



▶ All opinions are those of the presenter.

Disclosure

- ▶ This presentation reflects the techniques, approaches and opinions of the individual presenter. This sponsored presentation is not intended to be used as a training guide or promotion.
- ▶ Before using any medical device, review all relevant package inserts with particular attention to the indications, contraindications, warnings and precautions, and steps for the use of the device(s).

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Healthmark's Policy

Healthmark's Policy is to provide our customers and the healthcare community with the highest quality, state of the art medical products and support services in a timely and cost-effective manner.

This goal is supported by a staff committed to individual accountability, professionalism, mutual respect, collaboration and service excellence. This presentation is part of that commitment, educating our customers.

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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



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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.



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



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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.





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

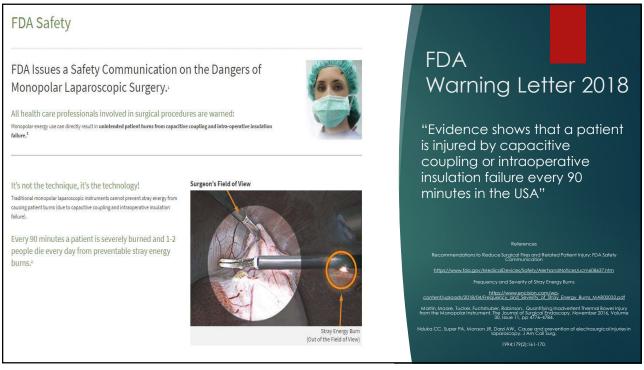
Pool of the instrument is not visualized by the surgeon/surgery team

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 stroy electrosurgical burns," thealthcare Purchasing News.





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/

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Things to consider when purchasing an insulation tester

- What kind of insulated instrumentation in your inventory will you be testing?
- Is it a plug in, battery operated, or both?
- ▶ Is it portable, or a fixed stand alone?
- Are you able to adjust voltage? Or how sensitive is the tester?

Things to consider when purchasing an insulation tester

- Remember that insulted instruments and devices are not just for laparoscopic:
 - E.g. robotics, bipolar cords, bipolar scissor, bipolar
 - Forceps, etc.
- Ask what accessories that the tester in question comes with to be able to test a wide variety of instruments and devices and if they are user friendly.
- Quality doesn't cost it pays!
 - ▶ Don't let price or free override quality!



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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

Examples of IFUs for Insulated Instrumentation/devices



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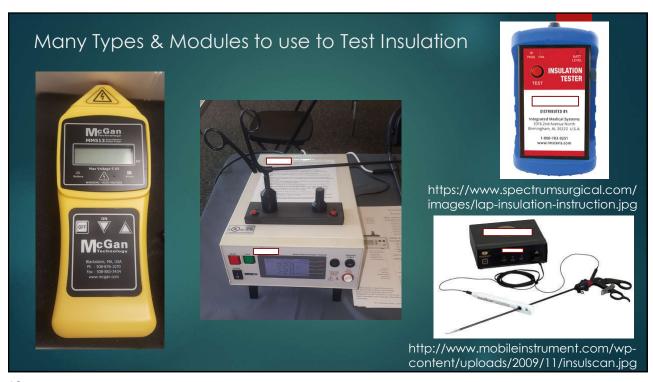
Examples of IFUs for Insulated Instrumentation/devices Cont.....



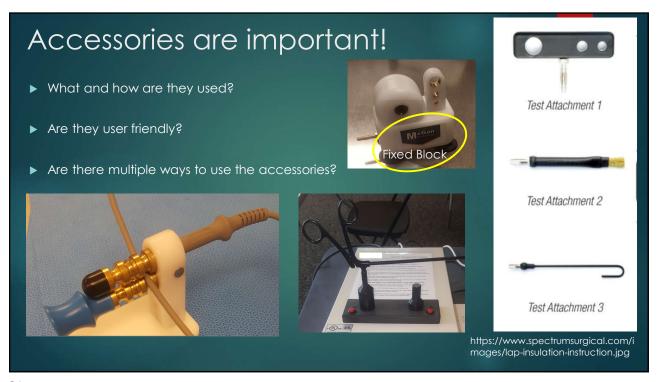
(Vmueller Bipolar Jewelers Insulted Forceps)

"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











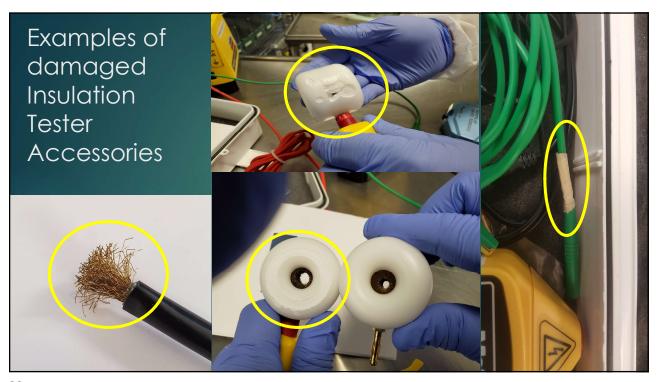














- ▶ AORN: 2018 pg. 922 X.a.5. RP; Care of Instruments "Insulated devices should be visually examined and tested using equipment designed to detect insulation failure."
- ▶ AAMI ST79: No specific information for insulation items, but do recommend visual inspection for defects on all instrumentation

AORN, AAMI ST79, <mark>AST</mark>, ST90 & ISO



"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."

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AORN, AAMI ST79, <mark>AST</mark>, ST90 & ISO

► 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

AORN, AAMI ST79, AST, ST90 & ISO

- ► 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

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AORN, AAMI ST79, <mark>AST</mark>, ST90 & ISO

- ► 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

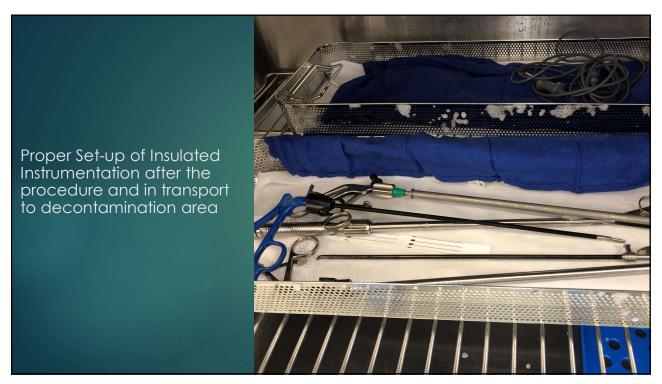


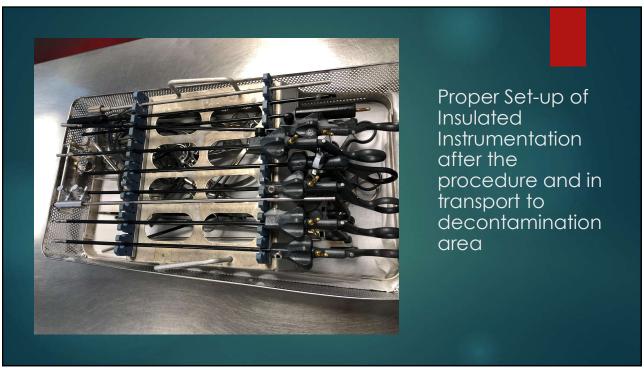
DDLP-1123
Customizable Laparoscopic ProTech Trays

AORN, AAMI ST79, AST, ST90 & ISO

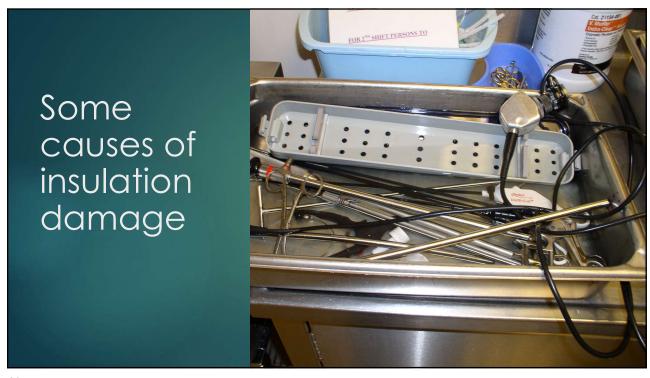
- ► ANSI/AAMI ST90 & ISO-13485:2016:
 - A focus on quality
 - ▶ Performance Qualification (PQ): demonstrating that the process is constantly producing acceptable quality; the user usually performs this verifies
 - ▶ Visual inspect for defects
 - ► Check for leakage Insulation testing
 - ▶ Verify integrity 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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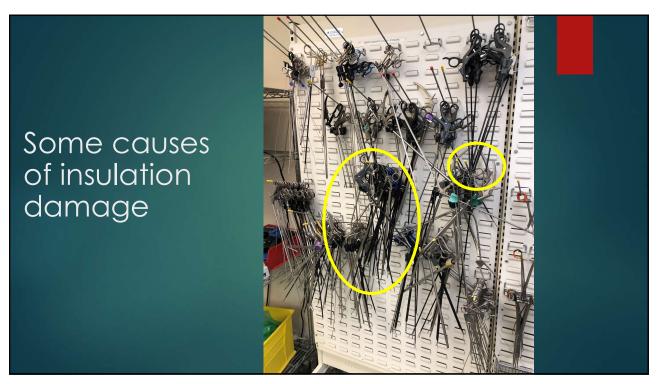


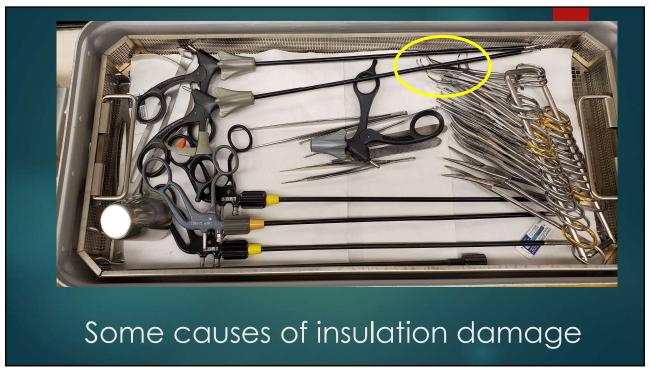


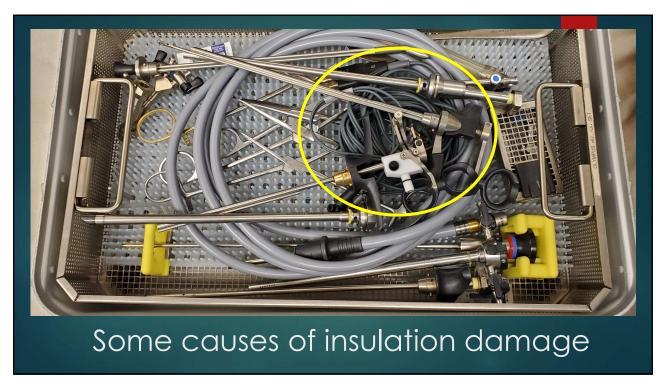




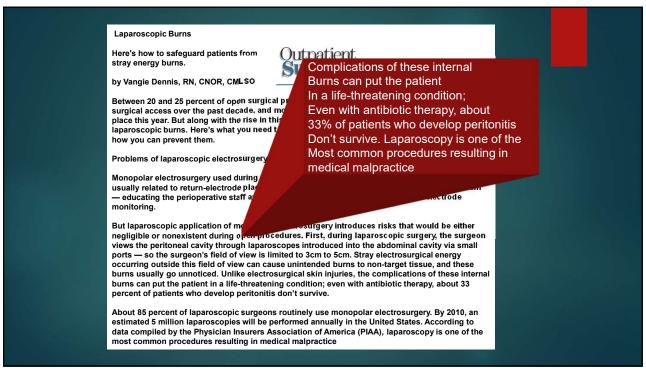












Laparoscopic Burns

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



by Vangie Dennis, RN, CNOR, CMLSO

Between 20 and 25 percent of open surgical 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

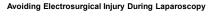
Monopolar electrosurgery used during open surgery has always carried a risk of skin injury, usually related to return-electrode placement. Two initiatives have all but eliminated this problem — educating the perioperative staff and instituting isolated generators with return-electrode monitoring.

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.

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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The dramatic increase in the number of minimally invasive surgeries performed in the U.S. each year has lead 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

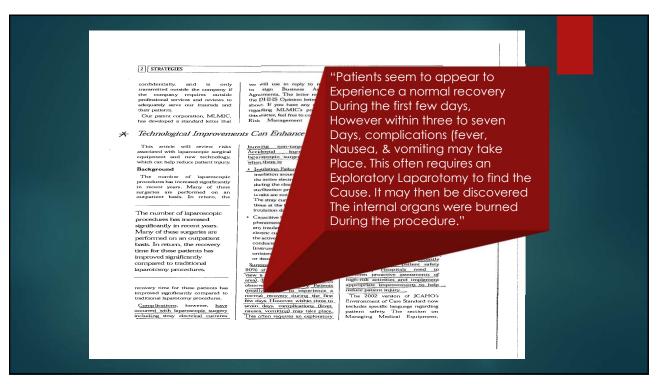
These examples represent just a small cross-section of the malpractice cases filed as a result of electrosurgical burns. The number of cases that have actually gone to trial is likely dwarfed by the number of cases in which surgeons and/or insurance companies have settled claims out of court.

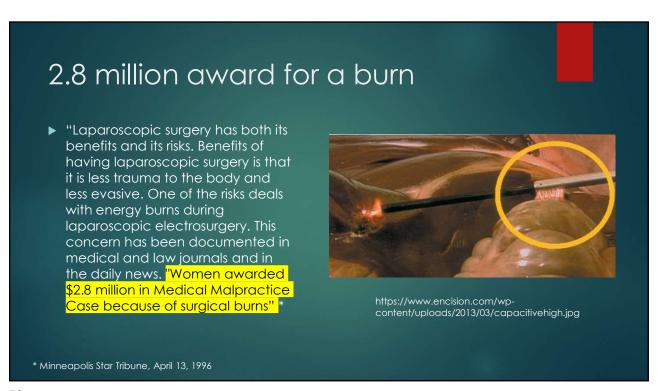
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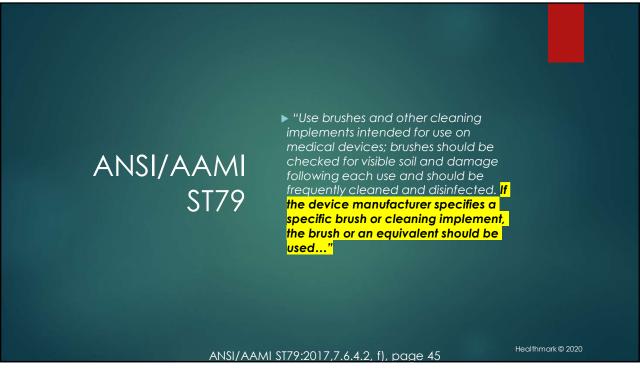
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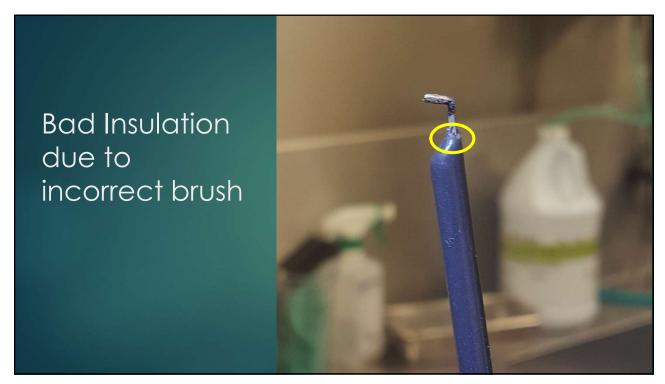


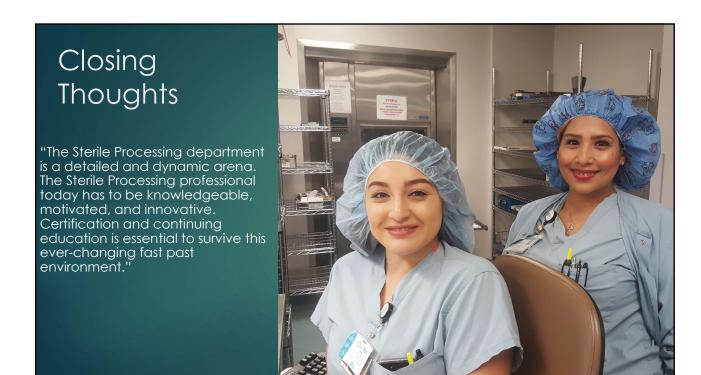




Examples of IFU for Cleaning Brushes • (ASSI Bipolr & Monopolar Forceps) "MANUAL CLEANING | Rinse forceps thoroughly with sterile, purified water to remove any accumulated debris. | Hand wash the surface of the forceps using a soft bristled cleaning brush and enzyme cleaner e.g., Terg-A-Zyme solution (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. "1.1-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=913445













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