Megadyne™

Geometric Electron Modulation (GEM) Technology: technical monograph

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Electrosurgical history

Electrosurgery is used in eighty percent or more of all surgical procedures today.[1] It is standard practice in a wide variety of surgical cases and continues to grow.

The first use of an electrosurgical generator in an operating room occurred on October 1, 1926 at Peter Bent Brigham Hospital in Boston,[2] enabling a surgeon to remove a portion of a tumor that could not be taken out using traditional methods, and with almost no bleeding. While so many other significant advancements have happened in general electronic technology since the 1920s, until recently, the advancements of electrosurgery have been few and far between.

Megadyne, now part of Ethicon, has been a pioneer in electrosurgery, and has been designing, innovating, and manufacturing electrosurgical products for more than thirty years.[3]

1985 — Megadyne founder, Dr. G. Marsden Blanch, develops MEGADYNE™ E-Z CLEAN™ Electrosurgical Electrode, the first PTFE coated non-stick electrosurgical tips.[4]

1990

1991 — The release of MEGADYNE™ E-Z CLEAN™ Laparoscopic Electrode provided improved dissection and coagulation for a variety of surgical applications and was a pivotal time in the electrosurgical industry, as many manufacturers looked to provide added safety and efficiency features to their offerings.

1995

1999 — The introduction of the Indicator Shaft™. The patented, inner yellow insulation shaft alerts clinicians to nicks or holes in the outer insulation, indicating it is time to discard and replace the electrode. This was yet another big leap in electrosurgical safety for both surgical staff and patients.

2000

2001 — A significant breakthrough in electrosurgery comfort and safety came with the launch of the MEGADYNE™ MEGA SOFT™ Reusable Patient Return Electrode. This pad provided an alternative to the traditional "sticky pad" and offered a new level of safety and comfort.

2005 — The MEGADYNE™ MEGA POWER™ Electrosurgical Generator was released with one goal in mind: to improve overall functionality in a surgical setting and to increase the proficiency of the surgical staff. Proprietary Advanced Cutting Effect (ACE) Mode is launched, which modulates the power to create a low voltage plasma.

2010

2015 — Megadyne launched the MEGADYNE™ ZIP-PEN™ Smoke Evacuation Pencil, which removes electrosurgical smoke from the OR. The unique design allows surgeons to experience comfortable and precise electrosurgery while minimizing the hazards of inhaling surgical smoke.

1 http://www.quickmedical.com/downloads/aaron_understanding-r2_pr.pdf **2** http://old.repertoiremag.com/Article.asp?Id=1458 **3** https://www.surgicalproductsmag.com/blog/2016/01/reflecting-decades-electrosurgery-progress **4** https://www.dicardiology.com/company/megadyne-medical-products-inc

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Introduction

What is electrosurgery?

Standard monopolar electrosurgical devices are used for cutting tissue and controlling bleeding in millions of procedures each year.[5] In simplest terms, electrosurgery is the cutting and coagulation of tissue using high-frequency electrical current. It is understood that the use of radio frequency (RF) electrosurgery causes thermal necrosis to tissue, but, for the most part, the speed of cutting and controlling of bleeding with RF energy far outweighs the amount of thermal damage created.[6] It is often considered a safer method compared with the traditional scalpel.[7]

Electrosurgical generator: traditional cut mode

Most electrosurgical generators require the Cut and Coag modes to be set prior to the surgical procedure based on the surgeon's preference. These are most commonly called "constant power modes" and are displayed in Watts (for example 30 Cut, 30 Coag).

Constant power modes work to deliver the same amount of energy to tissue regardless of the tissue impedance. Electrosurgical cutting of tissue occurs when the applied voltage reaches a minimum value of about 200 Volts[8] (the industry accepted value necessary to initiate and maintain plasma is near or just above 200 Volts,[9] depending on the actual impedance, waveform and setup).[10] Traditional electrosurgical generators utilizing constant power modes often have been associated with excessive thermal damage to tissues and have been discouraged for use on the skin for many years.[11]

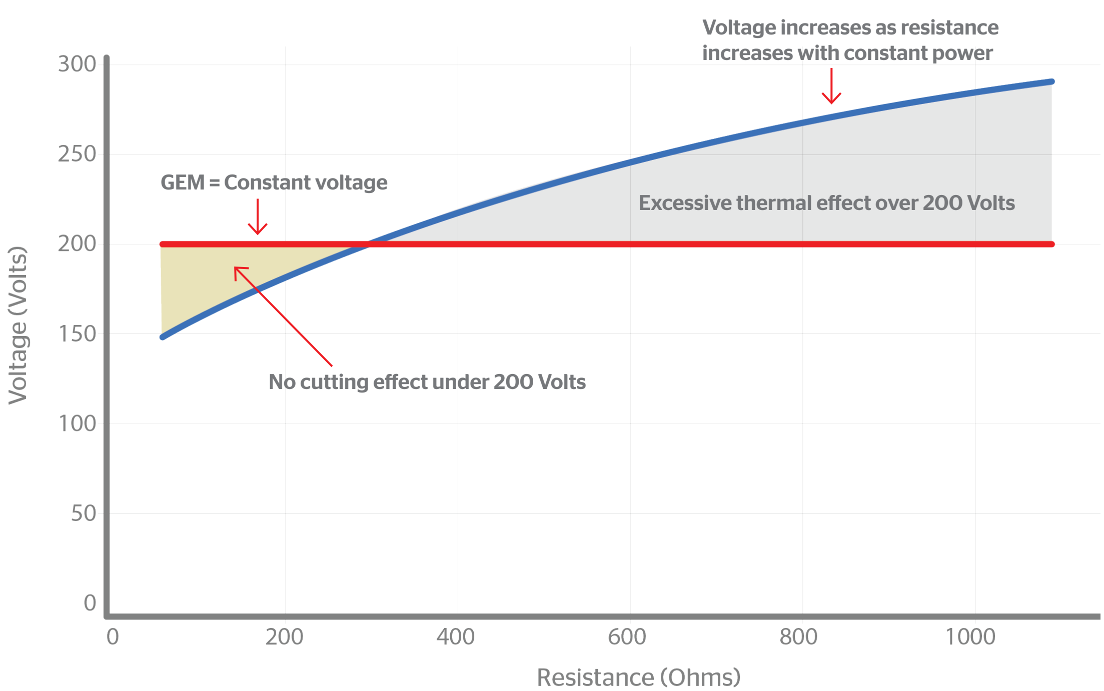
Physics: voltage vs. resistance

It is important to understand the relationships between power, current, impedance (also known as resistance) and voltage. The key terms and various formulas which demonstrate their interdependency are shown below.

V = Voltage (force to move electron charge)
i = current (flow of electron charge)
R = resistance to current flow
Ohm's Law $V = i \times R$ or $i = V / R$
Power is defined as $P = i \times V$ or $P = V^2/R$

Most electrosurgery generators use constant power modes (Pure Cut, Coag, etc.)

With constant power modes, the power output remains constant as impedance (load resistance) increases. Because $P = V^2/R$, in constant power modes, the voltage increases as the impedance (resistance) increases. Increased voltage causes thermal damage to tissue.



5 http://www.hhmglobal.com/knowledge-bank/articles/enhancing-surgical-precision-and-patient-safety-through-advancements-in-electrosurgery **6** Lewis RD, et al., Comparative damage to tissue created by the Medtronic PEAK® surgery system and the Megadyne ACE Blade® cutting system. Megadyne white paper. **7** Kisch T, Liodaki E, Kraemer R, et al. Electrocautery devices with feedback mode and teflon-coated blades create less surgical smoke for a quality improvement in the operating theater. Medicine. 2015;94(27). **8** Palanker D, Vankov A, Jayaraman P. On mechanisms of interaction in electrosurgery. New journal of physics. 2008;10(12):123022. **9** Woloszko J, Stalder KR, Brown IG. Plasma characteristics of repetitively-pulsed electrical discharges in saline solutions used for surgical procedures. IEEE transactions on plasma science. 2002;30(3):1376-1383. **10** Slivka A, Bosco JJ, Barkun AN, et al. Electrosurgical generators. Gastrointestinal endoscopy. 2003;58(5):656-660. **11** Wu AW, Baldwin TJ. Comparison of Incisions Made with ACE Blade®, Cold Steel Scalpel, and Standard Electrosurgical Blade: a Porcine, Cutaneous Wound Healing Study. Megadyne white paper.

Geometric Electron Modulation Technology

Patented Geometric Electron Modulation (GEM) Technology is a new category of intelligent energy that focuses the energy to the tapered edges of a blade and modulates the power level to create a low voltage plasma. GEM Technology maintains the constant minimum voltage required for cutting at the surgical site.

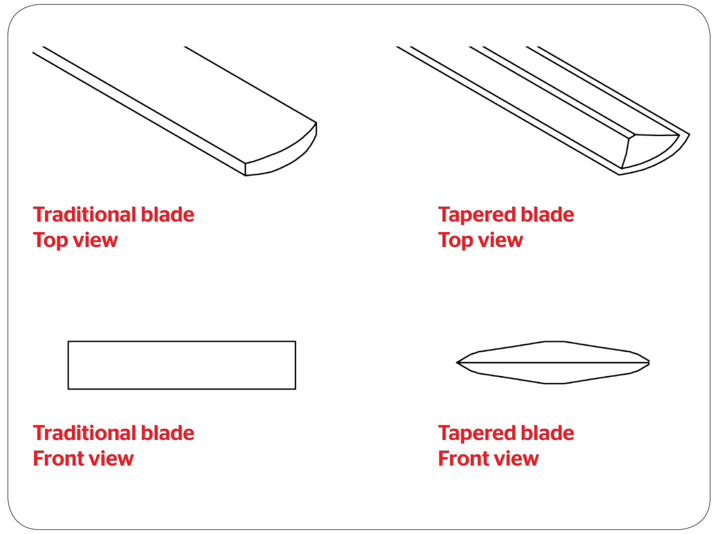
GEM Technology achieves an optimal cutting effect by optimizing voltage for the blade geometry and modulating power based on tissue impedance, resulting in significantly less thermal damage vs. standard monopolar electrosurgery.[12] To obtain a "GEM effect," there are two components required: a tapered blade and a generator mode that modulates power.

Blade design

First, the blade utilized must have tapered blade edges, so that the energy rides along a vapor film or plasma (i.e. ionized air), which is created by electrical arcs traveling from the blade to the tissue.[13]

The tapered blade edges are geometrically designed to allow plasma formation at low voltages to lyse the cells with the least amount of energy required.

In contrast, wider blades disperse the current very broadly and reduce the total energy delivered to the target tissue, minimizing the ability to form a consistent plasma and achieve effective cutting. Therefore, they require increased power to achieve the electrosurgical cutting effect.



Generator mode

Second, the generator must modulate the power in order to maintain the voltage as close as possible to the minimum voltage required for cutting at the surgical site. In order to obtain an arc plasma and cut, current is pushed by voltage from the tip to the tissue. This takes a minimum of approximately 200 Volts. Cutting with greater than 200 Volts increases thermal damage and cutting with less than 200 Volts results in minimal arcing and drag in the tissue. The ideal goal for cutting is to utilize the minimum voltage possible that will still form an arc plasma and cut.

GEM Technology uses a proprietary feedback algorithm to adjust the generator power to maintain constant minimum voltage at the surgical site as impedance dynamically changes. Different tissue types have different impedance levels, and therefore require different power levels.

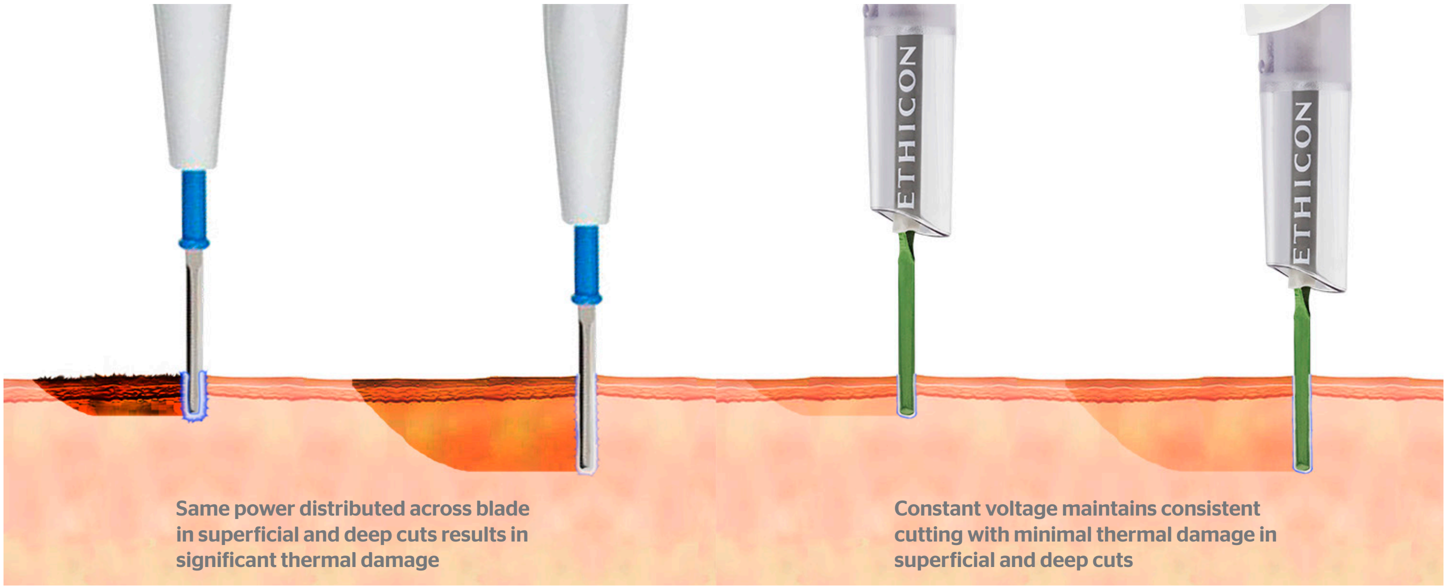
With GEM, the generator maintains 200 Volts by sensing tissue impedance and making power adjustments to hold voltage constant. As a result of this innovative technology, no power adjustments are required to be made during procedures. The constant voltage allows the user to cut through multiple different tissue types with minimal thermal damage.

12 In ACE Mode: In a preclinical porcine model on abdominal wall dermis that measured thermal damage via histology ($p<0.05$).(075571-170630) **13** Schneider Jr B, Abatti PJ. Electrical characteristics of the sparks produced by electrosurgical devices. IEEE Transactions on Biomedical Engineering. 2008;55(2):589-593.

Traditional cut mode vs. GEM Technology: a scenario

With traditional cut mode utilizing constant power, the power would be the same regardless of blade depth in the tissue. For instance, if a surgeon makes an incision to a depth of .5 inches (12.7mm), and then changes to a depth of .25 inches (6.4mm), the interface resistance is increased by approximately a factor of 2 and therefore the voltage must increase to maintain the set power. Voltage beyond 200 Volts creates added thermal damage.

However, with GEM Technology, the depth of cut does not affect thermal damage. In the same scenario, if a surgeon makes an incision to a depth of .5 inches (12.7mm), and then changes to a depth of .25 inches (6.4mm), the generator modulates the power to maintain a constant voltage of approximately 200 Volts. Therefore, the power is optimized to maintain minimal thermal damage.



Since $P = V^2/R$, the Power from the electrosurgical generator for the blade that is .25 inch (6.4mm) deep is about half that for the blade that is .5 inch (12.7mm) deep. Thus, a surgeon would need about ½ the power for ½ the depth. GEM Technology uses a proprietary feedback algorithm to adjust the generator power to maintain constant voltage at the surgical site as impedance dynamically changes.

GEM Technology in action: MEGADYNE ACE BLADE™ 700 Soft Tissue Dissector

An example of a product that utilizes GEM Technology is the MEGADYNE ACE BLADE™ 700 Soft Tissue Dissector. The MEGADYNE ACE BLADE™ 700 uses GEM Technology to create a low voltage plasma.

This multifunctional tool can be used for incision, coagulation and dissection, which may increase surgical efficiency and eliminate the need for a surgical scalpel in the OR.[14]

Notably, the MEGADYNE ACE BLADE™ 700 produces equivalent thermal necrosis to the Medtronic PEAK PlasmaBlade™ in cut setting 7[15] and produces significantly less thermal necrosis than the Medtronic PEAK PlasmaBlade™ in cut setting 9.[16]

The MEGADYNE ACE BLADE™ 700 works with the MEGADYNE™ MEGA POWER™ Electrosurgical Generator. Unlike traditional monopolar generators, the MEGADYNE™ MEGA POWER™ Generator was designed with proprietary ACE Mode that modulates the power. The ACE Mode on the MEGADYNE™ MEGA POWER™ Generator combined with the MEGADYNE ACE BLADE™ 700 produces a true "GEM Effect," resulting in significantly less thermal damage vs. standard monopolar electrosurgery.[17]

14 In a clinical study vs. cold steel scalpel that demonstrated noninferior wound healing/scar formation via the Patient Scar Assessment Scale (PSAS) (p<0.0001). Lee BJ, et al. Advanced Cutting Efect System versus Cold Steel Scalpel: Comparative Wound Healing and Scar Formation in Targeted Surgical Applications. Plast Reconstr surgery Glob open. 2014;2(10). (075570-170630) **15** In ACE Mode: In a clinical study of excised abdominal tissue that compared thermal necrosis (non-inferiority test, p<0.001). (072190-170502) **16** In ACE Mode: In a clinical study of excised abdominal tissue that compared thermal necrosis (p<0.001). (072191-170502) **17** In ACE Mode: In a preclinical porcine model on abdominal wall dermis that measured thermal damage via histology (p<0.05). (075571-170630)

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