

ARE YOU PUTTING YOUR PATIENT IN DANGER?

Laparoscopic surgery has overtaken many abdominal and thoracic procedures. Between cholecystectomy, appendectomy, hernia repair, bowel resection and a range of other therapeutic and diagnostic (i.e., exploratory surgery) procedures, there are upwards of 7.5 million laparoscopic procedures performed annually worldwide.

It is no wonder, with that many surgeries being performed, that in November of 2018 the FDA issued a Safety Communication on the Dangers of Monopolar Laparoscopic Surgery. Could this warning letter have been prevented if real quality management programs were in place? Could some of these injuries (burns to patients while undergoing surgery) been prevented?

Laparoscopic surgery has both its benefits and its risks. Benefits of having laparoscopic surgery are that it is less traumatic to the body and less invasive. One of the risks of laparoscopic surgery, however, is energy burns. This concern has been documented in medical and law journals and in the daily news. For example, one headline publicized recently is, "Women awarded \$2.8 million in Medical Malpractice Case because of surgical burns."¹

What causes these surgical burns? What, if anything, are we doing about this? Are medical device reprocessing professionals solely responsible? Or are other professionals involved? Does anyone understand the life cycle of these devices and their role in preventing failures from occurring?

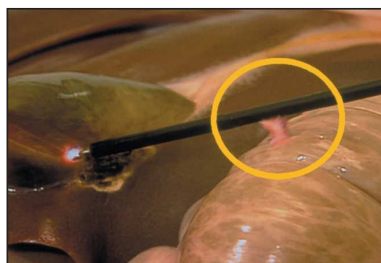
Hemostasis in laparoscopic surgery is usually obtained with the use of some type of thermal cautery or application of clips, ligatures or sutures. Monopolar electrocautery is widely used for coagulation as well as dissection. It can be delivered through a variety of probes, spatulas, hooks, forceps, scalpels and scissors. These medical devices come in single and reusable design. It is the reusable design that we are focusing on in this poster.

LAPAROSCOPIC SURGICAL BURNS HAPPEN IN TWO WAYS:

DIRECT OR CAPACITATIVE COUPLING

"Capacitive coupling occurs when two conductors of electricity are separated by a nonconductor. In electrosurgery, the conductors are the active electrode and the metal cannula, and the nonconductor is the insulation on the electrode. A serious burn can result from creation of a capacitor on the shaft of the instrument or an electrical charge which has transferred into the metal cannula even through intact insulation. Direct can occur when an active electrode accidentally touches a non-insulated metal instrument causing metal to metal sparking resulting in a patient burn."²

INTRAOPERATIVE INSULATION FAILURE



"Instrument insulation fails when the insulation on an electrode is cracked, worn down by frequent use, punctured by a sharp object or compromised by high voltage. Even a small break in insulation can leak substantial energy, causing unintended injury to organs and other tissue."³

MANUFACTURER IFU

Medical device reprocessing professionals are told to follow the manufacturers Instruction for Use (IFU). We examined five IFUs to see what the medical device professional was being told to do.

Company	IFU States to Visually Inspect Instrument	IFU States to Test Instrument with Voltage Tester	IFU States to Visually Inspect All Cords/Cables	IFU States to Test All Cords and Cables with Voltage Tester
A ⁴	YES	NO	YES	YES
B ⁵	YES	NO	YES	NO
C ⁶	YES	NO	N/A	N/A
D ⁷	YES	NO	N/A	N/A
E ⁸	YES	NO	YES	NO

Note: N/A in the chart means the IFU reviewed did not cover a cord

In reviewing just a few IFUs, we noticed an inconsistency in requirements when it comes to using a voltage type tester on cords or the insulation of the medical device. The simple solution would be to require this step in the final assembly and inspection of these devices.

HOW DOES INSTRUMENT INSULATION BECOME DAMAGED?

STAFF:

- Poorly trained on the process of insulation testing
- Not understanding the importance of ensuring there are no failures in insulation
- Not performing basic visual inspection
- Not utilizing an insulation tester on each insulated instrument before placing in a tray

INSULATION TESTER:

- Incorrect type of insulating tester or adapters used for testing
- Not all insulation testers test the same way. Some insulation testers are very basic with just one adapter to use on specific instrumentation. Other insulation testers can offer more options of adapters to ensure all types of insulated instrumentation can be tested.

POST-INSPECTION DAMAGE:

- Poor tray selection to hold instruments in the tray
- Damaged holders/inserts that hold the instrumentation (does not hold correctly because they are loose and move)
- Incorrect and rough handling of the tray when placing on the sterilization cart/carriage
- Removing from the sterilization cart/carriage
- Transport
- Temporary storage of the tray
- Designated location of the tray
- Location in another department
- Case cart
- Operating room care and handling of the tray
- Extras not stored properly
- Cords not tested (they can also be a source of electrical strays)
- No testing performed by user in the operating room before procedure to make sure nothing has happened to the insulation since assembly, sterilization and transportation

SOLUTIONS TO PREVENTING INSULATION DAMAGE:

STAFF:

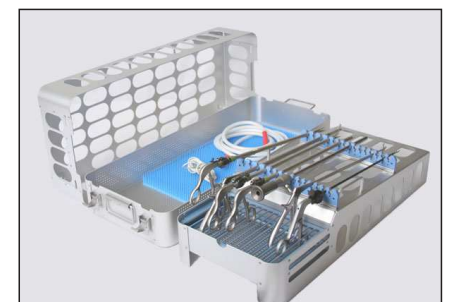
- Read the IFU to understand what needs to be done each time the instrument is used in order to ensure the integrity of the insulation is intact
- Use critical thinking skills
- Train on the importance of both visual and electrical inspection; all surgeons and perioperative team members need to understand their role in preventing surgical burns
- Write a Standard Operating Procedure for testing all insulated instruments using standards and guidelines: ANSI/AAMI ST 79, AORN, FDA, etc.
- Construct a Performance Qualification (PQ) function
- Audit and record your work

RESOURCES:

- Peer-reviewed literature & non-peer reviewed articles
- Manufacturer research and guidance
- Research and science

PRODUCTS THAT SOLVE THE ISSUE:

- Find a leak tester that can be used on all of your insulated instrumentation each time during the final assemble in sterile processing
- Find a leak tester that can be used by the operating team to do a final check before being used
- Trays that protect the insulation during sterilization and transport
- New technology, such as Active Electrode Monitoring during the procedure



Left: An example of an insulation tester. Right: An example of a proper tray for insulated instruments.

Reducing insulation failure is more than just testing the insulation for breakage. Look at the total process from the beginning (surgeons and all perioperative team members) to the end (medical device reprocessing staff) using a Quality Management System (QMS). Reducing the risk of insulation failure should be a team approach in order to provide the institution with a better understanding of its process and provide the quality care we all want for ourselves and our patients. The solutions are simple and, if implemented, surgical burns could be reduced drastically closer to zero. The authors believe that testing of the cords and insulation should be a required step in the final assembly and inspection process within sterile processing of these types of medical devices.