Findings of an Internal Auditing Study of Insulation Testing Practices to Improve Healthcare Facility Testing Practices and Patient Outcomes

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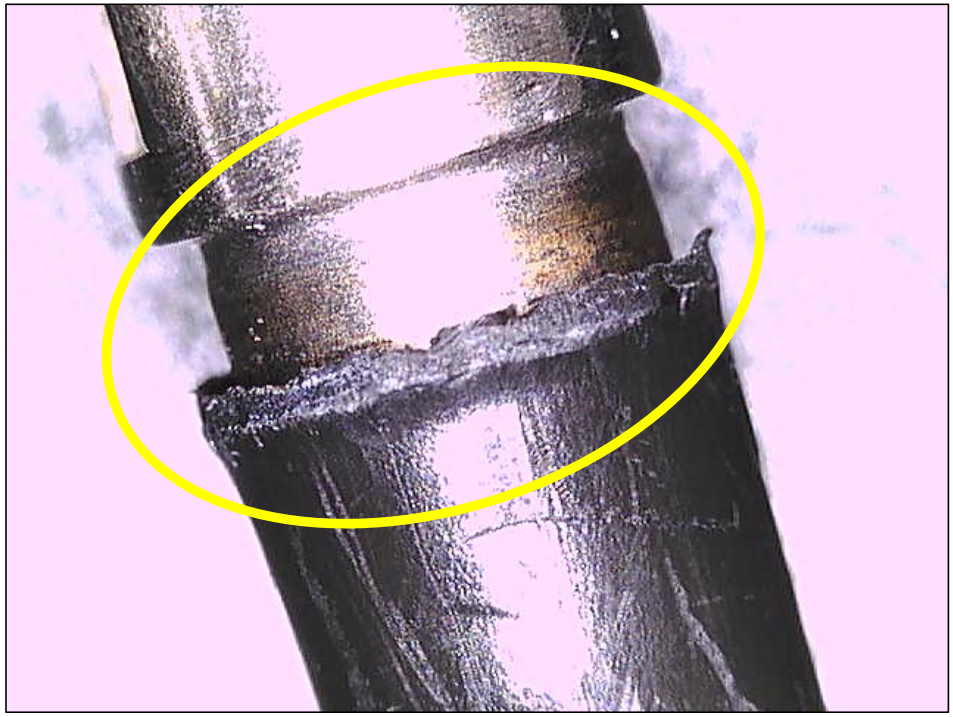
The Root-Cause of the AIM

- September of 2020 my daughter became ill
- Emergency lap appendectomy
- Facility did not perform insulation testing
- 7-days later daughter returned to emergency with complications (not related to arching)
- This incident was a (near miss)
- Had some data for a 2019 from a preliminary study, published in 2021
- Then a more robust study in 2021-2022

AIM

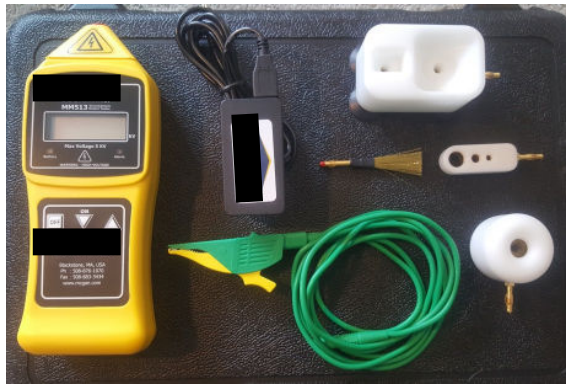
- The aim of the study was to identify how common insulation testing failures and malfunctions are in insulated medical devices used in healthcare facilities.
- The study is a retrospective cross-section 12-month study that was conducted from May 2021 to May 2022 at 49 healthcare facilities that consisted of 416 insulted instrumentations.
- The study was published in the 2023 March/April Edition of the PROCESS Magazine (HSPA).



Methods

- Auditing of random laparoscopic insulated trays
- Bipolar insulated forceps using an insulation tester with variable power settings and a variety of adapters to fit the instrument being tested.
- A cable continuity tester was utilized to identify any disruption of the electrical current within reusable monopolar and bipolar cables.
- An enhanced inspection microscope was used to evaluate the damage identified with the insulation tester and other visible damage observed.

NOTE: Personnel at the healthcare facility observing the audit were notified of any failures.



Methods Continued…

- A qualitative survey question was administered to operating room nurses randomly across the United States asking if they had experienced events such as arcing of electrical current during a procedure.

- In addition, the FDA MAUDE database was searched for adverse events on insulation failures reported within the same timeframe to determine if any significant patient risk existed.

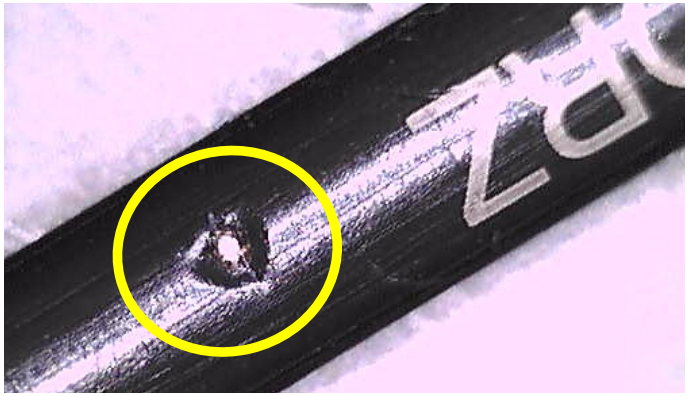
fda maude database - Bing images

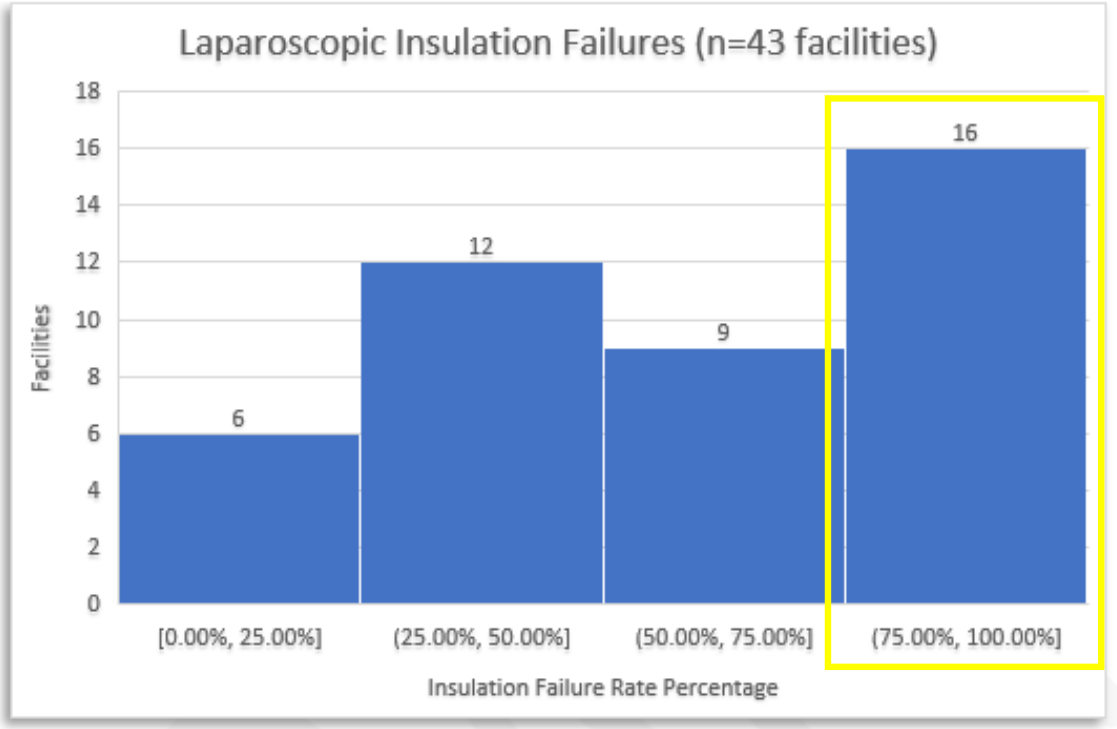
Limitations

- The inconsistencies between each facility's insulation inventory and the amount of insulated laparoscopic instruments within a container/tray skewed the percentage of failures.
- The amount of insulated bipolar forceps a facility could afford to release to test was another factor and made the sample size smaller.
- There were also inconsistencies with not all facilities using reusable cables, resorted to single use, and/or a mixture of both, which affected the sample size for that category of instrumentation.

Results

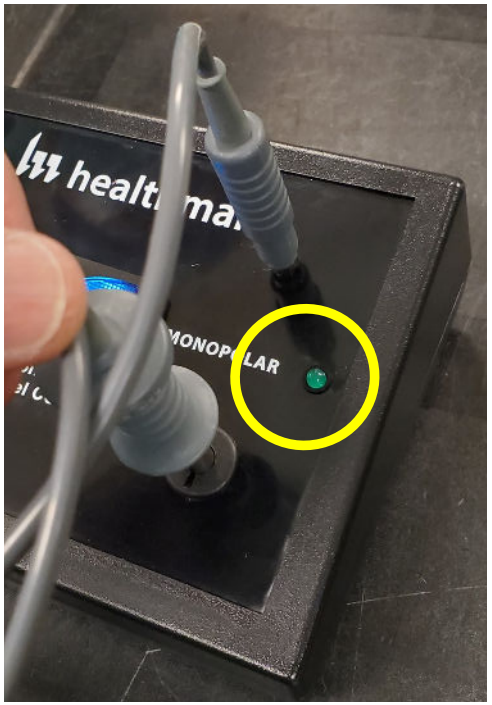
- Of the total 416 instruments tested, 223 showed failures on insulation testing or inspection.
- With 16 facilities showing a failure rate of 75%–100% of all devices tested.

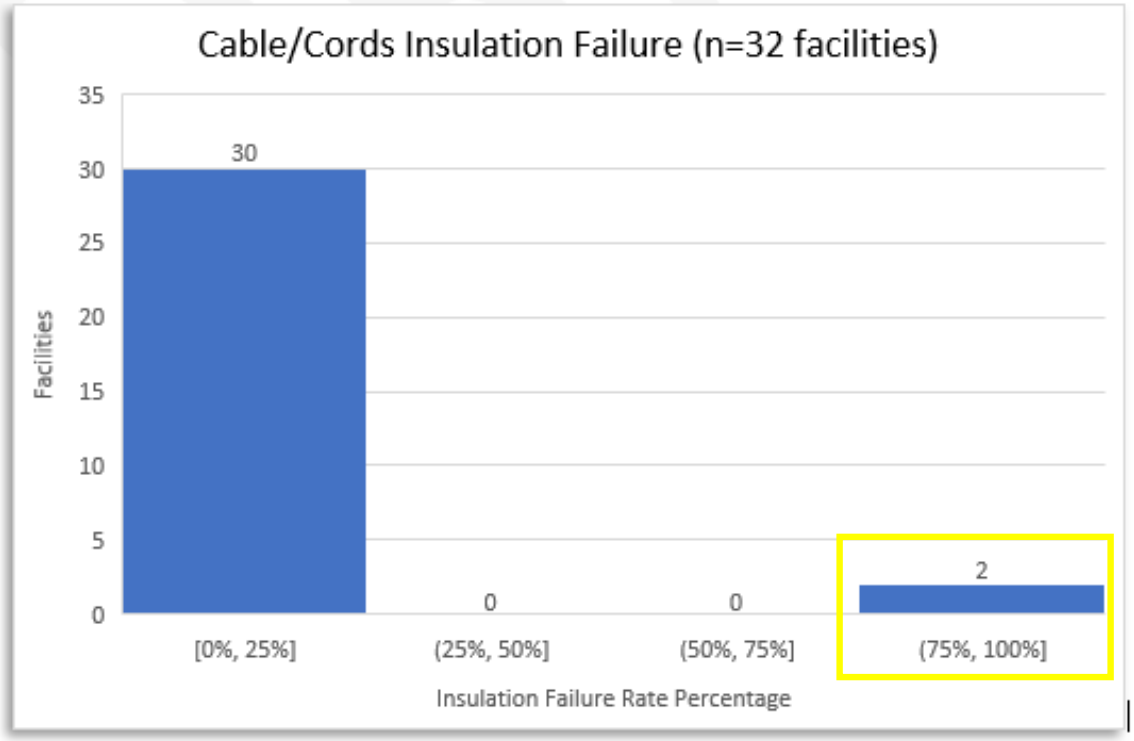




Results

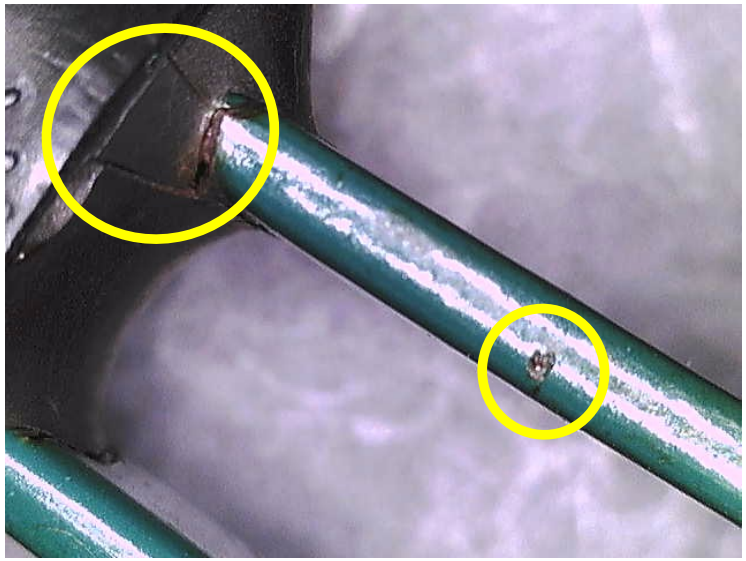
- On average, insulated cables demonstrated a 6% failure rate for continuity across 32 facilities.

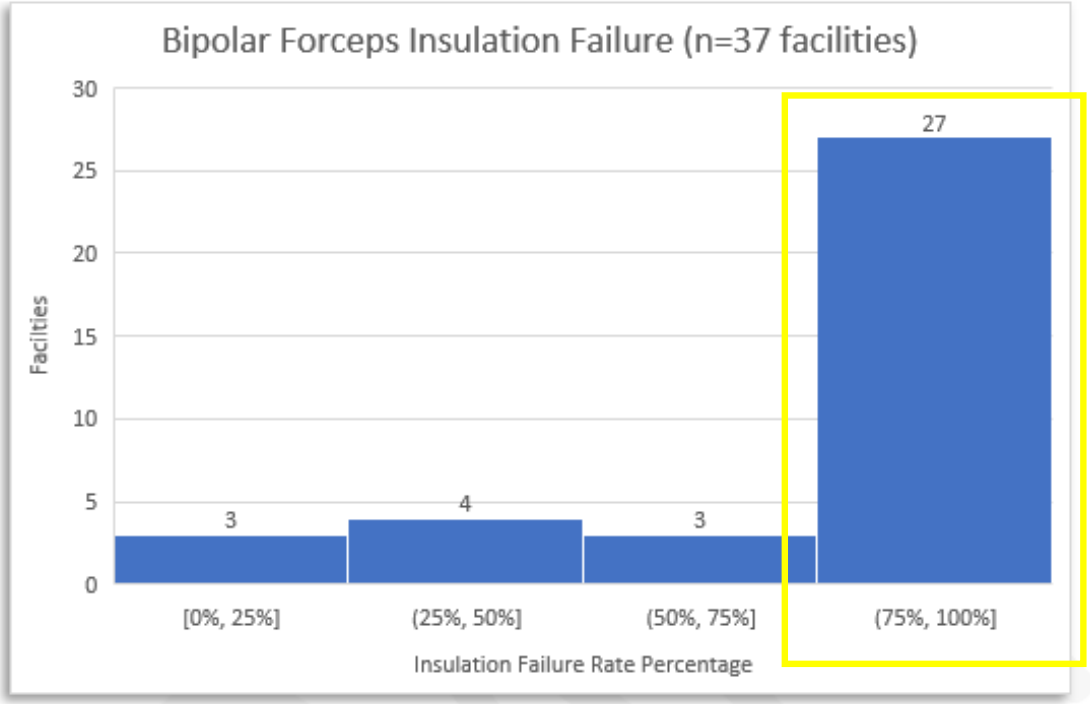




Results

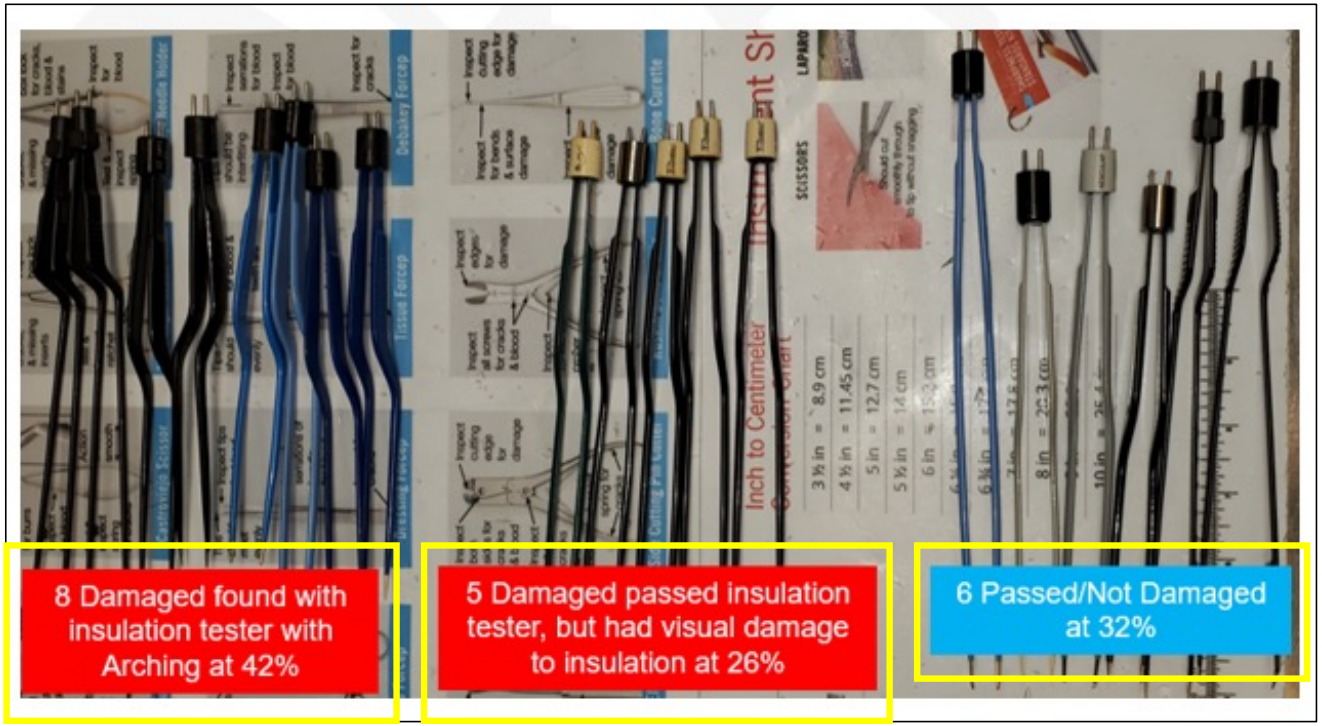
- Bipolar forceps had the highest failure rate with 27 facilities having a 75%–100% failure rate for those devices





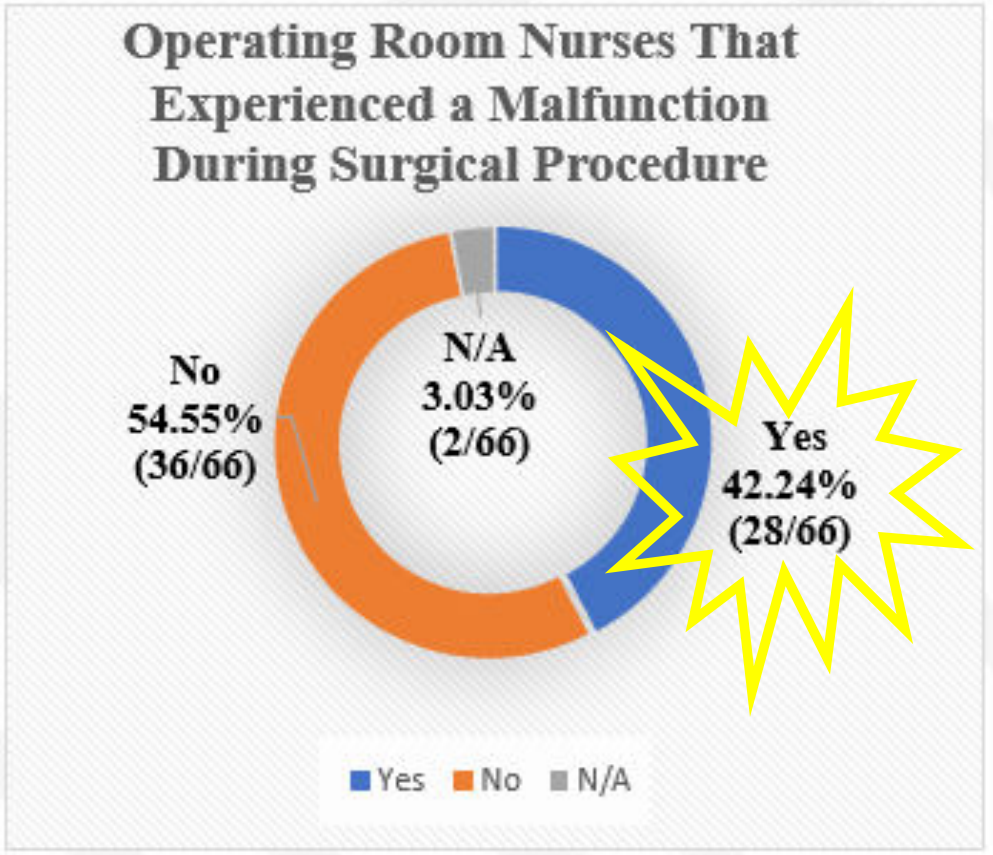
Results

- In one of the 27 facilities, 19 insulated bipolar forceps were tested from ready-to-use backup inventory.
- 13 of the 19 were identified as having insulation failures



Results

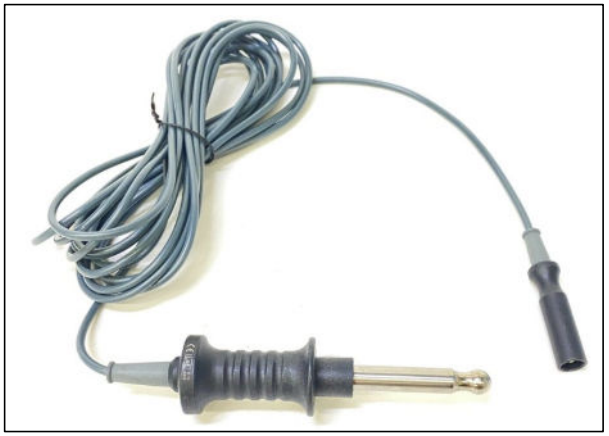
- For the qualitative aim of the study, operating room (OR) nurses were asked about their personal experience with insulation malfunctions during a surgical procedure during their career.
- A total of 66 responses were received by respondents: Yes: 42.24% (28/66), No: 54.55% (36/66), N/A: 3.03% (2/66).

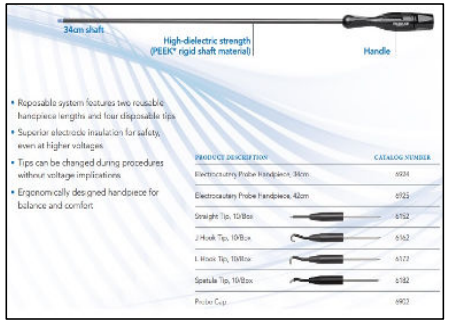


Results

Concurrent Adverse Events (FDA) Food & Drug Administration, Maude Reporting System (United States)

- **07-26-2021**: an insulated laparoscopic handle was found to have an insulation integrity failure and, "… it was reported that product arced resulting in blisters to the patient's skin."
- **08-10-2021**: an insulated laparoscopic 34CM Cautery Probe was identified with damage to the insulation coating and, "the instrument melted and arced from the side, burning an unintended portion of the liver."
- **03-15-2022**: a monopolar-HF cable "… reportedly exploded during [the] procedure and burnt towards the end where the HF cord connects to the generator unit, and a minor deformation/kink was noted on the cable."





Results

Instruction-For-Use in (Adverse Events Reported)

- 07-26-21

Insulated Handle

"… inspect for burns, cuts, and abrasions in the electrical insulation on the insert and/or the handle for instruments equipped with electrosurgical capabilities."

"These instructions were developed using the guidance from AAMI TIR 12, ISO 17665, and AAMI ST79, and (_____) recommends users observe these standards."

- 08-10-21

Laparoscopic Instrument

"Conduct a visual and functional inspection of the device per the Assembly and Disassembly instructions."

"Insulation failures may result in burns or other injuries. Visual inspection alone may not be sufficient to confirm that the insulation is intact, and dielectric strength testing should be additionally considered."

- 03-15-22

Monopolar Cable

"Visually inspect the cable and the plugs for irregularities on the surface,"

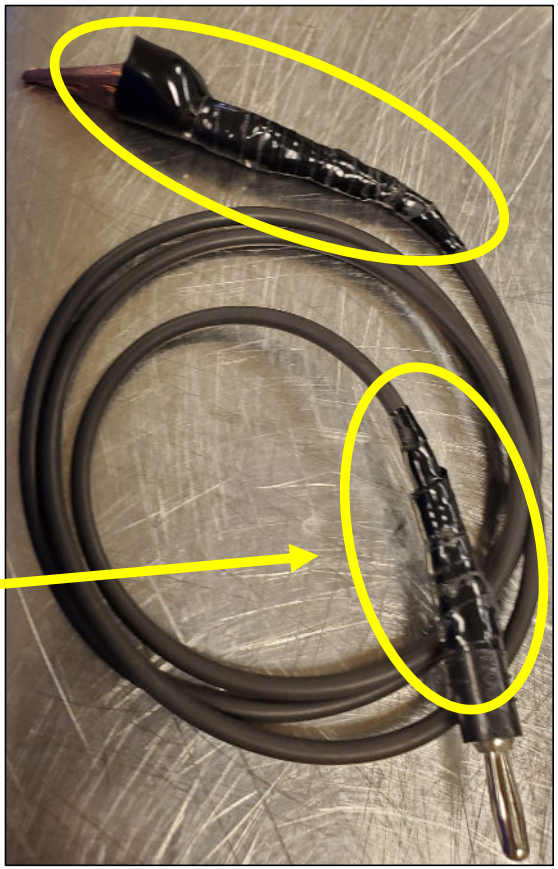
"Before use make sure that the product has been properly reprocessed, inspected, and tested."

Contributing Factors from the Results

- The results shown revealed that there were numerous contributing factors to unnoticed insulation damage.

The factors included:

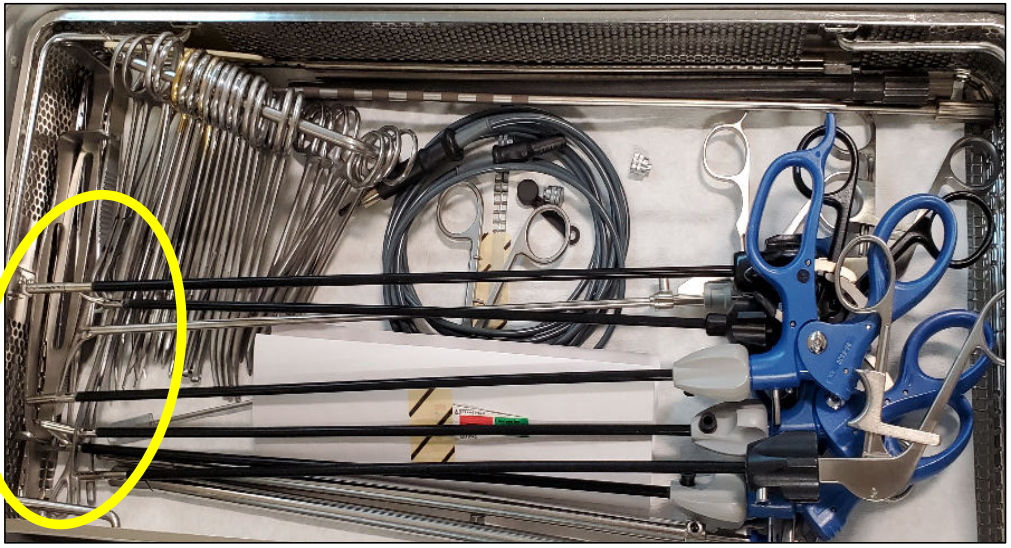
- Inadequate magnification to clearly identify the damage (e.g., only standard lighted magnification and not enhanced magnification microscopes to visualize at a higher magnification).
- Insufficient insulation testers lacking the sensitivity and the ability to test a wide range of insulated instrumentation (e.g., bipolar forceps). Damaged and missing accessories and insulation unit.
- Lack of education for technicians in identifying damage and operation of the insulation testers.



Contributing Factors from the Results

Factors also included:

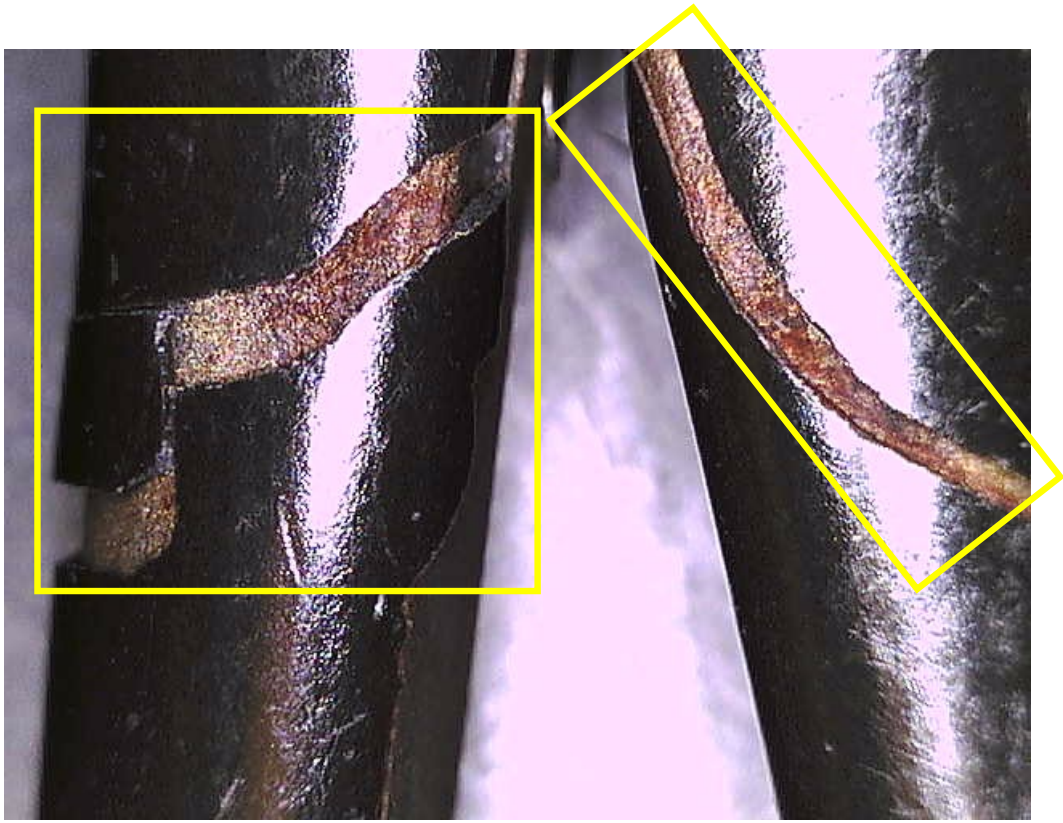
- Deficient containers/trays housing insulated laparoscopic instrumentation or correct container/tray but with the overflow of insulated instruments damaged by mixing with metal instrumentation.
- Inappropriate storage for backup insulated instruments (e.g., bins too small, excess amount of instrumentation, and tight spaces).



Contributing Factors from the Results

Factors also included:

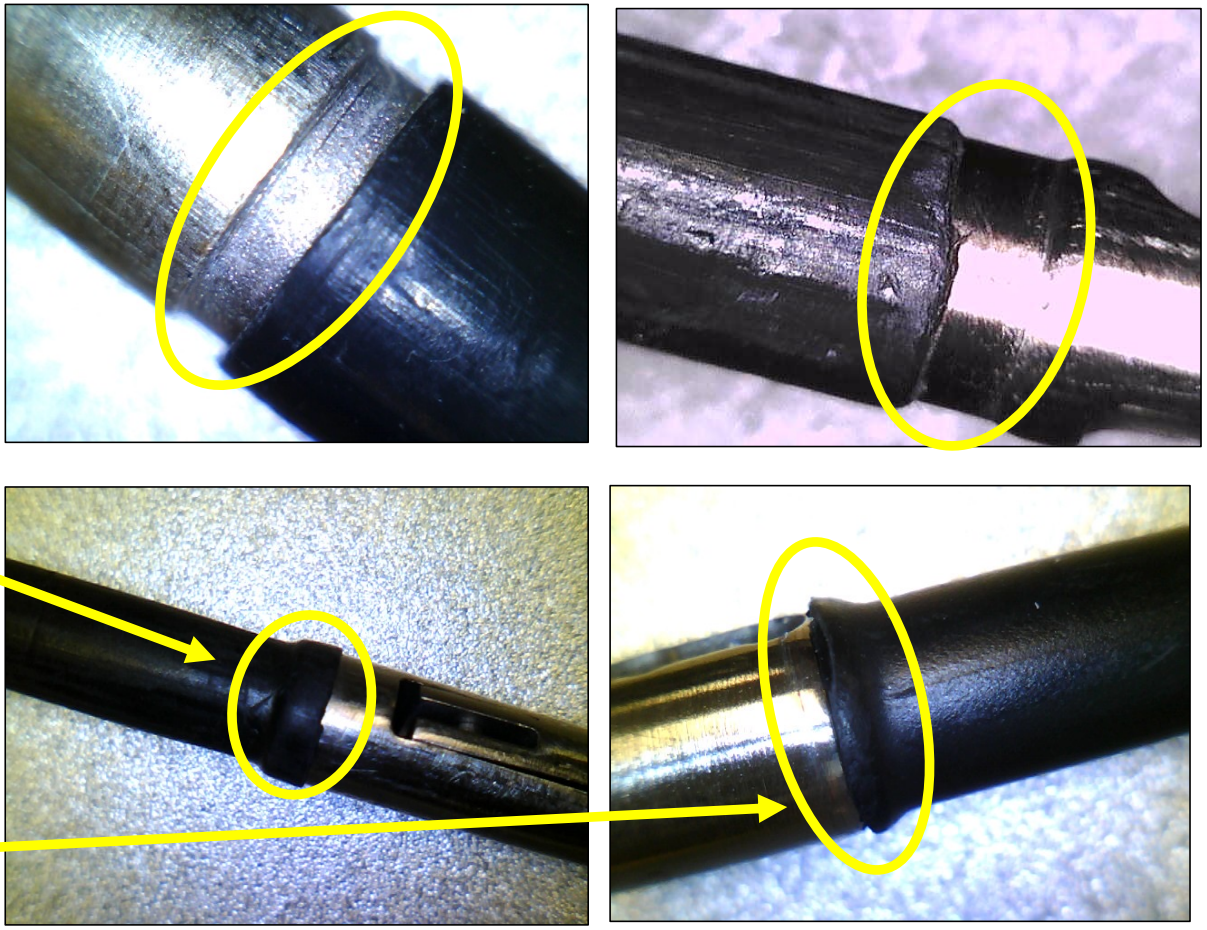
- Insufficient repair service for insulated instrumentation (e.g., poor repairs, not in the contract, not frequent enough).



Contributing Factors from the Results

Insufficient repair service included the following:

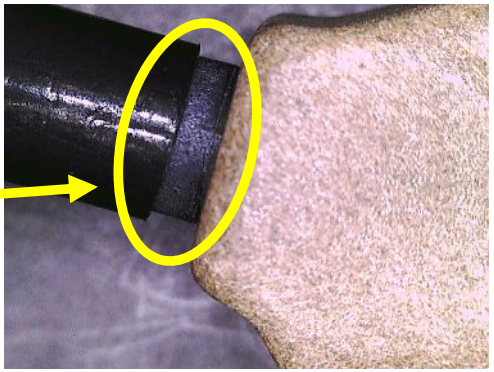
- Pull back (new damage) at the distal end of laparoscopic insulated instrumentation with no fraying for non-take-apart
- Pull back (old damage) at the distal end for laparoscopic instrumentation that has frayed insulation for non-take-apart
- Insulation layover '**Hangnail Effect**', where the insulation is laid over the distal working mechanism instead of being flush against it.
- Over time, this can cause the insulation to separate and/or pieces of the insulation to fray and pull back like a hangnail

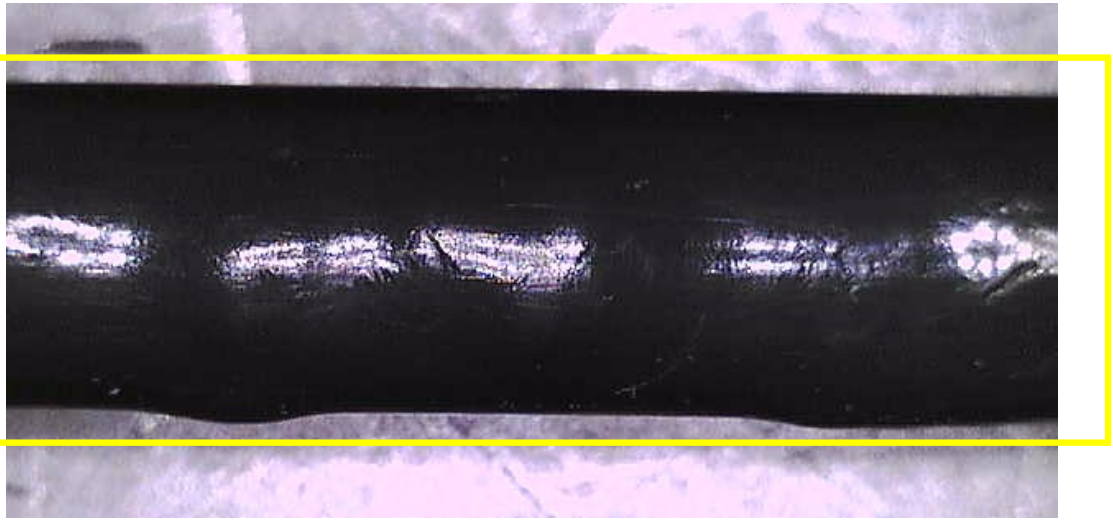


Contributing Factors from the Results

Insufficient repair service included the following:

- Pull back at the proximal end for laparoscopic instrumentation that has separated from the base/handle for non-take-apart
- Newly insulated laparoscopic instrumentation with a glossy look and bumps along the shaft
- This is an insufficient repair where the inner insert was not completely cleaned/removed of old insulation, then insulated over the existing pieces.

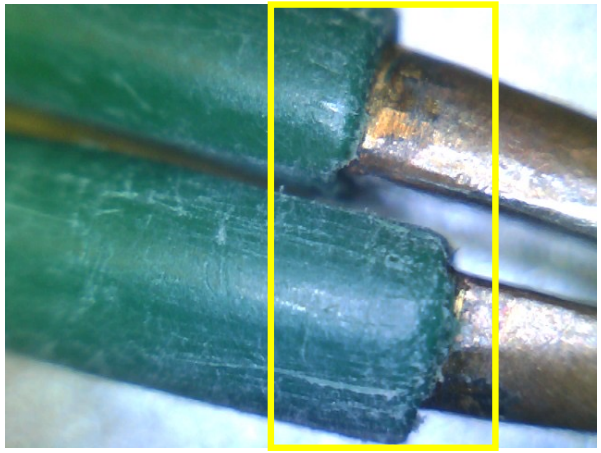


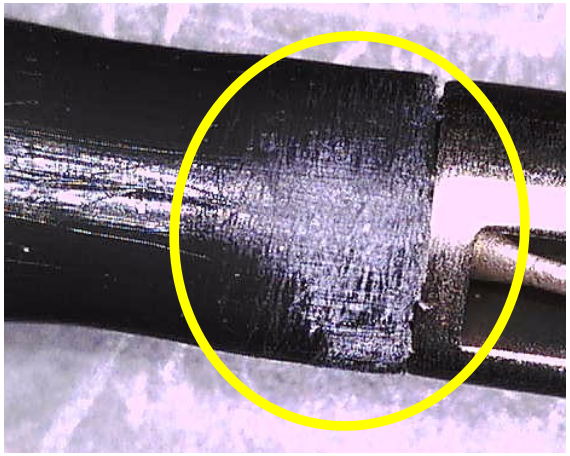


Contributing Factors from the Results

Insufficient repair service included the following:

- Worn and weathered (old damage) nicks, scratches, and gouges on insulated instrumentation
- Insulation (old damage) that is gray, white, dull in color, and/or fuzzy for all insulated instrumentation





Contributing Factors from the Results

Insufficient repair service included the following:

- Separation or excessive amount of epoxy resin that lifts from the base at the proximal end of an insulated bipolar forceps where the base connects to the tins of the forceps

Conclusion

- The study identified numerous failures in insulation integrity found in patient-ready instruments and trays awaiting assembly, which is a clear patient safety risk.
- These failures highlight the need for improved internal testing practices, audits, and continuing education on insulation testing practices.
- A robust quality system consisting of a high-quality insulation testing program will decrease adverse events in the patient population and healthcare staff related to stray electrical energy in insulated devices, which can cause burns, fires, shocks, and even death.

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Thank you

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