The risk of intraoperative nerve palsy or injury is significant in head and neck procedures, up to 30% of parotidectomies and 10% of thyroidectomies. Furthermore, nerve injury rates are likely underestimated in the literature as many injuries are often unreported.

Nerve injuries represent significant quality of life consequences for the patient as well as economic and legal consequences for the doctor and hospital. Thus, there is a need for devices to assist doctors with intraoperative neuroprotection.

Current American Thyroid Association management guidelines strongly recommend that at a minimum, surgeons should visually confirm the location of the recurrent laryngeal nerve during a thyroidectomy. However, visual identification of the nerve can be difficult due to anatomical challenges, and nerve visualization does not confirm the nerve is functional.

Use of intraoperative nerve monitoring (IONM) devices in head and neck procedures has been increasing as a tool to assist doctors with nerve protection. The implementation of intraoperative stimulation during the use of IONM is responsible for the majority of the benefits.

Direct current stimulators, representing an older intraoperative stimulation technology, are poorly suited to safely and reliably deliver repeated stimulations throughout a procedure.

Checkpoint Head and Neck’s advanced technology provides surgeons with a safe and reliable intraoperative stimulator and its stimulation frequency produces a muscle contraction that can be easily visualized or felt.

Section 1 – Clinical Need

The utilization of medical devices within the operating room to assist surgeons with identification and preservation of neural structures continues to grow, especially with head and neck procedures. The anatomical location of the facial nerve relative to the parotid gland, and recurrent laryngeal nerve (RLN) to the thyroid gland, places these nerves at great risk for injury during thyroidectomy and parotidectomy procedures. Injury to the facial nerve during a parotidectomy can result in temporary facial nerve weakness in up to 35% of cases and permanent muscle paralysis in up to 7% of cases (Sood et al., 2015). Similarly, iatrogenic injury of the RLN is estimated to occur in 5%-10% of thyroidectomies and in up to 30% of revision cases (Chandrasekhar et al., 2013). It is important to note that nerve injuries are often underreported, and therefore the true rate of nerve injury is likely higher. The resulting facial muscle weakness or vocal cord paresis has significant quality of life consequences for the patient, as well as significant economic consequences for both the surgeon and the hospital. In 2015, the American Thyroid Association (ATA) treatment guidelines strongly recommended that visual identification of the RLN during dissection should be required in all thyroidectomy cases as a means to reduce the likelihood of RLN injury (Haugen et al., 2016). However, visual identification and preservation of the RLN is greatly complicated by a large number of variations in RLN anatomy (Chiang et al., 2010), and identification may be further complicated by tumor growth.

Additionally, visual evaluation of anatomical integrity does not provide sufficient evidence to determine the functional integrity of the nerve. This gap in intraoperative knowledge has led to technological solutions aimed at assisting surgeons in locating neural tissue and assessing nerve function intraoperatively.
Section 2 – Overview of Nerve Monitoring Technologies

Intraoperative nerve monitoring (IONM) is one such technology that surgeons can utilize to protect the RLN during thyroidectomy procedures. IONM devices combine intraoperative electrical stimulation with audio and/or visual feedback of muscle activity, to provide surgeons with an ability to both identify neural structures and evaluate nerve function. The development of IONM systems, designed to be operated by the surgeon alone, without requiring a trained electrophysiologist technician, has helped to increase utilization in thyroidectomy and other head and neck procedures. These systems also provide surgeons with an audible and/or visual alert of muscle activity. IONM systems require the surgeon or an additional monitoring technician to decipher the type and quality of information conveyed by the alert, to determine if the surgical plan or techniques should be adjusted or halted. Typically, surgeons are most concerned when these warnings may indicate the potential for impending nerve injury. However, muscle activity-based alerts do not always correlate with nerve function or injury, as muscle activity has been shown to occur in the absence of impending nerve injury (Prass and Lüders, 1986; Romstöck et al., 2000), and nerve injury can occur without producing significant muscle activity (Randolph and Kamani, 2016).

While monitoring of muscle activity may provide some additional information for the surgeon, current literature suggests that intraoperative stimulation is the key component within IONM that facilitates neuroprotection and assessment of nerve function.

Section 3 – Current Clinical Recommendations and Guidelines

The International Nerve Monitoring Study Group outlines three modes for IONM application in thyroid surgery: 1) Identification (neural mapping) of RLN, 2) aid in dissec- tion, and 3) prognostication of postoperative neural function and lesion site identification (Randolph et al., 2010). All three of these IONM uses in thyroid surgery center upon the use of intraoperative electric stimulation. Additionally, the 2015 ATA guidelines recommend “Intraoperative neural stimulation (with or without monitoring) may be considered to facilitate nerve identification and confirm neural function” (Haugen et al., 2016). The importance of intraoperative stimulation within IONM devices, demonstrates that there is an opportunity and need for innovation and technological advancement of traditional intraoperative stimulation devices to better assist surgeons with intraoperative neuroprotection and decision making.
Section 4 – Checkpoint Head & Neck

The Checkpoint Head & Neck Stimulator provides surgeons with a reliable, easy to use, handheld stimulator to intraoperatively locate and assess nerves. Checkpoint utilizes a biphasic, charge balanced, stimulating waveform, which enables continuous stimulation of nerves and tissue without risk of tissue damage, unlike direct current stimulators, which if left in contact with nerve tissue can produce severe neural damage (Hughes et al., 1980; 1981).

The ability to safely stimulate nerves and tissue multiple times enables Checkpoint stimulators to be used to map the location of nerves which is especially beneficial during difficult cases such as revision surgeries. Additionally, advanced electronics within the Checkpoint Head & Neck device continuously monitors the internal electronics and stimulator output throughout the procedure, ensuring delivery of safe and reliable stimulation. This reliability and consistency gives the surgeon confidence in the information provided by Checkpoint, empowering the surgeon to make informed decisions during the course of surgery.

Feedback of muscle activity is obtained by visualization or palpation of the resulting contraction within the surgical field, engaging the surgeon as an active participant in the feedback loop. The Checkpoint Head & Neck stimulates the nerve at 16Hz, producing a tetanic or fused muscle contraction easily visualized and/or palpated. Thus, the Checkpoint Head & Neck provides the benefits of intraoperative stimulation, without the additional overhead associated with IONM devices.

Comparison of Direct Current and Biphasic Stimulating Waveforms.
Section 5 - References


