COMPACTA

CompactaSteril

Reducing Surgical Site Infections

Disclaimer

This product brochure depicts a future product.
The current CompactaSteril is a prototype having most (but not all) of the functionality present but will be further developed and optimized.
CompactaSteril is not yet a medically approved device.

COMPACTA

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Ultra Clean Air Zone Reducing Surgical Site Infections

CompactaSteril is designed to reduce surgical site infections (SSI) and provide optimal comfort and safety for physicians and patients.

SSIs are the second most common type of hospital acquired infections (HAI) and affect up to 15% of all patients undergoing a surgical procedure.[1] It causes suffering for the patients and a considerable extra burden on the healthcare system. SSIs are the most expensive type of HAI to treat and the estimated annual cost in Europe is 1.5-19 billion EUR.[2,3]

A primary cause of SSIs is airborne particles carrying bacteria. With an increasing prevalence of multidrug-resistant bacteria in the healthcare settings, SSI is becoming an even greater clinical concern.

CompactaSteril provides a well defined ultra clean air zone irrespective of the environment it is placed in. It produces a laminar airflow (LAF) of ultra clean air over the patient and tests have shown that the technology works well. An early prototype not only provides an ultra clean air zone but also proved to reduce the overall particle content in the room significantly.

The CompactaSteril system is intended to significantly reduce the number of SSIs, enable larger flexibility, increase number of surgical procedures due to shorter time between patients, and lower the cost per procedure compared to current alternatives.

Uses

CompactaSteril is optimized for minor surgical procedures such as hand, wrist, foot, and ankle surgery, minor trauma and fracture surgery, ophthalmic, dermatologic, and laparoscopic surgery, as well as treatment of infection prone wounds.

The flexibility and function of Compacta Steril allows for treatment in e.g. general practitioners' office, emergency and operating rooms, dermatology, rheumatology clinics, and for keeping surgical instruments sterile in operating rooms.

CompactaSteril – A Modular System

CompactaSteril is a modular system which allows the customer to choose desired components and design an optimal product for the intended use.

Available modules:

- **Ultra Clean Air Zone**
- **Lighting**
- **Camera and Monitor**
- **Flexible Installation Systems**

Ultra Clean Air Zone

CompactaSteril provides a well defined zone of 50 x 50 x 60-80 cm (b x w x h) with ultra clean air. The unique design and combination of the hood, fan, HEPA filter, and UV light provide an optimal vertical laminar air flow (LAF) of ultra clean air.

Ultra clean air is defined as having <10 cfu/m^3 (colony forming units). The system's HEPA filter and the UV light ensure that the air flow produced by CompactaSteril is ultra clean. The LAF of ultra clean air then hinders any surrounding microbial-containing particles from entering the ultra clean air zone. CompactaSteril thus helps maintain sterility of the surgical site, wound and instruments.

CompactaSteril produces an air flow with air velocity of minimum 0.45 m/s along the sides and corners of the zone, which ensures that surrounding air does not contaminate the ultra clean air zone. There is in principle no air flow in the center of the zone, meaning that the surgical site or the wound will not be negatively affected.

Data from test and simulations can be found on page 8.

Lighting

The lighting available on CompactaSteril is designed to provide a comfortable working environment without shadows, reflections, and blinding. It delivers optimal illumination of the relevant area of the patient through a surgical light system consisting of general lighting and focused surgical light. Light-emitting diodes (LED) serve as light sources for both the general lighting and the surgical light. This design reduces energy requirements and consumption as well as emitted heat.

The general lighting illuminates the area of relevance without shadows and the intensity can be adjusted to accommodate diverse needs and preferences.

The surgical light is mounted on a flexible arm and the intensity can be adjusted. Also the color temperature of the surgical light can be adjusted to provide optimal contrast and ability to distinguish true tissue color.

CompactaSteril will be possible to order with the complete lighting system or with one or none of the lighting components.

Camera and Screen

High quality, magnified images with high level of detail can be provided by a camera and accompanying screen.

The camera is mounted on the control panel with a lens situated together with the surgical lamp. This enables the physician to a) view the area of interest in larger detail and b) reduce the need to lean over the patient to get an optimal view, which increase the risk for surgical site infections and discomfort for the physician.

The image is projected on a screen which can be mounted on a flexible arm. Wireless transfer of the image allows real time sharing and recording of the procedure. The camera and surgical light are synchronized through a PC.

The camera provides images with excellent quality due to e.g. image stabilization, exceptional resolution, high contrast, extremely low distortion, reduction of reflections and shadows.

Flexible Installation Systems

CompactaSteril can be used with a free standing holder or be attached to standard flexible ceiling-mounted arms available in e.g. operating rooms. It has a convenient size and low weight of 20 kg, which makes it easy to handle and move between different locations.

The distance between CompactaSteril and the patient can be adjusted between 60 cm and 80 cm. This allows for use of other equipment such as roentgen apparatuses during shorter periods of time.

The only prerequisite for using a CompactaSteril on a free standing holder is a 240 volt power outlet.

Why Ultra Clean Air is Important

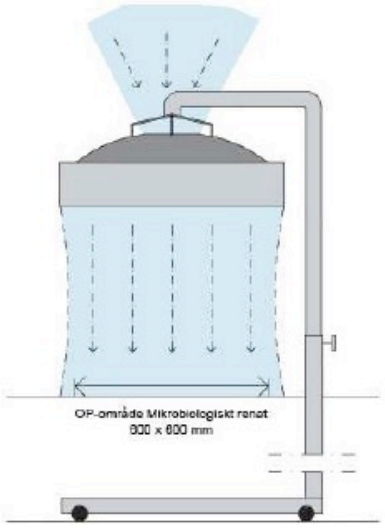
Surgical site infections (SSI) are among the most common healthcare-associated infections and affects both inpatient and outpatient procedures at private as well as state provided healthcare. The impact of SSIs is immense for both the affected patients as well as the healthcare provider, as SSIs are associated with longer post-operative hospital stays, additional surgical procedures, intensive care treatment, and often higher mortality.[4] The estimated annual cost in Europe is 1.5-19 billion EUR and corresponding figures for USA are 3.5 - 10 billion USD.

One common cause of SSIs is the abundant occurrence of air-borne particles carrying pathogens that contaminate the surgical site, instruments and wounds. Current ORs have a ventilation system that is designed to lower the concentration of such air-borne pathogens to levels acceptable for carrying out surgical procedures. Some of the older facilities and ventilation systems are no longer suitable for open surgery and must be rebuilt at a significant cost, if at all possible. So called “office surgery” is performed in facilities lacking clean air which increase the risk of acquiring SSIs.

A number of drug-resistant bacteria exist in the healthcare settings and make the treatment of SSIs potentially extremely difficult. This is an increasing global problem that affects surgical interventions and treatment of infection-prone wounds. The common antibiotic prophylaxis used prior to a surgical procedure may prove ineffective with increasing number of drug-resistant bacteria. The combination of drug-resistant bacteria and SSI may, according to orthopedic surgeons, lead to that certain surgical interventions such as implant surgery no longer can be performed due to the increased risk of mortality and morbidity.

CompactaSteril could therefore be a flexible and affordable solution for avoiding SSIs and also increase the availability of surgical interventions.

Specifications



Basic CompactaSteril Model

Size (cm): 60 W x 60 D x 60-80 H

Weight: max 20 kg (without free standing holder)

Power: 240 V

Filters:
1) HEPA H 14, EN 1822 at MPPS<99.995%
2) Prefilter, placed before inlet of air for reduction of larger particles

Operation:

Distance between patient and CompactaSteril: 60-80 cm

Area covered by ultra clean air: 60 x 60 cm

Level of cfu at patient: < $10/m^3$

Air velocity: 0.45 m/s

Additional Accessories

Lighting

General lighting: LED light, 24 V, without shadows, adjustable illuminance 3000 – 6000 lux with max. 1200 lux at patient.

Surgical light: LED light, 12 V, 3 cm in diameter, mounted on flexible arm, distance to surgical site 30 cm, adjustable illuminance with max. 20000 lux at patient, adjustable color temperature 3500-5500 K

Camera and Monitor:
Camera:
Zoom, Wireless image transfer, Recording, Synchronized with surgical light, Image stabilization, resolution 1600x1200, 60fps, Extremely low distortion, High contrast, Anti-reflective coating, and electronic interference shielding.

Monitor:
21,5" MED-DISPLAY, 1920x1080

UV LED Light:
UV light can be added to CompactaSteril for elimination of primarily viruses, but also bacteria after at least 30 minutes of use.

Wavelength: 270 nm

Preventive Maintenance

Cleaning and Decontamination

CompactaSteril shall be used together with a protective cover which shall be exchanged between each patient. If severe contamination occurs, clean and disinfect CompactaSteril using standard procedures as described in appropriate SOP (e.g. isopropanol, 45 volume percent, containing surfactant).

Replacement of Filters

An alarm will notify when the HEPA filter shall be replaced. The filter is easily replaced and the used filter shall be sent for destruction. The pre-filter shall be exchanged weekly when used in a hospital setting.

Tests and Simulations

Aerosol tests* with Prototypes have showed that the probability of contamination by the surrounding air is significantly reduced, with a reduction in particle concentration down to 0.0001-0.01% compared to the surrounding air, see figure 1 and figure 2. The particle concentration remains low when personnel move their hands in and out of the protected zone. The CompactaSteril recirculates the air in the room. Measurements outside the ultra clean air zone also showed that the total amount of particles in the room was reduced significantly.

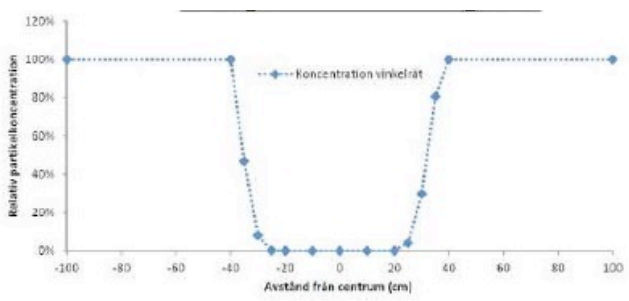


Figure 1. Test in lab

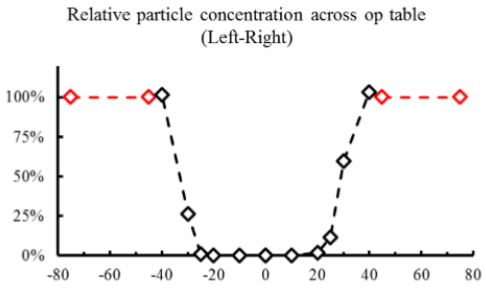


Figure 2. Test in OP-room simulator

Digital air flow simulations which show air flow and air velocity over a patient in simulated operating rooms confirm an optimal airflow with desired air velocity along the sides and in the corners of the air zone, see figure 3. There is no direct air flow in the center, meaning that the surgical site or the wound will not be negatively affected by the air flow.

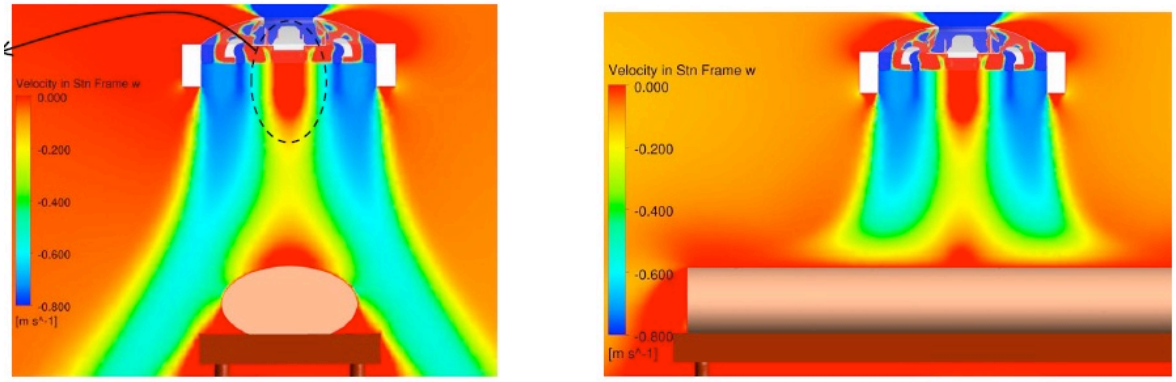


Figure 3. Illustration of vertical air flow from CompactaSteril over patient.

*The aerosol test resembles the international standard DIN 1946-4 and was performed by Department for Ergonomics and Aerosol Technology, Faculty of Engineering, LTH, Lund University. Tests have been performed in an operating room simulator with a mannequin torso placed on the operating table, simulating a human subject.

References

1. *WHO, 2002, Prevention of hospital-acquired infections, A practical guide, 2nd edition;*
2. *European Centre for Disease Prevention and Control. Point prevalence survey of healthcare-associated infections and antimicrobial use in European acute care hospitals. Stockholm: ECDC; 2013,*
3. *Magill SS. et al., N Engl J Med. 2014; 370(13):1198-1208*
4. *ECDC, Surveillance Report, Surveillance of surgical site infections in Europe 2010-2011*