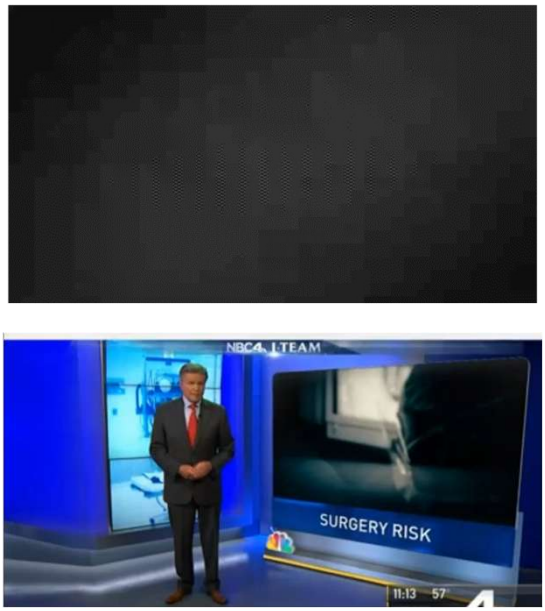

The Overlooked Risk; How A Near-Miss Inspired a Study on Insulation Testing and Patient Safety

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1

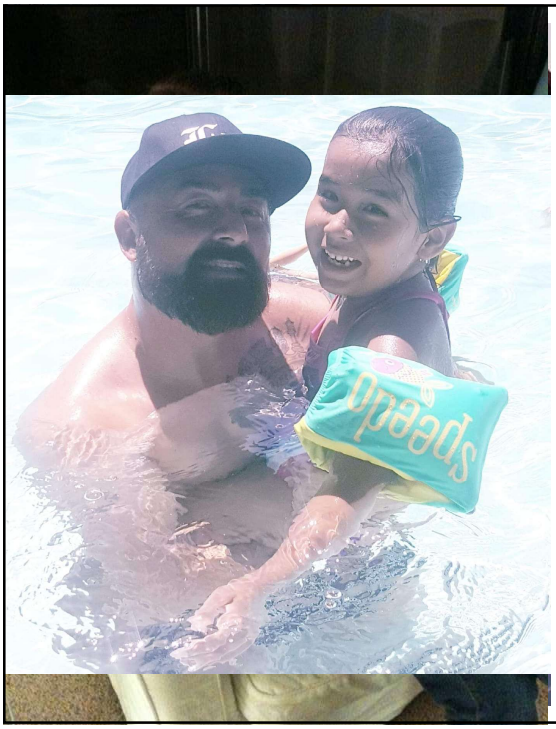
Objectives

Reflect on	Analyze	Examine
Reflect on a personal near-miss that led to multiple studies on insulation inspection and testing.	Analyze the findings of two insulation testing studies conducted in 2019 and from 2021 to 2022.	Examine the recommendations and standards highlighting the importance of insulation inspection and testing.

2

Reflect on a personal near-miss that led to multiple studies on insulation inspection and testing.

3



The Root-Cause

- September of 2020 my daughter became ill
- Emergency lap appendectomy
- Had some data from 2019 for a preliminary article.
- 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)
- Eventually the study was published in 2022 HSPA Process Magazine.
- Received my HSPA Fellowship from this study.
- Then a more robust study in 2021-2022 published in 2023 in HSPA Process Magazine

4

Analyze the findings of two insulation testing studies conducted in 2019 and from 2021 to 2022.

5

2019 Insulation Study

6

2019 Study Design & Setting

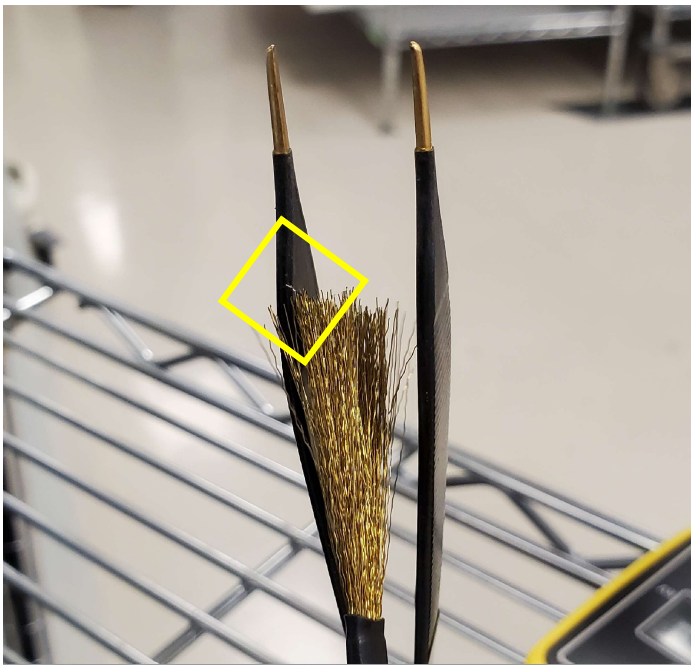
- Conducted in 2019 (8-month study)
- Consisted of 4 states, 7 facilities
- Randomized experiment e.g., sterile patient-ready laparoscopic tray, non-sterile insulated forceps, & non-sterile cables/cords
- the FDA MAUDE database was searched for adverse events on insulation failures reported within the same timeframe to determine if any significant patient risk existed.
- The aim of the study was to determine whether the type of insulation tester and/or accessories being used detected insulation failures.

7

Results

Overall:

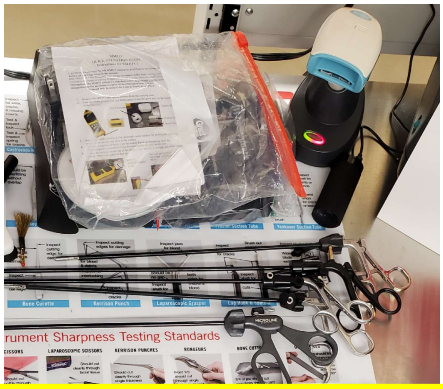
- Back-up insulated instrumentation failures at 7% out of 14 tested.
- Insulated cables/cords failures at 11% out of 9 tested.
- Insulated laparoscopic instrumentation failures at 18% out of 104.
- Insulated forceps highest integrity failures at 50% out of 10 tested.



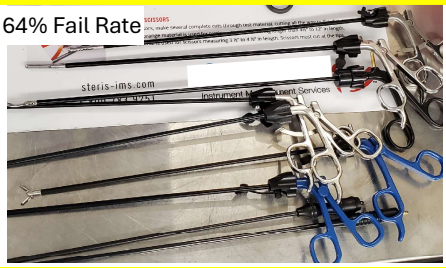
8

Results Continued..

- One facility had a 75% failure rate for their laparoscopic tray.
- Another one had a 50% failure rate for their laparoscopic tray.
- A facility had a 33% failure rate for just cables/cords & 67% failure rate for their laparoscopic tray.
- Other facilities were at 27%, 25%, 23%, & 22% failure rates for their laparoscopic trays.



64% Fail Rate



9

Results Continued..

Control Insulation Tester (more sensitive) vs experimental insulation tester (less sensitive)

- In one case, experiment tester (facility's insulation tester) identified 1 integrity failure, control insulation tester identified 5 integrity failures on the same instrument shaft.
- Control insulation tester vs the experimental insulation tester failure rate difference detected is 20%

10

Results

FDA Maude Reports

09-02-2020: **Monopolar Cord**, 4 additional complaints recoded for similar occurrences, A fire started while the surgeon was using an :- hook attached to the monopolar cord. The cord frayed near the plastic end, came off , fell into the pocket of the drape and started the fire.

03-12-20: Adson Bipolar Forceps, the surgeon was cauterizing a vessel underneath the patient's tongue. The forceps arced and burnt the patients' lip.

11-27-2019: Hook 3.5mm Monopolar: Electric arc occurred near the wall of the small intestine. The surgeon inspected the hook, and the coating was damaged. The patient had peritonitis with loss of fluid in the peritoneum and hole in the colon.

11

10-11-19

12

Contributing Factors

Results showed numerous contributing factors to damage:

- Using inadequate insulation testing equipment e.g., cumbersome to use, not sensitive enough/low voltage
- Using inadequate accessories to the equipment e.g., only test laparoscopic, not able to test other insulated items in inventory
- Performing testing inadequately and/or incorrectly e.g., not allowing sufficient time, lack of education/training, & competence

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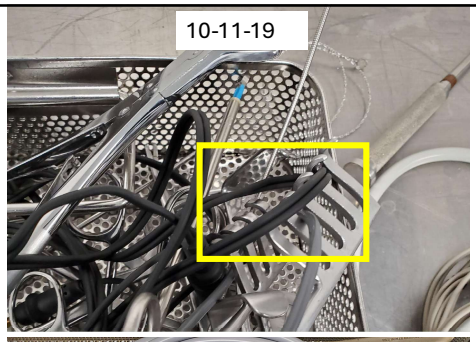
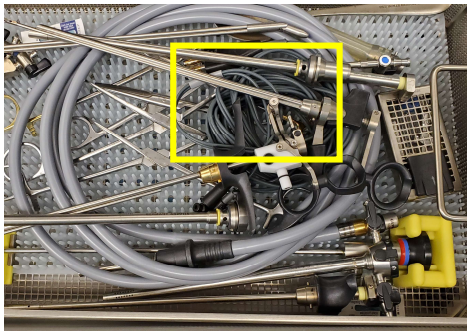
Contributing Factors..

- Incorrect care at point of use
- Incorrectly arranging insulated instrumentation for post transport.
- Incorrect staging in decontam for the washer.
- Incorrect set up within the tray/set e.g., not separating the cable/cord, insulated items from metal items
- Incorrect storing or failing to monitor stored back-up of insulated instrumentation e.g., inadequate storage space, maintaining excessive amounts of back-up, etc.





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2021-2022 Insulation Study

15

The Study Design & Setting

- Conducted in 2021-2022 (12-month study)
- Consisted of 9 states, 49 facilities
- Randomized experiment e.g., sterile patient-ready laparoscopic tray, non-sterile insulated forceps, & non-sterile cables/cords
- 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.
- 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.
- The aim of the study was to identify how common insulation testing failures and malfunctions are in insulated medical devices used in healthcare facilities.

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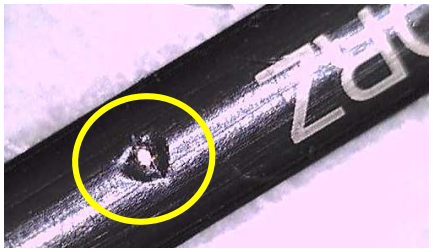
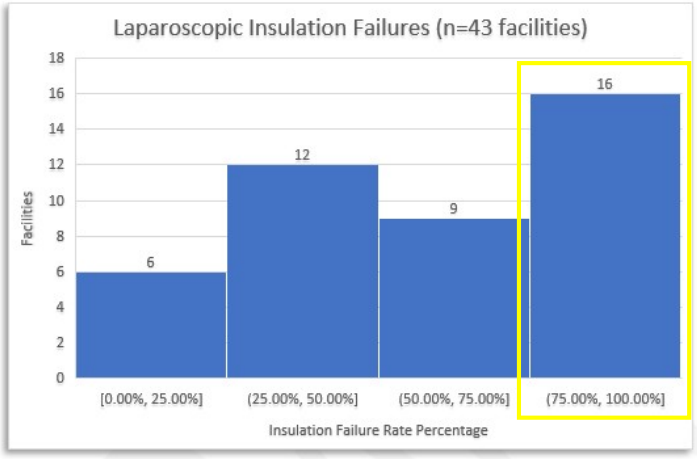


Results

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



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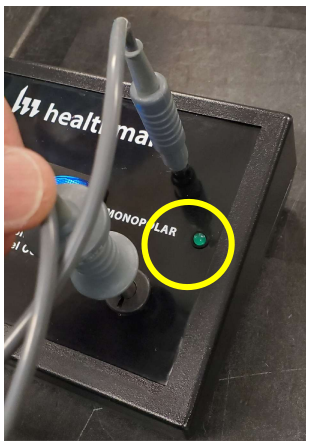
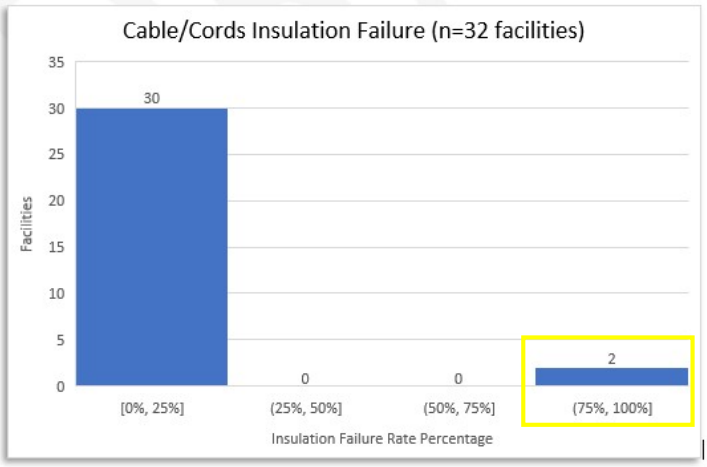


Results

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



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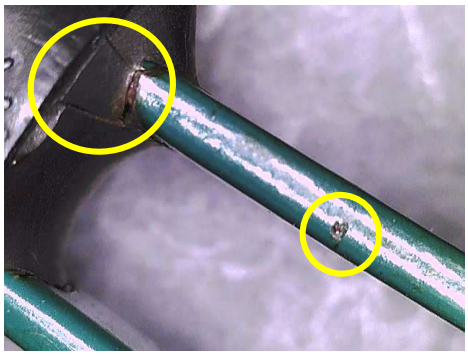
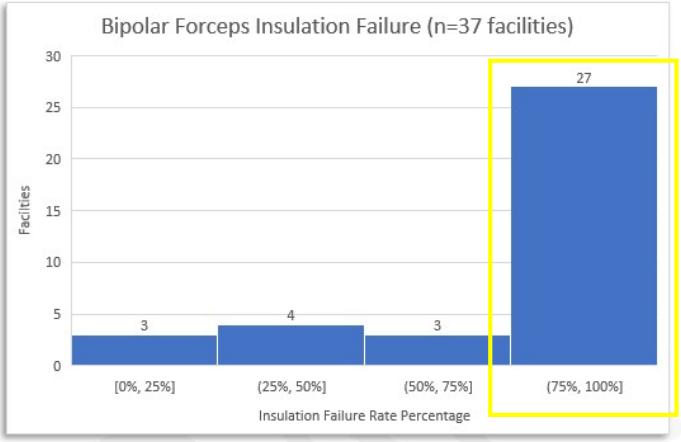


- Bipolar forceps had the highest failure rate with 27 facilities having a 75%–100% failure rate for those devices

Results



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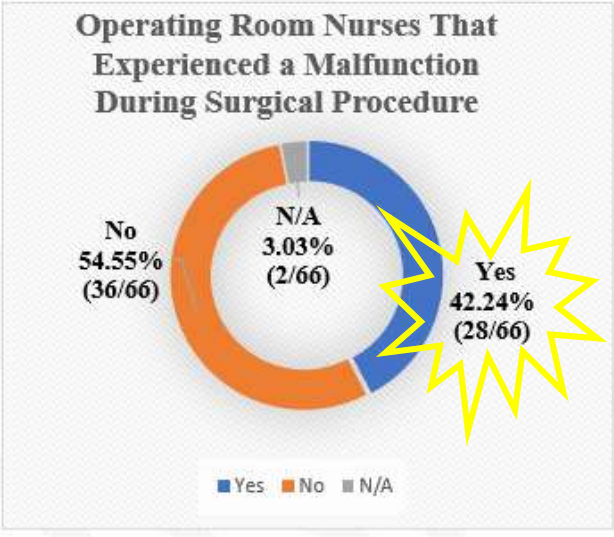
Results

- 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).



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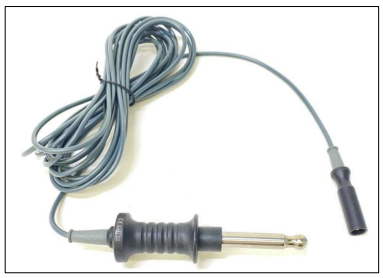
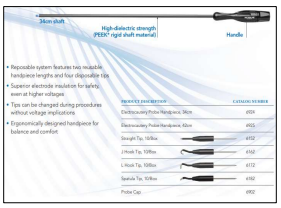
Results





FDA Maude Reports

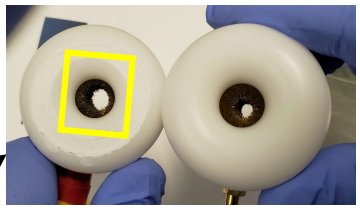
- **07-26-2021**: an insulated laparoscopic handle was found to have an insulation integrity failure and, "… it was reported that product arced resulting in blisters to the patient's skin."
- **08-10-2021**: an insulated laparoscopic 34CM Cautery Probe was identified with damage to the insulation coating 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."

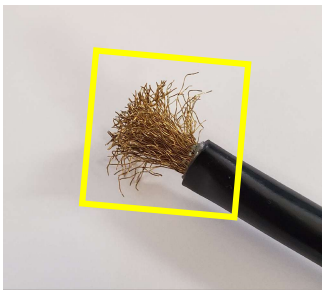
21

Contributing Factors from the Results

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.

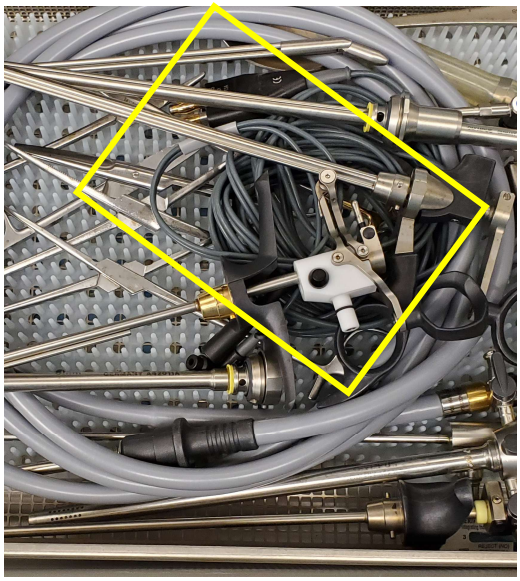




22

Contributing Factors from the Results

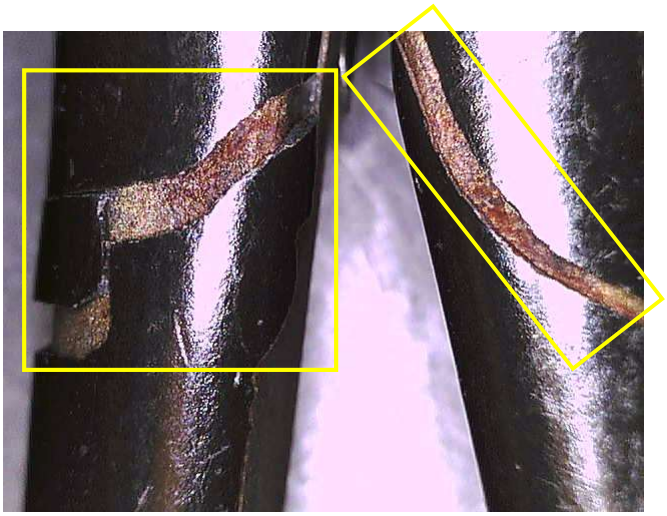
- Deficient containers/trays housing insulated laparoscopic instrumentation or correct container/tray but with the overflow of insulated instruments damaged by mixing with metal instrumentation.
- Inappropriate storage for backup insulated instruments (e.g., bins too small, excess amount of instrumentation,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



23

Contributing Factors from the Results

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

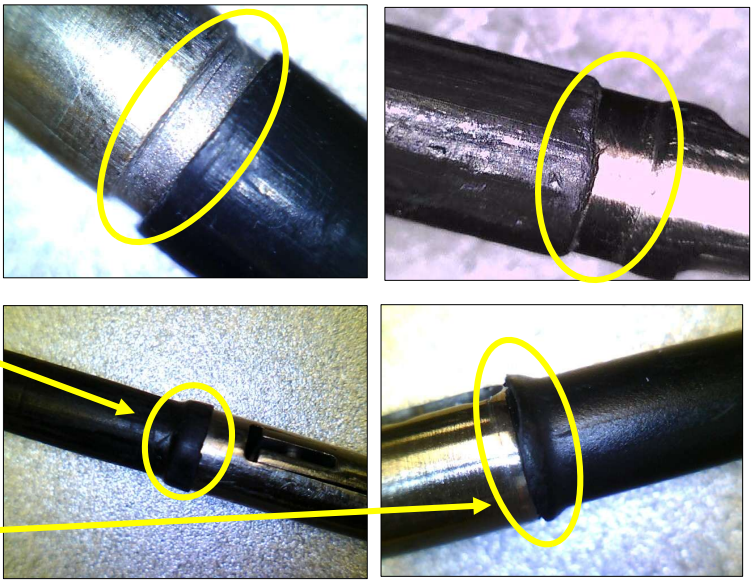


24

Contributing Factors from the Results

Insufficient repair service included the following:

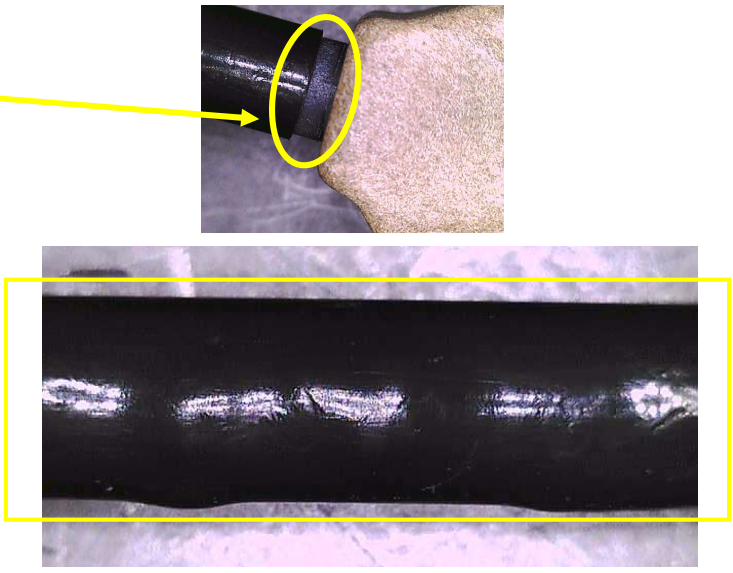
- Pull back (new damage) at the distal end of laparoscopic insulated instrumentation with no fraying for non-take-apart
- Pull back (old damage) at the distal end for laparoscopic instrumentation that has frayed insulation for non-take-apart
- Insulation layover '**Hangnail Effect**', where the insulation 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



25

Contributing Factors from the Results

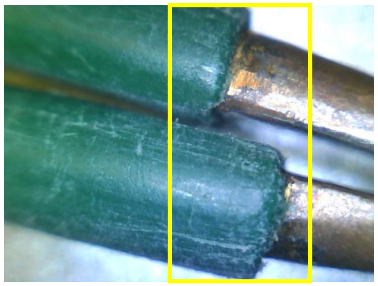
- Pull back at the proximal end for laparoscopic instrumentation that has separated from the base/handle for non-take-apart
- Newly insulated laparoscopic instrumentation with a glossy look and bumps along the shaft
- This is an insufficient repair where the inner insert was not completely cleaned/removed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

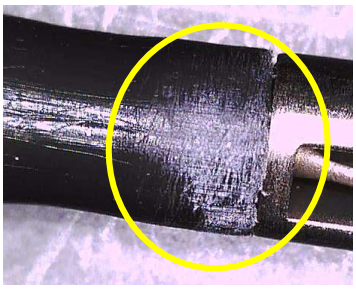


26

Contributing Factors from the Results

- 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





27

Contributing Factors from the Results

- 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

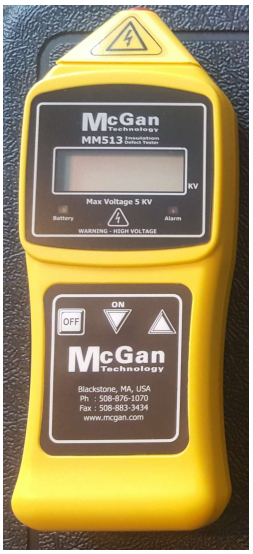
28

Examine the recommendations and standards highlighting the importance of insulation inspection and testing.

29

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)



30

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
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

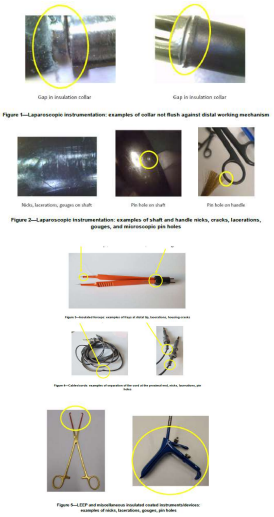


Figure 1—Laparoscopic instrumentation: examples of collar not flush against distal working mechanism

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

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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)

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Key Considerations

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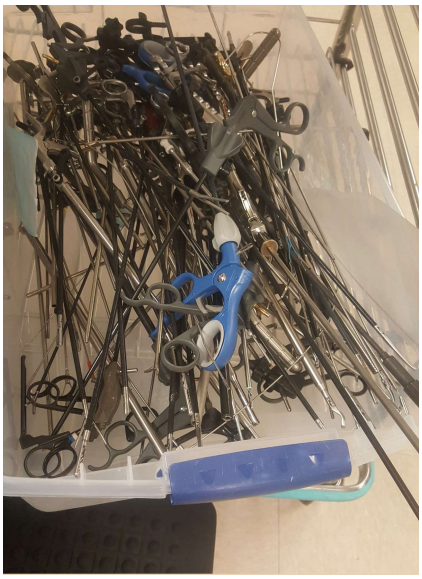
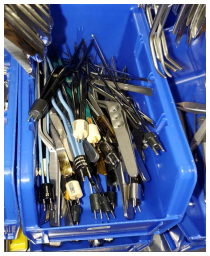
Key Considerations

- Re-evaluate your insulated instrument back-up & repair bins.





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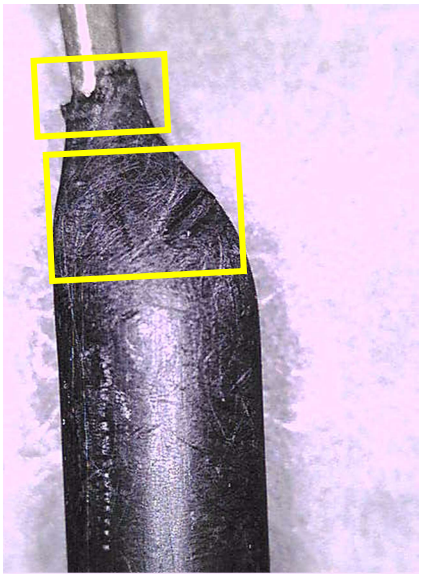
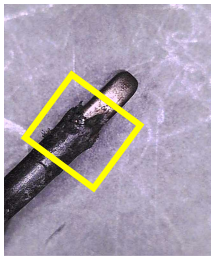
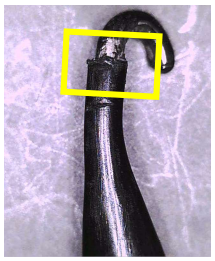
Key Considerations

- Re-evaluate your cleaning brushes used in the decontamination area.







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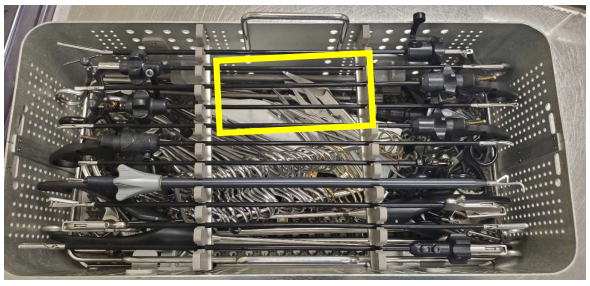
Key Considerations

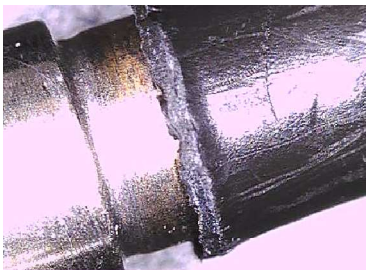
- Re-evaluate current tray/set up



36

Key Considerations

- Re-evaluate your current repair service e.g., send an insulated instrument out and evaluate again when it comes back.



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Voltage Output/Car	Type of Insulation Tester	Limitations	Voltage Settings
Toyota/One Fixed Setting	• Non-adjustable, fixed setting • Requires Pressing/holding the button.	• Uses a 9V battery • No Display • Does not meet manufacturer specific output voltage	2.9kV
Buick/Two Fixed Setting	• Non-adjustable, fixed settings • Requires selecting low and high buttons	• No Display • Does not meet manufacturer specific output voltage	Low Setting 2.6kV High Setting 4.3kV
Tesla/Various Flexible Settings	• Adjustable voltage settings, 0kV to 5kV • Meet manufacturer require output voltage • Requires recommended accessories for specific instrumentation	• No limitations	Brush Electrode 3.0kV LS Ring Electrode 2.8kV Tri-Hole Electrode 4.2kV Wire Tester 4.2kV Bi-Polar Fixture 2.8kV

A Crest meter aka voltmeter was used to detect the voltage/voltage range.

Key Considerations

- Audit the insulation testing practices e.g., test too cumbersome, lost/damaged accessories, tester itself damaged?
- Re-evaluate the current insulation tester e.g., is it sensitive enough to pick up pinholes?

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Key Considerations

- Audit the inspection of insulated instrumentation e.g., type of magnification, is it being used? Why not?
- Have vendors provide initial and continuous education e.g., insulated instrument vendor, insulation tester vendor, etc.

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Conclusion

- Both studies 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.
- The next time you are insulation testing or inspecting, and tell yourself, I am doing this “for patient safety” remember it could be a loved one.

40

REFERENCES

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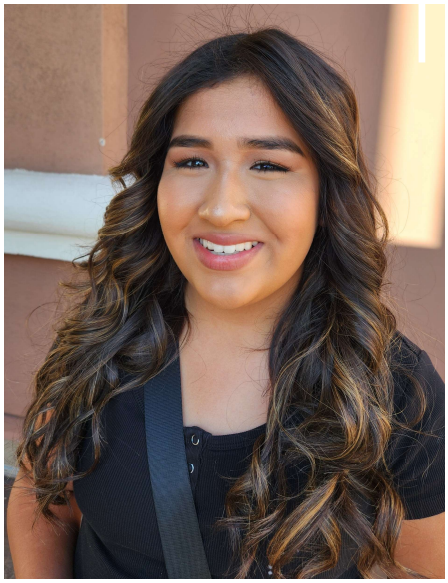
Thank you, Questions?



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