This value analysis brief presents potential economic benefits of using the Checkpoint Surgical Nerve Stimulator/ Locator in surgical procedures that require precise nerve location, identification, and testing of nerve and muscle excitability. An assessment of the true value of any technology must consider multiple factors that impact the delivery of health care including direct and indirect costs of using or not using the technology. In this brief we examine the total cost associated with using the Checkpoint in relevant procedures versus the cost of competing technologies and methods.

**Checkpoint Facilitates Reduced OR Procedure Time**

In a survey of surgeon users of the Checkpoint completed in 2012, 35 of 61 surgeon respondents (57%) reported that Checkpoint reduces operating room time for the surgical procedures in which they use Checkpoint compared to how the same procedures were conducted without Checkpoint. Among those who note time savings, the average estimated reduction in operating room time was 21.1 minutes among DC based stimulator users and 27.5 minutes among surgeons who had specifically converted from a console based neuromonitoring system to Checkpoint. Due to the small sample size of the console user respondent group, statistical conclusions are not possible. According to research published by Shippert in 2005, the average cost of operating room time was determined to be $66 per minute. Using these values, the cost savings associated with the use of Checkpoint as a function of reduced OR procedure time is $1,320. Thus using Checkpoint may result in a net cost savings of $657 per case.

**OR Time Savings (Minutes)**

<table>
<thead>
<tr>
<th>Prior Console Users</th>
<th>Prior DC-Based Stimulator Users</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>27.5</td>
</tr>
<tr>
<td></td>
<td>21.1</td>
</tr>
</tbody>
</table>

**Neuromonitoring Devices.** Data on file from ECRI indicates a cost of $153 for an Incrementing Stimulation Probe (part number 8225825 and an additional $130 for the use of the (required) Paired Subdermal EMG electrodes (part number 8227411). The combined cost of these technologies is $283 per case. When this technology is applied to particular otolaryngology patients who require the use of the NIM Contact EMG Endotracheal Tube (8229506) the total component cost increases to $514 per case.

**Direct Current (DC) Nerve Stimulators.** Similarly, data on file from IMS Health indicates a cost of $47 per case for a single-use DC-based nerve stimulator. Most surgeons interviewed indicate the use of 2-3 units per case on average and a cost per case related to the device only should be assumed to be $94.

In light of the reduced OR procedure time attributable to Checkpoint, the cost of using neuromonitoring or DC-based stimulators is substantially greater than using Checkpoint.

**Cost of Non-Use/Ineffective Technology**

The costs of not using intra-operative nerve stimulation and the potential consequent injury and liability expense must also be considered. The principal reasons a surgeon may opt not to use intra-operative nerve stimulation include the belief that:

- the potential for injury is low and that a nerve stimulator may not be cost-justified,
- the available device or nerve monitoring system is more complex than needed in the operating room,
- the available device delivers a low level of DC-based stimulation which limits nerve response and does not provide sustained nerve and muscle excitation,
- the addition of nerve monitoring system technology adds time, complexity and staffing to the case that cannot be justified.

In any event, the failure to use intra-operative nerve stimulation technology, whatever the reason, potentially adds substantial expense that exceeds the cost of using the technology. These additional expenses may include Unreimbursed Medical Expense and Amortization of Liability-related Expenses. When these additional costs, characterized and referenced in the model below, are considered, the true cost of the technology is understood.
Cost of Non-Use/Ineffective Technology

<table>
<thead>
<tr>
<th></th>
<th>DC-Based Stimulator</th>
<th>Nerve Monitoring Console System</th>
<th>Checkpoint</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR Procedure Time Saved⁴</td>
<td>21.1 min</td>
<td>27.5 min</td>
<td>$1,815</td>
</tr>
<tr>
<td>OR Turnover/Set-up Time Saved⁴</td>
<td>8.9 min</td>
<td>22.5 min</td>
<td>$1,485</td>
</tr>
<tr>
<td>Unreimbursed Medical Expenses³</td>
<td></td>
<td>$1,320</td>
<td></td>
</tr>
<tr>
<td>Liability Expense Amortization⁴</td>
<td></td>
<td>$2,694</td>
<td></td>
</tr>
<tr>
<td>Device Cost⁵,⁶</td>
<td></td>
<td>$94</td>
<td>$283 - $514</td>
</tr>
<tr>
<td>TOTAL Cost</td>
<td></td>
<td>$6,088</td>
<td>$7,547 - $7,828</td>
</tr>
</tbody>
</table>

References and Model Assumptions:
3. Per case amortization following iatrogenic injury due to limitations of existing technology, failure to use technology due to complexity, misinterpreting data, etc. Assumes $20,000 in unreimbursed medical expense for iatrogenic injury management at a 6.6% rate of injury in select cases in which the nerves are at risk. See Malpractice Costs below for references in support of this model.
4. The average amortized cost per nerve injury case for surgeries in which there is data to be referenced. See Malpractice Costs below for references in support of this model.
5. ECRI Data on File July 2012.
6. IMS Data on File Feb 3, 2012

Malpractice Costs

<table>
<thead>
<tr>
<th>Legal Costs of nerve injury per 1,000 surgeries</th>
<th>Total Shoulder Arthroplasty</th>
<th>Shoulder Surgery</th>
<th>Total Hip Arthroplasty</th>
<th>Total Knee Arthroplasty</th>
<th>Thyroid Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Surgeries</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
</tr>
<tr>
<td>Rate of Nerve Injury</td>
<td>16.7%³</td>
<td>7.5%²</td>
<td>1.6%³</td>
<td>1.3%⁴</td>
<td>5.9%⁵</td>
</tr>
<tr>
<td>Number of Surgeries resulting in Nerve Injury</td>
<td>167</td>
<td>75</td>
<td>16</td>
<td>13</td>
<td>59</td>
</tr>
<tr>
<td>Number of Lawsuits Filed (assumes 10% chance of lawsuit)</td>
<td>16.7</td>
<td>7.5</td>
<td>1.6</td>
<td>1.3</td>
<td>5.9</td>
</tr>
<tr>
<td>Average Cost per Lawsuit Filed (regardless of outcome of lawsuit)</td>
<td>$408,182</td>
<td>$408,182</td>
<td>$408,182</td>
<td>$408,182</td>
<td>$408,182</td>
</tr>
<tr>
<td>Lawsuit Costs per Surgeries</td>
<td>$6,816</td>
<td>$3,061</td>
<td>$653</td>
<td>$530</td>
<td>$2,408</td>
</tr>
</tbody>
</table>

From this table we can calculate the average rate of nerve injury from the above studies to be 6.6%. Assuming $20,000 in unreimbursed expenses for iatrogenic injury cases and a 6.6% nerve injury incidence rate, the average incremental cost per case if these injuries are not avoided is: $1,320 amortized per case.

Similarly, the average amortized cost per nerve injury case using the above assumptions is $2,694 (for surgeries in which there is data to be referenced).

Nerve Injury Avoidance

The following information provides background on the incidence and outcomes of peripheral nerve injury during surgery and resultant malpractice claims.

Medical Malpractice can only be shown when the four elements of negligence are present: the physician has a duty to the patient, that duty is breached, the patient is injured, and the breach “reasonably” led to the injury. A 1990 Harvard Medical Practice study cited by Mark McClellan, then Administrator of CMS, in his testimony to the Joint Economic Committee found that only 2% of those with an adverse event related to negligence filed a malpractice suit. (CMS Testimonies 2005)1 In 2002, 18,999 medical malpractice payment reports were made in the US. Over 80% of these were against physicians per the 2002 Annual Report of the National Practitioner Data Bank, US DHHS.2 Half to 2/3 of hospital adverse events are attributed to surgery and most are technical in nature. A retrospective study of 444 randomly sampled malpractice claims revealed that 14% were peripheral nerve injuries. (Regenbogen et al 2007)3 Even though only a proportion of adverse events lead to malpractice suits, all result in negative, unintended outcomes for the patient and the surgeon. (Regenbogen et al 2007, Studdert et al 2006)4 A random sample of 1452 closed malpractice claims from 5 liability insurers (covering 33,000 physicians) revealed that 889 involved injuries due to error; 573 resulting in “significant physical injury” and 220 in “major physical injury”. 73% of those injured due to error were compensated; at an average rate of $521,560. Settlements were on average half the size of plaintiff awards ($462,099 vs. $799,365). In addition to the award and settlement payments, the defense cost was almost $73 million and took on average 5 years to resolve. (Studdert et al 2006).5

Active members of the American Association of Hip and Knee Surgeons were surveyed regarding adverse events. Nerve injury was the most frequently reported malpractice claim (22%) following total hip or knee arthroplasty. Although only ¼ resulted in claim payment, the cost related to administration and overhead were significant. (Upadhyay et al 2007).6

Nerve injury following Total Hip Arthroplasty (THA) occurs in 0-3% of primary surgeries and 2.9 – 7.6% of revision surgeries. The sciatic nerve is most commonly involved. The exact cause of injury is unclear but may include direct nerve trauma, nerve tension or compression, or pressure from hematoma, adhesive extrusion, wires, screws or rings. Only 20% of patients with these nerve injuries recover completely. (Hoffman & Skrzynski 2000).7

A review of the WestLaw database identified 53 medical malpractice suits filed from 1/1/1985 through 12/31/2000 for intraoperative facial nerve injury throughout the United States. Surgical categories were: 13 otologic, 12 cosmetic, 9 benign tumor of parotid, 1 malignant tumor of parotid, 15 benign head & neck surgery, 3 TMJ. Forty five percent (45%) of the surgeons were ENT and almost 30% plastic surgeons. 22 (42%) were found in favor of the defendant. The remainder was settled 12 (33%) or found in favor of the Plaintiff 19 (36%). The mean settlement was $337,313 and the mean award was $567,944. Thirty-one (31) - (84%) of these suits alleged “surgical misadventure” as the cause of nerve injury and 19 specifically alleged, “The surgeon had negligently injured the nerve”. Of those 19, 6 resulted in settlements and 6 resulted in plaintiff awards. (Lydiatt Jan, 2003).8

“Note that a surgeon who attempts to identify and preserve the nerve is likely less vulnerable to allegations of breach of duty. Regardless of whether surgeons consider careful surgical technique and preservation of the nerve to be the standard of care, the legal system clearly treats it as such,...” (Morris, et al 2008)10

“We believe that during any orthopaedic operation the fact that nerves are actively identified and protected at all times should be recorded. This will obviously not eliminate all nerve palsies, but will aid the defense of such cases.” Gidwani S., The Journal of Bone and Joint Surgery Vol. 91-B, No.2, Feb. 09
A similar review of the WestLaw database from 1987-2000 identified 30 suits with jury verdicts involving the thyroid gland. Unilateral injury to the recurrent laryngeal nerve was alleged in 6 cases and bilateral injury in 3 cases. Of the unilateral injury cases, 1 resulted in a defendant verdict, 1 in a settlement and 4 in a plaintiff verdict. In the bilateral cases, 2 were found in favor of the defendant and 1 in favor of the plaintiff. (Lydiatt June, 2003).9

Spinal Accessory Nerve (Cranial Nerve XI) injury is a common risk of posterior triangle lymph node biopsies, estimated to occur in 3% to 8% of those biopsies. This nerve is also at risk during neck dissections, carotid endarterectomies and face-lift surgery. A retrospective review of Medical Liability Mutual Insurance Company records in New York State 1985-2007 identified 41 suits for spinal accessory nerve injury and the WestLaw database review identified 81 cases nationally. These injuries were related to cervical lymph node biopsy in 39 (95%) of the insurance cases and 55 (68%) of the court cases. Of the insurance cases, 82% of the plaintiffs were compensated. The mean award for settled cases was $264,395 (range $7,150 to $512,000) and for trial award was $443,538 (range $82,080 to $935,000). In the trial cases, 98% alleged surgical misadventure or error. 12 cases were settled during the trial and 32 cases were found in favor of the plaintiff. The mean settlement was $356,132 (range $22,281 to $622,988) and the mean plaintiff award was $515,968 (range $50,260 to $1,299,720). Overall, in 81% of the cases, the plaintiff was compensated.