

# A simplified, low power system for effective vessel sealing

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## ABSTRACT

The first bipolar vessel sealing system was developed nearly 15 years ago and has since become standard of care in surgery. These systems make use of radio frequency current that is delivered between bipolar graspers to permanently seal arteries, veins and tissue bundles. Conventional vessel sealing generators are based off traditional electrosurgery generator architecture and deliver high power (150-300 Watts) and high current using complex control and sense algorithms to adjust the output for vessel sealing applications. In recent years, a need for small-scale surgical vessel sealers has developed as surgeons strive to further reduce their footprint on patients. There are many technical challenges associated with miniaturization of vessel sealing devices including maintaining electrical isolation while delivering high current in a saline environment. Research into creating a small, 3mm diameter vessel sealer revealed that a highly simplified generator system could be used to achieve excellent results and subsequently a low power vessel sealing system was developed. This system delivers 25 Watts constant power while limiting voltage ( $\leq 80$  V<sub>rms</sub>) and current ( $\leq 2$  Amps) until an impedance endpoint is achieved, eliminating the use of complicated control and sensing software. The result is optimized tissue effect, where high seal strength is maintained ( $> 360$ mmHg), but seal times ( $1.7 \pm 0.7$ s versus  $4.1 \pm 0.7$ s), thermal spread ( $< 1$ mm vs  $\leq 2$ mm) and total energy delivery are reduced, when compared to an existing high power system.

**Keywords:** electrosurgery, advanced bipolar, vessel sealing, low power, tissue effect

## 1. INTRODUCTION

The methods for ligating vessels in open and laparoscopic surgery have evolved in both technique and effectiveness since the advent of energy-based surgery devices. The applications for monopolar ES, standard bipolar and ultrasonic coagulation and vessel sealing systems are broad and overlapping<sup>1,2,3</sup>. A recent development in radio frequency (RF) bipolar vessel sealing, comprising a low-power energy delivery system designed for small scale instruments, will be described along with a discussion of its quantitative and qualitative benefits.

## 2. TRADITIONAL RADIOFREQUENCY GENERATOR POWER DELIVERY

### 2.1 Standard bipolar

The benefits and limitations of monopolar and standard bipolar coagulation for sealing vessels and tissue bundles are well known<sup>1,3,4,5</sup>. Standard bipolar generators deliver RF energy at high power (95 Watts) and high voltage ( $\geq 350$  V<sub>rms</sub>), but at the expense of current ( $< 0.4$ A)<sup>6</sup>. Without temperature sufficient to melt elastin, vessel wall fusion is not achieved, thus standard bipolar is not a robust option for larger vessels ( $> 2$ mm)<sup>5</sup>.

### 2.2 Traditional vessel sealing

RF vessel sealing generators on the market today vary from standard bipolar in that they deliver high power (up to 350W) with relatively low voltage ( $< 200$ V<sub>rms</sub>) and high current (3.5-5.5A)<sup>6</sup>. Lower voltage is necessary to reduce arcing and tissue sticking, which drives high current believed necessary to fuse tissue. These generators are designed to power a variety of instruments with end effectors of different shapes and sizes, delivering energy to variable tissue loads. The

result is an extensive architecture platform with complicated control and sense software. The generators monitor and respond to changes in impedance with real-time power modifications, until an impedance endpoint is reached.

### 3. LOW POWER VESSEL SEALING

#### 3.1 Description of JustRight Surgical® Vessel Sealing System

Current vessel sealing instruments range from 5 – 10mm in shaft diameter with large jaw surfaces designed to accommodate vessels up to 7mm in diameter. However, when working in small, delicate spaces where access is limited, a shorter jaw and shaft length can allow more dexterity and greater visibility to benefit the surgeon. Smaller diameter instruments allow for smaller incisions which may offer improved cosmesis, smaller wounds and less pain.

When designing small bipolar ES instruments, insulation and isolation of electrical connections becomes challenging, specifically when working with the high voltages of traditional vessel sealing. Reducing the dielectric requirements of the insulation is one way to mitigate these challenges. As a result, a low power, low voltage vessel sealing system was developed.

The JustRight Surgical® Vessel Sealing System comprises a generator and a disposable, 3mm hand piece, shown in Figure 1. The hand piece is connected to the generator via cable and is button-activated. The instrument has a 20cm shaft length, 3mm shaft diameter with Maryland style, dual-action jaws. The device, approximately four times smaller than other existing sealing instruments, is capable of grasping, dissecting and sealing vessels up to 5mm in diameter. The vessel size limit is a function of the jaw length rather than a limitation of the technology. The reduced jaw length controls the tissue volume to which the generator must respond. A ratcheting handle provides requisite jaw pressure to appose the vessel walls for tissue fusion.



Figure 1. JustRight Surgical® Vessel Sealing System

The RF generator delivers up to 25 Watts of constant power and is voltage limited to 80 Volts<sub>rms</sub> maximum and operates under 2 Amperes of current. A typical output power curve as a function of impedance is shown in Figure 2.

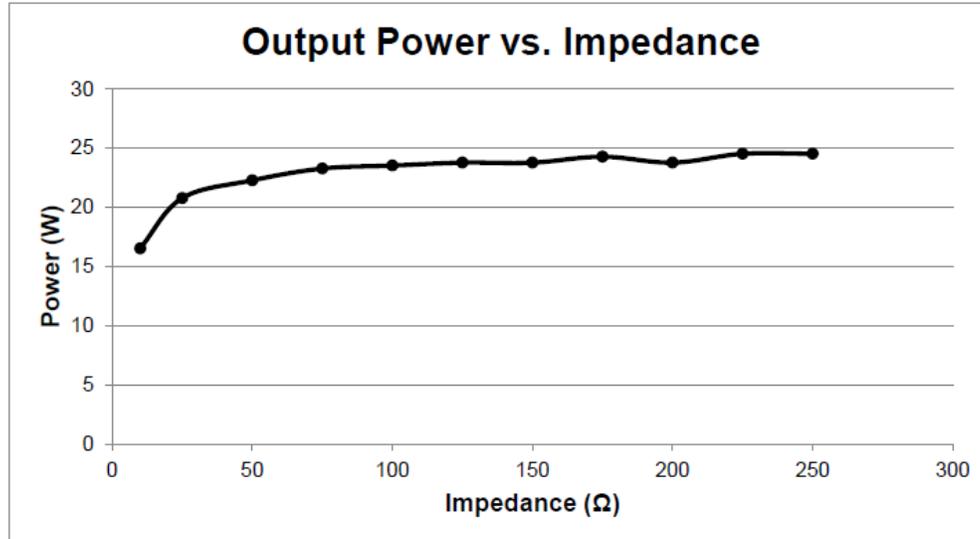


Figure 2. Output Power vs. Impedance Graph for JustRight™ Generator

The generator was designed with simplicity in mind. A basic user interface, with no adjustments or input capability, allows the surgical staff to “plug and go.” With moderate, fixed tissue volume, no real-time power adjustments are necessary, allowing for simplified software architecture. The control algorithm confines the operational parameters to deliver non-pulsing power with the specific current and voltage limits, with a simple impedance shutoff point. This differs from traditional RF vessel sealing power delivery, in that the power is not cycled in response to changes in tissue impedance. Rather, the current flow is limited in response to the rising impedance of the tissue while constant power is maintained. As a result, there is no stored energy which must be dispersed at the end of the sealing cycle. This design results in reduced occurrence of arcing and charring.

Low operating voltages reduce the potential leakage current as well as the dielectric requirements to isolate conducting components within the instrument. Lower operating current is possible because critical current density can be achieved with the instrument’s reduced jaw surface area.

### 3.2 Bench performance

Seal quality, seal time, vessel pressure and thermal spread were evaluated. Results of the JustRight™ sealing system were compared to those of an existing vessel sealing device, Covidien’s LigaSure™ 1000 (LS1000). Testing was conducted on arteries, veins and tissue bundles ranging from 1.5 – 7mm in diameter, within porcine models. Renal vessels were used for bench pressure testing. *In vivo* testing, to include thermal spread evaluation and a chronic study, was conducted using a variety of splenic, saphenous, epigastric, mesometrium, uterine, and ovarian vessels.

To assess seal quality, 30 vessels were sealed using the JustRight™ sealing system and 30 vessels were sealed using the LigaSure™ sealing system. Optimal seal quality was characterized by translucency and plastic resistance to deformation. Unacceptable results include tissue charring, opaque seal site or visible vessel lumen. Seal quality was scored on a scale of 1 – 3 (3 being optimal). All seals in both groups showed acceptable qualitative seal quality. A representative photo of a vessel sealed using the JustRight™ system is shown in Figure 3.



Figure 3. Porcine renal artery sealed using the JustRight Surgical® Vessel Sealing System

Seal time was evaluated by sealing 30 vessels using the JustRight™ sealing system and 30 vessels using LigaSure™ technology. Equivalent vessel diameters were selected for each time comparison, ranging from 2-7mm. Seal duration was measured by a blind, independent observer. The JustRight™ system produced seals more quickly ( $p < 0.001$ ), averaging  $1.7 \pm 0.7$  seconds. Average time using the LigaSure™ System was  $4.1 \pm 0.7$ s.

Vessel seal strength was evaluated by cannulating and infusing sealed vessels with saline and pressurizing arteries to three times systolic pressure, or 360mmHg, and holding for 15 seconds. Veins were pressurized to three times venous systolic pressure, or 45mmHg. 30 of 30 seals created with the JustRight™ sealing system met the acceptance criteria. 29 of 30 seals created using LigaSure™ met the acceptance criteria.

Six vessels (epigastric and saphenous arteries, veins and bundles) ranging from 3-7mm were sealed with each device, *in vivo*, and harvested for the thermal spread study. Photomicrographs of picosirius red stained sections were taken of each artery, vein or bundle at 50x (artery) or 25x (vein, bundle). Thermal spread measurements were collected by using a combination of polarized and non-polarized imaging techniques and analyzed by an independent pathologist. All measurements of lateral thermal spread were less than 1mm for both devices. While not statistically different, there was a trend toward increased damage with the Covidien device in veins and bundled arteries and veins. Current published literature for the LigaSure™ sealing system indicates thermal spread less than 2mm.

These data show that the JustRight™ sealing system is at least equivalent in performance to the LigaSure™ sealing system. A sample histology slide of an artery sealed using the JustRight™ sealing system is provided in Figure 4.



Figure 4. Histology slide of porcine saphenous artery sealed using JustRight Surgical® Vessel Sealing System (50x).

#### 4. DISCUSSION

The optimization of the JustRight™ Generator to operate at low power and low voltage is a benefit to the surgical environment in a number of ways. Low power over time results in less energy being delivered in to the operating cavity. Low voltage minimizes the potential for arcing and reduced current limits tissue charring and other damaging tissue

effects. The result is reduced heat and volatility when working in confined spaces. With a small jaw comes improved visibility within the operating window. Reduced thermal mass of the jaw limits the potential for thermal damage to adjacent tissue and, coupled with shorter seal times, permits the surgeon to quickly and efficiently attend to the target tissue structure. The bilateral actuation of the jaws provides precise dissecting and grasping capabilities, making the device a multi-functional instrument. When using the JustRight™ Sealer as the primary instrument, fewer instrument exchanges are required, allowing for streamlined operating technique.

## 5. CONCLUSION

The simplified, low power RF vessel sealing system described above represents a significant advancement in tissue sealing technology. It produces clinical results that are at least equivalent to vessel sealing technology which exists today, with added benefits of improved visualization, dexterity and reduced seal time. This development allows surgeons working in confined spaces to advance their technique with the necessary instrumentation and confidence in seal quality that currently exists in general surgery.

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