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Frequently Asked O.R. Value Analysis Committee Questions

1. Are the products/devices cleared by the FDA?

Yes. The PEAK PlasmaBlade™ and both the PULSAR® and the PULSAR® II generators, which make up the PEAK® Surgery System, received 510(k) clearances from the FDA. The initial PULSAR generator was cleared via K073057 on July 22nd 2008 and the PULSAR II generator cleared via K102029 on December 16, 2010. PEAK PlasmaBlade devices were also cleared by these submissions and several others.

- 510(k) Number: K073057
  - July 22, 2008
  - Device Name: PULSAR Generator and PEAK PlasmaBlade Tissue Dissection Device
  - Indications for Use: The PULSAR Generator with the PEAK PlasmaBlade Tissue Dissection Device is intended to be used for cutting and coagulation of soft tissue during surgical procedures.

- 510(k) Number: K082786
  - December 3, 2008
  - Device Name: PEAK Surgery System (PULSAR Generator and PEAK PlasmaBlade Tissue Dissection Devices)
  - Indications for Use: The PEAK Surgery System is indicated for cutting and coagulation of soft tissue during General, Plastic and Reconstructive (including but not limited to skin-incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological surgical procedures.

- 510(k) Number: K102029
  - December 16, 2010
  - Device Name: PEAK Surgery System (PULSAR Generators and PEAK PlasmaBlade Tissue Dissection Devices)
  - Indications for Use: The PEAK Surgery System is indicated for cutting and coagulation of soft tissue during General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological surgical procedures.

Additional indications for use received 510(k) clearance from the FDA:

- 510(k) number: K083415
  - June 5, 2009
  - Device Name: PEAK PlasmaBlade TnA Tonsil and Adenoid Tissue Dissection Device
  - Indications for Use: The PEAK PlasmaBlade TnA Tonsil and Adenoid Dissection Device is only indicated for cutting and coagulation of soft tissue during otolaryngology (ENT) surgery including adenoidectomy and tonsillectomy (Pharyngeal, Tubal, Palatine).

- 510(k) number: K093695
  - April 13, 2010
  - Device Name: PEAK PlasmaBlade 3.0S
  - Indications for Use: The PEAK PlasmaBlade 3.0S Tissue Dissection Device is indicated for cutting and coagulation of soft tissue during General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopedic, Arthroscopic, Spinal and Neurological surgical procedures.

- 510(k) Number: K102709
  - December 17, 2010
  - Device Name: PEAK PlasmaBlade PLUS
  - Indications for Use: The PEAK PlasmaBlade PLUS Tissue Dissection Device is indicated for cutting and coagulation of soft tissue during General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological surgical procedures.
2. Briefly describe this product and the operational and clinical impact.

The PEAK PlasmaBlade is a precise dissection instrument that utilizes pulsed plasma radiofrequency (RF) energy for the cutting and coagulation of soft tissue during surgical procedures. The pulsed plasma RF energy, combined with a proprietary insulation technology, allows the PEAK PlasmaBlade to dissect with the precision of a scalpel while producing minimal thermal damage to surrounding tissue. Clinical research has demonstrated that this low thermal injury technology offers intra-operative and post-operative benefits when compared to the current standard of care, scalpel and traditional electrosurgery.2,3,9

3. Why is it necessary to introduce and use this new product?

The PEAK PlasmaBlade offers clinical and economic advantages compared to the current surgical standard of care, scalpel and traditional electrosurgery (i.e. the “Bovie”), and other advanced energy devices.2,3,5,8

Intra-operatively, the PEAK PlasmaBlade allows the surgeon to cut skin with equivalent scarring and healed strength to a scalpel incision yet with less bleeding,9 the PEAK PlasmaBlade also allows the surgeon to dissect tissue with improved cutting efficiency compared to traditional electrosurgery, even when completely submerged in liquefied fat and blood.42 Compared to the scalpel, the PEAK PlasmaBlade allows improved dissection performance, and provides operative time reduction and a safer operating environment for the operating room staff.6,9,41 Additionally, because the PEAK PlasmaBlade operates at nearly half the temperature of traditional electrosurgery, it may produce less surgical smoke.9,43

Published peer-reviewed studies have demonstrated that post-operatively, surgical incisions created by the PEAK PlasmaBlade heal with less inflammation than those created by traditional electrosurgical instruments, with equivalent healed strength and scarring to those created by a standard scalpel blade.3,4,9

In addition, a retrospective review in total knee arthroplasty demonstrated that the PEAK PlasmaBlade resulted in a 12% reduction in operative time (p = 0.0001), yielding a consistent cost reduction for the hospital.41 In a randomized, controlled trial of abdominoplasty patients, those treated with the PEAK PlasmaBlade experienced 25.6% less serous drain output (p = 0.11), 22% less intra-operative narcotic consumption (p = 0.07), 28% less post-operative narcotic consumption (p = 0.59), 50% of normal diet by day 2 (median) vs. day 6.5 (median) for SOC (p = 0.0047), and 50% normal activity in 5 days (median) vs. 8 days (median) for SOC (p = 0.14).45

4. Is it a proven technology? (Supported by randomized controlled trials or well-conducted cohort studies, provide URL’s or attach documentation)

Yes, although the PEAK PlasmaBlade performance has not been established in all surgical specialties. Beginning in December 2008, the PRECISE (Pulsed Plasma Radiofrequency Energy to Reduce Thermal Injury and Improve Surgical HEaling) family of clinical studies have been underway to examine the effect of the PEAK PlasmaBlade in specific applications. Despite being a relatively new technology, results from these studies have been published in major peer-reviewed scientific journals and presented at significant surgical society meetings (see References). Briefly, these include the following:
5. What are the relative benefits/expected outcomes of the new technology?

The PEAK PlasmaBlade provides the precise dissection of a scalpel with the bleeding control of traditional electrosurgery without the extensive thermal damage to surrounding tissue and structures. Intra-operatively, these features result in greater operating time efficiency and surgical precision; post-operatively, the benefits of low thermal injury technology have been associated with reduced thermal injury to tissue and lower inflammatory cell count as well as quicker return to normal diet for patients following abdominoplasty.

**Post-Operative Outcomes (data documented in the PRECISE Patient Outcomes Study)**

- 22% less intra-operative narcotic consumption (p = 0.07)\(^{45}\)
- 28% less post-operative narcotic consumption (p = 0.59)\(^{45}\)
- 25.6% less serous drain output (p = 0.11)\(^{45}\)
- 50% normal diet by day 2 (median) vs. day 6.5 (median) for SOC (p = 0.0047)\(^{45}\)
- 50% normal activity in 5 days (median) vs. 8 days (median) for SOC (p = 0.14)\(^{45}\)
- 58% reduction in post-operative hemoglobin drop (p = 0.08)\(^{45}\)
- Equivalent healed incision strength and skin scar width to scalpel\(^{3,4,9}\)

**Increased operating efficiency**

- 12% reduction in operative time (p<0.05)\(^{41}\)
  - 24min x $35/min = $840 Cost Savings
- 24% improvement in dissection performance per gram of tissue (p<0.01)\(^{42}\)
- No scalpel exchanges necessary\(^{8}\)
- Unimpeded cutting performance through liquid media\(^{31,42}\)

**OR Staff and Patient**

- 99.5% insulated electrode to provide precise dissection and efficient coagulation during surgical procedures
- Non-sharp, single use, precise cutting and coagulation device for use during surgical procedures
  - Each incident can cost a facility $4,838 depending on infection status\(^{8}\)
- May produce less surgical smoke\(^{8,43}\)
6. Has this technology already been adopted/endorsed by a recognized medical specialty body? (ASPS, etc.)

No.

7. What type of equipment is currently used for this application?

There is no single device that is able to simultaneously cut with the precision of a scalpel, control bleeding like traditional electrosurgery and reduce thermal injury to surrounding tissues and structures. Other technologies attempt to do this and succeed in part: the Harmonic Scalpel Synergy Blade (Ultracision®, Ethicon/Johnson & Johnson, Somerville, NJ), Coblation Technology (ArthroCare, Inc., Sunnyvale, CA), Colorado Needle (Stryker Corp., Kalamazoo, MI), CO2 lasers, Argon Beam Coagulators, and various traditional electrosurgical technologies, etc. The PEAK PlasmaBlade is the first instrument to combine the benefits of all the above technologies.

8. What are the relative risks associated with the new technology?

The PEAK PlasmaBlade is a highly efficient, energized cutting device and should always be handled with care by a trained surgeon. Standard surgical precautions still apply. However, it is considered a “plug and play” technology, so the training for surgeon and staff by an authorized Medtronic sales representative is minimal. As with most new technologies, there is a short learning period that is overcome after a few cases.

9. What continuing medical education courses will this technology require prior to its use?

None – there is no new surgical approach or procedure training required.

10. Are there other resources required for using this equipment in our facility?

The PEAK Surgery System’s radiofrequency energy is delivered from the PULSAR generator which must go through a Biomedical Engineering Department inspection and check-in. Additionally, an authorized Medtronic sales representative will be available to train (in-service) the surgeon and staff on proper setup and use of the system.

11. Staff training requirements (including nursing staff and other clinicians):

An authorized Medtronic sales representative will provide training for the surgeon and staff on proper setup and use of the PEAK Surgery System. Standard surgical set up and precautions apply. A Quick Start Guide attached to the PULSAR Generator provides simple guidelines: powering unit, attaching the PEAK PlasmaBlade family of disposable instruments, attaching patient return pad, attaching general wall suction (if applicable), establishing Cut and Coag settings on the PULSAR Generator.

12. Please outline the qualifications and/or criteria for safe use of the technology:

With the PEAK PlasmaBlade there are no new approaches, procedures or technical changes required of the surgeon or Operating Room staff. Surgeons will use their standard surgical technique; they typically find the device intuitive to use and easy to understand.
### 13. Value Analysis Criteria Summary

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient/Staff Safety</strong></td>
<td>The reduced thermal injury profile of the PEAK PlasmaBlade may offer a risk reduction compared to traditional electrosurgery. In addition, operators may be able to use the PEAK PlasmaBlade in closer proximity to adjacent fragile structures and near sensitive anatomy or in confined spaces. With use of the PEAK PlasmaBlade, scalpel exchanges between operating room personnel are not necessary. Therefore the risk of inadvertent cuts or sharp injuries is eliminated.</td>
</tr>
<tr>
<td><strong>Patient Outcomes</strong></td>
<td>Significantly improves wound strength, wound healing and the appearance of scars; enables patients to return to a normal diet earlier; reduces thermal injury to tissue and inflammatory cell count and reduces serous drain output.</td>
</tr>
<tr>
<td><strong>Pacemaker/ICD Implants and Revisions</strong></td>
<td>Use of the PEAK PlasmaBlade may reduce damage to pacemaker leads compared to traditional electrosurgery due to its lower operating temperature. Revision to these leads carries high operative expense and patient morbidity.</td>
</tr>
<tr>
<td><strong>Operative Time</strong></td>
<td>Operative time reduced by 12%, and dissection performance improved by up to 24%.</td>
</tr>
<tr>
<td><strong>Staff Requirement Outside Procedure</strong></td>
<td>Simple user interface with “Plug and Play” technology allows for rapid, easy setup.</td>
</tr>
<tr>
<td><strong>Hospital Supply/Implant Expenses</strong></td>
<td>Compared to other advanced energy devices like the Ultracision/Harmonic Scalpel or Coblation Technology, the PEAK PlasmaBlade is less expensive and delivers equivalent or improved patient outcomes compared to standard of care. The PEAK PlasmaBlade may displace the aforementioned devices.</td>
</tr>
</tbody>
</table>
Scientific Literature

Research documenting the preclinical and clinical performance of the PEAK PlasmaBlade has been published in major peer-reviewed journals and awarded podium presentations at international surgical conferences including the annual meetings of the American College of Surgeons, Plastic Surgery Research Council, American Society of Breast Surgeons, American College of Obstetrics and Gynecology, and the European Plastic Surgery Research Council. Below please find a list of our publications and recent presentations.

Peer-Reviewed Publications Describing the PEAK PlasmaBlade


Invited Podium Presentations

Peer Reviewed Posters/Abstracts


Other Publications


Internal Testing References

42. Data on file. VR-0065.
44. Data on file. ETR-0127.
PEAK PlasmaBlade™

THE PRECISION OF A SCALPEL AND THE BLEEDING CONTROL OF TRADITIONAL ELECTROSURGERY WITHOUT THE EXTENSIVE COLLATERAL TISSUE DAMAGE$^{1-3}$
The PEAK® Surgery System combines a unique radiofrequency power source (PULSAR® II Generator) with a family of disposable devices (PEAK PlasmaBlade) to address a broad range of surgical applications.

PEAK PlasmaBlade Technology Overview
The PEAK PlasmaBlade strikes a unique balance between precision cutting and bleeding control. Using novel pulsed plasma technology along with a proprietary TPS (Thermal Protection Shield) insulation technology allows surgeons to:

- Cut precisely through any type of soft tissue
- Significantly reduce collateral thermal damage
- Maintain superior performance in both wet and dry fields

What is plasma?
Plasma is an electrically conductive cloud created when the RF energy contacts tissue. It is composed of water vapor and charged particles called ions (positive and negative charges) from the breakdown of the tissue. The conductive cloud or "plasma" allows the energy to cross at much lower power levels. This use of lower energy via plasma leads to lower operating temperatures and less thermal damage.

PEAK PlasmaBlade Thermocut Cut

PEAK PlasmaBlade Thermal Injury Depth vs. Traditional Electrosurgery

![Graph showing thermal injury depth comparison between PEAK PlasmaBlade and Traditional Electrosurgery]

- Cut mode incisions made with the PlasmaBlade demonstrated an average 92% reduction in thermal injury depth compared to traditional electrosurgery.
**Selected References**


* Average OR cost per minute (non-surgery specific)

** Performance has not been specifically established in all surgical procedures.
The PEAK PlasmaBlade™ Family

**PRODUCT** | **CATALOG NUMBER** | **DESCRIPTION**
--- | --- | ---
PEAK PlasmaBlade 4.0 | PS200-040 | 4.0mm wide spatula tip
PEAK PlasmaBlade PLUS | PS210-030P | 3.0mm wide spatula tip, variable length shaft with CoagCap
PEAK PlasmaBlade Needle | PS200-001 | Ultra-fine needle point tip
PEAK PlasmaBlade 3.0S | PS210-030S | 3.0mm wide spatula tip, variable length shaft, integrated suction
PULSAR Wireless Footswitch | PS100-200 |
PULSAR Cart | PS100-300 |
PULSAR II Generator | PS100-102 |

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The PULSAR II Generator features:
- Intuitive touchscreen user interface
- Simple 1 to 10 numeric set points
- Four memory settings for user preferences
- 1MHz operating frequency
- 0.5 to 50 Watts; 350 to 5200 Volts
- Patient Return Electrode (pad) Monitoring (REM) System

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The PULSAR II Generator features:
- Intuitive touchscreen user interface
- Simple 1 to 10 numeric set points
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- 0.5 to 50 Watts; 350 to 5200 Volts
- Patient Return Electrode (pad) Monitoring (REM) System

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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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International Telephone Numbers
Adriatic Regional Office 385-1-488-1120
Australia 1800-668-670
Baltic Regional Office 37-1-67560226
Belgium 32-2456-09-09
Canada 1800-217-1617
China 86-21-50800998
Czech Republic 420-2-9657-9580
France 33-470-679-800
Germany 49-2159-8149-209
Greece 30-210-67-79-099
Hong Kong 852-2919-1312
Hungary 36-30-5052987
India 91-22-26836733
Israel 972-9-972-4400
Italy 39-02-24137-324
Japan 81-6-4795-1506
Korea 82-2-3404-3600
Lebanon 961-1-370-670
Luxembourg 32-2456-09-09
Netherlands 31-45-566-8800
Poland 48-22-465-6942
Russian Federation 7-495-580-73-77
Singapore 65-676-6255
South Africa 27-11-466-1820
Spain 34-91-625-05-40
Taiwan 886-2-2183-6000
UK 44-1923-205-166
USA 1-603-742-1515

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PEAK PlasmaBlade™ 3.0S

The precision of a scalpel and the bleeding control of traditional electrosurgery without the extensive collateral tissue damage.¹-³

Features and Benefits

• Integrated suction for enhanced visibility
• Telescoping shaft from 5.5cm to 15cm
• 3.0mm-wide blade for greater precision
• Ergonomic handle design for comfort and control

Thermal Injury Comparison

[Images of PEAK PlasmaBlade Cut and Traditional Electrosurgery Cut]

¹-³ Reference numbers for further details.
**Temperature Profile**

PEAK PlasmaBlade Cutting Temperature vs. Traditional Electrosurgery

**Thermal Injury Profile**

PEAK PlasmaBlade Cutting Thermal Injury Depth vs. Traditional Electrosurgery

PEAK PlasmaBlade Coagulation Temperature vs. Traditional Electrosurgery

PEAK PlasmaBlade Coagulation Thermal Injury Depth vs. Traditional Electrosurgery

**Selected References**


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

You may also consult our website: [www.medtronicadvancedenergy.com](http://www.medtronicadvancedenergy.com).
PULSAR II

Empowering the PEAK PlasmaBlade™

The precision of a scalpel and the bleeding control of traditional electrosurgery WITHOUT the extensive collateral tissue damage

Less Energy. Less Heat. Less Tissue Damage...
Operative and Economic Outcomes

Compared to scalpel and traditional electrosurgery, the PEAK PlasmaBlade has demonstrated:

- Equivalent healed incision strength and skin scar width to scalpel\(^3\)
- Equivalent inflammatory response (CD3+ and CD68+ cells) to the scalpel at 3 and 6 weeks post incision\(^3\)
- 25.6% less serous drain output (\(p = 0.11\))\(^4\)
- 22% less intra-operative narcotic consumption (\(p = 0.07\)) and 28% less post-operative narcotic consumption (\(p = 0.59\))\(^4\)
- 58% reduction in hemoglobin drop (\(p < 0.08\))\(^4\)
- 12% operating room time savings (\(p < 0.05\))^5

The PULSAR II Generator Features:

- Intuitive touchscreen user interface
- Simple 1 to 10 numeric set points
- Four memory settings for user preferences
- 1MHz operating frequency
- 0.5 to 50 Watts; 350 to 5200 Volts
- Patient Return Electrode (pad) Monitoring (REM) System

Selected References**

* Average OR cost per minute (non-surgery specific)
** 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
PEAK PlasmaBlade™ for Orthopaedics
The importance of minimizing soft tissue damage in orthopaedic surgery

The goal of minimally invasive surgery (MIS) in orthopaedics is to optimize the surgical outcome by limiting the collateral damage to adjacent tissue and structures. A traditional approach to total knee arthroplasty (TKA) requires an incision 25 to 30cm in length through muscle and tendon creating significant surgical trauma. Alternatively, an MIS approach utilizes a shorter 4 to 16cm incision and can be accomplished through a modified version of the standard TKA exposures — subvastus, midvastus, or medial parapatellar arthrotomy — avoiding extensive muscle and tendon cutting and thereby minimizing trauma to the knee.

The PEAK PlasmaBlade device is a unique soft tissue dissection instrument that uses very brief (40μs range) pulses of radiofrequency (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 TPS insulation 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). Clinical studies have shown that the PEAK PlasmaBlade minimizes damage to soft tissue during dissection, which is an integral part of MIS approaches for orthopaedics, including procedures such as total knee and total hip arthroplasty and spine.

Clinical Benefits of the PEAK PlasmaBlade

Soft tissue dissection with the PEAK PlasmaBlade demonstrates:

- 74% less thermal damage compared to traditional electrosurgery ($p < 0.05$)
- 59% less bleeding than scalpel ($p < 0.05$)
- Equivalent inflammatory response (CD3+ and CD68+ cells) to scalpel at 3 and 6 weeks post incision
- Equivalent healed incision strength and skin scar width to scalpel
Retrospective reviews of total knee arthroplasty with the PEAK PlasmaBlade

Retrospective assessments of the PEAK PlasmaBlade compared to traditional electrosurgery and scalpel for TKA with Jeff Carter, DO, at Texas Health Arlington Memorial Hospital, Arlington, TX, and Blaine Farless, MD, at Texas Health Harris Methodist Hospital, Cleburne, TX have shown a 12% reduction in operative time (p < 0.05).

Use of the PEAK PlasmaBlade in MIS approaches for orthopaedics provides the surgeon with cutting precision of a standard scalpel and the bleeding control of traditional electrosurgery, without the unnecessary collateral thermal damage to surrounding tissue. Considering these advantages, the PEAK PlasmaBlade represents a significant improvement over traditional technology in MIS and allows for true “skin to skin” single-instrument surgery.

Economic Benefits of the PEAK PlasmaBlade

Based on the retrospective data cited above, the economic analysis reveals a potential cost savings of up to $840 per total knee arthroplasty.

Additional economic and safety benefits…

- Single instrument surgery eliminates scalp injury risk. Sharps injuries can cost up to $4,838 per incident
- Because of the lower temperature associated with the PEAK PlasmaBlade, it may reduce the possibility of surgical smoke associated with traditional electrosurgery, which can obscure the operating field
- Displacement of single purpose devices (e.g., ultrasonic scalpel)
- No loss of cutting performance through a wet field
- One instrument from “skin to skin”

<table>
<thead>
<tr>
<th></th>
<th>PEAK PlasmaBlade (n=43)</th>
<th>Standard of Care (n=40)</th>
<th>P value</th>
<th>Savings with PEAK PlasmaBlade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>67.1 ± 8.6</td>
<td>67.9 ± 8.7</td>
<td>0.55</td>
<td>-</td>
</tr>
<tr>
<td>Body Mass Index (BMI) kg/m2</td>
<td>32.8 ± 6.7</td>
<td>33.4 ± 9.3</td>
<td>0.91</td>
<td>-</td>
</tr>
</tbody>
</table>

Operating Room

<table>
<thead>
<tr>
<th></th>
<th>OR Time (min)</th>
<th>OR Cost* (time x $35/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>169</td>
<td>$5,915</td>
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<tr>
<td></td>
<td>193</td>
<td>$6,755</td>
</tr>
</tbody>
</table>

OR Cost* (time x $35/min) $5,915 vs $6,755

Savings with PEAK PlasmaBlade

<table>
<thead>
<tr>
<th></th>
<th>$5,915</th>
<th>$6,755</th>
<th>$840</th>
</tr>
</thead>
</table>

Total Savings $840

* Average OR cost per minute (non-surgery specific).
Selected References*


* Performance has not been specifically established in all orthopaedic surgeries.
PEAK PlasmaBlade™ for Breast Oncoplasty
Introduction

The principal goal of surgical intervention in general surgery for breast cancer is the complete removal of malignant tissue without the need for reoperation. Other critical goals for treatment include an uncomplicated postoperative course, straightforward healing and an optimum cosmetic outcome.

Until recently, these objectives have been hindered by the technological limits of traditional electrosurgical devices. Although widely used for efficient dissection and bleeding control, traditional electrosurgical devices are well known for the significant thermal damage they impart to incised tissue. This effect is inherent to the design of traditional electrosurgical instruments and has been associated with low surgical precision, increased wound inflammation, delayed wound healing, and cosmetically unacceptable skin scarring.1, 2

The PEAK PlasmaBlade is a surgical device that uses very brief, high-frequency pulses of radiofrequency energy to induce electrical plasma along the edge of a thin (12.5 μm), 99.5% insulated electrode. Due to the low duty cycle from RF pulsing and proprietary TPS insulation 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, 3 Comparatively, PEAK PlasmaBlade incisions demonstrate a 74% reduction in acute thermal damage.4

Given these properties, the PEAK PlasmaBlade has shown the ability to enhance the oncoplastic management of breast cancer. Several key benefits of using the PEAK PlasmaBlade for the surgical treatment of breast cancer patients are summarized here.

OPERATING TEMPERATURE PROFILE1, 3

| PEAK PlasmaBlade: 40 - 170°C |
| Traditional ESU: 200 - 350°C |

THERMAL INJURY PROFILE

| PEAK PlasmaBlade Cut |
| Electrosurgery Cut |
The PEAK PlasmaBlade: Advancing the Continuum of Care for Breast Oncoplasty

Cutaneous Flap Preparation for Reconstruction

Preservation of subcutaneous microvasculature may improve healing and cosmetic outcomes following mastectomy.

While the use of skin- and nipple-sparing oncoplastic surgical techniques during mastectomy is increasingly prevalent, partial necrosis of the skin and nipple-areola complex is relatively common and represents a significant source of postoperative morbidity and a barrier to optimal cosmetic outcome. Evidence suggests that thermal injury to the subcutaneous microvascular supply, caused during traditional electrosurgical development of the skin flap, may be a contributing factor.

Here we present a recent case report study to evaluate the use of the PEAK PlasmaBlade in bilateral simple mastectomy.

- **Patient:** A 61 year-old woman with a 17.5 pack-year history of smoking presented with recurrent, right-sided ductal carcinoma in situ (DCIS) one year after lumpectomy, partial breast radiation and sequential treatment with tamoxifen and raloxifene.

- **Procedure:** Right mastectomy with sentinel lymph node biopsy and prophylactic left mastectomy without reconstruction.

- **Randomization:** Right (interventional) with PEAK PlasmaBlade; Left (elective) with scalpel and traditional electrosurgery.

- **Results:** The PEAK PlasmaBlade site healed normally, with good contour and skin edges approximating as expected. Comparatively, at 16 days following surgery the patient presented with drainage from the scalpel/electrosurgery (left, elective) incision and an approximately 9-cm² area of necrosis that undermined in all directions, extending to the sternum and axilla. Following complete revision and closure, the wound healed progressively over a total of 10 weeks.

Unappreciated thermal damage to the subcutaneous microvasculature on the control (scalpel/electrosurgery) side, in a patient with a noted history of tobacco use, may have contributed to delayed healing and significant skin necrosis. These results are consistent with studies showing that the PEAK PlasmaBlade incises tissue with markedly reduced thermal damage than traditional electrosurgery, and suggest that the use of the PEAK PlasmaBlade for dissection may reduce the risk of skin necrosis following mastectomy. Reducing the incidence of tissue necrosis and preserving the subcutaneous vascular structure are imperative for optimal post-mastectomy breast reconstruction.
Improving Operative Performance

In large volume breast reduction surgery, the PEAK PlasmaBlade has demonstrated reduced operative time and improved dissection performance.

The PEAK PlasmaBlade’s novel pulsed RF energy and highly-insulated electrode design allow for significantly improved dissection performance over the standard of care. Especially in fluid-laden tumescent fields and liquified fat, the PEAK PlasmaBlade is able to cut unimpeded – areas where traditional technology fails. This performance advantage significantly reduces time spent by the patient – and the surgeon – in the operating room.

In a randomized controlled trial of the PEAK PlasmaBlade compared to traditional electrosurgery for large volume breast reduction surgery, the PEAK PlasmaBlade demonstrated a significant improvement of 10% in operative time over the standard of care. Compared to electrosurgical technology, use of the PEAK PlasmaBlade resulted in significantly more grams of tissue dissected each minute.

Conclusion

Historically, surgical treatment for breast cancer focused little on the patient and primarily on excision of the targeted lesion. With the advancement in oncoplastic surgical techniques and the prevalence of less invasive surgical devices, surgeons are now able to better locate and excise atypical tissue, leaving more healthy tissue behind for a faster recovery and a more cosmetically appealing result.

As general and plastic surgeons collaborate during the planning stages of breast cancer treatment, consideration should be given to the best skin-sparing, breast conserving surgical techniques, and the clinical and economic benefits the PEAK PlasmaBlade brings to the continuum of care for breast cancer.

Selected References*

5. Fine RE, Vose JG. Traditional electrosurgery and a low thermal injury dissection device yield different outcomes following bilateral skin-sparing mastectomy: a case report. Journal of Medical Case Reports 2011; 5:212.

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

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You may also consult our website: www.medtronicadvancedenergy.com
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.

Selected References*


* Performance has not been specifically established in all surgical procedures.
The PEAK PlasmaBlade: Pacemaker/ICD Implants and Revisions

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). Comparatively, PEAK PlasmaBlade incisions demonstrate 74% less thermal injury depth than traditional electrosurgical devices. (p<0.05).

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
- Decreases inflammatory cell counts and serous drainage
- Enables patients to return to a normal diet earlier
- Reduces patient intra-operative narcotic consumption by 22% (p=0.07)
- Reduces patient post-operative narcotic consumption by 28% (p=0.59)

Materials and Methods

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

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 copolymer 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.

Device Effect on Transvenous Lead Insulation

![Thermal Injury Profile](image)

**PEAK PlasmaBlade**

<table>
<thead>
<tr>
<th>Damage Score</th>
<th>Polyurethane</th>
<th>Copolymer</th>
<th>Silicone</th>
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**Traditional ESU**

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<td>PERPENDICULAR AT 30W</td>
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</table>
The PEAK PlasmaBlade: Pacemaker/ICD Implants and Revisions

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. 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. 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

PEAK PlasmaBlade Cutting Temperature vs. Traditional ESU

PEAK PlasmaBlade Coagulation Temperature vs. Traditional ESU

- PEAK PlasmaBlade demonstrated an average 64% reduction in blade temperature compared to traditional electrosurgery for similar Cut settings.
- PEAK PlasmaBlade demonstrated an average 40% reduction in blade temperature compared to traditional electrosurgery for similar Coag settings.
PEAK PlasmaBlade™ for Plastic & Reconstructive Surgery
Minimizing thermal damage to soft tissue during plastic and reconstructive surgery

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 instrument choice plays a critical role in this process. Traditional electrosurgical instruments are associated with significant thermal damage to surrounding tissue during cutting and coagulation. This thermal necrosis has been shown to negatively affect wound healing and the post-operative healing.1-4 In large tissue reduction surgeries requiring extensive electrosurgical dissection, such as abdominoplasty, reduction mammoplasty, and flap reconstructions, this effect may be magnified.

The PEAK PlasmaBlade is a unique soft tissue dissection instrument that uses very brief (40μs range) pulses of radiofrequency (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 TPS insulation 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).4, 5 Multiple clinical studies have shown that the PEAK PlasmaBlade minimizes damage to soft tissue during dissection — an integral element of plastic and reconstructive surgery.1-4
The PEAK PlasmaBlade: Reducing Thermal Damage in Plastic and Reconstructive Surgery

Clinical benefits of the PEAK PlasmaBlade in plastic and reconstructive surgery

Traditional electrosurgical instruments are widely used in plastic surgery for their efficient bleeding control and dissection capability. However, this surgical efficiency comes at a price: the creation of a deep zone of thermal damage to adjacent tissues that has been associated with delayed wound healing, increased inflammation, and cosmetically unacceptable skin scarring. Recent studies comparing the PEAK PlasmaBlade (PB) to the Standard of Care (SOC) - scalpel and traditional electrosurgery - in abdominoplasty and reduction mammoplasty have demonstrated improved wound healing and patient outcomes.

The PRECISE Outcomes Study

- 74% less thermal damage compared to traditional electrosurgery (p < 0.05)²
- Equivalent healed incision strength and skin scar width to scalpel²
- Equivalent inflammatory response (CD3+ and CD68+ cells) to the scalpel at 3 and 6 weeks post incision²
- 58% reduction in hemoglobin drop (p = 0.08)³
- 50% of normal diet achieved by day 2 (median) for PEAK PlasmaBlade vs day 6.5 (median) for standard of care (p = 0.0047)¹
- 50% of normal activity achieved in 5 days (median) for PEAK PlasmaBlade vs 8 days (median) for standard of care (p = 0.14)¹

The PRECISE Reduction Mammaplasty Study⁶

In this study the PEAK PlasmaBlade demonstrated:

- 24% more grams of tissue dissected per minute vs SOC (p < 0.01)
- 10% reduction in total operative time (p < 0.05)
- 12% reduction in estimated blood loss (p < 0.147)

Improving Operative Efficiency Reduces Procedure Cost⁷

- Overall operative time was reduced by 10% by using the PEAK PlasmaBlade. This improvement is attributed to the PEAK PlasmaBlade’s enhanced cutting performance (significantly more grams of tissue cut per minute) in liquefied fat and heavily fluid-laden tumescent fields where traditional electrosurgical technology is ineffective.
- Additional benefit was noted in the reduced risk for sharps injuries, as the PEAK PlasmaBlade is not sharp and eliminates sharp instrument exchanges. Historically, approximately 20% of sharps injuries in the OR are from a scalpel, and may cost a facility up to $4,838 per incident depending on infection status.⁸
- Preliminary data indicates that in the hands of expert users, greater cost savings may be achieved.

<table>
<thead>
<tr>
<th>(n = 41)</th>
<th>Operative Time (min:sec)</th>
<th>Reduction Volume (g)</th>
<th>Dissection Performance (g/min)</th>
<th>EBL (mL)</th>
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</thead>
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<td>PEAK PlasmaBlade</td>
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<td>685.9 ± 347</td>
<td>20 ± 11</td>
<td>56.6 ± 48.4</td>
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<td>SOC</td>
<td>41:33 ± 11:36</td>
<td>649.2 ± 322</td>
<td>16 ± 8</td>
<td>64.3 ± 34.2</td>
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<tr>
<td>% Diff</td>
<td>10%</td>
<td>-5%</td>
<td>24%</td>
<td>12%</td>
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<tr>
<td>p value</td>
<td>&lt; 0.05</td>
<td>0.08</td>
<td>&lt; 0.01</td>
<td>0.147</td>
</tr>
</tbody>
</table>

At $35/min⁸ the PEAK PlasmaBlade can save $140 for a unilateral procedure and $280* for a bilateral procedure.

Using the PEAK PlasmaBlade also conferred an advantage in preserving subcutaneous vascularity, leaving small points of perfusion without unnecessary obscuration of the surgical field from too much blood loss. When completed, the tissue retained a healthy appearance with none of the charring or damaged tissue inherent in the use of traditional electrosurgery.

PEAK PlasmaBlade De-epithelialization

- Using the PEAK PlasmaBlade also conferred an advantage in preserving subcutaneous vascularity, leaving small points of perfusion without unnecessary obscuration of the surgical field from too much blood loss. When completed, the tissue retained a healthy appearance with none of the charring or damaged tissue inherent in the use of traditional electrosurgery.
The PEAK PlasmaBlade: Reducing Thermal Damage in Plastic and Reconstructive Surgery

PEAK PlasmaBlade: A Skin-to-Skin Solution

- Equivalent skin scar width and inflammation to standard scalpel incisions²
- Significant improvement in dissection time, EBL, and hemoglobin drop¹,⁶
- Reduced narcotic consumption with improvement in diet volume and activity levels¹
- Elimination of scalpel injury risk to surgeon and staff
- Because of the lower temperature associated with the PlasmaBlade, it may reduce the possibility of surgical smoke associated with traditional electrosurgery, which can obscure the operating field⁴

Selected References*


* Performance has not been specifically established in all plastic and reconstructive surgeries.

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](http://www.medtronicadvancedenergy.com)
Dear Dr. Carlson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH’s Office of Surveillance and Biometric’s (OSB’s) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known): 

Device Name: PULSAR™ Generator and PEAK PlasmaBlade™ Tissue Dissection Device

Indications for Use:

The PULSAR Generator with the PEAK PlasmaBlade Tissue Dissection Device is intended to be used for cutting and coagulation of soft tissue during surgical procedures.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

PEAK Surgical, Inc.
PULSAR Generator and PEAK PlasmaBlade Premarket Notification
October 29, 2007

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number
Peak Surgical, Inc.
% Grace A. Carlson, MD
Consultant, Regulatory and Clinical Affairs
2464 Embarcadero Way
Palo Alto, California 94303

Re: K082786
Trade/Device Name: PEAK Surgery System (PULSAR™ Generator and PEAK PlasmaBlade™ Tissue Dissection Devices
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 22, 2008
Received: September 23, 2008

Dear Dr. Carlson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications for Use

510(k) Number (if known): K082786

Device Name: PEAK Surgery System (PULSAR™ Generator and PEAK PlasmaBlade™ Tissue Dissection Devices)

Indications for Use:

The PEAK Surgery System is indicated for cutting and coagulation of soft tissue during General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological surgical procedures.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082786
Certificate

Certificate no. CU 72121231 01

License Holder: Medtronic Advanced Energy, LLC
2464 Embarcadero Way
Palo Alto CA 94303
USA

Manufacturing Plant: BIT-California MedTech
15870 Bernardo Center Drive
San Diego CA 92127
USA

Test report no.: USA-DR 31091137 007
Tested to:
UL 60601-1: 2003 R4.06
CAN/CSA-C22.2 NO. 601.1-M90
CAN/CSA-C22.2 No. 60601-1-4-02 (R2006)
CAN/CSA-C22.2 NO. 60601-2-2-08
IEC 60601-1-4:1996+A1
IEC 60601-2-2:2006

Certified Product: PULSAR II Electrosurgical Generator

Model Designation: PULSAR PS100-102

Rated Voltage: AC 100-240V, 50/60Hz
Rated Current: 5.3A max.
Protection Class: I, Type CF
Output Ratings: 160W/200chms/1MHz, INT 10s/30s


Appendix: 1, 1-5

Licensed Test mark: TÜV Rheinland

Signature: 

Date of Issue (day/mo/yr) 08/05/2012

Dipl.-Ing. M. Glagla
QA Certification Officer

TÜV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, Tel (203) 426-9888 Fax (203) 426-4009

40

71-10-2416 Rev A
Certificate of Compliance

Certificate Number: 20090709- E323306
Report Reference: E323306, June 12, 2009
Issue Date: 2009 July 09

Issued to: PEAK SURGICAL INC
2464 EMBARCADERO WAY
PALO ALTO, CA 94303 USA

This is to certify that representative samples of

Medical Equipment
Model Descriptions: PULSAR Electrosurgical Generator - PS100-100

Have been investigated by Underwriters Laboratories Inc.® in accordance with the Standard(s) indicated on this Certificate.

Standard(s) for Safety:

Additional Information:
Ratings:
Input: 100-240 V~, 50/60 Hz, 400W

Only those products bearing the UL Classification Mark for the U.S. and Canada should be considered as being covered by UL's Classification and Follow-Up Service and meeting the appropriate U.S. and Canadian requirements.

The UL Classification Mark includes: the UL in a circle symbol; with the word “CLASSIFIED” (as shown); a control number (may be alphanumeric) assigned by UL; a statement to indicate the extent of UL’s evaluation of the product; and the product category name (product identity) as indicated in the appropriate UL Directory. The UL Classification Mark for Canada includes: the UL Classification Mark for Canada; with the word “CLASSIFIED” (as shown); a control number (may be alphanumeric) assigned by UL; a statement to indicate the extent of UL’s evaluation of the product; and the product category name (product identity) in English, French, or English/French as indicated in the appropriate UL Directory.

Look for the UL Classification Mark on the product

Issued by: Jim Larin
Reviewed by: Michael Howell
Jim Larin, Customer Service Specialist
Michael Howell, Staff Engineer
Underwriters Laboratories Inc.
Underwriters Laboratories Inc.
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