

There are currently ~3,600 mass tort lawsuits filed against 3M that have been consolidated into a MultiDistrict Litigation (MDL). It is expected that there could be more than 20,000 plaintiffs before this is finally settled. The following information was recently made public by the MDL court.

3M Admits Bair Hugger® Contaminates the Sterile Surgical Field

3M continues to promise clinicians that Bair Hugger is safe to use in orthopedic implant surgery—even while admitting in Federal Court documents that forced-air warming (FAW) increases contamination of the sterile field and joint infection risk.

3M authorized Al Van Duren, Global Director of Scientific Affairs and Education, to testify under oath on behalf of the company. In this context, Van Duren is not speaking for himself, but rather for the 3M Corporation.

Van Duren in sworn deposition testimony 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

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

10 A. In absolute numbers, yes.

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

13 A. No, we don't.

Q. Well you would agree with me, in every time the Bair Hugger is on the warm setting, even on the 635, that there's always more particles over the sterile field than when the Bair Hugger is off.

A. ...Yes, that is correct.

17 Q. And in fact, you're not -- 3M is not
 18 disputing that the Bair Hugger blower and hose can
 19 harbor bacteria inside the device.
 20 A. We are not disputing that.

Contrast that testimony with what 3M is telling its customers about contamination: "3M is not aware of any study that shows waste heat from a FAW device contaminating the sterile field." -Press Release July 14, 2017

Van Duren also created a chart labeled the "Advantages and disadvantages of convective prewarming." This appears to be in anticipation of FAW being banned from orthopedics. According to 3M's official designated spokesperson, **the advantages of NOT warming with Bair Hugger during surgery include:**

- "Reduces the incidence of surgical site infection."
- "Does not contaminate the sterile field."
- "Reduces the potential for nosocomial transmission of pathogens by eliminating the need for intraoperative warming."

Advantages	Disadvantages
Inexpensive	Interferes with current workflow practices
Safe	Current therapy adds at least 30 minutes of presurgical time
Can be used when intraoperative warming is contraindicated (aortic cross clamp, orthopedic cases)	Interferes with preoperative access to the patient
Permits unrestricted intraoperative patient access	Adds minor costs to short-duration surgery
Does not contaminate sterile field	Ineffective if patient begins to sweat
Does not interfere with OR equipment	
Generally well-tolerated and comfortable	
Effective during at least the first postinduction hour	
Reduces the incidence of surgical site infection	
Reduces the potential for nosocomial transmission of pathogens by eliminating the need for intraoperative warming	
Preoperative warming blanket may be used in surgery and PACU	
Sensate patients can control degree of heating	

Table 1 – Advantages and disadvantages of convective prewarming

In this chart, Van Duren admits not only to sterile field contamination, but also surgical site infection risk. Contrast that chart with 3M's marketing materials. In a published interview in Surgical Products Magazine, Van Duren himself said "There is absolutely no evidence—not one scientific study—that shows the 3M Bair Hugger system causes or contributes to surgical site infections."

This proves that the 3M Company has known for years that the waste heat from Bair Hugger is contaminating the sterile surgical field *and* increasing the risk of implant infections during ultra-clean surgery. All the while their marketing and sales teams have purposefully misled their customers into believing that Bair Hugger is safe in orthopedics, putting patients at higher risk of catastrophic joint implant infections.

Any company exhibiting this gross unethical behavior does not deserve to be your partner or supplier. For more about this litigation see: BairHuggerLitigationUpdate.org