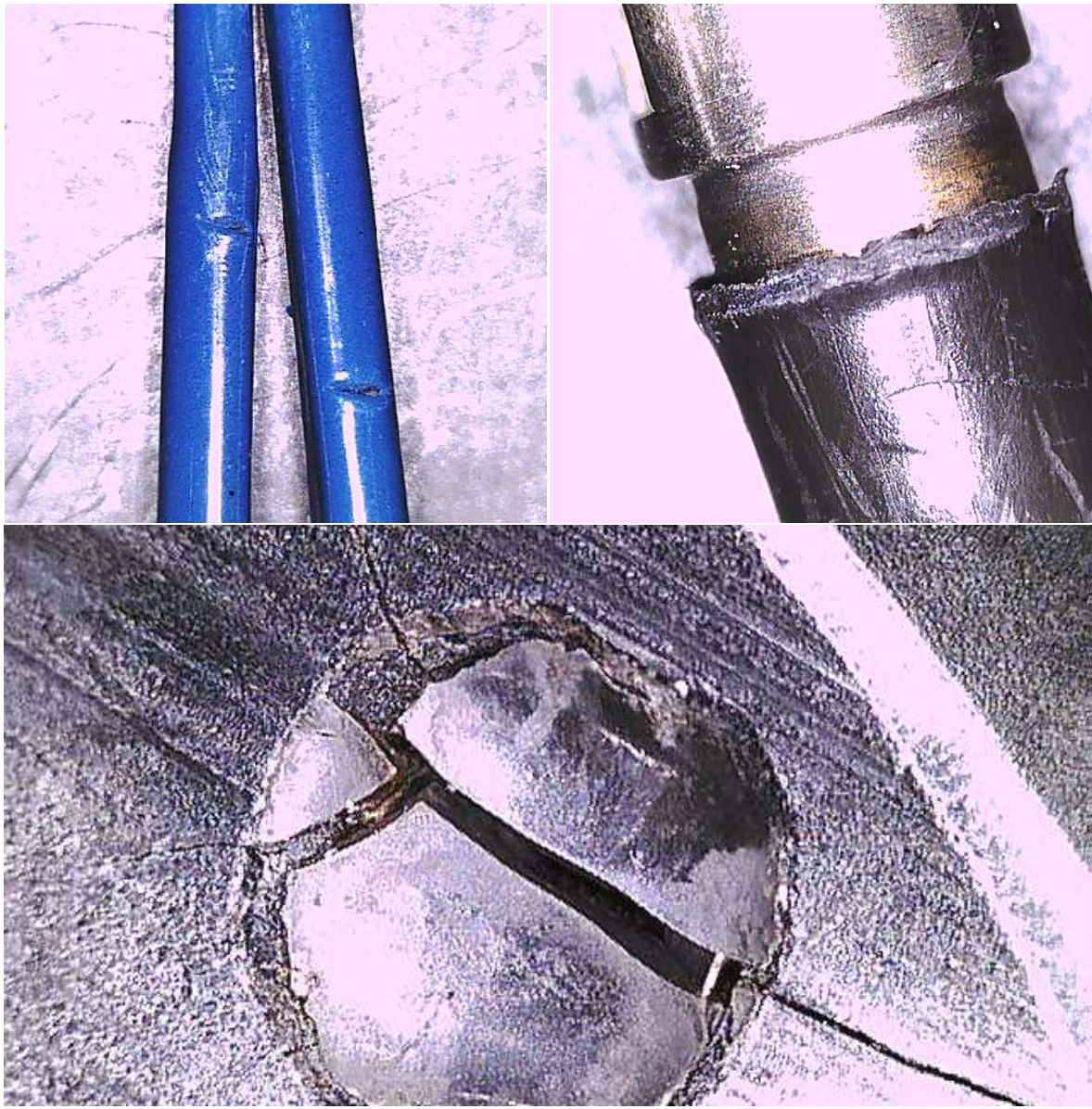
Where do you Stand on Your Insulation Testing & Inspection Practices: 2021-2022 Study



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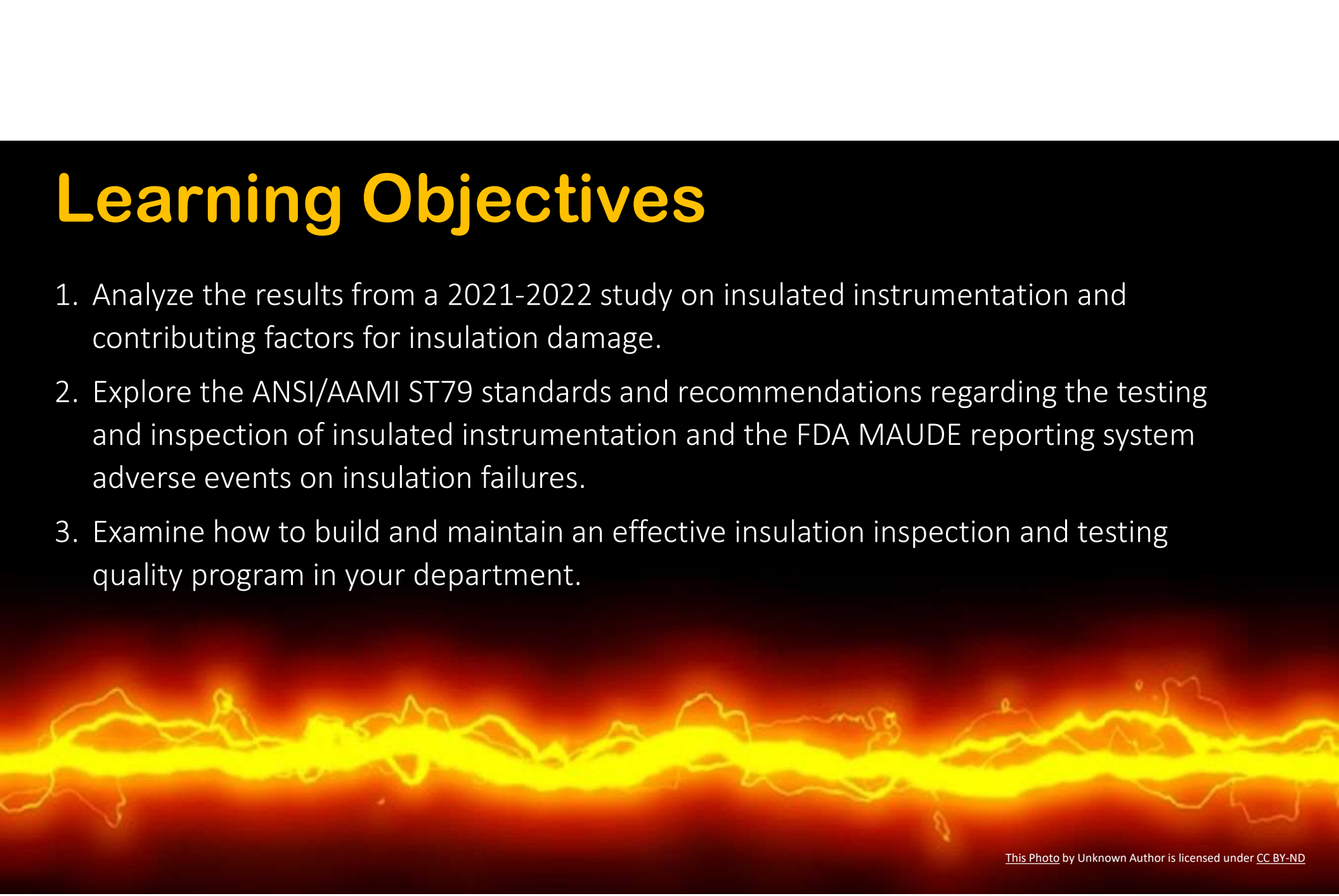
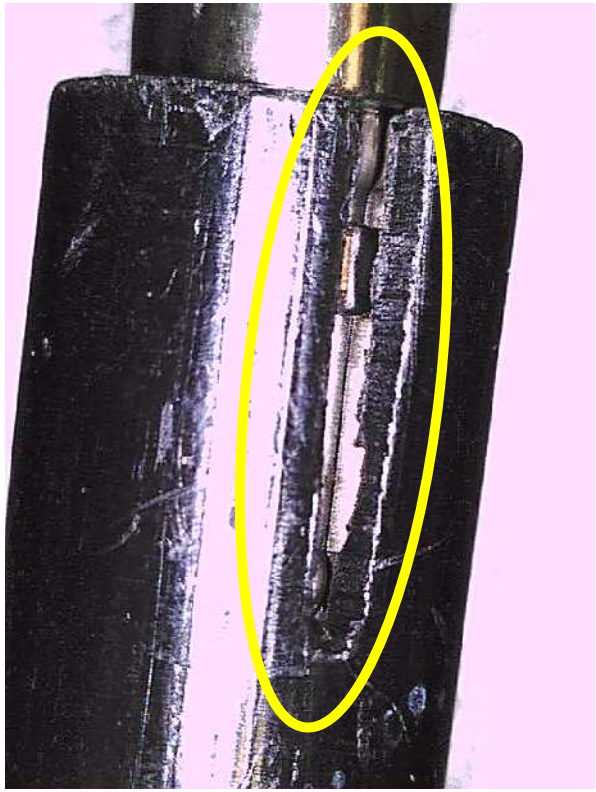
Learning Objectives

1. Analyze the results from a 2021-2022 study on insulated instrumentation and contributing factors for insulation damage.
2. Explore the ANSI/AAMI ST79 standards and recommendations regarding the testing and inspection of insulated instrumentation and the FDA MAUDE reporting system adverse events on insulation failures.
3. Examine how to build and maintain an effective insulation inspection and testing quality program in your department.



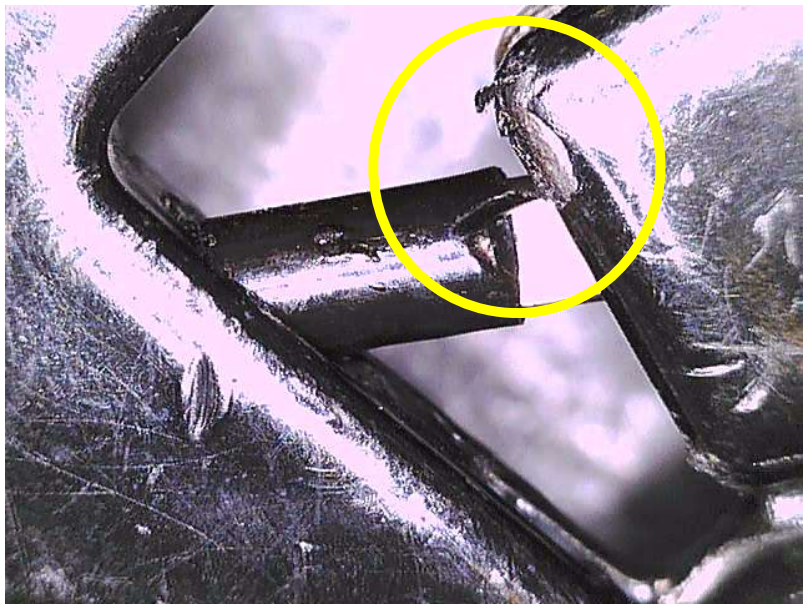
Description/Background

- Integrity inspection and testing practices of insulated instrumentation are critical steps in the process of assembly of medical devices.
- Shortfalls in any part of the processing of insulated instruments (e.g., bipolar forceps, laparoscopic, scissors, and cables) from the point of use treatment to the assembly for sterilization can have devasting complications to the patient (e.g., internal and surface wounds) and to the perioperative personnel (e.g., surgical fires, and burns).
- Human error/carelessness may be the first thing to blame for damage made to the insulation coating, but the process in place may be insufficient.



Description/Background Continued…

- Defects in the integrity of the insulation coating can also be attributed to:
  - a) inadequate repair service
  - b) lack of sufficient magnification
  - c) absence of an increased sensitivity insulation testing equipment
  - d) insulation testing equipment accessories designed for specific insulated instruments only
  - e) deficiencies in education for the use of these tools
  - f) the limited knowledge of recommendations and standards specific to insulated instrumentation.
- This study solidifies the importance of implementing an internal audit of the inspection and insulation testing practices in the assembly process, thereby reducing potential risks to patient safety.



Objective 1

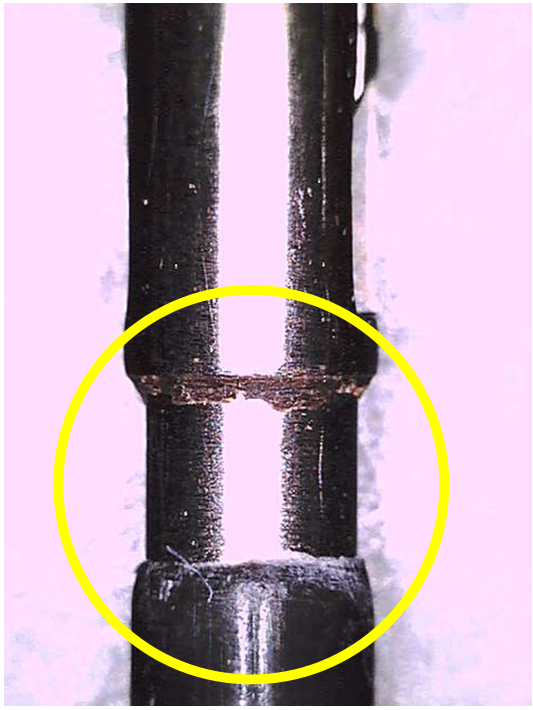
- Analyze the results from a 2021-2022 study on insulated instrumentation and contributing factors for insulation damage.

The Study

- The study was published in the **2023 March/April Edition of the PROCESS Magazine** (HSPA).
- 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**.

Methods (performed via)

- 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…Concurrently

- 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.

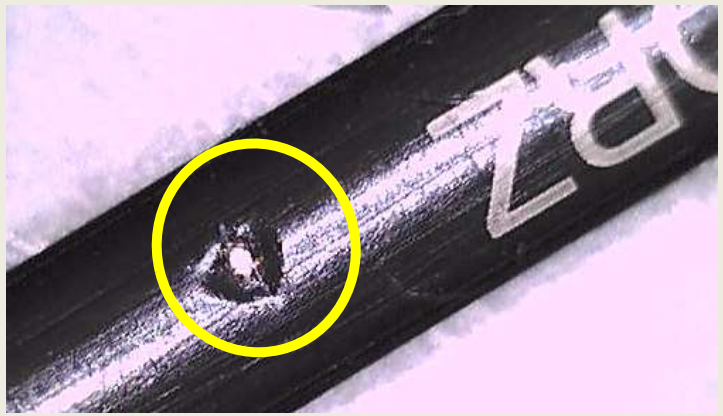
- In addition, the FDA MAUDE database was searched for adverse events on insulation failures reported within the same timeframe to determine if any significant patient risk existed.

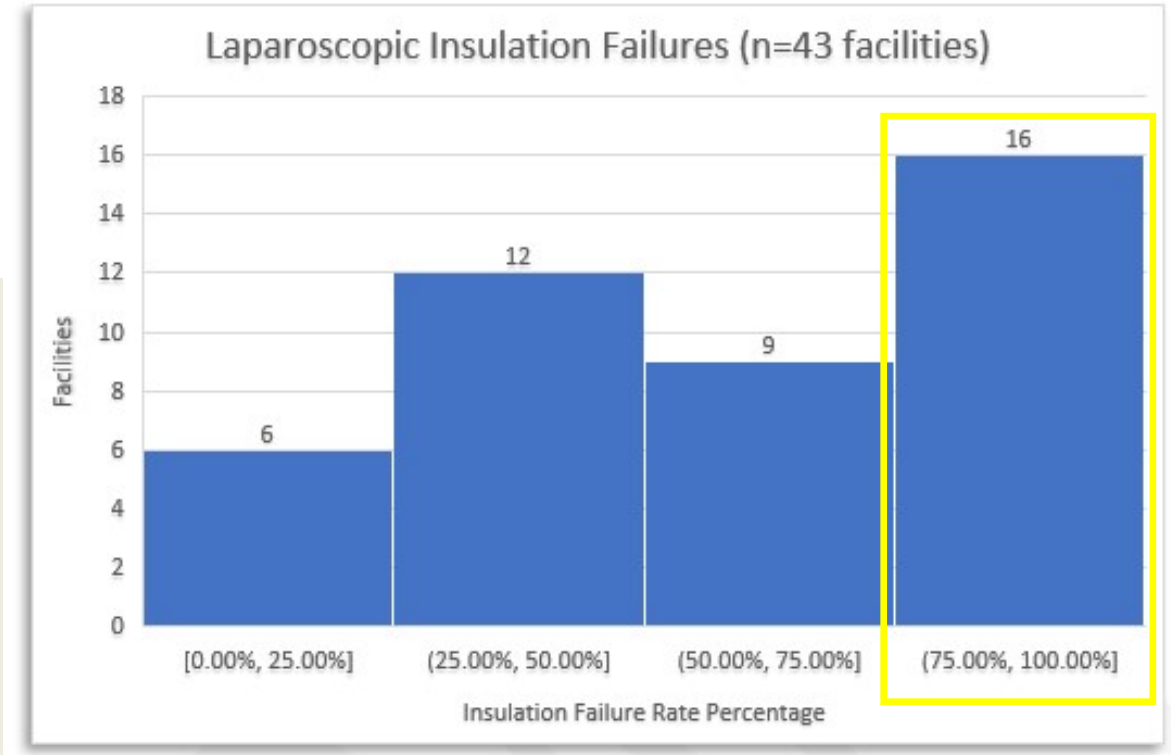
Limitations

- 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

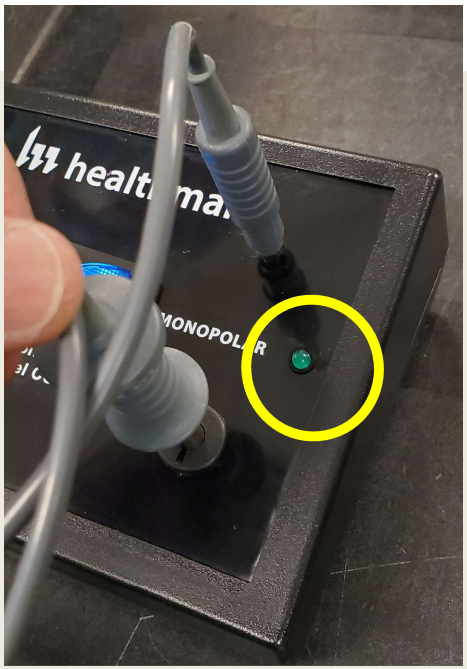
- Of the total 416 instruments tested, 223 showed failures on insulation testing or inspection.
- With 16 facilities showing a failure rate of 75%–100% of all devices tested.

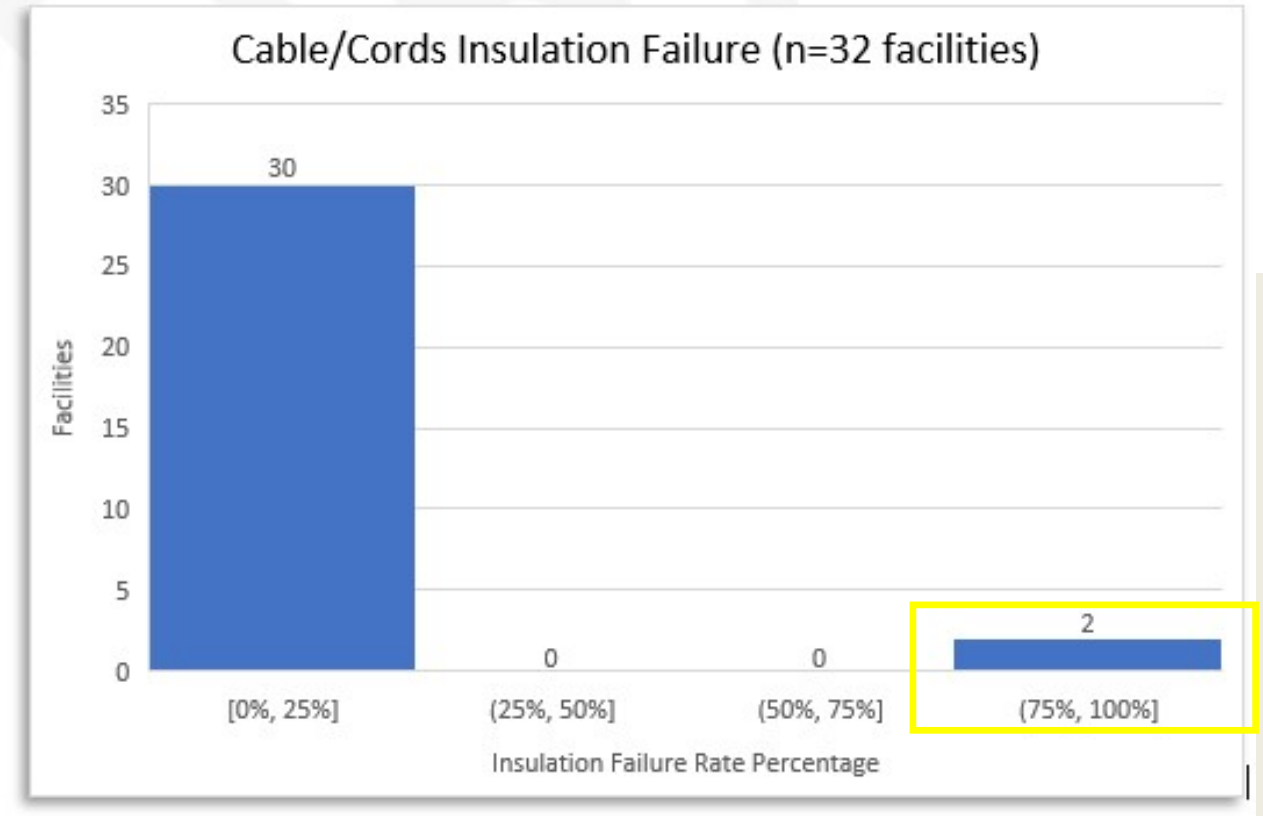




Results Continued…

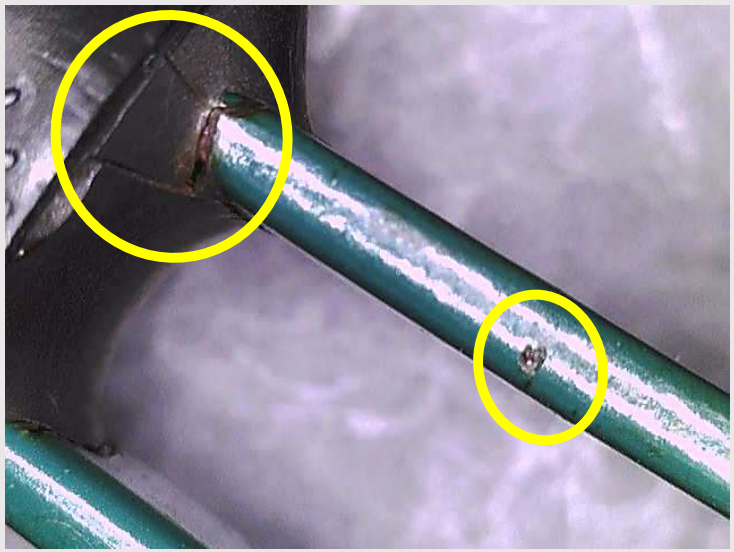
- On average, insulated cables demonstrated a 6% failure rate for continuity across 32 facilities.

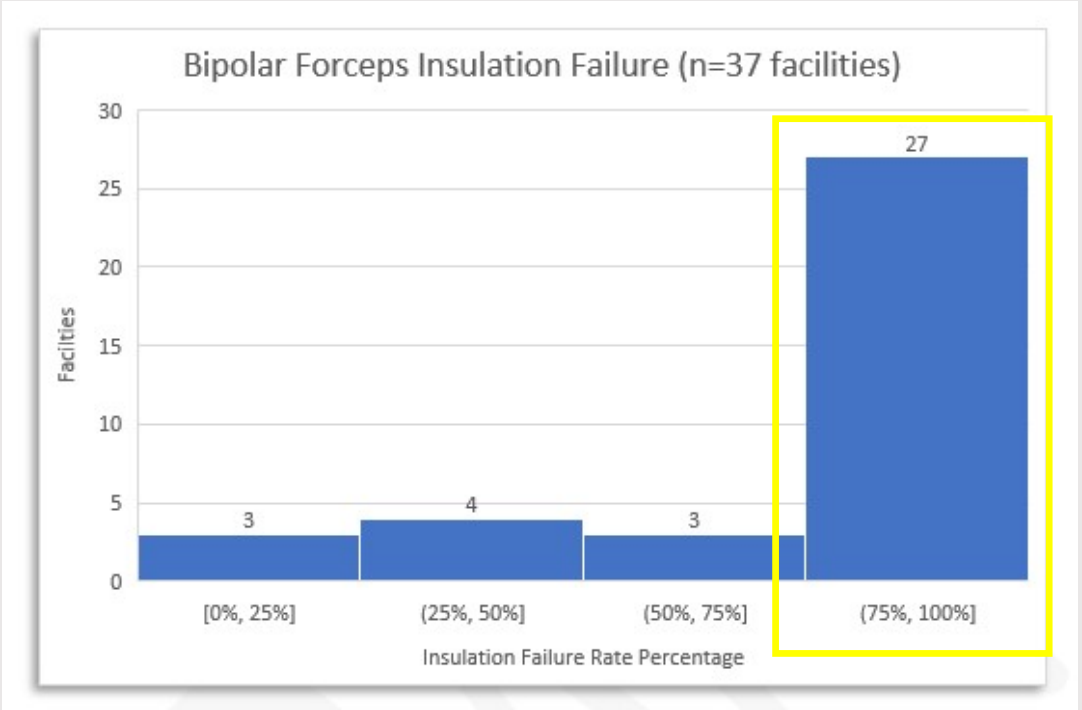




Results Continued…

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

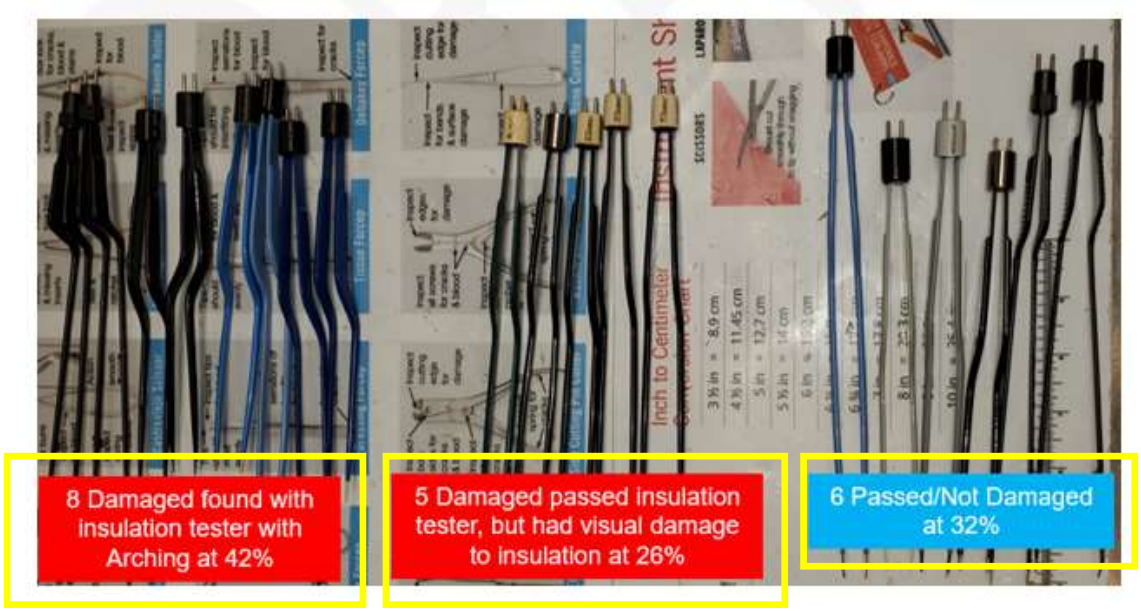




Results Continued…

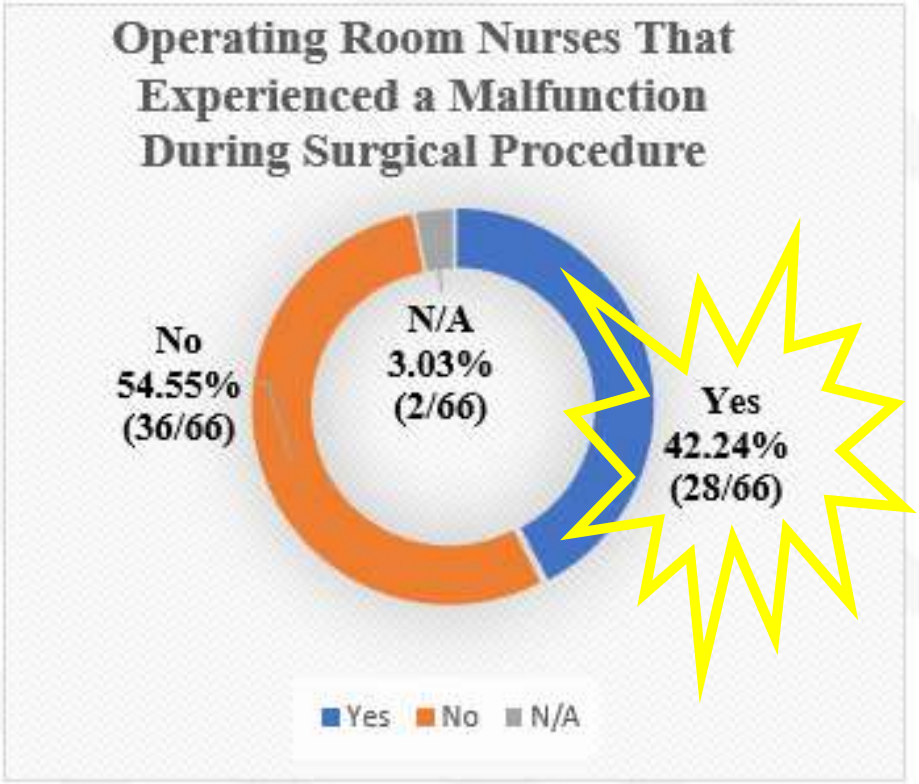
- In one of the 27 facilities, 19 insulated bipolar forceps were tested from ready-to-use backup inventory.

- 13 of the 19 were identified as having insulation failures



Results Continued…

- 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).

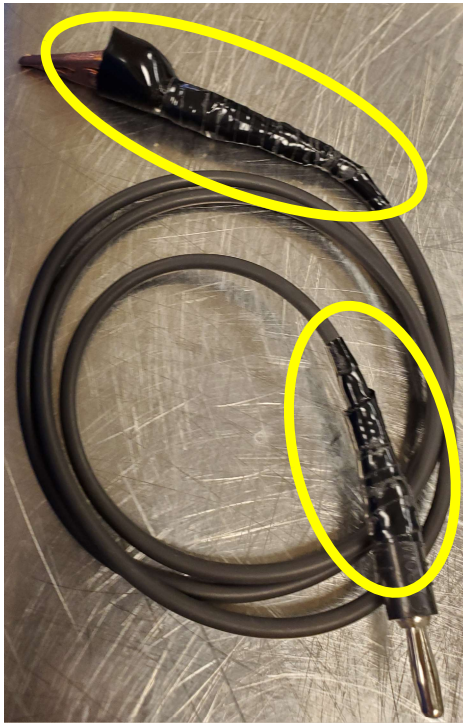


Contributing Factors from Results

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

The factors included:

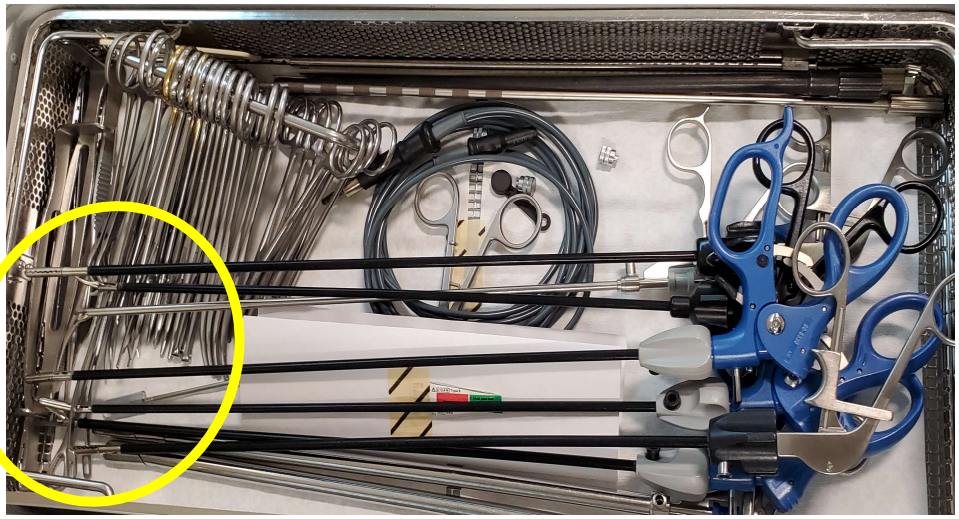
- Inadequate magnification to clearly identify the damage (e.g., only standard lighted magnification and not enhanced magnification microscopes to visualize at a higher magnification).
- Insufficient insulation testers lacking the sensitivity and the ability to test a wide range of insulated instrumentation (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 Results Continued…

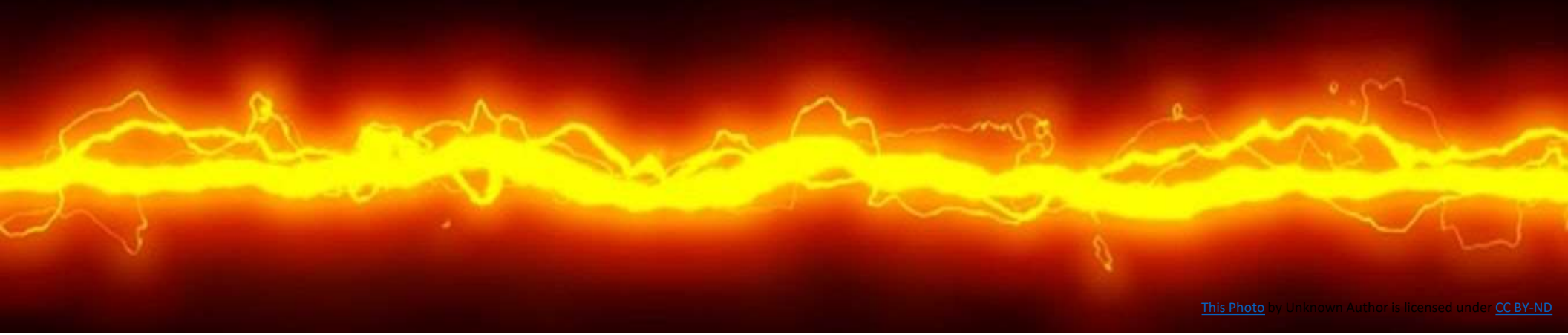
Factors also included:

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



Objective 2

- Explore the ANSI/AAMI ST79 standards and recommendations regarding the testing and inspection of insulated instrumentation and the FDA MAUDE reporting system adverse events on insulation failures.

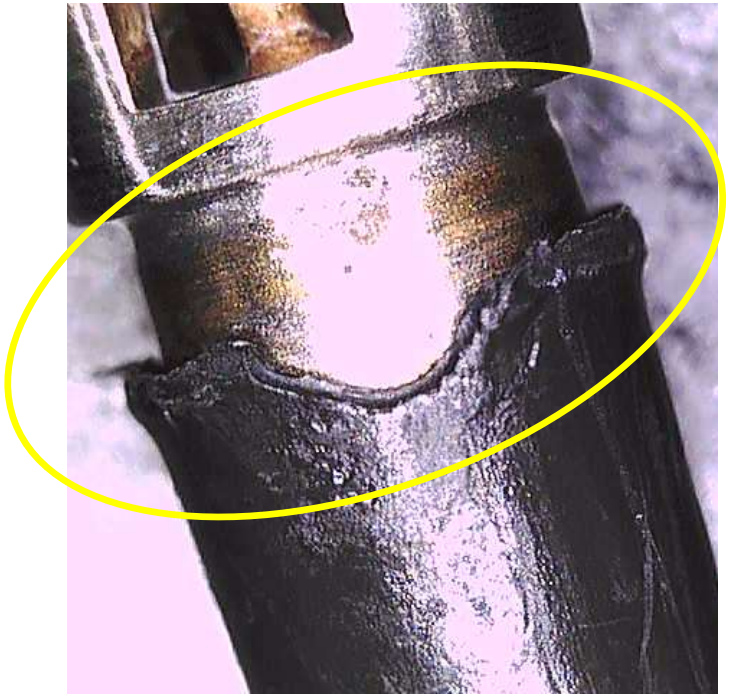


Technical Manuals, Standards & Recommendations on Inspection & Testing Practices

- (**HSPA**) 8th Edition Central Service Technical Manual states that “electronic testing devices can detect microscopic holes in the shaft of a laparoscopic instrument.” (HSPA ,pg. 203-242, 2016)

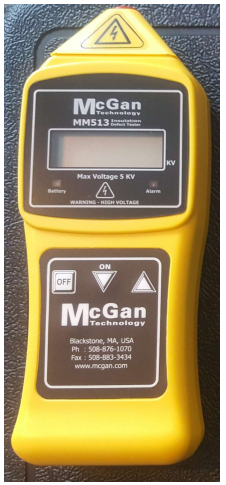
Technical Manuals, Standards & Recommendations on Inspection & Testing Practices Continued…

- (**AORN**) does support and recommend the inspection and testing practices on insulated instrumentation for damage to the insulation coating. AORN emphasizes under 10.3.5 that "… some insulation failures are not visible and damage to insulation may not be seen during visual inspection." (AORN, 2022)
- (**AORN**) also states that "… testing before use and after decontamination allows a defective device to be replaced before use or sterilization and provides an opportunity for corrective action in advance of the surgical procedure."(AORN, 2022)



Technical Manuals, Standards & Recommendations on Inspection & Testing Practices Continued…

- (**AAMI ST79**) Identifies and reinforces the need for the inspection and testing of insulated instrumentation and begins with, "… instruments should be organized and protected from damage." (ANSI/AAMI ST79, 8.2.1, 2020)
- (**AAMI ST79**) It states that insulated instrumentation "… intended for use with electric current should be tested for integrity each time it is processed." (ANSI/AAMI ST79, 8.2.1, 2020)
- (**AAMI ST79**) Recommendations continue with, "… cables/cords are also a source of concern and need to be inspected and checked for integrity and continuity." (ANSI/AAMI ST79, 8.2.1, 2020)



Technical Manuals, Standards & Recommendations on Inspection & Testing Practices Continued…

- (**AAMI ST79**) Furthermore, the section incorporates an inspection point and possible damage referencing table that lists four sections for:

1) instrument/device

2) inspection points

3) possible damage, and

4) methods to assist with inspection/testing that coincide with Figures 1–5. (ANSI/AAMI ST79, 8.2.1, 2020)

Table 1—Inspection points and possible damage for various instruments/devices

Instrument/Device	Inspection Points	Possible damage	Methods to assist with inspection/testing
Laparoscopic including robotic instrumentation	— shaft — handles if applicable	— distal tip collar not flush against distal working mechanism — frays at the distal tip of insulation — shaft and handle nicks, cracks, lacerations, gouges, and microscopic pin holes	— insulation tester — lighted magnification — enhanced magnification (microscope) — visual inspection — tactile inspection
Insulated forceps e.g., bipolar forceps	— forceps shaft sides — forceps base housing	— frays at the distal tip of insulation — shaft nicks, cracks, lacerations, gouges, and microscopic pin holes — housing cracks and separation	— insulation tester — lighted magnification — enhanced magnification (microscope) — visual inspection — tactile inspection
Insulated scissors	— shafts — handle — blades	— shaft nicks, cracks, lacerations, gouges, and microscopic pin holes — shaft nicks, cracks, lacerations, gouges, and microscopic pin holes — frays at the distal blades	— insulation tester — lighted magnification — enhanced magnification (microscope) — visual inspection — tactile inspection
Cables/cords	— distal (plugs into instrument — proximal (plugs into electrosurgical unit) — full length of the cord	— separation of the cord to the distal tip — separation of the cord at the proximal end — shaft nicks, cracks, lacerations, gouges, and microscopic pin holes	— insulation tester — lighted magnification — enhanced magnification (microscope) — visual inspection — tactile inspection

Instrument/Device	Inspection Points	Possible damage	Methods to assist with inspection/testing
LEEP/misc. coated instruments and devices	— full insulation coating	— shaft nicks, cracks, lacerations, gouges, and microscopic pin holes	— insulation tester — lighted magnification — enhanced magnification (microscope) — visual inspection — tactile inspection

Figure 1—Laparoscopic instrumentation: examples of collar not flush against distal working mechanism

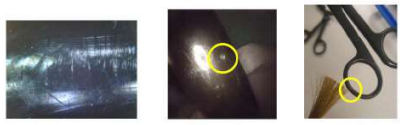


Figure 2—Laparoscopic instrumentation: examples of shaft and handle nicks, cracks, lacerations, gouges, and microscopic pin holes

Figure 5—LEEP and miscellaneous insulated coated instruments/devices: examples of nicks, lacerations, gouges, pin holes

Technical Manuals, Standards & Recommendations on Inspection & Testing Practices Continued…

- (**AAMI ST79**) Lastly, but most importantly, ANSI/AAMI recommends that “Personnel responsible for processing these instruments should receive education in the use of all testing equipment used before using the equipment. Competency should be verified and documented before the first assignment to use the equipment.”(ANSI/AAMI ST79, 8.2.1, 2020)

Concurrent Adverse Events (FDA Maude Reporting System

Reports were identified during the timeframe of the study:

- **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."

PEEK Monopolar Handle
250-181-164

Instructions-For-Use (Bipolar Insulated Forceps)

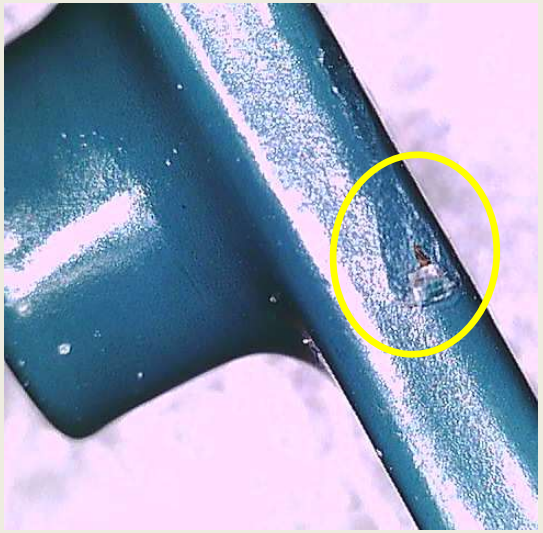
- Numerous Manufacturers' Instructions for Use (IFUs) for devices tested in this study were reviewed to determine if there were specific instructions for inspection and/or testing for insulated instrumentation for a user to follow.

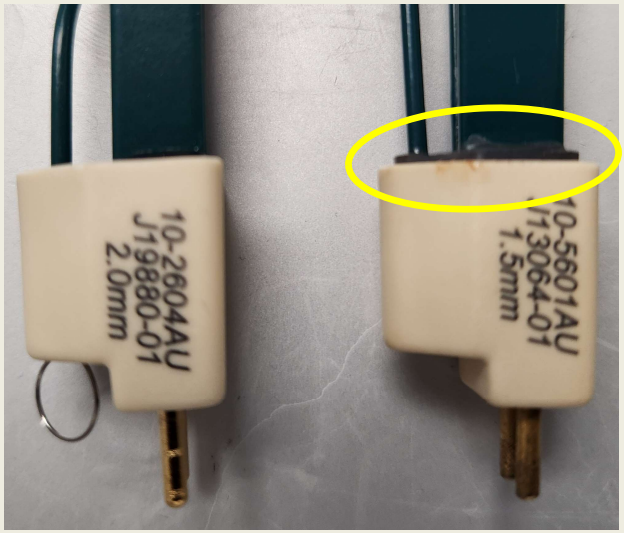
"… inspect devices before each use for broken, cracked, tarnished surfaces, movement of hinges, and chipped or worn parts."

"… examine insulated bipolar forceps for integrity; observe for cuts, gouges, or any exposed metal."

"… fires involving surgical drapes, and other combustible materials have been reported,"

"… alternate current pathways resulting in burns where the patient or physician or assistant is in contact with exposed metal."





Instructions-For-Use (Insulated Laparoscopic Instrumentation)

- For laparoscopic instrumentation, insulated shaft/tube, and insulated handles IFU were reviewed. An outer insulated tube five (5) mm x 30 cm
- Any vagueness leaves room for interpretations and possibly does not incorporate the accurate tools needed to examine and test.

Did not state anywhere in its documentation to inspect for damage or test with an insulation tester.

Instructions-For-Use (Monopolar Cable)

- Even though it did not specify what to use for the integrity testing, the IFU was specific with what to use for testing for the continuity of the insulation.

"… it is recommended to establish a procedural review by which the cord's electrical continuity is regularly tested with an ohmmeter as well as frequent inspection of the cord's insulation (before and after each use)."

Instruction-For-Use in (Adverse Events Reported)

- 07-26-21
Insulated Handle

- 08-10-21
Laparoscopic Instrument

- 03-15-22
Monopolar Cable

"… 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."

"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."

"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."

Objective 3

- Examine how to build and maintain an effective insulation inspection and testing quality program in your department.

Auditing Inspection and Testing Practices

- When auditing the inspection and testing practices within your department, there are several key areas to review.
- By doing so, the investigation is not as overwhelming and can be more easily remedied if issues are found.
- The key areas to review are as follows:

Auditing Inspection and Testing Practices

- Tools needed to inspect (e.g., magnification type and quantity).
- Tools needed to test (e.g., insulation tester type and quantity, accessories, and cable continuity tester if applicable).

Auditing Inspection and Testing Practices

- Education on the use of
  - a) magnification
  - b) insulation testers
  - c) identifying damage
  - d) return demonstration, and
  - e) past and current records of specific in-services.

Ask what is being examined while defining and demonstrating the inspection and testing being performed and the different types of damage to the insulation.

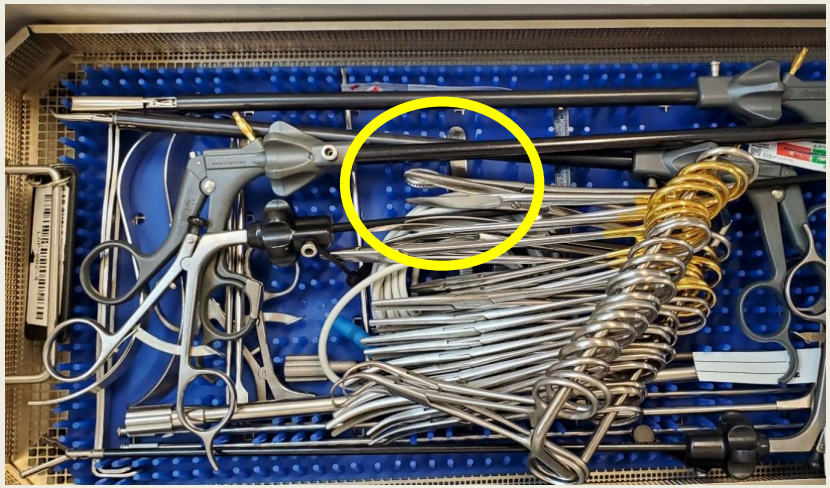
Refer to any internal policies and procedures that pertain to inspection and testing as a guide to ensure that it is being adhered to.

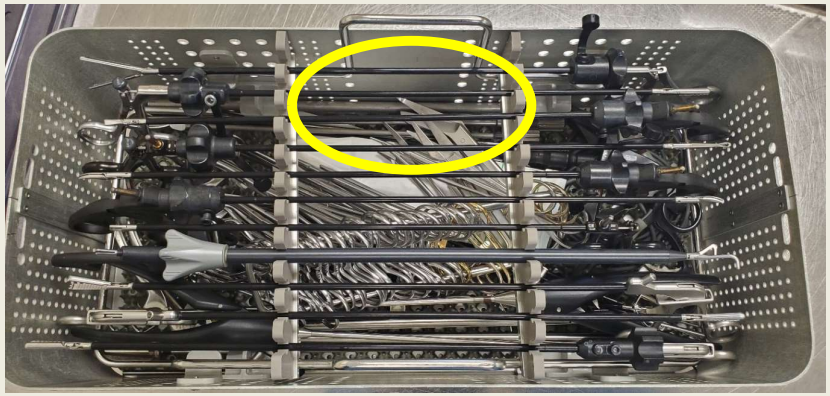
Understand that even if an insulated instrument passes insulation testing for exposed metal, it does not guarantee that damage is not present

If the laparoscopic container/trays consist of a mixture of insulated instruments that are actively monitored throughout the procedure that only need to be inspected and not tested, then the assessment will have specific questions to ask the employee

Auditing Inspection and Testing Practices

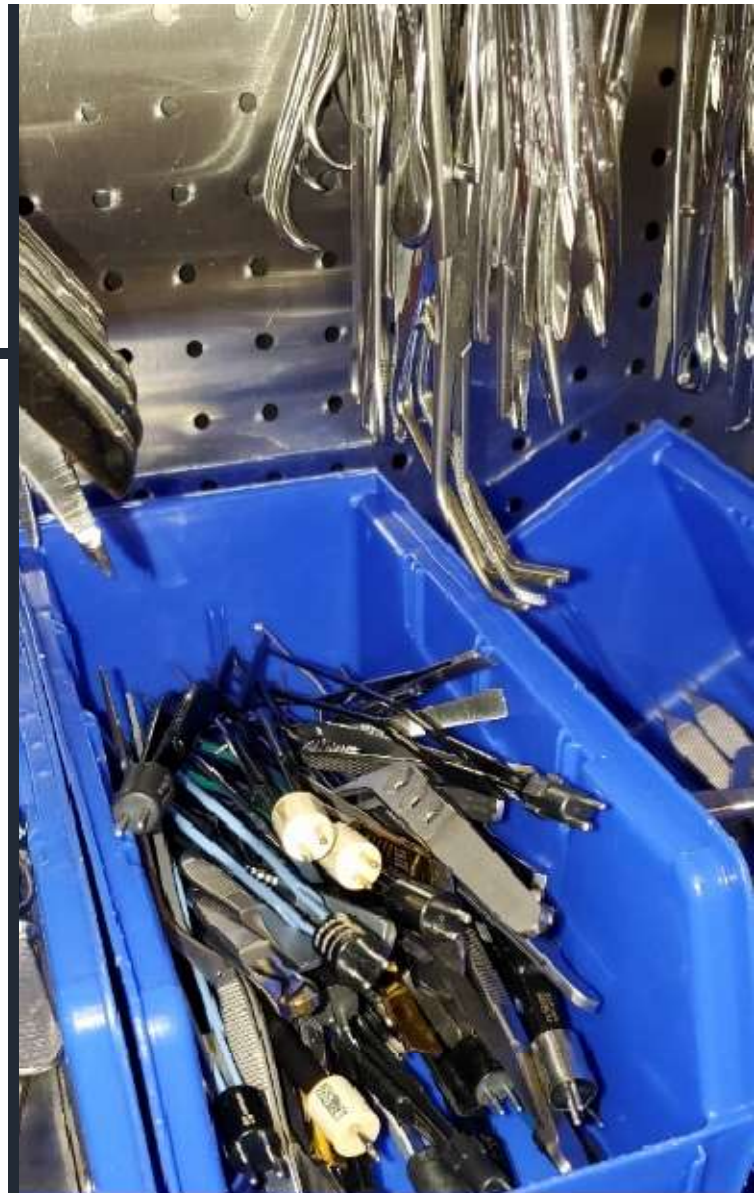
- Container or tray to house and separate insulated instrumentation (e.g., Are they being protected? Is there overflow that is being damaged?).
- Did the surgeon leave years ago?
- Build a multidisciplinary team that consists of key players to re-evaluate the trays.





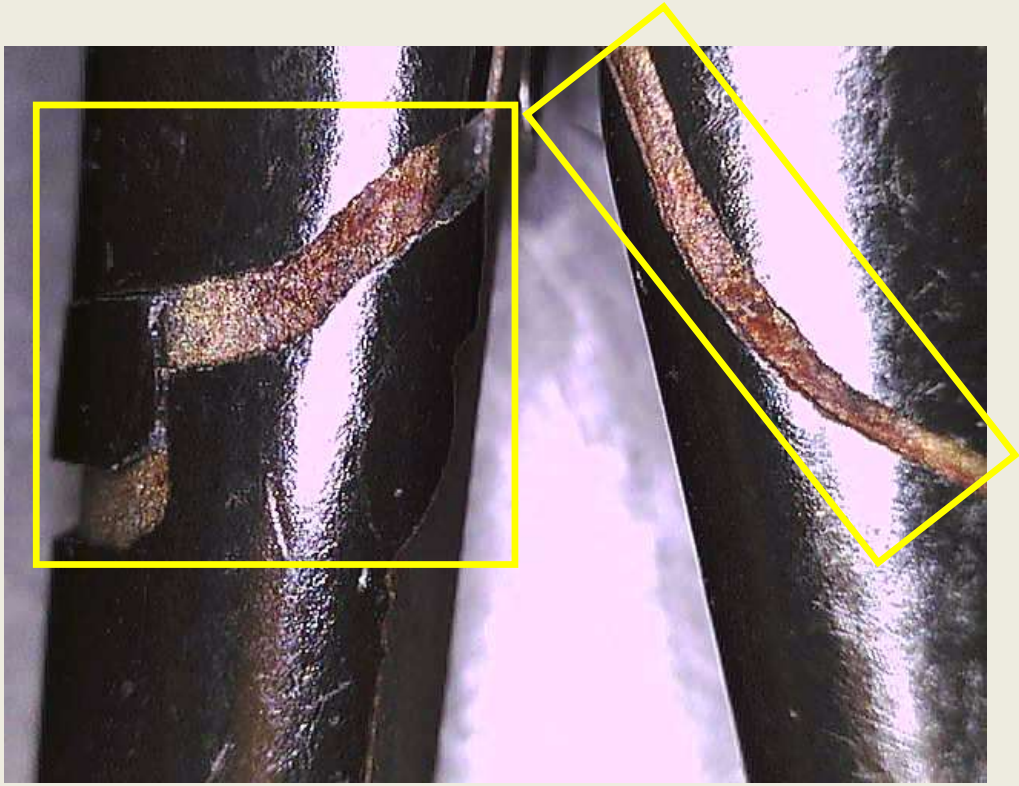
Auditing Inspection and Testing Practices

- Storage for backup insulated instrumentation (e.g., overcrowded, mixed with metal instruments).
- Laparoscopic instrumentation with insulated shafts should be separated from non-insulated.
- Insulated handles can be phased out or moved to another alternative.
- Insulated monopolar and bipolar cables should be kept separate from all instrumentation and left in the original package (if applicable) for additional protection to the insulation.
- If the insulated cables are in drawers, ensure the bin or drawer is large or deep enough so that the insulated cables do not get caught in the closing of the drawer.



Auditing Inspection and Testing Practices

- Repair service evaluation
  - Examine repairs when going out and coming back
  - Examine the current repair bin
  - Compare the last date checked to the current integrity/quality of the instrumentation being reviewed.
  - Current repair service may not catch the damage and the previous insufficient repair service
  - Current repair service is only evaluating the metal instrumentation in the container/tray (Insulated instrumentation not under contract)



Auditing Inspection and Testing Practices

- While using an enhanced inspection microscope gauge the condition of your insulation integrity. Review examples of deficient repair servicing in the following slides:

Auditing Inspection and Testing Practices

- Pull back at the distal end for laparoscopic instrumentation that is clean with no frayed insulation for non-take-apart.
- Attributed to insufficient repair overlooked by the repair service, or even lack of training for the technician to identify inadequate repair.

Auditing Inspection and Testing Practices

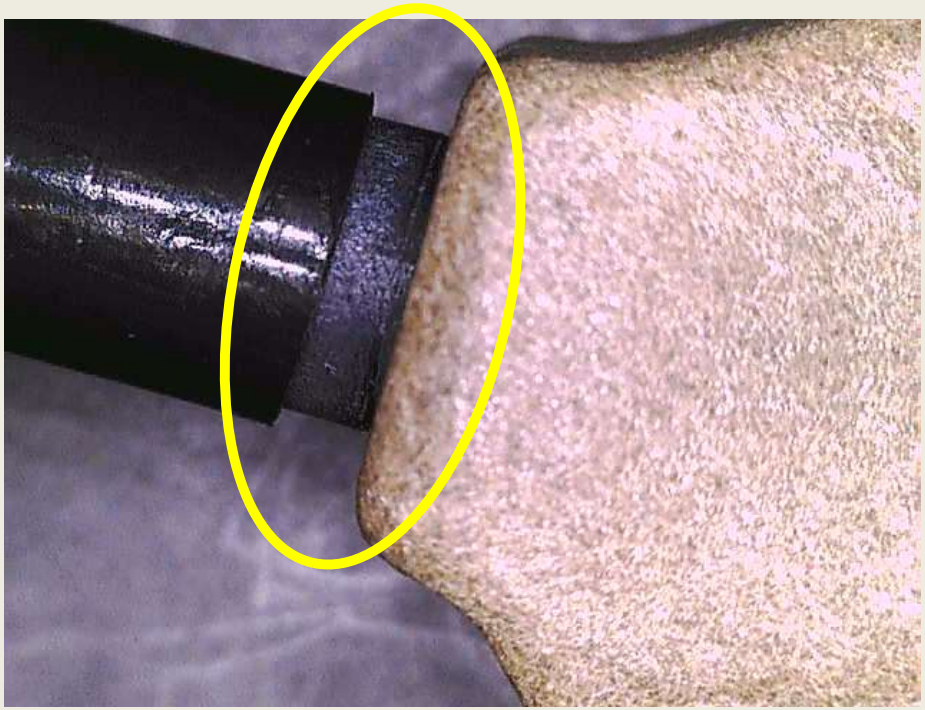
- Pull back at the distal end for laparoscopic instrumentation that has frayed insulation for non-take-apart
- This is old damage overlooked by the repair service as well a lack of education for the technician to identify insufficient repair.

Auditing Inspection and Testing Practices

- 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
- These issues can be attributed to an insufficient repair, can be overlooked by the repair service, or represent a lack of education for the technician to identify inadequate repair.

Auditing Inspection and Testing Practices

- Pull back at the proximal end for laparoscopic instrumentation that has separated from the base/handle for non-take-apart
- This can be contributed to the overlooked evaluation of damage by the repair service as well as the lack of education for the technician to identify damage.

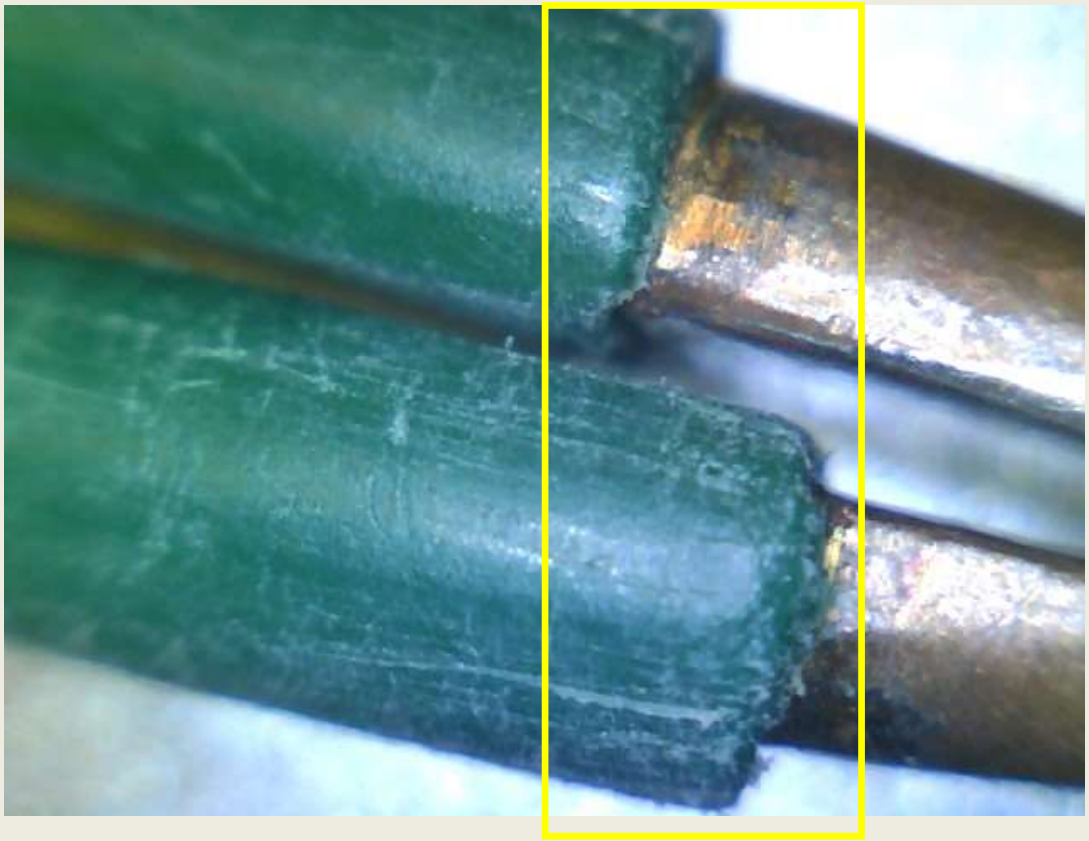


Auditing Inspection and Testing Practices

- 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.
- and overlooked by the technicians due to a lack of education to identify an inadequate repair.

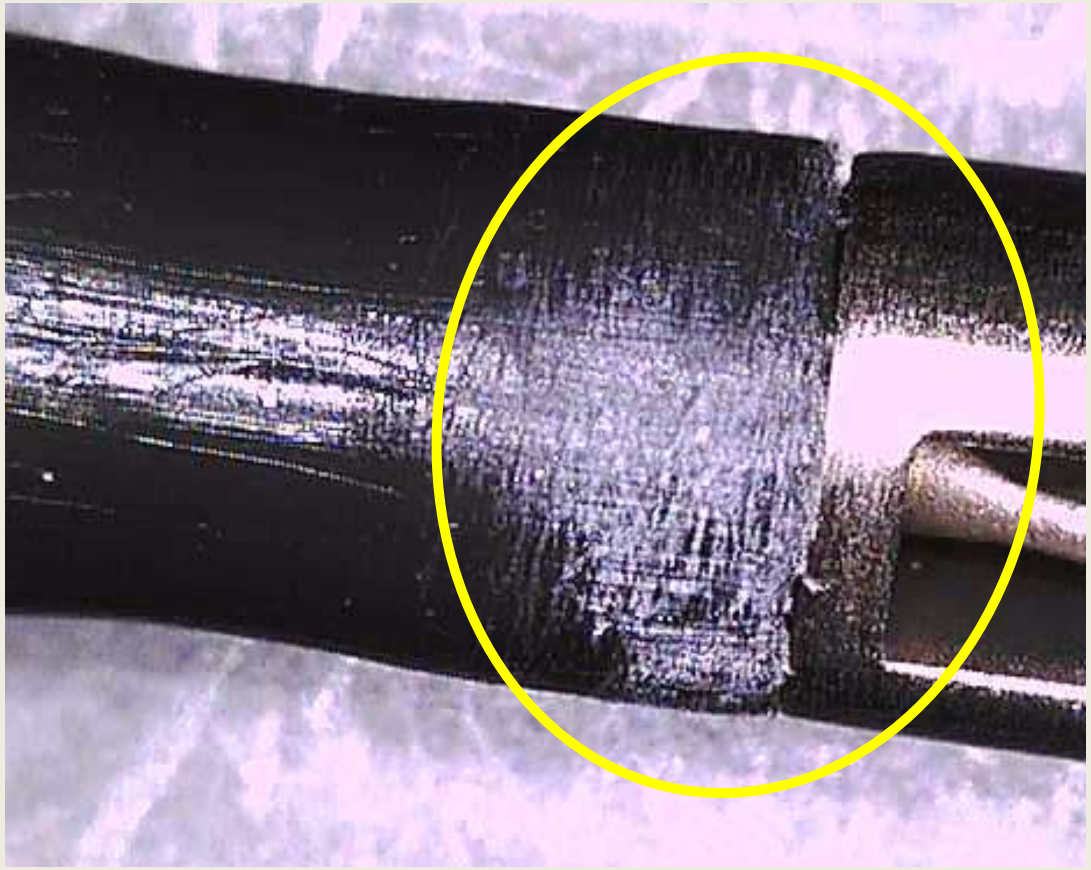
Auditing Inspection and Testing Practices

- Worn and weathered nicks, scratches, and gouges on insulated instrumentation
- This is old damage and overlooked by the repair service as well as lack of training for the technician to identify damage.



Auditing Inspection and Testing Practices

- Insulation that is gray, white, dull in color, and/or fuzzy for all insulated instrumentation
- This is old damage and overlooked by the repair service as well as a lack of education for the technician to identify damage.

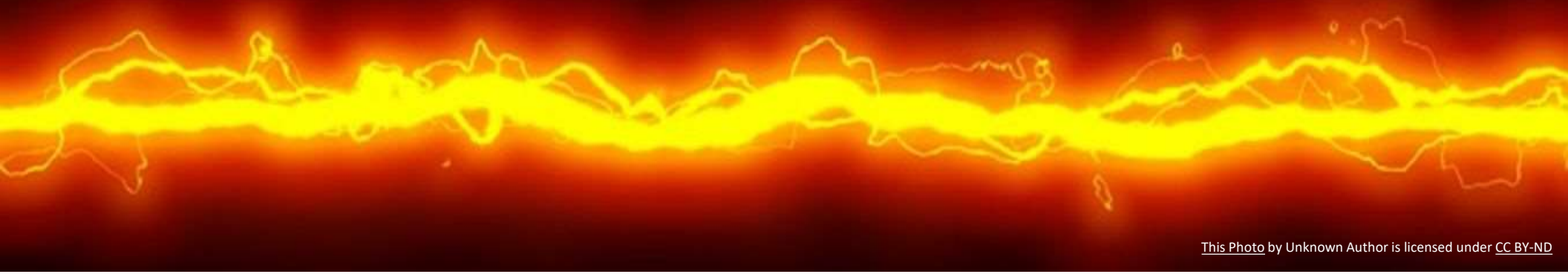


Auditing Inspection and Testing Practices

- 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
- This can be attributed to insufficient repair, overlooked by the repair service, or represent insufficient education of the technician to identify damage and/or adequate repair.

Conclusion

- This study identified numerous failures in insulation integrity found in patient-ready instruments and trays, a clear patient safety risk.
- These failures highlight the need for improved internal inspection and testing practices, reoccurring audits, and continuing education on inspection and insulation testing procedures.
- A robust quality system (consisting of a high-caliber insulation tester, correct technique, and sufficient magnification 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.



Our Patients,

Thank you

[redacted]

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