

3M Bair Hugger Q&A | Allegations of Infection Risk

Q: I've seen advertisements claiming that 3M™ Bair Hugger™ therapy caused infections in patients who underwent knee and hip replacement surgery. Are these advertisements true?

A: No. These advertisements are false, misleading, and contradicted by strong clinical evidence that demonstrates warming surgical patients with forced-air warming products actually reduces the risk of infection.¹

Q: As a patient who underwent or is about to undergo surgery, what do I need to know about surgical infections and the use of Bair Hugger therapy during surgery?

A: There are many factors affecting the risk of surgical site infections (SSIs), and countless potential sources of bacteria and other infectious agents. There is no evidence that Bair Hugger therapy causes surgical infections and, in fact, scientific evidence shows that maintaining a normal body temperature with forced-air warming can reduce the risk of infection.¹ Although hospitals and health care providers continue to improve practices to reduce the risk of infection, even the best health care providers and institutions have surgical patients who experience a surgical infection.

You can learn more about how patients and families can reduce the risk of infection from the Centers for Disease Control and Prevention (CDC), the National Patient Safety Foundation (NPSF), or the Institute for Healthcare Improvement (IHI).

Resource Materials:

- [CDC Frequently Asked Questions about Surgical Site Infections.](#)
- [NPSF Preventing Infections in the Hospital.](#)
- [IHI: Prevent Surgical Site Infection. Fact Sheet for Patients & Family Members \(pp. 22-23\).](#)

Q: How does Bair Hugger therapy help reduce the risk of surgical infection?

A: One well accepted practice for reducing the risk of infection is to maintain the patient's core body temperature greater than 36°C throughout the surgical procedure in order to prevent hypothermia. Hypothermia, or a temperature below 36°C, causes the constriction of blood vessels and impaired immune function.¹ Bair Hugger therapy is cleared by the FDA for use to maintain a patient's body temperature and to treat or prevent hypothermia.

Numerous national and international healthcare quality improvement initiatives and professional organizations alike confirm that forced-air warming is an effective technology for maintaining normothermia and preventing hypothermia-related complications, including surgical site infections. In fact, several professional associations^{2,3,4} specifically recommend the use of forced-air warming for patient warming.

Q: Has FDA ever issued any "warning" or concern about the safety or efficacy of 3M Bair Hugger therapy?

A: No. The FDA has issued no "warning" or concern about the use of 3M Bair Hugger forced-

air warming before, during or after surgical procedures. The FDA has been made aware of this alleged risk of infections, and has not recalled or taken any action related to the Bair Hugger system.

Q: Is 3M Bair Hugger therapy safe to use in orthopedic procedures?

A: Absolutely. In fact, more than 300 delegates from a wide range of surgical specialties (including orthopedic surgery) investigated the existing literature as to whether forced-air warming increases the incidence of SSI. A vote of these delegates, conducted at the 2013 International Consensus Meeting on Periprosthetic Joint Infection, showed that 89 percent agreed (with another 6 percent abstaining from the vote) with the following statement: “...no studies have shown an increase in SSI related to the use of these devices. We recommend further study but no change to current practice.”⁵

Earlier in 2013, the ECRI Institute—an independent, non-profit organization that researches the best approaches to improving the safety, quality, and cost-effectiveness of patient care—investigated the same issue and reached the same conclusion.⁶

Q: What is 3M’s position on the lawsuits that have been filed claiming that Bair Hugger therapy caused an infection in orthopedic patients?

A: 3M takes every allegation of patient injury very seriously. We are in the process of thoroughly investigating each of the lawsuits and allegations made by the plaintiffs. As with any lawsuit, the allegations are just that --allegations. They have yet to be evaluated by the Court or shown to be supported by scientifically reliable evidence.

3M has built its reputation as a credible, science based company by making products hospitals and their patients can trust to be safe, effective and improve the quality of care. 3M stands behind its products and will vigorously defend them in Court. Meanwhile, patients and health care providers can be confident that Bair Hugger will deliver the same safe and effective warming therapy that it has delivered to millions of patients for more than 25 years.

Q: Where can I go for more information on Bair Hugger products?

A: To learn more about 3M Bair Hugger therapy, please visit www.bairhugger.com. To learn more facts about forced-air warming, visit www.safepatientwarming.com.

References:

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2. Hooper VC, Chard R, Clifford T, et al. ASPAN’s Evidence-Based Clinical Practice Guideline for the Promotion of Perioperative Normothermia. 2nd Edition. *J of Perianesth Nurs*. 2010;25(6):346-65.
3. American Society of Anesthesiologists Task Force on Postanesthetic Care. Practice Guidelines for Postanesthetic Care. *Anesth*. 2002;96:742-52.
4. AORN. Recommended Practices for the Prevention of Unplanned Perioperative Hypothermia. Standards, Recommended Practices, and Guidelines. Denver, Colorado: AORN, Inc. 2012.
5. International Consensus Meeting on Periprosthetic Joint Infection Full Report (Workgroup 4: Operative Environment, pp. 125-127). Available at www.msis-na.org/international-consensus
6. Forced-Air Warming and Surgical Site Infections. Health Devices. ECRI Institute. April 2013;122-125.