OWNER'S MANUAL

MC-6A, Radio Surge®

Please read and comprehend before clinical use to avoid injury and assure positive outcomes.
Federal law restricts purchase and use of this device to or on the order of a dentist.

WARNING! Electrosurgery may cause interference with other equipment, adversely affecting the operation of that equipment.

Contents

INTRODUCTION

Dental electrosurgery is the sculpture of living tissue. Science and art combine in your hand to satisfy the clinical indications for soft tissue management in Dental Health Care practice.
Familiarization with the electrosurgical instrument is as much a matter of adjusting the unit to suit your surgical skills and professional expertise as it is learning the unit. After all, the instrument only induces histological changes in tissue, but you treat the patient.

No mechanism which can incise, excise, or coagulate tissue can be "perfectly safe," even a scalpel for that matter, if misapplied. Therefore, any instrument which can induce profound histological changes in tissue has safety considerations associated with it.

Electrosurgery generates intense, highly localized heat intra-cellularly in tissue to achieve a histological effect, much the same as laser does. Surgical techniques safely and effectively manage this. However, electrosurgery is unique among surgical methodologies. It uses high-frequency electrical energy applied directly to tissue, which raises the question of constraining the electrical energy to where it is required to achieve the desired histological effects without diverting harmfully into other areas. It may initially appear as though high-frequency electrical energy is like a precocious teenager: no matter how much you attempt to "ground" it, it seems to come and go as it pleases. Nevertheless, since electrosurgical technology has seven decades of clinical experience behind it, the precautions necessary to avoid such injury are well known. Every attempt has been made to present these precautions in logical relation to the relevant clinical aspects of tissue management as they are discussed, without resorting to deep electrical theory, rather than attempt to train you as an electrical engineer. Nor should you be, since the application of electrosurgery safely, consistently, and effectively is a matter of clinical practice.

This manual is limited to the instrument, controlling its histological effects, preparing for surgery, selection of accessories for specific surgical indications, and care of the accessories. Clinical discussion focuses on avoiding pitfalls (i.e., safety, both electrical and thermo-dynamic) and the suitability of techniques, accessories, and approaches to specific clinical indications. This manual does not presume to teach the practice of medicine.

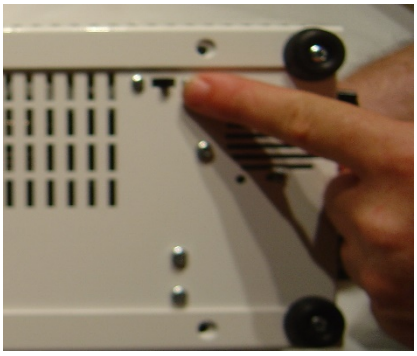
Do, please read the section on surgical fires. These are extremely rare in clinical practice, and that very fact makes the issue important: rarity places the issue out of range of our immediate attention. The question is not unique to electrosurgery since incidents have been reported with laser, thermal cautery, and even fiber optic surgical lights. The worst part is that prevention is so effortless. The hard part is maintaining awareness.

Thank you.

BEFORE CLINICAL USE: INSTRUMENT FAMILIARIZATION

SETTING UP THE RADIOSURGE MC6A UNIT

The Radiosurge unit emits an audible during unit activation to comply with recognized agency safety regulations. ***To turn off the audible tone, use the switch on the bottom of the unit.***

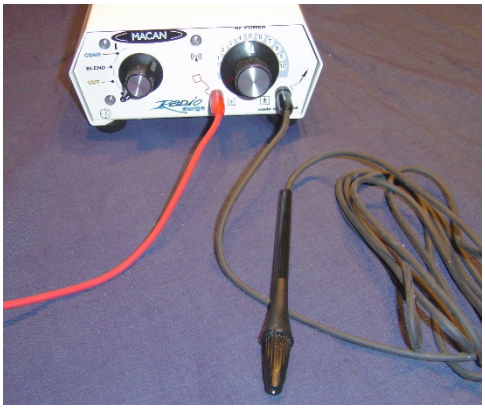


Insert the power cord set into the IEC 320 appliance entry. ***Be sure to seat the cord firmly.*** Connect the foot pedal by inserting the connector with the widest key facing up and turn the locking ring clockwise to secure it. ***The connector inserts easily and should not be forced.***

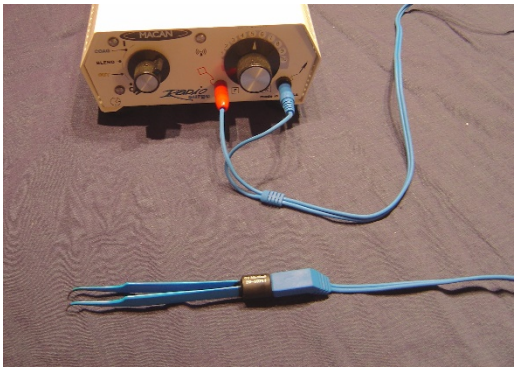
The red stabilization timer light comes on when the unit is switched on and then turns off automatically after 30 seconds. The red light must go off before the unit activates.

Place the W-Flexible Dispersive Pad on the chair. (Color may vary)
See the section on the W-Flexible Dispersive Pad for further information.

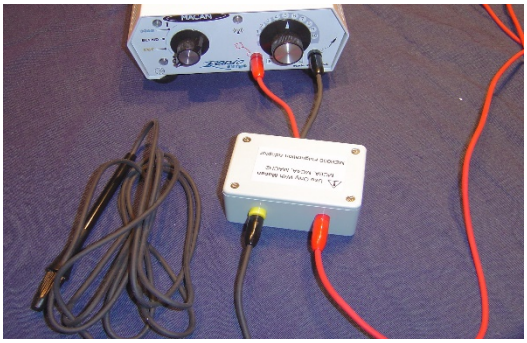
Monopolar set up. The red dispersive lead goes to the W-Flexible Dispersive Pad, not shown.



Bipolar forceps coagulation set up. Note that removal of the “Flexible-pad” from the chair is not necessary for bipolar forceps operation.



Fulguration set up.



IMPORTANT NOTES:

The bipolar cable and forceps are optional and not supplied with the unit.
The fulguration adaptor is optional and not supplied with the unit.
All items are shipped non-sterile. See appropriate sections for sterilization requirements.

SURGICAL TECHNIQUE

Because electrosurgery induces histological effects thermo-dynamically by rapidly raising the intracellular temperature to boil, thus causing the volatilization of cell contents, *the ability of the tissue to absorb heat, and the ability of the capillary bed to dissipate the absorbed heat safely, must be respected*. A simple analogy is to move one's hand over a lit candle. As long as the hand moves sufficiently rapidly, minimal sensation is noticed, however, slowing down becomes increasingly uncomfortable until hand motion becomes so slow that a painful burn occurs. In electrosurgery, net heat is spread out over the length of the incision or excision so that gross heat remains safely under the burn threshold. Several vital points ensue:

> **Keep the electrode moving during incision and excision. Do not stop.**
> **Maintain a steady, adequate stroke speed of 7mm/sec minimum.**
> **Do not repeat a stroke in the same area for at least 10 seconds.**

A straightforward procedure, like opening a flap, for example, is readily accomplished with simple, deliberate motion. On the other hand, more intricate procedures such as gingival troughing to establish the emergence profile for a crown preparation involve multiple very accurate motions. *Do not overlook the human tendency to slow down hand motion when concentrating on accuracy, and always maintain adequate, consistent motion. Break up any procedure into as many segments as required to achieve accuracy and speed simultaneously comfortably.*

Please remember intra-cellular fluid temperature must be raised rapidly to boiling to achieve volatilization, or else no incision or excision can occur. In other words, *there is a finite minimum heat generated within the tissue to achieve incision or excision, which cannot be reduced by merely "dialing down" the electrosurgical instrument. Therefore,* **the control of gross heat is in your hand and is achieved by proper surgical technique.**

Unlike lasers, electrosurgery induces histological effect over the entire surface of the electrode in contact with tissue. The significance is that *for larger electrodes such as loops, or deeper incisions, there is proportionally less tolerance for technique error.* **The deft, steady, adequate technique is *critical* for the successful use of large loop electrodes.** ***There is NO room for error during a biopsy, likewise, during donor graft tissue harvesting.***

Consider adequate surgical technique to be <u>the</u> constant in electrosurgery. Inadequate (slow) technique is the leading cause of poor electrosurgical results.

THERAPEUTIC CURRENT QUALITY (MODE) DESCRIPTION

Two incisional and excisional modes are offered by the Radiosurge instrument:

CUT, which is histologically characterized by ***minimal collateral heat****, minimal concurrent hemostasis,* ***microscopic collateral tissue denaturing****, and* ***no cicatrix expected*** *in the final healing.* The normal collateral tissue denaturing width is 375 to 400microns nominal, assuming .010" diameter electrode.

BLEND, which is histologically characterized by ***significant collateral heat, pronounced concurrent hemostasis****, and some* ***minor cicatrix*** *in the final healing.* The normal collateral tissue denaturing width is 3750 to 750microns nominal, assuming .010" electrode wire. *Maintaining adequate surgical stroke speed is more significant with BLEND owing to the greater collateral heat induced by this therapeutic current quality in comparison to CUT.*

NOTE: The expected collateral tissue denaturing widths given depend strongly on a minimum surgical stroke speed of 7mm/sec. *Improper surgical technique produces an exponentially non-linear adverse increase in the width of collateral tissue denaturing as it becomes too slow*. Similarly, improper energy dose titration can induce 3:1adverse variance in expected collateral denaturing width, particularly if too low. The width of collateral tissue denaturing is not a function of incision depth for electrode wires of uniform cross-section; however, the use of a non-uniform cross-section electrode, such as the UF-62 conical electrode, will demonstrate more significant tissue denaturing width perpendicular to an incision increasing toward the apex as a function of incision depth.

The Radiosurge instrument offers one hemostatic mode: COAG.

COAG is histologically characterized by inducing pure heat below the threshold required for incisional or excisional volatilization. Cicatrix will form in the final healing as a function of the electrode size and duration of application. *Monopolar coagulation is not effective in wet or bloody fields.* The field must be dried before monopolar coagulation may be effectively applied.

THERAPEUTIC CURRENT QUALITY (MODE) SELECTION

This is a matter of professional clinical judgment to correlate the histological characteristics of the respective therapeutic currents to the clinical indications at hand. *It is helpful to think of clinical indications in terms of the thermal artifact, cicatrix formation, concurrent hemostasis, and hemostasis since these criteria reflect the primary distinguishing characteristics of the respective therapeutic currents available.* It is also helpful to carefully consider the potentially harmful aspects associated with a clinical indication in choosing compromises.

For example, aesthetic clinical crown lengthening is sensitive to tissue recession arising from a thermal artifact, and cicatrix formation is undesirable. Therefore, this clinical indication is best served by CUT with the understanding that there is a compromise in terms of concurrent hemostasis. A similar situation exists in the case of crown preparation in terms of risk of tissue recession from a thermal artifact, again favoring CUT for this reason. Likewise, a biopsy sample can quickly be rendered unreadable from a thermal artifact, once again suggesting CUT therapeutic current. On the other hand, for posterior gingivectomy to allow placement of an orthodontic band or to expose sub-gingival care, neither minor cicatrix formation nor sub-millimeter tissue recession are significant issues and BLEND with its attendant pronounced concurrent hemostasis is eminently suitable. In flap reflection, bleeding control is a significant issue, and compromise in terms of subsequent minor cicatrix in the final healing is quite tolerable, suggesting BLEND. In implant exposure, gross heat is a critical issue, and CUT is the obvious choice. Similarly, in pulpotomy, the limited heat dissipation capacity favors CUT; however, the use of electrosurgery to accelerate endodontic canal sterilization favors judicious use of COAG.

Some practitioners with exceptionally deft technique achieve excellent, consistent clinical outcomes without any apparent cicatrix or recession in the final healing when doing aesthetic crown lengthening using BLEND current. This is offered to illustrate that there is an artistic aspect to medical practice, and *<u>experienced</u> professional clinical judgment is the primary criterion for effecting treatment.* Nevertheless, BLEND current is not recommended for that use.

THERAPEUTIC ENERGY QUANTITY: INITIAL RF POWER SETTING

Since the histological effect is induced over the entire surface area of the electrode in contact with tissue, and a finite minimum heat is required, then it follows mathematically as an integral over the surface of the electrode that *the gross quantity of therapeutic energy required to perform a given procedure depends first of all on electrode size and shape.*

The following are suggested starting points:

ELECTRODE	INDICATION	RF POWER	MODE
UF-11, UF-10, UF-F1	incision <2mm deep	3 to 3.5	CUT, BLEND
UF-11, UF10, UF-F1	incision >3mm deep	4 to 4.5	CUT, BLEND
UF-33 (3.5mm loop)	biopsy	6 to 7	CUT
UF-34 (5mm loop)	biopsy	8 to 9	CUT
UF-33	planing	4.5 to 5	CUT, BLEND
UF-34	planing	4.5 to 5	CUT, BLEND
UF-35 (oval loop)	excision or planing	4 to 4.5	CUT, BLEND
UF-22 narrow loop	shallow troughing	3 to 3.5	CUT
UF-22 narrow loop	planing, tag removal	4 to 4.5	CUT, BLEND
UF-SN62 pointed	troughing	3 to 3.5	CUT
UF-SN62 pointed	coagulation	4 to 4.5	COAG
UF-51 ball	coagulation	4 to 4.5	COAG

These *suggested* starting points assume an average build adult patient, with normal gingival health, in street clothing. Please note that these figures are not cast in stone: you are highly encouraged to take notes and to expand and refine the list accordingly, as you gain experience or add to your additional armament electrodes not listed here.

THERAPEUTIC ENERGY QUANTITY: DOSE TITRATION

In short: therapeutic energy dose titration (RF Power dial adjustment after initial setting) *is a matter of adjusting the instrument to suit your professional clinical judgment of correct histological effect as evidenced by pressure less, spark-free incision or excision with a clean electrode, within the context of your unique practiced and consistent surgical technique,* in compensation for varying patient body mass and tissue character, for a given electrode.

Pharmacological therapy affords a rough analogy since the dosage is titrated for individual patients to maintain an adequate blood serum level. In the case of electrosurgery, biological factors which
alter the ratio of intracellular fluid content to tissue mass from normative may require therapeutic current quantity dose titration to compensate, for example, fibrotic or fatty tissue may require slightly higher therapeutic current for equal histological effect in comparison to healthy tissue. Also, the patient is effectively an element in a circuit in monopolar electrosurgery and compensation for electrical losses as a function of body mass may be required. An adult bariatric patient will present higher electrical loss than an average build juvenile for example.

The criteria for clinical judgment of therapeutic energy dose titration are:

Way too low a setting will not cut, it will only induce a coagulation burn

Too low a setting will cause the electrode to "drag" or resist free motion

A slightly low setting will allow tissue detritus to adhere to the electrode

Correct setting allows pressure less motion, no sparking, and clean electrode

A slightly high setting shows slight sparking, particularly at the onset of incision

Too high a setting sparks and induces extra unwanted collateral coagulum

Way too high a setting sparks, induces collateral desiccation, and carbon on electrode

*It is important to note that biologically related power setting dose titrations do not vary by more than 1 to 2 numbers at most from nominal initial setting typically**. An abnormally high titration requirement strongly suggests an electrical compromise: IN THIS CIRCUMSTANCE NEVER TURN UP THE INSTRUMENT TO A DANGEROUS LEVEL BEFORE CHECKING THE DISPERSIVE PAD POSITION, COUPLING, AND CONNECTIONS FIRST, LIKEWISE, VERIFY THAT THE ELECTRODE IS CLEAN AND SEATED IN THE HAND PIECE PROPERLY.** *Make dose titrations a little at a time.*

Occasionally a patient presents with dry mouth as a result of pharmacological therapy or disease process. The recommended procedure in these cases is to moisten the tissue with water (but ***never saline solution)*** to allow a nominal initial power setting to be used with minimal, if any, titration.

Without delving into the electro-physics describing the inter-relation of therapeutic dose titration and surgical technique, suffice it to say that *too low a power setting will induce more gross heat into tissue than a slightly high one, assuming proper surgical technique, despite the lower energy setting since "drag" on electrode motion will allow more time for collateral net heat transfer*.

In sum: the range of ideal dose titration narrows as incision and excision become shallower whereas dose titration range relaxes as incision or excision become deeper, however, the *minimum* setting becomes more critical as incision and excision become deeper. This is in contrast to the situation for surgical technique where shallow incision and troughing are more tolerant of surgical technique stroke speed (however, the onset of adverse reaction to slow technique remains abrupt), but technique becomes increasingly more critical and less tolerant of error as electrode area increases becoming critical for large loops.

PRACTICE BEFORE CLINICAL USE

*Applying **any** medical instrumentation requires training and experience*. Self-education is perfectly viable for a practicing clinical professional although a "hands on" seminar is preferred. While there are individuals who have taken electrosurgical units out of the box and successfully treated patients with no experience, smoking in a dynamite factory is preferable to attempting this. *Please, do practice before the first clinical use.*

Even for experienced clinicians replacing an existing unit, at least brief practice is advised since just as two makes or models of cars differ, the Radiosurge instrument may differ significantly in electrical output characteristics from the unit they are used to.

Beef steak or beef roast provide a suitable practice medium to simulate gingival tissue which demonstrates histological changes fairly well, which chicken or pork do not. A mass of 1100g to 2000g is ideal.

Place five cheap kitchen paper towels folded in half on the dispersive pad to simulate the electrical losses encountered with a patient. It is helpful to put the towels in a plastic bag to prevent desiccation of the steak and to facilitate cleanup. Practice without the paper towels to simulate loss will result in using much lower power settings than those encountered in clinical use. *The five folded towels allow dose setting titrations obtained in practice to be close to those in clinical use with an average build adult patient*. To maintain the accuracy of this model, avoid fanfold or quilted paper towels, and do not use the Styrofoam package, the steak came in or the blotters in the package. The number of kitchen towels placed on the dispersive pad may be varied to simulate different patient body masses for practicing dose titration.

Be forewarned: under this practice condition, since the dispersive pad is electrically isolated at RF, touching the steak with bare hands during unit activation can result in an unpleasant tingle or "shock" sensation. *Either do not touch the steak or, better yet, use surgical gloves.*

The objective of practice is to:

develop an adequate, consistent surgical technique

become familiar with dose titration

observe the histological effects provided by the different modes of operation

observe the relationship between suggested initial settings and electrode size

It is suggested that you first concentrate on very fine shallow incisions and excisions such as used in crown preparation. The relatively narrow ideal dose titration associated with this clinical indication will become apparent. The next exercise is making deep loop excisions such as for biopsy. The admonition regarding surgical technique speed tolerance for this clinical indication and adequate minimum power setting will become apparent. The third exercise should involve exposure of a simulated implant to develop the speed required. The next exercise should be a series of 5mm to 6mm deep linear incisions. It should be apparent that you are working pretty much in the middle of surgical technique speed tolerance and the middle of dose titration range tolerance when working with these incisions (which is why vendors like to demo their units this way). Finally, practice soft tissue coagulation. The electrode may be brought into contact with tissue, then the unit activated until tissue blanches, or the unit may be activated first, and then the electrode brought into contact with tissue. The latter method allows finer control and is the only one practical when using the UF-62 conical electrode to perform extremely fine pinpoint coagulation, such as that used to control hemorrhagic weeping before impression in crown prep.
Of course, you will want to work with all the electrodes and try all anticipated clinical indications.

The W-Flexible Dispersive Pad

In monopolar electrosurgery, the therapeutic current introduced into the tissue by the electrode diffuses through the body to the dispersive pad. Current density at the electrode is very high resulting in correspondingly high localized heat production at the surgical site; however, due to the orders of magnitude of difference in area between the electrode and the dispersive pad, the current density is so low at the dispersive site that no significant heat develops in the dispersive area.

The Radiosurge unit has an isolated RF output, which means that ***the unit absolutely will not work without the dispersive pad.*** Furthermore, the Radiosurge has a relatively low internal impedance, which means that ***good dispersive pad coupling is essential for correct operation.*** On the other hand, the W-Flexible Dispersive Pad was designed to minimize operational intervention and optimize coupling efficiency while affording excellent patient comfort. *The W-Flexible Dispersive Pad is intended to work through regular street clothing and to be left in place on the chair to minimize attention.* Metallic brassier clasps or lift wires do not affect the operation and do not represent a hazard.

Dispersive current flow through the thorax is clinically undesirable in any case. Therefore, it is recommended that the W-Flexible Dispersive Pad be positioned on the chair at the shoulder level, preferably above the myocardium. *The W-Flexible Dispersive Pad is placed on the chair, and the two leads are pulled behind the chair like the strings on an apron, then are clipped together behind the headrest.* One lead is functional and has a plug for the dispersive cable, while the other is a dummy simply to provide a means of attachment to prevent the pad from sliding down the chair. Placing sanitary paper over the W-Flexible Dispersive Pad does not adversely reduce efficiency, nor does placing the W-Flexible Dispersive Pad under a protective plastic chair cover. Either alternative is perfectly acceptable.

For optimal coupling efficiency, the entire surface of the dispersive pad should be covered by the patient. *Once again, placement above the myocardium is desirable in all cases; however,* ***defer in favor of full coverage rather than placement above the myocardium when positioning compromise is required to achieve full coverage.*** It may be necessary to loosen the clip holding the W-Flexible Dispersive Pad leads together and slide the pad down the chair for petite or juvenile patients.

Do note that very thick clothing such as cardigan sweaters, jackets, or leather vests may adversely affect dispersive pad functioning, as evidenced by the need for abnormally high-power dose titration. It is recommended that such a sweater, jacket, or vest be removed rather than use a high-power setting. Loop excision or biopsy may be impractical under the latter circumstance.

THE W-Flexible Dispersive Pad IS NOT AUTOCLAVEABLE, THEREFORE, MUST NEVER DIRECTLY CONTACT BARE SKIN. The patient's street clothing, a surgical gown, or suitable sanitary medium must intervene between the W-Flexible Dispersive Pad and the patient's bare skin.

If dental surgery is performed in a hospital OR setting under general anesthesia rather than in a dentist's office and bare skin is anticipated, then the W-Flexible Dispersive Pad should be placed in a suitable *thin* sanitary plastic bag (preferably sterile and bio-compatible) to avoid direct skin contact. Although contrary to normal OR protocol, nevertheless the bagged W-Flexible Dispersive Pad *should be placed posteriorly under the supine patient at the shoulder level. DO NOT attempt to substitute a disposable pad from another unit in the OR.* If a hyper/hypothermia pad is used, place the bagged W-Flexible Dispersive Pad *between the patient and the pad.* The thin cross-section of the W-Flexible Dispersive Pad allows hyper/hypothermia pad thermal conduction with minimal reduction in efficiency.

Anterior placement of the W-Flexible Dispersive Pad is not recommended in any case.

PREPARING FOR SURGERY

Local anesthesia is required for electrosurgery. Since the Radiosurge unit enforces a 30 second stabilization period after initial turn on, it is recommended that the unit be switched on before administering anesthesia to avoid needless delay.

THE HANDPIECE AND ELECTRODES MUST BE AUTOCLAVED BEFORE USE. *Carefully inspect the handpiece and electrodes for damaged insulation or cracks before use.* ***If any faults are noted, DO NOT use the item: a crack or insulation fault represents a significant risk of accidental coagulation burn injury to the patient or clinician.***

Any metallic object, or electrically conductive object, becomes an extension of the electrosurgical electrode when contact is made. ***NEVER PLACE CONDUCTIVE INSTRUMENTS IN THE ORAL CAVITY IN CONJUNCTION WITH ELECTROSURGERY. Failure to heed this advice represents a very significant risk of accidental coagulation burn injury to the patient.***

Clearly, in the light of the previous, ***it is very strongly advised that tongue piercing jewelry, and lip piercing jewelry, be removed before electrosurgery is performed.***

VERIFY whether the patient has a pacemaker, cochlear implant, indwelling neurostimulator, or other indwelling electrical devices. If so, DO NOT PROCEED UNTIL CONSULTING WITH THE IMPLANTING PHYSICIAN. Note that at this time, cochlear implants and indwelling neuro-stimulators are absolute contra-indications to monopolar electrosurgery.

Pacemakers ALWAYS require consultation with the cardiologist BEFORE proceeding. Only shielded types are safe. AN UNSHIELDED TYPE PACEMAKER IS AN ABSOLUTE CONTRA-INDICATION FOR MONOPOLAR ELECTROSURGERY. Defibrillating types may require additional precautions before electrosurgery, once again reinforcing the need for consultation.

Regular hearing aids do not represent a hazard. However, radio interference from electrosurgery may cause the hearing aid to produce an unpleasant buzzing sound. Therefore, removal during electrosurgery is suggested. Similarly, the use of an "i-POD" or similar *battery powered* musical device by the patient is not hazardous but may suffer from radio interference. ***Patient use of headphones and/or earbuds from a PLUG-IN device must NEVER be allowed together with electrosurgery.***

External stimulators, such as TENS stimulators, should very definitely be removed or turned off during electrosurgery to preclude inadvertent activation from radio frequency interference.

Given that typical dental operatories are not generally spacious, dressing the cables from the electrosurgical unit to the treatment site often involves some compromise. Never the less, it is undesirable to dress a cable in such a manner that it is prone to be stepped on or tripped over by attending personnel. Coiling cables into loops is likewise undesirable. ***In any event, draping a cable over the patient's abdomen, chest, leg, or arm MUST be carefully avoided. Placing electrosurgery cables alongside monitoring cables must be carefully avoided.***

The Radiosurge unit is rated for safe concurrent use with physio-monitoring devices such as EKG monitors, apnea monitors, or pulse oximeters. Needle monitoring electrodes are not recommended. Place monitoring electrode pads anteriorly, preferably opposite to the area below the dispersive site. Patient contact with bare metal surfaces should be avoided. There are no implications concerning cardioversion, and it is not necessary to remove or disconnect the dispersive pad.

CLINICAL USE

General Remarks

It is crucial to carefully stow the handpiece between uses during electrosurgery to avoid contamination and to avoid an accidental coagulation burn to attending personnel arising from coincidental unit activation. Similarly, it is essential to ensure that the foot pedal is not depressed when changing electrodes. Changing mode during activation is not recommended.

The constraint of electrosurgical high-frequency electrical energy to the site where histological change is clinically indicated is a vitally important issue in electrosurgery since energy diverted into alternate areas will induce injury there. For monopolar electrosurgery, this is primarily a matter of approach to the surgical site falling to the clinician, and for bipolar electrosurgery falling primarily to the instrument internal configuration and electrodes (forceps).

The electrical qualities of the intervening anatomy are critically significant in terms of injury risk in monopolar electrosurgery.

Consider the following examples:

The folly of plugging in a large, heavy-duty window air conditioner with a light-duty Christmas tree type of extension cord is well known: the electrical current demanded by the air conditioner far exceeds the electrical capacity of the light-duty extension cord because the light-duty extension cord has a tiny cross-section of conductive copper wire which then becomes overheated to the point of catching on fire. This situation affords an analogy for interproximal tissue in dental electrosurgery: this tissue has a limited capacity to withstand therapeutic current without overheating beyond the burn threshold due to its narrow anatomic cross-section. Approaching this anatomic structure with electrosurgery requires caution.

The molecular qualities of matter determine electrical conductivity, and electrical conductors such as power cords are insulated to preclude shocks when the cords are plugged in and handled. This affords an analogy in dental electrosurgery: osseous tissue is marginally conductive in comparison to the contents of the nutrient foramen due to the molecular differences in the respective tissues. Therefore, when monopolar electrosurgical therapeutic current is introduced directly to the bone and seeks to diffuse to the dispersive pad, it does so through the more conductive nutrient foramen content rather than through the surrounding osseous structure. An electrical overload occurs when monopolar electrosurgical therapeutic current is applied directly to the bone resulting in necrosis of the nutrient foramen content due to the very narrow anatomic cross-section of the foramen. *The practical consequence of applying monopolar electrosurgical therapeutic current directly to bone, regardless of energy dose titration or contact duration, is that necrosis of the nutrient foramen content is inevitable. Subsequent osseous sequestration is a matter of degree.*

Note that during flap reflection, the incision electrode is very near, even touching bone, and yet the preceding prophesy of doom does not come to pass. This seeming contradiction arises from the fact that the therapeutic current travels collaterally through the gingiva and around the bone in the course of diffusion toward the dispersive pad: primary direct contact, in this case, is to the gingiva with good contact quality and bone contact is secondary, therefore ineffectual.

Attempting to codify the examples given into a set of general rules ignores clinical context and does not give a clear sense of relative risk and consequences by which to define the clinical practice. More importantly, such a list of general rules does not provide a sense of preferred approaches. Codifying the examples given in terms of electrical principles once again fails to give a clinical perspective. After all, the practicing clinician is not an electrician, and the patient is not an appliance. The subsequent clinical discussions seek to integrate the relevant precautions and preferred approaches into a context of specific clinical circumstances.

BIOLOGICAL WIDTH

Maintaining biological width during gingivectomy is physiologically essential to retain an adequate gingival barrier between the intra-oral cavity and underlying osseous structure. Depth should be gauged by probing before gingivectomy to ensure that an adequate biological width of 3mm minimum is maintained post-op. This applies to a scalpel, laser, and thermal cautery also.

Electrosurgery introduces a need to recognize additional potential complications: thermal artifact from grossly excessive therapeutic current may induce up to 1mm tissue recession. Similarly, poor, slow surgical technique may induce up to 1mm recession. The significance of such dramatic recession depends on the actual incision line: at 3mm such a recession is significant, at >4mm not. However, ***grossly exceeding biological width using electrosurgery can bring the electrode into contact with bone which is a significant hazard within this surgical context,*** since collateral therapeutic current conduction into the gingiva, thus around the bone, is compromised by the fact that half of the gingival tissue in contact with the electrode is in the process of being excised, therefore not an effective electrical conduction element. ***An error of grossly violating biological width to the point of exposing bone is egregiously compounded by attempting the application of monopolar coagulating current to the gingiva at the osseous boundary: subsequent osseous sequestration is certain, and is a matter of degree.*** *Loss of a vital tooth around which the biological width has been grossly violated is a significant risk within the context of this compounding error.* Unfortunately, such an incident has been reported.

The clinical recommendation for gingivectomy with electrosurgery is to probe first to establish a safe incision line at least equal to, but preferably greater than the minimum 3mm biologic width.

DO NOT USE MONOPOLAR ELECTROSURGERY TO INDUCE HEMOSTASIS IF MINIMUM BIOLOGICAL WIDTH HAS BEEN VIOLATED BY WHATEVER MISFORTUNE, WHETHER BONE SHOWS OR NOT.

IMPLANT EXPOSURE

Any metallic object in contact with the electrosurgical electrode is an extension of the electrode. In this case, direct contact with the implant qualifies, to the effect that therapeutic current is introduced into the osseo-integration. The significance here is that this vital constraint must be respected since a temperature rise of only 6^0C will induce necrosis in the osseo-integration. The area of implant contact with the osseo-integration is orders of magnitude greater than the active surface area of a .010" wire electrode, which allows monopolar electrosurgical implant exposure to be performed without excessive temperature rise.

The clinical recommendation is to use only CUT therapeutic current for direct contact with the implant, and to minimize direct contact as much as possible by reducing surrounding tissue first without direct contact with the implant. After allowing 10 to 15seconds cooling time, the remaining tissue directly adjacent to the implant should be addressed while strictly adhering to a limit of ¼ second direct contact with the implant at a time followed by a minimum cooling time of at least 10 seconds, preferably 15 seconds, before continuing. The ¼ second time limit allows direct approach to the implant in quadrants, assuming sufficiently deft technique. When cicatrisation is clinically desired in the surrounding tissue, the BLEND therapeutic current may be applied superficially to the exposure shoulder taking extreme care not to contact the implant directly. Employ proper therapeutic energy titration for a .010" wire electrode and CUT therapeutic current, maintain adequate surgical technique for the surrounding tissue, and do not compromise the limitation of ¼ second direct contact with the implant at a time.

Poor surgical technique, inadequate cooling time, or excessive therapeutic energy dose represent a significant risk of osseo-integration failure.

UNHEALTY TISSUE

In the section on therapeutic energy dose titration, reference to fibrotic and fatty tissue as "tissue in which biological factors have altered the ratio of intra-cellular fluid to tissue mass from normative" was most assuredly not an attempt at a facetious turn of phrase. While fibrotic and fatty tissues are abnormal, these tissues are nevertheless stable. The distinction between normal or abnormal but stable tissue, and tissue inflamed by disease, lies in the ratio of interstitial fluid to intra-cellular fluid and is a function of the disease process, therefore unstable. ***The significance is that the response of diseased tissue to electrosurgical therapeutic current is unpredictable.***

The clinical recommendation for unhealthy tissue is to delay electrosurgery until the underlying pathology is resolved and tissue health is restored (with the notable exception of lancing an abscess). This advice is also appropriate for scalpel, laser, or thermal cautery.

Electrosurgically reducing inflamed tissue represents significant risk of becoming morbidly excessive after the underlying pathology abates and the inflammation subsides. Experienced professional clinical judgment must be made regarding tissue health before electrosurgery is attempted if underlying pathology is evident or suspected. ***Note:*** gingiva exposed to radiation therapy should be considered unstable thus contra-indicating electrosurgical incision or excision, whereas drug induced gingival hyperplasia is readily treated electrosurgically. Consultation with the primary physician is advised in either case.

HEMOLYTIC COMPROMISE

Any of a number of disease processes such as hemophilia, leukemia, sickle cell disease, and diabetes result in clotting disorder. Similarly, any of a number of therapies such as anti-coagulant therapy, chemotherapy, and radiation therapy (see above) adversely affect clotting.

Since electrosurgery is thermo-dynamic, hemostasis and concurrent hemostasis are effective in cases of hemolytic compromise. Nevertheless, some degree of hemorrhagic response in treated tissue is to be expected as a function of the disease process or therapy which compromises clotting. The degree of concurrent hemostasis afforded by the BLEND therapeutic current may be extended with the use of a .025" wire electrode such as the R-55 along with appropriate energy dose titration. However, employing a .025" wire electrode is accompanied by greater collateral heat and greater collateral coagulum to the effect that final healing will be delayed as the additional denatured tissue is reabsorbed. The additional cicatrix expected in the final healing makes the .025" electrode unsuitable for aesthetically significant procedures.

The clinical recommendation for dealing with hemolytic compromise is to consult with the patient's primary physician prior to scheduling dental electrosurgery. The primary physician may find reducing anti-coagulant therapy prior to dental electrosurgery warranted or may find a blood transfusion for a hemophilia patient warranted. The use of electrosurgery in the presence of mild to moderate hemolytic compromise carries minimal possibility of marginal coagulation or marginal concurrent hemostasis, however, it is suggested that professional clinical analysis of the cost-benefit ratio is appropriate for aesthetic enhancement procedures involving electrosurgery with patients suffering from profound hemolytic compromise. Be especially cautious with diabetes.

DO NOT attempt to apply COAG current for abnormally long duration, and DO NOT attempt an abnormally high therapeutic energy titration, to force hemostasis in the case of profound hemolytic compromise. When it is necessary to apply additional coagulation to achieve clinically viable hemostasis, do so by repeating normal brief applications of COAG therapeutic current with appropriate cooling time between applications. Be aware that subsequent hemorrhagic response may not be immediate in such cases, and some time may elapse requiring a repeat visit.

SPARKING

Electrosurgical energy per se does not induce neuro-muscular stimulation in living tissue due to the disparity in the rate of change of the therapeutic energy electric field with respect to the rate of molecular transit across the permeable membranes of cells. However, the electrosurgical energy becomes distorted and some of the energy is displaced according to Fourier's Theorem into "side bands" (harmonics of the nominal operating frequency) when

sparking occurs. Sufficient sparking produces side bands which are low enough in frequency to induce neuro-muscular stimulation, and which do so readily under adverse conditions.

Clinical recommendation is to employ proper therapeutic energy dose titration to avoid sparking.

If a patient complains of "tingling" or "shocking" under normal anesthesia this very strongly suggests too high a therapeutic energy dose titration. Reiterate for pressure less, spark free, and clean electrode incision or excision. A slightly high dose titration is thermo-dynamically preferable to a low one, just refrain from favoring this to the degree that patient comfort is compromised.

AMALGAMS

Assuming proper energy dose titration, fleeting or brief (<1 sec) electrosurgical electrode contact with an amalgam is harmless from a thermo-dynamic perspective in large part due to the relatively large surface area. On the other hand, due to the Fourier side bands associated with sparking, patient comfort becomes an issue since the resultant "shock" sensation is exacerbated by the proximity of the sensitive underlying pulp to the amalgam.

Clinical recommendation is to avoid touching amalgams with the electrode during electrosurgery.

Depending on the access afforded within the surgical area, that advice may be much easier said than done. There are several alternatives:

Use inter-proximal specific electrodes in proximity to amalgams. The extra insulation and smaller active area reduce risk of accidental contact.

Use the UF-F1 electrode with the incision wire retracted as far as practical for the indication at hand. Minimal exposed active area reduces risk of accidental contact.

Electrically insulate the amalgam. Use a polymeric impression medium which sets up quickly and is readily removed post-op. (Alginate is unlikely to provide enough electrical insulation quality.) Alternately, a plastic matrix restoration form fitted around the tooth with the amalgam will provide suitable electrical insulation as will a rubber dam. The plastic form will take up less inter-proximal space. Note that only protection of the amalgam is significant; coverage of the whole tooth is unnecessary.

The least desirable alternative by far is to administer deep anesthesia under the tooth containing the amalgam, however, this would suffice thermo-dynamically in this case.

EXPOSED METALLIC MATRIX RESORATION SUPPORT PINS

Unlike amalgams, the intimate proximity of these pins to the pulp in a vital tooth together with the small surface area of the pin combine to present a significant hazard. ***Accidental contact with an exposed metallic matrix restoration support pin during monopolar electrosurgery represents a significant risk of pulp necrosis leading to subsequent loss of the vital tooth.*** Unfortunately, such an incident has been reported.

Clinical recommendation is to avoid accidental contact with an exposed metallic matrix restoration support pin during electrosurgery by using every precaution and means possible.

The simplest and most effective alternative is to defer electrosurgical intervention in the proximity of an exposed matrix support pin until after the polymeric matrix has been placed and has set. Note that contact with a finished matrix restoration is harmless since the polymeric matrix itself provides electrical insulation over an underlying pin.

The advice on insulation given for amalgams provides a viable alternative when electrosurgical intervention in the presence of an exposed matrix support pin is clinically indicated.

BRIDGES

Any metallic object in contact with the electrosurgical electrode becomes an extension of the electrode. This applies to the metallic sub-structure of a bridge. ***Accidental contact with a bridge by the electrosurgical electrode during monopolar electrosurgery represents a significant risk of severe burn injury to the underlying gingiva to the extent that grafting may be required.*** Unfortunately, such an incident has been reported.

The clinical recommendation is to remove bridges during monopolar electrosurgery.

This advice is appropriate for orthodontic tension wires as well, despite the lower risk associated with them.

Although actual risk is a matter of degree involving many factors, the potential for injury in comparison to the effort imposed by the recommendation stands highly in favor of the recommendation.

CORD PACKING

One of the advantages of electrosurgery in crown preparation is to eliminate cord packing. However, the use of CUT therapeutic current as insurance against tissue recession may lead to some minor hemorrhagic response requiring minor touch up with COAG current prior to impression. If a clinician prefers cord packing as an adjunct to electrosurgery to eliminate this step, or to further refine the profile, it is perfectly practical, and the packing may be left in for a significantly shorter time.

Cord packing tends to produce an optically smooth appearance in tissue which can interfere with optical CAD/CAM data acquisition for use with a CEBEC type crown CNC milling machine, requiring repeat digital photography. On the other hand, electrosurgery produces a microscopically grainy optical surface which precludes this minor annoyance.

INTER-PROXIMAL TISSUE

Two factors should be considered regarding this anatomic structure, both of which derive from its relatively narrow cross section: first, it has limited capacity to withstand monopolar electrosurgical therapeutic current, and second, it has limited thermal dissipation. Conservative approach is the only practical means of dealing with this anatomic structure electrosurgically.

The clinical recommendation is to use the finest loop electrode possible (UF-22 is suggested) along with CUT therapeutic current. Therapeutic energy titration should be set for shallow gingival troughing. Inter-proximal tissue should be reduced in small volumes in thin slices. Irrigation between slices is helpful along with adequate cooling time.

If the electrode reuses to cut at the setting recommended, this strongly suggests that the tissue has a high electrical resistance arising from exceptionally small cross section. Raising energy dose titration to compensate in that circumstance is likely to result in electrical overload of the tissue. The alternative in this circumstance is to use the UF-62 conical electrode or M-61 electrode without altering dose titration, approach the tissue with the fine point, then ablate the tissue in a series of fine lines allowing adequate cooling time between passes. Irrigation is helpful between passes.

The main point is to approach inter-proximal tissue conservatively since all reported incidents involve aggressive approach.

IRRIGATION

Any conductive object in contact with the electrosurgical electrode becomes an extension of the electrode during electrosurgery. Saline solution is electrically conductive. ***The use of saline solution for irrigation during monopolar electrosurgery represents a significant risk of coagulation burn along the flow path.***

The clinical recommendation is to use only sterile water for irrigation in conjunction with monopolar electrosurgery.

Sterile water is distilled and de-ionized which produces suitable electrical characteristics for use with monopolar electrosurgery. ***If saline solution has been applied to the area where monopolar electrosurgery is intended, flush the area with sterile water prior to performing monopolar electrosurgery.*** Note that the efficacy and safety of bipolar forceps coagulation are not adversely affected by saline solution and bipolar forceps coagulation is acceptable in the presence of saline.

Irrigation is helpful to reduce smoke production and to reduce risk of thermal artifact. However, the latter is only effective for shallow incision and troughing, and is not effective for deep incision, deep excision, implant exposure, or gingival curettage. Please do not rely on irrigation as a primary means of heat control since this is properly a function of surgical technique: irrigation is an adjunct most effective in crown preparation, and aesthetic crown lengthening. Note also that *initial power dose setting may be affected by irrigation*: verify during practice and note the difference. This is advised since irrigation volume, like all professional intervention, is a matter of individual technique. Low volumes of irrigation are advised. *Note also that **free flow of the irrigate is essential** since pooled stagnant water is counterproductive by trapping heat instead of removing it, and will induce adverse collateral therapeutic current spread instead of remaining indifferent as molecular contamination from the* volatilization *of tissue accumulating in the stagnant pool will render it conductive.*

EXTRACTION SOCKETS

Necrosis is certain if monopolar electrosurgical therapeutic current is applied directly to bone and subsequent sequestration is a matter of degree. Bone is intimately exposed in an extraction socket.

The clinical recommendation is: ***DO NOT ATTEMPT ELECTROSURGICAL COAGULATION WITHIN AN EXTRACTION SOCKET.***

PROFOUND COMPLICATION WILL ACCOMPANY MONOPOLAR ELECTROSURGICAL COAGULATION IN AN EXTRACTION SOCKET. This is assured by the particularly intimate, large, and electrically effective contact with bone provided by the electrically conductive frank blood in the extraction socket. While bipolar forceps coagulation shows theoretical promise as an effective alternative in this circumstance, this has not been clinically investigated by MACAN and at this time cannot be recommended, therefore, the clinical recommendation stands as given.

TISSUE PLANING

Tissue planing, pontic recess sculpting, and gingivoplasty all involve a significant volume of tissue. Controlling the volume of tissue removed and thermal artifact are considerations.

The clinical recommendation for gingivoplasties, tissue planing, and pontic recess sculpting is to approach in thin slices rather than as a single mass.

Adequate cooling time should be maintained between repeated slices to prevent excess heat accumulation when planing. Use of CUT therapeutic current for most slices and use of BLEND current for the final one or two is suggested where hemostasis is indicated.

GRAFT DONOR TISSUE HARVESTING

Donor tissue is extremely sensitive to thermal artifact even more so than biopsy sample. This factor must be respected for positive clinical outcome.

The clinical recommendation for donor graft harvesting is to use practiced deft technique with appropriate energy dose titration, adequate minimum setting, and CUT current.

Electrosurgical graft harvesting provides some hemostasis at the donor site inherently. Although the CUT current is characterized by minimal concurrent hemostasis, nevertheless, this minimal level of hemostasis is surprisingly effective in healthy gingival tissue. The UF-31 square loop electrode and the UF-26 triangular loop electrode are suggested for donor graft tissue harvesting.

GENERAL REMARKS ON TROUGHING AND EXCISION

The choice of an electrode for troughing, gingivoplasty, or pontic recess sculpting is guided by artistic principle as much as technology and is inspired by dialog used in police dramas: “it fits the profile”. Use it if the coronal cross section of the electrode matches the intended trough or recess profile and remember to use an appropriate initial power dose setting. Suggestions are given in the “Ultra-flex” electrode catalog.

Please note that the UF-62 “Ultra-flex” electrode supplied with the Radiosurge is made of annealed brass which tarnishes easily when used for troughing. The electrode will function perfectly, however, the R-62 is suggested instead to make cleanup easier since it is stainless steel. The narrower R-61 stainless steel fulgurating electrode is also suitable for very fine troughing as well as allowing good access for conservatively approaching inter-proximal tissue.

BIPOLAR COAGULATION

Electrosurgery (except for the "Hyfrecator" type of mono-terminal coagulation device) always employs two wires and two electrodes for connection to the patient in order to complete an electrical circuit. Monopolar electrosurgery is distinct in that therapeutic current diffuses through the body to the dispersive pad and bipolar electrosurgery is distinct in that therapeutic current is significantly constrained to the immediate volume of tissue being treated and does not diffuse into the body.

Bipolar forceps coagulation is safe on or near bone *(except for an extraction socket)* ***since bipolar*** electrosurgery ***significantly constrains therapeutic current to the immediate volume of tissue.*** *When approaching bone with bipolar coagulation keep treatment duration short to avoid thermal desiccation of the alveolar osseous tissue. Apply only to small areas and allow adequate cooling time before repeating application in the same area*

If the biological width has been violated for any reason, bipolar coagulation is the only safe electrosurgical intervention for hemostasis in the gingiva involved with the biological width violation.

Bipolar forceps coagulation has the additional advantage of being effective in wet fields, a virtue not shared by monopolar electrosurgical coagulation. *The only constraint is the size of the forceps tips which makes pin-point coagulation in a crown preparation problematic for bipolar coagulation.*

"Isolated output" monopolar electrosurgical instruments and "bipolar" electrosurgical instruments both have similar internal RF output isolation circuitry, and both significantly restrain therapeutic current from diffusing into the electrical supply grid earth ground. There is a distinction in that the degree of therapeutic current isolation afforded by a "bipolar" instrument is significantly greater than that afforded by an "isolated output" instrument.

While the RF leakage rating of the Radiosurge instrument does qualify as "bipolar" for use with bipolar coagulation forceps using COAG therapeutic current, the Radiosurge is not rated for bipolar incision or excision, and this should not be attempted, neither should BLEND or CUT therapeutic currents be applied with a bipolar forceps when using the Radiosurge instrument.

Clinical application of bipolar coagulation involves addressing the forceps to the treatment site and then activating the unit until the histological effect obtains. This can be done by placing the forceps tips astride a bleed, or by grasping soft tissue between the forceps tips. Superficial coagulation may be achieved by using a curved forceps upside down on the tissue and moving the forceps back and forth during activation to spread the coagulation over the area being treated, and histological effect may be intensified as the gap between the tips is held narrower in this use.

Control of therapeutic effect in bipolar forceps coagulation is through ***time.*** If too high an initial energy dose is used, the histologic effect may occur before the clinician can release the foot pedal. Since bipolar behavior differs from monopolar behavior, it is advised that practice with steak prior to clinical use be done, and initial settings are noted for reference.

Note that the forceps tips should not touch each other during treatment since therapeutic current will then circumvent the tissue precluding histological effect!

FULGURATION

Named after the Latin word for "lightning," this electrosurgical technique involves the application of electrosurgical energy through an electrical arc or spark, without direct electrode contact to tissue. The column of ionized atmospheric gas between the electrode and tissue provides the conduction medium for therapeutic current, distributes histological effect over a circular area defined by the inherent dynamic radial motion of the spark as a function of voltage and electrode distance from tissue, and limits the therapeutic current. Very significant heat is produced as a function of the treated area.

The histological effect is the desiccation of tissue to a limited depth, typically .5mm to .75mm, with a thin underlying layer of coagulum. Adequate local anesthesia must be maintained since active sparking is used.

The primary dental applications are:

Treatment of enucleated cysts or fistulous tracts to address remnant bacteria.

Treatment of tumor excision beds to address remnant metastatic cells.

The location of occult micro-fissures in enamel is accomplished by panning an activated electrode very closely over the face of the tooth until a spark jumps, simultaneously revealing the location of the micro-fissure and coagulating it.

Pulpotomy in pediatric teeth with fulguration current has been suggested as a means of easier gross heat control, which is problematic in pediatric loop pulpotomy. A power setting of 3 is suggested for this technique.

The optional ME6000 adaptor accessory is required to raise the voltage up to a level sufficient for fulguration because the Radiosurge instrument is inherently a low voltage device. Arc length is limited to about 1mm at most. **The power setting should be set to, but not exceed, 5 for most applications and only COAG current is recommended.**

The UF-62 or R-61 pointed electrodes are used for pin-point fulguration. The UF-51 or R-52 ball electrodes are recommended for the treatment of enucleated cysts or tumor excision beds. Significant carbon deposits associated with fulguration make electrode cleanup difficult.

Fulguration is also used in monopolar electrosurgery to control bleeding from bone facilitated by the superficial histological character of fulgurating current; however, this has largely been supplanted in practice by bipolar forceps coagulation since bipolar technique is much easier to apply and avoids the very significant accidental tissue contact risk associated with fulguration.
Never the less, the fulguration technique remains a viable method for bleeding control on bone, and when a clinician prefers this method the recommendation is to use an optical loupe to help avoid accidental osseous tissue contact and a power setting of 5 to maximize arc length.

“Soft coagulation” for pin-point hemostasis may be achieved with the ME6000 fulguration adaptor by very carefully approaching the tissue with the activated conical electrode until an arc is struck without directly contacting tissue, and then immediately retracting the electrode as quickly as possible. A power setting of 2 to 3 is recommended for this technique along with an optical loupe.

SMOKE AND ODOR

Electrosurgical smoke is identical to that from laser and thermal cautery and is considered a mild carcinogen, therefore of greater concern to staff than the patient due to continual exposure. Electrosurgery volatizes bacteria and fungus along with target tissue, however, viruses can survive.

The clinical recommendation is to evacuate smoke from the surgical site. Either a dedicated smoke evacuator or high-speed suction are suggested.

Evidence of viral pathology should be carefully considered prior to electrosurgery since electrosurgery can allow viral pathogens to become airborne in the smoke. Precaution in the form of viral filter masks for staff and especially cautious cleanup of the high-speed suction or dedicated smoke evacuator using appropriate biohazard procedure are recommended in such cases.

Odor itself falls into the realm of annoyance; however, it may be a significant issue with sensitive patients. Diligent use of smoke evacuation reduces odor diffusion significantly and judicious use of irrigation reduces odor production.

Two alternatives to further reducing odor annoyance are:

Place a 2 x 2 gauze on the patient's apron saturated with a pleasant-smelling deodorant, astringent, or mouthwash to mask any residual odor left over from evacuation.

Place a 4 x 4 gauze folded lengthwise into quarters lightly moistened with a pleasant-smelling deodorant, astringent or mouthwash and tape it under the patient's nose on the lip.

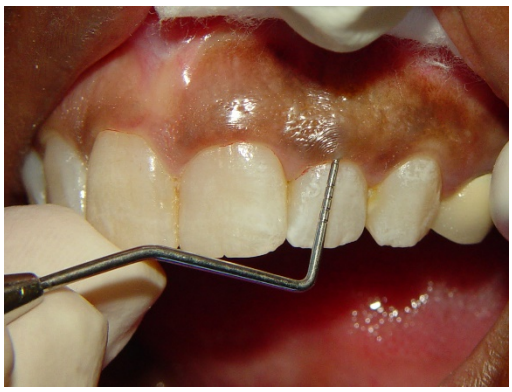
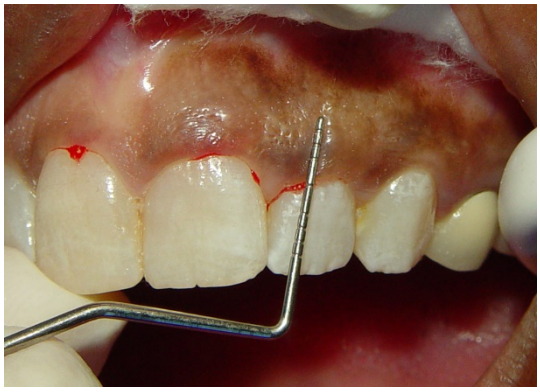
POST-OP CARE

Electrosurgical intervention requires the same post-operative care as any other surgical intervention. The healing rate for tissue treated electrosurgically is on a par with scalpel excision; however, see the section on hemolytic compromise for further discussion regarding that condition.

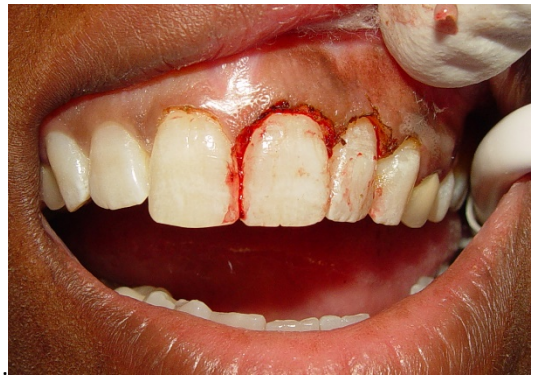
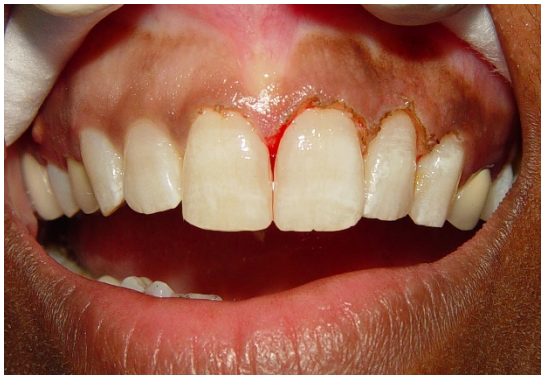
Topical wound protection medications suggested for most procedures are Tincture of Myrrh, Benzoin, and Ora5.

See the reference section for sources of additional clinical advice.

ILLUSTRATIONS

Probing to determine biological width prior to gingivectomy for clinical crown lengthening. Note sub-optimal gingival tissue health.

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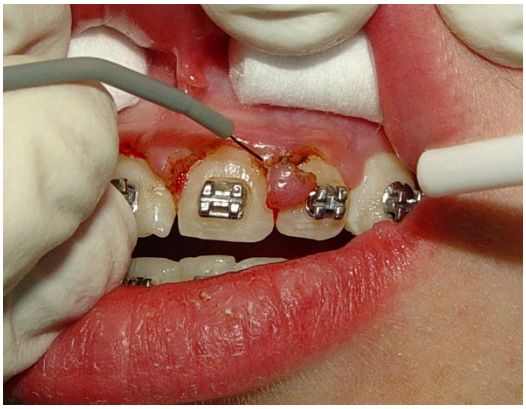
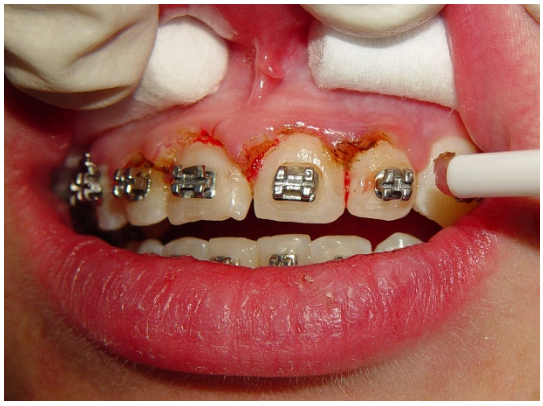
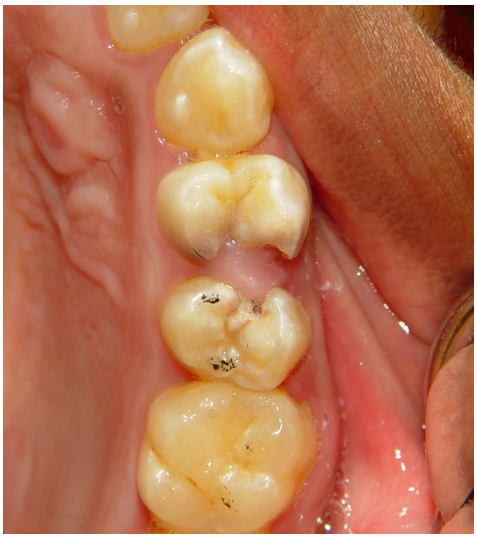
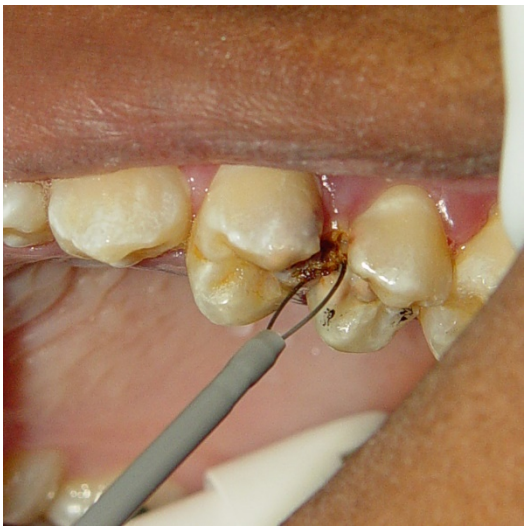
Mild hemorrhagic response is evident immediately post-op. Slight weepage is still evident after lavage. This example represents sound clinical judgment since concurrent hemostasis was compromised out of respect for the sub-optimal state of tissue health. The final healing is expected to be sans circatrix due to good thermal control.

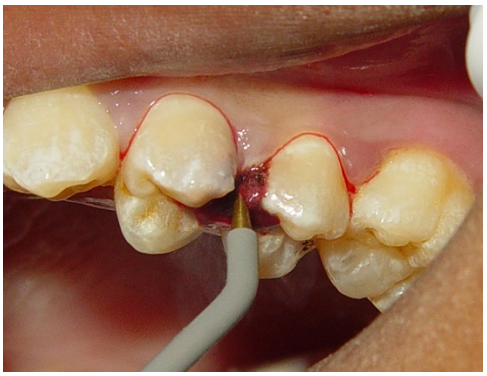



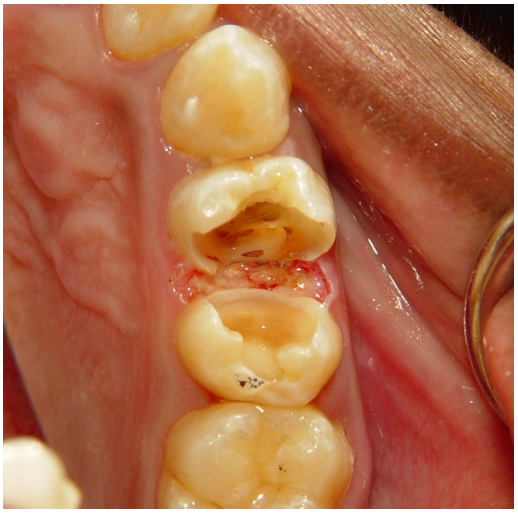
Optimal thermal artifact control is evidenced by the patency of the excised tissue suggesting good energy dose titration and adequate technique. The negligible hemorrhagic response is typical of normal healthy gingival tissue. Note orthodontic tension wire removal.





Inter-proximal granulation tissue developed because patient delayed seeking treatment for fractured cusp and sub-gingival care. Initial approach to this tissue was conservative. Tissue detritus adhering to the loop electrode suggests inadequate dose titration for this circumstance.





Sound clinical judgment was exercised by selecting the conical electrode in lieu of the loop electrode rather than reiterate energy dose out of respect for the limited inter-proximal tissue capacity to withstand therapeutic current. Completed preparation for matrix restoration: note freedom from thermal artifact and good hemostasis affording negligible risk of interference with matrix placement.

CLEANING, STERILIZING, MAINTENTENCE

HAND PIECE STERILIZATION AND CARE

The hand piece must be steam autoclave sterilized before clinical use. FDA regulations do not recognize chemical sterilization as effective for Dental electrosurgery. Dry heat WILL damage the item.

The hand piece must be visually inspected for cracks or insulation damage prior to use. If any bare metal shows, a crack is evident, or an insulation fault is evident, DO NOT use the item. Failure to observe this precaution represents significant risk of coagulation burn injury to the patient or clinician.

The hand piece must be dry prior to and during use. Frank fluid entering the nose cap represents a burn or shock hazard to the patient or clinician. Minor splashing is not hazardous.

Steam autoclave at 275^{0}F and 15PSI for 30 minutes or at 275^{0}F and 30PSI for 15 minutes. The nose cap must be removed prior to autoclaving and placed in bag. Coil the cord loosely when placing in an autoclave bag.

To insert an electrode, loosen the cap counterclockwise one or two turns. It is not necessary to remove the cap. Do be sure that the electrode fully seats *and no part of the metal shaft shows.* Tighten the cap by clockwise rotation to secure the electrode in place. If electrode fit is a little tight, remove the nose cap and insert an electrode several times to "break in" the combination. ***Do not operate without the nose cap.***

Chemical cleaning to remove detritus and fluid stains in preparation for autoclave may be done with mild detergents, 70% ethyl alcohol, hydrogen peroxide solution, or an EPA hard surface rated disinfectant. The hand piece should not be soaked. Rinse thoroughly in clean water after pre-cleaning.

The use of disposable sterile protective covers is encouraged to prevent fluids from entering the hand piece during use and reduce pre-cleaning prior to autoclaving. ***The use of sterile covers is not an alternative to autoclaving.***

NOTICE: ***the hand piece has a finite life in clinical service***. ***It should be routinely replaced after two years of use or 800 autoclave cycles.***

ELECTRODE STERILIZATION AND CARE

The electrode must be steam autoclave sterilized before clinical use. FDA regulations do not recognize chemical sterilization as effective for Dental electrosurgery. Dry heat WILL damage the item.

The electrode must be visually inspected for insulation damage prior to use. If any insulation fault is evident, DO NOT use the item. Failure to observe this precaution represents significant risk of coagulation burn injury to the patient.

Steam autoclave in an autoclavable bag at 275^{0}F and 15PSI for 30 minutes, or at 275^{0}F and 30PSI for 15 minutes.

To insert the electrode into a hand piece, loosen the nose cap counterclockwise one or two turns. It is not necessary to remove the cap. Do be sure that the electrode fully seats *and no part of the metal shaft shows.* Tighten the cap by clockwise rotation to secure the electrode in place. If electrode fit is a little tight, remove the nose cap and insert the electrode several times to "break in" the combination. ***Do not operate without the nose cap.***

Chemical cleaning to remove fluid stains in preparation for autoclave may be done with mild detergents, 70% ethyl alcohol, hydrogen peroxide solution, or an EPA hard surface rated disinfectant. The insulation should not be soaked. Rinse thoroughly in clean water after pre-cleaning.

To remove detritus on the wire portion, place the electrode on a flat surface to avoid breakage and use very fine emery cloth or pumice paste applied with a finger. Do not scrape the electrode since nicks will cause failure in service. Soaking *only* the wire portion of the electrode (never *the insulation*) in hydrogen peroxide will help with removal of stubborn detritus. Brief ultrasound cleaning is acceptable. To maintain optimal efficiency, remove oxidation by rubbing with an aluminum oxide paste between the fingers. Rinse thoroughly in clean water after removing detritus or polishing the wire.

W-Flexible DISPERSIVE PAD CLEANING AND CARE

The W-Flexible Dispersive Pad may be cleaned with mild detergent, 70% isopropyl alcohol, or an EPA hard surface rated disinfectant. Wipe down with clean water to remove cleaner residue. The W-Flexible Dispersive Pad should not be soaked. The pad may be towel dried or air dried, however, it should not be placed in service damp or wet. Do not blow dry since heat may adversely affect the material.

The W-Flexible Dispersive Pad outer material is polyurethane and should not be exposed to acetone, metylethyketone, or volatile hydrocarbon-based solvents which may damage the material.

Do not attempt to autoclave the W-Flexible Dispersive Pad since it will be damaged.

Although the W-Flexible Dispersive Pad is mechanically durable, ***any damage which causes the inner conductive metallic fabric to show renders the pad unfit for use.*** No repairs are permissible for the polyurethane material.

CARE AND CLEANING OF THE UNIT

Disconnect the unit from the electrical supply outlet prior to cleaning. The unit may be cleaned with mild detergent applied with a clean moistened towel. Do not saturate the towel. Avoid spray disinfectants since frank fluid entering the unit represents a significant electrical shock hazard.

Spraying onto a clean towel and then wiping the unit with the moist towel is the alternative when the contents of a spray can disinfectant are clinically indicated. Disinfectants applied by means of a moistened clean towel are permissible. Disinfectant residue or cleaner removal from the unit is not necessary. Allow to air dry.

WARNING! Frank fluid entering the unit represents significant risk of injury or death due to possible contact with lethal electrical potentials within the unit. Disconnect the unit from mains power at the electrical supply outlet, not at the unit, and refer the unit for qualified service. Do not attempt use if fluid has entered the unit.

Treat the medical grade power cord set the same way as the unit itself. Be sure to air dry and do not allow fluid to enter the female portion of the cord set.

FOOT PEDAL CARE AND CLEANING

The foot pedal may be cleaned with mild detergent, 70% isopropyl alcohol, or an EPA hard surface rated disinfectant. Allowing frank fluid to enter the foot pedal should be avoided since the foot pedal is rated IP20 “splash-proof” not IP68 “water-proof”. The foot pedal is rust proof.

If the foot pedal is inundated the electrosurgical unit should be switched off and the foot pedal should be replaced or referred for service prior to subsequent use.

Inundation of the foot pedal does not represent any electrical shock hazard since the circuit is a low voltage isolated type. ***However, conductively contaminated fluid entering the foot pedal internal mechanism can cause the unit to activate continually without depressing the foot pedal.*** Replacing or referring an inundated foot pedal for servicing is recommended as the surest way to ensure proper operation; however, if the inundating fluid is relatively clean the alternative of allowing the foot pedal to air dry may be effective and is permissible since no electrical shock hazard is represented. ***In no case should unit operation be attempted until the foot pedal is fully dried.*** Only air drying is permissible since heat from blow drying may damage the material.

OPERATIONAL DIFFICULTIES

UNIT

Unit fails to turn on.

- *Verify that the electrical outlet is functional by plugging in another appliance known well.*
- *Verify that power cord is firmly seated in the appliance entry.*

Unit turns on OK, timing indicator goes out OK, but unit will not activate when pedal is pressed.

- *Verify that the foot pedal connector is attached and seated properly.*
- *Verify that the foot pedal cord is not damaged.*
- *Check foot pedal for obvious faults: does it "click" when pressed?*

Sometimes depressing the foot pedal activates the unit, sometimes not.

- *If the foot pedal is depressed on the very extreme corner it may not "click". Be sure to step on it as fully as practical to avoid this annoyance.*

NO OPERATION

The yellow "active" indicator comes on OK, but I get no cutting.

- *Verify that the W-Flexible Dispersive Pad is plugged in at the chair and at the unit.*
- *Verify that the electrode is fully seated, and insulation is not caught in the chuck.*
- *Verify that the dispersive cable is undamaged and functional.*
- *Verify that the hand piece cable is undamaged and functional.*
- *Electrodes must be clean (see NOTE below)*

POOR OPERATION

- *Verify that proper initial power setting for the electrode selected is established.*
- *Verify that COAG has not been inadvertently selected for an incision or excision.*
- *Verify that heavy, thick clothing is not adversely affecting dispersive efficiency*
- *Verify dispersive pad positioning*

NOTE! *Unlike conventional high voltage units which can "blast" through proteinaceous deposits on the electrode, the low voltage Radiosurge cannot do so. Electrode tissue contact areas MUST be clean with bare metal showing. The use of single use sterile "scratch pads" available from medical suppliers are recommended to deal with deposits and detritus during surgery.*

BASIC UNIT OPERATION: IS IT WORKING AT ALL?

The beef steak recommended in the practice section is not the only potential test medium: hot dogs, citrus fruits, apples, cooked chicken, lunch meats, and even bar soap will demonstrate basic operation when placed on the dispersive pad and cut with an incision electrode. Soap should be moistened for this test. Paper, plastic, or metal cannot be cut with electrosurgery. Sparking to ground or the dispersive pad is not a valid test for the isolated low voltage MC6A.
The electrode tip will not get hot outside tissue or a suitable test medium.

CHECKING CABLES

There are several methods to test cable integrity:

Palpation. Drape the cable over the forefinger and press the insulation firmly with the thumbnail. A soft spot in the insulation reveals an occult fracture in the conductor. A gentle pull on the cable where it enters the hand piece likewise reveals an occult fracture in the conductor hidden within the hand piece when the insulation stretches. Faults typically occur within 3" of the ends, however, running over a cable with a chair or heavy cart can also cause a conductor fracture. The latter condition is usually accompanied by obvious damage or visible scuffing of the insulation.

Electrical continuity test. Any electrician, clinical engineer, electronic repair shop, most hardware stores, or most automotive repair shops can do this. It is advisable to flex the suspect cable, particularly near the ends to reveal occult or intermittent conditions.

Radiography. X-ray will reveal occult fractures readily. Fluoroscopy is also very effective.

NOTE: Repairs to damaged or faulty cables are not permissible. Replace them if faulty.

FUSES

Fuse failure almost inevitably occurs as a result of an internal component failure which cannot be resolved without referring the unit for service.

To replace a fuse, ***first disconnect the unit from mains power*** by unplugging from the electrical outlet. Push in and turn the fuse holder cap ¼ turn counterclockwise to extract the fuse. Replace with the exact type and rating as they appear on the adjacent fuse label.

WARNING! Do not substitute fuse type or rating: risk of fire or injury to the patient or operator.

WARNING! Do not remove cover: risk of injury or death due to exposed lethal electrical potentials. Refer all servicing to qualified personnel.

TECHNICAL SUPPORT

Advice is available via telephone between 9AM and 5PM Eastern Time Monday through Friday
302-645-8068
Info@macanmanufacturing.com

WARRANTY INFORMATION

The Radiosuge® MC6A dental electrosurgery is warranted for 3 years from date of purchase, exclusive of accessories.

The warranty does not cover accidental damage. Damage arising from dropping, falling, or inundation will be assessed at normal repair rates. Damage from shipping must be reported to the common carrier and will be assessed at normal repair rates. Damage arising from improper packing will be assessed at repair rates. If the correct carton and packing materials are required to safely return a unit, please request them when the warranty claim is made.

All domestic warranty claims must be made through the MACAN business office to obtain a Return Authorization number for prompt service, proper credit, and accurate tracking. Warranty claims made through domestic dealers will be honored but do please be aware that this will take a little more time. Customers outside the USA should submit warranty claims to their dealer.

The warranty is void if the unit cover is opened. Hospital clinical engineering departments, military medical equipment maintenance departments, and dealer repair departments should make special arrangements with the MACAN Customer Service Department before attempting repairs to a unit under warranty.

The warranty and all liability to MACAN is void if the unit or accessories are modified or tampered with. For special requirements, such as requests for schematic diagrams, contact the MACAN Customer Service Department.

Units returned for credit are subject to a restocking charge. Units returned for credit must be complete with all accessories since charges will be assessed for missing items.

USED ELECTRODES CANNOT BE RESTOCKED.

NOTICE! Do not return a unit under warranty or for service which is biologically contaminated. Please clean a contaminated unit or accessory or else pack it in an appropriate bio-hazard bag and label it accordingly.

DISCLAIMER: MACAN does not accept responsibility for the use of accessories other than those supplied by MACAN or those authorized in writing for use with the Radiosurge® MC6A. Failure to function, damage to the unit, and injury to the patient or operator arising from the use of non-approved accessories are hereby disclaimed.

TECHNICAL SPECIFICATIONS

IEC CLASSIFICATION class II medical, high frequency surgical, non-ionizing radiation device
CONFIGURATION: monopolar, isolated output, type BF ports
OPERATING MODES:

CUT CW, 5% ripple, max 50watts into 100ohms +20%/-10%, crest factor 1.4

SURGE 50%cut 50%coag blended 50watts into 100ohms +20%/-20%, crest factor 1.9
Modulation: 2 x line frequency, 100 or 120Hz, sinusoidal

COAG 50% duty cycle 25watts into 100ohms +25%/-25%, crest factor 2.6
Modulation: line frequency, 50 or 60Hz, sinusoidal

OUTPUT VOLTAGE 500V p-p (.5kVp p-p) maximum, open load, CUT mode
SOURCE IMPEDANCE 500ohms, nominal
OPERATING FREQUENCY: 3.0mHz +/-5%, nominal
POWER CONTROL manual analog, continuously variable
OPERATIONAL DUTY CYCLE 10 seconds ON, 20 seconds OFF (not electronically enforced)
TEMPERATURE RANGE -20^{0}C to +85^{0}C storage, 00C to +35^{0}C operating, <80% RH noncondensing
COOLING convection
SPALSH RATING IP0
ACTUATION single foot pedal (isolated low voltage circuit, IP20 rust proof plastic pedal)
DISPERSIVE MONITOR N/A
ACTIVE INDICATION LED light, tone (defeatable)
POWER REQUIREMENTS 120V 60Hz, +/-10%, 240watts maximum consumption
230V 50Hz, +/-10%, 240VA maximum consumption
NOTE: field selection of operating voltage requires a skilled technician

SIZE AND WEIGHT 6 ½" w, 2 3/4"h, 11 ½" d exclusive of knobs and jacks, 6# (10# shipping)

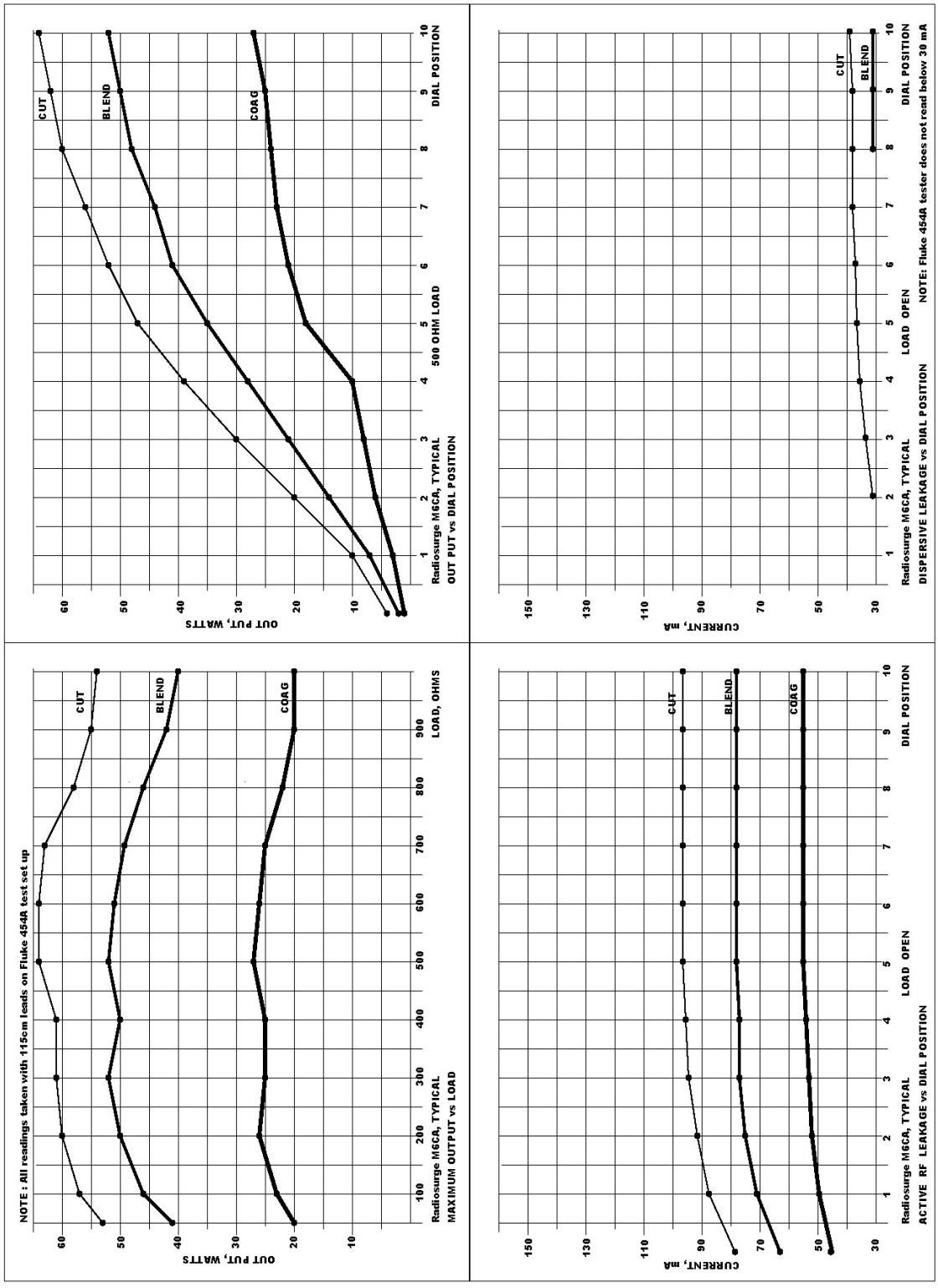
16,5cm w; 7cm h; 29,2cm d exclusive of knobs and jacks; 2,73kg (4,55kg shipping)

WARRANTY 3 years (exclusive of accessories)

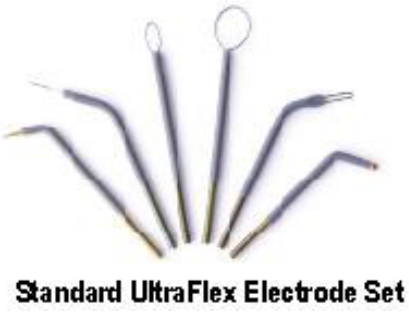
SAFETY APPROVAL Notified Body: MET Labs
Standard: UL 60601-1 & CSA C22.2 No. 601.1
Mark: C/US "Classified" mark, registration number E112955

Tested to: IEC 60601-1-1 Medical Safety
IEC 60601-1-2 Electromagnetic Compatibility
IEC 60601-1-2 High Frequency Surgical Particular Standards

Tech Graph


Radiosurge M6CA, TYPICAL
OUT PUT vs DIAL POSITION
500 OHM LOAD
DIAL POSITION
OUT PUT, WATTS
CUT
BLEND
COAG
Radiosurge M6CA, TYPICAL
DISPERSIVE LEAKAGE vs DIAL POSITION
LOAD OPEN
NOTE: Fluke 454A tester does not read below 30 mA
CURRENT, mA
NOTE : All readings taken with 115cm leads on Fluke 454A test set up
Radiosurge M6CA, TYPICAL
MAXIMUM OUTPUT vs LOAD
LOAD, OHMS
Radiosurge M6CA, TYPICAL
ACTIVE RF LEAKAGE vs DIAL POSITION
LOAD OPEN

REPLACEMENT PARTS

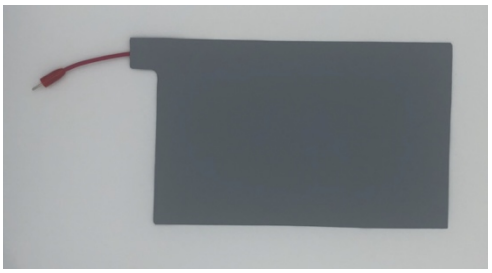


UF-62
UF-F1
UF-35
UF-34
UF-22
UF-51

HPAC-1

NCS-1

DPC-2



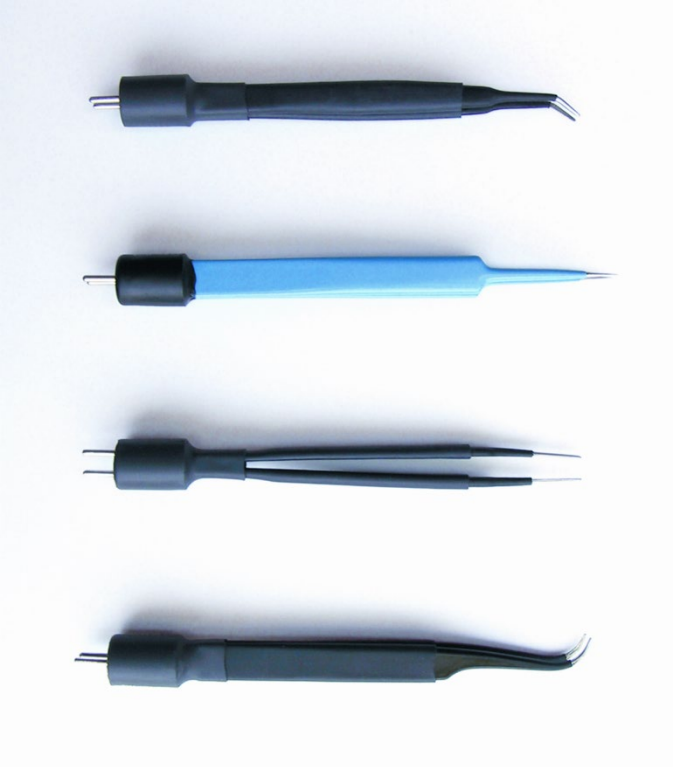
FDP-1

61.102

01.096

OPTIONAL ITEMS

Bipolar Forceps and Cable



BPF-C2 (color may vary)
angled style, serrated
100mm, .75mm tips

BPF-S1 (color may vary)
Jeweler's style, smooth
114mm, micro tip

BPF-S2 (color may vary)
straight iris style, serrated
100mm, .75mm tip

BPF-C1 (color may vary)
curved Jeweler's style, smooth
114mm, micro tip

Forceps are normally supplied with a cable. For cable alone, please contact Customer Service.

WARNING! Do not use MACAN supplied bipolar accessories with a ground referenced electrosurgical instrument due to risk of injury to the patient or failure to perform the intended bipolar function under adverse conditions.

MACAN Manufacturing
21 Shay Lane
Milton, DE 19968

Phone: 1-302-645-8068
FAX: 1-302-645-7049

www.macanmanufacturing.com
Info@macanmanufacturing.com

ME6000

230V 50Hz Operation, Proper Mains Cordage

230V 50Hz configuration is optional and will be supplied with appropriate mains cordage for the destination country, so be sure to specify when ordering.

Units may be converted from 120V to 230V and vice versa, however, this requires the services of a skilled technician, the proper fuse labels, proper fuses, proper fuse holder caps, the correct mains cordage for the destination country and the correct metal oxide varistor surge suppressor for the intended use. Please contact Customer Support for further information.

IP68 Water-proof Foot Pedal

An IP68 rated foot pedal is available for use in hospital operating rooms or in countries which do not recognize class B patient care environments. Contact Customer service directly.

Air Switch Foot Pedal, Integration into Dental Stand

No air switches are optional for the Radiosurge MC6A since the low voltage isolated foot pedal circuit eliminate the need for them. It is recommended that a foot pedal cable sans pedal be ordered with the Radiosurge unit in addition to the foot pedal and cable supplied with the unit for integration into a dental stand since the foot pedal is attached to the unit with a connector and this scheme allows portability to be maintained. Once again, the low voltage nature of the foot pedal circuit makes this practical. Contact Customer Service regarding warranty implications.

FIRE PREVENTION

Algebra affords the simplest way to describe fire hazard:

Let (**)** represent the confined space of the oral cavity

Let O_2 represent itself or an atmosphere enriched with nitrous oxide

Let CM represent Combustible Material such as cotton or gauze

Let **IG** represent an Ignition source (spark, thermal cautery, laser)

(O_2 + CM + IG) = FIRE

It follows that leaving out a term will not result in fire, thus defining fire safety.

Fire prevention is a simple and easy matter of not allowing all three elements necessary for disaster to combine at once within the oral cavity.

IF AN ENRICHED ATMOSPHERE EXISTS BECAUSE OF ADMINISTERING NITROUS OXIDE OR HIGH CONCENTRATION OF O_2, THEN DO NOT USE ELECTROSURGERY!

If O_2 or N_2O are used, discontinue prior to electrosurgery, allow 60 seconds for dissipation, and use high speed suction in the oral cavity to remove residual gas concentration.

ABSOLUTELY DO NOT USE SURGICAL DRAPES FOR ORAL ELECTROSURGERY WHEN O_2 OR N_2O ARE USED!

The drape will form a cavity for the accretion of O_2 or nitrous oxide resulting in a serious hazard.

DO NOT ASSUME A TRACHEAL TUBE PROVIDES A SEAL AGAINST HIGH O_2 OR NITROUS OXIDE CONCENTRATION IN THE ORAL CAVITY!

A high concentration of O_2 or nitrous oxide WILL occur in the oral cavity when a tracheal tube is used.

BE AWARE OF THE COMBUSTIBLE NATURE OF ADHESIVES, CEMENTS AND ASTRINGENTS!

Allow adequate time for fumes to dissipate and use high speed suction to evacuate the oral cavity before applying electrosurgery.

NOTIFIED BODY REQUIRED WARNINGS

Reference: 60601-2-2 IEC: 1998 (E), 6.8.2, bb

WARNING! An internal failure of the electrosurgical unit may result in an unintended increase of output power.

NOTIFIED BODY REQUIRED TECHNICAL DATA

ADDITIONAL READING

The Electrosurgery Handbook (clinical guide) by Ira Lanski		MACAN Engineering
Oral Radiosurgery (clinical guide) by Dr. J. A. Sherman		Martin Dunitz
Dentistry Today		
Implants	Dr. B. Guillaume	Nov 2003, Vol 22, No 11
Periodontics	Dr. J. A. Sherman	May 2002

WEB SITES

www.macanmanufacturing.com		MACAN home Page
www.osha.gov/SLTC/laserelectrosurgeryplume		smoke
www.osha.gov/SLTC	select “DENTISTRY”	safety
www.guideline.gov/	enter search: “surgical fires”	fire safety
www.valleylab.com/education/		technology