

## Know the truth: the CDC, FDA and forced-air warming

Once again, a 3M competitor is bending the truth in an effort to incite more litigation and unease about the market-leading Bair Hugger patient warming device.

Augustine Temperature Management is claiming that the FDA and CDC have warned against allowing anything in an operating room that blows air. The FDA and CDC have had recent discussions about medical devices and surgical site infections, but those discussions have focused largely on heater-cooler units used in cardiac surgery.

Augustine, who has been warned by the FDA about making spurious claims and who pled guilty to Medicare fraud, has made a series of claims in presentations and written materials, attempting to link the heater-cooler units to the Bair Hugger device.

### **These facts provide the truth:**

- Do not be fooled by claims that the Centers for Disease Control and FDA have issued warnings about forced-air patient warming devices. They haven't.
- The Bair Hugger warming system is safe and effective. Dozens of scientific studies show that forced-air warming devices effectively warm patients before, during and after surgery and can reduce the risk of surgical site infections.
- A 3M competitor has published erroneous claims that the CDC and FDA have warned people to avoid the use of forced-air warming devices such as the Bair Hugger. The CDC and FDA have done no such thing.
- This is not the first time that the competitor, Augustine Temperature Management, has made blatantly false claims.
- Augustine sells a competing product that is not widely used nor accepted in the marketplace. The company's founder, Scott Augustine, has a history of making erroneous claims and has been warned by the FDA to stop doing so.
- Augustine has selectively highlighted phrases from CDC and FDA meetings and publications, with the intent of maligning forced-air warming devices.
- For example, he has highlighted a line from CDC discussion of heater-cooler devices that noted "nothing that blows air should be in an operating theater, if possible." The discussion was focused entirely on Heater-Cooler Units, which have water tanks that have been identified as a source of a very rare water-borne infection in cardiothoracic surgery. Those units use a completely different technology than forced-air warming devices.
- In fact, an article in a CDC journal about airborne contaminants specifically noted that "there appears to be no definite link for surgical site infections" from forced-air warming devices.
- When an FDA official was asked whether the prohibitions on heater-cooler units would extend to forced-air devices, she responded that the issue was specific to heater-cooler devices. Of course, Augustine fails to note that fact in his materials.