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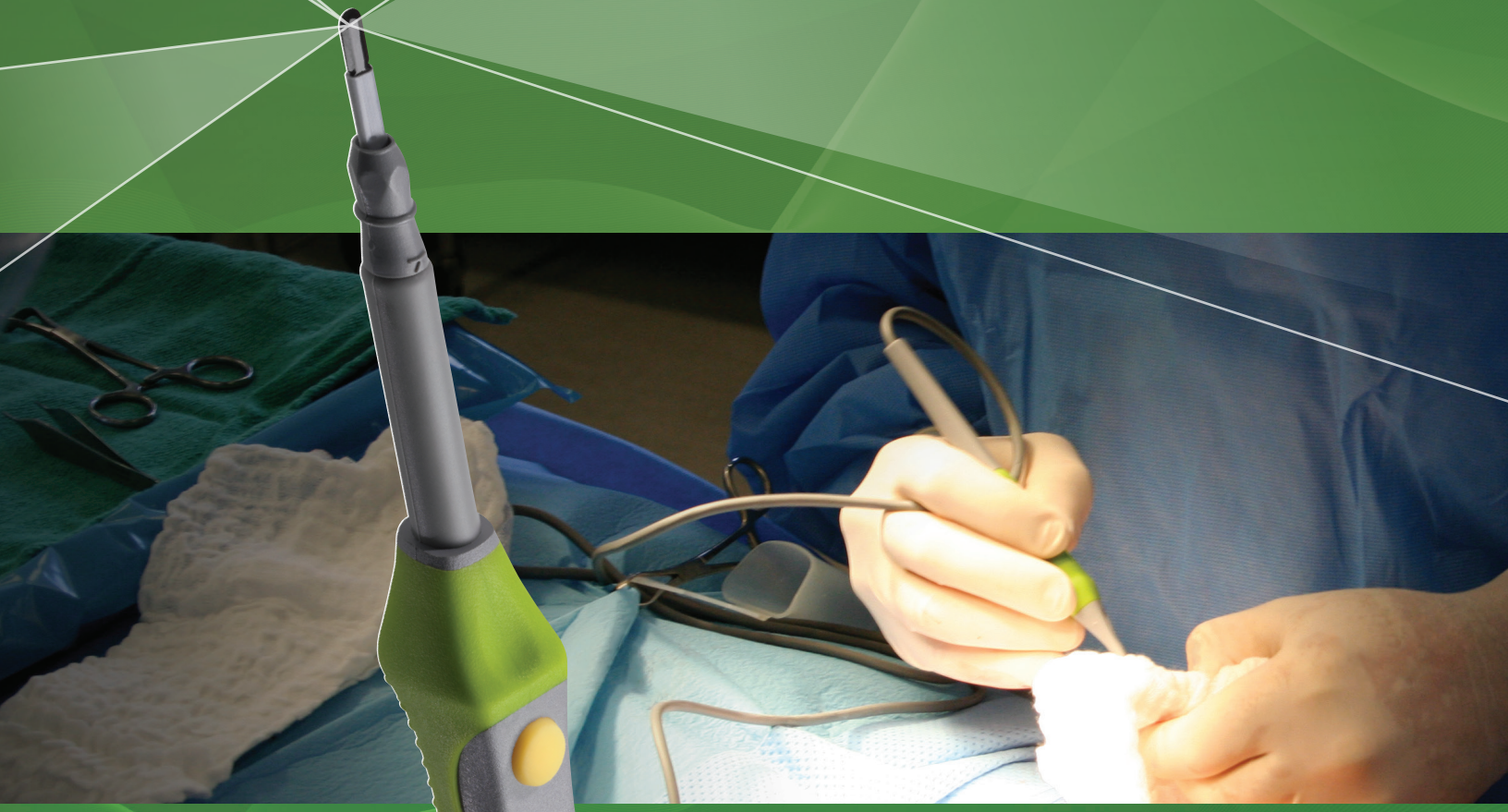
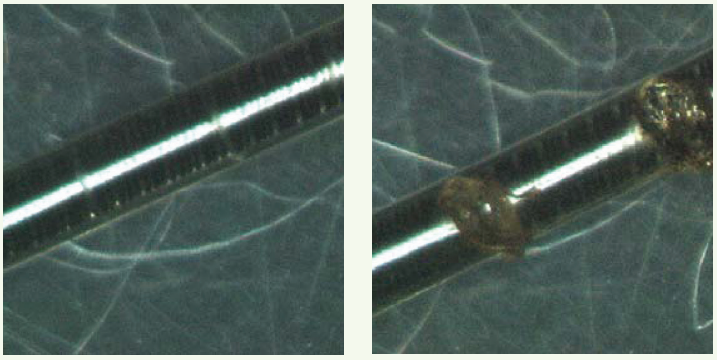
PEAK PlasmaBlade™ for Pacemaker/ICD Implants and Revisions



Conclusion

Use of the PEAK PlasmaBlade for pacemaker/ICD implants and revisions may reduce the likelihood of transvenous lead damage compared to traditional electrosurgery. Although the overall risk of transvenous lead injury is relatively low, the patient and financial consequences are serious and the use of additional measures to reduce potential risk, such as the PEAK PlasmaBlade, should be considered.



PEAK PlasmaBlade: Setting 5 *Traditional ESU: 30 Watts*

Copolymer lead, perpendicular device orientation, cut mode

Selected References*

1. Loh SA, Carlson GA, Chang EI et al. Comparative healing of surgical incisions created by the PEAK PlasmaBlade, conventional electrosurgery and a scalpel. *Plas Reconstr Surg* 2009; 124(6):1849-1859. Chronic wound healing study conducted in living porcine model.
2. Data on file. ETR-00023.
3. Ruidiaz ME, Messmer D, Huang EJ et al. Comparative healing of human cutaneous surgical incisions created by the PEAK PlasmaBlade, conventional electrosurgery, and a standard scalpel. *Plas Reconstr Surg* 2011; 128(1): 104-111. Chronic wound healing study conducted in subjects undergoing abdominoplasty.
4. Chang E, Carlson GA, Vose JG, et al. Comparative healing of rat fascia following incision with three surgical instruments. *J Surg Res* 2011; 167:e47-e54.
5. Data on file. VR-0055.
6. Weisberg IL, Desai S, Davison P et al. Effects of pulsed RF energy compared to standard electrosurgery on transvenous lead insulation materials. Heart Rhythm Society Annual Meeting 2010. Denver, Colorado.
7. Lim K, Reddy S, Desai S et al. Effects of electrocautery on transvenous lead insulation materials. *J Cardiovasc Electrophysiol* 2009; 20(4):429-435.
8. Reynolds MR, Cohen DJ, Kugelmass AD et al. The frequency and incremental cost of major complications among medicare beneficiaries receiving implantable cardioverter-defibrillators. *J Am Coll Cardiol* 2006; 47:2493-2497.

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

Rx only. For a listing of indications, contraindications, precautions, and warnings, please refer to the Instructions For Use (IFU) that accompany PEAK PlasmaBlade disposable devices and/or the PEAK Surgery System User Guide.

For further information, please call 866-777-9400 or 603-742-1515.
You may also consult our website:
www.medtronicadvancedenergy.com

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Significant Reduction in Transvenous Lead Damage When Compared to Traditional Electrosurgical Devices

The PEAK PlasmaBlade is a surgical device that uses very brief (40µs range), high frequency pulses of RF energy to induce electrical plasma along the edge of a thin (12.5µm), 99.5% insulated electrode. Due to the low duty cycle from RF pulsing and proprietary TPS insulating technology, the PEAK PlasmaBlade uses less total energy and operates at significantly lower temperatures than traditional electrosurgical technology (40 – 170°C vs. 200 - 350°C).[1,2] Comparatively, PEAK PlasmaBlade incisions demonstrate 74% less thermal injury depth than traditional electrosurgical devices. ($p<0.05$).[3]

Pre-clinical and clinical studies with the PEAK PlasmaBlade have demonstrated that the improved thermal injury profile of the device, compared to traditional electrosurgery, results in the following benefits:

- Improves wound strength, wound healing and the cosmetic appearance of scars[1,3,4]
- Decreases inflammatory cell counts[3] and serous drainage[5]
- Enables patients to return to a normal diet earlier[5]
- Reduces patient intra-operative narcotic consumption by 22% ($p=0.07$)[5]
- Reduces patient post-operative narcotic consumption by 28% ($p=0.59$)[5]

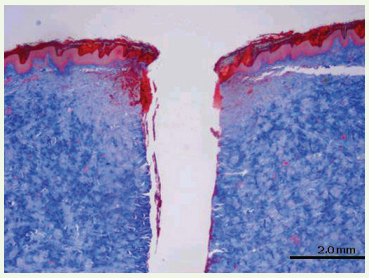
Materials and Methods[6]

A series of ten polyurethane, silicone, and silicone-urethane copolymer transvenous leads were superficially tunneled into chicken breasts maintained at 37°C. These leads were then subjected to simulated surgical extraction using traditional electrosurgery or the PEAK PlasmaBlade. Extraction was performed with either parallel or perpendicular-to-lead technique using purely Cut or Coag mode at 3 second power outputs of either 20W or 30W. Lead damage was numerically characterized (0 to 3 scale, by severity) in a blinded fashion by visual and microscopic inspection.

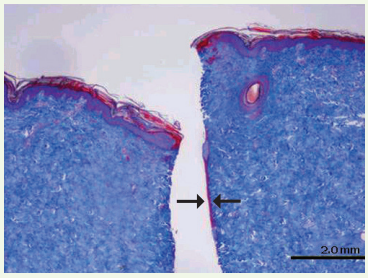
Results[6]

Using traditional electrosurgery, significant lead damage was noted in all polyurethane leads, with more damage occurring with 30W vs. 20W, Cut vs. Coag mode, and perpendicular vs. parallel orientation. Considering alternative materials, silicone leads demonstrated less damage than polyurethane, and co-polymer leads demonstrated the greatest amount of damage of all three lead types with traditional technology. **Comparatively, the PEAK PlasmaBlade did not damage the silicone or polyurethane lead in Coag mode with either parallel or perpendicular technique. Using Cut mode, only minimal damage was demonstrated with perpendicular technique in the polyurethane and co-polymer leads.** Of the three insulation materials, silicone lead insulation demonstrated the highest tolerance to electrosurgery, regardless of technique or energy mode.

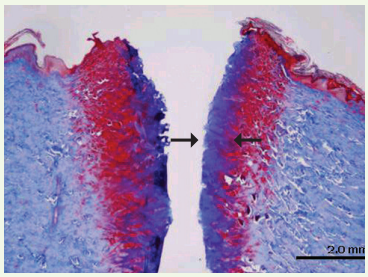
Thermal Injury Profile[1]



Scalpel



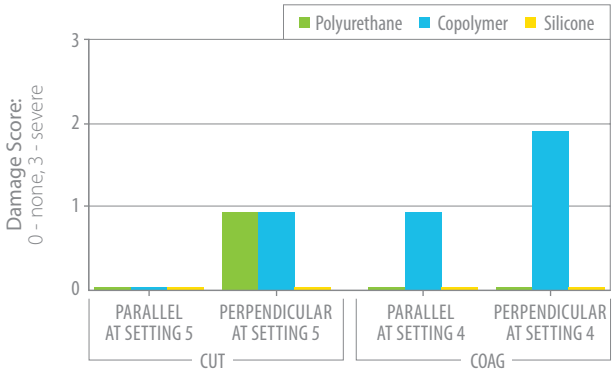
PEAK PlasmaBlade Cut



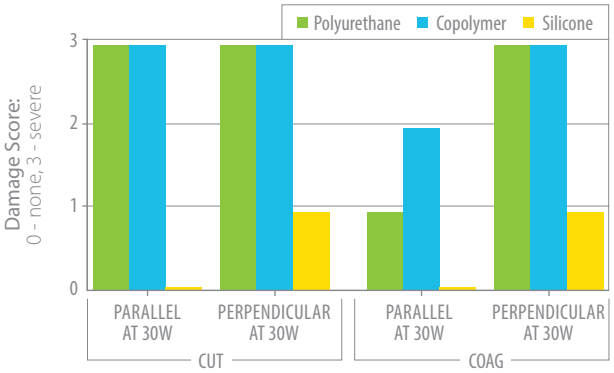
Electrosurgery Cut

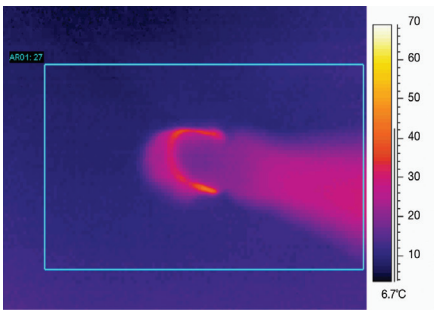
Device Effect on Transvenous Lead Insulation

PEAK PlasmaBlade

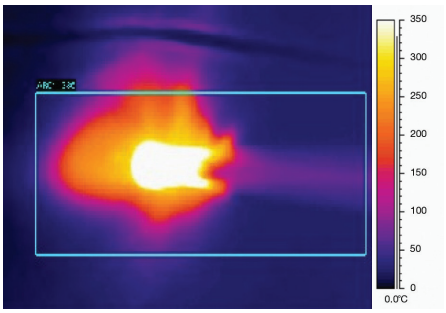


Traditional ESU





PEAK PlasmaBlade: 40 - 170°C[1]



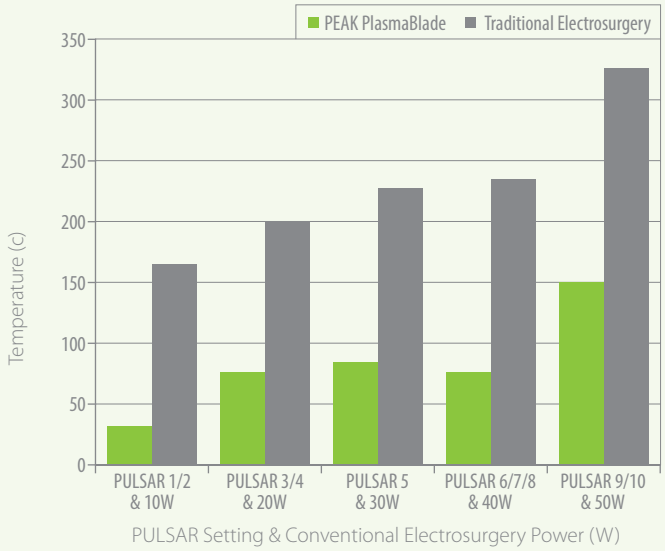
Traditional ESU: 200 - 350°C[1]

Discussion

Silicone, polyurethane, and copolymers are widely used in transvenous pacing leads due to their favorable flexibility, insulative, and tunneling characteristics. While they are readily available and cost-effective, polyurethane and copolymers in particular are also susceptible to damage from high-temperature electrosurgical instruments.[6,7] Surgeons are advised by lead manufacturers to use low power settings and maintain operative vigilance during dissection to prevent damage. However, this is not always possible. The consequences of lead damage during generator or battery replacement carry significant morbidity and mortality risk, including increased length of stay and death, and serious financial implications – averaging between $5,000 and $20,000 per incident.[8] The PEAK PlasmaBlade's lower operating temperature and thermal spread resulted in reduced damage regardless of orientation or mode when compared to traditional electrosurgery.

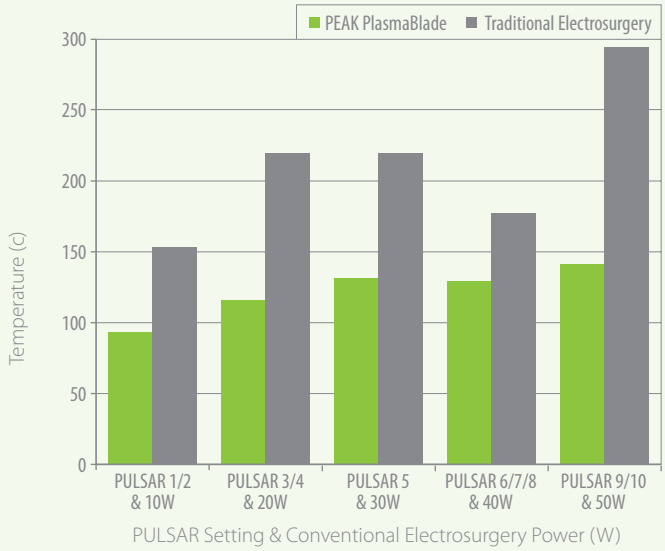
Temperature Profile[2]

PEAK PlasmaBlade Cutting Temperature vs. Traditional ESU



- The PEAK PlasmaBlade demonstrated an average 64% reduction in blade temperature compared to traditional electrosurgery for similar Cut settings

PEAK PlasmaBlade Coagulation Temperature vs. Traditional ESU



- The PEAK PlasmaBlade demonstrated an average 40% reduction in blade temperature compared to traditional electrosurgery for similar Coag settings