

3M™ Bair Hugger™ System is Safe and Effective Patient Warming Therapy - Response to Misstatements in Lawsuits, September 2016



“3M is sympathetic to patients who experience surgical site infections. Any surgery that causes a break in the skin can lead to a post-operative infection. About one of every 100 patients undergoing a joint arthroplasty procedure develops an infection after surgery. The U.S. Centers for Disease Control notes that the majority of surgical site infections come from bacteria in the patient’s own body. There are many factors that are known to increase the risk of surgical site infections, including having other medical conditions such as diabetes, high blood pressure or heart disease, being elderly or overweight, and smoking. There is absolutely no evidence that [3M™ Bair Hugger™ warming therapy](#) causes or increases the risk of surgical site infections.

In fact, there is not one scientific study – not even the studies the plaintiffs’ lawyers rely upon to support these lawsuits – that provides scientific evidence that the 3M Bair Hugger system causes or contributes to surgical site infections. The authors of those studies all explicitly acknowledge that their studies do not establish that the Bair Hugger system causes surgical site infections.

Two separate clinical studies (Kurz, 1996; Melling, 2001) compared the surgical site infection rates of patients not warmed during surgery to patients warmed during surgery using the Bair Hugger system. Both studies demonstrated a reduction in surgical site infections for those patients warmed using the Bair Hugger patient warming system.”



Numerous clinical studies exploring the impact of the Bair Hugger system on movement of bacteria in the operating room demonstrate that the Bair Hugger system does not increase bacteria at the surgical site:

The Bair Hugger warming system “does not increase the risk for airborne bacterial wound contamination in the operating room...In fact, there were “no differences seen in the amount of bacteria present between the group that used the Bair Hugger system and the group that did not.” – (Zink, R. and Iazzo, P., 1993)

There was a decrease in bacteria at test sites in the operating room at the end of surgery. No patients developed postoperative wound or prosthetic infections during the next six months. “Use of the Bair Hugger system during prolonged abdominal surgery does not lead to increased bacterial contamination of the operating theatre atmosphere, and it is therefore unlikely to cause contamination of the surgical field.” – (Huang, J. et. al., 2003)

“The Bair Hugger system does not pose a real risk for [hospital-acquired] infections, whereas it does offer the advantage of preventing the potentially very severe consequences of hypothermia during major orthopaedic surgery...No patients developed a surgical site infection...The main potential contamination factor in the operating theatre is the presence of the theatre medical staff themselves, their movements, and in general their behavior.” – (Moretti et. al., 2009)

When Bair Hugger system warming blankets were placed over agar plates and air was blown over the plates for 30 minutes at 43 degrees Celsius, the agar plates grew no [bacterial] organisms. – (Avidan, M.S. et. al., 1997)

“Bair Hugger system use does not increase the risk of surgical wound infection...There were no detectable differences in contamination rates...None of the study patients experienced a post-operative wound infection.” – Hall, A.C. and Teenier, R., 1991)

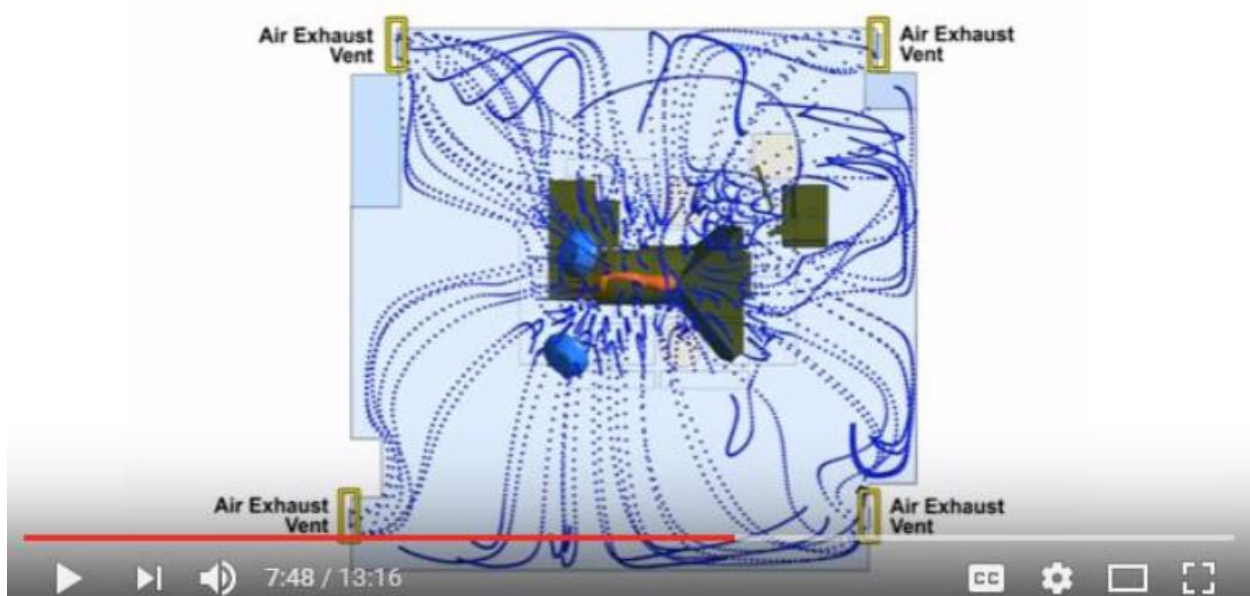
“By far the greatest effect on the number of colony forming units appeared to be the movement and presence of the patient and... staff in the operating room.” – (Tumia, N. et. al., 2002)

Although bacterial growth was detected when another warming unit was used, there was no bacterial growth when the Bair Hugger system was used. – (Dirkes, W.E. and Minton, W.A., 1994)

Bacterial counts of surgical drapes were taken before and after each surgery...There were no significant difference in the number of contaminated drapes or bacterial counts between Bair Hugger system group and the control group (no warming). – (Occhipinti, Lindsay, et. al., 2013)

Using computational fluid dynamics (CFD) and particle tracking methodology, the National Institutes of Health (NIH) assessed whether forced-air patient warming systems increase the risk of nosocomial infections at the surgical site. The NIH looked at both “heat-generating factors and ventilation factors” and concluded: “there is zero percent deposition on the patient for the contaminant sources.” NIH also concluded that “forced-air warmers seem to cause minimal disruption to laminar airflow systems.” Memarzadeh F., Active Warming Systems to Maintain Normothermia in Hip Replacement Surgery, *J. Hosp. Infect.*, at 1 (2010) (letter to the editor). Ultimately, the NIH found that “[t]his investigation validates Moretti et al.’s conclusion that forced-air warming technology does not increase the risk of surgical wound infection.”

Blue bubbles show clean operating room airflow from ceiling (59°F)



ECRI, a widely respected nonprofit that assesses the quality and effectiveness of medical devices, reviewed more than 180 studies about patient warming and surgical site infections. ECRI concluded that there is a lack of evidence to establish that the use of forced-air warming, like the Bair Hugger system, increases the risk of surgical site infections compared to other warming methods. Based on its review, ECRI found insufficient evidence to justify switching from the use of forced-air warming devices such as the Bair Hugger system.

Other independent reviews of forced-air warming further support that it does not increase the risk of surgical site infections:

- According to The Journal of Bone & Joint Surgery, Dec. 17, 2014, "...any actual clinical impact on surgical site infections must be considered unproven at this time."

- According to the AORN Journal, October 2013, "Our review uncovered no conclusive evidence that the use of forced-air warmers increases the risk of surgical site infections... The evidence also does not support the concern that use of a forced-air warmer may cause an increase in bacteria near or on the patient that cause unwanted airflow disturbances."

- According to the Duke Infection Control Outreach Network, November 2015, "To the best of our knowledge, no adequately powered, properly controlled, statistically significant, reproducible study has been published that demonstrates an increased risk of surgical site infections due to the use of forced-air warming (FAW) devices... We believe that it is reasonable and appropriate to continue to use FAW warming devices... Indeed, our data and that collected by the NHSN suggest that approximately 99 percent of patients undergoing joint replacement procedures do not develop a surgical site infection despite the fact that FAW warming devices continue to be widely and appropriately used... they are the only devices proven to decrease the risk of developing a post-operative infection."

Here are the studies cited by plaintiff lawyers, with passages they don't discuss: "

"Because of the nature of our experiment we are unable to conclude that the use of the forced air warming device . . . would actually lead to an increased risk of surgical site infection."— Legg et al. Do forced air patient-warming devices disrupt unidirectional downward airflow? J Bone and Joint Surg-Br. 2012;94-B:254-6

"Our findings do not establish a direct link between forced air warming and increased surgical site infection rates . . ."— Albrecht M, Leaper D et al. Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room. Am J Infect Control 2011;39:321-8

"Thus, we are unsure of the exact degree of ventilation disruption that might occur in a working OR during orthopedic surgery . . . future research is warranted to characterize the clinical conditions under which forced air warming excess heat results in ventilation disruption during surgery."— Belani et al. Patient warming excess heat: The effects on orthopedic operating room ventilation performance. Anesthesia & Analgesia 2012 (prepublication on-line) 2013;117(2):406-411

“This study does not show that forced-air warming increases the risk of infection...”—
Legg A, et al. Forced-air patient warming blankets disrupt unidirectional airflow. *Bone
Joint J.* 2013 Mar;95- B(3):407-10 (Ex. V)

“Another limitation of the study is that the definitive effects of this excess heat on
clinical outcomes is presently unknown. ”— Dasari et al. Effect of forced air warming
on the performance of operating theatre laminar flow ventilation. *Anaesthesia*
2012;67:244-249

“[T]he present study did not evaluate the link between forced air warming and surgical
site infection rates . . .”— Leaper D et al. Forced-air warming: a source of airborne
contamination in the operating room? *Orthopedic Rev.* 2009;1(2):e28

“This study does not establish a causal basis for this association [the patient warming
device and the risks of surgical site infections in the study.]”— McGovern et al.
Forced-air warming and ultra-clean ventilation do not mix. *J Bone and Joint Surg-Br.*
2011;93(11):1537-1544

“Last, we did not track hospital infections, nor did we study the association between
FAW [forced- air warming] contamination generation/emission and hospital infection
rates . . .”— Reed M, et al. Forced-air warming design: evaluation of intake filtration,
internal microbial buildup, and airborne-contamination emissions. *AANA J.* 2013
Aug;81(4):275-80 (Ex. W)