rather than the desired tissue, was the conductive path to ground.

In bipolar coagulation the electrical difference is only in the isolated output and in the lower power requirements. The output of the bipolar generator should be isolated from ground as much as possible, so all current flow takes place between the two tips of the separated forceps. There should be virtually no current flow from either side of the forceps to ground. The current geometry will now be dependent upon the tip size and the angle at which the tips meet, as well as the medium in which they are immersed. If the forceps blades are virtually parallel, and the forceps are deep in saline, there will be major shunting in the saline. If the forceps are bowed or angled so the tips almost meet while the blades are still well separated, the current flow will be mainly between the tips with little shunting. The lowest possible generator output impedance provides the best maintenance of power at the forceps tips with the least decrease in coagulation due to shunting.

The MALIS Bipolar Coagulator and Bipolar Cutter System CMC-II provided a stiffly regulated isolated output with the impedance in the 5 to 10 ohm range. By contrast, output impedance of previously available solid state systems is approximately 150 to 500 ohms. Even the spark-gap MALIS Bipolar Coagulator CMC-I has an output impedance of 40 to 50 ohms. The lower impedance output of the MALIS CMC-II facilitated its use under the constant irrigation desirable for cooling and protecting adjacent delicate structures. Cutting with the CMC-II, using sharp forceps or bipolar loop forceps, was particularly effective for the precise coring of nervous system tumors with minimal bleeding, as compared to other techniques. It was less effective for cutting fibrous tissues or opening skin or fascia.

The MALIS CMC-III Electrosurgical System now provides the higher energy output needed for rapid cutting of all tissues, including dense fibrous layers, shifting the low impedance of the micro cutting automatically to match the power requirements of the high power cut settings. At the same time, the CMC-III continues all of the other advantages already noted for the CMC-II and provides a still lower output impedance for even more effective control of coagulation.

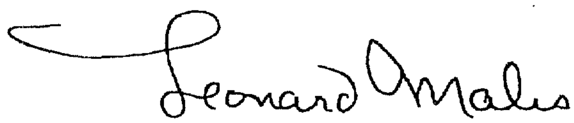
The Value of Irrigation During Bipolar Coagulation

One of the significant advantages of bipolar coagulation technique over the older unipolar method is the ability to coagulate under irrigation. With unipolar coagulation the saline bath of irrigation fluid simply disperses the apparent electrode size with little actual coagulation and some general heating. When bipolar coagulation is used the concentration of current is between the electrode tips and not out into the saline bath so that coagulation can be effectively carried out under saline. Saline solution of course produces some current shunting between the two blades of the forceps depending in degree on how deep the saline accumulation may be. This shunting effect is minimized by having a very well regulated constant voltage low impedance coagulation generator. With a poor generator the shunting effect can be decreased by insulating the forceps. The Malis solid state bipolar coagulator has the lowest generator impedance and the most constant solidly regulated output achieved in any generator, therefore facilitating its use under irrigation.

Irrigation decreases charring and sticking of the area coagulated while keeping adjacent areas cool. In addition it can aid in demonstrating the actual bleeding point particularly in microtechnique where the field is virtually always kept completely bloodless. Saline irrigation removes small amounts of blood and pinpoints tiny bleeding points which require sealing.

Many years ago, working in the research laboratory without a surgical assistant, I cemented a spinal needle to the outside of one blade of the bipolar forceps and connected it to a saline drip bottle. In the operating room in that same early era, I preferred irrigation with a bulb syringe used by my assistant and had the same assistant operate the bipolar foot pedal switch. This brought the assistant into close cooperation in the procedure. The assistant made judgements as to when, where, and how much irrigation to use and had the responsibility of making sure that the fluid had reached the field before stepping on the coagulator pedal. This technique was illustrated in the *Codman Neuro News* in 1966. Much more recently with the increased emphasis on cost cutting, many surgeons have been operating with less than adequate assistance and it has become necessary to go back to a variant of the old laboratory technique. A totally electrically isolated pump system uses a newly designed quiet pump providing better control and easier loading than the rotary pumps. Pressure and volume are matched to the irrigation tubing on the inner blade of the bipolar forceps. The bipolar forceps will now be supplied in all the standard models with the irrigating tube tapered to permit irrigating fluid to precisely cover the forceps field, whether the forceps is used pointing downward, horizontally or upward. The tapered tip of the irrigating tubing forms a sort of nozzle to accomplish this result. With the supplied cable the irrigator can be automatically controlled with the Malis* CMC-II® coagulator or the Malis CMC-II PC coagulator. It may also be used with an independent foot switch with other coagulators. Based on many years of evoked potential work in the laboratory, our department had standardized on the use of room temperature normal saline as our irrigating fluid instead of warmed saline or any of the more complex solutions. We have continued to use this solution with the automatic irrigation. Of course it would be equally adaptable to Ringer's solution or any other desired fluid. With the Malis CMC-II Bipolar Coagulator, the fraction of a second of lag time for the voice announcement permits the saline flow to just precede the actual coagulation.

Regardless of the technique of irrigation used, the importance of keeping the tissues moist and protecting them from heating cannot be overemphasized for the neurosurgical field. The improved quality of coagulation with the prevention of blood baking on the forceps and the avoidance of charring or sticking of vessels to the forceps are essential reasons for irrigation in coagulation. Additionally, forceps tips are less readily pitted or eroded when used under saline. The higher the polish of the forceps surface, the smoother the operative function. I simply never use the bipolar coagulator except with saline irrigation.



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