OWNER'S MANUAL

MC-4A

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.

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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 personal 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 histological effect, much the same as laser does. This is safely and effectively managed by surgical technique. However, electrosurgery is unique among surgical methodologies in that 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 very easy. The hard part is maintaining awareness.

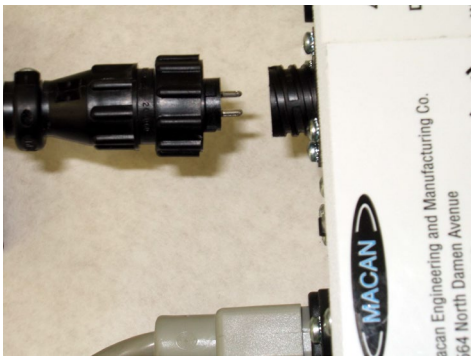
Thank you.

BEFORE CLINICAL USE: INSTRUMENT FAMILIARIZATION

SETTING UP THE MACAN MC-4A UNIT

The MC-4A unit emits an audible during unit activation in order to comply with recognized agency safety regulations. ***To turn off the audible tone, use the switch on the back of the unit.***

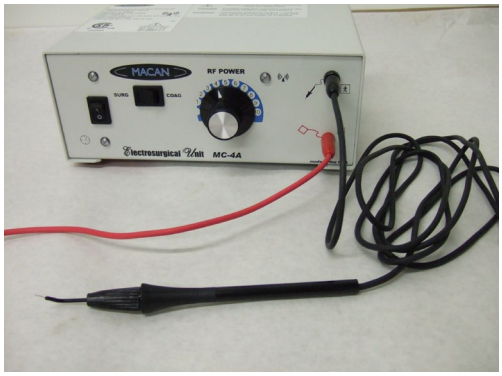
Insert the power cord set into the IEC 320 appliance entry. ***Be sure to seat the cord firmly.*** Connect the foot pedal by inserting the connector with the widest key facing up and turn the locking ring clockwise to secure it. ***The connector inserts easily and should not be forced.***



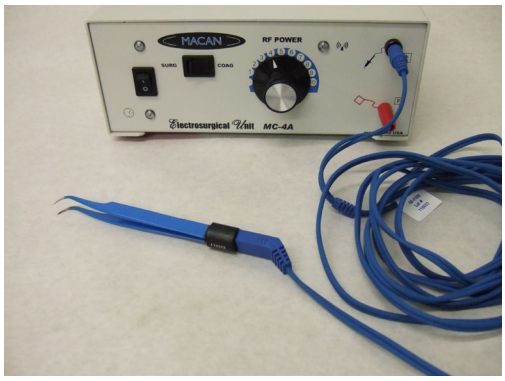
The red stabilization timer light comes on when the unit is switched on and then turns off automatically after 30 sec. The red light must go off before the unit will activate.

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

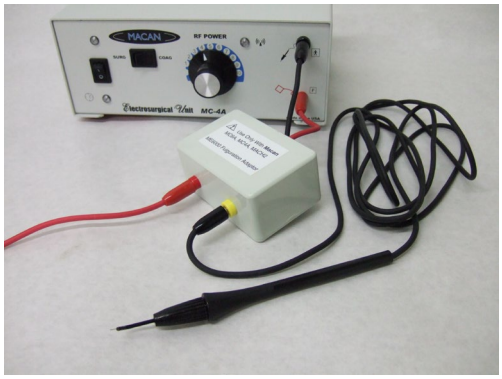
Monopolar set up. The red dispersive lead goes to the W-Flexible Dispersive Pad not shown.



Bipolar forceps coagulation set up. Note that removal of the W-Flexible Dispersive 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 intra-cellular temperature to boiling thus causing the volatilization of cell contents, *the ability of 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, very little 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 important 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 in order to comfortably achieve accuracy and speed simultaneously.*

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 that cannot be reduced by simply "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.* Deft, steady, adequate technique is *critical* for the successful use of large loop electrodes.

There is NO room for error during biopsy in particular, likewise, during donor graft tissue harvesting.

Consider adequate surgical technique to be the constant in electrosurgery. Inadequate (slow) technique is the leading cause of poor electrosurgical result.

THERAPEUTIC CURRENT QUALITY (MODE) DESCRIPTION

The MC-4A instrument offers one incisional and excisional mode:

SURGE, which is histologically characterized by *significant collateral heat, pronounced concurrent hemostasis, microscopic collateral tissue denaturing, and minor cicatrix expected in the final healing.* Expected collateral tissue denaturing width is 350 to 750microns nominal, assuming .010" diameter electrode.

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 greater tissue denaturing width perpendicular to an incision increasing toward the apex as a function of incision depth.

The MC-4A 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

The MC-4A is a very simple unit in this respect: incision and excision are accomplished with SURGE and hemostasis is accomplished with COAG.

Remember however, that the SURGE therapeutic current is a modulated form which induces more collateral heat than an unmodulated current (not available on the MC-4A) and this represents some limitation in usage.

While the MC-4A is appropriate for the vast majority of clinical indications in general dentistry, periodontics, orthodontics, and endodontics, these limitations become more significant in prosthodontics where tissue recession in aesthetic crown lengthening and crown preparation are significant issues, as well as in implant exposure.

The MC-4A is ***not*** suitable for biopsy or tissue graft donor harvesting; it is ***not*** suitable for implant exposure.

Aesthetic crown lengthening is possible with the MC-4A; however, it is ***imperative*** that a deft, practiced, adequate surgical technique be used to avoid tissue recession.

THERAPEUTIC ENERGY QUANTITY: INITIAL RF POWER SETTING

Since 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	3.5 to 4	SURGE
UF-11, UF10, UF-F1	incision >3mm deep	4 to 4.5	SURGE
UF-33 (3,5mm loop)	biopsy	***not recommended***	
UF-34 (5mm loop)	biopsy	***not recommended***	
UF-33	planning	4.5 to 5	SURGE
UF-34	planning	4.5 to 5	SURGE
UF-35 (oval loop)	excision or planning	4 to 4.5	SURGE
UF-22 narrow loop	shallow troughing	3 to 3.5	SURGE
UF-22 narrow loop	planning, tag removal	4 to 4.5	SURGE
UF-SN62 pointed	troughing	3 to 3.5	SURGE
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 armament additional electrodes not listed here.

THERAPUETIC 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 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 intra-cellular 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 normal 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 MC-4A instrument may differ significantly in electrical output characteristics from the unit they are used to.

Beefsteak or beef roast provide a suitable practice medium to simulate gingival tissue, that 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 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 (this relates to use on inter-proximal tissue). 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 excision. The admonition regarding surgical technique speed tolerance for this clinical indication and adequate minimum power setting will become apparent. The third exercise should involve practice 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 in 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. 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 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, current density is so low at the dispersive site that no significant heat develops in the dispersive area.

The MC-4A unit has an isolated RF output which means that ***the unit absolutely will not work without the dispersive pad.*** Furthermore, the MC-4A has 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 normal*

street clothing and to be left in place on the chair to minimize attention. Metallic brassier clasps or lift wires do not affect 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 shoulder level, preferably above the myocardium.*** *The* W-Flexible Dispersive Pad *is placed on the chair, 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 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 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. In fact, loop excision or biopsy may be impractical under the latter circumstance.

THE W-Flexible Dispersive 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 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 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 *should be placed posteriorly under the supine patient* ***at shoulder level.*** *DO NOT attempt to substitute a disposable pad from another unit in the OR.* If a hyper/hypo-thermia pad is used, place the bagged W-Flexible Dispersive *between the patient and the pad.* The thin cross section of the W-Flexible Dispersive allows hyper/hypo-thermia pad thermal conduction with minimal reduction in efficiency.

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

PREPARING FOR SURGERY

MUST READ INFORMATION!

Local anesthesia is required for electrosurgery. Since the MC-4A unit enforces a 30 second stabilization period after initial turn on it is recommended that the unit be switched on prior to administering anesthesia to avoid needless delay.

THE HAND PIECE AND ELECTRODES MUST BE AUTOCLAVED BEFORE USE. *Carefully inspect the hand piece 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 foregoing, ***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 neuro stimulator, or other indwelling electrical device. 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 prior to 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 iPod or similar *battery powered* musical device by the patient is not hazardous but may suffer from radio interference. ***Patient use of headphones 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.

Nevertheless, it is undesirable to dress a cable in such a manner that it is prone to being 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 scrupulously avoided. Placing electrosurgery cables along side monitoring cables must be scrupulously avoided.***

The MC-4A 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 with respect to cardioversion and it is not necessary to remove or disconnect the dispersive pad.

CLINICAL USE

CLINICAL INDICATIONS AND LIMITATIONS

MC-4A is a surgical instrument for incising and excising soft tissue in the oral cavity, as well as for providing hemostasis. The MC-4A is suitable for any dental procedure surgically treating soft tissue within the oral cavity, with certain limitations.

Since the list of soft tissue procedures in clinical dental practice is so extensive, it is simpler to list the procedures for which MC-4A is not suited:

The MC-4A should NOT be used for

- Biopsy
- Donor graft tissue harvesting
- Implant exposure

The "Surge" function of the MC-4A provides modulated therapeutic current. This type of current induces pronounced concurrent hemostasis during incision and excision that is generally beneficial, however it comes at a price: significant collateral tissue heating. While the vast majority of clinical procedures can tolerate the heat without healing compromise, biopsy samples are very sensitive to thermal artifact; graft donor tissue is very easily overheated; and the osseo-integration supporting implants are very sensitive thermally, hence the constraints.

See the Additional Reading section on page 35 for supplemental resources giving clinical application detail beyond the scope of this manual.

GENERAL REMARKS

Because the therapeutic current provided by the MC-4A is electrical energy, it is very tempting to use deep electrical theory to discuss safety and arrive at a "general rule." However, the clinical intent is to treat a live patient and not to repair an appliance. In that light, electrical theory will not enlighten but confuse. The precautions are therefore laid out along clinical lines, given in context.

Nevertheless, to put the case in general terms, the main precautions are:

Avoid overheating tissue

- Use proper surgical technique (pg. 3)
- Use proper dose titration (pg. 5, pg. 6)

Avoid co-incidental burn from contact with conductive materials in the oral cavity

- Instruments, tongue and mouth jewelry, saline solution (pg. 9, pg. 16)
- Amalgams, matrix support pins, bridges (pg. 13, pg. 14, pg. 15)
- Faulty electrode insulation, faulty hand piece (pg. 9, pg. 23)

Avoid using excess therapeutic current on small anatomic structure or thin tissue

- Inter-proximal tissue (pg. 15)

Never touch exposed bone with monopolar electrosurgery

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 prior to gingivectomy to ensure that an adequate biological width of 3mm minimum is maintained post-op. This applies to scalpel, laser, and thermal cautery also.

Electrosurgery introduces a need to recognize a potential complication: *electrosurgery must not contact exposed bone*. Therefore, if biological width is violated for any reason, see the caution below.

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.

NOTE: see the advice for bipolar on page 18 for additional insight on dealing with exposed bone.

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 clinically abnormal, these tissues are nevertheless biologically 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 SURGE 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. Retitrate 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 sufficient 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.

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.***

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.***

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. If a clinician prefers cord packing as an adjunct to electrosurgery, 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 particular 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 thus precluding bipolar from being an automatically suitable substitute. *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 and monopolar technique (UF-22 is suggested). 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 PLANNING

Tissue planning, 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 planning, and pontic recess sculpting is to approach in thin slices rather that as a single mass.

Adequate cooling time should be maintained between repeated slices to prevent excess heat accumulation when planning

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 is made of annealed brass that 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.

CAUTION: since the MC-4A provides only a modulated therapeutic incision and excision current, a *deft technique and proper therapeutic dose titration are absolutely essential* for troughing or aesthetic crown lengthening. A significant risk of permanent tissue recession exists if these factors are compromised in any way.

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 (*with the exception of 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 that makes pinpoint 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 MC-4A instrument does qualify as "bipolar" for use with bipolar coagulation forceps using COAG therapeutic current, the MC-4A is not rated for bipolar incision or excision and this should not be attempted, neither should SURGE therapeutic currents be applied with a bipolar forceps when using the MC-4A instrument.

Clinical application of bipolar coagulation involves addressing the forceps to the treatment site and then activating the unit until histological effect obtains. This can be done by placing the forceps tips astride a bleed, or by grasping soft tissue between the forceps tips. 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 may achieve superficial coagulation. 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 by means of ***time.*** If too high an initial energy dose is used, 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 be 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 by means of 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 treated area.

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

Although largely supplanted by bipolar techniques, dental applications for fulguration are:

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

Treatment of tumor excision beds to address remnant metastatic cells.

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 voltage up to a level sufficient for fulguration because the MC-4A 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 pinpoint 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.

Nevertheless, 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.

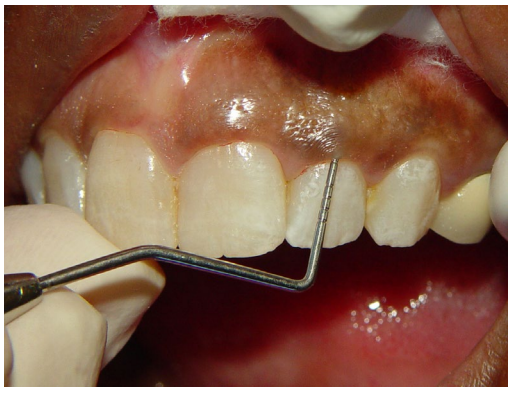
POST-OP CARE

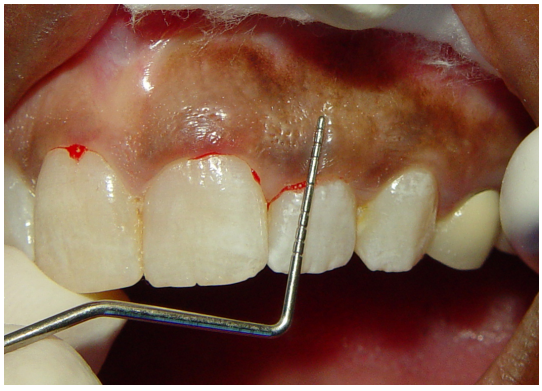
Generally speaking, electrosurgical intervention requires the same post operative care as any other surgical intervention. The healing rate for tissue treated electrosurgically is on a par with scalpel excision; however, see the section on hemolytic compromise for further discussion regarding that condition.

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

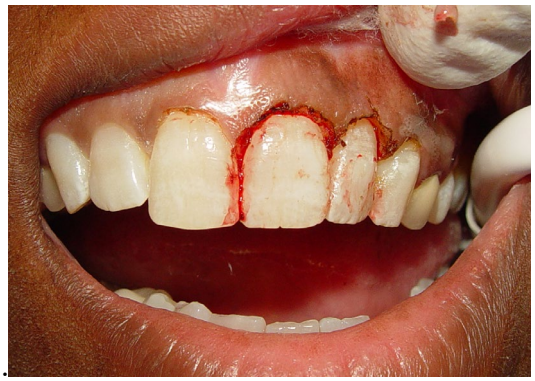
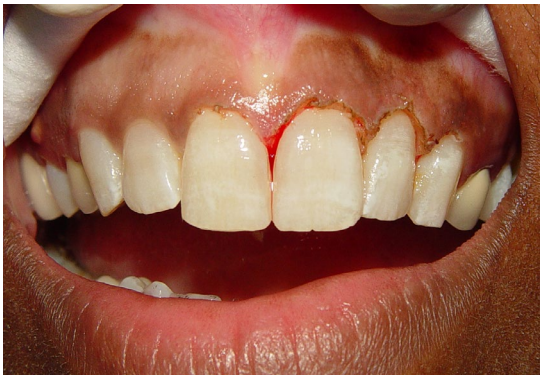
See the reference section for sources of additional clinical advice.

ILLUSTRATIONS

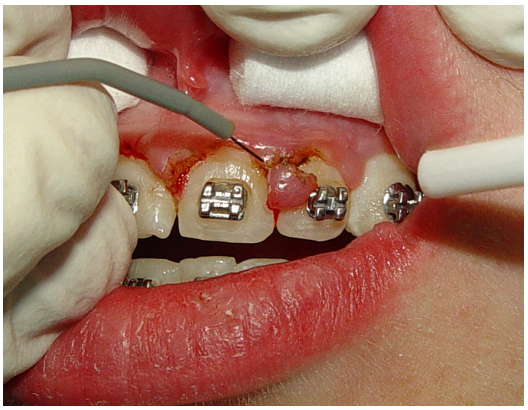
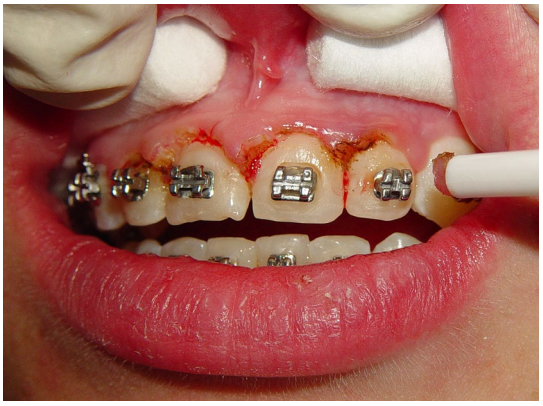




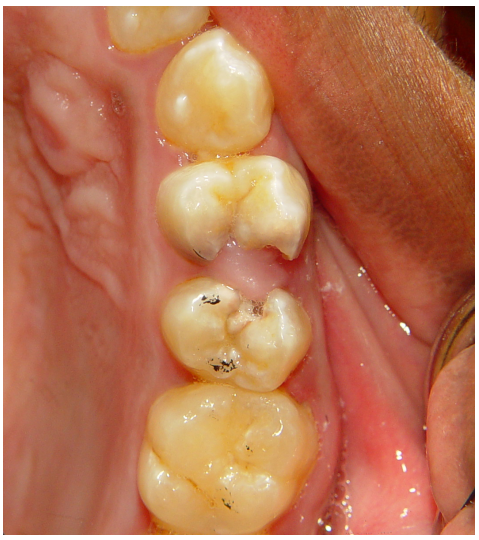
robing to determine biological width prior to gingivectomy for clinical crown lengthening. Note sub-optimal gingival tissue health.

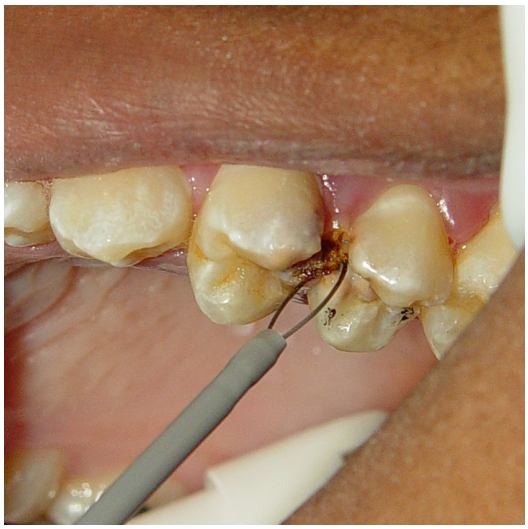



Mild hemorrhagic response is evident immediately post-op. Slight weeping is still evident after lavage. This example represents sound clinical judgment since concurrent hemostasis was compromised out of respect for the sub-optimal state of tissue health. The final healing is expected to be sans cicatrix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

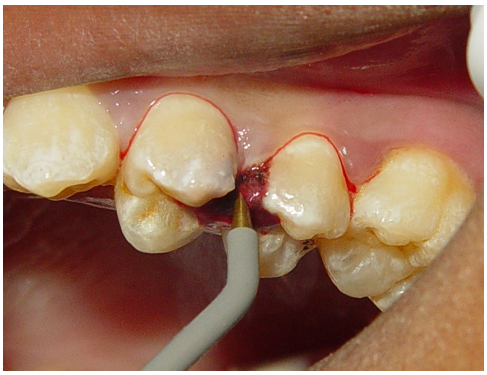



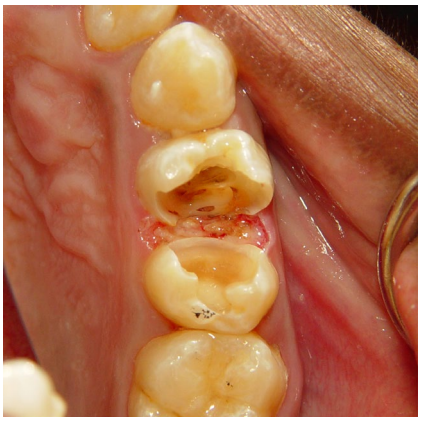
Optimal thermal artifact control is evidenced by the patency of the excised tissue suggesting good energy dose titration and adequate technique. The negligible hemorrhagic response is typical of normal healthy gingival tissue. Note orthodontic tension wire removal.





Inter-proximal granulation tissue developed because patient delayed seeking treatment for fractured cusp and sub-gingival curie. 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, MAINTANENCE

HAND PIECE STERILIZATION AND CARE

The hand piece must be steam autoclave sterilized before clinical use in a bag. FDA regulations do not recognize chemical sterilization alone as effective for 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 270^0 F (132^0 C) for 15 minutes in a bag. The nose cap **should be removed** during autoclave. Coil the cord loosely when placing in an autoclave bag.

To insert an electrode, loosen the cap by turning 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 an EPA listed quaternary disinfectant cleaner according to manufacturer's instructions. 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 to 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.***

ELECTRODE STERILIZATION AND CARE

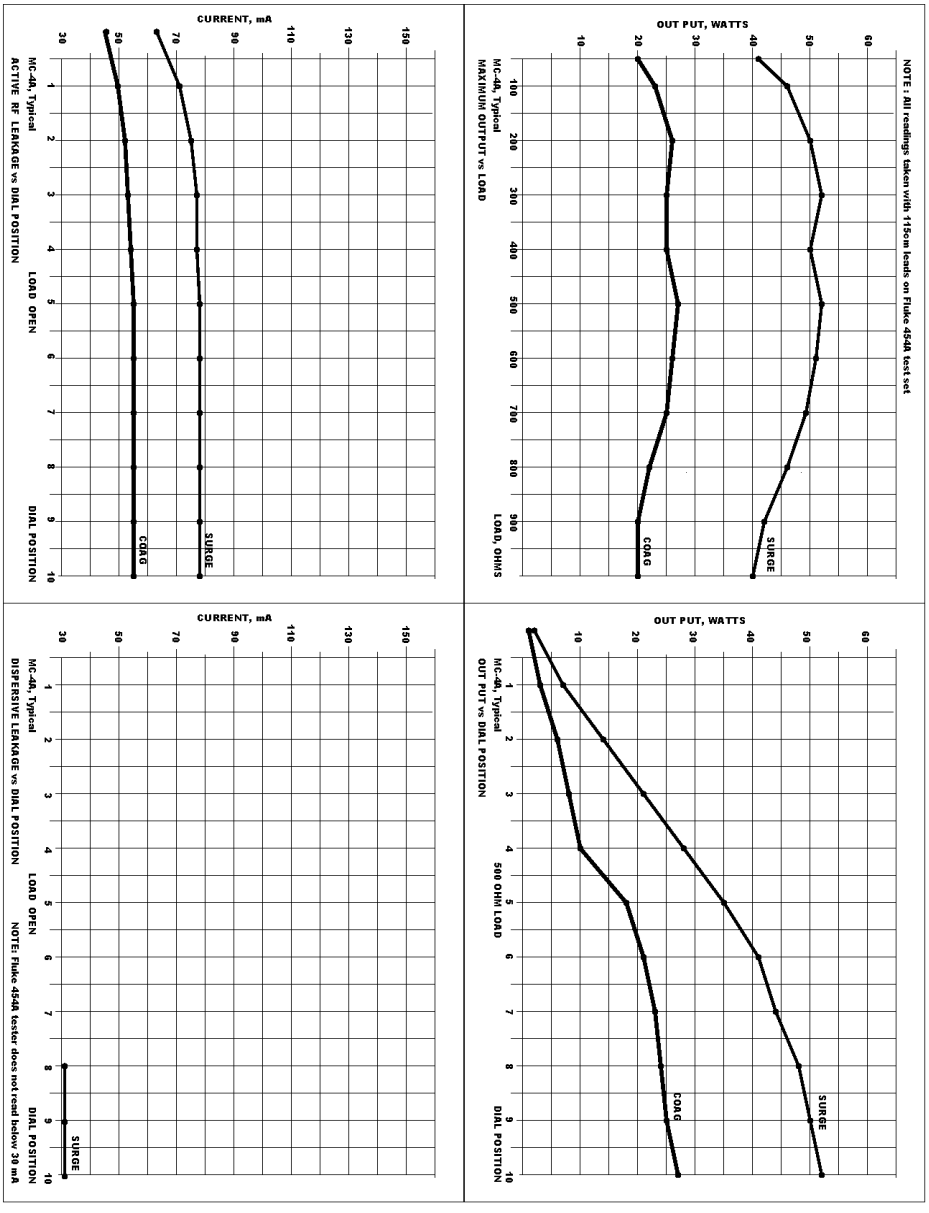
The electrode must be steam autoclave sterilized before clinical use. FDA regulations do not recognize chemical sterilization alone as effective for electrosurgery. Dry heat WILL damage the item.

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 at 270^0 F (132^0 C) 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

GRAPH


NOTE : All readings taken with 115cm leads on Fluke 454A test set
OUT PUT, WATTS
MC-4A, Typical
MAXIMUM OUTPUT vs LOAD
LOAD, OHMS
SURGE
COAG
OUT PUT, WATTS
MC-4A, Typical
OUT PUT vs DIAL POSITION
500 OHM LOAD
DIAL POSITION
SURGE
COAG
CURRENT, mA
MC-4A, Typical
ACTIVE RF LEAKAGE vs DIAL POSITION
LOAD OPEN
DIAL POSITION
SURGE
COAG
CURRENT, mA
MC-4A, Typical
DISPERSIVE LEAKAGE vs DIAL POSITION
LOAD OPEN
DIAL POSITION
NOTE: Fluke 454A tester does not read below 30 mA
SURGE

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 an EPA listed quaternary disinfectant cleaner according to manufacturer’s instructions. 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 a fine grit abrasive pad moving unilaterally along the wire portion away from the insulation and then do the brass portion. The metal portions of the electrode must be kept mechanically clean to insure proper conduction of electrosurgical therapeutic current into tissue at the operative site.

W-FLEXIBLE DISPERSIVE PAD CLEANING AND CARE

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

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

Although the W-Flexible Dispersive 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 good*
- *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 electrode is clean and bare metal shows in the tissue contact area.*
- *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.*

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 that can "blast" through proteinaceous detritus on the electrode, the low voltage MC-4A cannot do so. A badly contaminated electrode will result in poor operation or no cutting.* ***Electrodes must be kept clean so that bare metal is showing.*** *The use of sterile disposable "scratch pads' available from medical suppliers are recommended.*

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 MC-4A.

The electrode tip will not get hot outside tissue or 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

302-645-8068

Info@macanmanufacturing.com

Monday through Friday, 9am-5pm EST

WARRANTY INFORMATION

The MC4A dental electrosurgery is warranted for 2 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 MC4A. 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

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

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

OUTPUT VOLTAGE 500V p-p (.5kVp p-p), open load, SURGE 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 -20^0C to $+85^0$C storage, 0^0C to $+35^0$C operating, <80% RH noncondensing

COOLING convection

SPALSH RATING IP0

ACTUATION single foot pedal (isolated low voltage circuit, IP20 splash resistant rust proof plastic pedal)

DISPERSIVE MONITOR N/A

ACTIVE INDICATION LED light, tone (defeatible)

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 8.5" w, 3.5"h, 5.75" d, not including controls and jacks 5.5# (9# shipping)

WARRANTY 2 years (exclusive of accessories)

SAFETY APPROVAL Notified Body: MET Labs

Standard: UL 60601-1 & CSA C22.2 No. 601.1

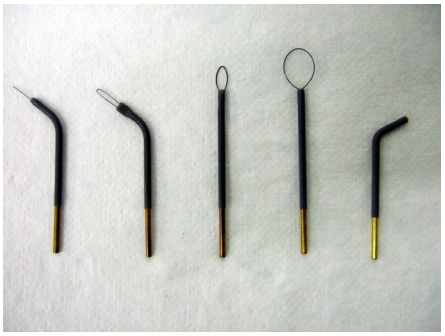
Mark: C/US "Classified" mark, registration number E112955

Tested to IEC 60601-1-1 Medical Safety

IEC 60601-1-2 Electromagnetic Compatibility

IEC 60601-1-2 High Frequency Surgical Particular Standard

REPLACEMENT PARTS



UF-F11

UF-22

UF-34

UF-35

UF-51

HPAC-1

NCS-1

DPC- 2

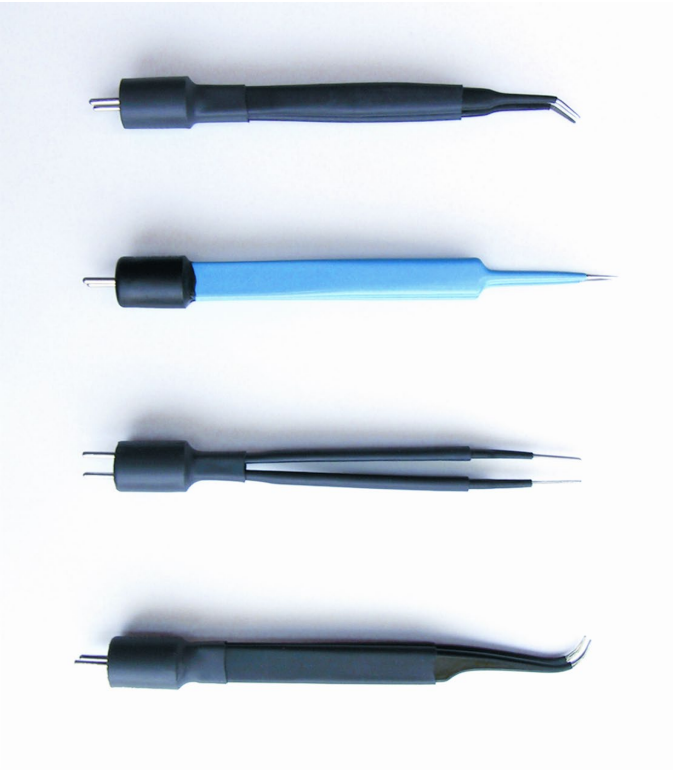
FDP-1

Foot Switch 61.102

Hospital Grade Power Cord 01.096

OPTIONAL ITEMS

Bipolar Forceps and Cable (color may vary)



BPF-C2

angled style, serrated

100mm, .75mm tips

BPF-S1

Jeweler's style, smooth

114mm, micro tip

BPF-S2

straight iris style, serrated

100mm, .75mm tip

BPF-C1

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.**

Please request the "Ultra-flex" Dental Electrode catalog or visit online.

OPTIONAL ACCESSORIES

Fulguration Adaptor

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.

Air Switch Foot Pedal, Integration into Dental Stand

No air switches are optional for the MC-4A 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 MC-4A 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

MUST READ INFORMATION!

Surgical fires occur when these essential ingredients come together in the same place at the same time:

Oxygen enriched atmosphere

Confined space

Spark or heat

Combustible material

Fire prevention is a simple and easy matter of not allowing all the 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 Manufacturing

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