

Instead of addressing Bair Hugger’s safety issues, 3M has launched personal attacks on respected researchers, top-tier journals and Dr. Scott Augustine, the inventor of Bair Hugger®, to distract from the real issues. Meanwhile, the false forced-air warming (FAW) safety claims continue to endanger patients undergoing joint replacement surgery.



Real facts about the safety of forced-air warming (FAW) in orthopedics

3M Forced-air Warming “Fact”	Real FAW Fact
<p><u>3M ATTACKS TOP-TIER JOURNALS</u></p> <p>“Commercially driven junk science that has no basis in reality whatsoever.”</p>	<ul style="list-style-type: none"> • This “junk science” characterization was developed by 3M’s marketing department because there is <i>no</i> science showing that FAW is safe in orthopedic implant surgery. • The peer-reviewed studies are published in top-tier medical journals (eg. <i>Anesthesia & Analgesia, Journal of Bone and Joint Surgery</i>) by respected researchers...by definition, that is <u>credible research</u>.
<p><u>3M CITES IRRELEVANT STUDIES</u></p> <p>“More than 170 studies and 60 randomized controlled trials show the safety and effectiveness of this system.”</p>	<ul style="list-style-type: none"> • 3M fails to mention that <u>not one</u> of these studies applies to peri-prosthetic joint infections—the subject of more than 100 lawsuits in Federal Courts around the country.
<p><u>3M BLURS THE DIFFERENCE BETWEEN SSI AND PJI</u></p> <p>“Numerous studies have indicated that patients warmed with forced air have a reduced risk of SSI because it is so effective at preventing hypothermia.”</p>	<ul style="list-style-type: none"> • 3M obviously knows the difference between soft-tissue surgical site infections (SSI) and peri-prosthetic joint infections (PJI), but they <u>intentionally</u> blur the two in marketing communications. • The oft-referenced Kurz study showed that normothermic patients are less likely to develop infections...in colorectal surgery (soft-tissue).² • Implantation of foreign material in the body fundamentally changes the infectious process for PJI vs SSI: <ul style="list-style-type: none"> ○ An inoculum of >1 million bacteria is required to cause a soft-tissue SSI, and bacteria usually enter the wound from adjacent skin or cut bowel.³⁵ ○ In sharp contrast, a single bacterium can cause a PJI, and it usually enters the wound as airborne contamination.^{18, 25, 36}
<p><u>3M REJECTS LOGICAL REASONING</u></p> <p>“None of the articles cited to support this false claim actually conclude that the Bair Hugger system or forced-air warming causes <u>an increased risk in orthopedic infections</u>.”</p>	<ul style="list-style-type: none"> • Multiple studies show an increase in the level of airborne contamination with FAW; one links FAW to higher infection rates.¹¹ • If airborne bacteria increases risk of infection and FAW increases airborne bacteria, then by logical reasoning FAW <u>increases risk of infection</u>. If A=B and B=C, then A=C. Follow the equation: <ul style="list-style-type: none"> A. Waste heat from FAW rises, mobilizing infectious contaminants from the floor up into the sterile surgical field. <u>Five published studies</u> have found this to be true.¹¹⁻¹⁵ B. The risk of developing a PJI is directly related to the amount of contamination in the air. The concentration of airborne contaminants correlates directly with the concentration of contaminants in the wound.^{8, 16-24} The concentration of contaminants in the wound correlates with the risk of PJIs, as PJIs can develop from just one bacterium.^{18, 20, 25} C. FAW waste heat, therefore, increases <u>the risk</u> of acquiring an orthopedic infection.

3M CLAIMS THAT 3M'S HOT AIR DOESN'T RISE

3M insists the excess heat produced by Bair Hugger defies the laws of physics, claiming it “quickly dissipates” in the OR, and it could not possibly rise because it comprises “less than one percent of the airflow” in the OR. They also fervently deny the existence of waste hot air convection currents.

- Only about 15% of the 1000 watts of heat produced by the Bair Hugger blower is actually transferred to the patient.⁹ The excess waste heat forms convection currents that mobilize contaminants.¹¹⁻¹⁵
- According to the *APIC Guide to the Elimination of Orthopedic Surgical Site Infections*, “If airflow is interrupted, rapid air turbulence can stir settled particles, enabling them to become airborne thus increasing the risk for wound contamination.”¹⁰
- Waste heat from FAW disrupts laminar flow, enabling contaminants to reach the surgical site, and should be contraindicated in orthopedic implant surgery, where a single bacterium can cause a catastrophic infection.

3M PRODUCES BIASED RESEARCH

“All the papers that Augustine Temperature Management cites were written by Augustine employees or consultants.”

- Three of the studies cited were completely unrelated to ATM, and ATM's minimal involvement in the other three is clearly disclosed. All prove that waste heat from FAW mobilizes contaminants into the sterile field.
- On the contrary, 3M frequently cites “research” produced by paid consultants, including:
 - A “white paper” (not peer-reviewed or published in any scientific journal) written by Dr. Javad Parvizi, a member of the Scientific Advisory Board of 3M's Infection Prevention Division and paid consultant of 3M.
 - A deceptive study by Dr. Daniel Sessler,²⁶ the design of which was so deeply flawed that it should be labeled “research fraud.” Read a detailed critique of this study and its dishonest design on our website.

3M MISREPRESENTS QUALITY OF FILTRATION”

“Bair Hugger warming units provide a second level of filtration. Operating room air is already filtered, and the Bair Hugger unit filters inlet air again with a high efficiency 0.2 micron filter.”

- 3M/Arizant represented to the FDA that Bair Huggers have HEPA filters. They don't. Research showed that the Model 750 filters that were purported to be HEPA-quality were, in fact, only 63.8% efficient.²⁷ The 0.2 micron filters on the Model 505 blowers had been reduced from 93.8% efficiency to 61.3%.²⁸
- Results from these studies testing blower contamination:
 - Micro-organisms were cultured from the internal air-flow paths of 92.3% of forced-air blowers and 100% of blowers.^{28,29}
 - 58% of the blowers tested were found to be internally generating and emitting significant levels of airborne contaminants larger than 0.3 microns in size (germ size), up to 80 million particles/hr.²⁸
 - 100% of the blowers were emitting internally generated particles greater than 0.3 microns in size, up to 112,000 particles per ft³ of air (300 million particles per hour). Emitted particle count was 40 times greater than the intake particle count for that blower.²⁹

Bair Hugger is a registered trademark of 3M/Arizant

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Visit RealFAWfacts.com for references to citations, links, and additional patient warming facts.