

## Rate of Insulation Failure:

### Non-AEM® Reusable Monopolar Laparoscopic Instruments:

Data	Study I <sup>1</sup> SAGES 2005	Study II <sup>2</sup> 2007	Study III <sup>3</sup> Mayo Clinic 2008	Study IV <sup>4</sup> University of Colorado 2010	Total
Instruments Tested	1,438	98	299	165	2,000
Insulation Failures	267	28	105	31	431
Incidence of Insulation Failure	18.6%	28.6%	35.1%	18.8%	<b>21.6%</b> <b>(1 in 5)</b>

NOTE: 57% of insulation failures cannot be seen with the naked eye<sup>1</sup>

## Rate of Insulation Failure:

### Non-AEM® Disposable Monopolar Laparoscopic Instruments

Study Description	Conclusion
<b>2010 study from the University of Colorado<sup>4</sup></b> <ul style="list-style-type: none"> <li>Looked at new disposable instruments for insulation failure</li> <li>Found that 3% of all disposable instruments have a hole in the insulation, that can lead directly to a patient burn</li> </ul>	<b>3% of disposables have an insulation failure</b>



#### References:

- Frei R. Safety study of laparoscopic instruments rings alarm bells. *General Surgery News*. 2005;32(8):17.
- Yazdani A, Krause H. Laparoscopic instrument insulation failure: the hidden hazard. *J Minim Invasive Gynecol*. 2007;14(2):228-232.
- Espada M, Munoz R, Noble BN, Magrina JF. Insulation failure in robotic and laparoscopic instrumentation: a prospective evaluation. *Am J Obstet Gynecol*. 2011;205(2):121.e1-5.
- Montero PN, Robinson TN, Weaver JS, Stiegmann GV. Insulation failure in laparoscopic instruments. *Surg Endosc*. 2010;24(2):462-465.

## **2010 University of Colorado Study<sup>4</sup>:**

- Study was conducted by Montero, et al to determine the incidence of insulation failures, to compare the incidence of insulation failure in reusable and disposable instruments, and to determine the location of insulation failures. This study tested 226 laparoscopic instruments (165 reusable; 61 disposable). Reusable laparoscopic instruments were examined for insulation failure with the use of a high-voltage porosity detector; disposable L-hooks were collected after laparoscopic cholecystectomy procedures and similarly evaluated for insulation failure.
- Insulation failure occurred more often in reusable (19%; 31 out of 165) than in disposable instruments (3%; 2 out of 61).
- When reusable sets were evaluated, 71% (12 out of 17) were found to have at least one instrument with insulation failure.
- The insulation failure incidence in reusable instruments was similar between hospitals that routinely checked for insulation failure (19%; 25 out of 130) and hospitals that do not routinely check for insulation failures (33%; 7 out of 21). Insulation failure was most common in the distal third of the instruments (54%; 25 out of 46) compared to the middle or proximal third of the instruments.
- The investigators concluded that 1 in 5 reusable laparoscopic instruments has insulation failure, which is not altered by whether the hospital routinely checks for insulation defects; 1 in 33 disposable instruments have an insulation failure; and the distal third of laparoscopic instruments is the most common site of insulation failure.

## **2008 Mayo Clinic Study<sup>3</sup>:**

- Espada, et al conducted a two-phase study to detect the incidence, prevalence, and location of insulation failures in laparoscopic and robotic instruments. In phase A, 78 robotic and 298 laparoscopic instruments were tested at 20 W and 2.64 kV; in phase B, 60 robotic and 308 laparoscopic instruments were tested at 20 W/1 kV and 20 W/4.2 kV, respectively.
- The test results demonstrate that in phase A, the robotic instruments showed a higher prevalence (25 out of 78; 32%) and incidence of insulation failures after 10 uses (35 out of 44 instruments; 80%) when compared with laparoscopy instruments (prevalence, 39 out of 298 [13%]; incidence, 68 out of 189 [36%]).
- In phase B, insulation failures were detected in 81.7% of the robotic instruments and in 19.5% of the laparoscopic instruments.

## **2007 Study<sup>2</sup>:**

- A study conducted by Yazdani, et al examined the prevalence of insulation failure in 111 gynecologic laparoscopic instruments and assessed the impact of routine static insulation failure testing.
- The results demonstrated that insulation failure occurred in 27% of instruments, with a rate of 39% in dedicated monopolar instruments.
- The sensitivity of visual inspection to predict a damaged instrument was only 10%. Furthermore, even when the site of the failure was identified, the defect was detectable only in 35% of instruments without magnification. The mean site of insulation failure was at 71 mm from the tip of the instrument, which means that most insulation defects are 14 within the abdomino-pelvic cavity during surgery.
- The authors concluded that there is an unacceptably high prevalence of instrument insulation failure in gynecologic laparoscopic instruments. Visual inspection is not an appropriate screening mechanism for insulation failure, but routine biomedical testing reduces the prevalence of defective laparoscopic instruments.

## **2005 SAGEs Study<sup>1</sup>:**

- An evaluation of 1,438 laparoscopic instruments by Meijer in the Netherlands demonstrated that 267 of the instruments (18.6%) had insulation defects. Each of these defective instruments typically had more than one insulation failure per instrument, with an average of 1.8 defects.
- 25 Of these defects, 42% were located in the distal 10% portion of the instrument, which is within the surgeon's field of vision; however, another 33% were in the next 30% of the instrument, which is usually outside the surgeon's field of view but is still within the abdominal cavity, where an inadvertent injury can occur.
- In addition, 57.3% of the insulation defects could not be seen by the naked eye under careful visual inspection. The descriptions and results of these studies are outlined in Table 2.