



**Airborne contamination in the operating theatre is one of the causes of healthcare-related infections.**







Toul Meditech guarantee ultra-clean air of  $\leq 5\text{cfu}/\text{m}^3$  in critical areas, such as the wound site as well as over surgical instruments.

## Ultra-clean air in the operating theatre means increased patient safety

**Airborne contamination in the operating theatre is one of the reasons for infections in connection with surgery. The cardio clinic at Danderyd Hospital is currently investing in new, Swedish, mobile innovation technology, providing ultra-clean air at the surgical site and over the instruments, at the hospital angio lab. Dr. Johanna Sjöblom states “Our aim is to get the number of infections down to zero, which means nothing can be left to chance.”**

The number of healthcare-related infections must be halved during 2009. That is the national patient safety objective of the Swedish Association of Local Authorities and Regions. The situation at present, where as many as 10 per cent of the patients run the risk of contracting healthcare-related

infections, is problematic as, at the same time, resistance against antibiotics is increasing. Apart from the suffering experienced by those who are affected, healthcare-related infections result in costs for hospitals and society of hundreds of millions of Euros.

“There’s a need for new preventive methods that will lower the risk of infection during surgery. Considerable efforts are made to prevent direct contact contamination, by, for instance, sterile draping of equipment and surgical instruments. These measures alone will not suffice if the air surrounding everything in the operating theatre is allowed to contain airborne, sedimenting, bacteria-carrying particles,” says Tomas Hansson of the Swedish Toul Meditech company. The company manufactures mobile units that produce an ultra-clean airflow, directly above the surgical site and instruments. The



Doctor Johanna Sjöblom at Danderyd Hospital and Tomas Hansson from Toul Meditech.

airflow acts as a barrier, preventing bacteria-carrying particles from coming into contact with the wound.

### **Air free from bacteria**

Together with basic hygiene routines, the right attire and good discipline in the operating theatre (such as avoiding opening doors during surgery), the supply of clean air over the surgical site and instruments is crucial, if one wants to minimise the risk for infection. The current sensitive implant surgery, antibiotics resistance and the fact that surgery is performed on patients of increasing age means that normal ventilation of the operating theatre no longer suffices.

“Airborne contamination is a big problem. A study of total hip replacements showed that 98 per cent of the bacteria present in the wound at the end of surgery came from the

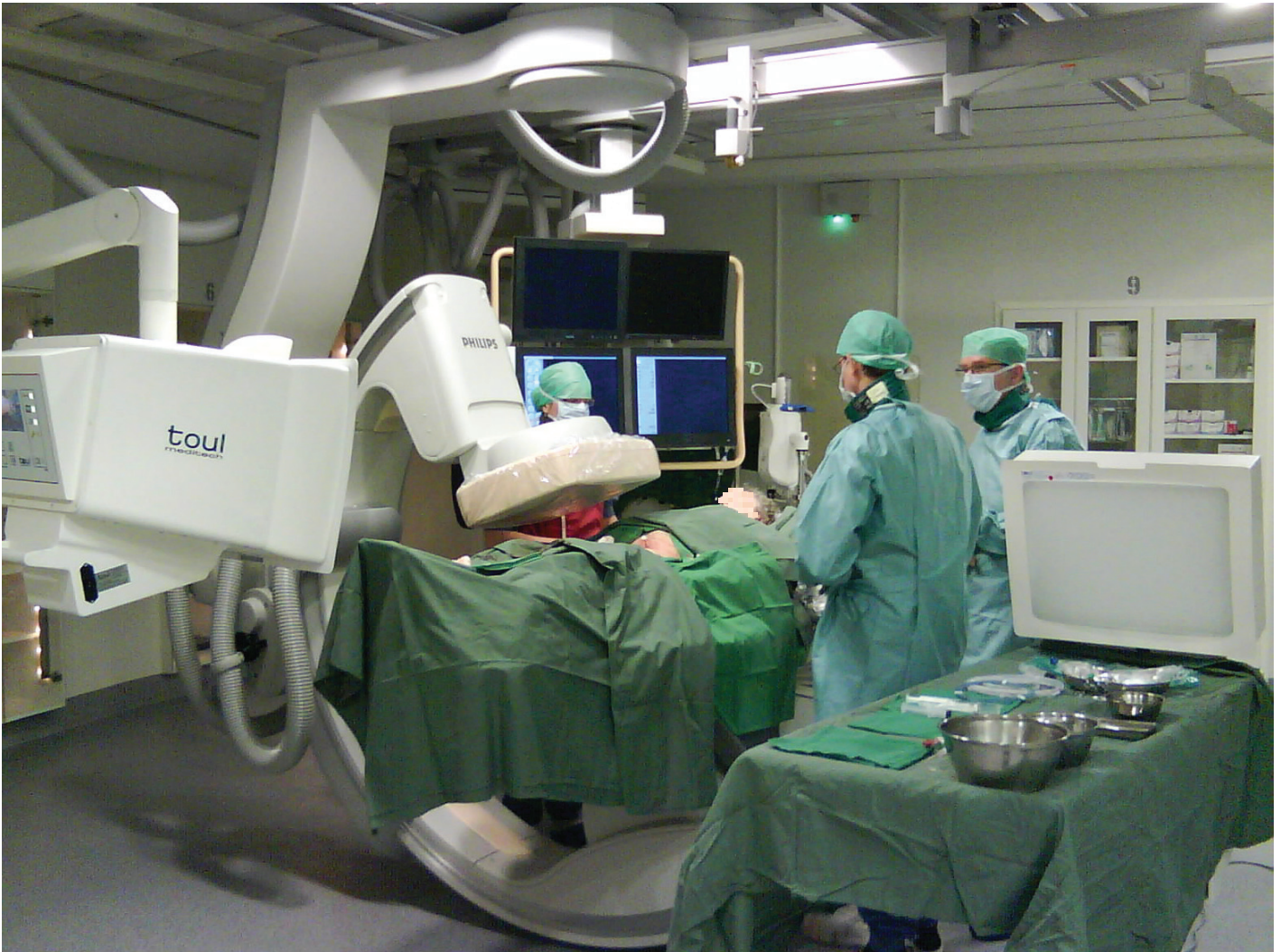
air. Apart from the surgical site, one also has to protect the instruments and implants that come into contact with the wound from airborne bacteria,” Tomas Hansson continues.

### **New vision zero**

The cardiology clinic at Danderyd Hospital recently commissioned technology from Toul Meditech AB, as a complement to existing ventilation at an angio lab which will be used for pacemaker surgery. Infections at surgical operations like transplants, pacemaker surgery and angiography are critical, and may require complicated re-surgery.

“We believe this will lower the risk of infection at surgery. Our aim is getting the number of infections down to zero, which means nothing can be left to chance,” says Dr. Johanna Sjöblom at the Danderyd Hospital cardiology clinic.





Radiology clinic at Kalmar County Hospital: angiography using ceiling-mounted Toul 200 and Toul 300 instrument table.

## “The number of bacteria around the surgical site and instruments must not exceed 10 cfu/m<sup>3</sup> of air”

In connection with the installation of a new and advanced angio lab at the radiology clinic, we also wanted to quality assure the immediate environment and the air quality in the operating theatre. We found that Toul Meditech were able to provide a flexible concept for the distribution of ultra-clean air that was well adapted for an angio lab, where the clean air stream would not interfere with – or be interfered with by other equipment.

The angio operating theatre is designed for advanced invasive surgery, such as the placement of stent grafts and other invasive techniques, where an infection might have very serious consequences. That is why we look at these operations as “clean surgery” and put demands on the number of bacteria in the air of the operating theatre environment - they must not exceed 10 cfu/m<sup>3</sup> of air. Also other design

aspects of the operating theatre aim at achieving the highest standards of hygiene for staff and patients, with air locks and pre-surgery wash. This means the operating theatre can be used, when need be, also for traditional and infection-sensitive surgery, as required.

We currently use two ceiling-mounted Toul 200 units on rails, protecting the surgical site, combined with the Toul 300 instrument table, in order to achieve maximum flexibility and complete protection against airborne contamination. Toul Meditech technology has resulted in greater flexibility and the ability to provide even safer surgery.

**Consultant Doctor Björn Holmgren, Kalmar County Hospital, angiography at the radiology clinic**

# “Will you be able to prepare for a world without antibiotics?”

So far we have performed a total of 500 operations, and we have not had one infection to date. And this is without us using any antibiotics prophylactically, says Dr. Ola Collin, senior lecturer and hand surgery specialist.

In the future, we can no longer rely on antibiotics to prevent and fight infections. Therefore we must try already now to use every possible means to prevent post-operative complications from occurring.

An important part of this work is preventing airborne contamination, which means there is an absolute requirement that we keep the air surrounding surgical sites and instruments completely free from airborne bacteria. We were given the opportunity to try laminar airflow technology from Toul Meditech, and it proved very effective and at the same very easy to use.



Dr. Ola Collin, senior lecturer and hand surgery specialist



GOTHENBURG HAND CENTER – GHC is a comprehensive hand surgery clinic that investigates and treats all types of hand surgery conditions.

Our ambition is to provide hand surgery of the highest quality based on modern and established principles of treatment, in order to achieve optimum hand function and quality of life for the individual patient. We always make patient safety our first priority.

## What is a healthcare-related infection?

One of the most common forms of healthcare injuries is healthcare-related infections. But, with the right expertise, methods and technology, they can to a large extent be prevented.

*A healthcare injury is an injury that occurs – not as a result of an individual’s medical condition – but as a result of healthcare measures taken, as of themselves, or the lack of such measures, when they ought to have been taken, considering a patient’s need of healthcare.*

*SOSFS 2005:12 (Policy guidelines issued by The Swedish National Board of Health and Welfare.)*

### One of ten patients is a victim

The Swedish Association of Local Authorities and Regions have launched a national campaign to increase patient safety, where the aim is to halve the occurrence of healthcare-related infections – from ten to five per cent before the end of 2009. If we could lower the risks of contracting an infection, our patients would be spared unnecessary suffering and extended hospitalisation. This would, at the same time, mean there would be more hospital beds available for other patients. At one of Sweden’s larger hospitals calculations showed that halving the number of

healthcare-related infections would result in **savings** of 65 million Swedish kronor (approx 6,8 million Euros) per year, and **free up 21 hospital beds** around the clock. The three most frequent healthcare-related infections are:

Urinary tract infections	approx 25 %	(extended hospitalisation around 1 day)
Pneumonia	approx 15 %	(extended hospitalisation around 4 days)
Post-operative wound infections	approx 20 %	(extended hospitalisation around 7 days)

### How much does this cost us?

Treatment costs increase by a factor of 3.6, when an infection sets in. Example:

1.3 million patients

10 % of patients contract a healthcare-related infection *results in* average extended hospitalisation of approx 4 days *or* 500,000 additional days in hospital, at a cost per patient of 7,373 Swedish kronor

**ADDITIONAL HEALTHCARE COSTS of 3,7 billion Swedish kronor (approx 390 million Euros)**

Source: The Swedish National Board of Health and Welfare, 2006

## What does the future hold in store?

Increased resistance to antibiotics and MRSA infections threaten to push us back to the early 1900s, and we have to adapt to a new reality, already at this stage. The easiest, cheapest and safest way – perhaps the only one in future – of dealing with an infection is to minimise the risk of it occurring.

## How can post-operative infections be prevented?

Bacteria that cause infections are not able to “jump”, but they do avail themselves of various media, so that they end up in the surgical wound.

*Examples of contamination paths in connection with surgery:*

- Patient’s own bacteria
- Direct contact contamination – through direct touching
- Droplet contamination – when somebody speaks, coughs or sneezes
- **Airborne contamination** – in the form of bacteria-carrying particles that use the air as a medium and sediment into the surgical wound or on the surgical instruments.

*Preventive measures to ensure a minimum level of bacteria on critical surfaces and in the ambient air:*

- **Most important of all: basic hygiene routines** (hand wash, disinfection, sterile gloves, sterile drapes etc.)
- Appropriate and all-protective clothing (protection against airborne and direct contact contamination)
- Avoid opening doors during surgery (protection against airborne contamination)
- Good ventilation with a supply of (ultra-)clean air, with a minimum air speed of 0.4 m/s over critical areas for efficient particle transportation.

*“Everything which is to come into contact with the wound has been made sterile, except the air, which is in contact with everything”*

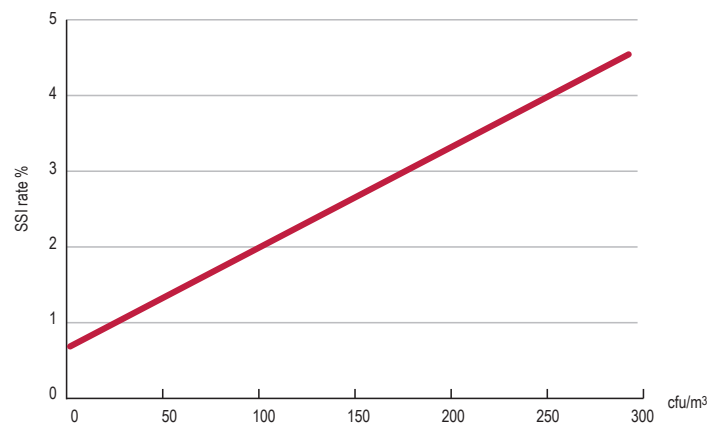
Whyte 1973

## Is there a connection between post-operative wound infections and airborne contamination?

Everything that has been draped or undergone sterile handling runs the risk of becoming unsterile and contaminated by sedimenting bacteria-carrying particles after no more than a short space of exposure, in the surrounding air. To avoid airborne contamination one has to ensure that all critical target areas are surrounded by (ultra-)clean air.

Conventionally operating air changing ventilation yields, at best, a bacterial level of between 50 and 100 cfu/m<sup>3</sup> of air. (Cfu=colony forming units, i.e. bacteria-carrying particles.) The definition of ultra-clean air and current requirements for “clean” surgery are <10 cfu/m<sup>3</sup> of air.

The relationship between airborne contamination, measured in cfu/m<sup>3</sup> of air, and SSI (surgical site infections) has been established in a number of studies:



Correlation SSI rate % - cfu/m<sup>3</sup> (Lidwell 1983), 6 000 hip replacement

Every person in an operating theatre gives off 1,000 to 10,000 particles per minute. Some 10% of those particles carry bacteria. The particles sediment on every surface, including critical areas such as the wound site and surgical instrument table – to the effect of 30 cm per minute.

The number of bacteria-carrying particles in the air at an operating theatre is determined by:

- The number of people in the room
- Physical activity and patterns of movement
- Surgical attire
- Type of ventilation

*“Not all bacteria can be washed away or eliminated with alcohol, some of them have to be blown away.”*

A study\* of total hip replacements showed that 98% of the bacteria that were in the wound at the end of the operation came from the air, of which 30% was direct sedimentation. The remaining 70% could be traced to indirect sedimentation, such as through contaminated surgical instruments that had been contaminated by airborne, sedimenting bacteria, which were then put in contact with the wound site. This emphasises the importance of protecting all working surfaces and all equipment, such as the surgical site, instrument table and implants to prevent airborne contamination.

\* Source: Whyte et al. 1982



## Our solution



Our self-developed, patented and medicine-technically classified mobile units for laminar airflow have been successfully utilised in Scandinavia since 2003.

Toul technology provides an ultra-clean airflow that is directed right above the surgical site and instruments. It thus works as a barrier and minimises the occurrence of bacteria-carrying particles and consequently the risk of post-operative infections.

An easy-to-use control system means the user can direct the airflow, so that it becomes as effective as possible. A camera helps to determine the direction of the airflow, and a built-in sensor establishes the correct distance from the surgical wound, for maximum effect. An easy-to-read control panel makes it easy for the user to control and confirm the setting. The air in the room is HEPA-filtered

and is subsequently pushed through a laminar flow screen. The laminar ultra-clean airflow leaves the screen (without any turbulence) and pushes contaminated air ahead of it, away from the risk zone and out into the room, where it is absorbed by the regular ventilation system.

Sterile disposable screens for laminar airflow guarantee ultra-clean airflow. The laminar flow screen is sterile-packed and equipped with a unique bar code that is registered in the system software on mounting the screen for surgery. The bar code is logged to ensure the technology was correctly used, as well as to enable checking up, in retrospect, how the technology was used at a particular surgical operation.

We guarantee ultra-clean air\* of  $\leq 5 \text{ cfu/m}^3$  in critical areas, such as the wound site as well as over surgical instruments during setup and throughout surgery. Our technology also contributes to increasing the number of HEPA-filtered air changes, and reducing particle concentration in the entire operating theatre.

\* definition of ultra-clean air and current "clean operation" requirements are  $<10 \text{ cfu/m}^3$  of air (cfu = colony forming units, i.e. bacteria-carrying particles).



**SteriStay** is our surgical instrument table with ultraclean laminar airflow for effective protection of the instruments during setup and throughout surgery.



**Operio Ceiling** is our ceiling-mounted sterile air zone unit for effective protection of the wound site.



**Operio Mobile** is our mobile sterile air zone unit for effective protection of the wound site.

- Useful for every kind of surgery
- Requires a minimum of training
- Short startup time
- Provides superior hygienic safety over the wound site
- Swedish innovation technology
- Eliminates the risk of contaminating surgical instruments, prosthetics and implants
- Medicine-technical classified equipment
- Requires no re-building, fixed installations or adaptation of existing ventilation in the operating theatre



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