Anprolene ® Study Guide

For models AN74i, AN74ix and AN74J

The active ingredient in the Anprolene system is ethylene oxide (EO). EO is a powerful anti-microbial agent; it needs to be handled with care. To help ensure that your sterilise is operated safely, ALL personnel who operate or maintain the equipment should be properly trained.
The Andersen Anprolene Key Operator Certification Program is free of charge for the lifetime of your steriliser. We recommend that all operators at your facility are trained before they use the steriliser for the first time.
The information in this study guide should be reviewed prior to the on-site visit from our staff.
If training is to be done remotely, please answer the Anprolene® Test Paper and return to ennio@austvetendoscopy.com.au and then give us a call on 03 9543 3991 to go through your answers and any questions you may have, this should take no longer than 30 minutes.
Once the training, either on-site or by phone, has been completed, you will receive a registered training certificate.

Key points of the Anprolene® Sterilisation System

- The Anprolene system is a room temperature Ethylene Oxide (EO) steriliser. The sterilisation system must be installed and operated in an environment that maintains a minimum temperature of 20˚C to be effective.

- The usual anprolene cycle is 12 hours, plus 2-hour bag ventilation (purge) to remove excess gas and prevent the operator from being exposed to the gas.

- When sterilising tubing over a meter long (i.e. an endoscope) or a full load of absorbent items, the 24-hour cycle should be used, and it may be necessary to use 2 gas ampoules. Gas absorbent items will also require additional aeration if they are to come into contact with living tissue

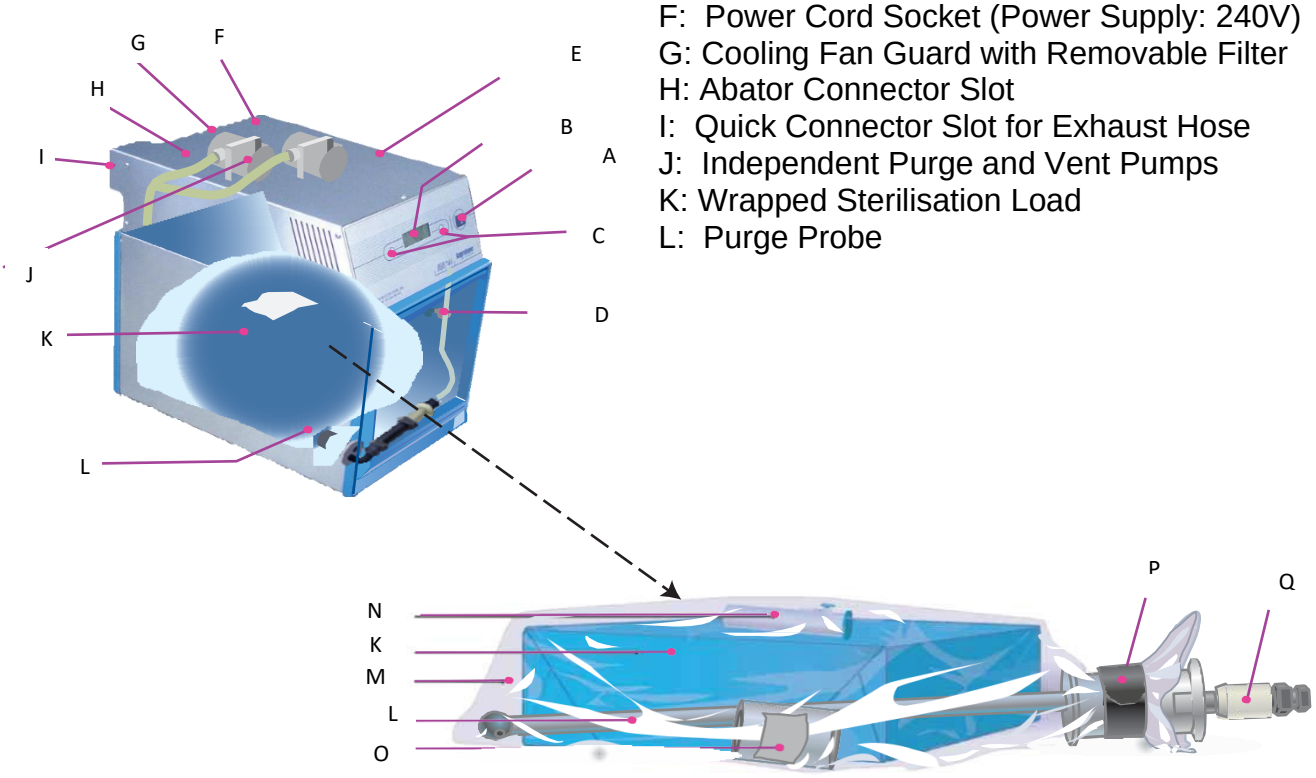
- A successful cycle requires humidity of 35%. If below this level, an AN1071 humidichip should be used with the Humiditube.

- AN87 dosimeter® provides immediate confirmation at the end of the cycle that adequate time, temperature and EO concentration have been met.

Anprolene®
Gas sterilisation

Anprolene Supplies & Parts Index

A: Power Switch
B: Cabinet Digital Display C: Program Buttons
D: Steriliser Lock and Key
E: Sturdy Stainless Steel Cabinet
F: Power Cord Socket (Power Supply: 240V)
G: Cooling Fan Guard with Removable Filter
H: Abator Connector Slot
I: Quick Connector Slot for Exhaust Hose
J: Independent Purge and Vent Pumps
K: Wrapped Sterilisation Load
L: Purge Probe



Anprolene Sterilisation Cabinet

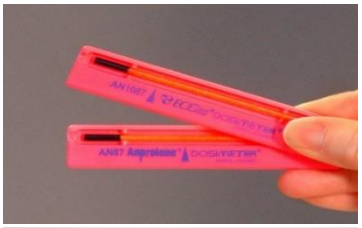
Loaded Sterilisation Bag

M: Gas Sterilisation Bag
N: EO Ampoule in Release Bag
O: Humidichip and Tube
P: Black Velcro® Strap with Buckle
Q: Quick Release Connector

Anprolene Sterilisation Consumables

AN-79.16

Gas Refill Kits contain replacement gas ampoules and liner bags in a convenient storage/dispenser box. Two different bag/ampoule combinations to match your sterilisation needs



AN-87

AN87 Dosimeter Chemical Integrators present visual assurance that proper time, temperature and EO concentration were reached during the sterilisation cycle.

AN-2203

AN2203 EZ Test Biological Indicators reliably verify that sufficient concentration of EO killed one million B.atrophaeus spores, the spore most resistant to EO gas. Biological Indicators are the best method to ensure sterility after a cycle.

Indicator tape

AN1071

AN1072

Exposure Indicator Tape change colour to provide an immediate assurance of gas exposure at the end of the cycle. They have self-stick backing to be used on paper or cloth. THEY DO NOT PROVE STERILITY – JUST EXPOSURE

AN1071 Humidichips and AN1072 Humiditube

The Humidichip is a unique product designed as a relative humidity stabiliser for the Andersen sterilisation system. It ensures that the humidity inside the liner bag is in the required 35%-90% range throughout the sterilisation cycle. Humidity is required for EO to be an effective sterilant. In ambient temperature cabinets, Humidichips may not always be necessary. However, their use ensures effective sterilisation without having to assess and monitor ambient conditions.

The Humiditube guarantees free air circulation around the Humidichip, thereby ensuring that the chip performs at maximum efficiency. Humiditubes can be re-used over and over.

Characteristics of Ethylene Oxide and why it is safe to use as a sterilant

- **EO boils at 10.5˚C**
- **EO is not an effective sterilant below 20˚C**
- **EO is toxic**
- **EO is flammable**
- **EO is potentially human carcinogenic**
- **Some items sterilised in EO will require additional aeration prior to use on living tissue**
- **Workplace exposure limits are 1ppm TWA (time-weighted average)**
- **There are no restrictions on EO into the atmosphere; it is NOT a greenhouse gas**
- **At 200-700ppm, you will smell EO, and you may have the following symptoms of exposure: runny eyes or nose, scratchy throat.**

Why is it safe to use?

- **Your steriliser has 2 pumps that ensure that the cabinet is kept at negative pressure whilst in operation, ensuring that the gas is exhausted to the outside.**

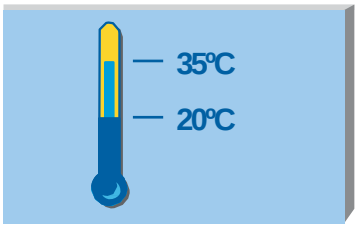
- **The glass ampoule is in a protective sheaf and a gas release bag that ensures that no gas will escape for several minutes, giving you plenty of time to start your cycle.**

- **At the end of the cycle, your steriliser will do a 2-hour purge. This means alternately every 2 minutes; it will remove gas and then pump in the fresh air, effectively washing fresh air over your items. This 2-hour purge ensures that when you open the cabinet to remove your load, you will not be exposed to gas levels above OHS recommendations.**

- **To ensure that the cabinet is operated safely, it should only be used by staff having completed the training. This training is FREE for the lifetime of your steriliser.**

1 Preparing for Sterilisation

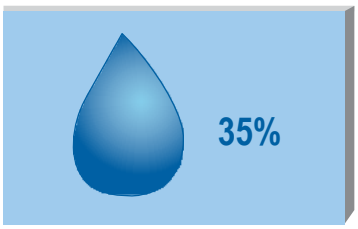
A. Environmental Considerations



1 Temperature

Gas Storage Temperature: Store your Anprolene gas refill kits in a cool, secure area. We recommend storage below 30°C.
Operational Temperature: The steriliser must be used in an area where the temperature is not less than 20°C or more than 35°C.

EO FACTS: At sea level, ethylene oxide is a liquid below 11°C. Above 11°C, EO begins to boil and converts into a gas. EO does not become an effective sterilant until it is 20°C. Make sure that the room where your Anprolene steriliser is installed remains above 20°C during the entire sterilisation cycle. This is especially important during the winter months!

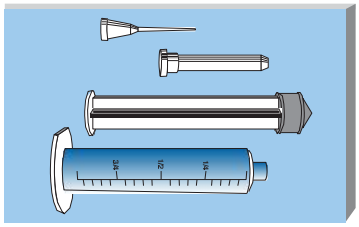


2 Humidity

Humidity is very important to the Anprolene process. Relative Humidity (RH) must be at least 35% in the room where item preparation and sterilisation take place. Spores that might be on the instruments may become desiccated and more resistant to EO if the RH is below 35%.
The simplest way to humidify items prior to sterilisation is to wash them. Items that cannot be washed (such as laptops, cameras, and delicate electronics) should be humidified by placing the wrapped or pouched items in a plastic bag with an Andersen Humidichip® for four hours in a warm area (above 20°C).
If room RH is lower than 35% during the sterilisation cycle, a Humidichip is placed into the sterilisation bag to maintain proper humidity.

B. Four Basic Steps of Pre-cleaning

Follow manufacturer's instructions for cleaning and preparing reusable devices for EO sterilisation whenever possible. In the absence of the manufacturer's instructions, these general steps should be followed:



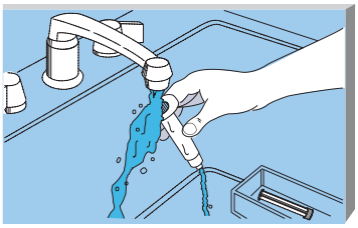
1 Disassemble

Items containing removable parts such as syringes must be taken apart before washing, drying, and wrapping them to allow the EO an unobstructed path around all parts.

WARNING: Instruments which contain batteries must be taken apart and the batteries removed and wrapped separately to protect against a spark occurring.

2 Wash

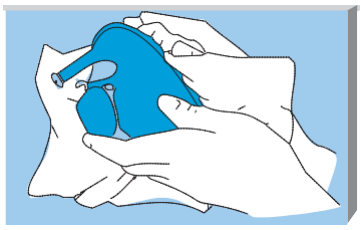
Presoak the items, if appropriate. Items must be washed surgically clean prior to sterilisation using detergent and water.



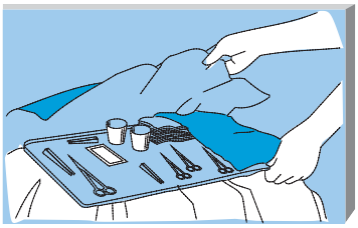
③ Dry

Three accepted ways to dry any item prior to sterilisation with Anprolene are:

1. Towel drying
2. Drain drying (air drying)
3. Compressed air for tubing and long lumens.



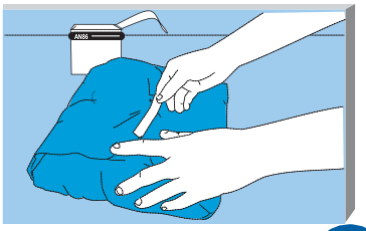
WARNING: Heat or hot air should not be used to dry an item prior to sterilising it with Anprolene because it may dehydrate or desiccate bacteria spores making them more resistant to the ethylene oxide gas.
WARNING: Any water left on items may react with ethylene oxide. Items must be thoroughly dried.



④ Wrap

The following types of wrapping material are recommended for use with Anprolene; always follow manufacturer's use and shelf-life guidelines for all packaging. If not supplied, our guidelines are in brackets:

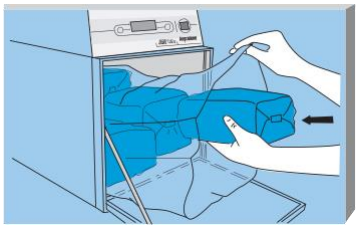
1. Heat-sealed packaging such as Tyvek/plastic® (2years)
2. Self-seal pouches (6 months).
3. Cloth, paper, or Central Supply Room (CSR) wrap (30 days).



HINT: Exposure indicators such as the Exposure Indicator Tape are used to seal or label items. Indicators will change colour in the presence of EO, helping to later identify items that have been sterilised. Exposure indicators DO NOT indicate sterility.

2 The Sterilisation Cycle

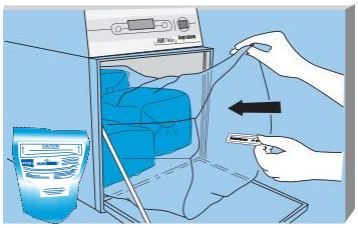
A. Loading the Liner Bag and Steriliser



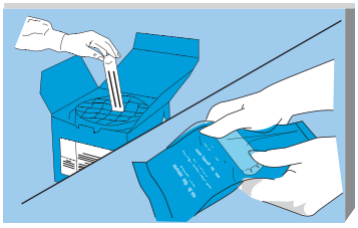
① Place prepared items in a new sterilisation liner bag.

WARNING: Do not reuse sterilisation liner bags. Even a tiny pinhole in a liner bag can allow gas to escape and cause cycle failure!

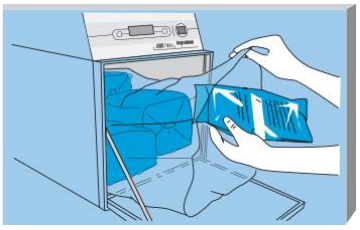
WARNING: Liquids, powders, food, and drugs should not be sterilised in ethylene oxide because it may change their chemical composition in unpredictable ways. If you have any questions about whether an item may be sterilised using EO, please call Austvet Endoscopy Customer Service.



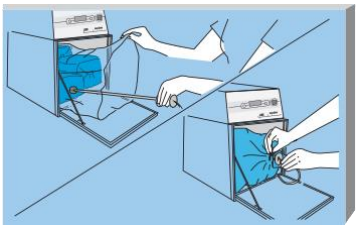
② **Insert appropriate controls** such as a chemical integrator (Dosimeter) or a biological indicator (EZ Test) into the least accessible part of the sterilisation liner bag. If room relative humidity is below 35%, add a Humidichip to a Humiditube and place it into the sterilisation liner bag.



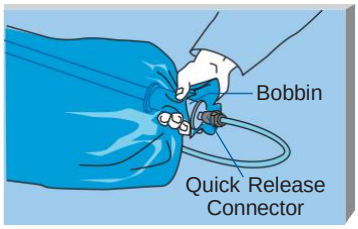
③ **Unroll the gas release bag** containing the gas ampoule and, without opening it, gently move the ampoule to the centre of the gas release bag. Place it on top of items in the sterilisation liner bag where it will be easy to break. Never open the gas release bag. This prevents liquid from coming into contact with the skin, and gas from escaping too quickly to achieve sterilisation.



WARNING: Reasons why the gas release bag containing the ampoule should never be opened:
- **To prevent the liquid ethylene oxide from coming in contact with the user or the items to be sterilised.**
- **To prevent the gas from escaping too quickly to achieve sterilisation.**



④ **Insert the purge probe** into the sterilisation liner bag with the bobbin and quick release fitting at the open end. Place the Velcro® strap around the sterilisation liner bag and the bobbin of the purge probe, and pull it snug through its loop to completely close the sterilisation liner bag. The strap must tightly secure the sterilisation liner bag around the purge probe bobbin in order to keep gas from escaping.

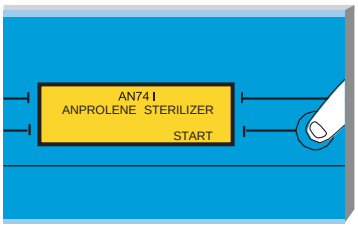


⑤ **Connect the quick release connector** to the purge hose if it is not already connected.

HINT: The sterilisation liner bag may be loaded and closed away from the steriliser cabinet and connected to the purge hose once you are ready to start a cycle.

The 'rule of thumb' for loading the bag is 10Kg of mixed items reducing to 5Kg for a load of absorbent items.

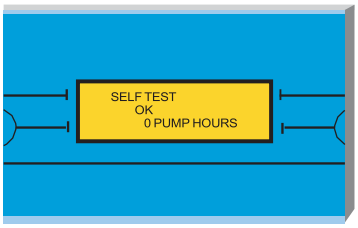
B. Starting the Cycle

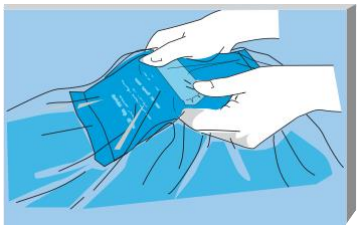


① Make sure the steriliser is connected to power. Press the power switch on the front panel. Wait to see the "(model #) ANPROLENE STERILISER" and the "START" message to appear on the cabinet display.

② Push the button to the right of START.

③ Wait for the SELF TEST and number of elapsed PUMP HOURS to appear.



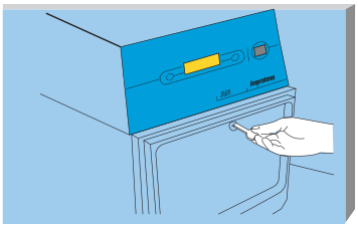


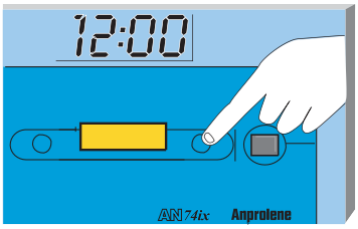
4. Press the button next to the **PURGE** message on the right of the display and wait for 1 minute 30 seconds until the display reads '00:00:00'. The sterilisation liner bag should vacuum down as excess air is removed.

5. When the display indicates **BREAK AMPOULE**, carefully, so as not to puncture the sterilisation liner bag, grasp the ampoule through the sterilisation liner bag and activate it by snapping off the top.

> **WARNING:** Use only genuine Anprolene® gas products in your steriliser. Use of other gas sources may result in operator injury and/or non-sterile loads.

C. Selecting Cycle Length





1. Once the ampoule is broken, close the door.

2. Lock the steriliser and remove the key.

3. SELECT CYCLE LENGTH. (Right button = 12 Hour, Left button = 24 Hour). The cycle length cannot be selected until the door is closed.

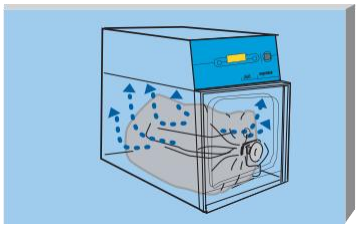
> **WARNING:** The usual Anprolene sterilisation cycle is 12 hours, plus a 2-hour purge cycle. When sterilising tubing over 1 metre (eg endoscopes) the 24 hour cycle should be selected. A full load of gas absorbent items (eg rubber tubing, bandages, swabs) may require two gas ampoules to ensure the dosimeter reaches the triangular mark.

4. If a cycle length is not selected within 5 seconds after closing the door, an alarm will sound to remind you to choose one.

5. After the cycle length is selected, the steriliser display will countdown the time remaining until the sterilisation cycle is complete.

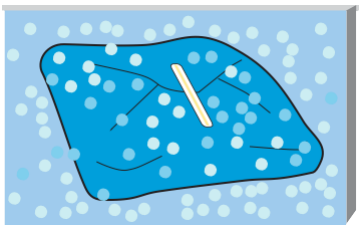
> **WARNING:** Never interrupt a cycle once the gas ampoule has been activated. An alarm will sound if the door is opened during the cycle.

6. Log sterilisation data if required.



D. Additional Aeration

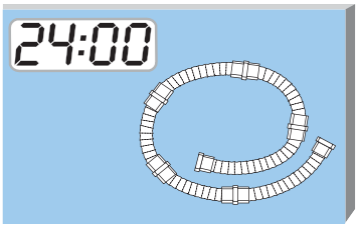
Throughout the entire cycle, the ventilation system is always running to prevent EO gas from entering the room. Once the 2-hour purge cycle is complete, the steriliser will continue to ventilate and purge the liner bag.



A count-up timer will begin on the steriliser display to keep track of additional aeration time, and the steriliser will reset only after the door is opened and the exit button is pressed. The temperature in the room should continue to remain at least 20°C during the aeration period.

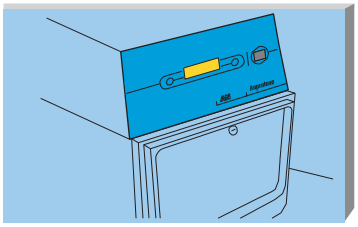
Some gas absorbent items require additional aeration after the regular sterilisation/purge cycle and before they can be removed and used. This extra aeration prevents chemical burns to living tissue that can be caused by residual EO absorbed during the sterilisation cycle.

E. Aeration Guidelines



Some large, gas absorbing items (especially implants, long lengths of tubing, and devices that will contact blood or living tissue) require additional aeration time:

1. If the item's manufacturer provides guidelines on aeration required after EO sterilisation, follow those guidelines.

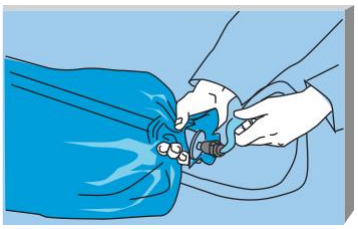


2. Two types of materials that do not require additional aeration are metal and glass. Items made of these materials do not absorb EO.

3. If the item's manufacturer does not provide guidelines on aeration required after EO sterilisation, the item should remain in the Anprolene steriliser or placed outside the cabinet in a well-ventilated room to aerate for an additional 24 hours after the sterilisation and purge cycles are complete.

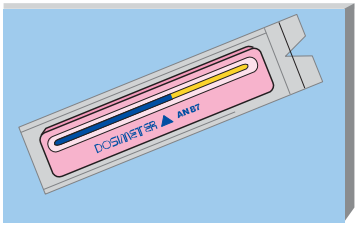
3 Unloading the Steriliser and Determining sterility

A. Unloading The Liner Bag:



1. Remove the sterilised items only after the sterilisation cycle, 2-hour purge cycle, and any additional aeration have been completed, and the display indicates "UNLOAD STERILISER".

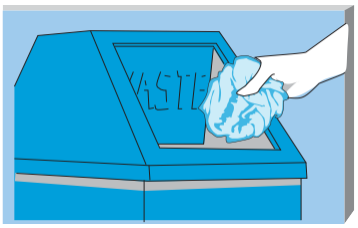
> HINT: To unload the sterilisation liner bag away from the steriliser, simply detach the purge hose from the bag using the quick release connector.



2. Remove the sterilised items and examine the Dosimeter. Make sure the blue line has progressed up to or beyond the triangular mark.

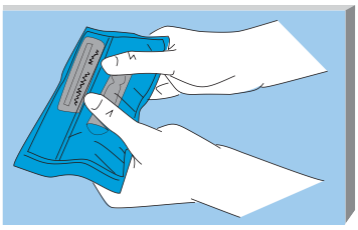
3. Discard the sterilisation bag, Humidichip, and used ampoule with ordinary waste. Incubate Biological Indicator if using one. Retain Humiditube to use again.

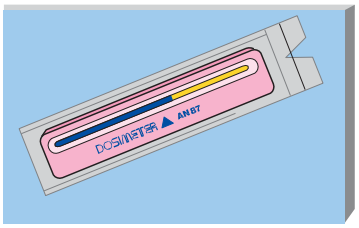
4. Press EXIT to end the cycle and return the steriliser to the standby state. Switch the power button off.



WARNING: Never remove items before the full sterilisation and 2-hour purge cycles have completed. The purge cycle is designed to aerate most products sufficiently to avoid operator exposure to EO by meeting the OHS short-term exposure level (STEL) of 5.0 ppm over 15 mins.

B. Important Notes About Indicators:





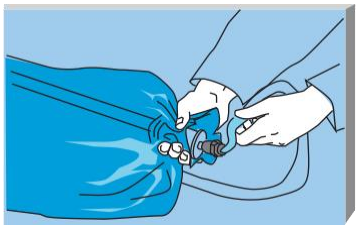
1. **Biological Indicators** (BI's) such as the AN 2203 EZ Test use live spores and are the best confirmation of the success or failure of a sterilisation cycle. Always follow manufacturer's recommendations when using BI's.

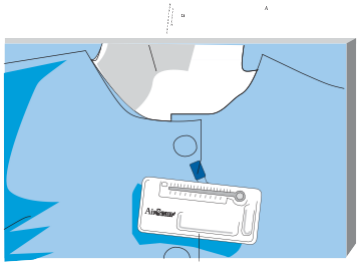
2. **Chemical Exposure INTEGRATORS** such as the **AN87 Dosimeter** provide immediate visual confirmation that time, temperature, and EtO concentration were sufficient for sterilisation to occur.

3. **Chemical Exposure INDICATORS** such as Exposure Indicator Tape do not prove sterilisation. They only change colour to show that the items have been exposed to ethylene oxide.

4 Safety Precautions

A. Ethylene Oxide Safety





1. Do not allow open flame or sparks near the steriliser during the sterilisation cycle. Ethylene oxide gas is highly flammable in concentrations above 3.0% (30,000 ppm).

2. Never interrupt a cycle in progress.

3. Sterilisation liner bags should never be re-used because they may have a puncture or tear.

4. The 12 and 24-hour sterilisation cycles both end with a 2-hour purge cycle, which flushes fresh air around the items in the sterilisation load.

5. Personnel exposure to ethylene oxide can be monitored by using personal exposure badges, both STEL (15 min.) and TWA (8 hours) badges. We recommend that exposure testing be performed on an annual basis or whenever a steriliser is relocated.

6. If an ampoule is accidentally activated outside of the bag, immediately place it in the sterilisation cabinet and start a cycle.

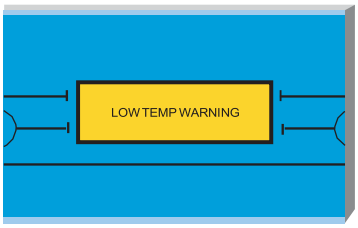
7. **Always store Anprolene gas ampoules and refill kits in a secure cabinet that is kept cool (30ºC or below) and out of direct sunlight.**

B. Reasons for Locking the Anprolene Steriliser:

- **To ensure that no one is able to access the liner bag during a cycle**

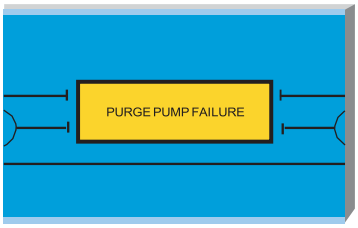
> **Note: No other container or steriliser can be used with Anprolene sterilising gas.**

C. Malfunctions and Power Failures



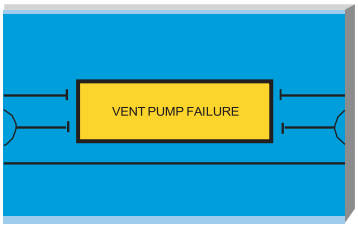
Low-Temperature Warning

If, at any time during the cycle, the temperature around the steriliser drops below 20°C, a low-temperature warning will be displayed. This warning may indicate that the cycle was unsuccessful due to inadequate temperature. Check your sterility indicators to confirm the success of the cycle.



Purge Pump Failure

In the event of a purge pump failure, the vent pump will continue to ventilate the interior of the cabinet, exhausting gas as it diffuses through the sterilisation liner bag. A **PURGE PUMP FAILURE** error message will be displayed, and the steriliser will add 24 hours of aeration before the display indicates that you may remove your products. **If this happens, please call Customer Service for assistance, 03 9543 3991 or 0408 053 100 out of hours.**



Vent Pump Failure

In the event of a **VENT PUMP FAILURE**, the cycle will be aborted, and the purge pump will evacuate the liner bag of any remaining gas **If this happens, please call Customer Service for assistance, 03 9543 3991 or 0408 053 100 out of hours.**

Power Outage

If a power outage occurs during any part of the cycle, the steriliser is equipped with a battery back up to the circuit board that will keep track of elapsed cycle time. When power is restored, the cycle will continue. Do not open the door of the steriliser until power is restored and the vent/purge systems have removed any residual gas from the liner bag. When the cycle is complete, the display will indicate **UNLOAD STERILISER**.

> **HINT: In the case of any steriliser malfunction or power failure, you can determine whether sterilisation was achieved by examining the sterility indicators (biological indicator, and Dosimeter) included in the load.**

D. Emergency Procedures

① If liquid EO comes into contact with a part of the body, you must wash with water thoroughly for at least 15 minutes. Consult the Material Safety Data Sheet (MSDS) for further information.

② The Material Safety Data Sheet (MSDS) for EO Gas should be readily available at your facility. Do you know where to find your MSDS?
- Operator's Manual
- List of physical and chemical hazards is provided with each Anprolene refill kit.

IN CASE OF CHEMICAL EMERGENCY CALL:
000
FOR *ALL* OTHER PROBLEMS CALL Austvet Endoscopy CUSTOMER SERVICE
03 9543 3991 (0408 053 100 OUT OF HOURS)

5 Study Guide Review

Here is what you should know after reading this study guide:

- The minimum temperature needed in the room for the entire sterilisation cycle
- The length (in time) of the standard cycle
- Why the ventilation system is running during the entire cycle
- Why the sterilization liner bag is purged
- The required relative humidity in the room where the items are prepared
- How to prepare items for sterilisation
- The types of indicators that should be used in the Anprolene system
- Ethylene oxide safety and precautions
- Basic operation of your Anprolene steriliser from start to finish

When you feel comfortable with answers to these subjects, please fill in the Answer Booklet and send it over to us by e-mail ennio@austvetendoscopy.com.au Then, please call Austvet Endoscopy at 03 9543 3991 whenever it is convenient for you, to complete your Key Operator test over the phone (this will take around 30 minutes).

Operator training records should be maintained at your facility.
Key Operator Tests will also be kept on file at Austvet Endoscopy.

If you would like to have an Andersen representative come to your facility for in-person training, please contact Ennio Matutini at ennio@austvetendoscopy.com.au

Many thanks for using the Andersen Anprolene steriliser. Please do not hesitate to call us if you have any questions in the future.

Austvet Endoscopy Customer Services
03 9543 3991 (out of hours 0408 053 100)
www.austvetendoscopy.com.au

Ref: Anpro Study Guide 202101