Hazard Analysis Report: Bair Hugger Patient Warming System

Expert Report of Yadin David, Ed.D., P.E., C.C.E.

Dr. Yadin David examined the potential hazard raised by the use of the Bair Hugger device in orthopedic implant surgeries. As an expert in federal court litigation, he was provided access to the manufacturer's confidential internal documents relating to the device and its development.

Key Findings:

- **"In totality, my review has led me to conclude that the Bair Hugger suffers from a troubling regulatory history, and that its design and marketing were unreasonably dangerous because the devices are more likely than not contributing to infections during orthopedic implant surgeries."** (Pg. 1)
- **"I would recommend that the Bair Hugger not be used during these procedures."** (Pg. 1)
- "[T]he potential airborne contamination risk from the device is credible and supported by experimental and clinical evidence." (Pg. 8)
- "[T]he device more likely than not contributes to infections during its use in orthopedic implant surgeries." (Pg. 8)
- "These studies support the conclusion that the Bair Hugger harbors bacterial growth, interferes with operating room airflow, and introduces particles into the sterile field." (Pg. 27)
- "[I] conclude that the Defendant did not act as a reasonably prudent medical device manufacturer would act in response to these issues, and that the Defendant willfully failed to meet its obligations to adequately ensure patient safety." (Pg. 44)
- "[T]he Defendant did not provide adequate warnings and precautions about airborne contamination, despite its awareness of the likelihood of joint infection." (Pg. 44)

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Dr. David presently serves as Chairman of the Medical Device Good Manufacturing Practice Advisory Committee of the Food and Drug Administration (FDA). He serves on the FDA's Medical Device Advisory Panel. He has been awarded the FDA Commissioner's Special Citation.