

Facts About 3M™ Bair Hugger™ therapy

A safe, effective warming technology for the maintenance of normothermia

As a leader in patient warming, we believe it's our responsibility to address the misleading advertising being done by law firms and Augustine Temperature Management, the manufacturer of a competing warming technology. The Bair Hugger system's record of safety and efficacy is well established. We urge you to review the facts below and consider your own experience in assessing the important role Bair Hugger therapy plays in patient care.

- Bair Hugger therapy is a leader in the management of perioperative normothermia and can be found in more than 80 percent of U.S. hospitals.
- The Bair Hugger system is used by 8 of the top 10 orthopedic facilities according to the 2016 *U.S. News & World Report* Best Hospitals rankings.¹
- Since 1987, more than 200 million patients worldwide have been warmed using the Bair Hugger and system. In its entire history, there has not been a single confirmed case of infection caused by the Bair Hugger system.
- Bair Hugger therapy has been studied extensively. In fact, its clinical benefits, efficacy and safety have been well documented in more than 170 studies, far more than any other patient warming modality.
- Published research papers have shown that the use Bair Hugger therapy does not increase either the risk of wound contamination in the operating room or bacterial contamination of operating rooms.²⁻⁴
- Normothermia is an important tool in the fight against surgical site infections (SSIs).⁵⁻⁸ Quality initiatives, including the Institute for Healthcare Improvement (IHI) and the Surgical Care Improvement Project (SCIP), and professional organizations such as the Association of PeriOperative Registered Nurses (AORN), the American Society of Anesthesiologists (ASA) and the American Society of PeriAnesthesia Nurses (ASPAN), all note the important role of normothermia maintenance in SSI reduction.^{9,10} Several of these organizations specifically mention forced-air warming as a key means of maintaining normothermia.
- At the 2013 International Consensus Meeting on Periprosthetic Joint Infection, delegates from various disciplines—including orthopedic surgery, infectious disease, musculoskeletal pathology, and anesthesiology—evaluated the available evidence on whether forced-air warming increases the incidence of SSI. With agreement from 89 percent of voting members (6 percent abstained from voting), the consensus states, “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.”¹¹
- An independent, systematic review of the published literature by ECRI—a non-profit organization recognized by *The New York Times* as “the country’s most-respected laboratory for testing medical products”—found “[b]ased on our focused systematic review of the published literature, we believe that there is insufficient evidence to establish that the use of FAW systems leads to an increase in SSIs compared to other warming methods.”¹²

- Orthopedic surgeon and leading SSI researcher Dr. Javad Parvizi authored a white paper that substantiates the safety of forced-air warming technology.¹³ This research examines existing literature on forced-air warming's use in laminar flow operating rooms and affirms forced-air warming as a safe, effective technology for surgical patients.
- Another study concluded that the Bair Hugger system does not disrupt laminar flow or compromise the protection of the surgical site.¹⁴
- The Bair Hugger system is designed to produce local, short-range increases in airflow velocity. Flow visualization techniques demonstrate that the airflow from Bair Hugger blankets has no significant effect on operating room airflow.¹⁴⁻¹⁶

As a leading provider of trusted, innovative products used in thousands of hospitals around the world, 3M strongly disagrees with any competitive misuse of science and rejects competitive tactics that negatively impact patients by discouraging the use of safe, effective intraoperative warming. Bair Hugger therapy is the original forced-air warming system, and has become an indispensable component in the care of surgical patients, providing safe and effective warming therapy to patients across the globe.

References:

1. U.S. News & World Report (online edition); 2015-16 Top Hospitals edition, Best Hospitals for Adult Orthopedics. <http://health.usnews.com/best-hospitals/rankings/orthopedics>. Published July 21, 2015.
2. Zink RS, Iaizzo PA. Conductive warming therapy does not increase the risk of wound contamination in the operating room. *Anesth Analg* 1993;76:50-3.
3. Huang JK, Shah EF, Vinodkumar N, Hegarty MA, Greatorex RA. The Bair Hugger patient warming system in prolonged vascular surgery: an infection risk? *Crit Care* 2003; 7:R13-R16.
4. Moretti, B., Larocca, A.M., Napoli, C., et al. Active warming systems to maintain perioperative normothermia in hip replacement surgery: a therapeutic aid or a vector of infection? *J Hospital Infect* 2009; 73: 58-63.
5. Kurz A, Sessler DI, Lenhardt R. Perioperative Normothermia to reduce the incidence of surgical-wound infection and shorten hospitalization. *N Engl J Med* 1996;334:1209-15.
6. Melling AC, Ali B, Scott EM, Leaper DJ. Effects of preoperative warming on the incidence of wound infection after clean surgery: a randomized controlled trial. *Lancet*. 2001;358:876-880.
7. Barie PS. Surgical site infections: epidemiology and prevention. *Surgical Infections* 2002; 3:S9-S21.
8. Seamon, M.J., et.al. The Effects of Intraoperative Hypothermia on Surgical Site Infection: An Analysis of 524 Trauma Laparotomies. *Annals of Surgery*. Volume 255, Number 4, April 2012.
9. Jeran L. Patient temperature: An introduction to the clinical guideline for the prevention of unplanned perioperative hypothermia. *Jnl PeriAnesthesia Nursing* 2001; 16:303-14.
10. Practice Guidelines for Postanesthetic Care: A report by the American Society of Anesthesiologists Task Force on Postanesthetic Care. *Anesthesiology* 2002; 96:742-52.
11. Parvizi J, Gehrke T. Proceedings of the International Consensus Meeting on Periprosthetic Joint Infection: Final Report. www.msis-na.org/internationalconsensus.
12. ECRI Institute. Forced-air Warming and Surgical Site Infections. *Health Devices Journal* April 2013.
13. Parvizi, J. Karam, J. Do Forced-Air Warming Blankets Increase Surgical Site Infections? 2012.
14. Sessler DI, Olmsted RN, Kuelpmann R. Forced-Air Warming Does Not Worsen Air Quality in Laminar Flow Operating Rooms. *Anesth Analg*.113 (6): 1416-1421. 2011.
15. Sharp RJ, et al. Do warming blankets increase bacterial counts in the operating field in a laminar-flow theatre? *J Bone Joint Surg Br* 2002; 84-B:486-8.
16. Memarzadeh F, Active warming systems to maintain perioperative normothermia in hip replacement surgery. *J Hosp Infect*. 2010; doi:10.1016/j.jhin.2010.02.006.