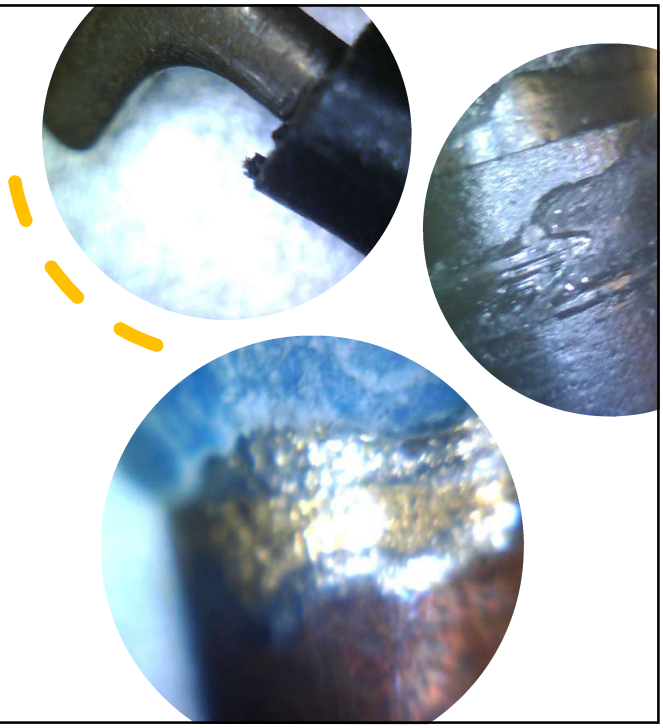
1

Objectives:

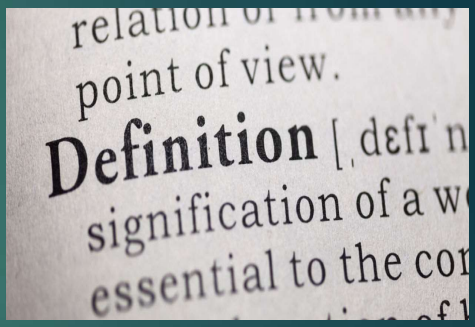
- Review the FDA's issued warning letter released in November 2018 on the Safety Communication on the dangers of monopolar laparoscopic surgery
- Identify the different ways insulated instrumentation and devices become damaged
- Review recommendations for insulation testing from various standards and guidelines: AORN, AAMI, AST, ISO,……
- Discuss medical malpractice from electrical strays for damaged insulated instrumentation and devices
- Describe solutions to preventing surgical burns caused by insulation failures



2

Definitions:

- **Electrosurgery**: Using a high-frequency electric current to heat and cut tissue with great precision.
- (**MIS**): Minimally Invasive Surgery
- **Monopolar**: The current passes through the patient to a return pad and then back to the ESU generator to complete the circuit.
- **Bipolar**: The electrical current passes from one side of the forcep, through the target tissue to the other side of the forcep, then back to the generator.



3

Why must I test insulated devices?

4

Why must I test insulated devices?

- Patient and staff burns with electrical stray currents
- Possible fires in the OR
- With limited field of view the surgical team only views a section of the devices usually at the distal end of the device
- Many different types of insulated instruments/devices to be tested

5

Statistics:

- There are over 3 million laparoscopic procedures done annually in the U.S. and worldwide it is more than 7.5 million including:
  - Cholecystectomy
  - Appendectomy
  - Hernia repair
  - Bowel resection
  - And a range of other therapeutic and diagnostic (i.e. exploratory surgery) procedures
- Approximately 5.4% of these operations will have unintentional tissue burns. 405,000 patients will have a burn.
- Of over 192,000 laparoscopic procedures identified in CA and FL resulted in 3.6 per 1000 cases of patient morbidity and mortality, which were likely related to stray energy burns during laparoscopy.

6

Statistics Continued….

One study showed that 1 in 4 patients who suffer internal injuries from stray burns….. Die.

1 in 5 reusable laparoscopic instruments has insulation failure with the most common failure site at the distal third of the instrument.

7

Insulation Failure Cited as Being the Primary Cause of Burns During Laparoscopic Procedures

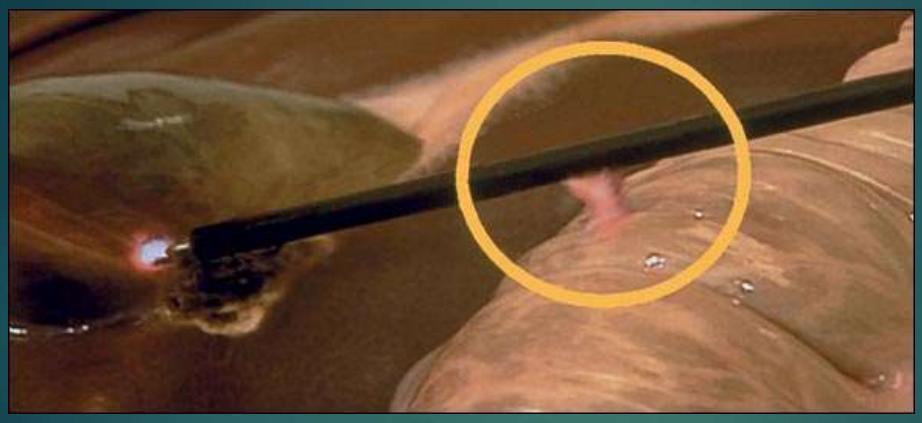
- 90% of the instrument is not visualized by the surgeon/surgery team
- 67% of stray electrosurgical burns go unnoticed during surgery
- 25% of the patients who suffer internal injuries stemming from these burns during laparoscopic procedures die

Source: Werner, C. (June 2002). "Guarding against an unseen killer: stray electrosurgical burns", Healthcare Purchasing News.

06-21

8

New York Times



A burn/Stray (circled) from an insulation failure on an electrical instrument.

Source: Barnaby J. Feder, NY Times, "Surgical Device Poses a Rare but Serious Peril", March 17, 2006

9

FDA Safety

FDA Issues a Safety Communication on the Dangers of Monopolar Laparoscopic Surgery.[1]

All health care professionals involved in surgical procedures are warned:

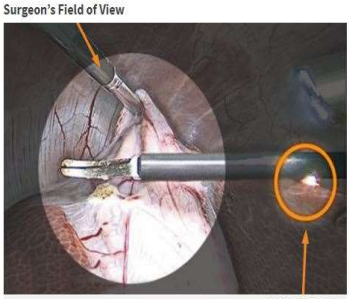
Monopolar energy use can directly result in **unintended patient burns from capacitive coupling and intra-operative insulation failure.**[1]

It's not the technique, it's the technology!

Traditional monopolar laparoscopic instruments cannot prevent stray energy from causing patient burns (due to capacitive coupling and intraoperative insulation failure).

Every 90 minutes a patient is severely burned and 1-2 people die every day from preventable stray energy burns.[2]

Surgeon's Field of View



Stray Energy Burn
(Out of the Field of View)

FDA Warning Letter 2018

"Evidence shows that a patient is injured by capacitive coupling or intraoperative insulation failure every 90 minutes in the USA"

References

Recommendations to Reduce Surgical Fires and Related Patient Injury: FDA Safety Communication

https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm608637.htm

Frequency and Severity of Stray Energy Burns

https://www.encision.com/wp-content/uploads/2018/04/Frequency_and_Severity_of_Stray_Energy_Burns_MAR00032.pdf

Martin, Moore, Tucker, Fuchshuber, Robinson., Quantifying Inadvertent Thermal Bowel Injury from the Monopolar Instrument. The Journal of Surgical Endoscopy. November 2016, Volume 30, Issue 11, pp 4776–4784.

Nduka CC, Super PA, Monson JR, Darzi AW., Cause and prevention of electrosurgical injuries in laparoscopy. J Am Coll Surg.

1994;179(2):161-170.

10

Da Vinci Robot Lawsuit Numbers Continue to Climb

March 27, 2013 By: Ava Lawson MEDICAL MALPRACTICE

Da Vinci robotic surgery is marketed as a less-invasive option for routine operations such as hysterectomies, prostate and gallbladder removal, and other common procedures, but a recent *Bloomberg* article points out the escalating number of injuries and deaths linked to this cutting-edge technology. One case in point is Bronx resident Gilmore McCalla, who filed a da Vinci robot lawsuit after his 24 year-old daughter Kimberly died following robotic surgery.

Kimberly was admitted to Montefiore Medical Center on August 12, 2010 for a straightforward hysterectomy to remove her uterus, as she had been diagnosed with early-stage cancer. Her parents expected her home the next day, but the young woman never came home due to fatal complications during her operation.

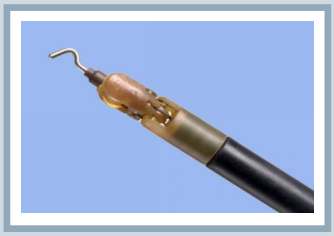
Allegations raised in NY da Vinci robot lawsuit

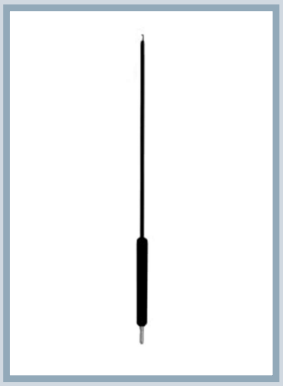
According to the family's New York medical malpractice lawyers, Kimberly suffered a lacerated iliac artery during her da Vinci robotic surgery, and just eleven days after the procedure, was rushed into emergency surgery, where doctors first discovered this life-threatening problem. The surgeons repaired the artery, but the damage was already done and Kimberly died of small bowel injuries. Gilmore McCalla first filed a products liability lawsuit, claiming the robot's equipment lacked sufficient insulation. A separate medical malpractice suit was also filed, which held the attending doctors responsible for the woman's untimely death, since they allegedly failed to react promptly to signs of early complications.

The *American Journal of Obstetrics & Gynecology* conducted a study in 2011 showing that some forms of insulation failed on the da Vinci robot as much as four times the rate of conventional surgical equipment. Da Vinci robot surgery is utilized in hospitals throughout the nation and just last summer, the prestigious Sloan Kettering Cancer Center reported three cases of artery burns resulting from poor insulation on the robot, all of which were addressed

https://thesandersfirm.com/da-vinci-robot-lawsuit-numbers-continue-climb/

11





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.*
- ***03-06-2019: Robotic Endowrist Cautery Hook**, Electrical energy from the permanent cautery hook instrument allegedly caused a thermal injury on the patients' bowel. The fenestrated bipolar and cautery forceps instrument were in use along with the permanent cautery hook instrument when the arcing event occurred.*

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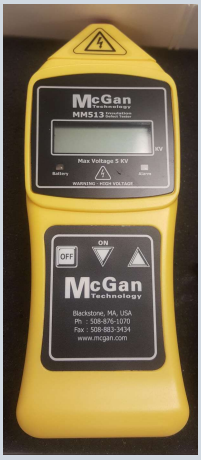
Things to Consider when Purchasing/Evaluating an Insulation Tester

1. Is the tester rechargeable? Or battery operated
2. Fixed or stand alone?
3. What type of accessories? E.g., wire tester, bipolar forceps tester, etc.
4. Any yearly maintenance or calibration?
5. Is it a standard test? Or is it more sensitive? E.g., voltage settings
6. Easy to use for front-line teams?
7. Demo? In-services available? IFU?
8. When accessories go bad e.g., damaged, how will you know? And are they replaced? Fixed?



13

Laparoscopic Insulation Testing

- Insulation is a temporary coating that retains the electrical current within the instrument.
- Defects must be discovered during laparoscopic instrument set assembly
- Electricity can escape through these holes causing burns, infections, and extended recovery time
- IFU of the device may state you need to test every time

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Examples of IFUs for Insulated Instrumentation/devices

- (Spectrum Laparoscopic Instrumentation) under Inspection and Assembly ***"Important Note: At this point in the process, Spectrum recommends testing the insulation for cracks, gaps where the shaft meets the tip assembly, and pinholes"***

  NOTE: This IFU does not come out and state every use, but how the IFU reads is after the decontam process, which is every instrument being used.

- (ASSI Bipolar Scissor) under Inspection of instruments ***"Recommends establishing a procedural review, by which the instrumentation are inspected frequently (before and after each use) for damage such as: Bullet three, For insulated instruments: cracks, nicks, lacerations, or abrasions in insulation."***

- (Vmueller Bipolar Jewelers Insulted Forceps)***"Prior to use, inspect devices to ensure proper function and condition. Do not use devices if they do not satisfactorily perform their intended function or if they have physical damage."***

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Examples of IFUs for Insulated Instrumentation/devices Cont…..

- (Vmueller Bipolar Jewelers Insulted Forceps)

"Adverse events reported while using bipolar electrosurgical devices include:

- *Inadvertent activation with resultant tissue damage at the wrong site and/or equipment damage.*
- ***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.***
- *Explosions caused by electrosurgical sparking in a flammable gas environment (i.e. explosive anesthetic gases).*
- *Organ perforation. Sudden massive hemorrhage*

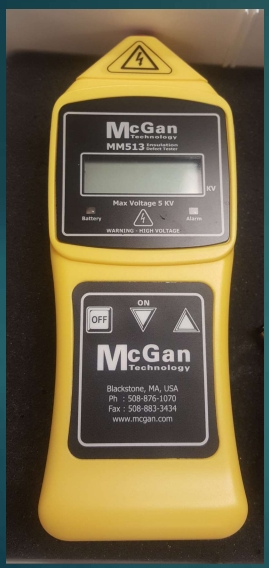
16



An enhanced view with the use of a borescope of damage.

17

Many Types & Modules to use to Test Insulation

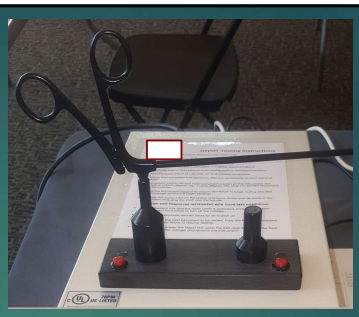


https://www.spectrumsurgical.com/images/lap-insulation-instruction.jpg

http://www.mobileinstrument.com/wp-content/uploads/2009/11/insulscan.jpg

18

What Accessories Does The Tester Provide?



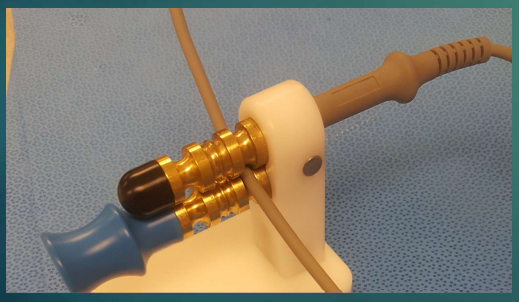
http://www.mobileinstrument.com/wp-content/uploads/2009/11/insulscan.jpg

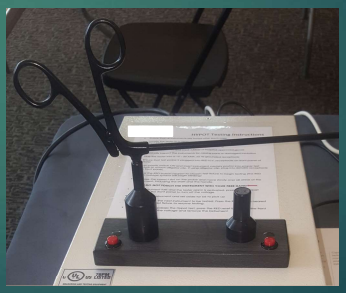
https://www.spectrumsurgical.com/images/lap-insulation-instruction.jpg

19

Accessories are important!

- What and how are they used?
- Are they user friendly?
- Are there multiple ways to use the accessories?





https://www.spectrumsurgical.com/images/lap-insulation-instruction.jpg

20

Many types of accessories to test insulated instruments/devices

21

NEW!

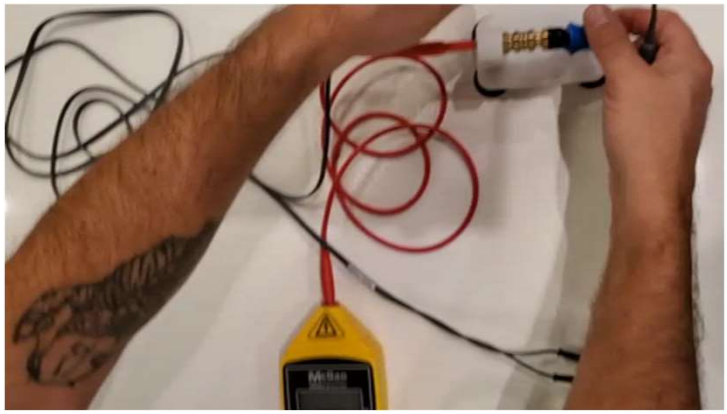
Bipolar Forceps (IDEAL)

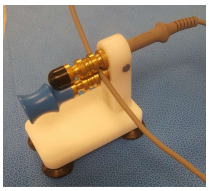
- Using Bi-Polar Test Fixture (MMBPT-190) w/Brush Electrode (MMBRU-0007) and w/ Saddle Block unit tester (MMSBT-170) option using HV red wire

22

NEW!

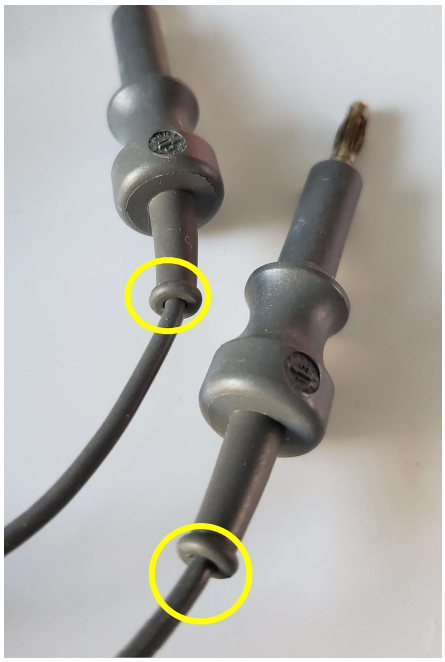
Bipolar or Monopolar Cables/Cords (IDEAL)





- You can use the (MMWIT-200A) Wire Testing Fixture w/HV Red Wire

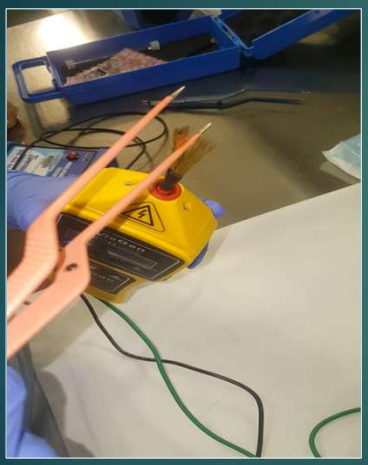
23



Cable/Cords:
Separation of the cord at the proximal end, nicks, lacerations, pin holes

24

Examples of damaged insulated devices



25

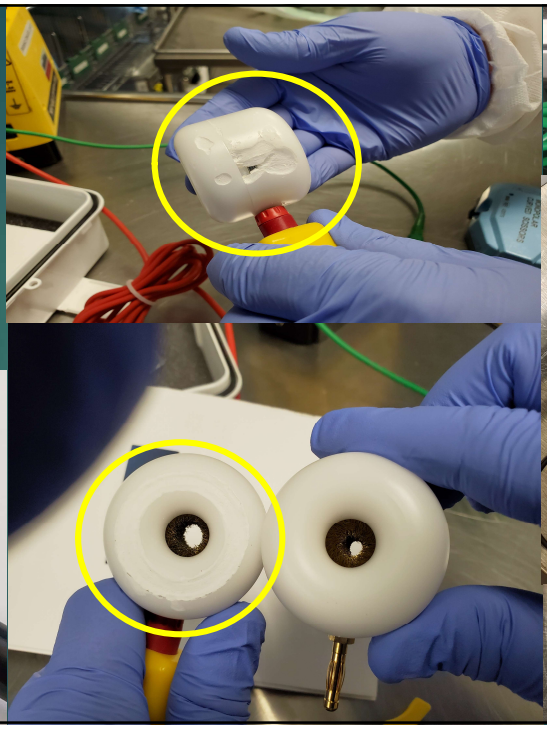
Examples of damaged insulated devices Cont….

26

Example of damaged Insulation Tester

27

Examples of damaged Insulation Tester Accessories



28

AORN, AST, ST90, ISO, AAMI ST79

- AORN: 2020 *"Visually examine insulated devices and test them using equipment designed to detect insulation failure".*

"Test insulated equipment for current leakage before use and after decontamination".

29

AORN, AST, ST90, ISO, AAMI ST79

- AST:

"Standard of Practice XII Unique risk factors exist when electrosurgery is used during minimally invasive surgical (MIS) procedures. The CST should work with the surgical team to implement the safety principles to reduce perioperative injuries to the patient and personnel."

"Insulation failure is now considered the primary cause of laparoscopic electrosurgical injuries.31 If the insulation is compromised such as a crack or hole, the electrical current can escape at the point and burn untargeted tissue. A decrease in power at the tissue target site will not occur even with the escape of electrical current.40 Escaped electrical currents can quickly cause extensive tissue death due to their extremely high temperature. The burns may not be seen by the surgical team and often do not cause symptoms in the patient for several postoperative days. Complications from these types of burns include life-threatening organ perforations and peritonitis."

30

AORN, AST, ST90, ISO, AAMI ST79

- AST:

"1. Insulated instruments and electrodes should be inspected in the Central Supply Department (CSSD) prior to sterilizing. ***The following is a five-step recommended method for inspecting the insulation in the CSSD****.38"*

https://www.ast.org/uploadedFiles/Main_Site/Content/About_Us/Standard%20Electrosurgery.pdf

31

AORN, AST, ST90, ISO, AAMI ST79

- AST:

a) *"Visually inspect the insulation prior to completing the cleaning process. Instruments and electrodes with cracks or holes in the insulation should be removed from service and sent for re-insulation repair.*

b) *Instrument or electrode should be cleaned with a soft brush and nonabrasive cleaning agent and rinsed.*

c) *A microscope should be used to visualize the integrity of the insulation of each item."*

https://www.ast.org/uploadedFiles/Main_Site/Content/About_Us/Standard%20Electrosurgery.pdf

32

Example of a Microscope

USB Microscope

(MICR008)

33

AORN, AST, ST90, ISO, AAMI ST79

- AST:

d) *"An insulation scanner should be used to detect the release of stray electrical energy along the length of the insulation.28 (1) Cost-effective, user-friendly insulation scanners are commercially available that can be used to test the insulation on reusable and disposable electrosurgical instruments. When the instrument is scanned, a full-thickness break in the insulation will activate an audible and visible alarm.40*

e) *Instruments and electrodes are securely packaged for sterilization. (1) The items should be packaged in such a manner as to minimize movement during handling in order to prevent damage to the insulation."*

https://www.ast.org/uploadedFiles/Main_Site/Content/About_Us/Standard%20Electrosurgery.pdf

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Examples of Securely Packaged (Laparoscopic Containers)

4-1130
Lightweight Poly Double Decker Tray

DDLP-1123
Customizable Laparoscopic ProTech Trays

35

AORN, AST, ST90 & ISO, AAMI ST79

- ANSI/AAMI ST90 & ISO-13485:2016:
  - A focus on quality
    - Performance Qualification (PQ): demonstrating that the process is constantly producing acceptable quality; the user usually performs this - verifies
      - Visual inspect for defects
      - Check for leakage - Insulation testing
        - Verify integrity of all insulation with tester
      - Don't forget the handle!!
  - The "Q" help define your quality
    - Is my equipment and instrumentation performing properly (IQ/OQ/PQ)
      - Installation Qualification (IQ)
      - Operational Qualification (OQ)

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NEW!

AMENDMENT 2: Inspection of Insulated Instruments

Section 8.2

- New section 8.2 and 8.2.1
  - Inspection of Instruments
  - Inspection of Instruments Intended to be Used with Electric Current

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AMENDMENT 2

(IFU) Instructions-For-Use Arthroscopy Shaver (Stryker) Under Manual Cleaning (Decontamination Area)

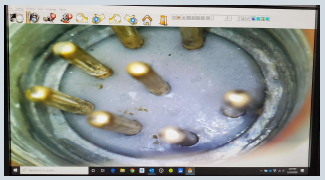
Manual Cleaning 9. Inspect *"Visulaly inspect the handpiece, including all internal surfaces, for remaining soil. Use an endoscopic camera and endoscope if necessary, to see the inner surface of the lumen".*

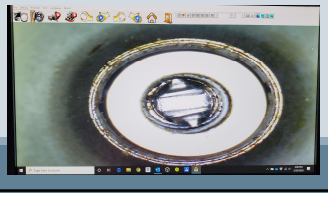
IFU Reviewed: 06-08-21

https://search.onesourcedocs.com/document/view/revision/2102290/model/1355322?source=search

8.2 Inspection of Instruments

- "When recommended in the IFU, enhanced inspection should be used and the enhanced visualization tool manufacturer's written IFU should be followed" (ANSI/AAMI ST79 Amendment 2, 2020).



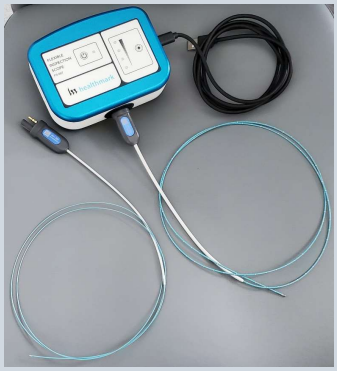


38

AMENDMENT 2

8.2 Inspection of Instruments

- "Borescopes or other methods may be used to check internal channels of instrumentation for cleanliness and integrity unless otherwise recommended in the IFU" (ANSI/AAMI ST79 Amendment 2, 2020).

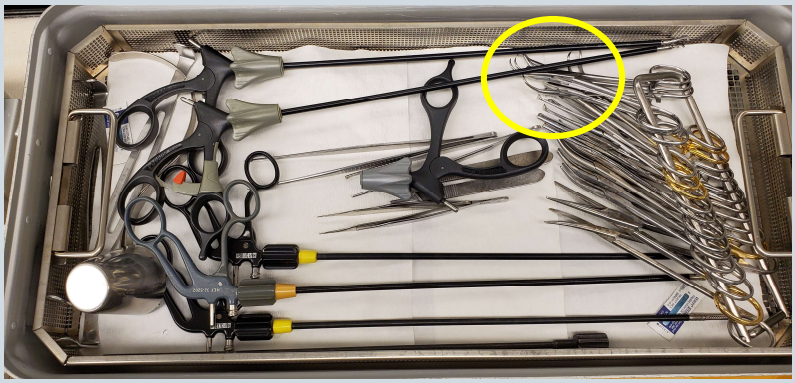


39

AMENDMENT 2

8.2.1 Inspection of Instruments Intended to be Used with Electric Current

- "Instruments should be organized and protected from damage" (ANSI/AAMI ST79 Amendment 2, 2020).



40

AMENDMENT 2

8.2.1 Inspection of Instruments Intended to be Used with Electric Current

- "Instrumentation intended for use with electric current should be tested for integrity each time it is processed" (ANSI/AAMI ST79 Amendment 2, 2020).

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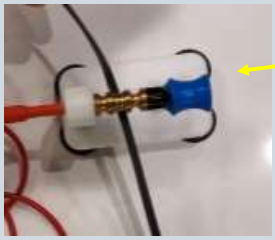
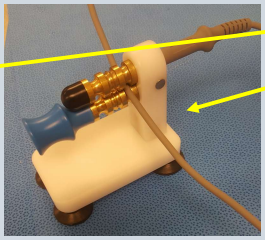
AMENDMENT 2





8.2.1 Inspection of Instruments Intended to be Used with Electric Current

- "Each insulation tester may be supplied with a variety of accessories to test specific instrumentation and cables/cords based on their design" (ANSI/AAMI ST79 Amendment 2, 2020).
- "Cables/cords are also a source of concern and need to be inspected and checked for integrity and continuity" (ANSI/AAMI ST79 Amendment 2, 2020).

42

Cable/Cord Continuity Testing

- Designed to test the continuity/inside of monopolar and bipolar cords

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Cable Continuity Testing

- Designed to test the quality of monopolar and bipolar cords

44

AMENDMENT 2

Table 1

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

(ANSI/AAMI ST79 Amendment 2, 2020)

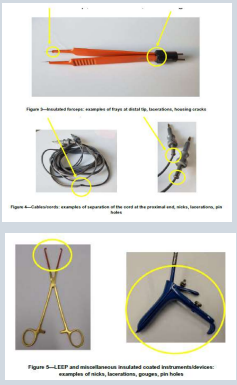
8.2.1 Inspection of Instruments Intended to be Used with Electric Current

- "The insulation should be checked at appropriate inspection points for the instrument (see Table 1 and Figure 1 through Figure 5" (ANSI/AAMI ST79 Amendment 2, 2020).

Figure 1-5

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



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AMENDMENT 2

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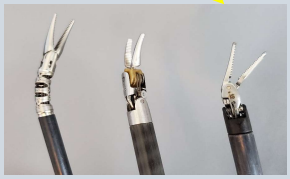
USB (Microscope)

8.2.1 Inspection of Instruments Intended to be Used with Electric Current

- "Laparoscopic including robotic instrumentation" (ANSI/AAMI ST79 Amendment 2, 2020).
- "Methods to assist with Inspection/Testing"
  - Insulation tester
  - Lighted magnification
  - Enhanced magnification (Microscope)
  - Visual inspection
  - Tactile inspection (ANSI/AAMI ST79 Amendment 2, 2020)



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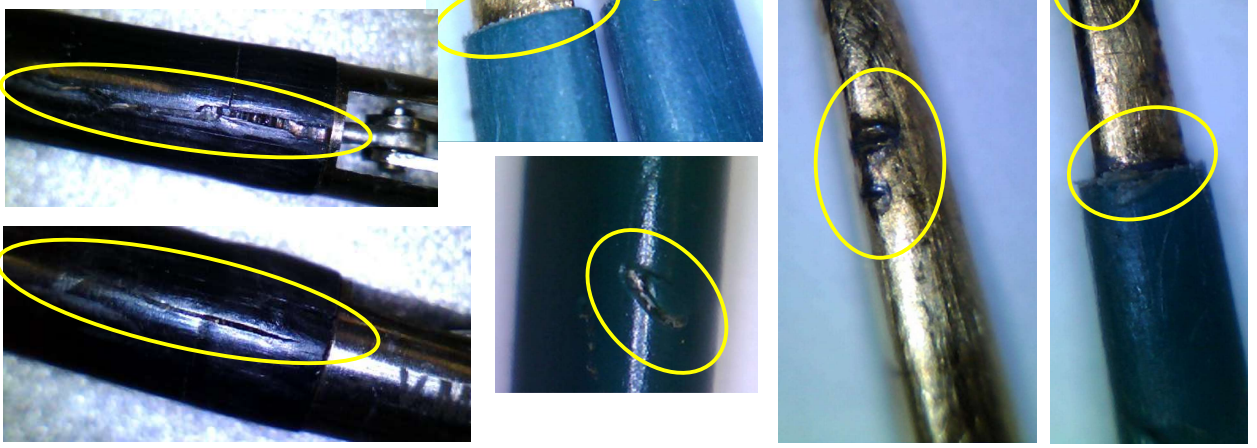
October 2021 in a CPR (Consultative Practice Review)

- 3 sterile bipolar forceps were inspected
- 3 out of the 5 insulated laparoscopic instrumentation were damaged.
- An Enhanced Inspection (Microscope) was used to identify the damaged close-up.



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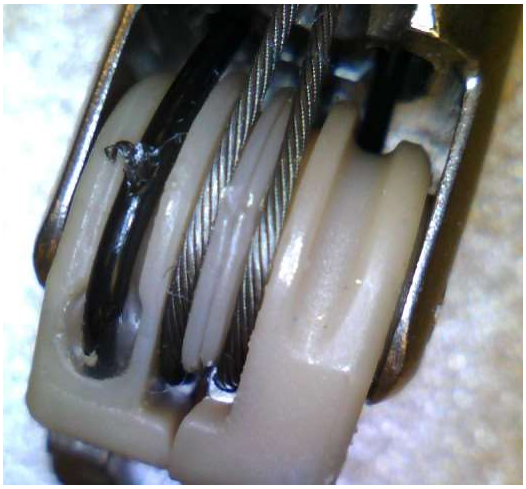
Prime example for enhance inspection of robotics



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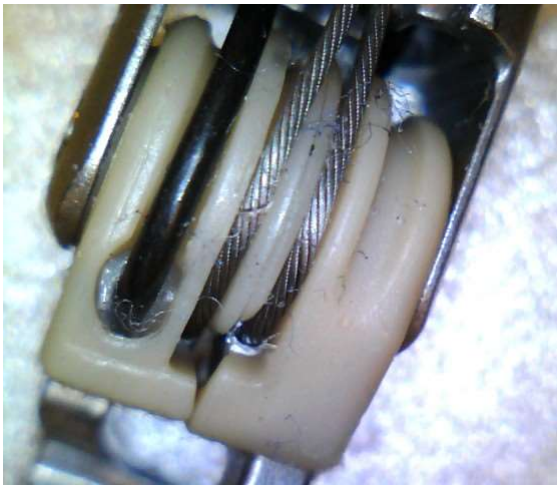

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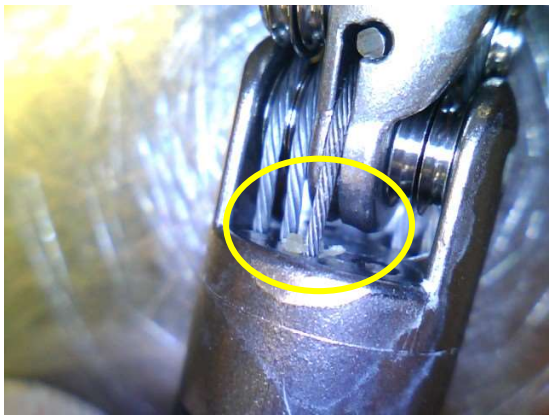
Prime example for enhance inspection of robotics



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AMENDMENT 2

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	— shaft nicks, cracks,	— insulation tester

(ANSI/AAMI ST79 Amendment 2, 2020)

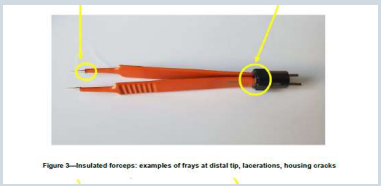
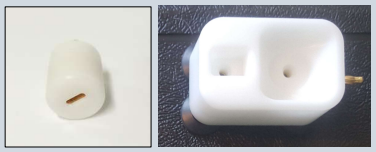


Figure 3—Insulated forceps: examples of frays at distal tip, lacerations, housing cracks

(ANSI/AAMI ST79 Amendment 2, 2020)

8.2.1 Inspection of Instruments Intended to be Used with Electric Current

- "Insulated forceps e.g., bipolar forceps" (ANSI/AAMI ST79 Amendment 2, 2020).



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Bad Practice/Issues that Support the Recommendations

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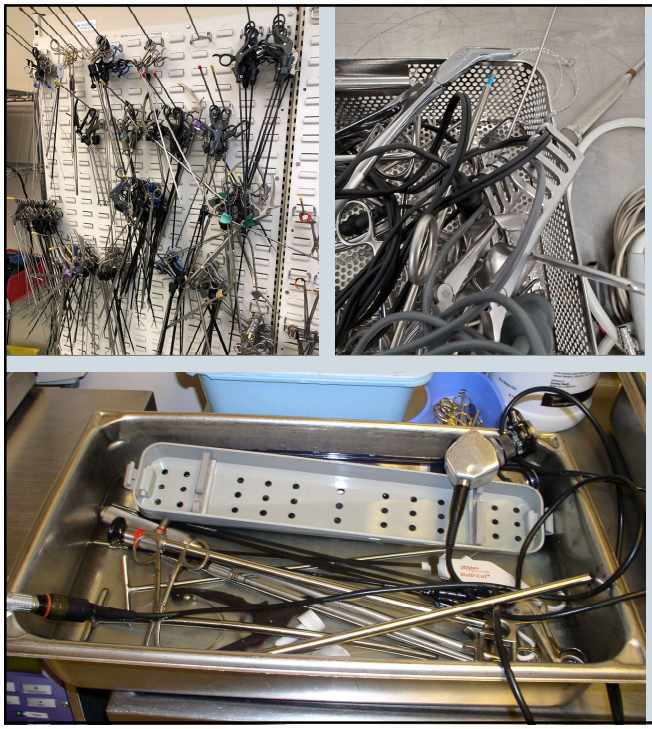

Bad Practice/Issues that Support the Recommendations

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ELECTRO-LUBE
KeySurgical

- Anti-stick solution
- Designed to keep tissue from sticking to electrode instrument tip
- Protects instrument from damage caused by charring and scraping
- Keeps instrument clean during procedure
- Sterile
- Single-use

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Laparoscopic Burns

Here's how to safeguard patients from stray energy burns.

by Vangie Dennis, RN, CNOR, CMLSO

Between 20 and 25 percent of open surgical p surgical access over the past decade, and m place this year. But along with the rise in thi laparoscopic burns. Here's what you need t how you can prevent them.

Problems of laparoscopic electrosurgery

Monopolar electrosurgery used during usually related to return-electrode pla — educating the perioperative staff a monitoring.

But laparoscopic application of m surgery introduces risks that would be either negligible or nonexistent during open procedures. First, during laparoscopic surgery, the surgeon views the peritoneal cavity through laparoscopes introduced into the abdominal cavity via small ports — so the surgeon's field of view is limited to 3cm to 5cm. Stray electrosurgical energy occurring outside this field of view can cause unintended burns to non-target tissue, and these burns usually go unnoticed. Unlike electrosurgical skin injuries, the complications of these internal burns can put the patient in a life-threatening condition; even with antibiotic therapy, about 33 percent of patients who develop peritonitis don't survive.

About 85 percent of laparoscopic surgeons routinely use monopolar electrosurgery. By 2010, an estimated 5 million laparoscopies will be performed annually in the United States. According to data compiled by the Physician Insurers Association of America (PIAA), laparoscopy is one of the most common procedures resulting in medical malpractice

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54

Laparoscopic Burns

Here's how to safeguard patients from stray energy burns.

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Outpatient Surgery Magazine

Between 20 and 25 percent of open surgical procedures have been converted to laparoscopic surgical access over the past decade, and more than 4 million laparoscopic procedures will take place this year. But along with the rise in this techniques comes a rise in a risk unique to it: laparoscopic burns. Here's what you need to know about the causes of laparoscopic burns and how you can prevent them.

Problems of laparoscopic electrosurgery

Monopolar electrosurgery used during open surgery has always carried a risk of skin injury, usually related to return-electrode placement. Two initiatives have all but eliminated this problem — educating the perioperative staff and instituting isolated generators with return-electrode monitoring.

But laparoscopic application of monopolar electrosurgery introduces risks that would be either negligible or nonexistent during open procedures. First, during laparoscopic surgery, the surgeon views the peritoneal cavity through laparoscopes introduced into the abdominal cavity via small ports — so the surgeon's field of view is limited to 3cm to 5cm. Stray electrosurgical energy occurring outside this field of view can cause unintended burns to non-target tissue, and these burns usually go unnoticed. Unlike electrosurgical skin injuries, the complications of these internal burns can put the patient in a life-threatening condition; even with antibiotic therapy, about 33 percent of patients who develop peritonitis don't survive.

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Avoiding Electrosurgical Injury During Laparoscopy

The dramatic increase in the number of minimally invasive surgeries performed in the U.S. each year has led to a corresponding increase in iatrogenic complications, especially those associated with electrosurgical procedures. These complications generally result from unintentional and usually undetected burns to otherwise normal tissues, with consequent tissue trauma, necrosis, infection, and even death. Available technology, including active electrode monitoring, can effectively protect patients from this entirely avoidable negative outcome. Accompanies Issues Video of the same title. **1997**, 26 pp.

In the previously discussed case involving the 38-year-old nurse who suffered complications from laparoscopic monopolar electrosurgery to dissect pelvic adhesions, a malpractice suit was brought against the gynecologist. The Florida jury found the gynecologist liable for medical negligence and awarded the victim $551,891—$51,891 for past medical expenses, $300,000 for past pain and suffering, and $200,000 for *future* pain and suffering. **30** Two of the *surgeon's* expert witnesses testified that bowel ischemia resulting from stray energy burns coincidental to the monopolar electrosurgery caused the damage.

In 1994, a Washington woman sued her surgeon following the laparoscopic removal of her gallbladder. Although the surgeon had previously performed only 10 cholecystectomies and had a total of eight hours of advanced training in laparoscopic electrosurgery, he assured his patient that there was *absolutely* no risk involved in minimally invasive electrosurgery. The operating room record indicated that throughout the surgery, the video monitor registered "electrical interference" that "made continuing the procedure extremely difficult." Seven days after the procedure, the patient was found during open surgery to have a high-grade stricture of the common hepatic duct. The injury required repeated surgeries for repair and dilation of the duct. The *surgeon's* own expert witness testified that the injury was most likely the result of electrosurgical burns to the hepatic duct during the periods of "electrical interference." It took the jury less than one hour to conclude that the surgeon was negligent in causing the injury and to award the victim $250,000.**32**

These examples represent just a small cross-section of the malpractice cases filed as a result of electrosurgical burns. The number of cases that have gone to trial is likely dwarfed by the number of cases in which surgeons and/or insurance companies have settled claims out of court.

* * * *

Excerpt of References:

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30. Trudy Karl vs. Rufus S. Armstrong, M.D. Florida Jury Verdict Reporter. 1993;14:47-48.

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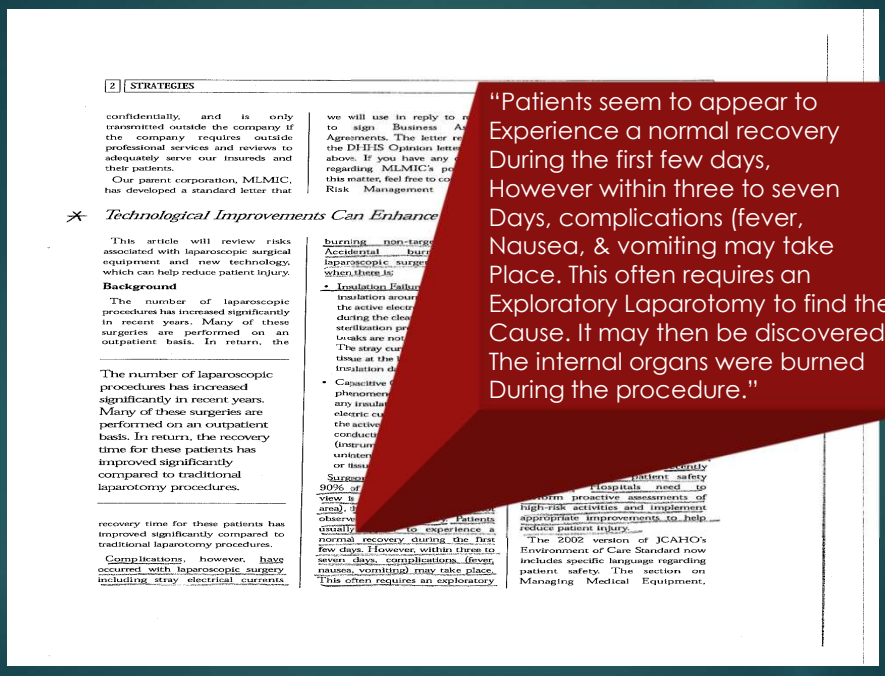

2 STRATEGIES

confidentially, and is only transmitted outside the company if the company requires outside professional services and reviews to adequately serve our insureds and their patients.

Our parent corporation, MLMIC, has developed a standard letter that we will use in reply to r to sign Business A Agreements. The letter re the DHHS Opinion lette above. If you have any regarding MLMIC's po this matter, feel free to co Risk Management

Technological Improvements Can Enhance

This article will review risks associated with laparoscopic surgical equipment and new technology, which can help reduce patient injury.

Background

The number of laparoscopic procedures has increased significantly in recent years. Many of these surgeries are performed on an outpatient basis. In return, the

The number of laparoscopic procedures has increased significantly in recent years. Many of these surgeries are performed on an outpatient basis. In return, the recovery time for these patients has improved significantly compared to traditional laparotomy procedures.

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Complications, however, have occurred with laparoscopic surgery including stray electrical currents

burning non-targe

Accidental bur

laparoscopic surge

when there is:

- Insulation Failur insulation arou the active electr during the clea sterilization pr breaks are not The stray cu tissue at the insulation d
- Capacitive phenomen any insula electric cu the active conduct (inadver unintent or tissu

Surgeon 90% of view is area), observe usually normal few days. However, within three to seven days, complications (fever, nausea, vomiting) may take place. This often requires an exploratory

patient safety Hospitals need to form proactive assessments of high-risk activities and implement appropriate improvements to help reduce patient injury.

The 2002 version of JCAHO's Environment of Care Standard now includes specific language regarding patient safety. The section on Managing Medical Equipment,

"Patients seem to appear to Experience a normal recovery During the first few days, However within three to seven Days, complications (fever, Nausea, & vomiting may take Place. This often requires an Exploratory Laparotomy to find the Cause. It may then be discovered The internal organs were burned During the procedure."

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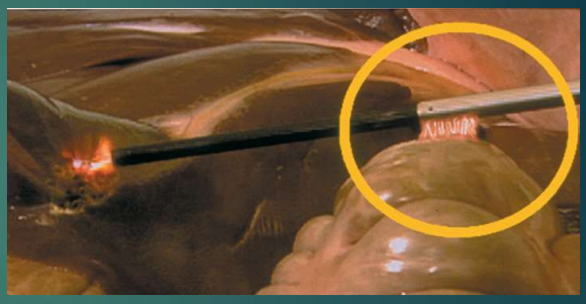
2.8 million award for a burn

- "Laparoscopic surgery has both its benefits and its risks. Benefits of having laparoscopic surgery is that it is less trauma to the body and less evasive. One of the risks deals with energy burns during laparoscopic electrosurgery. This concern has been documented in medical and law journals and in the daily news. "Women awarded $2.8 million in Medical Malpractice Case because of surgical burns" *



https://www.encision.com/wp-content/uploads/2013/03/capacitivehigh.jpg

* Minneapolis Star Tribune, April 13, 1996

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Correct Cleaning Brush For Insulated Instrumentation

60

(AST) Association of Surgical Technologists

- *Instrument or electrode should **be cleaned with a soft brush** and nonabrasive cleaning agent and rinsed.*

https://www.ast.org/uploadedFiles/Main_Site/Content/About_Us/Standard%20Ele...

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ANSI/AAMI ST79

- *"Use brushes and other cleaning implements intended for use on medical devices; brushes should be checked for visible soil and damage following each use and should be frequently cleaned and disinfected. **If the device manufacturer specifies a specific brush or cleaning implement, the brush or an equivalent should be used…**"*

ANSI/AAMI ST79:2017,7.6.4.2, f), page 45

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Examples of IFU for Cleaning Brushes

- *(ASSI Bipolr & Monopolar Forceps) "MANUAL CLEANING Rinse forceps thoroughly with sterile, purified water to remove any accumulated debris. **Hand wash the surface of the forceps using a soft bristled cleaning brush** and enzyme cleaner e.g., Terg-A-Zyme solution (Alconox, Inc.) or equivalent, to remove visible residual debris. For irrigating forceps, also flush irrigating lumen with approximately 10 ml of enzyme detergent."*

- *(Millennium Surgical Electrosurgical Bipolar Coagulating Forceps) "CLEANING Deviations from the suggested cleaning method may result in damage to the instruments. Should you choose to try alternate cleaning procedures, Stingray Surgical Products is not responsible for any adverse consequences that may occur.*

  "1.Hand wash using a low-sudsing, neutral pH (pH 7-9), protein dissolving detergent. Follow manufacturers' directions regarding concentration, temperature, and contact time.

  *2.Totally immerse instruments during cleaning to prevent aerosolization. **Gently scrub the tips of the forceps with a soft non-metallic brush**. This practice should loosen any bulk solids residuals at the tips, particularly between serrated tips. Next, lightly brush the remainder of the forceps body, including connector pins."*

https://www.onesourcedocs.com/member/show-document.html?id=450717

https://www.onesourcedocs.com/member/show-document.html?id=913445

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Cleaning Brushes for Insulated Instrumentation/Devices

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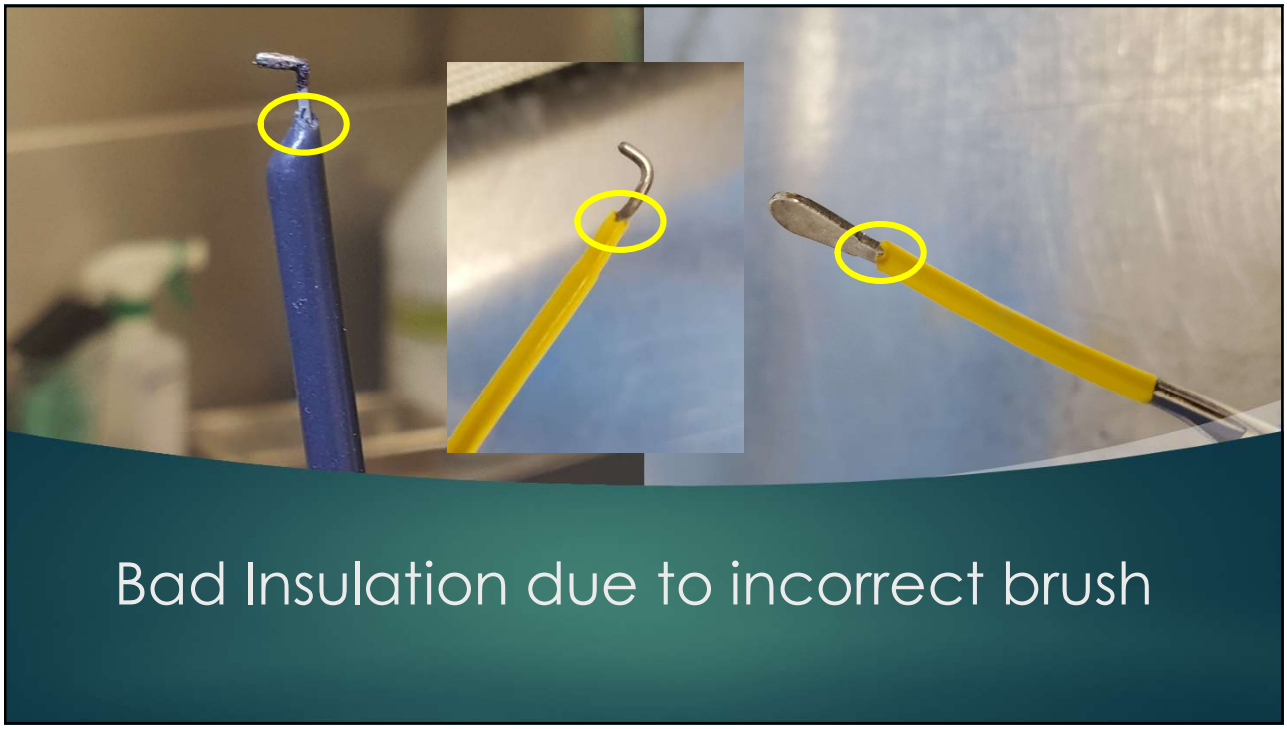
Bad Insulation due to incorrect brush

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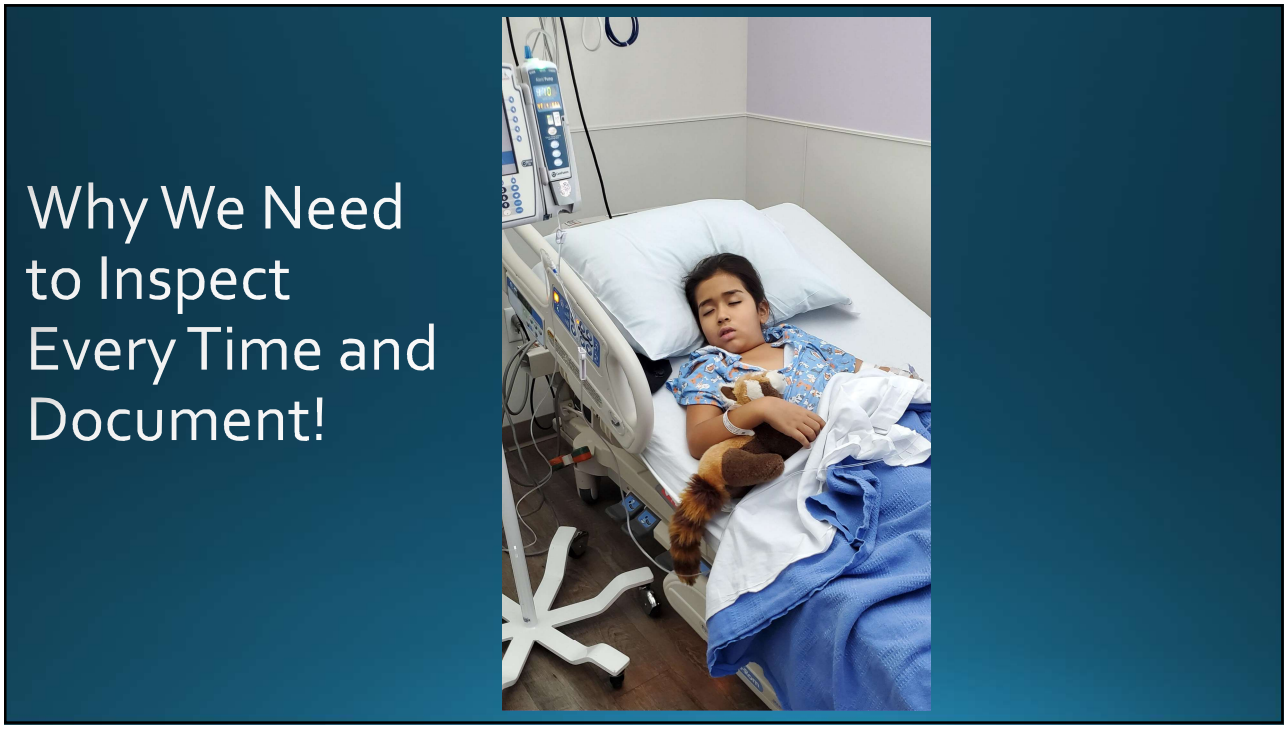
Why We Need to Inspect Every Time and Document!

66

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Thank You

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