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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 CMC-II introduced in 1985. (Please see the attached background article 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 Valley Forge Scientific 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 Corp., the manufacturer of several electrosurgical systems, now plans to introduce a new MINI-SYMM Bipolar System which enables the surgeon to coagulate while irrigating the surgical field.

Some of the effective safety features of Bipolar Electrosurgery are:

- * Bipolar Technology eliminates the need for grounding pads and the possibility of patients burns.
- * Bipolar 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 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 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.
- * Unlike monopolar systems, the new Bipolar Electrosurgery System provides smooth, progressive coagulation with the option of precise, flow-controlled irrigation.
- * The System permits the physician to coagulate in an Irrigated Field thereby minimizing heat build-up or thermal damage to adjacent tissues.
- * The waveform parameters of the MINI-SYMM Bipolar Electrosurgery System are programmed for the smoothest, most gentle, precise and efficient cutting and coagulation of tissue during any surgical procedure.

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 the best 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 television and monitoring equipment interference.

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 perforating of vessels being coagulated, as a result of molecular resonance. For this reason, the original MALIS Bipolar Coagulator and its present day version, the CMC-I (catalog no. 80-1114) continued to be the choice of most microsurgeons.

The MALIS Precision-Control Bipolar Coagulator CMC-II-PC simulates 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 the smoothest coagulation, the least neuromuscular stimulation, and the least 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 a small vessel being coagulated, thereby coagulating the parent vessel inadvertently. Use of the unipolar coagulator under saline irrigation was not feasible, as the saline was the conductive path to ground rather than the desired tissue.

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 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 solu-



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tions. 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.