

White Paper: Technology and Clinical Overview of the Genii TouchSoft Coagulator® monopolar probe

Prepared by Genii, Inc. St. Paul, MN, January 2012. (Updated April, 2015)
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US Endoscopy acquired Genii, Inc. on April 7th, 2017

Introduction

The Genii TouchSoft Coagulator® monopolar probe (TSC) is indicated for use through flexible endoscopes to provide monopolar hemostasis or tissue ablation in the gastrointestinal tract. It was developed specifically to meet a need for a lower cost alternative to argon plasma coagulation or bipolar coagulation for small, discrete lesions and to take advantage of the increasing prevalence of low voltage, depth limited, electrosurgery generator outputs. These contact coagulation outputs are typically known by such names as TouchSoft® coagulation, Gentle Coag, Soft Coag®, and the like*.

While the TSC is an ideal design for newer TouchSoft® coagulation, and other low voltage, depth limited, contact coagulation outputs, it can also successfully be used with standard coagulation (“Coag”) outputs of the type commonly used for polypectomy.

The TSC has a Teflon sheath, 2.3 mm outer diameter, and a working length of 300 cm. It is compatible with all flexible endoscopes that can accommodate these dimensions. The product is shipped sterile and is intended for single use.

Certifications

The TSC has been certified to meet all IEC 60601-2-2 electrical standards for a high frequency rating of 6 kilo volts peak to peak. The TSC has passed all applicable biocompatibility testing and was cleared by FDA August 2, 2010 (K093079). The product is manufactured and sterilized in an ISO 13485 Registered CE and FDA compliant facility in the United States.

Current Use

The TSC was released for sale on May 12, 2011. Since then, it has been used on more than 4,000 patients with no reported complications. Physicians report successful use of the TSC for hemostasis or residual polyp tissue cleanup after cold biopsy of small sessile polyps, hemostasis or residual polyp tissue cleanup after snare polypectomy, and hemostasis of discrete oozing or bleeding lesions, AVMs, ESD applications and others.



TouchSoft Coagulator[®]
 monopolar probe treatment
 of a Jejunal Angioectasias
 during Double-Balloon
 Endoscopy.

Electrosurgery Generator Considerations

In electrosurgery, the terms monopolar and bipolar refer to the way the circuit is completed. In a monopolar application all of the energy leaving the active electrode (snare, TSC, sphinctertome, etc) at the treatment site returns to the generator via a dispersive (grounding) pad. In a bipolar (or multipolar) application all of the output energy both leaves and returns to the generator through the accessory (BiCap, GoldProbe and others).

The final tissue effect from the use of any type of electrosurgery is most determined by the tissue, the type of accessory (broad surface or thin wire for example), the type of waveform (coag, cut, etc), the power curve (how the microprocessor responds to changing impedance during the power application), the time that the operator delivers power, and the power setting (in watts). The final tissue effect is much less dependent on the way the circuit is completed (bi, multi, or mono polar). Bipolar circuits may sometimes be more advantageous for some patients including those with some types of implanted devices.

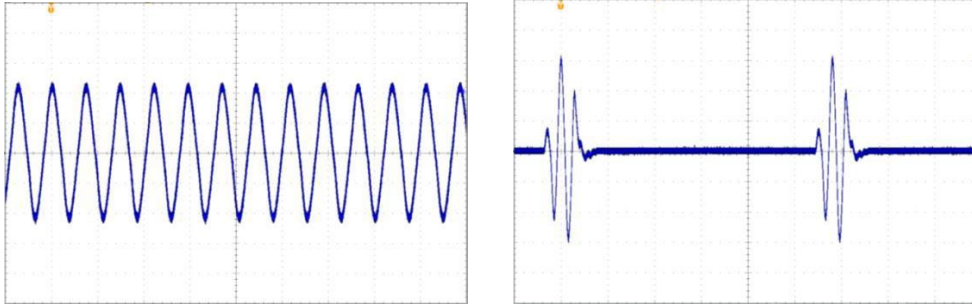
Accessory choice, power selected and time of power delivery is quite straightforward; nearly entirely operator dependent, and will not be addressed further here, nor will differences in impedances of tissue types. The waveform type and power curve both affect an understanding of the technology associated with the TSC and will be reviewed.

Electrosurgery (ES) technology depends on high frequency alternating current delivered in one of two wave form patterns: continuous or modulated. In a continuous waveform, power is flowing 100% of the time that the operator is pressing the activation foot pedal. Continuous high frequency sine waves are associated with electrosurgical cutting if they reach peak voltages over 200 which can create a high enough current density to heat cellular water so quickly that the cell membranes burst. These bursting cells along a cleavage plane are what we refer to as electrosurgical cutting.

Continuous waveforms held below this 200 Vp threshold are too weak to initiate cutting or to drive coagulation deeply into tissue. Consequently they are an ideal waveform for gentle, limited depth, contact coagulation.

To increase coagulation and hemostasis further, and to balance the 'blend' of cutting and coagulation, waveforms are interrupted or *modulated* to allow slower heating with lower current density. Voltage peaks are increased to drive the coagulation deeper into tissue. Names given to particular waveforms are not standardized, but typical "Coag" waveforms are modulated, being interrupted with the "off" or 'resting' cycle taking up 94% of the time (a 6% duty cycle) that a foot pedal is depressed.

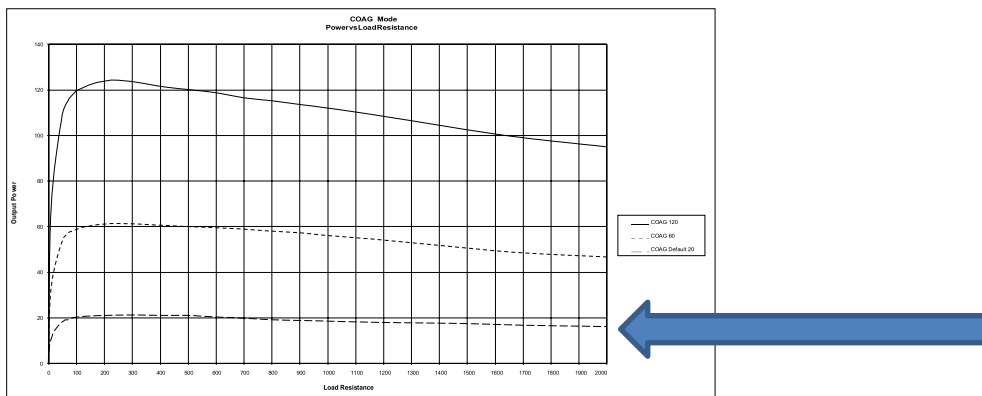
A continuous waveform is shown on the left, a modulated type on the right:



As tissue becomes coagulated, it becomes more resistant to electric flow. Electrosurgery follows the law of Ohms which dictates that as this impedance rises, the power must decrease unless either the voltage or the current rises to compensate. Modern ES units use microprocessor control to manage this impedance to output ratio. A graph of the power versus the rise in impedance over time is referred to as a “power curve”. It is used to demonstrate how the software has been designed to change the power delivered in changing impedance conditions.

Shown below are examples of widely available power curves. Note that in each case the microprocessor is responding to increasing impedance with increasing coagulation (increasing from left to right along the horizontal axis). Three initial power settings are shown on the vertical axis. Note the blue arrow. It shows that at the initial power setting of twenty watts, this microprocessor is maintaining the power output pretty much constantly over time as the tissue becomes increasingly coagulated and impedance is increasing.

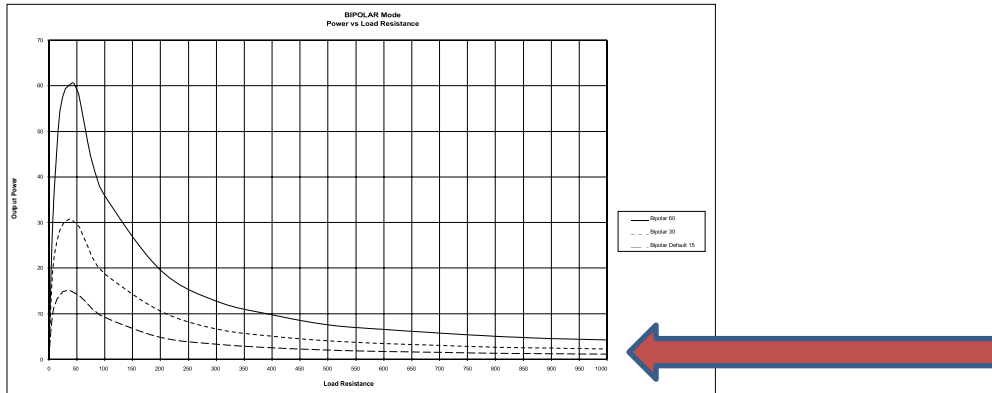
A usual “Broad” power curve (often used for polypectomy)



Note the red arrow below. This graph shows an ideal power curve for use with a bipolar endostasis probe (BiCap or Goldprobe) in GI. The selected power ramps up quickly in the low impedance beginning stage (as in frank blood) to produce coagulation quickly; but the power drops off rapidly as the tissue impedance increases over time with continued application of power. By the time that tissue is observed clinically to be quite ‘white’ and coagulated, the power still being delivered is less than 3 or 4

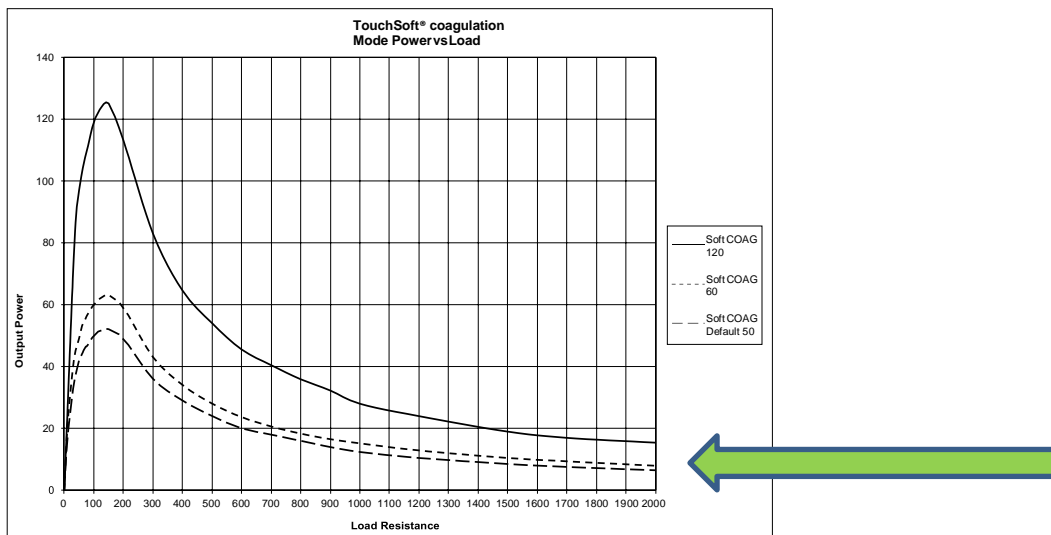
watts. This 'drop off' from the starting power is what gives these therapies their desired self-limiting tissue effect. They tend to produce coagulation with a limited depth of injury.

A "Narrow" Bipolar power curve



Note the Green arrow below which points out how similar a TouchSoft® coagulation power curve is to the Ideal outputs for GI bipolar. The initial power is set higher to be able to 'drive' a monopolar circuit, but the power still ramps up quickly and drops off quickly to give the self-limited, superficial tissue effect which is so desirable.

A TouchSoft® coagulation "Narrow" power curve

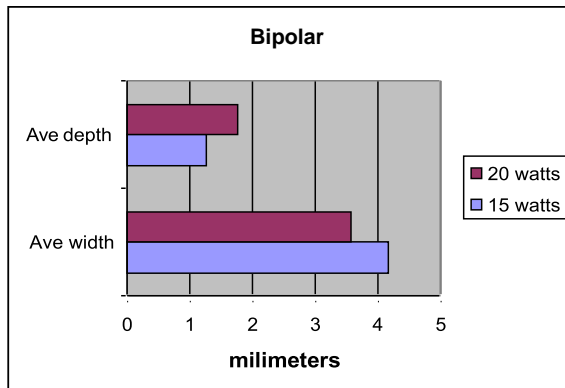


Most newer electrosurgery generators marketed to GI include correct waveforms for bipolar probes and TouchSoft® coagulation or Soft Coag® outputs similar to these graphs. They all control voltage peaks to stay under about 200Vp most of the time, which means that no electrosurgical cutting is promoted. Only gentle, limited depth coagulation is created.

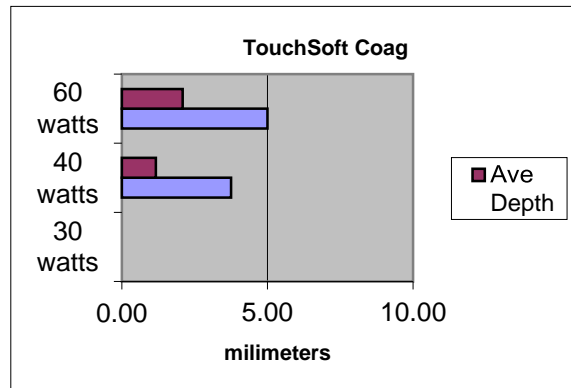
TouchSoft® coagulation Pre-Clinical Performance Data

The following data was generated from a third-party testing lab using an ex vivo tissue model protocol. Three generator outputs were tested: Bipolar, TouchSoft® coagulation and a standard Coag output labeled "Forced". Accessories tested were the TouchSoft Coagulator® monopolar probe and a commercially available brand of bipolar endostasis probe.

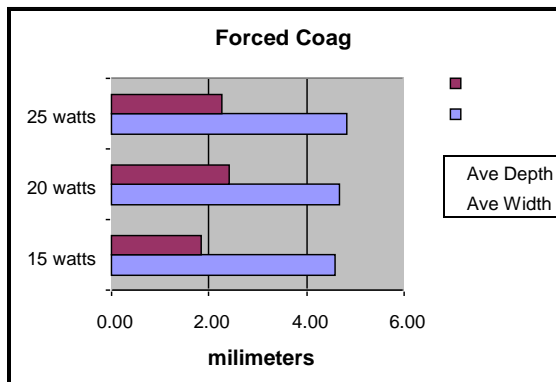
Bipolar Probe with Bipolar output.



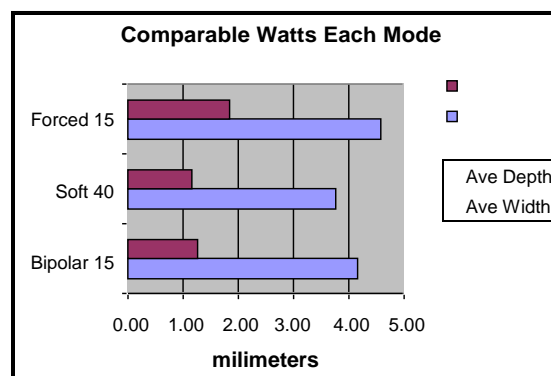
TouchSoft Coagulator® monopolar probe with TouchSoft® coagulation output.



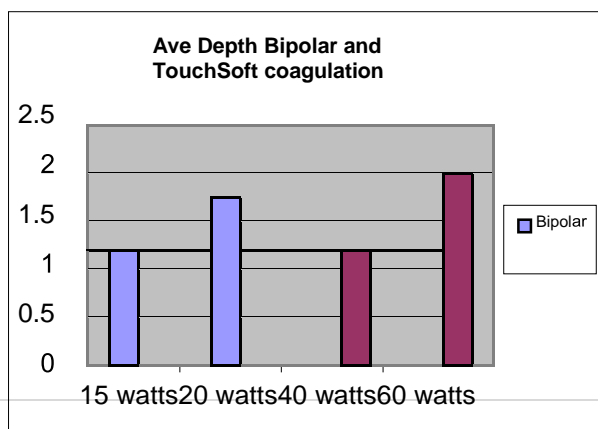
TouchSoft Coagulator® with Standard Coag (Forced)



Power settings comparable per output mode.



TouchSoft Coagulator® monopolar probe with Bipolar and TouchSoft® coagulation output modes



Conclusion

If width measurement alone is used, a Bipolar application of 20 watts is most like a TouchSoft® coagulation waveform with the TouchSoft Coagulator® monopolar probe at 40 watts. For depth, TS with TouchSoft Coagulator® monopolar probe at 40 is most like Bipolar at 15. TS with Forced Coag 25 watts is most like TS with TouchSoft® coagulation at 60 watts.

In all cases, the tissue effect produced and performance of the TouchSoft Coagulator® monopolar probe falls within the expected ranges of similar devices. It is anticipated that in the clinical setting, the TS will produce safe and efficacious results comparable to current technology.

Genii gi4000 settings recommendation

With TouchSoft® coagulation, Soft Coag® or other low voltage, depth limited modes, it is recommended that the physician begin between a range of 40 to 60 watts. 50 is a good starting point. A range of 20 to 30 watts as a start point is best for a Conmed 6500 Beamer “Gentle” output mode. If a standard, wide power curve “Coag” (“Standard”) mode is used, the recommendation is that a power setting of 25 watts or less be used and the physician should carefully limit the application time. Please see the “Instructions for Use” insert shipped with each box of TouchSoft Coagulator® monopolar probes for complete information.

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