

FINDINGS FROM INTERNAL
AUDITING STUDY *of*
**INSULATION
INTEGRITY
PRACTICES**
to IMPROVE INSPECTION,
TESTING AND PATIENT
OUTCOMES

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ABSTRACT

Insulation integrity failures in patient-ready instruments and trays pose a clear safety risk that highlights the need for improved internal inspection and testing practices, recurring audits, and continuing education on inspection and insulation testing procedures in healthcare facilities. The study addressed in this paper served to identify how common insulation testing failures and malfunctions of insulated medical devices are in healthcare facilities. Results were based on a 12-month study across 49 different healthcare facilities that tested 416 instruments, and the findings were alarming:

- 223 instruments showed failures on insulation testing or inspection
- 16 facilities showing a failure rate of 75%–100% of all devices tested
- 32 facilities had a six percent average failure rate of insulated cables for continuity
- 27 facilities had the highest failure rate (75%–100%) of insulated bipolar forceps devices

Auditing of random laparoscopic insulated trays and bipolar insulated forceps was performed using an insulation tester with variable power settings and a variety of adapters—as well as insulated cables using a cable continuity tester. An enhanced inspection microscope was used to evaluate damage identified with the insulation tester and other visible damage observed.

Concurrently, a qualitative survey question was administered to Operating Room (OR) nurses, asking if they ever experienced events such as arcing of electrical current during a procedure. Additionally, the U.S. Food and Drug Administration's (FDA's) Manufacturer and User Facility Device Experience (MAUDE) database was searched for adverse events regarding insulation failures reported within the same timeframe to demonstrate if any significant patient risk existed as reported to the FDA.

The failures found over the course of this study highlight the need for a robust quality system that improves insulation inspection and testing procedures.



Background

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

Defects in the integrity of insulation coating may also be attributed to inadequate repair service; lack of sufficient magnification; absence of an increased sensitivity insulation testing equipment; insulation testing equipment accessories designed only for specific insulated instruments; educational deficiencies regarding the use of these tools; and limited knowledge of recommendations and standards specific to insulated instrumentation. The 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.

Concurrent adverse events

During the FDA MAUDE database search, three documented reports were identified in the date range of the study.¹⁻³ On April 9, 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.”¹ In another occurrence, on July 26, 2021, an insulated laparoscopic handle was found to have insulation integrity failure and, “... it was reported that the product arced, resulting in blisters to the patient’s skin.”²(Manufacturer Narrative). Lastly, on March 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.”³

In previously reported MAUDE reports before 2018, there were adverse events to patients with unintentional internal and surface burns due to insulation integrity, failures that contributed to bowel perforation, and surgical fires. As a result, a May 29, 2018, FDA communication safety alert stressed the importance of surgical fire prevention and provided guidance and recommendations on the inspection of insulated instrumentation for insulation integrity failures.⁴

Methods

The study was performed by auditing random laparoscopic insulated trays and 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. Additionally, an enhanced inspection microscope was used to evaluate the damage identified with the insulation tester and other visible damage observed. Personnel at the healthcare facility observing the audit were notified of any failures.

A qualitative survey question was administered concurrently to OR nurses across the U.S. to ask 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 whether any significant patient risk existed.

Results

The retrospective, cross-sectional, 12-month study was conducted from May 2021 to May 2022 at 49 healthcare facilities. Of the 416 instruments tested, 223 showed failures on insulation testing or inspection, and 16 facilities showed a failure rate of 75%–100% across all devices tested (See **Figure 1**). On average, insulated cables demonstrated a 6% failure rate for continuity across 32 facilities (See **Figure 2**). The study also revealed that insulated bipolar forceps had the highest failure rate, with 27 facilities experiencing a 75%–100% failure rate for those devices (See **Figure 3**). In one of the 27 facilities, 19 insulated bipolar forceps were tested from ready-to-use back=up inventory, and 13 of the 19 were identified as having insulation failures (See **Figure 4**).

For the qualitative aim of the study, OR nurses were asked about their personal experience with insulation malfunctions during a surgical procedure over the course of their careers. 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). (See **Figure 5**).

The results (shown in Figures 1–4) revealed 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, not enhanced magnification microscopes, was used).
- Insufficient insulation testers lacking the sensitivity and ability to test a wide range of insulated instrumentation

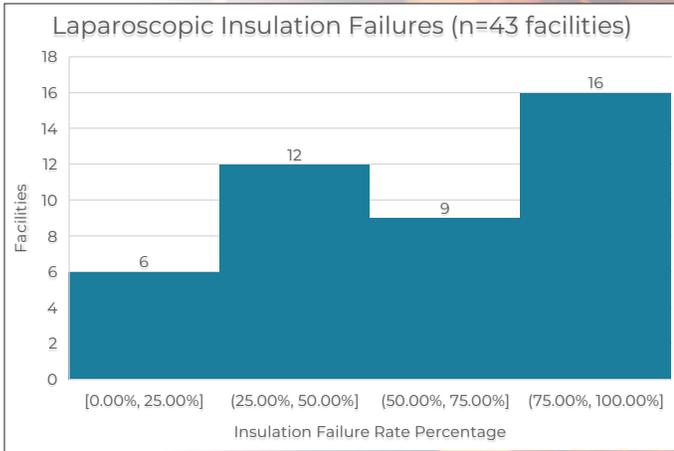


Figure 1: Insulated laparoscopic failures

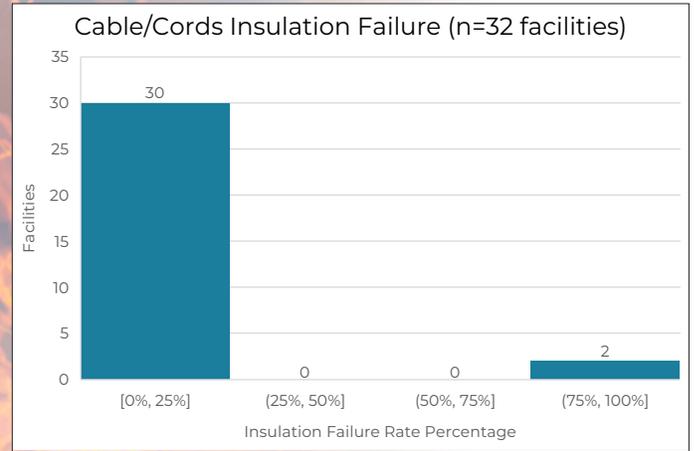


Figure 2: Insulated cable failures

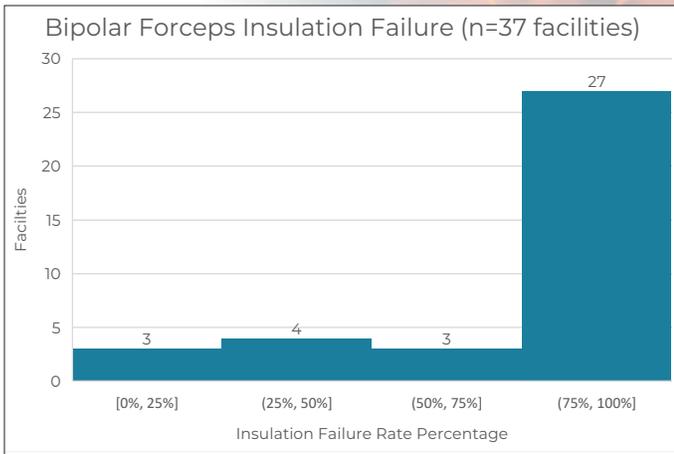


Figure 3: Insulation bipolar forceps failures

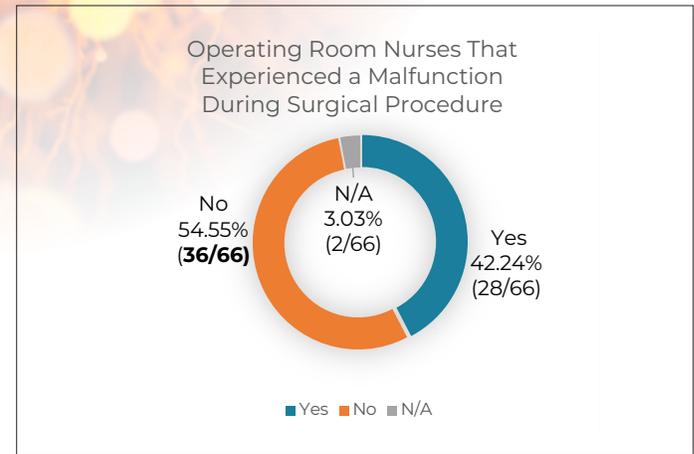


Figure 5: Survey response results for OR nurses who experienced a malfunction during surgical procedure

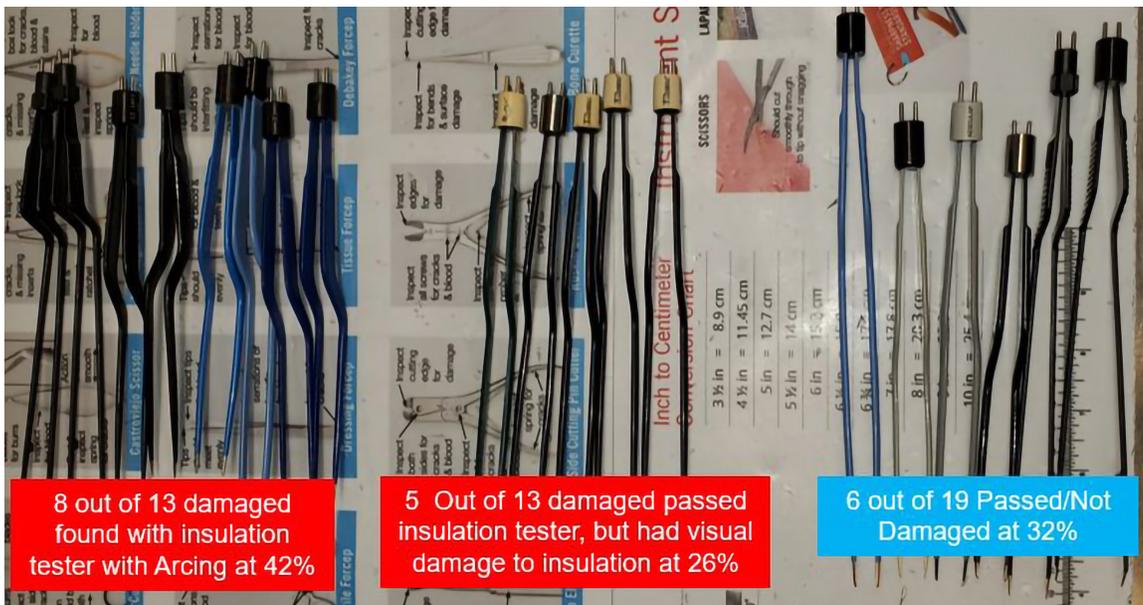


Figure 4: Facility with 13 out of 19 failures for insulated bipolar forceps in ready-to-use back-up instrumentation



- (e.g., bipolar forceps). Damaged and missing accessories and an insulation unit were identified.
- Lack of technician education to identify damage and operate insulation testers properly.
 - Deficient containers/trays housing insulated laparoscopic instrumentation, or the correct container/tray but with insulated instruments damaged by mixing with metal instrumentation.
 - Inappropriate storage for back-up insulated instruments (e.g., bins too small, excess amount of instrumentation, and tight spaces).
 - Insufficient repair service for insulated instrumentation (e.g., poor repairs, infrequent repairs, not under contract).

Standards and recommendations for inspection and testing practices

The Healthcare Sterile Processing Association's (HSPA's) *Central Service Technical Manual*, eighth edition, states that "electronic testing devices can detect microscopic holes in the shaft of a laparoscopic instrument."⁵ Guidelines from the Association of periOperative Registered Nurses (AORN) support and recommend the inspection and testing practices on insulated instrumentation for damage to the insulation coating. In section 10.3.5 of the Guideline for instrument cleaning (in the Guidelines for Perioperative Practice), AORN states that "... some insulation failures are not visible and damage to insulation may not be seen during visual inspection."⁶ The guideline 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."⁶

Additionally, in 2020, a new section (8.2.1) was added to the American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) ST79:2017 *Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities*.⁷ The section identifies and reinforces the need for the inspection and testing of insulated instrumentation and begins with, "... instruments should be organized and protected from damage."⁷ It further states that insulated instrumentation "... intended for use with electric current should be tested for integrity each time it is processed" and that "... cables/cords are also a source of concern and need to be inspected and checked for integrity and continuity."⁷

Furthermore, section 8.2.1 incorporates an inspection point and reference table for possible damage, with four sections that identify: instrument/device; inspection points; possible

damage, and methods to assist with inspection and testing. Lastly, but most importantly, ANSI/AAMI ST79 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."⁷

Instructions for use

Numerous manufacturers' instructions for use (IFU) for devices tested in this study were reviewed to determine whether they included specific instructions for inspection and/or testing for insulated instrumentation. One manufacturer's IFU for a bipolar forceps, for example, stated (under the section for testing/preparation) to "... examine insulated bipolar forceps for integrity; observe for cuts, gouges, or any exposed metal."⁸ An IFU for bipolar forceps from another manufacturer stated to "... inspect devices before each use for broken, cracked, tarnished surfaces, movement of hinges, and chipped or worn parts."⁹ Neither IFU included specifics regarding how to inspect or what to use for inspection, nor did they state the use of an insulation tester of any kind as a requirement. One of the manufacturers did affirm under the contraindications section that "... fires involving surgical drapes, and other combustible materials have been reported,"⁹ and it also noted that alternate current pathways resulted in burns where the patient or physician or assistant was in contact with exposed metal.⁹

IFU were also reviewed for laparoscopic instrumentation, insulated shaft/tube and insulated handles. The manufacturer of an outer insulated tube (5mm x 30cm) did not state in the IFU to inspect the insulated tube for damage or test with an insulation tester.¹⁰ The lack of clarity and detail in IFU can leave the user with a range of interpretations regarding how and what to use for insulation inspection and testing; therefore, it is possible users may not incorporate the accurate tools needed for inspection and testing.

Alternatively, the IFU from a reusable monopolar cable IFU was reviewed, which stated, "... 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)."¹¹ Even though the instructions did not specify what to use for integrity testing, it was specific with what to use for testing for the insulation's continuity.

Additionally, each IFU for the three documented adverse events reported in the FDA MAUDE database during the study were reviewed to identify any discrepancies or



ambiguity that could have contributed to the insulation failures. The first incident on July 26, 2021, pertained to an insulated handle. The IFU's reprocessing section recommends that users "... inspect for burns, cuts, and abrasions in the electrical insulation on the insert and/or the handle for instruments equipped with electrosurgical capabilities."¹³ Further, the manufacturer stated that the instructions were developed using guidance from AAMI TIR12, ISO 17665, and ANSI/AAMI ST79, and recommended that users also observe the standards.¹³

The second incident, received by the FDA on August 10, 2021, was for a 34cm reusable laparoscopic instrument. The instrument manufacturer's IFU recommends that users "Conduct a visual and functional inspection of the device per the assembly and disassembly instructions."¹² The IFU's "warnings" section states that "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."¹²

The final adverse event on March 15, 2022, was for a monopolar cable. Under the inspection and testing section, the manufacturer's IFU recommends users "visually inspect the cable and the plugs for irregularities on the surface,"¹⁴ and that "before use, make sure that the product has been properly reprocessed, inspected, and tested."¹⁴

All three IFU were inconsistent regarding insulated instrumentation testing instructions; two manufacturers stated to test, and one did not. All recommended some sort of inspection to identify damage but did not indicate which type of magnification to use during the examination. One manufacturer recommended the user refer to standards, such as ANSI/AAMI ST79, for guidance and more detail about inspection and testing practices.

Auditing inspection and testing practices

When auditing inspection and testing practices within a medical device reprocessing department, the following key areas should be reviewed:

- 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)
- Education on the use of magnification, insulation testers, identifying damage, returning demonstration, and past records of specific inservice training
- Container or tray to house and separate insulated instrumentation (it is important to assess whether the instruments are being protected and whether any overflow devices are being damaged)

- Storage for back-up insulated instrumentation (ensure instruments are not overcrowded or mixed with metal instruments)
- Repair service evaluation
 - » Examine repairs when instruments are sent out and returned
 - » Ensure current container/tray and peel pouches of insulated items are suitable and appropriate
 - » Compare the last date checked to the current integrity/quality of the instrumentation being reviewed

In-depth investigation of key areas

Tools needed for inspection

Most facilities have a desktop magnifier at the workstations in Sterile Processing, but that alone is insufficient due to the level of magnification found in desktop magnifiers. Typically, desk magnifiers range from 1.8x to 2.0x magnification, which are some of the lowest found on the market. Although they have their use and place in the department, a much higher magnification is needed to examine insulated instrumentation (see **Figure 6**).

Evaluating an enhanced inspection microscope may be a better solution for identifying insulation damage. Enhanced inspection microscopes can range in magnification (e.g., a USB microscope is 10x to 230x). An enhanced inspection microscope can be used with a variety of instruments and provide image capture and recording, if applicable, as well as a reference library for some models where the images can be stored for users to compare images being examined and observed (e.g., a new instrument compared to the current instrument). Best practice is that high-powered inspection microscopes are available at every workstation to ensure user compliance, as is seen with desktop magnifiers.



Figure 6: Image on left is an examples of enhanced inspection microscope in use; image on right shows damage seen under magnification



Figure 7: Example of overdue calibration identified in December 2021

Voltage Output	Type of Insulation Tester	Limitations	Voltage Settings
One Fixed Setting	<ul style="list-style-type: none"> Non-adjustable, fixed setting Requires Pressing/holding the button. 	<ul style="list-style-type: none"> Uses a 9V battery No Display Does not meet manufacturer specific output voltage 	2.9kV
Two Fixed Settings	<ul style="list-style-type: none"> Non-adjustable, fixed settings Requires selecting low and high buttons 	<ul style="list-style-type: none"> No Display Does not meet manufacturer specific output voltage 	Low Setting 2.6kV High Setting 4.3kV
Various Flexible Settings	<ul style="list-style-type: none"> Adjustable voltage settings, 0kV to 5kV Meet manufacturer require output voltage Requires recommended accessories for specific instrumentation 	<ul style="list-style-type: none"> 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

Figure 8: Sensitivity table for insulation testers. Note: A crest meter/voltmeter was used to detect voltages of insulation testers.



Figure 9: Examples of integrity and continuity testing

Tools needed for testing

Insulation testers check insulated instrument integrity by detecting and locating insulation defects. Testers on the market today have different sensitivities and accessories and may be designed only to test specific insulated instrumentation (e.g., laparoscopic instruments). For testing, it is important to:

1. Investigate the current inventory of different types of insulated instruments to be tested (e.g., bipolar forceps, reusable monopolar and bipolar cords) within the facility and outlining areas, if applicable.
2. Gauge the type of insulation tester currently being used (and its accessories, if applicable), and determine if the tester can test all those types of insulated instruments.
3. Compare the insulation tester in question to a new one of the same kind, ensuring there are no missing or damaged accessories—and that the tester is calibrated (if applicable), which is typically annually (see **Figure 7**). This can be accomplished by working with the insulation tester manufacturer. Compare the current tester to another type in question to evaluate where it lacks in sensitivity. While performing a test on the same insulated instrument with both testers, one can more easily evaluate the depth of detectability (see **Figure 8**).

Remember, for consistency, all insulation testers within the department should be the same model/type and not having variations in education for each type of tester that could present room for error. If reusable monopolar or bipolar cables are used in the facility, in addition to testing the integrity of the insulation, a continuity tester would be necessary to test for electrical continuity within the cable. This test demonstrates that an electrical path can be established between two points (see **Figure 9**). Continuity testing is an essential, proactive measure to prevent a damaged cable from being used in a procedure, which can lead to surgical fires.

Education for inspection and testing practices

Education on the use of magnification, insulation testers, and identification of damage needs to be assessed within a reprocessing department. While a random insulated set and individual insulated instrument are being assembled, ask questions of the staff regarding use of the magnification and insulation tester. Consider the following:

- Ask what is being examined while defining and demonstrating the inspection and testing being performed and the different types of insulation damage (e.g., look at a bipolar forceps at the distal tip for frayed insulation, and the proximal end for any cracks and/or separation between the base and tins of the forceps).



Figure 10: Example of a single-layer tray with insulated and metal instrumentation mixed together



Figure 11: Example of a single-layer tray with insulated and metal instrumentation mixed together

- Understand that even if an insulated instrument passes insulation testing for exposed metal, it does not guarantee that damage is not present (e.g., scratches, gouges and laceration that did not expose the metal interior). That is an area for bioburden to settle.
 - Refer to any internal policies and procedures that pertain to inspection and testing as a guide to ensure they are followed.
 - If the laparoscopic container/trays consist of a mix of insulated instruments that are actively monitored throughout the procedure and only need to be inspected, not tested, then the assessment will have specific questions for the employee (e.g., “What is the difference between the other insulated instruments in the container/tray?” and, “Which insulated instruments are inspected and tested versus just inspected?”).
- Investigate past education records for each employee to evaluate the length of time since the last training (e.g., insulation tester inservices, education on damage identification from the current repair service), making sure there is annual or biannual education in those areas. It is also important to evaluate employee signoff for inspection and testing policies and procedures.

Container/tray assessment

Evaluating the current container/tray that houses insulated laparoscopic instrumentation is the simplest step; however it can also become complex and expensive if areas of opportunity are identified. If the current container or tray is a standard, single-level model where insulated and metal instruments are placed together (see **Figure 10**), then a multi-level container is essential to separate insulated and metal instrumentation. If a multi-level container or tray is used, an evaluation becomes essential for any overflow of insulated instruments being placed on the bottom with metal instruments (see **Figure 11**). It is then vital to analyze for missing or damaged pieces to the insert, protectors, etc., which can diminish instruments’ insulation.

Forming a multidisciplinary team that consists of OR and SP professionals is critical for container and tray evaluation, as is having a conversations to ask and answer questions about every insulated instrument needed in the container/ tray. Some questions to consider may include: has a surgeon left the facility and an instrument is no longer being used and can be removed? Are there duplicate instruments that can be separated in a peel pouch? Can a reusable monopolar cable be separated because single-use cables are being used? *Note: In an emergency, the reusable cable may be used and can be separated in a peel pouch when needed.* Containers and trays of insulated laparoscopic instruments need to be evaluated annually. Doing so can also prevent processing delays where additional time is needed to inspect and test.

Appraisal of back-up instrumentation storage area(s)

When auditing back-up insulated instrumentation, identify any excessive amount or mixed insulated and metal instruments for any specific insulated instrument category (e.g., bipolar forceps, insulated scissors). (See **Figure 12**). Adson insulated forceps need to be separated from

7/8-inch insulated forceps; this is because Adson forceps are half the size, and the distal metal tips can scratch against the insulation of the larger forceps when users retrieve or sift through the bin or drawer. Laparoscopic instrumentation with insulated shafts should be separated from non-insulated devices, and laparoscopic devices with insulated handles need to be separated from non-insulated handles to prevent scratching the insulated handles (alternatively, the insulated handles can be phased out or moved). For third-generation, laparoscopic take-apart instrumentation, the insulated sheaths should be separated from the metal working mechanism inserts as those will also scratch against the insulated shafts. Insulated monopolar and bipolar cables should be separated from all instrumentation and left in the original package



Figure 12: Insulated bipolar forceps mixed with metal instrumentation



Figure 13: Clean pull-back from an insufficient repair



Figure 14: Old and frayed pull-back from an insufficient repair

(if applicable) for additional insulation protection. 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 drawer when it closes.

Evaluate repair service

Evaluating repair service quality can present opportunities for process and repair improvements. All steps in repair services procedures need to be investigated (e.g., repair bin, examining repairs when they are sent out and return). Start with the repair bin location and size. If the repair bin is located too far from workstations, damaged insulated instrumentation may not make its way there. It is helpful to have separate bins for insulated instruments (e.g., one for laparoscopic, one for bipolar forceps, and so on). *Note: If only a single bin is used for everything, delicate insulated instrumentation can become damaged further.*

The next step is taking the current container/tray and peel pouches of insulated items, comparing them to the previous date checked and examining the current integrity and quality of the insulated instrumentation being reviewed. If integrity or quality issues are discovered for insulated instruments, they could be caused by:

- A previous insufficient repair service
- A repair service provider failing to detect the damage
- Insulated instruments that are not under contract
- A current repair service that is only evaluating the metal instrumentation in the container/tray

Review the most current repair service contracts and address any instrumentation that has been overlooked. While using an enhanced inspection microscope gauge, be cognizant of issues with insulation integrity. Some repair deficiencies noted in the following section and photos include:

- Pull-back at the distal end for laparoscopic instrumentation that is clean, with no frayed insulation for non-take-apart devices (see **Figure 13**). *Note: This can be attributed to an insufficient repair overlooked by the repair technician, or lack of training for the service technician to identify an inadequate repair.*
- Pull-back at the distal end for laparoscopic instrumentation that has frayed insulation for non-take-apart devices (see **Figure 14**). *Note: This example shows old damage overlooked by the repair technician and also reflects lack of education for the technician to identify an insufficient repair.*
- Insulation lay over (“hangnail effect”), where the insulation is laid over the distal working mechanism instead of being flush against it. Over time, this can cause insulation to separate, or pieces of insulation may fray and pull back like a hangnail (see **Figure 15**). These issues can be attributed to an insufficient repair, overlooked damage by the service technician, or lack of education education for the technician to identify an inadequate repair.
- Pull-back at the proximal end for laparoscopic instrumentation that has separated from the base/handle for non-take-apart (see **Figure 16**). This can be contributed to inadequate damage evaluation by the repair service as well as lack of education for the technician to identify damage.



Figure 15: Example of “hangnail effect”; image on top shows insulation laid over, and image on bottom shows pulled-back insulation pieces



Figure 16: Pull-back/separation from insulated shaft (from proximal handle)



Figure 17: Inadequate repair of laparoscopic insulated shaft

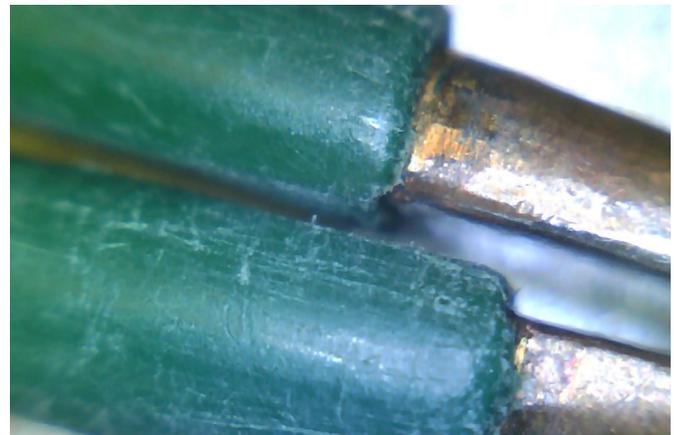


Figure 18: Example of old insulation damage

- Newly insulated laparoscopic instrumentation with a glossy look and bumps along the shaft (see **Figure 17**). 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 adequate repair.
- Signs of wear, including nicks, scratches and gouges on insulated instrumentation (see **Figure 18**). *Note: This represents previous damage overlooked by the repair technician and a lack of training for the technician to identify damage.*
- Insulation that is gray, white, dull in color, and/or fuzzy (for all insulated instrumentation) (see **Figure 19**). *Note: This also represents previous damage overlooked by the repair technician and lack of education for the technician to identify damage.*
- 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) (see **Figure 20**). *Note: This, too, can be attributed to insufficient repair overlooked by the repair technician or insufficient repair technician education to help them identify damage or inadequate repairs.*

Limitations

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

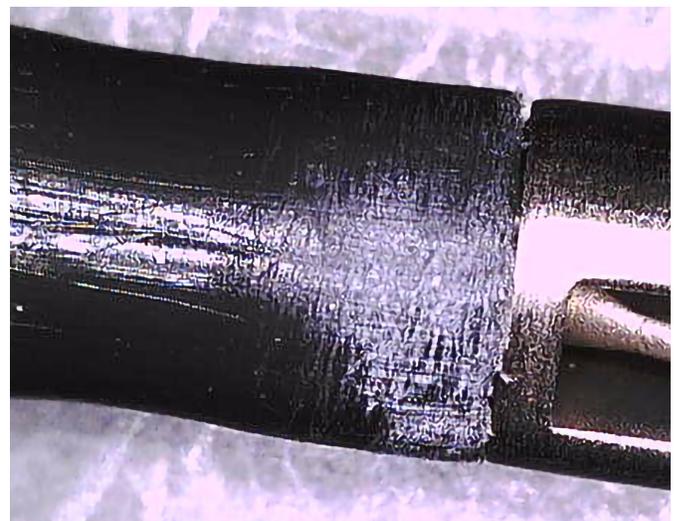


Figure 19: Discoloration and old damage

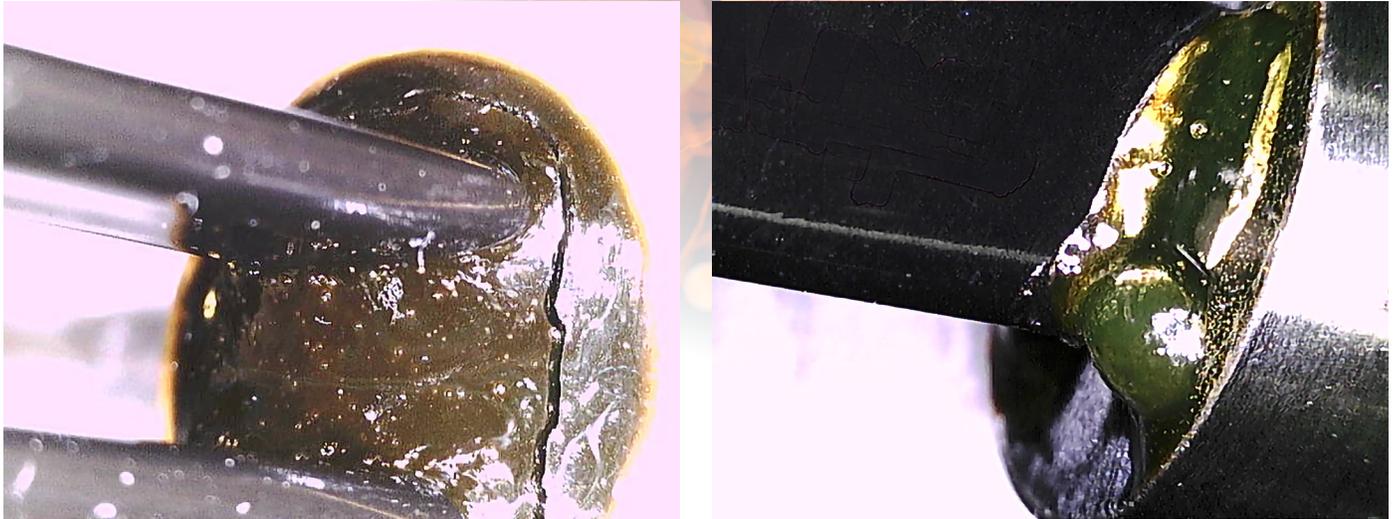


Figure 20: Image on left shows separation of base in an insulation bipolar forceps; image on right show excessive amounts of epoxy resin

release for testing was another factor and made the sample size smaller. There were also some inconsistencies; not all facilities used reusable cables and resorted to single use and/or a mixture of both, which affected the sample size for that instrumentation category.

Conclusion

This study identified numerous insulation failures in patient-ready instruments and trays, which presented clear patient safety risks. The failures highlight the need for improved internal inspection and testing practices, recurring audits, and continuing education on inspection and insulation testing procedures. A robust quality system that consists of a high-caliber insulation tester, proper technique, and training, and a sufficient magnification program will decrease adverse events in patients and healthcare professionals by preventing stray electrical energy in insulated devices that can cause burns, fires, electrical shock, and even death. 

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