

Cabin for air quality control



to enable rooms to perform surgical procedures

to improve the asepsis conditions in operating theaters

to generate isolation rooms

General description

General characteristics

This machine is designed for those processes in which it is vital to have an extremely low level of particles and microorganisms suspended in the air. The sterile air serves to protect and prevent pollution in a given area. The arcSterile, with its fans of filtered air, sweep the particles that come from the environment or that are generated during the surgical process, beyond the surgical field.

What is Arc Sterile?

It is an aluminum structure cabin, with sliding screens panel and folding front opening polyvinyl door for entry of patients.

The equipment can act as a chamber of controlled indoor air quality for both, surgical procedures as well as for those that require aseptically special conditions, as isolation rooms.

In the technological design, it includes two columns of impulsion and air filtration to generate the sterile horizontal laminar flow.

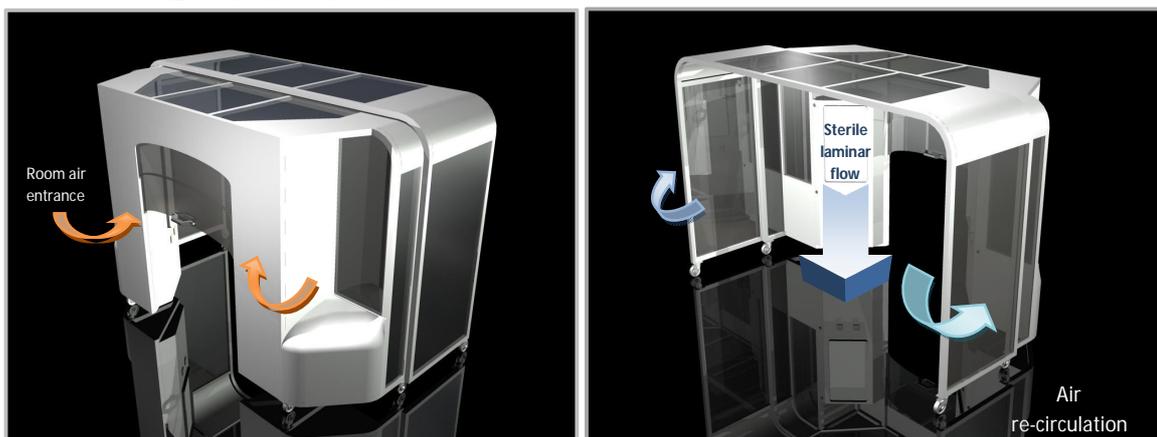


Figure 1 – Air circulation cabin

Moreover, it also incorporates upper and lateral diffuse lighting, and allows you to incorporate accessories that improve overall working conditions (surgical lamps, technical bar, computers, isolation transformer, UPS, etc.).

arcSterile recreates the asepsis conditions and electrical safety of an operating theater:

- to enable new rooms to perform surgical procedures
- to improve the asepsis conditions in an existing operating theaters
- to generate isolation rooms for immunosuppressed patients

What about the air quality...

arcSterile ensures ISO 5¹ air quality in the operative field, throughout the duration of the surgical process. It keeps a low level of suspended particles in the air, below the pre-

¹ The air quality is classified according to the number of particles within a given area, being the best quality classification that which receive the lowest number. For surgical procedures must reach ISO 7 or ISO 5.

established limits, thanks to: the ultra-filtration, the laminated characteristics, the air renewal, and the positive pressure generated.

- **ULTRA-FILTRATION:** The equipment performs a double air filtration, the first one through the pre-filter G3 before of the fan, and blowing the air through HEPA filter 14². The ultra-filtration assures us that there is no entry of polluted air particles to the system.
- **LAMINATED CHARACTERISTICS:** Just as important is ultra-filtration as laminated characteristics of the flow, that allows this protective air flow does not mix or suction unwished particles close to the most critical area.
- **RENEWAL:** The renewal of the air allows you to dilute the impurities contained in the surgical area, keeping the air quality independent from the time surgery.
- **POSITIVE PRESSURE:** By using it in close mode (using the closing device for the bigger cabin arch, or by placing the bigger cabin arch faced with some wall of the surgery room) the room air is aspirated, filtering, introduced in such a critical area like a tunnel of sterile laminar flow, and returned to the room, repeatedly. In this way a difference of pressure (positive pressure) improves the process security and enhances the features of the room asepsis (prevents outside air penetrate inside the cabin).

arcSterile guarantees an ISO 5 quality level air classification at the critical area because it reduces the number of microorganisms in the air (bacteria, fungi, and viruses) and prevents the sedimentation of microorganisms inside the wounds. This is possible because the laminar flow sweeps over the surgical area with clean air, without turbulence, reducing the amount of particles that are suspended in the air. In this way moves the contaminated air away from the operations table.

How to use...

The room should be previously equipped with an air-conditioned system. The laminar air flow tunnel can be switched to be generated from left to right or vice versa, to fit the work organization of the surgical team and the instrumental location.

To ensure the correct location of the surgical field inside the tunnel air flow, the cabin incorporates a double reference laser linear positioning system.

Through an e-panel the user controls the speed of the air and the alarms level activation (saturation of HEPA filters or need for technical assistance). This panel also allows control the lighting, the operating time and show information for the devices in use during its operation.

The cabin could be used in the "open mode" or in the "close mode". With the first one, the users must make sure the location of the surgical field inside the laminar flow tunnel. In the other case, the cabin must be faced to a wall (like the figure) o must include the closing device.

² The HEPA filters are known as "absolute" filters by its very high filtration efficiency. Category H-14 is the most effectively within the HEPA group, presenting a highest effectiveness for particles of 0.3 mm, 99.995 %, which includes bacteria and viruses.



Figure 2 –Cabin in open mode



Figure 3 –Cabin in close mode

In order to keep the quality of the tunnel of laminar flow it is recommended to follow the guidelines regarding the location of the members of the healthcare or surgical team:

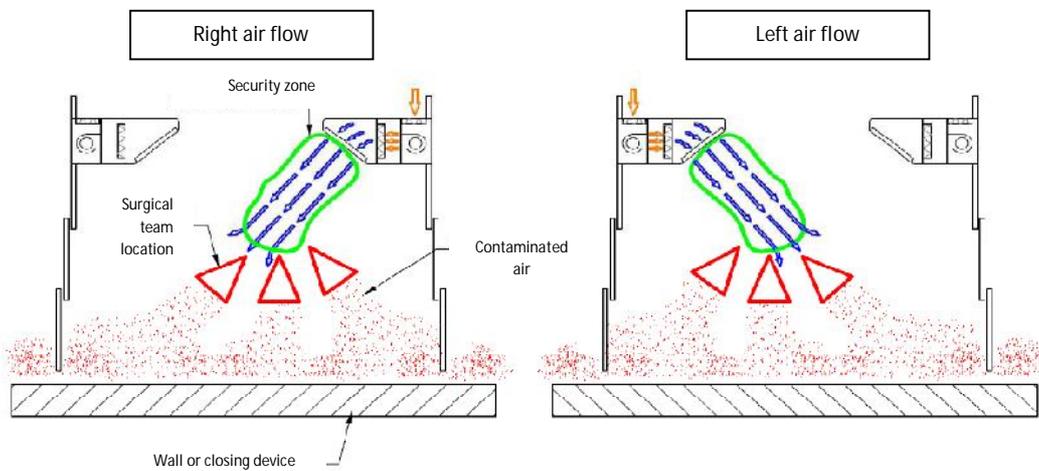


Figure 2 – Surgical team location

What about electrical requirements...

Electrical power: 230V (L+N+T) / 50Hz.

Power consumption: 500W (increasing the power consumption as they saturate the HEPA filters) and the power available in sockets is 2.3 KW, which makes a total of 3.1 KW.

arcSterile incorporates an UPS to maintain operation for 20 minutes, but it could be changed by an UPS for 120 minutes as an optional device that include an extension of the power available to connect the surgical instruments, too.

To optimize the general conditions of the room arcSterile could add optional modules that help to complete the electrical requirements, records, or biological control. These are detailed in the configuration section.

Optional module for electrical safety in surgery

For those procedures that require to reach electrical safety for operating theaters it could be incorporated to the structure of the arcSterile the optional module BT38, which consists in an isolated electrical system with 8 outlets, an isolated transformer with isolation monitor, with an UPS to keep the service for 120 minutes for the cabin and the 400W of additional consumption.

For the procedures that do not use electrosurgical instrumental, BT38 module is not required..

Dimensions

Base Module

MB20: 2 m. width, 1,60 m. depth, and 2 m. height.

MB25: 2,5 m. width, 1,60 m. depth, and 2 m. height.

MB30: 3,0 m. width, 1,60 m. depth, and 2 m. height.

Lateral screens:

M2: Screens for depth extension until 2,4 m.



When the arcSterile is folded it shall have a width of 0.8 m and 2 m from height. The width depends on the model chosen.

The maximum volume of transport reaches: two pallets 1,10 x 0,92 x 2,10 meters (height x width x length). If it is necessary because of the destinations and the means of transport the cabin could be transported in boxes specially designed. The approximate weight is 300kg.

Cabin configuration

There are three alternatives for the basic configuration, having each one of them a different width, but keeping the same dimensions in regard to height and the same optional accessories.

The final configuration will depend on the dimensions of the room where arcSterile will be located, the type of procedures to implement inside it, the instrumental that will be used during the procedures.



Basic configuration

Arch

M20 – 2 meters Width Basic Module

It is a structure in the arch of 2 meters width, 2 modules of sterile air in laminar flow for not simultaneous use. Lighting is included in modules of air. The cabin also includes a digital touch screen control panel, velocity sensors, a linear laser positioner, and a minimum of 4 sockets to connect electronic or electrical equipment.

M25 - 2,5 meters Width Basic Module

It is a structure in the arch of 2,5 meters width, 2 modules of sterile air in laminar flow for not simultaneous use. Lighting is included in modules of air. The cabin also includes a digital touch screen control panel, velocity sensors, a linear laser positioner, and a minimum of 4 sockets to connect electronic or electrical equipment.

M30 - 3 meters Width Basic Module

It is a structure in the arch of 3 meters width, 2 modules of sterile air in laminar flow for not simultaneous use. Lighting is included in modules of air. The cabin also includes a touch screen digital control panel, velocity sensors, a linear laser positioner, and a minimum of 4 sockets to connect electronic or electrical equipment.

Structural modules

M2 – Double lateral screen

Second lateral screen that allows to achieve a depth of 2,40 meters in the cabin.

MC – Closing device

Module to close de cabin, to ensure positive pressure.

Recommended Optional Modules

The optional modules offer additional functionality to the cabin in its basic configuration and are integrated into the configuration chosen by the client in the assembly line of the cab.

BT38 Module

It is an isolated electrical system in compliance with surgery safety regulations. Includes 8 (eight) sockets, and a monitor of isolation, UPS for 120 min (that maintains the fans in operation and 400W for additional computers connected to it).

SAI 1 – UPS 20 min.

Uninterrupted power system to keep the cabin working during 20 minutes.

SAI 2 – Extended Uninterrupted Power System

Uninterrupted power system to keep the cabin working during 20 minutes and an additional capacity of 500W to other devices connected to the cabin sockets.

SC - Conductive surface carpet

3.5 x 2 meters carpet, with electrical conductive surface to put under the arcSterile cabin and the surgical table.

SC4 - Conductive surface carpet

3.5 x 4 meters carpet, with electrical conductive surface to put under the arcSterile cabin and the surgical table.

Complemented Optional Modules

These options allow to certify the quality of medical practice carried out, being an element of control to add to the surgical report if necessary. They do not substitute the good medical practice at the technical level, nor do it replace the preservation of the sterility on the surgical field, but improving it and certify it.

CP – Particle counter

It requires the computer device and implies to carry out a maintenance and verification protocol.

LQ – Surgical lighting

Cold light system (LED) with articulated arm >30.000 lux.

VC – Central Video System

Video system to record surgical treatments thanks to a panoramic camera with central storage capacity.

CR – Computer device

Computer device adapted, with touch screen and control systems. The screen allows to see recording videos and display diagnostic tests during the intervention

Clinical applications

General clinical applications

arcSterile could be used in the following medical specialties.

OPHTHALMOLOGY	DIGESTIVE SURGERY
DERMATOLOGY	ENDOSCOPIES
OTOLARYNGOLOGY	MAXILLOFACIAL SURGERY
TRAUMATOLOGY	BRACHYTHERAPY
CARDIOLOGY	HEMATOLOGÍA
PLASTIC SURGERY	U. INTENSIVE CARE
FERTILITY SURGERY	PAEDIATRIC OR NEONATAL SURGERY

arcSterile like isolated room...

This equipment allows to dispose spaces as isolation rooms for immune-suppressed patients anywhere in the building, quickly and easily, always by using it in the “close mode” to achieve positive pressure and incorporating additional plastic devices to increase the air cabin flow.

arcSterile inside a surgery room...

arcSterile applies to any surgical procedure that because of the characteristics of work and composition of the surgical team could be carried out within the volume that it contains. It also allows to obtain a higher quality of the surgical procedures performed in traditional operating theaters, which contributes to the reduction of number of surgical infections.

When arcSterile is being used inside a surgical room, it can hold a high air quality over the critical area even:

- long duration surgical procedures (more than 1 hour)
- surgical procedures that requires a maximum of sterility by its high risk of infection and mortality associated, such as neurological surgery, cancer, organ transplants, neonatology and immune-suppressed patients
- surgical procedures in operating theaters which do not guarantee the minimum asepsis conditions required



arcSterile to enable spaces as operating theaters...

To clarify the clinical applications we expose it by medical specialties³, indicating the cabin recommended configuration in order to ensure the quality of the air.

The tables shown below represent a summary of some of the surgical procedures that can be carried out by making use of the arcSterile cabin⁴. The relationship has been based on the criterion of different surgeons from various medical specialties, using this cabin and evaluating its benefits knowing the type of procedure to reach their benefits.

There could be incorporated many other procedures depending on the gear available, on the surgical team and the particular needs of each service.

OPHTHALMOLOGY

Procedures	M20/M25 <i>simple</i>	M25/M30 M1 <i>close mode</i>	M30 M1 <i>Close mode</i>
Intravitreal Injections	✓	✓	✓
Surgery of conjunctiva and Pterygium	✓	✓	✓
Eyelid surgery and Lacrimal Sac	✓	✓	✓
Pneumatic retinopexy	✓	✓	✓
Erbium laser treatments	✓	✓	✓
Cataract surgery		✓	✓
Glaucoma surgery		✓	✓
Minimal vitrectomy		✓	✓
Strabismus surgery		✓	✓
Vitrectomy			✓
Retinal detachment repair			✓
Orbital surgery			✓
Corneal transplant surgery			✓

BURNT UNIT APPLICATION

For burned patients of variable degree 2 -3
with surface area affected <10% y entre 10 y 100%

Procedures	M20 <i>Simple</i>	M25/M30 M1 <i>close mode</i>	M30 M1 <i>Close mode</i>
Cures	✓	✓	✓
Skin grafts	✓	✓	✓

³ The physician will evaluate the possibility of implementing these procedures, and many other, and the configuration will be limited by the size of the equipment and instruments available for the specialty.

⁴ eléctrica podemos contemplar configuraciones más sencillas que las que a continuación se detallan. For rooms that are right now being used as operating theaters, but which require an improvement in the air quality and/or in the electrical installation we can contemplate simpler configurations than the spelled out below.

GYNECOLOGY

Procedures	M20 Simple	M25/M30 M1 close mode	M30 M1 Close mode
Abortion with >12 weeks		✓	✓
Hysteroscopies for diagnostic		✓	✓

CARDIOLOGY

Procedures	M20 Simple	M25/M30 M1 close mode	M30 M1 Close mode
Pacemaker Implantation		✓	✓

DERMATOLOGY

Procedures	M20 Simple	M25/M30 M1 close mode	M30 M1 Close mode
Small skin surgery	✓	✓	✓
warts, nevus treatments	✓	✓	✓
Melanomas, basalioma	✓	✓	✓
Biopsy	✓	✓	✓
Physical therapies and chemical therapies for dysplasias and skin tumors	✓	✓	✓

UROLOGY

Procedures	M20 Simple	M25/M30 M1 close mode	M30 M1 Close mode
Vasectomy	✓	✓	✓
Testicle pain surgery treatments	✓	✓	✓
Phimosis	✓	✓	✓
Hypospadias	✓	✓	✓
Endourology	✓	✓	✓
Prostate adenoma and carcinoma surgery		✓	✓
Polyps laser surgery		✓	✓
Endoscopies		✓	✓

DIGESTIVE SURGERY

Procedures	M20 Simple	M25/M30 M1 close mode	M30 M1 Close mode
Colonoscopies		✓	✓
Intragastrics balloons		✓	✓
Stomach or esophagus biopsies esófago		✓	✓
Colonic biopsy		✓	✓
Temporo-mandibular joint surgery		✓	✓
Mandibular fractures surgery		✓	✓
Dental implants surgery		✓	✓

TRAUMATOLOGY

Procedures	<i>M20 Simple</i>	<i>M25/M30 M1 close mode</i>	<i>M30 M1 Close mode</i>
Not intra-articular Infiltrations	✓	✓	✓
Spurs	✓	✓	✓
Metacarpal Fractures	✓	✓	✓
Spring - claw fingers	✓	✓	✓
Joints Infiltrations		✓	✓
Repair surgery fractures with external fixation		✓	✓
Spurs and bunions		✓	✓
Hand surgery		✓	✓
Foot surgery		✓	✓
endoscopic surgery of joints, ligaments, menisci, etc.		✓	✓

OTOLARINGOLOGY

Procedures	<i>M20 Simple</i>	<i>M25/M30 M1 close mode</i>	<i>M30 M1 Close mode</i>
Tonsillectomy	✓	✓	✓
Adenoidectomy	✓	✓	✓
Septoplasty	✓	✓	✓
Rhinoplasty	✓	✓	✓
Tympanoplasty	✓	✓	✓
Drains - Implants - Explants	✓	✓	✓
Laryngeal Surgery		✓	✓
Ethmoid sinuses surgery		✓	✓
Maxillary sinus surgery		✓	✓
Frontal sinus surgery		✓	✓

IN VITRO FECUNDATION

Procedures	<i>M20 Simple</i>	<i>M25/M30 M1 close mode</i>	<i>M30 M1 Close mode</i>
Embryo transfer	✓	✓	✓
Transvaginal ovum retrieval	✓	✓	✓
Aspiration of the epididymis (MESA)	✓	✓	✓
Testicular biopsy (TESA)	✓	✓	✓

MAXILOFACIAL SURGERY

Procedures	<i>M20 Simple</i>	<i>M25/M30 M1 close mode</i>	<i>M30 M1 Close mode</i>
Oral Surgery		✓	✓

INTENSIVE CARE UNIT

Procedures	M20 Simple	M25/M30 M1 close mode	M30 M1 Close mode
Isolated rooms		✓	✓
Intravenous access	✓	✓	✓

PLASTIC SURGERY

Procedures	M20 Simple	M25/M30 M1 close mode	M30 M1 Close mode
Treatment Botox	✓	✓	✓
Sutures	✓	✓	✓
Points extraction	✓	✓	✓
Skin minor surgery and subcutaneous tissue	✓	✓	✓
Laser Treatment resurfacing (Erbium, CO2 and similar)	✓	✓	✓
Sclerosing superficial varicose veins treatment	✓	✓	✓
Rhinoplasty/ septoplasty		✓	✓
Auriculoplasty neck		✓	✓
Eyebrow Lifting		✓	✓
Middle Face Lifting (mini-lifting)		✓	✓
Endoscopic Lifting		✓	✓
Infiltrations of adipose cells, etc.		✓	✓
Subcutaneous Implants		✓	✓
Neck Lifting		✓	✓
Limited Liposuction		✓	✓

arcSterile advantages ...

