ULTRACLEAN AIR

GO WITH THE FLOW – DON'T RISK IT

Post-operative infections can occur from operating theatre personnel

> 90 % of airborne bacteria derives from the OR personnel. Every person shred 10 000 skin particles/minute where approximately 10 % are bacteria carrying particles.

SSIs – a major cause of concern

Prevention and cure of SSIs (surgical site infections) place an enormous burden on medical and financial resources, both during surgery and post-operative hospital care. SSIs generate costs for society and significant suffering for patients, often involving prolonged periods of hospitalization, which in turn create additional costs. The introduction of stricter hygiene requirements and regulations has made improvements, but the problem is still a major cause for concern.

A primary cause of SSI is airborne contamination from bacteria carrying skin particles which can sediment on surfaces sensitive for surgical asepsis. The most common source of bacteria is considered to be the operating theatre personnel working in close proximity to the site of the operation.

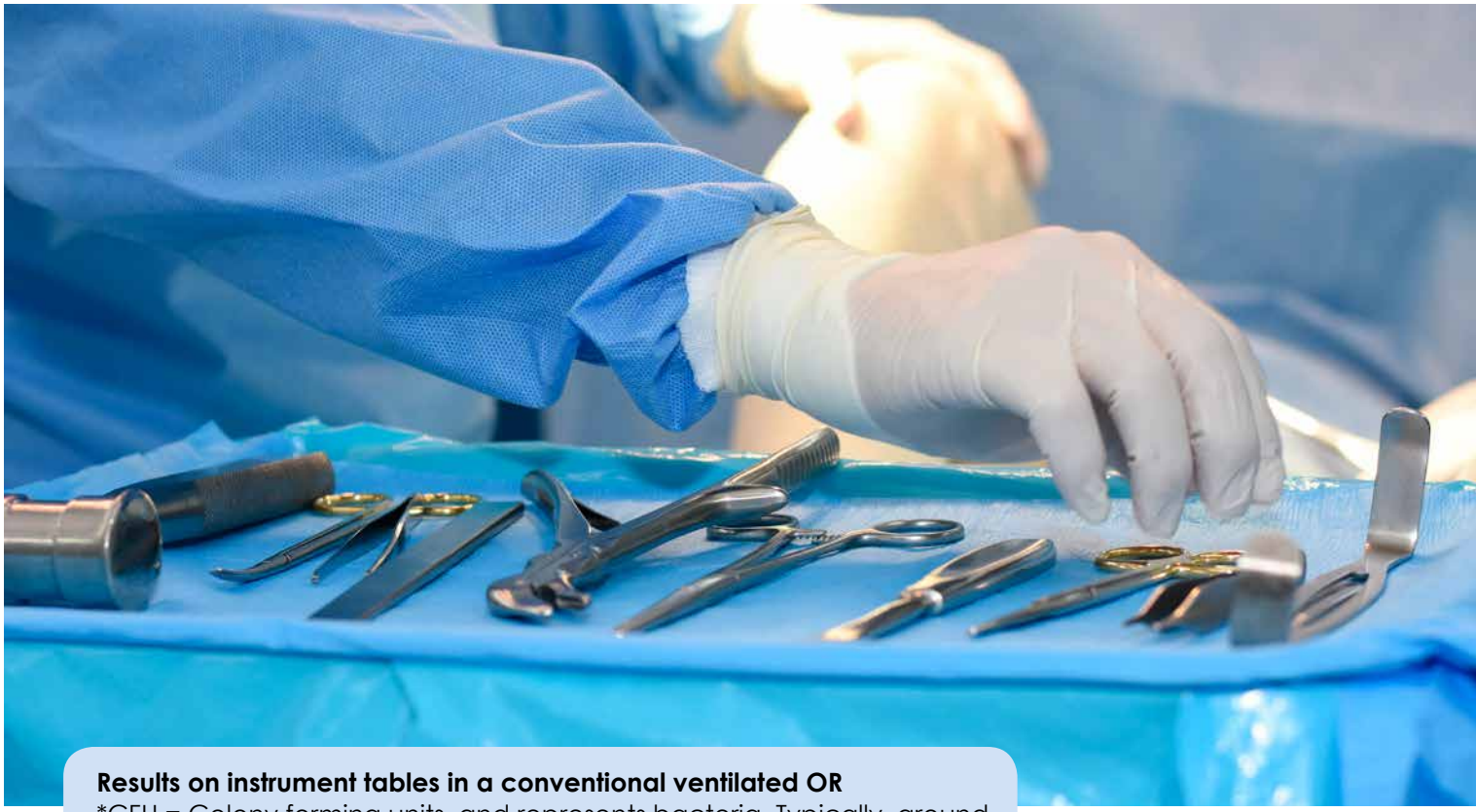
The European Centre for Disease Control estimates that 3.8 million people acquire a healthcare associated infection each year in acute care hospitals in EU countries and Norway and Iceland (Suetens et al., 2018), and an estimated 90 000 people in the EU die each year due to the six most common infections in health care settings (Cassini, 2016). At least 20% of healthcare associated infections are considered to be avoidable through better infection prevention and control (Harbath, 2003).

Exposure on instrument tables

Many infections occur due to sterile instruments contaminated by airborne bacteria carrying particles are left in the open air. In a test, two instrument tables were prepared – a regular instrument table and an instrument table supplied with ultraclean air from SteriStay. The tables were used for 45 minutes and 3 people in OR clothing were present in the room. The sterile goods and 6 agar plates were exposed for 2 hours in total.

The operation room had mixing ventilation from the ceiling.

After being exposed for 2 hours, all sample plates were incubated for 48 hours in 37° C (99° F). The result demonstrated that the regular instrument table had >120 CFU/m³* on all 3 plates and SteriStay instrument table had 0-5 CFU/m³ on all 3 plates.



Results on instrument tables in a conventional ventilated OR
*CFU = Colony forming units, and represents bacteria. Typically, around 50-200 colony forming units per cubic meter (CFU/m³) of air are found in conventionally ventilated operating rooms without Toul units.

CFU on conventional instrument table

CFU on SteriStay instrument table

SteriStay

The protective instrument table

To protect the exposed instruments and sterile goods with an ultraclean airflow minimizes the risk of down falling bacteria carrying particles, since these particles are always present in the operation room.

The unique protective instrument table SteriStay protects your instruments and sterile goods from airborne contamination.

SteriStay is a mobile instrument table, adjustable in height, that can be used as a conventional instrument table, but with the difference that the instruments will be supplied with an ultraclean airflow. Approx. 70% of the bacteria at wound site come from surgical instruments that have been contaminated by airborne sedimenting bacteria. SteriStay provides an ultraclean air environment with <5 CFU/m^3 air around your sterile instruments.

SteriStay has built-in protective barrier of ultraclean air that prevents dangerous, airborne bacteria-carrying particles from coming into contact with your surgical instruments. By using a unique sterile shield as a protective barrier, the SteriStay can be placed close to the OR table.

SteriStay can be used in operating rooms and surgical preparation rooms, independent of ventilation system, where sterile instruments are handled. With SteriStay you can expand the clean zone in the operating room.

Operio®

A mobile clean air zone

A mobile ultraclean air zone can be used in the operating enviroment over the surgical site and/or sterile instruments to prevent contamination of bacteria carrying particles.

With the help of the extendable pendant, **Operio Ceiling** can manually be adjusted easily to an optimal position where the ultraclean airflow is required. It is just as easy to move it out of the way when not in use, pushing it towards the ceiling.

The innovative ultraclean air zone unit Operio ensures that both the surgical site and instruments near the wound remain protected during entire surgical procedure. The ultraclean airflow is easily aimed over the surgical site or any other area where there is a need to keep the sterile integrity intact.

Operio has a unique sterile protective barrier in order for the unit to be placed close to the OR table. The unit circulates the ambient air through a HEPA filtration system, cleaning the air, which prevents dangerous, airborne bacteria carrying particles from coming into contact with the surgical site, as well as surgical instruments near the surgical site.

Apart from the ultraclean zones the unit also has a secondary effect on all ambient air in the room, with HEPA-filtered 400 m^3/hour.

Operio Mobile is easy to use and transport between operation rooms and/or preparation rooms. It can also be used as a stand-alone instrument table.

Applications

Hand & arm

Foot & ankle

Hip & knee

Ophthalmic

Thoracic

Neuro

Specifications

Physical	OPERIO MOBILE	OPERIO CEILING	STERISTAY
Overall size:	L 45 x W 60 x H 130-170 cm / L 18 xW 24 x H 47-67 inch	L 60 x W 25 x H 90 cm L 24 x W 10 x H 35 inch	L 170 x W 60 x H 80-120 cm /L 66 x W 24 x H 31-147 inch
Weight:	42 kg / 92 lb	15 kg / 33 lb	60 kg / 132 lb
Tray/table height:	80-120 cm / 31-47 inch	N/A	80-120 cm / 31-47 inch
Tray/table size:	45 x 60 cm / 18 x 24 inch	N/A	60 x 130 cm / 24 x 51 inch
Load limitation:	Max 5 kg / 11 lb	N/A	Max 50 kg / 110 lb
Power Data			
Power supply:	230/115 VAC, 50/60 Hz	230/115 VAC, 50/60 Hz	230/115 VAC, 50/60 Hz
Power consumption:	290 VA (23 VA in standby-mode)	160 VA (23 VA in standby-mode)	160 VA (23 VA in standby-mode)
Fuses:	230 VAC–3.5 A slow, 5 x 20 mm 115 VAC–5 A slow, 5 x 20 mm	230 VAC–3.5 A slow, 5 x 20 mm 115 VAC–5 A slow, 5 x 20 mm	230 VAC–3.5 A slow, 5 x 20 mm 115 VAC–5 A slow, 5 x 20 mm
Airflow Data			
Airflow speed:	0.4 – 0.5 m/s	0.4 – 0.5 m/s	0.4 – 0.5 m/s
Air cleaning capacity/hr:	400 m^3/hr	400 m^3/hr	400 m^3/hr
Clean air zone length:	120 cm / 47 inch	100 cm / 40 inch	133 cm / 52 inch
Cleanliness:	<5 cfu/m^3 air inside the sterile air zone.	5 cfu/m^3 air inside the sterile air zone.	5 cfu/m^3 air inside the sterile air zone.
HEPA Filter			
H14 Filter, High Efficiency Particles Filter:	Filters 99.995% particles >0.3 µm	Filters 99.995% particles >0.3 µm	Filters 99.995% particles >0.3 µm
Regulatory Compliance			
EU:	CE mark Class I according to Medical Device Regulation (EU) 2017/745	CE mark Class I according to Medical Device Regulation (EU) 2017/745	CE mark Class I according to Medical Device Regulation (EU) 2017/745

Toul Meditech's Quality Management System is conforming to the requirements of ISO 13485:2016.

Manufactured by:

Toul Meditech AB
Tunbytorpsgatan 31
721 37 Västerås
Sweden
www.toulmeditech.com

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