

**3M** Science.  
Applied to Life.™

# Let's spread good science.

Your everyday decisions  
are based on evidence.  
This should be no different.



# Claims vs. Facts

3M believes it's important to provide accurate, thorough and proven facts surrounding patient care. False representations or facts out of context are not "proof" of any kind, they are merely incorrect and deceptive. Below, you will find facts that have been proven to counter misconceptions being promoted in the marketplace.

## CLAIM:

Air-flow paths of 3M™ Bair Hugger™ units are contaminated with bacteria.

## FACT:

- The laboratory testing on which this claim is based does not indicate that the warming units tested were properly maintained in accordance with the manufacturer's instructions.
- Further, the testing draws no conclusive relationship between the detection of individual colonies of bacteria (CFU) counts in the air-flow path and emitted contaminants.
- Published studies performed on patients in real surgical settings have found that forced-air warming does not contaminate the sterile field or increase bacterial counts.<sup>1-3</sup>
- Huang et al concluded:<sup>1</sup> "The exhaust air from beneath the surgical drapes, which had passed over the patient's skin, showed a decrease in the number of bacterial counts at the end of the surgery, and this demonstrated that there was no increase in air contamination associated with the Bair Hugger patient warming system ..."

## CLAIM:

Waste hot air convection currents transport contaminated air into the surgical site.

## FACT:

- There are no "waste hot air convection currents" – the warm air that is gently released through the perforations of the Bair Hugger blanket is quickly dissipated when it mixes into the cooler operating room air and does not continue to rise.
- The air released from the perforations in the Bair Hugger blanket is isolated from the surgical site by the surgical drape, the anesthesia curtain, and taping of the Bair Hugger blanket.
- When tested in actual surgical conditions, research shows that forced-air warming actually does not increase the bacterial count at the surgical site and may decrease it.<sup>1-3</sup>
- Tests have demonstrated that airflow from the Bair Hugger system has no significant effect on operating room airflow.<sup>4-6</sup>

### VIEW VIDEO

- One study conducted to address airborne contaminant and ventilation flow questions found that convective warming had no negative effects on air quality in the operating room and is an efficient modality for maintaining normothermia in surgical patients.<sup>6</sup>
- These findings align with published testing that shows the downward stream of laminar air flow effectively reduces particle concentrations around the operative site, regardless of whether forced-air warming is in use.<sup>6</sup>

**CLAIM:**

One facility demonstrated 74% reduction in deep joint infections after switching from forced-air warming to conductive electric warming.

**FACT:**

- In a guidance article examining claims of a link between FAW and SSIs, the ECRI Institute stated that the study, “has serious limitations such that its findings on PJI rates cannot be considered conclusive.”<sup>7</sup> [READ ARTICLE](#)
- The authors of the study on which this claim is based acknowledge that, “This study does not establish a causal basis for this association...the data are observational and may be confounded by other infection control measures instituted by the hospital.”<sup>8</sup>
- Test conditions were not well controlled between historical and test periods. Importantly, changes were made to the antibiotic and thromboprophylaxis protocols used during the study.<sup>8</sup>
- An interview with one study author revealed an additional eight significant changes that were made as part of a facility-wide SSI reduction effort that was not disclosed in the study.<sup>9</sup>

**CLAIM:**

Forced-air warming has been linked to increased orthopedic infections.

**FACT:**

- After analyzing all available research relating to convective warming as a potential source of O.R. contamination, Dr. Javad Parvizi, Professor of Orthopedic Surgery, Rothman Institute at Thomas Jefferson University, concluded, “there is no scientific proof that the use of forced-air warming blankets lead to an increase in surgical site infection regardless of the type of surgical procedure and the type of operating room.”<sup>10</sup> [READ WHITEPAPER](#)
- Moretti’s study of 30 patients undergoing hip implantations indicates that Bair Hugger therapy does not pose a risk for hospital-acquired infections. Not a single patient who participated in the study suffered a hospital-acquired infection.<sup>3</sup>
- None of the articles cited to support this false claim actually conclude that the Bair Hugger system or forced-air warming causes an increased risk in orthopedic infections.
- A recent report from January 2015 by the CDC demonstrates a 27% decrease in surgical site infections after hip arthroplasty and a 40% decrease in surgical site infections after knee arthroplasty from 2008 – 2013.
- In a separate study, the first group of orthopedic surgeons to examine trends in infection rates following arthroplasty showed that after adjusting for risk factors, infection rates and infection-related hospital mortality rates actually declined between 2002 – 2010.<sup>11</sup>

**CLAIM:**

An International Orthopedic Consensus Statement declares, “We recognize the theoretical risk posed by forced-air warming blankets.”

**FACT:**

- The findings of the International Consensus Meeting on Periprosthetic Joint Infection in 2013 conference have been misrepresented. With a strong 89 percent consensus among voting members (6 percent abstained from voting), the ICC statement reads: “We recognize the theoretical risk posed by FAW blankets and that no studies have shown an increase in SSI related to the use of these devices.”<sup>12</sup> [VIEW VIDEO](#) [READ ICC REPORT](#)

**CLAIM:**

ECRI Institute released guidance that the convection currents created by forced-air warming were “especially concerning” during orthopedic implant surgery.

**FACT:**

- In 2013, the ECRI Institute examined over 180 potentially relevant studies, and 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.”<sup>7</sup>
- After learning that this claim was being widely distributed via email, direct mail and web sites, ECRI added the following editor’s note to the article: “ECRI Institute states that it did not participate in or approve of the above-mentioned materials, and warns that they should not be construed as representing our opinion or judgment.”<sup>7</sup> [READ ARTICLE](#)

## References

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