PLASMABLADE™

FOR PLASTIC AND RECONSTRUCTIVE SURGERY

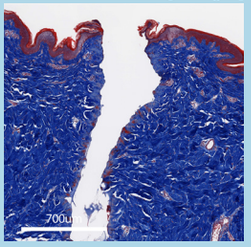
Medtronic

THE PLASMABLADE™ ADVANTAGE

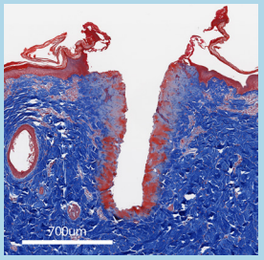
The PlasmaBlade™ is a unique soft tissue dissection instrument that uses very brief (40µs range) pulses of radio frequency (RF) energy to induce electrical plasma along the edge of a thin (12.5µm), 99.5% insulated electrode. Due to the low duty cycle and proprietary Thermal Protection Shield (TPS) insulation technology, it uses less total energy and operates at significantly lower temperatures than traditional electrosurgical technology (40 - 170°C vs. 200 - 350°C).[1,*] Clinical studies have shown that the PlasmaBlade™ reduces thermal damage to soft tissue during dissection compared to traditional electrosurgery,[2,**] which is critical for plastic and reconstruction procedures.

Plastic and reconstructive surgical techniques continue to evolve towards the least invasive approach – minimizing soft tissue damage and operative time to optimize post-operative outcomes. Surgical instruments play a critical role in this process. Traditional electrosurgery is associated with significant thermal damage to surrounding tissue during dissection and bleeding control.[2] This thermal necrosis has been shown to negatively affect wound healing[2] and the post-operative course.[3,4] In large tissue reduction surgeries requiring extensive electrosurgical dissection, such as abdominoplasty, reduction mammoplasty, and flap reconstructions, this effect may be magnified.

Thermal injury profile[8]



PlasmaBlade™ CUT 6

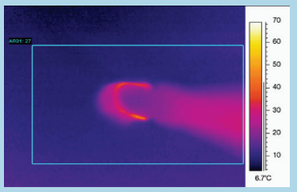


Traditional electrosurgery CUT 35W

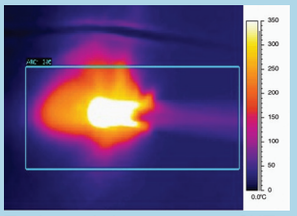
One device from skin-to-skin

- Reduced inflammatory response following skin incision compared to traditional electrosurgery[2,***]
- Reduced mean drainage volume and duration following mastectomy compared to traditional electrosurgery[3]
- 24% more grams of tissue dissected per minute than traditional electrosurgery (p=0.0 002)[5,**]
- Equivalent healed incision strength, inflammatory cell counts, and healed scar width compared to scalpel[2,6,7,**]

Operating temperature[1]



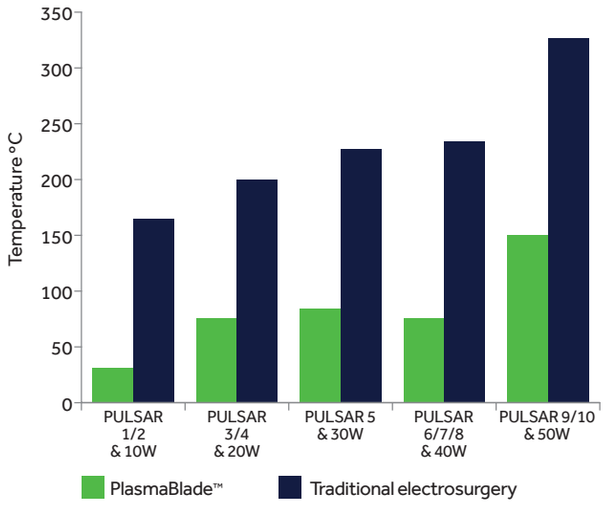
PlasmaBlade™ CUT 6



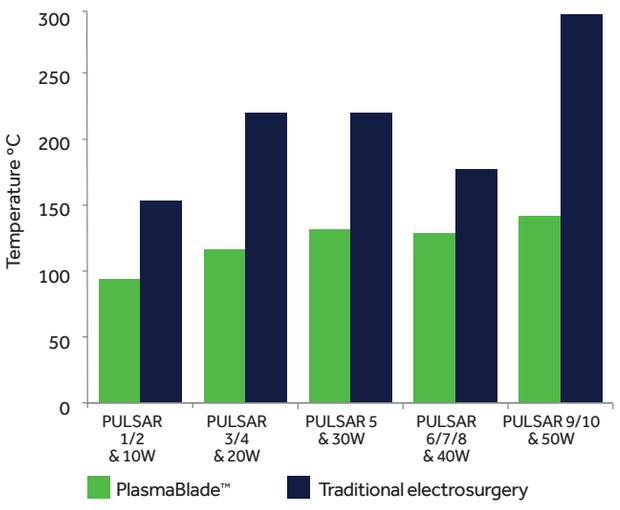
Traditional electrosurgery CUT 35W

Operating temperature profile[1]

PlasmaBlade™ CUT Mode Temperature vs. Traditional Electrosurgery



PlasmaBlade™ COAG Mode Temperature vs. Traditional Electrosurgery



“We wouldn’t think of doing a nipple sparing mastectomy without using this device.”

William L. Scarlett, D.O., FACS
Associate Professor of Plastic Surgery
PCOM Philadelphia PA

Ordering Information

Description	Catalog Number
PlasmaBlade™ 4.0	PS200-040
PlasmaBlade™ 3.0S	PS210-030S
AEX™ Generator	40-405-1

Rx only. Refer to product instruction manual/package insert for instructions, warnings, precautions and contraindications.

References

1. Data on file. PEAK PlasmaBlade operating temperature study summary. 71-10-2475.
2. Ruidiaz ME, Messmer D, Atmodjo DY, et al. Comparative healing of human cutaneous surgical incisions created by the PEAK PlasmaBlade, conventional electrosurgery, and a standard scalpel. *Plast Reconstr Surg*. 2011 Jul;128(1):104-111.
3. Dogan L, Gulcelik MA, Yuksel M, et al. The effect of plasmakinetic cautery on wound healing and complications in mastectomy. *J Breast Cancer*. 2013;16(2):198-201.
4. Fine RE, Vose JG. Traditional electrosurgery and a low thermal injury dissection device yield different outcomes following bilateral skin-sparing mastectomy: a case report. *J Med Case Rep*. 2011;5:212.
5. Data on file. VR-00065 study summary. 71-10-2453.
6. Loh SA, Carlson GA, Chang EI, Huang E, Palanker D, Gurtner GC. Comparative healing of surgical incisions created by the PEAK PlasmaBlade, conventional electrosurgery, and a scalpel. *Plast Reconstr Surg*. 2009;124(6):1849-1859.
7. Chang EI, Carlson GA, Vose JG, Huang EJ, Yang GP. Comparative healing of rat fascia following incision with three surgical instruments. *J Surg Res*. 2011;167(1):47-54.
8. Data on file. Histology Images for PEAK PlasmaBlade 71-10-2559.

* Operating temperature is a function of device settings, electrode configuration and treatment time. Operating temperatures outside this range may be observed.

** Performance has not been specifically established in all procedures.

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Medtronic Advanced Energy LLC
180 International Drive
Portsmouth, NH 03801
USA
Tel: (866) 777-9400
Fax: (866) 222-0900

For further information, please call 866-777-9400 or 603-742-1515.

medtronicadvancedenergy.com

71-10-2545 3.17 Rev B