

The FDA sent an ‘Information About Use’ Letter to Healthcare Providers about Forced-air Thermal Regulating Systems on August 30, 2017. As experts on patient thermal regulating systems, Augustine Temperature Management has prepared a list of frequently asked questions to address the content of this communication. The following are statements of opinion.

### **Why did the FDA issue this Letter?**

The FDA reviewed the published research and Medical Device Reports linking forced-air warming (FAW) to hip and knee periprosthetic joint infections (PJI), to determine if a recall of FAW from orthopedics is warranted. *We know this because we supplied the FDA with research and requested the review*. As noted in the Letter, the FDA responded to the rapidly growing number of orthopedic surgeons all over the country who are wisely refusing to allow FAW on their implant patients due to concerns about increased risks of infection. The FDA is also aware of the mass-tort litigation involving more than 3,000 plaintiffs who are suing 3M, the manufacturer of Bair Hugger® forced-air warming system, for allegedly causing peri-prosthetic joint infections.

### **What are the most important takeaways from the FDA Letter?**

1. The FDA urged clinicians to report adverse events from FAW to the MedWatch Safety Information and Adverse Event Reporting Program. The FDA stated that it is actively monitoring the situation.
2. The FDA reminded healthcare providers that patient normothermia during surgery is critically important for many patient outcomes including less bleeding, faster recovery times, and decreased risk of infection for patients. Using thermoregulation devices is necessary for achieving peri-operative normothermia. Due to concerns about FAW, many healthcare providers have discontinued warming, which exposes patients to negative outcomes of hypothermia. The FDA urged healthcare providers to continue to warm patients.

### **What did the FDA say about forced-air warming specifically?**

The FDA said, “After a thorough review of available data, the FDA has been unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection.”

### **What does that mean?**

The FDA is looking strictly at the documented link between FAW use and infection. There are two retrospective studies showing 74%<sup>1</sup> and 78%<sup>2</sup> reductions in infection rates when FAW was discontinued (HotDog® was used as the replacement warming technology). In contrast, there are ZERO studies showing that FAW is safe in implant surgery. The FDA, however, evidently feels that there isn’t enough “conclusive evidence” to initiate FDA action and indicated that FAW systems can still be used at the providers’ discretion. It is important to understand that the FDA did *not* say that FAW is safe in orthopedics. They said that there is currently not enough evidence to warrant a recall of FAW. There is a huge difference between these two statements. They stated: “The FDA will continue to actively monitor this situation and will update this communication if significant new information becomes available.”

1. McGovern et al. Forced-air warming and ultra-clean ventilation do not mix. J Bone and Joint Surg-Br. 2011;93(11):1537-1544.  
2. Augustine S. Forced-air warming discontinued: periprosthetic joint infection rates drop. Orthopedic Reviews 2017; 9:6998

### **Is this an endorsement of forced-air technology?**

Absolutely not. It is an endorsement of maintaining surgical normothermia. The FDA typically seeks an overwhelming amount of evidence before taking affirmative action on established products. We, on the other hand, believe there already is sufficient evidence to issue a warning about the risks of FAW systems in implant surgery.

### **What was missing from the FDA commentary?**

The FDA conspicuously ignored the issue of contamination. FAW systems are proven to increase airborne contamination around the surgical field. That fact is now indisputable, with 5 studies showing nearly all FAW blowers are internally contaminated and emit contaminants; 10 studies showing waste heat contaminates the air around the surgical field; 3 studies linking waste heat to infection, and; 2 studies documenting infection reduction when FAW was discontinued. In sworn deposition testimony in the 3,500 + product liability suits, Al Van Duren, 3M's Director of Science Affairs and Education, stated that **every single study shows that Bair Hugger FAW causes contamination of the air of the sterile surgical field.**

Van Duren deposition transcript March 7, 2017 (p-258)

Q. Okay. Based on the data that we have today, including the study funded by 3M as well as other studies, every single study indicates that the Bair Hugger increases the particle count over the sterile field; correct?

A. In absolute numbers, yes.

Q. Yes. Okay. And you have no internal studies to refute that; correct?

A. No, we don't.

Furthermore, the Healthcare Infection Control Practices Advisory Committee of the CDC has continued to say that devices that blow air should not be in the operating room because air currents are a vector for transporting germs. Surgeons and other healthcare providers are rightly concerned about the risks of infection due to airborne contamination, which is why many have discontinued warming.

### **Does this change the way healthcare providers should warm their patients?**

The FDA has acknowledged that many orthopedic surgeons are concerned about the risks of forced-air warming systems. Use of forced-air devices in orthopedics clearly increases risk of infection due to higher levels of airborne contamination. The science and the physics are clear; the Letter does not impact that at all. The Letter does, however, reaffirm the need to actively warm surgical patients. Healthcare providers should consider warming with the air-free HotDog Patient Warming System to avoid airborne contamination risks from FAW, and to more consistently achieve normothermia.