PEAK PlasmaBlade™

Pacemaker/ICD Replacement, Upgrade, and Lead Revision Procedures

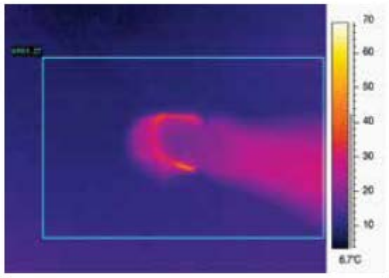
Introduction

The PEAK PlasmaBlade is an advanced electrosurgical soft-tissue dissection instrument with properties that are particularly relevant to Pacemaker and ICD generator replacement, upgrade, and lead revision procedures. With an operating temperature range of between 40°C and 170°C,[1] the PEAK PlasmaBlade has demonstrated a significant reduction in transvenous lead damage compared to conventional electrosurgical devices.[2] Further published benefits* include significant reductions in thermal injury to the tissue[3] and inflammatory response,[1,3,4] as well as improved operative efficiency.[1,5] To date, the instrument has been used in over 50,000 such procedures.

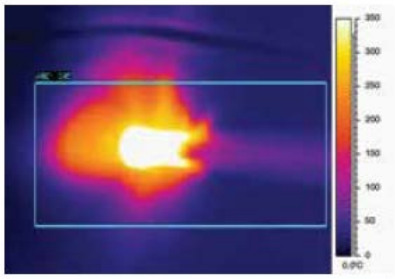
Reduced Risk of Transvenous Lead Damage

Polyurethane and copolymer lead insulation materials are highly susceptible to thermal damage during generator change procedures.[2,6] Conventional electrosurgical instruments have been shown to operate in a temperature range of 200°C – 350°C.[1] The melting point of polyurethane insulation (PU55D) is between 185°C and 225°C.[6]

In a recent study of the PEAK PlasmaBlade compared to conventional electrosurgery on transvenous lead insulation materials, a series of ten polyurethane, silicone, and silicone-urethane copolymer transvenous leads were tunneled into chicken breasts. These leads were then subjected to simulated surgical extraction using conventional electrosurgery or the PEAK PlasmaBlade. Dissection was performed with either parallel or perpendicular-to-lead technique using pure 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 microscopic inspection. Use of the PEAK PlasmaBlade resulted in significantly less damage than conventional electrosurgery, regardless of lead material, instrument mode, or approach technique ($p < 0.0001$).[2]



PEAK PlasmaBlade: 40 - 170°C[1]



Traditional ESU: 200 - 350°C[1]

Operative Efficiency

The PEAK PlasmaBlade has demonstrated reductions in operative time in surgical procedures.[5] In generator changeouts, upgrades, and lead revision procedures where fibrous encapsulation presents a challenge, the PEAK PlasmaBlade's dissection performance with decreased risk of transvenous lead damage may improve operative efficiency, potentially shortening procedure length.[2]

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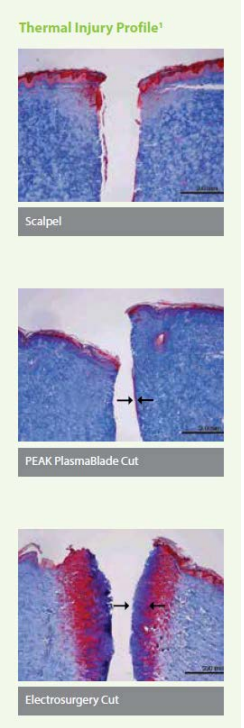
Incision Healing

Three separate, peer-reviewed, published studies have demonstrated no difference in healed incision strength, inflammatory cell counts, and healed scar width between scalpel and PEAK PlasmaBlade.[1,3,4] Additionally, compared to scalpel, the PEAK PlasmaBlade resulted in a 59% reduction in blood loss (p = 0.002).[1]

In humans, the following differences were observed while using the PEAK PlasmaBlade compared to conventional electrosurgical instruments[3]:

- Thermal injury depth was reduced 74% with PEAK PlasmaBlade compared to conventional electrosurgical devices ($p < 0.05$).
- Inflammatory CD3+ response (T-Lymphocytes) was not different between the PEAK PlasmaBlade and scalpel (p = 0.12), but was 40% higher for the conventional electrosurgery instrument (p = 0.01) compared to scalpel and PEAK PlasmaBlade.
- CD68+ response (monocytes/macrophages) was not different between the PEAK PlasmaBlade and scalpel (p = 0.35), but was 52% higher for a conventional electrosurgical instrument (p = 0.05) compared to scalpel and PEAK PlasmaBlade.
- Scar width was not different between the PEAK PlasmaBlade and the scalpel at 3 and 6 weeks, and was 25% (p = 0.01) less for PEAK PlasmaBlade compared to conventional electrosurgery at 3 weeks.
- Burst strength was not different for PEAK PlasmaBlade and the scalpel at 3 and 6 weeks, and was 65% (p = 0.001) and 42% (p = 0.001) stronger for PEAK PlasmaBlade compared to conventional electrosurgery at 3 and 6 weeks, respecitvely.



Infection Risk

Generator changes and device upgrades have been shown to be associated with a 3% incidence of infection, as compared to 0.5% in primary implants. Factors that may explain this difference include[7]:

- Length of the procedure
- Larger incisions with more extensive dissection
- Fibrosis within the pocket, limiting adequate blood supply

The relationship between PEAK PlasmaBlade use and infection has not been studied. However, the instrument may offer particular value in generator change-out, upgrade, and lead revision procedures characterized by the factors above, which are thought to influence infection rates,[7] by enabling efficient dissection with reduced risk of lead damage,[2] and the healing characteristics of a scalpel.[3] Infection is one of three indications for device extraction, and carries with it particular risks including death in 0.3% of patients, hemopericardium and tamponade (0.7%), hemothorax (0.2%), and transfusion (0.1%).[7]

Cost Considerations

While the rate of lead failure due to thermal damage from electrosurgical instruments is not known, the overall rate of lead complication and corresponding cost has been reported.

Poole et al[8] studied complication rates associated with pacemaker or implants, ICD generator replacements, and upgrade procedures (results from the REPLACE registry); reoperation due to lead dislodgement or replacement was the most common complication in both cohorts:

- Unplanned transvenous lead addition for replacement or upgrade (cohort 1) – 1.0%
- Planned transvenous lead addition for replacement or upgrade (cohort 2) – 7.9%

Reynolds et al[9] analyzed the frequency and nature of early complications after 30,984 ICD and CRT implants in general practice using Medicare Provider and Analysis Review (MedPAR) data. Mechanical complication with lead or pocket revision was the second most common complication and demonstrated:

- Incremental increase in length of stay (LOS) of 1.3 days
- Average additional incremental cost of $5,436

Groarke et al[10] studied cost implications of defibrillator lead failures across two cardiac device implant centers, each in an urban public-access university teaching hospital in Europe, and reported:

- EP laboratory staffing costs for lead replacement with/without lead extraction of EU 375/hour ($489/hour)
- Median cost per lead replacement of EU 7,660 ($10,025)

Summary

With an operating temperature range of between 40°C and 170°C,[1] the PEAK PlasmaBlade offers physicians a significantly reduced risk of transvenous lead damage, precision dissection through tissue, and improved incision healing .[1,3,4]

References

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* References for benefits are cited. Most benefits are observed in comparison to conventional electrosurgery. Benefits have not been established in all general surgeries.

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