Active Electrode Monitoring in Robotic Surgery Could Eliminate Patient Injury from Stray Energy

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Background

- The risk of patient injury from stray monopolar energy during MIS is 3.6 per 1000 procedures.[1]
- At least half of these injuries are preventable.[2]
- Active Electrode Monitoring (AEM®) Shield™ Technology eliminates the risk of stray energy injury from monopolar energy.[2] (Figure 1)

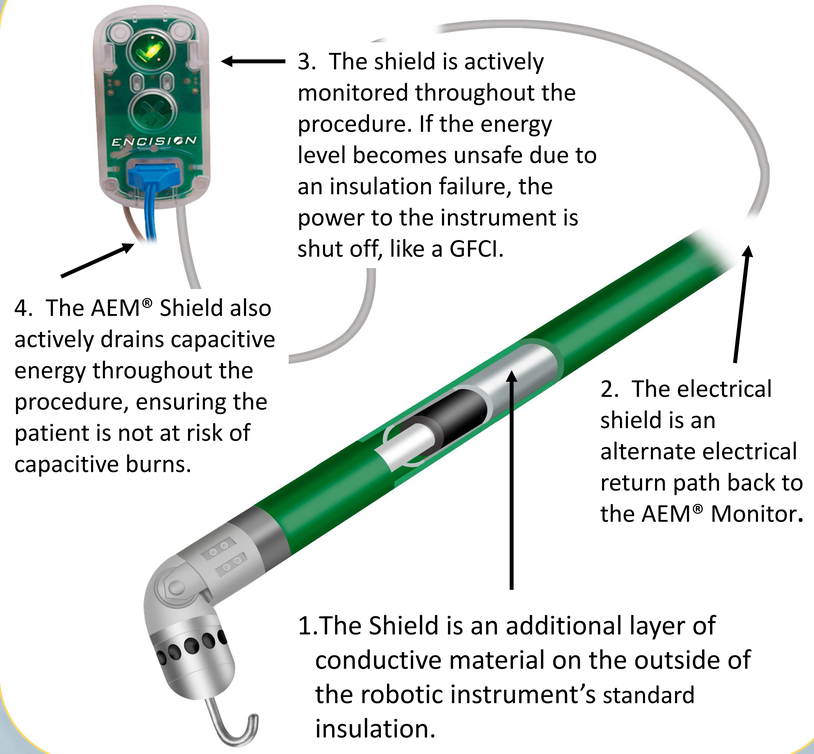
Description of the Technology

- AEM Shield Technology is available for laparoscopic surgery and has been proven to eliminate the risk of stray energy burns. (Figure 2)
- AEM Shield Technology works by adding an additional layer of conductive material on the outside of the standard insulation.
- This electrical shield is actively monitored and controlled, ensuring the risk to the patient is eliminated.

New Application

- AEM Shield Technology can be applied to robotic surgery platforms to eliminate the risk of stray energy burns.
- When using AEM Shield Technology, there is an elimination of burns from both intra-operative insulation failure and capacitive energy, no matter the power setting and mode; allowing surgeons to use all ESU power levels and modes without the increased risk.

Figure 1 – Mechanism of Action



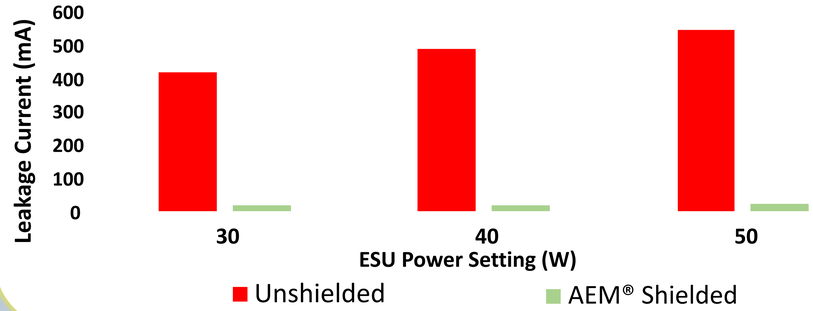
References

1. Guzman C, et al. Estimating the Incidence of Stray Energy Burns during Laparoscopic Surgery based on Two Statewide Databases and Retrospective Rates: An Opportunity to Improve Patient Safety. Surg Technol Int. 2019 May 15;34:30-34
2. Martin KE, et al. Quantifying inadvertent thermal bowel injury from the monopolar instrument. Surg Endosc. 2016 Nov;30(11):4776-4784.
3. Data on file at Encision Inc.

Preliminary Results

- Prototypes of shielded robotic instruments reduce stray energy by over 95% compared to conventional, unshielded robotic instruments.[3]
- This effectively eliminates the chance of stray energy burns from both intra-operative insulation failure and capacitive or antenna coupling.

Figure 2 - Leakage Current of Robotic Instruments



Conclusions

1. Patient injury and death has occurred because of stray energy injury during minimally invasive surgery.
2. Robotic platforms are at risk of significant stray energy transfer.
3. The incorporation of AEM Shield Technology in future platforms would eliminate the risk of patient injury as a result of insulation failure, capacitive coupling and other common mechanisms for stray energy injury.