



## Fact-Check: Augustine's latest email blast – October 2017

You may have received or seen a recent communication from Augustine Temperature Management regarding the FDA and the 3M™ Bair Hugger™ warming system.

Augustine's email blast, titled *FDA: No Bair Hugger recall...but the investigation is ongoing*, contains a number of significant errors.

Not only does the [FDA letter](#) *not* mention a recall nor investigation, it *encourages* medical providers to continue using patient warming devices, including forced-air warming systems such as the Bair Hugger system. Warming patients during surgery has been demonstrated to result in less bleeding, faster recovery times and decreased risk of infections.

Here are the facts, point-by-point.

**Augustine Claim:** *Two outcome studies linking forced-air warming (FAW) to 74% and 78% of joint implant infections apparently were not enough for the FDA to order the recall of the Bair Hugger.*

**Truth:** There are no such studies. In two papers connected to Augustine, it is claimed that infection rates declined 74% and 78%, respectively, when the medical facilities switched to Augustine's device from the Bair Hugger system. Both of those studies are factually compromised. In the first study (McGovern), experts discovered that the data was cherry-picked and failed to account for many other confounding factors. Also, the McGovern study explicitly disclaims any finding of causation between use of the Bair Hugger system and increased surgical infections. In the other study (by Augustine himself), all three healthcare facilities from which the data was taken have provided information that significantly undermines the study's credibility and Augustine's claims. One stated that there is no data to support a direct correlation to Augustine's device and the hospital's reduced infection rates; the second said in a sworn affidavit that Augustine's report contained multiple errors, including the fact that the hospital *never* used the Bair Hugger system (making Augustine's before-and after-representation false); and the third facility, like the other two, has shared information that reveals Augustine's presentation of data was inconsistent with the stated protocol.

**Augustine Claim:** *The Letter emphasized that the review is still ongoing, and the Agency asked for more infection reports from clinicians.*

**Truth:** Here is the [FDA letter](#); it speaks for itself.

**Augustine Claim:** *The FDA communication failed to mention the 10 studies that clearly show that waste heat from FAW causes airborne contamination of the sterile surgical field.*



Truth: There are no studies that show FAW causes surgical site infections. Not one. In fact, Augustine has attempted – and failed – on numerous occasions to detect bacteria emanating from the Bair Hugger system. The system is safe.

*Augustine Claim: The FDA conspicuously did not say that FAW is safe in orthopedics. In fact, the FDA made no comment at all about FAW safety, perhaps because there are no outcome studies showing FAW safety in orthopedics.*

Truth: Again, here is the [FDA letter](#); it speaks for itself. The Bair Hugger system is the preferred patient warming device of U.S. healthcare facilities, and of 8 of the top 10 orthopedic hospitals in the United States.

*Augustine Claim: Al Van Duren, 3M’s Director of Science Affairs and Education, testified in a sworn deposition that every single study shows that Bair Hugger FAW contaminates the sterile surgical field.*

Truth: Augustine refers to a portion of Mr. Van Duren’s deposition testimony taken out of context. Mr. Van Duren has never testified that the Bair Hugger system “contaminates the sterile surgical field” or that any study shows that it does. The portion of Mr. Van Duren’s deposition testimony relied on by Augustine refers to “particles” in the air which, as the examiner noted in a portion of the transcript not provided in Augustine’s email, “are everywhere.” But particles are not the same as bacteria. Augustine’s repeated and misleading references to snippets of testimony taken out of context are simply pieces of his ongoing scare campaign, and are belied by the fact that every respected, independent medical authority that has examined the issue has consistently rejected the conclusion that the Bair Hugger system causes surgical infections.

### Facts about the 3M Bair Hugger system

The Bair Hugger system has been safely used more than 200 million times in the past 30 years. There is no proof that the Bair Hugger warming system has ever caused an infection.

A large number of studies continue to recommend patient warming, which has been shown to provide valuable benefits to surgical patients, including reducing the risk of surgical site infections, reduced mortality, fewer post-operative heart attacks, reduced blood loss and faster recovery times. A compendium of studies can be found [here](#).

Patient Safety is 3M’s No. 1 priority and we stand behind our products, patients and customers. For more information, go to the following websites: [www.FAWfacts.com](http://www.FAWfacts.com), [www.TruthAboutBairHugger.com](http://www.TruthAboutBairHugger.com), and [www.BairHuggerfacts.com](http://www.BairHuggerfacts.com)