

Risk of Patient Safety Posed by Bair Hugger® Patient Warming System

Expert Report of Dr. William Jarvis

Dr. William Jarvis analyzed sources of prosthetic joint infections and peer-reviewed research demonstrating problems with the Bair Hugger. He also analyzed the impact of reduced air-quality in joint surgeries.

Key Findings:

- **“These studies provide substantial evidence of the patient safety risk posed by the Bair Hugger FAWs.** While the individual results of these studies are not definitive, collectively they firmly support the following contentions:
 - ...
 - Bair Hugger FAWs markedly increase the bioburden (i.e., particulates and CFUs) of the OR directly (via exhaust air) and indirectly by disruption of OR air ventilation (directional or non-directional) through the excess heat produced; and
 - Bair Hugger FAWs promote circulation of microbial contaminants into the "sterile" surgical field.” (Pg. 13)
- “The CDC and HICPAC have expressed strong concern about any air blowing devices in the OR and specifically have recommended, "Nothing that blows air should be in an operating theater, if possible."(CDC-A, B, and C). (Pg. 21)
- “In my medical opinion, the mechanism of infection with the Bair Hugger FAWs is virtually identical to that documented with the HCUs.” (Pg. 23)
- **“[T]he use of such devices should be abandoned or used only in low risk surgeries not involving implant patients.”** (Pg. 25)

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Dr. Jarvis worked in various leadership roles at the CDC in Atlanta, GA for 23 years, focusing on the investigation and prevention of infectious diseases. He received the CDC’s Lifetime Scientific Achievement Award. Currently he is the chairman of the Food and Drug Administration’s (FDA’s) General Hospital and Personal Use Committee.