

Subdermal Needle Designed to Reduce or Eliminate Accidental Needle Injuries during Intraoperative Neuromonitoring (IONM) and Continuous EEG (cEEG)

Abstract:

Objective: Compare published statistics regarding the prevalence and cost of accidental needle sticks/injuries occurring during continuous EEG (cEEG) and intraoperative neuromonitoring (IONM) with comparison of various safety practices to reduce accidental needles sticks/ injuries.

Keywords: EEG, cEEG (Continuous EEG), Intraoperative Neuromonitoring (IONM), Subdermal Needle, FDA (Federal and Drug Administration), MRI (Magnetic Resonance Imaging), American Society for Testing and Materials (ASTM), MRI, MR Compatible, MR Conditional, MR Safe, MR Unsafe, Healthcare Acquired Infections (HAIs), disposable single patient electrodes; reusable electrodes, Neurodiagnostic Technologist, ICU (Intensive Care Unit), ER (Emergency Room), NSIs (needle stick injuries or needle and sharps injuries) OSHA (Occupational Safety and Health Administration)

Introduction: For the past several decades, healthcare systems have amplified their focus on the identification and handling of sharps in order to decrease accidental needle sticks/injury. Attention to the safety and prevention of accidental needle sticks/injuries became a high priority during the 1980s, when the HIV/AIDS epidemic required additional safety precautions to be established and implemented.

Despite increased attention to sharps-use safety, those who provide intraoperative neuromonitoring (IONM) or continuous EEG (cEEG) using subdermal needle electrodes have not seen substantial improvements in product design to reduce the risk of injury. Clinical practice has utilized tape to secure the needle electrodes to the patient. This technique and other protective strategies provide limited assistance, but the design of the subdermal needle itself, has not been improved to mitigate and eliminate accidental sticks until recently. The Guardian Needle® is the first IONM and cEEG product to be specifically designed to help reduce accidental needlesticks by incorporating a protective casing to eliminate exposure to the needle when not in use. The protective design does not impact data quality or speed and efficiency in surgical or critical care departments. In some Operating Rooms (OR) and Intensive Care Units (ICU) environments use of the Guardian Needle has been reported to reduce clinical set up time.

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Current challenge: The efficacy and quality of data acquisition by disposable subdermal needle electrodes have been well reported and established for IONM and cEEG (Young, 2006). However, the challenge lies within the IONM and cEEG industry's historical resistance to the use of subdermal needle electrodes due to risk of accidental injury by needle sticks. While reducing accidental needle sticks, the Guardian Needle electrode enhances the quality and reliability of data acquisition. Additionally, this electrode requires minimal user training and expedites application and overall set-up time. Furthermore, the advancement of the design improves staff workflow and safety, along with high quality patient care. Finally, the configuration of the new design improves hospital processes by eliminating lengthy applications and excess time and resources for user training. This challenge is addressed by the Guardian Needle® design which eliminates the exposure of the subdermal needle when the product is deployed or not in use.

This paper concentrates on the following: Outlining the challenges of the standard subdermal needle electrode design in comparison to the Guardian Needle design, the costs associated with an accidental sharps/needle injury, and the patient benefit of quick application with minimal user training.

Design of a standard subdermal needle vs Guardian Needle®

Sterile packaging with plastic needle tip caps are prevalent across the market, but no included safety features are designed to prevent needle sticks/injuries before or after the needle is inserted into the patient. Most needle stick injuries occur during the removal of the needle (52%) or repositioning of the patient (67.7%). Needle safety with standard subdermal needles requires the use of additional resources, such as nonsterile adhesive tape or skin staples. Extra time and expertise are required to position the needle leadwires by braiding and/or twisting them to prevent entanglement and dislodgement which can result in an accidental needle stick (Tamkus, 2014).

The Guardian Needle® has built in safety-engineered features. The design incorporates a protective casing that houses the needle tip when not inserted into the patient. The casing is also surrounded by a sterile, adhesive bandage to replace the use of tape to keep the needle in place. Adhesive tape commonly used is not sterile, or single-patient use, thereby introducing another risk to the patient through the potential presence of bacteria that can remain after removal and potentially lead to higher infection rates (Harris, 2012).

In similar healthcare settings involving accidental needle sticks, the use of safety-engineered devices, specifically those that cover the needle tip after use, has lowered the rate of NSI by as much as 43.4% to 100% compared to

Data quality of a standard subdermal needle vs a Guardian Needle®

Through user testing it was determined that the data quality of the Guardian Needle is effectively identical to that of a standard subdermal needle. Figures 1 and 2, shown below, illustrate this point.



Fig 1: Data Quality Shows all traces with Guardian Needle, with the exception of EEG traces.

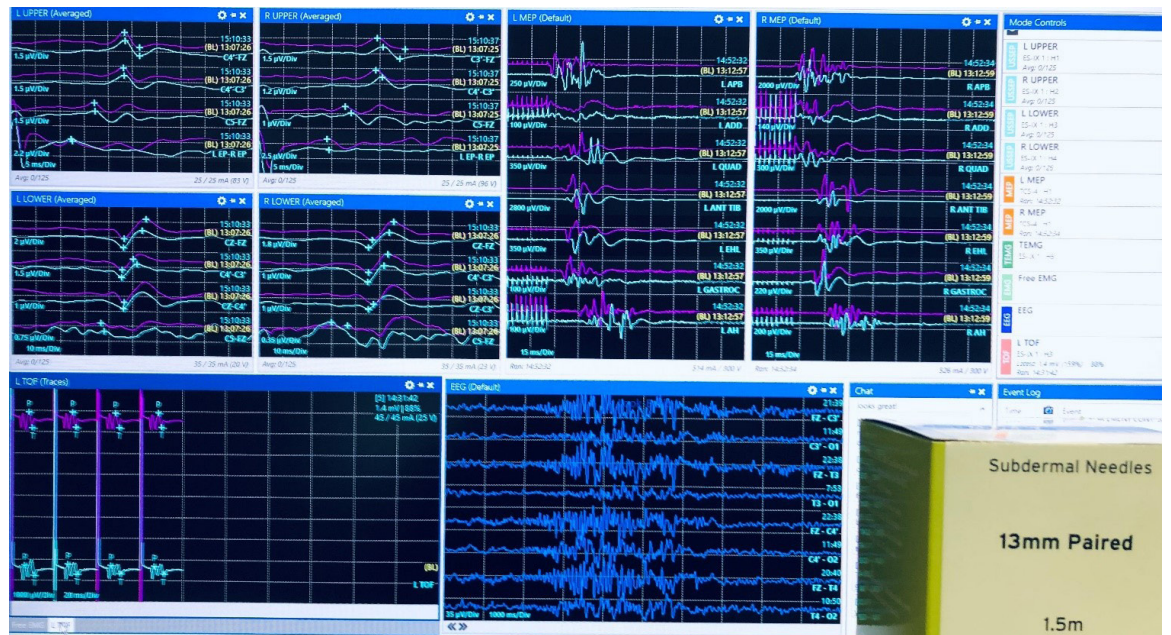


Fig 2: Data Quality Standard subdermal needles in all traces.

Cost related to a needle injury:

The reported rate of accidental needle stick injury varies with some sources reporting a 0.34% in IONM settings (Tamkus, 2014). Though less than 1% of procedures may result in accidental needle stick, the rate of transmission of blood borne pathogens is potentially high within these incidences. “For every 1,000 NSIs from an infected patient, 300 HCWs will become infected with HBV. For HCV and HIV, seroconversion rates are 30 per 1,000 and three per 1,000, respectively” (Tamkus, 2014).

Guardian Needle Cost Analysis for IONM + cEEG

	Ex. 1	Ex. 2	Ex. 3	Ex. 4
Number of Cases (patients)/year IONM + cEEG	25,000	50,000	100,000	150,000
Number of electrodes (25 per patient)	625,000	1,250,000	2,500,000	3,750,000
Number of injuries/year (assume rate of 0.29%)	73	145	290	435
Avg Cost Per Injury	\$5,000	\$5,000	\$5,000	\$5,000
Total Cost	\$362,500	\$725,000	\$1,450,000	\$2,175,000
Cost per year for standard subdermal needle (\$0.95)	\$539,750	\$1,187,500	\$2,375,000	\$3,562,500
Cost per year for subdermal Guardian Needle (\$1.50)	\$937,500	\$1,875,000	\$2,375,000	\$3,562,000
Difference	\$343,750	\$687,500	\$1,375,000	\$2,062,500
Investment vs Injury	-\$18,750	-\$37,500	-\$75,000	-\$112,500
Difference Per Month	-\$1,563	-\$3,125	-\$6,250	-\$9,375

Speed of application standard EEG Cup Electrode vs Guardian Needle®

Average application time for a 24-lead EEG set of cup electrodes is approximately 45 minutes equal to the equivalent of \$30 in labor costs (calculated using salary data supplied by ASET for resource time per patient). Average application time for a 24-lead set of Guardian Needles using a RLI template for placement averages approximately 5 (additionally only a 5 min IONM set up for experienced care team members)mins and eliminates the need for additional staff to assist application. In addition to the cost analysis outlined above, this resource difference accounts for \$25 per patient which offsets the price of the Guardian Needle by more than 50% in a cEEG scenario.

- The average salary of a Neurodiagnostic Technologist is \$65,226 per year but this number does not include any additional benefits or overhead for the employee. Using data from September 2013 Bureau of Labor Statistics 30% is an average additional cost for employee benefits. With 30% added the average salary of a Neurodiagnostic Technologist is \$84,973 per year.
- The average yearly salary with benefits calculates into hourly wage of \$40.77.

Conclusion: Accidental needle sticks/injuries caused by subdermal needles used in IONM or cEEG can be reduced and/or avoided by using devices with safety features and without impacting data integrity, such as the Guardian Needle™. Use of a Guardian Needle in ICU for cEEG and IONM can also enhance staff workflow, reduce time and resources by utilizing staff already interacting with the patients to apply the electrodes.

Conflict of Interest Disclaimer: Authors include employees of Rhythmlink International, LLC. Rhythmlink is a medical device manufacturer and distributor of both reusable and disposable EEG electrodes.

Additional References

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