White Paper

Shortcomings of Monopolar Electrosurgery & An Alternative Solution

C2Dx®
Thermal Scalpel

The Challenge

Monopolar electrosurgery is a widely used surgical technique that creates serious potential risks by using an electrical current to generate the heat necessary to achieve surgical outcomes. Monopolar electrosurgery (MES) conducts an electrical current through a thin electrode at the surgical site to a larger electrode on the patient's body and is used to dissect soft tissues, promote hemostasis, and destroy malignant tissues.

Although MES rapidly provides division and cauterization to the surgical site, the unintended consequences of using electrosurgery can be: **severe collateral tissue damage, nerve damage, tissue edema, seroma/fluid accumulation from tissue liquefaction, surgical smoke, as well as fire ignition hazard.**

Collateral Thermal Spread

MES collateral tissue damage is a significant surgical shortcoming that continues to be evaluated by physicians and researchers to seek a safer method of achieving hemostasis and surgical precision.[2] The electrical current used to achieve hemostasis and incise tissue causes substantial heat dissemination that readily spreads to surrounding tissues.[3]

A 2020 study concerning MES in rabbit appendectomies found that intestinal perforation was strongly correlated with the length of exposure to the electrode, as **thermal spread led to tissue damage in approximately 1.5 seconds.**[4]

The damage caused by this thermal spread can significantly diminish the viability of adjacent healthy tissue, and in specimen resection, monopolar alters the tissue sample artifact and surgical margins for pathology. Scorched tissues may swell, creating patient pain and leading to increased incidence of seroma. Potential for unintended tissue injury is intensified by the conductivity of surgical instruments and patient jewelry.

Nerve Damage

Nerve damage is a concern when MES is used because central nervous tissue does not regenerate.[5] Although peripheral nervous tissue has functional regenerative capacity, there is evidence of myelin and axon damage as a result of electrocautery.[6] A study examining injury to the sciatic nerve following three types of dissection techniques concluded that MES was responsible for a reduction in electromyographic potential far more frequently than alternative techniques.[7]

Safety Concerns

The use of MES during surgery for patients with implanted electronic devices can lead to malfunctions in how these devices interact with their target tissues. The electromagnetic interference created by MES can be mistaken for cardiac signals, thereby preventing pacemakers from responding appropriately.[8] Electrosurgery is also contraindicated for patients with cochlear implants, cardioverter-defibrillators, nerve stimulators, deep brain stimulators, and spinal cord stimulators.[9] Surgeons must be aware of the brand and specifications of each implanted device in patients undergoing an operation in order to ensure surgical and patient safety.

Smoke and Fire

Monopolar electrosurgery releases smoke as the focused electrical current destroys tissue at extremely high temperatures. Surgical smoke is not just composed of cauterized tissues - it also disperses viral and carcinogenic particulate matter in MES plumes that can be harmful for the surgical team.[10] The average daily impact of surgical smoke to the OR team is equivalent to inhaling the smoke of 27-30 unfiltered cigarettes.[11] The Association of Registered Nurses (AORN) has spearheaded a workplace safety initiative to instate policy efforts to make every state surgical-smoke free. Furthermore, the risk of fire is exacerbated by conduction through surgical instruments or by the spark within the oxygen-rich environment.[12]

THE SOLUTION– A THERMAL SCALPEL

The Hemostatix Thermal Scalpel is the only surgical instrument that uses controlled thermal energy (heat) to seal blood vessels as they are incised.

This thermal blade is a hybrid device that provides the best traits of a traditional scalpel and what IS desired from electrosurgery - WITHOUT the consequences of radiofrequency monopolar electrosurgery.

The Blades

The Hemostatix Thermal Scalpel blades are engineered for performance. The 5-layer laminated copper and stainless steel blade with a micro-printed circuit allows for precise, sharp, non-stick dissection with instantaneous heat transfer to bleeding surfaces. Surgeons can control and maintain desired blade temperatures (between 70-300°C) via a continual feedback loop. The blade can be used seamlessly with or without the application of heat, mitigating switching from a traditional steel scalpel to a monopolar.

When energized, the thermal scalpel completely insulates the patient from electrical currents and traditional grounding techniques are not required. The lack of muscle excitation creates a stable surgical field and tissue planes, enhancing operative efficiency. Small vessel bleeding and collateral tissue damage are minimized, promoting visibility during surgical procedures.

The Handle

The Hemostatix Thermal Scalpel handle provides the same, trusted feel from the traditional steel scalpel. The intuitive, built-in handle controls allow for intra-operative blade temperature adjustments while you control the speed and rate of cut depending on tissue type, density, and vascularity.

The Proof

The re-engineered Hemostatix Thermal Scalpel, previously known as the "Shaw Scalpel," has been used in over 1 million procedures over the last 40 years. It enables physicians to enhance their surgical technique and achieve extraordinary patient outcomes.

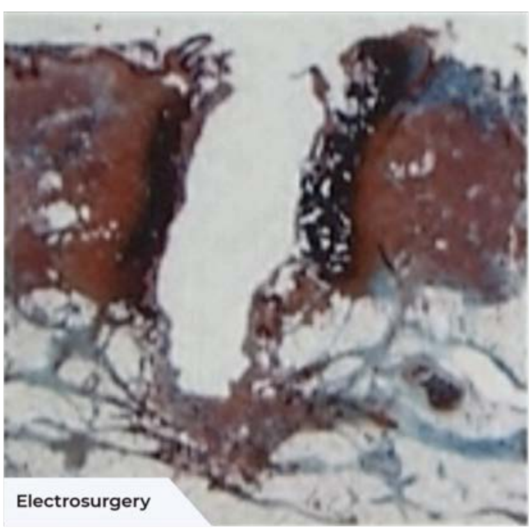
The Thermal Scalpel is an advantageous and effective surgical tool for all surgeons, particularly those who work around nerves, critical anatomy, and those focused on surgical oncology.

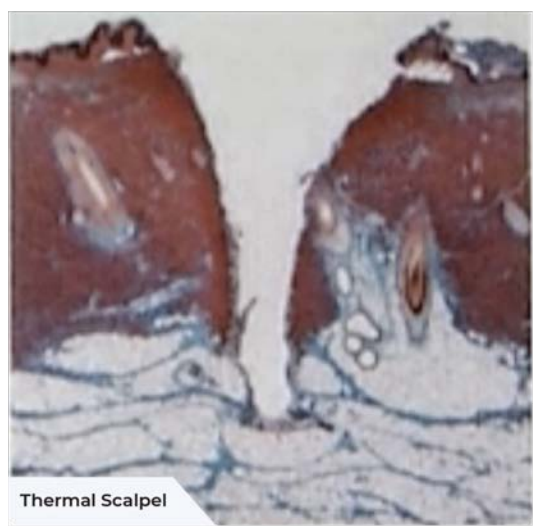
To date, this technology has greatly benefited head and neck procedures, as these are the most vascular areas of the body and require more hemostasis after dissection.[13]

Gentle on Tissue

The Hemostatix Thermal Scalpel preserves tissue as it dissects. Heat from the blade is transferred to incised tissue within a narrow margin and with no undesirable spread.
A study analyzing wound healing with the thermal scalpel compared to the "cold steel scalpel" found no statistically significant difference in healing, from both a histologic and tensile strength perspective, at the 8-week post-operative time.[14] Moreover, another study concluded a reduced incidence of nerve weakening and recovery time compared to traditional methods.[15] When comparing traditional hemostatic methods, such as MES and Raney Clips, Raney Clips resulted in the greatest alopecia width.[16]

Dissected Tissue Comparison





No Nerve Damage

A study evaluating parotid gland surgeries found that only 31% of patients who underwent a superficial parotidectomy via thermal scalpel experienced temporary partial facial nerve paralysis, versus 43% of patients who were operated on with electrocautery.[15]

The Proof (continued)

Safety and Control

The Hemostatix Thermal Scalpel is a safe dissection instrument for patients with CIEDs. A patient with breast cancer was scheduled for a mastectomy 2 cm away from her pacemaker, and the Hemostatix Thermal Scalpel System ensured successful tissue removal while protecting the electrical function of the pacemaker.[17]

While electrosurgery is contraindicated for cochlear implant surgery due to the electrical current, the Hemostatix Thermal Scalpel can be used to safely implant and replace such devices without compromising their internal components.[18]

> "It has become an indispensable part of my surgical technique. It minimizes blood loss for the patient, maximizes my surgical efficiency, and nicely preserves visibility during my dissection. It has a limited radius of energy dispersion which is essential for working in the crowded anatomy of the neck where many important nerves and other structures are in close proximity." – Donald B. Kamerer Jr., MD

Smoke-Free

The absence of a high-temperature electric current in the surgery site not only promotes better visibility for dissection but also promotes enhanced patient safety. The Thermal Scalpel modernizes the operating room by eliminating the risk of potentially carcinogenic and viral smoke plumes.[19] The Thermal Scalpel will become an integral part of your operative suite clean air initiatives. Although surgical masks provide some protection from surgical smoke, the particles released into the air via traditional electrosurgery are preventable risks that are currently present in every procedure.[20]

The Hemostatix Thermal Scalpel ensures complete protection from fire, and potentially dangerous airborne particles, by preventing the release of particles at the surgical site due to the transfer of precise heat to tissue, rather than radiofrequency MES.

About C2Dx

C2Dx is a medical device company that acquires and invests in underserved products to propel their impact worldwide.

Founded in early 2019 by industry experts, C2Dx is committed to providing leading medical products and superior customer service while continually evolving to ensure that healthcare providers have the devices and technology they need.

Contact C2Dx to learn how the Hemostatix Thermal Scalpel can lessen tissue damage during surgical procedures

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Sources

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