

PRODUCT FACT SHEET

For decades, surgeons have relied on scalpels to cut skin and delicate tissues and have used electro-surgical devices to cut and coagulate fat and other thicker, tougher tissues. Although scalpels precisely cut tissue, they do not control bleeding. Electro-surgical devices, on the other hand, cut efficiently and control bleeding but cause extensive thermal damage to surrounding tissue. In cases where the risk of collateral damage or scarring from electro-surgery is considered to be unacceptable, surgeons must use both a traditional scalpel for cutting and an electro-surgical device for coagulation.

PEAK Surgical's flagship product, the PEAK[®] Surgery System, includes the **PULSAR[®] Generator** and the **PEAK PlasmaBlade[™]** family of disposable, low-temperature surgical cutting and coagulation devices. The generator supplies pulsed plasma radiofrequency energy to the PlasmaBlade to incise tissue and control bleeding, while the PlasmaBlade offers the precision of a scalpel and the bleeding control of a traditional electro-surgery device in a single surgical device. By combining these, the PEAK Surgery System is expected to revolutionize the way surgery is performed today.

The PEAK Surgery System is cleared for use in the United States for general, plastic and reconstructive, ENT (ear, nose and throat), gynecologic, orthopedic, arthroscopic, spinal and neurological surgical procedures, and for use in general surgery in the EU. Since U.S. Food and Drug Administration clearance was received in July 2008, surgeons in the United States have used the PlasmaBlade in more than 1,200 surgical procedures.

The following **PlasmaBlade** tissue dissection tools are FDA-cleared and commercially available:



- The PlasmaBlade 4.0, which is designed to be used to cut through all types of soft tissue, including skin, fat and muscle
- The PlasmaBlade Needle, which has a fine needlepoint tip and is specifically designed for ultra-precise surgical procedures
- The PlasmaBlade EXT, which is designed for use in surgical procedures, requires an extended-reach tip



Unlike most radiofrequency-based surgical products that use continuous voltage waveforms to cut tissue, the **PULSAR Generator** supplies pulsed plasma-mediated electrical discharges through the PlasmaBlade. Because the radiofrequency energy is provided through short on-and-off pulses via a highly insulated cutting electrode, the PlasmaBlade cuts at an average temperature that is half that of a conventional electro-surgery device and can be as low as 50 degrees Centigrade. This temperature reduction results in significantly less damage to surrounding tissues compared to traditional electro-surgical devices. The PlasmaBlade can dissect tissue in a wet or dry surgical field.

The PlasmaBlade provides surgeons with a single tool that offers:

- the precision of a traditional scalpel;
- the bleeding control of an electrosurgery device;
- the ability to quickly and easily cut through all types of soft tissue, including skin, fat and muscle;
- the ability to dissect in a wet or dry surgical field;
- the ability to cut tissue at an average temperature that is half that of a conventional electrosurgery device, which results in reduced heat transfer and significantly less damage to surrounding tissues compared with traditional electrosurgical devices.

Results Validated in Clinical Studies

PEAK Surgical has initiated a series of clinical studies, called the PRECISE Studies (Pulsed Plasma Radiofrequency Energy to Reduce Thermal Injury and Improve Surgical HEaling), to evaluate the use of the PEAK Surgery System in plastic and reconstructive, gynecologic and oncologic surgery.

The first of a series of PRECISE Outcomes studies focused on patient recovery following abdominoplasty and showed that PlasmaBlade patients demonstrated a better overall recovery than Standard of Care patients (scalpel and traditional electrosurgery).

Compared to the Standard of Care, PlasmaBlade patients demonstrated:

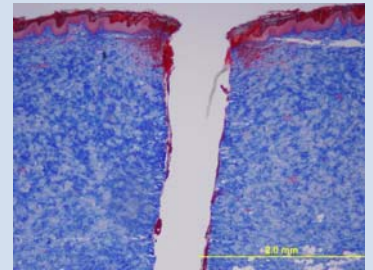
- 34% improved reported diet volume over 10 post-operative days ($p < 0.05$)
- 26% improved reported activity level over 10 post-operative days ($p = 0.09$)
- 57% less drop in Hemoglobin ($1.6 \pm 0.7g$ vs. $0.7 \pm 0.2g$, $p = 0.07$)
- Equivalent skin scarring compared to scalpel ($p < 0.05$)
- Equivalent operative time ($p < 0.05$)
- 75% less thermal injury depth in adjacent tissue ($p < 0.005$)
- 65% and 42% stronger healed wound strength at 3 and 6 weeks ($p < 0.005$)

Based on these clinical results and other results from preclinical studies, PEAK Surgical believes that the PlasmaBlade offers a new alternative for surgeons to provide better outcomes for their patients, including increased procedure efficiency, reduced scarring, faster and stronger wound healing and faster recovery.

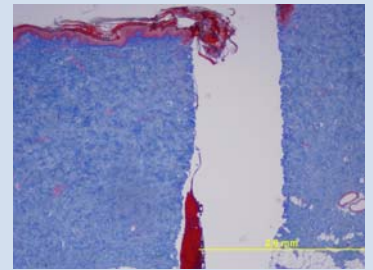
Advantages of the PEAK PlasmaBlade

LESS THERMAL DAMAGE

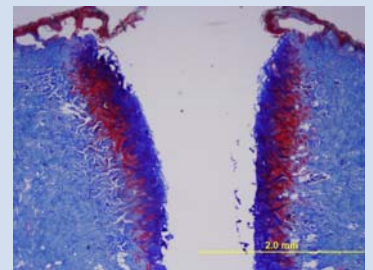
The PlasmaBlade is associated with significantly less thermal damage and stronger wound healing than traditional electrosurgery.



Scalpel



PEAK PlasmaBlade



Traditional Electrosurgery

STRONGER WOUND HEALING

Wounds made by the PlasmaBlade healed as quickly as a scalpel. After six weeks, they were three times stronger than wounds made by traditional electrosurgery.

LESS SURGICAL SMOKE

The PlasmaBlade significantly reduces surgical smoke, compared to traditional electrosurgery.

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