

The Andersen Concept

Micro-Dose Ampoule



The Andersen system supplies the EtO for sterilisation in a glass ampoule. In the Anprolene refill kits the glass ampoule is held within a break shield. In the EOGas refill kits the ampoule is held within a plastic cartridge.

The ampoule avoids the use of compressed gas cylinders and the health and safety issues, and cost, associated with that.

Delivers gas to the heart of the load, achieving the highest level of sterilisation for any given amount of gas.

The gas is released by breaking the neck of the ampoule. The EtO boils, giving a very distinctive bubbling and cooling feeling as it does so. This provides very clear, positive feedback that the ampoule has been properly activated.

Sterilisation Bag

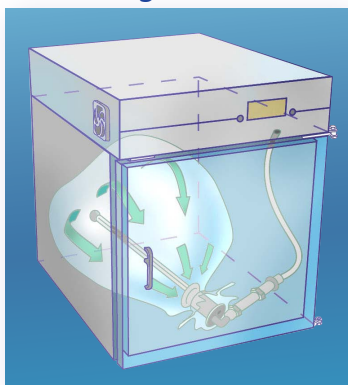


The Sterilisation chamber in the Andersen system is not the cabinet, but rather it is the sterilisation bag. The packaged items, ready to be sterilised, are placed inside this bag.

The cabinet holds the space around the liner bag below room pressure. This ensures that any leak is from the room into the cabinet. Any EtO released through the bag is taken to the outside through the exhaust tube at the back of the cabinet.

The sterilisation bag volumes vary in size up to 60 litres, giving great flexibility in the volume, size and shape of items that can be sterilised.

Purge Probe



The Anprolene and EOGas Series 4 sterilisers use a purge probe. The sterilisation bag is sealed around the bobbin on the purge probe.

At the start of the cycle the purge probe is used to draw any excess air out of the sterilisation bag. This achieves a high level of sterility using a very small amount of EtO.

At the end of the cycle the purge probe is used to "wash" clean air over the load, to remove residual EtO. Air enters through the bobbin and passes down the probe, before being drawn back around the packages in the load and then out of the exhaust tube.

Even gas absorbent items, which may require additional aeration before patient use, may be handled by the operator directly out of the cabinet.

Dosimeter



A unique chemical integrator has been developed by Andersen Products, with specific versions for use at room temperature and at 50°C. These integrate the effects of EtO gas concentration, temperature and exposure duration. A colour change from orange to blue proceeds up the tube (from left to right) and signals a successful cycle when it passes the blue triangle on the pink backing plate.

The Dosimeter gives a measurable result compared to other integrators that require subjective assessment of the colour change achieved. An operator who runs a load with highly gas absorbing items can easily see if the dosimeter has only just passed the mark, and adjust their future loads accordingly.

The Whole Andersen Package

Accessibility

The Andersen system makes EtO technology accessible on a small scale, either for in house sterilisation or for small lot contract sterilisation. The elegant design means cabinets are available for under £3,500, with the most expensive cabinet selling for around £22k. The consumables for all of the cabinets come at around £15 per cycle.

The size of the Anprolene and Series 4 cabinets means they can fit on a standard workbench and our largest cabinet only has a 0.7m² footprint. The size and weight of the Andersen cabinets greatly facilitates their installation.

Installation involves; 1) installing the exhaust tubing, which requires one hole to the outside and 2) plugging the cabinet into a wall socket for power. No need for compressed gas cylinders or compressed air, vacuum, steam or water lines.

There are very few restrictions on EtO emissions to atmosphere around the world. However, abators absorbing 99.9% of EtO in the exhaust are available for all our cabinets.

Most Effective Sterilant

EtO has long been recognised as a very effective sterilant. It remains the most common form of sterilisation worldwide for single use devices.

The Andersen system makes this tried and trusted technology available on a small scale. The Sterility Assurance Level (SAL) of 10⁻⁶ required by EN 556-1 is available using at most 17.6g of EtO.

Its unique ability to pass through plastics, along with its natural mobility give EtO an unparalleled ability to sterilise even the most complicated shapes, including the long narrow lumens found in endoscopes.

Where other technologies require adaptors and special cycles for difficult shapes, the Andersen system simply uses the fundamental properties of EtO.

Safety

The delivery of the EtO to the heart of the load in means that Andersen sterilisers use very small quantities of EtO. The largest ampoule holds just 17.6g of EtO, which makes the whole system inherently much safer than any other EtO steriliser.

Our system is also the only one, in the world, to hold the sterilisation chamber (sterilisation bag) within a negative pressure cabinet. Coupled with the many fail safe elements and warnings built into the Andersen cabinets these features protect the operator from EtO exposure.

Aeration within the cabinet also helps ensure that the operators are not exposed to residual EtO. Whether the devices are immediately suitable for use will depend on what they are made of and what they are to be used for. In the Andersen system even the most difficult devices may be suitable for use on a patient after aeration for 24 hours at 20°C, or as little as 1 hour at 50°C.

Most Efficient Steriliser

The use of the Andersen micro-dose system allows the Andersen system to be much more efficient by using only a fraction of the EtO used by other systems.

This has benefits in terms of safety for the patient, the operator and the environment. Starting with a very small amount of EtO means it is inevitably easier and quicker to ensure that neither the patient nor the operator are exposed to EtO.

EtO will degrade in the environment, reacting with any organic matter or with water. That degradation happens more quickly and more safely if you start by using a much smaller quantity of EtO in the first place.

Unlike alternatives, our sterilisers do not require compressors, three-phase power supplies, large tanks of gas, or a pressure vessel with high maintenance costs.

Items suitable for sterilisation with EtO

EtO is a very versatile sterilising agent and is used to sterilise a wide range of items other than food, drugs and liquids. The table to the right compares the compatibility of different sterilisation methods on different materials.

1= not recommended, 4 = excellent

Raw material designation	Radiation	EtO	Moist Heat	Dry Heat	Hydrogen Peroxide	Ozone
Cellulose ester	2	4	1-2	1-3	1	1-3
Cellulose, paper, cardboard	2-3	4	1-2	1-2	1	1-3
EPDM	3-4	4	3-4	2-3	2-3	2
Perfluoro alkoxy (PFA)	1	4	4	4	4	4
Polyamides (eg. Nylon)	2-3	4	1-4	1-4	3	3
Polycarbonates (PC)	3-4	4	1-3	2	4	4
Polyethylene (PE)	3-4	4	1-3	1-2	4	4
Polypropylene (PP) stabilised	2-3	4	2-3	1-3	4	4
Polytetrafluoroethylene (PTFE)	1	4	4	4	4	4
Polyvinylchloride (PVC)	3	4	1-2	1-2	4	4
Silicone adhesives	2-3	4	1-3	2-4	2	3

Raw material process compatibility examples, (from standard AAMI-TIR17:2008)